Gesynta Pharma's drug candidate GS-073 approved for clinical development in chronic inflammatory pain

Stockholm, August 24, 2023 - Gesynta Pharma AB today announces that the Swedish Medical Products Agency has approved the company's application to initiate a clinical phase I study of GS-073. This marks the entry of GS-073 into clinical development for the treatment of chronic inflammatory pain – an area of significant medical need. With this approval, two drug candidates from Gesynta Pharma's portfolio of potent and selective mPGES-1 inhibitors have reached clinical phase.

GS-073 is an anti-inflammatory analgesic drug candidate for oral administration. With a mechanism of action based on potent and selective inhibition of the enzyme mPGES-1, GS-073 reduces production of the proinflammatory prostaglandin E2 (PGE2). GS-073, which originates from AstraZeneca, has demonstrated a highly effective suppressive effect on both inflammation and pain in a recently conducted preclinical disease model of inflammatory arthritis. The approvals from the Swedish Medical Products Agency as well as from the Swedish Ethical Review Authority to study GS-073 in humans confirm the good safety profile documented in the preclinical safety package.

The primary objective of the planned phase I study is to study the safety, tolerability and pharmacokinetic properties of GS-073 in healthy volunteers as well as its effect on relevant biomarkers. This will provide important knowledge for the planning of the continued clinical program.

"The advancement of our second drug candidate, GS-073, towards clinical phase is another significant milestone for Gesynta Pharma. With two clinical stage projects in our portfolio, we are strengthening the company's leading position in the development of new effective treatments based on mPGES-1 inhibition. We are excited about the potential of addressing several chronic inflammatory diseases, reaching large patient groups with significant medical needs," said Patric Stenberg, CEO of Gesynta Pharma.

In parallel with the development of GS-073, Gesynta Pharma is preparing a phase II study of its leading mPGES-1 inhibitor, vipoglanstat (GS-248), in patients with endometriosis, a chronic inflammatory disease affecting about ten percent of women of reproductive age. Vipoglanstat, an anti-inflammatory and non-hormonal drug candidate, has shown disease-modifying effects in an advanced preclinical model of endometriosis by significantly reducing both pain and the number of endometrial lesions.

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About Gesynta Pharma
Gesynta Pharma is a clinical stage pharmaceutical company, developing a portfolio of compounds which inhibit the pro-inflammatory enzyme mPGES-1 (microsomal prostaglandin E synthase-1). Gesynta Pharma's research originates from Karolinska Institutet.

The company's most advanced drug candidate, vipoglanstat (GS-248), is in development for the non-hormonal treatment of endometriosis. In an advanced preclinical disease model of endometriosis, vipoglanstat has demonstrated disease-modifying properties by significantly reducing pain as well as the number of endometrial lesions. Clinical studies of vipoglanstat have demonstrated a favorable safety profile and excellent pharmacological properties, with a clinical phase II study in patients with endometriosis being prepared. Endometriosis is a chronic inflammatory disease which affects about ten percent of all women of reproductive age and can cause symptoms such as severe and chronic pain, and reduced fertility.

A second drug candidate in the Gesynta Pharma portfolio, GS-073, is ready to enter clinical phase I for the treatment of chronic inflammatory pain.

Gesynta Pharma was founded in 2017 and is based in Stockholm. The company's shareholders include Hadean Ventures, Industrifonden, Linc, and a group of successful life science industry entrepreneurs. For more information, please visit www.gesynta.se.