

## Press Release

### **Apogenix Receives Orphan Drug Designation for APG101 in the US and Positive Opinion on Orphan Product Designation in Europe**


Heidelberg, November 16, 2009 - Apogenix GmbH, a biopharmaceutical company developing novel drugs for malignant and inflammatory diseases, today announced that the European Medicines Agency adopted a positive opinion on orphan medicinal product designation for the company's lead candidate APG101 for the treatment of Glioblastoma multiforme (GBM), and that it has already been granted orphan drug status in the US by the US Food and Drug Administration (FDA).

GBM is the most common and aggressive type of primary brain tumors. The designation entitles Apogenix to market exclusivity in the US for a period of seven years and in Europe for a period of ten years following approval of its drug candidate. In 2006, APG101 was already granted orphan drug status for the prevention of Graft-versus-Host Disease (GvHD) in Europe.

"We are delighted about receiving orphan drug designations in Europe and the US, both of which are key markets for Apogenix," said Dr Harald Fricke, CMO of Apogenix. "This, in addition with the recently granted patents, significantly enhances the protection of our key asset, APG101. We expect to bring this compound into a clinical phase II study very soon to provide a new treatment option for GBM patients."

#### **About APG101**

APG101 is a human, soluble fusion protein combining the extracellular domain of the CD95 receptor and the Fc portion of IgG. CD95 is a crucial receptor for initiating apoptosis or the invasive growth of cancer cells once it is triggered by the CD95 ligand (CD95L). APG101 specifically binds to CD95L and thereby blocks CD95L-mediated signaling pathways, preventing either apoptosis or cell migration. Therefore, APG101 has huge therapeutic potential in indications requiring the protection of cells or the inhibition of invasive cell growth.



In a phase I trial, APG101 showed excellent tolerability in healthy volunteers. Moreover, APG101 has demonstrated a dose-dependent effect in animal models of diseases characterized either by an excess of apoptosis (e.g. acute Graft-versus-Host Disease; aGvHD) or by an excess of migration (Glioblastoma multiforme; GBM). In 2008, Apogenix announced the publication of new research findings of its scientific advisor, Dr Ana Martin-Villalba, which demonstrate that the so-called death system CD95/CD95L is involved in the development and growth of GBM.

### **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.

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