Press Release

Apogenix Enrolls First Patients in Pivotal Phase III Trial for the Treatment of Hospitalized COVID-19 Patients with Asunercept

- **The ASUCOV trial assesses efficacy and safety of asunercept on top of standard of care**
- **Over 600 patients to be enrolled at 50 trial sites in Europe, India, and South Africa**
- **Trial funded by the German Federal Government and dievini Hopp BioTech**

Heidelberg, Germany, December 14, 2022 – Apogenix, a biopharmaceutical company developing next generation immunotherapeutics, announced today that the first patients have been enrolled in a pivotal phase III trial to investigate the efficacy and safety of asunercept on top of standard of care (SoC) for the treatment of hospitalized patients with moderate to severe COVID-19 disease (ASUCOV; NCT05639192). The multicenter, double-blind, placebo-controlled trial aims to enroll more than 600 hospitalized patients requiring oxygen in nine different countries.

Following the successful controlled ASUNCTIS phase II study, the ASUCOV trial aims to confirm the clinical results in a larger study population. The primary endpoint is the efficacy measured as time to sustained recovery with an improvement of at least two grades on the WHO clinical progression scale for at least two consecutive days or discharge from hospital. The secondary endpoints of the ASUCOV trial assess the reduction of progression to more severe disease, all-cause mortality, and progression to invasive ventilation.

Thomas Hoeger, PhD, Chief Executive Officer of Apogenix, said: *"After the encouraging results of our phase II ASUNCTIS trial we are very pleased to take this next important step that will pave the way towards regulatory approval of asunercept. We hope to provide an effective treatment option for hospitalized COVID-19 patients because we still see too many deaths worldwide. As asunercept is expected to prevent disease progression and reduce the number of COVID-19 patients who require intensive care or die from this disease, we believe that this treatment could become an attractive therapeutic option."*

CD95 ligand mediated dysregulation of the immune homeostasis by induction of apoptotic cell death has been observed in various diseases and might be a key driver for reduced lymphocyte counts (lymphopenia) and massive lung tissue damage during progression of COVID-19. Currently, there are no approved treatments that could re-balance the immune system and prevent disease deterioration. Especially elderly patients with co-morbidities still face high mortality rates and are in urgent need of new treatments. Asunercept, a CD95 ligand (CD95L) inhibitor, represents a novel and unique therapeutic approach for COVID-19 and other viral infections. As asunercept is not targeting the virus itself, treatment with asunercept is independent of viral strains.

The ASUCOV pivotal trial and related activities are funded with 20.7m EUR by the German Federal Government through grant number 16LW0102 as well as Apogenix' lead investor dievini Hopp BioTech Holding GmbH & Co. KG. All responsibility for the content of this work lies with Apogenix.

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 in order to restore the anti-tumor immune response in cancer patients and reduce lymphopenia and lung epithelial cell death in patients with viral infections. Checkpoint inhibitor asunercept, the company's lead immunotherapy candidate, is in late-stage clinical development for COVID-19 and glioblastoma. PRIME (PRIority MEdicines) designation has been granted 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, Apogenix develops CD40 and GITR receptor agonists for cancer immunotherapy. The TRAIL receptor agonist program was out licensed to AbbVie and is currently in clinical phase I trials.

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 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. For the region China, Macao, Hong Kong, and Taiwan, Asunercept is exclusively licensed to CANbridge Life Sciences under a development and commercialization agreement.

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