# Übersicht Klinische Studien

Klinische Abteilung für Onkologie

Medizinische Universität Wien

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# Kontakt für Studienanfragen

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# Studienübersicht – Inhaltsverzeichnis

- **Programmdirektion Mammakarzinom**
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- **Programmdirektion Tumore des Respirationstraktes**
  - HNO Tumoren
  - Bronchuskarzinome
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  - Sarkome
- **Programmdirektion Urogenitale Tumoren**
  - Nierenzellkarzinome (dzt. keine)
  - Prostatakarzinome, Hodentumoren, gynäkologische Tumoren (dzt. keine)
  - Urothelkarzinome (dzt. keine)

# Studienübersicht – Inhaltsverzeichnis

- **Programmdirektion Gastrointestinale Tumoren**
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# Programmdirektion Mammakarzinom

# pionERA / CO 44657

- Titel: **A Study to Evaluate Efficacy and Safety of Giredestrant Compared With Fulvestrant (Plus a CDK4/6 Inhibitor), in Participants With ER-Positive, HER2-Negative Advanced Breast Cancer Resistant to Adjuvant Endocrine Therapy (pionERA Breast Cancer)**
- ClinicalTrials.gov Identifier: NCT06065748
- Principle Investigator: Bartsch
- Haupteinschlusskriterien: Locally advanced or metastatic adenocarcinoma of the breast, not amenable to treatment with curative intent, documented estrogen receptor-positive (ER+), HER2-negative (HER2-) tumor assessed locally on the most recent tumor biopsy (or an archived tumor sample if a recent tumor sample is not available for testing), confirmed ESR1 mutation status (ESR1m versus ESR1nmd) in baseline circulating tumor DNA (ctDNA) through central laboratory testing
- Studienphase: III
- Sponsor: Hoffmann-La Roche

# DB-Respond HER2low (NIS)

- Titel: **A prospective, non-interventional study (NIS) with trastuzumab deruxtecan for patients with HER2-low expressing unresectable and/or metastatic breast cancer accompanied by a disease registry of patients treated with conventional chemotherapy (Destiny Breast HER2-low Respond Europe )**
- EK-Nr.: 2114/2023
- Principle Investigator: Bartsch
- Haupteinschlusskriterien: Adult patient (age ≥ 18 years) with histological or cytological, confirmed diagnosis of unresectable and/or mBC, documented HER2-low status (IHC1+, IHC2+/ISH-), patients who have received prior chemotherapy in the metastatic, setting or patients who have developed disease recurrence during or within 6 months of completing adjuvant chemotherapy
- Studienphase: NIS
- Sponsor: Daiichi-Sankyo

# AGMT mBC-Register - NIS

- Titel: **Metastatic breast cancer in Austria AGMT_MBC-Registry Protocol**
- ClinicalTrials.gov Identifier: NCT03870620
- Principle Investigator: Bartsch
- Haupteinschlusskriterien: Metastatic breast cancer
- Studienphase: NIS
- Sponsor: Arbeitsgemeinschaft Medikamentöser Tumortherapie (AGMT)

# TUXEDO-2

- Titel: **Phase II Study of daTopotamab-derUXtecan (Dato-DXd; DS-1026a) in triple-negative brEast cancer patients with newly Diagnosed or prOgressing brain metastases**
- ClinicalTrials.gov Identifier: NCT05866432
- Principle Investigator: Bartsch
- Haupteinschlusskriterien: Triple neg. Breast Cancer and BM
- Studienphase: II
- Sponsor: Daiichi Sankyo

# TUXEDO-4 / MEDOPP596

- Titel: **T-DXd Therapy for HER2-low Breast Cancer Patients With Brain Metastases (TUXEDO-4)**
- ClinicalTrials.gov Identifier: NCT06048718
- Principle Investigator: Bartsch
- Haupteinschlusskriterien: Patient must be capable to understand the purpose of the study and have signed written informed consent form (ICF) prior to beginning specific protocol procedures. Female or male patients ≥ 18 years of age at the time of signing ICF. Radiologically documented metastatic breast cancer with locally documented HER2-low status according to the 2018 ASCO/CAP guidelines.
- Studienphase: II
- Sponsor: MEDSIR

# MK-2870-012

- Titel: **A Phase 3, Randomized, Open-label, Study to Compare the Efficacy and Safety of Adjuvant MK-2870 in Combination with Pembrolizumab (MK-3475) Versus Treatment of Physician's Choice (TPC) in Participants With Triple-Negative Breast Cancer (TNBC) Who Received Neoadjuvant Therapy and Did Not Achieve a Pathological Complete Response (pCR) at Surgery**
- ClinicalTrials.gov Identifier: NCT06393374
- Principle Investigator: Bartsch
- Haupteinschlusskriterien: Has centrally confirmed TNBC, as defined by the most recent American Society of Clinical Oncology/College of American Pathologists (ASCO/CAP) guidelines. Has no evidence of locoregional or distant relapse, as assessed by the treating physician. Had neoadjuvant treatment based on the KEYNOTE-522 regimen (pembrolizumab with carboplatin/taxanes and pembrolizumab with anthracycline-based chemotherapy) followed by surgery according to National Comprehensive Cancer Network (NCCN) treatment guidelines for TNBC. Had adequate excision and surgical removal of all clinically evident disease in the breast and/or lymph nodes and have adequately recovered from surgery. Has non-pathologic complete response at surgery
- Studienphase: III
- Sponsor: Merck Sharp & Dohme

# JZP598-303 / EmpowHER303

- Titel: **A Phase 3, randomized, open-label, multicenter, controlled study to evaluate the efficacy and safety of zanidatamab in combination with physician's choice chemotherapy compared to trastuzumab in combination with physician's choice chemotherapy for the treatment of participants with metastatic HER2-positive breast cancer who have progressed on, or are intolerant to, previous trastuzumab deruxtecan treatment**
- ClinicalTrials.gov Identifier: NCT06435429
- Principle Investigator: Bartsch
- Haupteinschlusskriterien: Participants are eligible to be included in the study only if all of the following criteria apply: Is 18 years of age or of the legal adult age per local standard at the time of signing the informed consent. Has histologically confirmed HER2-positive breast cancer according to ASCO-CAP Guidelines as evaluated by a central laboratory. Participants with unresectable or metastatic HER2 positive breast cancer who have progressed on, or are intolerant to, previous T-DXd treatment. Has measurable disease per RECIST version 1.1. Is eligible to receive one of the chemotherapy options listed in the physician's choice of chemotherapy (eribulin, gemcitabine, vinorelbine, or capecitabine). Participants with history of treated or clinically inactive CNS metastases are eligible as specified in the protocol.
- Studienphase: III
- Sponsor: Jazz Pharmaceuticals

# J2J-NC-JZLH / EMBER-4

- Titel: **Neratinib in Patients With HER2+ Breast Cancer: a Multi-centric, Multi-national, Prospective, Longitudinal, Non-interventional Study in Germany and Austria**
- ClinicalTrials.gov Identifier: NCT05514054
- Principle Investigator: Bartsch
- Haupteinschlusskriterien: Have a diagnosis of ER+, HER2- early-stage, resected, invasive breast cancer without evidence of distant metastasis. Participants must have received at least 24 months but not more than 60 months of any adjuvant ET, from time of adjuvant ET initiation. Participants may have received (neo) adjuvant chemotherapy and/or targeted therapy with a CDK4/6- or PARP- inhibitor.
- Studienphase: III
- Sponsor: Eli Lilly and Company

# TRACE

- Titel: **Tucatinib in Patients With Locally Advanced or Metastatic HER2-positive Breast Cancer Who Received at Least Two Prior Anti-HER2 Treatment Regimens. (TRACE)**
- ClinicalTrials.gov Identifier: NCT05253911
- Principle Investigator: Bartsch
- Haupteinschlusskriterien:  Aged 18 years or older. Histologically confirmed HER2+ breast cancer with HER2 positivity defined as a 3+ score by immunohistochemistry (IHC) or a positive result by in situ hybridization (ISH), optionally combined with a IHC2+ score. Diagnosis of locally advanced or metastatic HER2+ breast cancer, including patients with brain metastases.
- Studienphase: NIS
- Sponsor: iOMEDICO AG

# ABCSG-55N / AMBHER

- Titel: **Description of patients with HER2 positive breast cancer undergoing neoadjuvant treatment and development of a dynamic composite risk score to predict the risk of distant recurrence**
- EK-Nr. 1390/2022
- Principle Investigator: Bartsch
- Haupteinschlusskriterien: Neoadjuvant treatment regimen with dual HER2 blockade (retro- und prospektiv)
- Studienphase: NIS
- Sponsor: ABCSG

# EvoPAR-Breast

- Titel: **AMG-Studie: A Randomised, Open-Label, Phase III Study of Saruparib (AZD5305) Plus Camizestrant compared with Physician's Choice CDK4/6 Inhibitor Plus Endocrine Therapy or Plus Camizestrant for the First-Line Treatment of Patients with BRCA1, BRCA2, or PALB2 Mutations and Hormone Receptor-Positive, HER2-Negative (IHC 0, 1+, 2+/ISH non-amplified) Advanced Breast Cancer (EvoPar Breast01) Prot.Nr: D9722C00001**
- NCT06380751
- Principle Investigator: Marhold
- Haupteinschlusskriterien: Adult females, pre/peri-menopausal and/or post-menopausal, and adult males. Histologically or cytologically documented diagnosis of HR-positive, HER2-negative breast cancer. Advanced breast cancer with either locally advanced disease not amenable to curative treatment or metastatic disease. ECOG performance status of 0 or 1 with no deterioration over the previous 2 weeks. FFPE tumour tissue from each participant. Documented germline tumour loss of function mutation in BRCA1, BRCA2, or PALB2. Adequate organ and marrow function
- Studienphase: III
- Sponsor: AstraZeneca

# Programmdirektion Tumoren des Respirationstraktes

# Nanoray-312

- Titel: **A Phase 3 (Pivotal Stage) Study of NBTXR3 Activated by Investigator's Choice of Radiotherapy Alone or Radiotherapy in Combination with Cetuximab for Platinum-based Chemotherapy-ineligible Elderly Patients with Locally Advanced Head & Neck Squamous Cell Carcinoma**
- ClinicalTrials.gov Identifier: NCT04892173
- Principle Investigator: Füreder
- Haupteinschlusskriterien: For participants with oropharyngeal cancer, human papilloma virus (HPV) p16 status must be known; Has one primary tumor lesion that is amenable for intratumoral injection, as determined by the Investigato; Age ≥65 years
- Studienphase: III
- Sponsor: Nanobiotix S.A.

# eVOLVE

- Titel: **A Phase III, Randomized, Open-Label, Multi-Center, Global Study of Volrustomig (MEDI5752) as Sequential Therapy Versus Observation in Participants with Unresected Locally Advanced Head and Neck Squamous Cell Carcinoma, Who Have Not Progressed Following Definitive Concurrent Chemoradiotherapie (eVOLVE-HNSCC)**
- ClinicalTrials.gov Identifier: NCT06129864
- Principle Investigator: Füreder
- Haupteinschlusskriterien: Histologically or cytologically documented locally advanced squamous cell carcinoma of the oropharynx, hypopharynx, oral cavity, or larynx with no evidence of metastatic disease (i.e. M0). Confirmed unresected Stage III, Stage IVA or IVB according to the eighth edition of the American Joint Committee on Cancer (AJCC) staging manual (tumor, node, metastasis (TNM) staging system). Participants will have completed definitive concurrent chemoradiotherapy (cCRT) with curative intent within 12 weeks prior to randomization.
- Studienphase: III
- Sponsor: AstraZeneca

# XL092-305 (Stellar)

- Titel: **A Phase 2/3, Randomized, Double-Blind, Controlled Study of Zanzalintinib (XL092) in Combination with Pembrolizumab versus Pembrolizumab in the First-Line Treatment of Subjects with PD-L1 Positive Recurrent or Metastatic Head and Neck Squamous Cell Carcinoma**
- NCT06082167
- Principle Investigator: Füreder
- Haupteinschlusskriterien: Histologically or cytologically-confirmed R/M HNSCC that is considered incurable by local therapy. Subjects should not have had prior systemic therapy administered in the recurrent or metastatic setting. Systemic therapy which was completed more than 6 months prior to randomization if given as part of multimodal treatment for locally advanced disease is allowed. The eligible primary tumor locations are the oropharynx, oral cavity, hypopharynx, and larynx.PD-L1 expression level Combined Positive Score (CPS) ≥ 1. Subjects with oropharyngeal cancer must have HPV status from tumor tissue.
- Studienphase: II/III
- Sponsor: Exelixis

# Enhance

- Titel: **H1-antihistamine treatment in combination with immunotherapy in patients with advanced non small cell lung cancer: A single- center phase II trial**
- EudraCT 2022-001284-27
- Principle Investigator: Kiesewetter-Wiederkehr
- Haupteinschlusskriterien: Capability of understanding the purpose of the study and have given written informed consent; Histologically confirmed squamous or non-squamous NSCLC; Radiologically documented metastatic unresectable disease
- Studienphase: II
- Sponsor: Medizinische Universität Wien

# AbbVie M18-868

- Titel: **Offene, randomisierte, kontrollierte globale Studie der Phase III mit Telisotuzumab-Vedotin (ABBV 399) im Vergleich zu Docetaxel bei Patienten mit vorbehandeltem, c-Met-überexprimiertem und lokal fortgeschrittenem/metastasierendem Nicht-Plattenepithel-, nicht kleinzelligem Lungenkarzinom (NSCLC) mit EGFR-Wildtyp**
- ClinicalTrials.gov Identifier: NCT04928846
- Principle Investigator: Kiesewetter-Wiederkehr
- Haupteinschlusskriterien: 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.
- Studienphase: III
- Sponsor: AbbVie Inc.

# AVANZAR

- Titel: **A Phase III, Randomised, Open-label, Multicentre, Global Study of Datopotamab Deruxtecan (Dato-DXd) in Combination With Durvalumab and Carboplatin Versus Pembrolizumab in Combination With Platinum-based Chemotherapy for the First-line Treatment of Patients With Locally Advanced or Metastatic NSCLC Without Actionable Genomic Alterations (D926NC00001; AVANZAR)**
- ClinicalTrials.gov Identifier: NCT05687266
- Principle Investigator: Kiesewetter-Wiederkehr
- Haupteinschlusskriterien: Participants ≥ 18 years at screening. Participants with histologically or cytologically documented NSCLC that is Stage IIIB or IIIC disease not amenable for surgical resection or definitive chemoradiation or Stage IV metastatic NSCLC disease at the time of randomisation, who have not received prior chemotherapy or other systemic therapy for first-line Stage IIIB, IIIC or IV. Lacks sensitising EGFR tumour tissue mutation and ALK and ROS1 rearrangements and has no documented tumour genomic alterations in NTRK, BRAF, RET, MET or other actionable driver oncogenes with approved therapies (actionable genomic alterations).
- Studienphase: III
- Sponsor: Astra Zeneca

# DeLLphi-306 (AMG757)

- Titel: **A phase 3, randomized, double-blind, placebo-controlled, multicenter study of Tarlatamab Therapy in subjects with limited-stage small-cell lung cancer (LS-SCLC) who have not progressed following concurrent chemoradiation therapy**
- ClinicalTrials.gov Identifier: NCT06117774
- Principle Investigator: Füreder
- Haupteinschlusskriterien: Participant has provided informed consent prior to initiation of any study specific activities/procedures. Age ≥ 18 years (or ≥ legal age within the country if it is older than 18 years). Histologically or cytologically confirmed small-cell lung cancer (SCLC). Diagnosed and treated for LS-SCLC with concurrent chemotherapy and radiotherapy.
- Studienphase: III
- Sponsor: Amgen

# REPOSE

- Titel: **A phase II study assessing safety and efficacy of REPpotrectinib in ROS1-positive non-Small cell lung cancer (NSCLC) patients with active brain mEtastasis (BMs) - The REPOSE Study**
- ClinicalTrials.gov Identifier: NCT06315010
- Principle Investigator: Füreder
- Haupteinschlusskriterien: Patients will be included in the study only if they meet all the following criteria: Patient must be capable to understand the purpose of the study and have signed written informed consent form (ICF) prior to beginning specific protocol procedures. Female or male patients ≥ 18 years of age at the time of signing ICF. Patients must be capable to swallow capsules intact (without chewing, crushing, or opening). Histologically documented NSCLC. Patients may have symptoms attributed to brain metastases.
- Studienphase: II
- Sponsor: MedSIR

# SPLFIO-174

- Titel: **A Phase 1b/2, Multicenter, Open-label Platform Study of Select Immunotherapy Combinations in Adult Participants With Previously Untreated Advanced Non-small Cell Lung Cancer (NSCLC) With High PD-L1 Expression**
- ClinicalTrials.gov Identifier: NCT06162572
- Principle Investigator: Raderer
- Haupteinschlusskriterien: Adult patient aged ≥ 18 years, Written informed consent, Histologically (squamous or non-squamous) or cytologically documented locally advanced NSCLC not eligible for surgical resection and/or definitive chemoradiation, or metastatic NSCLC, No prior systemic treatment for locally advanced or metastatic NSCLC. High tumor cell PD-L1 expression [Tumor Proportion Score (TPS) ≥50%] based on documented status as determined by an approved test. Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1. Measurable disease as determined by RECIST v1.1
- Studienphase: Ib/II
- Sponsor: Servier Bio-Innovation LLC

# SOHO-2

- Titel: **A Phase 3 Open-label, Randomized, Active-controlled, Multicenter Trial to Evaluate the Efficacy and Safety of Orally Administered BAY 2927088 Compared With Standard of Care as a First-line Therapy in Patients With Locally Advanced or Metastatic Non-small Cell Lung Cancer (NSCLC) With HER2-activating Mutations**
- ClinicalTrials.gov Identifier: NCT06452277
- Principle Investigator: Füreder
- Haupteinschlusskriterien: Participant must be ≥18 years of age or over the legal age of consent in countries where that is greater than 18 years at the time of signing the informed consent. Documented histologically or cytologically confirmed locally advanced non-squamous NSCLC, not suitable for definitive therapy or metastatic non-squamous NSCLC at screening (small cell or mixed histologies are excluded) (Stage III-IV NSCLC). Documented activating HER2 mutation in the tyrosine kinase domain (TKD) assessed by tissue molecular test in a CLIA-certified (US sites) or an equally accredited (outside of the US) local laboratory. However, participants may be included at the discretion of the investigator if the laboratory performing the assay is not CLIA or similar certified but the laboratory is locally accredited.
- Studienphase: III
- Sponsor: Bayer

# CA 239-0004 (KRYSTAL-4)

- Titel: **A Randomized, Double-Blind, Phase 3 Trial of Adagrasib Plus Pembrolizumab Plus Chemotherapy vs. Placebo Plus Pembrolizumab Plus Chemotherapy in Participants With Previously Untreated, Locally Advanced or Metastatic Non-squamous Non-small Cell Lung Cancer With KRAS G12C Mutation (KRYSTAL-4)**
- ClinicalTrials.gov Identifier: NCT06875310
- Principle Investigator: Füreder
- Haupteinschlusskriterien: Histologically or cytologically confirmed diagnosis of non-squamous NSCLC with evidence of KRAS G12C mutation via tumor tissue and/or circulating tumor deoxyribonucleic acid (ctDNA). Locally advanced or metastatic disease. Measurable disease via computed tomography (CT) or magnetic resonance imaging (MRI) per RECIST v1.1 criteria of at least 1 lesion.
- Studienphase: III
- Sponsor: BMS / Mirati Therapeutics Inc.

# Programmdirektion Sarkome

# SaLuDo

- Titel: **Randomized, Controlled, Open-label, Phase IIb/III Study of Lurbinectedin in Combination with Doxorubicin versus Doxorubicin Alone as First-line Treatment in Patients with Metastatic Leiomyosarcoma**
- ClinicalTrials.gov Identifier: NCT06088290
- Principle Investigator: Brodowicz
- Haupteinschlusskriterien: Voluntary signed and dated written informed consent of the patient obtained before any study-specific procedure. Age ≥ 18 years. Histologically confirmed diagnosis of metastatic LMS, in patients not candidates for curative resection. Radiologically measurable disease according to the RECIST v.1.1. No previous systemic therapy for metastatic disease (i.e., first-line setting) and no previous anthracyclines. Note: prior chemotherapy (without anthracycline) in the context of adjuvant or neoadjuvant therapy is allowed.
- Studienphase: IIb/III
- Sponsor: PharmaMar

# Programmdirektion Gastrointestinale Tumoren

# Sign

- Titel: Selective serotonin reuptake inhibition in patients with advanced gastroesophageal cancer receiving immunochemotherapy: A prospective phase II trial
- EudraCT 2022-001989-36
- Principle Investigator: Ilhan-Mutlu
- Haupteinschlusskriterien: Histologically confirmed gastric/gastroesophageal junction/esophageal adenocarcinoma
- Studienphase: II
- Sponsor: Medizinische Universtität Wien

# Prosperity

- Titel: A Prospective non-interventional study (NIS) of trastuzumab deRuxtecan (T-DXd) for adult patients with advanced HER2-pOsitive gaStric or gastroesoPhageal junction (GEJ) adEnocarcinoma who have Received a prIor Trastuzumab-based regimen, accompanied by a disease registrY of patients treated with conventional therapies in a real-world setting in Europe. (PROSPERITY)
- ClinicalTrials.gov Identifier: NCT05993234
- Principle Investigator: Ilhan-Mutlu
- Haupteinschlusskriterien: Male or female adult patient (age ≥ 18 years) with HER2 + advanced gastric or GEJ adenocarcinoma who have received a prior trastuzumab based regimen Histological or cytological confirmed diagnosis of advanced HER2 positive gastric cancer or GEJ Documented HER2 + status (archival sample or recent sample prior 2L therapy)  Decision to newly initiate monotherapy T-DXd or conventional therapies per SMPC according to the physician's choice Written dated and signed Informed Consent (ICF) to participate in the study
- Studienphase: NIS
- Sponsor: Daiichi Sankyo

# SERVIER (CL1-95029-002)

- Titel: Open-label, non-randomized, Phase 1b/2 trial investigating the safety, tolerability, and antitumor activity of SO95029 (anti-NKG2A antibody) as a part of combination therapy in participants with locally advanced and unresectable or metastatic MSI-H/dMMR gastroesophageal junction/gastric cancer
- ClinicalTrials.gov Identifier: NCT06116136
- Principle Investigator: Ilhan-Mutlu
- Haupteinschlusskriterien: Have a confirmed diagnosis of locally advanced and unresectable or metastatic gastric or gastro-esophageal junction adenocarcinoma, Participants' tumor must have an MSI-H or dMMR status according to institutional guidelines and/or according to the College of American Pathologists, determined at any time prior to enrolment.
- Studienphase: I/II
- Sponsor: Servier Bio-Innovation LLC

# CodeBreaK 301 (AMG510 20210081)

- Titel: **Phase 3 Multicenter, Radomized, Open-label, Active-controlled Study of Sotorasib, Panitumumab and FOLFIRI Versus FOLFIRI With or Without Bevacizumab-awwb for Treatment-naive Subjects With Metastatic Colorectal Cancer With KRAS p.G12C Mutation (CodeBreak 301)**
- ClinicalTrials.gov Identifier: NCT06252649
- Principle Investigator: Prager
- Haupteinschlusskriterien: Pathologically documented metastatic colorectal adenocarcinoma with KRAS p.G12C mutation by a locally validated assay. Central confirmation of KRAS p.G12C mutation. Measurable metastatic disease per RECIST v1.1 criteria. Eastern Cooperative Oncology Group (ECOG) Performance Status of ≤ 1. Adequate organ function.
- Studienphase: III
- Sponsor: Amgen

# Österreichweites Pankreasregister

- Titel: **Austrian registry for evaluation of treatment patterns and outcome in patients with advanced pancreatic ductal adenocarcinoma (PDAC)**
- ClinicalTrials.gov Identifier: NCT05526443
- Principle Investigator: Prager
- Haupteinschlusskriterien: 18 years, female and male; ECOG (Eastern Cooperative Oncology Group) Scale 0-2; Diagnosis of histologically confirmed locally advanced inoperable and/or metastatic PDAC; Patients undergoing palliative 1st line chemotherapy; Signed informed consent for prospective patients, for retrospective cases no informed consent is required
- Studienphase: Register
- Sponsor: MedUni Graz

# GUIDE.MRD

- Titel: **Guiding Multi-Modal Therapies against minimal Tresidual disease by liquid biopsies**
- EK-Nr. 36-077 ex 23/24 (MedUni Graz)
- Principle Investigator: Prager
- Haupteinschlusskriterien: Colon or rectal cancer, clinical tumor stage I-III. Patient 18 years or older. Patient able to understand and sign written informed consent. Scheduled for curative-intent resectianal surgery (including "compromised" curative resections).
- Studienphase: IIT
- Sponsor: MedUni Graz

# Circulate AIO-KRK 0217

- Titel: **Circulating Tumour DNA Based Decision for Adjuvant Treatment in Colon Cancer Stage II Evaluation (CIRCULATE) AIO-KRK-0217**
- ClinicalTrials.gov Identifier: NCT04089631
- Principle Investigator: Prager
- Haupteinschlusskriterien: 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
- Studienphase: III
- Sponsor: Technische Universität Dresden

# PRISM-1

- Titel: **A Randomized, Placebo-Controlled, Double-Blind, Multicenter, Phase 3 Trial of Quemliclustat and Chemotherapy Versus Placebo and Chemotherapy in Patients With Treatment-Naive Metastatic Pancreatic Ductal Adenocarcinoma**
- ClinicalTrials.gov Identifier: NCT06608927
- Principle Investigator: Prager
- Haupteinschlusskriterien: Have histologically or cytologically confirmed PDAC that is metastatic. Have not been previously treated for PDAC in the metastatic setting. Prior neoadjuvant and/or adjuvant therapy for PDAC is permitted if completed at least 12 months before randomization. Prior palliative radiotherapy is allowed if completed at least 2 weeks prior to randomization and AEs have resolved to Grade 1 or less before randomization. Prior and/or placement of a biliary stent/tube is permitted if any treatment-related AEs have improved to Grade ≤ 1 and the patient is not exhibiting any signs/symptoms of biliary obstruction. Eastern Cooperative Oncology Group PS of 0 to 1. At least 1 target lesion measurable by computed tomography (CT)/magnetic resonance imaging (MRI) per RECIST v1.1. not within a field of prior radiation therapy.
- Studienphase: III
- Sponsor: Arcus Biosciences, Inc.

# Programmdirektion Extranodale Lymphome

# IELSG48

- Titel: **Phase 3, interventional multicentre, open-label, randomized study comparing rituximab plus zanubrutinib to rituximab monotherapy in previously untreated, symptomatic splenic marginal zone lymphoma (RITZ)**
- ClinicalTrials.gov Identifier: NCT05735834
- Principle Investigator: Raderer
- Haupteinschlusskriterien: Ability to understand and willingness to sign a written informed consent in accordance with ICH/GCP regulations before registration and prior to any trial-specific procedures. Confirmed diagnosis of SMZL, including Matutes immunophenotype score <3, absence of CD103 and CD25 expression by flow cytometry, absence of Cyclin D1, BCL6, and CD10 expression by immunohistochemistry, and absence of the MYD88 L265P mutation. Patients with prominent splenomegaly and involvement of the splenic hilar and/or extra hilar lymph nodes are eligible, Previously untreated disease. Patients with prior hepatitis C virus (HCV) infection who underwent HCV eradication and have persistent SMZL after 3 months post-eradication can be included. Patients with previous splenectomy are excluded.
- Studienphase: III
- Sponsor: Medizinische Universität Wien

# POLA-RB

- Titel: **RO-IIS-2020-20598//RO5541077 ML42274 - Efficacy of Polatuzumab, Bendamustine and Rituximab in Patients with relapsed / refractory Mantle Cell Lymphoma - a Single Center Phase II Trial**
- ClinicalTrials.gov Identifier: NCT05868395
- Principle Investigator: Kiesewetter-Wiederkehr
- Haupteinschlusskriterien: To be included each patient must fulfill all of the following criteria: Patient must be capable of understanding the purpose of the study and have given written informed consent. Age greater than or equal to 18 years. Histologically or cytologically confirmed relapsed or refractory MCL. r/r MCL patients following standard first line chemotherapy who have received at least one prior regimen including ibrutinib. If the patient has received prior bendamustine, response duration must have been > 1 year - Presence of at least one lymph node evaluable or mass measurable for response. ECOG 0 - 2 . Adequate hematological, renal and hepatic function unless inadequate function is due to underlying disease
- Studienphase: II
- Sponsor: (IIT) Roch Austria GmbH

# Programmdirektion Internistische Neuroonkologie

# EORTC-2013-BTG

- Titel: **Observational study for assessing treatment and outcome of patients with primary brain tumors diagnosed accourding to cIMPACT-NOW recommendations and the 2021 WHO classification**
- ClinicalTrials.gov Identifier: NCT05259605
- Principle Investigator: Preusser
- Haupteinschlusskriterien: Newly diagnosed or recurrent primary brain tumours, notably those considered rare brain tumours or rare subtypes of common brain tumours. Archival tumour tissue from primary tumour available at the site. Representative tissue from first surgery is preferred, but tissue from surgery for recurrence is allowed. Before patient registration, written informed consent must be given according to ICH/GCP, and national/local regulations. Inclusion in interventional studies prior and after
- Studienphase: Observational
- Sponsor: EORTC

# EORTC-2334 (LUMEN-1)

- Titel: **77Lu-DOTATATE for Recurrent Meningioma: a Randomized Phase II Study**
- ClinicalTrials.gov Identifier: NCT06326190
- Principle Investigator: Bergmeister-Berghoff
- Haupteinschlusskriterien: Adult patient ≥ 18 years of age. Histologically confirmed diagnosis of meningioma (all grades, 1-3 per WHO CNS5, are eligible) WHO performance status 0-2. Measurable disease (at least 10 x10 mm contrast enhancing lesion) on cranial MRI no more than two weeks prior to randomization. Radiologically documented progression of any existing tumour (growth > 25% in the last two years) or appearance of new lesions (including intra- and extracranial manifestations). Somatostatin receptor (SSTR)-positive confirmed by PET imaging with scan performed within four weeks before randomization (baseline SSTR-PET is considered as positive when meningioma uptake intensity exceeds a SUVmax of 2.3).
- Studienphase: II
- Sponsor: EORTC

# VORA IDH /SO95032-211)

- Titel: **A Phase 1b/2, Multicenter Study of Vorasidenib in Combination With Temozolomide (TMZ) in Participants With IDH1- or IDH2-mutant Glioma**
- ClinicalTrials.gov Identifier: NCT06478212
- Principle Investigator: Preusser
- Haupteinschlusskriterien: Be ≥12 years of age with a weight at screening ≥40 kg. Have documented IDH1 or IDH2 mutation based on local testing of tumor tissue by an accredited laboratory. Have adequate renal function, defined as a creatinine clearance ≥40 mL/min based on the Cockcroft-Gault glomerular filtration rate estimation: (140 - Age) × (Weight in kg) × (0.85 if female) / 72 × serum creatinine (mg/dL).
- Studienphase: Ib/II
- Sponsor: Institut de Recherches Internationales Servier

# EORTC-2227-BTG (LEGATO)

- Titel: **Lomustine with and without reirradiation for first progression of glioblastoma: a randomized phase III study**
- ClinicalTrials.gov Identifier: NCT05904119
- Principle Investigator: Preusser
- Haupteinschlusskriterien: Before patient's enrolment, written informed consent must be given according to ICH/GCP, and national/local regulations. Patients with first progression or recurrent glioblastoma after standard chemoradiotherapy (any treatment other than use of nitroureas) having occurred at least 6 months after the end of prior radiotherapy. Measurable disease according to RANO criteria with a maximum tumour diameter of 5 cm (local investigator assessment). In case of surgery for recurrence: fully recovered from surgery, confirmation of recurrence by histology, and patient fit for treatment as per local investigator assessment.
- Studienphase: III
- Sponsor: EORTC

# ATTRACT

- Titel: Personalized Targeted Glioblastoma Therapies by ex Vivo Drug Screening: Advanced Brain Tumor TheRApy Clinical Trial (ATTRACT)
- ClinicalTrials.gov Identifier: NCT06512311
- Principle Investigator: Bergmeister-Berghoff
- Haupteinschlusskriterien: Age 18-75, ECOG performance status 0-2, Newly diagnosed glioblastoma, IDH wildtype - according to the 2021 WHO classification of Tumors of the Central Nervous System, MGMT promotor unmethylated per local investigator, Tissue available for drug screening (successful PDC establishment from surgical material), Scheduled for concomitant radio-chemotherapy with temozolomide, Written informed consent
- Studienphase: Not Applicable
- Sponsor: MedUni Wien / Bund / Forschungsförderung

# ONC 201

- Titel: **ONC201 for the Treatment of Newly Diagnosed H3 K27M-mutant Diffuse Glioma Following Completion of Radiotherapy: A Randomized, Double-Blind, Placebo-Controlled, Multicenter Study**
- ClinicalTrials.gov Identifier: NCT05580562
- Principle Investigator: Bergmeister-Berghoff
- Haupteinschlusskriterien: Able to understand the study procedures and agree to participate in the study by providing written informed consent (by participant or legally authorized representative), and assent when applicable. Body weight ≥ 10 kg at time of randomization. Histologically diagnosed H3 K27M-mutant diffuse glioma (new diagnosis). Detection of a missense K27M mutation in any histone H3-encoding gene detected by testing of tumor tissue (immunohistochemistry [IHC] or next-generation sequencing [NGS] in a Clinical Laboratory Improvement Amendments [CLIA]-certified or equivalent laboratory). [Site to provide (as available): ≥ 10 unstained formalin-fixed paraffin-embedded (FFPE) slides from tumor tissue.]
- Studienphase: II
- Sponsor: Chimerix, Inc.