SYNACT PHARMA

Press Release
04 June 2025 10:00:00 CEST

SynAct Pharma Refines Development Strategy for Lead Compound Resomelagon (AP1189)

SynAct Pharma AB ("SynAct") (Nasdaq Stockholm: SYNACT), a clinical-stage biotechnology company focused on treating inflammation through resolution, today updates on the development strategy for the lead compound resomelagon (AP1189). The compound offers an opportunity to promote inflammatory resolution and a novel treatment approach in inflammatory diseases.

Following internal prioritization and the prospect of external collaborations SynAct will focus on two parallel development tracks: 1) early intervention in autoimmune and inflammatory diseases with primary focus on rheumatoid Arthritis (RA) and 2) host-directed treatment in viral infections.

The aim in both development tracks will be to bring the immune system to a new homeostatic setpoint or balance in conditions with activated immune system. A successful development will show the vast potential of the compound and expand the proof of concept beyond single diseases, allowing SynAct and potential partners to create value for both patients and investors in the program.

In brief SynAct will execute the strategy as follows:

- Continue recruitment in the ADVANCE Ph2b study with the aim to have all patients dosed in 2025
- Initiate a Phase 2a Proof concept study in Polymyalgia Rheumatica
- Conduct the RESOVIR-2 study in Dengue
- Continue preclinical evaluation of the pharmacological potential of resomelagon in viral infection to support the setup and a phase 2 clinical proof of concept study in patients developing respiratory insufficiency due to respiratory viral infections.
- Continue recruitment to the ongoing study in idiopathic membranous nephropathy

"The refined development strategy for resomelagon optimizes the opportunity for commercial partnerships. Since the autumn we have succeeded on executing the ADVANCE phase 2b study with recruitment according to plan and setup and initiate the RESOVIR-2 study in dengue," said CEO Jeppe Øvlesen. "We have also been able to secure additional funding to support execution of additional development tasks that reflects our belief and trust in resomelagon."

In the ongoing Ph2b ADVANCE study the compound is tested in newly diagnosed Rheumatoid Arthritis (RA) patients with high disease activity including sign of systemic inflammation. This study aimes to include 240 randomized RA patients at sites in US and Europe is running according to plan, meaning that it is expected that the last patients will complete dosing in Q4 2025.

The potential of the compound in newly diagnosed RA patients is to be a safe and effective once daily oral dosing opportunity as alternative to glucocorticoid (GC) with the potential to postpone, or even reduce, the need for second line treatment as the biologics. As part of the continued development and to optimize the business opportunities for partnering, it is the intention to seek scientific and development advise from EMA and FDA for the Phase 3 development in H1 2026 in parallel with partnering discussions.

Early intervention with resomelagon could potentially be applied in other autoimmune and inflammatory diseases. SynAct has therefore decided to enter into as clinical collaboration with leading Nordic rheumatologist with the aim to test the compound's potential to reduce the use of GC in polymyalgia rheumatica (PMR), an inflammatory condition characterized by severe bilateral pain and morning stiffness of the shoulder, neck and pelvic girdle. PMR typically affects people that are middle aged to older and ranks at the second-most common rheumatic disease after RA in Northern Europe and North America. Consequently, a clinical trial application for a Phase 2a study, set up in a cost-effective way, will be filed in the near future.

The current first line treatment in PMR is GCs given orally. To reduce the risk for GC induced side effects the recommendation in the current treatment guideline is to tamper GCs over a few weeks. GC discontinuation is associated with high risk for relapses. Consequently, early intervention with resomelagon could be a treatment option to reduce the use of GC, reduce the risk for relapses, and provide better disease control.

The second track, host-directed treatment in viral infections, focuses on the compound's ability to treat viral-induced hyperinflammatory responses through resomelagon's unique ability to promote resolution.

The development track is supported by:

- Outcome of the RESOVIR-1 study showing significantly faster recovery and shorter hospital stay relative to placebo following resomelagon treatment to patients with severe COVID-19
- Recent preclinical studies showing significant disease modulating effects of resomelagon in virus infections including Dengue, Chikungunya and Influenza

The clinical activity includes the RESOVIR-2 study where the compound is given to patients with Dengue to evaluate the potential of the drug to reduce disease activity measured by a composite clinical end point.

The recent preclinical data support continued development of the compound in patients developing respiratory insufficiency due to respiratory viral infections. Respiratory insufficiency is a common reason to hospitalization following a number of virus infections including influenza, RS and COVID. Giving resomelagon as host-directed treatment to these patients to resolve inflammation has the potential to promote recovery and reduce the risk for further exacerbations.

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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: https://synactpharma.com/.

Attachments
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