Press Release

Apogenix Provides Update on Clinical Development of Asunercept

- **5-year overall survival rate for patients with recurrent glioblastoma treated with asunercept in phase II trial was 7% vs. 0% for patients treated with radiotherapy alone**
- **Apogenix is preparing for submission of conditional marketing authorization application for asunercept in the EU**

Heidelberg, Germany, May 23, 2018 – Apogenix AG, a biopharmaceutical company developing next-generation immuno-oncology therapeutics, today provides an update on the clinical development and approval strategy of its lead drug candidate asunercept.

In May 2017, asunercept received PRIME (PRIority MEdicines) designation by the European Medicines Agency (EMA) for the treatment of glioblastoma. In November 2017, Apogenix had the kick-off meeting for the PRIME procedure with the EMA and presented its plan to make asunercept available to patients suffering from recurrent glioblastoma as fast as possible. The company prepared an update of overall survival data from its phase II trial with asunercept in recurrent glioblastoma for the kick-off meeting. This update revealed that the five-year overall survival rate for patients treated with asunercept was 7 percent. There were no patients treated with radiotherapy alone who survived five years.

As an outcome of the kick-off meeting, the EMA invited Apogenix to discuss the entire asunercept data set in a pre-assessment meeting with the agency. Apogenix is working closely with the EMA to accelerate the approval process of asunercept and intends to submit a marketing authorization application (MAA) for conditional approval of asunercept in recurrent glioblastoma by the end of 2019.

Chinese licensing partner CANbridge recently announced the approval of an investigational new drug (IND) application by the China Food and Drug Administration for a pivotal phase II/III clinical trial with asunercept (CAN008) to treat patients with recurrent glioblastoma in China. The randomized, double-blind, placebo-controlled, multicenter phase II/III trial will evaluate the efficacy and safety of weekly re-radiation therapy in combination with asunercept. The study's primary endpoint is overall survival. CANbridge anticipates dosing the first patient later this year.

"We are excited about the support that Apogenix is receiving from the EMA in the PRIME process," said Harald Fricke, M.D., Chief Medical Officer of Apogenix. "We are also very pleased with the progress our Chinese licensing partner CANbridge is making in the clinical development of asunercept in China. The clinical and safety data from CANbridge's phase II/III trial with asunercept in China and our phase II trial in Europe will help both sides ensure that patients suffering from recurrent glioblastoma can benefit from this novel treatment option as fast as possible."

About Asunercept

Apogenix' 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. It is being developed for the treatment of solid tumors and malignant hematological diseases. Asunercept was granted orphan drug designation for the treatment of glioblastoma and myelodysplastic syndromes (MDS) in both the EU and the US. In 2017, asunercept received PRIME (PRIority MEdicines) designation by the European Medicines Agency (EMA) for the treatment of glioblastoma.

About Apogenix

Apogenix is a private company developing innovative immuno-oncology therapeutics for the treatment of cancer and other malignant diseases. The Heidelberg, Germany-based company has built a promising pipeline of immuno-oncology drug candidates that target different tumor necrosis factor (TNF) superfamily-dependent signaling pathways, thereby restoring the immune response against tumors. Checkpoint inhibitor asunercept, the company's lead immuno-oncology candidate, is in late-stage clinical development. Based on its proprietary technology platform for the construction of novel hexavalent TNF superfamily receptor agonists (HERA), Apogenix develops CD40, CD27, GITR, HVEM, 4-1BB, and OX40 receptor agonists for cancer immunotherapy.

In 2015, Apogenix entered into an exclusive licensing agreement with CANbridge Life Sciences for the development and commercialization of asunercept for the treatment of glioblastoma in China, Macao, Hong Kong, and Taiwan. CANbridge has received approval by the China Food and Drug Administration for a pivotal phase II/III trial with asunercept (CAN008) in glioblastoma in China. The HERA-TRAIL receptor agonist program was out-licensed to AbbVie in 2014. In 2017, AbbVie initiated a phase I trial with this HERA-TRAIL receptor agonist (ABBV-621) in 92 patients suffering from solid tumors, non-Hodgkins´s lymphoma, or acute myeloid leukemia.

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