# Press Release

## Apogenix to Start European Clinical Phase II Trial with Asunercept in COVID-19 Patients

**Heidelberg, Germany, July 28, 2020** – Apogenix, a biopharmaceutical company developing next generation immunotherapeutics, announced today that it has received regulatory approval to start a clinical phase II trial with asunercept in COVID-19 patients in Russia. The ASUNCTIS trial will be a multi-center, randomized, controlled, open-label trial to assess the efficacy and safety of asunercept in patients with severe COVID-19 disease. The plan is to include additional study centers in other European countries, in particular Spain. Published data indicate that the CD95 ligand (CD95L) – the target of asunercept – plays a role in the induction of life-threatening lymphopenia, lung epithelial damage, and inflammatory cell death in COVID-19 patients. By blocking CD95L, asunercept could reduce these complications reported in COVID-19 patients.

The ASUNCTIS trial will have four treatment arms to evaluate three different doses of asunercept plus standard of care versus standard of care alone. A total of 400 patients will be recruited, with an equal distribution across all four treatment arms. The primary endpoint is the time to sustained clinical improvement by at least one category on two consecutive days compared to the status at randomization, measured on the clinical performance scale proposed by the World Health Organization. Secondary endpoints include efficacy according to the National Early Warning Score (NEWS), oxygenation requirement, mechanical ventilation requirement, duration of hospitalization including length of stay in the ICU and percentage of patients admitted to the ICU, and mortality on days 15 and 29.

“We are very pleased to have received approval by the regulatory authorities in Russia to initiate our first clinical trial with our lead immunotherapy candidate asunercept in patients with severe COVID-19 disease and hope to expand the trial to other countries, such as Spain, soon,” said Thomas Hoeger, Ph.D., Chief Executive Officer of Apogenix. “The excellent safety and tolerability of asunercept have already been demonstrated in clinical trials in recurrent glioblastoma and myelodysplastic syndromes. We look forward to exploring the potential of asunercept in the treatment of COVID-19 patients.”

**About Apogenix**

Apogenix is a private company developing innovative immunotherapeutics for the treatment of cancer and viral infections, such as COVID-19. The company’s pipeline of immunotherapy drug candidates targets different tumor necrosis factor (TNF) superfamily-dependent signaling pathways, thereby restoring the anti-tumor immune response in cancer patients and reducing lymphopenia and inflammatory cell death in patients with viral infections. Checkpoint inhibitor asunercept, the company’s lead immunotherapy candidate, is in late-stage clinical development with PRIME (PRIority MEdicines) designation by the European

Medicines Agency for the treatment of glioblastoma. Based on its proprietary technology platform for the construction of novel TNF superfamily receptor agonists (HERA-ligands), Apogenix develops CD40, CD27, GITR, HVEM, and 4-1BB receptor agonists for cancer immunotherapy. The TRAIL receptor agonist program was outlicensed to AbbVie. AbbVie is conducting a phase I trial with TRAIL receptor agonist ABBV-621 in patients suffering from solid tumors, non-Hodgkins's lymphoma, or acute myeloid leukemia.

**About Asunercept**

Apogenix' lead immunotherapy 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, hematological malignancies, and viral infections, such as COVID-19. Asunercept was granted orphan drug designation for the treatment of glioblastoma and myelodysplastic syndromes (MDS) in both the EU and the US and PRIME (PRIority MEdicines) designation by the European Medicines Agency for the treatment of glioblastoma. Asunercept is exclusively licensed to CANbridge Life Sciences under a development and commercialization license covering China, Macao, Hong Kong, and Taiwan.

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