SYNACT PHARMA

Press Release
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SynAct Pharma completes dosing in part A of combined Phase 2a/b RESOLVE study of resomelagon (AP1189) in rheumatoid arthritis (RA)

SynAct Pharma AB (publ) ("SynAct") today announced that dosing has been completed in the Phase 2a portion of the RESOLVE Phase 2a/b clinical study of once-daily oral resomelagon (AP1189) in patients with an inadequate response to first-line disease-modifying antirheumatic drugs (DMARD-IR). A total of 125 patients were randomized into the study with over 20% recruited in the US. With dosing completed SynAct anticipates releasing top-line study data in October of this year.

"Patients not sufficiently responding to today's first-line disease modifying anti-rheumatic drugs continue to endure significant symptomology and accumulate joint disability," said Thomas Jonassen, CSO of SynAct Pharma. "Up to 70% of patients started on methotrexate, the main first-line agent for RA, will either not respond to methotrexate or will lose any initial response within a year of starting therapy. We are hopeful that resomelagon may become an excellent option for these patients."

Development of resomelagon in DMARD-IR patients is being done under an IND (Investigational New Drug) application with clinical sites in the both the US and in European countries. RESOLVE is designed in two parts with a 4 week Phase 2a dose selection and initial safety and efficacy assessment portion that will enable dose selection for the 12 week Phase 2b safety and efficacy assessment. Planning and preparation for the Phase 2b study, i.e. part B of the FDA approved RESOLVE protocol, has begun.

"We are excited to see the upcoming RESOLVE Phase 2a as well as the upcoming data from the EXPAND Phase 2b trial in severe treatment naïve RA patients. We believe that together these studies will demonstrate the potential for resomelagon to help RA patients when DMARD therapy is insufficient," said Torbjørn Bjerke, CEO SynAct Pharma. "We think there is a tremendous need for new safe, efficacious and convenient therapies for these patients."

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About SynAct Pharma AB
SynAct Pharma AB (Nasdaq Stockholm: SYNACT) is a clinical stage biotechnology company focused on the resolution of inflammation through the selective activation of the melanocortin system. The company has a broad portfolio of oral and injectable selective melanocortin agonists aimed at inducing anti-inflammatory and inflammation resolution activity to help patients achieve immune balance and overcome their inflammation. For more information: www.synactpharma.com.

About resomelagon (AP1189)
Resomelagon (AP1189), is a once-daily oral melanocortin agonist that selectively activates melanocortin receptors 1 and 3 that are directly involved in inflammation and its resolution. These receptors are located on immune cells 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).

About RESOLVE
The RESOLVE Phase 2a/b study (SynAct-CS006) is a two-part, randomized, double-blind, multi-center, placebo-controlled study of once-daily oral resomelagon added to background MTX therapy in adult RA patients with an inadequate response to MTX alone. The Phase 2a portion of the RESOLVE study was designed to enable effective dose selection for the Phase 2b study and to obtain proof of concept data on the safety and efficacy or resomelagon in this important patient population. The Phase 2a study was not powered to demonstrate a statistically significant difference between active and placebo groups. A total of 125 patients with moderate to severely active RA despite an adequate course of MTX therapy were randomized to treatment with either resomelagon dosed at 60 mg, 80 mg, or 100 mg or with placebo once daily for 4 weeks as add-on treatment to stable MTX.

In the Phase 2b portion of the RESOLVE study, patients will be randomized into up to 3 resomelagon dose groups or placebo, all administered once daily for 12 weeks as add-on treatment to stable background MTX treatment. The total study population may be up to 300 patients, depending on the number of dose groups of resomelagon selected for evaluation.

The objectives of the RESOLVE study are to evaluate the efficacy and safety of resomelagon vs placebo when added to background MTX therapy in DMARD-IR patients. The safety of resomelagon will be assessed by comparing resomelagon against placebo for adverse events, physical examinations, vital sign measurements, ECG, and clinical laboratory testing (hematology, chemistry, and urinalysis). The primary efficacy endpoint is the effect of resomelagon (AP1189) compared to placebo evaluated by the ACR20 response. The effect will additionally be evaluated by ACR50, ACR70, CDAI, DAS-28, CRP, the need for rescue medication, inflammatory and collagen turnover biomarkers, HAQ-DI and FACIT-Fatigue. In part B changes in imaging parameters reflecting joint inflammation (DCE-MRI) from baseline to week 12 will be evaluated in a subgroup of patients.

Attachments

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