ObsEva Randomizes First Patient in Phase 2b EDELWEISS Study of OBE2109 for the Treatment of Endometriosis

- Clinical trial to assess safety and efficacy of novel GnRH antagonist in patients with pelvic pain associated with endometriosis -

GENEVA, SWITZERLAND, 12 October, 2016 – ObsEva SA, a Swiss biopharmaceutical company focused on the development and commercialization of novel therapeutics for serious conditions that compromise a woman's reproductive health and pregnancy, today announced randomization of the first patient in its Phase 2b clinical study (EDELWEISS) of OBE2109 for the treatment of endometriosis. OBE2109 is a novel, orally administered, gonadotropin-releasing hormone (GnRH) antagonist that has been tested in more than 150 Japanese patients with endometriosis. In those Phase 2a studies, conducted by Kissei Pharmaceutical Co., Ltd. (Kissei), a dose-dependent suppression of estradiol was observed with treatment with OBE2109. In addition, patients reported significant reductions of endometriosis-associated pelvic pain, analgesic use and bleeding days.

EDELWEISS, a Phase 2b, randomized, double-blind, placebo-controlled, dose-ranging study, will assess the efficacy and safety of OBE2109 in patients with pelvic pain associated with endometriosis. The study will be conducted in North America and Europe, with 46 centers located in the United States and 15 centers located in Central and Eastern Europe. ObsEva expects to randomize approximately 330 endometriosis patients who will be treated daily for 24 weeks, with an option to receive OBE2109 for another 28 weeks. After treatment, all patients will be followed for an additional, treatment-free 24-week period. The primary endpoint of this trial will be average combined menstrual and non-menstrual pelvic pain. Various dosing regimens will also be evaluated without add-back therapy, to support varying dosing alternatives for women coping with endometriosis.

"Unlike other GnRH antagonists in development, OBE2109's consistent PK/PD profile potentially allows for personalized dosing aiming to maintain estradiol levels within an acceptable range to relieve symptoms while mitigating patient bone density loss," said Ernest Loumaye, CEO and Co-Founder of ObsEva. "Randomization of the first EDELWEISS patient represents a major step forward in the clinical development of OBE2109 and brings us closer to providing a potentially best-in-class therapeutic solution for women suffering from endometriosis."

Endometriosis is a painful, debilitating condition that affects approximately 176 million women globally between the ages of 15 and 49 and is a leading cause of infertility.[1] In addition to symptoms such as painful periods, painful ovulation, pain during or after sexual intercourse, excessive menstrual bleeding, chronic pelvic pain, fatigue and infertility, endometriosis can also have a significant impact on a patient's general physical, mental and social well-being.[2]

"There has been little innovation in the field to treat this chronic condition over the last thirty years and currently available drugs have significant limitations," said Hugh S. Taylor, MD, Chair of the Department of Obstetrics Gynecology and Reproductive Sciences at Yale School of Medicine and Chief of Obstetrics and Gynecology at Yale-New Haven Hospital. "OBE2109's potential to relieve symptoms while mitigating bone density loss and other adverse effects associated with currently approved therapies well positions it to address a high unmet need in this often debilitating women's reproductive health condition."

ObsEva's Investigational New Drug (IND) application to begin enrolling patients in the EDELWEISS study was submitted to the U.S. Food and Drug Administration (FDA) in May 2016. For more information on the EDELWEISS study, please visit www.clinicaltrials.gov.

About Endometriosis

Endometriosis is a disease in which the endometrium (tissue lining the inside of the uterus) is found outside the uterus, where it induces a chronic inflammatory reaction that may result in scar tissue. It is primarily found on the pelvic peritoneum, on the ovaries, in the rectovaginal septum, on the bladder and bowel.[3] The most common symptom of endometriosis is pelvic pain, which often correlates to the menstrual cycle. Patients may also experience painful ovulation, pain during or after sexual intercourse, heavy bleeding, chronic pelvic pain, fatigue and infertility. For many, endometriosis pain can be so severe and debilitating that it impacts do day-to-day activities and has a negative effect on general physical, mental and social well-being.[4] The World Endometriosis Research Foundation (WERF) EndoCost study, the first ever prospective study of the actual cost of endometriosis, estimated the annual cost of endometriosis at EUR 70.9 billion in the US and EUR 58.8 billion in Germany, the UK, France and Italy.[5]

About OBE2109 and GnRH

OBE2109 is a novel, orally administered GnRH receptor antagonist with a potentially best-in-class profile in late-stage clinical development for the treatment of pain associated with endometriosis and heavy menstrual bleeding associated with uterine fibroids. OBE2109 acts by binding to and blocking the GnRH receptor in the pituitary gland, ultimately reducing estrogen production by the ovaries. Through previously reported results from this class of drugs and sophisticated pharmacological modelling, it has been established that maintaining estradiol within a specific target range provides the optimal balance between reducing the pain symptoms associated with endometriosis while mitigating bone density loss associated with excessive estradiol suppression.[6] In Phase 2a studies conducted in Japan, patients treated with OBE2109 were observed to have a reduction of endometriosis-associated pain, analgesic use and bleeding days. ObsEva licensed OBE2109 from Kissei in late 2015 and retains worldwide commercial rights, excluding Asia, for OBE2109.

About Kissei

Kissei is a Japanese pharmaceutical company with approximately 70 years of history, specialized in the field of obstetrics/gynecology, renal dialysis, urology, metabolism and ophthalmology. Silodosin is a Kissei product for the treatment of the signs and symptoms of benign prostatic hyperplasia which is sold worldwide through its licensees. KLH-2109/OBE2109 is a new chemical entity discovered by Kissei R&D which contributes to Kissei's obstetrics/gynecology franchise.

About ObsEva

ObsEva is a clinical-stage biopharmaceutical company focused on the clinical development and commercialization of novel therapeutics for serious conditions that compromise a woman's reproductive health and pregnancy. ObsEva is focused on providing therapeutic solutions for women between the ages of 15 and 49 who suffer from reproductive health conditions that affect their quality of life or ability to conceive, or that complicate pregnancy and the health of newborns. ObsEva's goal is to build a leading women's reproductive health and pregnancy company focused on conditions where current treatment options are limited and significant unmet need exists. Through strategic in-licensing and disciplined drug development, ObsEva has established a late-stage clinical pipeline with development programs focused on treating endometriosis, uterine fibroids, preterm labor and improving in vitro fertilization outcomes. ObsEva is supported by leading healthcare investors and a

globally recognized board and is well-positioned to establish a leadership position in women's reproductive therapeutics. For more information, please visit www.ObsEva.com.

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