

Press Release

Apogenix Reports Positive Phase I Results on its Lead Compound AGP101

Heidelberg, May 13, 2009 - Apogenix GmbH, a biopharmaceutical company developing novel drugs for malignant and inflammatory diseases, today reported clinical phase I results on its lead compound AGP101. APG101 is a protein influencing an important signaling mechanism involved in the onset and maintenance of these diseases.

The randomized study, which was initiated in September 2008 to explore the safety and tolerability of APG101, included 34 healthy volunteers. All endpoints of the double-blind, placebo-controlled, mono-centric study were met. APG101 was well tolerated and no serious adverse events were observed. The study was designed as a dose escalation trial with seven cohorts of patients who received increasing single doses of APG101.

"These results are an important step for the further clinical development of APG101 in various disease indications," said Dr Harald Fricke, Chief Medical Officer of Apogenix. "We have already demonstrated the mode of action of AP101 as an inhibitor of cell migration, invasive growth, and apoptosis in preclinical studies, and we are now very much looking forward to demonstrate the compound's therapeutic potential in patients."

Apogenix is currently preparing a phase II study with patients suffering from Glioblastoma, a brain tumor characterized by its highly aggressive invasive growth. The trial is expected to start in the first half of 2010 and will be designed as an open-label, controlled study to achieve clinical proof of concept. Result should be available in 2011. Furthermore, it is planned to initiate additional phase II trials with APG101 such as for the prevention of acute "Graft-versus-Host Disease", an indication for which the European Commission has granted orphan drug status.

About Apogenix

Apogenix is a biopharmaceutical company developing novel drugs based on the targeted modulation of CD95 and Interleukin-4 receptor mediated signaling pathways. These pathways play an important role in a variety of malignant and inflammatory diseases.

Apogenix is a spin-out from the German Cancer Research Center (DKFZ), and is based in Heidelberg, Germany. Since 2005, the company has raised EUR 43 million in two financing rounds, mainly from the family of the renowned biotech investor and SAP co-founder Dietmar Hopp.

About APG101

APG101 is a human, soluble fusion protein combining the extracellular domain of the CD95-receptor and the Fc portion of IgG1. CD95 is a receptor with pleiotropic functions transmitting apoptotic and non-apoptotic signals such as migration and invasion of tumor cells, and it is triggered by the CD95 ligand (CD95L). APG101 blocks CD95-mediated signaling pathways by binding to the ligand, thereby blocking activation of the CD95 system.

Available research data shows that the blockade of CD95L plays an important role in the pathophysiology of diseases characterized either by an invasion-prone phenotype such as, e.g. Glioblastoma or by an excess of apoptosis, such as acute "Graft-versus-Host Disease" (aGvHD) or myocardial infarction. APG101 has demonstrated a dose-dependent effect in a variety of animal models of the above mentioned diseases and is in clinical development for the treatment of Glioblastoma and the prevention of aGvHD.

Apogenix has been granted orphan drug status for APG101 for the prevention of aGvHD by the European Commission in 2006. The product candidate is covered by four different patent families claiming the composition of matter as well as its use for different indications.

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