SYNACT PHARMA

Press Release
02 February 2024 07:00:00 CET

SynAct Pharma announces its 2024 strategic plan and milestones

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 announced that the SynAct Board of Directors has approved a 2024 strategic plan that focuses development programs in areas of high unmet need and high partner interest. SynAct will hold a Capital Markets Day later in Q1 to provide further detail and insight on the strategic plan.

After an exhaustive review of available pre-clinical and clinical data, in consultation with leading rheumatology key opinion leaders and in light of partnering discussions to date, a proposed strategic plan was prepared and adopted by the Board after thorough discussion. The new strategy focuses development in high unmet need areas judged to have the greatest chance to drive investor and partner interest and ultimately shareholder value.

“We firmly believe, based upon BEGIN and the post-hoc analyses of patients with elevated CRP in EXPAND, in the continued development of resomelagon in RA, and our conviction has only increased after speaking with our rheumatology KOL advisors. Our task is to apply the lessons learned from our previous clinical studies to give resomelagon every chance to succeed in our new planned studies and our new Chief Medical Officer Kirsten Harting will take the responsibility for the set-up and management of all further clinical studies,” said Torbjørn Bjerke, CEO of SynAct Pharma.

“We feel that further development of resomelagon in a tightly controlled study of primary DMARD-IR patients who are having an incomplete response to their initial course of DMARDs allows us to apply our learnings in a patient population with both high unmet need and a high degree of partner interest. This strategy is supported by the recommendations of our advisors. We are also planning a trial of resomelagon in influenza patients experiencing respiratory insufficiency and we are excited to further the development of the TXP peptides.”

“The report of the independent audit of the RESOLVE study that we announced in Q4 of last year will soon be finalized and the audit outcome will then be communicated”, he continued. “We have not nor do we plan to conduct an audit of the EXPAND study,” said Torbjørn Bjerke.

“The team has spent the past months combing through available data and received advice from leading experts in the field in choosing this development strategy. The communicated milestones will help drive development and provide transparency of how we will measure our progress. We have come through some challenges in 2023, but we remain resolute to apply the lessons learned to prove out the value of resomelagon and resolution therapy in 2024 and beyond,” stated Uli Hacksell, Chairman of SynAct Pharma.

For resomelagon (AP1189), SynAct will initiate a 3-month phase 2 study in rheumatoid arthritis patients experiencing an incomplete response (IR) to their initial trial of methotrexate (MTX, a commonly used first-line agent) who have elevated CRP at baseline. These patients, known as primary MTX-IR, are the next therapeutic step after the treatment-naïve patients who were recruited for the BEGIN and EXPAND studies but represent a key unmet need population and an attractive partnering and market position.

SynAct anticipates initiating this trial in the US and Europe in the second half of 2024. SynAct also plans to initiate a phase 2 trial with resomelagon in patients experiencing respiratory insufficiency (requiring supplemental oxygen) due to influenza as part of its ongoing RESOVIR collaboration in H2-24. SynAct will also continue to invest in mechanism of action studies to further demonstrate the potential of resomelagon and resolution therapy. Given the increased strategic focus, SynAct has decided to withdraw the ongoing iMN trial due to low enrollment.

For the TXP melanocortin peptide agonists, SynAct plans to initiate a Phase 1 study for TXP-11 in an IV form that is being developed for acute use in the critical care setting. SynAct will also advance other peptides utilizing sustained release or other formulation or delivery technologies which could be used to target a wide range of conditions including orphan diseases and inflammatory diseases. SynAct will initiate pharmacology studies and assess sustained release prototypes by the end of 2024. SynAct will also explore potential collaborations as a means to further advance the TXP peptides.

Key 2024 Milestones for SynAct Pharma include:

- Q1-24 – SynAct to hold Capital Markets Day
- H2-24 – Initiate phase 2 resomelagon study in primary MTX-IR
- H2-24 – Initiate PoC resomelagon study in respiratory insufficiency due to influenza
- H2-24 – Prepare for initiation of a P1 IV study of TXP-11 in healthy volunteers in H1-2025

For further information, please contact:
Torbjørn Bjerke
CEO, SynAct Pharma AB
Phone: +46 727 44 41 58
Mail: TBJE@synactpharma.com
Mail: investor.relations@synactpharma.com

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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