

ObsEva Announces Additional Efficacy Results for Linzagolix 200 mg with Add-Back Therapy (ABT) and Linzagolix 75 mg without ABT in the Phase 3 EDELWEISS 3 Trial in Patients with Moderate-to-Severe Endometriosis-Associated Pain

-Reductions in dysmenorrhea (DYS) and non-menstrual pelvic pain (NMPP), the co-primary efficacy endpoints, compared to placebo were observed for both doses after 1 and 2 months of treatment, respectively, and these reductions increased up to 6 months-

-A similar pattern of improved symptoms was also observed for secondary endpoints of dyschezia and worst pelvic pain-

-The reductions in endometriosis pain resulted in improved quality of life and a reduced intention for surgery after 6 months-

-Results continue to support further development of linzagolix with ABT and non-ABT doses for the treatment of endometriosis-

-Results from the post-treatment follow-up of EDELWEISS 3 are expected in early 3Q2022. Results from the treatment phase of the extension study (EDELWEISS 6) and its post-treatment follow-up phase are expected in early 3Q2022 and 4Q2022, respectively-

Ad hoc announcement pursuant to Art. 53 LR of the SIX Swiss Exchange

GENEVA, Switzerland March 22, 2022 – ObsEva SA (NASDAQ: OBSV; SIX: OBSN), a biopharmaceutical company developing and commercializing novel therapies for women’s health, today announced additional efficacy results from the Phase 3 EDELWEISS 3 trial of linzagolix, an oral GnRH antagonist, in women with moderate-to-severe endometriosis-associated pain (EAP). The results build upon the positive topline results announced in January 2022.

Two dose regimens were tested, a 200 mg once-daily dose of linzagolix in combination with hormonal add-back therapy (ABT) and a 75 mg dose of linzagolix without ABT. The co-primary efficacy endpoints were reduction in dysmenorrhea (DYS) and non-menstrual pelvic pain (NMPP) at 3 months. The average reduction of DYS and NMPP at each month up to 6 months are shown in Figure 1. Both DYS and NMPP showed rapid reductions compared to placebo (after 1 and 2 months of treatment, respectively), with continued reduction up to 6 months of treatment and with higher reductions with linzagolix 200 mg + ABT compared to linzagolix 75 mg. A similar pattern was seen for the secondary endpoints of dyschezia (painful bowel movements) and worst pelvic pain (defined as the 5 days with worst pain during a 28-day period) as shown in Figure 2.

The reductions in endometriosis pain were associated with improvements in quality of life and a reduction in physician and patient intentions to undergo surgery for endometriosis as shown in Table 1 below.

“Endometriosis is a common and painful condition that affects approximately 10 percent of women of reproductive age. Every day it seriously impacts women’s ability to go about their daily activities, their relationships, and their overall quality of life,” said Hugh Taylor, MD, Professor and Chair of Obstetrics and Gynecology at Yale University. “These data build on the positive data announced earlier this year and importantly support the early onset of efficacy with linzagolix treatment.”

Elizabeth Garner, MD, MPH, Chief Medical Officer of ObsEva, commented, “We are pleased with these additional EDELWEISS study results, which demonstrate the rapid onset of treatment effect, impact on quality of life and intentions for surgery, and continue to support the promising clinical profile of linzagolix in the treatment of women with moderate-to-severe endometriosis-associated pain. We look forward to

advancing the endometriosis program for linzagolix, which will include exploration of a non-add back therapy option, consistent with our strategy to address the individual treatment needs and preferences of all women.”

Additional Efficacy Analyses

DYS and NMPP up to 6 months

The efficacy endpoints of DYS and NMPP were based on subject-reported symptoms recorded daily via an electronic diary (eDiary) using a verbal rating scale (VRS) of 0 (no pain) through 3 (severe pain).

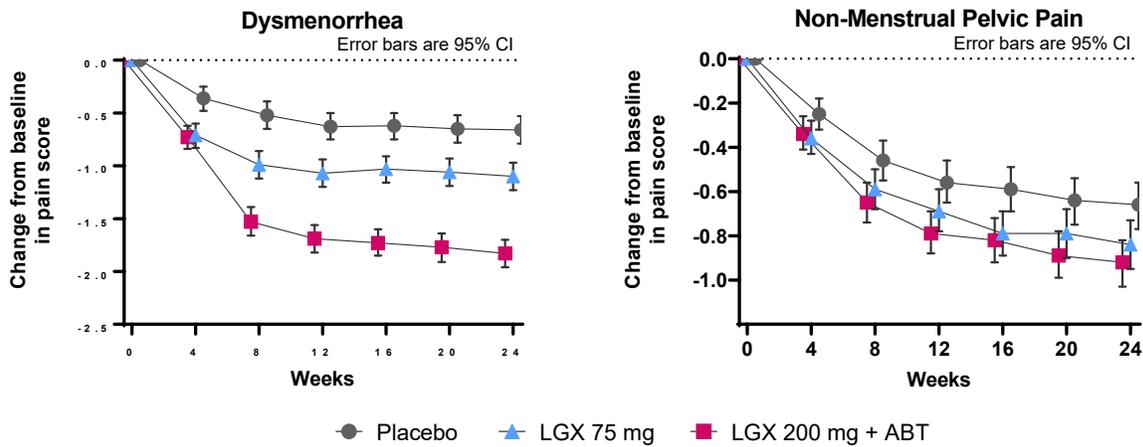


Figure 1. Change from baseline in DYS and NMPP scores from 1 to 6 months

Dyschezia and worst pelvic pain

Dyschezia and worst pelvic pain scores were measured on a 0-10 numerical rating scale self-reported by subjects via the eDiary, with 0 representing no pain and 10 representing the worst pain imaginable.

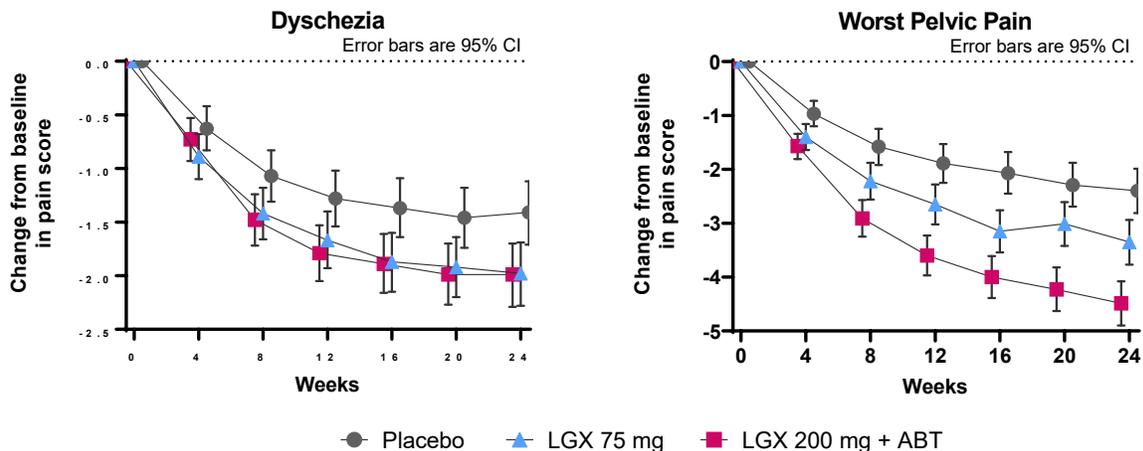


Figure 2. Change from baseline in dyschezia and worst pelvic pain

Quality of life and intention for surgery

Quality of life was measured using the Endometriosis Health Profile – 30 (EHP-30), a patient-reported questionnaire developed and validated for assessing quality of life in women with endometriosis including 5 domains – pain, control and powerlessness, emotional well-being, social support, and self-image. Intention of surgery was rated by the physician and the patient by answering the question “How likely are you to recommend/consider having laparoscopic surgery to treat her/your endometriosis if her/your symptoms continue as they are now?” on a 0 to 10 scale, with 0 representing not at all and 10 representing very likely.

Table 1. Quality of life and intention for surgery

<i>Change from baseline at 6 Months</i>	<i>Placebo</i>	<i>LGX 75 mg</i>	<i>p-value</i>	<i>LGX 200 mg + ABT</i>	<i>p-value</i>
<i>EHP-30 – pain</i>	-19.47	-27.37	0.001	-35.60	<0.001
<i>EHP-30 – control and powerlessness</i>	-21.75	-28.12	0.044	-37.38	<0.001
<i>EHP-30 – emotional well-being</i>	-12.57	-19.04	0.022	-22.03	<0.001
<i>EHP-30 – social support</i>	-13.82	-18.48	0.183	-25.89	<0.001
<i>EHP-30 – self-image</i>	-9.57	-16.43	0.020	-20.69	<0.001
<i>Physician intention for surgery</i>	-0.8	-1.5	0.037	-1.5	0.017
<i>Patient intention for surgery</i>	-0.7	-1.5	0.022	-1.6	0.005

"These additional results from the EDELWEISS 3 trial provide further promising evidence of linzagolix's potential to be the only approved GnRH antagonist offering an effective once daily oral treatment with and without additional hormonal add-back therapy for women suffering from endometriosis and uterine fibroids," said Brian O'Callaghan, CEO of ObsEva. "We look forward to further development of linzagolix in the endometriosis indication as we advance our mission of providing flexible treatment options in areas of significant unmet need in women's health."

About the Phase 3 EDELWEISS Program in Endometriosis

EDELWEISS 3 (Europe and the U.S.) was a randomized, double-blind, placebo-controlled, Phase 3 trial that analyzed 484 women with moderate-to-severe EAP. The study was designed to evaluate the long-term efficacy and safety of linzagolix, with a co-primary endpoint of reduction in both dysmenorrhea and non-menstrual pelvic pain at 3 months, along with stable or decreased use of analgesics for EAP. The study included a 200 mg once-daily dose in combination with ABT (1 mg estradiol / 0.5 mg norethindrone acetate), and a 75 mg once-daily dose without ABT. Subjects who completed the initial 6-month treatment period were offered to enter a 6-month treatment extension under the Edelweiss 6 protocol or to enter a 6-month post-treatment follow-up period. Results from the post-treatment follow-up of EDELWEISS 3 are expected in early 3Q2022. Results from the treatment phase of the extension study (EDELWEISS 6) and its post-treatment follow-up phase are expected in early 3Q2022 and 4Q2022, respectively. Additional information about this study can be found [here](#).

About Endometriosis

The World Endometriosis Research Foundation estimates that endometriosis affects one in ten women during their reproductive years, representing approximately 176 million women worldwide between the ages of 15 and 49.

Endometriosis is a disease in which the endometrium (tissue lining the inside of the uterus) is found outside the uterus, where it induces a chronic inflammatory reaction that may result in scar tissue. It is primarily found on the pelvic peritoneum, on the ovaries, in the rectovaginal septum, on the bladder and bowel. The most common symptom of endometriosis is pelvic pain, which often correlates to the menstrual cycle. Patients may also experience painful ovulation, pain during or after sexual intercourse (dyspareunia), dyschezia (difficult or painful defecation), heavy bleeding, fatigue, and infertility. Endometriosis pain can be so severe and debilitating that it affects day-to-day activities and has a negative impact on general, physical, mental, and social well-being. Endometriosis treatments aim first to alleviate pain, then to remove or decrease the size and number of endometrial lesions, and possibly improve fertility.

About Linzagolix

Linzagolix is a novel, once daily, oral GnRH receptor antagonist with a potentially best-in-class profile.^{1,2,3} Linzagolix has completed clinical trial development for the treatment of uterine fibroids and is currently in late-stage clinical development for the treatment of 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 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 new therapies for the treatment of uterine fibroids, endometriosis, and preterm labor. ObsEva is listed on the Nasdaq Global Select Market and is traded under the ticker symbol "OBSV" and on the SIX Swiss Exchange where it is traded under the ticker symbol "OBSN". For more information, please visit www.ObsEva.com

About Kissei Pharmaceutical Co., Ltd.

Kissei is a Japanese pharmaceutical company based on the management philosophy "contributing to society through high-quality, innovative pharmaceutical products" and "serving society through our employees." As a strong R&D-oriented corporation, it concentrates on providing innovative pharmaceuticals to patients worldwide in the focus fields of urology, nephrology/dialysis, gynecology and rare/intractable diseases.

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 "anticipate", "believe", "continue", "could", "estimate", "expect", "intend", "may", "might", "ongoing", "objective", "plan", "potential", "predict", "should", "will", "would", or the negative of these 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 of, and potential therapeutic benefits of such product candidates, including linzagolix, the anticipated milestones and pipeline updates, the timing of expected results from the EDELWEISS clinical trial, the potential for such product candidates to be commercially competitive, the success of the Company's partnerships with third parties, expectations regarding regulatory and development milestones and ObsEva's ability to obtain and maintain regulatory approvals for its product candidates. 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, and the capabilities of such third parties, the impact of the ongoing 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, 2021 filed with Securities and Exchange Commission (SEC) on March 10, 2022, and other filings ObsEva makes with the SEC. These documents are available on the Investors page of ObsEva's website at 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

Investor Contact

Katja Bühler

Katja.buhler@obseva.com

+1 (917) 969-3438

¹ Stewart E, ASRM 2020; Late-breaker abstract P-930

² Al-Hendy A, NEJM 2021; 384:630-42

³ Schlaff W, NEJM 2020; 382:328-40