

ObsEva Provides Update on Yselyt[®] (Linzagolix) Clinical Development Program

- European Medicines Agency Validates Yselyt MAA for Uterine Fibroids; US NDA Planned for 1H 2021
- Phase 3 EDELWEISS 3 (Conducted in Europe and US) Study of Yselyt for Treatment of Endometriosis is Progressing as Planned; Primary Endpoint Readout Expected 4Q 2021
 - Phase 3 EDELWEISS 2 (Conducted in the United States) Yselyt Endometriosis Study Discontinued Due to Enrollment Challenges; No Safety Concerns Identified

GENEVA, Switzerland and BOSTON, MA (Jan 11, 2021) – ObsEva SA (NASDAQ: OBSV; SIX: OBSN), a biopharmaceutical company developing and commercializing novel therapies to improve women’s reproductive health, today announced several important updates on its Yselyt program.

Validation of Marketing Authorization Application for the Treatment of Uterine Fibroids

The Marketing Authorization Application (MAA) is an application for approval submitted to the European Medicines Agency (EMA) and is a critical step in marketing a product in the EU. Validation marks the beginning of the review period. The Yselyt MAA for the uterine fibroids’ indication is based on data from the Phase 3 PRIMROSE 1 study (conducted in the US, which enrolled 574 women with uterine fibroids) and PRIMROSE 2 (conducted in Europe and the US, which enrolled 535 women with uterine fibroids). In both studies, patients with heavy menstrual bleeding (HMB) associated with uterine fibroids were administered Yselyt doses of 100 mg or 200 mg, with and without hormonal add-back-therapy (ABT; 1 mg estradiol/0.5 mg norethisterone acetate), or placebo.

“We are very pleased that the EMA has validated our application for Yselyt, a potential best-in-class treatment for women suffering from heavy menstrual bleeding associated with uterine fibroids,” said Elizabeth Garner, M.D., M.P.H., Chief Medical Officer of ObsEva. “Yselyt is the only GnRH antagonist to provide flexible dosing options that will allow us to better address the individual needs of the diverse population of women with uterine fibroids. This marks a major milestone in making Yselyt available in the E.U., and we look forward to working closely with the EMA as we advance Yselyt towards commercialization. We also remain on track to submit the US NDA during the first half of 2021, a key objective for the company this year.”

PRIMROSE 1 and 2 successfully met their 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. Highly significant efficacy was also achieved for the low-dose 100 mg non-ABT regimen. Substantial improvements were also observed with all doses for the secondary endpoints of amenorrhea, time to reduced menstrual blood loss, hemoglobin levels in anemic subjects, pain, and quality of life.

ObsEva anticipates follow-up data and 6-month post treatment assessment data in Q1 2021. Additional information about this study can be found [here](#).

Clinical Development Program for the Treatment of Endometriosis-Associated Pain

The clinical development program for the endometriosis indication is a key priority for ObsEva. The EDELWEISS 3 trial in the EU is progressing as planned, with primary endpoint data expected in 4Q 2021. Screening and enrollment for EDELWEISS 2 in the US has been increasingly challenging, particularly in the context of the persisting difficult environment of the ongoing pandemic and has led to ObsEva's decision to discontinue the study. No new or significant safety issues have been observed.

"After careful consideration, we strongly believe halting the EDELWEISS 2 study is the right decision for ObsEva, given the ongoing enrollment challenges. This decision also gives us the ability to conserve over \$30 million," said Brian O'Callaghan, CEO of ObsEva. We remain fully committed to developing and commercializing Yselty in both uterine fibroids and endometriosis and are continuing to explore partnership and other financing opportunities to support the program. We also plan to conduct, as soon as is feasible, a new Phase 3 endometriosis study with a number of design and operational changes to facilitate faster enrollment, with a goal to maintain the original MAA and NDA filing timelines for this important indication. In addition, this cost-efficient approach will also help ObsEva progress our other pipeline programs, including ebopirant, which recently yielded positive Phase 2 results in the treatment of preterm labor. We are also considering and planning for the potential development of linzagolix in prostate cancer, possibly in combination with estrogen add-back, a known approach to lowering side effects of androgen deprivation therapy. Overall, our strategy to more efficiently complete the development of the endometriosis indication development while improving utilization of capital will support our clinical development strategy and bring us another step closer to addressing unmet needs in women's reproductive health."

The ongoing Phase 3 EDELWEISS 3 study will enroll approximately 450 patients with endometriosis associated pain, with a co-primary endpoint of response on both dysmenorrhea (menstrual pain) and non-menstrual pelvic pain. The study includes a 75 mg once daily dose without hormonal ABT, and a 200 mg once daily dose in combination with hormonal ABT (1mg E2 / 0.5mg NETA). Subjects who have completed the initial six-month treatment period will have the option to enter a 6-month treatment extension. Data from the primary endpoint readout are expected in 4Q 2021. Additional information about this study can be found [here](#).

About Yselty®

Yselty® (linzagolix, previously known as OBE2109) is a novel, oral, once daily, GnRH receptor antagonist with a potentially best-in-class profile. Yselty 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 Yselty from Kissei in late 2015 and retains worldwide commercial rights, excluding Asia, for the product.

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

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.

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 ongoing novel coronavirus pandemic, 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.

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