

ObsEva SA Initiates Phase 3 Clinical Program for OBE2109 in Uterine Fibroids

- PRIMROSE 1 and PRIMROSE 2, pivotal Phase 3 clinical trials to assess efficacy and safety of novel oral GnRH receptor antagonist OBE2109 in patients with heavy menstrual bleeding associated with uterine fibroids -

Geneva, Switzerland – 25 April 2017 – ObsEva SA (Nasdaq: OBSV), 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 commencement of its Phase 3 clinical program evaluating gonadotropin-releasing hormone (GnRH) receptor antagonist OBE2109 for the treatment of uterine fibroids (UF). The first clinical centers are opened and started the recruitment of patients. The program is comprised of PRIMROSE 1 and PRIMROSE 2, two double-blind, placebo-controlled, Phase 3 international clinical trials in women with heavy menstrual bleeding (HMB) associated with UF.

OBE2109 is a novel, oral GnRH receptor antagonist that potentially provides effective management of UF-associated HMB by reducing estrogen production by the ovaries in pre-menopausal women.

The PRIMROSE Phase 3 clinical trials will be conducted at up to 200 sites in the United States and Europe, enrolling, in total, approximately 1,000 women with a diagnosis of HMB associated with UF. Eligible women will be randomized to receive either 100 mg or 200 mg of OBE2109 or placebo. Active treatment arms will be tested with and without low doses of hormonal add-back therapy. Patients will be treated for up to 52 weeks to evaluate the safety of long-term treatment. The primary outcome of the PRIMROSE clinical trials is a clinically meaningful and statistically significant reduction in menstrual bleeding as assessed by the alkaline hematin method, a reliable quantitative measurement of menstrual blood loss. Safety assessments will include a centralized assessment of bone mineral density changes measured by dual-energy x-ray absorptiometry (DXA).

“We are evaluating long term administration of OBE2109 in two dosing regimens – as a stand-alone therapy or in association with add-back therapy – designed to offer the broad patient population the personalized options needed for symptom relief with fewer side effects and complications” said Ernest Loumaye, MD, PhD, OB&GYN, CEO and Co-Founder of ObsEva. *“Owing to its consistent PK/PD profile, the lower dose of OBE2109 is designed to allow for the maintenance of estradiol levels within an acceptable range that reduces HMB while mitigating bone mineral density loss and other adverse effects, eliminating the need for systematic add-back therapy.”*

About Uterine Fibroids

Uterine fibroids are common non-cancerous tumors that grow within the muscular wall of the uterus. They can vary in size and number and when symptomatic, are most often accompanied by heavy menstrual bleeding (HMB), anemia, abdominal pressure and pain, bloating, increased urinary frequency and reproductive dysfunction. Uterine fibroids are associated with an increased risk of pregnancy complications such as infertility, miscarriage, placental abruption and early onset of labor. According to a study published in the American Journal of Obstetrics & Gynecology in 2003, uterine fibroids affect an estimated 20 to 40 percent of women over the age of 30 in the United States based on clinical cases and women who undergo treatment.



For the millions of women with symptomatic uterine fibroids seeking treatment options, selection is driven by symptom severity, the woman's age, and her desire to have children now or in the future. While medical, surgical and minimally invasive treatments are available, the standard of care for symptomatic uterine fibroids is a hysterectomy or, in women who wish to preserve their fertility, surgical removal of the fibroid(s).

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 symptoms while mitigating bone density loss associated with excessive estradiol suppression. 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. 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 ART outcomes. ObsEva is listed on The NASDAQ Global Select Market and is trading under the ticker symbol "OBSV". For more information, please visit www.ObsEva.com.

Cautionary Note Regarding Forward-Looking Statements

Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements may be identified by words such as "believe", "expect", "may", "plan," "potential," "will," and similar expressions, and are based on ObsEva's current beliefs and expectations. These forward-looking statements include expectations regarding the clinical development of OBE2109. These statements involve risks and uncertainties that could cause actual results to differ materially from those



reflected in such statements. Risks and uncertainties that may cause actual results to differ materially include uncertainties inherent in the conduct of clinical trials, ObsEva's reliance on third parties over which it may not always have full control, and other risks and uncertainties that are described in the Risk Factors section of ObsEva's Annual Report on Form 20-F for the year ended December 31, 2016, and other filings ObsEva makes with the SEC from time to time. These documents are available on the Investors page of ObsEva's website at <http://www.obseva.com>. Any forward-looking statements speak only as of the date of this press release and are based on information available to ObsEva as of the date of this release, and ObsEva assumes no obligation to, and does not intend to, update any forward-looking statements, whether as a result of new information, future events or otherwise.

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