SYNACT PHARMA

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SynAct Pharma initiates Phase 2 study in respiratory insufficiency

SynAct Pharma AB (publ) ("SynAct") (Nasdaq Stockholm: SYNACT), a clinical-stage biotechnological company focused on treating inflammation through resolution therapy, today announced that it has initiated a Phase 2 study (RESPIRE) with resomelagon in patients hospitalized with respiratory insufficiency due to viral infections.

The SynAct-CS009-RESPIRE study has been approved and the first visit of a study participant is expected in Q1 2026. Thus, SynAct Pharma is executing on its dual strategy for resomelagon by progressing the development in host-directed therapy in viral infections alongside development in its lead indication in RA and other autoimmune diseases.

"With the respiratory viral season hitting Europe it's critical to test resomelagon as a safe and effective therapy to avoid the potential devastating consequences of respiratory insufficiency leading to hospitalizations of millions of people in Europe and the U.S. annually," said Thomas Jonassen, Chief Scientific Officer of SynAct Pharma. "The Phase 2 RESPIRE trial builds on convincing results in Covid-19 patients[1] showing faster recovery with fewer days in hospital and intensive care needs, and results from influenza models[2] showing that resomelagon had significant treatment effects including prevention of mortality. In this new study, we want to demonstrate a reduction in events leading to intensive unit care and prolonged hospitalization."

The study is a randomized, double-blind, multicenter, placebo-controlled study enrolling 96 patients. The study population will consist of hospitalized participants with respiratory insufficiency expected to be caused by respiratory viral infection.

"This opportunity is a significant expansion of the potential use of resomelagon in the hospital setting", said Mads Bjerregaard, Chief Business Officer of SynAct Pharma. "By executing on our dual development strategy, we are also expanding on our discussions with partners driving innovation in the hospital business."

About hyperinflammation from respiratory viral infections:

Respiratory viral infections include Influenza, Covid-19, and RSV, which are the most common respiratory viral infections leading to an estimated two million people hospitalized annually in Europe and the U.S.[3] Respiratory viral infections may worsen to a condition involving hyperinflammation in the respiratory system that renders the patient unable to provide enough oxygen to the body. Consequently, the patient would need to go to a hospital to get adequate treatment including oxygen therapy. If symptoms worsen, the patient may experience acute respiratory distress syndrome (ARDS) and require escalating oxygen support or mechanical ventilation.

Current treatments rely largely on supportive care and immunomodulators—such as corticosteroids (e.g., dexamethasone), IL-6 receptor blockers (e.g., tocilizumab), and JAK inhibitors (e.g. baricitinib) - which mitigate inflammation but carry risks of immunosuppression or unwanted adverse effects, highlighting the need for resolution-based therapies that clear the inflammation without dampening host defense.

Resomelagon has been shown to induce a relative shift in the phenotype of macrophages (MACs) from pro-inflammatory TYPE 1 alike MACs to type 2 alike proresolving MACs and in parallel modulate the recruitment of polymorph nuclear cells. These effects induce a new setpoint for the hyperinflammatory state in the patients. Consequently, resomelagon has the potential to boost the pro-resolving capabilities of the patient's immune system to safely maintain the elevated inflammation needed to fight the viral infection and facilitate the system's return to a healthy state.

About the SynAct-CS009-RESPIRE study:

A randomized, double-blind, multicentre, placebo-controlled study with repeated once daily doses of AP1189/placebo. The study population will consist of hospitalized participants with respiratory insufficiency expected to be caused by respiratory viral infection.

The study is to include male and female participants, 18 years and older, with expected respiratory viral infection, and positive for either SARS-COV-2, Influenza A or B, or RSV on bedside LAF test. Symptomatic participants needing respiratory support, as defined by Saturation of O2 ≤ 93% at ambient air or requiring significantly greater FiO2 to maintain SpO2 > 93% (i.e., need for supplementary oxygen supply by a nasal catheter or facial mask), and who agrees to participate in the study.

The investigational product treatment will be maintained for 14 days during the hospital stay. If participants are discharged before day 14, they should continue with the treatment at home.

The treatment effects of resomelagon versus placebo will be evaluated from baseline to day 28 on the composite endpoint: Occurrence of any one of the following: Death; Invasive mechanical ventilation; Extracorporeal Membrane Oxygenation (ECMO); Cardiovascular organ support (balloon pump or inotropes/vasopressors); or Renal failure (Cockcroft-Gault estimated creatinine clearance <15 ml/min), hemofiltration or dialysis.

References:

1. Almeida et al., Br J Pharmacol. 2024;1–16. Effects of a pro-resolving drug in COVID-19: preclinical studies to a randomized, placebo-controlled, phase Ib/IIa trial in hospitalized patients.
2. Data on file. Pre-clinical model of influenza.
3. CDC.gov; RESP-NET for U.S.; company estimate for Europe

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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 further information: https://synactpharma.com/.

Attachments
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