SynAct Pharma completes recruitment and 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 part 2 of the exploratory clinical Phase 2 study with AP1189 in Covid-19 patients conducted under the RESOVIR collaboration has been completed. The study is a randomized double-blind placebo-controlled study in 54 Covid-19 patients at clinical sites at Universidade Federal de Minas, Belo Horizonte, Brazil.

The aim of the study is to evaluate the safety and efficacy of a two-week 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. 54 patients have been 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).

“We will now review the blinded data, and we expect to share top-line results later in June,” said Jeppe Øvlesen, CEO SynAct Pharma. “Our main focus is to determine the safety and efficacy of AP1189 as a potential treatment for COVID-19. There is still a tremendous need for treatment options in this devastating pandemic around the world.”

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.

The information was submitted, through the agency of the contact persons below, for publication on June 1, 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).