

Press Release

Apogenix Granted PRIME Designation by European Medicines Agency for Asunercept to Treat Glioblastoma

PRIME program designed to help patients benefit as early as possible from therapies that may significantly improve their quality of life

Heidelberg, Germany, May 29, 2017 – Apogenix AG, a biopharmaceutical company developing next-generation immuno-oncology therapeutics, announced today that it has been awarded PRIME (PRiority MEDicines) designation by the European Medicines Agency (EMA) for its lead product candidate, asunercept (APG101), for the treatment of glioblastoma. The PRIME designation was based on the results of a Phase 2 trial (APG101_CD_002) of 86 adult patients with relapsed glioblastoma treated with asunercept. Data from this trial have been published in a peer-reviewed medical journal (Clin Cancer Res. 2014 Dec 15;20(24):6304-13).

In March 2016, the EMA launched the PRIME program to enhance support for the development of medicines that target an unmet medical need. Eligibility criteria are similar to those of the U.S. Food and Drug Administration (FDA) breakthrough therapy program. The goal of the PRIME program is to help patients to benefit as early as possible from therapies that may significantly improve their quality of life. The program focuses on medicines that may offer a major therapeutic advantage over existing treatments, or benefit patients without treatment options. These medicines are considered priority medicines by EMA. To be accepted for PRIME, a medicine has to show its potential to benefit patients with unmet medical needs based on early clinical data. Since the inception of the program in March 2016 only 23% (25 of 108) of requests were granted for access to the program (www.ema.europa.eu/docs/en_GB). Through PRIME, the agency offers early and proactive support to medicine developers to optimize the generation of robust data on a medicine's benefits and risks and enable accelerated assessment of marketing applications.

“There is a high unmet need for new medicines to treat glioblastoma patients, who have very few treatment options. The PRIME designation by the EMA supports our belief that asunercept has the potential to improve the lives of patients suffering from glioblastoma, a deadly form of brain cancer,” said Harald Fricke, M.D., Chief Medical Officer of Apogenix. “We are committed to working closely with the agency to make asunercept available to patients as expeditiously as possible.”

About glioblastoma

Glioblastoma is an aggressive form of brain cancer that quickly spreads into other parts of the brain. In the US, an estimated 23,800 new cases of brain and central nervous system cancers are expected in 2017 and 16,700 deaths due to the disease. The five-year survival rate is less than 35%. In the European Union (EU-28) recent statistics indicate over 43,000 cases and nearly 33,000 deaths due to the disease. Treatment options today involve surgery, radiation

therapy and/or chemotherapy, but these treatments are often inadequate and there remains a major need for more effective treatments.

About asunercept (APG101)

Apogenix's lead immuno-oncology candidate asunercept is a fully human fusion protein that consists of the extracellular domain of the CD95-receptor and the Fc domain of an IgG1 antibody. Asunercept is being developed for the treatment of solid tumors and malignant hematological diseases. The World Health Organization (WHO) has assigned the international nonproprietary name (INN) "asunercept" for APG101.

About Apogenix

Apogenix is a private company developing innovative immuno-oncology therapeutics for the treatment of cancer and other malignant diseases. The company has built a promising pipeline of immuno-oncology drug candidates that target different tumor necrosis factor superfamily (TNFSF)-dependent signaling pathways, thereby restoring the immune response against tumors. Since its inception in 2005, Apogenix has raised more than 100 million euros in financing rounds, public grants, as well as upfront and milestone payments from licensing agreements. The company is based in Heidelberg, Germany.

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