SYNACT PHARMA

Press Release
16 September 2026 11:35:00 CEST

WHO identifies resomelagon as one of six dengue drug candidates with evidence supporting further clinical development

SynAct Pharma AB (publ) ("SynAct") (Nasdaq Stockholm: SYNACT), a clinical-stage biotechnology company focused on treating inflammation through a novel therapeutic approach known as "pro-resolution", today announced that the World Health Organization (WHO) has identified resomelagon, the company's once daily oral pro-resolution therapy, as one of six dengue therapeutic candidates with evidence supporting further clinical development.

In a review to guide and accelerate clinical development of treatments in dengue, published in Lancet Microbe, WHO outlined a comprehensive review of the global dengue treatment pipeline and named only six candidates with sufficient supporting efficacy data to warrant inclusion in the advanced therapeutic landscape. Resomelagon is the only host-directed therapy included, alongside several small-molecule antiviral and monoclonal antibody antiviral programs and has a differentiated development position to the antiviral approaches that would have to be administered early in disease for optimal effect.

"Being identified in this WHO-led global review provides important external validation of the potential of resomelagon in dengue worldwide," said Thomas Jonassen, Chief Scientific Officer of Synact Pharma. "Resomelagon has been shown to promote resolution of active inflammation as well as properties protecting against severe disease, and our ongoing clinical work aims to demonstrate the effect of these properties in dengue."

The WHO analysis also establishes target product profiles intended to guide and accelerate the development of future dengue therapeutics, reflecting the increasing international focus on identifying effective pharmacological treatments.

The ongoing Phase 2 study RESOVIR-2 is evaluating resomelagon in dengue patients with reduction in symptom duration as the primary endpoint. This aligns well with WHO identification of symptom resolution as an appropriate and clinically meaningful endpoint for development of therapies targeting non-severe dengue. Results from Part 1 of the RESOVIR-2 study are expected in 2026 pending feedback from regulatory authorities. Resomelagon is also being evaluated in respiratory viral infections, in a phase 2 study, and is in preparation for a phase 3 trial in rheumatoid arthritis.

WHO's preferred profile for a drug treatment of non-severe dengue emphasizes oral administration; strong safety profile; broad use across patient populations; reduction of symptom burden; and prevention of progression to severe disease. Resomelagon's oral small-molecule profile is highly aligned with these requirements, supporting potential broad outpatient use.

WHO reported more than 14 million dengue cases in 2024, the highest number on record, and identified the lack of safe and effective dengue-specific treatments as a major unmet medical need. Dengue is now endemic in more than 100 countries, with nearly half the world's population at risk. The WHO framework formally establishes dengue therapeutics as a global health priority and is intended to guide regulators, funders, procurement agencies and pharmaceutical developers toward accelerated product development and access.

“WHO’s work underlines the urgency of developing effective dengue treatments that can benefit patients globally,” said Mads Bjerregaard, Chief Business Officer. “Our collaboration with Brazilian company Hipolabor is a first step to setup the right strategic partnerships for global development and commercialization of resomelagon to patients affected by dengue virus”.

The publication is available in Lancet Microbe 2026; Published Online https://doi.org/10.1016/ j. lanmic.2026.101451

About Resomelagon for Dengue

Resomelagon is currently being evaluated in dengue in the investigator-initiated Phase 2 RESOVIR-2 study in Brazil. The study is led by Professor Mauro Teixeira at the Federal University of Minas Gerais and is designed to evaluate the potential of resomelagon in patients with dengue.

Unlike conventional anti-inflammatory approaches that broadly suppress the immune response, resomelagon is designed to promote inflammatory resolution through selective activation of melanocortin receptors. This mechanism has the potential to control excessive inflammation while supporting the body’s natural resolution and repair processes.

About Dengue

Dengue is a viral infection caused by the dengue virus (DENV), which is transmitted to humans through the bite of infected mosquitoes. About half of the world's population is now at risk of dengue, with an estimated 100–400 million infections occurring each year. Dengue is found in tropical and sub-tropical climates worldwide, mostly in urban and semi-urban areas.

While many DENV infections are asymptomatic or produce only mild illness, DENV can occasionally cause more severe cases, and even death. Prevention and control of dengue rely on vector control. There is no specific treatment for dengue/severe dengue, and early detection and access to proper medical care greatly lower fatality rates of severe dengue.

Source: https://www.who.int/news-room/fact-sheets/detail/dengue-and-severe-dengue accessed on 13 August 2026

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About SynAct Pharma AB
SynAct Pharma AB (Nasdaq Stockholm: SYNACT) is a clinical-stage biotechnology company pioneering pro-resolution therapies for inflammation through selective activation of the melanocortin system. Its lead asset, resomelagon (AP1189), is a once-daily oral, first-in-class biased agonist of the MC1 and MC3 melanocortin receptors, that has completed Phase 2b development in rheumatoid arthritis, and is in Phase 2 development as host-directed therapy to treat inflammation caused by infections, including respiratory viral infection and dengue. Behind resomelagon, SynAct is building a broad portfolio of oral small molecule and injectable peptide melanocortin agonists designed to induce anti-inflammatory pro-resolution activity, helping patients restore immune balance. For more information, please visit www.synactpharma.com.

Attachments
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