AP1189 can be dosed for three months in future clinical studies

SynAct Pharma AB ("SynAct") today announced that the company successfully has completed preclinical toxicology studies aimed to support 3 months dosing in future clinical trials with its lead candidate product, AP1189.

No unforeseen observations were identified and importantly, the studies identified no-observed-adverse-effect levels (NOAEL) at the same or higher levels as identified in the four weeks preclinical toxicology studies conducted prior to initiation of the clinical development of the AP1189 compound.

The preclinical studies have been conducted in accordance with international guidelines for non-clinical safety studies for the conduct of human clinical trials and marketing authorization for pharmaceuticals (ICH M3(R2) guideline) and included studies in two species.

“The results of these preclinical studies together with the possibility to use our newly developed tablet brings the development of AP1189 to a new level. First and foremost, it gives the possibility to run studies with up to three months dosing. This means that we can conduct Phase 2b development in rheumatoid arthritis (RA) in line with the current guidelines on clinical investigation of medicinal products for the treatment of RA and gives complete new opportunities in our nephrology program,” said Thomas Jonassen, CSO.

SynAct intends to update on the development plan for AP1189 after the release of key results of the BEGIN study in RA, planned for end of November 2021.

The information was submitted, through the agency of the contact person below, for publication on November 5, 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. The safety and efficacy of AP1189 is being tested and has not been reviewed by any regulatory authority worldwide.
https://clinicaltrials.gov/ct2/show/NCT04004429?term=AP1189&draw=2&rank=1)
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