Press release

*March 31, 2020*

# SynAct Pharma investigates the possibility of AP1189 as additional therapy in hospitalized patients with COVID-19

**SynAct Pharma AB ("SynAct") today announced that the company investigates the possibility of developing its clinical anti-inflammatory lead candidate drug AP1189 as an additional therapy in hospitalized patients with COVID-19 infection, to prevent Acute Respiratory Distress Syndrome (ARDS). ARDS is the most common cause of death among patients with COVID-19 (SARS-CoV-2).**

SynAct intends to explore the possibility of applying AP1189 to clinics through potential funding from government institutions and commercial partners operating in the COVID-19 area. This is exploratory and conditional on funding, as well as the permission to start a clinical trial. In light of the acute crisis that the pandemic is causing to patients and society, combined with the company's knowledge of the mechanisms of action of AP1189, it is important to investigate whether the compound could contribute positively to the treatment of patients with COVID-19

A serious consequence of COVID-19 infection is that patients develop severe pneumonia. Uncontrolled, the pneumonia can develop into Acute Respiratory Distress Syndrome (ARDS), a very serious condition where ventilatory treatment often is needed. In addition, ARDS is associated with a high risk of developing Systemic Inflammation Distress Syndrome (SIDS), sometimes called a "cytokine storm", when the immune system is overactivated and the risk of a fatal outcome is high.

In order to prevent inflammation in the lungs, anti-inflammatory treatment is required, which is complicated as this treatment can also act immunosuppressant and weaken the immune system, making it difficult for the patient to fight back the infection.

"To control the inflammatory response in severe Covid-19 infection seems crucial and that is why specific IL-6 blockers are reported to be investigated as treatment options to reduce ARDS in severe COVID-19 inflammation. That is why we have decided to investigate the potential for development of AP1189 as add-on therapy in hospitalized patients with COVID-19 infection", said Dr. Thomas Jonassen, CSO of SynAct.

"It is important to point out that we believe that the dual mechanism of action of AP1189, currently in Phase 2 development in patients with active rheumatoid arthritis (RA), can be beneficial in both reducing and counteracting inflammation without acting immunosuppressive and thus enabling the patient's immune system to function and fight the infection, which is crucial in severe infections such as COVID-19", said Dr. Jonassen.

AP1189 treats inflammation through so-called resolution therapy, which is believed to have a beneficial effect in patients with ARDS. Resolution therapy is a new method of inhibiting the immune system more selectively, which allows for better maintenance of the immune system's function so that the patient has more opportunities to cope with the infection through his or her immune system. The resolution therapy also activates the macrophages, the so-called "cleansing cells" in the immune system that "cleans" inflamed tissues and organs to allow for faster healing of the infection.

Because resolution therapy does not depress the patient's immune system, use is also made possible in severe infections such as COVID-19. AP1189 has been tested in animal models with SIDS with good effects and selectively reduces both inflammation via inhibition of neutrophil cells and the production of important pro-inflammatory mediators such as Il-6, TNF-α and IL-1β. AP1189 also shows a potent stimulation of macrophages that cleanse the inflamed tissue.

"An urgent task is to secure sufficient respiratory function in patients with COVID-19 pneumonia. Insufficient oxygenation is associated with an exacerbated inflammatory response that untreated can develop into ARDS. A key objective, therefore, is to dampen the inflammatory responses without dampening anti-viral immunity. Resolution therapy could be a novel innovative treatment approach in these patients, as the combination of a modulated anti-inflammatory effect not causing immunosuppression and the ability to stimulate resolution, could protect against development of devastating exacerbated inflammatory responses", said Mauro Perretti, Professor of immunopharmacology and Dean of Research at Barts and London School of Medicine and member of SynAct's Scientific council.

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It is estimated that the cost for a clinical trial with AP1189 in COVID-19 patients is not to exceed SEK 15-20 million, the funding of the possible clinical activities will be made separately and will not affect SynAct's ongoing activities for existing projects. The company expects today's cash and expected SEK 32.8 million from the redemption of subscription rights T0 2 July 2020 will fund the company to important milestones, including the Phase II study with AP1189 in RA and Proof-of-Concept with AP1189 in Nephrotic Syndrome.

SynAct Pharma intends to update shareholders and the market on an ongoing basis.

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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.

**About AP1189**

SynAct Pharma's drug candidate AP1189 is a melanocortin receptor agonist on MC1 and MC3 receptors and is in clinical phase II development for the treatment of active Rheumatoid Arthritis (RA): https://clinicaltrials.gov/ct2/show/NCT04004429?term=AP1189&draw=2&rank=1).