

Press Release

Apogenix Successfully Completes Patient Recruitment for Glioblastoma Phase II Trial with APG101

- Recruitment of 83 patients completed
- Final study results expected in the first quarter of 2012

Heidelberg, September 20, 2011 - The biopharmaceutical company Apogenix GmbH today announced the completion of patient recruitment for the ongoing clinical phase II trial with APG101 for the treatment of glioblastoma, which started in December 2009. As a result of an interim analysis for efficacy and safety evaluation in June 2011, the Data Safety Monitoring Board recommended to continue the study until completion as planned. Final results of the phase II trial are expected in the first quarter of 2012.

In the open-label, randomized, controlled study a total of 83 patients with first or second relapse/progression of Glioblastoma Multiforme (GBM, brain tumor) were included in 25 centers in Germany, Austria, and Russia. Patients were either treated with APG101 plus reirradiation or reirradiation only. Primary endpoint of the study is the 6-month-rate of progression free survival (PSF6). Secondary endpoints include overall survival, safety and tolerability of APG101, and parameters measuring the patients' quality of life.

APG101 is a fully human protein and provides an innovative therapeutic approach for the treatment of GBM. APG101 is the first inhibitor of the CD95 ligand (CD95L) which is currently in clinical development and which has been granted orphan drug designation in Europe and the US in 2009.

GBM is the most frequent and aggressive glioma (tumor deriving from glia cells). The tumor cells are characterized by a high resistance to radio- and chemotherapy and the disease often has a devastating impact on patients. Approximately 28,000 new cases of malignant glioblastomas are diagnosed in the US and EU each year.

Dr. Harald Fricke, CMO of Apogenix, commented: "The completion of the patient recruitment is an important milestone for Apogenix and our first clinical development program. The evaluation of the study is being conducted with great effort by everyone involved and the results are eagerly anticipated. First results of the preliminary evaluation in June 2011 are encouraging."

The study's lead clinician, Prof. Wolfgang Wick (Clinical Cooperation Unit Neurooncology, German Cancer Research Center, and Department of Neurooncology, University Hospital of Heidelberg), added: "This is one of only a few controlled phase II trials in glioblastoma and scientists, physicians as well as glioblastoma patients are impatiently awaiting the results. Besides investigating APG101's innovative mechanism of action, the efficacy of reirradiation is also studied in a multicenter controlled trial for the first time."



About Apogenix

Apogenix, a spin-out from the German Cancer Research Center (DKFZ), is developing novel protein therapeutics for the treatment of cancer and inflammatory diseases, based either on the targeted modulation of apoptosis (programmed cell death) or on blocking the invasive growth of tumor cells. The company's lead product candidate APG101 is being developed for the treatment of Glioblastoma Multiforme (GBM), the most common and aggressive type of primary brain tumor. Since its inception in autumn 2005, the company has raised €43 million and has been awarded public grants totaling of more than €6 million. Apogenix is based in Heidelberg, Germany.

About APG101

The company's lead product candidate, APG101, a fully human, soluble fusion protein combining the extracellular domain of the CD95 receptor and the Fc portion of IgG, successfully completed a phase I study in 2009. In December 2009, Apogenix started a controlled phase II trial with APG101 for the treatment of Glioblastoma Multiforme. The patient recruitment for this study has been recently completed. Apogenix has been granted orphan drug designation for APG101 in 2009 for the treatment of GBM in Europe and the US.

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