SYNACT PHARMA

Press Release
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SynAct Pharma completes patient recruitment for Phase 2b EXPAND study of AP1189 in early severe Rheumatoid Arthritis

SynAct Pharma AB (publ) ("SynAct") today announced that it has completed patient recruitment to the company's Phase 2b clinical trial EXPAND which is evaluating its lead candidate compound AP1189 in early Rheumatoid Arthritis (RA) patients with severe disease activity.

With all patients included into the study, dosing will be concluded in July and the last patient's safety follow-up visit to be conducted in August. Top-line data will be reported following clean file and database lock. SynAct therefore anticipates releasing top-line study data in about five months.

"It's satisfying to announce that the last patient in the EXPAND study was enrolled well ahead of schedule. We now look forward to completing the dosing and reporting the study," said Thomas Jonassen CSO of SynAct Pharma.

The EXPAND study is a continuation of the BEGIN study where SynAct showed AP1189 had the ability to induce a fast and clinical meaningful reduction in the patient's disease activity compared to placebo treatment already after 4 weeks treatment. In EXPAND, SynAct doses AP1189 in combination with first-line treatment Methotrexate in previously treatment naïve patients with severe RA. A total of 127 have been randomized to be dosed for 12 weeks using the company's new patient-friendly tablet formulation developed for once daily dosing.

Key results focusing on the primary efficacy readout (ACR20), secondary read outs (ACR50, ACR70; reduction in DCAI and DAS28) as well as safety will be presented in a press release followed by an investor call when the data are available. The company will continue to update the market on the further progress and the process to finalize the EXPAND study.

Ongoing safety challenges with key classes of RA therapeutics underscore the need for new treatment modalities. AP1189 promotes inflammatory resolution, a very promising approach to circumvent the safety issues related to suppression of the immune system encountered with other therapies.

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About SynAct Pharma AB
SynAct Pharma AB (publ) (Nasdaq Stockholm: SYNACT) 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 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, the plan is to randomize 120 RA patients with high disease activity (CDAI > 22) 1:1 for treatment with either the newly developed 100 mg resomelagon (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 resomelagon (AP1189) on biomarkers and by evaluation of synovial inflammation using magnetic resonance imaging (MRI).

This information is information that SynAct Pharma is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2023-04-24 09:35 CEST.

Attachments
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