SynAct Pharma announces additional data from the EXPAND P2b clinical trial and identifies population with responsiveness to resomelagon

- A sub-population of patients with a baseline marker of systemic inflammation (CRP > 3mg /L) demonstrated a consistent response to therapy over placebo across all assessed outcome measures
- In the subpopulation of patients with baseline CRP >3mg/L (61% of study population) 70.6% of patients treated with 100mg once-daily oral resomelagon achieved an ACR20 at week 12 compared to 54.3% of placebo patients
- SynAct management will hold an investor webcast to discuss this update

SynAct Pharma AB (Nasdaq Stockholm: SYNACT), a clinical stage biotechnology company focused on the resolution of inflammation through the selective activation of the melanocortin system, today reported additional data from the 12-week P2b EXPAND study of 100mg once-daily oral resomelagon (AP1189) in newly diagnosed rheumatoid arthritis (RA) patients experiencing severe disease activity. SynAct previously announced that the study did not meet the primary endpoint of a significantly higher ACR20 response at 12 weeks as compared to placebo. This release identifies a patient population with active systemic inflammation, where resomelagon demonstrated activity over placebo on the ACR20 primary endpoint as well as all other assessed secondary outcome measures. SynAct management will hold a webcast to discuss this announcement later today (details below).

The EXPAND (SynAct-CS007) study was a multicenter, randomized, double-blind, placebo-controlled, 12-week study in newly diagnosed, treatment naïve patients with highly active RA (Clinical Disease Activity Score (CDAI) > 22) conducted in sites in Bulgaria and Moldova. 127 patients presenting with high disease activity (CDAI > 22) were randomized 1:1 for treatment with once daily 100 mg resomelagon or placebo added to a background of methotrexate (MTX) therapy.

In patients with baseline CRP levels of >3mg/L (c-reactive protein, a blood marker of systemic inflammation, 61% of the full study population), resomelagon demonstrated consistent activity over placebo with 70.6% of resomelagon treated patients achieving an ACR20 response at 12weeks compared to 54.3% of patients on placebo. Similar strong trends favoring resomelagon treatment were seen across the individual ACR component scores as well as other key secondary outcome measures including reduction in Clinical disease activity index (CDAI) and disease activity evaluated by Disease Activity Score (DAS28). The HAQ score, a self-assessment of patient physical ability that is a component of ACR scoring, demonstrated at 12 weeks that resomelagon treated patients achieved a 60% higher improvement over placebo treatment. This assessment adds to the previously announced favorable safety and tolerability profile of resomelagon.

"We are pleased with the activity and efficacy seen in those patients with ongoing systemic inflammation at baseline. The high level of response seen in these patients is an important finding allowing us to both better understand the EXPAND results and to better target those patients more likely to respond to resomelagon moving forward", stated Thomas Jonassen, CSO of SynAct Pharma. "The higher rate of responsiveness seen in patients with evidence of systemic inflammation supports our belief in the potential of inflammation resolution with resomelagon".

"We are excited to announce the results from the highly relevant group of patients with systemic inflammation as these data confirm the resomelagon activity we have seen in previous trials. We are particularly encouraged that this activity was detectable over placebo across all outcome measures" said Torbjørn Bjerke, CEO of SynAct Pharma. "We are now looking forward to report the EXPAND magnetic resonance imaging (MRI) sub study evaluating synovial inflammation using Dynamic Contrast Enhanced MRI Quantification in newly diagnosed RA patients later in September and the RESOLVE Part 2a study in DMARD-IR patients in October this year. Patients in the ongoing P2a portion of the RESOLVE study were in part selected for having markers of active RA including elevated CRP with an estimated 70% of the patients in the 2a portion of the trial having a baseline CRP value >3mg/L. We look forward to the upcoming release of these data."

Investor webcast Information - September 13th, 2023, 15:00 (Europe/Stockholm)
Webcast: https://ir.financialhearings.com/pressconference-september-2023

Teleconference:
Dial-in number to the teleconference will be received by registering on the link below. After the registration you will be provided phone numbers and a conference/user ID to access the conference.
https://conference.financialhearings.com/teleconference/?id=5007643

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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 in autoimmune and inflammatory diseases to help patients achieve immune balance and overcome their inflammation. For more information: www.synactpharma.com.

About resomelagon (AP1189)
Resomelagon (AP1189), is a once-daily oral selective melanocortin agonist that selectively activates melanocortin receptors 1 and 3 that are directly involved in inflammation and its resolution. These receptors are located on immune cell types including macrophages and neutrophils. Activation of these receptors can result in both anti-inflammatory effects like lowering the level of pro-inflammatory molecules and in pro-resolution effects like switching macrophages to perform inflammation 'clean-up', known as efferocytosis (J Immun 2015, 194: 3381-3388). This dual effect has shown to be effective in disease models of inflammatory and autoimmune diseases and the clinical potential of the approach is currently tested in clinical programs in patients with rheumatoid arthritis (RA).

About EXPAND
The EXPAND (SynAct-CS007) study is a multicenter, randomized, double-blind, placebo-controlled, 12-week study in newly diagnosed, treatment naïve patients with highly active RA (Clinical Disease Activity Score (CDAI) > 22) In EXPAND, 127 RA patients with high disease activity (CDAI > 22) were randomized 1:1 for treatment with either 100 mg resomelagon (AP1189) tablets or placebo tablets for a once daily dose for 12 weeks, concurrently with the initiation of dosing with methotrexate. The primary efficacy read-out in the EXPAND is proportion of patients achieving 20% improvement in ACR (ACR20) at week 12 relative to placebo. The safety evaluation included adverse event monitoring, biochemical and hematological evaluation, physical examinations, and vital sign measurements. In addition, several secondary efficacy endpoints are defined, including, ACR50, ACR70, CDAI, and Disease activity score 28 (DAS-28) change over time, Change in Health Assessment Questionnaire – Disability Index (HAQ-DI) and Functional Assessment of Chronic Illness Therapy [FACIT]-Fatigue), as well as use of corticosteroids as rescue medication. Tertiary endpoints are included to further explore the effect of resomelagon (AP1189) on biomarkers and by evaluation of synovial inflammation using magnetic resonance imaging (MRI).

This information is information that SynAct Pharma is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2023-09-12 20:34 CEST.

Attachments
SynAct Pharma announces additional data from the EXPAND P2b clinical trial and identifies population with responsiveness to resomelagon