Press Release

Apogenix provides update in the ongoing Phase II clinical trial of APG101 to treat Glioblastoma

Data Safety Monitoring Board recommends continuation of patient recruitment

Heidelberg, January 24, 2011 – The biopharmaceutical company Apogenix GmbH gave an update on the status of patient recruitment in its ongoing clinical Phase II trial with APG101 for the treatment of Glioblastoma Multiforme (GBM). The independent Data Safety Monitoring Board (DSMB) has recommended the unchanged continuation of the efficacy trial with APG101 in its second meeting on the basis of 25 patients treated. Clinical data show that APG101 is safe and well tolerated by patients.

In Germany, the trial is being conducted in 21 study centers and 11 additional sites in Austria and Russia. In the open-label, randomized, controlled trial, patients with first or second relapse of Glioblastoma are being treated.

Patients will either be treated with APG101 and radiotherapy or with radiotherapy alone. Primary endpoint of the trial is the 6-month-rate of progression-free survival (PFS6). Secondary endpoints include overall survival, safety and tolerability of APG101, and parameters assessing the patients' quality of life.

"The positive assessment of the study by the DSMB allows us to confidently pursue our objective to prove the effectiveness of APG101 to treat Glioblastoma, thus providing a new treatment option for patients," said Dr Harald Fricke, Chief Medical Officer of Apogenix.

The principle investigator of the trial, Prof Wolfgang Wick (Clinical Cooperation Unit Neurooncology German Cancer Research Center and Department of Neurooncology University Hospital of Heidelberg) added: "Besides investigating APG101's innovative mechanism of action we will also study its efficacy in combination with reirradiation in a multicenter controlled study for the first time. We are confident that the addition of APG101 to radiotherapy is a combination that will significantly improve the treatment of recurrent Gliobastoma."

In Germany, the trial centers are located in Heidelberg, Mannheim, Frankfurt/Oder, Frankfurt/Main, Berlin, Hamburg, Ulm, Dresden, Bochum, Leipzig, Bonn, Munich, Tübingen, Stuttgart, Mainz, Regensburg, Marburg and Aachen. In Austria, the trial is being conducted in Vienna, Graz, Linz and Innsbruck.

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 by blocking the invasive growth of tumour cells. The company is developing APG101, its lead product candidate, to treat Glioblastoma multiforme (GBM), the most common and aggressive type of primary brain tumour. Since its inception in autumn 2005, the company has raised €43 million and has been awarded public grants totalling of more than €6 million. Apogenix is based in Heidelberg, Germany.

About APG101

The company's lead product candidate, APG101, a soluble fusion protein combining the extracellular domain of the CD95-receptor and the Fc-portion of IgG, completed Phase I studies in 2009. In December 2009, APG101 entered a controlled Phase II trial for the treatment of Glioblastoma multiforme (GBM). Apogenix plans to out-license APG101 no later than the completion of proof of concept Phase II trials. Apogenix has been granted orphan drug status for APG101 to treat GBM in Europe and the U.S. and for the prevention of "acute Graft-versus-Host Disease" in Europe.

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