Press Release

Apogenix Announces that APG101 Meets Primary Endpoint in a Controlled Phase II Trial with Glioblastoma Patients

- Study objective of increasing percentage of patients reaching PFS6 by 100% was substantially exceeded
- No drug-related adverse effects observed

Heidelberg, Germany, March 8, 2012 - The biopharmaceutical company Apogenix GmbH announced today that the phase II clinical efficacy trial with APG101 has met its primary endpoint in the 2nd line treatment of Glioblastoma Multiforme (GBM), following a six month follow up of the last patient treated. The primary endpoint of the trial was the six-month-rate of progression-free survival (PFS6) and secondary endpoints include overall survival (OS), safety and tolerability of APG101, plus parameters assessing the patients' quality of life (QoL). In the controlled, randomized, open-label trial, patients were treated with APG101 and radiotherapy or with radiotherapy alone.

The phase II clinical trial recruited 83 patients in 27 centers throughout Germany, Austria, and Russia. Patients were eligible for inclusion if they had suffered from first or second relapses and if they no longer responded to treatment with Temozolomide. GBM patients participated in this study until tumor progression. Currently, there are no approved treatment options for second line GBM patients with proven efficacy data from an actively controlled study.

The primary objective of the trial was to increase the percentage of patients reaching PFS6 by 100%. This objective was exceeded substantially. Data on secondary endpoints including OS and QoL are expected within the next few months and will be presented at major cancer conferences in the US and Europe later this year. During treatment with APG101 for up to two years, no drug-related adverse effects were observed.

GBM is the most frequent and aggressive brain tumor. The tumors are characterized by a high resistance to radio- and chemotherapy and the disease often has a devastating impact on the quality of life and life expectancy of patients. Approximately 28,000 new cases of malignant glioblastomas are diagnosed in the US and EU each year.

"Current treatment options for GBM are very limited, and the treatment of relapses is predominantly based on experimental approaches. In view of the results of our controlled efficacy study, we are optimistic that APG101 will be of significant patient benefit in this difficult-to-treat disease", said Dr Harald Fricke, Chief Medical Officer of Apogenix. "Through the support of our investors, we plan to investigate the effect of APG101 in other cancer types."

The principle investigator of the study, Prof Wolfgang Wick of the Clinical Cooperation Unit Neuro-Oncology, German Cancer Research Center and Department of Neuro-Oncology, University Hospital of Heidelberg, added: "The promising data of a combination therapy of APG101 with radiotherapy in relapsed GBM patients leads to the suggestion that a next development step could be the combination therapy of APG101 with standard radio-chemotherapy in newly diagnosed Glioblastoma patients. The main goal should be to significantly improve the standard therapy by adding APG101."

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 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. In 2013, it is planned to initiate a phase II trial with APG101 for the treatment of Myelodysplastic Syndromes (MDS). Since its inception in 2005, the company has raised more than € 50 million with dievini Hopp BioTech Holding GmbH & Co. KG as main investor, and has been awarded public grants totaling over € 8 million. Apogenix is based in Heidelberg, Germany.

About APG101

The company's lead product candidate, APG101, a first-in-class, fully human 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 was completed in September 2011. The primary endpoint of the trial was successfully reached in March 2012. Apogenix was granted orphan drug designation for APG101 in 2009 for the treatment of GBM in Europe and in the US.

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