SYNACT PHARMA

Press Release
23 September 2024 07:00:00 CEST

SynAct initiates the Phase 2b ADVANCE study with resomelagon (AP1189) in the US

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 that the ADVANCE study, a Phase 2b randomized, double-blind placebo controlled clinical multi-center study in patients with newly diagnosed severe rheumatoid arthritis (RA) with the company's lead compound resomelagon (AP1189) actively recruits patients following initiation of sites in the USA.

"We are very excited about the perspective of having the ADVANCE study up running in the US. Pending approval in Europe we plan to have active recruitment at more than 20 sites in a total of 7 countries in Q4 2024," said Thomas Jonassen, CSO at SynAct Pharma.

Resomelagon (AP1189) 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 to confirm the treatment potential of the compound and to identify optimal doses for Phase 3 development in patients with newly diagnosed RA.

"The initiation of the ADVANCE is a cornerstone in the strategy put forward in the spring and we are pleased that the team in in collaboration with our CRO and advisors has been able to execute on the ambitious schedule that was laid out for updating the IND in the US, filing trial applications in Europe as well as managing the complex operations related to initiation of a clinical trial," said Jeppe Øvlesen, CEO at SynAct Pharma. "We have focused resomelagon as a new innovative oral treatment option in early RA with high disease activity where there is a need for new safe medicines. We strongly believe in resomelagon as a treatment option for these patients as well as for several groups of patients suffering from autoimmune and/or inflammatory disease. Our strategy balances the risks and the opportunities to create most value for the patients, our investors and for our potential partners."

In the ADVANCE study four cohorts of RA patients, diagnosed within 6 months and showing signs of severe RA (DAS28-CRP >5.1; CDAI >22) including signs of systemic inflammation, defined as hsCRP to be above normal range (>3 mg/L) are given either placebo or one of three doses of resomelagon (40, 70, 100 mg) once daily for 12 weeks in combination with MTX treatment. The study is designed to randomize 240 patients using treatment induced reduction in DAS28-CRP as the primary efficacy readout in line with the current guidelines from FDA and EMA. The study will be conducted at clinical sites in the US and in Europe with enrolment of all patients planned to be completed in Q4 2025.

Capital Markets Day

SynAct Pharma will hold a Capital Markets Day on Monday, September 23, 10:00-13:00 CEST at GT30, Grev Turegatan 30 in Stockholm. The presentations will give an update on SynAct Pharma's strategy and offer an opportunity for participants to learn more about resomelagon's role in resolving inflammation through selective activation of the melanocortin system and the company's next clinical development of resomelagon with the Phase IIb clinical study ADVANCE in the US and Europe.

Location: Grev Turegatan 30, 114 38 Stockholm
Date: Monday, September 23, 2024
Time: 10:00-13:00. The venue opens at 09:30.

The Capital Markets Day will be held in English. Presentation material will be available on SynAct's website afterwards. Registration for the Capital Markets Day is made by emailing: investor.relations@synactpharma.com

For further information, please contact:
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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.

Attachments
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