# Press Release

**Apogenix receives positive opinion on orphan medicinal product designation from the European Medicines Agency for APG101, for prevention of Graft-versus-Host Disease**

Heidelberg, September 15, 2006 **The Heidelberg-based biotechnology company, Apogenix GmbH, today announced that the Committee for Orphan Medicinal Products (COMP) at the European Medicines Agency (EMEA) in London, UK, adopted a positive opinion on orphan medicinal product designation for the recombinant fusion protein APG101 for prevention of Graft-versus-Host Disease (GvHD) at their meeting on 5-6 September 2006 [Ref. EMEA/COMP/357633/2006 of 7 September 2006]. The clinical development of APG101 for this indication is planned to start in the first quarter of 2008.**

The positive opinion for orphan medicinal product designation was based on preclinical data, allowing the conclusion that APG101 could prove to be of significant benefit to patients affected by GvHD. With this substance, Apogenix is pursuing an innovative medical approach: APG101 inhibits the programmed cell death (apoptosis) that essentially contributes to the organic damage caused by GvHD. “We hope that APG101 will be available in a few years as a new therapeutic option for the treatment of this severe disease,” comments Dr. Harald Fricke, CMO of Apogenix GmbH. “The successful application for orphan medicinal product designation facilitates our strategy to establish an intensive dialogue with the regulatory authorities towards successful development of the product” says Dr. Thomas Hoeger, CEO of Apogenix GmbH.

**About the orphan drug status**

The European Commission can grant orphan medicinal product designation for the treatment of severe or life-threatening diseases, if the prevalence of the disease is less than 5 of 10,000 people in the Community, including EU Member States, Norway, Iceland and Liechtenstein. Applications are assessed by the COMP, which issues an opinion for subsequent adoption by the Commission. Besides a reduction in the fees payable to the EMEA for Scientific Advice, including Protocol Assistance, during the development process, and reduced fees associated with a Marketing Authorisation Application (MAA), the product may qualify for up to 10 years of marketing exclusivity following approval of the MAA.

**About GvHD**

GvHD is a disease that primarily affects the liver, skin, and intestine occurring after bone marrow transplantation. It is caused by an immune reaction of the donor bone marrow (graft) versus the recipient's (host) tissue, and is associated with a high mortality. GvHD mainly occurs in leukaemia patients who received allogeneic bone marrow (i.e. bone marrow from another donor) following the deletion of their own, diseased bone marrow. Annually, there are about 8,000 allogeneic bone marrow transplantations in the EU. The risk of developing GvHD depends, i.a. on the degree of relationship between donor and recipient, and is least frequent in monozygotic twins.

**About APG101**

APG101 is a recombinant fusion protein consisting of the extracellular part of the CD95-receptor (CD95) and an IgG molecule. The molecule inhibits apoptosis by blocking the interaction between the CD95-ligand and the CD95-receptor. APG101 is currently in an advanced preclinical development phase, and has shown a dose-dependent effect in a variety of animal models for GvHD and other indications. The phase I study in patients is scheduled to start in the first quarter of 2008.

**About Apogenix GmbH**

Apogenix is a biopharmaceutical company that focuses on the preclinical and clinical development of innovative drug candidates, which exert their therapeutic effect by modulating apoptosis. Besides Graft-versus-Host Disease, more prevalent, non-orphan indications are acute cerebro- and cardiovascular diseases where apoptosis is abnormally increased, and cancer diseases where apoptosis is abnormally decreased.
The company has received 15 M Euro of funding from private investors and currently has 15 employees.

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