SYNACT PHARMA

Press Release
25 August 2022 07:00:00 CEST

CTA approved for the Phase 2b study EXPAND

SynAct Pharma AB (publ) ("SynAct") today announced that the Clinical Trial Application (CTA) to initiate the clinical Phase 2b study, EXPAND, with the Company's candidate drug, AP1189, in patients with newly diagnosed rheumatoid arthritis (RA) has been approved in Moldova with the aim to start recruitment of patients as soon as the study sites has been initiated in September. Approval in Bulgaria is expected in the weeks to come.

EXPAND is part of SynAct's strategy to further develop AP1189 as a new oral treatment option in RA. The study is designed to identify the full treatment potential of the compound given in combination with methotrexate (MTX) in previously treatment naïve patients with high disease activity.

"This is a major achievement for SynAct to mature our clinical program further and to bring AP1189 into Phase 2b. I am pleased that the SynAct team and our collaborators are delivering according to the ambitious plans we have laid out and communicated. A positive outcome of the study, planned to be completed in second half of 2023 will provide state-of the art data to demonstrate AP1189 as a very attractive asset, that can be benchmarked directly against other treatments in RA", says Jeppe Øvlesen, CEO of SynAct Pharma.

The purpose of the EXPAND study is to confirm the encouraging effects of AP1189 demonstrated in the BEGIN study, where 100 mg AP1189 once daily for four weeks in combination with MTX treatment was found to be safe and well tolerated and met the primary endpoint of a significantly greater than placebo reduction in clinical disease activity (reduction in CDAI; Placebo: 9.3 points vs 100 mg AP1189: 15.5 points, $P<0.05$). In addition, treatment with AP1189 was associated with a statistically significant higher proportion of patients achieving 20% improvement in American College of Rheumatology (ACR20) score. (ACR20; Placebo: 33% vs 100 mg AP1189: 61%, $P<0.05$).

The information was submitted, through the agency of the contact person below, for publication at 07: 00 a.m. CEST on August 25, 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.

About EXPAND
The EXPAND (SynAct-CS007) study is a multicenter, randomized, double-blind, placebo-controlled, 12-week study in newly diagnosed, treatment naïve patients with highly active RA (Clinical Disease Activity Score (CDAI) > 22) who are to start treatment with methotrexate (MTX). In EXPAND, 120 RA patients with high disease activity (CDAI > 22) will be randomized 1:1 for treatment with either the newly developed 100 mg AP1189 tablets or placebo tablets for a once daily dose for 12 weeks, concurrently with the prescribed dosing with MTX. The primary efficacy read-out in the EXPAND is proportion of patients achieving 20% improvement in ACR (ACR20) at week 12 relative to placebo. The safety evaluation read-outs include adverse event monitoring, biochemical and hematological evaluation, physical examinations, and vital sign measurements. In addition, several secondary efficacy endpoints are defined, including, ACR50, ACR70, CDAI, and Disease activity score 28 (DAS-28) change over time, Change in Health Assessment Questionnaire – Disability Index (HAQ-DI) and Functional Assessment of Chronic Illness Therapy [FACIT]-Fatigue), as well as use of corticosteroids as rescue medication. Tertiary endpoints are included to further explore the effect of AP1189 on biomarkers and by evaluation of synovial inflammation using magnetic resonance imaging (MRI).

Attachments
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