Website address:
https://www.gesundheitsindustrie-bw.de/en/article/press-release/apogenixs-asunercept-zeigt-wirksamkeit-phase-ii-studie-zur-behandlung-von-covid-19-patienten-im-krankenhaus

Apogenix' Asunercept Demonstrates Efficacy in Phase II Trial for the Treatment of Hospitalized COVID-19 Patients

Apogenix, a biopharmaceutical company developing next generation immunotherapeutics, announced today that asunercept showed statistically significant benefits for hospitalized COVID-19 patients in the ASUNCTIS trial. The open-label multi-center phase II trial investigated efficacy and safety of asunercept in 435 patients with moderate to severe COVID-19 disease. COVID-19 patients were randomized equally into four study arms, receiving 25, 100, or 400 mg asunercept (once weekly, i.v.) on top of standard of care (SOC), respectively, or SOC alone.

Efficacy was assessed against the WHO-suggested endpoints, including time to clinical improvement according to WHO scale and mortality. The results show strong trends for clinical efficacy in all treatment groups, indicating a robust activity of asunercept. Consistently, patients showed faster clinical improvement by approximately 40 % compared to the control group (8-9 days for the three different treatment groups vs. 13 days with SOC). The combined asunercept dose groups (25, 100 and 400 mg arms) revealed statistically significant faster clinical improvement compared to SOC group (p= 0.038; HR=1.37). Statistical significance was closely missed when comparing the individual treatment groups with SOC group.

Furthermore, the pre-specified analysis of patients with WHO score 4 (n=342) at the beginning of the trial showed an approximately 40 % faster clinical improvement in all asunercept groups compared to control. In these patients, a statistically significant clinical benefit for the 100 mg asunercept group (n=83) could be achieved (p=0.044; HR=1.53). All patients receiving asunercept showed a marked reduction of all-cause mortality at all time points and for each dose compared to patients receiving SOC. Furthermore, asunercept reduces the time to recovery from lymphopenia, confirming its presumed mechanism of action. As the extent of lymphopenia correlates with severity of the COVID-19 disease, asunercept accelerates recovery from disease.

Safety in all asunercept plus SOC treatment arms was comparable to the SOC arm, confirming the favorable safety profile of asunercept observed in all previous clinical trials. No trend or pattern was identified among serious and non-serious adverse events across all treatment arms. Apogenix intends to publish detailed results from this study in a peer-reviewed journal.

Univ.-Prof. Felix JF Herth, MD, PhD, Chairman and Head Department of Pneumology and Critical Care Medicine at Thoraxklinik University of Heidelberg and Chairman of the Data Safety Monitoring Board (DSMB) of the ASUNCTIS trial, commented: "Despite some progress in the treatment of hospitalized COVID-19 patients requiring additional oxygen, there still remains a high unmet medical need for this patient group. Asunercept is a novel immune-modulating treatment approach which seems to work independently of COVID-19 strains. It combines an excellent safety profile with encouraging efficacy data, warranting the advancement of clinical development and initiation of a pivotal phase III study."

Thomas Hoeger, PhD, Chief Executive Officer of Apogenix, said: "We are very pleased to see asunercept displaying a robust efficacy and favorable safety profile in the ASUNCTIS trial. Asunercept is expected to prevent the death of immune 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. Based on our promising phase II results and given the high need for effective COVID-19 medication in hospitalized patients, we are initiating a pivotal phase III trial (ASUCOV) with asunercept to confirm the encouraging results in a larger number of patients."

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 by Apogenix' leading investor dievini Hopp BioTech Holding GmbH & Co. KG. All responsibility for the conduct of this project 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 inflammatory 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 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, 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, 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.

Apogenix acted as sponsor of the ASUNCTIS phase II study. The clinical study protocol has been developed together with Prof. Walczak, University of Cologne, Prof. Bergmann and colleagues, Medical University Vienna and Dr. Pilar Ruiz Seco, Hospital Infanta Sofia, Spain.

Press release

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