SynAct Pharma AB Announces Positive Data from a Phase 2a Trial of AP1189 in Covid-19 Infected Patients

SynAct Pharma AB ("SynAct") today announced topline results from the Phase 2a clinical trial of AP1189 in Covid-19 infected patients with pulmonary insufficiency. Patients treated with 100mg AP1189 orally once-daily for 2-weeks achieved respiratory recovery (time to normalization of oxygen saturation on ambient air) on average 3.5 days (35%) quicker than placebo treated patients (6.4 days and 9.9 days on average respectively). Data from this exploratory pilot clinical trial supports that AP1189 may help Covid-19 infected patients recover impaired lung function.

Patients treated with AP1189 recovered respiratory function on average 3.5 days quicker than did placebo treated patients, a 35% increase in recovery time. Supplemental oxygen requirements decreased at a significant rate in AP1189 treated patients. By day 4, AP1189 treated patients had decreased their average supplemental oxygen requirements by 65% on average compared to a 31% reduction in placebo treated patients ($p<0.05$, compared with per group baseline oxygen requirements).

AP1189 treatment appeared to decrease the rate of progression to ventilator use by 50% with 8.3% (3/36) and 16.7% (3/18) of patients requiring a ventilator in AP1189 and placebo groups respectively. In addition, AP1189 treated patients were on average discharged from the hospital 2.8 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 patients with 22% of AP1189 patients and 33% of placebo patients demonstrating signs of kidney impairment. Importantly AP1189 was well tolerated and safe with no serious adverse events in the AP1189 group. The study data will be submitted for presentation at an upcoming scientific meeting and/or for publication in an appropriate scientific journal.

“While the standard of care for infected Covid-19 patients has improved there remains a tremendous unmet need to prevent infected patients from becoming more severely afflicted”, stated principal investigator Professor Mauro Teixeira, MD, PhD, Universidade Federal de Minas, Belo Horizonte, Brazil. “We are excited about this important data generated with AP1189 and I look forward to discussing next steps with the Brazilian health authority and with the RESOVIR collaborators. There are still many parts of the world like Brazil still dealing head-on with the Covid-19 pandemic and we are hopeful that AP1189 may be able to play a role in this fight.”

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 54 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. 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).

"The results of this exploratory Phase 2a trial demonstrate the ability of once-daily oral AP1189 to resolve excessive or dysregulated inflammation like the cytokine storm caused by infectious agents like Covid-19", stated Thomas Jonassen, CSO, SynAct Pharma. "The impact seen on supplemental oxygen requirements as well as additional respiratory parameters and even the preliminary data on the incidence of AKI highlights the potential organ protectives benefits of AP1189. We remain committed to seeing if AP1189 may be able to help with the ongoing Covid-19 pandemic. We sincerely appreciate the efforts of our RESOVIR collaborators and the study patients for their dedication to the trial. 2021 will continue to be an exciting year for SynAct Pharma as we anticipate completion of our Phase 2a trials in rheumatoid arthritis and in nephrotic syndrome in the second half of the year."

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.

"It is truly gratifying to note how the ongoing collaborative work between the William Harvey Research Institute at Queen Mary and SynAct Pharma have led to the RESOVIR collaboration and these exciting results", stated Professor Perretti. AP1189 is leading the way to a new class of pharmacological molecules which harness the patients' own resources to fight infectious inflammation."

SynAct will hold a management call beginning of next week to discuss the study results. Joining SynAct management on the call will be the study principal investigator, Dr. Mauro Teixeira. A separate announcement will be published shortly.

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 June 30, 2021.

For further information about SynAct Pharma AB, please contact:

Jeppe Øvlesen
CEO, SynAct Pharma AB
Phone: +45 28 44 75 67
Mail: joo@synactpharma.com

Thomas Jonassen
CSO, SynAct Pharma AB
Phone: +45 40 15 66 69
Mail: tj@synactpharma.com

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 patient with active Rheumatoid Arthritis. https://clinicaltrials.gov/ct2/show/NCT04004429?term=AP1189&draw=2&rank=1).