ObsEva Announces Positive Results from Uterine Fibroids Phase 3 Study (PRIMROSE 2) of Linzagolix

- Phase 3 trial (PRIMROSE 2) met primary and secondary efficacy endpoints
- 93.9% responder rate for 200 mg with ABT ($p < 0.001$)
- 56.7% responder rate for 100 mg without ABT ($p < 0.001$)
- Both doses achieved important clinically relevant secondary endpoints including amenorrhea ($p < 0.001$), reduction in pain ($p < 0.001$), improvement in quality of life ($p < 0.001$) and improvement in hemoglobin levels ($p < 0.002$)

GENEVA, Switzerland and BOSTON, MA (December 9, 2019) – ObsEva SA (NASDAQ: OBSV; SIX: OBSN), a biopharmaceutical company developing and commercializing novel therapies to improve women's reproductive health, today reported positive Phase 3 trial results from the PRIMROSE 2 trial of linzagolix for the treatment of heavy menstrual bleeding (HMB) due to uterine fibroids.

The PRIMROSE 2 trial enrolled 535 women with HMB due to uterine fibroids. The trial was conducted in Europe and the US and evaluated the efficacy and safety of once daily oral linzagolix, including 100 mg and 200 mg doses, both with and without hormonal add-back therapy (ABT). The primary efficacy endpoint was the reduction in HMB. Responders were defined as patients with menstrual blood loss volume of ≤ 80 mL and ≥ 50% reduction from baseline in menstrual blood loss volume at 24 weeks, measured using the alkaline hematin method. Bone mineral density (BMD) was assessed centrally using Dual Energy X-ray Absorptiometry (DEXA) scan at baseline and 24 weeks.

The responder rate was 93.9% ($p < 0.001$) for women receiving 200 mg with ABT and 56.7% for women receiving 100 mg without ABT ($p < 0.001$), compared to 29.4% in the placebo group. Both doses achieved significant rates of amenorrhea ($p < 0.001$), reduction in pain ($p < 0.001$), and improvement in quality of life ($p < 0.001$). Additionally, significant improvement ($p < 0.001$) in hemoglobin levels, a reduction in number of days of bleeding and reduction in uterine volume were observed. Furthermore, a significant reduction in fibroid volume was also observed for the 200 mg dose with ABT ($p < 0.008$).

The overall safety profile was in line with expectations and confirmed that linzagolix was well-tolerated. The most frequently observed adverse events (occurring in > 5% of patients) were headache, hot flushes, and anemia. Mean percentage change from baseline in BMD was consistent with previous clinical data.

"We are extremely pleased with these results for linzagolix in our first phase 3 study in women with heavy menstrual bleeding due to uterine fibroids," said Dr. Ernest Loumaye, ObsEva CEO and Co-Founder. "The excellent responder rates for the 200 mg with ABT and the 100 mg dose without ABT strongly support our dual strategy of development for linzagolix. The full suppression 200 mg dose with ABT achieved a potentially best in class, 94% responder rate. Importantly, the 100 mg dose without ABT with over 50% of women responding, provides a meaningful option for the significant proportion of women who cannot or do not want to take exogenous hormones. We look forward to the results from our second pivotal study, PRIMROSE 1 conducted in the US, in Q2 2020. Assuming positive results, we expect that it would lead to a

Marketing Authorization Application submission with the European Medicines Agency by year-end 2020 and a New Drug Application submission with the U.S. Food and Drug Administration by Q1 2021."

Dr. Hugh Taylor, Professor and Chair of Obstetrics and Gynecology at Yale University, said, "Women with uterine fibroids need non-surgical alternatives to reduce the often unbearable effects of heavy menstrual bleeding. The prospects for a medical treatment with multiple dosing options would address a need for this diverse population of women. I am particularly impressed with the 94% responder rate and 80% amenorrhea rate that linzagolix has shown."

Conference Call and Webcast Today

ObsEva will host a conference call and audio webcast today beginning at 8:00 a.m. Eastern Time/2:00 p.m. Central European Time to discuss Phase 3 PRIMROSE 2 trial results of linzagolix. Investors may participate by dialing (844) 419-1772 for U.S. callers or +1 (213) 660-0921 for international callers and referring to conference ID 1764134. A live or archived webcast of the conference call can be accessed under the "Investors" section of ObsEva's website www.ObsEva.com.

About Linzagolix

Linzagolix (previously known as OBE2109) is a novel, oral, once daily, GnRH receptor antagonist with a potentially best-in-class profile. Linzagolix is currently in late-stage clinical development for the treatment of heavy menstrual bleeding associated with uterine fibroids and pain associated with endometriosis. ObsEva licensed linzagolix from Kissei in late 2015 and retains worldwide commercial rights, excluding Asia, for the product.

About PRIMROSE 2

PRIMROSE 2 is a prospective, randomized, parallel group, double-blind, placebo-controlled phase 3 trial investigating the efficacy and safety of two dosing regimens of linzagolix, 100mg and 200mg once daily, alone and in combination with hormonal ABT for the treatment of HMB associated with uterine fibroids. Women participating in the trial did not receive Vitamin D or calcium supplementation. The trial was conducted in Europe and the US and enrolled 535 women for a treatment period of 12 months.

About ObsEva

ObsEva is a biopharmaceutical company developing and commercializing novel therapies to improve women'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 and preterm labor. 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.

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.

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, the timing of data from clinical trials, ObsEva's expectations regarding its plan to submit its Marketing Authorization Application with the European Medicines Agency and New Drug Application with the FDA, and the results of interactions with regulatory authorities. 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 and clinical development, including the risk that the results of earlier clinical trials may not be predictive of the results of later stage clinical trials, 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, the Risk Factors filed as Exhibit 99.1 to ObsEva's Form 6-K filed on August 7, 2019, 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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