

## **KURZPROTOKOLL** **CA209-498**

<b>Öffentlicher Titel</b>	Phase III Studie zu Radiotherapie mit Nivolumab oder Temozolide bei neu diagnostizierten Glioblastom-Patienten mit unmethyliertem MGMT-Promoter
<b>Wissenschaftl. Titel</b>	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 methyltransferase) Glioblastoma
<b>Kurztitel</b>	CA209-498
<b>Studienart</b>	multizentrisch, Therapiestudie, randomisiert, Pharma-Studie, zweiarmig
<b>Studienphase</b>	Phase III
<b>Erkrankung</b>	Nervensystem: Gliome: Glioblastom (WHO Grad IV) - Erstlinie
<b>Ziele</b>	<ul style="list-style-type: none"><li>- 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</li><li>- 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</li><li>- Overall survival [ Time Frame: Approximately 24 months ] [ Designated as safety issue: No ]</li></ul>
<b>Einschlusskriterien</b>	<ul style="list-style-type: none"><li>- Males and Females, age 18 years old</li><li>- Newly-diagnosed brain cancer or tumor called glioblastoma or GBM</li><li>- Tumor test result shows MGMT unmethylated type</li><li>- Karnofsky performance status of 70 (able to care for self)</li></ul>
<b>Ausschlusskriterien</b>	<ul style="list-style-type: none"><li>- Prior treatment for GBM (other than surgical resection)</li><li>- Any known tumor outside of the brain</li><li>- Recurrent or secondary GBM</li><li>- Active known or suspected autoimmune disease</li><li>- Biopsy with less than 20% of tumor removed</li></ul>
<b>Alter</b>	18 Jahre und älter
<b>Molekularer Marker</b>	MGMT Promoter, nicht methyliert
<b>Fallzahl</b>	550
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<b>Registrierung in anderen Studienregistern</b>	ClinicalTrials.gov NCT02617589 EudraCT 2015-003739-37