ObsEva SA Submits Marketing Authorization Application to the European Medicines Agency for YSELTY® (linzagolix) for the Treatment of Women with Uterine Fibroids

- If approved, linzagolix will be the only GnRH antagonist with flexible dose regimen options for the management of uterine fibroids:
  - 100 mg once daily for women with a contraindication to or who prefer to avoid hormonal add-back therapy (ABT)
  - 200 mg once daily with concomitant ABT for long-term use (beyond 6 months)
  - 200 mg once daily for short-term use, in particular when rapid reduction in fibroid volume is desired
- ObsEva expects to submit a new drug application to U.S. Food and Drug Administration in 1H:21

GENEVA, Switzerland and BOSTON, MA (November 24, 2020) – ObsEva SA (NASDAQ: OBSV; SIX: OBSN), a biopharmaceutical company developing and commercializing novel therapies to improve women's reproductive health, today announced the submission of a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for YSELTY® (linzagolix 100mg and linzagolix 200mg) for the management of heavy menstrual bleeding (HMB) associated with uterine fibroids.

"The MAA submission is a major milestone for the company as it represents more than 5 years of drug development work by ObsEva team. I want to thanks all those who in the company or as subcontractors, as well as the more than 2,000 patients who contributed to this milestone. In developing multiple dose options, our long-term strategy has always been to meet the needs of the diverse population of women with uterine fibroids," said Dr. Ernest Loumaye, founder and CEO of ObsEva. "Successful submission of the MAA brings us a step closer toward commercialization of Yselty, which will provide more women a potential best-in-class treatment for uterine fibroids."

The Phase 3 clinical program in uterine fibroids comprises two pivotal trials, PRIMROSE 1 and PRIMROSE 2, that were designed to demonstrate the effectiveness and safety to support the claimed indication: management of HMB associated with uterine fibroids. The application is being submitted at this time as both Phase 3 studies have met their success criteria: both low and high doses of linzagolix with and without ABT are effective in the treatment of HMB associated with uterine fibroids and have an acceptable benefit risk profile.

The EMA is expected to notify ObsEva in December 2020 regarding the outcome of its validation of the MAA to ensure all essential regulatory elements required for a scientific assessment are included in the application prior to the start of the procedure.

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 1 AND 2

PRIMROSE 1 (conducted in the United States, which enrolled 574 women with uterine fibroids) and the PRIMROSE 2 (conducted in Europe and in the United States, which enrolled 535 women with uterine fibroids) clinical trials are two Phase 3 clinical trials of linzagolix in patients with HMB associated with uterine fibroids. In both trials, patients were administered linzagolix doses of 100 mg or 200mg, both with and without hormonal ABT, or placebo. The primary endpoint of both trials was reduction in HMB at 24 weeks; responders were defined as patients with menstrual blood loss (MBL) of ≤ 80 mL and a ≥ 50 percent reduction from baseline in MBL, measured using the alkaline hematin method. Secondary endpoints included amenorrhea, time to reduced MBL, hemoglobin (Hb), pain, and quality of life (QoL). Safety endpoints included bone mineral density (BMD), and adverse events (AEs). Calcium/vitamin D were not provided. BMD was measured centrally via Dual Energy X-ray Absorptiometry (DEXA) scan at baseline and 24, 52, and 76 weeks (6-month post treatment assessment).

Both PRIMROSE trials successfully met the primary endpoint, with all doses showing statistically significant and clinically relevant reductions in HMB compared to placebo. There was a clear efficacy dose response, with the highest responder rates for the primary endpoint observed in women who received the 200 mg with ABT dose. Substantial improvements were also observed in all doses for the secondary endpoints of amenorrhea, time to reduced MBL and amenorrhea, hemoglobin levels in anemic subjects, pain, and quality of life. The 200 mg dose alone showed rapid and substantial reduction in uterine and fibroid volume.

In PRIMROSE 1, the responder rate was 75.5% ($p < 0.001$) for patients receiving 200 mg with ABT and 56.4% for patients receiving 100 mg without ABT ($p = 0.003$), compared to 35.0% in the placebo group. The overall safety profile was in line with expectations. The most frequently observed adverse events (occurring in > 5% of patients) were headache and hot flushes. Mean percentage changes from baseline in BMD were minimal, as expected with any GnRH antagonist treatment.

In PRIMROSE 2, the responder rate was 93.9% ($p < 0.001$) for patients receiving 200 mg with ABT and 56.7% for patients receiving 100 mg without ABT ($p < 0.001$), compared to 29.4% in the placebo group. The overall safety profile was in line with expectations. The most frequently observed adverse events (occurring in > 5% of patients) were headache, hot flushes, and anemia. Mean percentage changes from baseline in BMD were minimal and consistent with previous clinical data. 52-week results demonstrated that continued treatment with linzagolix provided sustained efficacy in the reduction of

HMB; responder rates of 91.6% and 53.2% were observed in women receiving 200 mg with ABT and 100 mg without ABT, respectively. In addition, small incremental changes in BMD were observed at week 52 compared to week 24, suggesting the onset of plateauing BMD loss.

Additional follow-up data to be collected include PRIMROSE 1 52-week treatment results and 6-month post treatment assessment from both studies.

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, preterm labor, and improving embryo transfer outcomes following in vitro fertilization. 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 timing, advancement, best-in-class efficacy and potential therapeutic benefits of linzagolix, the potential for linzagolix to be a commercially competitive product, expectations regarding regulatory and development milestones, including the potential timing of regulatory submissions to 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, the impact of the novel coronavirus outbreak, 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, 2019, the Risk Factors disclosed in ObsEva's Report on Form 6-K filed with the Securities and Exchange Commission (SEC) on November 5, 2020 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.

For further information, please contact:

CEO Office contact
Shauna Dillon
Shauna.dillon@obseva.ch
+41 22 552 1550