

ObsEva Announces Enrollment Completion of Linzagolix Phase 3 EDELWEISS 3 Trial for Patients with Moderate to Severe Endometriosis-Associated Pain

- EDELWEISS 3 trial of Yselty® expected to report topline data as planned in Q4:21-

GENEVA, Switzerland and BOSTON, MA – May 4, 2021 – ObsEva SA (NASDAQ: OBSV) (SIX: OBSN), a biopharmaceutical company developing and commercializing novel therapies to improve women’s reproductive health, today announced that it has completed enrollment for the Phase 3 EDELWEISS 3 trial of Yselty® for patients with moderate to severe endometriosis-associated pain (EAP). Enrollment completion is an important milestone, and data from the primary endpoint readout are expected in Q4 2021.

“Endometriosis is an emotionally and physically painful condition that affects approximately 176 million women worldwide and can be debilitating for many women. We continue to be in need of alternative treatment options that improve quality of life,” said Jacques Donnez, M.D., Ph.D., Distinguished Professor of Obstetrics and Gynecology at the Catholic University of Louvain, Belgium. “The Phase 2b EDELWEISS data underscored Yselty’s potential to address this critical unmet need while offering unique dosing options. Importantly, linzagolix 75mg dose significantly improved EAP symptoms at 12 weeks and these effects were maintained or increased at 24 weeks and 52 weeks, without clinically relevant decreases in bone mineral density. This is particularly encouraging, and I look forward to seeing additional informative data from the EDELWEISS 3 trial.”

EDELWEISS 3 (Europe and the US) is a randomized, double-blind, placebo-controlled, Phase 3 trial that enrolled 486 women with moderate to severe EAP. The study is designed to evaluate the long-term efficacy and safety of Yselty, with a co-primary endpoint of reduction in both dysmenorrhea (menstrual pain) and non-menstrual pelvic pain at Month 3, along with stable or decreased use of analgesics for EAP. The study includes a 75 mg once-daily dose without hormonal ABT (1 mg estradiol / 0.5mg norethindrone acetate), and a 200 mg once-daily dose in combination with ABT. Subjects who complete the initial six-month treatment period will have the option to enter a six-month treatment extension, followed by a post-treatment follow-up. Additional information about this study can be found [here](#).

“The clinical development of Yselty for our endometriosis indication is a key priority for ObsEva, and we are pleased that the pivotal Phase 3 EDELWEISS 3 trial has continued to progress as planned,” said Brian O’Callaghan, CEO of ObsEva. “This milestone reflects significant progress and builds on the encouraging data from our Phase 2b trial, which demonstrated sustained improvement in overall endometriosis symptoms. With enrollment now completed for our Phase 3 trial, we are one step closer to providing women with better long-term treatment options. We will continue to build on this momentum and look forward to sharing top-line results later this year.”

About Yselty®

Yselty® (linzagolix) 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.

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 other similar expressions, and are based on ObsEva's current beliefs and expectations. These forward-looking statements include expectations regarding the potential therapeutic benefits and the clinical development of ObsEva's product candidates, the potential for new indications for any of ObsEva's product candidates, the timing of enrollment in and data from clinical trials, expectations regarding regulatory and development milestones, including the potential timing of regulatory submissions to the EMA and FDA, the timing of and ObsEva's ability to obtain and maintain regulatory approvals for its product candidates, the results of interactions with regulatory authorities and the potential to raise additional funds or enter into strategic partnerships in the future. 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 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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