SynAct has initiated dosing in part 2 of the clinical Phase II study with AP1189 in Covid-19 infected patients

SynAct Pharma AB ("SynAct") today announced that dosing in the second part of the exploratory clinical Phase 2 study with AP1189 in Covid-19 patients conducted under the RESOVIR collaboration has been initiated following completion of the initial open label part of study. The second part is a randomized double-blind placebo-controlled study in 56 Covid-19 patients at clinical sites at Universidade Federal de Minas, Belo Horizonte, Brazil.

The initial open label part of the study was conducted in 6 patients referred to hospital with Covid-19 induced pulmonary insufficiency, defined as a need for supplementary oxygen to maintain normal saturation. The patients, 4 women and 2 men aged between 38 and 59, all had $SaPO_2$ lower than 93% on spontaneous respiration, and all 6 patients were treated with oxygen on nasal catheter with flow between 2-5 LO_2/min.

The patients were treated with once daily oral dosing of 100 mg AP1189 as add-on to standard therapy. The compound was found to be safe and well tolerated, and the patients were discharged between day 3 and 9 of treatment as none of them developed a need for more intensive pulmonary support.

As no safety concerns have been identified, recruitment to part 2 of the study has been initiated. As of March 16, 2021, 16 patients had been included to the second part of the study.

The second part of the study is set up to evaluate the safety and efficacy of a two-weeks dosing regimen with AP1189 vs placebo as add on therapy in patients with Covid-19 induced pulmonary insufficiency, defined as a need for supplementary oxygen to maintain normal saturation. Up to 54 patients will be randomized in a 2:1 ratio to receive AP1189 100 mg or placebo once daily, in addition to standard of care. The primary clinical objective of the study is to show reduction in time to respiratory recovery (i e time to normalization of oxygen saturation on ambient air). The top line results for the study are expected in Q2 2021.

“There is an increasing need for effective treatments stopping the severe inflammation we see in the Covid-19 infected patients. I am indeed happy that we have started the second phase of the study to investigate whether AP1189 can promote inflammatory resolution and thereby reduce time to recovery and reduce the risk of development of severe ARDS,” said primary investigator Prof. Mauro Teixeira at Universidade Federal de Minas, Belo Horizonte, Brazil.

“Samples from patients with Covid-19 pneumonitis have shown that macrophages make up to 80% of total cells in the lung alveoli and play a key role for the hyperinflammation associated with the devastating effects of Covid-19 infections. As the AP189 specifically targets macrophages, we look very much forward to studying the potential benefits provided by treatment of Covid-19 patients with AP1189. Importantly, the study is not only aimed to test potential effect on clinical readouts as time to recovery, but also to investigate the effect of the compound on the activated inflammatory pathways in the Covid-19 infected patients. This work has been initiated with continued collection of samples from the patients and will be conducted in the laboratories in Belo Horizonte as well as in London as an integrated part of the RESOVIR collaboration,” said Dr Thomas Jonassen, CSO SynAct Pharma.

The RESOVIR collaboration is a scientific and clinical collaboration between Professor Mauro Teixeira, MD, PhD, Universidade Federal de Minas, Belo Horizonte, Brazil, and Professor Mauro

Perretti, PhD William Heavy Research Institute, Barts and the London School of Medicine, Queen Mary University, London, UK, and SynAct Pharma AB.

This information is such information that SynAct Pharma AB is obliged to publish in accordance with the EU Market Abuse Regulation. The information was submitted, through the agency of the below contact person, for publication on March 18, 2021.

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About SynAct Pharma AB

SynAct Pharma AB conducts research and development in inflammatory diseases. The company has a platform technology based on a new class of drug candidates aimed at acute deterioration in chronic inflammatory diseases with the primary purpose of stimulating natural healing mechanisms. For more information: www.synactpharma.com.

About AP1189

The mechanism of action of SynAct Pharma´s lead compound AP1189 is to promote resolution of inflammation through melanocortin receptor activation directly on macrophages, thereby reducing the pro-inflammatory activity of macrophages and by stimulating so-called macrophage efferocytosis, a specific ability to clear inflammatory cells (J Immun 2015, 194:3381-3388). This effect has shown to be effective in disease models of inflammatory and autoinummune diseases and the clinical potential of the approach is currently tested in a clinical phase 2 study in patient with active Rheumatoid Arthritis.
https://clinicaltrials.gov/ct2/show/NCT04004429?term=AP1189&draw=2&rank=1).