SYNACT PHARMA

Press Release
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SynAct Pharma announces the completion of dosing in the Phase 2b EXPAND study of resomelagon (AP1189) in early severe rheumatoid arthritis patients

SynAct Pharma AB (publ) ("SynAct") today announced that dosing has been completed in the company's 12-week EXPAND Phase 2b clinical trial evaluating once-daily resomelagon (AP1189) in early rheumatoid arthritis (RA) patients with severe disease. SynAct anticipates being able to release top-line study data in September.

"We very much look forward to seeing the EXPAND data, the first phase 2b study of our lead compound resomelagon. The compound is being tested in combination with methotrexate for newly diagnosed patients presenting with severe disease activity," said Thomas Jonassen, CSO of SynAct Pharma. "Severe disease activity is recognized as a key indicator of poor patient prognosis in both the American and European treatment guidelines. We are optimistic that the results of the EXPAND study will further demonstrate the benefit of treating these newly diagnosed severely active patients with resomelagon. Recruitment has gone well ahead of schedule, and we are excited to see the top-line data in September."

The EXPAND study builds upon the BEGIN phase 2a RA study where resomelagon (AP1189) demonstrated the ability to induce a significant and clinical meaningful reduction in patient disease activity when compared to placebo through 4 weeks of treatment. In both the BEGIN and EXPAND trials, resomelagon (AP1189) is given in combination with the first-line treatment methotrexate in treatment naïve patients with severely active RA.

"Ongoing efficacy and safety challenges with key classes of RA therapeutics underscore the need for new treatment modalities with improved risk benefit profiles," said Torbjørn Bjerke, CEO SynAct Pharma. "Resomelagon promotes inflammatory resolution, a very promising approach to provide efficacy without suppressing of the immune system which is 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 resomelagon (AP1189)
The mechanism of action of resomelagon (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 can result in both anti-inflammatory effects like lowering the level of pro-inflammatory molecules and in pro-resolution effects like switching macrophages to perform inflammation "clean-up", known as efferocytosis (J Immun 2015, 194:3381-3388). This dual 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.

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) In EXPAND, approximately 120 RA patients with high disease activity (CDAI > 22) will be randomized 1:1 for treatment with either 100 mg resomelagon (AP1189) tablets or placebo tablets for a once daily dose for 12 weeks, concurrently with the initiation of dosing with methotrexate. 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).

Attachments
SynAct Pharma announces the completion of dosing in the Phase 2b EXPAND study of resomelagon (AP1189) in early severe rheumatoid arthritis patients