Trialfinder
Offene Studien

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

Solide Tumore I		Solide Tumore II		Hämatologische Erkrankungen	
1	Bronchial-Ca	13	Mamma-Ca	24	ALL
2	Kopf-Hals-Tumore	14	Gynäkologische Tumore	25	AML
3	Ösophaguskarzinome	15	Keimzelltumore	26	CLL
4	Magen-Ca und gastroösophagealer Übergang	16	Sarkome	27	CML
5	Pankreaskarzinome	17	Hepatozelluläre Karzinome	28	MDS
6	Cholangiozelluläres Karzinome	18	Nierencell-Ca	29	Morbus Hodgkin
7	Dünndarm-Ca	19	Hauttumore	30	MPN
8	Kolorektale Karzinome / Colon	20	Hirntumoren	31	Multiple Myelome
9	Urothel-Harnblasenkarzinome	21	GIST-Tumore	32	NHL / Waldenström
10	Prostatakarzinome	22	Nebenwirkungen onkologischer Therapien	33	ZNS-NHL
11	Neuroendokrine Tumore / Karzinome	23	Studien der pädiatrischen Onkologie-Hämatologie	34	Anämien
12	**Entitätsübergreifende Studien**			35	Amyloidosen
		36	Zelluläre Therapien	37	ITP

Sehr geehrte Damen und Herren,

in dieser PowerPoint Präsentation finden Sie **aktuell offene onkologisch-hämatologische Studien.** Über Links gelangen Sie in Menüs und dann in die einzelnen Studien.

Verantwortlich für die Richtigkeit der Studieninformationen ist der jeweilige Hauptprüfer (PI). Über Anregungen, Ergänzungen oder Korrekturvorschläge freuen wir uns. Wenden Sie sich bitte diesbezüglich an Frau Böhlke, Telefon: 040-7410-57118, E-Mail: i.boehlke@uke.de.

Gern stellen wir Ihnen auch eine Vorlage zur Verfügung, über die Sie uns Informationen für zu veröffentlichende Studien bereit stellenkönnen.

Studienbaum
Bronchial-CA

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
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NSCLC

RET Fusion positiv →

adjuvant

ADCA Stadium I / IIA, R0-Resektion →

- Razor14
- RELA-104

Mesotheliom

adjuvant

Epitheloid (ggf. biphasisch) →

Bitte auch die Möglichkeit eines Studieneinschlusses in die BASKET –Studien überprüfen!

Studienbaum
Bronchial-CA

Hubertus Wald Tumorzentrum
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NSCLC

1st Line

All NSCLC advanced , metatstatic, w/o actionable genomic alteration	
ADCA und PECA sq und non-sq Stadium IIIA und IIIB	
unresctable, locally Stadium IIIA und IIIC	MK-7339-012/ KEYLINK-012
Non-sqamous, RET positiv, Stadium IIIB und IV	LIBRETTO-431
LCNEC, Stadium IIIB und IV	
NSCLC, Stadium IV (PD-L1)	I3LUNG / Skyscraper-01 / TROPION-Lung08
ADCA und PECA Stadium IIIB und IV	I3LUNG
ADCA und PECA Stadium IIIA und IIIC	
Stadium IV	KRYSTAL-7 / RELA-104/ CA224-104
ADCA und PECA Stadium IV	STAR-121 / BO44178 "TOBE"
MeTex14 skipping alteration	MOMENT (Register)
Stadium IIIB und IV, EGFRm	PACE-Lung
Stadium III und IV	BNT 116-01 LuCa-MERIT-1

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Studienbaum
Bronchial-CA

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NSCLC

Zweitlinie
- nur ADCA EGFR Mutation, T790M positiv Stadium IIIB und IV → ABC-lung (ETOP15-19)
- ADCA, nur bei KRAS G12c, Stadium IIIC und IV
- Nach definitiver Therapie, Stadium IB bis IIIA
- c-Met Überexpression → AbbVie M18-868

Zweit- u. Drittlinie
- All NSCLC → Entree GSK
- ADCA und PECA, MET exon 14 skipping mutation
- ADCA und PECA Stadium IIIB und IV
- ADCA und PECA Stadium IIIC und IV

Andere Therapielinie → HUDSON, MK-3475-587

Ab Drittlinie
- → DeLLphi-301
- Stadium IIIB und IV → CRISP

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Studienbaum
Bronchial-CA

SCLC

Erstlinie

- extensive disease Stadium IV → SPACE /AIO-TRK-0119
- extensive disease Stadium III → KeyVibe-008
- ES-SCLC, Stadium IV
- With IPSS-R Low- or Intermediate-risk Myelodysplastic Syndrome (MDS) → BMS-CA055-026
- ES-SCLC → Imforte

Register

- alle Lungentumore, NIS Biomarker → Info Fr. Axenfeld/ 04102 / 601-2457
- NSCLC ADCA und PEC IA bis IV, NIS → Info DZL/ Dr. Abdo/ 04102/ 601-2412
  Vergleich PD-L1 Expression Zyto versus Histo, Korrelation mit zirkulierenden Biomarkern, reine Gewebeuntersuchungen

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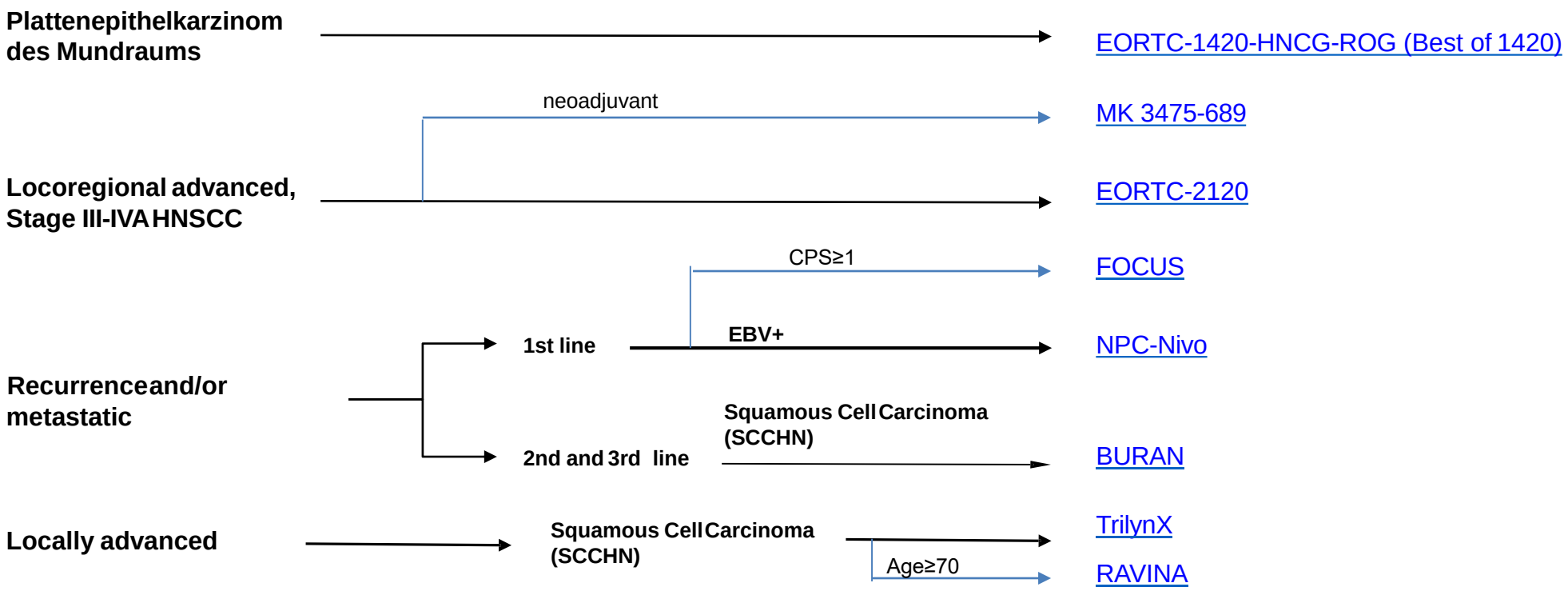
Studienbaum
Kopf-Hals Tumore (SCCHN)



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Studienbaum
Ösophaguskarzinom

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
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Ansprechpartner im Zentrum für Onkologie
PD Dr. Andreas Block, Tel.: 040-7410-55470
PD Dr. Marianne Sinn, Tel.: 040-7410-70434

Ösophagus–irresektabel oder metastasiert

Ösophaguskarzinom + Gastroösophagaler Übergang –resektabel

Bitte auch die Möglichkeit eines Studieneinschlusses in die BASKET –Studien überprüfen!

Entitäten

Studienbaum

Ösophaguskarzinom (irresektabel oder metastasiert)

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
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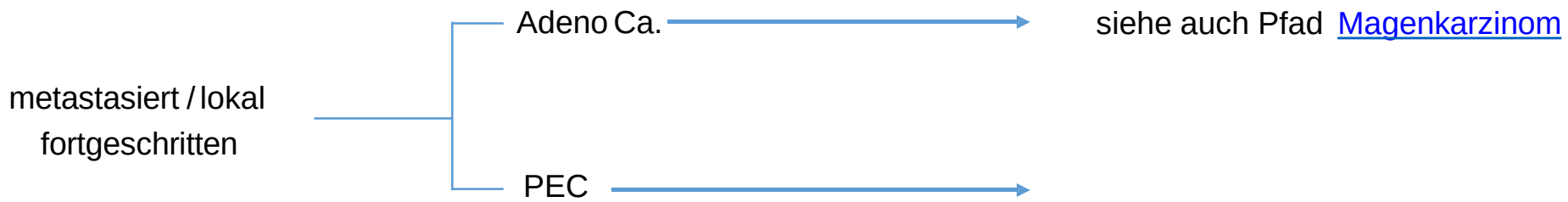
PD Dr. Andreas Block, Tel.: 040-7410-55470
PD Dr. Marianne Sinn, Tel.: 040-7410-70434



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Studienbaum

Ösophaguskarzinom und Gastroösophagealer Übergang (resektabel)

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Universitäres Cancer Center Hamburg
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Ansprechpartner im Zentrum für Onkologie
PD Dr. Andreas Block, Tel.: 040-7410-55470
PD Dr. Marianne Sinn, Tel.: 040-7410-70434

*** UKE**= Universitätsklinikum Hamburg Eppendorf-II. Medizinische Klinik, **HOPA** = Hämatologisch Onkologische Praxis Altona, **HOPE** = Hämatologisch Onkologische Praxis Eppendorf

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Entitäten

Studienbaum
Magenkarzinom

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

Ansprechpartner im Zentrum für Onkologie
PD Dr. Andreas Block, Tel.: 040-7410-55470
PD Dr. Marianne Sinn, Tel.: 040-7410-70434

Magen Ca. +
Gastroösophagealer Übergang

- lokal (resektabel)
- nicht resektabel / metastasiert

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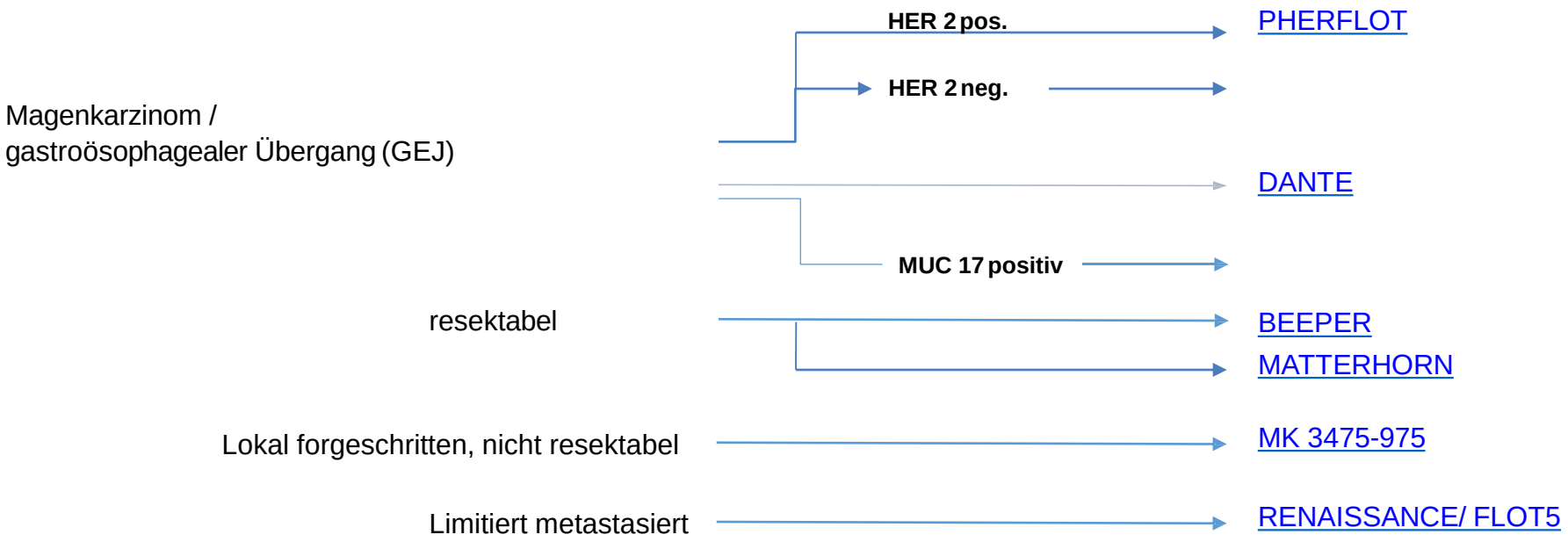
Studienbaum

Magenkarzinom und Gastroösophagealer Übergang (resektabel)



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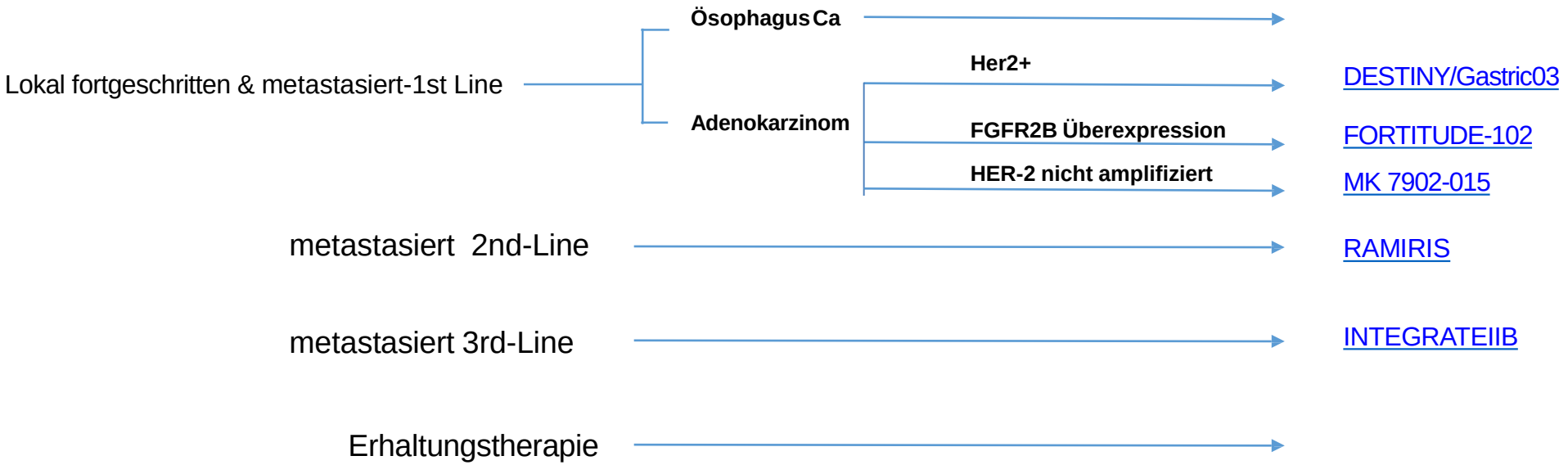
Studienbaum

Magenkarzinom und Gastroösophagealer Übergang (nicht resektabel / metastasiert)



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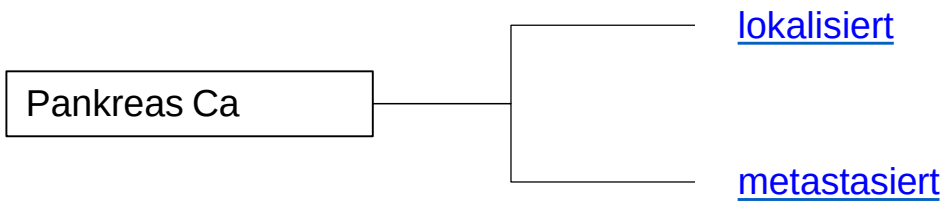
Studienbaum
Pankreaskarzinom

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

Ansprechpartner im Zentrum für Onkologie
PD Dr. Andreas Block, Tel.: 040-7410-55470
PD Dr. Marianne Sinn, Tel.: 040-7410-70434



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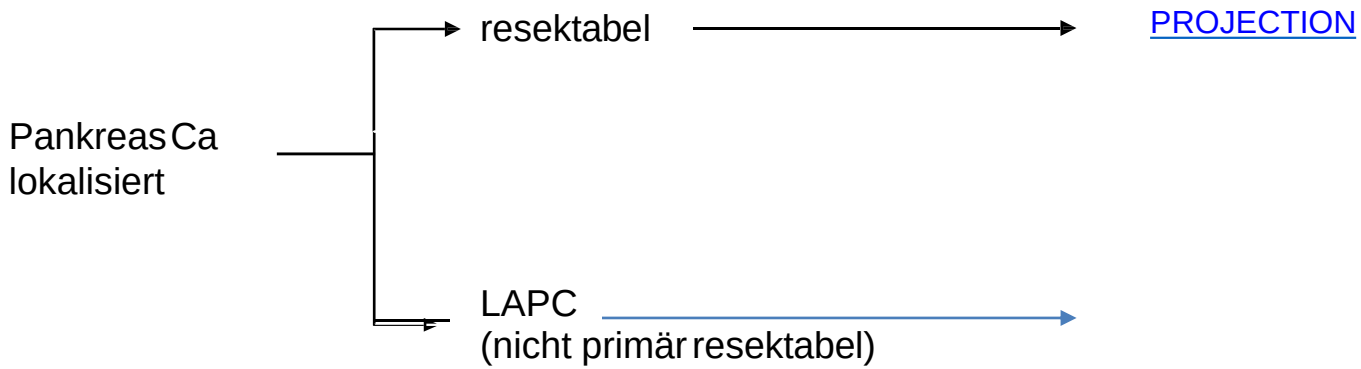
Entitäten

Studienbaum
Pankreaskarzinom (lokalisiert)



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Studienbaum

Pankreaskarzinom (metastasiert)

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Pankreas Ca
metastasiert

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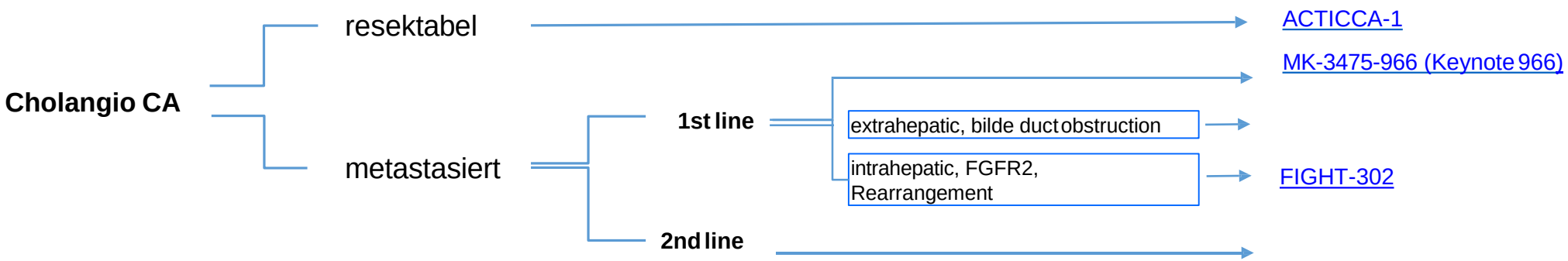
Entitäten

Studienbaum
Cholangiozelluläres Karzinom



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Entitäten

Studienbaum
Dünndarm-Tumore

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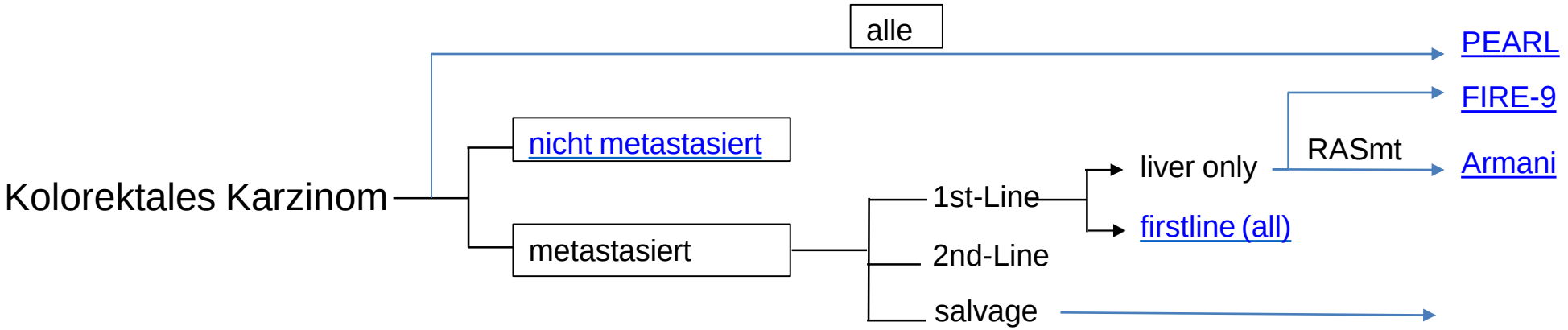
Studienbaum
Kolorektales Karzinom



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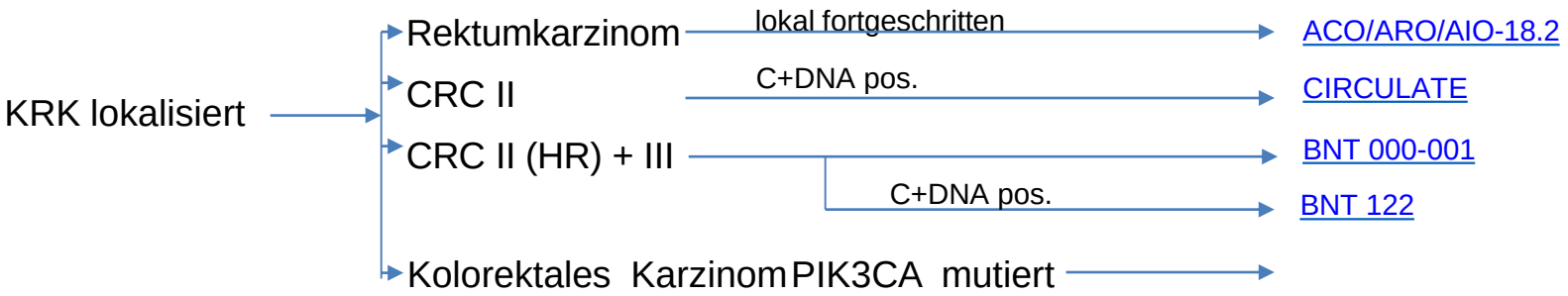
Studienbaum
Kolorektales Karzinom (lokalisiert)



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Studienbaum
Kolorektales Karzinom (metastasiert)

Primärtumormanagement

Colorectales Ca/ Colon → BRAF V600E/ BRAF V600 mut./ Localized Cancer → NEOBRAF

asymptomatischer Primärtumor mit synchronen irresektablen Metastasen → BRAF V600E/ MSI-H/dMMR → SEAMARK

Fortgeschrittenes Colorectales Ca → MEFOX

Bitte auch die Möglichkeit eines Studieneinschlusses in die BASKET –Studien überprüfen!

Studienbaum
Kolorektales Karzinom (metastasiert)

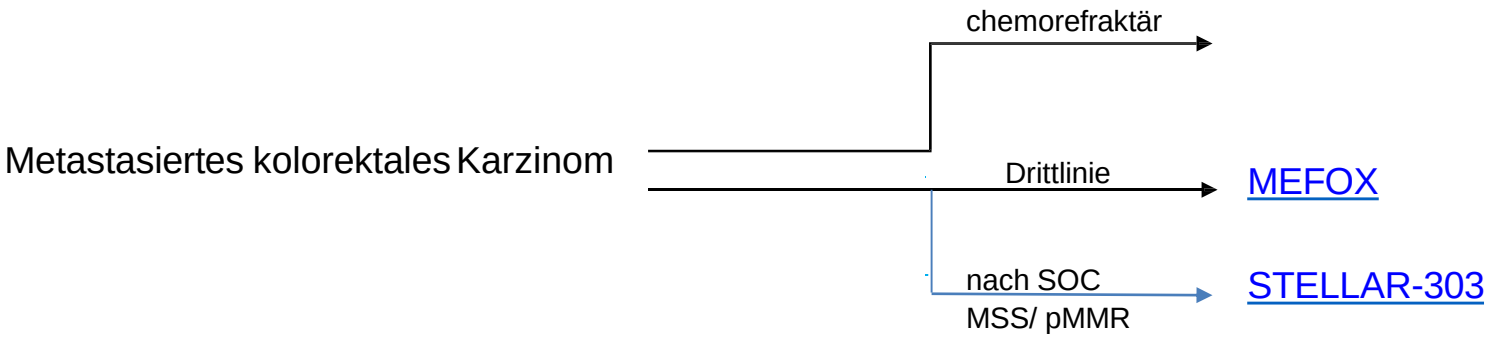
Erhaltungstherapie

nicht resektables KRK
RAS-Wildtyp, 5-FU/FA+/-Panitumab 

Bitte auch die Möglichkeit eines Studieneinschlusses in die BASKET –Studien überprüfen!

Studienbaum
Kolorektales Karzinom (metastasiert)

Zweitlinientherapie



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Studienbaum

Kolorektales Karzinom (nicht resektabel / metastasiert)

RAS-Wildtyp →

BRAF^{V600E}-Mutation →

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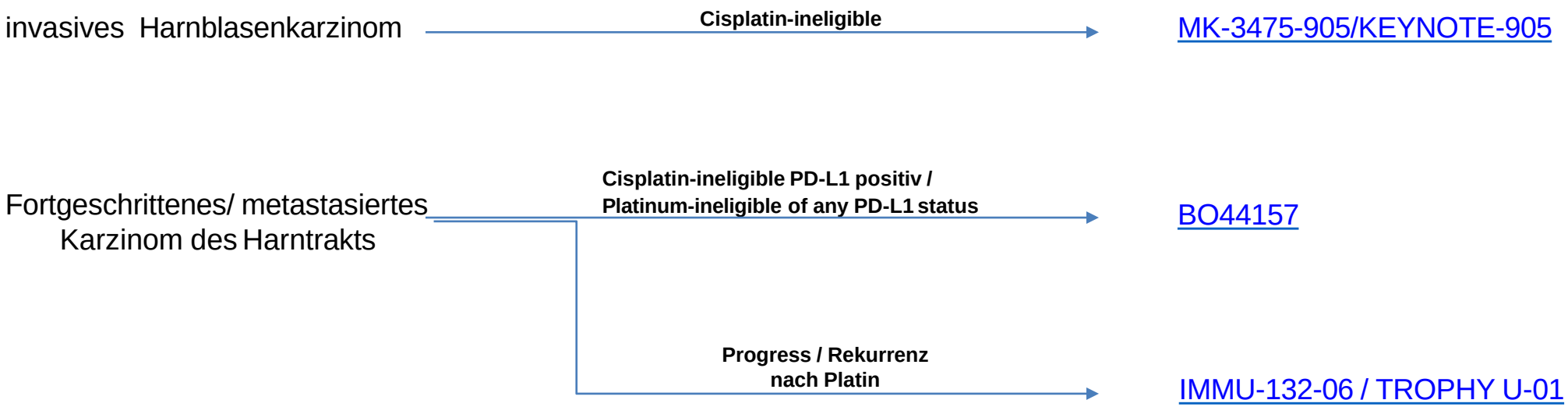
Studienbaum
Urothel-Harnblasenkarzinom



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Studienbaum
Prostatakarzinom

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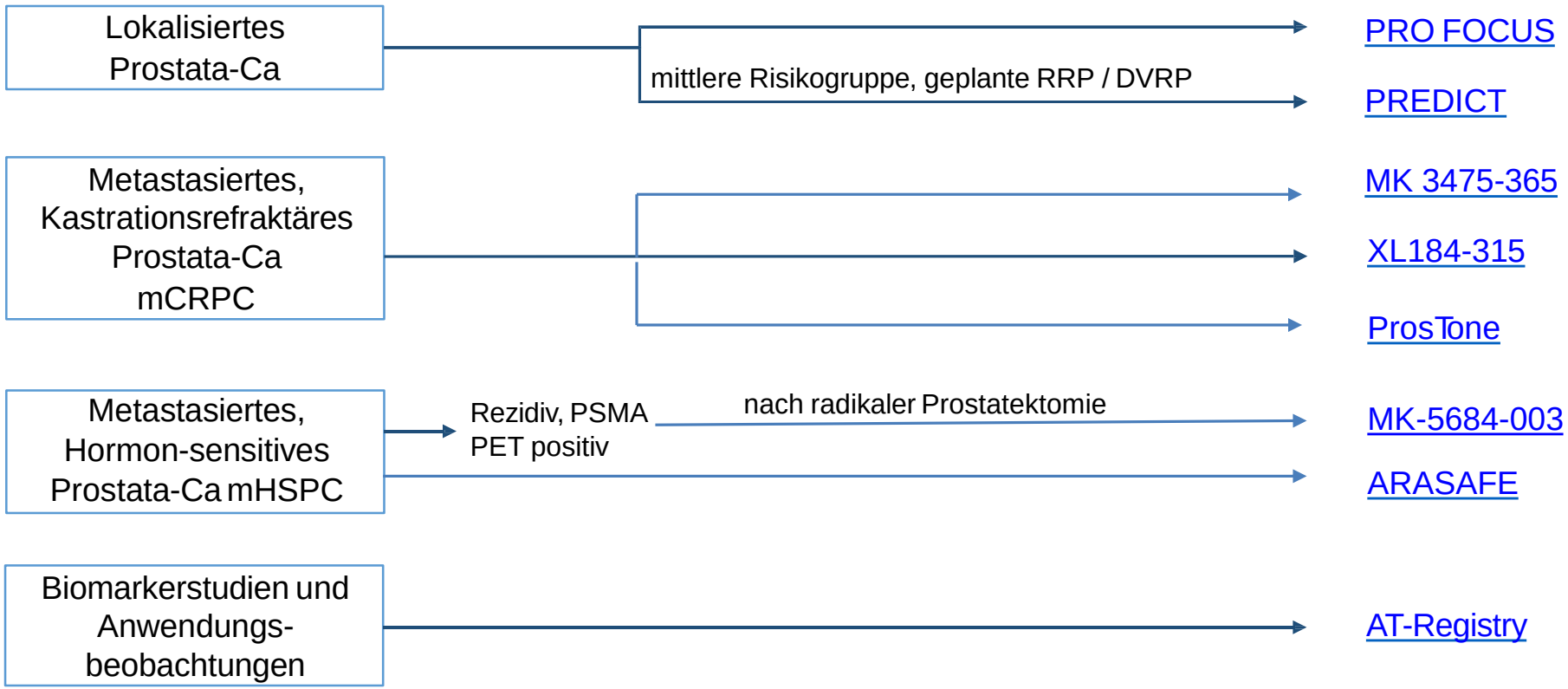

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Studienbaum
Neuroendokrine Tumoren/Karzinome

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GEP-NET → Inoperabel, progressiv, SSTR + → SORENTO

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Studienbaum

Entitätsübergreifende Studien

Hubertus Wald Tumorzentrum
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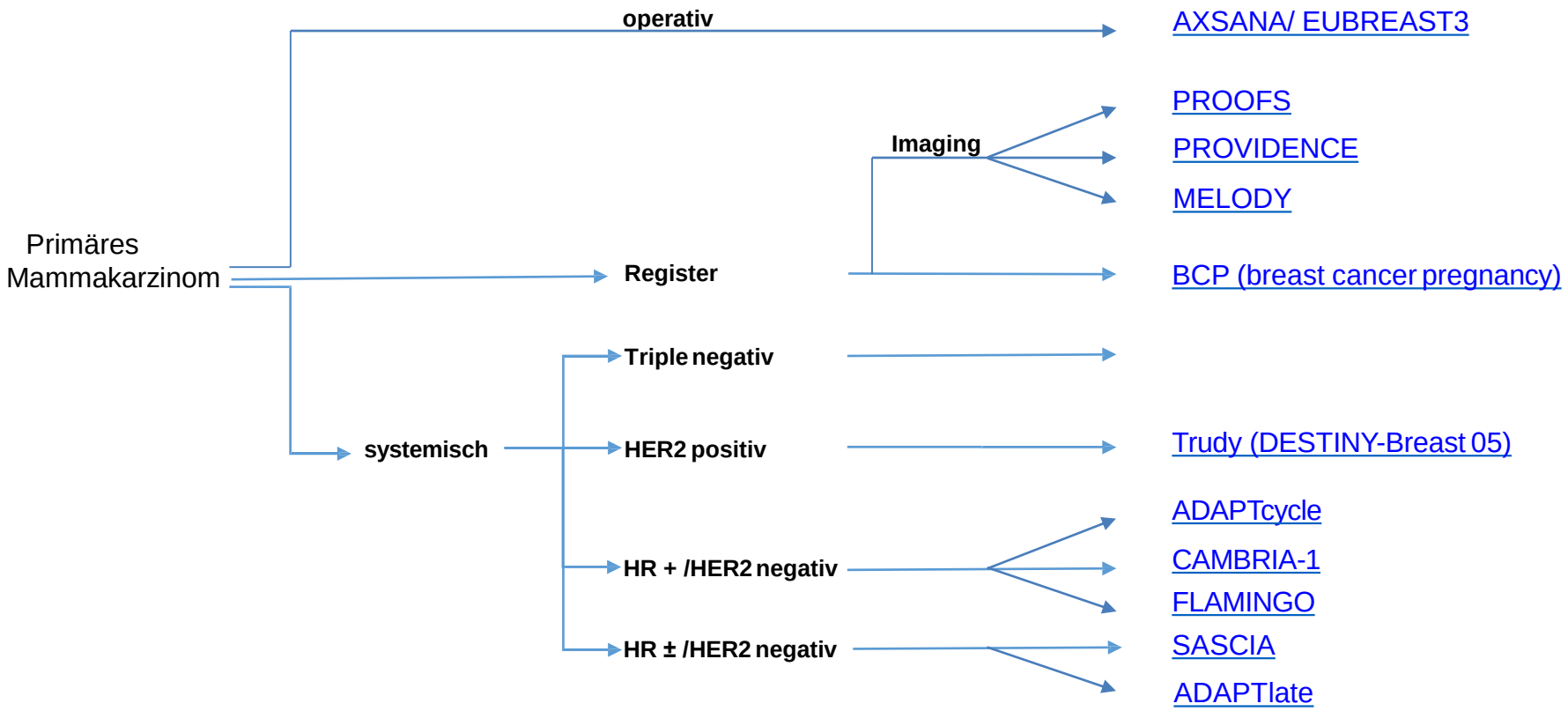
CUP		
Thrombose		
Solide Tumoren	RCC/ HR+BC/ mPCA/ mCRC	STELLAR-001
	PDCA/ mCRC/ mSCCA	REO 029/ GOBLET
		Tapistry (BO41932)
		INJURMET
		L1st-Liquid First
	2nd- & 3rd-Line	CA030-001
Solide Tumoren/Lymphome	Immuntherapiesensible solide Tumoren oder Lymphome mit PD nach Checkpoint-Blokade Therpie mit klinischem Benefit (CR/PR/SD)	PH-IL12L19L19-01/19 - Dodekin
Psychoonkologisches Interventionsprogramm	für schwerkranke Krebspatienten	ORPHYS
Prävention	Junge Menschen zwischen 15 und 39 Jahren nach überstandener Krebserkrankung	
Versorgungsforschung	sek. Immundefekt	PRIVIGEN
	Distress	EXBEL
Pat. in vorheriger Pembrolizumabstudie	Phhase III Extension	MK 3475-587

Entitäten

Studienbaum
Mammakarzinom (primär)



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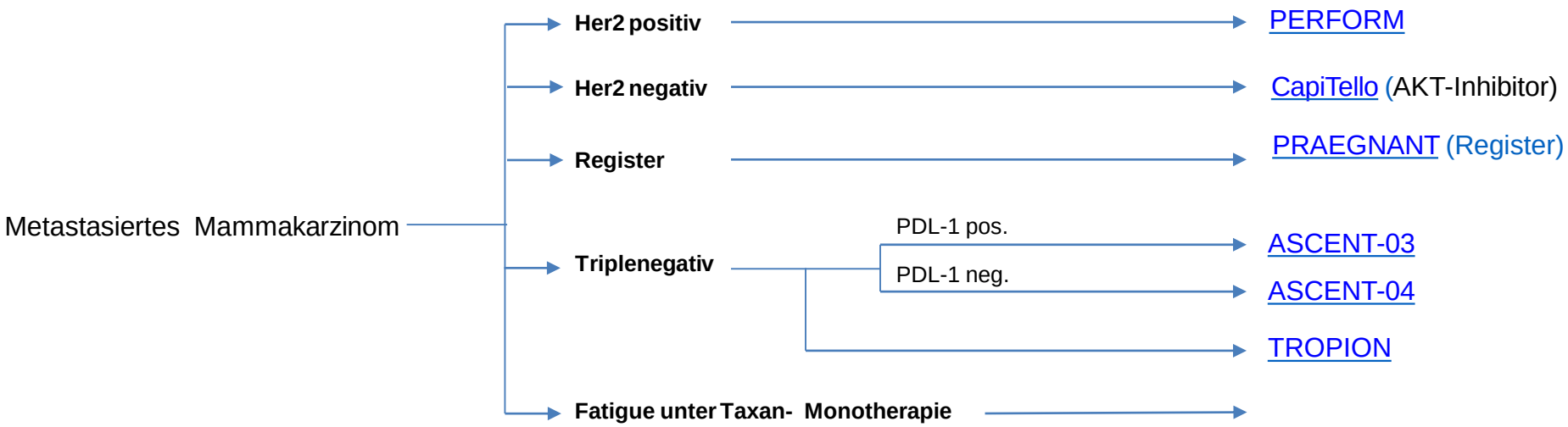
Studienbaum
Mammakarzinom (metastasiert)



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Studienbaum
Gynäkologische Tumore

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

Ansprechpartner im Zentrum für Onkologie
Dr. Jan Dieckmann Tel.: 040-7410-50505

Ansprechpartner Mammazentrum HH
Silke Kaßner, Tel.: 040-44190 669

Ovarialkarzinom

Zervixkarzinom

Endometriumkarzinom

Bitte auch die Möglichkeit eines Studieneinschlusses in die BASKET –Studien überprüfen!

Entitäten

Studienbaum
Ovarialkarzinom

Primäres Ovarialkarzinom → Systemtherapie → AGO-OVAR 28
Systemtherapie → NOGGO ov32 – MAKEI V

Ovarialkarzinom-Rezidiv → Systemtherapie → MIROVA

Bitte auch die Möglichkeit eines Studieneinschlusses in die BASKET –Studien überprüfen!

Entitäten

Studienbaum
Zervix- und Vulvakarzinom

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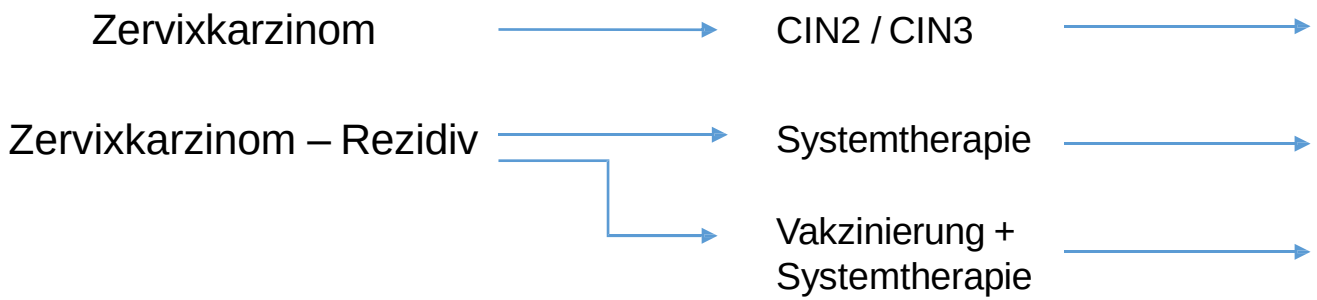

Vulvakarzinom:
Registerstudie zur pelvinen
Lymphonodektomie

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Studienbaum
Endometriumkarzinom

Primäres Endometriumkarzinom → operativ → Eclat

Endometriumkarzinom - Rezidiv → Systemtherapie →

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Studienbaum

Keimzelltumore (Nicht-eminome und Seminome)

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Universitäres Cancer Center Hamburg
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Primärtherapie	→ Seminom IIA/B	→ SAKK 01/18
Salvagetherapie	→ Seminom / Nichtseminom	→ BNT211
Prophylaxe von Hörverlust	→ Hodenkarzinom	→ Acousia

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GOP-Register	Ansprechpartner	PD Dr. Christoph Seidel	01522-2817710	c.seidel@uke.de
Mikro-RNA-Studie	Ansprechpartner	Dr. Christoph Oing	040-7410-52358	c.oing@uke.de

Studienbaum
Sarkome

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

Ansprechpartner im Zentrum für Onkologie
Dr. med. Jana Käthe Striefler Tel. 040/7410-53674

First line metastatic → FIBROSARC

Register → COSS-Register

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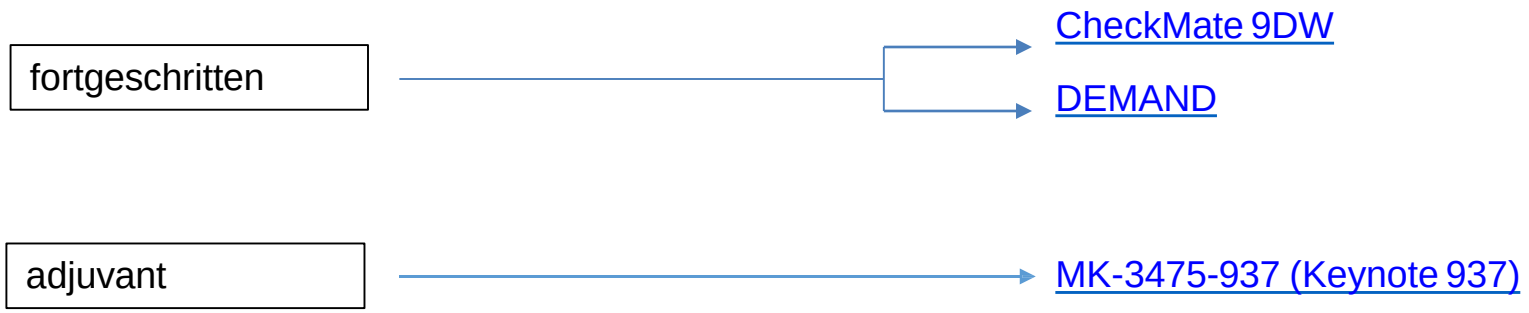
Entitäten

Studienbaum
Hepatocelluläres-Ca



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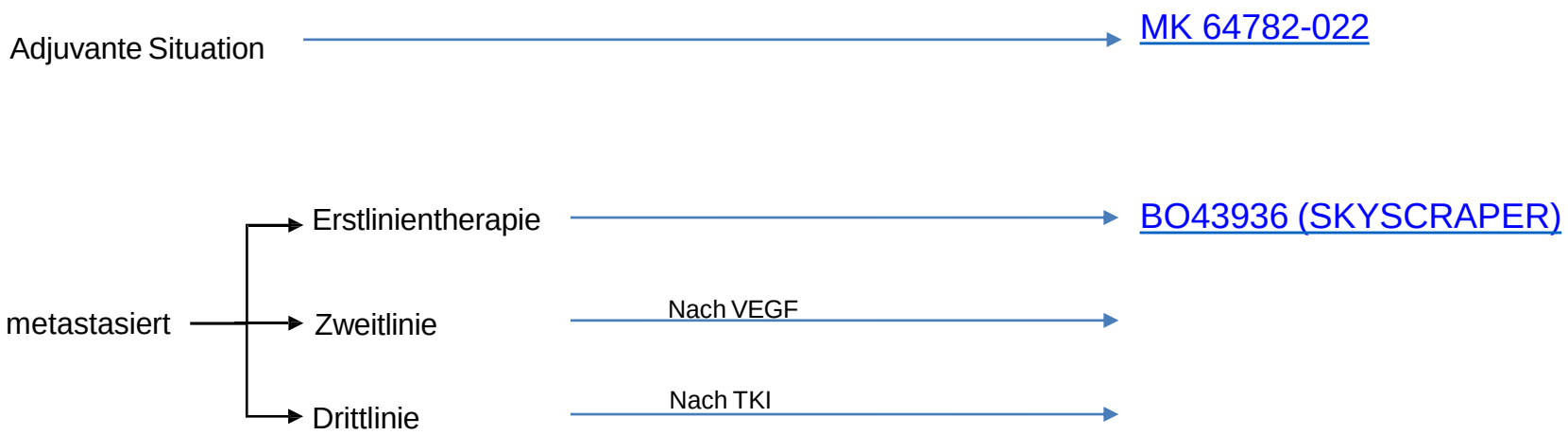
Studienbaum
Nierenzell-Ca



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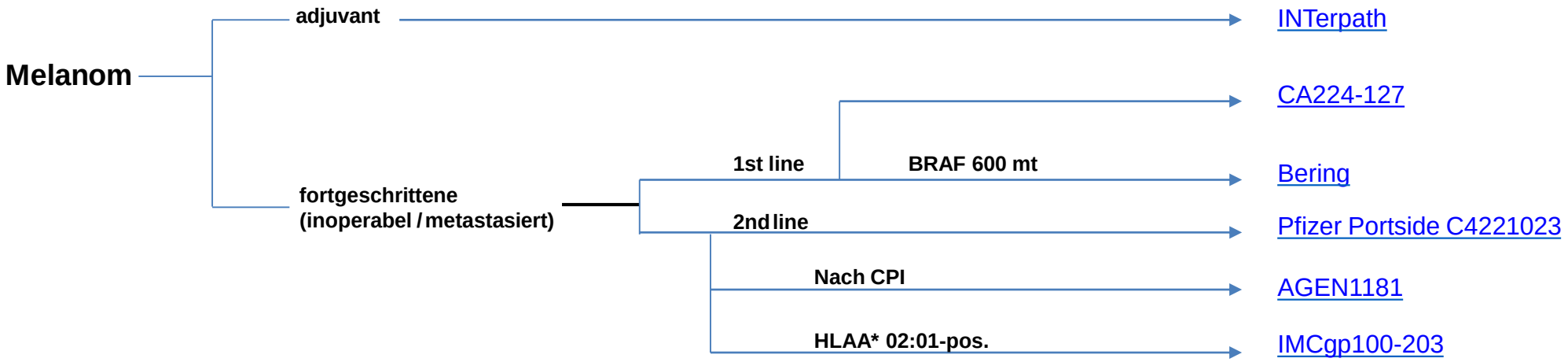
Studienbaum
Dermatoonkologie (Melanom)



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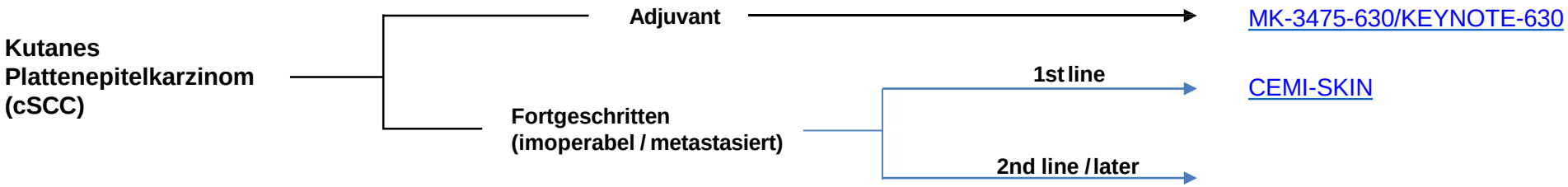
Studienbaum

Dermatologische Neoplasien (cSCC)



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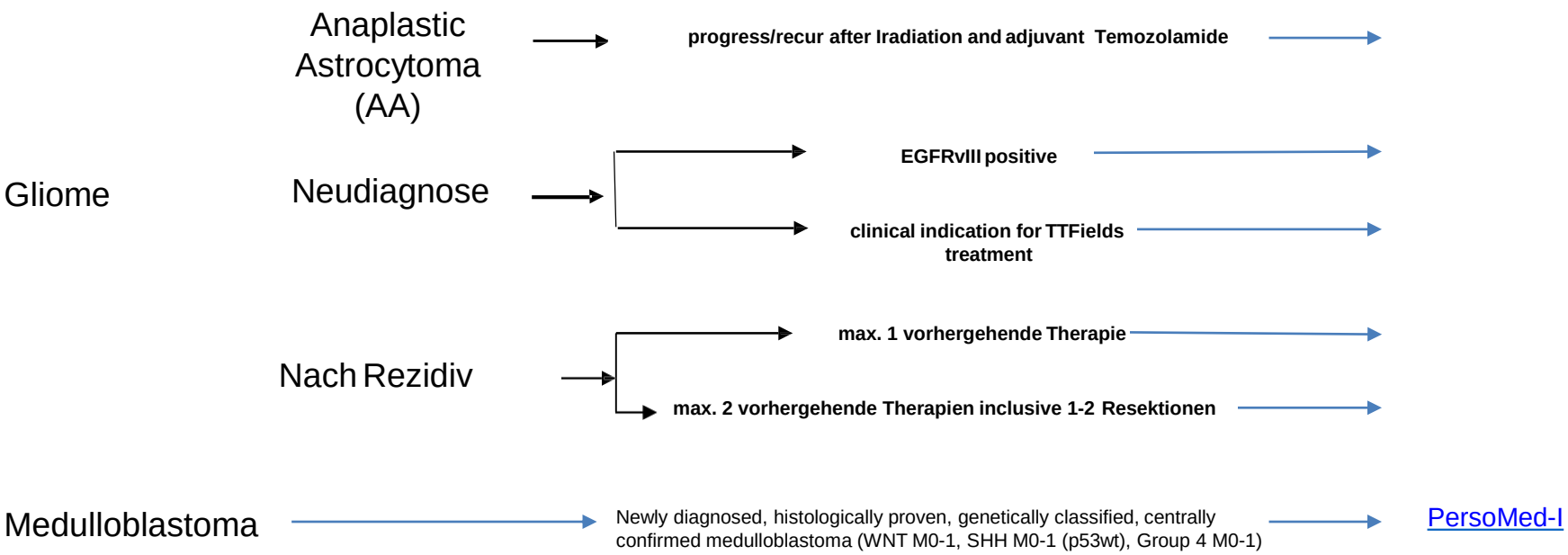
Studienbaum
Hirntumore



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Entitäten

Studienbaum
GIST-Tumore

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

Ansprechpartner im Zentrum für Onkologie
PD Dr. Marianne Sinn, Tel.: 040-7410-70434

GIST —adjuvant→ SSGXXII

Bitte auch die Möglichkeit eines Studieneinschlusses in die BASKET –Studien überprüfen!

Studienbaum

Nebenwirkungen onkologischer Therapien

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

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Studienbaum
Pädiatrische Onkologie und Hämatologie

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

Ansprechpartner im Zentrum für Onkologie
Kay Witetschek, Tel.: 040-7410-56822

Studien und Registerstudien der GPOH

http://www.kinderkrebsinfo.de/e1676/e9032/index_ger.html

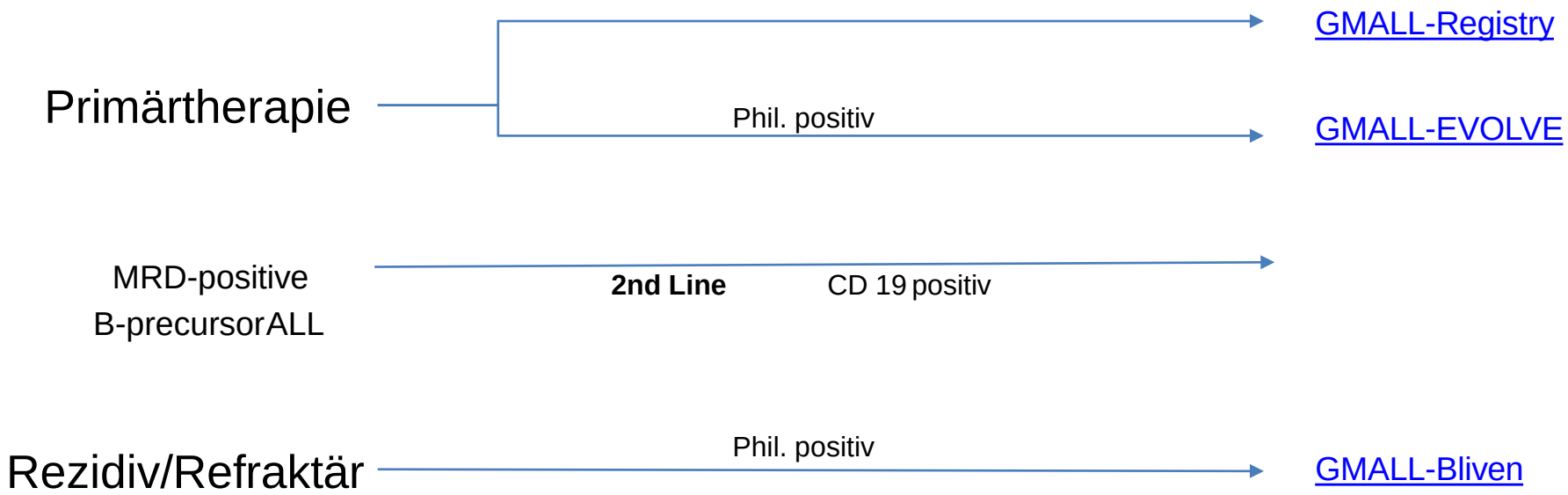
Studienverbund Pädiatrische Hämatologie und Onkologie Nordwest – Gemeinsam für eine bessere Medizin. (studienverbund-nordwest.de)

Neurofibromatosis Type I → D1346R00004

Studienbaum
ALL

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

Ansprechpartner im Zentrum für Onkologie
Prof. Dr. Walter Fiedler, Tel.: 040-7410-53919



Bitte auch die Möglichkeit eines Studieneinschlusses in die BASKET –Studien überprüfen!

Studienbaum
AML

Hubertus Wald Tumorzentrum
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Ein Kompetenznetzwerk des UKE

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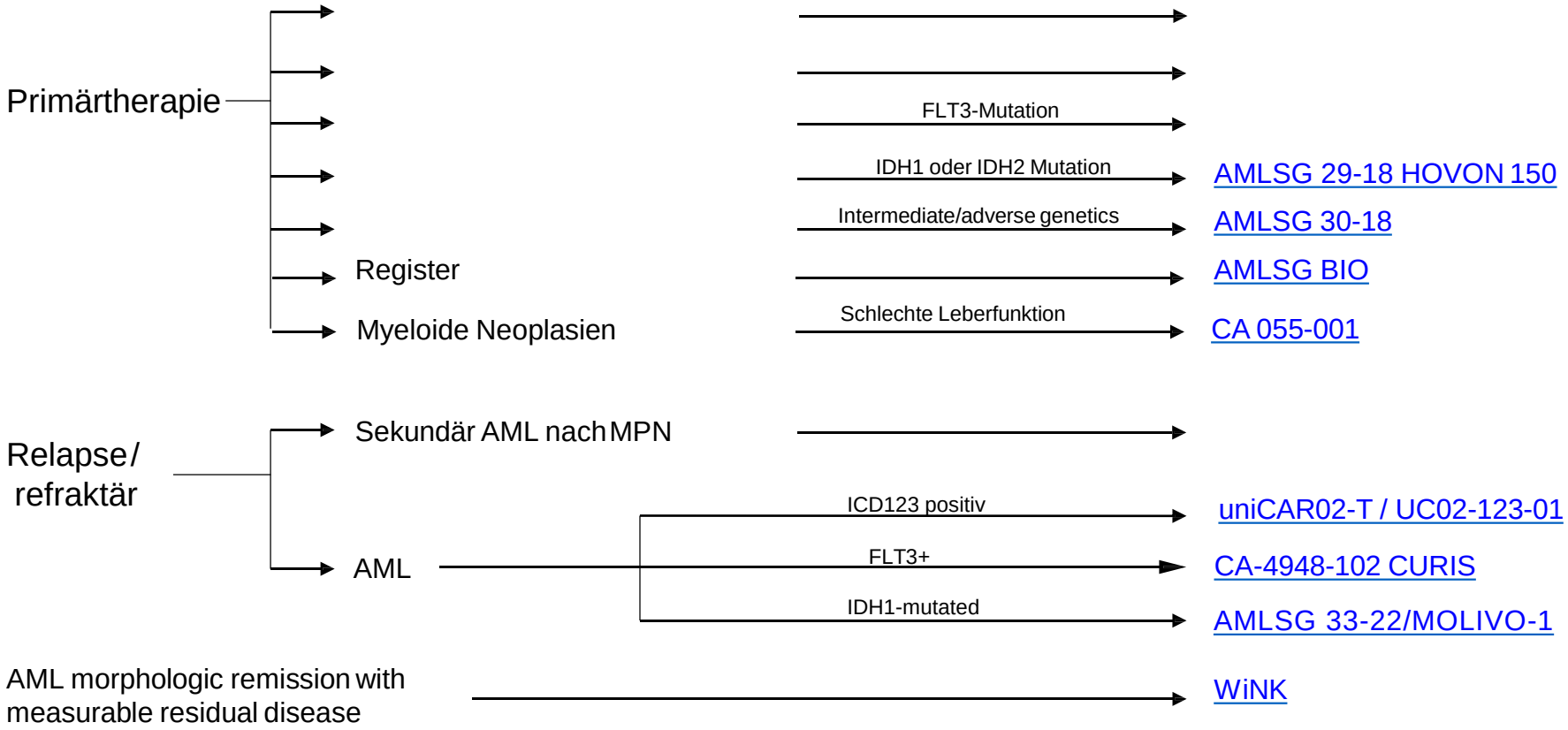
Alle AML-Patienten werden in die AML-Registerstudie aufgenommen!



Bitte auch die Möglichkeit eines Studieneinschlusses in die BASKET – Studien überprüfen!

Entitäten

Studienbaum
CLL

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
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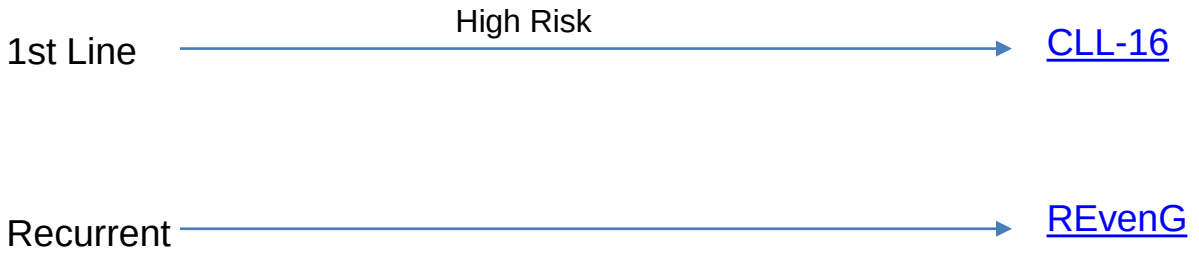

Bitte auch die Möglichkeit eines Studieneinschlusses in die BASKET –Studien überprüfen!

Studienbaum
CML

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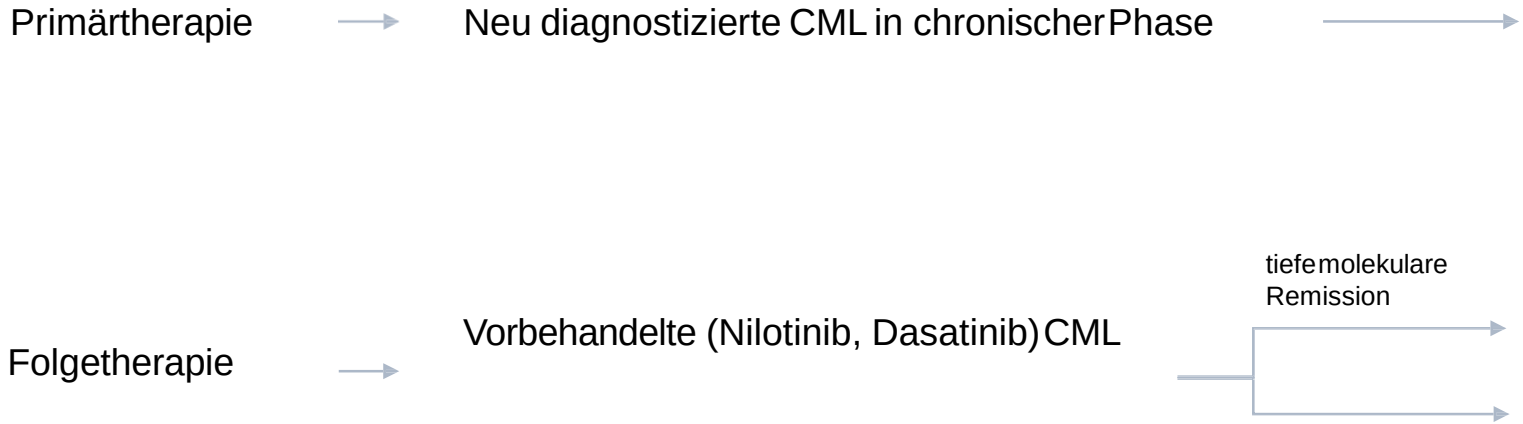

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Entitäten

Studienbaum
MDS

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

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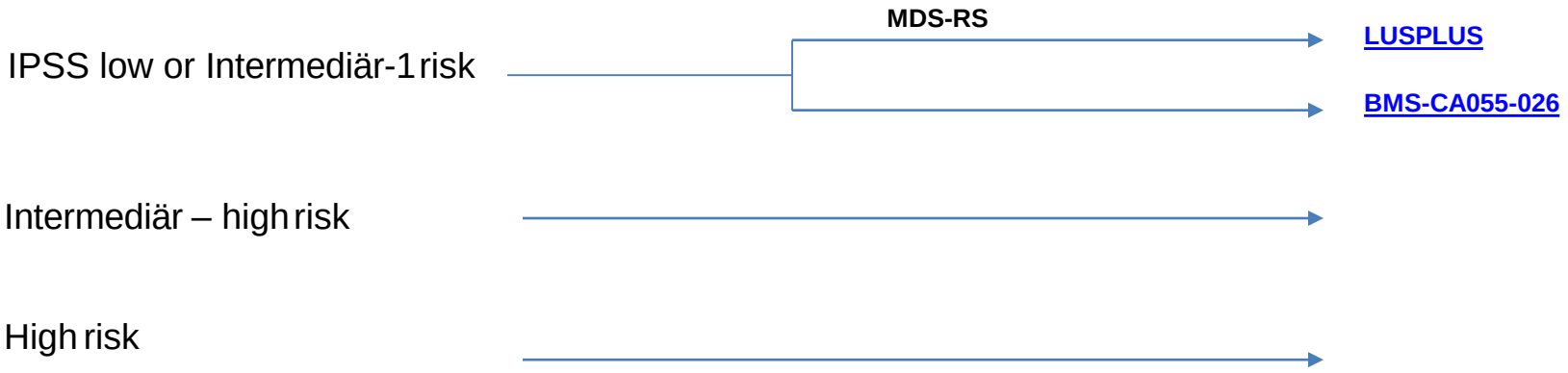
Dr. Anne Marie Asemissen, Tel.: 040-7410-0



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Studienbaum
Morbus Hodgkin

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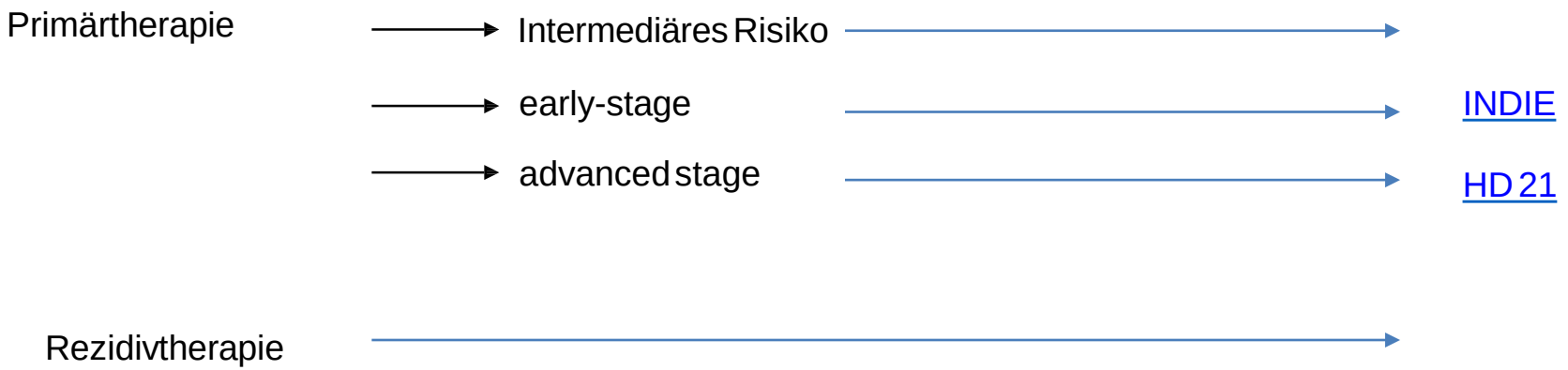

Bitte auch die Möglichkeit eines Studieneinschlusses in die BASKET –Studien überprüfen!

Entitäten

Studienbaum
MPN

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PD Dr. Gunhild von Amsberg Tel.: 040-7410-53962

Patienten mit Primärer and SekundärerMyelofibrose	→	INDEPENDENCE
Relapsed/ Refractory	→	TRANSFORM-2
Polycythemia vera (PV) oderr essentielle Thrombocythemia (ET)	→	
Register	→	GSG - MPN-Register

Bitte auch die Möglichkeit eines Studieneinschlusses in die BASKET –Studien überprüfen!

Studienbaum
Multiples Myelom

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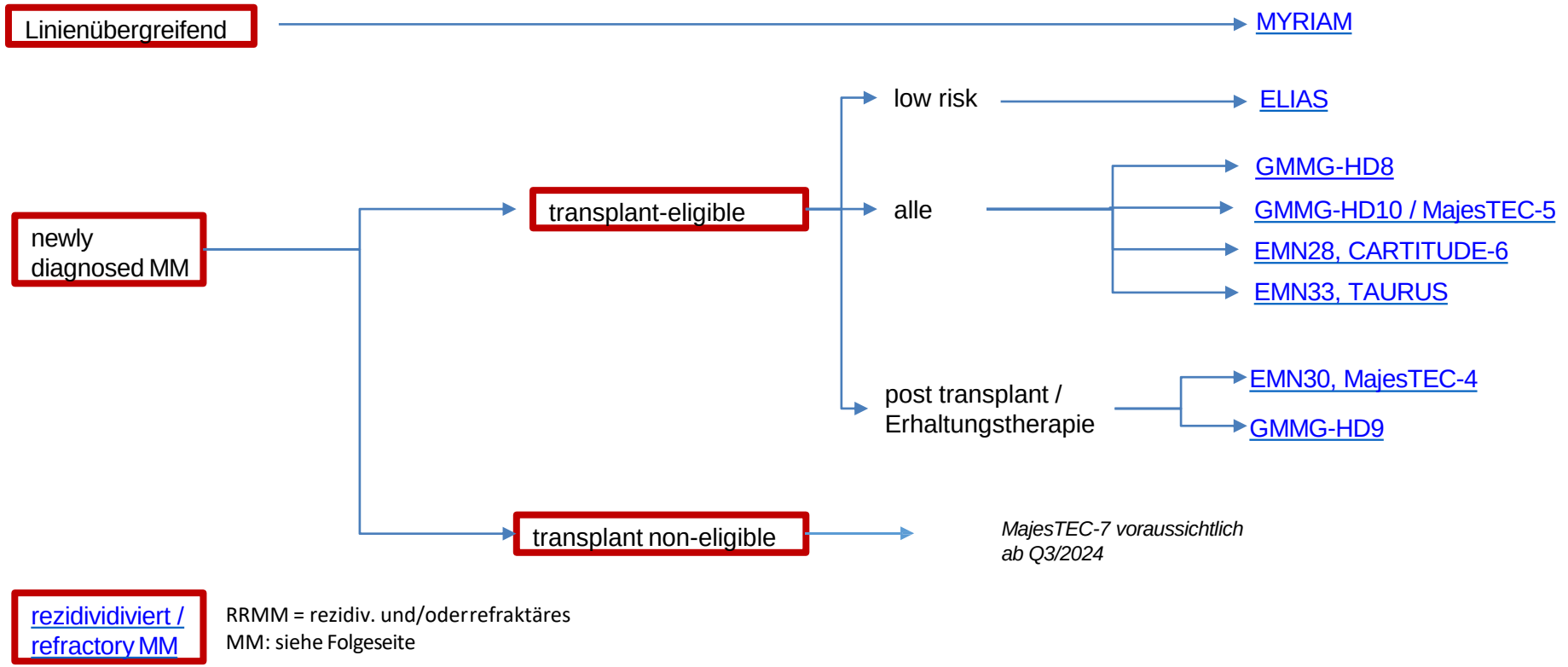
Prof. Dr. Katja Weisel, Tel.: 040-7410-58787



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Studienbaum
Multiples Myelom

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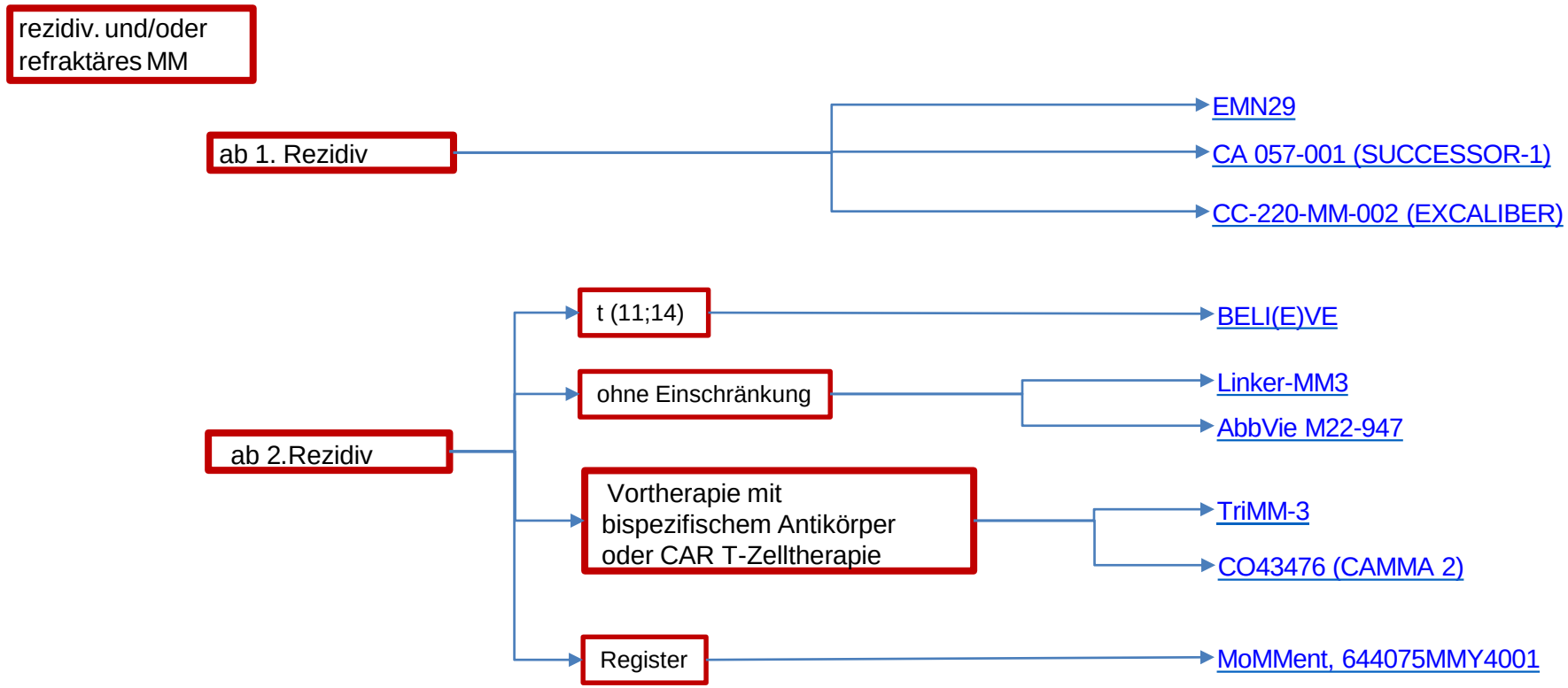

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Entitäten

Studienbaum
Multiples Myelom

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Ein Kompetenznetzwerk des UKE

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Prof. Dr. Katja Weisel, Tel.: 040-7410-58787

RRMM, ≥ 3 Vortherapien

Bitte auch die Möglichkeit eines Studieneinschlusses in die BASKET –Studien überprüfen!

Studienbaum
NHL

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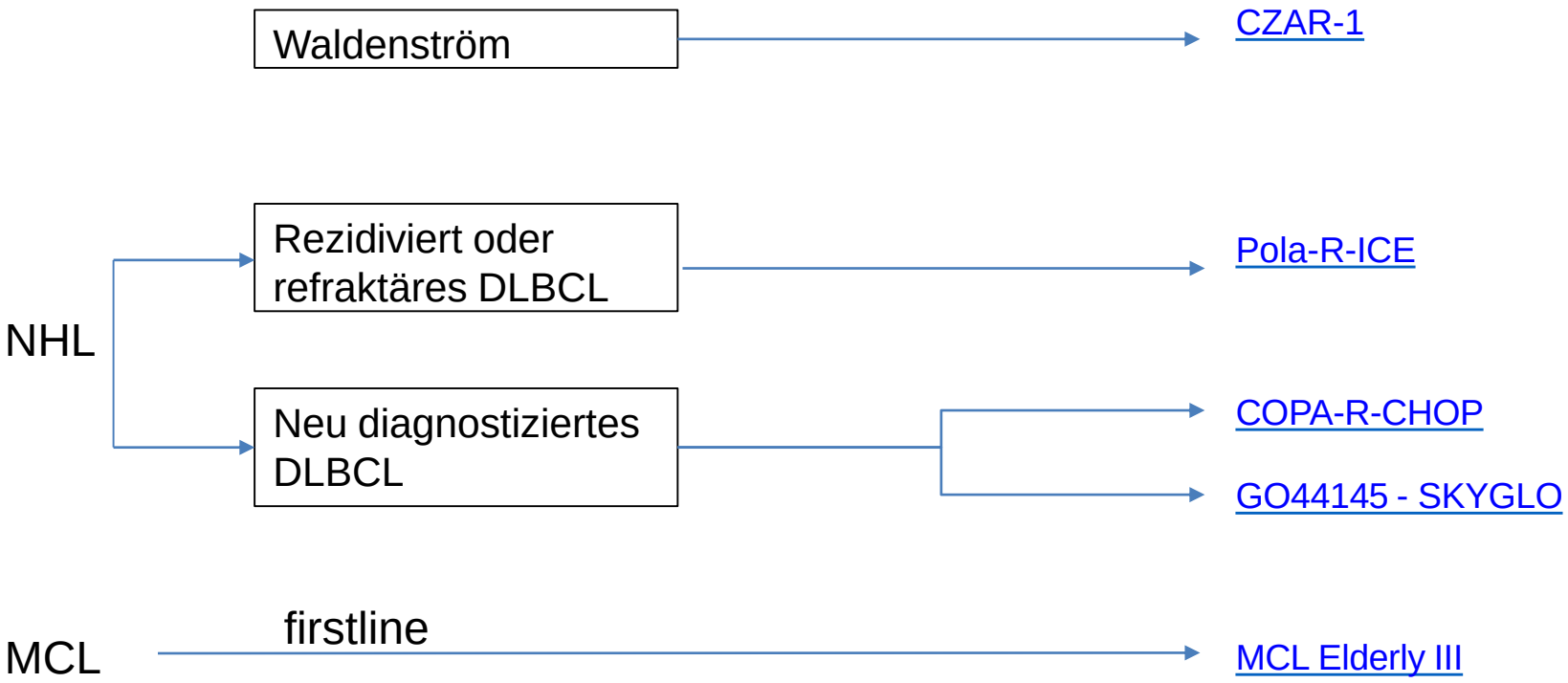

Bitte auch die Möglichkeit eines Studieneinschlusses in die BASKET –Studien überprüfen!

Studienbaum
ZNS-NHL

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Primary → OptiMATe

Bitte auch die Möglichkeit eines Studieneinschlusses in die BASKET –Studien überprüfen!

Entitäten

Studienbaum
Anämien

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Dr. Anne Marie Asemissen, Tel.: 040-7410-0

Sickle cell anemia → HIBISCUS

Aplastic anemia →

Bitte auch die Möglichkeit eines Studieneinschlusses in die BASKET –Studien überprüfen!

Entitäten

Studienbaum
Amyloidose

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

Neudiagnose Systemische AL Amyloidose → Cardiag

Bitte auch die Möglichkeit eines Studieneinschlusses in die BASKET – Studien überprüfen!

Entitäten

Studienbaum
Zelluläre Therapien

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Prof. Dr. med. Katja Weisel, Tel.: 040-7410-58787

Prof. Dr. med. Walter Fiedler, Tel.: 040-7410-53919
Dr. med. Winfried Alsdorf, Tel.: 01522-281 7664

AML/ALL/BPDCN → **(CD 123+) rezidiviert/refraktär**

Solide Tumore
HLA Genotyp A 02*01 → **PRAME +, Standardtherapien ausgeschöpft** → IMA 203-101

Solide Tumore → **CLAUDIN 6 +, Standardtherapien ausgeschöpft** → BNT 211

Bitte auch die Möglichkeit eines Studieneinschlusses in die BASKET –Studien überprüfen!

Entitäten

Studienbaum
ITP

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

ITP —Primär/ sekundär→ ITP-Registry

Bitte auch die Möglichkeit eines Studieneinschlusses in die BASKET –Studien überprüfen!

ABC-lung (ETOP_15-19)

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

A Randomised Non-comparative Open Label Phase II Trial of Atezolizumab Plus Bevacizumab, With Carboplatin-paclitaxel or Pemetrexed, in EGFR-mutant Non-small Cell Lung Carcinoma With Acquired Resistance

Recruitment Status: ACTIVE, NOT RECRUITING

ETOP 15-19 ABC-lung is an international, multi-centre open-label, randomized phase II trial with two non-comparative parallel arms of atezolizumab plus bevacizumab with carboplatin-paclitaxel (Arm A) or atezolizumab, bevacizumab and pemetrexed (Arm B) in patients with stage IIIB-IV non-squamous non-small cell lung cancer (NSCLC) harbouring EGFR mutations after failure of standard EGFR tyrosine kinase inhibitors (TKIs).

Condition: EGFRmutant Stage IIIB/C or IV Non-squamous NSCLC

Primary Completion Date: 2024-12

Intervention / Treatment: Drug (Atezolizumab/ Bevacizumab/ Carboplatin/ Paclitaxel/ Pemetrexed)

Inclusion criteria: Patients (male/female) must be ≥18 years of age. Chemotherapy naïve, non-squamous NSCLC, stage IIIB/C (not amenable to radical therapy) or IV. Patients who have received previous adjuvant or neoadjuvant chemotherapy are eligible if the date of last dose of treatment was at least 12 months before randomisation. Known EGFR mutations genotypes by tissue or ctDNA, patients with common mutations (L858R or Del19) and other rare mutations (e.g. S768I, G719X) are eligible. Measurable or evaluable disease by RECIST v1.1. Disease progression (during or after) or unacceptable side effects from prior treatment with at least one EGFR TKI (washout period = 7 days). If most recent line of treatment (1st or 2nd line) was a third-generation EGFR TKI (e.g. osimertinib):Patient must be known to be EGFR mutation positive, either on fresh tumour biopsy taken >7 days prior to protocol treatment start or by recent ctDNA analysis (informative ctDNA test, local test). T790M genotype is allowed If most recent line of treatment (1st or 2nd line) was a first- or second-generation EGFR TKI (e.g. afatinib, dacomitinib, erlotinib, gefitinib): - Patient must be known to be tissue EGFR T790M wild type (local test) on most recent line of EGFR TKI or if no tissue re-biopsy, no evidence of T790M on ctDNA but identified L858R, del19, S768I or G719X genotypes (informative ctDNA test, local test) Treatment with an EGFR TKI therapy for at least 30 days Adequate haematological function: Haemoglobin greater or equal 90 g/L Absolute neutrophils count (ANC) greater or equal 1.5× 109/L Platelet count greater or equal 100× 109/L Adequate renal function: • Creatinine clearance greater or equal 45 mL/min (using the Cockcroft-Gault formula) Adequate liver function: ALT and AST less or equal 2.5× ULN. If the patient has liver metastases, ALT and AST must be less or equal 5× ULN Total bilirubin less or equal 1.5x ULN. Willingness to provide any surplus tumour sample obtained at the time of acquired resistance to prior EGFR TKI Men and women of childbearing potential must agree to use adequate contraception Eastern Cooperative Oncology Group (ECOG) performance status 0-1 Life expectancy greater or equal 12 weeks Women of childbearing potential, including women who had their last menstrual period in the last 2 years, must have a negative serum or urine pregnancy test within 7 days before randomisation. Patient is willing and able to comply with the protocol for the duration of the trial including undergoing treatment and scheduled visits and examinations including follow up.

Weitere Informationen unter ClinicalTrials.gov/NCT04245085

Lungenclinic Großhansdorf

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	Dr. med. Marlitt Horn	04102 / 601 2104	m.horn@lungenclinic.de

Entitäten

„DeLLphi-301“

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

A **Phase 2** Study Evaluating the Efficacy, Safety, Tolerability, and Pharmacokinetics of AMG 757 in Subjects With Relapsed/Refractory Small Cell Lung Cancer After Two or More Prior Lines of Treatment

Recruitment Status: ACTIVE, NOT RECRUITING

The main aim of this study is to:
-evaluate safety and efficacy (per Response Evaluation Criteria in Solid Tumors version 1.1 [RECIST 1.1] by investigator) of 2 dose levels of Tarlatamab for Part 1 only

-evaluate anti-tumor activity of Tarlatamab as determined by objective response rate (ORR) per RECIST 1.1 by blinded independent central review (BICR) for Part 1 and 2

Condition: Relapsed/Refractory Small Cell Lung Cancer
Primary Completion Date: 2024-10-31
Intervention / Treatment: Drug: Tarlatamab

Inclusion criteria: Participant has provided informed consent/assent prior to initiation of any study specific activities/procedures. Male and female participants ≥ 18 years of age (or legal adult age within country) at the time of signing the informed consent. Histologically or cytologically confirmed relapsed/refractory SCLC Participants who progressed or recurred following 1 platinum-based regimen and at least 1 other prior line of therapy. Participants willing to provide archived tumor tissue samples or willing to undergo pretreatment tumor biopsy. Eastern Cooperative Oncology Group (ECOG) performance status of 0 1. Minimum life expectancy of 12 weeks. Measurable lesions as defined per RECIST 1.1 within 21 days prior to the first dose of tarlatamab. Participants with treated brain metastases are eligible provided they meet defined criteria.

Weitere Informationen unter: **https://clinicaltrials.gov/NCT05060016**

Lungenclinic Großhansdorf

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	Dr. med. Marlitt Horn	04102 / 601 2104	m.horn@lungenclinic.de

Entitäten

HUDSON

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

An Open-Label, Multi-Drug, Biomarker-Directed, Multi-Centre Phase II Umbrella Study in Patients With Non-Small Cell Lung Cancer, Who Progressed on an Anti-PD-1/PD-L1 Containing Therapy (HUDSON).

Recruitment Status: ACTIVE, NOT RECRUITING

This is an open-label, multi-centre, umbrella Phase II study in patients with metastatic NSCLC who have progressed on an anti-PD-1/PD-L1 containing therapy. This study is modular in design, allowing initial assessment of the efficacy, safety, and tolerability of multiple treatment arms.

Condition: Non-Small Cell Lung Cancer

Primary Completion Date: 2024-10-31

Intervention / Treatment: Drug: Durvalumab/ AZD9150/ AZD6738/ Vistusertib/ Olaparib/ Oleclumab/ Trastuzumab deruxtecan/ Cediranib/ AZD6738

Inclusion criteria: At least 18 years of age at the time of signing the informed consent form.Patient must have histologically or cytologically confirmed metastatic or locally advanced and recurrent NSCLC which is progressing. Patients eligible for second- or later-line therapy, who must have received an antiPD1/PD-L1 containing therapy and a platinum-doublet regimen for locally advanced or metastatic NSCLC either separately or in combination. Prior durvalumab is acceptable. The patient must have had disease progression on a prior line of antiPD1/PD-L1 therapy. ECOG/WHO performance status of 0 to 1, and a minimum life expectancy of 12 weeks. Patient must have at least 1 lesion that can be accurately measured. A previously irradiated lesion can be considered a target lesion if the lesion has clearly progressed. Evidence of post-menopausal status or negative urinary or serum pregnancy test for female pre-menopausal patients.

Exclusion Criteria: Patients whose tumour samples have targetable alterations in EGFR and/or ALK at initial diagnosis are excluded. In addition, patients whose tumour samples are known to have targetable alterations in ROS1, BRAF, MET or RET, are to be excluded. Active or prior documented autoimmune or inflammatory disorders. Active infection including tuberculosis, hepatitis B (known positive HBV surface antigen [HBsAg] result), hepatitis C, or human immunodeficiency virus (positive HIV 1/2 antibodies). Female patients who are pregnant or breastfeeding, or male or female patients of reproductive potential who are not willing to employ effective birth control. Known allergy or hypersensitivity to any of the study drugs or any of the study drug excipients, or history of severe hypersensitivity reactions to other monoclonal antibodies. Patient has spinal cord compression or symptomatic brain metastases. Any concurrent chemotherapy, immunotherapy, biologic or hormonal therapy for cancer treatment. Patients may receive treatment with bisphosphonates or receptor activator of nuclear factor kappa-B ligand (RANKL) inhibitors for the treatment of bone metastases. history of active primary immunodeficiency

Weitere Informationen unter: https://clinicaltrials.gov/NCT03334617

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Entitäten

KRYSTAL-7

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

A **Phase 2/3** Trial of MRTX849 Monotherapy and in Combination With Pembrolizumab in Patients With Advanced Non-Small Cell Lung Cancer With KRAS G12C Mutation

Recruitment Status: RECRUITING

Condition: Advanced or/and Metastatic Non-Small Cell Lung Cancer,

Primary Completion Date: 2029-10-31

Intervention / Treatment: Drug: Adagrasib/ Pembrolizumab

Inclusion Criteria:
Phase 2: Histologically confirmed diagnosis of unresectable or metastatic NSCLC with KRAS G12C mutation and any PD-L1 TPS
Phase 3: Histologically confirmed diagnosis of unresectable or metastatic squamous or nonsquamous NSCLC with KRAS G12C mutation and PD-L1 TPS >=50%
Phase 3: Presence of evaluable or measurable disease per RECIST
Phase 3: CNS Inclusion - Based on screening brain imaging, patients must have one of the following: No evidence of brain metastases Untreated brain metastases not needing immediate local therapy Previously treated brain metastases not needing immediate local therapy
Exclusion Criteria:
Phase 2 and Phase 3: Prior systemic treatment for locally advanced or metastatic NSCLC including chemotherapy, immune checkpoint inhibitor therapy, or a therapy targeting KRAS G12C mutation (e.g., AMG 510).
Phase 2: Active brain metastases
Phase 3: Patients with known central nervous system (CNS) lesions must not have any of the following: Any untreated brain lesions > 1.0 cm in size Any brainstem lesions Ongoing use of systemic corticosteroids for control of symptoms of brain lesions at a total daily dose of > 10 mg of prednisone (or equivalent) prior to randomization. Have poorly controlled (> 1/week) generalized or complex partial seizures, or manifest neurologic progression due to brain lesions notwithstanding CNS-directed therapy Phase 3: Radiation to the lung > 30 Gy within 6 months prior to the first dose of study treatment

Weitere Informationen unter: **https://clinicaltrials.govNCT04613596**

Lungenclinic Großhansdorf

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Entitäten

MK-3475-587/ KEYNOTE-587

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

A Multicenter, Open Label, Phase III Extension Trial to Study the Long-term Safety and Efficacy in Participants With Advanced Tumors Who Are Currently on Treatment or in Follow-up in a Pembrolizumab Trial

Recruitment Status: RECRUITING

Weitere Informationen unter: **https://clinicaltrials.gov/NCT03486873**

The purpose of this study is to evaluate the long-term safety and efficacy of pembrolizumab (MK-3475) in participants from previous Merck pembrolizumab-based parent studies who transition into this extension study.

Condition: Solid Tumors, Hematologic Malignancies

Primary Completion Date: 2043-08-04

Intervention / Treatment: Drug: (Pembrolizumab [MK-3475(Keytruda]/ Standard of Care [SOC]/ Lenvatinib

Inclusion criteria: Treated on the parent pembrolizumab studies established by the Sponsor as MK-3475-587 ready. Currently receiving pembrolizumab, pembrolizumab based combinations or lenvatinib from parent studies or in a follow-up phase. Additional eligibility criteria for participants who enter Second Course Phase once they are enrolled on MK-3475-587: Has not received any anticancer systemic treatment since the last dose of embrolizumab or a pembrolizumab-based combination in First Course Phase. Has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1. Demonstrates adequate organ function. Have resolution of any toxic effect(s) of First Course Phase trial treatment with pembrolizumab or a pembrolizumab-based combination to Grade 1 or less (except alopecia) before trial treatment in Second Course Phase is started. If participant received major surgery or radiation therapy of >30 Gray (Gy), they must have recovered from the toxicity and/or complications of the intervention. A female participant is eligible to enroll if she is not pregnant, not breastfeeding, and ≥1 of the following conditions applies: A woman of childbearing potential (WOCBP) who agrees to use contraception during the study treatment period and for ≥120 days (corresponding to time needed to eliminate any study combination reatment(s) plus 30 days (a menstruation cycle) for study treatments with risk of genotoxicity. Additional eligibility criteria for participants who enter dosing with Lenvatinib: Adequately controlled blood pressure (BP) to <150/90 mmHg, with or without antihypertensive medications. For male agrees to be abstinent from penile-vaginal intercourse OR agrees to use a highly effective contraceptive method while receiving study drug and for 7 days after the last dose of lenvatinib. Is female and not pregnant/breastfeeding and at least one of the following applies during the study and for ≥4 days after: is not a woman of childbearing potential (WOCBP), is a WOCBP and uses highly effective contraception (low user dependency method OR a user dependent hormonal method in combination with a barrier method) or is a WOCBP who is abstinent from heterosexual intercourse.

	Lungclinic Großhansdorf			HOPE		
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Study Nurse						

Entitäten

STAR-121/ GS-US-626-6216

Hubertus Wald Tumorzentrum
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Ein Kompetenznetzwerk des UKE

Zimberelimab and Domvanalimab in Combination With Chemotherapy Versus Pembrolizumab With Chemotherapy in Patients With Untreated Metastatic Non-Small Cell Lung Cancer (STAR-121)

Recruitment Status: RECRUITING

A Randomized, Open-Label, Phase 3 Study to Evaluate Zimberelimab and Domvanalimab in Combination With Chemotherapy Versus Pembrolizumab With Chemotherapy for the First-Line Treatment of Patients With Metastatic Non-Small Cell Lung Cancer With No Epidermal Growth Factor Receptor or Anaplastic Lymphoma Kinase Genomic Tumor Aberrations

Weitere Informationen unter: **https://clinicaltrials.gov/NCT05502237**

Condition: Non-small Cell Lung Cancer

Primary Completion Date: 20274-09

Intervention/ Treatment: Drug (Zimberelimab/ Domvanalimab/ Pembrolizumab/ Carboplatin/ Cisplatin/ Paclitaxel/ Nab-paclitaxel/ Pemetrexed

Inclusion Criteria: Life expectancy ≥ 3 months. Pathologically documented NSCLC that meets both of the criteria below: Have documented evidence of Stage IV NSCLC disease at the time of enrollment (based on American Joint Committee on Cancer (AJCC), Eighth Edition). Have documented negative test results for epidermal growth factor receptor (EGFR) and anaplastic lymphoma kinase (ALK) mutations. Have no actionable genomic alterations such as ROS proto-oncogene 1 (ROS1), neurotrophic tyrosine receptor kinase (NTRK), proto-oncogene B-raf (BRAF), RET mutations, or other driver oncogenes with approved frontline therapies. Have not received prior systemic treatment for metastatic NSCLC. Measurable disease per RECIST v1.1 criteria by investigator assessment. Eastern Cooperative Oncology Group performance status (ECOG PS) score of 0 or 1. Have adequate organ functions.
Exclusion Criteria: Have mixed small-cell lung cancer (SCLC) and NSCLC histology. Positive serum pregnancy test or individuals who are breastfeeding or have plans to breastfeed during the study period. Received prior treatment with any anti-PD-1, anti-PD-L1, or any other antibody targeting an immune checkpoint. Known hypersensitivity to the study drug, its metabolites, or formulation excipient. Have an active second malignancy or have had an active second malignancy within 3 years prior to enrollment. Have an active autoimmune disease that required systemic treatment in past 2 years (i.e., with use of disease-modifying agents, corticosteroids, or immunosuppressive drugs). Are receiving chronic systemic steroids. Have significant third-space fluid retention. Have untreated central nervous system (CNS) metastases and/or carcinomatous meningitis. Active chronic inflammatory bowel disease (ulcerative colitis, Crohn's disease) or gastrointestinal perforation within 6 months of enrollment. Has a history of (noninfectious) pneumonitis/interstitial lung disease that required steroids or has current pneumonitis/interstitial lung disease. Has had an allogenic tissue/solid organ transplant. Have received a live-virus vaccination within 30 days of planned treatment start. Seasonal flu and COVID-19 vaccines that do not contain live virus are permitted. Have known active hepatitis B virus (HBV) or hepatitis C virus (HCV) infection. Note: Other protocol defined Inclusion/Exclusion criteria may apply.

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SI	Dr. med. Barbara Storbeck	04102 / 601 2420	b.storbeck@lungenclinic.de			goekkurt@hope-hamburg.de
Study Nurse						

Entitäten

BO44178 "TOBE" PD1-LAG3 in 1L NSCLC

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

A Study of Tobemstomig Plus Platinum-Based Chemotherapy vs Pembrolizumab Plus Platinum-Based Chemotherapy in Participants With Previously Untreated Non-Small Cell Lung Cancer

Recruitment Status: RECRUITING

A Phase II, Randomized, Multicenter, Double-Blind, Controlled Study Of RO7247669 Plus Platinum-Based Chemotherapy Versus Pembrolizumab Plus Platinum-Based Chemotherapy In Patients With Previously Untreated Locally Advanced Or Metastatic Non-Small Cell Lung Cancer

Condition: Non-small Cell Lung Cancer

Primary Completion Date:

Intervention/ Treatment: Drug (Pembrolizumab)

NCT05775289

Inclusion criteria: Age ≥ 18 years • Eastern Cooperative Oncology Group Performance Status of 0 or 1 • Histologically or cytologically documented locally advanced, unresectable (Stage IIIB) or metastatic (Stage IV) SCLC who are not eligible for curative surgery and/or definitive chemoradiotherapy • No prior systemic treatment for metastatic NSCLC • Known tumor PD-L1 status through a documented local assessment using a health authority-approved PD L1 immunohistochemistry assay • Confirmed availability of representative tumor specimens in formalin-fixed, paraffin-embedded blocks or preferably 15 unstained serial slides, along with an associated pathology report • Measurable disease, as defined by Response Evaluation Criteria in Solid Tumors, Version 1.1 (RECIST v1.1) • Life expectancy ≥ 12 weeks • Adequate hematologic and end-organ Function • Negative human immunodeficiency viruses (HIV) test at screening • Negative hepatitis B surface antigen test at screening • Positive hepatitis B surface antibody (HBsAb) test at screening, or negative HBsAb at screening • Negative hepatitis C virus (HCV) antibody test at screening or positive HCV antibody test by a negative HCV RNA test at screening • Adequate cardiovascular function • For female participants of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraception methods with a failure rate of < 1% per year during the treatment period and for 4 months after the final dose of RO7247669, 5 months after the final dose of pembrolizumab, and 6 months after the final dose of platinum-based chemotherapy. Women must refrain from donating eggs during this same period • For male participants: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive methods that together result in a failure rate of < 1% per year during the treatment period and for 4 months after the final dose of RO7247669 and 6 months after the final dose of pemetrexed, paclitaxel, and carboplatin. Men must refrain from donating sperm during this same period

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Weitere Informationen unter: https://clinicaltrials.gov/NCT05775289

LIBRETTO-431 (LOXO)

Hubertus Wald Tumorzentrum
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A Multicenter, Randomized, Open-Label, **Phase 3** Trial Comparing Selpercatinib to Platinum-Based and Pemetrexed Therapy With or Without Pembrolizumab as Initial Treatment of Advanced or Metastatic RET Fusion-Positive Non-Small Cell Lung Cancer

Recruitment Status: ACTIVE, NOT RECRUITING

Loxo-292 (RET inhibitor) bei NSCLC-Patienten

RET Fusion-positive

- Single agent RET inhibitor vs. Platinum + Alimta +/- Pembrolizumab
- Open-label

Condition: Non-small Cell Lung Cancer

Primary Completion Date: 2023-05-01

Intervention/ Treatment: Drug (Selpercatinib/ Carboplatin/ Cisplatin/ Pemetrexed/ Pembrolizumab

Inclusion Criteria: Histologically or cytologically confirmed, Stage IIIB-IIIC or Stage IV non-squamous NSCLC that is not suitable for radical surgery or radiation therapy. A RET gene fusion in tumor and/or blood from a qualified laboratory. Eastern Cooperative Oncology Group (ECOG) performance status of 0-2. Adequate hematologic, hepatic and renal function. Willingness of men and women of reproductive potential to observe conventional and highly effective birth control for the duration of treatment and for 6 months after. Ability to swallow capsules.
Exclusion criteria: Additional validated oncogenic drivers in NSCLC if known. Prior systemic therapy for metastatic disease. Treatment (chemotherapy, immunotherapy, or biological therapy) in the adjuvant/neoadjuvant setting is permitted if it was completed at least 6 months prior to randomization. Major surgery within 3 weeks prior to planned start of selpercatinib. Radiotherapy for palliation within 1 week of the first dose of study treatment or any radiotherapy within 6 months prior to the first dose of study treatment if more than 30 Gy to the lung. Symptomatic central nervous system (CNS) metastases, carcinomatous meningitis, or untreated spinal cord compression. Clinically significant active cardiovascular disease or history of myocardial infarction within 6 months prior to planned start of selpercatinib or prolongation of the QT interval corrected for heart rate using Fridericia's formula (QTcF) > 470 milliseconds. Active uncontrolled systemic bacterial, viral, or fungal infection or serious ongoing intercurrent illness, such as hypertension or diabetes, despite optimal treatment. Clinically significant active malabsorption syndrome or other condition likely to affect gastrointestinal absorption of the study drug. Pregnancy or lactation. Other malignancy unless nonmelanoma skin cancer, carcinoma in situ of the cervix or other in situ cancers or a malignancy diagnosed ≥2 years previously and not currently active. Uncontrolled, disease related pericardial effusion or pleural effusion. Requiring chronic treatment with steroids. Exclusion Criteria for Participants Receiving Pembrolizumab: History of interstitial lung disease or interstitial pneumonitis. Active autoimmune disease or any illness or treatment that could compromise the immune system.

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Weitere Informationen unter: https://clinicaltrials.gov/NCT04194944

SPACE / AIO-TRK-0119

Hubertus Wald Tumorzentrum
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Single-Arm Phase II-Study in Patients With Extensive Stage Small Cell Lung Cancer (ES-SCLC) With Poor Performance Status Receiving Atezolizumab-Carboplatin-Etoposide

Recruitment Status: ACTIVE NOT RECRUITING

Single-Arm-Studie bei Patienten mit SCLC extensive disease Firstline
With Poor Performance Status = ECOG 2 !!
Mit Atezolizumab-Carboplatin-Etoposide
(SPACE) AIO-Studie, Phase II für „real-life-Daten“

Condition: SCLC, Extensive Stage

Primary Completion Date: 2024-04

Intervention/Treatment: Drug (Atezilizumab)

Inclusion Criteria: Written informed consent including participation in translational research obtained from the subject prior to performing any protocol-related procedures, including screening evaluations that are not SOC. ECOG 2 At least one measurable tumor lesion (according to RECIST1.1) Histologically confirmed small cell lung cancer (SCLC) Stage IV disease (according to UICC8) No active autoimmune disease Adequate organ function defined as: neutrophil count > 1.5 x 109/L thrombocytes ≥ 100 x 109/L hemoglobin ≥ 9 g/dL INR ≤ 1.4 or aPTT ≤ 40 sec during the last 7 days before therapy [Subjects under therapeutic anticoagulation are permitted.] bilirubin < 1.5 x ULN AST (SGOT)/ALT (SGPT) < 3 x institutional ULN (< 5 x ULN in case of liver metastases) creatinine ≤ 1.5 x ULN or creatinine clearance ≥ 45 mL/min Availability of tumor tissue/blockWomen of childbearing potential (WOCBP) must have a negative serum or urine pregnancy test (minimum sensitivity 25 IU/L or equivalent units of HCG) within 72 hours prior to the first dose of IMP. Women of childbearing potential (WOCBP) must use appropriate method(s) of contraception. [WOCBP should use an adequate method to avoid pregnancy for 6 months after the last dose of IMP.] Men who are sexually active with WOCBP must use any contraceptive method with a failure rate of less than 1% per year. Men receiving IMP and who are sexually active with WOCBP will be instructed to adhere to contraception for a period of 6 months after the last dose of IMP. Women who are not of childbearing potential (ie, who are postmenopausal or surgically sterile) and men who are azoospermic do not require contraception. Subject is willing and able to comply with the protocol for the duration of the study including undergoing treatment and scheduled visits and examinations including follow-up.

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MK-7339-012 / KEYLINK-012

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The purpose of this study is to assess the efficacy and safety of pembrolizumab in combination with concurrent chemoradiation therapy followed by either pembrolizumab with olaparib placebo (Arm 1) or with olaparib (Arm 2) compared to concurrent chemoradiation therapy followed by durvalumab (Arm 3) in participants with unresectable, locally advanced NSCLC. Arms 1 and 2 will be studied in a double-blind design and Arm 3 will be open-label.

Recruitment Status: ACTIVE NOT RECRUITING

The purpose of this study is to assess the efficacy and safety of pembrolizumab in combination with concurrent chemoradiation therapy followed by either pembrolizumab with olaparib placebo (Arm 1) or with olaparib (Arm 2) compared to concurrent chemoradiation therapy followed by durvalumab (Arm 3) in participants with unresectable, locally advanced NSCLC. Arms 1 and 2 will be studied in a double-blind design and Arm 3 will be open-label.

Condition: Lung Neoplasms, Carcinoma, Non-Small Cell Lung Cancer

Primary Completion Date: 2026-07-06

Intervention/ Treatment: Drug (Olaparib/ Placebo for Olaparib/ Etoposide/ Carboplatin/ Cisplatin/ Paclitaxel/ Pemetrexed/ Durvalumab, **Radiation:** Thoracic Radiotherapy, **Biological:** Pembrolizumab

Inclusion Criteria**:** Has pathologically (histologically or cytologically) confirmed diagnosis of NSCLC Has Stage IIIA, IIIB, or IIIC NSCLC by American Joint Committee on Cancer Version 8 Is unable to undergo surgery with curative intent for Stage III NSCLC Has no evidence of metastatic disease indicating Stage IV NSCLC Has measurable disease as defined by RECIST 1.1 Has not received prior treatment (chemotherapy, targeted therapy or radiotherapy) for Stage III NSCLC; participants who have received neoadjuvant and/or adjuvant therapy for early stage disease are not eligible Has provided a tumor tissue sample (tissue biopsy [core, incisional, or excisional]) Has an Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1 assessed within 7 days prior to the first administration of study intervention Has a life expectancy of at least 6 months A male participant must agree to use contraception and refrain from donating sperm during the intervention period and for at least the time needed to eliminate each study intervention after the last dose of study intervention unless confirmed to be azoospermic (vasectomized or secondary to medical cause). The length of time required to continue contraception for each study intervention is as follows: Olaparib, platinum doublet, and radiotherapy: 90 days A female participant is eligible to participate if she is not pregnant, not breastfeeding, and agrees to use contraception and refrain from donating eggs (ova, oocytes) to others or freeze/store for her own use for the purpose of reproduction during the treatment period and for at least the time needed to eliminate each study intervention after the last dose of study intervention and agrees to abstain from breastfeeding during the study intervention period and for at least 120 days after the last dose of study intervention. The length of time required to continue contraception for each study intervention is as follows: Pembrolizumab: 120 days; Olaparib, platinum doublet, and radiotherapy: 180 days Has a negative highly sensitive pregnancy test ([urine or serum] as required by local regulations) within 24 hours for urine or within 72 hours for serum before the first dose of study intervention. If a urine test cannot be confirmed as negative (e.g., an ambiguous result), a serum pregnancy test is required. In such cases, the participant must be excluded from participation if the serum pregnancy result is positive. Has had her medical history, menstrual history, and recent sexual activity reviewed by the investigator to decrease the risk for inclusion of a woman with an early undetected pregnancy. Has adequate pulmonary function tests Has adequate organ function Has provided written informed consent

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Weitere Informationen unter: **https://clinicaltrials.gov**

PACE-LUNG

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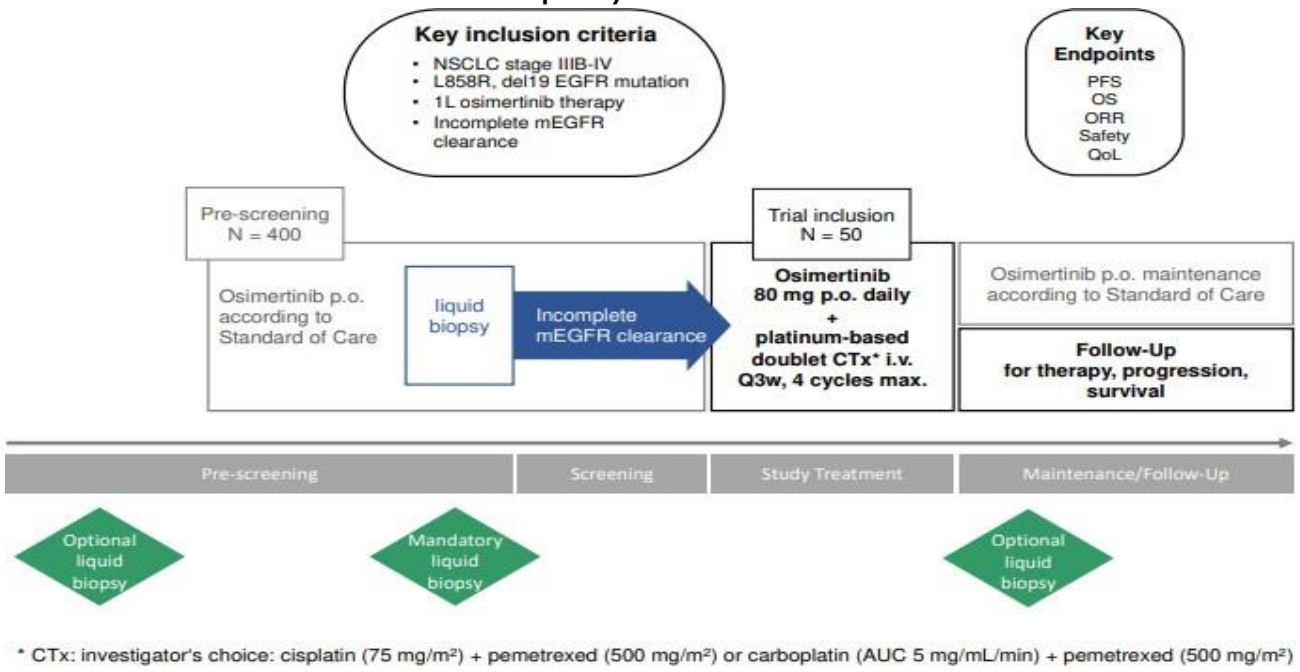
Additional chemotherapy for EGFRm patients with the continued presence of plasma ctDNA EGFRm at week 3 after start of osimertinib 1st-line treatment

Recruitment Status: RECRUITING

Condition: NSCLC Stage IIIB or IV

Primary Completion Date: 2026-07-06

Intervention/ Treatment: Drug (Osimertinib, Pemetrexed, Cisplatin, Carboplatin)



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EORTC-1420-HNCG-ROG (Best of 1420)

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Phase III Study Assessing the "Best of" Radiotherapy Compared to the "Best of" Surgery (Trans-oral Surgery (TOS)) in Patients With T1-T2, N0-N1 Oropharyngeal, Supraglottic Carcinoma and With T1, N0 Hypopharyngeal Carcinoma

Recruitment Status: RECRUITING

Condition: Oropharyngeal Cancer, Supraglottic Squamous Cell Carcinoma, Hypopharyngeal Squamous Cell Carcinoma
Primary Completion Date: 2025-09
Intervention/ Treatment:
Radiation: Intensity-Modulated Radiation Therapy (IMRT) → PTV prescription to tumor and high risk areas will be delivered daily for 5 days per week to a total dose of 66-70Gy in 2 Gy/fraction over 6 weeks, elective/prophylactic mucosal and nodal areas will receive a total dose of 54.25- 54.45 Gy in 33-35 fractions of 1.55-1.65 Gy over 6 weeks.

Procedure: Trans Oral Surgery (TOS) → The following surgical techniques are allowed:
Transoral Robotic Surgery (TORS) Transoral Microsurgery (TLM) Conventional trans-oral Surgery (CTOS)
Intervention: Procedure: Trans Oral Surgery (TOS)

Inclusion Criteria:
•OPSCC in one of the following sub-sites: base of tongue, lateral pharyngeal wall, tonsil, glosso-tonsillar sulcus, vallecula or SGSCC in one or more of the following sub-sites: epiglottis, aryepiglottic fold, false cord or HPSCC in one or more of the following subsites: Lateral and medial wall of piriform sinus (sub-sites are defined as lateral (lateral pharyngeal wall, tonsil, glosso-tonsillar sulcus, lateral piriform sinus) vs. central lesions (base of tongue, vallecula, all supraglottic sites, medial wall of piriform sinus)) TNM stage I-III (7th AJCC classification): T1 or T2, N0 or T1 or T2, N1 with one single neck node ≤ 3cm without radiographic signs of extracapsular extension (ECE), M0; TNM stage I for HPSCC: T1, N0, M0. ;Within 2 weeks before randomization, assessment by a Multi-Disciplinary Team (MDT) composed of at least a head and neck/ENT surgeon, oncologist, radiologist, radiotherapist, and pathologist of the treatment naïve patient and suitable for either TOS or IMRT based on: CT with contrast and/or MRI done within 4 weeks prior to randomization Pan-endoscopy with assessment of trans-oral exposure for resection. Age 18 and older; Age 18 to 70 for SGSCC ECOG Performance status ≤ 2; Availability of biological material for HPV/p16 testing for OPSCCs Study information and Informed consent discussed by the surgeon and radio-oncologist and signed by the patient. Within 2 weeks prior randomization: Baseline MDADI score available; Adequate bone marrow function as demonstrated by neutrophils count > 1,5 109 /L , platelets count > 75 109 /L, WBC≥ 3.0 109 /L; Prothrombin time (PT) with an international normalized ratio (INR) ≤ 1.2 Partial thromboplastin time (PTT) ≤ 1.2 times ULN Normal 12-lead ECG; Women of child bearing potential (WOCBP) must have a negative serum or urine pregnancy test no more than 72 hours prior to randomization. Patients of childbearing / reproductive potential should agree to use adequate birth control measures for 3 months, especially if they will undergo any radiotherapy treatment at any time during the study. A highly effective method of birth control is defined as those which result in low failure rate (i.e. less than 1% per year) when used consistently and correctly.

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Ergänzende Informationen unter ClinicalTrials.gov/NCT02984410

NPC-Nivo

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Nivolumab in combination with cisplatin and 5-fluorouracil as induction therapy in children and adults with EBV-positive nasopharyngeal carcinoma

Recruitment Status: RECRUITING

Condition: Malignant neoplasm of the nasopharynx
Primary Completion Date: /
Intervention/ Treatment:

Arm 1:
Alle Patienten ≤ 25 Jahre und Patienten > 25 Jahre ohne Metastasen: Nivolumab 4,5 mg/kg IV alle 3 Wochen + Cisplatin (100 mg/m2) an Tag 1 und Fluorouracil (1000 mg/m2 pro Tag für 5 Tage) alle 3 Wochen für 3 Zyklen. Bei Patienten mit nicht-metastasierter Erkrankung, die nach drei Zyklen Chemotherapie nicht auf die Induktionstherapie ansprechen, wird Nivolumab (4,5 mg/kg IV alle 3 Wochen) während der Radiochemotherapie fortgesetzt. Bei Erwachsenen > 25 Jahre und metastasierter Erkrankung: Nivolumab 4,5 mg/kg IV alle 3 Wochen + Cisplatin (80 mg/m2) an Tag 1 und Gemcitabin (1000 mg/m2 pro Tag an Tag 1 und Tag 8) alle 3 Wochen für 3 Zyklen. Bei Patienten, die auf die Chemotherapie ansprechen, kann ein vierter Zyklus hinzugefügt werden. Nivolumab (4,5 mg/kg IV alle 3 Wochen) wird während der Radiochemotherapie fortgesetzt. Die Behandlung mit dem Studienmedikament wird so lange fortgesetzt, bis zu einer inakzeptable Toxizität, maximal 5 Dosierungen von Nivolumab bei nicht-metastasierten Patienten, die auf eine Induktionschemotherapie ansprechen, oder 7 Dosierungen bei allen anderen Patienten, oder bis die Einwilligung zurückgezogen wird.

Einschluskriterien:
1. Histologisch bestätigte Neudiagnose eines Nasopharynxkarzinoms nach der aktuellen WHO-Klassifikation bei Kindern und Jugendlichen zwischen 3 und 17 Jahren ODER histologisch bestätigte Neudiagnose eines EBV-positiven Nasopharynxkarzinom, WHO-Stadium II oder III, bei Personen ≥ 18 Jahren 2. Stadium II oder höher bei Patienten bis 26 Jahren und Stadium III oder IV bei Patienten ab 26 Jahren (AJCC, 8. Auflage) 3. Messbare Erkrankung durch MRT nach RECIST 1.1-Kriterien 4. Ausreichend Tumorgewebe aus Biopsien für Referenzbefundung und PD-L1 Färbung, entweder in 1 Block oder mindestens 25 Leerschnitten 5. Schriftliche Einwilligung nach Aufklärung durch die Erziehungsberechtigten (falls der Patient nicht ≥ 18 und des Patienten vor der Teilnahme an der Studie

Weitere Info`s unter: DRKS - Deutsches Register Klinischer Studien/DRKS00027098

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TrilynX (Debio 1143)

Hubertus Wald Tumorzentrum
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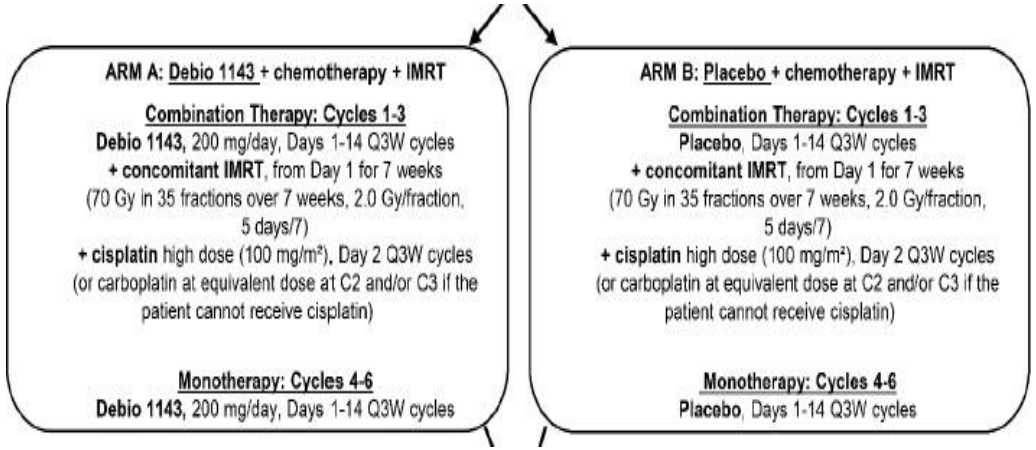
A Randomized, Double-Blind Placebo-Controlled, Phase 3 Study of Debio 1143 in Combination With Platinum-Based Chemotherapy and Standard Fractionation Intensity-Modulated Radiotherapy in Patients With LocallyAdvanced Squamous Cell Carcinoma of the Head and Neck, Suitable for Definitive Chemoradiotherapy (TrilynX)

Recruitment Status: ACTIVE, NOT RECRUITING

Condition: Squamous Cell Carcinoma of the Head and Neck
Primary Completion Date: 2027-04-30
Intervention/ Treatment: Drug (Xevinapant [Debio 1143]/ Cisplatin/ Placebo
Radiation: Intensity Modulation Radiation Therapy (IMRT)



Inclusion Criteria: Eastern Cooperative Oncology Group performance status (ECOG PS) 0 or 1 Histologically confirmed diagnosis of previously untreated Locally Advanced Squamous Cell Carcinoma of the Head and Neck (LA-SCCHN) participant (stage III, IVa or IVb according to the American Joint Committee on Cancer(AJCC))/Classification of malignant tumors: T=size of the primary tumor, N=regional lymph node involvement, M=distant metastasis (TNM) Staging System, 8th Edition.) suitable for definitive ChemoRadiotherapy (CRT), of at least one of the following sites: oropharynx, hypopharynx and larynx For OroPharyngeal Cancer (OPC) participants, primary tumors must be human papillomavirus (HPV)-negative as determined by p16 expression using immunohistochemistry Evaluable tumor burden (measurable and/or non-measurable tumor lesions) assessed by computed tomography scan (CT-scan) or magnetic resonance imaging (MRI), based on Response evaluation criteria in solid tumors (RECIST) version 1.1 Peripheral neuropathy less than (<) grade 2 Adequate hematologic, renal and hepatic function
Other protocol defined inclusion criteria may apply
Exclusion Criteria:
Primary tumor of nasopharynx, paranasal sinuses, nasal or oral cavity, salivary, thyroid or parathyroid gland pathologies, skin or unknown primary site Metastatic disease (stage IVc as per AJCC/TNM, 8th Ed.) Prior definitive or adjuvant Radiotherapy (RT) and/or radical surgery to the head and neck region which may jeopardize the primary tumor irradiation plan, or any other prior SCCHN systemic treatment, including investigational agents
Documented weight loss of >10% during the last 4 weeks prior to randomization (unless adequate measures are undertaken for nutritional support), OR plasmatic albumin < 3.0 g/dL. No albumin transfusions are allowed within 2 weeks before randomization Known allergy to Xevinapant (Debio 1143), cisplatin, carboplatin, other platinum-based agent or any excipient known to be present in any of these products or in the placebo formulation other protocol defined exclusion criteria may apply

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Ergänzende Informationen unter ClinicalTrials.gov /NCT04459715

Entitäten

FOCUS

Hubertus Wald Tumorzentrum
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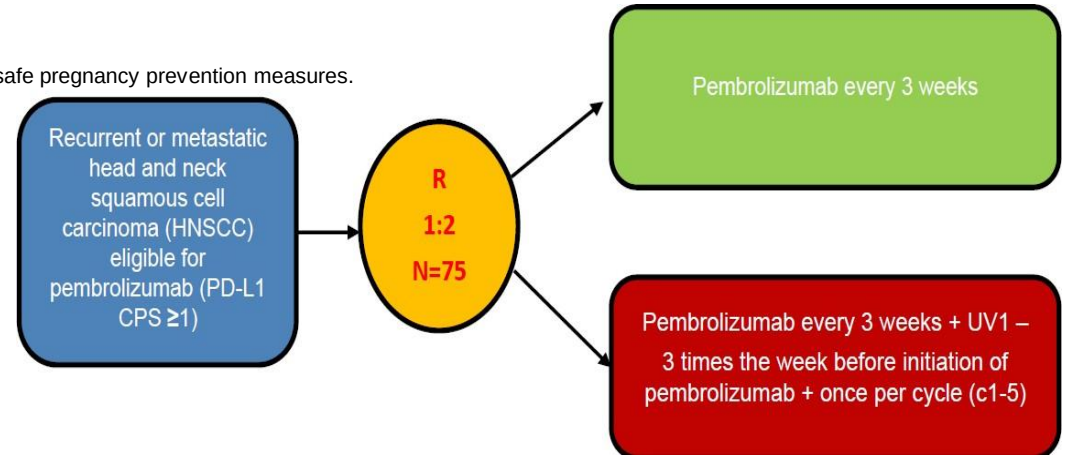
Phase 2 Multicenter Study Investigating the Tolerability and Efficacy of UV1 Vaccine in Patients With Recurrent or Metastatic PD-L1 Positive (CPS≥1) Head and Neck Squamous Cell Carcinoma Planned for First-line Treatment With Pembrolizumab

Recruitment Status: RECRUITING

Condition: Head and Neck Squamous Cell Carcinoma
Primary Completion Date: 2025-02
Intervention/ Treatment: Drug (Sargramostim for Injection/ Pembrolizumab injection, Biological: UV1

Inclusion Criteria:
Histologically confirmed diagnosis of a non-resectable recurrent or metastatic head and neck squamous cell carcinoma (not necessarily reconfirmed at time of enrolment)
At least one measurable tumor lesion as per RECIST v1.1, (Scan not older than 4 weeks before randomization)
Eligible for pembrolizumab monotherapy (PD-L1 CPS >/= 1% and adequate laboratory parameters for pembrolizumab monotherapy as assessed by the investigator)
ECOG-performance score 0-2
Written informed consent obtained according to international guidelines and local laws
Ability to understand and give informed consent.
Safe contraception measures for males and females. Procedures with a pearl index of less than 1% apply as safe pregnancy prevention measures.



Ergänzende Informationen unter ClinicalTrials.gov/NCT05075122

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Entitäten

UKE HAMBURG

BURAN

Hubertus Wald Tumorzentrum
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The BURAN Study of Buparlisib (AN2025) In Combination with Paclitaxel Compared to Paclitaxel Alone, in Patients with Recurrent or Metastatic Head and Neck Squamous Cell Carcinoma

Recruitment Status: ACTIVE, NOT RECRUITING

Purpose and Study Rationale

The BURAN study is a randomized, open-label phase III study to assess the treatment effect of once-daily buparlisib in combination with weekly paclitaxel compared to weekly paclitaxel alone in patients with refractory, recurrent, or metastatic head and neck squamous cell carcinoma (HNSCC) that have progressed after prior anti-PD-1/anti-PD-L1 monotherapy; prior anti-PD-1/anti-PD-L1 therapy in combination with platinum-based therapy; or after sequential treatment of anti PD 1/anti PD L1 therapy, either prior to or post, platinum-based therapy.

Condition: Head and Neck Cancer
Primary Completion Date: 2026-06-30
Intervention/ Treatment: Drug (Buparlisib & Paclitaxel)

Inclusion Criteria: Aged ≥18 years old. Able to provide informed consent obtained before any trial related activities and according to local guidelines. Patient has histologically and/or cytologically-confirmed HNSCC.
Patient has archival or new tumor tissue for the analysis of biomarkers and confirmation of HPV status (if unknown). One tumor block (preferred) or a recommended minimum of 5 unstained slides for patients with known HPV status (for tumor DNA characterization) or a recommended minimum of 10 slides for patients whose HPV status is unknown (5 slides for HPV testing plus 5 slides needed for biomarker testing). Enrollment in the study is contingent on confirmation of the availability of an adequate amount of tumor tissue, except in rare special circumstances, which must be reviewed and approved by the sponsor. Patient has either progressive or recurrent disease after treatment with PDL1/PD1 based therapy for recurrent or metastatic disease: PDLl/PD1 therapy alone for metastatic (monotherapy) disease PDL1/PD1 in combination with chemotherapy for metastatic and recurrent diseasePDL1/PD1 used for metastatic disease, after or prior to receiving a platinum agent for locally advanced or metastatic disease. 6. Patient has received no more than two prior lines of systemic treatment for HNSCC (single agent chemotherapy used as a radiosensitizer is not counted as a prior line of therapy). Patient has measurable disease as determined per RECIST version 1.1. If the only site of measurable disease is a previously irradiated lesion, documented progression of disease and a four-week period since radiotherapy completion is required. Patient has adequate bone marrow function and organ function as shown by the following: Absolute neutrophil count (ANC) ≥1.5 x 109/L. Hemoglobin ≥9 g/dL (which may be reached by transfusion). Platelets ≥100 x 109/L (which may be reached by transfusion). International normalized ratio (INR) ≤1.5. Calcium (corrected for serum albumin) within normal limits (WNL) or ≤ grade 1 severity according to NCI-CTCAE version 5.0 if judged clinically not significant by the Investigator. Patients concomitantly taking bisphosphonates or denosumab for calcium correction are eligible. Normal potassium and magnesium levels. Alanine aminotransferase (AST) and aspartate aminotransferase (ALT) ≤ 1.5 x upper limit of normal (ULN) or < 3.0 x ULN if liver metastases are present. Total serum bilirubin ≤ ULN or ≤ 1.5 x ULN if liver metastases are present; or total bilirubin ≤ 3.0 x ULN with direct bilirubin below or within normal range in patients with well documented Gilbert's Syndrome. Gilbert's syndrome is defined as presence of episodes of unconjugated hyperbilirubinemia with normal results from cells blood count (including normal reticulocyte count and blood smear), normal liver function test results, and absence of other contributing disease processes at the time of diagnosis. Serum creatinine ≤ 1.5 x ULN or calculated and directly measured creatinine clearance (CrCL) > 30 mL/min. Haemoglobin A1c (glycosylated hemoglobin; HbA1c) ≤8%. Patient has Eastern Cooperative Oncology Group (ECOG) performance status ≤1. Patient is able to swallow and retain oral medication. Patients able to swallow oral medication but mostly self-nourished through gastric or jejunal feeding tube are eligible. Patients must apply highly effective contraception during and throughout the study, as well after the final dose of study treatment

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Ergänzende Informationen unter ClinicalTrials.gov/ NCT04338399

Entitäten

MK 3475-689

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Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

A Phase III, Randomized, Open-label Study to Evaluate Pembrolizumab as Neoadjuvant Therapy and in Combination With Standard of Care asAdjuvant Therapy for Stage III-IVAResectable LocoregionallyAdvanced Head and Neck Squamous Cell Carcinoma (LAHNSCC)

Recruitment Status: ACTIVE, NOT RECRUITING

This is a randomized, active-controlled, open-label study of pembrolizumab (Pembro) given prior to surgery and pembrolizumab in combination with standard of care radiotherapy (with or without cisplatin), as post-surgical therapy in treatment naïve participants with newly diagnosed Stage III/IVA, resectable, locoregionally advanced, head and neck squamous cell carcinoma (LA-HNSCC). Efficacy outcomes will be stratified by programmed cell death ligand 1 (PD-L1) combined positive score (CPS) status. The primary hypothesis is that pembrolizumab given before surgery and after surgery in combination with radiotherapy (with or without cisplatin) improves major pathological response and event-free survival compared to radiotherapy (with or without cisplatin) given after surgery alone.

Condition: Head and Neck Neoplasms
Primary Completion Date: 2025-09-10
Intervention/ Treatment: Drug (Cisplatin 100mg/m^2), Biological (Pembrolizumab 200mg), Radiation (60 Gray/day/ 66 Gray/ 70 Gray/day)

Inclusion Criteria:
Has histologically confirmed new diagnosis of resectable, non-metastatic, squamous cell carcinoma that is either: Stage III Human Papillomavirus (HPV) positive oropharyngeal primary that is tumor size (T) 4, lymph node involvement (N) 0-2, no distant metastases (M0); Stage III or IVA oropharyngeal HPV negative; or Stage III or IVA larynx/hypopharynx/oral cavity primaries.
Is eligible for primary surgery based on investigator decision and per local practice
Female and male participants of reproductive potential must agree to use adequate contraception throughout the study period and for up to 180 days after the last dose of study therapy.
Male participants must refrain from donating sperm throughout the study period and for up to 180 days after the last dose of study therapy
Female participant that is not pregnant or breastfeeding
Has evaluable tumor burden (measurable and/or non-measurable tumor lesions) assessed by computed tomography (CT) scan or magnetic resonance imaging (MRI), based on RECIST version 1.1
Has provided newly obtained core or excisional biopsy of a tumor lesion not previously irradiated
Has results from testing of HPV status for oropharyngeal cancer defined as p16
Has Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 performed within 10 days of randomization

	Head and Neck		
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Ergänzende Informationen unter ClinicalTrials.gov/NCT03765918

Entitäten

RAMIRIS

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

Ramucirumab Plus FOLFIRI Versus Ramucirumab Plus Paclitaxel in Patients With Advanced or Metastatic Gastric Cancer, Who Failed One Prior Line of Palliative Chemotherapy (RAMIRIS)

Recruitment Status RECRUITING

This clinical trial will evaluate whether it is beneficial in terms of prolongation of survival to combine FOLFIRI (standard treatment) with ramucirumab compared to the standard treatment of ramucirumab plus paclitaxel in patients with advanced gastric cancer after failure of one prior line of palliative chemotherapy. This trial aims to investigate the efficacy and safety of ramucirumab plus FOLFIRI (investigational arm A) compared to paclitaxel plus ramucirumab (control arm B)

Condition: Advanced Gastric or EGJ Cancer
Primary Completion Date: 2025-03
Intervention/ Treatment:

-ramucirumab plus FOLFIRI (investigational arm A)
-paclitaxel plus ramucirumab (control arm B)

Inclusion Criteria:
Signed written informed consent
Male or female* ≥ 18 years of age; Patients in reproductive age must be willing to use adequate contraception (that results in a failure rate of <1% per year) during the study and for 3 months after the end of ramucirumab treatment (appropriate contraception is defined as surgical sterilization (e.g. bilateral tubal ligation, vasectomy), hormonal contraception (including oral contraceptive pills (combination of estrogen and progesterone), vaginal ring, injectables, implants, intrauterine devices (IUDs) and intrauterine hormone-releasing system (IUS)), nonhormonal IUDs and complete abstinence). Female patients with childbearing potential need to have a negative pregnancy test within 7 days before study start. Histologically proven gastric adenocarcinoma including adenocarcinoma of the esophagogastric junction Metastatic or locally advanced disease, not amenable to potentially curative resection Phase II only: Documented objective radiological or clinical disease progression during or within 6 months of the last dose of first-line platinum and fluoropyrimidine doublet with or without anthracycline or docetaxel. Neoadjuvant/adjuvant treatment is not counted unless progression occurs <6 months after completion of the treatment. In these cases neoadjuvant/adjuvant treatment is counted as one line. OR Phase III only: Radiological or clinical disease progression during or after the last dose of a first-line platinum, fluoropyrimidine-containing therapy. Patients must also have received a taxane with the first-line or during their adjuvant or neoadjuvant therapy or both. Neoadjuvant/adjuvant platinum containing therapy is permitted and is counted as first-line therapy if progression occurs <12 months after completion of the treatment. If progression occurred ≥ 12 months after completion of neoadjuvant/adjuvant therapy, the therapy is not counted as a treatment line. At decision of the investigator, different regimens can be considered as one line of prior treatment, in case these were administrated as a sequential or alternating therapy. Measurable or non-measurable but evaluable disease ECOG performance status 0-1 Life expectancy > 12 weeks Adequate hematological, hepatic and renal functions: Absolute neutrophil count (ANC) ≥ 1.5 x 10^9/L Platelets ≥ 100 x 10^9/L Hemoglobin ≥9 g/dL (5.58 mmol/L) Total bilirubin ≤ 1.5 times the upper normal limit (UNL) AST (SGOT) and ALT (SGPT) ≤ 2.5 x UNL in absence of liver metastases, or ≤ 5 x UNL in presence of liver metastases; AP ≤ 5 x UNL Serum creatinine ≤ 1.5 x upper limit of normal, or creatinine clearance (measured via 24-hour urine collection) ≥40 mL/minute (that is, if serum creatinine is >1.5 times the ULN, a 24-hour urine collection to calculate creatinine clearance must be performed) Urinary protein ≤1+ on dipstick or routine urinalysis (UA; if urine dipstick or routine analysis is ≥2+, a 24-hour urine collection for protein must demonstrate <1000 mg of protein in 24 hours to allow participation in this protocol) Adequate coagulation function as defined by International Normalized Ratio (INR) ≤ 1.5, and a partial thromboplastin time (PTT) ≤ 5 seconds above the ULN (unless receiving anticoagulation therapy). Patients receiving warfarin/ phenprocoumon must be switched to low molecular weight heparin and have achieved stable coagulation profile prior to first dose of protocol therapy. Ability to comply with scheduled assessments and with management of toxicities

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Weitere Informationen unter: https://clinicaltrials.gov/ NCT03081143

Entitäten

DANTE

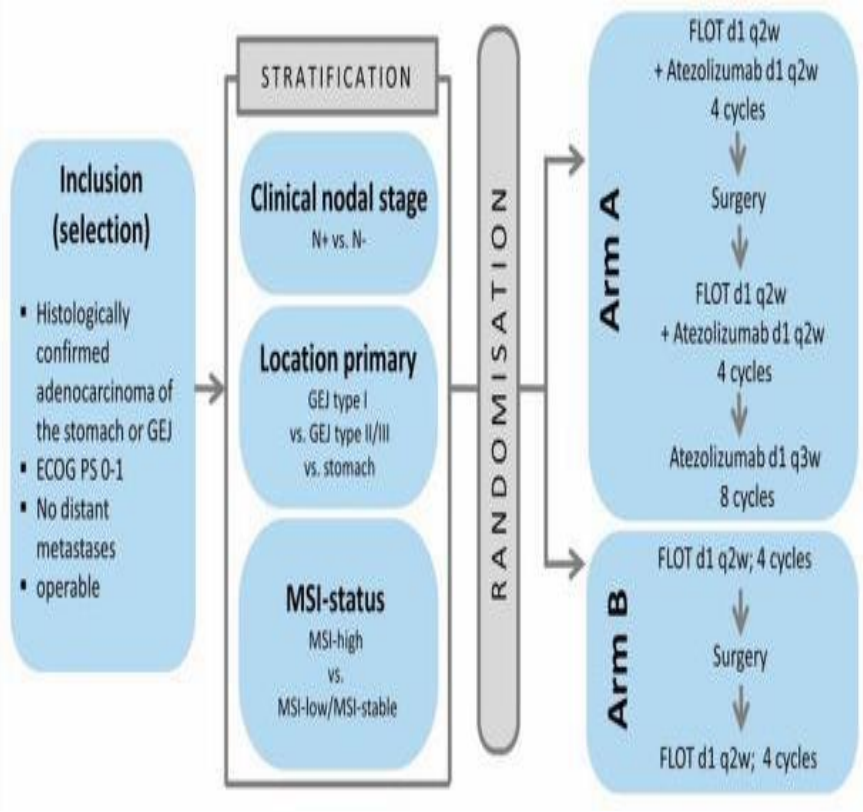
A Randomized, Open-label Phase II Efficacy and Safety Study of Atezolizumab in Combination With FLOT Versus FLOT Alone in Patients With Gastric Cancer and Adenocarcinoma of the Oesophago-gastric Junction (MO30039/MO43340) - The DANTE Trial

Recruitment Status RECRUITING

Condition:Gastric Cancer Gastroesophageal Junction Adenocarcinoma
Primary Completion Date: 2027-05-31
Intervention/ Treatment: Drug (Atezolizumab/ 5-Fluorouracil/ Calciumfolinat/ Oxaliplatin/ Docetaxel

Inclusion Criteria: Have provided written informed consent In the investigator's judgement, is willing and able to comply with the study protocol including the planned surgical treatment Female and male patients* ≥ 18 years of age Diagnosed with histologically confirmed adenocarcinoma of the GEJ (Type I-III) or the stomach (cT2, cT3, cT4, any N category, M0), or (any T, N+, M0)
that: is not infiltrating any adjacent organs or structures by CT or MRI evaluation does not involve peritoneal carcinomatosis
is considered medically and technically resectable Note: the absence of distant metastases must be confirmed by CT or MRI of the thorax and abdomen, and, if there is clinical suspicion of osseous lesions, a bone scan. If peritoneal carcinomatosis is suspected clinically, its absence must be confirmed by laparoscopy. Diagnostic laparoscopy is mandatory in patients with T3 or T4 tumors of the diffuse type histology in the stomach or upon request of the central review. No prior cytotoxic or targeted therapy No prior partial or complete esophagogastric tumor resection ECOG ≤ 1
Phase II only: Availability of a representative tumor specimen that is suitable for determination of PD-L1 and MSI status; MSI assessment will be performed locally or centrally, and result must be available prior to randomization (for details, see chapter 9). PD-L1 will be assessed centrally but is not used for enrolment of the patients. The analysis requires paraffin embedded biopsy samples of the tumor.
Phase III only: Assessment of MSI and PD-L1 [and optional TMB/EBV] must be performed locally and results for either of the following MSI-high, PD-L1 CPS≥1, TMB ≥10/MB or EBV+ must be available prior to randomization (for details, see chapter 9).

Weitere Informationen unter: https://clinicaltrials.gov/NCT03421288



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PROJECTION

Hubertus Wald Tumorzentrum
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Ein Kompetenznetzwerk des UKE

Prognostic role of circulating tumor DNA in resectable pancreatic cancer

Recruitment Status RECRUITING

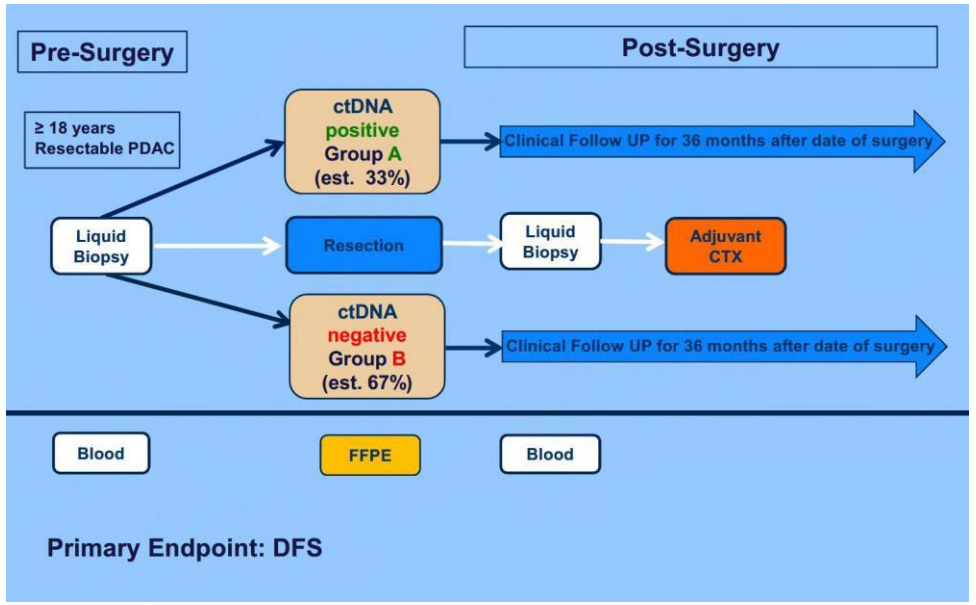
Condition:Gastric Cancer Gastroesophageal Junction Adenocarcinoma
Primary Completion Date: 2027-05-31
Intervention/ Treatment: Drug (Atezolizumab/ 5-Fluorouracil/ Calciumfolinat/ Oxaliplatin/ Docetaxel

Inclusion Criteria:

1. Adult patients ≥ 18 years of age
2. Pancreatic mass, suspicious of pancreatic cancer, deemed resectable and resection planned.
3. Patient deemed medically fit for adjuvant chemotherapy by the investigator
4. Patient's legal capacity to consent to study participation
5. Signed and dated informed consent to participate in the study

Ausschlusskriterien:

1. Non-resectable disease as determined by a local tumor board
2. Metastatic pancreatic disease
3. Previous neoadjuvant chemotherapy
4. Previous neoadjuvant radiotherapy
5. Histology other than PDAC such as acinar, neuroendocrine, mixed histology etc. in the resection specimen
6. Malignant disease other than PDAC within previous year (***exception***: patients with adequately treated and completely resected basal cell or squamous cell skin cancer; in situ cervical, breast or prostate cancer within previous year may be included)



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Ergänzende Informationen unter ClinicalTrials.gov/NCT04246203

Entitäten

MK-3475-966 (Keynote 966)

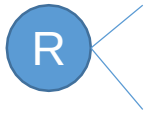
Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

A Phase 3 Randomized, Double Blind Study of Pembrolizumab Plus Gemcitabine/Cisplatin Versus Placebo Plus Gemcitabine/Cisplatin as First-Line Therapy in Participants WithAdvanced and/or Unresectable Biliary Tract Carcinoma

Recruitment Status ACTIVE, NOT RECRUITING

Condition:Biliary Tract Carcinoma
Primary Completion Date: 2024-11-29
Intervention/ Treatment: Drug (Gemcitabine / Cisplatin / Placebo), Biological: (Pembrolizumab)

Inclusion Criteria:



Experimental: Arm A (Pembrolizumab+Gemcitabine+Cisplatin) Pembrolizumab, 200 mg, every 3 weeks (Q3W), Day 1 of each 3-week cycle for up to 35 cycles PLUS Gemcitabine, 1000 mg/m^2, Q3W, Day 1 and Day 8 of each cycle until progressive disease or unacceptable toxicity PLUS Cisplatin, 25 mg/m^2, Q3W, Day 1 and Day 8 of each cycle for up to 8 cycles.

Placebo Comparator: Arm B (Placebo+Gemcitabine+Cisplatin) Placebo to Pembrolizumab, 200 mg, every 3 weeks (Q3W), Day 1 of each 3-week cycle for up to 35 cycles PLUS Gemcitabine, 1000 mg/m^2, Q3W, Day 1 and Day 8 of each cycle until progressive disease or unacceptable toxicity PLUS Cisplatin, 25 mg/m^2, Q3W, Day 1 and Day 8 of each cycle for up to 8 cycles.

Has histologically confirmed diagnosis of advanced (metastatic) and/or unresectable (locally advanced) biliary tract cancer (intra-or extrahepatic cholangiocarcinoma or gallbladder cancer)
Has measurable disease based on Response Evaluation Criteria in Solid Tumors (RECIST 1.1), as determined by the site investigator Participants with a history of hepatitis B or hepatitis C can be enrolled if they meet study criteria Is able to provide archival tumor tissue sample or newly obtained core or excisional biopsy of a tumor lesion
Has a life expectancy of greater than 3 months Has adequate organ function

Exclusion Criteria

Has had previous systemic therapy for advanced (metastatic) or unresectable (locally advanced) biliary tract cancer (intra-or extra hepatic cholangiocarcinoma or gallbladder cancer) Has ampullary cancer
Has small cell cancer, neuroendocrine tumors, lymphoma, sarcoma, mixed tumor histology and/or mucinous cystic neoplasms Has received prior therapy with an anti-programmed cell death 1 (anti-PD-1), anti- programmed cell death ligand 1 or 2 (anti-PD-L1, anti-PD-L2) agent or with an agent directed to another stimulatory or coinhibitory T-cell receptor (e.g., cytotoxic T-lymphocyte-associated protein 4 [CTLA-4], OX-40, CD137) Has a known history of, or any evidence of, central nervous system (CNS) metastases and/or carcinomatous meningitis, as assessed by local site investigator
Has had an allogenic tissue/solid organ transplant

Ergänzende Informationen unter ClinicalTrials.gov/ NCT04003636

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Entitäten

ACTICCA-1

Adjuvant chemotherapy with Gemcitabine and Cisplatin compared to observation after curative intent resection of cholangiocarcinoma

Recruitment Status ACTIVE, NOT RECRUITING

Condition:Cholangiocarcinoma Gall Bladder Carcinoma
Primary Completion Date: 2024-04
Intervention/ Treatment: Drug: (Gemcitabine / Cisplatin / Capecitabine)

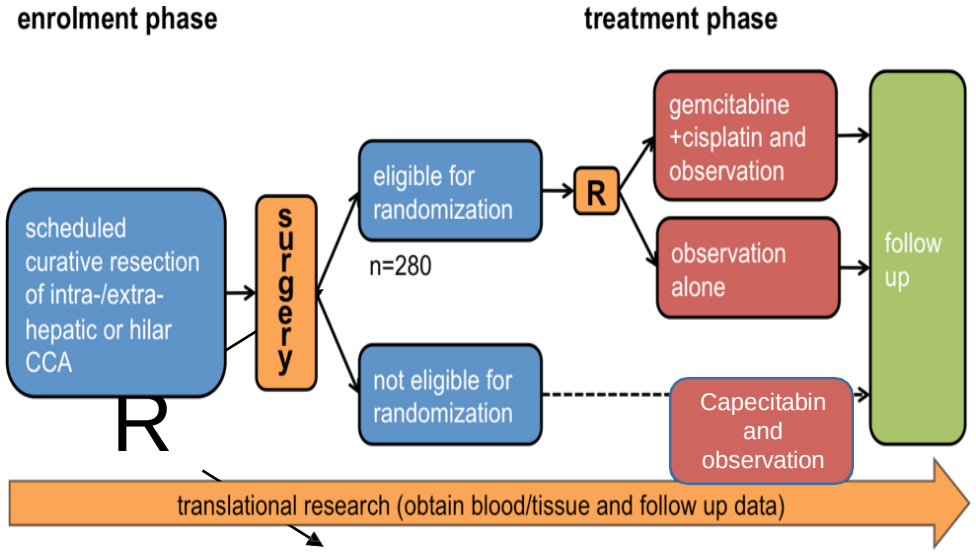
Inclusion Criteria:

Eligibility criteria for enrolment phase

1. Suspicion of or histologically/cytologically confirmed adenocarcinoma of biliary tract (intrahepatic, hilar or extrahepatic cholangicarcinoma) scheduled for radical surgical therapy
2. No prior chemotherapy for cholangiocarcinoma

Eligibility criteria for treatment phase

1. Histologically confirmed adenocarcinoma of biliary tract (intrahepatic, hilar or extrahepatic cholangicarcinoma) after radical surgical therapy with macroscopically complete resection (Carcinoma of the gallbladder and mixed tumor entities (HCC/CCA) are excluded)
2. Macroscopically complete resection (R0/1) within 6 (-16) weeks before scheduled start of chemotherapy



Ergänzende Informationen unter ClinicalTrials.gov/ NCT02170090

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MEFOX

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

A phase I/II trial of D,L-MEthadone and mFOLFOX6 in treatment of advanced colorectal cancer
- The AIO-MEFOX trial (AIO-KRK-0119)

Recruitment Status RECRUITING

Condition:Chemo-refractory Colorectal Carcinoma
Primary Completion Date: 2025-06-15
Intervention/ Treatment: Maximum tolerated dose, MTD: D,L-methadone hydrochloride (Methasan® 10 mg/ml)

Inclusion Criteria:
Advanced, histologically confirmed, metastatic colorectal carcinoma not suitable for resection and chemorefractory or Previously employed chemotherapy regimens and agents should comprise the following: Fluoropyrimidines, oxaliplatin, irinotecan, antiangiogenic agents (bevacizumab, aflibercept or ramucirumab), anti-EFGR-mAbs (in case of all-Ras-wildtype and left-sided primary tumor) and Trifluridin/Tipiracil (TAS102)
Microsatellite stable subset (MSS) of colorectal cancer Prior antineoplastic therapy or radiochemotherapy is allowed up to two weeks prior to start of the study medication. However, for the phase II part of the trial, failure of this strategy must be confirmed. In case of prior radiotherapy/radiochemotherapy the target lesion used for tumor evaluation must not be in the radiation field. There must be an oxaliplatin free period of at least 6 months prior to start of the study medication. No polyneuropathy of > grade 1 Tumor-related ECOG performance status 0-2 Anticipated life expectancy ≥ 12 weeks
Creatinine clearance ≥ 30 ml/min Serum total bilirubin level ≤ 3 x ULN.
ALT and AST ≤ 2.5 x ULN or ≤ 5.0 x ULN in the presence of liver metastasis (established after adequate biliary drainage) White blood cell count ≥ 3.5 x 106/ml, neutrophil granulocytes count ≥ 1,5 x 106/ml, platelet count ≥ 100 x 106/ml Pain that has to be controllable without concomitant use of opioids
Signed informed consent according to ICH/GCP and national/local regulations (participation in translational research is obligate) None of the following concomitant medications: MAO-B-Inhibitors, strong inductors or inhibitors of CYP3A4, antiarrhythmic drugs of class I and III or other drugs that have potential for QT-prolongation Age ≥ 18 years
At least one measurable target lesion according to RECIST 1.1. Pre-irradiated or locally treated lesions must not be used as target lesions.

Ergänzende Informationen unter ClinicalTrials.gov/ NCT05212012

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ACO/ARO/AIO-18.2

Hubertus Wald Tumorzentrum
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Ein Kompetenznetzwerk des UKE

This is a multicenter, prospective, randomized, stratified, controlled, open-label study comparing preoperative FOLFOX versus postoperative risk-adapted chemotherapy in patients with locally advanced rectal cancer and low risk for local failure

Recruitment Status RECRUITING
Condition: Rectal Cancer
Primary Completion Date: 2030-08
Intervention/ Treatment: Drug (mFOLFOX (neoadjuvant)/ XELOX (neoadjuvant)/ mFOLFOX (adjuvant)/ XELOX (adjuvant)/ Capecitabine (adjuvant)/ infusional 5-FU/FA "AIO" regimen (adjuvant)/ infusional 5-FU/FA "de Gramont" (adjuvant)

Experimental: A (experimental arm)The experimental arm A starts with 6 cycles of mFOLFOX or 4 cycles of XELOX. Surgery is scheduled four or six weeks after day 1 of the last mFOLFOX or XELOX cycle, respectively. No postoperative chemotherapy is planned Interventions:Drug: mFOLFOX (neoadjuvant) Drug: XELOX (neoadjuvant) Active Comparator:
B (control arm)In the standard arm B, patients undergo surgical resection of the primary tumor followed by stage- (risk-)adapted adjuvant chemotherapy 4-8 weeks after surgery according to recommendations of the S3 guidelines in analogy to colon cancer. Details of the recommended protocols are provided in the protocol. Interventions:Drug: mFOLFOX (adjuvant) Drug: XELOX (adjuvant) Drug: Capecitabine (adjuvant) Drug: infusional 5-FU/FA "AIO" regimen (adjuvant) Drug: infusional 5-FU/FA "de Gramont" (adjuvant)

Inclusion Criteria: Male and female patients with histologically confirmed diagnosis of rectal adenocarcinoma localised 0 - 16 cm from the anocutaneous line as measured by rigid rectoscopy (i.e. lower, middle and upper third of the rectum), depending on MRI-defined inclusion criteria (see below). Staging requirements: High-resolution magnetic resonance imaging (MRI) of the pelvis is the mandatory local staging procedure. Transrectal endoscopic ultrasound (EUS) is used to help discriminate between T1/2 and early T3 tumors. MRI-defined inclusion criteria: Lower third (0-6 cm): cT1/2 with clear cN+ based on MRI-criteria (see SOP in chapter 13.3 of the appendix), provided CRM- and EMVI- (defined as MRI-EMVI score 0-3; see SOP in chapter 13.3 of the appendix) Middle third (≥ 6-12 cm): cT1/2 with clear cN+ provided CRM- and EMVI-; cT3a/b, i.e. evidence of extramural tumor spread into the mesorectal fat of ≤ 5 mm provided N-, CRM-, and EMVI- Upper third (≥ 12-16 cm): cT1/2 with clear cN+ provided CRM- and EMVI-; any cT3-4 irrespective of nodal status. Spiral-CT of the abdomen and chest to exclude distant metastases.
Aged at least 18 years. No upper age limit. WHO/ECOG Performance Status ≤1. Adequate haematological, hepatic, renal and metabolic function parameters: Leukocytes ≥ 3.000/mm³, ANC ≥ 2.000/mm³, platelets ≥ 100.000/mm³, Hb > 9 g/dl Serum creatinine ≤ 1.5 x upper limit of normal Bilirubin ≤ 2.0 mg/dl, SGOT-SGPT, and AP ≤ 3 x upper limit of normal. QTc interval (Bazett**) ≤ 440 ms Informed consent of the patient. "**" Formula for QTc interval calculation (Bazett): QTc= ((QT)¯¨ (ms)")/√(RR (sec))= ((QT)¯¨ (ms)")/√(60/(frequency (1/min)))

Ergänzende Informationen unter ClinicalTrials.gov

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Entitäten

XL184-315 (Contact-02)

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

A Phase 3, Randomized, Open-Label, Controlled Study of Cabozantinib (XL184) in Combination with Atezolizumab vs Second Novel Hormonal Therapy (NHT) in Subjects with Metastatic Castration-Resistant Prostate Cancer

Recruitment Status ACTIVE, NOT RECRUITING

Condition:Metastatic Prostate Cancer Prostate Adenocarcinoma
Primary Completion Date: 2024-08-31
Intervention/ Treatment: Drug (Cabozantinib / Atezolizumab / Abiraterone Acetate / Enzalutamide / Prednisone)

Inclusion Criteria:
Men with histologically or cytologically confirmed adenocarcinoma of the prostate
Prior treatment with one, and only one, NHT (eg, abiraterone, apalutamide, darolutamide, or enzalutamide) for castration-sensitive locally advanced (T3 or T4) or mCSPC, M0 CRPC, or mCRPC
Surgical or medical castration, with serum testosterone ≤ 50 ng/dL (≤ 1.73 nmol/L) at screening Measurable (extrapelvic soft tissue) metastatic disease per Investigator assessment defined by at least one of the following: measurable visceral disease (eg, adrenal, kidney, liver, lung, pancreas, spleen) per RECIST 1.1; OR measurable extrapelvic adenopathy (ie, adenopathy above the aortic bifurcation)
Progressive disease at study entry as defined by specific criteria for prostate specific antigen (PSA) progression OR soft tissue disease progression in the opinion of the Investigator (Note: subjects with bone disease progression alone are not eligible) Age ≥ 18 years old or meeting country definition of adult, whichever is older, on the day of consent ECOG performance status of 0 or 1
Recovery to baseline or ≤ Grade 1 per Common Terminology Criteria for Adverse Events (CTCAE) v5 from toxicities related to any prior treatments, unless AE(s) are clinically nonsignificant and/or stable on supportive therapy in the opinion of the Investigator Adequate organ and marrow function based upon specific laboratory assessments obtained within 21 days prior to randomization Understanding and ability to comply with protocol requirements

Ergänzende Informationen unter ClinicalTrials.gov/NCT04446117

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Entitäten

MK 3475-365

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

Phase Ib/II Trial of Pembrolizumab (MK-3475) Combination Therapies in Metastatic Castration-Resistant Prostate Cancer (mCRPC) (KEYNOTE-365)

Recruitment Status RECRUITING

Condition:Metastatic Castration-Resistant Prostate Cancer
Primary Completion Date: 2027-10-22
Intervention/ Treatment: Drug (Drug: Olaparib 400 mg / Docetaxel 75 mg/m^2 / Prednisone 5 mg / Enzalutamide 160 mg / Olaparib 300 mg / Abiraterone acetate 1000 mg / Lenvatinib)
Other: Dexamethasone 8 mg
Biological: (Pembrolizumab 200 mg / Pembrolizumab/Vibostolimab coformulation / Belzutifan 120mg

Inclusion Criteria:

Ergänzende Informationen unter ClinicalTrials.gov / NCT02861573

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Entitäten

AT-Registry: Anwendungsbeobachtung der Therapie mit Hochintensivem Fokussierten Ultraschall (HIFU) bei Prostatakrebs

Recruitment Status RECRUITING

Eine internetbasierte Datenbank zur Erfassung der geforderten Parameter existiert bereits seit 2009: Die sogenannte „@-Registry“. In dieser Datenbank werden die klinischen sowie epidemiologischen Daten des Patienten, die Therapieparameter und der postoperative Verlauf hinsichtlich Lebensqualität und onkotherapeutischem Ergebnis dokumentiert. Mit der hier vorliegenden Anwendungsbeobachtung streben wir ein flächendeckendes System zur nahezu lückenlosen Erfassung sämtlicher HIFU-Therapien in der Bundesrepublik Deutschland an.

Die Datenbank wird zentral bei der Firma EDAP TMS (Frankreich)/IOMTech GmbH Berlin geführt. Die Datenbank wurde bezüglich der Auflagendes Datenschutzes geprüft und durch die französische Datenschutzinstitutionen für diese Anwendung freigegeben.
Die Studienteilnehmer erhalten bei Behandlung und im weiteren Verlauf (im ersten Jahr zweimal, dann je einmal jährlich) mehrere Fragebögen. Darin wird nach dem aktuellen PSA und eventuellen weiteren Therapien, sowie nach der Lebensqualität gefragt. Es geht dabei insbesondere um die Kontinenz und die Potenz, sowie eventuelle Probleme beim Wasserlassen. Der Inhalt des Fragebogens wird digital in die Datenbank eingegeben, die Papierversion verbleibt unter den üblichen Bedingungen der ärztlichen Schweigepflicht in der Patientenakte.

Einschlusskriterien

- Patienten mit Prostatakarzinom, bei denen eine lokale Therapie eine Verbesserung der Krankheitssituation verspricht.
- Einverständnis zur freiwilligen Teilnahme an der An¬wendungsbeobachtung nach vollständiger Aufklärung über Natur und Zweck der Beobachtung, bestätigt durch Unterschrift auf Aufklärungsdokument.

Ausschlusskriterien

- Akute, unbehandelte Harnwegsinfektion.
- Vorbestehende Harnwegs- oder Rektumfistel.
- Analstenosen, die das Einführen des HIFU-Schallkopfes nicht ermöglichen.

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PRO FOCUS „Machbarkeit einer fokalen Behandlung des lokalisierten Prostatakrebses unter MRT/TRUS-Bildfusion mit Hilfe des Focal One® “

Recruitment Status RECRUITING

Das Ziel dieser Studie liegt darin, nur die Teile der Prostata zu behandeln, die den Tumor tragen. Dadurch soll die Rate an Komplikationen möglichst gering gehalten und den-noch die bösartige Erkrankung therapiertwerden.
Als Behandlungstechnik ist für eine solche Strategie die HIFU-Therapie mit Focal One geeig-net. Die Nerven, die für die Potenz (Gliedsteife) verantwortlich sind, verteilen sich um die Außenfläche der Prostata. Es besteht somit eine hohe Wahrscheinlichkeit, dass die Potenz weitgehenderhalten werden kann, wenn die Nerven komplett oder zumindest zu großen Teilen geschont werden können. Weiterhin ist zu erwarten, dass sich Probleme mit der Bla-senentleerung reduzieren, wenn die Region der Harnröhre bei der Teilbehandlung nicht be-einträchtigt wird (eine Blasenauslassverengung bei kompletter HIFU-Therapie tritt bei ca. 25% auf). Erwartungsgemäß sinkt die bei kompletter HIFU schon niedrige Rate an Inkonti-nenz (ca. 6 %) durch eine Teilbehandlung weiter ab.

Einschlusskriterien

Patienten bis 75 Jahre mit einem lokal begrenzten Tumor der Prostata gemäß Niedrigrisiko oder frühem intermediären Risiko nach D’Amico, bei denen ein Befall von maximal 30% der betroffenen Biopsien einer leitliniengerechten Biopsie vorliegt und die Standardverfahren, wie perkutane Radiotherapie, radikale Prostatektomie oder aktive Überwachung, ablehnen. Im präoperativ durchgeführten multiparametrischen MRT (mpMRT) muss mindestens eine suspekte Läsion mit einem PI-RADS Score von 4/5 beschrieben sein.

Ausschlusskriterien

Ausschlusskriterien sind ein Befall in mehr als 30% der Biopsien in der Prostata sowie eine Tumorklassifikation oberhalb des o. g. Risikos. Mehr als zwei suspekte Läsion im mpMRT mit einem PI-RADS Score von 4/5. Weiterhin eine Symptomatik, die bereits präoperativ zusätzliche Behandlungen der Prostata notwendig macht (z. B. TUR-P) sowie anderweitige Hindernisse, welche die Durchführung der Therapie nichtgestatten (z. B. Rektumstenose). Die Tumorlokalisationen im MRT müssen mit der Lokalisation aus der Biopsie übereinstimmen.

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UKE HAMBURG

PREDICT

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

Prospective randomized trial to evaluate the prognostic role of lymphnode dissection in men with prostate cancer treated with radical prostatectomy

Recruitment Status RECRUITING

Condition:Metastatic Prostate Cancer
Primary Completion Date: 2024-12
Intervention/ Treatment: lymph node dissection

Derzeit ist es in der Martini-Klinik bei der Operation von Tumoren der mittleren Risikogruppe üblich, zusätzlich eine Lymphadenektomie durchzuführen. Dabei ist die Entfernung der Lymphknoten nicht unumstritten und es existieren bislang keine Daten, die einen Vorteil im Krebsspezifischen- beziehungsweise Gesamtüberleben zugunsten der Lymphadenektomie belegen. Es ist unklar, ob die Risiken einer zusätzlichen Entfernung von Lymphknoten im Rahmen der Prostatektomie bei Tumoren der mittleren Risikogruppe im Hinblick auf den weiteren Krankheitsverlauf zu rechtfertigen sind.

Ablauf der Studie
Die in die Studie eingeschlossenen Patienten werden nach der Einwilligungrandomisiert: Arm A: Bei den in Arm A randomisierten Patienten wird im Rahmen der Prostatektomie eine bilaterale pelvine Lymphadenektomie durchgeführt, die im Standard die Fossa obturatoria sowie die Externus-, Internus- und Communisgruppe beiderseits umfasst. Es müssen mindestens 10 Lymphknoten entfernt werden. Arm B: Anwendung der standardisierten Operationstechnik ohne Lymphadenektomie. Sollte sich wider Erwarten intraoperativ der Verdacht auf eine lymphogene Metastasierung ergeben, wird eine Lymphadenektomie durchgeführt und der Patient aus der Studie ausgeschlossen (Therapiefreiheit des Operateurs).

Inclusion Criteria:
Lokal-begrenztes Prostatakarzinom der mittleren Risikogruppe (Risikogruppe: PSA >10 ng/ml - 20 ng/ml oder Gleason-Score 7 oder cT-Kategorie 2b) Geplante RRP oder DVRP
Inclusion Criteria:
ASA (American Society of Anesthesiology)-Klassifikation >3 Patienten, bei denen Kontraindikationen zur Durchführung einer Lymphadenektomie bestehen Neoadjuvante Hormontherapie

Ergänzende Informationen unter ClinicalTrials.gov / NCT04269512

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Entitäten

Prostatakarzinomrezidiv mit PSMA PET positiver einseitig-pelviner Metastasierung: ist die einseitige Salvage-Lymphadenektomie ausreichend? (ProSTone)

Recruitment Status RECRUITING

Condition: Prostate Cancer
Primary Completion Date: 2024-12-31
Intervention/ Treatment: Salvage Lymphnode dissection

Ziel der vorliegenden Studie ist es, zu untersuchen, ob bei der einseitig pelvin auffälliger PSMA PET auf die chirurgische Behandlung der Gegenseite verzichtet werden kann und dadurch den Patienten die potentiellen zusätzlichen Komplikationen durch die Entfernung des Lymphgewebes auf der gegenüber liegende Seite erspart werden können ohne dabei einen negativen Einfluss auf die onkologischen Langzeitergebnisse zu nehmen.

Inclusion Criteria:

Patienten im guten Allgemeinzustand mit einer erwarteten Lebenserwartung > 10 Jahren
Vorliegen eines hormonsensitiven Prostatakarzinomrezidives nach radikaler Prostatektomie (Patienten mit Z.n. Salvage-Prostatektomie können eingeschlossen werden; ebenso stellt eine Salvage-Strahlentherapie der Prostataloge und/oder des pelvinen Lymphabflusses nach radikaler Prostatektomie kein Ausschlusskriterium dar) Unilateraler Nachweis von ≤ 3 PSMA PET positiver Lymphknotenmetastasen im pelvinen Lymphabflussgebiet (bis Abgang der A. mesenterica inferior) PSA zum Zeitpunkt der PSMA PET Bildgebung < 4 ng/ml

Exclusion Criteria:

Kontraindikation für einen chirurgischen Eingriff bzw. für eine beidseitige Salvage-Lymphadenektomie Verdacht auf Vorliegen eines Prostatakarzinomrezidives im Bereich der Prostataloge (Lokalrezidiv) oder einer extrapelvinen Metastasierung in der PSMA PET Alter der PSMA PET Untersuchung > 4 Monate zum Operationszeitpunkt
Hormontherapie innerhalb von 6 Monaten vor Studieneinschluss

Ergänzende Informationen unter ClinicalTrials.gov/ NCT04271579

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Tapistry (BO41932)

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

Tumor-Agnostic Precision Immuno-Oncology and Somatic Targeting Rational for You (TAPISTRY) Phase II Platform Trial

Recruitment Status RECRUITING

Condition:Metastatic Solid Tumors
Primary Completion Date: 2032-09-25
Intervention/ Treatment: Drug (Entrectinib/ Entrectinib/ Alectinib/ Atezolizumab/ Ipatasertib/ Trastuzumab emtansine/ Idasanutlin/ Inavolisib/ Drug: Belvarafenib/ Pralsetinib/ GDC-6036/ Camonsertib)

Inclusion Criteria:
Histologically or cytologically confirmed diagnosis of advanced and unresectable or metastatic solid malignancy Measurable disease as defined by Response Evaluation Criteria in Solid Tumors, Version 1.1 (RECIST v1.1), Response Assessment in Neuro-Oncology (RANO) criteria, or International Neuroblastoma Response Criteria (INRC) Performance status as follows: Participantss aged >= 18 years: Eastern Cooperative Oncology Group (ECOG) Performance Status 0-2; Participantss aged 16 to < 18 years: Karnofsky score >= 50%; Participants aged < 16 years: Lansky score >= 50% For participants aged >= 18 and <18 years: adequate hematologic and end-organ function Disease progression on prior treatment, or previously untreated disease with no available acceptable treatment Adequate recovery from most recent systemic or local treatment for cancer Life expectancy >= 8 weeks Ability to comply with the study protocol, in the investigator's judgment For female participants of childbearing potential: Negative serum pregnancy test <= 14 days prior to initiating study treatment; agreement to remain abstinent or use single or combined contraception methods that result in a failure rate of < 1% per year for the period defined in the cohort-specific inclusion criteria; and agreement to refrain from donating eggs during the same period For male participants: Willingness to remain abstinent or use acceptable methods of contraception as defined in the cohort-specific inclusion criteria
In addition to the general inclusion criteria above, participants must meet all of the cohort-specific inclusion criteria for the respective cohort

Exclusion Criteria:
Current participation or enrollment in another therapeutic clinical trial Any anticancer treatment within 2 weeks or 5 half-lives prior to start of study treatment Whole brain radiotherapy within 14 days prior to start of study treatment Stereotactic radiosurgery within 7 days prior to start of study treatment Pregnant or breastfeeding, or intending to become pregnant during the study History of or concurrent serious medical condition or abnormality in clinical laboratory tests that, in the investigator's judgment, precludes the participant's safe participation in and completion of the study or confounds the ability to interpret data from the study Incomplete recovery from any surgery prior to the start of study treatment that would interfere with the determination of safety or efficacy of study treatment Significant cardiovascular disease, such as New York Heart Association cardiac disease (Class II or higher), myocardial infarction, or cerebrovascular accident within 3 months prior to enrollment, unstable arrhythmias, or unstable angina History of another active cancer within 5 years prior to screening that may interfere with the determination of safety or efficacy of study treatment with respect to the qualifying solid tumor malignancy
In addition to the general exclusion criteria above, in order to be enrolled in a treatment cohort of the study, participants must not meet any of the cohort-specific exclusion criteria

Ergänzende Informationen unter ClinicalTrials.gov/NCT04589845

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Entitäten

BCP (breast cancer pregnancy)

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

Prospective and Retrospective Register Study of the German Breast Group (GBG) for Diagnosis and Treatment of Breast Cancer in Pregnancy

Recruitment Status RECRUITING

Condition:Breast Cancer
Primary Completion Date: 2025-04
Intervention/ Treatment: --

Women who were diagnosed with breast cancer during their pregnancy may be registered in thistrial.
Data is collected on the foetal outcome 4 weeks after delivery, maternal outcome of pregnancy as well as the breast cancer therapy applied (treatment, response to chemotherapy, type of surgery), diagnostic procedures applied (palpation, US, mammogram) and the outcome of mother and child after 5 years of therapy.

Inclusion Criteria:
Cohort 1: Women with histologically confirmed breast cancer during pregnancy
Cohort 2: Patients ≤ 40 years with histological confirmed breast cancer who are not pregnant (patients who have been pregnant recently can also be collected into this cohort)
Informed consent for data collection (for prospective participants) and biomaterial collection. For retrospective participants an informed consent is not required as long as the data are anonymously captured

Exclusion Criteria:
Cohort 1: Diagnosis of breast cancer outside the period of pregnancy
Cohort 2: Age at diagnosis of breast cancer > 40 years

Ergänzende Informationen unter ClinicalTrials.gov/NCT00196833

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Trudy (DESTINY-Breast05)

A Phase 3, Multicenter, Randomized, Open-Label, Active-Controlled Study of Trastuzumab Deruxtecan (T-DXd) Versus Trastuzumab Emtansine (T-DM1) in Participants With High-Risk HER2-Positive Primary Breast Cancer Who Have Residual Invasive Disease in Breast or Axillary Lymph Nodes Following Neoadjuvant Therapy (DESTINY-Breast05)

Recruitment Status ACTIVE, NOT RECRUITING

Condition: HER2-Positive Primary Breast Cancer Residual Invasive Breast Cancer
Primary Completion Date: 2025-12-31
Intervention/ Treatment: Drug: DS-8201a/ T-DM1

Inclusion Criteria:

Adults ≥18 years old (local regulatory requirements will apply if the legal age of consent for study participation is >18 years old). Pathologically documented HER2-positive breast cancer (BC): HER2-positive expression defined as an immunohistochemistry (IHC) score of 3+ and/or positive by in situ hybridization (ISH) confirmed prior to study randomization. Histologically confirmed invasive breast carcinoma. Clinical stage at disease presentation: T1-4, N0-3, M0; patients presenting with T1N0 tumors are not eligible. Pathologic evidence of residual invasive carcinoma in the breast and/or axillary lymph nodes following completion of neoadjuvant therapy meeting one of the following high-risk criteria: Inoperable breast cancer at presentation (prior to neoadjuvant therapy), defined as clinical stages T4, N0-3, M0 or T1-3, N2-3, M0. Operable at presentation, defined as clinical stages T1-3,N0-1,M0, with axillary node positive disease (ypN1-3) following neoadjuvant therapy.
Completion of neoadjuvant systemic therapy, including taxane-based chemotherapy and HER2-directed treatment prior to surgery. Systemic therapy must consist of at least 6 cycles of neoadjuvant therapy with a total duration of at least 16 weeks, including at least 9 weeks of trastuzumab (± pertuzumab) and at least 9 weeks of taxane-based chemotherapy to be completed prior to surgery.
Patients may have received an anthracycline as part of neoadjuvant therapy in addition to taxane chemotherapy. Adequate excision as confirmed per medical records: surgical removal of all clinically evident disease in the breast and axillary lymph nodes. An interval of no more than 12 weeks between the date of last surgery and the date of randomization. Known hormone receptor (HR) status, per local laboratory assessment, as defined by ASCO-CAP guidelines (≥1%): HR positive status defined by either positive estrogen receptor (ER) and/or positive progesterone receptor (PR). status. HR-negative status defined by both known negative ER and known negative PR. Left ventricular ejection fraction (LVEF) ≥50% within 28 days prior to randomization. Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 at Screening. Has adequate organ function within 14 days before randomization.

Ergänzende Informationen unter ClinicalTrials.gov/NCT04622319

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ADAPTcycle

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

Adjuvant Dynamic Marker - Adjusted Personalized Therapy Comparing Endocrine Therapy Plus Ribociclib Versus Chemotherapy in Intermediate Risk, HR+/HER2- Early Breast Cancer

Recruitment Status RECRUITING
Condition: Breast Cancer Female
Primary Completion Date: 2027-07-31
Intervention/ Treatment: Drug: Ribociclib 200Mg Oral Tablet

Inclusion Criteria:
A. Prior to REGISTRATION in the study: 1. Written informed consent prior to any screening procedures. 2. Female. 3. ≥ 18 years of age. 4a. EITHER: (Post)menopausal status at the time of initiation of (neo)adjuvant study medication patient underwent bilateral oophorectomy, or age ≥ 60, or age < 60 and amenorrhea for 12 or more months (in the absence of chemotherapy, tamoxifen, toremifene, or ovarian suppression) and/or FSH and estradiol in the postmenopausal range per local normal range. 4b. OR: Pre-menopausal patients: confirmed negative serum pregnancy test (β-hCG) before starting study treatment, or patient has had a hysterectomy. 5. Histologically confirmed diagnosis of primary estrogen-receptor positive and/or progesterone-receptor positive (> 1%) early breast cancer by local laboratory. 6. Patient has HER2-negative breast cancer defined as a negative in-situ hybridization test or an IHC status of 0, 1+, or 2+, if IHC is 2+, a negative in-situ hybridization (FISH, CISH, or SISH) test is required (based on the most recently analyzed tissue sample and all tested by a local laboratory). 7. Local therapy of breast cancer (if adjuvant treatment or planned if neoadjuvant treatment) according to current guidelines. Note: This may include radiotherapy of breast cancer. B. Prior to RANDOMIZATION in the study 8. No evidence of distant metastasis (confirmed prior to randomization by, preferentially, CT thorax / abdomen, X-ray chest, ultrasound liver, bone scan, or PET-CT). 9. Patient has available tumor tissue from diagnostic biopsy. 10. Patient is classified as intermediate risk according to the ADAPT intermediate-risk definition (i) (as follows), or (only in case of missing Oncotype DX or Ki-67 response data), according to the clinical intermediate-risk definition (ii) (as follows). (i). ADAPT intermediate-risk definition: Patient meets one of the following criteria: c/pN0, RS ≤ 25 with luminal-B-like (Ki-67 ≥20% or G3) or c/pT2-4 without endocrine response (post-endocrine Ki-67 > 10 %) c/pN1, RS ≤ 25 without endocrine response (post-endocrine Ki-67 > 10 %) c/pN0, RS > 25 with luminal-B-like (Ki-67 ≥20% or G3) or c/pT2-4 with endocrine response (Ki-67 ≤ 10 %) c/pN1, RS > 25 with endocrine response (Ki-67 ≤ 10 %) c/pN2-3, RS ≤ 25 with endocrine response (Ki-67 ≤ 10 %). Note: Postmenopausal patients with pT1-2/pN0 disease and RS < 25, as well as premenopausal patients with pT1-2/pN0 disease and RS<16, are recommended to be treated by endocrine therapy alone and not to be randomized (at investigator´s discretion). (ii). Clinical intermediate-risk definition (ascertained by investigator): Clinical intermediate risk may be ascertained by the investigator prior to randomization if at maximum two of the following three risk factors are present (according to primary diagnosis / 1st sample): cT2-4 c/pN positive G3 and / or Ki-67 ≥ 20% Note: Inclusion of a patient according to "clinical intermediate risk" is permitted only in case of missing baseline Oncotype DX® or Ki-67 decrease. In this case, investigators will follow a risk-based, step-wise assessment process. 11. No contraindication for (neo)-adjuvant ET. 12. Eastern Cooperative Oncology Group (ECOG) performance status 0 or 1. 13. Patient has adequate bone marrow and organ function as defined by the following laboratory values: absolute neutrophil count ≥ 1.5 × 109/L, platelets ≥ 100 × 109/L, hemoglobin ≥ 9.0 g/dL, estimated glomerular filtration rate (eGFR) ≥ 30 mL/min by a Cockcroft-Gault formula, INR ≤ 1.5, serum creatinine < 1.5 mg/dL, total bilirubin < ULN, except for patients with Gilbert's Syndrome who may only be included if the total bilirubin is ≤ 3.0 × ULN or direct bilirubin ≤ 1.5 × ULN, aspartate transaminase (AST) < 2.5 × ULN, alanine transaminase (ALT) < 2.5 × ULN. 14. 2-lead-ECG (CANKADO) with: QTcF interval at screening < 450 msec (using Fridericia's correction), mean resting heart rate 50-90 bpm (determined from the ECG). 15. Ability to swallow ribociclib tablets or to administer other study medication, respectively. 16. Ability to communicate with the investigator and comply with study procedures. 17. Willing to remain during therapy at the clinical site, as required by the protocol.

Ergänzende Informationen unter ClinicalTrials.gov/NCT04055493

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SASCIA

Phase III Postneoadjuvant Study Evaluating Sacituzumab Govitecan, an Antibody Drug Conjugate in Primary HER2-negative Breast Cancer Patients With High Relapse Risk After Standard Neoadjuvant Treatment – SASCIA

Recruitment Status RECRUITING

Condition:HER2-negative Breast Cancer Triple Negative Breast Cancer

Primary Completion Date: 2027-03-30

Intervention/ Treatment: Drug: Capecitabine/ Carboplatin/ Cisplatin/ Sacituzumab govitecan

Inclusion Criteria:

Written informed consent prior to beginning specific protocol procedures, including expected cooperation of the patients for the treatment and follow-up, must be obtained and documented according to the local regulatory requirements. Age at diagnosis at least 18 years. Willingness and ability to provide archived formalin fixed paraffin embedded tissue (FFPE) block from surgery after neoadjuvant chemotherapy and from core biopsy before start of neoadjuvant chemotherapy, which will be used for centralized prospective confirmation of HR status, HER2 status, Ki-67 and tumor-infiltrating lymphocytes (TILs) and for retrospective exploratory correlation between genes, proteins, and mRNAs relevant to sensitivity/resistance to the investigational agents. For patients with bilateral carcinoma, FFPE blocks from both sides have to be provided for central testing. Histologically confirmed unilateral or bilateral primary invasive carcinoma of the breast, confirmed histologically by core biopsy. The lead tumor has to be defined by the investigator based on the inclusion criteria for the respective subtype and on the risk status. Centrally confirmed HER2-negative (IHC score 0-1 or FISH negative according to ASCO/CAP guideline) and either HR-positive (≥1% positive stained cells) disease or HR-negative (<1% positive stained cells) assessed preferably on tissue from postneoadjuvant residual invasive disease of the breast, or if not possible, of residual nodal invasion. If not evaluable, core of diagnostic biopsy will be used. In case of bilateral breast cancer, HER2-negative status has to be confirmed for both sides. Patients with residual invasive disease after neoadjuvant chemotherapy at high risk of recurrence defined by either: For HR-negative: any residual invasive disease > ypT1mi and/or ypN1>1mm For HR-positive disease: a CPS+EG score ≥ 3 or CPS+EG score 2 and ypN+ using local ER and grade assessed on core biopsies taken before start of neoadjuvant treatment. Adequate surgical treatment including resection of clinically evident disease and ipsilateral axillary lymph node dissection. SNB before NACT is discouraged. Axillary dissection before NACT is not permitted. Axillary dissection, including Targeted Axillary Dissection (TAD) should be performed according to guidelines. Histologic complete resection (R0) of all invasive and in situ tumors is required. Patients must have received neoadjuvant taxane-based chemotherapy for 16 weeks (anthracyclines are permitted). This period must include 6 weeks of a taxane containing neoadjuvant chemotherapy (exception: for patients with progressive disease that occurred after at least 6 weeks of taxane-containing neoadjuvant chemotherapy, a total treatment period of less than 16 weeks is also eligible). No clinical evidence for locoregional or distant relapse during or after preoperative chemotherapy. Local progression during chemotherapy is not an exclusion criterion if adequate local control could be obtained. In case of local progression during neoadjuvant therapy, distant metastases must be excluded by adequate imaging (CT/MRI recommend) prior to entering the trial. Immune checkpoint inhibitor / immunotherapy during (neo)adjuvant therapy is allowed until the completion of radiotherapy. Patients with known gBRCA1/2 mutation without indication to adjuvant olaparib therapy are allowed to participate in the trial. An interval of less than 16 weeks since the date of final surgery or less than 10 weeks from completing radiotherapy (whichever occurs last) and the date of randomization is required. Radiotherapy should be delivered before the start of study treatment. Radiotherapy to the breast is indicated in all patients with breast conserving surgery and to the chest wall and lymph nodes according to local guidelines as well as in all patients with cT3/4 or ypN+ disease treated by mastectomy. Eastern Cooperative Oncology Group (ECOG) performance status 0 or 1. Resolution of all acute toxic effects of prior anti-cancer therapy or surgical procedure or radiotherapy to NCI CTCAE v 5.0 grade ≤ 1 (except alopecia or other toxicities not considered a safety risk for the patients at the investigator´s discretion). Estimated life expectancy of at least 5 years irrespective of the diagnosis of breast cancer. The patient must be accessible for scheduled visits, treatment and follow-up. Normal cardiac function after neoadjuvant chemotherapy must be confirmed according to local guidelines. Results for LVEF must be above the normal limit of the institution.

Ergänzende Informationen unter ClinicalTrials.gov/NCT04595565

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UKE HAMBURG

CapiTello

Hubertus Wald Tumorzentrum
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Ein Kompetenznetzwerk des UKE

A Phase Ib/III Randomised Study of Capivasertib Plus Palbociclib and Fulvestrant Versus Placebo Plus Palbociclib and Fulvestrant in Hormone Receptor-Positive and Human Epidermal Growth Factor Receptor 2-Negative LocallyAdvanced, Unresectable or Metastatic Breast Cancer

Recruitment Status RECRUITING

Condition: Locally Advanced (Inoperable) or Metastatic Breast Cancer
Primary Completion Date: 2027-11-01
Intervention/ Treatment: Drug: Capivasertib/ Fulvestrant/ Palbociclib/ Ribociclib/ Abemaciclib

Inclusion Criteria:

Key inclusion criteria for both phases: Adult females (pre-/peri-/ and post-menopausal), and adult males. Histologically confirmed HR+/ HER2- breast cancer determined from the most recent tumour sample (primary or metastatic) per the American Society of Clinical Oncology and College of American Pathologists guideline. To fulfil the requirement of HR+ disease, a breast cancer must express ER with or without co-expression of progesterone receptor. Eligible for fulvestrant therapy and at least one of the following: palbociclib, ribociclib, or abemaciclib, as per local investigator assessment. Previous tolerance to specific CDK4/6 inhibitors and dose levels required. Adequate organ and bone marrow functions. Consent to provide a mandatory FFPE tumour sample. Key inclusion criteria only for phase III: Previous treatment with an ET (tamoxifen, AI, or oral SERD) as a single agent or in combination, with radiological evidence of breast cancer recurrence or progression while on, or within 12 months of, completing a (neo)adjuvant ET regimen. Provision of mandatory blood samples at screening for central testing using an investigational ctDNA test to be stratified based on PIK3CA/AKT1/PTEN status. Be eligible for fulvestrant and at least one out of palbociclib or ribociclib (depending on the available CDK4/6i options at time of enrolment), as per local investigator assessment. Have measurable lesion(s) according to Response Evaluation Criteria in Solid Tumours version 1.1 (RECIST v1.1) or, in the absence of measurable disease, lytic or mixed bone lesions that can be assessed by computed tomography (CT) or magnetic resonance imaging (MRI). Key exclusion criteria for both phases: History of another primary malignancy except for malignancy treated with curative intent with no known active disease ≥ 2 years before the first dose of study intervention and of low potential risk for recurrence. Radiotherapy within 2 weeks prior to study treatment initiation. Major surgery or significant traumatic injury within 4 weeks of the first dose of study treatment. Persistent toxicities (CTCAE Grade >1) caused by previous anticancer therapy, excluding alopecia. Participants with irreversible toxicity that is not reasonably expected to be exacerbated by study intervention may be included (eg, hearing loss or peripheral sensory neuropathy) after consultation with the AstraZeneca study physician. Spinal cord compression, brain metastases or leptomeningeal metastases unless these lesions are definitively treated (eg. radiotherapy, surgery) and clinically stable off steroids for management of symptoms for at least 4 weeks prior to study treatment initiation. Any of the following cardiac criteria at screening: (a). Mean resting corrected QT interval (QTcF): (i) Participants to be treated with palbociclib:: QTcF ≥ 470 ms obtained from the average of 3 consecutive (triplicate) ECGs (ii) Participants to be treated with ribociclib: QTcF ≥ 450 ms obtained from the average of 3 consecutive (triplicate) ECGs (iii) Participants to be treated with abemaciclib (Phase Ib only): QTcF ≥ 470 ms obtained from the average of 3 consecutive (triplicate) ECGs (b). Any clinically important abnormalities in cardiac rhythm, conduction or morphology of resting ECG (eg, complete left bundle branch block, third-degree heart block) (c). Any factors that increase the risk of QTc prolongation or risk of arrhythmic events (d). Experience of any of the following procedures or conditions in the preceding 6 months: coronary artery bypass graft, angioplasty, vascular stent, myocardial infarction, unstable angina pectoris, congestive heart failure New York Heart Association (NYHA) grade ≥ 2 (e). Uncontrolled hypotension (f) uncontrolled hypertension (g). Cardiac ejection fraction outside institutional range of normal or < 50% (whichever is higher) uncontrolled or high grade or symptomatic arrhythmia and atrial fibrillation Any of these clinically significant abnormalities of glucose metabolism at screening: . diabetes mellitus type I or type II requiring insulin treatment . Glycated haemoglobin (HbA1c) ≥ 8.0% (63.9 mmol/mol) Previous allogeneic bone marrow transplant or solid organ transplant. Key exclusion criteria for the phase III only: Any prior treatment with, AKT, PI3K or mTOR inhibitors. Prior treatment with CDK4/6 inhibitors in the metastatic setting (prior CDK4/6 inhibitors permitted in the adjuvant setting provided there was a CDK4/6i treatment free interval of at least 12 months). More than 1 line of chemotherapy for metastatic disease.

Ergänzende Informationen unter ClinicalTrials.gov/NCT04862663

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PRAEGNANT

Prospective Academic Translational Research Network for the Optimization of the Oncological Health Care Quality in the Adjuvant and Advanced/Metastatic Setting: Health Care Research, Pharmacogenomics, Biomarkers, Health Economics

Recruitment Status RECRUITING

Condition: Advanced/Metastatic Breast Cancer Breast Cancer (Early Breast Cancer)
Primary Completion Date: 2026-03
Intervention/ Treatment: Procedure: Blood sampling

PRAEGNANT (Prospective Academic Trans- lational Research Network for the Optimization of Oncological Health CareQuality in the Advanced Therapeutic Setting). Ein prospektives transtationales Forschungsnetzwerk für die Optimierung der onkologischen Behandlungsqualität im Rahmen der Fortschritte im Bereich der molekularen Medizin von Patientinnen mit metastasiertem Brustkrebs. Aufbau eines Registers für translationale Studien und molekulare Testungen sowie die Erfassung von therapieinduzierten Toxizitäten und Lebensqualität. Aktuell in PHASE I – offen für Patientinnen mit fortgeschrittenem Mammakarzinom.

Inclusion Criteria:
Inclusion Criteria for the early breast cancer setting: Adult breast cancer patients (age ≥18 years) Patients with breast cancer and no evidence of distant metastases with a diagnosis not longer than 91 days before study entry. Patients, who are able and willing to sign the informed consent form. Inclusion Criteria for the advanced/metastatic setting: Adult women aged ≥18 years. Patients with the diagnosis of invasive breast cancer (in German: Mammakarzinom, as op-posed to "non-invasive"= ductales Carcinoma in situ; irrespective of status of BC, e.g. TNM, re-ceptor status etc.) and Patients, who are willing and able to sign the informed consent form Patients with metastatic or locally advanced, inoperable disease proven by clinical measures (i.e. standard imaging)

Exclusion Criteria:
Patients who did not sign the informed consent form. Patients, who are not eligible for observation due to non-availability and/or severe comor-bidities as evaluated by the treating physician

Ergänzende Informationen unter ClinicalTrials.gov

	Gynecology		
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SK	Sandra Bertram-Schemmel	040 / 7410 – 58143	s.bertram-schemmel@uke.de

Entitäten

UKE HAMBURG

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

Metastasiertes Mammakarzinom (Hirnmetastasen, jeder Subtyp)

Alle Ärzte

Dokumentar: D.Engelen

BMBC

Multizentrische prospektive und retrospektive klinische Datenerfassung von Patientinnen mit Hirnmetastasen, Kooperation der GBG, AGO-Trafo, AGO-B und des UKE. Erhebungen von Erkrankungsverläufen mit Hirnmetastasen, Durchführung von wissenschaftlichen Projekten zur Verbesserung des Managements von Patientinnen mit Hirnmetastasen und um die Ursachen für die Entstehung von Hirnmetastasen bei einer Brustkrebserkrankung besser zu verstehen.

Einschlusskriterien	Ausschlusskriterien
Nachweis von Hirnmetastasen (Bildgebung, Operation)	Andere maligne Erkrankungen in der Anamnese
Mammakarzinom in der Anamnese	Fehlende histologische Sicherung des Mammakarzinoms
ED der cerebralen Metastasierung 2000	Präexistente neurologische Erkrankungen

Kooperationspartner

Eclat, AGO-OP.6 KKS 228

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

Pelvic and Para-aortic Lymphadenectomy in Patients With Stage I or II Endometrial Cancer With High Risk of Recurrence

Recruitment Status RECRUITING

Condition: Cancer of Endometrium Stage I/ Cancer of Endometrium Stage II
Primary Completion Date: 2028-02-15
Intervention/ Treatment: Procedure: Standard surgical procedure for endometrial cancertotal hysterectomy, bilateral salpingo-oophorectomy, omentectomy (type 2 cancers)
Procedure: systematic lymphadenectomy (LNE)systematic pelvic and para-aortic lymphadenectomy (LNE) up to the renal vessels

Active Comparator: Arm A standard surgical procedureStandard surgical procedure for endometrial cancer:
total hysterectomy, bilateral salpingo-oophorectomy, omentectomy (type 2 cancers)
Intervention: Procedure: Standard surgical procedure for endometrial cancer
Experimental: Arm B systematic lymphadenectomy (LNE)In addition to standard procedures as defined for Arm A:
systematic pelvic and para-aortic lymphadenectomy (LNE) up to the renal vessels
Interventions:Procedure: Standard surgical procedure for endometrial cancer
Procedure: systematic lymphadenectomy (LNE)

Inclusion Criteria: histologically confirmed EC of clinical stages T1b and T2 (all histological types) and stage T1a G3 type 1 (endometrioid, endometriod with squamous differentiation, mucinous) or type 2 tumors (any percentage of serous or clear cell component) or carcinosarcoma a) no previous surgery concerning EC (primary surgery) or b) surgery after hysterectomy (e.g. for presumed low risk endometrial cancer) is allowed within 8 weeks after hysterectomy if no LNE was performed (secondary surgery) absence of bulky lymph nodes performance status ECOG 0-1 age 18 - 75 years written informed consent adequate compliance
Exclusion Criteria: stage pT1a, G1 or G2 tumors of type 1 histology sarcomas (except for carcinosarcoma = malignant mixed Müllerian tumor) EC of FIGO stages III or IV (except for microscopical lymph node metastases) vidence of extrauterine disease by visual inspection recurrent EC preceding chemo-, radio, or endocrine therapy for EC any concomitant disease not allowing surgery including lymphadenectomy and/or chemotherapy any medical history indicating excessive peri-operative risk any current medication containing considerable surgical risk (e.g. bleeding: due to oral anticoagulating agents) any known disorder or circumstances making participation in trial and follow-up questionable. Insufficient compliance is expected. patients with second malignancies if disease or treatment might have an impact on the patient's prognosis known HIV-infection or AIDS simultaneous participation in other clinical trials if not permitted by the steering committee (translational or QoL studies not interfering with the objectives of ECLAT are allowed)

Weitere Informationen unter: NCT03438474

Gynecology		
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NOGGO ov32 – MAKEI V

Prospective, multicentre phase III-trial in malignant extracranial germ cell tumours including a randomization between Carboplatin – and Cisplatin – combination standard chemotherapy based on a risk – stratification derived frm preceding MAKEI 96 trial and publised data

Recruitment Status RECRUITING

Condition: Cancer of Endometrium Stage I/ Cancer of Endometrium Stage II
Primary Completion Date: /
Intervention/ Treatment: DRUG (Cisplatin)

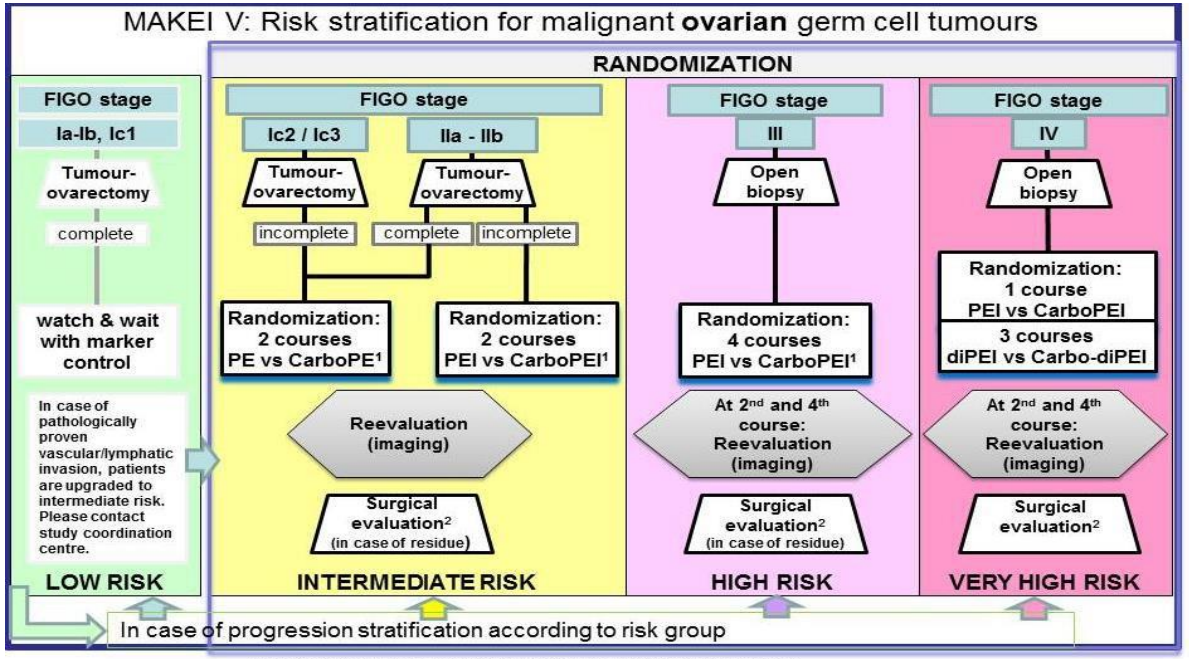
Inclusion criteria

•Confirmed extracranial MGCT up to 17 11/12 years of age or patients with ovarian primaries up to 29 11/12 years of age on the date of written informed consent Diagnosis of a chemotherapy-naïve extracranial MGCT Karnofsky-Index of >70% or ECOG-Status 0-II Negative pregnancy test within 7 days prior to start of treatment for female patients of childbearing potential, in case of ß-HCG secreting MGCT pregnancy has to be excluded by appropriate methods

Exclusion criteria in general:

- Pregnancy, Lactation HIV-positivity Live vaccine immunization within two weeks before start of protocol treatment Sexually active adolescents not willing to use highly effective contraceptive method (pearl index <1) until 12 months after end of chemotherapy Any other medical, psychiatric or drug related condition, or social condition incompatible with protocol treatment. **Exclusion criteria in special indication:**
- Second malignancies Negative preoperative tumour markers AFP and ß-HCG and solely pure teratoma histology Hearing impairment Grade 3 and 4 (CTCAE Vers.4.03)

Weitere Informationen unter: EudrCT Number: 2016-001784-36



Important notes: (Please contact the study coordinator immediately)

1) Intermediate and high risk group: reports of tumour marker are recommended (see Attachment 3.8h), if unfavourable standard tumour marker decline at day 18-21 after start of 1st cycle of chemotherapy patients are considered for intensification of treatment and should undergo stem cell apheresis after the 2nd cycle of standard Carboplatin or Cisplatin chemotherapy. If tumour marker decline is still unfavourable after the 2nd cycle of chemotherapy two cycles of dose-intensified Etoposide, Ifosfamide and Carboplatin or Cisplatin (Carbo-di-PEI or di-PEI) with stem cell support are administered.
2) in case of vital malignant cells at final surgery: patient is valued as non-responder and will receive individual treatment.

	Gynecology			Pediatric Oncology		
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SI						
SK	Juliane Granzow					

Entitäten

Acousia PROHEAR Study Synopsis

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

Phase IIa randomized, double-blind, and placebo-controlled multicenter split body trial to determine safety, tolerability, and efficacy of repeated doses of ACOU085 for the prevention of hearing loss in testicular cancer patients receiving cisplatin

Recruitment Status RECRUITING

Condition: Testicular Cancer
Primary Completion Date: /
Intervention/ Treatment: DRUG (ACOU085/ Placebo)

Inclusion Criteria: • Confirmed diagnosis of testicular cancer with indication for a cis-Pt-containing chemotherapeutic regimen according to current treatment guidelines and site-specific tumor board recommendations • Male adult patients at an age between 18 and 45 years • Planned cis-Pt treatment with a cumulative dose of ≥300 mg/m2 which has to be administered in three chemotherapeutic cycles • Normal or not clinically relevant otoscopic findings in both ears • Normal hearing at both ears according to current WHO criteria for air-conduction 4PTA (0.5/1/2/4 kHz; 0 to 19 dB HL; average of audiometric thresholds at 0.5/1/2/4 kHz) at baseline • Normal hearing at both ears according to ASHA criteria with a hearing threshold at any frequency (0.25 to 12 kHz) not exceeding 20 dB and a 4PTA (0.5/1/2/4 kHz) showing ≤15 dB HL at baseline • Normal distortion product oto-acoustic emissions (DPOAE) present in both ears at baseline • Patient shows normal results at trial start (V1) concerning heart rate (50 to 90 bpm), blood pressure (according to commonly accepted ranges), ECG (no pathological findings), and laboratory parameters (ie, liver and renal function values not clinically significant) • Male patients and their female partner(s) must agree to use 2 forms of contraception (one of which must be a barrier method) during 6 months after trial start (V1) • Patient is cooperative, able to understand all aspects of the trial, and able to speak German comparable to native speakers as per the investigator's discretion • Patient has signed an approved informed consent form indicating that he understands the purpose of and procedures required for the trial, will follow the trial-specific measures, and is willing to participate in the trial
Exclusion Criteria: Suspected or diagnosed genetic predisposition to hearing loss (incl. DFNA2 rel. to KCNQ4) • History of middle ear pathology or surgery, otitis externa, chronic otitis media, or recent acute otitis media (within ≤3 months) • History of otologic surgery (excluding myringotomy tubes or simple tympanoplasty) • Meniere‘s disease or secondary endolymphatic hydrops, auto immune hearing loss, inner ear pathology, fluctuating hearing loss, perilymph fistula, cochlear baro-trauma, radiation-induced hearing loss, retro-cochlear lesion, severe tympanosclerosis, atrophic tympanic membrane • Hearing loss of >45 dB averaged at 6 and 8 kHz in either ear • Sudden hearing loss or conductive hearing loss >10 dB at two frequencies in either ear • Asymmetry in hearing thresholds between left and right ear ≥20 dB at any single frequency or ≥10 dB at any 3 consecutive frequencies ≤ 8 kHz • Intake of any ototoxic drugs other than the intended cis-Pt-containing chemotherapeutic drug regimen prior to start of the trial and during the trial period • Previous radiation exposure >35 Gray to complete or parts of the cochlea • Severe concomitant diseases such as heart failure (NYHA II-IV), COPD, bronchial asthma, ongoing malignancies other than testicular cancer, auto-immune or chronic-inflammatory diseases, endocrinological diseases, advanced hepatic or renal failure, and primary complaint of tinnitus • Planned consumption of medications, herbal preparations, and specific food ingredients to treat hearing problems and/or tinnitus during the trial period • Hypersensitivity against any primary or secondary ingredient of IMP/Placebo medication • Male patients with female partners who are pregnant or planning to become pregnant during 6 months after trial start (V1) • Use of any other investigational medicinal product (IMP) within five times the half-life of that IMP/relevant metabolites or one month (whichever is longer) prior to screening and planned use during the trial or up to 30 days after trial completion • Patient has any dependent relationship or employment status with respect to the trial site, the sponsor, the investigator, or any supervisor

Ergänzende Informationen sind unter EudraCT 2023-503696-15-00

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Entitäten

SAKK 01/18

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

Reduced Intensity Radio-chemotherapy for Stage IIA/B Seminoma. A Multicenter, Open Label Phase II Trial With Two Cohorts

Recruitment Status: ACTIVE, NOT RECRUITING

Condition: Seminoma, Testicular Cancer
Primary Completion Date: /
Intervention/ Treatment: DRUG (**Carboplatin**-Patients in cohort 1 will receive a 60-minute i.v. infusion of carboplatin AUC 7 at day 1 of treatment./ **Cisplatin**-Patients in cohort 2 will receive on day 1 to day 5: a 60-minutes i.v. infusion of etoposide 100mg/m2 per day followed by a 60-120 minutes i.v. infusion of cisplatin 20mg/m2 per day/ **Etoposide** Patients in cohort 2 will receive on day 1 to day 5: a 60-minutes i.v. infusion of etoposide 100mg/m2 per day followed by a 60-120 minutes i.v. infusion of cisplatin 20mg/m2 per day.

Inclusion Criteria: • Written informed consent according to ICH/GCP (International Council on Harmonization/Good Clinical Practice) regulations before registration and prior to any trial specific procedures Histologically confirmed classical seminoma treated with primary inguinal orchidectomy or partial orchidectomy Patients with a seminoma stage IIA or IIB, either newly diagnosed or recurrent after primary active surveillance, adjuvant carboplatin or radiotherapy for stage I disease. The tumor stage is pT1-4 cN1-2 cM0 according to UICC TNM 8th edition 2016. Patients with a recurrent seminoma stage IIA or IIB are only eligible in case of progression under active surveillance or recurrence after adjuvant carboplatin or radiotherapy for stage I disease Stage IIA, in patients with equivocal lymph node enlargement, needs to be confirmed with a repeated CT/MRI scan of the abdomen (suggested timeframe: 4 weeks after the previous scan) in order to rule out false positive lymph node enlargement. Patients with a prior malignancy treated with curative intention are eligible if all treatment of that malignancy was completed at least 5 years before registration and the patient has no evidence of disease at registration. Less than 5 years is acceptable for malignancies with low risk of recurrence and/or no late recurrence. Patients with a germ cell neoplasia in situ (GCNIS) or contralateral localized treated seminoma are eligible Diagnostic CT or MRI or FDG-PET-CT of the chest, abdomen and pelvis within 28 days prior to registration, showing stage IIA/B disease. I.v. contrast medium has to be administered Age ≥ 18 years WHO performance status 0-2 Baseline PRO questionnaires have been completed Adequate bone marrow function: neutrophil count ≥ 1.0 x 109/L, platelet count ≥ 100x 109/L Adequate renal function: creatinine clearance ≥ 60 ml/min calculated according to the CKD-EPI (Chronic Kidney Disease Epidemiology Collaboration) formula Patient agrees to use highly effective contraception and not to donate sperm or to father a child during trial treatment and during 12 months thereafter. Patient has been proposed sperm conservation.
Exclusion Criteria: Any other histological component than seminoma Elevated levels of Alpha-1-Fetoprotein AFP (≥ 2x ULN) Involved nodes (metastatic) in previously irradiated localizations in the abdomen or pelvis Any anti-cancer therapy after primary tumor resection in patients presenting with primary stage IIA/B seminoma Any serious underlying medical condition (i.e. current renal insufficiency, severe hepatic insufficiency, severe bone marrow dysfunction, tumor bleeding, major hearing defects) or serious co-morbidity which could impair the ability of the patient to participate in the trial (according to investigator's judgment) Any treatment in a clinical trial within 28 days prior to registration Any concomitant drugs contraindicated for use with the trial drugs according to the approved product information or contraindicated for use with radiotherapy Known hypersensitivity to trial drugs or to any component of the trial drugs Any other serious underlying medical, psychiatric, psychological, familial or geographical condition, which in the judgment of the investigator may interfere with the planned staging, treatment and follow-up, affect patient compliance or place the patient at high risk from treatment-related complications. Additional German specific exclusion criteria - not to be considered for Swiss patients Patient who is dependent on the sponsor or the investigators according to ICH/GCP E6(R2), guideline Patient who has been committed to an institution by virtue of an order issued either by the judicial or the administrative authorities according to § 40a (2) AMG.

Weitere Informationen unter: Clinicaltrials.gov/NCT03937843

	Medical Oncology		
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Entitäten

CheckMate 9DW

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

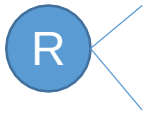
A Randomized, Multi-center, Phase 3 Study of Nivolumab in Combination With Ipilimumab Compared to Sorafenib or Lenvatinib as First-Line Treatment in Participants With Advanced Hepatocellular Carcinoma

Recruitment Status: ACTIVE, NOT RECRUITING

Condition: Hepatocellular Carcinoma
Primary Completion Date: 2026-09-30
Intervention/ Treatment: DRUG (Nivolumab i.v./ **Ipilimumab** i.v./ **Sorafenib** tablets/L**envatinib** oral capsules.

Inclusion Criteria:
Participants must have a diagnosis of HCC based on histological confirmation
Participants must have an advanced HCC
Participants must have at least one Response Evaluation Criteria in Solid Tumors (RECIST) 1.1 measurable previously untreated lesion
Child-Pugh score 5 or 6
Eastern Cooperative Oncology Group (ECOG) performance status(PS) 0 or 1

Exclusion Criteria:
Known fibrolamellar HCC, sarcomatoid HCC, or mixed cholangiocarcinoma and HCC
Prior liver transplant
Episodes of hepatic encephalopathy (greater than or equal to [>=] Grade 2) within 12 months prior to randomization
Active brain metastases or leptomeningeal metastases
Other protocol-defined inclusion/exclusion criteria apply.



Experimental: Nivolumab + Ipilimumab

Active Comparator: Sorafenib/lenvatinib

Ergänzende Informationen sind unter ClinicalTrials.gov verfügbar

	Gastroenterology		
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SI			
SK			

MK-3475-937 (Keynote 937)

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

A Phase 3 Double-blinded, Two-arm Study to Evaluate the Safety and Efficacy of Pembrolizumab (MK-3475) Versus Placebo as Adjuvant Therapy in Participants With Hepatocellular Carcinoma and Complete Radiological Response After Surgical Resection or Local Ablation (KEYNOTE-937)

Recruitment Status: ACTIVE, NOT RECRUITING

Condition: Hepatocellular Carcinoma
Primary Completion Date: 2027-10-31
Intervention/ Treatment: DRUG (Placebo)/ Biological: (Pembrolizumab)

R

Experimental: Pembrolizumab Participants receive intravenous (IV) pembrolizumab at 200 mg on Day 1 of each 21- day cycle for up to 17 cycles.

Placebo Comparator: Placebo Participants receive IV placebo on Day 1 of each 21-day cycle for up to 17 cycles.

Inclusion Criteria: Has a diagnosis of HCC by radiological criteria and/or pathological confirmation. Has an eligibility scan (CT of the chest, triphasic CT scan or MRI of the abdomen, and CT or MRI of the pelvis) confirming complete radiological response ≥4 weeks after complete surgical resection or local ablation. Randomization needs to occur within 12 weeks of the date of surgical resection or local ablation. Has no radiologic evidence of disease prior to enrollment.

•Has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 within 7 days prior to Cycle 1, Day 1. Has a Child-Pugh class A liver score (5 to 6 points) within 7 days prior to Cycle 1, Day 1. Has alpha fetoprotein (AFP) concentration lower than 400 ng/mL within 28 days prior to Cycle 1, Day 1. Has controlled hepatitis B (Hep B). Has recovered adequately from toxicity and/or complications from the local intervention (surgical resection or local ablation) prior to starting study treatment. If female, is not pregnant or breastfeeding, and at least one of the following conditions applies: 1) Is not a woman of childbearing potential (WOCBP); or 2) Is a WOCBP and using a contraceptive method that is highly effective or be abstinent from heterosexual intercourse as their preferred and usual lifestyle (a WOCBP must have a negative pregnancy test within 72 hours before the first dose of study reatment).

•If undergoing surgical resection, has submitted a tumor tissue sample during Screening. Has adequate organ function. Main

•Exclusion Criteria: Has a known additional malignancy that is progressing or has required active antineoplastic treatment (including hormonal) or surgery within the past 3 years. Has had esophageal or gastric variceal bleeding within the last 6 months. Has clinically apparent ascites on physical examination. Has had clinically diagnosed hepatic encephalopathy in the last 6 months. Has received local therapy to liver ablation other than with radiofrequency or microwave ablation. Has a history of (noninfectious) pneumonitis that required steroids or has current pneumonitis. Has an active infection requiring systemic therapy. Has dual active Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV) infection at study entry. Has a known history of human immunodeficiency virus (HIV) infection. Has known active tuberculosis (TB; Bacillus tuberculosis). Has received prior therapy with an anti-PD-1, anti-PD-L1, or anti PD-L2 agent or with an agent directed to another stimulatory or co-inhibitory T-cell receptor (eg, CTLA-4, OX-40, CD137). Has received prior systemic anti-cancer therapy for HCC including investigational agents. Is receiving any of the following prohibited concomitant therapies:1) Antineoplastic systemic chemotherapy or biological therapy; 2) Immunotherapy not specified in this protocol; 3) Investigational agents other than pembrolizumab; 4) Radiation therapy; 5) Oncological surgical therapy; or systemic glucocorticoids for any purpose other than to modulate symptoms from an AE that is suspected to have an immunologic etiology. Has received a live vaccine within 30 days prior to the first dose of study treatment.

Ergänzende Informationen sind unter ClinicalTrials.gov verfügbar

	Gastroenterology		
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MK 6482-022

A Multicenter, Double-blind, Randomized Phase 3 Study to Compare the Efficacy and Safety of Belzutifan (MK-6482) Plus Pembrolizumab (MK-3475) Versus Placebo Plus Pembrolizumab, in the Adjuvant Treatment of Clear Cell Renal Cell Carcinoma (ccRCC) Post Nephrectomy (MK-6482-022)

Recruitment Status: ACTIVE, NOT RECRUITING

Condition: Renal Cell Carcinoma
Primary Completion Date: 2026-10-28
Intervention/ Treatment: DRUG (Belzutifan + Placebo)/ Biological: **Pembrolizumab**

Inclusion Criteria: Has a histologically or cytologically confirmed diagnosis of RCC with clear cell component per American Joint Committee on Cancer (AJCC) (8th Edition), with or without sarcomatoid features Has intermediate-high risk, high risk, or M1 no evidence of disease (NED) RCC as defined by the following pathological tumor-node metastasis and tumor grading: Intermediate-high risk RCC: pT2, Grade 4 or sarcomatoid, N0, M0; pT3, any grade, N0, M0 High risk RCC: pT4, any Grade N0, M0; pT any stage, any Grade, N+, M0 M1 NED RCC participants who present not only with the primary kidney tumor but also solid, isolated, soft tissue metastases that can be completely resected at one of the following: the time of nephrectomy (synchronous) or, ≤2 years from nephrectomy (metachronous) Has undergone complete resection of the primary tumor (partial or radical nephrectomy) and complete resection of solid, isolated, soft tissue metastatic lesion(s) in M1 NED participants Must have undergone a nephrectomy and/or metastasectomy ≤12 weeks prior to randomization
Has Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1 within 10 days before randomization. Male participants must agree to continue contraception at least 7 days after the last dose of belzutifan/placebo Female participants of childbearing potential must be willing to use an adequate method of contraception, for the course of the study through 120 days after the last dose of pembrolizumab or at least 30 days after last dose of belzutifan/placebo, whichever occurs last Has adequate organ function
Exclusion Criteria: Has had a major surgery, other than nephrectomy plus resection of preexisting metastases for M1 NED participants, within 4 weeks prior to randomization Has a pulse oximeter reading <92% at rest, requires intermittent supplemental oxygen, or requires chronic supplemental oxygen Has clinically significant cardiovascular disease within 6 months from first dose of study intervention Has other clinically significant disorders such as: serious active nonhealing wound/ulcer/bone fracture; requirement for hemodialysis or peritoneal dialysis Has preexisting brain or bone metastatic lesions Has received prior systemic therapy for RCC
Has received prior radiotherapy for RCC Has received a live or live-attenuated vaccine within 30 days before the first dose of study intervention; administration of killed vaccines are allowed Has a diagnosis of immunodeficiency or is receiving chronic systemic steroid therapy Has a known additional malignancy (other than RCC treated with nephrectomy and/or metastasectomy) that is progressing or has required active treatment within the past 3 years Has an active autoimmune disease that has required systemic treatment in past 2 years (i.e., with use of disease modifying agents, corticosteroids, or immunosuppressive drugs); replacement therapy is allowed Has a history of (noninfectious) pneumonitis/interstitial lung disease that required steroids or has current pneumonitis/interstitial lung disease
Has an active infection, requiring systemic therapy Has a known history of human immunodeficiency virus (HIV) infection, a known history of Hepatitis B or known active Hepatitis C virus infection Has had an allogenic tissue/solid organ transplant

Ergänzende Informationen sind unter ClinicalTrials.gov verfügbar

	Medical Oncology		
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CA030-001

A Phase 1/2 First-in-Human Study of BMS-986249 Alone and in Combination With Nivolumab in Advanced Solid Tumors

Recruitment Status: ACTIVE, NOT RECRUITING
Condition: Advanced Cancer
Primary Completion Date: 2024-09-19
Intervention/ Treatment: Biological (**BMS-986249/ Nivolumab/ Ipilimumab**

Inclusion Criteria:
•Histologic or cytologic confirmation of a solid tumor that is advanced (metastatic, recurrent, and/or unresectable) with measurable disease and have at least 1 lesion accessible for biopsy
•Eastern Cooperative Oncology Group Performance Status of 0 or 1
•Some participants must have received, and then progressed, relapsed, or been intolerant to, at least 1 standard treatment regimen in the advanced or metastatic setting according to solid tumor histologies
•Prior anti-cancer treatments such as chemotherapy, radiotherapy, or hormonal are permitted for some participants
•Understand and sign an IRB/IEC-approved ICF prior to any study-specific evaluation
•Willing and able to comply with all study procedures Exclusion
Criteria:
•Primary CNS malignancies, tumors with CNS metastases as the only site of disease or active brain metastases will be excluded
•Other active malignancy requiring concurrent intervention
•Prior organ allograft
•Active, known, or suspected autoimmune disease Other protocol
defined inclusion/exclusion criteria apply

Ergänzende Informationen unter ClinicalTrials.gov/NCT03369223

	Dermatology		
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AGEN1181, C-800-23

A Multicohort, Open Label, Phase 2 Study of Botensilimab (AGEN1181) for Treatment of Advanced Melanoma Refractory to Prior Checkpoint Inhibitor Therapy

Recruitment Status: **SUSPENDED! As a business decision, this study has been paused. There are no safety concerns.**
Condition: Advanced Melanoma
Primary Completion Date: 2028-05
Intervention/ Treatment: Drug (**Botensilimab**/ **Balstilimab)**

Wichtigste Einschlusskriterien:
- Kohorte A: Progress unter PD-1 Monotherapie (metastasiert <12 Wochen, adjuvant <24 Wochen)
- Kohorte B: Progress unter Ipilimumab + Nivolumab
- Verfügbares Tumormaterial
- ECOG 0-1

Wichtigste Ausschlusskriterien:
- Okuläres, uveales oder mukosales Melanom
- Grad 3 Toxizitäten unter vorheriger ICI (außer Endokrinopathien oder nicht-bullöser Rash)
- aktive Hirnfiliae (stabile, behandelte, oder nicht behandlungsbedürftige erlaubt)
- aktive Zweitmalignome in den letzten 2 Jahren

Ergänzende Informationen sind unter ClinicalTrials.gov/ NCT05529316

	Dermatology		
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SK	Studienteam	0152-22800599	studien-htz@uke.de

INTerpath-001/V940-001

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

A Phase 3, Randomized, Double-Blind, Placebo- and Active-Comparator-Controlled Clinical Study of Adjuvant V940 (mRNA-4157) Plus Pembrolizumab Versus Adjuvant Placebo Plus Pembrolizumab in Participants With High-Risk Stage II-IV Melanoma (INTerpath-001)

Recruitment Status: **ACTIVE, NOT RECRUITING!**
Condition: Melanoma
Primary Completion Date: 2029-10-26
Intervention/ Treatment: Biological (**V940/ Pembrolizumab/** Placebo

Inclusion Criteria:
The main inclusion criteria include but are not limited to the following:
Has surgically resected and histologically/pathologically confirmed diagnosis of Stage IIB or IIC, III, or IV cutaneous melanoma
Has not received any prior systemic therapy for their melanoma beyond surgical resection
No more than 13 weeks have passed between final surgical resection that rendered the participant disease-free and the first dose of pembrolizumab
Is disease free at the time of providing documented consent for the study
Human immunodeficiency virus (HIV)-infected participants must have well controlled HIV on anti-retroviral therapy (ART)
Exclusion Criteria:
The main exclusion criteria include but are not limited to the following:
Has ocular or mucosal melanoma
Has cancer that has spread to other parts of the body and cannot be removed with surgery
Has heart failure within the past 6 months
Has received prior cancer therapy or another cancer vaccine
Has another known cancer that that has spread to other parts of the body or has required treatment within the past 3 years
Has severe reaction to study medications or any of their substance used to prepare a drug
Have not recovered from major surgery or have ongoing surgical complications

Ergänzende Informationen sind unter ClinicalTrials.gov verfügbar

	Dermatology		
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CA224-127 / Relativity-127

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

A Phase 3, Randomized, Open-label, Study of Subcutaneous Nivolumab + Relatlimab Fixed-dose Combination Versus Intravenous Nivolumab + Relatlimab Fixed-dose Combination in Participants With Previously Untreated Metastatic or Unresectable Melanoma

Recruitment Status: **RECRUITING!**
Condition: Melanoma
Primary Completion Date: 2025-02-28
Intervention/ Treatment: Drug (**Nivolumab + Relatlimab/ rHuPH20)**

Inclusion Criteria:
Participants must have an Eastern Cooperative Oncology Group (ECOG) performance status of ≤ 1/Lansky Performance Score ≥ 80% for adolescents (≥ 12 to < 18 years of age).
Participants must have histologically confirmed Stage III (unresectable) or Stage IV (metastatic) melanoma, per the American Joint Committee for Cancer (AJCC) staging system.
Participants must have measurable disease by computed tomography (CT) or magnetic resonance imaging (MRI) per Response Evaluation Criteria in Solid Tumors version 1.1 (RECIST v1.1).
Participants must be ≥ 12 years of age. Participants who are ≥ 12 years of age and < 18 years of age (adolescents) must weigh ≥ 40 kg at the time of signing the informed consent (assent).
Participants must have histologically confirmed Stage III (unresectable) or Stage IV (metastatic) melanoma, per the AJCC staging system (8th edition).
Exclusion Criteria:
Participants must not have ocular melanoma.
Participants must not have a history of myocarditis, regardless of etiology.
Participants must not have a condition requiring systemic treatment with either corticosteroids (>10 milligrams [mg] daily prednisone equivalent) or other immunosuppressive medications within 14 days of start of study treatment. Inhaled or topical steroids, and adrenal replacement steroid doses >10 mg daily prednisone equivalent, are permitted in the absence of active autoimmune disease.
Other protocol-defined Inclusion/Exclusion criteria apply.

Ergänzende Informationen sind unter ClinicalTrials.gov verfügbar

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IMCgp100-203/ TEBE-AM

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

Eine Phase 2/3 randomisierte Studie mit Tebentafusp Monotherapie und in Kombination mit Pembrolizumab gegen Investigator's Choice in HLAA* 02:01-positiven Patienten mit vorbehandeltem fortgeschrittenen Melanom

Recruitment Status: RECRUITING!
Condition: Advanced Melanoma
Primary Completion Date: 2026-12
Intervention/ Treatment: Drug (**Tebentafusp/ Tebentafusp with Pembrolizumab/**
Drug: Investigators Choice

Inclusion Criteria: HLA-A*02:01-positive. unresectable Stage III or Stage IV non-ocular melanoma archival tumor tissue sample or a newly obtained biopsy of a tumor lesion not previously irradiated has been provided. measurable or non-measurable disease per RECIST 1.1 Eastern Cooperative Oncology Group (ECOG) performance status score of 0 or 1 If applicable, must agree to use highly effective contraception Capable of giving signed informed consent which includes compliance with the requirements and restrictions listed in the Informed Consent (ICF) and protocol Must agree to provide protocol specified samples for biomarker analyses.
Exclusion Criteria: Pregnant or lactating women diagnosis of ocular or metastatic uveal melanoma history of a malignant disease other than those being treated in this study ineligible to be retreated with pembrolizumab due to a treatment-related AE known untreated or symptomatic central nervous system (CNS) metastases and/or carcinomatous meningitis previous severe hypersensitivity reaction to treatment with another monoclonal antibody (mAb)
active autoimmune disease requiring immunosuppressive treatment with clinically significant cardiac disease or impaired cardiac function known psychiatric or substance abuse disorders received prior treatment with a licensed or investigative Immune-mobilizing monoclonal T-cell receptor Against Cancer (ImmTAC) medication who have not completed adequate washout from prior medications. received chemotherapy or biological cancer therapy (excluding anti-PD(L)1 mAb, ipilimumab, and BRAF TKI regimen) within 14 days of first dose received cellular therapies within 90 days of study intervention ongoing Common Terminology Criteria for Adverse Events(CTCAE) Grade ≥ 2 clinically significant who in the opinion of the investigator could affect the outcome of the study received systemic treatment with steroids or any other immunosuppressive drug within 2 weeks of first dose have not progressed on treatment with an anti-PD(L)1 mAb have not received prior ipilimumab a BRAF V600 mutation, who have not received a prior BRAF/MEK TKI regimen currently participating or have participated in a study of an investigational agent or using an investigational device within 30 days of the first dose known history of chronic viral infections such as hepatitis B virus (HBV) or hepatitis C virus (HCV) Out of range Laboratory values
history of allogenic tissue/solid organ transplant

Ergänzende Informationen sind unter ClinicalTrials.gov verfügbar

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Entitäten

RAVINA/ EORTC 2120-HNCG

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

Radiotherapy plus xevinapant or placebo in older patients with locally advanced head and neck squamous cell carcinoma: a randomized phase II study RAVINA

Recruitment Status: **RECRUITING!**
Condition: Locally Advanced Head and Neck Squamous Cell Carcinoma
Primary Completion Date: 2029-07
Intervention/ Treatment: Drug (**Xevinapant/ Placebo)**

Main Inclusion Criteria: Age ≥ 70 years. Pathologically proven new diagnosis of HNSCC of oral cavity, oropharynx, hypopharynx and larynx tumor. cT3-4 cN0 cM0 or cT1-4 cN1-3 cM0 except for T1-2N1 p16 positive oropharyngeal cancer (AJCC 8th edition). HPV status using p16 immunohistochemistry (IHC) available for oropharyngeal squamous cell carcinoma. Measurable disease per RECIST 1.1. Eastern Coperative Oncology Group Performance Status (ECOG PS) ≤ 1. Intention to treat with curative intent primary radiotherapy alone. Able to swallow liquids or has an adequately functioning feeding tube, gastrostomy or jejunostomy placed. Adequate hematologic, renal, and hepatic function as indicated by: Creatinine clearance ≥ 30 mL/min, measured with the Cockroft and Gault formula. Absolute neutrophil count ≥ 1 500 cells/μL. Platelets ≥ 100 000 cells/μL.
Hemoglobin ≥ 9.0 g/dL or ≥5.6 mmol/L (blood transfusions during screening are permitted). AST and ALT ≤ 3.0 × upper limit of normal (ULN). Total bilirubin ≤ 1.5 × ULN (up to 2.0 × ULN is allowed if the direct bilirubin level is normal and the elevation is limited to indirect bilirubin). Written informed consent must be signed according to ICH/GCP, and national/local regulations.
Main Exclusion Criteria: Unknown primary, primary nasopharynx and paranasal sinus. Two primaries. Any previous or current treatment for invasive head and neck cancer, including induction chemotherapy, surgery, concomitant chemotherapy and cetuximab. Gastrointestinal disorders that could affect drug absorption. Another malignancy in the previous 3 years with exception of curatively treated disease with no evidence of recurrence.
Known allergy to xevinapant or any excipient known to be present in active or placebo formulation. Active gastrointestinal bleeding, or any other uncontrolled bleeding requiring more than 2 red blood cell transfusions or 4 units of packed red blood cells within 4 weeks prior to enrolment Non-Decompensated or symptomatic liver cirrhosis (Child-Pugh score: B or C). Impaired cardiovascular function or clinically significant cardiovascular diseases
Any uncontrolled, intercurrent illness or clinical situation that would in the judgment of investigator, limit compliance with study requirements. This includes but is not limited to uncontrolled active infections, defined as any infection requiring IV antibiotics within 7 days prior to enrolment.

Ergänzende Informationen unter ClinicalTrials.gov

	Radiotherapy		
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SI			

Pfizer Portside C4221023

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

A PHASE 2, RANDOMIZED, OPEN-LABEL STUDY OF ENCORAFENIB AND BINIMETINIB PLUS PEMBROLIZUMAB VERSUS NIVOLUMAB AND IPILIMUMAB IN PARTICIPANTS WITH BRAF V600E/K MUTATION-POSITIVE MELANOMA WHO PROGRESSED DURING OR AFTER PRIOR TREATMENT WITH ANTI-PD-1 THERAPY

Recruitment Status: RECRUITING

Condition: Melanoma
Primary Completion Date: 2025-05-23
Intervention/ Treatment: Drug: encorafenib/ binimetinib/ pembrolizumab/ ipilimumab/ nivolumab

Inclusion Criteria:
Male or female participants ≥18 years of age at the time of informed consent. Histologically confirmed unresectable (Stage IIIB, IIIC, or IIID) or metastatic (Stage IV) cutaneous melanoma, according to the AJCC 8th edition. Documented evidence of a BRAF V600E or V600K mutation. Availability of adequate tumor tissue (archival or newly obtained; block or slides) to submit to the sponsor central laboratory(ies) during the screening period for central biomarker analyses. Must have received only 1 prior line of systemic therapy for melanoma (either adjuvant therapy or first-line anti-PD-1 monotherapy (ie, nivolumab or pembrolizumab). Must have anti-PD-1 resistant disease (primary or secondary) with confirmed disease progression per RECIST v1.1 either during or after receipt of an approved anti-PD-1 monotherapy (ie, nivolumab or pembrolizumab) for melanoma, defined according to the SITC Immunotherapy Resistance Taskforce (Kluger et al, 2020). Have at least one measurable lesion per RECIST v1.1. ECOG PS of 0-1, and adequate organ and cardiac function, including LVEF ≥50% by cardiac imaging.

Inclusion Criteria:
Mucosal or ocular melanoma. Diagnosis of immunodeficiency or an active autoimmune disease that required systemic treatment with chronic systemic steroid therapy or any other form of immunosuppressive therapy within the past 2 years. Clinically significant cardiovascular diseases. History of thromboembolic or cerebrovascular events ≤12 weeks prior to randomization. History or current evidence of RVO or current risk factors for RVO. Concurrent neuromuscular disorder that is associated with the potential of elevated CK. Active bacterial, fungal, or viral infection requiring systemic therapeutic treatment within 2 weeks prior to randomization. Current non-infectious pneumonitis/interstitial lung disease or history of noninfectious pneumonitis/interstitial lung disease requiring steroids. Prior or current symptomatic brain metastasis, leptomeningeal disease or other active CNS metastases. Participants who permanently discontinued prior anti-PD-1 therapy due to toxicity or will be unable to tolerate combination therapy based on investigator judgement are excluded. Prior treatment with ipilimumab; prior combined immunotherapy blockade with anti-PD-1/L-1; prior treatment with a BRAFi and/or MEKi; or previous administration of an investigational anti-cancer agent for the adjuvant or first-line treatment of melanoma prior to randomization.

Ergänzende Informationen unter ClinicalTrials.gov

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MK-3475-630 / KEYNOTE-630

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

A Phase 3, Randomized, Double-blind, Placebo-controlled Study to Evaluate Pembrolizumab Versus Placebo as Adjuvant Therapy Following Surgery and Radiation in Participants With High-risk Locally Advanced Cutaneous Squamous Cell Carcinoma (LA cSCC)

Recruitment Status: ACTIVE, NOT RECRUITING
Condition: Carcinoma, Squamous Cell
Primary Completion Date: 2025-05-05
Intervention/ Treatment: Biological: Pembrolizumab 400 mg/ Drug: Placebo

Inclusion Criteria:
Has histologically confirmed cutaneous squamous cell carcinoma (cSCC) as the primary site of malignancy (metastatic skin involvement from another type of primary cancer or from an unknown primary cancer is not permitted) Has histologically confirmed LA cSCC with ≥1 high-risk feature(s) as the primary site of malignancy Has undergone complete macroscopic resection of all known cSCC disease with or without microscopic positive margins. For those participants with residual microscopic positive margin involvement, confirmation that additional re-excision is not possible must be provided Has completed adjuvant radiotherapy (RT) for LA cSCC with last dose of RT ≥4 weeks and ≤16 weeks from randomization Has received an adequate post-op dose of RT (either hypofractionated or conventional) Is disease free as assessed by the investigator with complete radiographic staging assessment ≤28 days from randomization Is not pregnant or breastfeeding Is not a person of childbearing potential (POCBP) Has a negative pregnancy test ≤72 hours before the first dose of study intervention. Has provided an archival or newly-obtained tumor tissue sample adequate for Programmed Cell Death Ligand 1 (PD-L1) testing as determined by central laboratory testing. Has a life expectancy of >3 months.Has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 ≤10 days prior to the first dose of study intervention.

Inclusion Criteria:
Has macroscopic residual cSCC after surgery and/or recurrence with active cSCC disease before randomization. Has any other histologic type of skin cancer other than invasive cSCC (eg, basal cell carcinoma) that has not been definitively treated with surgery or radiation; Bowen's disease; Merkel cell carcinoma; or melanoma Has received prior therapy with an anti-programmed cell death receptor 1(PD-1), anti-PD-L1, or anti-programmed cell death receptor ligand 2 (PD-L2) agent or with an agent directed to another costimulatory or coinhibitory T-cell receptor (eg, cytotoxic T-lymphocyte-associated protein 4 [CTLA-4], OX-40, CD137) Has received prior systemic anticancer therapy including investigational agents for cSCC ≤4 weeks prior to before start of study intervention. Has not recovered from all radiation-related toxicities and has not had radiation pneumonitis. Has received a live vaccine ≤30 days prior to the first dose of study intervention. Has received an investigational agent or has used an investigational device within 4 weeks prior to the first dose of study treatment. Has known additional malignancy that is progressing or has required active treatment within the past 2 years. Note: Participants with basal cell carcinoma of the skin, squamous cell carcinoma of the skin or carcinoma in situ, excluding carcinoma in situ of the bladder, that have undergone potentially curative therapy are not excluded. Other exceptions may be considered with Sponsor consultation. Note: Participants with low risk early-stage prostate cancer defined as below are not excluded: Stage T1c or T2a with a Gleason score ≤6 and a prostate-specific antigen (≤10 ng/ml) either treated with definitive intent or untreated in active surveillance that has been stable for the past year prior to study allocation. Early stage asymptomatic CLL without prior treatment and without any of the risk features (unmutated IGHV, lymphocytes >15,000µL, palpable lymph nodes) will be eligible for the study. Has an active autoimmune disease that has required systemic treatment in past 2 years except replacement therapy (eg, thyroxine, insulin, or physiologic corticosteroid). Has a history of (noninfectious) pneumonitis/interstitial lung disease that required steroids or has current pneumonitis/interstitial lung disease Has an active infection requiring systemic therapy. Has a known history of human immunodeficiency virus (HIV) infection. Has a known history of hepatitis B (defined as hepatitis B surface antigen [HBsAg] reactive) or known active hepatitis C virus (HCV; defined as HCV RNA [qualitative] is detected) infection. Is pregnant or breastfeeding or expecting to conceive or father children within the projected duration of the study, starting with the screening visit through 120 days after the last dose of study intervention. Has had an allogeneic tissue/solid organ transplant.

Ergänzende Informationen unter ClinicalTrials.gov

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AMLSG 30-18

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

Randomized Phase III Study of Standard Intensiv Chemotherapy versus Intensiv Chemotherapy with CPX-351 in Adult Patients with Newly diagnosed AML and Intermediate-orAdverse Genetics

Recruitment Status: RECRUITING

Condition: Acute Myeloid Leukemia
Primary Completion Date: 2024-04-03
Intervention/ Treatment: Drug: Cytarabine/ Daunorubicin/ CPX-351

Inclusion Criteria:

Patients with newly diagnosed AML and intermediate- or adverse-risk genetics (according to 2017 ELN criteria [Appendix B]), including AML with myelodysplasia-related changes (AML-MRC) and therapy-related AML according to the World Health Organization (WHO) classification Age ≥ 18 years, no upper age limit Patient considered eligible for intensive chemotherapy Eastern Cooperative Oncology Group (ECOG) performance status ≤ 2 at screening Genetic assessment in AMLSG central laboratory Adequate renal function as evidenced by serum creatinine ≤ 2.0 × ULN or creatinine clearance >40 mL/min based on the Cockcroft-Gault glomerular filtration rate (GFR) Adequate hepatic function as evidenced by: Serum total bilirubin ≤ 1.5 × upper limit of normal (ULN) unless considered due to Gilbert's disease, or leukemic involvement following approval by the Coordinating Investigator or Co-Coordinating Investigator Aspartate aminotransferase (AST), alanine aminotransferase (ALT), and alkaline phosphatase (ALP) ≤ 3.0 × ULN, unless considered due to leukemic involvement following approval by the Coordinating Investigator or Co-Coordinating Investigator No prior chemotherapy for acute leukemia except hydroxyurea for up to 7 days during the diagnostic screening phase for the control of peripheral leukemic blasts in patients with leukocytosis (e.g., white blood cell [WBC] counts >30x109/l); prior treatment of myelo-dysplastic syndrome with hypomethylating agents is allowed Non-pregnant and non-nursing women of childbearing potential (WOCBP) must have a negative serum or urine pregnancy test within a sensitivity of at least 25 mIU/mL within 72 hours prior to randomization ("Women of childbearing potential" is defined as a sexually active mature woman who has not undergone a hysterectomy or bilateral oophorectomy or who has had menses at any time in the preceding 24 consecutive months) Female patients of childbearing potential must agree to avoid getting pregnant while on therapy and for 27 weeks after the last dose of study drug Women of childbearing potential must either commit to continued abstinence from heterosexual intercourse or apply one highly effective method of birth control (such as IUD, bilateral tubal ligation, or partner's vasectomy) in combination with one acceptable method of birth control at the same time (such as hormonal contraception or the male partner has to use a latex condom coated with spermicide lubricant or combined with spermicide gel or foam) while on therapy and for 27 weeks after the last dose of study drug. Hormonal contraception is only a highly effective method of birth control in case of combined (estrogen and progestogen containing) associated with inhibition of ovulation or progestogen-only hormonal contraception associated with inhibition of ovulation is used Men must use a latex condom coated with a spermicide lubricant or combined with spermicide gel or foam during any sexual contact with women of childbearing potential, even if they have undergone a successful vasectomy and must agree to avoid to father a child (while on therapy and for 6 months after the last dose of study drug). In addition, their female partners of childbearing potential have to use a highly effective method of birth control Able to understand and willing to sign an informed consent form (ICF).

Ergänzende Informationen unter ClinicalTrials.gov/NCT03897127

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CA-4948-102 CURIS

A Phase 1/2A, Open Label Dose Escalation and Expansion Study of Orally Administered CA-4948 as a Monotherapy in Patients With Acute Myelogenous Leukemia or Myelodysplastic Syndrome

Recruitment Status: RECRUITING

Condition: Acute Myelogenous Leukemia Myelodysplastic Syndrome
Primary Completion Date: 2026-04-01
Intervention/ Treatment: Drug: Emavusertib/ Venetoclax/ Emavusertib

Inclusion Criteria:
Males and females ≥18 years of age Life expectancy of at least 3 months Eastern Cooperative Oncology Group (ECOG) Performance Status of ≤1 Cytomorphology based confirmed diagnosis of MDS or AML (as per WHO 2016 classification) with the following characteristics. Phase 1 Dose Escalation (Monotherapy) • AML (primary or secondary, including treatment-related) after failing at least 1 standard treatment (may include chemotherapy, re induction therapy or stem cell transplantation). OR • Higher-risk R/R MDS that are considered resistant/refractory following at least 2 to 3 cycles of hypermethylating agent (HMA) or evidence of early progression Phase 2a Dose Expansion (Monotherapy) Patients with: R/R AMLwith FLT3 mutations who have been previously treated with a FLT3 inhibitor R/R AML with spliceosome mutations of SF3B1 or U2AF1 R/R hrMDS (IPSS-R score > 3.5) with spliceosome mutations of SF3B1 or U2AF1 Number of pretreatments: 1 or 2 Acceptable organ function at screening Ability to swallow and retain oral medications Negative serum pregnancy test in women of childbearing potential Women of childbearing potential and men who partner with a woman of childbearing potential must agree to use highly effective contraceptive methods for the duration of the study and for 90 days after the last dose of emavusertib Willing and able to provide written informed consent and comply with the requirements of the trial Able to undergo serial bone marrow sampling and peripheral blood sampling.

Inclusion Criteria:
Diagnosed with acute promyelocytic leukemia (APL, M3) Has known active central nervous system (CNS) leukemia Allogeneic hematopoietic stem cell transplant (Allo-HSCT) within 60 days of the first dose of emavusertib, or clinically significant graft-versus-host disease (GVHD) requiring ongoing up titration of immunosuppressive medications prior to start of emavusertib Chronic myeloid leukemia (CML) Any prior systemic anti-cancer treatment such as chemotherapy, immunomodulatory drug therapy, etc., received within 3 weeks (or 5 half-lives) prior to start of emavusertib. Localized radiation or surgical resection of skin cancers allowed. Use of any investigational agent within 3 weeks or 5 half-lives, whichever is shorter, prior to start of emavusertib Presence of an acute or chronic toxicity resulting from prior anti-cancer therapy, with the exception of alopecia that has not resolved to Grade ≤ 1within 7 days prior to start of emavusertib; presence of any acute or chronic non-hematological toxicity ≥ Grade 3 at Screening, or prior to start of emavusertib must resolve to ≤ Grade 2. Known allergy or hypersensitivity to any component of the formulation of emavusertib Major surgery, other than diagnostic surgery, <28 days from the start of emavusertib; minor surgery <14 days from the start of emavusertib Patients with active advanced malignant solid tumors Known to be human immunodeficiency virus (HIV) positive or have an acquired immunodeficiency syndrome-related illness Hepatitis B virus (HBV) DNA positive or Hepatitis C virus (HCV) infection <6 months prior to start of emavusertib unless viral load is undetectable, or HCV with cirrhosis Uncontrolled or severe cardiovascular diseaseincluding myocardial infarction or unstable angina within 6 months prior to CA-4948, New York Heart Association Class II or greater congestive heart failure, or left ventricular ejection fraction < 40% by echocardiogram or multi-gated acquisition scan, serious arrhythmias uncontrolled on treatment, clinically significant pericardial disease, cardiac amyloidosis, congenital long QT syndrome, or QTc with Fridericia's correction (QTcF) that is unmeasurable or > 450 msec on Screening electrocardiogram (ECG) Gastrointestinal disease or disorder that could interfere with the swallowing, oral absorption, or tolerance of emavusertib Pregnant or lactating Systemic fungal, bacterial, viral, or other infection that is not controlled Any other severe, acute, or chronic medical, psychiatric or social condition, or laboratory abnormality that may increase the risk of trial participation or emavusertib administration.

Ergänzende Informationen unter ClinicalTrials.govNCT04278768

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WiNK

A Prospective Phase I/IIa, open-label, multicentre trial to evaluate the safey and efficay of oNKord®, an off-the-shelf, ex vivo- cultured allogenic NK cell preparation, in subjects with acute myeloid leukaemia who are in complete morphologic remission with measurable residual disease and without a strong indication for stem cell transplantation

Recruitment Status: RECRUITING

Condition: Acute Myeloid Leukemia
Primary Completion Date: 2023-04
Intervention/ Treatment: Drug: Cyclophosphamide-Fludarabine (Cy/Flu) Drug: oNKord®

Inclusion Criteria:
Male or female subjects ≥ 18 years old Subjects with a diagnosis of AML and related precursor neoplasms according to the WHO 2016 classification (excluding acute promyelocytic leukemia), including secondary AML after an antecedent hematological disease (e.g. myelodysplastic syndrome) and therapy-related AML Subjects who have achieved morphologic CR, including CRi and complete clinical remission, with MRD documented at screening, as assessed by centralized MFC, after one or two courses of remission induction chemotherapy and who have completed consolidation chemotherapy or who achieved morphologic CR with documented MRD with hypomethylating agents or other relevant appropriate therapies Subjects who are currently (at the time of screening) not proceeding to allo-HSCT Life expectancy ≥ 6 months at screening Adequate renal and hepatic functions within 14 days of study screening, unless clearly disease related, as indicated by the following laboratory values: Serum creatinine ≤ 3 times the upper limit of normal (ULN) and estimated glomerular filtration rate (eGFR) ≥ 30 ml/min/1.73m2 Serum total bilirubin < 2.0 mg/dl, unless due to Gilbert's syndrome Alanine transaminase (ALT) ≤ 2.5 x ULN Karnofsky Status ≥ 50% Seropositivity for EBV Male subjects with partners who are women of childbearing potential must use an effective contraceptive method during the trial and for a minimum of 6 months after trial treatment, or have undergone successful vasectomy at least 6 months prior to entry into the trial (confirmed by semen analysis). Female subjects of childbearing potential must have a negative serum pregnancy test at screening and agree to use an effective contraceptive method during the trial and for a minimum of 6 months after trial treatment. Able to understand and willing to provide written informed consent to participate in the trial Affiliation to a national health insurance scheme (according to applicable local requirements)

Ergänzende Informationen unter clinicaltrialsregister.eu/NCT04632316

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AMLSG 29-18/ HOVON 150

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

A Phase 3, Multicenter, Double-blind, Randomized, Placebo-controlled Study of Ivosidenib or Enasidenib in Combination With Induction Therapy and Consolidation Therapy Followed by Maintenance Therapy in Patients With Newly Diagnosed Acute Myeloid Leukemia or Myelodysplastic Syndrome With Excess Blasts-2, With an IDH1 or IDH2 Mutation, Respectively, Eligible for Intensive Chemotherapy.

Recruitment Status: RECRUITING

Condition: Acute Myeloid Leukemia Myelodysplastic Syndrome With Excess Blasts-2
Primary Completion Date: 2033-03
Intervention/ Treatment: Drug: AG-120/ Placebo for AG-120/ AG-221/ Placebo for AG-221/

Key Inclusion Criteria:
Age ≥18 years Newly diagnosed AML or MDS-EB2 defined according to WHO criteria, with a documented IDH1 or IDH2 gene mutation (as determined by the clinical trial assay) at a specific site (IDH1 R132, IDH2 R140, IDH2 R172). AML may be secondary to prior hematological disorders, including MDS, and/or therapy-related (in which prior disease should have been documented to have existed for at least 3 months). Patients may have had previous treatment with hypomethylating agents (HMAs) for MDS. HMAs have to be stopped at least four weeks before registration Patients with dual mutant FLT3 and IDH1 or IDH2 mutations may be enrolled only if, for medical or other reasons, reatment with a FLT3 inhibitor is not considered. Considered to be eligible for intensive chemotherapy. ECOG/WHO performance status ≤ 2 Adequate hepatic function as evidenced by: Serum total bilirubin ≤ 2.5 × upper limit of normal (ULN) unless considered due to Gilbert's disease (e.g. a mutation in UGT1A1) (only for patients in IDH2 cohort), or leukemic involvement of the liver - following written approval by the (Co)Principal Investigator. Aspartate aminotransferase (AST), alanine aminotransferase (ALT), and alkaline phosphatase (ALP) ≤ 3.0 × ULN, unless considered due to leukemic involvement of the liver, following written approval by the Principal Investigator. Adequate renal function as evidenced by creatinine clearance > 40 mL/min based on the Cockroft-Gault formula for glomerular filtration rate (GFR). Able to understand and willing to sign an informed consent form (ICF). Written informed consent Female patient must either: o Be of nonchildbearing potential: Postmenopausal (defined as at least 1 year without any menses) prior to screening, or Documented surgically sterile or status posthysterectomy (at least 1 month prior to screening) o Or, if of childbearing potential: Agree not to try to become pregnant during the study and for 6 months after the final study drug administration And have a negative urine or serum pregnancy test at screening And, if heterosexually active, agree to consistently use highly effective* contraception per locally accepted standards in addition to a barrier method starting at screening and throughout the study period and for 6 months after the final study drug administration. Highly effective forms of birth control include: Consistent and correct usage of established hormonal contraceptives that inhibit ovulation, Established intrauterine device (IUD) or intrauterine system (IUS), Bilateral tubal occlusion, Vasectomy (A vasectomy is a highly effective contraception method provided the absence of sperm has been confirmed. If not, an additional highly effective method of contraception should be used.) Male is sterile due to a bilateral orchiectomy. Sexual abstinence is considered a highly effective method only if defined as refraining from heterosexual activity during the entire period of risk associated with the study drug. The reliability of sexual abstinence needs to be evaluated in relation to the duration of the clinical study and the preferred and usual lifestyle of the patient. List is not all inclusive. Prior to enrollment, the investigator is responsible for confirming patient will utilize highly effective forms of birth control per the requirements of the CTFG Guidance document 'Recommendations related to contraception and pregnancy testing in clinical trials', September 2014 (and any updates thereof) during the protocol defined period. Female patient must agree not to breastfeed starting at screening and throughout the study period, and for 2 months and 1 week after the final study drug administration. Female patient must not donate ova starting at screening and throughout the study period, and for 6 months after the final study drug administration. Male patient and their female partners who are of childbearing potential must be using highly effective contraception per locally accepted standards in addition to a barrier method starting at screening and continue throughout the study period and for 4 months and 1 week after the final study drug administration Male patient must not donate sperm starting at screening and throughout the study period and for 4 months and 1 week after the final study drug administration. Subject agrees not to participate in another interventional study while on treatment.

Ergänzende Informationen unter ClinicalTrials.gov/NCT03839771

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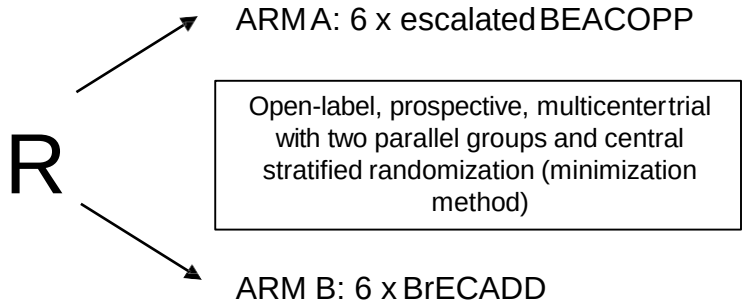
HD 21 for advanced stages

Treatment optimalization trial in the first-line treatment of advanced stage Hodgkin lymphoma; comparison of a 6 cycles of escalated BEACOPP with 6 cycles of BrECADD

Recruitment Status: ACTIVE, NOT RECRUITING
Condition: Classical Hodgkin Lymphoma
Primary Completion Date: 2025-09
Intervention/ Treatment: Drug: Bleomycin/ Drug: Etoposide/ Doxorubicin/ Cyclophosphamide/ Vincristine/ Procarbazine/ Prednisone/ Brentuximab Vedotin/ Dacarbazine/ Dexamethasone

Einschlusskriterien:
Histologically proven classical Hodgkin lymphoma
First diagnosis, no previous treatment, 18 to 60 years of age
Stage IIB with large mediastinal mass and/or extranodal lesions, stage III or IV

Ausschlusskriterien:
Composite lymphoma or nodular lymphocyte-predominant Hodgkin lymphoma
Previous malignancy (exceptions: basalioma, carcinoma in situ of the cervix uteri, completely resected melanoma TNMpT1)
Prior chemotherapy or radiotherapy
Concurrent disease which precludes protocol treatment
Pregnancy, lactation
Non-Compliance



Ergänzende Informationen unter ClinicalTrials.gov/NCT02661503

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Study Nurse	Petra Kühne	040 / 7410 - 54353	p.kuehne@uke.de	Dorothea Zäch	040 – 35071 777 - 526	zaech@onkologie-hamburg.de

DREAMM 5 (GSK 208887)

A Phase I/II, Randomized, Open-label Platform Study Utilizing a Master Protocol to Study Belantamab Mafodotin (GSK2857916) as Monotherapy and in Combination With Anti-Cancer Treatments in Participants With Relapsed/Refractory Multiple Myeloma (RRMM) - DREAMM 5

Recruitment Status: ACTIVE, NOT RECRUITING
Condition: Multiple Myeloma
Primary Completion Date: 2026-02-24
Intervention/ Treatment: Drug: Belantamab mafodotin/ GSK3174998/ Feladilimab/ Nirogacestat/ Dostarlimab/ Isatuximab/ Lenalidomide/ Dexamethasone/ Pomalidomide

Inclusion Criteria:

- Participant must be 18 years of age inclusive or older, at the time of signing the informed consent.
- Participants must have histologically or cytologically confirmed diagnosis of Multiple Myeloma (MM), as defined by the IMWG.
- Participants having at least 3 prior lines of prior anti-myeloma treatments including an immunodilating agent (IMID) a proteasome inhibitor (PI) and an anti- CD38 monoclonal antibody.
- Participants with a history of autologous stem cell transplant are eligible for study participation when, transplant was >100 days prior to study enrolment and with no active infection(s).
- Participants with Eastern Cooperative Oncology Group (ECOG) performance status of 0-1, unless ECOG less than equal to (<=)2 is due solely to skeletal complications and/or skeletal pain due to MM.
- Participants with measurable disease defined as at least one of the following: Serum M-protein greater than equal to (>=)0.5 gram per deciliter (>=5 gram per liter) or Urine M-protein >=200 mg per 24 hours or Serum free light chain (FLC) assay: Involved FLC level >=10 mg per deciliter (>=100 mg per Liter) and an abnormal serum FLC ratio (<0.26 or >1.65).

Exclusion Criteria:

- Participants with current corneal epithelial disease except mild punctate keratopathy.
- Participants with evidence of cardiovascular risk
- Participants with known immediate or delayed hypersensitivity reaction or idiosyncrasy to drugs chemically related to belantamab mafodotin or any of the components of the study treatment. History of severe hypersensitivity to other mAb.
- Participants with active infection requiring antibiotic, antiviral, or antifungal treatment.
- Participants with other monoclonal antibodies within 30 days or systemic anti-myeloma therapy within <14 days.
- Participants with prior radiotherapy within 2 weeks of start of study therapy.
- Participants with prior allogeneic transplant are prohibited.
- Participants who have received prior Chimeric Antigen T cell therapy (CAR-T) therapy with lymphodepletion with chemotherapy within 3 months of screening.
- Participants with any major surgery (other than bone-stabilizing surgery) within the last 30 days.
- Participants with prior treatment with an investigational agent within 14 days or 5 half-lives of receiving the first dose of study drugs, whichever is shorter.
- Participants with >=grade 3 toxicity considered related to prior check-point inhibitors and that led to treatment discontinuation.
- Participants who have received transfusion of blood products within 2 weeks before the first dose of study drug.
- Participants must not receive live attenuated vaccines within 30 days prior to first dose of study treatment or whilst receiving belantamab mafodotin +- partner agent in any sub-study arm of the platform trial and for at least 70 days following last study treatment.

Ergänzende Informationen unter ClinicalTrials.gov/NCT04126200

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DREAMM-9

Study of Belantamab Mafodotin Plus Standard of Care (SoC) in Newly Diagnosed Multiple Myeloma –A Phase 1, Randomized, Dose and Schedule Evaluation Study to Investigate the Safety, Pharmacokinetics, Pharmacodynamics and Clinical Activity of Belantamab Mafodotin Administered in Combination With Standard of Care in Participants With Newly Diagnosed Multiple Myeloma

Recruitment Status: RECRUITING

Condition: Multiple Myeloma
Primary Completion Date: 2024-11-15
Intervention/ Treatment: Drug: Belantamab mafodotin/ Bortezomib/ Lenalidomide/ Dexamethasone

Key Inclusion Criteria:

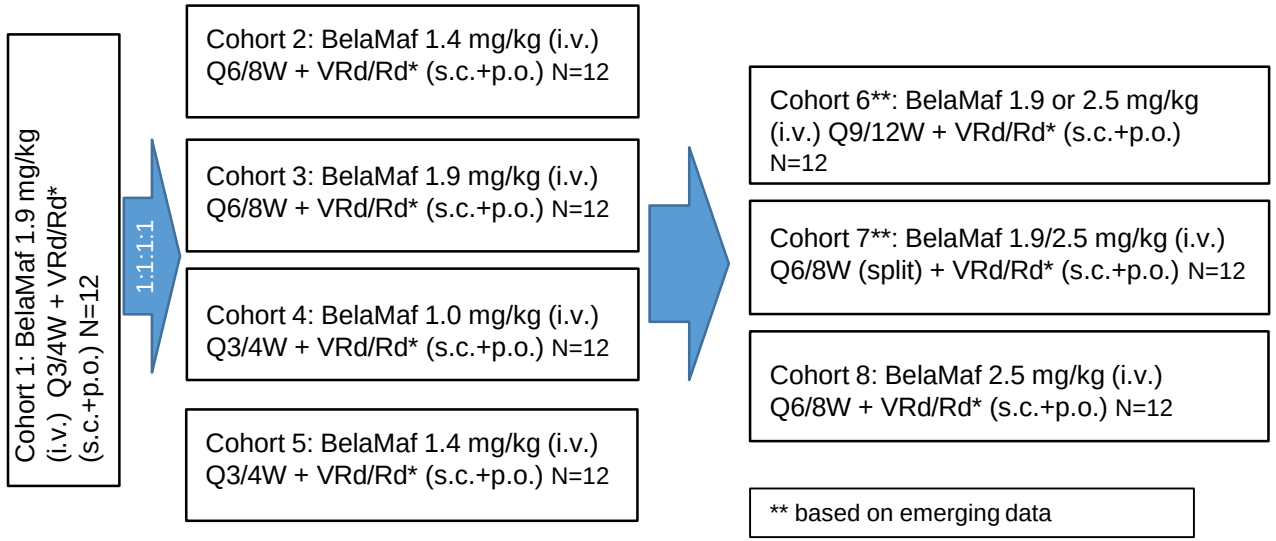
- Male or female, 18 years or older (at the time consent is obtained)
- Eastern Cooperative Oncology Group (ECOG) performance status of 0-2
- Subjects must have a documented diagnosis of MM requiring treatment as documented per international myeloma working group (IMWG) criteria
- Subjects must have measurable disease defined as:

a. M-protein (sPEP or uPEP): sPEP >0,5 g/dL or uPEP ≥ 200 mg/24 hours and/or
b.Light chain MM: Serum FLC assay: Involved FLC level ≥100 mg/L and abnormal SFLC ratio

- Subject is not a candidate for high-dose chemotherapy with autologous stem cell transplant (ASCT)

Key Exclusion Criteria:

- Prior systemic therapy for multiple myeloma, or smouldering MM. An emergency course of steroids (max. 160 mg of dexamethasone) is permitted.
- Hemoglobin <8,0 g/dL, Absolute neutrophil count (ANC) < 1,500/µL, Platelet count < 75,000/µL
- Serious renal impairment (creatinine clearance [CrCl] < 30 mL/min), peripheral neuropathy ≥Grade 2, LVEF < 35 %
- Major surgery within 4 weeks of first dosing
- Current corneal epithelial disease except for mild punctate keratopathy



**VRd for 8 21-day cycles, Rd in 28-day cycles thereafter*

Ergänzende Informationen unter ClinicalTrials.gov/NCT04091126

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Entitäten

Pola-R-ICE

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

Open-label, Prospective Phase III Clinical Study to Compare Polatuzumab Vedotin Plus Rituximab, Ifosfamide, Carboplatin and Etoposide (Pola-R-ICE) With Rituximab, Ifosfamide, Carboplatin and Etoposide (R-ICE) Alone as Salvage Therapy in Patients With Primary Refractory or Relapsed Diffuse Large B-cell Lymphoma (DLBCL)

Recruitment Status: RECRUITING
Condition: Relapsed Diffuse Large B-cell Lymphoma Refractory Diffuse Large B-Cell Lymphoma
Primary Completion Date: 2024-10-31
Intervention/ Treatment: Drug: Polatuzumab Vedotin/ Mabthera/ Ifosfamide/ Carboplatin/ Etoposide

Inclusion Criteria:

The informed consent form must be signed before any study specific tests or procedures are done. Adult male and female patients ≥18 years (≥16 years in the UK*) at the time of inclusion in the study (* In the UK an "adult" means a person who has attained the age of 16 years, according to The Medicines for Human Use (Clinical Trials) Regulations 2004, Part 1 Point 2.) Ability to understand and follow study-related instructions Risk group: All patients with one of the following histologically defined entities: Histological diagnosis of primary refractory or relapsed aggressive B-cell non-Hodgkin lymphoma (B-NHL), confirmed by a biopsy of involved nodal or extranodal site. Patients with any of the following histologies can be included: DLBCL not otherwise specified (NOS) T-cell/histiocyte-rich large B-cell lymphoma Primary cutaneous DLBCL, leg type Epstein-Barr virus (EBV)-positive DLBCL, NOS DLBCL associated with chronic inflammation Primary mediastinal (thymic) large B-cell lymphoma High-grade B-cell lymphoma, with MYC and BCL2 and/or BCL6 rearrangements High-grade B-cell lymphoma, NOS Refractory disease is defined as no complete remission to first line therapy; subjects who are intolerant to first line therapy are excluded. Three groups of patients are eligible: Progressive disease (PD) as best response to first line therapy (biopsy not mandatory if diagnostic sample available). Stable disease (SD) as best response after at least 4 cycles of first line therapy (e.g., 4 cycles of R-CHOP) (biopsy not mandatory if diagnostic sample available). Partial response (PR) as best response after at least 6 cycles, and biopsy-proven residual disease or disease Progression after the partial response. Relapsed disease is defined as complete remission to first line therapy followed by biopsy proven disease relapse. Performance Status ECOG 0-2 at time of randomization or ECOG 3 at screening if this is DLBCL-related and has improved to ECOG 2 or less with a 7-day steroid treatment during the screening Phase (e.g. 1 mg/kg prednisone). Information on all 5 International Prognostic Index (IPI) factors Staging (PET-CT based-staging according to Lugano criteria 2014). Patients must have PET-positive lesions. Subjects must have received adequate first line therapy including at a minimum: i) anti-CD20 monoclonal antibody unless Investigator determines that tumor is CD20 negative, and ii) an anthracycline containing chemotherapy Regimen Intent to proceed to high-dose therapy (HDT) and stem cell transplantation (SCT) if response to second line therapy Adequate hematological function, as defined by: hemoglobin ≥ 8 g/dL, absolute neutrophil count (ANC) ≥ 1.0 x 109/L OR ≥ 0.5 x 109/L if neutropenia is attributable to underlying disease and before the administration of steroids, and platelet count ≥ 75 x 109/L OR ≥ 50 x 109/L if thrombocytopenia is attributable to Underlying disease Women of childbearing potential must have a negative pregnancy test result within 7 days prior to the first study drug Administration For women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive measures, and agreement to refrain from donating eggs For men: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive measures, and agreement to refrain from donating sperm

Ergänzende Informationen unter ClinicalTrials.gov/NCT04833114

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COPA-R-CHOP

A prospective multicenter phase 2 study of copanlisib in combination with rituximab and CHOP chemotherapy (COPA-R-CHOP) in patients with previously untreated diffuse large B-cell lymphoma (DLBCL)

Recruitment Status: ACTIVE, NOT RECRUITING
Condition: Diffuse Large B Cell Lymphoma
Primary Completion Date: 2025-04
Intervention/ Treatment: Drug: Copanlisib/ R-CHOP Chemotherapy

Inclusion Criteria:
Histologically confirmed DLBCL (NOS) or High-grade B-cell lymphoma with MYC and BCL2 and/or BCL6 rearrangements or High-grade B-cell lymphoma (NOS) Follicular lymphoma Grade 3B (primary diagnosis without history of indolent lymphoma) with a diagnostic biopsy performed within 3 months before study entry and with material available for central review and complimentary scientific analyses 18-80 years of age International Prognostic Index (IPI) 2-5. Eastern Cooperative Oncology Group Performance status (ECOG) 0-2. Life expectancy of at least 3 months. Women of childbearing potential and men must agree to use effective contraception when sexually active. This applies for the time period between signing of the informed consent form and 6 months after the last administration of study treatment. A woman is considered of childbearing potential, i.e. fertile, following menarche and until becoming post-menopausal unless permanently sterile. Permanent sterilization methods include but are not limited to hysterectomy, bilateral salpingectomy, and bilateral oophorectomy. A postmenopausal state is defined as no menses for continuous 12 months without an alternative medical cause. A high follicle stimulating hormone (FSH) level in the postmenopausal range may be used to confirm a post-menopausal state in women not using hormonal contraception or hormonal replacement therapy. The investigator or a designated associate is requested to advise the patient how to achieve highly effective birth control (failure rate of less than 1%), e.g. intrauterine device, intrauterine hormone-releasing system, bilateral tubal occlusion, vasectomized partner and sexual abstinence. The use of condoms by male patients is required unless the female partner is permanently sterile. Adequate baseline laboratory values collected no more than 7 days before starting study treatment: Total bilirubin ≤ 1.5 x ULN (< 3 x ULN for patients with Gilbert syndrome, patients with cholestasis due to compressive adenopathies of the hepatic hilum or documented liver involvement or with biliary obstruction due to lymphoma) Alanine aminotransferase (ALT) and aspartate aminotransferase (AST) ≤ 2.5 x ULN (≤ 5 x ULN for patients with liver involvement by lymphoma) Lipase ≤ 1.5 x ULN Glomerular filtration rate (GFR) ≥ 40 mL/min/1.73 m2 according to the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) formula. If not on target, this evaluation may be repeated once after at least 24 hours either according to the CKD-EPI formula or by 24-hour sampling. If the later result is within acceptable range, it may be used to fulfill the inclusion criteria instead. INR and PTT ≤ 1.5 x ULN. Platelet count ≥ 75,000 /mm3. Hemoglobin (Hb) ≥ 8 g/dL Absolute neutrophil count (ANC) ≥ 1,500/mm3 Left ventricular ejection fraction ≥ 50%. No prior lymphoma therapy Ability to understand and willingness to sign written informed consent. Signed informed consent must be obtained before any study specific procedure.

Ergänzende Informationen unter ClinicalTrials.gov/NCT04263584

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Entitäten

OptiMATe

Hubertus Wald Tumorzentrum
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Ein Kompetenznetzwerk des UKE

Optimizing MATRix as Remission Induction in PCNSL: De-escalated Induction Treatment in Newly Diagnosed Primary CNS Lymphoma - a Randomized Phase III Trial

Recruitment Status: RECRUITING

Condition: Primary Central Nervous System Lymphoma
Primary Completion Date: 2027-08
Intervention/ Treatment: Drug: Experimental Treatment: one course Rituximab/HD-Methotrexate, two courses of MATRix/ Control intervention: four courses of MATRix

Inclusion Criteria:
Immunocompetent patients with newly diagnosed primary diffuse large B-cell lymphoma of the central nervous system (PCNSL). Male or female patients aged 18-65 years irrespective of ECOG or 66-70 years with ECOG Performance Status ≤2. Histologically or cytologically assessed diagnosis of B-cell lymphoma by local pathologist. Diagnostic sample obtained by stereotactic or surgical biopsy, CSF cytology examination or vitrectomy. Disease exclusively located in the CNS. At least one measurable lesion. Previously untreated patients (previous or ongoing steroid treatment admitted). Negative pregnancy test. Written informed consent obtained according to international guidelines and local laws by patient or authorized legal representative in case patient is temporarily legally not competent due to his or her disease. Ability to understand the nature of the trial and the trial related procedures and to comply with them.

Exclusion Criteria:
Congenital or acquired immunodeficiency including HIV infection and previous organ transplantation. Systemic lymphoma manifestation (outside the CNS). Primary vitreoretinal lymphoma without manifestation in the brain parenchyma or spinal cord. Previous or concurrent malignancies with the exception of surgically cured carcinoma in situ of the cervix, carcinoma of the skin or other kinds of cancer without evidence of disease for at least 5 years. Previous Non-Hodgkin lymphoma at any time. Inadequate renal function (clearance < 60 ml/min). Inadequate bone marrow, cardiac, pulmonary or hepatic function according to investigator´s decision Active hepatitis B or C disease. Concurrent treatment with other experimental drugs or participation in an interventional clinical trial with study medication being administered within the last 30 days before the start of this study. Third space fluid accumulation > 500 ml. Hypersensitivity to study treatment or any component of the formulation. Taking any medications that are likely to cause interactions with the study medication. Known or persistent abuse of medication, drugs or alcohol. Active COVID-19-infection or non-compliance with the prevailing hygiene measures regarding the COVID-19 pandemic Patients without legal capacity who are unable to understand the nature, significance and consequences of the trial and without designated legal representative. Previous participation in this trial. Persons who are in a relationship of dependency/employment with the sponsor and/or the investigator. Any familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule Current or planned pregnancy, nursing period For fertile patients: Failure to use one of the following safe methods of contraception: intra-uterine device or hormonal contraception in combination with a mechanical method of contraception.

Ergänzende Informationen unter ClinicalTrials.gov/ NCT04931368

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Entitäten

IMA 203-101

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

Phase 1 Study Evaluating Genetically ModifiedAutologous T Cells Expressing a T-cell Receptor Recognizing a Cancer/Germline Antigen as Monotherapy or in Combination With Atezolizumab in Patients With Recurrent and/or Refractory Solid Tumors (ACTengine IMA203-101)

Recruitment Status: RECRUITING

Condition:Advanced Refractory Cancer Recurrent Cancer Solid Tumor, Adult Cancer
Primary Completion Date: 2028-12
Intervention/ Treatment: Biological: IMA203 Product/ IMA203CD8 Product/ Device: IMADetect®/ Drug: nivolumab (Opdivo®)

Inclusion Criteria:
Patients must have recurrent/progressing and/or refractory solid tumors and must have received or not be eligible for all available indicated standard of care treatment. Eastern Cooperative Oncology Group (ECOG) performance status 0-1. HLA phenotype positive for the study Measurable disease according to RECIST 1.1. Adequate selected organ function per protocol. Patient's tumor must express tumor antigen by "IMADetect® RT-qPCR Life expectancy more than 3 months. Female patient of childbearing potential must use adequate contraception prior to study entry until 12 months after the infusion of IMA203/IMA203CD8. Male patient must agree to use effective contraception or be abstinent while on study and for 6 months after the infusion of IMA203/IMA203CD8. The patient must have recovered from any side effects of prior therapy to Grade 1 or lower prior to lymphodepletion.

Exclusion Criteria:
History of other malignancies (except for adequately treated basal or squamous cell carcinoma or carcinoma in situ) within the last 3 years. Pregnant or breastfeeding. Serious autoimmune disease Note: At the discretion of the investigator, these patients may be included if their disease is well controlled without the use of immunosuppressive agents. History of cardiac conditions as per protocol. Prior stem cell transplantation or solid organ transplantation Concurrent severe and/or uncontrolled medical disease that could compromise participation in the study. History of or current immunodeficiency disease or prior treatment compromising immune function at the discretion of the treating physician Positive for HIV infection or with active hepatitis B virus (HBV) or active hepatitis C virus (HCV) infection. Patients with LDH greater than 2.5-fold ULN. Any condition contraindicating leukapheresis, lymphodepletion, low-dose IL-2, and/or IMA203/IMA203CD8 treatment. Patients with active brain metastases.Concurrent treatment in another clinical trial. For nivolumab treatment, patients must not have a history of severe immune-related toxicities, defined as any Grade 3 or 4 toxicities related to prior PD1/PD-L1 inhibitor therapy (e.g., atezolizumab, pembrolizumab or nivolumab etc.).

Ergänzende Informationen sind unter ClinicalTrials.gov/NCT03686124 verfügbar

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BNT 211

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

Phase I/IIa, First-in-human (FIH), Open-label, Dose Escalation Trial With Expansion Cohorts to Evaluate Safety and Preliminary Efficacy of CLDN6 CAR-T +/- CLDN6 RNA-LPX in Patients With CLDN6-positive Relapsed or Refractory Advanced Solid Tumors

Recruitment Status: RECRUITING
Condition:Advanced Solid Tumor Metastatic Solid Tumor
Primary Completion Date: 2025-12
Intervention/ Treatment: Drug: IL12-L19L19/ IL12-L19L19

Inclusion Criteria:

Each patient enrolled in the trial must have CLDN6-positive tumor regardless of tumor histology defined as ≥ 50% of tumor cells expressing ≥ 2+ CLDN6 protein using a semi-quantitative immunohistochemistry (IHC) assay in a central laboratory for specific detection of CLDN6 protein expression in formalin-fixed, paraffin-embedded (FFPE) neoplastic tissues. Availability of a FFPE tumor tissue sample. FFPE can be from an archival tumor tissue sample, and it should be from the most recent tumor tissue obtained. If this is not available, patient must be biopsied for CLDN6 staining. Must have histological documentation of the original primary tumor via a pathology report.
Must have measurable disease per RECIST 1.1 (except for germ cell tumors, where patients can be evaluated according to Cancer-Antigen (CA)-125, Alpha-fetoprotein or human chorionic gonadotropin [as applicable] or ovarian cancer, where patients can be evaluated according to CA-125. The pre-treatment sample must be at least twice the upper limit of normal). Must have a histologically confirmed solid tumor that is metastatic or unresectable and for which there is no available standard therapy likely to confer clinical benefit, or patient who is not a candidate for such available therapy. Must be ≥ 18 years of age at the time the pre-screening informed consent is signed.
Must sign an informed consent form (ICF) indicating that he or she understands the purpose of and procedures required for the trial and are willing to participate in the trial prior to any trial-related assessments or procedures.
Must have an Eastern Cooperative Oncology Group performance status of 0 to 1. Must have adequate coagulation function at screening as defined in the protocol. Must have adequate hematologic function at screening as defined in the protocol. Must have adequate hepatic function at screening as defined in the protocol. Must have adequate renal function at screening as defined in the protocol. Must be able to attend trial visits as required by the protocol. Women of childbearing potential (WOCBP) must have a negative serum (beta-human chorionic gonadotropin) test/value at screening. Patients who are post-menopausal or permanently sterilized can be considered as not having reproductive potential. WOCBP must agree not to donate eggs (ova, oocytes) for the purposes of assisted reproduction during the entire trial and thereafter. WOCBP and men that are sexually active with a WOCBP and have not had a vasectomy must agree to use highly effective birth control method(s), as defined in the protocol. True abstinence is an acceptable alternative to the use of contraception. Men must agree not to father a child or donate sperm, and WOCBP must agree not to become pregnant during the trial and for at least 12 months after the CLDN6 CAR-T infusion or CLDN6 RNA-LPX treatment. For Part 2 only: Histologically or cytologically confirmed solid tumor fulfilling inclusion criteria 1-4 that is metastatic or unresectable, and for whom there is no available standard therapy likely to confer clinical benefit, or patient who is not a candidate for such available therapy.

Exclusion Criteria:

Has received prior CAR-T therapy, except CLDN6 CAR-T therapy. Has received vaccination with live virus vaccines within 6 weeks prior to the start of lymphodepletion (LD). Receives concurrent systemic (oral or i.v.) steroid therapy > 10 mg prednisolone daily, or its equivalent, for an underlying condition. Has side effects of any prior therapy or procedures for any medical condition not recovered to national cancer institute common terminology criteria for adverse events (CTCAE v.5) Grade ≤ 1.

Ergänzende unter ClinicalTrials.gov/NCT04503278

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Entitäten

PH-IL12L19L19-01/19 - DODEKA

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

A Phase I Study to Evaluate Safety and Early Signs of Efficacy of the Human Monoclonal Antibody-cytokine Fusion Protein IL12-L19L19.

Recruitment Status: RECRUITING

Condition:Advanced Solid Tumor Metastatic Solid Tumor
Primary Completion Date: 2025-12
Intervention/ Treatment: Drug: IL12-L19L19/ IL12-L19L19

Inclusion Criteria:
Male or female aged 18 to 80 years old. histological or cytological diagnosis of advanced/metastatic immunotherapy responsive solid carcinoma or lymphoma, that has progressed on immune checkpoint-blockade therapy. Patients with primary brain tumors will be excluded. Patients must have received an immune checkpoint blockade therapy-based regimen as immediate prior treatment. Subjects must have had clinical benefit (CR/PR/SD) while on checkpoint inhibitor treatment defined as ≥ 3 months free from progression from initial imaging documenting metastatic disease followed by radiographic disease progression after checkpoint inhibitor per investigator's opinion. Only patients without other therapeutic alternatives but with curative or survival prolonging potential per investigator judgement are able to participate. Tumor types of primary interest include malignant melanoma, non-small cell lung cancer (NSCLC), renal cell carcinoma, urothelial carcinoma, head and neck squamous cell carcinoma (HNSCC), microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer, hepatocellular cancer, gastric cancer, squamous cell carcinoma of the skin and cervical cancer. For the dose expansion part, DLBCL can be considered in addition. Patients may have previously received chemotherapy, immunotherapy or radiation therapy. Such therapies must be completed at least 4 weeks prior to study drug administration. Radiotherapy within 4 weeks of the first dose of study drug, is allowed for palliative radiotherapy to a limited field, such as for the treatment of bone pain or a focally painful tumor mass. During the expansion part, to allow evaluation of response to treatment, patients must have remaining measurable disease that has not been irradiated. Eastern cooperative oncology group (ECOG) performance status ≤2 Patient has an estimated life expectancy of at least 12 weeks. At least one unidimensionally measurable lesion either by computed tomography (CT), MRI or PET/CT as defined by RECIST (v. 1.1) for solid tumors or by LUGANO criteria for malignant lymphoma. Absence of active and uncontrolled infections or other severe concurrent disease, which, in the opinion of the investigator, would place the patient at undue risk or interfere with the study lead to exclusion from the study population. A personally signed and dated informed consent document indicating that the subject has been informed of all pertinent aspects of the study and has given consent to participate in the study. All acute toxic effects (excluding alopecia and fatigue) of any prior therapy (including surgery, radiation therapy, chemotherapy) must have resolved to National Cancer Institute (NCI) CTCAE (v. 5.0) Grade ≤ 1. Full resolution of checkpoint blockade therapy-related adverse effects (including immune-related adverse effects) and no treatment for these AEs for at least 4 weeks prior to the time of enrollment. The only exception are patients with checkpoint blockade induced hypothyroidism and hypophysitis if these patients are on stable maintenance therapy with levothyroxine or steroids (≤ 10 mg prednisone equivalent) for at least 2 months prior dosing. No history of severe immune related adverse effects from prior given immune checkpoint blockade therapy (CTCAE Grade 4; CTCAE Grade 3 requiring treatment >4 weeks).

Additional Information are available on ClinicalTrials.gov/NCT04471987

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Encorafenib Plus Binimetinib in Patients With Locally Advanced, Unresectable or Metastatic BRAFV600-mutated Melanoma: a Multi-centric, Multinational, Prospective, Longitudinal, Non-interventional Study in Germany, Austria and Switzerland

Recruitment Status: RECRUITING
Condition: Melanoma Stage IV/ Melanoma Stage III
Primary Completion Date: 2026-12
Intervention/ Treatment: Drug: (**Encorafenib/ Binimetinib**)

Inclusion Criteria:
Written informed consent of the patient with regard to the pseudonymized documentation as well as the transfer and processing of his/her data within the study and the ADOREG [Cancer Registry of German Working Group of Dermato-Oncology] registry (data transfer to ADOREG registry only for patients from German sites);
Legally capable male or female patient ≥ 18 years of age (no upper limit);
Decision was taken to treat the patient with encorafenib plus binimetinib in accordance with the current SmPC [Summary of Product Characteristics] and by prescription; this decision was taken prior to and independent from the inclusion into the study;
Treatment with encorafenib plus binimetinib has been started ≤ 6 months prior to providing written informed consent for this study or is planned to be started in the near future;
Unresectable advanced or metastatic malignant melanoma with BRAF [Rapidly Accelerated Fibrosarcoma isoform B] V600 mutation;
Treatment-naive or after one prior line of checkpoint inhibitor treatment (anti-CTLA4 [Cytotoxic T-Lymphocyte Antigen-4] and/or anti-PD(L)1 [Programmed cell Death protein 1]) in the unresectable advanced or metastatic setting.
Exclusion Criteria:
Previous treatment with a BRAF- and/or MEK [Mitogen-Activated Protein/Extracellular-signal Regulated Kinase]- inhibitor except for:
-- prior adjuvant treatment with BRAF+MEK-inhibitor combination therapy that ended > 6 months prior start of Encorafenib/Binimetinib treatment;
More than one prior line of checkpoint inhibitor treatment in the unresectable advanced or metastatic setting;
Any previous chemotherapeutic treatment of the melanoma disease;
Presence of any contraindication with regard to the encorafenib-binimetinib-treatment as specified in the corresponding SmPCs;
Current or upcoming participation in an interventional clinical trial;
Current or upcoming systemic treatment of any other tumor than melanoma;
Prisoners or persons who are compulsorily detained (involuntarily incarcerated).

Further Information at ClinicalTrials.gov

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Cemi Skin/ OBS16381)

Zwei-Kohorten-Registerstudie für Patienten mit fortgeschrittenem CSCC, die mit Cemiplimab oder anderen Methoden behandelt werden

Recruitment Status: ACTIVE
Condition: Plattenepithelkarzinom
Primary Completion Date: /
Intervention/ Treatment: Register

Inclusion Criteria: Patientinnen und Patienten mit fortgeschrittenem Plattenepithelkarzinom der Haut, die mit Cemiplimab oder anderen Ansätzen behandelt werden

	Dermatology		
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Armani, VTG-08

the ARMANI trial will test the hypothesis, if an anatomic resection (AR) improves long-term outcome vs. a non-anatomical resection (NAR) in patients undergoing surgery for RAS-mutated colorectal liver metastasis (CRLM).

Recruitment Status: RECRUITING
Condition: Colorectal Liver Metastasis**Primary Completion Date**: 2025-12
Primary Completion Date: 2027-12
Intervention/ Treatment: Procedure: Resection of colorectal liver metastases

Inclusion Criteria:

Colorectal cancer with RAS mutation (KRAS or NRAS)
Colorectal liver metastases (single or multiple)
Planned R0 resection of liver metastases (and primary tumor, if present)
Anatomical and non-anatomical liver resection technically feasible
Male and female patients, age ≥ 18 years
Written informed consent

Exclusion Criteria:

Extrahepatic metastases
Planned staged liver resection (e.g. two-stage hepatectomy)
Diagnosis of another cancer < 5 years prior to randomization Exceptions: curatively treated in situ cervical cancer, curatively resected non-melanoma skin cancer
Expected lack of compliance
Addiction or other illnesses which do not allow the person concerned to assess the nature and extent of the clinical trial and its possible consequences

Further Information at ClinicalTrials.gov

	General Surgery		
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RENAISSANCE/ FLOT5, AIO-STO-0215

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

Previously untreated patients with limited metastatic stage (see protocol for details on criteria) will receive 4 cycles of FLOT (5-Fluorouracil, Leucovorin, Oxaliplatin and Docetaxel). Patients without disease progression will be randomized 1:1 to receive additional chemotherapy cycles (4-8 cycles of FLOT) or surgical resection followed by subsequent chemotherapy (4-8 cycles of FLOT). Main objective of the study is overall survival. Most important secondary objective is the quality of life under treatment and during follow-up.

Recruitment Status: ACTIVE, NOT RECRUITING
Condition: Gastric Cancer
Primary Completion Date: 2026-02
Intervention/ Treatment: Drug (**5-Fluorouracil/ Leucovorin/ Oxaliplatin/ Docetaxel/ Trastuzumab/ sodium folinate)**
Procedure (Surgery)

Inclusion Criteria:

Histologically confirmed limited metastatic gastric or GEJ adenocarcinoma.* Medical and technical operability of the primary. Metastatic lesions are resectable or can be controlled by local ablative procedure (central evaluation). No prior chemotherapy and no prior tumor resection. Female and male patients ≥ 18 years. Patients in reproductive age must be willing to use adequate contraception during the study and 3 months after the end of the study (appropriate contraception is defined as surgical sterilization (e.g., bilateral tubal ligation, vasectomy), hormonal contraception (implantable, patch, oral), and double-barrier methods (any double combination of: intrauterine device, male or female condom with spermicidal gel, diaphragm, sponge, cervical cap)). Female patients with childbearing potential need to have a negative pregnancy test within 7 days before study start. ECOG (Eastern Cooperative Oncology Group) Performance Status 0 or 1 Adequate hematological, hepatic and renal function parameters: Leukocytes ≥ 3000/µl Platelets ≥ 100,000/µl Serum creatinine ≤ 1.5 x upper limit of normal, or glomerular filtration rate (GFR) > 40 ml/min Bilirubin ≤ 1.5 x upper limit of normal AST (aspartate aminotransferase) and ALT (alanine transaminase) ≤ 3.5 x upper limit of normal Alkaline phosphatase ≤ 6 x upper limit of normal Written informed consent of the patient. (*) Definition of the limited metastatic status is: Retroperitoneal lymph node metastases (RPLM) (e.g., para-aortal, intra-aorto-caval, parapancreatic or mesenterial lymph nodes) only (Note: in duodenum invading gastric cancer, retropancreatic nodes are not regarded M1) or/and at maximum one organ involved with or without RPLM according to the following schema: I. Localized potentially operable peritoneal carcinomatosis: stage P1 according to classification of the "Japanese Research Society for Gastric Cancer" (Clinically visible carcinomatosis of the peritoneum or of the pleura and >P1 peritoneal carcinomatosis are not allowed!) or II. Liver: maximum of 5 metastatic lesions that are potentially resectable or III. Lung: unilateral involvement, potentially resectable or IV. Uni- or bilateral Krukenberg tumors (ovarian met.) in the absence of macroscopic peritoneal carcinomatosis or V. Uni- or bilateral adrenal gland metastases or VI. Extra-abdominal lymph node metastases such as supraclavicular or cervical lymph node involvement or VII. Localized bone involvement (defined as being within one radiation field) or VIII. Other metastatic disease location that is considered limited by the investigator and is confirmed by the review committee

Further Information at ClinicalTrials.gov

	General Surgery		
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Cardiag/ FBB-02-01-21

This is an open-label, multi-center pivotal Phase 3 study to visually and quantitatively assess PET images obtained after single application of 300 MBq [18F]florbetaben and PET scanning of patients with suspected cardiac amyloidosis or with a putative diagnosis of cardiac amyloidosis but with remaining diagnostic uncertainty (e.g., unclear etiology or cardiac manifestation) or patients with diagnosis of amyloidosis but unclear cardiac involvement.
The diagnostic efficacy of the visual and quantitative assessments of [18F]florbetaben PET images for diagnosis of cardiac AL Amyloidosis will be determined by comparison to the standard of truth (SoT) obtained through standard of care clinical diagnosis.

Recruitment Status: RECRUITING
Condition: Cardiac Amyloidosis/ AL Amyloidosis/ ATTR Amyloidosis
Primary Completion Date: 2025-03
Intervention/ Treatment: Drug [18F]florbetaben)

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Inclusion Criteria:
Males and females age ≥18 years
Able to understand, sign and date written informed consent
Written informed consent must be obtained before any assessment is performed
Subjects being considered for a possible diagnosis of cardiac amyloidosis by
1. One of the following conditions:
    Established systemic amyloidosis without proven cardiac involvement,
    Known plasma cell dyscrasia (MGUS, multiple myeloma),
    Pathological free light chain levels in urine or serum,
    Presence of heart failure with preserved ejection fraction
2. AND one of the following parameters, indicative of cardiac manifestation:
    Mean (left ventricular (LV) wall + septum) thickness >12mm as measured by echocardiography in absence of other known cause of left ventricular hypertrophy (LVH),
    NT-proBNP >335 ng/L
Planned diagnostic procedure to establish diagnosis and cardiac involvement (e.g., endomyocardial biopsy or extracardiac biopsy in conjunction with cardiac magnetic resonance imaging/echocardiography or bone scintigraphy)
Female subjects must be documented by medical records or physician's note to be either surgically sterile (by means of hysterectomy, bilateral salpingectomy, or bilateral oophorectomy) or post-menopausal for at least 1 year (no menses for 12 months without an alternative medical cause). If they are of child-bearing potential, they must commit to use of a highly effective contraceptive measure for at least one week following the PET scan
Male subjects and their partners of childbearing potential must commit to the use of a highly effective method of contraception for a minimum of 90 days following the PET scan
Male subjects must commit to not donate sperm for a minimum of 90 days after the PET scan
Exclusion Criteria:
Any known allergic reactions or hypersensitivity towards any compound of the study drug Severe hepatic impairment (AST/ALT >5 x ULN; bilirubin >3 x ULN) Inability to lay flat for up to 60 min Pregnant, lactating or breastfeeding
Unwilling and/or unable to cooperate with study procedures Having been administered a radiopharmaceutical within 10 radioactive half-lives prior to study drug administration in this study

Further Information at ClinicalTrials.gov

CRISP, AIO-TRK-0315

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

Open, non-interventional, prospective, multi-center clinical research platform with the main objective to assess molecular biomarker testing, treatment and outcome of patients with NSCLC or SCLC in Germany

Recruitment Status: RECRUITING
Condition: Metastatic Non-small Cell Lung Cancer (NSCLC)/ Non-small Cell Lung Cancer Metastatic/ Non-small Cell Lung Cancer Stage I,II or III/ Small-cell Lung Cancer
Primary Completion Date: 2026-09
Intervention/ Treatment: Other: data collection

Inclusion Criteria:
Patients who meet all of the following criteria are eligible for the project:
Age ≥ 18 years
Able to understand and willing to sign written Informed Consent and to complete patient-reported-outcome assessment instruments
Main project (Metatstatic NSCLC):
Confirmed non-small cell lung cancer (NSCLC)
Informed consent no later than four weeks after start of first-line systemic treatment or no later than four weeks after diagnosis for patients receiving "best supportive care only"
Stage IV, or stage IIIB/C (UICC8) if patient is ineligible for curative surgery and/or radiochemotherapy
Systemic therapy or best supportive care
Satellite Stage I/II/III (NSCLC):
Confirmed non-small cell lung cancer (NSCLC)
Informed consent no later than four weeks after start of first anti-tumor treatment (including surgery and radiotherapy) or no later than four weeks after diagnosis for patients receiving "best supportive care only" (i.e. no anti-tumor treatment = no surgery, radiotherapy or systemic therapy)
Stage I, Stage II, stage IIIA, or stage IIIB/C (UICC8)
Systemic (chemo)therapy and/or radiation therapy and/or surgery or best supportive care
Satellite SCLC
Confirmed Small cell lung cancer (SCLC)
Informed consent no later than four weeks after start of first anti-tumor treatment or no later than four weeks after diagnosis for patients receiving "best supportive care only" (i.e. no anti-tumor treatment = no surgery, radiotherapy or systemic therapy)
Systemic (chemo)therapy and/or radiation therapy and/or surgery or best supportive care
Exclusion Criteria: none

Further Information at ClinicalTrials.gov

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Study Nurse						

GAM-36

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

kurze Zusammenfassung der Studie (**Schrift 14/ Arial**)

Recruitment Status: RECRUITING
Condition: (**Schrift 10/ Arial**)
Primary Completion Date: **Intervention/ Treatment:**

Inclusion Criteria:

Exclusion Criteria **Schrift 8 oder 10 Arial** :

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Further Information at Clini

GMMG-DADA

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

Daratumumab for First Line Treatment of Transplant-ineligible Myeloma Patients Followed by Daratumumab Re-treatment at First Relapse

Recruitment Status: RECRUITING
Condition: Multiple Myeloma
Primary Completion Date: 2029-12
Intervention/ Treatment: Drug (Daratumumab)

Inclusion Criteria: Signed Written Informed Consent 1.1 Study participants must have signed and dated an IEC approved written informed consent form in accordance with regulatory and institutional guidelines. This must be obtained before the performance of any protocol-related procedures that are not part of normal study participant care. 1.2 Study participants must be willing and able to comply with scheduled visits, treatment schedule, laboratory tests and other requirements of the study. Target Population 2.1. Untreated patients with multiple myeloma diagnosis to the IMWG diagnostic criteria 2.2. Subject must have documented multiple myeloma as defined by the criteria below: Monoclonal plasma cells in the bone marrow ≥10% at some point in their disease history or presence of a biopsy proven plasmacytoma. Measurable disease as defined by any of the following: IgG multiple myeloma: Serum monoclonal paraprotein (M-protein) level ≥1.0 g/dL or urine M-protein level ≥200 mg/24 hours; or IgA, IgD, IgE, IgM multiple myeloma: serum M-protein level ≥0.5 g/dL or urine M-protein level ≥200 mg/24 hours; or Light chain multiple myeloma without measurable disease in the serum or the urine: Serum immunoglobulin free light chain ≥10 mg/dL and abnormal serum Immunoglobulin kappa lambda free light chain ratio. ECOG ≤2 Not eligible for autologous transplantation Age 18 years or above Reproductive Status Women of childbearing potential (WOCBP) must use appropriate method(s) of contraception and must agree to use adequate method to avoid pregnancy for 5 months (30 days plus the time required for durvalumab to undergo five half-lives) after the last dose of study drug. Appropriate methods of contraception are: female sterilization or tubal ligation (at least 6 weeks prior to the start of the study treatment), male sterilization (at least 6 months prior to the start of the study treatment) and/or a combination of a hormonal method of contraception with a barrier method or/and an intrauterine device or system Women of childbearing potential must have a negative serum or urine pregnancy test (minimum sensitivity 25 IU/L or equivalent units of β-HCG) within one until two weeks prior to the start of durvalumab at time of neoadjuvant treatment and after surgery before starting adjuvant treatment. Women will be not be considered to be of childbearing potential if they are post-menopausal and/or underwent surgical sterilization (bilateral oophorectomy, bilateral salpingectomy or hysterectomy). To be considered post-menopausal the appropriate age-specific requirements have to be met: Women < 50 years of age would be considered post-menopausal if they have been amenorrheic for 12 months or more following cessation of exogenous hormonal treatments and if they have luteinizing hormone and follicle-stimulating hormone levels in the post-menopausal range for the institution. Women ≥ 50 years of age would be considered post-menopausal if they have been amenorrheic for 12 months or more following cessation of all exogenous hormonal treatments, had radiation-induced menopause with last menses > 1 year ago, had chemotherapy-induced menopause with last menses > 1 year ago. Women must not be breastfeeding. Men who are sexually active with WOCBP must use any contraceptive method with a failure rate of less than 1% per year. Men receiving durvalumab and who are sexually active with WOCBP must be willing to adhere to contraception for a period of 7 month post treatment completion.

Further Information at ClinicalTrials.gov

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ITP-Registry

Multicenter National ITP Registry and Accompanying Biospecimen Collection. The objective of this ITP registry is to collect clinical information, including biosampling, from consenting patients with a variety of ITPs at different points in the course of their disease.

Recruitment Status: RECRUITING
Condition: Immune Thrombocytopenia
Primary Completion Date: 2026-09
Intervention/ Treatment: Registry

Inclusion Criteria:
Primary or secondary Immune Thrombocytopenia (ITP)
Age ≥18 years
signed declaration of consent

Exclusion Criteria:
diagnoses that cannot be reconciled with the diagnosis of ITP (esp. heparin-induced thrombocytopenia, pregnancy-associated thrombocytopenia, pseudothrombocytopenia)
no informed consent possible (this covers patients who are unable to understand the nature and scope of participation)

Further Information at ClinicalTrials.gov

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MYRIAM

MYRIAM is a national, observational, prospective, longitudinal, multicenter cohort study (tumor registry platform) with the purpose to record information on the antineoplastic treatment of multiple myeloma in Germany. The registry will follow patients for up to five years. It will identify common therapeutic sequences and changes in the treatment of the disease. At inclusion, data in patient characteristics, comorbidities, tumor characteristics and previous treatments are collected. During the course of observation data on all systemic treatments, radiotherapies, surgeries, and outcome are documented.
Health-realted quality of life in patients with multiple myeloma (MyLife) will be evaluated for up to five years.

Recruitment Status: RECRUITING
Condition: Multiple Myeloma
Primary Completion Date: 2026-12
Intervention/ Treatment: Other: Routine care as per site standard.

Inclusion Criteria:
MM requiring systemic (first-, second- or third-line) treatment (closed for first-line recruitment)
Age ≥ 18 years
Written informed consent
Patients participating in the PRO satellite: signing of informed consent and completion of baseline questionnaire before, but not more than eight weeks before the start of respective systemic treatment
Patients not participating in the PRO satellite: signing of informed consent not later than four weeks after start of respective treatment, and not more than eight weeks before the start of respective systemic treatment
Sufficient German language skills for participation in the PRO satellite
Exclusion Criteria:
No systemic therapy for myeloma
Patients already enrolled in studies that prohibit any participation in other studies

Further Information at ClinicalTrials.gov

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OPAL

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

Treatment and Outcome of Patients With Breast Cancer: Clinical Research Platform for Real World Data

Recruitment Status: RECRUITING
Condition: Breast Cancer
Primary Completion Date: 2029-04
Intervention/ Treatment: Registry.

Inclusion Criteria:
EBC cohort:
Female and male patients with early breast cancer (stage I-III defined as breast cancer that has not spread beyond the breast or the axillary lymph nodes)
Patients at the start of their initial systemic treatment for EBC, i.e. at start of neoadjuvant treatment for patients receiving neoadjuvant thera-py or at start of adjuvant treatment if no neoadjuvant therapy is given. Treatment can be cytotoxic, endocrine, or targeted substances, what-ever was given first
ABC cohort:
Female and male patients with advanced breast cancer (stage IV defined as synchronous or metachronous diagnosis of distant metastases at inclusion)
Patients at the start of their initial first-line systemic treatment for ABC, which can be cytotoxic, endocrine or targeting a specific signaling pathway, whatever is given first
All cohorts:
Written informed consent
- Patients participating in the PRO module: signing of informed consent form and completion of baseline questionnaire before start of initial systemic treatment for EBC or systemic first-line treatment for ABC
- Patients not participating in the PRO module: within six weeks after start of initial systemic treatment for EBC or systemic first-line treatment for ABC

Age ≥ 18 years
Exclusion Criteria:
Patients with prior systemic therapy (cytotoxic, endocrine, or targeted) for EBC or ABC
Patients who do not receive any systemic therapy for EBC or ABC

Further Information at ClinicalTrials.gov

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Three Versus Five Years of Adjuvant Imatinib as Treatment of Patients With Operable GIST With a High Risk for Recurrence: A Randomised Phase III Study

Recruitment Status: ACTIVE, NOT RECRUITING
Condition: Sarcoma
Primary Completion Date: 2026-05
Intervention/ Treatment: Drug (**Imatinib**)

Inclusion Criteria:
Age ≥ 18 years.
Morphological and immunohistological documentation of GIST (immunostaining for KIT and/or DOG-1 positive, or mutation of KIT or PDGFRA present in tumor tissue).
Macroscopically complete surgical resection of GIST (either R0 or R1 resection).
Mutation analysis of KIT and PDGFR genes has been carried out.
A high risk of GIST recurrence; either gastric GIST with mitotic count >10/50 HPFs, or non-gastric GIST with mitotic count >5/50 HPFs, or tumor rupture.
Eastern Cooperative Oncology Group performance status ≤ 2.
Adequate organ function.
Female patients of childbearing potential must have a negative pregnancy test within 14 days before initiation of study drug dosing. Postmenopausal women must have amenorrhea for at least 12 months to be considered of non-childbearing potential. Male and female patients of reproductive potential must agree to employ an effective barrier method of birth control throughout the study and for up to 3 months following discontinuation of study drug.
Patient willing to be followed up at the study site regardless of the result of randomization.
Patient has provided a written, voluntary informed consent prior to study-specific screening procedures.
Exclusion Criteria: Presence of distant metastases or local recurrence of GIST. Not willing to donate tumor tissue and/or blood samples for the study molecular studies. Presence of a substitution mutation at PDGFRA codon D842 (usually D842V). Administration of adjuvant imatinib longer than for 3 years is planned regardless of the result of randomization, or "life long" imatinib administration is planned.
Prior adjuvant (+ neoadjuvant) therapy with imatinib mesylate for at least 35 months has not been completed, or the total duration of prior adjuvant (+ neoadjuvant) imatinib administration exceeds the total duration of 37 months. Neoadjuvant imatinib for a duration that exceeds 9 months. Longer than 4-week break during adjuvant imatinib administration. The dose of imatinib at completion of 3 years of adjuvant imatinib was 200 mg per day or less or greater than 800 mg per day. Patient has received any investigational anti-cancer agents during adjuvant imatinib or between completion of adjuvant imatinib and the date of randomization. Patient has been free of another malignancy for less than 5 years except if the other malignancy is not currently clinically significant nor requiring active intervention, or if the other malignancy is a basal cell skin cancer or a cervical carcinoma in situ. Recent existence of any other malignant disease is not allowed. Patient with Grade III/IV cardiac disease as defined by the New York Heart Association Criteria (i.e., congestive heart failure, myocardial infarction within 6 months of study entry). Female patients who are pregnant or breast-feeding. Severe and/or uncontrolled medical disease (i.e., uncontrolled diabetes, severe chronic renal disease, or active uncontrolled infection). Known diagnosis of human immunodeficiency virus (HIV) infection. Patient with a significant history of non-compliance to medical regimens or with inability to grant reliable informed consent.

Further Information at ClinicalTrials.gov

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AdvanTIG-302, BGB-A317-A1217-302

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

A Phase 3, Randomized, Double-Blind Study of Ociperlimab, an Anti-TIGIT Antibody, in Combination With Tislelizumab Compared to Pembrolizumab in Patients With Previously Untreated, PD-L1-Selected, and Locally Advanced, Unresectable, or Metastatic Non-Small Cell Lung Cancer

Recruitment Status: RECRUITING
Condition: Non-small Cell Lung Cancer/ NSCLC
Primary Completion Date: 2026-04
Intervention/ Treatment: Drug (**Tislelizumab** [Other Name: BGB-A317]/ **Ociperlimab** [Other Name: BGB-A1217]/ **Pembrolizumab** [Other Name: KEYTRUDA]/ **Placebo**

Inclusion Criteria:

Histologically or cytologically documented locally advanced or recurrent non-small cell lung cancer (NSCLC) that is not eligible for curative surgery and/or definitive radiotherapy with or without chemoradiotherapy, or metastatic-nonsquamous or squamous NSCLC.
No prior systemic treatment for metastatic NSCLC.
Agreement to provide archival tissue or fresh biopsy (if archival tissue is not available).
Tumors with PD-L1 expressed in ≥ 50% tumor cells.
At least 1 measurable lesion as defined per RECIST v1.1.
ECOG Performance Status ≤ 1.

Exclusion Criteria:

Known mutations in the epidermal growth factor receptor (EGFR) gene, anaplastic lymphoma kinase (ALK) fusion oncogene, BRAF V600E, or ROS1.
Prior therapy with an anti-programmed cell death protein (anti-PD)-1, anti-PD-ligand (L)-1, anti-PD-ligand-2, anti-T-cell immunoglobulin and ITIM (anti-TIGIT) domain, or any other antibody or drug specifically targeting T-cell costimulation or checkpoint pathways.
Active leptomeningeal disease or uncontrolled, untreated brain metastasis.
Active autoimmune diseases or history of autoimmune diseases that may relapse.
Note: Other protocol defined Inclusion/Exclusion criteria may apply

Further Information at ClinicalTrials.gov

	Lung Clinic		
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Entree GSK/ 205801

A Phase II, Randomized, Open-label Platform Trial Utilizing a Master Protocol to Study Novel Regimens Versus Standard of Care Treatment in NSCLC Participants

Recruitment Status: RECRUITING
Condition: Neoplasms
Primary Completion Date: 202-07-08
Intervention/ Treatment: Drug (**Docetaxel/ Feladilimab/ Ipilimumab/ GSK4428859A** [Other Names:belrestotug/ EOS884448]/ Dostarlimab/ GSK6097608GSK6097608)

Inclusion Criteria:
Participants capable of giving signed informed consent/assent.
Male or female, aged 18 years or older at the time consent is obtained. Participants in Korea must be age 19 years or older at the time consent is obtained.
Participants with histologically or cytologically confirmed diagnosis of NSCLC (squamous or non-squamous) and
a) Documented disease progression based on radiographic imaging, during or after a maximum of 2 lines of systemic treatment for locally/regionally advanced recurrent, Stage IIIb/Stage IIIc/Stage IV or metastatic disease. Two components of treatment must have been received in the same line or as separate lines of therapy: i) No more than or less than 1 line of platinum-containing chemotherapy regimen, and ii) No more than or less than 1 line of Programmed cell death ligand 1 (PD[L]1) monoclonal antibody (mAb) containing regimen.
b) Participants with known BRAF molecular alterations must have had disease progression after receiving the locally available SoC treatment for the molecular alteration.
c) Participants who received prior anti-PD(L)1 therapy must fulfill the following requirements: i) Have achieved a CR, PR or SD and subsequently had disease progression (per RECIST 1.1 criteria) either on or after completing PD(L)1 therapy ii) Have not progressed or recurred within the first 12 weeks of PD(L)1 therapy, either clinically or per RECIST 1.1 criteria
Measurable disease, presenting with at least 1 measurable lesion per RECIST 1.1.
Eastern Cooperative Oncology Group (ECOG) Performance Status (PS) score of 0 or 1.
A tumor tissue sample obtained at any time from the initial diagnosis of NSCLC to time of study entry is mandatory. Although a fresh tumor tissue sample obtained during screening is preferred, archival tumor specimen is acceptable.
Adequate organ function as defined in the protocol.
A male participant must agree to use a highly effective contraception during the treatment period and for at least 120 days after the last dose of study treatment and refrain from donating sperm during this period.
A female participant is eligible to participate if she is not pregnant, not breastfeeding, and at least 1 of the following conditions apply:
i) Not a woman of childbearing potential (WOCBP) or ii) A WOCBP who agrees to follow the contraceptive guidance during the treatment period and for at least 120 days after the last dose of study treatment.
Life expectancy of at least 12 weeks.

Further Information at ClinicalTrials.gov

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EVOKE 02, Sacituzumab-ADC, KEYNOTE-D15

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

An Open-label, Multicenter, Phase 2 Study of Sacituzumab Govitecan Combinations in First-line Treatment of Patients With Advanced or Metastatic Non-Small-Cell Lung Cancer (NSCLC) Without Actionable Genomic Alterations

Recruitment Status: ACTIVE, NOT RECRUITING
Condition: Non-small Cell Lung Cancer
Primary Completion Date: 2024-08
Intervention/ Treatment: Drug (**Sacituzumab Govitecan-hziy (SG)/ Pembrolizumab/ Carboplatin/ Cisplatin**)

Inclusion Criteria:
Individuals with pathologically documented evidence of Stage IV non-small cell lung Cancer (NSCLC) disease at the time of enrollment
Measurable disease by computed tomography (CT) or magnetic resonance imaging (MRI) as per RECIST Version 1.1 criteria by investigator
No prior systemic treatment for metastatic NSCLC
Eastern Cooperative Oncology Group (ECOG) performance status score of 0 or 1
Adequate hematologic counts
Adequate hepatic function
Exclusion Criteria:
Mixed SCLC and NSCLC histology
Active second malignancy
NSCLC that is eligible for definitive local therapy alone
Has a diagnosis of immunodeficiency or is receiving chronic systemic steroid therapy
Has an active autoimmune disease that has required systemic treatment in past 2 years
Has had an allogenic tissue/solid organ transplant.
Has severe (≥ Grade 3) hypersensitivity to SG, pembrolizumab, carboplatin, or cisplatin, their metabolites, or formulation excipient
Has received radiation therapy to the lung
Individuals may not have received systemic anticancer treatment within the previous 6 months
Is currently participating in or has participated in a study of an investigational agent
Clinically severe pulmonary compromise resulting from intercurrent pulmonary illnesses
Known active central nervous system (CNS) metastases
History of cardiac disease
Active chronic inflammatory bowel disease
Active serious infection requiring antibiotics
Active or chronic hepatitis B infection
Positive hepatitis C antibody
Positive serum pregnancy test or women who are lactating
Note: Other protocol defined Inclusion/Exclusion criteria may apply.

Further Information at ClinicalTrials.gov

	Lung Clinic		
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I3LUNG, INT147/22

I3LUNG is an international project aiming to develop a medical device to predict immunotherapy efficacy for NSCLC patients using the integration of multisource data (real word and multi-omics data). This objective will be reached through a retrospective - setting up a transnational platform of available data from 2000 patients - and a prospective - multi-omics prospective data collection in 200 NSCLS patients - study phase.

Recruitment Status: RECRUITING
Condition: Non Small Cell Lung Cancer/ Lung Cancer Metastatic/ Lung Cancer/ Nonsmall Cell Lung Adenocarcinoma
Primary Completion Date: 2025-10-01
Intervention/ Treatment: Observational

Inclusion Criteria:
Age >/= 18 years.
Eastern Cooperative Oncology Group (ECOG) performance status </= 2.
Histologically confirmed diagnosis of stage IIIB/C-IV Non-Small-Cell Lung Cancer
Received any line immunotherapy (maintenance therapy with Durvalumab is allowed) for retrospective cohort; clinical indication for frontline treatment with immunotherapy as first line treatment for prospective cohort.
Patients with CNS metastasis are allowed
Patients with driver genomic alterations are allowed (only for retrospective cohort)
Evidence of a personally signed and dated ICF indicating that the patient has been informed of and understands all pertinent aspects of the study before enrolment (only for prospective cohort)
Availability of at least one FFPE block for -omics data generation (only for prospective cohort)
Exclusion Criteria:
Patients without minimal treatment information data to be included in the retrospective cohort
Prior treatment for advanced disease (only for prospective cohort)
Unavailability or inability to comply with the requested study procedures, including compilation of QoL questionnaires

Further Information at ClinicalTrials.gov

	Lung Clinic		
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Imforte, GO43104

A Phase III, Randomized, Open-Label, Multicenter Study of Lurbinectedin in Combination With Atezolizumab Compared With Atezolizumab as Maintenance Therapy in Participants With Extensive-Stage Small-Cell Lung Cancer (ES-SCLC) Following First-Line Induction Therapy With Carboplatin, Etoposide and Atezolizumab

Recruitment Status: ACTIVE, NOT RECRUITING
Condition: Small Cell Lung Cancer
Primary Completion Date: 2025-10-01
Intervention/ Treatment: Drug **(Atezolizumab/ Lurbinectedin/ Carboplatin/ Etoposide**)

Inclusion Criteria for the Induction Phase:
ECOG PS of 0 or 1
No prior systemic therapy for ES-SCLC
Treatment-free for at least 6 months since last chemo/radiotherapy, among those treated (with curative intent) with prior chemo/radiotherapy for limited-stage SCLC
Histologically or cytologically confirmed ES-SCLC
Adequate hematologic and end-organ function to receive 4 cycles of induction treatment with carboplatin, etoposide and atezolizumab
Measurable disease, as defined by RECIST v1.1
Negative HIV test and no evidence of active Hepatitis B or Hepatitis C at screening
Exclusion Criteria for the Induction Phase:
Presence or history of CNS metastases
Active or history of autoimmune disease or deficiency
History of malignancies other than SCLC within 5 years prior to enrollment
Prior treatment with CD137 agonists or immune checkpoint blockade therapies, including anti-CTLA-4, anti-PD-1, and anti-PD-L1 therapeutic antibodies, or lurbinectedin or trabectedin
History of idiopathic pulmonary fibrosis, organizing pneumonia, drug induced pneumonitis, or idiopathic pneumonitis, or evidence of active pneumonitis on screening chest computed tomography (CT) scan
Treatment with investigational therapy within 28 days prior to enrollment
Inclusion Criteria for the Maintenance Phase:
ECOG PS of 0 or 1
Ongoing response or stable disease per RECIST 1.1 after 4 cycles of induction therapy
Toxicities attributed to prior induction anti-cancer therapy or PCI resolved to Grade <=1
Adequate hematologic and end-organ function
Exclusion Criteria for the Maintenance Phase:
Presence or history of CNS metastases
Receiving consolidative chest radiation
Severe infection within 2 weeks prior to randomization into the maintenance
Treatment with therapeutic oral or IV antibiotics at the time of randomization

Further Information at ClinicalTrials.gov

	Lung Clinic		
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KeyVibe-008, MK-7684A-008 SCLC

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

A Phase 3, Randomized, Double-Blind Study of MK-7684A in Combination With Etoposide and Platinum Followed by MK-7684A vs Atezolizumab in Combination With Etoposide and Platinum Followed by Atezolizumab for the First-Line Treatment of Participants With Extensive-Stage Small Cell Lung Cancer

Recruitment Status: ACTIVE, NOT RECRUITING
Condition: Small Cell Lung Carcinoma
Primary Completion Date: 2025-05-08
Intervention/ Treatment: Drug **(Saline placebo/ Etoposide/ Cisplatin/ Carboplatin)**
Biological (**Atezolizumab/ Pembrolizumab/Vibostolimab Co-Formulation**

Inclusion Criteria:

Has histologically or cytologically confirmed diagnosis of ES-SCLC in need of first-line therapy
Has ES-SCLC defined as Stage IV (T any, N any, M1a/b/c) by the American Joint Committee on Cancer, Eighth Edition or T3-T4 due to multiple lung nodules that are too extensive or have tumor/nodal volume that is too large to be encompassed in a tolerable radiation plan
Males agree to use contraception, refrain from donating sperm, and abstain from heterosexual intercourse
Females are not pregnant or breastfeeding, is not a woman of childbearing potential (WOCBP) or is a WOCBP who uses a highly effective contraceptive method, or is abstinent from heterosexual intercourse
Has measurable disease per Response Evaluation Criteria In Solid Tumors (RECIST) 1.1
Has a predicted life expectancy of >3 months

Further Information at ClinicalTrials.gov

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MOMENT (Register bei MET), MS200095_0050

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

Disease Registry on Patients With Advanced NSCLC Harboring METex14 Skipping Alterations (MOMENT)

Recruitment Status: RECRUITING
Condition: Cancer
Primary Completion Date: 2027-03-31
Intervention/ Treatment: Register

Inclusion Criteria:
Participants who signed ICF
Participants with advanced stage (stages IIIB-IV) NSCLC (all histologies) and Confirmed METex14 skipping alterations (by valid assay)
Participants who are starting or are already being treated with systemic therapy
Exclusion Criteria:
Participants who are enrolled in a clinical trial

Further Information at ClinicalTrials.gov

	Lung Clinic		
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Razor 14-Gene-NSCLC nach R0-Resektion

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

A Randomized Prospective Trial of Adjuvant Chemotherapy in Patients with Completely Resected Stage I or IIA Non-Squamous Non-Small Cell Lung Cancer Identified as High or Intermediate Risk by a 14-Gene Prognostic Assay

Recruitment Status: RECRUITING
Condition: Completely resected stage I or IIA non-squamous non-small cell lung cancer (NSCLC)
Primary Completion Date: /
Intervention/ Treatment: Register

Inclusion Criteria:
1. Written informed consent (the informed consent document must have been approved by the appropriate Institutional Review Board/Independent Ethics Committee (IRB/IEC). Consent must be obtained and signed and witnessed PRIOR to any study specific activity.
2. Age ≥ 18 years 3. Able to comply with the protocol, including acceptable candidacy for adjuvant chemotherapy consisting of cisplatin or carboplatin along with paclitaxel, vinorelbine or pemetrexed, according to investigator choice and administered in accordance with the protocol SmPCs and likely compliance with follow-up for anticipated length of study (i.e. 5 years from the initiation of enrollment). 4. Willing to be randomized to chemotherapy.
5. Histologically documented completely resected (R0) Stage I or IIA non-squamous NSCLC per 8th edition, TNM staging system. Mixed histologies that include a squamous cell or small cell or neuroendocrine component are eligible for the study, as long as they contain at least some component that is neither squamous cell, nor small cell nor neuroendocrine. Eligible resections include segmentectomy, lobectomy, bi-lobectomy, sleeve lobectomy, and pneumonectomy. Resections via wedge resection will not be eligible. Complete resection must also be accompanied by mediastinal lymph node sampling via mediastinoscopy, bronchoscopic sampling (e.g., endobronchial ultrasound guided biopsy) or surgical sampling. Nodes must be sampled from at least one of the following nodal stations: levels 2, 4, 7, 8, 9 for a right-sided cancer and levels 2, 4, 5, 6, 7, 8, 9 for left-sided cancers.
6. Adequate tissue sample available for 14-Gene Prognostic Assay (paraffin block with tumor occupying at least 25% of the tissue surface area) 7. Life expectancy excluding NSCLC diagnosis ≥ 5 years 8. ECOG performance status 0-1 - Completely healed incisions For Germany: 9. Women without childbearing potential or women of childbearing potential who have a negative hCG pregnancy test (either serum or urine) and who agree to meet one of the following criteria from the first administration of chemotherapy, during the treatment and for a period of 6 months following the last administration of chemotherapy: • Correct use of two reliable contraception methods. This includes every combination of a hormonal implant, transdermal hormonal patch, hormonal vaginal device, hormonal injection or of an intrauterine device or system (IUD/IUS) with a barrier method (condom or occlusive cap), • True abstinence (periodic abstinence and withdrawal are not acceptable methods of contraception), • Sexual relationship only with female partners and/or sterile male partners. 10. Men who agree to meet one of the following criteria from the first administration of chemotherapy, during the treatment and for a period of 6 months following the last administration of chemotherapy: • Correct use of two reliable contraception methods with female partners. This includes every combination of a hormonal implant, transdermal hormonal patch, hormonal vaginal device, hormonal injection or of an intrauterine device or system (IUD/IUS) with a barrier method (condom or occlusive cap), • True abstinence (periodic abstinence and withdrawal are not acceptable methods of contraception), • Sexual relationship only with male partners and/or sterile female partners.

Further Information at EU Clinical Trials Register

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RELA-104 Relatlimab (anti-LAG-3)/ CA224-104

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

A Randomized Prospective Trial of Adjuvant Chemotherapy in Patients with Completely Resected Stage I or IIA Non-Squamous Non-Small Cell Lung Cancer Identified as High or Intermediate Risk by a 14-Gene Prognostic Assay

Recruitment Status: RECRUITING
Condition: Non-small Cell Lung Cancer/ Recurrent Non-small Cell Lung Cancer/ Metastatic Non-small Cell Lung Cancer
Primary Completion Date: 2025-06-16
Intervention/ Treatment: Drug (**Carboplatin/ Cisplatin/ Paclitaxel/ Nab-Paclitaxel/ Pemetrexed**) Biological (**Nivolumab/ Relatlimab**)

Inclusion Criteria:
Histologically confirmed metastatic non-small cell lung cancer (NSCLC) of squamous (SQ) or non-squamous (NSQ) histology with Stage IV A/B (as defined by the 8th International Association for the Study of Lung Cancer Classification) or recurrent disease following multi-modal therapy for locally advanced disease
Eastern Cooperative Oncology Group (ECOG) performance status (PS) of less than or equal to 1 at screening and confirmed prior to randomization
Measurable disease by computed tomography (CT) or magnetic resonance resources (MRI) per response evaluation criteria in solid tumor version 1.1 (RECIST 1.1) criteria
No prior systemic anti-cancer treatment (including epidermal growth factor receptor (EGFR) and anaplastic lymphoma kinase (ALK) inhibitors) given as primary therapy for advanced or metastatic disease
Exclusion Criteria:
Participants with EGFR, ALK, ROS-1, or known B-rapidly accelerated fibrosarcoma proto-oncogene (BRAF V600E) mutations that are sensitive to available targeted therapy
Untreated CNS metastases
Leptomeningeal metastases (carcinomatous meningitis)
Concurrent malignancy requiring treatment or history of prior malignancy active within 2 years prior to randomization (ie, participants with a history of prior malignancy are eligible if treatment was completed at least 2 years before randomization and the participant has no evidence of disease)
Prior treatment with an anti-programmed cell death protein 1 (PD-1), anti-programmed death-ligand 1 (PD-L1), anti-programmed death-ligand 2 (PD-L2), or anti-cytotoxic T-lymphocyte-associated protein 4 (CTLA-4) antibody, or any other antibody or drug specifically targeting T-cell co-stimulation or checkpoint pathways
Other protocol-defined inclusion/exclusion criteria apply

Further Information at Clinical Trials.gov

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Skyscraper-01/ GO41717

Hubertus Wald Tumorzentrum
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Ein Kompetenznetzwerk des UKE

A Phase III, Randomized, Double-Blinded, Placebo-Controlled Study of Tiragolumab, an Anti-Tigit Antibody, in Combination With Atezolizumab Compared With Placebo in Combination With Atezolizumab in Patients With Previously Untreated Locally Advanced Unresectable or Metastatic PD-L1-Selected Non-Small Cell Lung Cancer

Recruitment Status: ACTIVE, NOT RECRUITING
Condition: Non-small Cell Lung Cancer
Primary Completion Date: 2025-02-21
Intervention/ Treatment: Drug (**Atezolizumab/ Tiragolumab/ Matching Placebo)**

Inclusion Criteria:
Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1
Histologically or cytologically documented locally advanced or recurrent NSCLC not eligible for curative surgery and/or definitive radiotherapy with or without chemoradiotherapy, or metastatic Stage IV non-squamous or squamous NSCLC
No prior systemic treatment for metastatic NSCLC
High tumor tissue PD-L1 expression
Measurable disease per Response Evaluation Criteria in Solid Tumors, Version 1.1 (RECIST v1.1)
Adequate hematologic and end-organ function
For participants enrolled in the extended China enrollment phase: current resident of mainland China or Taiwan and of Chinese ancestry.
Exclusion Criteria:
Known mutation in the EGFR gene or an ALK fusion oncogene
Symptomatic, untreated, or actively progressing central nervous system metastases
Active or history of autoimmune disease or immune deficiency
History of idiopathic pulmonary fibrosis, organizing pneumonia, drug-induced pneumonitis, or idiopathic pneumonitis, or evidence of active pneumonitis
Malignancies other than NSCLC within 5 years, with the exception of those with a negligible risk of metastasis or death treated with expected curative outcome
Severe infection within 4 weeks prior to initiation of study treatment
Positive test result for human immunodeficiency virus (HIV)
Active hepatitis B or hepatitis C
Treatment with investigational therapy within 28 days prior to initiation of study treatment
Prior treatment with CD137 agonists or immune checkpoint blockade therapies, anti-CTLA-4, anti-TIGIT, anti-PD-1, and anti-PD-L1 therapeutic antibodies
Treatment with systemic immunostimulatory agents within 4 weeks or 5 drug elimination half-lives prior to initiation of study treatment.

Further Information at Clinical Trials.gov

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TROPION-Lung08

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

A Randomized, Open-label, Phase 3 Trial of Dato-DXd Plus Pembrolizumab vs Pembrolizumab Alone in Treatment-naïve Subjects With Advanced or Metastatic PD-L1 High (TPS ≥50%) Non-small Cell Lung Cancer Without Actionable Genomic Alterations (TROPION-Lung08)

Recruitment Status: RECRUITING
Condition: Metastatic Non-small Cell Lung Cancer
Primary Completion Date: 2025-02-21
Intervention/ Treatment: Drug (**Datopotamab Deruxtecan/ Pembrolizumab**)

Inclusion Criteria:

Participants eligible for inclusion in the study must meet all inclusion criteria within 28 days of randomization into the study.
Sign and date the Tissue Screening and Main Informed Consent Forms, prior to the start of any study-specific qualification procedures.
Adults ≥18 years or the minimum legal adult age (whichever is greater) at the time of informed consent.
Histologically documented NSCLC that meets all of the following criteria:
- Stage IIIB or IIIC disease and not candidates for surgical resection or definitive chemoradiation, or Stage IV NSCLC disease at the time of randomization (based on the American Joint Committee on Cancer, Eighth Edition). Participants with early-stage NSCLC who have relapsed should be restaged during screening to ensure their eligibility for the study.
- Documented negative test results for epidermal growth factor receptor (EGFR), lymphoma kinase (ALK), and proto-oncogene1 (ROS1) actionable genomic alterations based on analysis of tumor tissue.
- No known actionable genomic alterations in neurotrophic tyrosine receptor kinase (NTRK), proto-oncogene B-raf (BRAF), rearranged during transfection (RET), mesenchymal-epithelial transition factor (MET), or other actionable driver kinases with locally approved therapies.

Has provided a formalin-fixed tumor tissue sample for the measurement of trophoblast cell surface protein 2 (TROP2) protein expression and for the assessment of other exploratory biomarkers.
Tumor has high programmed death receptor-1 (PD-L1) expression (TPS ≥50%) as determined by PD-L1 immunohistochemistry (IHC) 22C3 pharmDx assay by central testing (minimum of 6 slides).
Has an adequate treatment washout period before Cycle 1 Day 1.
Measurable disease based on local imaging assessment using RECIST Version 1.1.
Has left ventricular ejection fraction (LVEF) ≥50% by either an echocardiogram (ECHO) or multigated acquisition scan (MUGA) within 28 days before randomization.
Eastern Cooperative Oncology Group (ECOG) performance status (PS) of 0 or 1 at screening.
Has a life expectancy of at least 3 months.
Adequate bone marrow function within 7 days before randomization.

Further Information at Clinical Trials.gov

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BMS-CA055-026

A Phase 2/3, Multicenter, Randomized, Dose Optimization (Part I), Double-blind (Part II) Study to Compare the Efficacy and Safety of Oral Azacitidine (Oral-Aza, ONUREG®) Plus Best Supportive Care (BSC) Versus Placebo Plus BSC in Participants With IPSS-R Low- or Intermediate-risk Myelodysplastic Syndrome (MDS)

Recruitment Status: RECRUITING
Condition: Myelodysplastic Syndromes
Primary Completion Date: 2026-01-31
Intervention/ Treatment: Drug (**Oral Azacitidine/ Placebo for Oral Azacitidine**)

Inclusion Criteria:

Participant has a documented diagnosis of MDS according to WHO 2016 classification that meets International Prognostic Scoring System Revised (IPSS-R) classification of low- or intermediate-risk disease (IPSS-R score between 1.5 and 4.5).
MDS diagnosis, WHO classification, and IPSS-R risk classification will be prospectively determined by independent central pathology and cytogenetics review, and applicable central laboratory results.
• Participant must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1, or 2.

Exclusion Criteria:

Participants with prior malignancies must have an expected median life expectancy of at least 12 months at the time of inclusion and no active treatment of any sort for at least 24 weeks prior to randomization (including but not limited to immunotherapy or targeted therapy)
Hypoplastic Myelodysplastic Syndrome (MDS) with a marrow cellularity of ≤ 10%
Participants diagnosed with MDS with excess blasts-2 (MDS-EB2)
Prior treatment with azacitidine (any formulation), decitabine, or other hypomethylating agent
Other protocol-defined inclusion/exclusion criteria apply

Further Information at Clinical Trials.gov

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CLL-16

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

A Prospective, Open-label, Multicentre, Randomized, Phase-3-trial of Acalabrutinib, Obinutuzumab and Venetoclax (GAVE) Compared to Obinutuzumab and Venetoclax (GVE) in Previously Untreated Patients With High Risk (17P-deletion, TP53-mutation or Complex Karyotype) Chronic Lymphatic Leukemia (CLL)

Recruitment Status: RECRUITING
Condition: Chronic Lymphocytic Leukemia
Primary Completion Date: 2026-05
Intervention/ Treatment: Drug (**Obinutuzumab/ Venetoclax/ Acalabrutinib**)

Inclusion Criteria:
Documented CLL/SLL requiring treatment according to iwCLL criteria
Age at least 18 years
At least one of the following risk factors: 17p-deletion, TP53-mutation or complex karyotype (defined as defined as the presence of 3 or more chromosomal aberrations in 2 or more metaphases.).
Life expectancy ≥ six months
Adequate bone marrow function indicated by a platelet count >30 x10^9/l
Creatinine clearance ≥ 30ml/min
Adequate liver function as indicated by a total bilirubin ≤ 2 x, AST/ ALT ≤ 2.5 x the institutional ULN value, unless directly attributable to the patient's CLL or to Gilbert's Syndrome
Negative testing for hepatitis B (HbsAg negative and anti-HBc negative; patients positive for anti-HBc may be included if PCR for HBV DNA is negative and HBV-DNA PCR is performed every month until 12 months after last treatment cycle),or hepatitis C (negative testing for hepatitis C RNA within 6 wee
ks prior to registration for study screening (i.e. PCR only required when serology was positive))
ECOG (Eastern Cooperative Oncology Group Performance Status) status 0-2
Exclusion Criteria:
Any prior CLL-specific therapies (except corticosteroid treatment administered due to necessary immediate intervention; within the last 10 days before start of study treatment, only dose equivalents up to 20 mg prednisolone are permitted)
Absence of high risk disease (17p-deletion, TP53-mutation complex karyotype
An individual organ/system impairment score of 4 as assessed by the CIRS definition (e.g. advanced cardiac disease (NYHA class 3 or 4) limiting the ability to receive the study treatment or any other life-threatening illness, medical condition or organ system dysfunction that, in the investigator´s opinion, could compromise the patients safety or interfere with the absorption or metabolism of the study drugs (e.g. inability to swallow tablets or impaired resorption in the gastrointestinal tract)
Transformation of CLL (Richter transformation)
Malignancies other than CLL currently requiring systemic therapies
Uncontrolled or active infection of HIV/PML or any other active infection
Anticoagulant therapy with warfarin or phenoprocoumon
Pregnant women and nursing mothers

Further Information at ClinicalTrials.gov

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Entitäten

CZAR-1

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

Efficacy and Safety of Carfilzomib in Combination With Ibrutinib vs Ibrutinib Alone in Waldenström's Macroglobulinemia (CZAR-1)

Recruitment Status: RECRUITING
Condition: Waldenstrom Macroglobulinemia
Primary Completion Date: 2028-02
Intervention/ Treatment: Drug (**Carfilzomib + Ibrutinib/ Ibrutinib)**

Inclusion Criteria:
Each patient must meet all of the following inclusion criteria to be enrolled in this study:
Proven clinicopathological diagnosis of WM as defined by consensus panel one of the Second International Workshop on WM. Histopathology has to occur before randomization within the last 4 months. In addition, pathological specimens have to be sent to the pathological reference center prior to randomization for the determination of the mutational status of MYD88 and CYCR4. Immunophenotyping will be performed in each center and saved locally. The positivity for CD20 can be assumed from any previous bone marrow immunohistochemistry or flow cytometry analysis performed up to 4 months prior to enrollment. Flow cytometry of bone marrow and blood cells will include at least one double staining and assess the disease specific expressions. De novo and relapsed/refractory WM independent of the genotype. Determination of mutational status of MYD88 and CXCR4. Patients must have at least one of the following criteria to initiate treatment as partly defined by "Consensus Panel Two" recommendations from the Second International Workshop on Waldenström Macroglobulinemia: Recurrent fever, night sweats, weight loss, fatigue (at least one of them). Hyperviscosity. Lympadenopathy which is either symptomatic or bulky (≥ 5 cm in maximum diameter). Symptomatic hepatomegaly and/or splenomegaly. Symptomatic organomegaly and/or organ or tissue infiltration. Peripheral neuropathy due to WM. Symptomatic cryoglobulinemia. Cold agglutinin anemia. IgM related immune hemolytic anemia and/or thrombocytopenia. Nephropathy related to WM. Amyloidosis related to WM. Hemoglobin ≤ 10 g/dL (patients should not have received red blood cells transfusions for at least 7 days prior to obtaining the screening haemoglobin). Platelet count < 100 x 109/L (caused by BM infiltration of the lymphoma). Serum monoclonal protein > 5 g/dL, even with no overt clinical symptoms. IgM serum concentration ≥ 5g/dl. and other WM associated relevant symptoms. World Health Organization (WHO)/ECOG performance status 0 to 2. Left ventricular ejection fraction ≥ 40% as assessed by transthoracic echocardiogram (TTE).
Other criteria Age ≥ than 18 years (male and female). Life expectancy > 3 months. Baseline platelet count ≥ 50 x 109/L, absolute neutrophil count ≥ 0.75 x 109/L. (if not due to BM infiltration by the lymphoma). Meet the following pre-treatment laboratory criteria at the Screening visit conducted within 30 days prior to randomization: ASAT (SGPOT): < 3.0 times the ULN. ALAT (SGPT): < 3.0 times the ULN. Total Bilirubin: < 1.5 times the ULN, unless clearly related to the disease (except if due to Gilbert's syndrome). Serum creatinine: ≤ 2 mg/dl. Women of childbearing potential (WOCBP) must agree to use a highly effective method of birth control for the duration of the therapy up to 6 months after end of therapy. A highly effective method of birth control is defined as those which result in a low failure rate (i.e. less than 1% per year) when used consistently and correctly such as combined (estrogen and progestogen containing) hormonal contraception associated with inhibition of ovulation (oral, intravaginal or transdermal), progestogen-only hormonal contraception associated with inhibition of ovulation (oral, injectable or implantable), intrauterine device (IUD), intrauterine hormone-releasing system (IUS), bilateral tubal occlusion, vasectomized partner or sexual abstinence. A postmenopausal state is defined as no menses for 12 months without an alternative medical cause. Contraception and pregnancy testing are required according the CTFG recommendations. Men must agree not to father a child for the duration of therapy and 6 months after (use of a condom) and must agree to advice a female partner to use a highly effective method of birth control. Males must refrain from sperm donation for at least 6 months after the last dose of treatment. Voluntary written informed consent in the native language of the patient before performance of any study-related procedure not part of normal medical care, with the understanding that consent may be withdrawn by the subject at any time without prejudice to future medical care.

Further Information at ClinicalTrials.gov

	Oncoresearch Lerchenfeld		
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INDEPENDENCE, ACE-536-MF-002

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

A Phase 3, Double-blind, Randomized Study to Compare the Efficacy and Safety of Luspatercept (ACE-536) Versus Placebo in Subjects With Myeloproliferative Neoplasm-Associated Myelofibrosis on Concomitant JAK Inhibitor Therapy and Who Require Red Blood Cell Transfusions

Recruitment Status: RECRUITING
Condition: Myeloproliferative Disorders/ / Myelofibrosis/ Primary Myelofibrosis/ Post-Polycythemia Vera Myelofibrosis/ Anemia
Primary Completion Date: 2025-03-27
Intervention/ Treatment: Drug (**ACE-536/ Placebo)**

Inclusion Criteria:

Subject is ≥18 years of age at the time of signing the ICF. Subject has a diagnosis of PMF according to the 2016 World Health Organization (WHO) criteria or diagnosis of post-ET or post-PV MF according to the IWG-MRT 2007 criteria, confirmed by the most recent local pathology report. Subject is requiring RBC transfusions as defined as:. i) Average RBC-transfusion frequency: 4 to 12 RBC units/12 weeks immediately up to randomization. There must be no interval > 6 weeks (42 days) without ≥ 1 RBC transfusion. ii) RBC transfusions are scored in determining eligibility when given for treatment of:. A. Symptomatic (ie, fatigue or shortness of breath) anemia with a pretransfusion Hgb ≤ 9.5 g/dL or. B. Asymptomatic anemia with a pretransfusion Hgb ≤ 7 g/dL. iii) RBC transfusions given for worsening of anemia due to bleeding or infections are not scored in determining eligibility.
- Subjects on continuous (eg, absent of dose interruptions lasting ≥ 2 consecutive weeks) JAK2 inhibitor therapy as approved in the country of the study site for the treatment for MPN-associated MF as part of their standard-of-care therapy for at least 32 weeks, on stable daily dose for at least 16 weeks immediately up to the date of randomization and anticipated to be on a stable daily dose of that JAK2 inhibitor for at least 24 weeks after randomization. Subject has an Eastern Cooperative Oncology Group (ECOG) performance score of ≤ 2. A female of childbearing potential (FCBP) for this study is defined as a female who: 1) has achieved menarche at some point, 2) has not undergone a hysterectomy or bilateral oophorectomy or 3) has not been naturally postmenopausal (amenorrhea following cancer therapy does not rule out childbearing potential) for at least 24 consecutive months (eg, has had menses at any time in the preceding 24 consecutive months). Females of childbearing potential (FCBP)participating in the study must:. i) Have 2 negative pregnancy tests as verified by the Investigator prior to starting study therapy. She must agree to ongoing pregnancy testing during the study, and after end of IP. This applies even if the subject practices true abstinence* from heterosexual contact. ii) Either commit to true abstinence* from heterosexual contact (which must be reviewed on a monthly basis and source documented) or agree to use, and be able to comply with, effective contraception** without interruption, 28 days prior to starting IP, during the study therapy (including dose interruptions), and for 12 weeks (approximately 5 times the mean terminal half-life of IP based on multiple-dose PK data) after discontinuation of study therapy. - Male subjects must: Practice true abstinence* (which must be reviewed on a monthly basis) or agree to use a condom during sexual contact with a pregnant female or a female of childbearing potential** while participating in the study, during dose interruptions and for at least 12 weeks (approximately 5 times the mean terminal half-life of IP based on multiple-dose PK data) following IP discontinuation, even if he has undergone a successful vasectomy.
i) True abstinence is acceptable when it is in line with the preferred and usual lifestyle of the subject. [Periodic abstinence (eg, calendar, ovulation, symptothermal, postovulation methods) and withdrawal are not acceptable methods of contraception.]. ii) Agreement to use highly effective methods of contraception that alone or in combination result in a failure rate of a Pearl index of less than 1% per year when used consistently and correctly throughout the course of the study. Such methods include: Combined (estrogen and progestogen containing) hormonal contraception: Oral, Intravaginal, Transdermal; Progestogen-only hormonal contraception associated with inhibition of ovulation: Oral, Injectable hormonal contraception, Implantable hormonal contraception; Placement of an intrauterine device (IUD); Placement of an intrauterine hormone-releasing system (IUS); Bilateral tubal occlusion; Vasectomized partner; Sexual Abstinence. Subject must understand and voluntarily sign an ICF prior to any study-related assessments/procedures being conducted. Subject is willing and able to adhere to the study visit schedule and other protocol requirements including the use of the electronic patient reported outcomes device.

Further Information at ClinicalTrials.gov

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LUSPLUS

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

A Phase IIIb, Open-label, Single Arm Study to Evaluate the Efficacy and Safety of Luspatercept in Patients With Lower-risk MDS and Ring-sideroblastic Phenotype (MDS-RS)

Recruitment Status: RECRUITING
Condition: Myelodysplastic Syndromes
Primary Completion Date: 2024-12-31
Intervention/ Treatment: Drug (**Luspatercept)**

Inclusion Criteria:

Subject is 18 years of age or older at the time of signing the informed consent form (ICF) Subject is able to understand and voluntarily sign the ICF prior to any study-related assessments/procedures being conducted Subject has documented diagnosis of MDS according to WHO classification that meets IPSS-R classification[3] of very low-, low-, or intermediate-risk disease, and the following: Ring sideroblasts (RS) ≥ 15% of erythroid precursors in bone marrow or ≥ 5% if SF3B1 mutation is present Less than 5% blasts in bone marrow Peripheral blood white blood cell (WBC) count < 13,000/µL Subject must be one of the following: Refractory to prior ESA treatment: Documentation of non-response or response that was no longer maintained to prior ESA-containing regimen, either as a single agent or in combination (e.g. with granulocyte colony-stimulating factor [G-CSF]). The ESA regimen must be either: Recombinant human erythropoietin ≥ 40,000 IU/week for at least 8 weeks (=doses) or equivalent; or Darbepoetin-α ≥ 500 µg q3w for at least 4 doses or equivalent Intolerant to prior ESA treatment: Documentation of discontinuation of prior ESA containing regimen, either as a single agent or in combination (e.g. with G-CSF), at any time after introduction due to intolerance or an adverse event (AE) ESA ineligible: Low chance of response to ESA based on endogenous serum erythropoietin (EPO) level > 200 U/L for subjects not previously treated with ESAs Refractory to- /relapsed after prior HMA treatment1: Treatment failure/relapse after at least six (azacitidine) or four (decitabine) 4-week treatment cycles except for del(5q) MDS Refractory to- /relapsed after prior lenalidomide treatment1 except for del(5q) MDS If previously treated with ESAs or G-CSF/granulocyte-macrophage colony-stimulating factor (GM-CSF), both agents must be discontinued ≥ 4 weeks prior to the date of starting treatment with the Investigational medicinal Product (IMP) in this study Required RBC transfusions, as documented by the following criteria: Average transfusion requirement of ≥ 2 units/8 weeks of packed RBCs confirmed for a minimum period of 16 weeks immediately preceding start of treatment with IMP Hemoglobin (Hb) levels at the time of or within 7 days prior to administration of an RBC transfusion must be ≤ 10.0 g/dL in order for the transfusion to be counted towards meeting eligibility criteria. RBC transfusions administered when Hb levels are > 10 g/dL and/or RBC transfusions administered for elective surgery do not qualify as a required transfusion for the purpose of meeting eligibility criteria No consecutive 56-day period that is RBC transfusion-free during the 16 weeks immediately prior to starting treatment with IMP Eastern Cooperative Oncology Group (ECOG) score of 0, 1, or 2 A female of childbearing potential (FCBP) for this study is defined as a sexually mature woman who: (1) has not undergone a hysterectomy or bilateral oophorectomy; or (2) is not naturally postmenopausal (amenorrhea following cancer therapy does not rule out childbearing potential) for at least 24 consecutive months (i.e. had menses at any time in the preceding 24 consecutive months). An FCBP participating in the study must: Have 2 negative pregnancy tests as verified by the investigator prior to starting IMP (unless the screening pregnancy test is done within 72 hours of Cycle 1 Day 1). She must agree to ongoing pregnancy testing during the course of the study and after end of treatment (EOT). If sexually active, agree to use, and be able to comply with, highly effective contraception** without interruption, 5 weeks prior to starting IMP, during treatment with IMP (including dose interruptions), and for 12 weeks after discontinuation of IMP. ** Highly effective contraception is defined in this protocol as the following (information also appears in the ICF): Hormonal contraception (e.g. birth control pills, injection, implant, transdermal patch, vaginal ring), intrauterine device, tubal ligation, or a partner with a vasectomy Male subjects must agree to use a condom, defined as a male latex condom or nonlatex condom NOT made out of natural (animal) membrane (e.g. polyurethane), during sexual contact with a pregnant female or an FCBP while participating in the study, during dose interruptions, and for at least 12 weeks following IMP discontinuation, even if he has undergone a successful vasectomy Subject is willing and able to adhere to the study visit schedule and other protocol requirements

Further Information at [ClinicalTrials.gov]

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ReVenG-M20-356

A Multicenter, Open-Label, Phase 2 Study to Evaluate the Efficacy and Safety of Venetoclax-Obinutuzumab Retreatment in Patients With Recurring Chronic Lymphocytic Leukemia

Recruitment Status: RECRUITING
Condition: Chronic Lymphocytic Leukemia (CLL)
Primary Completion Date: 2025-02-22
Intervention/ Treatment: Drug (**Venetoclax/ Obinutuzumab)**

Inclusion Criteria:
Documented diagnosis of chronic lymphocytic leukemia (CLL) that requires treatment for CLL according to International Workshop for Chronic Lymphocytic Leukemia (iwCLL) 2018 criteria.
Previously completed venetoclax + anti-CD20 antibody +/- X regimen as a fixed duration first-line (1L) therapy and achieved documented response, defined as complete remission, complete remission with incomplete marrow recovery, partial remission, or nodular partial remission.
More than 24 months (Cohort 1) or 12-24 months (Cohort 2) have elapsed between last dose of venetoclax and disease progression after completion of 1L treatment.
Exclusion Criteria:
- Received intervening treatment for CLL after completing previous treatment with a venetoclax + anti-CD20 antibody +/- X regimen.

Further Information at ClinicalTrials.gov

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Entitäten

TRANSFORM-2, M20-178

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

A Randomized, Open-Label, Phase 3 Study Evaluating Efficacy and Safety of Navitoclax in Combination With Ruxolitinib Versus Best Available Therapy in Subjects With Relapsed/Refractory Myelofibrosis (TRANSFORM-2)

Recruitment Status: ACTIVE, NOT RECRUITING
Condition: Myelofibrosis (MF)
Primary Completion Date: 2024-08-15
Intervention/ Treatment: Drug (**Navitoclax/ Ruxolitinib/ Best Available Therapy (BAT)**)

Inclusion Criteria:

Must complete the Myelofibrosis Symptom Assessment Form (MFSAF) v4.0 on at least 4 out of the 7 days immediately prior to the date of randomization and must agree to collect MFSAF data daily by ePRO device during the study collection window.
-- Has at least 2 symptoms each with an average score >= 3 or an average total score of >= 12, as measured by the MFSAF v4.0.
Documented diagnosis of primary myelofibrosis (MF) as defined by the World Health Organization (WHO) classification, post polycythemia vera (PPV)-MF, or post essential thrombocytopenia (PET)-MF, characterized by bone marrow fibrosis grades 2 or 3.
Classified as intermediate-2 or high-risk MF, as defined by the Dynamic International Prognostic Scoring System Plus (DIPSS+).
Must currently be on treatment or have received prior treatment with a single Janus Kinase 2 (JAK2) inhibitor, ruxolitinib, and meet one of the following criteria (in addition to the minimum splenomegaly and symptom burden also required for eligibility):

- Treatment with ruxolitinib for >= 24 weeks that was stopped due to lack of spleen response (refractory), or loss of spleen response or symptom control after a previous response (relapsed), or was continued despite relapsed/refractory status.
- Treatment with ruxolitinib for < 24 weeks with documented disease progression while on therapy as defined by any of the following:
  - Appearance of new splenomegaly that is palpable to at least 5 cm below the left costal margin (LCM) in participants with no evidence of splenomegaly prior to the initiation of ruxolitinib.
  - A >= 100% increase in the palpable distance below the LCM in participants with measurable spleen distance 5 to 10 centimeters (cm) prior to the initiation of ruxolitinib.
  - A >= 50% increase in the palpable distance below the LCM in participants with measurable spleen distance > 10 cm prior to the initiation of ruxolitinib.
  - A spleen volume increase of >= 25% (as assessed by Magnetic Resonance Imaging [MRI] or Computed Tomography [CT] scan) in participants with a spleen volume assessment prior to the initiation of ruxolitinib.
- Prior treatment with ruxolitinib of at least 10 mg twice daily (BID) for >= 28 days with intolerance defined as new RBC transfusion requirement (at least 2 units/month for 2 months) while receiving a total daily ruxolitinib dose of >= 30 mg but unable to reduce dose further due to lack of efficacy.

Note: Participant must not require a ruxolitinib dose less than 10 mg BID (20 mg daily) due to prior history of ruxolitinibrelated ≥ Grade 3 toxicity.
Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1, or 2.
Splenomegaly defined as palpable spleen measurement >= 5 cm below left costal margin or spleen volume >= 450 cm3 as assessed centrally by MRI or CT scan.
Baseline platelet count >= 100 × 10^9/L.

Further Information at ClinicalTrials.gov

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CCC-PalliAng

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

kurze Zusammenfassung der Studie (**Schrift 14/ Arial**)

Recruitment Status: RECRUITING
Condition: (**Schrift 10/ Arial**)
Primary Completion Date:
Intervention/ Treatment:

Inclusion Criteria:

Exclusion Criteria **Schrift 8 oder 10 Arial** :

Further Information at ClinicalTrials.gov

	Palliativ		
PI	Prof. Dr. med. Karin Oechsle	**(9) 50667, 01522/ 281 5893**	kaoechsl@uke.de
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EXBEL, DKH70113404

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

Existential Distress in Patients With Advanced Cancer and Their Caregivers: A Longitudinal Cohort Study

Recruitment Status: ACTIVE, NOT RECRUITING
Condition: Neoplasms Malignant/ Carcinoma/ Palliative Care
Primary Completion Date: 2024-06
Intervention/ Treatment: Other: Self-report questionnaires

Inclusion Criteria:
18 years and older
UICC stage IV solid tumor or UICC stage III lung or ovarian tumor
Informed consent
Exclusion Criteria:
Severe cognitive
Severe physical impairment
Insufficient German to give informed consent and complete self-report questionnaires

Further Information at ClinicalTrials.gov

	Psycho-Oncology		
PI	PD Dr. Sigrun Vehling	(040) 7410-56805	s.vehling@uke.de
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ORPHYS

ORPHYS - Short-term Psychodynamic Psychotherapy in Serious Physical Illness

Recruitment Status: RECRUITING
Condition: Neoplasms Malignant/ Carcinoma/ Palliative Care
Primary Completion Date: 2024-06-30
Intervention/ Treatment: Behavioral: Short-term psychodynamic psychotherapy for patients with serious physical illness

Inclusion Criteria:
18 years and older
UICC stage IV solid tumor
Informed consent
Current physical condition that allows for at least 12 therapy sessions
Indication: Presence of a mental disorder with existential stress and limitations in coping capacity

Exclusion Criteria:
Acute suicidality
Psychotic disorder (ICD-10: F2 diagnosis)
Substance dependence or abuse (ICD-10: F1 diagnosis)
Structural deficits that interfere with attending to regular appointments
Other psychotherapeutic treatment
Severe cognitive impairment
Severe physical impairment
Insufficient German to give informed consent and complete self-report questionnaires

Further Information at ClinicalTrials.gov

	Psycho-Oncology		
PI	PD Dr. Sigrun Vehling	(040) 7410-56805	s.vehling@uke.de
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BEEPER, PV5387

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

Prospektiv-randomisierter Vergleich Von En-bloc- Versus Piecemeal-Resektion Von Barrett Neoplasien Des Ösophagus Neoplastic Barrett Esophagus: Endoscopic Piecemeal vs. En Bloc Resection

Recruitment Status: RECRUITING
Condition: Barrett Esophagus/ Barrett Adenocarcinoma/ Esophagus Neoplasm
Primary Completion Date: 2025-10
Intervention/ Treatment: Procedure (**Endoscopic mucosal resection/ Endoscopic submucosal dissection**)

Inclusion Criteria:
patients to be treated for Barrett's esophagus by mucosal resection and following ablative therapy
Barrett's mucosal extension up to 10 cm maximum.
patient's ability for compliance to therapy
signed Informed Consent

Exclusion Criteria:
any lesion questionable to be resectable by mucosectomy, e.g. bulky lesions ≥10 mm in endoscopy und endosonography, suspected deep submucosal infiltration, ulcers, suspected or by FNA confirmed lymph node infiltration
Barrett's esophagus > 10 cm
lesions that would afford resection of more than 2/3rd of esophagal circumference
two or more single Barrett's lesions with bulky HGIN or early cancer histology, not to be resectable in one half of esophageal circumference
planned circumferencial resections
very serious general illness and metastatic carcinoma
coagulation disorder or anticoagulants that make biopsies and resections impossible
American Society of Anesthesiologists (ASA) status > III
pregnancy and lactation
remainders or recurrences after therapeutic history of Barrett's espohagus

Further Information at ClinicalTrials.gov

	Radiology/ Endoscopy		
PI	Prof. Dr. Thomas Rösch	(040) 7410-56972	t.roesch@uke.de
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Gammadelta_TCR_MRD_AML

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

kurze Zusammenfassung der Studie (**Schrift 14/ Arial**)

Recruitment Status: RECRUITING
Condition: (**Schrift 10/ Arial**)
Primary Completion Date:
Intervention/ Treatment: Drug:

Inclusion Criteria:

Exclusion Criteria **Schrift 8 oder 10 Arial** :

Further Information at ClinicalTrials.gov

	Stem Cell Transplantation		
PI	Prof. Dr. med. Nikolaus Kröger	(040) 7410-55864	nkroeger@uke.de; bmt@uke.de
SI	Evgeny Klyuchnikov	**01522/ 281 7716**	e.klyuchn@uke.de
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INJURMET

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

Impact of tissue injury induced by diagnostic biopsies and surgery on cancer metastasis

Recruitment Status: RECRUITING
Condition: Cancer
Primary Completion Date:
Intervention/ Treatment: Procedure (**Endoscopic mucosal resection/ Endoscopic submucosal dissection**)

Inclusion Criteria:
diagnostic biopsies and surgery on cancer

Further Information at ClinicalTrials.gov

	Tumorbiology		
PI	Dr. Simon Joosse	(040) 7410-51970	s.joosse@uke.de
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SK			

L1st-Liquid First, MO43989

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

An International Prospective Study to Evaluate the Impact of Liquid Biopsy in Participants With a Clinical Diagnosis of Advanced Cancer (L1ST)

Recruitment Status: RECRUITING
Condition: Metastatic Lung Cancer/ Metastatic Gastrointestinal Cancer
Primary Completion Date: 2024-11-15
Intervention/ Treatment: Diagnostic Test (**FoundationOne® Liquid CDx Assay/ Standard of Care Diagnostic Pathway**)

Inclusion Criteria:
Participants presenting with a clinical diagnosis of advanced cancer, falling into one of the following two clinical presentations:
i) De novo metastatic lung cancer as evidenced by imaging demonstrating a lung nodule/mass and objective evidence of a metastatic process; OR, ii) De novo metastatic gastrointestinal cancer as evidenced by imaging demonstrating a metastatic process in the abdomen/pelvis
Participants who are treatment naïve for the metastatic setting under study
Ability to comply with the study protocol
Participants must either:
i) Have a tissue biopsy intended/planned to confirm malignant disease and histology; OR, ii) Have a tissue biopsy already performed but pathology has not yet been finalized.
If a tissue biopsy has already been performed prior to ICF signature, then the subtyping of primary tumor may have already been assessed (i.e., for lung cancer TTF1, p40, and napsin A IHC staining may have already been performed).

Exclusion Criteria:
Participants deemed not fit for treatment with systemic therapy
Participants deemed not fit for tissue biopsy
Participants with hematological neoplasm
Participants with primary malignant neoplasm of the brain
Participants with any previous molecular testing (NGS or other methods) e.g., all immunohistochemistry staining recommended by ESMO aiming to define the treatment decision (i.e., for lung cancer ALK, EGFR, and PD-L1 IHC staining must not have already been performed). Participants in which tissue biopsy and primary histotyping have been performed can be included in the study.
Prior treatment for metastatic cancer with the exception of participants who have already been diagnosed and treated for cancer, other than the cancer type under study, who have no evidence of relapse
History of malignancy within 5 years prior to screening, with the exception of the cancer under investigation in this study and malignancies with a negligible risk of metastasis or death (e.g., 5-year overall survival rate > 90%), such as adequately treated carcinoma in situ of the cervix, non-melanoma skin carcinoma, localized prostate cancer, ductal carcinoma in situ, or Stage I uterine cancer

Further Information at ClinicalTrials.gov

	UCCH		
PI	PD Dr. med. Maximilian Christopeit	(040) 7410-51384	m.christopeit@uke.de
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TASTE Guide

kurze Zusammenfassung der Studie (**Schrift 14/ Arial**)

Recruitment Status: RECRUITING
Condition: ?
(**Schrift 10/ Arial**)
Primary Completion Date: ?
Intervention/ Treatment: ?

Inclusion Criteria:

Exclusion Criteria

Schrift 8 oder 10 Arial :

Further Information at ?

	Department		
PI	PD Dr. med. Marianne Sinn	**0152 22830613**	ma.sinn@uke.de
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Psychoonkologische Registerstudie

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

kurze Zusammenfassung der Studie (**Schrift 14/ Arial**)

Recruitment Status: RECRUITING
Condition: Colon Cancer, Panrceatic Cancer, Breast Cancer
Primary Completion Date: 2025-12
Intervention/ Treatment: Register

Inclusion Criteria:

Exclusion Criteria **Schrift 8 oder 10 Arial** :

Further Information at ?

	Onkolog. Zentrum an den Krankenhäusern Buchholz und Winsen		
PI	Dr. med. Mark Thomé (viszeral) Julia Weidner (Breast)	04171 130 04171 - 13 4701	Mark.thome@krankenhaus-buchholz.de Julia.weidner@krankenhaus-buchholz.de
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PERFORM, A5481152

PERFORM: An EPidEmiological, PRospective Cohort Study to Generate Real-world Evidence in Patients With HR+/HER2- Advanced Breast Cancer Treated in the First Line Setting as Per Current Standard Of Care With an EndocRine-based Palbociclib CoMbination Therapy

Recruitment Status: RECRUITING
Condition: Breast Neoplasms
Primary Completion Date: 2028-04-03
Intervention/ Treatment: Drug(**Palbociclib + endocrine therapy**)

Inclusion Criteria
Patients must meet all of the following inclusion criteria to be eligible for inclusion in the study:
Evidence of a personally signed and dated informed consent document indicating that the patient has been informed of all pertinent aspects of the study.
Diagnosis of HR+/HER2- locally advanced, inoperable or metastatic breast cancer.
Physician has determined that first-line treatment with palbociclib (i) in combination with an aromatase inhibitor, or (ii) in combination with fulvestrant in women who received prior endocrine therapy as per current local product label is indicated. In pre- or perimenopausal women, the endocrine therapy should be combined with a luteinizing hormone-releasing hormone (LHRH) agonist.
Patients who in the opinion of the investigator are willing and able to comply with regular clinic visits as per local standard of care practice at the study site.
Age of 18 years or older.
Patients meeting any of the following criteria will not be included in the study:
Any contraindication as per current local product label.
Prior systemic antineoplastic treatment for advanced disease. Exception: Start of first line treatment with palbociclib in combination with aromatase inhibitor or fulvestrant as per current local product label is allowed up to 4 weeks prior to inclusion.
Patients currently participating in any interventional clinical trial that includes investigational or marketed products at the time of enrollment. Note: A concomitant participation in other non-interventional/observational studies, registries and translational research networks (e.g., PRAEGNANT, OPAL) or chart reviews is allowed.
Patients who are unable to understand the nature of the study or are unwilling to sign an informed consent.
Patient eligibility should be reviewed, documented, and confirmed by an appropriately qualified member of the investigator's study team before patients are enrolled in the study.

Further Information at ClinicalTrials.gov

	Onkolog. Zentrum an den Krankenhäusern Buchholz und Winsen			**Helios Mariahilf Klinik Hamburg**			**Westküstenklinikum**			**Klinikum Itzehoe**		
PI	**Dr. med. Heike Schieder**	**04181 131390**		**Dr. med. Christoph Großmann**	(040) 790 06-896	sekretariat.mariahilf@helios-gesundheit.de	Dr. med. Sandra Rauen		0481 7855100	Dr. med. Antje Schroeder		antje.schroeder@kh-itzehoe.de
SI												
SK												

Entitäten

DEMAND (AIO-HEP-0418)

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

A Randomized, 2-arm Non-comparative Phase II Study on the Efficacy of Atezolizumab and Roche Bevacizumab (Atezo/Bev) Followed by On-demand Selective TACE (sdTACE) Upon Detection of Disease Progression or of Initial Synchronous Treatment With TACE and Atezo/Bev on 24-months Survival Rate in the Treatment of Unresectable Hepatocellular Carcinoma Patients

Recruitment Status: RECRUITING
Condition: Hepatocellular Carcinoma Non-resectable
Primary Completion Date: 2025-03-01
Intervention/ Treatment: Combination Product: Atezolizumab Injection, Bevacizumab Injection

Inclusion Criteria:

Patient's signed informed consent. Age ≥18 years at time of signing Informed Consent Form. Ability to comply with the study protocol, according to investigator's judgement Life expectancy of at least 12 weeks. HCC with histologically confirmed diagnosis. Disease that is not amenable to curative surgical and/or local ablation but eligible for TACE. ECOG Performance Status of 0 or 1. Child-Pugh class A or B7. Adequate hematologic and end-organ function. Negative HIV test at screening.

Further Information at ClinicalTrials.gov

	Gastroenterology		
PI	Dr. med. Kornelius Schulze	01522/ 2817169	k.schulze@uke.de
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FIGHT-302

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

A Phase 3, Open-Label, Randomized, Active-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Pemigatinib Versus Gemcitabine Plus Cisplatin Chemotherapy in First-Line Treatment of Participants With Unresectable or Metastatic Cholangiocarcinoma With FGFR2 Rearrangement (FIGHT-302)

Recruitment Status: RECRUITING
Condition: Unresectable Cholangiocarcinoma Metastatic Cholangiocarcinoma
Primary Completion Date: 2027-10-26
Intervention/ Treatment: Drug: Pemigatinib Gemcitabine/ Cisplatin

Inclusion Criteria:

Male and female participants at least 18 years of age at the time of signing the informed consent form (ICF). Histologically or cytologically confirmed cholangiocarcinoma that is previously untreated and considered unresectable and/or metastatic (Stage IV per the American Joint Committee on Cancer (AJCC) Cancer Staging Manual). Radiographically measurable or evaluable disease by CT or MRI per RECIST v1.1 criteria. Eastern Cooperative Oncology Group performance status 0 to 1. Documented FGFR2 rearrangement. Willingness to avoid pregnancy or fathering children.

Further Information at ClinicalTrials.gov

	Gastroenterology		
PI	Dr. med. Kornelius Schulze	01522/ 2817169	k.schulze@uke.de
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SORENTO HS-19-657

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

A Randomized, Multi-center, Open-label, Active-controlled Phase 3 Trial to Assess the Efficacy and Safety of Octreotide Subcutaneous Depot (CAM2029) Versus Octreotide LAR or Lanreotide ATG in Patients With GEP-NET

Recruitment Status: ACTIVE, NOT RECRUITING
Condition: astro-enteropancreatic Neuroendocrine Tumor
Primary Completion Date: 2024-12
Intervention/ Treatment: Drug: CAM2029/ Octreotide LAR/ Lanreotide ATG

Inclusion Criteria:
Male or female patient ≥18 years old. Histologically confirmed, advanced (unresectable and/or metastatic), and well-differentiated NET of GEP or presumed GEP origin. At least 1 measurable, somatostatin receptor-positive lesion according to RECIST 1.1 determined by multiphasic CT or MRI (performed within 28 days before randomization). ECOG performance status of 0 to 2.

Exclusion Criteria:
Documented evidence of disease progression while on treatment (including SSAs) for locally advanced unresectable or metastatic disease. Known central nervous system metastases Consecutive treatment with long-acting SSAs for more than 6 months before randomization. Carcinoid symptoms that are refractory to treatment (according to the Investigator's judgement) with conventional doses of octreotide LAR or lanreotide ATG and/or to treatment with daily doses of ≤600 µg of octreotide IR. Previous treatment with more than 1 cycle of targeted therapies such as mTOR inhibitors or vascular endothelial growth factor inhibitors, or more than 1 cycle of chemotherapy or interferon for GEP-NET. Treatment of GEP-NET with trans-arterial chemoembolization or trans-arterial embolization within 12 months before screening. Previously received radioligand therapy (PRRT) at any time.

Further Information at ClinicalTrials.gov

	Gastroenterology		
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Niraparib vs Niraparib in Combination With Bevacizumab in Patients With Carboplatinum-taxane Based Chemotherapy in Advanced Ovarian Cancer (A Multicentre Randomised Phase III Trial)

Recruitment Status: RECRUITING
Condition: Ovarian Cancer Fallopian Tube Cancer Peritoneal Cancer
Primary Completion Date: 2028-02
Intervention/ Treatment: Drug: Carboplatin/ Paclitaxel/ Bevacizumab/ Niraparib

Inclusion Criteria:

Signed written informed consent obtained prior to initiation of any study-specific procedures and treatment as confirmation of the patient's awareness and willingness to comply with the study requirements. Female patients ≥ 18 years with histologically confirmed primary advanced invasive high grade epithelial ovarian cancer, peritoneal cancer, or fallopian tube cancer FIGO III/IV (except FIGO stage IIIA2 without nodal involvement) according to recent FIGO classification (= FIGO stage IIIB - IV according to FIGO 2009 classification). All patients must have had either upfront primary debulking surgery OR plan to undergo chemotherapy with interval debulking surgery. Patients must have available tumor samples to be sent to central laboratory as formalin-fixed, paraffin-embedded (FFPE) sample for determination of BRCA status prior to randomization for stratification. Patients must be able to commence systemic therapy within 8 weeks of cytoreductive surgery. Eastern Cooperative Oncology Group (ECOG) performance status (PS) 0-1. Estimated life expectancy > 3 months. Adequate bone marrow function (within 28 days prior to day 1, cycle 1). Absolute Neutrophil Count (ANC) ≥ 1.5 x 10^9/L. Platelets (PLT) ≥ 100 x 10^9/L. Hemoglobin (Hb) ≥ 9 g/dL (can be post-transfusion). Adequate coagulation parameters (within 28 days prior to day 1, cycle 1). Patients not receiving anticoagulant medication who have an International Normalized Ratio (INR) ≤ 1.5 and an Activated ProThrombin Time (aPTT) ≤ 1.5 x institutional upper limit of normal (ULN). The use of full-dose oral or parenteral anticoagulants is permitted as long as the INR or aPTT is within therapeutic limits (according to institution medical standard) and the patient has been on a stable dose of anticoagulants for at least two weeks at the time of day 1, cycle 1. Adequate liver and kidney function (within 28 days prior to day 1, cycle 1). Total bilirubin ≤ 1.5 x ULN (≤ 2.0 x ULN in patients with known Gilbert's syndrome) OR direct bilirubin ≤ 1.0 x ULN. Aspartate aminotransferase / Serum Glutamic Oxaloacetic Transaminase (ASAT/SGOT) and Alanine aminotransferase / Serum Glutamic Pyruvate Transaminase (ALAT/SGPT) ≤ 2.5 x ULN, unless liver metastases are present, in case of liver metastases values must be ≤ 5 x ULN. Urine dipstick for proteinuria < 2+. If urine dipstick is ≥ 2+, 24 hour urine must demonstrate ≤ 1 g of protein in 24 hours. Serum creatinine ≤ 1.5 x upper limit of normal (ULN) or calculated creatinine clearance ≥ 30 mL/min using the Cockcroft-Gault equation. Patients must have normal blood pressure (BP) or adequately treated and controlled BP, with a systolic BP of ≤ 140 mmHg and diastolic BP of ≤ 90 mmHg for eligibility. Patients must have a BP of ≤ 140/90 mmHg taken in the clinic setting by a medical professional within 4 weeks prior to day 1, cycle 1. Negative urine or serum pregnancy test within 7 days prior to day 1, cycle 1 in women of childbearing potential (WOCBP), confirmed prior to treatment on day 1. For women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use a highly effective contraceptive method with a failure rate of < 1% per year during the treatment period and for at least 6 months after administration of the last dose of medication. A woman is considered to be of childbearing potential if she is postmenarcheal, has not reached a postmenopausal state (≥ 12 continuous months of amenorrhea with no identified cause other than menopause), and has not undergone surgical sterilization (removal of ovaries, fallopian tubes, and/or uterus). Examples of contraceptive methods with a failure rate of < 1% per year include but are not limited to bilateral tubal ligation and/or occlusion, male sterilization, and intrauterine devices. The reliability of sexual abstinence should be evaluated in relation to the duration of the clinical study and the preferred and usual lifestyle of the patient. Periodic abstinence (e.g., calendar, ovulation, symptothermal, or postovulation methods) and withdrawal are not acceptable methods of contraception. Willingness and ability to comply with scheduled visits, treatment plans, laboratory tests, and other study procedures, that include the completion of patient-reported outcomes questionnaires.

Further Information at ClinicalTrials.gov

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SI	SI					
Study Nurse	SK					

Entitäten

ASCENT-03 GS-US-592-6238

A Randomized, Open-label, Phase 3 Study of Sacituzumab Govitecan Versus Treatment of Physician's Choice in Patients With Previously Untreated, Locally Advanced, Inoperable or Metastatic Triple-Negative Breast Cancer Whose Tumors Do Not Express PD-L1 or in Patients Previously Treated With Anti-PD-(L)1 Agents in the Early Setting Whose Tumors Do Express PD-L1

Recruitment Status: RECRUITING
Condition: Triple Negative Breast Cancer PD-L1 Negative
Primary Completion Date: 2027-05
Intervention/ Treatment: Drug: Sacituzumab Govitecan-hziy/ Paclitaxel/ nab-Paclitaxel/ Gemcitabine/ Carboplatin

Inclusion Criteria:

Individuals, regardless of race and ethnic group, with previously untreated locally advanced, inoperable or metastatic triple-negative breast cancer (TNBC). Individuals whose tumors are programmed cell death ligand 1 (PD-L1) negative at screening or individuals whose tumors are PD-L1 positive at screening if they have received an anti-PD-(L)1 inhibitor in the (neo) adjuvant setting or if they cannot be treated with a checkpoint inhibitor due to a comorbidity. Centrally confirmed TNBC and PD-L1 status on fresh or archival tissue. Individuals must have completed treatment for Stage I-III breast cancer, if indicated, and ≥ 6 months must have elapsed (with the exception of endocrine therapy) between completion of treatment with curative intent and first documented local or distant disease recurrence. Individuals presenting with de novo metastatic TNBC are eligible. Measurable disease based on computed tomography (CT) or magnetic resonance imaging (MRI) in accordance with per Response Evaluation Criteria in Solid Tumors (RECIST) Version 1.1. as evaluated locally. Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1. Demonstrates adequate organ function. Male individuals and female individuals of childbearing potential who engage in heterosexual intercourse must agree to use protocol-specified method(s) of contraception. Individuals with human immunodeficiency virus (HIV) must be on antiretroviral therapy (ART) and have a well-controlled HIV infection/disease.

Exclusion Criteria:

Positive serum pregnancy test or women who are lactating. Received systemic anticancer treatment within the previous 6 months or radiation therapy within 2 weeks prior to enrollment
Have not recovered from adverse events (AEs) due to a previously administered agent at the time study entry. May not be participating in a study with an investigational agent or investigational device within 4 weeks prior to randomization. Individuals participating in observational studies are eligible. Previously received topoisomerase 1 inhibitors or antibody drug conjugates containing a topoisomerase inhibitor. Active second malignancy. Active serious infection requiring antibiotics. Positive for HIV-1 or 2 with a history of Kaposi sarcoma and/or Multicentric Castleman Disease. Active hepatitis B virus (HBV) or hepatitis C virus (HCV) infection.

Further Information at ClinicalTrials.gov

	HOPE			Gynecology		
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Study Nurse						

ASCENT-04 GS-US-592-6173

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

A Randomized, Open-label, Phase 3 Study of Sacituzumab Govitecan and Pembrolizumab Versus Treatment of Physician's Choice and Pembrolizumab in Patients With Previously Untreated, Locally Advanced Inoperable or Metastatic Triple-Negative Breast Cancer, Whose Tumors Express PD-L1

Recruitment Status: RECRUITING
Condition: Triple Negative Breast Cancer PD-L1 Negative
Primary Completion Date: 2027-05
Intervention/ Treatment: Drug: Sacituzumab Govitecan-hziy/ Pembrolizumab/ Paclitaxel/ nab-Paclitaxel/ Gemcitabine/ Carboplatin

Inclusion Criteria:
Individuals with locally advanced, inoperable, or metastatic triple-negative breast cancer (TNBC) who have not received previous systemic therapy for advanced disease and whose tumors are programmed cell death ligand 1 (PD-L1) positive at screening. Individuals must have completed treatment for Stage I to III breast cancer, if indicated, and ≥ 6 months must have elapsed between completion of treatment with curative intent and first documented local or distant disease recurrence. Individuals presenting with de novo metastatic TNBC are eligible for this study. TNBC status and tumor PD-L1 combined positive score (CPS) will be confirmed centrally on a recent or archival tumor specimen. Individuals must have measurable disease by computed tomography (CT) or magnetic resonance imaging (MRI) as per Response Evaluation Criteria in Solid Tumors (RECIST) Version 1.1 criteria as evaluated locally. Eastern Cooperative Oncology Group (ECOG) performance status score of 0 or 1. Demonstrates adequate organ function. Male and female individuals of childbearing potential who engage in heterosexual intercourse must agree to use protocol-specified method(s) of contraception. Individuals with HIV must be on antiretroviral therapy (ART) and have a well-controlled HIV infection/disease.

Exclusion Criteria:
Positive serum pregnancy test or women who are lactating. Received prior therapy with an agent directed to another stimulatory or coinhibitory T-cell receptor. Individuals may not have received systemic anticancer treatment (with the exception of endocrine therapy) within the previous 6 months or radiation therapy within 2 weeks prior to enrollment. Individuals may not be participating in a study with an investigational agent or investigational device within 4 weeks prior to randomization. Individuals participating in observational studies are eligible. Have previously received topoisomerase 1 inhibitors or antibody drug conjugates containing a topoisomerase inhibitor. Have active serious infection requiring antibiotics. Individuals positive for HIV-1 or 2 with a history of Kaposi sarcoma and/or Multicentric Castleman Disease. Have active hepatitis B virus (HBV) or hepatitis C virus (HCV) infection.
Has an active autoimmune disease that has required systemic treatment in the past 2 years.

Further Information at [ClinicalTrials.gov]

	HOPE			Gynecology		
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Study Nurse						

AXSANA, EUBREAST 3

A Prospective Multicenter Cohort Study to Evaluate Different Surgical Methods of Axillary Staging (Sentinel Lymph Node Biopsy, Targeted Axillary Dissection, Axillary Dissection) in Clinically Node-positive Breast Cancer Patients Treated With Neoadjuvant Chemotherapy

Recruitment Status: RECRUITING
Condition: Breast Cancer
Primary Completion Date: 2030-04
Intervention/ Treatment: Not provided

Inclusion Criteria:
Signed informed consent form. Primary invasive breast cancer (confirmed by core biopsy). cN+ cT1-4c. Scheduled for neoadjuvant systemic therapy. Female / male patients ≥ 18 years old

Exclusion Criteria:
Distant metastasis.Recurrent breast cancer.Inflammatory breast cancer. Extramammary breast cancer. Supraclavicular lymph node metastasis. Pregnancy Less than 4 cycles of NACT administered. Patients not suitable for surgical treatment

Further Information at ClinicalTrials.gov

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	Onkolog. Zentrum an den Krankenhäusern Buchholz und Winsen			**Helios Mariahilf Klinik Hamburg**			**Westküstenklinikum**		
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MIROVA AGO-OVAR 2.34

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

A Randomized Phase II Trial of Mirvetuximab Soravtansine (IMGN853), in Folate Receptor Alpha (FRα) High Recurrent Ovarian Cancer Eligible for Platinum-based Chemotherapy. Supported by: DIAGNOSTIC PROTOCOL for the VENTANA FOLR1 (FOLR1-2.1) CDx Assay Ventana No. RD004881; Protocol Document No. D152967

Recruitment Status: RECRUITING
Condition: Recurrent Epithelial Ovarian, Fallopian or Peritoneal Carcinoma
Primary Completion Date: 2025-12
Intervention/ Treatment: Not provided

Inclusion Criteria:

All patients must have a pathologically documented, definite diagnosis of epithelial cancer of the ovary, the fallopian tube or the peritoneum. Relapsed disease with a platinum-free interval >3 months. All histologic subtypes of ovarian carcinoma including carcinosarcoma (malignant mixed Mullerian tumors, MMMT). Patients with wildtype BRCA1/2 mutation status or with a deleterious BRCA1/2 mutation in germline or somatic testing if they underwent PARP inhibitor therapy in previous treatment line. Patients must be willing to provide archival tumor tissue from current relapse or previous surgeries/biopsies for central confirmation of FRα high status by PS2+ scoring: all tumors must exhibit ≥75% of tumor cells with FRα membrane staining and ≥ 2+ intensity by immunohistochemistry (IHC) using the Ventana FOLR1 (FOLR1 2.1) CDx assay. Patients must have measurable disease or evaluable disease in combination with GCIG CA-125 criteria. Patients had one or more prior lines of chemotherapy. The last line of chemotherapy should have included platinum and has resulted in a partial or complete response. Major surgery (not including placement of vascular access device, tumor punch/scrape biopsies or secondary wound closure) must be completed four weeks prior to Day 1. Patients must have adequate hematological, liver, cardiac and kidney function: Hemoglobin ≥ 10.0 g/dL. Absolute neutrophil count (ANC) ≥ 1.5 x 109/L. Platelet count ≥ 100 x 109/L. Total bilirubin ≤ 1.5 x institutional upper limit of normal (ULN). Aspartate aminotransferase/Serum Glutamic. Oxaloacetic Transaminase (ASAT/SGOT)) and Alanine aminotransferase/Serum Glutamic Pyruvate Transaminase (ALAT/SGPT)) ≤ 2.5 x ULN, unless liver metastases are present in which case they must be ≤ 5 x ULN. Serum creatinine ≤ 1.5 x institutional ULN and glomerular filtration rate of at least 40 ml/minute according to Cockroft-Gault formula. Patient is female and ≥18 years of age at the time of the first screening visit. Eastern Cooperative Oncology Group (ECOG) performance status (PS) 0 or 1. Patients must be willing and able to sign the informed consent form, and to adhere to the study visit schedule and other protocol requirements. Women of childbearing potential (a woman is considered of childbearing potential (WOCBP), i.e. fertile, following menarche and until becoming post-menopausal unless permanently ster-ile. Permanent sterilization methods include hysterectomy, bi-lateral salpingectomy and bilateral oophorectomy) must have a negative serum pregnancy test within 3 days from day 1 of cycle 1 and agree to use a highly effective method of contraception while on study treatment and for at least 6 months after end of treatment. Such methods include: Combined (estrogen and progestogen containing) hor-monal contraception associated with inhibition of ovulation: oral intravaginal transdermal Progestogen-only hormonal contraception associated with inhibition of ovulation: oral injectable implantable Intrauterine device (IUD) Intrauterine hormone-releasing system (IUS) Bilateral tubal occlusion Vasectomized partner Sexual abstinence

Further Information at ClinicalTrials.gov

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BNT000-001

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

Epidemiological Study to Determine the Prevalence of ctDNA Positivity in Participants With Stage II (High Risk) or Stage III CRC After Surgery With Curative (R0) Intent and Subsequent Adjuvant Chemotherapy With Monitoring of ctDNA During Clinical Follow-up

Recruitment Status: RECRUITING
Condition: Colorectal Cancer Stage II Colorectal Cancer Stage III
Primary Completion Date: 2024-07
Intervention/ Treatment: Procedure: Regular blood sample collection for ctDNA assessment

Inclusion Criteria:
Must have given informed consent indicating that they understand the purpose of and procedures required for the study and are willing to participate in the study. Age ≥ 18 years old at time of signing the informed consent form. Ability to comply with the study protocol, in the investigator's judgment. Must have Stage II/Stage III rectal cancer or Stage II (high risk)/Stage III colon cancer per AJCC 2017 that has been surgically totally resected (R0 confirmed by pathology report). Stage II (high risk) colon cancer is defined as (any of): T4 Grade ≥ 3 Clinical presentation with bowel obstruction or perforation Histological signs of vascular, lymphatic or perineural invasion < 12 nodes examined. Adequate tumor material in formalin-fixed paraffin embedded (FFPE) blocks or as sectioned tissue (only upon approval by sponsor) must be available, preferably from resection. The specimen should be submitted along with an associated pathology report. Multiple samples may be provided as available, but priority should be given to tissue with the highest tumor content and lowest necrotic area. Intention to receive a standard of care adjuvant chemotherapy (AdCTx) within 8 weeks post-surgery, and be scheduled for at least 3 months of treatment (including rest days) according to the treating physician or investigator. Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1. Adequate end-organ function.

Exclusion Criteria:
Induction of neoadjuvant systemic therapy prior to resection of CRC. Prior systemic investigational therapy. Positive serology for hepatitis B (unless immune due to vaccination or resolved natural infection or unless passive immunization due to immunoglobulin therapy): Positive test for antibodies to hepatitis B core antigens (anti HBc) and Negative test for antibodies to hepatitis B surface antigens (anti HBs). Active hepatitis C virus (HCV) infection; participants who have completed curative antiviral treatment with HCV viral load below the limit of quantification by polymerase chain reaction (PCR) are allowed. Participant has a history of human immunodeficiency virus (HIV) antibody positivity, or tests positive for HIV at screening. Residual tumor classification following surgery other than R0 (microscopic margin-negative resection). Participants with known past or current malignancy other than inclusion diagnosis, except for: Cervical carcinoma of Stage 1B or less. Non-invasive basal cell or squamous cell skin carcinoma. Non-invasive, superficial bladder cancer. Prostate cancer with a current PSA level < 0.1 ng/mL. Any curable cancer with a complete response (CR) of > 2 years duration. Participant has not started standard of care AdCTx within 8 weeks post-surgery. Participant has received less than 3 months (including rest days) of AdCTx treatment. Inadequate tumor material (either quality or quantity) to support circulating tumor DNA (ctDNA) analysis. Participants who have had prior splenectomy..

Further Information at ClinicalTrials.gov

	HOPE		
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Study Nurse			

BNT122-01

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

A Multi-site, Open-label, Phase II, Randomized, Controlled Trial to Compare the Efficacy of RO7198457 Versus Watchful Waiting in Resected, Stage II (High Risk) and Stage III Colorectal Cancer Patients Who Are ctDNA Positive Following Resection

Recruitment Status: RECRUITING
Condition: Colorectal Cancer Stage II Colorectal Cancer Stage III
Primary Completion Date: 2024-07
Intervention/ Treatment: Drug: RO7198457 intravenous (IV) Other: Observational group (no intervention)

Inclusion Criteria:

Patients must be a man or woman of at least 18 years of age. Patients must have Stage II/Stage III rectal cancer or Stage II (high risk)/Stage III colon cancer per American Joint Committee on Cancer 2017 that has been surgically totally resected (R0 confirmed by pathology report). Stage II (high risk) colon cancer is defined as Stage II disease with any of the following risk factors for recurrence: T4 Grade ≥ 3. Clinical presentation with bowel obstruction or perforation. Histological signs of vascular, lymphatic or perineural invasion. < 12 nodes evaluated after surgery. Patients must have detectable ctDNA prior to start of adjuvant chemotherapy (AdCTx) (except for the Biomarker Cohort). • ctDNA assay must be performed through this trial or study BNT000-001 ctDNA screening protocol. Patients must have an Eastern Cooperative Oncology Group Performance Status of 0-1. Patients must have adequate hematologic, bone marrow and organ function as defined by the protocol. Adequate tumor material in formalin-fixed paraffin embedded blocks or as sectioned tissue (only upon approval by sponsor) must be available (as described in the laboratory manual). The patient has started a standard of care AdCTx preferably within 8 weeks but no later than 10 weeks post-surgery and has completed at least 3 months of treatment of a 3- or a 6-month course of chemotherapy (including rest days).

Exclusion Criteria:

Patients with uncontrolled intercurrent illness as defined by the protocol. Diagnosed microsatellite instability high tumors. Prior therapy with any of the following: Neo-adjuvant (radio)chemotherapy prior to surgery. Treatment with systemic immunosuppressive medication within 2 weeks prior to initiation of trial treatment or anticipation of need for systemic immunosuppressive medication during trial treatment, with the exception of low dose steroids defined as 10 mg oral prednisone (or equivalent). Current or recent (within the 28 days prior to randomization) treatment with another investigational drug. Toxicities from previous anti-cancer therapies that have not resolved to baseline levels or to Grade 1 or less except for alopecia and peripheral neuropathy. Patients who developed metastatic disease during screening/receiving standard of care treatment (not applicable for Exploratory Cohort). Patients with known past or current malignancy other than inclusion diagnosis, except for: Cervical carcinoma of Stage 1B or less. Non-invasive basal cell or squamous cell skin carcinoma. Non-invasive, superficial bladder cancer. Prostate cancer with a current prostate-specific antigen level < 0.1 ng/mL. Any curable cancer with a complete response of > 2 years duration. Patients with known allergies, hypersensitivity, or intolerance to RO7198457 or its excipients. Patients who had major surgery (e.g., surgery requiring general anesthesia) within 4 weeks before screening, or will not have fully recovered from surgery, or have surgery planned during the time the patient are expected to participate in the trial. Patients with positive serology for hepatitis B (unless immune due to vaccination or resolved natural infection or unless passive immunization due to immunoglobulin therapy): Based on a test for antibodies to hepatitis B core antigens (anti-HBc) and Negative test for antibodies to hepatitis B surface antigens (anti-HBs). Active Hepatitis C virus (HCV) infection; patients who have completed curative antiviral treatment with HCV viral load below the limit of quantification are allowed. Patients who have a history of human immunodeficiency virus (HIV) antibody positivity, or tests positive for HIV at screening. Patients who have had prior splenectomy

Further Information at ClinicalTrials.gov

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Study Nurse						

Entitäten

CIRCULATE TUD-CIRC01-071

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

Circulating Tumour DNA Based Decision for Adjuvant Treatment in Colon Cancer Stage II Evaluation (CIRCULATE) AIO-KRK-0217

Recruitment Status: RECRUITING
Condition: Colon Cancer Stage II
Primary Completion Date: 2023-06
Intervention/ Treatment: Drug: Capecitabine

Inclusion Criteria:
Inclusion criteria for screening phase: Resected colon cancer stage II, OR Resected rectal cancer stage II, if there was no indication for radiotherapy (i.e. due to the localisation in the upper third of the rectum), so that the treatment follows the recommendations for colon cancer. Patients, in whom the tumour stage is not yet know, can be enrolled into the screening. Signed informed consent for the screening Phase. Inclusion criteria for the randomised phase: Resected colon cancer stage II, OR resected rectal cancer stage II, if there was no indication for radiotherapy (i.e. due to the localisation in the upper third of the rectum), so that the treatment follows the recommendations for colon cancer. Known microsatellite or mismatch repair status. Confirmation, that the ctDNA result is available. Signed second informed consent (for the randomised phase).

Exclusion Criteria:
Exclusion criteria for Screening: Patients with known microsatellite instability (MSI-H) or mismatch repair deficiency (dMMR). Known clinical high risk situation if it is regarded as certain indication for an adjuvant chemotherapy Patients, who have an obvious contra-indication for adjuvant chemotherapy (i.e. due to the performance status, comorbidity, active second cancer or age). It should be considered that patients with an age of more than 75 years frequently not fulfil criteria for adjuvant chemotherapy. R1- or R2-status (patients with [still] unknown R-status can be screened). Patients, in whom the randomisation or chemotherapy is unfeasible due to logistic reasons (travel distance, compliance). Age < 18 years. Pregnant or breast feeding patients. Exclusion criteria for randomised phase: Patients with microsatellite instability (MSI-H) or mismatch repair deficiency (dMMR). Known clinical high risk situation if it is regarded as certain indication for an adjuvant chemotherapy. R1- or R2- status, or unknown R- status (Rx). Number of investigated lymph nodes < 10. WHO performance status ≥ 2. Colon or rectal cancer with UICC stage III or IV Second cancer, except simultaneous or metachronous colon or rectal cancer with UICC stage ≤ I, curatively treated basal cell carcinoma or squamous cell carcinoma of the skin and in-situ cervical carcinoma tumours with a disease free survival of more than five years. Contra indications for chemotherapy, especially: Leukocytes < 3,0 Gpt/l. Neutrophil granulocytes < 1,5 Gpt/l. Thrombocytes < 100 Gpt/l. alanine aminotransferase (ALAT) or (aspartate aminotransferase) ASAT > 3x ULN. Creatinine clearance (calculated according Cockcroft-Gault) < 30 ml/min. Comorbidities relevantly interfering with the prognosis of the patients, i.e.: heart insufficiency NYHA III/IV. relevant coronary heart disease, Diabetes mellitus with late sequelae. Organ, stem cell or bone marrow transplantation. Known hypersensitivity to capecitabine In case of known hypersensitivity to oxaliplatin, the patients can participate, but not receive oxaliplatin. Medication with brivudine, sorivudine or analogues in the last four weeks before planned treatment start. Known dihydropyrimidine dehydrogenase (DPD)-deficiency. Acute infections. Known HIV- infections, known active hepatitis B or C-infection. Participation at another interventional study for medical treatment during the last four weeks before randomization. Neoadjuvant therapy before resection Patients, in whom the randomisation or chemotherapy is unfeasible due to logistic reasons (travel distance, compliance). Age < 18 years. Pregnant or breast feeding patients. Women of childbearing potential and men with partner with childbearing potential who are not willing to take appropriate precautions to avoid pregnancy with a highly effective method in case they are randomised to "chemotherapy"

Further Information at ClinicalTrials.gov

	HOPE		
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Study Nurse			

DESTINY-Gastric03 DG-03

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

A Phase 1b/2 Multicenter, Open-label, Dose-escalation and Dose-expansion Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, and Antitumor Activity of Trastuzumab Deruxtecan (T-DXd) Monotherapy and Combinations in Adult Participants With HER2-expressing Gastric Cancer (DESTINY-Gastric-03)

Recruitment Status: RECRUITING
Condition: Gastric Cancer
Primary Completion Date: 2026-07-30
Intervention/ Treatment: Drug: Fluorouracil (5-FU)/ Capecitabine/ Biological: Durvalumab/ Oxaliplatin/ Trastuzumab/ Drug: Trastuzumab deruxtecan/ Cisplatin/ Biological: Pembrolizumab/ Volrustomig/ Rilvegostomig

Inclusion Criteria:

Male and female participants must be at least 18 years of age. Other age restrictions may apply as per local regulations.Disease Characteristics: Locally advanced, unresectable, or metastatic disease based on most recent imaging. For Part 1, 2, 3a, 4a pathologically documented adenocarcinoma of the stomach/GEJ/esophagus, HER2-positive (IHC 3+ or IHC 2+/ISH+) based on local tissue testing results. For Part 3b and 4b, pathologically documented adenocarcinoma of the stomach/GEJ/esophagus, HER2-low (IHC 2+/ISH-negative or IHC 1+) based on local tissue testing results. For Part 1, progression on or after at least one prior trastuzumabcontaining regimen For Part 2, Part 3 and Part 4, previously untreated for unresectable or metastatic adenocarcinoma of the stomach/GEJ/ esophagus with with HER2-positive (Part 2 and Part 3 [Arm 3A] and Part 4 [Arm 4A]) or HER2-low (Part 3 [Arm 3B] and Part 4 [Arm 4B])) status. Has measurable target disease assessed by the Investigator based on RECIST version 1.1. Has protocol defined adequate bone marrow and organ function including cardiac, renal and hepatic function. If of reproductive potential, agrees to use a highly effective form of contraception or avoid intercourse during and upon completion of the study.

Exclusion Criteria:

History of active primary immunodeficiency, known HIV, active chronic, or past hepatitis B infection, or hepatitis C infection. Uncontrolled intercurrent illness. History of non-infectious pneumonitis/ILD, current ILD, or where suspected ILD that cannot be ruled out by imaging at screening. Lung-specific intercurrent clinically significant severe illnesses. Uncontrolled infection requiring intravenous (IV) antibiotics, antivirals, or antifungals. Pleural effusion, ascites or pericardial effusion that requires drainage, peritoneal shunt, or Cell-free and Concentrated Ascites Reinfusion Therapy (CART). Has spinal cord compression or clinically active central nervous system metastases.

Further Information at ClinicalTrials.gov

	HOPE		
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Study Nurse			

FORTITUDE-102

A Phase 1b/3 Study of Bemarituzumab Plus Chemotherapy and Nivolumab Versus Chemotherapy and Nivolumab Alone in Subjects With Previously Untreated Advanced Gastric and Gastroesophageal Junction Cancer With FGFR2b Overexpression

Recruitment Status: RECRUITING
Condition: Gastric Cancer Gastroesophageal Junction Adenocarcinoma
Primary Completion Date: 2026-09-26
Intervention/ Treatment: Drug: Bemarituzumab/ Nivolumab/ Chemotherapy/ Other: Placebo

Inclusion Criteria Part 1 and Part 2:

Adult with unresectable, locally advanced or metastatic (not amenable to curative therapy) histologically documented gastric or gastroesophageal junction adenocarcinoma. Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1. Measurable disease or non-measurable, but evaluable disease, according to Response Evaluation Criteria in Solid Tumours version 1.1 (RECIST v1.1). Participant has no contraindications to nivolumab and either mFOLFOX6 or CAPOX chemotherapy as per local prescribing information. Participants in Part 1 must have no contraindications to mFOLFOX6. Participants in Part 2 with contraindications to mFOLFOX6 are permitted and may be administered the CAPOX regimen, if no contraindications for this regimen exist. Participants in Part 2 with contraindications to CAPOX are permitted and may be administered the mFOLFOX6 regimen, if no contraindications for this regimen exist. Adequate organ function as follows: Absolute neutrophil count ≥ 1.5 x 10^9/L. Platelet count ≥ 100 x 10^9/L. Hemoglobin ≥ 9 g/dL without red blood cell (RBC) transfusion within 7 days prior to the first dose of study treatment. Aspartate aminotransaminase (AST) and Alanine aminotransaminase (ALT) <3 x upper limit of normal (ULN) (or < 5 x ULN if liver involvement). Total bilirubin <1.5 x ULN (or < 2 x ULN if liver involvement or Gilbert's disease). Part 1 only: Calculated or measured creatinine clearance (CrCl) of ≥ 50 mL/minute calculated using the formula of Cockcroft and Gault ([140 - Age] × Mass [kg]/[72 × Creatinine mg/dL]) (x 0.85 if female). Part 2 only: Calculated or measured creatinine clearance (CrCl) of ≥ 30 mL/minute calculated using the formula of Cockcroft and Gault ([140 - Age] × Mass [kg]/[72 × Creatinine mg/dL]) (x 0.85 if female). INR or prothrombin time (PT) < 1.5 × ULN except for participants receiving anticoagulation, who must be on a stable dose of anticoagulant therapy for 6 weeks prior to enrollment. Additional Inclusion Criteria Part 2: No prior treatment for metastatic or unresectable disease except for a maximum of 1 dose of chemotherapy with or without nivolumab; prior adjuvant, neo-adjuvant, and peri-operative therapy is allowed, provided it has been completed more than 6 months prior to the first dose of study treatment. Fibroblast growth factor receptor 2b (FGFR2b) ≥ 10% 2+/3+ tumor cells (TC) as determined by centrally performed immunohistochemistry (IHC) testing, based on tumor sample either archival (obtained within 6 months/180 days prior to signing pre-screening informed consent) or a fresh biopsy.

Exclusion Criteria:

Prior treatment with any selective inhibitor of the fibroblast growth factor (FGF)-FGFR pathway. Known positive human epidermal growth factor receptor 2 (HER2) status. Untreated or symptomatic central nervous system disease metastases and leptomeningeal disease. Peripheral sensory neuropathy grade 2 or higher. Clinically significant cardiac disease. Other malignancy within the last 2 years (exceptions for definitively treated disease). Chronic or systemic ophthalmologic disorders. Major surgery or other investigational study within 28 days prior to randomization. Palliative radiotherapy within 14 days prior to randomization. Abnormalities of the cornea that may pose an increased risk of developing a corneal ulcer. Active autoimmune disease that has required systemic treatment (except replacement therapy) within the past 2 years or any other diseases requiring immunosuppressive therapy while on study.

Further Information at ClinicalTrials.gov

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UKE HAMBURG

HIPEC/FLOT9 PREVENT

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

A Phase 1b/3 Study of Bemarituzumab Plus Chemotherapy and Nivolumab Versus Chemotherapy and Nivolumab Alone in Subjects With Previously Untreated Advanced Gastric and Gastroesophageal Junction Cancer With FGFR2b Overexpression

Recruitment Status: RECRUITING
Condition: Gastric Cancer Gastroesophageal Junction Adenocarcinoma
Primary Completion Date: 2026-09-26
Intervention/ Treatment: Drug: 5-Fluorouracil/ Leucovorin/ Oxaliplatin/ Docetaxel/ Cisplatin/

Inclusion Criteria:
Histologically confirmed, medically operable, resectable diffuse or mixed type (according to Lauren's classification) adenocarcinoma of the gastroesophageal junction (AEG II-III) or the stomach (uT3, uT4a, any N category, M0), or any T N+ M0 patient. Patient has received 3 to 6 cycles of neoadjuvant FLOT (de-escalation or dose modification allowed). No preceding cytotoxic or targeted therapy other than neoadjuvant FLOT (including de-escalated or dose reduced schema) therapy. No prior partial or complete tumor resection. Female and male patient ≥ 18 and ≤ 75 years. Female patient with childbearing potential needs to have a negative pregnancy test within 7 days prior to study start. Males and females of reproductive potential must agree to practice highly effective contraceptive measures* during the study. Male patients must also agree to refrain from father a child during treatment and additionally to use a condom during treatment period. Their female partner of childbearing potential must also agree to use an adequate contraceptive measure. *highly effective (i.e. failure rate of <1% per year when used consistently and correctly) methods: intravaginal and transdermal combined (estrogen and progestogen containing) hormonal contraception; injectable and implantable progestogen-only hormonal contraception; intrauterine device (IUD); intrauterine hormone-releasing system (IUS); bilateral tubal occlusion; vasectomised partner; sexual abstinence (complete abstinence is defined as refraining from heterosexual intercourse during the entire period of risk associated with the study treatments). ECOG ≤ 1. Exclusion of distant metastases by CT or MRI of abdomen, pelvis, and thorax, bone scan or MRI (if bone metastases are suspected due to clinical signs). Exclusion of the infiltration of any adjacent organs or structures by CT or MRI. Laparoscopic exclusion of peritoneal carcinomatosis at initial staging, before start of FLOT chemotherapy. Hematological, hepatic and renal function parameters adequate to allow surgical procedure and HIPEC at investigator´s discretion. Patient able and willing to provide written informed consent and to comply with the study protocol and with the planned surgical procedure

Exclusion Criteria:
Patient without neoadjuvant therapy or those who received a neoadjuvant therapy other than FLOT. Known hypersensitivity against 5-FU, leucovorin, oxaliplatin, or docetaxel. Other known contraindications against, 5-FU, leucovorin, oxaliplatin, or docetaxel. Clinically significant active coronary heart disease, cardiomyopathy or congestive heart failure, NYHA III-IV. Clinically significant valvular defect. Past or current history of other malignancies not curatively treated and without evidence of disease for more than 3 years, except for curatively treated basal cell carcinoma of the skin and in situ carcinoma of the cervix. Criteria of primary unresectability, e.g.: Radiologically documented evidence of major blood vessel invasion or invasion of adjacent organs (T4b). Patients with involved retroperitoneal (e.g. para-aortal, paracaval or interaortocaval lymph nodes) or mesenterial lymph nodes (distant metastases!). Other severe internal disease or acute infection. Patient has undergone major surgery within 28 days prior to enrollment. Cirrhosis at a level of Child-Pugh B (or worse) or cirrhosis (any degree) and a history of hepatic encephalopathy or ascites. On-treatment participation in another interventional clinical study in the period 30 days prior to inclusion and during the study. Patient pregnant or breast feeding, or planning to become pregnant. Patient in a closed institution according to an authority or court decision (AMG § 40, Abs. 1 No. 4). Any other concurrent antineoplastic treatment including irradiation. Known intraabdominal adhesion situs Pre-existing peritoneal seeding.

Further Information at ClinicalTrials.gov

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UKE HAMBURG

INTEGRATEIIb AG0315OG/CTC0140

Hubertus Wald Tumorzentrum
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Ein Kompetenznetzwerk des UKE

A Randomised Phase III Open Label Study of Regorafenib + Nivolumab vs Standard Chemotherapy in Refractory Advanced Gastro-Oesophageal Cancer (AGOC)

Recruitment Status: ACTIVE, NOT RECRUITING
Condition: Gastro-Oesophageal Cancer
Primary Completion Date: 2025-06-01
Intervention/ Treatment: Drug: Regorafenib/ Biological: Nivolumab/ Drug: Docetaxel/ Paclitaxel/ Irinotecan/ Trifluridine/Tipracil

Inclusion Criteria:

Adults (18 years or over) with metastatic or locally recurrent gastro-oesophageal cancer which: has arisen in any primary gastro-oesophageal site (oesophago-gastric junction (GOJ) or stomach); and is of adenocarcinoma or undifferentiated carcinoma histology; and is evaluable according to Response Evaluation Criteria in Solid Tumours (RECIST Version 1.1) by computed tomography (CT) scan performed within 21 days prior to randomisation. A lesion in a previously irradiated area is eligible to be considered as measurable disease as long as there is objective evidence of progression of the lesion prior to study enrolment; and has failed or been intolerant to a minimum of 2 lines of prior anti-cancer therapy for recurrent/metastatic disease which must have included at least one platinum agent and one fluoropyrimidine analogue. Note: Neoadjuvant or adjuvant chemotherapy or chemoradiotherapy will be considered as first line treatment where people have relapsed or progressed within 6 months of completing treatment; Radiosensitising chemotherapy given solely for this purpose concurrent with palliative radiation will not be considered as a line of treatment. Ramucirumab monotherapy, or immunotherapy with a checkpoint inhibitor, will be considered a line of treatment. HER2-positive participants must have received trastuzumab. Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1 (Appendix 1). Ability to swallow oral medication. Adequate bone marrow function (Platelets ≥100x109/L; Absolute Neutrophil Count (ANC) ≥1.5x109/L and Haemoglobin ≥ 9.0g/dL). Adequate renal function (Creatinine clearance >50 ml/min) based on either the Cockcroft-Gault formula (Appendix 2), 24-hour urine or Glomerular Filtration Rate (GFR) scan; and serum creatinine ≤1.5 x Upper Limit of Normal (ULN). Adequate liver function (Serum total bilirubin ≤1.5 x ULN, and INR ≤ 1.5 x ULN, and Alanine aminotransferase (ALT), Aspartate aminotransferase (AST), Alkaline phosphatase (ALP) ≤2.5 x ULN (≤ 5 x ULN for participants with liver metastases)). Participants being treated with an anti-coagulant, such as warfarin or heparin, will be allowed to participate provided that no prior evidence of an underlying abnormality in these parameters exists. Willing and able to comply with all study requirements, including treatment, timing, and/or nature of required assessments and follow-up. Study treatment both planned and able to start within 7 days after randomisation (note: subjects randomised on a Friday should commence treatment no earlier than the following Monday). Signed, written informed consent.

Further Information at ClinicalTrials.gov

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MATTERHORN D910GC00001

A Randomized, Double-blind, Placebo-controlled, Phase III Study of Neoadjuvant-Adjuvant Durvalumab and FLOT Chemotherapy Followed by Adjuvant Durvalumab in Patients With Resectable Gastric and Gastroesophageal Junction Cancer (GC/GEJC)

Recruitment Status: ACTIVE, NOT RECRUITING
Condition: Gastrointestinal Neoplasms Esophagogastric Junction
Primary Completion Date: 2025-10-31
Intervention/ Treatment: Drug: Durvalumab Drug: FLOT chemotherapy

Inclusion Criteria:

Patients with histologically documented gastric or gastroesophageal junction adenocarcinoma with resectable disease (Stage II or higher per AJCC 8th edition). Patients must undergo radical surgery. No prior anti-cancer therapy for the current malignancy. World Health Organization (WHO)/ECOG performance status of 0 or 1 at enrollment. Adequate organ and marrow function. Availability of tumor sample prior to study entry. Must have a life expectancy of at least 24 weeks.

Exclusion Criteria:

Patients with peritoneal dissemination or distant metastasis. Patients with adenosquamous cell carcinoma, squamous cell carcinoma, or GI stromal tumor. Current or prior use of immunosuppressive medication within 14 days before the first dose of durvalumab. Contra-indication to any of the study drugs. History of allogeneic organ transplantation.

Further Information at ClinicalTrials.gov

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MK 3475-975 KEYNOTE-975

Hubertus Wald Tumorzentrum
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Ein Kompetenznetzwerk des UKE

A Randomized, Double-blind, Placebo-controlled Phase 3 Trial of Pembrolizumab (MK-3475) Versus Placebo in Participants With Esophageal Carcinoma Receiving Concurrent Definitive Chemoradiotherapy (KEYNOTE 975)

Recruitment Status: ACTIVE, NOT RECRUITING
Condition: Esophageal Squamous Cell Carcinoma (ESCC) Gastroesophageal Junction Carcinoma (GEJC) Esophageal Adenocarcinoma (EAC)
Primary Completion Date: 2027-02-01
Intervention/ Treatment: Biological: pembrolizumab/ Drug: placebo/ cisplatin/ 5-FU/ Radiation: radiotherapy/ Drug: leucovorin/ levoleucovorin/ oxaliplatin

Inclusion Criteria:

Has histologically or cytologically confirmed diagnosis of CTX N+ M0 or cT2-T4a NX M0 ESCC, GEJC, EAC, or histologically or cytologically confirmed diagnosis of cTX N+ M1 cervical or upper thoracic esophageal carcinoma with supraclavicular lymph node metastases only. Is deemed suitable for dCRT. Is ineligible for curative surgery based on the documented opinion of a qualified medical/surgical/radiation oncologist. Is not expected to require tumor resection during the course of the study. Has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1 within 3 days of the first dose of study treatment. Has adequate organ function. Male participants must use adequate contraception (a male condom plus partner use of an additional contraceptive method) unless confirmed to be azoospermic (vasectomized or secondary to medical cause) and refrain from donating sperm during the study treatment period and through 90 days after the last dose of chemotherapy. Female participants who are a Woman of Childbearing Potential (WOCBP) must use contraception that is highly effective (with a failure rate of <1% per year), with low user dependency, or be abstinent from heterosexual intercourse as their preferred and usual lifestyle, during the study treatment period through 180 days after the last dose of chemotherapy or 120 days after the last dose of pembrolizumab, whichever is greater, and agree not to donate eggs to others or freeze/store for her own use for the purpose of reproduction during this period. Female participants must not be pregnant or breastfeeding

Exclusion Criteria:

Has direct invasion of tumor into adjacent organs such as the aorta or trachea or has radiographic evidence of >90 degree encasement or invasion of a major blood vessel, or of intratumoral cavitation. Has had major surgery other than for insertion of a feeding tube, open biopsy, or significant traumatic injury within 28 days prior to randomization, or anticipates the need for major surgery during study treatment; participants with gastric or esophageal fistulae are excluded. Has had weight loss of >20% in the previous 3 months. Has had prior chemotherapy or radiotherapy for esophageal cancer. Has had a myocardial infarction within the past 6 months. Has symptomatic congestive heart failure. Has received prior therapy with an anti-programmed cell death-1 (anti PD-1), anti-programmed cell death-ligand 1 (anti-PD-L1), or anti-programmed cell death-ligand 2 (anti-PD-L2) agent or with an agent directed to another stimulatory or coinhibitory T-cell receptor (e.g. cytotoxic T-lymphocyte-associated protein 4 [CTLA-4], OX-40, CD137). Has received a live or live-attenuated vaccine within 30 days prior to the first dose of study intervention; administration of killed vaccines is allowed. Has received any prior systemic anticancer therapy for esophageal cancer including investigational agents. Has not recovered from all adverse events (AEs) due to previous non-anticancer therapies to ≤Grade 1 or Baseline. Has a diagnosis of immunodeficiency or is receiving chronic systemic steroid therapy or any other form of immunosuppressive therapy within 7 days prior the first dose of study treatment. Has a known additional malignancy that is progressing or has required active treatment within the past 3 years. Note: Participants with basal cell carcinoma of the skin, squamous cell carcinoma of the skin, or carcinoma in situ (e.g. breast carcinoma, cervical cancer in situ) that have undergone potentially curative therapy are not excluded from the study. Participants with localized prostate cancer that has undergone potentially curative treatment can be enrolled in the study. Has severe hypersensitivity (≥Grade 3) to pembrolizumab, any of the study chemotherapy agents, or their excipients.Has an active autoimmune disease that has required systemic treatment in past 2 years Has a history of (non-infectious) pneumonitis that required steroids or has current pneumonitis. Has an active infection requiring systemic therapy. Has a known history of human immunodeficiency virus (HIV) infection. Has a known history of Hepatitis B or known active Hepatitis C virus infection. Has a known history of active tuberculosis (TB; Bacillus tuberculosis). Is pregnant or breastfeeding or expecting to conceive or father children within the projected duration of the study, starting with the screening visit through 120 days after the last dose of study treatment (180 days for participants receiving cisplatin who are breastfeeding). Has had an allogenic tissue/solid organ transplant.

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MK7902-015 LEAP-015

Hubertus Wald Tumorzentrum
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Phase 3, Randomized Study to Evaluate the Efficacy and Safety of Lenvatinib (E7080/MK-7902) Plus Pembrolizumab (MK-3475) Plus Chemotherapy Compared With Standard of Care Therapy as First-line Intervention in Participants With Advanced/Metastatic Gastroesophageal Adenocarcinoma (LEAP-015)

Recruitment Status: ACTIVE, NOT RECRUITING
Condition: Advanced/Metastatic Gastroesophageal Adenocarcinoma
Primary Completion Date: 2026-02-02
Intervention/ Treatment: Biological: Pembrolizumab/ Lenvatinib/ Drug: Oxaliplatin/ Capecitabine/ Leucovorin (or Levoleucovorin)/ 5-FU

Inclusion Criteria:

Has histologically and/or cytologically confirmed diagnosis of previously untreated, locally advanced unresectable or metastatic gastroesophageal adenocarcinoma. Is not expected to require tumor resection during the treatment course. Has gastroesophageal adenocarcinoma that is not HER-2/neu positive. Has measurable disease as defined by RECIST 1.1 by scan with IV contrast as determined by the local site investigator Male participants agree to refrain from donating sperm and agree to either remain abstinent from heterosexual intercourse as their preferred and usual lifestyle OR agree to use contraception, during the intervention period and for ≥7 days after last dose of lenvatinib or 90 days after last dose of chemotherapy-whichever comes last. Female participants not pregnant or breastfeeding are eligible to participate if not a women of childbearing potential (WOCBP), or if a WOCBP they either use a contraceptive method that is highly effective OR remain abstinent from heterosexual intercourse as their preferred and usual lifestyle, and do not donate eggs (ova, oocytes) to others or freeze/store for their own use, and abstain from breastfeeding during the intervention period through 120 days after last dose of pembrolizumab, 30 days after last dose of lenvatinib, or 180 days after last dose of chemotherapy-whichever occurs last
Has a performance status of 0 or 1 on the Eastern Cooperative Oncology Group (ECOG) Performance Scale within 3 days prior to the first dose of study treatment. Has adequately controlled blood pressure with or without antihypertensive medications Has adequate organ function.

Exclusion Criteria:

Has had previous therapy for locally advanced unresectable or metastatic gastric/gastroesophageal junction (GEJ) esophageal adenocarcinoma. Has had major surgery within 28 days prior to first dose of study interventions
Has had radiotherapy within 14 days of randomization. Has a known additional malignancy that is progressing or has required active treatment within the past 5 years. Has known CNS metastases and/or carcinomatous meningitis Has severe hypersensitivity (≥Grade 3) to treatment with an monoclonal antibody (mAb) or known sensitivity or intolerance to any component of lenvatinib, pembrolizumab, study chemotherapy agents and/or to any excipients, murine proteins, or platinum containing products. Has had an allogeneic tissue/solid organ transplant. Has perforation risks or significant gastrointestinal (GI) bleeding. Has GI obstruction, poor oral intake (CAPOX participants), or difficulty in taking oral medication (CAPOX participants). Has received prior therapy with an anti-PD-1, anti-PD-L1, or anti-PD-L2 agent or with an agent directed to another stimulatory or coinhibitory T-cell receptor
Has received prior therapy with anti- vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor or anti-VEGF mAb. Has received a live or live-attenuated vaccine within 30 days before the first dose of study drug
Has an active autoimmune disease that has required systemic treatment in past 2 years (i.e., with use of disease modifying agents, corticosteroids or immunosuppressive drugs). Has radiographic evidence of encasement or invasion of a major blood vessel, or of intratumoral cavitation. cHas inadequate cardiac function. Has a history of (noninfectious) pneumonitis/interstitial lung disease that required steroids or has current pneumonitis/interstitial lung disease Has poorly controlled diarrhea. Has accumulation of pleural, ascitic, or pericardial fluid requiring drainage or diuretic drugs within 2 weeks prior to enrollment. Has peripheral neuropathy ≥Grade 2. Has a known history of human immunodeficiency virus (HIV) or HIV 1/2 antibodies. Has a known history of hepatitis B (defined as HBsAg reactive) or known active hepatitis C virus (defined as HCV RNA [qualitative] is detected) infection Has weight loss of >20% within the last 3 months.

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NeoBRAF AIO-KRK-0420

Hubertus Wald Tumorzentrum
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AIO-KRK-0420 NeoBRAF is a single arm, multicenter, phase II trial with neoadjuvant encorafenib, binimetinib and cetuximab for patients with BRAF V600E mutated/pMMR localized colorectal cancer.

Recruitment Status: RECRUITING
Condition: Colorectal Cancer Colon Cancer BRAF V600E BRAF V600 Mutation Localized Cancer
Primary Completion Date: 2024-07-31
Intervention/ Treatment: Drug: Binimetinib

Inclusion Criteria:

Biopsy-confirmed adenocarcinoma of the colon or upper rectum if too high for radiotherapy. Radiologically (CT/MRI) staged disease as: T3-4 (as invasion of surrounding tissue structures or organs) and/or nodal positive (N+ defined as regional lymph node(s) without fat hilus and short axis diameter of ≥1 cm), M0. BRAF V600E mutation and pMMR or MSS (as determined by a validated test, preferably PCR or NGS). ECOG performance status ≤ 1. Age ≥ 18 years. Adequate hematologic function at screening as follows: ANC ≥ 1.5 x 109/L, platelets ≥ 100 x109/L, hemoglobin ≥ 9.0 g/dL. Adequate liver function at screening as measured by serum transaminases (AST & ALT) ≤ 2.5 x ULN and total bilirubin ≤ 1.5 x ULN. Patients with known Gilbert disease who have serum bilirubin level ≤ 3 × ULN may be enrolled. Adequate renal function at screening: serum creatinine ≤ 1.5 x ULN. Adequate serum electrolytes at screening defined as serum potassium and magnesium levels within institutional normal limits (Note: replacement treatment to achieve adequate electrolytes will be allowed. Adequate cardiac function at screening characterized by left ventricular ejection fraction (LVEF) ≥ 50% as determined by ECHO and QT interval corrected for heart rate using Fridericia's formula (QTcF) value ≤ 480 msec. Negative serum pregnancy test at screening for women of childbearing potential. Highly effective contraception for both male and female subjects if the risk of conception exists. (Note: The effects of the trial drugs on the developing human fetus are unknown; thus, women of childbearing potential and men able to father a child must agree to use highly effective contraception, defined as methods with a failure rate of less than 1 % per year, containing at least 1 form of non-hormonal contraception. Highly effective contraception is required at least 28 days prior, throughout and for at least 6 months after interventional study treatment (encorafenib, binimetinib and cetuximab). Signed and dated written informed consent. Ability to take oral medication. Ability to comply with the protocol for the duration of the study, including hospital/office visits for treatment and scheduled follow-up visits and examinations.

Further Information at ClinicalTrials.gov

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PHERFLOT

Pembrolizumab and Trastuzumab in Combination With FLOT in the Perioperative Treatment of HER2-positive, Localized Esophagogastric Adenocarcinoma - A Phase II Trial of the AIO Study Group - PHERFLOT -

Recruitment Status: ACTIVE, NOT RECRUITING
Condition: Esophagogastric Adenocarcinoma
Primary Completion Date: 2027-10
Intervention/ Treatment: Drug: Pembrolizumab/ Trastuzumab/ FLOT

Inclusion Criteria:

The participant provides written informed consent for the trial. Male/female* participants who are at least 18 years of age on the day of signing informed consent. *There are no data that indicate special gender distribution. Therefore, patients will be enrolled in the study gender-independently. In the investigator's judgement, participant is willing and able to comply with the study protocol including the planned surgical treatment Histologically confirmed adenocarcinoma of the GEJ (Type I-III according to Sievert´s classification) or the stomach (cT2, cT3, cT4, any N category, M0), or (any T, N+, M0) that: is not infiltrating any adjacent organs or structures by CT or MRI evaluation does not involve peritoneal carcinomatosis, is considered medically and technically resectable Note: the absence of distant metastases must be confirmed by CT or MRI of the thorax and abdomen, and, if there is clinical suspicion of osseous lesions, a bone scan. If peritoneal carcinomatosis is suspected clinically, its absence must be confirmed by laparoscopy. Diagnostic laparoscopy is mandatory in patients with T3 or T4 tumors of the diffuse type histology in the stomach. Participants must have HER2-positive disease defined as either IHC 3+ or IHC 2+, the latter in combination with ISH+, as assessed locally by a certified test on primary tumor (see Appendix 4). Participants must be candidates for potential curative resection as determined by the treating surgeon No prior systemic-anti cancer therapy (e.g. cytotoxic or targeted agents or radiotherapy). No prior partial or complete esophagogastric tumor resection. ECOG (Eastern Cooperative Oncology Group) performance status score of 0 or 1. Male participants: A male participant must agree to use a contraception as detailed in Appendix 2 of this protocol during the treatment period and for at least 6 months after the last dose of study intervention and refrain from donating sperm during this period. Female participants: A female participant is eligible to participate if she is not pregnant (see Appendix 2), not breastfeeding, and at least one of the following conditions applies: Not a woman of childbearing potential (WOCBP) as defined in Appendix 2 OR A WOCBP who agrees to follow the contraceptive guidance as given in Appendix 2 during the treatment period and for at least 7 months after the last dose of study intervention. Participants have adequate organ function as defined in the following table (Table 2). Specimens must be collected within 14 days prior to enrolment (also to be repeated if older than 14 days at day of first treatment).
Hematological: Absolute neutrophil count (ANC) ≥ 1500/µL. leucocytes ≥ 3000/µLThrombocytes ≥ 100 000/µL. Hemoglobin ≥ 9.0 g/dL or ≥ 5.6 mmol/L (Criteria must be met without erythropoietin dependency and without packed red blood cell (pRBC) transfusion within the last 2 weeks). Renal: • Measured or calculated (b) creatinine clearance≥ 50 mL/min. Hepatic: Total bilirubin ≤ 1.5 ×ULN OR direct bilirubin ≤ ULN for participants with total bilirubin levels > 1.5 × ULN AST (SGOT) and ALT (SGPT) ≤ 2.5 × ULN Coagulation. International normalized ratio (INR) OR prothrombin time (PT) and Activated partial thromboplastin time (aPTT) ≤ 1.5 × ULN unless participant is receiving anticoagulant therapy as long as PT or aPTT is within therapeutic range of intended use of anticoagulants ALT (SGPT)=alanine aminotransferase (serum glutamic pyruvic transaminase); AST (SGOT)=aspartate aminotransferase (serum glutamic oxaloacetic transaminase); GFR=glomerular filtration rate; ULN=upper limit of normal.

Further Information at ClinicalTrials.gov

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SEAMARK C4221022

A PHASE 2, RANDOMIZED, OPEN-LABEL STUDY OF ENCORAFENIB AND CETUXIMAB PLUS PEMBROLIZUMAB VERSUS PEMBROLIZUMAB ALONE IN PARTICIPANTS WITH PREVIOUSLY UNTREATED BRAF V600E-MUTANT, MSI H/DMMR METASTATIC COLORECTAL CANCER

Recruitment Status: RECRUITING
Condition: Metastatic Colorectal Cancer
Primary Completion Date: 2026-03-28
Intervention/ Treatment: Drug: Encorafenib/ Biological: Cetuximab/ Pembrolizumab

Inclusion Criteria:

Locally confirmed microsatellite instability-high/ deficient mismatch repair (MSI-H/dMMR) stage IV colorectal carcinoma. Locally confirmed BRAF V600E mutation in tumor tissue or blood. Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1. Have not received prior systemic regimens for metastatic disease. Measurable disease per RECIST 1.1. Adequate organ function

Exclusion Criteria:

Colorectal adenocarcinoma that is RAS mutant or for which RAS mutation status is unknown Known active central nervous system metastases and/or carcinomatous meningitis; leptomeningeal disease. Immunodeficiency or active autoimmune disease requiring systemic treatment in the past 2 years. Presence of acute or chronic pancreatitis. Clinically significant cardiovascular diseases (eg, thromboembolic or cerebrovascular accident events ≤ 12 wks prior). Received a live or live-attenuated vaccine within 30 days of planned start of study medication. Previous treatment with any selective BRAF inhibitor (eg, encorafenib, dabrafenib, vemurafenib, XL281/BMS-908662) or any epidermal growth factor receptor (EGFR) inhibitor (eg, cetuximab, panitumumab). Previous treatment with an immune checkpoint inhibitor (eg, anti-programmed cell death [PD-1], anti-PD-L1 or anti-PD-L2 agent); or with an agent directed to another stimulatory or co-inhibitory T-cell receptor (eg, CTLA-4, OX 40, CD137).

Further Information at ClinicalTrials.gov

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Stellar-001 XL-092-001

A Dose-Escalation and Expansion Study of the Safety and Pharmacokinetics of XL092 as Single-Agent and Combination Therapy in Subjects With Inoperable Locally Advanced or Metastatic Solid Tumors

Recruitment Status: ACTIVE, NOT RECRUITING
Condition: Neoplasm Malignant Renal Cell Carcinoma Hormone Receptor Positive Breast Carcinoma Metastatic Castration-resistant Prostate Cancer Colorectal Cancer
Primary Completion Date: 2024-11
Intervention/ Treatment: Drug: XL092/ Atezolizumab/ Avelumab

Inclusion Criteria:
Cytologically or histologically confirmed solid tumor that is inoperable locally advanced, metastatic, or recurrent. Dose-escalation (single-agent and combination therapy): Subjects with a solid tumor that is unresectable or metastatic and for which life-prolonging therapies do not exist or available therapies are intolerable or no longer effective. Expansion Cohort A (ccRCC): Subjects with previously treated advanced RCC with clear cell histology (including those with a sarcomatoid component) who have radiographically progressed following treatment with at least one prior systemic anticancer regimen for inoperable locally advanced or metastatic disease. Expansion Cohorts B and E (nccRCC): Subjects with previously treated advanced RCC with non-clear cell histology who have radiographically progressed following treatment with at least one prior systemic anticancer regimen for inoperable locally advanced or metastatic disease. Expansion Cohorts C and F (HR+ BC): Subjects with breast cancer that is hormone receptor positive (ER+ and/or PR+) and negative for human epidermal growth factor receptor 2 (HER-2) and who have radiographically progressed during or following treatment with at least one prior systemic anticancer regimen for inoperable locally advanced or metastatic disease. Expansion Cohorts D and G (mCRPC): Subjects with metastatic CRPC (adenocarcinoma of the prostate). Neuroendocrine differentiation and other features permitted if adenocarcinoma is the primary histology. Expansion Cohort H (CRC): Subjects with histologically confirmed unresectable, locally advanced, or metastatic adenocarcinoma of the colon or rectum, KRAS/NRAS wild-type (confirmed via local testing report) and determined NOT to have microsatellite instability high (MSI-high) or mismatch repair deficient (dMMR) by local testing, who received the following standard of care chemotherapy regimens as prior therapy for metastatic CRC: Fluoropyrimidine, irinotecan and oxaliplatin, with or without an anti-VEGF monoclonal antibody (bevacizumab). Anti-EGFR monoclonal antibody (cetuximab or panitumumab). BRAF inhibitor (in combination with cetuximab +/- binimetinib) for subjects with BRAF V600E mutations Expansion Cohorts: Subjects must have measurable disease per RECIST 1.1. Tumor tissue material: Subjects in the non-biomarker cohort provide archival, if available, or fresh tumor tissue if it can be safely obtained. Recovery to baseline or ≤ Grade 1 severity (CTCAE v5) from adverse events (AEs), including immune-related adverse events (irAEs), related to any prior treatments, unless AE(s) are clinically nonsignificant and/or stable on supportive therapy.
Eastern Cooperative Oncology Group (ECOG) Performance Status of 0-1. Adequate organ and marrow function. Sexually active fertile subjects and their partners must agree to use highly effective methods of contraception.
Female subjects of childbearing potential must not be pregnant at screening.

Further Information at ClinicalTrials.gov

	HOPE		
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Study Nurse			

STELLAR-303 XL-092-303

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

A Randomized Open-Label Phase 3 Study of XL092 + Atezolizumab vs Regorafenib in Subjects With Metastatic Colorectal Cancer

Recruitment Status: RECRUITING
Condition: Colorectal Cancer
Primary Completion Date: 2025-08
Intervention/ Treatment: Drug: XL092/ Atezolizumab/ Regorafenib

Inclusion Criteria:
Subjects with histologically or cytologically confirmed adenocarcinoma of the colon or rectum. Documented RAS status (mutant or wild-type [WT]), by tissue-based analysis. Documented NOT to have microsatellite instability-high (MSI-high) or mismatch repair deficient (dMMR) CRC by tissue-based analysis. Has received standard-of-care (SOC) anticancer therapies as prior therapy for metastatic CRC and has radiographically progressed, is refractory or intolerant to these therapies. Systemic SOC anticancer therapy if approved and available in the country where the subject is randomized. Radiographic progression during treatment with or within 4 months following the last dose of the most recent approved SOC chemotherapy regimen. Measurable disease according to RECIST v1.1 as determined by the Investigator. Available archival tumor biopsy material. If archival tissue is unavailable, must provide fresh tumor tissue biopsy prior to randomization. Recovery to baseline or ≤ Grade 1 severity (CTCAE v5) from adverse events (AEs) related to any prior treatments, unless AE(s) are clinically nonsignificant and/or stable on supportive therapy. Age 18 years or older on the day of consent. Eastern Cooperative Oncology Group (ECOG) performance status of 0-1. Adequate organ and marrow function. Fertile subjects and their partners must agree to use highly effective methods of contraception during the course of the study and after the last dose of treatment. Female subjects of childbearing potential must not be pregnant at screening.

Exclusion Criteria:
Prior treatment with XL092, regorafenib, trifluridine/tipiracil, or PD-L1/PD-1 targeting immune checkpoint inhibitors (ICIs). Receipt of a small molecule kinase inhibitor (including investigational agents) within 2 weeks before randomization. Receipt of any type of anticancer antibody therapy, systemic chemotherapy, or hormonal anti-cancer therapy within 3 weeks (or bevacizumab within 4 weeks) before randomization. Radiation therapy for bone metastasis within 2 weeks, any other radiation therapy within 4 weeks before randomization. Known brain metastases or cranial epidural disease unless adequately treated with radiotherapy and/or surgery (including radiosurgery) and stable for at least 4 weeks before randomization. Subject has uncontrolled, significant intercurrent or recent illness. Major surgery (e.g., GI surgery, removal or biopsy of brain metastasis) within 4 weeks prior to randomization. Systemic treatment with, or any condition requiring, either corticosteroids (> 10 mg daily prednisone equivalent) or other immunosuppressive medications within 14 days prior to randomization. Corrected QT interval calculated by the Fridericia formula (QTcF) > 460 ms within 10 days before randomization. History of psychiatric illness likely to interfere with ability to comply with protocol requirements or give informed consent. Pregnant or lactating females. Inability to swallow study treatment formulation, inability to receive IV administration, or presence of GI condition that might affect the absorption of study drug. Previously identified allergy or hypersensitivity to components of the study treatment formulations. Any other active malignancy or diagnosis of another malignancy within 2 years before randomization. Exceptions are noted in the protocol. Administration of a live, attenuated vaccine within 30 days before randomization.

Further Information at ClinicalTrials.gov

	HOPE		
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Study Nurse			

REO 029/GOBLET, AIO-KRK-0320ass

AIO-KRK-0320ass: A phase 1 / 2 multiple-indication biomarker, safety, and efficacy study in advanced or metastatic Gastrointestinal cancers explOring treatment comBinations with peLarEorep and aTezolizumab (GOBLET)

Recruitment Status: RECRUITING
Condition: Cohort 1: First-line locally advanced/metastatic unresectable pancreatic ductal adenocarcinoma (PDAC) Cohort 2: First-line mCRC, MSI-H or dMMR Cohort 3: Third-line mCRC, independent of MSI/dMMR status Cohort 4: Second-line (or higher) locally advanced/metastatic unresectable squamous cell carcinoma of the anal canal (SCCA) after prior systemic chemotherapy
Intervention/ Treatment: : Pelareorep and atezolizumab added to SOC gemcitabine and nab paclitaxel Cohort 2: pelareorep and atezolizumab Cohort 3: pelareorep and atezolizumab added to SOC trifluridine/tipiracil Cohort 4: pelareorep and atezolizumab

Inclusion Criteria:

Cohort 1: Locally Advanced/Metastatic Unresectable Pancreatic Ductal Adenocarcinoma 1L Patients with histologically or cytologically confirmed locally advanced/metastatic unresectable PDAC who are eligible for 1L SOC chemotherapy with gemcitabine plus nab-paclitaxel. Cohort 2: Metastatic Colorectal Cancer 1L (MSI-H/dMMR) Patients with histologically or cytologically confirmed metastatic colorectal adenocarcinoma (mCRC) with MSI-H/dMMR tumors and no prior systemic treatment for metastatic disease. Cohort 3: Metastatic Colorectal Cancer 3L Patients with histologically or cytologically confirmed mCRC, independent of MSI/dMMR status, who failed (and/or did not tolerate) 2 prior lines of treatment, including oxaliplatin, irinotecan, 5-FU, ± targeted agents such as bevacizumab and/or an anti-epidermal growth factor receptor (EGFR) antibody who are eligible for 3L SOC chemotherapy with trifluridine/tipiracil. (See Appendix 6 for guidance on determining eligibility for this cohort). Cohort 4: Locally Advanced/Metastatic Unresectable Anal Cancer ≥2L Patients with histologically or cytologically confirmed locally advanced/metastatic unresectable SCCA of viral (HPV) or non-viral origin who failed (and/or did not tolerate) prior systemic chemotherapy. All Cohorts: Patients must: 1. Provide written informed consent prior to study participation. 2. Be at least 18 years of age on the day of providing consent. 3. Have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 within 7 days of start of treatment. 4. Have measurable lesions per RECIST v1.1 5. Have adequate organ function at the time of enrollment as defined by: • Absolute neutrophil count ≥1200/mm3 • Platelet count ≥7.5 × 104/mm3 • Hemoglobin >8 g/dL (blood transfusion >2 weeks before testing is permitted) • Aspartate aminotransferase (AST), alanine aminotransferase (ALT) ≤2.5 x the upper limit of normal (ULN; ≤5 x ULN in patients with liver metastasis) • Total bilirubin ≤1.5 x ULN • Creatinine ≤1.5 x ULN • Lipase ≤1.5 x ULN • International normalized ratio (INR) ≤1.5 x ULN and partial thromboplastin time (PTT) or activated partial thromboplastin time (aPTT) ≤1.5 x ULN unless receiving treatment with therapeutic anticoagulation. Patients being treated with anticoagulant, e.g., heparin, will be allowed to participate provided no prior evidence of an underlying abnormality in these parameters exists. Close monitoring per local SOC will be performed until INR and PTT are stable based on a pre-dose measurement as defined by the local SOC. 6. Have recovered to ≤grade 1 or baseline for all adverse events (AEs) due to previous therapies or surgeries. For female patients of childbearing potential and male patients with partners of childbearing potential, agreement (by patient and/or partner) to use a highly effective form(s) of contraception (i.e., one that results in a low failure rate (<1% per year) when used consistently and correctly) and to continue its use for 6 months after the last dose of study drug.

Further Information at aio-portal.de

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Study Nurse			

HSI Studie

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

XXX

Recruitment Status: RECRUITING
Condition:Advanced xxx **(Schrift 10/ Arial)**
Primary Completion Date: xxx
Intervention/ Treatment: xxx

Inclusion Criteria:

Exclusion Criteria **Schrift 8 oder 10 Arial** :

Further Information at ClinicalTrials.gov

	MKG		
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SI			
SK			

TriMM-2, CR108620, 64407564MMY1002

A Phase 1b Study of Subcutaneous Daratumumab Regimens in Combination With Bispecific T Cell Redirection Antibodies for the Treatment of Subjects With Multiple Myeloma

Recruitment Status: ACTIVE, NOT RECRUITING
Condition: Multiple Myeloma
Primary Completion Date: 2024-09-09
Intervention/ Treatment: Drug: XL092/ Atezolizumab/ Regorafenib

Inclusion Criteria:
Documented initial diagnosis of multiple myeloma according to International Myeloma Working Group (IMWG) diagnostic criteria. Must have either of the following: a) received at least 3 prior lines of therapy including a proteasome inhibitor (PI) (greater than or equal to [>=] 2 cycles or 2 months of treatment) and an immunomodulatory drug (IMiD) (>=2 cycles or 2 months of treatment) in any order during the treatment or b) disease that is double refractory to a PI and an IMiD. Measurable disease at screening as defined by any of the following: Serum monoclonal protein (M-protein) level >=1.0 grams per deciliter (g/dL) (in non- immunoglobulin G (IgG) myeloma, an M-protein level >=0.5 g/dL); or Urine M-protein level >=200 milligrams (mg)/24 hours; or Light chain multiple myeloma: Serum immunoglobulin (Ig) free light chain (FLC) >=10 milligrams per deciliter (mg/dL) and abnormal serum Ig kappa lambda FLC ratio. Eastern Cooperative Oncology Group (ECOG) performance status grade of 0 or 1 at screening and at Cycle 1, Day 1 predose. Female participants of childbearing potential must have a negative highly-sensitive serum beta-human chorionic gonadotropin (beta-hCG) pregnancy test (less than [<] 5 international units per milliliter [IU/mL]) at screening and a negative urine or serum pregnancy test within 1 day before the first dose of study drug.

Exclusion Criteria:
Treatment in the prior 3 months with an anti- cluster of differentiation 38 (CD38) therapy (example, daratumumab), or discontinuation of a prior anti-CD38 therapy at any time due to an adverse event related to the anti-CD38 therapy. Live, attenuated vaccine within 4 weeks prior to the first dose of study drug unless approved by sponsor. Active Central nervous system involvement or exhibits clinical signs of meningeal involvement of multiple myeloma. If either is suspected, brain magnetic resonance imaging (MRI) and lumbar cytology are required. Seropositive for hepatitis B (defined by a positive test for hepatitis B surface antigen [HBsAg]). Participants with resolved infection must be screened using real-time polymerase chain reaction (PCR) measurement of hepatitis B virus (HBV) deoxyribonucleic acid (DNA) levels. Those who are PCR positive will be excluded. Active hepatitis C infection as measured by positive hepatitis C virus- ribonucleotide (HCV)-RNA testing. Participants with a history of Hepatitis C virus antibody positivity must undergo HCV-RNA testing.

Further Information at ClinicalTrials.gov

	Medical Oncology		
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ADAPTlate WSG-AM11

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

Adj. Dynamic Marker - Adjusted Personalized Therapy Comparing Abemaciclib Combined With Standard Adjuvant Endocrine Therapy Versus Standard Adjuvant Endocrine Therapy in (Clinical or Genomic) High Risk, HR+/HER2- EBC

Recruitment Status RECRUITING

Condition: Breast Cancer Female
Primary Completion Date: 2026-08
Intervention/ Treatment: Drug: Abemaciclib 50 MG; 150mg 1-0-1 per os

Inclusion Criteria:

A. Prior to REGISTRATION: 1. Written informed consent prior to any study procedures (outcomes of standard-of-care procedures performed before signing of informed consent by the patient but within allowed screening period can be used for screening of patient). 2. Female. 3. ≥ 18 years of age. 4a. EITHER: (Post)menopausal status at the time of initiation of adjuvant study medication. patient underwent bilateral oophorectomy, or age ≥ 60, or age < 60 and amenorrhea for 12 or more months (in the absence of chemotherapy, tamoxifen, or ovarian suppression) and/or FSH and estradiol in the postmenopausal range per local normal range. 4b. OR: Pre-/perimenopausal patients: confirmed negative serum or urine pregnancy test (β-hCG) before starting study treatment, or patient has had a hysterectomy. 5. Histologically confirmed diagnosis(by local laboratory) of estrogen-receptor positive and/or progesterone-receptor positive (>1%) primary early breast cancer or local relapse. In case the receptor status from local pathology is unclear a central pathology review is obligatory. Results must be known prior to randomization. 6. Patient has HER2-negative breast cancer defined as a negative in-situ hybridization test or an IHC status of 0, 1+, or 2+, if IHC is 2+, a negative in-situ hybridization (FISH, CISH, or SISH) test is required (based on the analyzed tissue sample at initial diagnosis by a local laboratory). 7. Patients are eligible with completed (i.e., 5 years according to SoC), planned or ongoing adjuvant endocrine therapy, without any signs of distant relapse or secondary malignancy AND if primary diagnosis was 6 years or less before enrollment 8a. Intermediate to high clinical or genomic risk, defined as either one of the following criteria: c or p or ypN 2-3 with/without (neo)adjuvant chemotherapy; in patients with c/ypN0-1: non-pCR in patients with G3 or c/ypN1 high biological risk defined as G3 with Ki-67 ≥40% or high genomic risk (RS>25 (known or Oncotype Dx® in screening phase) or another test) high CTS5 score or UICC stage IIb (clinical if neoadjuvant chemotherapy or pathological). OR, if patients do not fulfill above criteria: patients ≤50 years old or pre-/perimenopausal and c or (y)pN1 disease (in particular if ET-non-response or no chemotherapy). patients >50 years old and postmenopausal and c or (y)pN1 with intermediate genomic risk (RS≥18) or non-low risk by another test ET non-response definition: Ki-67 post-treatment > 10% (central or local pathology value) OR 8b. Patients after isolated locoregional relapse with high-risk patterns (e.g., rpT2-3 or rpN1-3 or G3 or Ki-67 pre-treatment ≥20%), once surgery with free margins was completed Note: Inclusion is only possible for the first locoregional relapse removed by surgery (free margins) OR 8c. Patients with any high clinical risk at Investigator´s assessment but not fulfilling above criteria: consultation with sponsor required B. Prior to RANDOMIZATION in the study 9. Completed primary therapy of breast cancer according to current guidelines, i.e., after (neo)adjuvant treatment, definite surgery and radiotherapy, if applicable. 10. No clinical evidence of distant metastasis (confirmation recommended prior to randomization by either combination of or either one of the following examinations: CT thorax / abdomen, chest X-ray, liver ultrasound, bone scan, PET-CT). 11. Patient has available tumor tissue from primary diagnostic biopsy. 12. No contraindication for adjuvant ET. 13. Eastern Cooperative Oncology Group (ECOG) performance status 0-1. 14. Patient has adequate bone marrow and organ function as defined by the following laboratory values: absolute neutrophil count ≥ 1.5 × 109/L, platelets ≥ 100 × 109/L, hemoglobin ≥ 8.0 g/dL, total bilirubin ≤ 1.5 ULN, except for patients with Gilbert's Syndrome who may only be included if the total bilirubin is ≤ 2.0 × ULN or direct bilirubin within normal ranges, aspartate transaminase (AST) ≤ 3 × ULN, alanine transaminase (ALT) ≤ 3 × ULN, serum creatinine ≤ 1.5 x ULN. 15. Ability to swallow abemaciclib tablets or to administer other study medication, respectively. 16. Ability to communicate with the investigator and comply with study procedures. 17. Willing to receive therapy by clinical site, as required by the protocol.

Further Information at ClinicalTrials.gov

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PI	Prof. Dr. med. Christian Schem	040 / 44190-500	
SI			
SK			

TROPION-Breast03

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

A Phase 3 Open-label, Randomised Study of Datopotamab Deruxtecan (DatoDXd) With or Without Durvalumab Versus Investigator's Choice of Therapy in Patients With Stage I-III Triple-negative Breast Cancer Who Have Residual Invasive Disease in the Breast and/or Axillary Lymph Nodes at Surgical Resection Following Neoadjuvant Systemic Therapy (TROPION-Breast03)

Recruitment Status RECRUITING
Condition: Breast Cancer
Primary Completion Date: 2027-09-20
Intervention/ Treatment: Drug: Dato-DXd/ Durvalumab/ Capecitabine/ Pembrolizumab

Inclusion Criteria:

Participant must be ≥ 18 years at the time of screening. Histologically confirmed invasive TNBC, as defined by the ASCO/CAP guidelines. Residual invasive disease in the breast and/or axillary lymph node(s) at surgical resection following neoadjuvant therapy. Completed at least 6 cycles of neoadjuvant therapy containing an anthracycline and/or a taxane with or without platinum chemotherapy, with or without pembrolizumab. No evidence of locoregional or distant relapse. Surgical removal of all clinically evident disease in the breast and lymph nodes. ECOG performance status of 0 or 1 with no deterioration over the previous 2 weeks prior to randomisation.
All participants must provide an FFPE tumour sample from residual invasive disease at surgery for tissue-based analysis. No adjuvant systemic therapy. Radiotherapy (if indicated) delivered before the start of study intervention. If post-operative radiation therapy is given, an interval of no more than 6 weeks between the completion of radiation therapy and the date of randomisation (radiation therapy can be completed during screening period). If no post-operative radiation therapy is given, an interval of no more than 16 weeks between the date of breast surgery and the date of randomisation. Has LVEF ≥ 50% by either an ECHO or MUGA scan within 28 days before randomisation. Eligible for one of the therapy options listed as investigator's choice per investigator assessment. No known germline BRCA1 or BRCA2 pathogenic mutation. Adequate bone marrow reserve and organ function within 7 days before randomisation.

Exclusion Criteria:

Stage IV (metastatic) TNBC. History of prior invasive breast cancer, or evidence of recurrent disease following preoperative therapy and surgery. Severe or uncontrolled medical conditions including systemic diseases, history of allogeneic organ transplant and active bleeding diseases, ongoing or active infection, serious chronic gastrointestinal conditions associated with diarrhea chronic diverticulitis or previous complicated diverticulitis. History of another primary malignancy except for adequately resected basal cell carcinoma of the skin or squamous cell carcinoma of the skin, in situ disease (including ductal carcinoma in situ) that has undergone potentially curative therapy, or other solid malignancy treated with curative intent with no known active disease within 5 years before randomisation and of low potential risk for recurrence. Persistent toxicities caused by previous anticancer therapy, excluding alopecia, not yet improved to Grade ≤ 1 or baseline. Participants with irreversible toxicity that is not reasonably expected to be exacerbated by study intervention may be included (eg, hearing loss). Active or prior documented autoimmune or inflammatory disorders. Clinically significant corneal disease. Active or uncontrolled hepatitis B or C virus infection. Known HIV infection that is not well controlled. Active tuberculosis infection. Mean resting corrected QTcF > 470 ms regardless of gender, obtained from triplicate 12-lead ECGs performed at screening. Uncontrolled or significant cardiac disease. History of non-infectious ILD/pneumonitis including radiation, pneumonitis that required steroids, has current ILD/pneumonitis, or has suspected ILD/pneumonitis that cannot be ruled out by imaging at screening. Has severe pulmonary function compromise. Any known active liver disease. Grade ≥ 2 peripheral neuropathy of any aetiology. Prior exposure to a PD-1/PD-L1 inhibitor other than pembrolizumab. Current or prior use of immunosuppressive medication within 14 days prior to randomisation. Participants with a known severe hypersensitivity to Dato-DXd or any of the excipients of these products including but not limited to polysorbate 80 or other monoclonal antibodies. Participants with a known severe hypersensitivity to PD-1/PD-L1 inhibitors. Participation in another clinical study with a study intervention or nvestigational medicinal device administered in the last 4 weeks prior to randomisation, randomisation into a prior Dato-DXd, T-DXd, or durvalumab study regardless of treatment assignment. Currently pregnant (confirmed with positive pregnancy test), breastfeeding or planning to become pregnant.

Further Information at [ClinicalTrials.gov]

	MZ-HH		
PI	Prof. Dr. med. Christian Schem	040 / 44190-500	
SI			
SK			

PersoMed-I, EORTC 1634-BTG, NOA 23

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

Personalized Risk-Adapted Therapy in Post-Pubertal Patients With Newly-Diagnosed Medulloblastoma (PersoMed-I)

Recruitment Status: RECRUITING
Condition: Medulloblastoma
Primary Completion Date: 2030-03-01
Intervention/ Treatment: Drug: onidegib/ Cisplatin/ Lomustine/ Vincristine/ Radiation: radiotherapy

Inclusion Criteria:

Newly diagnosed, histologically proven, genetically classified, centrally confirmed medulloblastoma (WNT M0-1, SHH M0-1 (p53wt), Group 4 M0-1). Molecular subtype: medulloblastoma, SHH-activated and TP53-wildtype, M0-1; medulloblastoma, WNT-activated, M0-1; medulloblastoma, Group 4, M0-1. Histologic subtype: medulloblastoma, classic (CMB); medulloblastoma, desmoplastic/nodular (DNMB); medulloblastoma, with extensive nodularity MBEN); medulloblastoma, large cell/anaplastic (LCA). Adult (18 years and above): in WNT-activated and Group 4 medulloblastoma. Post-pubertal, defined as females with a bone age of at least 15 years and males with a bone age of at least 17 years, or adult (greater than 18 y of age) (see appendix N) in SHH-activated and TP53-wildtype medulloblastoma. Availability of prognostic markers (MYC/MYCN amplification, MYC/MYCN mutation). Availability of paraffin embedded tumour tissue (FFPE) (1 block or 30 unstained slides) and whole blood sample (10 ml) for central review. For patients with SHH activated tumours: exclusion of germline alteration of TP53, PTCH, SUFU, BRCA2 and PALB2 if known before randomization. Clinical status within 2 weeks of randomization: Karnofsky 50-100. NANO-score 0 to 9 (allowing full-blown cerebellar symptoms). Clinically standard-risk (centrally assessed MRI review) defined as: total or near total surgical resection with less than or equal to 1.5 cm2 (measured in axial plane) of residual tumour on early post-operative MRI, without and with contrast; no CNS metastasis on MRI (cranial and spinal); Chang stage M0-1 with no clinical evidence of extra-CNS metastasis. Full recovery from surgery or any post-surgical complication (e.g. Bleeding, infections etc). Pre-surgery and/or post-surgery MRI available. Baseline brain MRI and spinal MRI available within 2 weeks of randomization. Normal liver, renal and haematological function within 2 weeks of randomization. WBC greater than or equal to 3×10^9/L. ANC greater than or equal to 1.5×10^9/L Platelet count of greater than or equal to 100×10^9/L independent of transfusion. Hemoglobin greater than or equal to 10 g/dl. Total Bilirubin less than or equal to 1.5 ULN. ALT (SGPT), AST (SGOT), alkaline phosphatase (ALP) less than or equal to 2.5 × ULN Serum creatinine less than 1.5 x ULN or creatinine clearance (CrCl) greater than 30 mL/min (using the Cockcroft-Gault formula). Negative serum or urine pregnancy test within 7 days of randomization for WOCBP. Patients of childbearing / reproductive potential (WOCBP) must use two methods of adequate birth control, including a highly effective method and a barrier method during the study treatment period and for at least 20 months after the last study treatment is mandatory for the patients that received sonidegib, for all other patients this period is at least 6 months after the last study treatment. A highly effective method of birth control is defined as those which result in low failure rate (i.e. less than 1% per year) when used consistently and correctly. Male patients even those who have had a vasectomy must always use a condom during treatment and for 6 months after last treatment. Men should not donate semen during treatment and for at least 6 months after ending treatment (donation of semen for the semen analyses of the fertility project 1 b is allowed). Appendix H. Female subjects who are breast feeding must discontinue nursing prior to the first dose of study treatment and until 20 months after the last study treatment. Before patient registration/randomization, written informed consent must be given according to ICH/GCP, and national/local regulations. For patients less than 18 years of age, consent has to be obtained from the parent(s) or legal representative.

Further Information at ClinicalTrials.gov

	Neurosurgery			Pediatric Oncology		
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SI	SI					
Study Nurse	SK					

ALCL-VBL

Internationale kooperative prospektive Studie für Kinder und Jugendliche mit Standardrisiko ALK positiven ALCL zur Wirksamkeit einer Vinblastin Therapie

Recruitment Status: RECRUITING
Condition: Anaplastisch großzelliges Lymphom
Primary Completion Date: 2027-03-30
Intervention/ Treatment: Drug: Vinblastin: 6 mg/m2 (max. 10 mg) intravenös (i.v.) über eine Behandlungsdauer von 18 Monaten wöchentlich und zwei-wöchentlich für weitere 6 Monate.

Inclusion Criteria:
Stratifizierung in den Standardarm im Screening: Neu diagnostiziertes ALK-positives ALCL, Stadium I nicht komplett resiziert oder Stadium II oder III, MDD negativ Alter < 18 Jahre Vorliegen einer Einwilligungserklärung zur Studienteilnahme, Datensammlung, Datenspeicherung und Datennutzung. Zustimmung zur Durchführung der Histologie auch durch die nationalen Referenzpathologie. Zu erwartendes Follow-up für wenigsten 3 Jahre nach dem Studieneinschluss. Nutzung hocheffektiver Kontrazeptiva bei sexuell aktiven Studienteilnehmern. Applikation einer Gabe intrathekaler triple Therapie vor dem Start der Protokollbehandlung.

Exclusion Criteria:
Krankheitsprogress während einer klinisch indizierten Vorphase vor Studieneinschluss. Gabe von Steroiden für mehr als 2 Tage oder Chemotherapie-Vorbehandlung vor Bestimmung des Minimal Disseminated Disease (MDD) im Screening. Chemotherapie-Vorbehandlung vor Start der Studienbehandlung außer: Gabe der obligaten triple i.th. Gabe und einer klinisch indizierten Vorphase. Schwangerschaft oder Stillperiode. Gegenanzeige für die Behandlung mit Vinblastin: Hypersensitivität gegen VBL oder andere Vincaalkaloide, Vorliegen einer Leukopenie ohne Zusammenhang zum ALCL, Vorliegen einer schweren, nicht kontrollierbaren Infektion. Anderer medizinischer, psychiatrischer, familiärer oder sozialer Zustand, der eine Behandlung nach dem Protokoll nicht möglich macht.

Further Information at gpoh.de

	Pediatric Oncology		
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SI			
SK			

ALLTogether1

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

LLTogether1 - A Treatment Study Protocol of the ALLTogether Consortium for Children and Young Adults (0-45 Years of Age) With Newly Diagnosed Acute Lymphoblastic Leukaemia (ALL)

Recruitment Status: RECRUITING
Condition: Leukemia, Acute Lymphoblastic
Primary Completion Date: 2027-06-30
Intervention/ Treatment: Drug: Omitted Doxorubicin/ Omitted Vincristine+Dexamethasone pulses/ Inotuzumab Ozogamicin+Standard Maintenance Therapy/ Imatinib/ 6-tioguanine+Standard/ Maintenance Therapy/ Blinatumomab

Inclusion Criteria:
Patients newly diagnosed with T-lymphoblastic (T-cell) or B-lymphoblastic precursor (BCP) leukaemia (ALL) according to the WHO-classification of Tumours of Haematopoetic and Lymphoid Tissues (Revised 4th edition 2017) and with a diagnosis confirmed by an accredited laboratory at a participating paediatric oncology or adult haematology centre. Age 0 - < 46 years (one day before 46th birthday) at the time of diagnosis with the exception of infants with KMT2A-rearranged (KMT2A-r) BCP ALL. Patients with surface immunoglobulin negative (sIG-) BCP-ALL and an IG::MYC rearrangement, unless they have a concurrent BCL2/6 rearrangement. T-ALL patients with MYC translocations. Informed consent signed by the patient and/or parents/legal guardians according to country-specific age-related guidelines. The ALL diagnosis should be confirmed by an accredited laboratory at a participating paediatric oncology or adult haematology centre. The patient should be diagnosed and treated at a participating paediatric oncology or adult haematology centre in the participating countries. The patient should be a resident in one of the participating countries on a permanent basis or should intend to settle in a participating country, for instance by an application for asylum. Patients who are visiting the country as tourists should not be included. However, returning expatriots with primary diagnosis abroad may be included if no treatment has been administered and the diagnostic procedures are repeated at a participating centre. All women of childbearing potential (WOCBP) have to have a negative pregnancy test within 2 weeks prior to the start of treatment. For each intervention/randomisation an additional set of inclusion-criteria is provided.

Exclusion Criteria:
Age < 365 days and KMT2A-rearranged (KMT2A-r) BCP-ALL (documented presence of a KMT2A-split by FISH and/or a KMT2A fusion transcript). Age >45 years at diagnosis. Patients with a previous malignant diagnosis (ALL as a second malignant neoplasm - SMN). Relapse of ALL. Patients with mature B-ALL (as defined by surface IG positivity) or any patients with IG::MYC and a concurrent BCL2/6 rearrangement. Patients with Ph-positive ALL (documented presence of t(9;22)(q34;q11) and/or of the BCR::ABL fusion transcript). These patients will be transferred to an appropriate trial for t(9;22) if available. Previously known ALL prone syndromes (e.g. Li-Fraumeni syndrome, germline ETV6 mutation), except for Down syndrome. Exploration for such ALL prone syndromes is not mandatory and patients in whom genetic work-up reveals a new germ-line mutation (index-cases) will remain in the study. Treatment with systemic corticosteroids (>10mg/m2/day) for more than one week and/or other chemotherapeutic agents in a 4-week interval prior to diagnosis (pre-treatment). Pre-existing contraindications to any treatment according to the ALLTogether protocol (constitutional or acquired disease prior to the diagnosis of ALL preventing adequate treatment). Any other disease or condition, as determined by the investigator, which could interfere with the participation in the study according to the study protocol, or with the ability of the patients to cooperate and comply with the study procedures. Women of childbearing potential who are pregnant at the time of diagnosis. Women of childbearing potential and fertile men who are sexually active and are unwilling to use adequate contraception during therapy. Efficient birth control is required. Female patients, who are breast-feeding. Essential data missing from the registration of characteristics at diagnosis (in consultation with the protocol chair). For each intervention/randomisation an additional set of exclusion-criteria is provided.

Further Information at ClinicalTrials.gov

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B-NHL 2013 - Treatment Protocol of the NHL-BFM and the NOPHO Study Groups for Mature Aggressive B-cell Lymphoma and Leukemia in Children and Adolescents

Recruitment Status: RECRUITING
Condition: Mature B-cell Non-Hodgkin Lymphoma
Primary Completion Date: 2024-08
Intervention/ Treatment: Drug: Rituximab window/ Additional doses of Rituximab/ Cyclophosphamide/ Cytarabine/ Dexamethasone/ Doxorubicin hydrochloride/ Vindesine Sulfate/ Etoposide/ Ifosfamide/ Methotrexate/ Prednisolone/ Vincristine/

Inclusion Criteria:

Newly diagnosed, histological or cytological and immunological proven aggressive mature B-cell Non-Hodgkin lymphoma including Burkitt lymphoma (BL), Burkitt leukemia (B-AL), diffuse large B-cell lymphoma (DLBCL), or mature B-cell NHL not further classified according to current WHO classification124. For rare subtypes (e.g. primary mediastinal large B-NHL, PMLBL, double hit lymphoma or high-grade B-cell lymphoma with MYC and BCL2 and/or BCL6 rearrangements), consultation of the study center is recommended. availability of slides/blocks for reference pathology and international pathology panel (except in cases with immunological and cytomorphological assurance of diagnosis). age at diagnosis < 18 years. diagnostics and treatment in one of the participating centers of the trial. no previous chemotherapy, no previous lymphoma-directed treatment. No application of steroids for more than two days during the last month. adequate hepatic, renal and cardiac function, except if alteration is due to lymphoma infiltration. Please contact the study center in case of unclear cases. signed informed consent of patient and/or parents/guardians for treatment according to the protocol, participation and transfer of data follow-up of at least two years after initial diagnosis is expected. Certificate of vaccination against hepatitis B or negative serology, defined as evidence of immunization with HBs-antigen negative, anti-HBs positive and anti-HBc negative or negative hepatitis B serology with HBs-antigen negative, anti-HBs and anti- HBc negative.

Exclusion Criteria:

patients with insufficient work up not allowing a correct stratification into the risk groups. B-cell neoplasia as second malignancy. any other medical, psychiatric or social condition prohibiting treatment according to the protocol (e.g. previous malignancy, prior organ transplant, HIV infection or AIDS or severe immunodeficiency, etc.). participation within a different trial for treatment of B-cell malignancies and/or concurrent treatment within any other clinical trial. Exceptions to this are the NHL-BFM Registry 2012 and trials with different endpoints, involving aspects of supportive treatment which can run parallel to B-NHL 2013 without influencing the outcome of this trial e.g. trials on antiemetics, antibiotics, strategies for psychosocial support etc. overt hepatitis B or history of hepatitis B. hypersensitivity to rituximab or to murine proteins or to any of the other excipients of the Investigational Medicinal Product rituximab (MabThera®) or to ingredients of other IMPs. lack of CD20 expression of the lymphoma cells pregnancy and lactation.

Further Information at ClinicalTrials.gov

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D1346R00004

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

Post-Authorisation Safety Study of Paediatric Patients Initiating Selumetinib: A Multiple-Country Prospective Cohort Study

Recruitment Status: RECRUITING
Condition: Neurofibromatosis Type 1
Primary Completion Date: 2028-05-23
Intervention/ Treatment: N/A

Inclusion Criteria:

Have been diagnosed with NF1 with symptomatic, inoperable PN. Have initial treatment with selumetinib up to 6 months (i.e.182 days)prior to enrolment into the study (i.e. signature of the ICF). Are aged 3 years and above, and are < 18 years of age on the index date. Parent or legal guardian, as required by country-specific regulation, have provided informed consent (unless a country-specific waiver is obtained) Additional Criteria for Nested Prospective Cohort. Are at least 8 years old and Are prior to attainment of Tanner Stage V on the index date

Exclusion Criteria:

Have received treatment with a mitogen-activated protein kinase inhibitor before the index date. Are participating in an interventional study at index date

Further Information at ClinicalTrials.gov

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Dabrafenib + Trametinib CDRB436G2401

Hubertus Wald Tumorzentrum
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An Open Label, Multi-center Roll-over Study to Assess Long-term Effect in Pediatric Patients Treated With Tafinlar (Dabrafenib) and/or Mekinist (Trametinib)

Recruitment Status: RECRUITING
Condition: Diffuse Astrocytoma/ Anaplastic Astrocytoma/ Astrocytoma/ Oligodendroglioma, Childhood/ Anaplastic Oligodendroglioma/ Glioblastoma/ Pilocytic Astrocytoma/ Giant Cell Astrocytoma/ Pleomorphic Xanthoastrocytoma/ Anaplastic Pleomorphic Xanthoastrocytoma/ Angiocentric Glioma/ Chordoid Glioma of Third Ventricle/ Gangliocytoma/ Ganglioglioma/ Anaplastic Ganglioglioma/ Dysplastic Gangliocytoma of Cerebrellum/ Desmoplastic Infantile Astrocytoma and Ganglioglioma/ Papillary Glioneuronal Tumor/ Rosette-forming Glioneurona Tumor/ Central Neurocytoma Extraventricular Neurocytoma/ Cerebellar Liponeurocytoma/ Neurofibromatosis Type 1
Primary Completion Date: 2026-05-29
Intervention/ Treatment: Drug: dabrafenib/ trametinib

Inclusion Criteria:
All Subjects:
Written informed consent, according to local guidelines, signed by the subjects and/or by the parents or legal guardian prior to any study related screening procedures are performed. Participation in a Novartis sponsored study such as CTMT212X2101, CDRB436G2201, CDRB436A2102, regardless of current age. Parent study (or cohort of parent study) is planned to be closed. Subject has demonstrated compliance, as assessed by the investigator, within the parent study protocol requirement(s). Willingness and ability to comply with scheduled visits, treatment plans and any other study procedures. For Subjects Entering the Treatment Period: Subject is currently receiving treatment with dabrafenib/trametinib monotherapy or combination within a Novartis Sponsored Drug Development study. Note that subjects who were on the chemotherapy arm of the CDRB436G2201 study are eligible for treatment period of this study only after crossing over into the experimental treatment arm of the CDRB436G2201 study. In the opinion of the investigator is likely to benefit from continued treatment.

Exclusion Criteria:
Subject has participated in a combination trial where dabrafenib and/or trametinib was dispensed in combination with another study medication. For Subjects Entering the Treatment Period: Subject has permanently discontinued from study treatment in the parent protocol due to any reason. Treatment with dabrafenib and/or trametinib for the subject's indication is approved for marketing and the appropriate dosage form is commercially available and reimbursed in the local country. Subject currently has unresolved drug related severe toxicities for which dabrafenib and/or trametinib dosing has been interrupted in the parent study. If the subject should meet criteria to resume treatment on the parent protocol then they may be eligible for treatment in this study. Other protocol-defined inclusion/exclusion may apply.

Further Information at ClinicalTrials.gov

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EsPhALL2017 - COGAALL 1631

LLTogether1 - A Treatment Study Protocol of the ALLTogether Consortium for Children and Young Adults (0-45 Years of Age) With Newly Diagnosed Acute Lymphoblastic Leukaemia (ALL)

Recruitment Status: RECRUITING
Condition: Acute Lymphoblastic Leukemia/ B Acute Lymphoblastic Leukemia/ Mixed Phenotype Acute Leukemia/ T Acute Lymphoblastic Leukemia/
Primary Completion Date: 2027-09-30
Intervention/ Treatment: Procedure: Allogeneic Hematopoietic Stem Cell Transplantation/ Drug: Calaspargase Pegol/ Cyclophosphamide/ Cytarabine/ Daunorubicin Hydrochloride/ Dexamethasone/ Dexrazoxane Hydrochloride/ Doxorubicin/ Etoposide/ Biological: Filgrastim/ Drug: Ifosfamide/ Imatinib Mesylate/ Other: Laboratory Biomarker Analysis/ Drug: Leucovorin Calcium/ Mercaptopurine/ Mercaptopurine/ Methotrexate/ Methylprednisolone/ Pegaspargase/ Prednisolone/ Other: Questionnaire Administration/ Drug: Therapeutic Hydrocortisone/ Thioguanine/ Vincristine Sulfate

Inclusion Criteria:
For patients enrolled on APEC14B1 prior to enrollment on AALL1631, the required diagnostic bone marrow sample has been fulfilled. For patients who have not previously enrolled on APEC14B1 prior to enrollment on AALL1631, a baseline diagnostic sample (or peripheral blood sample with blasts if marrow sample unavailable) must be available to develop an MRD probe. In addition, laboratory reports detailing evidence of BCR-ABL1 fusion or ABL-class fusion must be submitted for rapid central review within 72 hours of study enrollment. >= 1 year (365 days) and =< 21 years at ALL diagnosis. Ph+ (BCR-ABL1 fusion): newly diagnosed de novo ALL (B-ALL or T-ALL) or mixed phenotypic acute leukemia (MPAL meeting 2016 World Health Organization [WHO] definition) with definitive evidence of BCR-ABL1 fusion by karyotype, fluorescence in situ hybridization (FISH) and/or molecular methodologies ABL-class fusion: newly diagnosed B-ALL with definitive evidence of ABL-class fusions. ABL-class fusions are defined as those involving the following genes: ABL1, ABL2, CSF1R, PDGFRB, PDGFRA. Methods of detection include fluorescence in-situ hybridization (FISH, e.g. using break-apart or colocalization signals probes), multiplex or singleplex reverse-transcription polymerase chain reaction (RT-PCR), whole transcriptome or panel-based ribonucleic acid (RNA)-sequencing (e.g. TruSight RNA Pan-Cancer Panel; Illumina, San Diego, CA, USA or similar)ö. Ph+ patients must have previously started Induction therapy, which includes vincristine, a corticosteroid, pegaspargase, with or without anthracycline, and/or other standard cytotoxic chemotherapy. Ph+ patients have not received more than 14 days of multiagent Induction therapy beginning with the first dose of vinCRIStine Ph+ patients may have started imatinib prior to study entry but have not received more than 14 days of imatinib. ABL-class fusion patients must have previously completed the 4 or 5 weeks of multiagent Induction chemotherapy (Induction IA phase). ABL-class fusion patients may have started imatinib during Induction IA, at the same time of or after the first vinCRIStine dose. Patients must have a performance status corresponding to Eastern Cooperative Oncology Group (ECOG) scores of 0, 1, or 2. Direct bilirubin =< 2.0 mg/dL. Shortening fraction of >= 27% by echocardiogram. Ejection fraction of >= 50% by radionuclide angiogram or echocardiogram. Corrected QT interval, QTc < 480 msec. Note: Repeat echocardiogram and electrocardiogram are not required if they were performed at or after initial ALL diagnosis, before study enrollment. Creatinine clearance or radioisotope glomerular filtration rate (GFR) >= 70 mL/min/1.73 m^2 or serum creatinine within normal limits based on age/gender, as follows: 1 to < 2 years: maximum serum creatinine 0.6 mg/dL (both male and female). 2 to < 6 years: maximum serum creatinine 0.8 mg/dL (both male and female). 6 to < 10 years: maximum serum creatinine 1 mg/dL (both male and female). 10 to < 13 years: maximum serum creatinine 1.2 mg/dL (both male and female). 13 to < 16 years: maximum serum creatinine 1.5 mg/dL (male), 1.4 mg/dL (female). >= 16 years: maximum serum creatinine 1.7 mg/dL (male), 1.4 mg/dL (female).

Further Information at ClinicalTrials.gov

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HIBISCUS 4202-HEM-301

Hubertus Wald Tumorzentrum
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Ein Kompetenznetzwerk des UKE

An Adaptive, Randomized, Placebo-controlled, Double-blind, Multi-center Study of Oral Etavopivat, a Pyruvate Kinase Activator in Patients With Sickle Cell Disease (HIBISCUS)

Recruitment Status: RECRUITING
Condition: Sickle Cell Disease
Primary Completion Date: 2025-12
Intervention/ Treatment: Etavopivat Tablets Low dose/ Etavopivat Tablets High dose/ Placebo Tablets/ Etavopivat Tablets

Inclusion Criteria:
Provision of consent. Patient has a confirmed diagnosis of sickle cell disease. At least 2 episodes of vaso-occlusive crises in the past 12 months. Hemoglobin ≥ 5.5 and ≤ 10.5 g/dL (≥ 55 and ≤ 105 g/L) during screening Patients taking hydroxyurea, must demonstrate a stable dose for at least 90 days prior to start of study treatment. Patients on crizanlizumab or L-glutamine treatment at the time of consent must be on a stable dose for ≥ 12 months and must be ≥ 80% compliant with the planned regimen at the time of consent and meet the VOC eligibility criteria. Female patients of childbearing potential must use highly effective methods of contraception, male patients are willing to use barrier methods of contraception.

Exclusion Criteria:
More than 10 vaso-occlusive crises within the past 12 months. Female who is breastfeeding or pregnant. Hepatic dysfunction characterized by: Alanine aminotransferase (ALT) > 4.0 × upper limit of normal (ULN) Direct bilirubin > 3.0 × ULN Known HIV positivity. Active hepatitis B or hepatitis C infection. Severe renal dysfunction or on chronic dialysis. History of unstable or deteriorating cardiac or pulmonary disease within 6 months prior to consent including but not limited to the following: Unstable angina pectoris or myocardial infarction or elective coronary intervention. Congestive heart failure requiring hospitalization. Uncontrolled clinically significant arrhythmias. Symptomatic pulmonary hypertension. History of overt clinical stroke within previous 2 years or any history of an intracranial hemorrhage. History of deep venous thrombosis requiring systemic anti-coagulation therapy for ≥ 6 weeks, occurring within 6 months prior to Day 1 of study treatment. Prior/Concomitant Therapy. Patients receiving regularly scheduled blood (RBC) transfusion therapy (also termed chronic, prophylactic, or preventive transfusion) Receiving or use of concomitant medications that are strong inducers of CYP3A4/5 within 2 weeks of starting study treatment or anticipated need for such agents during the study. Use of voxelotor within 28 days prior to starting study treatment or anticipated need for this agent during the study. Use of an experimental selectin antagonist (eg, monoclonal antibody or small molecule) within 28 days of starting study treatment or anticipated need for such agents during the study. Use of erythropoietin or other hematopoietic growth factor treatment within 28 days of starting study treatment or anticipated need for such agents during the study. Receipt of prior cellular-based therapy (eg, hematopoietic cell transplant, gene modification therapy).

Further Information at ClinicalTrials.gov

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RANDOMET 2017

Hubertus Wald Tumorzentrum
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Randomisierte, multizentrische, offene, Phase III, Äquivalenzstudie (non-inferiority) für Patienten mit Nierentumor des Kindesalters im Stadium IV zum Vergleich der präoperativen Chemotherapie bestehend aus Vincristin, Actinomycin – D und Doxorubicin (VAD, Standardarm) mit der präoperativen Chemotherapie bestehend aus Vincristin, Carboplatin und Etoposid (VCE, Vergleichsarm)

Recruitment Status: RECRUITING
Condition: Nierentumor Stadium IV mit Lungenmetastasen und/oder extrapulmonale Metastasen
Primary Completion Date: N/A
Intervention/ Treatment: Die gesamte klinische Prüfung umfasst die 6 – wöchige präoperative Therapie. Hieran schließt sich eine Beobachtung der weiteren Behandlung an, die in der Regel 29 Woche dauert (2 Wochen perioperative Phase und 27 Wochen Therapie).

Inclusion Criteria:

Kinder <18 Jahre und älter als 3 Monate, die bei Erstdiagnose an einem metastasierten Nierentumor erkrankt sind und bei denen mindestens ein umschriebener, nicht kalzifizierter (pulmonaler) Knoten festgestellt wurde (oder eine andere Läsion bei der ein hochgradiger Verdacht auf Metastasen gemäß den Kriterien für eine Metastasierung besteht), dessen/ deren Größe ≥3 mm beträgt ermittelt durch Thorax-CT-Scan und Abdominellem-CT-Scan/MRI. Die Metastasierung muss durch ein zentrales Review bestätigt werden.

Exclusion Criteria:

Ablehnung der Einwilligung zur Studienteilnahme und Randomisierung. Primäre Nephrektomie. Nachverfolgung des Patienten bis zwei Jahre nach Behandlungsende ist nicht möglich Eine andere bekannte Histologie als Nephroblastom. Bereits erfolgte Chemotherapie vor Studieneinschluß. Schwangerschaft oder Stillzeit. Zeugungsfähige Patienten, die die Nutzung einer effektiven Verhütung ablehnen. Behandlung mit irgendeinem Studienmedikament in den letzten 4 Wochen vor Einschluss. Überempfindlichkeit auf eine der aktiven Substanzen oder der Galenik, die in der Studienmedikation vorkommt und in der Fachinformation SmPC) aufgeführt ist, oder in der Prüfarzt Broschüre. Vorerkrankung die eine sichere Behandlung in der Studie signifikant beeinträchtigt.

Further Information at gpoh.de

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Klinische Prüfung der Phase III von CPX-351 zur Behandlung von Kindern mit Myeloischer Leukämie mit Down-Syndrom 2018

Recruitment Status: RECRUITING
Condition: Akute myeloische Leukämie assoziiert mit Down Syndrom
Primary Completion Date: N/A
Intervention/ Treatment: Es wird untersucht, ob der Austausch der Standardtherapieblöcke 1 und 2 aus der ML-DS 2006 Studie mit CPX-351 - einem Kombinationspräparat, in dem Cytarabin und Daunorubicin im Verhältnis 5:1 in Liposomen eingekapselt sind - und die Reduktion der Behandlungsintensität im 4. Therapieblock für Patienten mit einem guten Therapieansprechen (< 0,1% Blasten nach dem 1. CPX-351 Block) nicht in einem schlechteren Event-free Survival resultiert. Alle Kinder erhalten den gleichen Studienarm, die Ergebnisse werden mit der historischen Kontrolle der Vorgängerstudie verglichen.

Inclusion Criteria:

Diagnose einer AML oder eines MDS nach WHO-Definition. Trisomie 21: Down Syndrom oder Mosaik mit/ohne GATA1 Mutation. Alter: > 6 Monate und ≤ 4 Jahre mit/ohne GATA1 Mutation ODER > 4 und < 6 Jahre mit GATA1 Mutation. Morphologie/Immunphänotyp: FAB M0, M6 or M7. Guter Allgemeinzustand (Lansky oder Karnofsky Score mind. 50). Einwilligungserklärung zur Studienteilnahme und zur Datenverarbeitung und -weitergabe liegen vor. Der Patient und seine Familie können den Zeitplan für Studienbesuche und andere Behandlungserfordernisse einhalten.

Exclusion Criteria:

Kinder mit einer transienten abnormalen Myelopoese (TAM), definiert nach WHO. Zytogenetik: AML mit bestimmten (rekurrenten) genetischen Veränderungen (WHO 2016). Vorangegangene Stammzell- oder Knochenmarktransplantation oder andere Organtransplantation. Bestimmte (schwere) Infektionen. Symptomatische Fehlfunktionen des Herzens Operationen innerhalb der vorangegangenen 21 Tage bei Start der Therapie. Bestimmte Vortherapien. Bestimmte Begleitmedikation. Behandlung in einer anderen Studie innerhalb der letzten vier Wochen. Bekannte Überempfindlichkeit auf das Studienmedikament. Wiederholte Teilnahme an dieser Studie.

Further Information at gpoh.de

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Kraniopharyngeom Registry 2019

Hubertus Wald Tumorzentrum
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KRANIOPHARYNGEOM Registry 2019 Multicenter Registry for Patients With Childhood-onset Craniopharyngioma, Xanthogranuloma, Cysts of Rathke's Pouch, Meningioma, Pituitary Adenoma, Arachnoid Cysts

Recruitment Status: RECRUITING
Condition: Craniopharyngioma Obesity
Primary Completion Date: 2024-06-30
Intervention/ Treatment: N/A

Inclusion Criteria:
Diagnosed with craniopharyngioma for the first time. Age at diagnosis 18 years or less of age. Agreement from patient's parents or legal guardian as well as the patient.

Exclusion Criteria:
Age at diagnosis over 18 years of age. Diagnosis different from craniopharyngioma.

Further Information at ClinicalTrials.gov

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LBL 2018 UKM17_0023

LBL 2018 - International Cooperative Treatment Protocol for Children and Adolescents With Lymphoblastic Lymphoma

Recruitment Status: RECRUITING
Condition: Lymphoblastic Lymphoma, Childhood
Primary Completion Date: 2027-07-22
Intervention/ Treatment: Drug: Cyclophosphamide/ Cytarabine/ Dexamethasone/ Daunorubicin/ Doxorubicin/ Ifosfamide/ 6-Mercaptopurine/ Methotrexate/ PEG asparaginase/ Prednisone/ Prednisolone/ Thioguanine/ Vincristine/ Vindesine

Inclusion Criteria:
Newly diagnosed lymphoblastic lymphoma age <18 years patient enrolled in a participating center written informed consent of patient (>14 years of age or according to local law and regulation) and parents to trial participation and transfer and processing of data willingness of patients and the investigator/pathologist to provide adequate slides/blocks for reference (molecular) pathology and international pathology panel and/or fresh or fresh frozen samples for genetic risk group stratification if these samples are available after standard diagnostic procedures.

Exclusion Criteria:
lymphoblastic lymphoma as secondary malignancy. non-lymphoma related relevant medical, psychiatric or social conditions incompatible with trial treatment, including among others. prior organ transplant. severe immunodeficiency. demyelinating Charcot-Marie Tooth syndrome. serious acute or chronic infections, such as HIV, VZV and tuberculosis. urinary tract infection, cystitis, urinary outflow obstruction, severe renal impairment (creatinine clearance less than 20 ml/min). severe hepatic impairment (bilirubin >3 times ULN, transaminases >10 times ULN). myocardial insufficiency, severe arrhythmias. ulcers of the oral cavity and known active gastrointestinal ulcer disease. known hypersensitivity to any IMP and to any excipient (listed in section 6.1 of the respective SmPC). steroid pre-treatment with ≥ 1 mg/kg/d for more than two weeks during the last month before diagnosis. vaccination with live vaccines within 2 weeks before start of protocol treatment. treatment started according to another protocol or pre-treatment with cytostatic drugs. participation in another clinical trial that interferes with the protocol, except NHL-BFM Registry 2012 and trials with different endpoints, involving aspects of supportive treatment, which can run parallel to LBL 2018 without influencing the outcome of this trial (e.g. trials on antiemetics, antibiotics, strategies for psychosocial support). evidence of pregnancy or lactation period. sexually active adolescents not willing to use highly effective contraceptive method (pearl index < 1) until 12 months after end of cytostatic therapy

Further Information at ClinicalTrials.gov

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SPRINKLE D1346C00004

Hubertus Wald Tumorzentrum
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A Phase I/II, Single-Arm, Open Label Study to Evaluate the Pharmacokinetics, Safety/Tolerability and Efficacy of the Selumetinib Granule Formulation in Children Aged ≥1 to <7 Years With Neurofibromatosis Type 1 (NF1) Related Symptomatic, Inoperable Plexiform Neurofibromas (PN) (SPRINKLE)

Recruitment Status: ACTIVE, NOT RECRUITING
Condition: Neurofibromatosis Type 1
Primary Completion Date: 2024-04-08
Intervention/ Treatment: Drug: Selumetinib granule formulation/ Selumetinib capsule formulation

Inclusion Criteria:

Male and female participants aged ≥ 1 to < 7 years of age at the time their legally authorised representative (parent or guardian) signs the informed consent. All study participants must be diagnosed with NF1 with symptomatic inoperable PN as defined in protocol. Participants must have at least one measurable PN, defined as a PN of at least 3 cm measured in one dimension, which can be seen on at least 3 imaging slices and have a reasonably well-defined contour. Participants who have undergone surgery for resection of a PN are eligible provided the PN was incompletely resected and is measurable. The target PN will be defined as the clinically most relevant PN, which is symptomatic, inoperable and measurable by volumetric MRI analysis. Performance status: Participants must have a Lansky performance of ≥ 70 except in participants who are wheelchair bound or have limited mobility secondary to a need for mechanical breathing support (such as an airway PN requiring tracheostomy or continuous positive airway pressure) who must have a Lansky performance of ≥ 40. Participants must have a BSA ≥ 0.4 and ≤ 1.09 m2 at study entry (date of ICF signature). Mandatory provision of consent for the study signed and dated by a participant's legally authorised representative (parent or guardian) along with the paediatric assent form, if applicable.

Exclusion Criteria:

Participants with confirmed or suspected malignant glioma or MPNST. Participants with low grade glioma (including optic glioma) not requiring systemic therapy are permitted. History of malignancy except for malignancy treatment with curative intent with no known active disease ≥ 2 years before the first dose of study intervention and of low potential risk of recurrence. Refractory nausea and vomiting, chronic gastrointestinal disease, inability to swallow the formulated product, or previous significant bowel resection that would preclude adequate absorption, distribution, metabolism, or excretion of selumetinib. A life-threatening illness, medical condition, organ system dysfunction or laboratory finding which, in the Investigator's opinion, could compromise the participant's safety, interfere with the absorption or metabolism of selumetinib, or put the study outcomes at undue risk. Participants with clinically significant cardiovascular disease as defined in the protocol. Liver function tests: Bilirubin > 1.5 × the ULN for age with the exception of those with Gilbert syndrome (≥ 3 × ULN) or AST/ALT > 2 × ULN. Renal Function: Creatinine clearance or radioisotope glomerular filtration rate < 60 mL/min/1.73 m2 or Serum creatinine > 0.8 mg/dL (for participants aged ≥ 1 to < 4 years) or > 1.0 mg/dL (for participants aged ≥ 4 years). Participants with ophthalmological findings/condition as listed in the protocol. Have any unresolved chronic toxicity with CTCAE Grade ≥ 2 which are associated with previous therapy for NF1-PN (except hair changes such as alopecia or hair lightening). Participants who have previously been treated with a MEKi (including selumetinib) and have had disease progression, or due to toxicity have either discontinued treatment and/or required a dose reduction.
Have inadequate haematological function defined as: An absolute neutrophil count < 1500/µL or Haemoglobin < 9g/dL or Platelets <100,000/µL or Have had a transfusion (of red cells or other blood derived products) within the 28 days prior to study entry (date of ICF signature). Have received or are receiving an IMP or other systemic NF1-PN target treatment (including MEKi) within 4 weeks prior to the first dose of study intervention, or within a period during which the IMP or systemic PN target treatment has not been cleared from the body (eg, a period of 5 'half-lives'), whichever is longer. Has received radiotherapy in the 6 weeks prior to start of study intervention or any prior radiotherapy directed at the target or non-target PN. Receiving herbal supplements or medications known to be strong or moderate inhibitors of the CYP3A4 and CYP2C19 enzymes or inducers of the CYP3A4 enzyme unless such products can be safely discontinued at least 14 days or 5 half-lives (whichever is longer) before the first dose of study medication. Inability to undergo MRI and/or contraindication for MRI examinations. Prosthesis or orthopaedic or dental braces that would interfere with volumetric analysis of target PN on MRI.

Further Information at ClinicalTrials.gov

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PEARL

Im Verbundvorhaben PEARL werden international anerkannte Experten für klinische und molekularpathologische Epidemiologie, Gastroenterologie und Künstliche Intelligenz zusammenarbeiten, um neue Wege zu beschreiten, Risikofaktoren und Ursachen für Darmkrebserkrankungen im frühen Erwachsenenalter zu verstehen. Ferner möchten sie neuartige Strategien der Primär- und Sekundärprävention dieser Erkrankungen entwickeln und evaluieren.

Recruitment Status: RECRUITING
Condition: Darmkrebs
Primary Completion Date: /
Intervention/ Treatment: Prevention

Further Information at BMBF

	Onkolog. Zentrum an den Krankenhäusern Buchholz und Winsen		
PI	Onkolog. Zentrum an den Krankenhäusern Buchholz und Winsen		
SI	**Dr. med. Frederik Felipe Fromm**	**04181 13-0**	
SK			

MELODY, EUBREAST-4

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

A Prospective Non-interventional Multicenter Cohort Study to Evaluate Different Imaging-guided Methods for Localization of Non-palpable Malignant Breast Lesions

Recruitment Status: RECRUITING
Condition: Darmkrebs
Primary Completion Date: 2025-12
Intervention/ Treatment: Observational

Inclusion Criteria:

Signed informed consent form
Malignant breast lesion requiring breast-conserving surgery and imaging-guided localization (either DCIS or invasive breast cancer; multiple or bilateral lesions and the use of neoadjuvant chemotherapy are allowed)
Planned surgical removal of the lesion using one or more of the following imaging-guided localization techniques:
- Wire-guided localization
- Intraoperative ultrasound
- Magnetic localization
- Radioactive seed localization
- Radioguided Occult Lesion Localization (ROLL)
- Radar localization
- Radiofrequency identification (RFID) tag localization
- Ink/carbon localization

Female / male patients ≥ 18 years old

Exclusion Criteria:

Patients not suitable for surgical treatment
Patients requiring mastectomy as first surgery
Surgical removal without imaging-guided localization

Further Information at ClinicalTrials.gov

	Helios Mariahilf		
PI	Onkolog. Zentrum an den Krankenhäusern Buchholz und Winsen		
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PROOFS, WSG-NIS04

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

A Prospective Non-interventional Multicenter Cohort Study to Evaluate Different Imaging-guided Methods for Localization of Non-palpable Malignant Breast Lesions

Recruitment Status: RECRUITING
Condition: Female Breast Cancer
Primary Completion Date: 2035-03
Intervention/ Treatment: Observational

Inclusion Criteria: Patients are eligible for participation in the registry only if they meet all the following criteria: Female breast cancer patients Pre- or perimenopausal at registry entry (age <60 years and state after hysterectomy or amenorrhea for <12 months; confirmation by blood hormone levels (FSH and estradiol in premenopausal range as per local normal range) recommended) Primary tumor diagnosis not older than three months prior to inclusion (primary diagnosis defined as date of initial tumor biopsy) Estrogen- and/or progesterone-receptor-positive/HER2 negative early breast cancer without any clinical signs of metastases Adequate risk for recurrence: intermediate clinical risk for recurrence, defined as (clinical in case of neoadjuvant treatment): c/pT1 and c/pN0 and Ki-67 15-24% or G2 or patients, who do not meet these criteria but are at intermediate clinical risk for recurrence at investigator decision (e.g., very young age, low expression of hormone receptors, existing co-morbidities, familial cancer burden, etc.) can be included on individual decision basis or high clinical risk for recurrence, defined as either (clinical in case of neoadjuvant treatment): c/pT2-4 or c/pN1 or Ki-67 ≥25% or G3 Low genomic risk of recurrence by MammaPrint® (tested on treatment naïve tumor specimen) Luminal-type by BluePrint® Treatment according to standard-of-care (e.g., AGO Guidelines) planned or started (until completion of local therapy the latest (including started or completed endocrine induction therapy), started, or planned adjuvant or neoadjuvant treatment) Availability of untreated tumor material (core biopsy if preoperative endocrine therapy performed or neoadjuvant treatment intended or surgery specimen) Capability to give written informed consent Nodal positive patients will be accepted to the registry up to 25% of the genomic low/ultralow-risk population (n=441).

Exclusion Criteria:

Patients will not be eligible for the registry for any of the following reasons: Any other genomic testing, besides MammaPrint®, has been performed on the tumor material Medical or psychological conditions that would not permit the patient to sign informed consent Legal incapacity or limited legal capacity Current participation in any interventional clinical trial which tests anticancer drugs, immunotherapeutics, or antibody treatment for any type of neoplasm Non-compliance of the patient

Further Information at ClinicalTrials.gov

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PROVIDENCE, D9673R00028

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

A Prospective Non-interventional Multicenter Cohort Study to Evaluate Different Imaging-guided Methods for Localization of Non-palpable Malignant Breast Lesions

Recruitment Status: RECRUITING
Condition: Breast Neoplasms/ Breast Cancer/ Neoplasm Metastasis
Primary Completion Date: 2030-12-31
Intervention/ Treatment: Observational

Inclusion Criteria:
Adults ≥ 18 years old
Patients with pathologically documented breast cancer that:
is unresectable or metastatic
has confirmed HER2+ or HER2-low tumor status by local pathology
was previously treated with one anti-HER2 directed therapy if the tumor is HER2+ or
was previously treated with prior chemotherapy in the metastatic setting or developed disease recurrence during or within 6 months of completing adjuvant chemotherapy if the tumor is HER2- low.
Has documented radiologic progression (during or after most recent treatment)
Patient is eligible for T-DXd treatment in line with the specifications mentioned in the ENHERTU® SmPC and is scheduled for T-DXd as second line treatment if the tumor is HER2+ or scheduled for T-DXd treatment if the tumor is HER2 low*
Patient is able to read and understand either German or English
Signed written informed consent *The prescription of the medicinal products are clearly separated from the decision to include the patient in this NIS.

Exclusion Criteria:
Known hypersensitivity to T-DXd or any of the excipients of the drug
Pregnancy or breast feeding
Current or planned participation in an interventional clinical trial
Current or planned systemic treatment of any tumor other than unresectable or metastatic BC

Further Information at ClinicalTrials.gov

	Helios Mariahilf		
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CAMBRIA-1

A Phase III, Open-Label, Randomised Study to Assess the Efficacy and Safety of Extended Therapy With Camizestrant Versus Standard Endocrine Therapy (Aromatase Inhibitor or Tamoxifen) in Patients With ER+/HER2- Early Breast Cancer

Recruitment Status: RECRUITING
Condition: Breast Cancer, Early Breast Cance
Primary Completion Date: 2027-04-19
Intervention/ Treatment: Drug (**Camizestrant/ Tamoxifen/ Anastrozole/ Letrozole/ Exemestane**)

Inclusion Criteria: Women and Men, ≥18 years at the time of screening (or per national guidelines) Histologically confirmed ER+/HER2- early-stage resected invasive breast cancer with high or intermediate risk of recurrence, based on clinical-pathological risk features, as defined in the protocol. Completed adequate (definitive) locoregional therapy (surgery with or without radiotherapy) for the primary breast tumour(s), with or without (neo)adjuvant chemotherapy Completed at least 2 years but no more than 5 years (+3 months) of adjuvant ET (+/- CDK4/6 inhibitor) Eastern Cooperative Oncology Group (ECOG) performance status of ≤ 1 Adequate organ and marrow function

Exclusion criteria:

Inoperable locally advanced or metastatic breast cancer
Pathological complete response following treatment with neoadjuvant therapy
History of any other cancer (except non-melanoma skin cancer or carcinoma in situ of the cervix or considered at very low risk of recurrence per investigator judgement) unless in complete remission with no therapy for a minimum of 5 years from the date of randomisation
Any evidence of severe or uncontrolled systemic diseases which, in the investigator's opinion precludes participation in the study or compliance
Known LVEF <50% with heart failure NYHA Grade ≥2.
Mean resting QTcF interval >480 ms at screening
Concurrent exogenous reproductive hormone therapy or non-topical hormonal therapy for non-cancer-related conditions
Any concurrent anti-cancer treatment not specified in the protocol with the exception of bisphosphonates (e.g. zoledronic acid) or RANKL inhibitors (eg, denosumab)
Previous treatment with camizestrant, investigational SERDs/investigational ER targeting agents, or fulvestrant
Currently pregnant (confirmed with positive serum pregnancy test) or breastfeeding
Patients with known hypersensitivity to active or inactive excipients of camizestrant or drugs with a similar chemical structure or class to camizestrant. In pre-/peri-menopausal female and male patients, known hypersensitivity or intolerance to LHRH agonists, that would preclude the patient from receiving any LHRH agonist

Further Information at ClinicalTrials.gov

	Helios Mariahilf		
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FLAMINGO, GLSI-21-01

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

A Phase III, Open-Label, Randomised Study to Assess the Efficacy and Safety of Extended Therapy With Camizestrant Versus Standard Endocrine Therapy (Aromatase Inhibitor or Tamoxifen) in Patients With ER+/HER2- Early Breast Cancer

Recruitment Status: RECRUITING
Condition: Breast Cancer, Early Breast Cancer
Primary Completion Date: 2027-04-19
Intervention/ Treatment: Drug (**Camizestrant/ Tamoxifen/ Anastrozole/ Letrozole/ Exemestane**)

Inclusion Criteria: Women and Men, ≥18 years at the time of screening (or per national guidelines) Histologically confirmed ER+/HER2- early-stage resected invasive breast cancer with high or intermediate risk of recurrence, based on clinical-pathological risk features, as defined in the protocol. Completed adequate (definitive) locoregional therapy (surgery with or without radiotherapy) for the primary breast tumour(s), with or without (neo)adjuvant chemotherapy Completed at least 2 years but no more than 5 years (+3 months) of adjuvant ET (+/- CDK4/6 inhibitor) Eastern Cooperative Oncology Group (ECOG) performance status of ≤ 1 Adequate organ and marrow function

Exclusion criteria:

Inoperable locally advanced or metastatic breast cancer
Pathological complete response following treatment with neoadjuvant therapy
History of any other cancer (except non-melanoma skin cancer or carcinoma in situ of the cervix or considered at very low risk of recurrence per investigator judgement) unless in complete remission with no therapy for a minimum of 5 years from the date of randomisation
Any evidence of severe or uncontrolled systemic diseases which, in the investigator's opinion precludes participation in the study or compliance
Known LVEF <50% with heart failure NYHA Grade ≥2.
Mean resting QTcF interval >480 ms at screening
Concurrent exogenous reproductive hormone therapy or non-topical hormonal therapy for non-cancer-related conditions
Any concurrent anti-cancer treatment not specified in the protocol with the exception of bisphosphonates (e.g. zoledronic acid) or RANKL inhibitors (eg, denosumab)
Previous treatment with camizestrant, investigational SERDs/investigational ER targeting agents, or fulvestrant
Currently pregnant (confirmed with positive serum pregnancy test) or breastfeeding
Patients with known hypersensitivity to active or inactive excipients of camizestrant or drugs with a similar chemical structure or class to camizestrant. In pre-/peri-menopausal female and male patients, known hypersensitivity or intolerance to LHRH agonists, that would preclude the patient from receiving any LHRH agonist

Further Information at ClinicalTrials.gov

	Helios Mariahilf		
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AbbVie M18-868

A Phase 3 Open-Label, Randomized, Controlled, Global Study of Telisotuzumab Vedotin (ABBV-399) Versus Docetaxel in Subjects With Previously Treated c-Met Overexpressing, EGFR Wildtype, Locally Advanced/Metastatic Non-Squamous Non-Small Cell Lung Cancer

Recruitment Status: RECRUITING
Condition: Non Small Cell Lung Cancer
Primary Completion Date: 2025-06-07
Intervention/ Treatment: Drug (**Docetaxel**), Biological (**Telisotuzumab Vedotin**)

Inclusion Criteria: Participants must have c-Met overexpressing non-small cell lung cancer (NSCLC) as assessed by an AbbVie designated immunohistochemistry (IHC) laboratory using the VENTANA MET (SP44) RxDx assay.
Archival or fresh tumor material must be submitted for assessment of c-Met levels during the Pre-Screening period. Tumor material from the primary tumor site and/or metastatic sites are allowed.If a participant was prescreened for Study M14-239 but did not enroll, tumor material previously submitted for Study M14-239 may be used for Study M18-868 Pre-Screening upon confirmation from AbbVie that sufficient evaluable tumor material is available (Except China).
A histologically documented non-squamous cell NSCLC that is locally advanced or metastatic.
A known epidermal growth factor receptor (EGFR) activating mutation status.
Actionable alterations in genes other than EGFR .
Measurable disease per Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1.
An Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 to 1.
Have received no more than 1 line of prior systemic cytotoxic chemotherapy in the locally advanced or metastatic setting.Neoadjuvant and adjuvant systemic cytotoxic chemotherapy will count as a prior line for eligibility purposes if progression occurred within 6 months of the end of therapy.
Have progressed on at least 1 line of prior therapy for locally advanced/metastatic NSCLC:
- Participants WITHOUT an actionable gene alteration: must have progressed on (or be considered ineligible for) platinum-based chemotherapy and immune checkpoint inhibitor (as monotherapy or in combination with chemotherapy).
- Participants WITH an actionable gene alteration for which immune checkpoint inhibitor therapy is not standard of care (e.g., anaplastic lymphoma kinase [ALK] translocation): must have progressed on (or be considered ineligible for) anti-cancer therapy targeting driver gene alterations and platinum-based chemotherapy.
  - Participants with actionable gene alterations for which immune checkpoint inhibitor is standard of care must have also progressed on (or be considered ineligible for) immune checkpoint inhibitor (as monotherapy or in combination with chemotherapy).

Must be considered appropriate for docetaxel therapy based on the assessment of the treating physician.
Participants with metastases to the central nervous system (CNS) are eligible only after definitive therapy (such as surgery or radiotherapy) is provided and:
- There is no evidence of progression of CNS metastases at least 2 weeks after definitive therapy.
- They are asymptomatic and off or on a stable or reducing dose of systemic steroids and/or anticonvulsants for at least 2 weeks prior to first dose of telisotuzumab vedotin.

Further Information at ClinicalTrials.gov

	Medical Oncology		
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AbbVie M22-947

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

A Dose Escalation and Expansion Study of ABBV-383 in Combination With Anti-Cancer Regimens for the Treatment of Patients With Relapsed/Refractory Multiple Myeloma

Recruitment Status: RECRUITING
Condition: Relapsed/Refractory Multiple Myeloma
Primary Completion Date: 2028-11-29
Intervention/ Treatment: Drug (**ABBV-383/ Dexamethasone/ Lenalidomide/ Pomalidomide/ Nirogacestat/ Daratumumab**)

Inclusion Criteria:
Eastern Cooperative Oncology Group (ECOG) performance of <= 2.
Must have confirmed diagnosis of Relapsed/Refractory (R/R) Multiple Myeloma (MM) with documented evidence of progression during or after the participant's last treatment regimen based on the investigator's determination of the International Myeloma Working Group (IMWG) criteria.
Must have measurable disease as outlined in the protocol. Must be naïve to treatment with ABBV-383 and must have never received BCMA-targeted therapy. Participants who have received targeted therapy against non-BCMA targets will not be excluded. Has received prior MM treatment in Arms A, B, C, and D.
Exclusion Criteria:
Received a peripheral autologous stem cell transplant (SCT) within 12 weeks, or an allogeneic SCT within 1 year of the first dose of study drug treatment.
Unresolved adverse event (AE)s >= Grade 2 (National Cancer Institute [NCI] Common Terminology Criteria for Adverse Events [CTCAE] version 5.0) from prior anticancer therapy.
Known central nervous system involvement Multiple Myeloma (MM). Has any of the following conditions: Nonsecretory MM. Active Plasma cell leukemia i.e., either 20% of peripheral white blood cells or > 2.0 × 10^9L circulating plasma cells by standard differential. Waldenstrom's macroglobulinemia. Light chain amyloidosis. Polyneuropathy, organomegaly, endocrinopathy, monoclonal protein and skin changes (POEMS) syndrome. Major surgery within 4 weeks prior to first dose or planned study participation. Acute infections within 14 days prior to first dose of study drug requiring therapy (antibiotic, antifungal or antiviral). Uncontrolled diabetes or hypertension within 14 days prior to first dose. Peripheral neuropathy >= Grade 3 or >= Grade 2 with pain within 2 weeks prior to first dose. Known active infection of evidence of active hepatitis B, evidence of active hepatitis C, human immunodeficiency virus.

Further Information at ClinicalTrials.gov

	Medical Oncology		
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AMLSG 33-22/MOLIVO-1

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

Phase Ia/IIb study of PHD inhibitor molidustat in combination with IDH1 inhibitor ivosidenib in IDH1-mutated relapsed/refractory AML or MDS/AML patients

Recruitment Status: RECRUITING
Condition: Myelodysplastic syndrom
Primary Completion Date: ongoing
Intervention/ Treatment: Drug (Ivosidenib)

Inclusion Criteria: 1. Age ≥ 18 years. 2. Patients with diagnosis of relapsed/refractory AML or relapsed/refractory MDS/AML with 10-19% bone marrow blasts at initial diagnosis and at screening defined according to 2022 ICC criteria after at least one prior line of treatment who are ineligible for intensive salvage chemotherapy and/or allogeneic hematopoietic cell transplantation or who decline standard treatment. 3. IDH1-mutated as determined by a validated assay at a specific site (IDH1 R132). 4. ECOG 0-2. 5. Adequate hepatic function as evidenced by: • Serum total bilirubin ≤ 3 × upper limit of normal (ULN) unless considered due to Gilbert's syndrome, or leukemic involvement of the liver – following written approval by the Principal Investigator. • Aspartate aminotransferase (AST) and alanine aminotransferase (ALT), ≤ 3.0 × ULN, unless considered due to leukemic involvement of the liver, following written approval by the Principal Investigator. 6. Adequate renal function as evidenced by creatinine clearance ≥ 30 mL/min based on the CKD-EPI formula for glomerular filtration rate (GFR). 7. Able to understand and willing to sign an informed consent form (ICF). 8. Written informed consent. 9. Female patient must either: • Be of non-childbearing potential: o Postmenopausal prior to screening defined as: □ ≥ 50 years and in postmenopausal state > 1 year or □ < 50 years and in postmenopausal state > 1 year with serum FSH > 40 IU/l and serum estrogen < 30 ng/l or a negative estrogen test, both at screening or o Documented surgically sterile by bilateral tubal ligation or bilateral oophorectomy or status post-hysterectomy or uterine agenesis (at least 1 month prior to screening).
• If of childbearing potential:
o Agree not to try to become pregnant during the study and for 6 months after the final study drug administration o And have a negative serum pregnancy test at screening o And, if heterosexually active, agree to consistently use highly effective* contraception per locally accepted standards in addition to a barrier method starting at screening and throughout the study period and for 6 months after the final study drug administration.
* Highly effective forms of birth control include: i. Established intrauterine device (IUD) or intrauterine system (IUS). ii. Bilateral tubal occlusion. iii. Vasectomy (A vasectomy is a highly effective contraception method provided the absence of sperm has been confirmed. If not, an additional highly effective method of contraception should be used). iv. Male is sterile due to a bilateral orchiectomy. v. Sexual abstinence is considered a highly effective method only if defined as refraining from heterosexual activity during the entire period of risk associated with the study drug. The reliability of sexual abstinence needs to be evaluated in relation to the duration of the clinical study and the preferred and usual lifestyle of the patient. * List is not all inclusive. Prior to enrollment, the investigator is responsible for confirming patient will utilize highly effective forms of birth control per the requirements of the CTFG Guidance document 'Recommendations related to contraception and pregnancy testing in clinical trials', September 2020 (and any updates thereof) during the protocol defined period. Since ivosidenib may decrease the concentrations of hormonal contraceptives, it is considered to use alternative methods of contraception as mentioned above (see section 5.5). • Female patient must agree not to breastfeed starting at screening and throughout the study period, and for 2 months after the final study drug administration. • Female patient must not donate ova starting at screening and throughout the study period, and for 6 months after the final study drug administration. 10. Male patient and their female partners who are of childbearing potential must be using highly effective contraception per locally accepted standards (see above *highly effective forms of birth control) in addition to a barrier method starting at screening and continue throughout the study period and for 4 months and 1 week after the final study drug administration. 11. Male patient must not donate sperm starting at screening and throughout the study period and for 4 months and 1 week after the final study drug administration. 12. Patient agrees not to participate in another interventional study while on treatment. 13. Ability to swallow and retain oral medication, no known malabsorption syndrome, adequate organ function.

Further Information at www.clinicaltrialsregister.eu

	Medical Oncology		
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AMLSG BIO

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

Registry Study on Patient Characteristics, Biological Disease Profile and Clinical Outcome in Acute Myeloid Leukemia and Related Neoplasms, and Higher Risk Myelodysplastic Syndrome - The Biology and Outcome (BiO)-Project

Recruitment Status: RECRUITING
Condition: AML, MDS with excess blasts 2
Primary Completion Date: ongoing
Intervention/ Treatment: Observational

Inclusion Criteria:
Patients with suspected diagnosis of AML and related precursor neoplasms, acute leukemias of ambiguous lineages, higher risk MDS (MDS with excess blasts 2 [MDS-EB2]), and myeloid neoplasm with germline predisposition, newly diagnosed or relapsed/refractory, classified according to the World Health Organization (WHO) classification
Age ≥ 18 years. There is no upper age limit.
Signed written informed consent

Exclusion Criteria:
Severe neurological or psychiatric disorder interfering with ability to give an informed consent
No consent for registration, storage and processing of the individual patient and disease characteristics and course as well as information of the family physician about study participation
No consent for biobanking of patient's biological specimens and performance of analyses on stored material.

Further Information at ClinicalTrials.gov

	Medical Oncology		
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ARASAFE

A Randomised, Phase 3 Trial Comparing 3-weekly Docetaxel 75 mg/m2 (in a 3 Week Cycle) Versus 2-weekly Docetaxel 50 mg/m2 (in a 4 Week Cycle) in Combination With Darolutamide + ADT in Patients With mHSPC

Recruitment Status: RECRUITING
Condition: Metastatic Hormone-Sensitive Prostate Cancer (mHSPC)
Primary Completion Date: 2025-02
Intervention/ Treatment: DRUG (Standard ADT [androgen deprivation therapy]/ Standard Darolutamide/ Docetaxe)l

Inclusion Criteria:
Written informed consent
Males ≥18 years of age
Histologically or cytologically confirmed adenocarcinoma of prostate
Investigator assessed metastatic disease documented either by a positive bone scan, or for soft tissue or visceral metastases, either by contrast-enhanced abdominal/pelvic/chest computed tomography (CT) or magnetic resonance imaging (MRI) scan assessed. Metastatic disease is defined as either malignant lesions in bone scan or soft tissue/visceral lesions according to Response Evaluation Criteria In Solid Tumors (RECIST) 1.1. Lymph nodes are measurable if the short axis diameter is ≥15 mm, soft tissue/visceral lesions are measurable if the long axis diameter is ≥10 mm.
Subjects with lymph node metastases only (either below the aortic bifurcation (N1) or above the aortic bifurcation (M1a)) will not be eligible for the study.
Subjects must be candidates for ADT, docetaxel and darolutamide therapy per Investigator's judgment
Started ADT (LHRH agonist/antagonist or orchiectomy) with or without first generation anti-androgen, but no longer than 12 weeks before randomization. For subjects receiving LHRH agonists, treatment in combination with a first generation anti-androgen for at least 4 weeks, prior to randomization is recommended. First generation anti-androgen has to be stopped prior to randomization.
An Eastern Cooperative Oncology Group performance status of 0 or 1
Blood counts at Screening: hemoglobin ≥9.0 g/dL, absolute neutrophil count ≥1.5x109/L, platelet count ≥100x109/L (subject must not have received any growth factor within 4 weeks or a blood transfusion within 7 days of the hematology laboratory sample obtained at Screening)
Screening values of serum alanine aminotransferase and/or aspartate transaminase ≤1.5x upper limit of normal (ULN), total bilirubin ≤ULN, creatinine ≤2.0x ULN
Sexually active male subjects must agree to use condoms as an effective barrier method and refrain from sperm donation, and/or their female partners of reproductive potential to use a method of effective birth control, during the treatment with darolutamide and for 3 months after the end of the treatment with darolutamide and 6 months after treatment with docetaxel.

Further Information at ClinicalTrials.gov

	Medical Oncology		
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BNT 116-01 LuCa-MERIT-1

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

LuCa-MERIT-1: First-in-human, Open Label, Phase I Dose Confirmation Trial Evaluating the Safety, Tolerability and Preliminary Efficacy of BNT116 Alone and in Combinations in Patients With Advanced Non-small Cell Lung Cancer

Recruitment Status: RECRUITING
Condition: Non-Small Cell Lung Cancer
Primary Completion Date: 2026-01
Intervention/ Treatment: Biological (**BNT116/ Cemiplimab**) DRUG (**Docetaxel/ Carboplatin/ Paclitaxel**)

Inclusion Criteria:

Patients must have histologically confirmed NSCLC and measurable disease by RECIST v1.1. Note: Patients in Cohort 1 and Cohort 5 do not have to present with measurable disease.
Patients in Cohorts 1 to 4 must present with unresectable Stage III or metastatic Stage IV NSCLC by American Joint Commission on Cancer (AJCC) Cancer Staging Manual, Eighth Edition.
Patients in Cohort 5 must present with unresectable Stage III NSCLC by AJCC Cancer Staging Manual, Eighth Edition before receiving pre-trial chemoradiotherapy.
Patients in Cohort 6 with the initial diagnosis of resectable Stage II and Stage III NSCLC by AJCC Cancer Staging Manual, Eighth Edition.
Patients in Cohorts 2, 4, 5, and 6 must be able to tolerate (additional) anti-PD-1 therapy (i.e., did not permanently discontinue anti-programmed death protein 1 [PD-1] / programmed death ligand 1 [PD-L1] therapy due to toxicity).
Patients in Cohorts 2, 3, and 6 must have an Eastern Cooperative Oncology Group performance status (ECOG-PS) ≤1. Patients in Cohort 1, 4, and 5 with an ECOG-PS of 0-2 are eligible.

Further Information at ClinicalTrials.gov

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BO44157

This study will evaluate the efficacy, safety, and pharmacokinetics of tobemstomig alone or in combination with tiragolumab compared with atezolizumab in participants with previously untreated, locally advanced or metastatic urothelial cancer (mUC) who are ineligible to receive a platinum containing chemotherapy.

Recruitment Status: RECRUITING
Condition: Urothelial Cancer
Primary Completion Date: 2026-12-030
Intervention/ Treatment: DRUG (**Atezolizumab/ Tobemstomig/ Tiragolumab**)

Inclusion Criteria:
Inclusion Criteria:
Eastern Cooperative Oncology Group (ECOG) Performance Status of ≤ 2
Histologically or cytologically documented locally advanced or metastatic transitional cell carcinoma (TCC) of the urothelium. Participants with squamous, sarcomatoid, micropapillary, and glandular variant histologies are eligible for inclusion in the study, provided that a urothelial component is present in the tumor specimen. Participants with other variant histologies or pure variant histologies are not eligible for inclusion in this study
Ineligible ("unfit") to receive platinum-based chemotherapy
No prior chemotherapy for inoperable locally advanced or metastatic or recurrent urothelial carcinoma (UC)
Measurable disease; at least one measurable lesion as defined by response evaluation criteria in solid tumors, version 1.1 (RECIST v1.1)
Availability of a representative leftover tumor specimen that is suitable for determination of PD-L1 status as assessed by a central laboratory
Adequate hematologic and end organ function
Negative for hepatitis B and hepatitis C virus (HCV)
Adequate cardiovascular function

Further Information at ClinicalTrials.gov

	Medical Oncology		
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CA 055-001

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

A Phase 1, Multicenter, Open-label Study to Evaluate the Pharmacokinetics of CC-486 (Onureg®) in Subjects With Moderate or Severe Hepatic Impairment Compared With Normal Hepatic Function in Adult Subjects With Myeloid Malignancies

Recruitment Status: RECRUITING
Condition: Hepatic Insufficiency / Neoplasms
Primary Completion Date: 2025-06-01
Intervention/ Treatment: DRUG (**ONUREG**)

Inclusion Criteria:

Documented diagnosis of Myelodysplastic syndrome, Acute myeloid leukemia, Non-acute promyelocytic leukemia, Chronic myelomonocytic leukemia, Philadelphia-negative myeloproliferative neoplasms, Myelodysplastic syndrome Myeloproliferative neoplasms overlap, Accelerated phase and blast phase Myeloproliferative neoplasms, Blastic plasmacytoid dendritic cell neoplasm according to the World Health Organization (WHO) 2016 classification. Life expectancy of ≥ 3 months. Stable renal function without dialysis for at least 2 months prior to investigational product administration. Has moderate or severe hepatic impairment as defined by National Cancer Institute Organ Dysfunction Working Group criteria.

Exclusion Criteria:

Chemotherapy or radiotherapy within 2 weeks or 5 half-lives, whichever is longer, prior to the first day of investigational product administration
Persistent, clinically significant non-hematologic toxicities from prior therapies which have not recovered to < Grade 2
Any condition including the presence of laboratory abnormalities, which places the participant at unacceptable risk if he/she were to participate in the study
History of inflammatory bowel disease, celiac disease, prior gastrectomy, gastric bypass, upper bowel removal, or any other gastrointestinal disorder or defect that would interfere with the absorption of the investigational product and/or predispose the participant to an increased risk of gastrointestinal toxicity
Other protocol-defined inclusion/exclusion criteria apply

Further Information at ClinicalTrials.gov

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CO43476 (CAMMA 2)

Hubertus Wald Tumorzentrum
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A Phase I/II, Open-Label, Multi-Cohort Study to Evaluate the Efficacy and Safety of Cevostamab in Prior B Cell Maturation Antigen-Exposed Patients With Relapsed/Refractory Multiple Myeloma

Recruitment Status: RECRUITING
Condition: Multiple Myeloma
Primary Completion Date: 2027-02-26
Intervention/ Treatment: DRUG (**Cevostamab/ Tocilizumab**)

Inclusion Criteria:

Inclusion Criteria:
Documented diagnosis of MM based on standard International Myeloma Working Group (IMWG) criteria
Evidence of progressive disease based on investigators determination of response by IMWG criteria on or after their last dosing regimen
Prior BCMA ADC or CAR-T Cohort: participants who have received a BCMA-targeted CAR-T or ADC therapy and are triple-class relapsed or refractory
Prior BCMA Bispecific Cohort: participants who have received a BCMA-targeting T-cell-dependent bispecific (TDB) antibody and are triple-class relapsed or refractory
Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1
Life expectancy is at least 12 weeks
Agreement to protocol-specified assessments, including bone marrow biopsy and aspirate samples as detailed in the protocol
Resolution of AEs from prior anti-cancer therapy to Grade =< 1
For female participants of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraception during the treatment period and for at least 5 months after the final dose of cevostamab and for 3 months after the last dose of tocilizumab was administered
For male participants: agreement to remain abstinent (refrain from heterosexual intercourse) or use a condom, and agree to refrain from donating sperm during the treatment period and for at least 2 months after the final dose of tocilizumab (if applicable) to avoid exposing the embryo

Further Information at ClinicalTrials.gov

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CLL-16

Hubertus Wald Tumorzentrum
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This multicenter, prospective, open-label, randomized, superiority phase 3 study is designed to demonstrate that treatment with a triple combination of acalabrutinib, obinutuzumab and venetoclax (GAVe) prolong the progression-free survival (PFS) as compared to treatment with the combination of obinutuzumab and venetoclax (GVe) in pa-tients with high risk CLL (defined as having at least one of the follow-ing risk factors: 17p-deletion, TP53-mutation or complex karyotype).

Recruitment Status: RECRUITING
Condition: CLL
Primary Completion Date: 2026-05
Intervention/ Treatment: DRUG (**Obinutuzumab/ Venetoclax/ Acalabrut**inib)

Inclusion Criteria:
Documented CLL/SLL requiring treatment according to iwCLL criteria
Age at least 18 years
At least one of the following risk factors: 17p-deletion, TP53-mutation or complex karyotype (defined as defined as the presence of 3 or more chromosomal aberrations in 2 or more metaphases.).
Life expectancy ≥ six months
Adequate bone marrow function indicated by a platelet count >30 x10^9/l
Creatinine clearance ≥ 30ml/min
Adequate liver function as indicated by a total bilirubin ≤ 2 x, AST/ ALT ≤ 2.5 x the institutional ULN value, unless directly attributable to the patient's CLL or to Gilbert's Syndrome
Negative testing for hepatitis B (HbsAg negative and anti-HBc negative; patients positive for anti-HBc may be included if PCR for HBV DNA is negative and HBV-DNA PCR is performed every month until 12 months after last treatment cycle),or hepatitis C (negative testing for hepatitis C RNA within 6 wee
ks prior to registration for study screening (i.e. PCR only required when serology was positive))
ECOG (Eastern Cooperative Oncology Group Performance Status) status 0-2
Exclusion Criteria:
Any prior CLL-specific therapies (except corticosteroid treatment administered due to necessary immediate intervention; within the last 10 days before start of study treatment, only dose equivalents up to 20 mg prednisolone are permitted)
Absence of high risk disease (17p-deletion, TP53-mutation complex karyotype
An individual organ/system impairment score of 4 as assessed by the CIRS definition (e.g. advanced cardiac disease (NYHA class 3 or 4) limiting the ability to receive the study treatment or any other life-threatening illness, medical condition or organ system dysfunction that, in the investigator´s opinion, could compromise the patients safety or interfere with the absorption or metabolism of the study drugs (e.g. inability to swallow tablets or impaired resorption in the gastrointestinal tract)
Transformation of CLL (Richter transformation)
Malignancies other than CLL currently requiring systemic therapies
Uncontrolled or active infection of HIV/PML or any other active infection
Anticoagulant therapy with warfarin or phenoprocoumon
Pregnant women and nursing mothers

Further Information at ClinicalTrials.gov

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EMN29

This phase 3 randomized, open-label multicenter trial will compare the efficacy, safety and the impact on health-related quality of life (HR-QoL) of SPd versus EloPd in pomalidomide-naïve patients with MM who have received 1 to 4 prior anti-MM regimens and been treated with an immunomodulatory imide drug (IMiD), proteasome inhibitor (PI) and an anti-CD38 monoclonal antibody (mAb).

Recruitment Status: RECRUITING
Condition: Multiple Myeloma
Primary Completion Date: 2026-03
Intervention/ Treatment: DRUG **(Selinexor/ Elotuzumab/ Pomalidomide/ Dexamethasone Oral**)

Inclusion Criteria: Relapsed or refractory MM with measurable disease per IMWG guidelines as defined by at least 1 of the following: Serum M-protein ≥0.5 g/dL (≥5 g/L) by serum protein electrophoresis (SPEP) or, for immunoglobulin (Ig) A or D myeloma, by quantitative serum IgA or IgD levels ≥ 0.5 g/dL. Urinary M-protein excretion ≥200 mg/24 hours Serum free light chain (FLC) ≥100 mg/L, provided that the FLC ratio is abnormal (normal FLC ratio: 0.26 to 1.65) Received at least 1 and no more than 4 prior anti-MM lines of therapy. Induction therapy followed by stem cell transplant and consolidation/maintenance therapy will be considered as 1 line of therapy. Prior therapy that includes ≥ consecutive cycles of lenalidomide and a proteasome inhibitor given alone or in combination Prior therapy with an anti-CD3 mAb as part of their immedicate last treatment prior to study entry (Before protocol version2.0, patient with any prior therapy with an anti-CD3 mAb were eligible for the study). Eastern Cooperative Oncology Group (ECOG) performance status of ≤2. Resolution of any clinically significant non-hematological toxicities (if any) from previous treatments to Grade ≤1 by Cycle 1 Day 1 (C1D1). Patients with Grade 2 non-hematological toxicities may be included. Adequate hepatic function within 28 days prior to C1D1: Total bilirubin <2 × upper limit of normal (ULN) (except patients with Gilbert's syndrome who must have a total bilirubin of <3 × ULN) Aspartate aminotransferase (AST) and alanine aminotransferase (ALT) <2.5 × ULN Adequate renal function within 28 days prior to C1D1 (estimated creatinine clearance [CrCl] of ≥15 mL/min (not requiring dialysis), calculated using the formula of Cockcroft and Gault or measured by 24-hour urine collection). Adequate hematopoietic function within 7 days prior to C1D1 defined as absolute neutrophil count ≥1.5 x 109/L , hemoglobin ≥8.5 g/dL, and platelet count ≥100 x 109/L (patients for whom <50% of bone marrow nucleated cells are plasma cells) or ≥75 x 109/L (patients for whom ≥50% of bone marrow nucleated cells are plasma cells). Patients receiving hematopoietic growth factor support, including erythropoietin, darbepoetin, granulocyte-colony stimulating factor (G-CSF), granulocyte macrophage-colony stimulating factor (GM-CSF), and platelet stimulators (e.g., eltrombopag, romiplostim, or interleukin-11) must have a 2-week interval between growth factor support and the Screening assessments, but they may receive growth factor support during the study. Patients must have: At least a 2-week interval from the last red blood cell (RBC) transfusion prior to the Screening hemoglobin assessment, and At least a 1-week interval from the last platelet transfusion prior to the Screening platelet assessment. However, patients may receive RBC and/or platelet transfusions as clinically indicated per institutional guidelines during the study. Patients with active hepatitis B virus (HBV) are eligible if antiviral therapy for hepatitis B has been given for >8 weeks and viral load is <100 IU/mL. Patients with evidence of non-active HBV should be discussed with the Medical Monitor and should be monitored or receive prophylaxis at the discretion of the Investigator and study site institutional guidelines Patients with a history of hepatitis C virus (HCV) are eligible if they have received adequate curative anti-HCV treatment and HCV viral load is below the limit of quantification. Patients with a history of human immunodeficiency virus (HIV) are eligible if they have CD4+ T cell counts ≥350 cells/µL, negative viral load, and no history of acquired immunodeficiency syndrome (AIDS)-defining opportunistic infections in the last year and should be on established antiretroviral therapy (ART) for at least 4 weeks. Female patients of childbearing potential must have a negative serum pregnancy test within 10 to 14 days and a second test within 24 hours prior to the first dose of study treatment. Female patients of childbearing potential and fertile male patients who are sexually active must use highly effective methods of contraception throughout the study and for 3 months following the last dose of study treatment. Age ≥18 years at the time of signing informed consent. Written informed consent signed in accordance with federal, local, and institutional guidelines. Patients must be able and willing to take enteric-coated aspirin according to clinical practice, or if history of prior thrombotic disease, must be fully anticoagulated with warfarin (international normalized ratio [INR] 2-3) or be treated with full-dose, low molecular weight heparin, as if to treat deep venous thrombosis (DVT)/pulmonary embolism (PE) at the Investigator's discretion. For patient on warfarin, INR should be repeated as clinically indicated. Use of alternative anticoagulants, such as direct oral anticoagulants, may be considered per Investigator discretion.

Further Information at: ClinicalTrials.gov

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Entitäten

FIBROSARC

A Phase III Study Comparing the Efficacy of the Combination of Doxorubicin and the Tumor-targeting Human Antibody-cytokine Fusion Protein L19TNF to Doxorubicin Alone as First-line Therapy in Patients With Advanced or Metastatic Soft Tissue Sarcoma

Recruitment Status: RECRUITING
Condition: Soft Tissue Sarcoma
Primary Completion Date: 2025-12-31
Intervention/ Treatment: DRUG **(Onfekafusp/Doxorubicin**)

Inclusion Criteria: Patients aged 18-75 years.
Patients must have histological evidence of advanced unresectable and/or metastatic high-grade soft tissue sarcoma (grade 2 - 3 according to the FNCLCC grading system) not amenable to curative treatment with surgery or radiotherapy and for which doxorubicin treatment is considered appropriate. Participants with Osteosarcoma, Chondrosarcoma, Ewing Sarcoma/ Primitive Neuroectodermal Tumor (PNET), Kaposi's Sarcoma, Dermatofibrosarcoma protuberans, and Gastrointestinal Stromal Tumors (GIST) will be excluded
Patients must have at least one unidimensionally measurable lesion by computed tomography as defined by RECIST criteria 1.1. This lesion should not have been irradiated during previous treatments.
Life expectancy of at least 3 months.
Eastern Cooperative Oncology Group (ECOG) performance status of ≤ 2.
Documented negative test for HIV-HBV-HCV. For HBV serology: the determination of HBsAg, anti-HBsAg-Ab and anti-HBCAg-Ab is required. In patients with serology documenting previous exposure to HBV (i.e., anti-HBs Ab with no history of vaccination and/or anti-HBc Ab), negative serum HBV-DNA is required. For HCV: HCV-RNA or HCV antibody test. Subjects with a positive test for HCV antibody but no detection of HCV-RNA indicating no current infection are eligible.
Female patients: negative serum pregnancy test at screening for women of childbearing potential (WOCBP)*. WOCBP must agree to use, from the screening to six months following the last administration of L19TNF and/or Doxorubicin, highly effective contraception methods, as defined by the "Recommendations for contraception and pregnancy testing in clinical trials" issued by the Head of Medicine Agencies' Clinical Trial Facilitation Group (www.hma.eu/ctfg.html) and which include, for instance, progesterone-only or combined (estrogen- and progesterone-containing) hormonal contraception associated with inhibition of ovulation, intrauterine devices, intrauterine hormone-releasing systems, bilateral tubal occlusion, vasectomized partner or sexual abstinence. Male patients: Male subjects able to father children must agree to use two acceptable methods of contraception from the screening to four months following the last administration of L19TNF and/or Doxorubicin (e.g. condom with spermicidal gel). Double-barrier contraception is required.
Informed consent signed and dated to participate in the study.
Willingness and ability to comply with the scheduled visits, treatment plan, laboratory tests and other study procedures.

Further Information at: ClinicalTrials.gov

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GMALL-Bliven

Hubertus Wald Tumorzentrum
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Venetoclax in Addition to Blinatumomab in Adult Patients With Relapsed/Refractory B Cell Precursor Acute Lymphoblastic Leukemia Relapsed/Refractory B Cell Precursor Acute Lymphoblastic Leukemia (BCP-ALL)

Recruitment Status: RECRUITING
Condition: ALL, Recurrent, Adult
Primary Completion Date: 2025-06-30
Intervention/ Treatment: DRUG **(Blinatumomab/ Venetoclax**)

Inclusion Criteria: Written informed consent in accordance with federal, local, and institutional guidelines. The patient must provide informed consent prior to the first screening procedure Age ≥ 18 years Eastern Cooperative Oncology Group (ECOG) performance status of ≤ 2 Availability of patient-specific molecular MRD markers of immunoglobulin/T-cell receptor gene rearrangementsas assessed by PCR with a sensitivity of at least 10E-04 Diagnosis of Philadelphia negative, CD19-positive B-precursor acute lymphoblastic leukemia according to WHO classification:
Refractory BCP-ALL to primary induction therapy, including at least three cycles of standard chemotherapy
Untreated first relapse of BCP-ALL with first remission duration < 12 months or
Second or greater relapse of BCP-ALL or refractory relapse or
Relapse of BCP-ALL any time after allogeneic HSCT or
Positivity of MRD marker of immunoglobulin/T-cell receptor gene rearrangements of greater than 0.01% if in first or second remission of BCP-ALL
Negative pregnancy test < 7 days before first study drug in women of childbearing potential, defined as all women physiologically capable of becoming pregnant, unless they fulfil at least one of the following criteria:
Post-menopausal (i.e. 12 months of natural amenorrhea or 6 months of amenorrhea with Serum FSH > 40 U/ml
Post-operative after bilateral ovariectomy with or without hysterectomy
Continuous and correct application of a contraception method with a Pearl index of < 1% (e.g. implants, depots, oral contraceptives, intrauterine device) from initial study drug administration until at least 3 months after the last dose of study drug. A hormonal contraception method must always be combined with a barrier method (e.g. condom)
Sexual abstinence Vasectomy of the sexual partner Ability to understand and willingness to sign a written informed consent Willingness to participate in the registry of the German Multicenter Study Group for Adult ALL (GMALL)

Further Information at: ClinicalTrials.gov

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GO44145 - SKYGLO

A Phase III, Multicenter, Randomized, Open-Label Study Comparing the Efficacy and Safety of Glofitamab (RO7082859) in Combination With Polatuzumab Vedotin Plus Rituximab, Cyclophosphamide, Doxorubicin, and Prednisone (Pola-R-CHP) Versus Pola-R-CHP in Previously Untreated Patients With Large B-Cell Lymphoma

Recruitment Status: RECRUITING
Condition: Large B-Cell Lymphoma
Primary Completion Date: 2026-06-01
Intervention/ Treatment: DRUG **(Glofitamab/ Polatuzumab vedotin/ Rituximab/ Cyclophosphamide/ Doxorubicin/ Prednisone**)

Inclusion Criteria: Inclusion Criteria:
Previously untreated participants with CD20-positive LBCL
Ability to provide tumor tissue
International prognostic index (IPI) score 2-5
Eastern cooperative oncology group (ECOG) performance status of 0, 1, or 2
At least one bi-dimensionally measurable lesion, defined as > 1.5 cm in its longest dimension as measured by CT or MRI
Left ventricular ejection fraction (LVEF) >/=50% on cardiac multiple-gated acquisition (MUGA) scan or cardiac echocardiogram (ECHO)
Adequate hematologic function
Negative HIV test at screening with exceptions as defined by the protocol
Negative SARS-CoV-2 antigen or PCR test

Further Information at: ClinicalTrials.gov

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GMMG-HD10 / DSMM-XX / 64007957MMY2003, MajesTEC-5

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A Phase 2 Study to Evaluate Safety and Efficacy of Teclistamab in Combination with Daratumumab, Lenalidomide, and Dexamethasone with or without Bortezomib as Induction Therapy and Teclistamab in Combination with Daratumumab and Lenalidomide as Maintenance Therapy in Participants with Newly Diagnosed Transplant Eligible Multiple Myeloma.

Recruitment Status: RECRUITING
Condition: Multiple Myeloma
Primary Completion Date: 2026-10-15
Intervention/ Treatment: DRUG **(Teclistamab/ Daratumumab/ Dexamethasone/ Lenalidomide/ Bortezomib**)

Inclusion Criteria: - 18 years of age to 70 years of age, inclusive
Have an ECOG performance status score of 0 to 2 at screening
Have clinical laboratory values meeting prespecified criteria during the Screening Phase.
Participants in Arm A, A1 and Arm B must also satisfy all of the following criteria to be enrolled in the study:
1. Documented multiple myeloma requiring treatment as defined by the criteria below:
Multiple myeloma diagnosis according to the IMWG diagnostic criteria
Measurable disease at screening as defined by any of the following:
- Serum M-protein level ≥1.0 g/dL or
- Urine M-protein level ≥200 mg/24 hours or
- Serum immunoglobulin free light chain level ≥10 mg/dL and abnormal serum free light chain ratio

2. Newly diagnosed participants for whom HDT and ASCT is part of the intended treatment plan.
Participants Arm C and C1 must also satisfy all of the following criteria:
- Newly diagnosed multiple myeloma according to IMWG criteria.
- Must have received 4 to 6 cycles of 3 or 4 drug-induction therapy that includes a proteasome inhibitor and/or an IMiD with or without anti-CD38 monoclonal antibody and a single or tandem ASCT. Post-ASCT consolidation is permitted for up to 2 cycles as long as the total number of induction plus consolidation cycles does not exceed 6.

3 Must have received only one line of therapy and achieved at least a PR as per IMWG 2016 without evidence of progression at the time of enrollment.
4. Must have received HDT and ASCT within 12 months of the start of induction therapy and be within 6 months of the last ASCT (7 months for participants who received consolidation) at the time of enrollment.

Further Information at: ClinicalTrials.gov

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IMMU-132-06 / TROPHY U-01

A Phase II Open-Label Study of Sacituzumab Govitecan in Unresectable Locally Advanced/Metastatic Urothelial Cancer.

Recruitment Status: RECRUITING
Condition: Metastatic Urothelial Cancer
Primary Completion Date: 2024-07
Intervention/ Treatment: DRUG **(Sacituzumab Govitecan-hziy/ Pembrolizumab/ Cisplatin/ Avelumab/ Zimberelimab/ Carboplatin/n Gemcitabine/ Domvanalimab**)

Inclusion Criteria: Female or male individuals, ≥ 18 years of age (19 Years old for South Korea).
Individuals with histologically confirmed urothelial cancer (UC).
Eastern Cooperative Oncology Group (ECOG) Performance status score of 0 or 1.
Cohort 1: Have had progression or recurrence of urothelial cancer following receipt of platinum-containing regimen (cisplatin or carboplatin):
Received a first-line platinum-containing regimen in the metastatic setting or for inoperable locally advanced disease;
Or received neo/adjuvant platinum-containing therapy for localized muscle-invasive urothelial cancer, with recurrence/progression ≤12 months following completion of therapy.
Cohort 1: In addition to above criterion, have had progression or recurrence of urothelial cancer following receipt of an Anti-programmed Cell Death Protein 1 (anti-PD-1)/ Anti-programmed Death Ligand 1 (PD-L1) therapy.
Cohort 2: Were ineligible for platinum-based therapy for first line metastatic disease and have had progression or recurrence of urothelial cancer after a first-line therapy for metastatic disease with anti-PD-1/PD-L1 therapy. Individual may not have received any platinum for treatment of recurrent, metastatic or advanced disease.
Cohort 3: Progression or recurrence of UC following a platinum containing regimen in the metastatic setting, or progression or recurrence of UC within 12 months of completion of platinum-based therapy as neoadjuvant or adjuvant therapy.
Cohort 4: Individual has not received any platinum-based chemotherapy in the metastatic or unresectable locally advanced setting. Creatinine clearance of at least 50 mL/min calculated by Cockcroft-Gault formula or another validated tool. For individuals receiving cisplatin at 70 mg/m^2 on Day 1 of every 21-day cycle, a creatinine clearance of least 60 mL/min calculated by Cockcroft -Gault formula or another validated tool is required. Individuals with creatinine clearance between 50 to 59 mL/min are to receive a split dose of cisplatin (35 mg/m^2 Day 1 and Day 8 of every 21-day cycle).
Cohorts 4, 5, 6: Archival tumor tissue comprising muscle-invasive or metastatic urothelial carcinoma, or a biopsy of metastatic urothelial carcinoma.
Cohort 5: Individuals received at least 4 cycles and no more than 6 cycles of GEM + cisplatin. No other chemotherapy regimens are allowed in this cohort, with the exception of prior adjuvant or neoadjuvant systemic therapy with curative intent after > 12 months from completion of therapy.
No evidence of progressive disease following completion of first-line chemotherapy (ie, CR, PR, or SD per RECIST v1.1 guidelines as per investigator).
Treatment-free interval of 4 to 10 weeks since the last dose of chemotherapy.
Cohort 6: Cis-ineligible and no prior therapy for metastatic disease or for unresectable locally advanced disease. Checkpoint inhibitor therapy naïve or >12 months from completion of adjuvant therapy are permitted.
Cohorts 4 and 6: Have measurable disease by CT or MRI as per RECIST 1.1 criteria. Tumor lesions situated in a previously irradiated area are considered measurable if progression has been demonstrated in such lesions.
Cohorts 1, 2, 3 and 5: Creatinine clearance ≥ 30 mL/min as calculated by the Cockcroft-Gault formula unless otherwise specified
Adequate renal and hepatic function.
Adequate hematologic parameters without transfusional support.
Individuals must have a 3-month life expectancy.

Further Information at: ClinicalTrials.gov

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MCL Elderly III

Venetoclax in combination with the BTK inhibitor Ibrutinib and Rituximab or conventional chemotherapy (Bendamustine) and Ibrutinib and Rituximab in patients with treatment naive Mantle Cell Lymphoma not eligible for high dose therapy.

Recruitment Status: RECRUITING
Condition: MCL
Primary Completion Date: /
Intervention/ Treatment: follow Link!

Inclusion Criteria: Histologically confirmed diagnosis of MCL according to WHO classification
- previously untreated stage II-IV (Ann Arbor)
- ≥ 60 years and not suitable for autologous SCT
- At least 1 measurable lesion; in case of bone marrow infiltration only, bone marrow aspiration and biopsy is mandatory for all staging evaluations.
- ECOG performance status ≤ 2

The following laboratory values at screening (unless related to MCL):
- Absolute neutrophil count (ANC) ≥ 1000 cells/µL
- Platelets ≥75.000 cells/µL
- Transaminases (AST and ALT) ≤3 x ULN
- Total bilirubin ≤ 2 x ULN unless other reason known (Gilbert-Meulengracht-Syndrome)
- Creatinine ≤ 2 mg/dL or eGFR ≥ 50 mL/min
- Written informed consent form according to ICH/EU GCP and national regulations
- Sexually active men with female partners of child-bearing potential potential must agree to use highly effective contraceptives
- Histologisch bestätigte Diagnose von MCL gemäß WHO-Klassifikation
- Bisher unbehandeltes Stadium II-IV (Ann Arbor)
- ≥ 60 Jahre und nicht für eine autologe ASZT geeignet
- Mindestens 1 messbare Läsion; ausschließlich im Falle einer Knochenmarkinfiltration ist eine Knochenmarkaspiration und -biopsie für alle Staging-Bewertungen obligatorisch.
- ECOG ≤ 2

Die folgenden Laborwerte beim Screening (sofern nicht auf MCL bezogen):
- Absolute Neutrophilenzahl (ANC) ≥ 1000 Zellen/µL
- Thrombozyten ≥75.000 Zellen/µL
- Transaminasen (AST und ALT) ≤3 x ULN
- Gesamtbilirubin ≤ 2 x ULN, sofern kein anderer Grund bekannt ist (Gilbert-Meulengracht-Syndrom)
- Kreatinin ≤ 2 mg/dL oder eGFR ≥ 50 mL/min
- Schriftliche Einverständniserklärung gemäß ICH/EU GCP und nationalen Vorschriften
- Sexuell aktive Männer mit Partnerinnen im gebärfähigen Alter müssen sich verpflichten, hochwirksame Verhütungsmittel zu verwenden .

Further Information at: www.clinicaltrialsregister.eu

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MoMMent, 644075MMY4001

The purpose of this study is to assess in real-life clinical practice, over a 24-month period, the effectiveness and safety of current standard of care (SOC) antimyeloma treatments in participants with previously treated relapsed and/or refractory multiple myeloma.

Recruitment Status: RECRUITING
Condition: Relapsed/Refractory Multiple Myeloma
Primary Completion Date: 2024-11-30
Intervention/ Treatment: No intervention

Inclusion Criteria:

Have a documented diagnosis of multiple myeloma according to International myeloma working group (IMWG) diagnostic criteria
Received at least 3 prior lines of therapy (induction with or without hematopoietic stem cell transplant and with or without maintenance therapy is considered a single regimen).
Undergone at least 1 complete cycle of treatment for each line of therapy, unless progressive disease (PD) was the best response to the line of therapy
Have an Eastern Cooperative Oncology Group (ECOG) Performance Status grade of 0 or 1
Must not be pregnant or must not plan to become pregnant within the study period
Must have documented evidence of progressive disease based on participating physician's determination of response by the IMWG response criteria on or after the last regimen.
Participants with documented evidence of progressive disease within the previous 6 months and who are refractory or non-responsive to their most recent line of treatment afterwards are also eligible

Further Information at: ClinicalTrials.gov

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BO43936 (SKYSCRAPER)

This study will evaluate the efficacy, safety, and pharmacokinetics of tobemstomig (also known as RO7247669) in combination with axitinib alone or with tiragolumab (anti-TIGIT) and axitinib, as compared to pembrolizumab and axitinib in participants with previously untreated, unresectable locally advanced or metastatic clear-cell renal cell carcinoma (ccRCC).

Recruitment Status: RECRUITING
Condition: Renal Cell Carcinoma
Primary Completion Date: 2024-09-30
Intervention/ Treatment: DRUG (Tobemstomig/ Tiragolumab/ Pembrolizumab/ Axitinib)

Inclusion Criteria:
Inclusion Criteria:
Eastern Cooperative Oncology Group Performance Status (ECOG PS) of 0 or 1
International Metastatic RCC Database Consortium (IMDC) risk intermediate (score of 1 or 2) or poor (score of 3-6)
Measurable disease with at least one measurable lesion
Histologically confirmed ccRCC with or without sarcomatoid features
Negative for HIV, hepatitis B, or hepatitis C virus (HCV)

Further Information at: ClinicalTrials.gov

	Medical Oncology		
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uniCAR02-T / UC02-123-01

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

Multicenter, Open-label, Adaptive Design Phase I Trial With Genetically Modified T-cells Carrying Universal Chimeric Antigen Receptors (UniCAR02-T) in Combination With CD123 Target Module (TM123) for the Treatment of Patients With Hematologic and Lymphatic Malignancies Positive for CD123

Recruitment Status: RECRUITING
Condition: AML
Primary Completion Date: 2025-05
Intervention/ Treatment: DRUG (Cyclophosphamide (Non-IMP)/ Fludarabine (Non-IMP)/ TM123 (IMP)/ UniCAR02-T (IMP))

Inclusion Criteria:

Male or female patients, age ≥ 18 years
Documented definitive diagnosis of Relapsed or refractory AML (according to standard of care testing) and CD123 positivity of ≥20 % of blasts. MRD+ AML without morphological relapse or refractoriness may be included with the sponsor's approval
Eastern Cooperative Oncology Group (ECOG) of 0 to 1
Life expectancy of at least 2 months
Adequate renal and hepatic laboratory assessments
Adequate cardiac function
Permanent venous access existing (e.g. port-system) resp. acceptance of implantation of a device
Able to give written informed consent
Weight ≥ 45 kg
Negative pregnancy test; routinely using a highly effective method of birth control

Further Information at: ClinicalTrials.gov

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BELI(E)VE

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

Combination Treatment of Belantamab Mafodotin and Venetoclax in Treatment of Relapsed and Refractory t(11;14) Multiple Myeloma (Phase I/IIa) The BELI(E)VE-Trial

Recruitment Status: RECRUITING
Condition: Multiple Myeloma / Multiple Myeloma in Relapse
Primary Completion Date: 2026-11
Intervention/ Treatment: Drug: Belantamab mafodotin, Venetoclax

Inclusion Criteria:

Subjects must be ≥ 18 years of age. Subjects must have an Eastern Cooperative Oncology Group (ECOG) performance status of ≤ 2. Subjects must voluntarily sign and date an in-formed consent form Subjects must have had documented multiple myeloma requiring treatment as defined by the criteria below: Monoclonal plasma cells in the bone marrow > 10% and/or presence of a biopsy proven plasmacytoma at some point in their disease history requiring treatment according diag-nostic criteria (IMWG updated criteria 2014, Rajkumar et al. 2014) with measurable dis-ease at screening (serum M-protein > 500 mg/dL or urine M protein 200 mg/24h, in case of ligosecretory MM serum free light chain > 10mg/dL and abnormal kap-pa/lambda free light chain ratio). Cytogenetics/FISH confirming t(11;14). Prior treatment requirements: Phase 1: Subjects must have received at least 4 prior treatments (induction, high-dose, consolida-tion and maintenance is considered as one treatment line) and are refractory to at least one proteasome inhibitor, at least one im-munomodulatory drug and at least one mon-oclonal anti CD38 antibody. Subjects must have documented evidence of progressive disease during their last treat-ment. Phase 2: Subjects must have received at least 1 prior treatment line (induction, high-dose, consoli-dation and maintenance is considered as one treatment line). All patients must have received at least one proteasome inhibitor and at least one immunomodulatory agent and at least one anti CD38 monoclonal anti-body. Subjects must have documented evidence of progressive disease on or after the last treatment line. Phase 1+2 e. Subjects with a history of autologous SCT are eligible for study participation provided the following eligibility criteria are met: i. ASCT was >100 days prior to initiating study treatment, and ii. No active bacterial, viral, or fungal in-fection(s) present. Subjects must have adequate organ function, defined as follows: a. Hemoglobin ≥8.0 g/dL (without transfusion of red blood cells for the past 14 days) b. Absolute neutrophil count ≥ 1.5 x109/L (with-out growth factor support for the past 14 days) c. Platelet count more or equal 75 x109/L (with-out growth factor or platelet stimulating agents for the past 14 days) d. Adequate hepatic function per local laborato-ry reference range as follows: i. Aspartate aminotransferase (AST) ≤ 2,5 x upper limit of normal (ULN); ii. Alanine minotransferase (ALT) ≤ 2.5 x ULN iii. Total bilirubin ≤ 1.5 x ULN, except in subjects with congenital bilirubinemia, such as Gilbert syndrome (direct bili-rubin ≤ 1.5 x ULN). Isolated bilirubin ≥1.5xULN is acceptable if bilirubin is fractionated and direct bilirubin <35%. e. Subjects must have adequate renal function as demonstrated by eGFR ≥30 mL/min/ 1.73 m2 as calculated by Modified Diet in Renal Disease (MDRD) formula f. Spot urine (albumin/creatinine ratios (spot urine) <500 mg/g (56 mg/mmol) OR Urine Dipstick Negative/trace (if 1+ only eligible if confirmed <500 mg/g (56 mg/mmol) by albumin/creatinine ratio (spot urine from first void) g. Corrected serum calcium ≤ 14 mg/dL (≤3,5 mmol/L); or free ionized calcium < 6,5 mg/dL (<1,6 mmol/L). A female participant is eligible to participate if she is not pregnant or breastfeeding, and at least one of the following conditions applies: Is not a woman of childbearing potential (WOCBP) OR Is a WOCBP and using a contraceptive method that is highly effective Male participants are eligible to participate if they agree to the refrain from donating sperm and either bei abstinent from heterosexual intercourse or agree to use a highly effective contraceptive method during the intervention period and for 6 months after the last dose of study treatment to allow for clearance of any altered sperm
All subjects must agree to refrain from donating blood while on study drug and for 28 days after discontinuation from this study treatment. All subjects must agree not to share study medication. All prior treatment-related toxicities (defined by National Cancer Institute- Common Toxicity Criteria for Adverse Events (NCI-CTCAE), version 5.0) must be ≤ Grade 1 at the time of en-rolment except for alopecia.

Further Information at ClinicalTrials.gov

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CA 057-001 (SUCCESSOR-1)

A Phase 3, Two-Stage, Randomized, Multicenter, Open-Label Study Comparing Mezigdomide (CC-92480), Bortezomib and Dexamethasone (MEZIVd) Versus Pomalidomide, Bortezomib and Dexamethasone (PVd) in Subjects With Relapsed or Refractory Multiple Myeloma (RRMM): SUCCESSOR-1

Recruitment Status: RECRUITING
Condition: Multiple Relapsed or Refractory Multiple Myeloma
Primary Completion Date: 2025-11-03
Intervention/ Treatment: Drug: Mezigdomide / Pomalidomide/ Bortezomib / Dexamethasone

Inclusion Criteria:
Participant has documented diagnosis of MM and measurable disease, defined as any of the following: i) M-protein ≥ 0.5 grams per deciliter (g/dL) by serum protein electrophoresis (sPEP) or ii) M-protein ≥ 200 milligrams (mg) per 24-hour urine collection by urine protein electrophoresis (uPEP). iii) For participants without measurable disease in sPEP or uPEP: serum free light chain (sFLC) levels > 100 mg/L (10 mg/dL) involved light chain and an abnormal kappa/lambda FLC ratio. Participants received 1 to 3 prior lines of antimyeloma therapy. Participants achieved minimal response [MR] or better to at least 1 prior antimyeloma therapy.

Exclusion Criteria:
Participant has had progression during treatment or within 60 days of the last dose of a proteasome inhibitor, except as noted below: i) Subjects who progressed while being treated with, or within 60 days of last dose of bortezomib maintenance given once every 2 weeks or less are not excluded. For participants with prior treatment of a bortezomib containing regimen, the best response achieved was not a minimal response (MR) or better, or participant discontinued bortezomib due to toxicity. Participant has had prior treatment with mezigdomide or pomalidomide. Other protocol-defined Inclusion/Exclusion criteria apply.

Further Information at ClinicalTrials.gov

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CC-220-MM-002 (EXCALIBER-RRMM)

Hubertus Wald Tumorzentrum
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Ein Kompetenznetzwerk des UKE

A Phase 3, Two-Stage, Randomized, Multicenter, Open-label Study Comparing Iberdomide, Daratumumab and Dexamethasone (IberDd) Versus Daratumumab, Bortezomib, and Dexamethasone (DVd) in Subjects With Relapsed or Refractory Multiple Myeloma (RRMM)

Recruitment Status: RECRUITING
Condition: Multiple Myeloma
Primary Completion Date: 2026-03-18
Intervention/ Treatment: Drug: Dexamethasone/ Daratumumab/ Bortezomib

Inclusion Criteria:
Documented diagnosis of multiple myeloma (MM) and measurable disease. Received 1 to 2 prior lines of anti-myeloma therapy. Must have documented disease progression during or after their last anti-myeloma regimen. Eastern Cooperative Oncology Group (ECOG) performance status score of 0, 1 or 2.

Exclusion Criteria:
Any condition that confounds the ability to interpret data from the study. Has plasma cell leukemia, Waldenstrom's macroglobulinemia or POEMS syndrome (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, and skin changes), or clinically significant amyloidosis. Known central nervous system involvement with MM. Prior therapy with iberdomide. Other protocol-defined Inclusion/Exclusion criteria apply.

Further Information at ClinicalTrials.gov

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COSS-Register

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

Registry For Children, Adolescents And Adults With Osteosarcoma And Biologically Related Bone Sarcomas (COSS-Registry)

Recruitment Status: RECRUITING
Condition: Osteosarcoma / Bone Tumor/ Bone Sarcoma/ High Grade Sarcoma
Primary Completion Date: 2032-03
Intervention/ Treatment: --

Inclusion Criteria:
high-grade osteosarcoma (conventional and non-conventional) parosteal, periosteal or extraosseous osteosarcoma low grade central osteosarcoma (osseous) Undifferentiated pleomorphic sarcoma (UPS) (osseous) leiomyosarcoma (osseous) dedifferentiated chondrosarcoma (osseous) mesenchymal chondrosarcoma (osseous) fibrosarcoma (osseous) angiosarcoma informed consent

Exclusion Criteria:
no informed consent

Ansprechpartner im Zentrum für Onkologie
Dr. med. Jana Käthe Striefler Tel. 040/7410-53674

Further Information at ClinicalTrials.gov

UKE HAMBURG

ELIAS

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

Phase II Trial for Newly Diagnosed Low-risk Multiple Myeloma Patients Comparing 6 Cycles of Isatuximab With Lenalidomide/Bortezomib/Dexamethasone (I-VRD) Compared to 3 Cycles of I-VRD Followed by One Cycle of High-dose Therapy and Both Arms Followed by Maintenance Therapy With I-R.

Recruitment Status: RECRUITING
Condition: Newly Diagnosed Multiple Myeloma
Primary Completion Date: 2027-08
Intervention/ Treatment: Drug: Isatuximab/ Lenalidomide/ Bortezomib/ Dexamethasone/ Other: autologous stem cell transplant

Inclusion Criteria:
newly diagnosed, untreated, symptomatic, documented myeloma (according to the revised Hypercalcaemia, renal dysfunction, anaemia and bone lesions (CRAB) criteria 2014, see Appendix 1) with clonal bone marrow (BM) plasma cells ≥10% or biopsy-proven osseous or extramedullary plasmacytoma and any one or more of the following myeloma defining events: I. Hypercalcemia: serum calcium >0,25 mmol/L (>1 mg/dl) higher than the upper limit of normal or >2,75 mmol/L (>11 mg/dL) II. Renal insufficiency: serum creatinine > 177 µmol/l (>2 mg/dl) III. Anemia: hemoglobin value of >20 g/l below the lower limit of normal or a hemoglobin value lower than 10g/dl. IV. Bone lesions: one or more osteolytic lesions on skeletal radiography, CT, or PET- CT (positron emission tomography) V. Clonal BM plasma cell percentage ≥60% VI. Involved: uninvolved serum free light chain ratio ≥100 VII. >1 focal lesion on MRI examination. Presence of measurable disease: I. Serum M-protein ≥ 0.5 g/dL or urine M-protein ≥ 200 mg/24 hours. II. Involved FLC (free light chain) level ≥ 10 mg/dl, provided sFLC (free light chain) ratio is abnormal. R-ISS stage I33 (see appendix 2). Standard gene expression pattern of isolated plasma cell based on SKY92 GEP assay Must be ≥ 18 and ≤70 years at the time of signing the informed consent form. Must be able to adhere to the study visit schedule and other protocol requirements in the investigator's opinion. WHO (see Appendix 3) performance status 0-2 (WHO=2 is allowed only if caused by MM and not by co-morbid conditions). Ability to understand and willingness to sign written informed consent. Signed informed consent must be obtained before any study specific procedure. Suitable for high-dose melphalan and stem cell retransfusion. Subjects must have adequate vascular access for leukapheresis.

Further Information at ClinicalTrials.gov

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EMN33, TAURUS

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

Phase 2 Study Applying Innovative Minimal Residual Disease (MRD) Techniques for Participants With Previously Untreated Multiple Myeloma Treated With D-VRd Prior To and After High-dose Therapy Followed by Autologous Stem Cell Transplantation (ASCT) - TAURUS

Recruitment Status: RECRUITING
Condition: Multiple Myeloma
Primary Completion Date: 2024-12
Intervention/ Treatment: Drug: Daratumumab/ Bortezomib/ Lenalidomide/ Dexamethasone

Inclusion Criteria:

18 to 70 years of age, inclusive. Must have a new diagnosis of MM as per IMWG criteria. Measurable disease. Newly diagnosed and treatment-naïve participants for whom high-dose therapy and autologous stem cell transplantation is part of the intended treatment plan. Eastern Cooperative Oncology Group (ECOG) performance status score of 0, 1, or 2. Clinical laboratory values meeting the required criteria during screening and ≤3 days prior to receiving first study treatment dose. Adequate bone marrow function. Adequate liver function. Adequate renal function. A female of childbearing potential (FOCBP) must have two negative serum or urine pregnancy tests at screening including within 24 hours of the start of study treatment. Willing to practicing at least 1 highly effective method of contraception starting 4 weeks prior to start of study treatment, while receiving study treatment including during any dose interruptions, and for at least 3 months after the last dose of any component of the study treatment.

Exclusion Criteria:

Prior or current systemic therapy or ASCT for any plasma cell dyscrasia, with the exception of emergency use of a short course (equivalent of dexamethasone 40 mg/day for a maximum 4 days) of corticosteroids before treatment. History of allogenic stem cell transplantation or prior organ transplant requiring immunosuppressive therapy. Peripheral neuropathy or neuropathic pain Grade 2 or higher, as defined by the National Cancer Institute-Common Terminology Criteria for Adverse Events (NCI-CTCAE) Version 5. Myelodysplastic syndrome or any malignancy within 24 months of signing consent. The only exceptions are malignancies treated within the last 24 months that are considered completely cured. Plasmapheresis ≤28 days of approval. Radiation therapy for treatment of plasmacytoma ≤14 days of approval of enrollment. Forced Expiratory Volume in 1 second (FEV1) <50% of predicted normal. Concurrent medical or psychiatric condition or disease. Myocardial infarction ≤6 months of enrollment, or an unstable or uncontrolled disease/condition related to or affecting cardiac function. Uncontrolled cardiac arrhythmia or clinically significant electrocardiogram (ECG) abnormalities. Allergy, hypersensitivity, or intolerance to boron or mannitol, corticosteroids, monoclonal antibodies or human proteins, or the excipients of daratumumab, lenalidomide, bortezomib or dexamethasone. Pregnant or breast-feeding females

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Further Information at ClinicalTrials.gov

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GMALL-Registry

Prospective Data Collection Regarding Diagnosis, Treatment and Outcome of Adult ALL Patients and Related Diseases Associated With a Prospective Collection of Biomaterial

Recruitment Status: RECRUITING
Condition: Blut: Akute lymphatische Leukämie (ALL): Neu diagnostiziert / de novo Blut: Non-Hodgkin-Lymphome (NHL), hoch-maligne: sonstige Studien hoch-maligne NHL
Primary Completion Date: 2025-12
Intervention/ Treatment: --

Inclusion Criteria:
Acute Lymphoblastic Leukemia (All Subtypes) if treated according to ALL protocols-- Age minimum 18 yrs Other Types of Leukemia (NK Cell Lymphoma/Leukemia, Biphenotypic Acute Leukemia) if treated according to ALL protocols Non-Hodgkin's Lymphoma of Following Subtypes: Burkitt Lymphoma, B Cell Lymphoma, B- or T-lineage Lymphoblastic Lymphoma, Anaplastic Large Cell Lymphoma, Other NHL) if treated according to B-ALL protocols

Further Information at ClinicalTrials.gov

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GMALL-EVOLVE

A Multicentre, Randomized Trial in Adults With de Novo Philadelphia-Chromosome Positive Acute Lymphoblastic Leukemia to Assess the Efficacy of Ponatinib Versus Imatinib in Combination With Low-intensity Chemotherapy, to Compare End of Therapy With Indication for SCT Versus TKI, Blinatumomab and Chemotherapy in Optimal Responders and to Evaluate Blinatumomab in Suboptimal Responders (GMALL-EVOLVE)

Recruitment Status: RECRUITING
Condition: Philadelphia Chromosome Positive Acute Lymphoblastic Leukemia
Primary Completion Date: 2029-07-01
Intervention/ Treatment: Drug: Imatinib / Ponatinib/ Blinatumomab/ Other: Indication for stem cell transplantation

Inclusion Criteria:
Male or female patients >= 18 years, <=65 years. Philadelphia chromosome or BCR-ABL1 positive ALL. Not previously treated except with corticosteroids ≤ 7 days, standard GMALL prephase with dexamethasone and cyclophosphamide including intrathecal therapy, hydroxyurea, a single dose vincristine or other cytostatic drugs and start of standard induction for Ph-positive ALL (1 dose vincristine, 1 dose of Rituximab, 2 doses dexamethasone and up to 5 days Imatinib). ECOG performance status ≤2. Signed written inform consent. Molecular evaluation for BCR-ABL1 performed. Negative pregnancy test in women of childbearing potential. Woman of childbearing potential willing to use 2 highly effective methods of contraception while receiving study treatment and for an additional 3 months after the last dose of study treatment (Pearl-Index <1%). Male who has a female partner of childbearing potential willing to use 2 highly effective forms of contraception while receiving study treatment and for at least an additional 3 months after the last dose of study treatment (Pearl-Index <1%). Normal serum levels > LLN (lower limit of normal) of potassium and magnesium, or corrected to within normal limits with supplements, prior to the first dose of study medication. Serum lipase ≤ 1.5 x ULN. For serum lipase > ULN - ≤ 1.5 x ULN, value must be considered not clinically significant and not associated with risk factors for acute pancreatitis. Normal QTcF interval ≤450 ms for males and ≤470 ms for females. Signed and dated written informed consent is available. Participation in the registry of the German Multicenter Study Group for Adult ALL (GMALL)

Further Information at ClinicalTrials.gov

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GSG-MPN-Register

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

Das MPN-Register trägt Informationen über die Krankheitsverläufe von MPN-Patient/innen zusammen, um diese auszuwerten und für die zukünftige Behandlung nutzbar zu machen

Recruitment Status: RECRUITING
Condition: MPN
Primary Completion Date: N/A
Intervention/ Treatment: ---

Das MPN-Register trägt Informationen über die Krankheitsverläufe von MPN-Patient/innen zusammen, um diese auszuwerten und für die zukünftige Behandlung nutzbar zu machen.
Öffentlicher Titel: Deutsches MPN-Register und Biomaterialbank
WissenschaftlicherTitel: Deutsches MPN-Register und Biomaterialbank für BCR-ABL1-negative myeloische Neoplasien
Leiter des MPN-Registers: Prof. Dr. med. Steffen Koschmieder, Universitätsklinikum Aachen
und Prof. Dr. med. Konstanze Döhner, Universitätsklinikum Ulm

Further Information at cto-im3.de

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INDIE

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

Phase II Trial of Individualized Immunotherapy in Early-Stage Unfavorable Classical Hodgkin Lymphoma

Recruitment Status: RECRUITING
Condition: Philadelphia Classical Hodgkin Lymphoma
Primary Completion Date: 2025-12
Intervention/ Treatment: Drug: Tislelizumab

Inclusion Criteria:
Age 18-60 for the main trial cohort. Age ≥ 61 years and eligible for AVD as determined by CIRS-G score and investigator for the exploratory cohort. First diagnosis of treatment-naïve cHL. Early-stage unfavorable disease (i.e. stage IA, IB and IIA with risk factors a-d, stage IIB with risk factors c-d): large mediastinal mass. extranodal lesion(s) elevated erythrocyte sedimentation rate. ≥ 3 nodal areas.

Exclusion Criteria:
Presence of nodular-lymphocyte predominant Hodgkin lymphoma, grey-zone lymphoma and/or central nervous system involvement of lymphoma.

Further Information at ClinicalTrials.gov

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MK-3475-905/KEYNOTE-905

Hubertus Wald Tumorzentrum
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Ein Kompetenznetzwerk des UKE

A Randomized Phase 3 Study Evaluating Cystectomy With Perioperative Pembrolizumab and Cystectomy With Perioperative Enfortumab Vedotin and Pembrolizumab Versus Cystectomy Alone in Participants Who Are Cisplatin-Ineligible or Decline Cisplatin With Muscle-Invasive Bladder Cancer (KEYNOTE-905/EV-303)

Recruitment Status: ACTIVE, NOT RECRUITING
Condition: Urinary Bladder Cancer, Muscle-invasive
Primary Completion Date: 2027-05-31
Intervention/ Treatment: Drug: Pembrolizumab/ Procedure: Surgery (radical cystectomy (RC) plus Pelvic Lymph Node Dissection [PLND])/ Drug: Enfortumab Vedotin

Inclusion Criteria:

Have a histologically confirmed diagnosis of urothelial carcinoma/muscle-invasive bladder cancer [MIBC] (cT2-T4aN0M0 or T1-T4aN1M0) with predominant (≥50%) urothelial histology to be confirmed by Blinded Independent Central Review (BICR) (central pathology and/or imaging). Clinically nonmetastatic bladder cancer determined by imaging Eligible for radical cystectomy (RC) + pelvic lymph node dissection (PLND), and agreement to undergo curative intent standard RC + PLND (including prostatectomy if applicable) Ineligible for treatment with cisplatin, as defined by meeting at least one of the following criteria OR be eligible for treatment with cisplatin but decline treatment with cisplatin-based chemotherapy: Impaired renal function with measured or calculated creatinine clearance (CrCl) 30 to 59 mL/min (calculated by Cockcroft-Gault method, Modification of Diet of Renal Disease [MDRD] equations, or measured by 24-hour urine collection). Eastern Cooperative Oncology Group (ECOG) Performance Status 2. Common Terminology Criteria for Adverse Events (CTCAE) v.4 Grade ≥2 audiometric hearing loss. New York Heart Association (NYHA) Class III heart failure. Transurethral resection (TUR) of a bladder tumor that is submitted for central pathology assessment and adequate to determine urothelial histology and PD-L1 expression assessment. ECOG performance status of 0, 1, or 2 Adequate organ function. A male participant is eligible to participate if he agrees to use contraception and refrain from donating sperm during the intervention period and for at least 180 days after the last dose of enfortumab vedotin. If the male participants are receiving pembrolizumab only or undergoing surgery only, there are no contraception requirements A female participant is eligible to participate if she is not pregnant, not breastfeeding, and at least 1 of the following conditions applies: Not a (woman of childbearing potential) WOCBP or a WOCBP who agrees to use a highly effective contraceptive method or be abstinent from heterosexual intercourse (as their preferred and usual lifestyle) during the intervention period and for at least 120 days after the last dose of pembrolizumab and at least 180 days after the last dose of enfortumab vedotin; whichever comes last. A female participant must agree not to donate eggs during this period as well A WOCBP must have a negative highly sensitive pregnancy test within 24 hours before the first dose of study intervention

Further Information at ClinicalTrials.gov

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NAPOLEON-Registry

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

National Acute Promyelocytic Leukemia (APL) Observational Study NAPOLEON-Registry of the German AML Intergroup

Recruitment Status: RECRUITING
Condition: Newly-diagnosed APL (de Novo or Therapy-related) / Relapsed APL
Primary Completion Date: N/A
Intervention/ Treatment: observational

Inclusion Criteria:
newly-diagnosed APL (either de novo or therapy-related), within 12 months of diagnosis or relapsed APL, within 12 months of diagnosis of relapse. Confirmed by the presence of the translocation t(15; 17). and / or confirmed by the detection of the fusion transcript of PML/RARa

Exclusion Criteria:
none

Further Information at ClinicalTrials.gov

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TriMM-3, CR109168, 64407564MMY1005

A Phase 1b Study of Bispecific T Cell Redirection Antibodies in Combination With Checkpoint Inhibition for the Treatment of Participants With Relapsed or Refractory Multiple Myeloma

Recruitment Status: RECRUITING
Condition: Relapsed/ Refractory Multiple Myeloma
Primary Completion Date: 2022-05-25
Intervention/ Treatment: Drug: Talquetamab/ Teclistamab/ PD-1 Inhibitor/

Inclusion Criteria:

Have documented initial diagnosis of multiple myeloma according to International Myeloma Working Group (IMWG) diagnostic criteria. Participants with relapsed or refractory disease that are not a candidate for available therapy with established clinical benefit. Have measurable disease at screening as defined by at least 1 of the following: a) Serum M-protein level greater than or equal to (>=) 0.5 grams per deciliter (g/dL); b) Urine M-protein level >= 200 milligrams (mg) per 24 hours; c) Light chain multiple myeloma: Serum immunoglobulin (Ig) free light chain (FLC) >= 10 milligrams/deciliter (mg/dL) and abnormal serum Ig kappa lambda FLC ratio. Have an Eastern Cooperative Oncology Group (ECOG) performance status score of 0 or 1

Exclusion Criteria:

Prior antitumor therapy within 21 days prior to the first dose of study treatment (proteasome inhibitor [PI] therapy or radiotherapy within 14 days, immunomodulatory drug (IMiD) agent therapy within 7 days, gene -modified adoptive cell therapy or autologous stem cell transplant within 3 months). Prior therapy with PD-1 inhibitors, allogeneic stem cell transplant or solid organ transplant. Active plasma cell leukemia, Waldenstrom's macroglobulinemia, POEMS syndrome (polyneuropathy, organomegaly, endocrinopathy, M-protein, and skin changes), or primary light chain amyloidosis. Active Central Nervous System (CNS) involvement or exhibition of clinical signs of meningeal involvement of multiple myeloma. If either is suspected, brain magnetic resonance imaging (MRI) and lumbar cytology are required. Live, attenuated vaccine within 4 weeks before the first dose of study treatment
Non-hematologic toxicity from prior anticancer therapy that has not resolved to baseline levels or to Grade less than or equal to (<=) 1 (except alopecia [any grade] or peripheral neuropathy to Grade <= 2). Received a cumulative dose of corticosteroids equivalent to >= 140 milligrams (mg) of prednisone within the 14-day period before the start of study treatment administration.

Further Information at ClinicalTrials.gov

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FIRE-9 - PORT / AIO-KRK-0418

Hubertus Wald Tumorzentrum
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Ein Kompetenznetzwerk des UKE

Post-resection/Ablation Chemotherapy in Patients With Metastatic Colorectal Cancer Prospective, Randomized, Open, Multicenter Phase III Trial to Investigate the Efficacy of Active Post-resection/Ablation Therapy in Patients With Metastatic Colorectal Cancer

Recruitment Status: RECRUITING
Condition: Colorectal Cancer
Primary Completion Date: 2022-05-25
Intervention/ Treatment: Drug:mFOLFOX6/ mFOLFOXIRI

Inclusion Criteria:

Patient's signed informed consent. Patient's age ≥18 years at the time of signing the informed consent. Histologically confirmed adenocarcinoma of the colon or rectum. Resected (R0 or R1) and/or effectively treated metastases (all techniques allowed) of colorectal cancer within 3-10 weeks before randomization (earlier randomisation allowed if at least 3 weeks interval between intervention and treatment start is guaranteed) AND resected primary tumor (synchronous or metachronous). In cases of synchronous metastases the interval of 3-10 weeks might be calculated following the removal of the primary tumor if this intervention was the last to address all tumor lesions. Absence of significant active wound healing complications (if applicable) at randomization. Resolved wound healing complications after resection/ablation are acceptable for inclusion into the trial. No radiographic evidence of active metastatic disease at study entry in a CT and/or MRI scan not older than 10 weeks prior randomization. Pre-surgery/ablation images are eligible for the study if all lesions have been addressed in the interval ECOG performance status 0-2. Adequate bone marrow, hepatic and renal organ function, defined by the following laboratory test results: Absolute neutrophil count ≥ 1.5 x 109/L (1500/µL). Hemoglobin ≥ 80 g/L (8 g/dL). Platelet count ≥ 100 x109/L (100000/µL) without transfusion. Total serum bilirubin of ≤ 1.5 x upper limit of normal (ULN). Aspartate aminotransferase (AST/GOT) ≤ 3.0 × ULN. Calculated glomerular filtration rate (GFR) according to Cockcroft-Gault formula or according to MDRD ≥ 50 mL/min or serum creatinine ≤ 1.5 x ULN. Patients without anticoagulation need to present with an INR < 1.5 x ULN and PTT < 1.5 x ULN. Patient with prophylactic or therapeutic anticoagulation are allowed into the trial. Proficient fluorouracil metabolism as defined: Prior treatment with 5-FU or capecitabine without unusual toxicity or If tested, normal DPD deficiency test according to the standard of the study site or If tested, in patients with DPD deficiency test with a CPIC activity score of 1.0-1.5 fluoropyrimidine dosage should be reduced by 50%. For women of childbearing potential (WOCBP): negative pregnancy test within 14 days before randomization and agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive methods with a failure rate of < 1% per year during the treatment period and for at least 6 months after the last dose of study treatment. A woman is considered to be of childbearing potential if she is post-menarcheal, has not reached a postmenopausal state (≥ 12 continuous months of amenorrhea with no identified cause other than menopause), and has not undergone surgical sterilization (removal of ovaries and/or uterus). Examples of contraceptive methods with a failure rate of < 1% per year include bilateral tubal ligation, male partner's sterilization, hormonal contraceptives that inhibit ovulation, hormone-releasing intrauterine devices, and copper intrauterine devices. For men: With female partners of childbearing potential, men must remain abstinent or use a condom plus an additional contraceptive method that together result in a failure rate of < 1% per year during the treatment period and for 6 months after the last dose of study treatment. Men must refrain from donating sperm during this same period. With pregnant female partners, men must remain abstinent or use a condom during the treatment period and for 6 months after the last dose of study medication to avoid exposing the embryo.

Further Information at ClinicalTrials.gov

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Entitäten

UKE HAMBURG

MK-5684-003

Hubertus Wald Tumorzentrum
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Ein Kompetenznetzwerk des UKE

A Phase 3 Randomized, Open-label Study of MK-5684 Versus Alternative Abiraterone Acetate or Enzalutamide in Participants With Metastatic Castration-resistant Prostate Cancer (mCRPC) Previously Treated With Next-generation Hormonal Agent (NHA) and Taxane-based Chemotherapy

Recruitment Status: RECRUITING
Condition: Prostate Cancer Metastatic
Primary Completion Date: 2028-08-02
Intervention/ Treatment: Drug: Opevesostat/ Abiraterone acetate/ Enzalutamide/ Hydrocortisone/ Fludrocortisone acetate/ Prednisone/ Dexamethasone

Inclusion Criteria:

Has histologically- or cytologically-confirmed adenocarcinoma of the prostate without small cell histology. Has prostate cancer progression while on androgen deprivation therapy (or post bilateral orchiectomy) within 6 months before Screening. Has current evidence of metastatic disease documented by either bone lesions on bone scan and/or soft tissue disease by computed tomography/magnetic resonance imaging (CT/MRI). Has disease that progressed during or after treatment with 1 novel hormonal agent (NHA). Has received 1 but no more than 2 taxane-based chemotherapy regimens for metastatic castration-resistant prostate cancer (mCRPC) and has had progressive disease (PD) during or after treatment. Has ongoing androgen deprivation with serum testosterone <50 ng/dL (<1.7 nM). Has provided tumor tissue from a fresh core or excisional biopsy from soft tissue not previously irradiated. Has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 assessed within 7 days of randomization Has had prior treatment with PARPi or were deemed ineligible to receive treatment by the investigator or have refused PARPi treatment. Has received prior 177Lu-PSMA-617 or were deemed ineligible to receive 177Lu-PSMA-617 treatment by the investigator or refused 177Lu-PSMA-617 treatment Participants who have not received cabazitaxel can be enrolled if they are ineligible for cabazitaxel treatment as determined by the investigator or have refused treatment. If participant received first generation anti-androgen therapy before screening, the participant has evidence of disease progression >4 weeks since the last flutamide treatment and >6 weeks since the last bicalutamide or nilutamide treatment. Participants receiving bone resorptive therapy (including, but not limited to, bisphosphonate or denosumab) must have been on stable doses for ≥ 4 weeks before the date of randomization. Participants with human immunodeficiency virus (HIV) infection must have well controlled HIV on antiretroviral therapy (ART). Participants who are hepatitis B surface antigen (HBsAg) positive are eligible if they have received hepatitis B virus (HBV) antiviral therapy for at least 4 weeks and have undetectable HBV viral load before randomization. Participants with history of hepatitis C virus (HCV) infection are eligible if HCV viral load is undetectable at Screening. Participants who can produce sperm must agree to the following during the study treatment period and for at least 7 days after the last dose of opevesostat, for at least 30 days after the last dose of abiraterone acetate, and for at least 3 months after the last dose of enzalutamide: EITHER be abstinent OR must agree to use male condom.

Further Information at ClinicalTrials.gov

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GMMG-HD8

A Randomized Phase III Non-inferiority Trial Assessing Lenalidomide, Bortezomib and Dexamethasone Induction Therapy With Either Intravenous or Subcutaneous Isatuximab in Transplant-eligible Patients With Newly Diagnosed Multiple Myeloma.

Recruitment Status: RECRUITING
Condition: Multiple Myeloma
Primary Completion Date: 2025-07-24
Intervention/ Treatment: Drug: Isatuximab/ Isatuximab/ Lenalidomide/ Bortezomib/ Dexamethasone

Inclusion Criteria:
Confirmed diagnosis of untreated MM requiring systemic therapy (diagnostic criteria according to IMWG). Patient is eligible for high-dose melphalan (200 mg/m^2 melphalan) and autologous stem cell transplantation Measurable MM disease according to IMWG criteria, defined as any quantifiable monoclonal protein value, defined by at least one of the following three measurements: serum M-protein ≥ 10 g/L; urine light-chain (M-protein) of ≥ 200 mg/24 hours; involved FLC level ≥ 10 mg/dL provided sFLC ratio is abnormal. Age 18-70 years at trial inclusion.

Exclusion Criteria:
Patient has known hypersensitivity (or contraindication) to any of the components of study therapy. Systemic amyloid light-chain amyloidosis (except for localized AL amyloidosis limited to the skin or the bone marrow) Plasma cell leukemia. Previous chemotherapy or radiotherapy during the past 5 years except local radiotherapy in case of local MM progression. Severe cardiac dysfunction (NYHA classification III-IV). Patients with active or uncontrolled hepatitis B or C or detectable liver disease due to hepatitis B or C. HIV positivity: Patients with active, uncontrolled infections. Patients with severe renal insufficiency or requiring hemodialysis. Patients with peripheral neuropathy or neuropathic pain, grade 2 or higher (as defined by the NCI Common Terminology Criteria for Adverse Events). Patients with a history of any active malignancy during the past 5 years with the exception of following malignancies after curative therapy: basal cell carcinoma of the skin, squamous cell skin carcinoma, stage 0 cervical carcinoma or any in situ malignancy. Platelet count < 75 x 10^9/L. Haemoglobin ≤ 8.0 g/dL, unless related to MM. Absolute neutrophil count (ANC) < 1.0 x 10^9/L (the use of colony stimulating factors within 14 days before the test is not allowed). Corrected serum calcium > 14 mg/dL (> 3.5 mmol/L)
Pregnancy and lactation

Further Information at ClinicalTrials.gov

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EMN28, CARTITUDE-6

A Phase 3 Randomized Study Comparing Daratumumab, Bortezomib, Lenalidomide and Dexamethasone (DVRd) Followed by Ciltacabtagene Autoleucel Versus Daratumumab, Bortezomib, Lenalidomide and Dexamethasone (DVRd) Followed by Autologous Stem Cell Transplant (ASCT) in Participants With Newly Diagnosed Multiple Myeloma Who Are Transplant Eligible

Recruitment Status: RECRUITING
Condition: Multiple Myeloma
Primary Completion Date: 2033-06
Intervention/ Treatment: Drug: Daratumumab/ Bortezomib/ Lenalidomide/ Dexamethasone/ Cilta-cel/ Cyclophosphamide/ Fludarabine

Inclusion Criteria:
Participants with documented NDMM according to IMWG diagnostic criteria, for whom high-dose therapy and ASCT are part of the intended initial treatment plan. Measurable disease, as assessed by central laboratory, at screening as defined by any of the following: Serum monoclonal paraprotein (M-protein) level ≥1.0 g/dL or urine M-protein level ≥200 mg/24 hours; or Light chain MM without measurable disease in serum or urine: serum Ig free-light chain (FLC) ≥10 mg/dL and abnormal serum Ig kappa lambda FLC ratio. ECOG performance status of grade 0 or 1. Clinical laboratory values within prespecified range.

Exclusion Criteria:
Prior treatment with CAR-T therapy directed at any target. Any prior BCMA target therapy. Any prior therapy for MM or smoldering myeloma other than a short course of corticosteroids. Received a strong cytochrome P450 (CYP)3A4 inducer within 5 half-lives prior to randomization. Received or plans to receive any live, attenuated vaccine (except for COVID-19 vaccines) within 4 weeks prior to randomization. Known active, or prior history of central nervous system (CNS) involvement or clinical signs of meningeal involvement of MM. Stroke or seizure within 6 months of signing Informed Consent Form (ICF).

Further Information at ClinicalTrials.gov

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EMN30, MajesTEC-4

Hubertus Wald Tumorzentrum
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Ein Kompetenznetzwerk des UKE

Phase 3 Study of Teclistamab in Combination With Lenalidomide and Teclistamab Alone Versus Lenalidomide Alone in Participants With Newly Diagnosed Multiple Myeloma as Maintenance Therapy Following Autologous Stem Cell Transplantation - MajesTEC-4

Recruitment Status: RECRUITING
Condition: Multiple Myeloma
Primary Completion Date: 2033-06
Intervention/ Treatment: Drug: Teclistamab/ Lenalidomide

Inclusion Criteria:
Must have a new diagnosis of multiple myeloma according to IMWG criteria and have received induction +/- consolidation. Must have received only one line of therapy and achieved at least a partial response (≥PR) as per IMWG 2016 response criteria (Kumar 2016) without evidence of progression at the time of first treatment dose. Must not be intolerant to the starting dose of lenalidomide. Must not have received any maintenance therapy. Have an ECOG performance status score of 0, 1, or 2 at screening and immediately prior to the start of administration of study treatment. Have clinical laboratory values within prespecified range.

Exclusion Criteria:
Received any prior BCMA-directed therapy. Any previous therapy with an immune cell redirecting agent or gene modified adoptive cell therapy (eg, chimeric antigen receptor modified T cells, NK cells). Discontinued treatment due to any AE related to lenalidomide as determined by the investigator. Progressed on multiple myeloma therapy at any time prior to screening. Received a cumulative dose of corticosteroids equivalent to ≥140 mg of prednisone within the 14 days prior to first treatment dose. Received a live, attenuated vaccine within 4 weeks before first treatment dose. Non-live vaccines or non-replicating authorized for emergency use (eg. COVID-19) are allowed.

Further Information at ClinicalTrials.gov

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UKE HAMBURG

GMMG-HD9

Hubertus Wald Tumorzentrum
Universitäres Cancer Center Hamburg
Ein Kompetenznetzwerk des UKE

A Randomized Phase III Trial Assessing Iberdomide Versus Iberdomide Plus Isatuximab Maintenance Therapy Post Autologous Hematopoietic Stem-Cell Transplantation in Patients With Newly Diagnosed Multiple Myeloma

Recruitment Status: RECRUITING
Condition: Multiple Myeloma
Primary Completion Date: 2028-12
Intervention/ Treatment: Drug: Iberdomide/ Isatuximab/ Dexamethasone/

Inclusion Criteria:

Prior inclusion and treatment within the GMMG-HD8 / DSMM XIX trial. Received at least one cycle high dose melphalan therapy (HDM) and autologous stem cell transplantation (ASCT). At least Partial Response (PR) according to IMWG criteria at inclusion in the trial. Age of at least 18 years at trial inclusion. WHO performance status of 0, 1, or 2
Negative pregnancy test at inclusion (women of childbearing potential). For all men and women of childbearing potential: patients must be willing and capable to use adequate contraception during the complete therapy. Ability of patient to understand character and individual consequences of the clinical trial. Written informed consent (must be available before enrolment in the trial).

Exclusion Criteria:

Subjects with gastrointestinal disease that may significantly alter the absorption of iberdomide. Patient has known hypersensitivity (or contraindication) to any of the components of study therapy that are not amenable to premedication with steroids or H1 blockers and that would prohibit further treatment with these agents (e.g. known intolerance or hypersensitivity to infused proteins products, sucrose, histidine, and polysorbate 80 as well as intolerance to arginine and Poloxamer 188). Patients with a history of serious allergic reaction to another immunomodulatory agent (thalidomide, lenalidomide, or pomalidomide)", as angioedema and severe dermatologic reactions, including Grade 4 rash and exfoliative or bullous rash. Patients currently being treated with strong inhibitors or inducers of CYP3A4/5. Systemic AL amyloidosis (except for localized AL amyloidosis limited to the skin or the bone marrow), plasma cell leukemia or polyneuropathy, organomegaly, endocrinopathy, monoclonal-protein and skin abnormalities or Waldenström macroglobulinemia. Previous systemic anti-myeloma treatment other than administered within the GMMG-HD8 / DSMM XIX trial (including up to two cycles cycle high dose melphalan therapy (HDM) and autologous stem cell transplantation (ASCT). Local, consolidative radiotherapy for myeloma disease is permitted unless performed in case of progressive disease according to IMWG criteria. Severe cardiac dysfunction (NYHA classification III-IV). Significant hepatic dysfunction (ASAT and/or ALAT ≥ 3 times normal level and/or serum bilirubin ≥ 1.5 times normal level if not due to hereditary abnormalities as Gilbert's disease), unless related to MM or HDM/ASCT. Patients with active or uncontrolled hepatitis B or C or detectable liver disease due to hepatitis B or C. In case of history of hepatitis B or C, it must be clarified whether it has been overcome and negative circulating HBV-DNA or HCV-RNA must be provided. Positive hepatitis B status may only be acceptable in absence of circulating HBV-DNA or signs of chronic or acute infection and if an adequate prophylaxis is being implemented during the course of the study. Prophylaxis for patients with history of hepatitis B or C should be set on a patient individual basis. HIV positivity: Patients with active, uncontrolled infections. Patients with severe renal insufficiency (Creatinine Clearance < 30ml/min) or requiring hemodialysis
Patients with peripheral neuropathy or neuropathic pain, grade 2 or higher (as defined by the NCI Common Terminology Criteria for Adverse Events (NCI CTCAE, version 5.0). Patients with a history of any active malignancy during the past 5 years with the exception of following malignancies after curative therapy: basal cell carcinoma of the skin, squamous cell skin carcinoma, stage 0 cervical carcinoma or any in situ malignancy. A history of an early stage malignancy during the past 5 years may be acceptable, however, in this case the GMMG study office has to be consulted prior to study inclusion. Patients with acute diffuse infiltrative pulmonary and/or pericardial disease. Autoimmune haemolytic anaemia with positive indirect Coombs test or immune thrombocytopenia. Platelet count < 75 x 109/l. Haemoglobin ≤ 8.0 g/dl, unless related to MM. Absolute neutrophil count (ANC) < 1.0 x 109/l (the use of colony stimulating factors within 14 days before the test is not allowed). Corrected serum calcium > 14 mg/dl (> 3.5 mmol/l). Unable or unwilling to undergo thromboprophylaxis. Pregnancy and lactation. Participant has any concurrent severe and/or uncontrolled medical condition or psychiatric disease that is likely to interfere with study procedures or results, or that in the opinion of the investigator would constitute a hazard for participating in this study or that confounds the ability to interpret data from the study. Subjects, who are committed to an institution by virtue of an order issued either by the judicial or the administrative authorities. Participation in other interventional clinical trials. This does not include long-term follow-up periods without active drug treatment of previous studies during the last 6 months.

Further Information at [ClinicalTrials.gov]

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Entitäten

LINKER-MM3, R5458-ONC-2245

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Ein Kompetenznetzwerk des UKE

An Open-label, Randomized, Phase 3 Study of Linvoseltamab (REGN5458; Anti- BCMA x Anti-CD3 Bispecific Antibody) Versus the Combination of Elotuzumab, Pomalidomide, and Dexamethasone (EPd), in Patients With Relapsed/Refractory Multiple Myeloma (LINKER-MM3)

Recruitment Status: RECRUITING
Condition: Relapsed Refractory Multiple Myeloma (RRMM)
Primary Completion Date: 2032-09-18
Intervention/ Treatment: Drug: Linvoseltamab/ Elotuzumab/ Pomalidomide/ Dexamethasone

Inclusion Criteria:
Age 18 years or older (or legal adult age in the country) at the time of the screening visit. Eastern Cooperative Oncology Group (ECOG) performance status ≤1. Patients with ECOG 2 solely due to local symptoms of myeloma (eg. pain) may be allowed after discussion with the Medical Monitor. Received at least 1 and no more than 4 prior lines of anti-neoplastic MM therapies, including lenalidomide and a proteasome inhibitor and demonstrated disease progression on or after the last therapy as defined by the 2016 IMWG criteria. Participants who have received only 1 line of prior line of antimyeloma therapy must be lenalidomide refractory, as described in the protocol. Note: Participants in Israel also must have previously received a CD38 antibody. Participants in the EU and the UK must have previously received 2 to 4 prior lines of therapy, including a CD38 antibody.
Patients must have measurable disease for response assessment as per the 2016 IMWG response assessment criteria, as described in the protocol. Adequate hematologic, hepatic, renal and cardiac function, as well as evidence of adequate bone marrow reserves. Life expectancy of at least 6 months

Exclusion Criteria:
Diagnosis of plasma cell leukemia, amyloidosis, Waldenström macroglobulinemia, or POEMS syndrome (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, and skin changes). Prior treatment with elotuzumab and/or pomalidomide. Participants with known MM brain lesions or meningeal involvement. Treatment with any systemic anti-cancer therapy within 5 half-lives or within 28 days before first administration of study drug, whichever is shorter. History of allogeneic stem cell transplantation within 6 months, or autologous stem cell transplantation within 12 weeks of the start of study treatment. Participants who have received an allogeneic transplant must be off all immunosuppressive medications for 6 weeks without signs of graft-versus-host disease. Steroids at doses equivalent to suppletion doses may be acceptable. Prior treatment with B-cell maturation antigen (BCMA) directed immunotherapies Note: BCMA antibody-drug conjugates are allowed. History of progressive multifocal leukoencephalopathy (PML), known or suspected PML, or history of a neurocognitive condition or central nervous system (CNS) movement disorder. Any infection requiring hospitalization or treatment with IV anti-infectives within 2 weeks of first administration of study drug. Uncontrolled infection with human immunodeficiency virus (HIV), hepatitis B virus (HBV) or hepatitis C virus (HCV); or another uncontrolled infection, as defined in the protocol.

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Further Information at ClinicalTrials.gov