

SynAct Pharma completes dosing for last patient in Phase 2b ADVANCE study

SynAct Pharma AB (publ) ("SynAct") (Nasdaq Stockholm: SYNACT), a clinical-stage biotechnological company focused on treating inflammation through resolution therapy, has successfully completed dosing of the last patient in the Phase 2b ADVANCE study of resomelagon in newly diagnosed patients with Rheumatoid Arthritis (RA). Topline data is expected in June.

"We are happy to complete the dosing of the last patient. With the study we aim to demonstrate the concept of improving early resolution of disease symptoms and thereby stopping or delaying disease progression without the risks associated with immunosuppressant therapies," said Thomas Jonassen, Chief Scientific Officer of SynAct Pharma. "With positive data we will commence Phase 3 readiness activities, and we will move strategic discussions forward to form the strongest possible path to getting resomelagon to patients suffering from RA worldwide."

The process of closing the database across more than 30 sites has commenced 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 company expects topline results to be shared in June 2026 in line with previous communication.

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 steroids 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. 246 newly diagnosed patients with Rheumatoid Arthritis (RA) have been recruited to the study, 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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