SynAct Pharma recieves pre-IND response from the US FDA

SynAct Pharma AB ("SynAct") today announced that the company was granted and has received written response from the US Food and Drug Administration (FDA) on the request for a Type B pre-IND meeting on the planned development of AP1189 oral tablets for treatment of rheumatoid arthritis in patients with an inadequate response to methotrexate alone (DMARD-IR). Based on the response, the Company will submit an investigational new drug (IND) application according to plan.

"FDA's guidance on our development program for AP1189 is of outmost importance. Not only does it help us to align with the agency's expectations for a proposed first-in-class drug, like AP1189, but it will also be valuable in our discussions with potential partners," said Thomas Jonassen, CSO, SynAct Pharma.

In response to the background package and questions submitted by SynAct, the FDA's Division of Regulatory Operations-Immunology and Inflammation, addressed questions about the study design, clinical development program, and preclinical development, as well as chemistry, manufacturing, and controls (CMC).

The response enables SynAct to proceed with the planning and, subject to regulatory approval, execution of Part A of the RESOLVE study, a 4-week dose-response study testing 3 doses of AP1189 vs placebo in a multicenter, double-blind, placebo-controlled study in DMARD-IR patients to be conducted at sites in Europe and USA. Part B of the study is planned as a 12-week study to be conducted in continuation of Part A, with its dose selection based on the outcome of Part A.

This information is such information that SynAct Pharma AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted, through the agency of the contact persons below, for publication at 6.00 p.m. CEST on June 29, 2022.

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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 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.