Gesynta Pharma initiates Phase II study of its first-in-class drug candidate GS-248 in patients with systemic sclerosis

Stockholm, Sweden, January 26, 2020 – Gesynta Pharma AB today announced that the first patients have been dosed in a Phase II study of its oral drug candidate GS-248 in patients with systemic sclerosis – a debilitating autoimmune disease that causes serious damage to the microvasculature. This proof-of-concept study will investigate the safety of GS-248 and its efficacy on Raynaud's phenomenon and peripheral blood flow in this patient group. Study results are expected towards the end of 2021 and will provide the basis for future clinical trials both in systemic sclerosis and potentially other chronic inflammatory diseases.

Systemic sclerosis is a progressive, autoimmune disease that leads to serious damage to the microvasculature. In the first stage, attacks of reduced blood flow to the fingers and toes (Raynaud's phenomenon) occur, which causes pain and impaired fine motor skills. Later during the course of the disease, patients are at risk for digital ulcers, which are extremely painful, and difficult-to-heal wounds on the fingers and/or toes. The lungs, kidneys and heart can also be severely damaged as a result of the inflammation in the microvasculature.

Gesynta Pharma's first-in-class drug candidate GS-248 provides a combination of anti-inflammatory and vasodilatory effects by potently and selectively inhibiting microsomal prostaglandin E synthase-1 (mPGES-1). A Phase I study has demonstrated that GS-248 is safe and well tolerated with a pharmacokinetic profile supporting once daily dosing and with potent and durable anti-inflammatory properties (PGE_2 decrease), as well as vasoprotective effects (prostacyclin increase). These encouraging results support development of GS-248 as a treatment of systemic sclerosis and a range of other medical conditions, such as cardiovascular diseases and rheumatic diseases.

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 at a dose of 120 mg orally once daily, or placebo, for four weeks. The proof-of-concept study will generate a multitude of safety, efficacy and pharmacokinetic data to support further clinical development in systemic sclerosis and potential additional chronic inflammatory diseases.

"Gesynta Pharma has already shown that GS-248 exerts strong effects on biomarkers of inflammation and vascular protection in humans, and we are excited to now initiate a Phase II study in patients with systemic sclerosis. This is a patient group with a high unmet medical need and results from the present study also have potential to serve as a solid foundation for expanding future clinical development of our first-in-class drug candidate to other chronic inflammatory conditions," comments Gesynta Pharma's CEO, Patric Stenberg.

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About Gesynta Pharma AB

Gesynta Pharma's most advanced drug candidate GS-248 reduces inflammation and increases blood flow in the microvessels, which may provide improved treatments for several serious diseases. In an ongoing proof-of-concept study GS-248 is being evaluated for its potential to normalise vascular 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 and a number of successful life science entrepreneurs. For more information, visit www.gesynta.se