SYNACT PHARMA

Press Release
01 July 2024 07:30:00 CEST

SynAct initiates filing process for Phase 2b ADVANCE study with resomelagon

SynAct Pharma AB ("SynAct") (Nasdaq Stockholm: SYNACT), a clinical-stage biotechnology company focused on resolving inflammation through selective activation of the melanocortin system, today announces it has initiated the filing process with submission in the US for a Phase 2b randomized, double-blind placebo controlled clinical multi-center study with the company's lead compound resomelagon (AP1189) to be conducted at sites in the US and in Europe.

Resomelagon is a biased melanocortin receptor type 1 and 3 agonist that in Phase 2 clinical trials in newly diagnosed RA patients with high disease activity and signs of systemic inflammation showed significant treatment effect compared to placebo treatment with a good safety profile supporting first line treatment with the compound in combination with methotrexate (MTX). The primary aim of the ADVANCE study is therefore to confirm the treatment potential of the compound and to identify optimal doses for Phase 3 development in patients with severe newly diagnosed RA.

"We are confident resomelagon has tremendous potential for early intervention in patients with severe RA," said Thomas Jonassen, CSO at SynAct Pharma. "These patients are often cotreated with glucocorticoids (GCs) and second line treatment with biologics, as the TNF-blockers, will often be introduced very early to increase the likely hood of obtaining disease control. However, these treatment options are associated with unwanted side effects. Resomelagon has the potential to be a novel treatment option thereby reducing the need for GCs and potentially postponing the use of the biologics to more advanced stages of the diseases in case of continued lack of disease control."

The ADVANCE study is set up as a double-blind placebo controlled multi-center study testing three doses of resomelagon (40, 70, 100 mg) given once daily for 12 weeks in combination with MTX treatment in patients showing signs of severe RA (DAS28-CPR >5.1; CDAI >22) including signs of systemic inflammation defined as hsCPR to be above normal range (>3 mg/L). The study is designed to randomize 240 patients using treatment induced reduction in DAS28-CRP as the primary efficacy readout in complete accordance with the current guidelines from FDA and EMA. The study will be conducted at clinical sites in the US and in Europe. The submission in the US will be followed by submission of clinical trials applications in Europe in the upcoming weeks. It is the intention to have active recruitment up running in late Q3 2024 with enrolment of all patients to be completed in Q4 2025.

"The submission is a part of the ambitious schedule that has been laid out in collaboration with our CRO and advisors to continue the development of resomelagon (AP1189) in RA. Our team and CRO have done a tremendous effort in getting the project back on track," said Jeppe Øvlesen, CEO at SynAct Pharma. "We will in parallel with the initiation of the ADVANCE study continue our discussion with potential partners and key opinion leaders for this very innovative new treatment option. Patients as addressed in the ADVANCE study are only one of several groups of patients suffering from autoimmune and/or inflammatory disease that could benefit from treatment with resomelagon."

For further information, please contact:
Jeppe Øvlesen
CEO, SynAct Pharma AB
Phone: + 45 2844 7567
E-mail: investor.relations@synactpharma.com

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).

Attachments
SynAct initiates filing process for Phase 2b ADVANCE study with resomelagon