SYNACT PHARMA

Press Release
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SynAct Pharma Announces Initiation of Phase II Study with resomelagon (AP1189) for the Treatment of Patients with Dengue

SynAct Pharma AB ("SynAct Pharma") today announced that the RESOVIR-2 study, an exploratory Phase 2 trial to evaluate the safety and efficacy of the company's lead candidate drug resomelagon (AP1189) in patients with Dengue has been initiated at clinical sites in Brazil.

Dengue is a viral infection that spreads from mosquitoes to people. It is more common in tropical and subtropical climates but has spread in recent years also to Europe and the US – probably due to global warming. The most common symptoms are high fever, headache, body aches, nausea, and rash. In a subset of patients, the disease can develop into a critical phase characterized by bleeding, organ dysfunction and hemodynamic shock. When symptoms are present no current specific pharmacological treatment is available.

"Resomelagon has shown to reduce severity of Dengue in experimental animal models and to reduce the proinflammatory activity of human white cells challenged with Dengue Virus" says Thomas Jonassen, CSO in Synact Pharma, and continue "these new data together with the significant positive clinical outcome of resomelagon in the RESOVIR-1 study in hospitalized COVID-19 patients support the rationale for resomelagon as a novel treatment approach for host-directed therapy in viral infections.

RESOVIR-2 is a randomized placebo-controlled, phase II study testing once daily oral dosing of Resomelagon (AP1189) 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.

The RESOVIR collaboration setup evaluate the potential of resomelagon and potential 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.

Information about the study has been uploaded to and will be available at www.clinicaltrials.gov

For further information, please contact:
Jeppe Øvlesen, CEO SynAct Pharma
Tel: +45 2844 7567
Email: JOO@synactpharma.com

About SynAct Pharma AB
SynAct Pharma AB (publ) (Nasdaq Stockholm: SYNACT) is a clinical stage biotechnology company focused on resolving inflammation through 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 anti-inflammatory activity in autoimmune and inflammatory diseases to help patients achieve immune balance and overcome their inflammation. For more information: www.synactpharma.com.

Attachments
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