

# 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**
  - *Mammakarzinome*
- **Programmdirektion Tumore des Respirationstraktes**
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  - *Bronchuskarzinome*
- **Programmdirektion Sarkome**
  - *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  $\geq 18$  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  $\geq 18$  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*

# 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

# 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 Investigator; Age  $\geq 65$  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*



# 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: Kieseewetter-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  $\geq$  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: AstraZeneca*

# LAGOON-PM1183-C-008-21

- *Titel: A Randomized, Multicenter, Open-label, Phase III Study of Lurbinectedin Single-Agent or Lurbinectedin in Combination With Irinotecan Versus Investigator's Choice (Topotecan or Irinotecan) in Relapsed Small Cell Lung Cancer Patients (LAGOON Trial)*
- *ClinicalTrials.gov Identifier: NCT05153239*
- *Principle Investigator: Kiesewetter-Wiederkehr*
- *Haupteinschlusskriterien: Voluntary written informed consent of the patient obtained before any study-specific procedure, Age  $\geq 18$  years, Histologically or cytologically confirmed diagnosis of SCLC.*
- *Studienphase: II*
- *Sponsor: PharmaMar*

# Seagen SGNB6A-002

- *Titel: A randomized, phase 3, open-label study to evaluate SGN-B6A compared with docetaxel in adult subjects with previously treated non-small cell lung cancer*
- *ClinicalTrials.gov Identifier: NCT06012435*
- *Principle Investigator: Kiesewetter-Wiederkehr*
- *Haupteinschlusskriterien: Histologically or cytologically confirmed diagnosis of locally advanced, unresectable (Stage IIIB, IIIC), or metastatic Stage IV (M1a, M1b, or M1c) NSCLC American Joint Committee on Cancer (AJCC) Staging Manual, Version 8.0, and the Union for International Cancer Control (UICC) Staging System (Eighth edition). Participants must have NSCLC with nonsquamous histology Tumors with squamous, or predominantly squamous histology are excluded, Tumors with small cell elements are excluded, Participants who have NSCLC with known actionable genomic alteration (AGAs) are permitted*
- *Studienphase: III*
- *Sponsor: Seagen Inc.*

# DeLLphi-306 (AMG 757)

- *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  $\geq 18$  years (or  $\geq$  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*

# SPFLIO-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  $\geq 18$  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)  $\geq 50\%$ ] 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*

# 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  $\geq 18$  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 Universität Wien*

# Prosperity

- *Titel: A Prospective non-interventional study (NIS) of trastuzumab deRuxtecán (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  $\geq 18$  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*

# BERING-CRC - NIS

- *Titel: Encorafenib and Cetuximab in Patients With Metastatic, BRAFV600E-mutated, Colorectal Carcinoma: a Multi-centric, Multi-national, Prospective, Longitudinal, Non-interventional Study in Germany and Austria*
- *ClinicalTrials.gov Identifier: NCT04673955*
- *Principle Investigator: Prager*
- *Haupteinschlusskriterien: Metastatic, BRAFV600E-mutated, colorectal carcinoma*
- *Studienphase: NIS*
- *Sponsor: Pierre Fabre Pharma GmbH*

# 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*

# 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: Kiese Wetter-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*

# CABONEN

- *Titel: CABONEN - A Phase II Trial of Cabozantinib in Patients With Advanced, Low Proliferative NEN G3*
- *ClinicalTrials.gov Identifier: NCT04524208*
- *Principle Investigator: Kiesewetter-Wiederkehr*
- *Haupteinschlusskriterien: Patient with histologically confirmed diagnosis of neuroendocrine neoplasia; Tumor proliferation rate has to be between Ki67 20% to 60% (local assessment); male, female, or diverse patients aged > 18 years without upper age limit; at least one measurable tumor lesions in CT or MRI scan; newly diagnosed or progressive disease assessed per RECIST criteria 1.1;*
- *Studienphase: II*
- *Sponsor: Karsten Gavenis*

# Programmdirektion Internistische Neuroonkologie

# EORTC-2013-BTG

- *Titel: Observational study for assessing treatment and outcome of patients with primary brain tumors diagnosed according 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-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  $\geq 10$  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):  $\geq 10$  unstained formalin-fixed paraffin-embedded (FFPE) slides from tumor tissue.]*
- *Studienphase: II*
- *Sponsor: Chimerix, Inc.*