SynAct Pharma completes dosing in the BEGIN study

SynAct Pharma AB ("SynAct") today announced that the last patient has completed dosing in its phase 2a clinical study of the company's lead candidate compound, AP1189, in early Rheumatoid Arthritis (RA) patients with severe disease activity, the BEGIN study.

The last patient received their final dosing in the trial on Friday, October 22, 2021. Per study protocol, a final safety follow-up visit is scheduled 28 days after the last dose. Once the clinic completes and reports that call, the process of validating, processing, and analyzing the data starts. As previously communicated, SynAct Pharma expects to announce the key results of this study before the end of November 2021.

"It is a pleasure to announce that all patients have now completed treatment in the study. Preparations for closing the study and reporting the results are planned and we are excited to see the full data and hope that it further establishes the potential of AP1189 in the treatment of RA," said Thomas Jonassen, CSO of SynAct Pharma.

The information was submitted, through the agency of the contact person below, for publication on October 25, 2021

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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 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 'cleanup", 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 phase 2a studies in patients with active rheumatoid arthritis (RA), nephrotic syndrome (NS) and COVID-19

About BEGIN

The BEGIN study is a multi-center, two-part, randomized, double-blind, placebo-controlled study evaluating two doses of AP1189 (50 and 100 mg given orally once daily) for four weeks against placebo as add-on therapy to methotrexate in patients with severe active RA.

The primary efficacy endpoint in the study is reduction in disease activity from severe (defined as clinical disease activity >22) to moderate or low disease activity within the four-week treatment period.

Interim data based on the evaluation of the first 26 patients demonstrate that 75% of patients treated with 100 mg and 67% of patients treated with 50 mg AP1189 reached the primary readout compared to 44% of the placebo treated patients within 4 weeks of treatment.

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