Press Release
27 November 2024 07:00:00 CET

SynAct Pharma receives EU trial approval for the Phase 2b ADVANCE study with resomelagon (AP1189)

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 company has received clinical trial approval in the EU for the Phase 2b ADVANCE study in newly diagnosed severe rheumatoid arthritis (RA) patients with the lead compound resomelagon (AP1189). Recruitment and dosing of patients is already underway in the US and Moldova.

"We are very pleased that we, following the approval in the EU though the centralized Clinical Trial Approved System (CTIS), can now continue with active patient recruitment and dosing at more than 20 sites in a total of 7 countries across Europe and the US. We expect the recruitment pace to accelerate and to have all 240 patients enrolled in Q4 2025," said Thomas Jonassen, CSO at SynAct Pharma.

The study is set up as double-blind placebo-controlled Phase 2b study with the aim to test three doses of the lead compound resomelagon (AP1189) vs placebo in combination with methotrexate as a new patient friendly first-line treatment option in RA.

Resomelagon (AP1189) is a biased melanocortin receptor type 1 and 3 agonist for once daily oral dosing. The compound induces resolution rather that suppression of system meaning that the compound has the potential to be an effective oral agent for early intervention in RA without the safety risks of immune suppression common to other therapies.

The primary aim of the ADVANCE study is to confirm the treatment potential of the compound, previously reported in the BEGIN study and in the subset of newly diagnosed patients with sign of systemic inflammation in the EXPAND study, and to identify optimal doses for Phase 3 development in patients with newly diagnosed RA.

In the ADVANCE study four groups 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 aim is to have enrolment and dosing of all patients completed in Q4 2025.

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.

Attachments
SynAct Pharma receives EU trial approval for the Phase 2b ADVANCE study with resomelagon (AP1189)