

SynAct Pharma Initiates RESOVIR: Scientific and clinical Collaboration to Explore AP1189 in Viral Infections

SynAct Pharma AB ("SynAct Pharma") hereby announces that the company together with Prof Mauro Teixeira, MD, PhD, Universidade Federal de Minas, Belo Horizonte, Brazil and Prof Mauro Perretti, PhD William Heavy Research Institute, Barts and the London School of Medicine, Queen Mary University, London, UK has established a scientific and clinical collaboration, RESOVIR (resolution in viral inflammation), aimed to investigate pharmacological promotion of inflammatory resolution as a novel approach to control viral infections. The first step of the collaboration will be to run an exploratory clinical study in Covid-19 infected patients aimed to investigate repeated dosing of SynAct Pharma's clinical stage compound AP1189. Later the collaboration will investigate the potential of promoting inflammatory resolution in other viral diseases such as Dengue and Influenza virus.

A large number of patients suffering from devastating viral diseases currently have limited or no treatment options. The COVID-19 pandemic has more than ever highlighted the need for treatments aimed to control unwanted hyperinflammatory responses associated with viral infections.

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.

Prof Perretti is a pioneer in the understanding of the clinical potential associated with promotion of inflammatory resolution through pharmacological targeting of specific pathways including the melanocortin system. Prof Perretti has played a major role for our understanding of the therapeutic potential of the AP1189 compound, which is now in Phase II study in Rheumatoid Arthritis patients.

Prof Teixeira is a pioneer in investigating the potential for promoting inflammatory resolution in viral infection settings, with main focus on Dengue and Influenza where viral-induced hyperinflammation, as in COVID-19 infection, plays a significant role for the development of severe life-threatening organ injuries.

The first task in the RESOVIR collaboration will be to investigate the potential benefits of SynAct Pharma's clinical stage compound AP1189 in COVID-19 patients presenting an hyperinflammation status. The investigation will be setup as an exploratory double-blind placebo-controlled study with once daily dosing of AP1189 in COVID-19 patients with pulmonary symptoms and will be initiated as soon as final approval has been granted by local authorities.

The RESOVIR collaboration will in addition to generate data on the potential clinical effects of AP1189 treatment, give crucial new insights into the potential of pharmacological promotion of resolution of the inflammation. It is the intention of partnership to investigate further the potential of promoting inflammatory resolution in other viral settings with a first focus on Dengue and Influenza virus.

"I look very much looking forward to continue the collaboration with SynAct Pharma. Promotion of inflammatory resolution has the potential to control the development of hyperinflammation in viral infections as is to be considered an innovative therapeutic approach to reduce prolonged morbidity and hospitalization in severely infected patients", said Prof Mauro Perretti, PhD.

The AP1189 compound is a biased melanocortin receptor agonist developed for once daily oral dosing and is currently tested in Phase 2 clinical trials in Rheumatoid Arthritis and Nephrotic Syndrome.

"We have recently had good progress in the study in patients with Rheumatoid Arthritis where the compound is tested in treatment naïve patients with severe active disease as an add on to Methotrexate treatment. In the study in patients with Nephrotic Syndrome, the compound is given to patients with continuous proteinuria following a minimum of two months treatment with ACE Inhibitors. We are now initiating a very fascinating scientific and clinical collaboration with Mauro Perretti and Mauro Teixeira to establish the potential for promoting resolution in viral infections, a study that could open up new important disease indications for AP1189", said Dr Thomas Jonassen, MD CSO SynAct Pharma.

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 August 28, 2020.

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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

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>).