



ObsEva Announces Final Results from the Phase 3 PRIMROSE Program of Yselty® (linzagolix) for the Treatment of Uterine Fibroids

-PRIMROSE 1 76-week results confirm PRIMROSE 2 data showing sustained post-treatment effects and evidence of bone mineral density (BMD) recovery following 52 weeks of treatment-

-Results continue to support the differentiated profile of Yselty with the unique low-dose option (100 mg without add-back therapy (ABT)) and the potentially best-in-class high dose (200 mg with ABT)-

-US NDA submission for uterine fibroids indication remains on track for submission in Q3 2021; EU MAA CHMP recommendation anticipated in Q4 2021-

GENEVA, Switzerland and BOSTON, MA (May 20, 2021) – ObsEva SA (NASDAQ: OBSV) (SIX: OBSN) (ObsEva or the Company), a biopharmaceutical company developing and commercializing novel therapies to improve women’s reproductive health, today announced final 76-week results from the PRIMROSE 1 clinical study of Yselty, in development for the treatment of women with heavy menstrual bleeding due to uterine fibroids. These results mark the final data measuring point for both the Phase 3 PRIMROSE 1 (US only) and PRIMROSE 2 (Europe and US) studies.

The PRIMROSE 1 and PRIMROSE 2 trials evaluated 100 mg and 200 mg doses with and without ABT. If approved, Yselty will be the only GnRH antagonist with flexible dose options that addresses the needs of three distinct groups of women suffering from uterine fibroids:

- 100 mg once daily for women with a contraindication to, or preference to avoid, hormonal ABT
- 200 mg once daily with concomitant ABT for long-term use (beyond 6 months)
- 200 mg once daily for short-term use (up to 6 months)

The PRIMROSE 1 post-treatment results are consistent with findings from the PRIMROSE 2 study, showing that off-treatment pain scores remained lower than baseline across all treatment arms. Improvements in other clinically relevant secondary endpoints, including hemoglobin levels and quality of life also persisted off-treatment, supporting the durability of the treatment effect of Yselty. Furthermore, as observed in PRIMROSE 2, the PRIMROSE 1 DXA results at Week 76 showed evidence of BMD recovery for patients treated with both the 100 mg and 200 mg+ ABT doses.

“The completion of the PRIMROSE 1 and PRIMROSE 2 clinical studies is a major achievement for the company,” said Brian O’Callaghan, CEO of ObsEva. “This milestone represents the next critical step in bringing Yselty forward as a well-differentiated, once daily oral GnRH antagonist with unique dosing options designed to treat more women with uterine fibroids. Our EU MAA review is ongoing and we continue to prepare for our US NDA submission in Q3 2021. We look forward to providing updates on our progress and sharing additional efficacy and safety data, which will be submitted for presentation at upcoming scientific conferences this year.”

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

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 the Phase 3 PRIMROSE Program in Uterine Fibroids

PRIMROSE 1 & 2 were prospective, randomized, parallel group, double-blind, placebo-controlled Phase 3 studies that investigated the efficacy and safety of two dosing regimens of Yselty, 100 mg and 200 mg once daily, alone and in combination with hormonal ABT (1 mg estradiol and 0.5 mg norethisterone acetate) for the treatment of heavy menstrual bleeding associated with uterine fibroids. PRIMROSE 1 was conducted in the United States and enrolled 574 women. PRIMROSE 2 was conducted in Europe and the United States and enrolled 535 women. Both trials comprised a 52-week treatment period followed by a 6-month post treatment follow-up period.

About Uterine Fibroids

Uterine fibroids are common benign tumors of the muscular tissue of the uterus. Uterine fibroids affect women of childbearing age and can vary in size from undetectable to large bulky masses. Few longterm medical treatments are available, and as a result, approximately 300,000 hysterectomies are performed for uterine fibroids every year in the US.

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, 2020 filed with Securities and Exchange Commission (SEC) on March 5, 2021 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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