

<b>Öffentlicher Titel</b>	APG101 bei erstem oder zweiten Progress eines Glioblastoms
<b>Wissenschaftl. Titel</b>	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
<b>Kurztitel</b>	APG101_CD_002
<b>Studienart</b>	multizentrisch, prospektiv, randomisiert, offen/unverblindet, zweiarmig, Investigator Initiated Trial (IIT)
<b>Studienphase</b>	Phase II
<b>Erkrankung</b>	NEURO: Glioblastom (WHO Grad IV): Zweitlinie oder höher RADIO: Verschiedene Tumoren
<b>Ziele</b>	<ul style="list-style-type: none"><li>- 6 months rate of progression-free survival (PFS6)</li><li>- Safety and tolerability of APG 101</li><li>- Progression-free survival</li><li>- Objective response rates (OR)</li><li>- Duration of response (DR) in responders</li><li>- Overall survival</li><li>- Quality of life as determined by EORTC QLQ-C15-PAL and the EORTC brain module QLQ-BN 20</li><li>- Cognitive function determined by MMSE</li></ul>
<b>Einschlusskriterien</b>	<ul style="list-style-type: none"><li>- 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</li><li>- Not more than two prior therapy regimens including one or two resections, one or two chemotherapies of which one must have been TMZ-containing and one radiotherapy (RT) for the brain tumour</li><li>- Previous irradiation therapy of the primary tumour with a maximal dose of 60 Gy; at least 8 months since the end of preirradiation</li><li>- Candidate for reirradiation with recurrent tumour visible on MRIT1 (Gd) and with the largest diameter measuring 1 cm to 4 cm</li><li>- Informed consent</li><li>- Age <math>\geq 18</math> years, smoking or non-smoking, of any ethnic origin</li><li>- Karnofsky performance index (KPI) <math>\geq 60\%</math></li><li>- Neutrophil counts <math>&gt; 1500/\mu\text{l}</math> / Platelet counts <math>&gt; 80.000/\mu\text{l}</math> / Haemoglobin <math>&gt; 10 \text{ g/dl}</math> / Serum creatinine <math>&lt; 1.5</math>-fold upper normal range / Bilirubin, AST or ALT <math>&lt; 2,5</math>-fold upper normal range</li><li>- Adequate contraception</li><li>- Stable or decreasing treatment with steroids within 5 days before treatment start</li></ul>
<b>Ausschlusskriterien</b>	<ul style="list-style-type: none"><li>- More than one RT of brain, prior first radiotherapy with more than 60 Gy</li><li>- Cumulative total dose on the optical chiasm <math>&gt; 54 \text{ Gy}</math> for 2 Gy/fraction, <math>\dot{\hat{a}}=2</math></li><li>- Prior treatment with bevacizumab, iodine seeds and/or brachytherapy</li><li>- Unable to undergo MRI</li><li>- 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</li></ul>

- 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)

<b>Alter</b>	18 Jahre und älter
<b>Status</b>	Geschlossen
<b>Beginn der Rekrutierung</b>	01.06.2010
<b>Fallzahl</b>	5
<b>Sponsoren</b>	Apogenix GmbH (Hauptsponsor)
<b>Förderer</b>	Apogenix GmbH
<b>Registrierung in anderen Studienregistern</b>	EUDRACT 2009-013421-42
<b>Therapie</b>	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.