Press Release
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SynAct Pharma submits IND for US Phase 2a/b clinical trial

SynAct Pharma AB (publ) ("SynAct") today announced that the company has submitted an Investigational New Drug (IND) application to the US Food and Drug Administration (FDA), with the aim to commence its Phase 2a/b clinical trial RESOLVE with AP1189 in the United States.

"We are happy to announce that we have now submitted the IND to the FDA in line with our previously communicated plans. The US market represents the largest commercial opportunity for AP1189 in Rheumatoid Arthritis (RA). The inclusion of the US adds to the attractiveness of AP1189 in our discussions with potential business partners," said Jeppe Øvlesen, CEO of SynAct Pharma.

The RESOLVE study is a randomized, placebo-controlled, double-blinded, two-part Phase 2a/b clinical study, testing daily treatment of AP1189 in patients with an incomplete response to first-line disease modifying antirheumatic drugs (DMARD), who are experiencing moderate to severe disease activity.

A large percentage of patients treated with DMARDs never achieve the full desired effect. Also, they have a diminishing treatment effect or suffer from side effects that can prevent further treatment. These patients who experience an inadequate response to DMARDs are referred to as DMARD-IR (inadequate responder). The company believes that AP1189 could be very well suited for DMARD-IR patients given the emerging profile of an efficacious, safe, and well tolerated once-daily oral therapy.

In parallel with the IND application, Clinical Trial Applications (CTAs) are filed in Europe. Subject to regulatory approval from the authorities, the study will be initiated in Q4 2022, with the aim of presenting data from the first part in the second half of 2023.

The information was submitted, through the agency of the contact person below, for publication at 4: 00 p.m. CEST on September 30, 2022.

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About SynAct Pharma AB
SynAct Pharma AB (publ) (Nasdaq Stockholm: SYNACT) 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 candidate drug, AP1189, is to promote resolution of inflammation through selective activation of melanocortin receptors 1 and 3. These receptors are located on all immune cell types including macrophages and neutrophils. Activation of these receptors results in two direct anti-inflammatory effects: it turns these cells to produce less pro-inflammatory molecules and also to switching them to perform inflammation "clean-up", known as efferocytosis (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 clinical programs in patients with rheumatoid arthritis (RA), nephrotic syndrome (NS) and COVID-19. The safety and efficacy of AP1189 is being tested and has not been reviewed by any regulatory authority worldwide.

About RESOLVE
The RESOLVE study (SynAct-CS006) is a two-part, randomized, double-blind, multi-center, placebo-controlled study of the safety, dose-range finding confirmation, and efficacy of 4 (Part A) and 12 weeks (Part B) of treatment with AP1189 in adult RA patients with an inadequate response to MTX alone.
In Part A approximately 120 randomized patients will be treated with either 60 mg AP1189, 80 mg AP1189, 100 mg AP1189 or placebo once daily for 4 weeks as add-on treatment to stable MTX treatment. Part A will conclude with an unblinded assessment for risk/benefit and a recommendation for dose selection for Part B.
In Part B patients will be randomized into groups of equal size evaluating 2-3 doses of AP1189 versus placebo, all doses will be administered once daily for 12 weeks as add-on treatment to stable MTX treatment. The proposed sample size per dose group/placebo group is 75 patients, by which the total study population of Part B may be either 225 or 300 patients, depending on the number of dose groups of AP1189 selected for evaluation based on Part A.
The objectives of the two-part study are to evaluate the efficacy and safety of multiple doses of AP1189 when combined with MTX in DMARD-IR patients. The safety of AP1189 will be assessed by comparing AP1189 against placebo for adverse events, physical examinations, vital sign measurements, ECG, and clinical laboratory testing (hematology, chemistry, and urinalysis). The primary efficacy endpoint is the effect of AP1189 compared to placebo evaluated by the ACR20 response. The effect will additionally be evaluated by ACR50, ACR70, CDAI, DAS-28, CRP, the need for rescue medication, inflammatory and collagen turnover biomarkers, HAQ-DI and FACIT-Fatigue. In Part B changes in imaging parameters reflecting joint inflammation (DCE-MRI) from Baseline to Week 12 will be evaluated in a subgroup of patients.

Attachments
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