Press Release

Apogenix: APG101 Exceeds Expectations with Controlled Phase II Clinical Trial in Treatment of Recurrent Glioblastoma

- Primary endpoint of PFS6 shows significant improvement
- PFS median P-value: 0.0114
- Positive results confirmed by secondary endpoints

Heidelberg, Germany, July 26, 2012 - The biopharmaceutical company Apogenix GmbH announced today that the phase II clinical proof of concept trial with APG101 as treatment of recurrent glioblastoma has met and exceeded expectations in the final analysis of the data. In this randomized controlled clinical study the patients were treated either with a combination of APG101 plus radiotherapy (APG101+RT group) or radiotherapy alone (RT group). The primary objective of the trial was to increase the percentage of patients reaching progression free survival for six months (PFS6) by >100%. In addition, all the important secondary endpoints evaluated so far, including safety and tolerability, indicate that APG101 is a potent new treatment option for glioblastoma, with an excellent safety profile. The quality of life (QoL) as measured by a standardized questionnaire was maintained and even improved in 67% of the patients in the APG101+RT group, but worsened in 66% of patients in the RT group. In addition, in more than 50% of the APG101 treated patients medication with corticosteroids could be reduced or even stopped compared to only 28% of patients from the RT group. During treatment with APG101 for up to two years, no drug-related serious adverse events were observed.

APG101 Study Results

	APG101+RT Group	RT Group	P-Value	Hazard Ratio
PFS6 (primary endpoint)	20.7%	3.8%	0.0485*	N.A.
PFS (median)	19.7 weeks	10.8 weeks	0.0114**	0.46

Notes: PFS6: Progression Free Survival for six months; * Chi^2-Test; ** Cox-Regression

Prof Wolfgang Wick of the Clinical Cooperation Unit Neuro-Oncology, German Cancer Research Center and Department of Neuro-Oncology, University Hospital of Heidelberg, the Principle Investigator, said: “The present study is an unexpectedly huge step forward in the development of new and innovative therapeutic concepts for patients with glioblastoma. The magnitude of the therapeutic effect of APG101 compensated the relatively small size of the study. More than 20% of relapsed patients being free of progression after 6 months in a controlled trial was last observed some 10 years ago when temozolomide was introduced into the care of glioblastoma patients.”

“The immediate patient benefit of APG101 is substantiated by the positive effect of the compound on the quality of life. This study represents a new development in the treatment of brain tumors that not only promises a clinical benefit but proves it in a randomized controlled clinical study and thus fuels the hope for better patient care,” Prof Wick added.

“The trial was designed as a randomized controlled phase II proof of concept study in GBM, which is an exception in phase II development, but in this way it was clearly demonstrated to our investors and potential licensing partners that APG101 is efficacious and offers a new treatment option for glioblastoma patients,” said Dr Harald Fricke, Chief Medical Officer of Apogenix GmbH. “We will now accelerate discussions with a number of pharma and biotech companies to decide on the next development steps plus potential new indications in order to make this innovative drug available to patients as soon and as widely as possible.”

The phase II, open label, randomized clinical trial recruited 84 patients in 25 centers throughout Germany, Austria, and Russia. Glioblastoma patients were eligible for inclusion if they had suffered from a first or second relapse and if they no longer responded to treatment with temozolomide. Patients participated in this study until tumour progression.

Apogenix is currently planning a phase II proof of concept trial with APG101 in Myelodysplastic syndromes (MDS). The trial is expected to begin in the first half 2013.

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 tumour cells. The company's lead product candidate APG101 is being developed for the treatment of glioblastoma, the most common and aggressive type of primary brain tumour. 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. 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 glioblastoma in Europe and in the US.

About Glioblastoma
Glioblastoma is the most frequent and aggressive brain tumour belonging to the group of gliomas. The tumour cells show a high resistance to radiation and chemotherapy. They spread and infiltrate the neighbouring tissue so quickly that eradicative surgery is often impossible. Due to the diffuse infiltration into brain tissue, recurrence is often experienced within months of the initial treatment. Approximately 28,000 new cases of malignant glioma are diagnosed in the US and EU each year (Source: US National Cancer Registry). The current standard therapy focuses on surgery, followed by radiotherapy and chemotherapy. The relative survival rate for adults diagnosed with glioblastoma is less than 30% within one year of diagnosis, only 3% of patients live longer than five years after primary diagnosis (Source: Central Brain Tumor Registry of the United States) showing the high unmet medical need in this indication. Currently, there are no approved treatment options for second line glioblastoma patients with proven efficacy data from an actively controlled study.

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