SYNACT PHARMA

Press Release
20 July 2023 07:30:00 CEST

SynAct Pharma completes patient recruitment for part A of combined Phase 2a/b RESOLVE study of resomelagon (AP1189) in rheumatoid arthritis (RA)

SynAct Pharma AB (publ) ("SynAct") today announced that it completed patient recruitment for part A of the P2a/b RESOLVE clinical study of resomelagon (AP1189) in patients with an inadequate response to first-line disease modifying anti- rheumatic drugs (DMARD-IR) who are experiencing moderate to severe disease activity. With all patients recruited SynAct anticipates releasing top-line study data in October this year.

"There is a need for an efficacious, safe and patient friendly oral treatment option for DMARD-IR patients as these patients suffer from uncontrolled disease despite being treated with first-line agents. We are happy that recruitment of part A of the RESOLVE study is finished, and we look forward to completing the dosing and reporting data for this first part of the study," said Thomas Jonassen, CSO of SynAct Pharma.

Development of resomelagon (AP1189) in DMARD-IR patients is done under an IND (Investigational New Drug) application with clinical sites in the both the US and in European countries. The clinical study RESOLVE is designed as a two-part safety and dose finding study with four weeks dosing in part A like in the BEGIN study, followed by a part B resembling the clinical study EXPAND with 12 weeks once daily dosing. Planning for part B has started and more information will be shared as the study progresses.

"We believe resomelagon could be very well suited for DMARD-IR patients given the emerging profile of an efficacious, safe, and well tolerated once daily oral therapy," said Torbjørn Bjerke, CEO of SynAct. "The DMARD-IR patient population has high commercial attractiveness given the resomelagon clinical profile."

For further information, please contact:

Torbjørn Bjerke
CEO, SynAct Pharma AB
Phone: +46 727 44 41 58
Email: TBJE@synactpharma.com
Email: investor.relations@synactpharma.com

Thomas Jonassen
CSO, SynAct Pharma AB
Phone: +45 40 15 66 69
Email: tj@synactpharma.com

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 RESOLVE
The RESOLVE study (SynAct-CS006) is a two-part, randomized, double-blind, multi-center, placebo-controlled study of the safety, dose-range finding confirmation, and efficacy of 4 (Part A) and 12 weeks (Part B) of treatment with resomelagon (AP1189) in adult RA patients with an inadequate response to MTX alone.

In Part A approximately 120 randomized patients will be treated with either 60 mg AP1189, 80 mg AP1189, 100 mg resomelagon (AP1189) or placebo once daily for 4 weeks as add-on treatment to stable MTX treatment. Part A will conclude with an unblinded assessment for risk /benefit and a recommendation for dose selection for Part B and was not powered to demonstrate a statistically significant difference between active and placebo.

In Part B, patients will be randomized into groups of equal size evaluating up to 3 doses of resomelagon (AP1189) versus placebo, all doses will be administered once daily for 12 weeks as add-on treatment to stable MTX treatment. The sample size per dose group/placebo group is 75 patients, by which the total study population of Part B may be up to 300 patients, depending on the number of dose groups of resomelagon (AP1189) selected for evaluation based on Part A.

The objectives of the two-part study are to evaluate the efficacy and safety of multiple doses of resomelagon (AP1189) when combined with MTX in DMARD-IR patients. The safety of resomelagon (AP1189) will be assessed by comparing resomelagon (AP1189) 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

SynAct Pharma completes patient recruitment for part A of combined Phase 2a/b RESOLVE study of resomelagon (AP1189) in rheumatoid arthritis (RA)