KURZPROTOKOLL
CA209-498

Öffentlicher Titel	Phase III Studie zu Radiotherapie mit Nivolumab oder Temozolide bei neu diagnostizierten Glioblastom-Patienten mit unmethyliertem MGMT-Promoter
Wissenschaftl. Titel	A Randomized Phase 3 Open Label Study of Nivolumab vs Temozolomide Each in Combination with Radiation Therapy in Newly Diagnosed Adult Subjects with Unmethylated MGMT (tumor 06-methylguanine DNA methylatransferase) Glioblastoma
Kurztitel	CA209-498
Studienart	multizentrisch, Therapiestudie, randomisiert, Pharma-Studie, zweiarmig
Studienphase	Phase III
Erkrankung	Nervensystem: Gliome: Glioblastom (WHO Grad IV) - Erstlinie
Ziele	- Overall survival (OS) [Time Frame: Approximately 3 years] [Designated as safety issue: No] Overall survival: Defined as the time between the date of randomization and the date of death due to any cause - Progression free survival (PFS) [Time Frame: Approximately 24 months] [Designated as safety issue: No] Progression free survival: Defined as the time from randomization to the date of the first documented tumor progression or death due to any cause - Overall survival [Time Frame: Approximately 24 months] [Designated as safety issue: No]
Einschlusskriterien	- Males and Females, age 18 years old - Newly-diagnosed brain cancer or tumor called glioblastoma or GBM - Tumor test result shows MGMT unmethylated type - Karnofsky performance status of 70 (able to care for self)
Ausschlusskriterien	- Prior treatment for GBM (other than surgical resection) - Any known tumor outside of the brain - Recurrent or secondary GBM - Active known or suspected autoimmune disease - Biopsy with less than 20% of tumor removed
Alter	18 Jahre und älter
Molekularer Marker	MGMT Promoter, nicht methyliert
Fallzahl	550
Prüfzentren	**Universitätsklinikum Frankfurt** (Geschlossen) Dr. Senckenbergisches Institut für Neuroonkologie Theodor-Stern-Kai 7 60590 Frankfurt am Main Prof. Dr. med. Joachim Steinbach Tel: 069 6301-87711 Joachim.Steinbach@kgu.de
Sponsor	Bristol-Myers Squibb (Hauptsponsor)
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT02617589 EudraCT 2015-003739-37