SynAct Pharma announces additional data from the BEGIN study

SynAct Pharma AB ("SynAct") today announced additional results on the secondary endpoints ACR50 and ACR70 from the Phase 2a study of AP1189 (BEGIN) in early rheumatoid arthritis (RA) patients experiencing severe disease activity.

This update includes evaluation of the treatment effects by ACR scoring, named after the American College of Rheumatology. In addition to the ACR20 scores (proportion of the patients that achieved a reduction of ACR score ≥ 20%), the company has analyzed the treatment effects using the ACR50 and ACR70 scores.

For ACR50 (≥50% improvement in the ACR score) the results for placebo, 50 mg AP1189 and 100 mg AP1189 were 6.7%, 3.5%, and 18.2%, respectively.

For ACR70 (≥70% improvement in the ACR score) the results were 3.3%, 0% and 9.1% for placebo, 50 mg AP1189 and AP1189 100 mg, respectively.

An updated presentation with the results from the BEGIN study, including the information above is available on the company's web site: www.synactpharma.com

SynAct continues to analyze the data set from BEGIN and additional results will be announced during the coming months.

The information was submitted, through the agency of the contact person below, for publication on December 2, 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 “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 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, both given in combination with methotrexate in previously treatment-naïve patients with severe active RA. The primary efficacy endpoint in the study is reduction in disease activity from severe (defined as CDAI >22) to moderate or low disease activity within the four-week treatment period.

https://clinicaltrials.gov/ct2/show/NCT04004429?term=AP1189&draw=2&rank=1