CHARITÉ

Comprehensive Cancer Center
Universitätstumorzentrum

Studientitel	**NCT Neuro Master Match - N²M² (NOA-20) (N²M²)**	
EudraCT-Nummer	**2015-002752-27**	
ClinicalTrials.gov Identifier	**NCT03158389**	
Sponsor	University Hospital Heidelberg	
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Studienziel	The objective of N²M² is the improvement of overall survival of patients with glioblastoma with an unmethylated MGMT promoter based on molecular characterization and use of targeted compounds in a modern trial design. The progression-free survival rate at six months (PFS-6) will be used to make decisions.	
Behandlung	Drug: APG101 Drug: Alectinib Drug: Idasanutlin Drug: Atezolizumab Drug: Vismodegib Drug: Temsirolimus Drug: Palbociclib	
Wichtigste 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	

Wichtigste Einschlusskriterien	• 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.