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Press release

Gesynta Pharma announces positive Phase I results with GS-248 for the treatment of microvascular disease - data to be presented at EULAR congress

Solna, Sweden – May 15th, 2020 – Gesynta Pharma AB ("Gesynta") announces the completion and positive results of a first clinical study with GS-248. The purpose of the study was to evaluate safety, tolerability, pharmacokinetic and pharmacodynamic properties of GS-248 after single and multiple ascending doses to healthy subjects. The results support the further clinical development of GS-248 in microvascular dysfunction and a Phase II clinical study in patients with Systemic Sclerosis is being planned. An abstract with the results from the Phase I study has been accepted for presentation at the 2020 EULAR e-congress June 3-6.

In April 2019, Gesynta announced the closing of a fundraising round with the main objective to enable the conduct of a First-in-Human Phase I study and all non-clinical activities to make GS-248 ready for Phase II clinical development. Today Gesynta announces the successful completion of the Phase I study with GS-248.

The Phase I study was designed to assess the safety, tolerability, pharmacokinetics and pharmacodynamics of single oral doses up to 300 mg and multiple once daily doses up to 180 mg for 10 days in healthy male and female subjects. In summary, GS-248 was safe and well tolerated with a pharmacokinetic profile supporting once daily dosing and with potent and durable effects on relevant anti-inflammatory and vasoprotective biomarkers. An abstract providing further details on the study outcome has been accepted for presentation as a poster at the 2020 EULAR e-congress on June 3rd. A Phase II study to investigate the safety and efficacy of GS-248 in Systemic Sclerosis patients is now being planned.

GS-248 is a potent and selective inhibitor of microsomal prostaglandin E synthase-1 (mPGES-1) in development for the treatment of microvascular diseases in chronic inflammatory conditions. Preclinical studies demonstrate that inhibition of mPGES-1 provides a combination of anti-inflammatory, vasodilatory and platelet inhibitory effects.

"The results obtained from the Phase I study are very positive for our efforts to develop new effective treatments for microvascular diseases where there still exist large unmet medical needs. The confirmation of strong effects on biomarkers of inflammation and vascular protection in humans demonstrate the potential of GS-248 as a unique treatment of microvascular dysfunction in Systemic Sclerosis and other chronic inflammatory conditions." says Patric Stenberg, CEO of Gesynta Pharma.

The study was conducted in collaboration with Clinical Trial Consultants AB in Uppsala, Sweden.

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About Gesynta Pharma AB
Based on research from Karolinska Institutet, Gesynta leverages expertise in arachidonic acid research to explore the anti-inflammatory and vasoprotective effects of mPGES-1 inhibition, for example in cardiovascular diseases and cancer. The clinical candidate, GS-248, is an oral small molecule being developed for the treatment of microvascular disease in chronic inflammatory conditions. When strategically optimal, Gesynta will seek pharma partners to efficiently make the new therapies available to patients and to achieve the full commercial potential of its products. Gesynta is a privately held Swedish company established in 2017 and located in Stockholm, operated by a team of experts in the fields of mPGES-1 medical research and drug and business development.

Gesynta Pharma has received support from Karolinska Institutet Innovations AB, NovoNordisk Foundation, Swelife and Vinnova.

For more information, please visit www.gesynta.se