



ObsEva Announces Positive Results from two Phase 3 Studies, PRIMROSE 1 and 2, of Yselyt[®] (linzagolix) for the Treatment of Uterine Fibroids

- PRIMROSE 1 achieved statistically significant and clinically meaningful results across primary and key secondary endpoints at week 24
- PRIMROSE 2 results demonstrate sustained efficacy and continued safety of linzagolix at week 52
- Results confirm linzagolix as a potential best-in-class GnRH antagonist, with a pooled responder rate of 84.7% for the 200 mg with Add Back Therapy* (ABT) dose from PRIMROSE 1 and 2
- Linzagolix is the only GnRH antagonist as a potential unique treatment option for up to 50% of US women with uterine fibroids for whom ABT therapy may be contraindicated
- Success of PRIMROSE 1 and 2 studies enables progression towards regulatory submissions, anticipated 4Q 2020 in the EU and 1H 2021 in the US

GENEVA, Switzerland and BOSTON, MA (July 6, 2020) – ObsEva SA (NASDAQ: OBSV; SIX: OBSN), a biopharmaceutical company developing and commercializing novel therapies to improve women's reproductive health, today announced top-line results from the PRIMROSE 1 and 2 studies of Yselyt[®] (linzagolix) to assess the efficacy and safety in women with heavy menstrual bleeding due to uterine fibroids.

PRIMROSE 1 met the primary endpoint at week 24, and showed that women receiving linzagolix experienced a statistically significant and clinically meaningful reduction in menstrual blood loss (≤ 80 mL and a $\geq 50\%$ reduction from baseline) compared to placebo. Women receiving 200 mg with ABT achieved a 75.5% ($P < 0.001$) responder rate and those receiving 100 mg without ABT achieved a 56.4% ($P = 0.003$) responder rate.

The pooled week 24 data from these two Phase 3 studies support a best-in-class profile, with a responder rate of 84.7% in women receiving linzagolix 200 mg with ABT, and 56.6% in women receiving linzagolix 100 mg without ABT.

In addition, new data from PRIMROSE 2 demonstrate that continued treatment with linzagolix for 52 weeks provides sustained efficacy and is well tolerated. Responder rates of 91.6% and 53.2% were observed in women receiving 200 mg with ABT and 100 mg without ABT, respectively, both of which are similar to the responder rates observed at week 24 of the study.

Across both studies, women receiving linzagolix experienced statistically significant improvements across a number of clinically relevant secondary endpoints, including reduction in pain, improvement in anemia and quality of life.

“We are extremely pleased by the overall performance of Yselty in addressing heavy menstrual bleeding, a major symptom of uterine fibroids. These data definitively confirm our belief that Yselty, with and without add-back therapy, has the potential to be an effective treatment for addressing the broad needs of women suffering from uterine fibroids,” said Dr. Ernest Loumaye, ObsEva CEO and cofounder. “Yselty’s unique and differentiated profile reinforces its potential as a promising, commercially competitive product, designed to offer more women a treatment adapted to their clinical and personal needs. These excellent data move us closer to the potential commercialization of Yselty and our immediate priority is to progress our regulatory filings.”

In PRIMROSE 1, the incidence of adverse events was similar between placebo and active treatment. The most frequently observed adverse events, with an incidence >5%, were headache and hot flushes. In addition, a minimal mean percentage change in lumbar spine bone mineral density (BMD) from baseline was observed in both treatment arms at week 24.

In PRIMROSE 2, the most frequently observed adverse events, with an incidence >5%, were headache, hot flushes and anemia. In addition, a small incremental change in BMD was observed at week 52 compared to week 24.

“Women with symptomatic uterine fibroids experience debilitating pain and discomfort from heavy menstrual bleeding, which often becomes progressively worse, impacting work, home life, and importantly, a woman’s overall health and well-being,” said Dr. Hugh Taylor, Professor at Yale School of Medicine, U.S. “New and effective treatment options that provide long lasting symptom relief are needed for women with uterine fibroids, including for the significant number of women who cannot receive, or wish to avoid, hormone replacement therapy. I am very pleased to see these results, which demonstrate that both regimens of linzagolix are effective in controlling bleeding, reducing fibroid related pain and improving anemia. This could provide a long-awaited medical treatment option to address current unmet needs.”

ObsEva is now preparing its regulatory submissions to the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) which it anticipates submitting in 4Q 2020 and 1H 2021, respectively. Data from across the clinical trial program will be submitted for presentation at upcoming scientific conferences.

Yselty® is a registered trademark owned by Kissei for use by ObsEva. Yselty® is not yet approved for use anywhere in the world.

* Add Back Therapy = 1 mg estradiol and 0.5 mg norethindrone acetate daily

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 1 & 2 study 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 6673575. A live or archived webcast of the conference call can be accessed via the following link: <https://www.obseva.com/event-detail/?event=3249>.

About Linzagolix

Yselty® (linzagolix) is a novel, once daily, oral 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. Linzagolix is not currently approved anywhere in the world.

About Phase 3 PRIMROSE Program in Uterine Fibroids

PRIMROSE 1 & 2 are prospective, randomized, parallel group, double-blind, placebo-controlled Phase 3 studies investigating the efficacy and safety of two dosing regimens of linzagolix, 100 mg and 200 mg once daily, alone and in combination with hormonal ABT for the treatment of heavy menstrual bleeding associated with uterine fibroids. Women participating in the study did not receive Vitamin D or calcium supplementation. PRIMROSE 1 is being conducted in the US and enrolled 526 women; PRIMROSE 2 is being conducted in Europe and the US and enrolled 535 women. Both trials comprised a 52 week treatment period followed by a 6-month post treatment follow-up period. Week 24 primary endpoint results were announced for PRIMROSE 2 in December 2019.

About Uterine Fibroids

Uterine fibroids is a common condition that consists of the growth of benign tumours of the muscular tissue of the uterus. Uterine fibroids affect women of childbearing age and can vary in size from undetectable to a large bulky mass.

The symptoms of uterine fibroids are wide-ranging and include heavy menstrual bleeding, anemia, pelvic pressure and bloating, urinary frequency and pain that can be extremely debilitating with a significant impact on quality of life. These symptoms can also have an impact on mental health, creating the additional burden of anxiety and distress.

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, including the timing, advancement and potential therapeutic benefits of linzagolix, the potential for linzagolix to be a commercially competitive product, the timing of data from clinical trials, expectations regarding regulatory and development milestones,

including the potential timing of regulatory submissions to the EMA and 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 May 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.

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