SYNACT PHARMA

Press Release
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SynAct Pharma announces evaluation of the 4-week RESOLVE P2a clinical trial in moderate to severely active rheumatoid arthritis patients with an incomplete response to methotrexate

- During the evaluation of the unblinded study data SynAct Pharma identified multiple issues that need further investigation before any conclusion on the outcome of the study can be made

- The RESOLVE study was designed to identify doses of resomelagon (AP1189) to be applied in part B of the trial and as an initial assessment of safety and tolerability in patients with moderate to severely active rheumatoid arthritis with an incomplete response to methotrexate (MTX)
- The study conducted under an US-IND at sites in the US, Moldova and Bulgaria and tested 3 doses of resomelagon vs placebo; a total of 125 patients were randomized and the study was conducted though a contracted full-service clinical research organization (CRO)
- SynAct Pharma has decided to initiate a full third-party investigation into the conduct and quality of the trial including a full study audit
- The audit will also include the EXPAND study as the previously announced trial was run by the same CRO with an overlap in clinical sites
- SynAct Pharma will further inform the market when the full investigation of the study has been finalized which it anticipates will be available in the beginning of 2024

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 update from the 4-week RESOLVE P2a study of three doses of once-daily oral resomelagon (AP1189) in rheumatoid arthritis (RA) patients experiencing an incomplete response to methotrexate (MTX) therapy. Unblinded data from the study identified multiple irregularities in the conduct of the study and SynAct therefore needs to investigate the quality of the study in much more detail before making any conclusion on the results.

“We are disappointed with the issues we have encountered in attempting to assess the RESOLVE study,” stated Torbjörn Bjerke, CEO of SynAct Pharma. “We have informed the clinical CRO that we will be initiating a third-party audit.”

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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 RESOLVE
The RESOLVE P2a/b study (SynAct-CS006) is a two-part, randomized, double-blind, multi-center, placebo-controlled study of once-daily oral resomelagon added to background MTX therapy in adult RA patients with an inadequate response to MTX alone. The Phase 2a portion of the RESOLVE study was designed to enable effective dose selection for the Phase 2b study and to obtain proof of concept data on the safety and efficacy or resomelagon in this important patient population. The P2a study was not powered to demonstrate a statistically significant difference between active and placebo groups. A total of 125 patients with moderate to severely active RA despite an adequate course of MTX therapy were randomized to treatment with either resomelagon dosed at 60 mg, 80 mg, or 100 mg or with placebo once daily for 4 weeks as add-on treatment to stable MTX.

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 2023-11-01 07:30 CET.

Attachments
SynAct Pharma announces evaluation of the 4-week RESOLVE P2a clinical trial in moderate to severely active rheumatoid arthritis patients with an incomplete response to methotrexate