

ObsEva SA Announces Completion of Patient Recruitment in PRIMROSE 1 Phase 3 Clinical Trial of Linzagolix for the Treatment of Heavy Menstrual Bleeding Associated with Uterine Fibroids

Geneva, Switzerland and Boston, MA – July 8, 2019 – ObsEva SA (NASDAQ: OBSV / SIX: OBSN), a clinicalstage biopharmaceutical company focused on the development and commercialization of novel therapeutics for serious conditions that compromise a woman's reproductive health and pregnancy, today reported completion of patient recruitment of its Phase 3 clinical trial PRIMROSE 1 evaluating oral gonadotropin releasing hormone (GnRH) receptor antagonist linzagolix for the treatment of heavy menstrual bleeding (HMB) associated with uterine fibroids (UF).

PRIMROSE 1 is being conducted at 117 sites, in the United States, randomizing approximately 500 patients with a diagnosis of HMB associated with UF. Eligible patients are either receiving a once daily dose of 100 mg or 200 mg of linzagolix, or they are receiving a placebo. Active treatment arms are being tested with and without low doses of hormonal add-back therapy (ABT). Patients are treated for up to 52 weeks to evaluate the safety of long-term treatment. A second Phase 3 clinical trial, PRIMROSE 2, is also being run in parallel in the U.S. and Europe— the trial is testing the same treatment arms at 102 sites where approximately 500 patients have also been randomized.

"The completion of patient recruitment for our second pivotal Phase 3 PRIMROSE 1 trial represents a key step toward the development of linzagolix for the treatment of uterine fibroids," said Ernest Loumaye, co-founder and Chief Executive Officer of ObsEva. "Linzagolix is the only GnRH receptor antagonist developed in UF with a dosing option without concomitant administration of ABT to achieve sustained symptom relief and one with concomitant ABT administration. We expect to report six-month primary endpoint data from the PRIMROSE 2 and PRIMROSE 1 trials in the fourth quarter of 2019 and in the first half of 2020, respectively."

About the PRIMROSE 1 Clinical Trial

PRIMROSE 1 is a pivotal, randomized, double blind, placebo controlled, Phase 3 clinical trial assessing the efficacy and safety of a novel oral GnRH receptor antagonist linzagolix in patients with heavy menstrual bleeding associated with uterine fibroids.

The primary endpoint of PRIMROSE 1 is a clinically meaningful and statistically significant reduction in menstrual bleeding as assessed by the alkaline hematin method, a validated, quantitative measurement of menstrual blood loss. The primary endpoint efficacy results are anticipated in 1H 2020.

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 linzagolix (formerly OBE2109)

Linzagolix is a novel, orally administered GnRH receptor antagonist with a potentially best-in-class profile in late-stage clinical development for the treatment of heavy menstrual bleeding associated with uterine fibroids and pain associated with endometriosis. Linzagolix 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 linzagolix 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 linzagolix from Kissei in late 2015 and retains worldwide commercial rights, excluding Asia, for linzagolix.

About Kissei

Kissei is a Japanese pharmaceutical company with approximately 70 years of history, specialized in the field of urology, kidney - dialysis and Unmet Medical Needs. 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.

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 IVF outcomes. ObsEva is listed on the Nasdaq Global Select Market and is trading under the ticker symbol "OBSV" and on the SIX Swiss Exchange where it is trading under the ticker symbol "OBSV".

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 ObsEva's product candidates. 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, clinical development and related interactions with regulators, 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, 2018, and other filings ObsEva makes with the SEC. 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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