

## **ObsEva SA Announces Completion of Patient Recruitment in PRIMROSE 2 Phase 3 Clinical Trial of Linzagolix for the Treatment of Heavy Menstrual Bleeding Associated with Uterine Fibroids**

**Geneva, Switzerland and Boston, MA – December 21, 2018** – ObsEva SA (NASDAQ: OBSV), a clinical-stage 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 2 evaluating oral gonadotropin releasing hormone (GnRH) receptor antagonist OBE2109 for the treatment of heavy menstrual bleeding (HMB) associated with uterine fibroids (UF).

PRIMROSE 2 is being conducted at 102 sites, in the United States and Europe, randomizing approximately 500 patients with a diagnosis of HMB associated with UF. Eligible patients are receiving once daily either 100 mg or 200 mg of linzagolix or 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.

“We are evaluating long term administration of linzagolix in two dosing regimens: primarily, we are assessing the efficacy of a lower-dose of linzagolix without add-back therapy, and of a higher dose option in association with add-back therapy for patients requiring higher levels of estrogen suppression. This strategy will potentially allow us to offer the broad patient population the personalized options needed for symptom relief with fewer side effects” said Ernest Loumaye, Chief Executive Officer and Co-Founder of ObsEva. “Patient recruitment completion is an important step in this pivotal trial for the lead indication of linzagolix, a potential best-in-class oral GnRH antagonist. We anticipate the primary endpoint read out of PRIMROSE 2 in Q4 2019, in line with our development plan.”

### **About the PRIMROSE 2 Clinical Trial**

PRIMROSE 2 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 2 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 Q4 2019.

### **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 "OBSN". For more information, please visit [www.obseva.com](http://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 ObsEva's product candidates and the timing of data from clinical trials. 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, 2017, and other filings ObsEva makes with the SEC. These documents are available on the Investors page of ObsEva's website at [www.obseva.com](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.

###

**For further information, please contact:**

**Media Contact Switzerland and Europe:**

Christophe Lamps  
Dynamics Group  
[cla@dynamicsgroup.ch](mailto:cla@dynamicsgroup.ch)  
+41 22 308 6220 Office  
+41 79 476 26 87 Mobile

**Media Contact U.S.:**

Marion Janic  
RooneyPartners LLC  
[mjanic@rooneyco.com](mailto:mjanic@rooneyco.com)  
+1 212 223 4047 Office  
+1 646 537 5649 Mobile

**CEO Office Contact:**

Shauna Dillon  
[Shauna.dillon@obseva.ch](mailto:Shauna.dillon@obseva.ch)  
+41 22 552 1550

**Investor Contact:**

Mario Corso  
Senior Director, Investor Relations  
[mario.corso@obseva.com](mailto:mario.corso@obseva.com)  
+1 857 972 9347 Office  
+1 781 366 5726 Mobile

# # #