SynAct Pharma AB Announces Additional Data from the Phase 2a Trial of AP1189 in Covid-19 Infected Patients and Reminds of Management Call to Discuss Results

SynAct Pharma AB ("SynAct") today announced additional results from all treated patients in the Phase 2a clinical trial of AP1189 in Covid-19 infected patients with pulmonary insufficiency. The study was setup with part 1, where all patients were treated with AP1189, and a part 2, a randomized placebo-controlled study testing AP1189 vs placebo, giving a total of 60 treated patients. In this full dataset, AP1189 treated patients achieved respiratory recovery 4 days quicker than placebo treated patients. A result that was statistically significant. Management is hosting a conference call on July 7 at 13:00 CEST to discuss the trial results.

In all, there were 42 patients treated with 100mg of AP1189, orally once-daily for 2-weeks. 6 patients were treated with AP1189 in a safety run-in arm and 36 patients were treated in the randomized arm to assess activity versus placebo. When data is pooled for all treated patients, those treated with AP1189 achieved respiratory recovery (time to normalization of oxygen saturation on ambient air) on average 4 days (40%) quicker than those treated with placebo, a statistically significant finding (5.9 days on average for AP1189 and 9.9 days for placebo, p=0.0406).

By day 4 of treatment, 50% of AP1189 patients had achieved respiratory recovery as compared to 33% treated with placebo and 33% of AP1189 patients had been discharged from the hospital compared to 0% for placebo. AP1189 treatment appeared to decrease the rate of progression to ventilator use by 57% with 7.1% (3/42) and 16.7% (3/18) of patients requiring a ventilator in the pooled AP1189 and placebo groups, respectively. In addition, AP1189 treated patients were on average discharged from the hospital 3.3 days earlier than placebo treated patients.

Data from an exploratory assessment indicated AP1189 may have a positive impact on decreasing the incidence of acute kidney injury (AKI) with 19% of AP1189 patients and 33% of placebo patients demonstrating signs of kidney impairment, a 42% reduction in the rate of AKI incidence.

It should be noted that in Brazil where the trial was conducted, the standard of care is to give steroids at hospitalization with confirmed Covid-19 infection, so all the patients in this study had AP1189 or placebo added onto their concurrent steroid use. Importantly, AP1189 was well tolerated and safe. The most frequent side-effect was, as previously reported in both healthy volunteers and rheumatoid arthritis patients, nausea.

The aim of the study was to evaluate the safety and efficacy of a two-week, once-daily dosing regimen of AP1189 vs placebo as add-on therapy in patients with Covid-19 induced pulmonary insufficiency. The study, conducted under the RESOVIR collaboration enrolled a total of 60

Covid-19 infected patients at clinical sites at Universidade Federal de Minas, Belo Horizonte, Brazil. The enrolled subjects had pulmonary insufficiency requiring the need for supplemental oxygen.

In part 1, 6 patients were enrolled in an open label fashion followed by part 2 where patients were randomized in a 2:1 ratio to receive AP1189 100 mg once daily for 2 weeks, in addition to standard of care. The primary clinical objective of the study was to explore if AP1189 could speed the time to respiratory recovery (time to normalization of oxygen saturation on ambient air).

"We are excited to see the full results of the P2a trial. In this study, AP1189 showed that it may be able to help patients recover respiratory function and be discharged from the hospital quicker than the placebo treated patients", stated Dr. Thomas Jonassen, CSO, SynAct Pharma. "We are working closely with the study primary investigator Dr. Mauro Teixeira and will be in contact with the Brazilian health authority to discuss the potential next clinical steps. With current geographic hotspots like Brazil and India, vaccine hesitancy, new and emerging virus variants and the possibility of seasonal reoccurrences, more effective treatments to help Covid-19 infected risk patients are needed. We have therefore as part of established RESOVIR collaboration, initiated work to setup a confirmative clinical study in Covid-19 patients. The aim is to have the study initiated as soon as possible using our newly developed tablet for once daily oral dosing. We will in parallel initiate discussion with relevant health authorities to explore the possibility to obtain an emergency use authorization."

The RESOVIR (Resolution Therapy for Viral Inflammation Research) collaboration is a scientific and clinical collaboration between Professor Mauro Teixeira, MD, PhD, Universidade Federal de Minas, Belo Horizonte, Brazil, Professor Mauro Perretti, PhD William Harvey Research Institute, Barts and the London School of Medicine, Queen Mary University, London, UK, and SynAct Pharma AB. The aims of the RESOVIR collaboration are to investigate the utility of resolution therapy to resolve the cytokine storm inflammation associated with significant viral infections.

SynAct management will host a conference call on July 7 at 13:00 CEST focused on the positive topline results from the Phase 2a clinical trial of AP1189 in Covid-19 infected patients with pulmonary insufficiency.

The call will be hosted by Chairman Dr. Torbjørn Bjerke, CEO Jeppe Øvlesen and CSO Thomas Jonassen. The study's principal investigator Dr. Mauro Teixeira will also join. The presentation will be in English and is followed by a Q&A session.

The conference call will be broadcast live on the web via the link: https://tv.streamfabriken.com/synact-pharma-2021-07-07

Telephone number for the conference call is:
SE: +46 8 5055 8359
UK: +44 3333 009 267

US: +1 6 467 224 957

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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 autoimmune diseases and the clinical potential of the approach is currently tested in a clinical phase 2 study in patients with active rheumatoid arthritis, nephrotic syndrome and Covid-19 ARDS.
https://clinicaltrials.gov/ct2/show/NCT04004429?term=AP1189&draw=2&rank=1.
https://clinicaltrials.gov/ct2/show/NCT04456816?term=AP1189&draw=2&rank=2.