Gesynta Pharma prepares Phase II study of GS-248 in endometriosis following ground-breaking data from a preclinical proof-of-concept study

Stockholm, Sweden, October 20, 2022 – Gesynta Pharma AB today announces the decision to advance the development of its clinical-stage drug candidate GS-248 in endometriosis – a chronic inflammatory condition affecting approximately 10 percent of all women of reproductive age. This strategically important decision follows a recent preclinical proof-of-concept study with GS-248 in an advanced model of endometriosis, where disease-modifying properties of the drug candidate were firmly established. These data together with the previously demonstrated favorable clinical safety profile of GS-248 and the significant unmet medical need form the basis for the decision to initiate preparations for a Phase II study in endometriosis.

Endometriosis is an estrogen-driven, chronic inflammatory disease characterized by the presence of tissue resembling endometrium (the lining of the uterus) outside the uterus. It causes a chronic inflammatory reaction that may result in the formation of scar tissue (adhesions and fibrosis) within the pelvis and other parts of the body. The disease affects about 190 million women globally and symptoms normally emerge in the teenage years or early twenties. Women with endometriosis suffer greatly from severe pelvic pain, dysmenorrhea, pain on defecation and urination, and painful sexual intercourse. The disease is also clearly linked to sub- and infertility. Due to the high disease burden over many years, overall quality of life is severely affected.

Available therapeutics for endometriosis are mainly hormone-based and aim to reduce the effect of endogenous estrogen. Therefore, hormonal contraceptives, as well as agents which completely shut off estrogen production, are often used. However, interfering with the normal female hormone levels often lead to side effects and such agents are not tolerated by all patients. In addition, various pain relievers are used. The most commonly used are NSAIDs, however due to their well-known side effects they should only be used intermittently.

GS-248 is a non-hormonal clinical-stage drug candidate targeting the pro-inflammatory enzyme mPGES-1, which via its product prostaglandin E_2 plays a key role in inducing and maintaining endometriosis lesions. In a recently conducted proof-of-concept study, GS-248 was evaluated in an advanced preclinical disease model of endometriosis. Results from this study show that the drug candidate markedly reduced the number of endometriosis lesions and had a positive impact on pain-related parameters and well-being.

“The successful preclinical proof-of-concept study of GS-248 provides strong evidence of our drug candidate’s disease-modifying and pain-relieving ability. Together with previously accumulated clinical data pertaining to the drug candidate’s safety profile, pharmacokinetic properties and target inhibition, we have now established a solid scientific platform for advancing the development of GS-248 as a non-hormonal game-changer in the treatment of endometriosis,” says Patric Stenberg, CEO, Gesynta Pharma.

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