Gesynta Pharma presents results from an exploratory clinical study of its drug candidate GS-248

Stockholm, Sweden, September 8 2022 – Gesynta Pharma AB today announces results from an exploratory Phase II study of the candidate drug GS-248 in systemic sclerosis patients. GS-248 was well tolerated, exhibited a favorable safety profile, and elicited a potent systemic inhibition of the target enzyme mPGES-1. However, no significant effects on the patients' symptoms could be demonstrated. For this reason, the company intends to concentrate the continued development of GS-248 in other disease areas, including endometriosis, where there is a high unmet medical need and a distinct mechanistic rationale.

GS-248 has a unique mechanism of action with the potential to treat patients with chronic inflammatory diseases. This is accomplished through a potent and selective inhibition of the enzyme microsomal prostaglandin E synthase-1 (mPGES-1). The objectives of the recently concluded explorative Phase II study included investigating the safety profile of GS-248, its ability to inhibit mPGES-1, as well as its effect on Raynaud's phenomenon and peripheral blood flow in systemic sclerosis patients. In total, 69 patients were included and received either 120 mg of GS-248, or placebo, once daily for four weeks. The study was conducted at clinical centers in four European countries under the leadership of Professor Ariane Herrick, Division of Musculoskeletal and Dermatological Sciences at the University of Manchester.

No significant effects were seen after treatment with GS-248 compared to placebo in terms of symptomatic relief in patients with systemic sclerosis. However, the tolerability and safety profile, pharmacokinetics, and unique ability to inhibit mPGES-1 and thus modify prostaglandin profile was confirmed for the first time in patients for GS-248. Collectively, the data strengthens the rationale to progress the development of the drug candidate in other chronic inflammatory diseases where mPGES-1 plays a key role.

Last year, Gesynta Pharma initiated an extensive evaluation of the drug candidate in a preclinical disease model of endometriosis – a painful inflammatory disease affecting millions of women, where the need for effective non-hormonal therapies is substantial. Scientific literature suggests a benefit of inhibiting mPGES-1 to relieve endometriosis symptoms for these patients. The results from the evaluation in endometriosis will serve as a foundation for the continued clinical development of GS-248.

"The results from the Phase II study establish the drug candidate's favorable safety profile and its ability to inhibit the target enzyme mPGES-1 in patients with an inflammatory disease. Still, we are of course disappointed with the lack of a significant effect from GS-248 on Raynaud attacks. We extend our most sincere gratitude to the patients, physicians and research nurses who contributed to this well performed study, which has generated important knowledge. We are now looking forward to using the valuable insights from this study to progress GS-248 in other indications of high unmet need, such as endometriosis" says Patric Stenberg, CEO, Gesynta Pharma.

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