

Press Release

Apogenix Receives €20.7 Million in Public Funding for Pivotal Study and Preparation for Market Production of Asunercept for the Treatment of COVID-19

- **Main investor dievini supports project with additional €5.1 million**
- **Apogenix is one of six therapeutics developers in Germany selected to receive funding totaling €150 million**

Heidelberg, Germany, December 9, 2021 – Apogenix, a biopharmaceutical company developing next generation immunotherapeutics, announced today that it has received a funding commitment from the German Federal Ministries of Health (BMG) and Education and Research (BMBF) in the amount of €20.7 million as part of the funding initiative “Clinical development of COVID-19 drugs and their manufacturing capabilities.” At the beginning of September, the two ministries held a press conference to announce the companies that had been selected for funding. Apogenix has just received the official funding notice. The funds will be used to finance a phase III clinical trial (ASUCOV) with CD95 ligand inhibitor asunercept in moderately to severely ill, hospitalized COVID-19 patients. In addition, the GMP production process for asunercept will be further developed to market maturity and the required material for the phase III clinical trial will be produced. The German government will fund 80 percent of these costs, and the remaining 20 percent will be covered by Apogenix’s main investor dievini Hopp BioTech Holding GmbH & Co. KG.

Interim data from the ongoing phase II trial for the treatment of moderately to severely ill COVID-19 patients provided initial evidence of the efficacy of asunercept in this patient population. The data were discussed with the Paul Ehrlich Institute (PEI) in June 2021. The PEI recommended to continue the phase II trial and to further investigate asunercept in a larger phase III trial in a similar COVID-19 patient population. The approach taken by Apogenix, the PEI said, has the potential to treat severely ill COVID-19 patients irrespective of the SARS-CoV2 virus variants, which are constantly evolving and may ultimately evade the immune response even in vaccinated individuals.

“We are excited about the financial support for the development and manufacture of drugs against COVID-19 and thank the BMG and the BMBF as well as our investor Dietmar Hopp,” said Thomas Hoeger, Ph.D., Chief Executive Officer of Apogenix. “It is becoming more and more evident that, in addition to COVID-19 vaccines, there is an urgent need for effective drugs to treat those who develop COVID-19 without or despite vaccination. The goal of our ASUCOV trial is to confirm the promising data from the phase II trial and to advance the development of asunercept to regulatory approval. Asunercept is expected to prevent the death of immune cells and lung cells leading to lymphopenia and acute respiratory distress syndrome, thus reducing the number of COVID-19 patients who require intensive care or even die from this disease.”

The phase III trial will recruit hospitalized COVID-19 patients with advanced disease who are being treated with oxygen in addition to standard therapy. These patients often present with signs of lymphopenia as well as severe hyperinflammatory reactions, such as cytokine storm. Despite treatment in the intensive care unit, the disease often takes a lethal course in this patient group.

Scientific data show that the CD95 ligand – the target of asunercept – plays a key role in the induction of life-threatening lymphopenia in COVID-19 patients. By directly targeting two critical pathogenic mechanisms, asunercept could represent a unique therapeutic approach for the treatment of COVID-19.

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 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 and bispecific agents), 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 two phase I trials with TRAIL receptor agonist ABBV-621 in patients suffering from solid tumors, non-Hodgkin'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.

Contacts

Thomas Hoeger, Ph.D., CEO
Jennifer Mogk, PR Manager
Apogenix AG
Phone: +49 6221 58608-0
E-Mail: contact@apogenix.com
Web: www.apogenix.com

Media Contacts

Katja Arnold
Andreas Jungfer
MC Services AG
Phone: +49 89 210228-0
E-Mail: apogenix@mc-services.eu