Gesynta Pharma completes patient enrollment in its Phase II study in systemic sclerosis

Stockholm, Sweden, 12 July 2022 – Gesynta Pharma AB today announces that all patients have been recruited for the company's clinical Phase II study with the drug candidate GS-248, which is being evaluated as a treatment for the rare disorder systemic sclerosis. The study is intended to demonstrate proof-of-concept and to evaluate the safety profile of GS-248. Top-line data is expected in the fall of 2022.

Systemic sclerosis (also known as scleroderma) is a chronic, autoimmune disease that leads to serious damage to the microvessels. Already in the first stages of the disease, patients are affected by episodes of reduced blood flow in fingers and toes. The episodes, known as Raynaud's phenomenon, are often followed by very painful and difficult-to-heal digital ulcers (ulcers of the fingers and toes). Current pharmaceutical treatments are often ineffective and may have safety and tolerability issues.

The randomized, placebo-controlled, double-blind Phase II study investigates the safety of GS-248 and its efficacy on Raynaud's phenomenon and peripheral vascular blood flow in patients with systemic sclerosis. In total, 69 patients have been recruited to the study. Patients receive GS-248, or placebo, orally once daily for four weeks.

Professor Ariane Herrick, Division of Musculoskeletal and Dermatological Sciences, The University of Manchester, is Coordinating Investigator for the study, which is conducted at clinical sites in four European countries. The study results will constitute an important basis and milestone in the planning of the continued development program in systemic sclerosis and will also provide valuable information on further opportunities for GS-248 in other inflammatory diseases.

"Through a strong effort by our clinical team and dedicated investigators, all patients needed to complete the study have now been included in the Phase II study of GS-248 even though recruitment was initiated in the midst of the covid-19 pandemic. We are looking forward to obtaining the results from the study and to the continued development of our candidate drug, GS-248, in a disease area where there is a large unmet medical need currently lacking adequate treatment", comments Gesynta Pharma's CEO, Patric Stenberg.

GS-248 has a unique and promising mode of action which could bring relief to patients with systemic sclerosis, as well as to patients with other chronic inflammatory diseases, by reducing inflammation and increasing blood flow in the microvessels. This is achieved through potent and selective inhibition of the microsomal prostaglandin E synthase-1 enzyme (mPGES-1). In April 2022, Gesynta Pharma announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation to GS-248 for the treatment of systemic sclerosis.

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About Gesynta Pharma AB

Founded in 2017, Gesynta Pharma bases its R&D on research from the Karolinska Institutet. The most advanced drug candidate, GS-248, reduces inflammation and increases blood flow in the microvasculature, thereby having the potential to provide improved treatments for several serious diseases. In an ongoing clinical Phase II study, GS-248 is being evaluated for its capacity to normalize vascular blood flow and reduce pain in patients with the autoimmune disease systemic sclerosis. Positive results from this study may lead to a rapid broadening of the development program towards additional chronic inflammatory diseases. Major shareholders include Industrifonden, Linc, Hadean Ventures, and a number of successful life science entrepreneurs. For more information, please visit www.gesynta.se.