Öffentlicher Titel	Phase I/II Studie zu zielgerichteten Therapien nach molekularer Charakterisierung bei Glioblastomen
Wissenschaftl. Titel	NCT Neuro Master Match (N²M²) - Phase I/IIa Studie basierend auf einer molekularen Charakterisierung unter Nutzung zielgerichteter Substanzen in Kombination mit Strahlentherapie zur Behandlung von Glioblastomen mit einem nicht-methyliertem MGMT-Promotor
Kurztitel	N²M²
Studienart	multizentrisch, prospektiv, Therapiestudie, offen/unverblindet, Investigator Initiated Trial (IIT), mehrarmig
Studienphase	Phase I
Erkrankung	NEURO: Glioblastom (WHO Grad IV): Erstlinie

Einschlusskriterien

- Histologically confirmed, newly diagnosed glioblastoma (astrocytoma World Health Organization (WHO) grade IV) with unmethylated MGMT promoter determined by one of the accepted methods (qPCR, pyrosequencing, 450k array) and without mutation of the isocitrate dehydrogenase genes
- Open biopsy or resection
- Craniotomy or intracranial biopsy site must be adequately healed
- Informed consent
- Standard MRI <= 48 (+ 6 h) post-surgery according to the present national and international guidelines
- Availability of fresh-frozen tissue, formalin-fixed, paraffin-embedded (FFPE) tissue, and blood
- Age: >=18 years
- Karnofsky performance status (KPS) >=70%
- Life expectancy > 6 months
- All female patients with reproductive potential must have a negative pregnancy test (serum or urine) within 6 days prior to start of therapy. All female patients must be surgically sterile or must agree to use adequate contraception during the period of therapy and 6 months after the end of study treatment, or women must be postmenopausal for at least 2 years. Acceptable methods of contraception comprise barrier contraception combined with a medically accepted contraceptive method for the female patient (e.g. intra-uterine device with spermicide, hormonal contraceptive since at least 2 month). Female patients must agree not to donate lactation during treatment and until 6 months after end of treatment
- Male patients willing to use contraception (condoms with spermicidal jellies or cream) upon study entry and during the course of the study and 3 months after the end of the study, have undergone vasectomy, or are practicing total abstinence. Sperm donation is not permitted for the same time interval.

Ausschlusskriterien

- Abnormal (>= Grade 2 CTCAE v4.03) laboratory values for hematology, liver or renal function
- HIV infection or active Hepatitis B or C infection, or active infections requiring oral or intravenous antibiotics or that can cause a severe disease and pose a severe danger to lab personnel working on patients' blood or tissue (e.g. rabies).
- Prior therapy for glioma (except surgery and steroids) including but not limited to carmustine wafers and immunotherapy.
- Concurrent participation in another interventional clinical trial studying a drug or treatment regimen.
- Insufficient tumor material for molecular diagnostics
- Pregnant and lactating women
- History of hypersensitivity to any of the additives of the study drug formulations

	- Co-administration of anti-cancer therapies other than those administered/allowed in this study - Any clinically significant concomitant disease or condition that could interfere with, or for which the treatment might interfere with, the conduct of the study or the absorption of oral medications or that would, in the opinion of the Principal Investigator, pose an unacceptable risk to the patient in this study - Any psychological, familial, sociological, or geographical condition potentially hampering compliance with the study protocol requirements and/or follow-up procedures; those conditions should be discussed with the patient before trial entry
Alter	18 Jahre und älter
Molekularer Marker	MGMT Promoter, nicht methyliert
Status	Aktiv
Beginn der Rekrutierung	01.11.2018
Prüfzentren	**Universitätsklinikum Frankfurt** Dr. Senckenbergisches Institut für Neuroonkologie Theodor-Stern-Kai 7 60590 Frankfurt am Main Dr. med. Michael Burger michael.burger@kgu.de
Sponsoren	Universitätsklinik Heidelberg
Förderer	Deutsches Krebsforschungszentrum Deutsche Krebshilfe e.V. Hoffmann-La Roche Ltd Apogenix GmbH Pfizer
Registrierung in anderen Studienregistern	ClinicalTrials NCT03158389 (primäres Register) EUDRACT 2015-002752-27