KURZPROTOKOLL
APG101_CD_002

Öffentlicher Titel	APG101 bei erstem oder zweiten Progress eines Glioblastoms
Wissenschaftl. Titel	Randomisierte, offene, multizentrische Phase II Studie mit APG101 (wöchentlich) plus Re-Bestrahlung versus Re-Bestrahlung alleine in der Behandlung von Patienten mit erstem oder zweiten Progress eines Glioblastoms
Kurztitel	APG101_CD_002
Studienart	multizentrisch, prospektiv, randomisiert, offen/unverblindet, zweiarmig, Investigator Initiated Trial (IIT)
Studienphase	Phase II
Erkrankung	Nervensystem: Gliome: Glioblastom (WHO Grad IV) - Zweitlinie oder höher
Ziele	- 6 months rate of progression-free survival (PFS6) - Safety and tolerability of APG 101 - Progression-free survival - Objective response rates (OR) - Duration of response (DR) in responders - Overall survival - Quality of life as determined by EORTC QLQ-C15-PAL and the - EORTC brain module QLQ-BN 20 - Cognitive function determined by MMSE
Einschlusskriterien	- Male and female patients with a recurrence / progression of glioblastoma either not being eligible for tumour resection or having macroscopic residual tumour after resection of the recurrence documented by MRI. MRI images must not be older than 2 weeks before inclusion - Not more than two prior therapy regimens including one or tworesections, one or two chemotherapies of which one must havebeen TMZ-containing and one radiotherapy (RT) for the brain tumour - Previous irradiation therapy of the primary tumour with a maximal dose of 60 Gy; at least 8 months since the end of preirradiation - Candidate for reirradiation with recurrent tumour visible on MRIT1 (Gd) and with the largest diameter measuring 1 cm to 4 cm - Informed consent - Age >=18 years, smoking or non-smoking, of any ethnic origin - Karnofsky performance index (KPI) >= 60% - Neutrophile counts > 1500/ìl / Platelet counts > 80.000/ìl / Haemoglobin > 10 g/dl / Serum creatinine < 1.5-fold upper normal range / Bilirubin, AST or ALT < 2,5-fold upper normal range - Adequate contraception - Stable or decreasing treatment with steroids within 5 days before treatment start
Ausschlusskriterien	- More than one RT of brain, prior first radiotherapy with more than 60 Gy - Cumulative total dose on the optical chiasm >54 Gy for 2 - Gy/fraction, á/â=2 - Prior treatment with bevacizumab, iodine seeds and/or - brachytherapy - Unable to undergo MRI - Past medical history of diseases with poor prognosis according to the judgement of the Investigator, e.g. severe coronary heart disease, severe diabetes, immune deficiency, residual deficits after stroke, severe mental retardation - HIV or hepatitis infection

	- Pregnancy or breast feeding - Treatment within any other clinical trial parallel to the treatment phase of the current study or within 30 days before inclusion - Known coronary artery disease, significant cardiac arrhythmias or severe congestive heart failure (NYHA class III – IV)
Alter	18 Jahre und älter
Status	Geschlossen
Fallzahl	5
Sponsor	Apogenix GmbH (Hauptsponsor)
Förderer	Apogenix GmbH
Registrierung in anderen Studienregistern	EudraCT 2009-013421-42
Therapie	Radiotherapy (RT) is considered standard of care and not a study procedure and will be carried out on an out-patient or in-patient basis at the discretion of the Investigator. Patients will receive 400 mg APG101 weekly as i.v. application. MRI tumour imaging will be carried out every 6 weeks. For a detailed overview of the study procedures.