SYNACT PHARMA

Press Release
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SynAct Pharma successfully reached recruitment goal in Ph2b ADVANCE study

SynAct Pharma AB (publ) ("SynAct") (Nasdaq Stockholm: SYNACT), a clinical-stage biotechnological company focused on treating inflammation through resolution therapy, has successfully reached the recruitment goal of 240 randomized subjects in the 12-week Ph2b ADVANCE study of resomelagon in newly diagnosed patients with Rheumatoid Arthritis (RA).

"Reaching our recruitment goal in the Phase 2b ADVANCE study is a critical milestone for our lead program in newly diagnosed patients with RA," said Jeppe Øvlesen, Chief Executive Officer of SynAct Pharma. "We're grateful to the participants, investigators and study teams who made this possible and look forward to sharing top#line results. The data will provide a clear direction for business development discussions on how best to position resomelagon as a strategic asset for future growth in an immune and inflammation disorders business."

After the last patient passes 12 weeks, follow-up visit, and completes the study, the process of closing the database across more than 30 sites will commence ensuring all data is included per protocol. Following this, statistical analysis and evaluation of the results will be done before top-line results are shared.

"The ADVANCE study is testing dose dependent safety and effect of resomelagon in a patient population shown in previous clinical phase 2 study to reach clinical effect early in the disease while retaining an attractive risk benefit ratio," said Thomas Jonassen, Chief Scientific Officer of SynAct Pharma. "The unique pro-resolution mechanism of resomelagon may present an attractive safety profile allowing early use to avoid therapeutic escalation and risks posed by biologic DMARDs and JAK-inhibitors."

About Rheumatoid Arthritis:
Rheumatoid Arthritis affects 18 million people and is expected to affect up to 32 million people by 2050 (ref. 1). About 50% of patients present with moderate to severe disease scores at time of diagnosis (ref. 2) and major medical societies recommend progressive treatment to prevent disease from progressing.
Resomelagon in addition to 1st line methotrexate therapy may be a safe and effective way to reduce disease symptoms and may prolong or prevent the need for additional therapy typically adding glucocoid steriods and biologic DMARDS.

About the Phase 2b ADVANCE study:
The ADVANCE study is a 12-week randomized, double-blind, multicenter, placebo-controlled Phase 2b study with repeated doses of 40mg, 70mg, and 100mg of AP1189 and placebo. The study includes 240 newly diagnosed patients with Rheumatoid Arthritis (RA), with elevated inflammation levels (CRP levels above 3mg/l), severe disease symptoms, and ready to initiate 1st line methotrexate therapy.

References: 1) Lancet Rheumatol 2023;5: e594–610; 2) Z Rheumatol. 2017 Jun;76(5):434-442

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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 further information: https://synactpharma.com/.

Attachments
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