Gesynta Pharma reports positive Phase I results with lead candidate GS-248 for microvascular disease at EULAR 2020

Phase II in Systemic Sclerosis now planned

Solna, Sweden, June 11, 2020 – Gesynta Pharma AB ("Gesynta"), a clinical stage company developing novel anti-inflammatory agents, today announced that the results from the successfully completed First-in-Human clinical study with its lead candidate GS-248 for the treatment of microvascular disease have been presented at the EULAR 2020 E-Congress. Following these results, Gesynta now intends to commence a Phase II study in patients with Systemic Sclerosis.

GS-248 is a potent and selective inhibitor of microsomal prostaglandin E synthase-1 (mPGES-1) and preclinical studies have demonstrated that inhibition of mPGES-1 provides a combination of anti-inflammatory, vasodilatory and platelet inhibitory effects.

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. The study demonstrated that 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 (PGE_2 decrease) and vasoprotective (prostacyclin increase) biomarkers. The biomarker response supports an effective shunting from PGE_2 to prostacyclin synthesis. More details can be found via this link.

Patric Stenberg, CEO of Gesynta Pharma commented, "The results obtained from the Phase I study are very promising for the development of new treatments for microvascular diseases, for which there is a large unmet medical need. The confirmation of strong effects on biomarkers of inflammation and vascular protection in humans demonstrates the potential of GS-248 as a unique treatment of microvascular dysfunction in Systemic Sclerosis and other chronic inflammatory conditions. We now intend to initiate a multicenter Phase IIa study with enrolment commencing in Q4, 2020."

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Notes to editors:

About Gesynta Pharma AB

Gesynta is a privately held Swedish company established in 2017 and located in Stockholm. Based on world leading research into arachidonic acids from Karolinska Institutet, Gesynta seeks to leverage the anti-inflammatory and vasoprotective effects of mPGES-1 inhibition across a range of indications including cardiovascular diseases and cancer. The lead clinical candidate, GS-248, is an oral small molecule which is being developed for the treatment of microvascular disease in chronic inflammatory conditions.

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

For more information visit www.gesynta.se