Gesynta Pharma receives UK approval for a Phase 2 trial of vipoglanstat in endometriosis

STOCKHOLM, SWEDEN – September 30, 2025. Gesynta Pharma AB today announced that its clinical trial application for the company's Phase 2 trial of vipoglanstat for the treatment of endometriosis has been approved by the UK authorities. The clinical trial, named NOVA, intends to evaluate the efficacy and safety of vipoglanstat against placebo in approximately 190 patients with endometriosis across several European countries.

The approvals from the UK Medicines and Healthcare products Regulatory Agency (MHRA) and Research Ethics Committee (REC) enable the company to now initiate the Phase 2 study with vipoglanstat in endometriosis.

"In our mission to provide innovative treatments for patients suffering from endometriosis, the approval to begin our Phase 2 clinical trial in the UK is a crucial step for Gesynta Pharma. We look forward to working closely with our UK clinical partners as we continue the development of vipoglanstat," says Patric Stenberg, CEO of Gesynta Pharma.

The NOVA* study is a Phase 2 clinical trial of vipoglanstat, a novel non-hormonal, non-opioid treatment for endometriosis. This chronic inflammatory disease, affecting one in ten women of reproductive age, can cause intense pain, impaired quality of life, and infertility. Vipoglanstat targets mPGES-1, an enzyme found in endometriotic lesions (tissue similar to the lining of the uterus, growing outside the uterus), with preclinical data demonstrating marked reductions in both pain and lesions.

This clinical proof-of-concept trial is estimated to include approximately 190 patients in several countries across Europe. The trial is designed to evaluate the efficacy and safety of two dose levels of vipoglanstat versus a placebo over a four-month period. This will also provide critical dosage information for future clinical development.

**NOVA: the Non-hormonal Option – a Vipoglanstat Assessment trial*

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About Gesynta Pharma
Gesynta Pharma is a clinical-stage pharmaceutical company developing innovative treatments by targeting mPGES-1, a key enzyme in inflammatory processes. Gesynta Pharma's research originated at Karolinska Institutet in Sweden.

The lead compound, vipoglanstat, is being developed for the treatment of endometriosis - a painful chronic inflammatory disease that affects about 10 percent of women of reproductive age. Endometriosis often leads to a severely reduced quality of life and current drug treatments are

inadequate for many patients, partly due to troublesome side effects. Vipoglanstat is a non-hormonal, non-opioid drug candidate with disease modifying potential that selectively inhibits mPGES-1; it has demonstrated a favorable safety profile and potent inhibition of mPGES-1 in Phase 1 and 2 clinical trials. A preclinical proof-of-concept study in an advanced disease model of endometriosis shows that vipoglanstat significantly reduced pain-related behavior and endometriotic lesions. The NOVA study, a Phase 2 clinical trial in patients with endometriosis, has recently started.

A second drug candidate in the Gesynta Pharma portfolio, GS-073, is ready to enter clinical Phase 1 for the treatment of chronic inflammatory pain.

The company's shareholders include Hadean Ventures, Industrifonden, Innovestor Life Science, Linc, HealthCap, and other internationally renowned specialist investors.

For more information, please visit www.gesynta.se.