Press Release

Apogenix Advances Clinical Development of CD95L Inhibitor Asunercept in European COVID-19 Phase II Trial

Heidelberg, Germany, October 13, 2020 – Apogenix, a biopharmaceutical company developing next generation immunotherapeutics, announced today that the first patient has been enrolled in the ASUNCTIS trial. The ASUNCTIS trial is a multi-center, randomized, controlled, open-label phase II trial to assess the efficacy and safety of asunercept in patients with severe COVID-19 disease. In four treatment arms, three different doses of asunercept plus standard of care versus standard of care alone are being evaluated in a total of 400 patients. Apogenix has received regulatory approval for the ASUNCTIS trial now in both Spain and Russia and will enroll patients in multiple study centers in Madrid and Saint Petersburg, among others.

"The increasing number of COVID-19 infections in Europe highlight the urgent need for safe and effective treatment options," said Thomas Hoeger, Ph.D., Chief Executive Officer of Apogenix. "We are very hopeful that our lead immunotherapy candidate asunercept will prove effective in patients with severe COVID-19 disease."

"The CD95 ligand – which is inhibited by asunercept – plays an important role in the induction of life-threatening lymphopenia and lung epithelial cell death, leading to pneumonia and acute respiratory distress syndrome (ARDS) in COVID-19 patients," Thomas Hoeger continued. "Since lymphopenia and ARDS are also complications of other viral infections, asunercept could represent a new therapeutic approach for viral infections beyond 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), 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.

Contacts
Peter Willinger, CFO
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