SYNACT PHARMA

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SynAct Pharma presents positive clinical data on resomelagon (AP1189) supporting development for the treatment of RA at ACR Convergence

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 will present the topline data from the EXPAND study evaluating resomelagon (AP1189) in rheumatoid arthritis (RA), at the American College of Rheumatology (ACR) Convergence 2024 conference in Washington DC on November 18th. The positive data support continued development of resomelagon in the recently initiated ADVANCE Phase 2b study.

Resomelagon is a biased melanocortin receptor agonist with pro-resolving properties developed by SynAct Pharma for once daily oral dosing as a novel treatment approach in RA focusing on early intervention in newly diagnosed RA patients with high disease activity including signs of systemic inflammation.

"The results of the EXPAND-study in early rheumatoid arthritis patients with very active disease are very encouraging," says co-author of the abstract, rheumatology Professor Philip Conaghan, MD PhD, University of Leeds, UK. "If confirmed in further studies, resomelagon could have great potential to become a new way of approaching treatment of rheumatoid arthritis, potentially providing patients and clinicians with an effective oral agent without the safety risks of immune suppression common to other therapies."

The abstract, which will be presented at the ACR Converge meeting, shows the results of the EXPAND study where the compound was given in combination with methotrexate (MTX), with focus on the subset of newly diagnosed patients with high disease activity and CRP-based signs of systemic inflammation. In this patient population 82% of resomelagon+MTX treated patients (n=28) reached ACR20, the primary efficacy readout, compared to 52% of the placebo+MTX patients (n=27) ($p<0.05$). The observations were consistent across other efficacy measures, including DAS28-CRP, CDAI, and HAQ-DI.

Based on the data the development of resomelagon is continuing in the recently initiated ADVANCE study, a Phase 2b study in newly diagnosed RA patients with high disease activity (CDAI>22; DAS28-CRP >5,1; hsCRP>3 mg/L), setup as a randomized placebo-controlled dose range multi-center study (n=240) conducted in the US and in Europe.

"We look very much forward to present at the ACR Convergence 2024, the world's premier rheumatology event. The data we present highlights the treatment potential of resomelagon in a highly relevant group of newly diagnosed RA patients with high disease activity where the compound's unique pro-resolving effects could be an attractive alternative to glucocorticoids and potentially postpone the use of second line treatments as the TNF-blockers," said SynAct's CSO Thomas Jonassen.

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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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