SYNACT PHARMA

Press Release
26 March 2026 14:30:00 CET

SynAct Pharma doses first patients in the Phase 2 RESOVIR-2 study with resomelagon

SynAct Pharma AB ("SynAct") (Nasdaq Stockholm: SYNACT), a clinical-stage biotechnological company focused on treating inflammation through resolution, today announces that the first patients were dosed in the RESOVIR-2 study, a randomized, placebo-controlled Phase 2 trial evaluating resomelagon as add-on therapy in patients with symptomatic Dengue infection.

"This marks an important milestone as we expand the clinical evaluation of resomelagon into viral infections beyond COVID-19. RESOVIR-2 allows us to further explore the compound's potential as a host-directed therapy aimed at resolving inflammation and improving clinical outcomes in Dengue, where there remains a significant unmet medical need," said Thomas Jonassen, Chief Scientific Officer at SynAct.

"This study addresses a significant unmet medical need in Dengue, where treatment options today are largely limited to supportive care despite the risk of rapid progression to severe disease. By targeting the underlying inflammatory response, resomelagon has the potential to not only accelerate recovery but also reduce the likelihood of complications, which remains a critical gap in current clinical practice," said Professor Mauro Teixeira, MD, PhD, Universidade Federal de Minas Gerais.

RESOVIR-2 is a randomized placebo-controlled, phase II study testing once daily oral dosing of resomelagon vs placebo (1:1 randomization, n=120) as add on to standard treatment in patients with symptomatic Dengue. The potential treatment effect of resomelagon will be evaluated by time to disease resolution though a composite clinical end point. Secondary clinical end points include the ability to reduce the incidence of warning signs of and/or the development of severe dengue.

The study is initiated and led by Professor Mauro Teixeira, MD, PhD Universidade Federal de Minas Gerais (UFMG), Belo Horizonte at clinical sites in Brazil. Recruitment to and completion of the study depends on the severity of this year's Dengue epidemic at sites.

Patient recruitment is expected to take place during the Dengue epidemic cycle, which is now beginning, with site activation aligned to regions experiencing active outbreaks. The timing and pace of enrollment will depend on the severity and geographic spread of the epidemic. Data is expected in Q3 2026.

The RESOVIR collaboration setup evaluates the potential of resomelagon and potentially other pro-resolving compounds as host-directed therapy for treatment of severe viral infections. Following on to RESOVIR-1 that showed clinical proof-of-concept in COVID-19 patients, RESOVIR-2 could add additional clinical proof-of-concept for the effect of resomelagon for resolving inflammation in patients with severe viral infections.

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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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