Gesynta Pharma announces significant progress across development program for first-in-class drug candidate GS-248

IND submitted for systemic sclerosis and 50% recruitment milestone in Phase II study reached

Stockholm, Sweden, June 14 2021 – Gesynta Pharma AB today announced that an IND (Investigational New Drug Application) has been submitted to the U.S. Food & Drug Administration for its oral drug candidate GS-248 in patients with systemic sclerosis. Concurrently, more than half of the patients in the ongoing Phase II study in four countries across Europe have been recruited. The study investigates the safety of GS-248 and its efficacy on Raynaud's phenomenon and peripheral vascular blood flow. Top-line data is expected in Q1/2022.

Coordinating Investigator Professor Ariane Herrick, The University of Manchester Centre for Musculoskeletal Research commented: "Systemic sclerosis is a chronic, autoimmune disease that leads to serious damage to the microvessels and which is associated with great unmet need. In the first stage, attacks of Raynaud's phenomenon occur, often followed by painful and difficult-to-heal digital ulcers (ulcers of the fingers and toes). The lungs, kidneys and heart can also be severely impaired as a result of the inflammation and damage in the microvessels. GS-248 has a promising mode of action which could bring relief to both patients with systemic sclerosis and with other chronic inflammatory diseases."

GS-248 provides a combination of anti-inflammatory, vasodilatory and platelet inhibitory effects by potently and selectively inhibiting microsomal prostaglandin E synthase-1 (mPGES-1). The randomized, placebo-controlled, double-blind Phase II study will include approximately 80 patients at clinical sites in four European countries. Patients will receive GS-248 orally once daily, or placebo, for four weeks.

"I am delighted with the response and hard work from our clinical trial team to reach the halfway point of the study recruitment despite of COVID-19, and this has allowed us to confidently submit an IND for the systemic sclerosis indication. Furthermore, we are accelerating research into other indications and are looking forward to announcing results from validation studies in pulmonary hypertension," comments Gesynta Pharma's CEO, Patric Stenberg.

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About Gesynta Pharma AB

Founded in 2017, Gesynta Pharma bases its R&D on Nobel Prize awarded research from the Karolinska Institutet. The most advanced drug candidate GS-248 reduces inflammation and increases blood flow in the microvessels, which may provide improved treatments for several serious diseases. GS-248 is being evaluated in a comprehensive Phase II program to normalize blood flow and reduce pain in patients with the autoimmune disease systemic sclerosis. The results of ongoing and planned clinical studies may allow for rapidly broadening the development towards additional indications, such as cardiovascular diseases and rheumatic diseases other than systemic sclerosis. The company's owners include Industrifonden, Hadean Ventures, Linc, and a number of successful life science entrepreneurs. For more information, visit www.gesynta.se