

ObsEva Presents Clinical Data on Oral GnRH Antagonist Linzagolix at Multiple Congresses

-Data featured in two oral presentations at the 8th Society of Endometriosis and Uterine Disorders Congress and a poster presentation at the International Society of Gynecological Endocrinology 20th World Congress-

GENEVA, Switzerland May 25, 2022 – ObsEva SA (NASDAQ: OBSV; SIX: OBSN), a biopharmaceutical company developing and commercializing novel therapies for women’s health, today announced the presentation of clinical data on linzagolix, an oral GnRH antagonist. These data were featured in two oral presentations at the 8th Society of Endometriosis and Uterine Disorders (SEUD) Congress held in Athens, Greece from May 18-21, 2022, and a poster presentation at the International Society of Gynecological Endocrinology (ISGE) 20th World Congress held in Florence, Italy from May 11-14, 2022.

“The encouraging data presented at these important medical congresses highlight the differentiated therapeutic potential of linzagolix to better address the individual needs of women with uterine fibroids and endometriosis,” said Dr. Brandi Howard, Chief Clinical Officer of ObsEva. “These data demonstrate that linzagolix with or without add-back therapy (ABT) significantly reduced heavy menstrual bleeding due to uterine fibroids. Even more so, approximately half the women who were defined as non-responders for the primary analysis demonstrated evidence of response and met at least one objective criteria for reduced menstrual blood loss.”

Details on the SEUD data presentations are provided below.

The presentation titled “Reduction of Fibroid-Related Heavy Menstrual Bleeding (HMB) in Women Defined as Non-Responders Following Linzagolix Treatment With or Without Add Back Therapy (ABT)” was presented by Dr. Jacques Donnez, MD, PhD, Catholic University of Louvain.

Summary of the data and key takeaway: At 24 weeks, once-daily doses of linzagolix (100 mg, 100 mg + ABT, 200 mg, and 200 mg + ABT) amongst women who did not meet both measures [menstrual blood loss (MBL) volume of ≤ 80 mL or a 50 percent or greater reduction from baseline] for the primary endpoint (non-responders), 27%, 63%, 49% and 58%, respectively, compared to 25% in the placebo group met at least one measure. The mean percent reduction from baseline in MBL in the linzagolix non-responder groups were 72%, 76%, 75% and 74%, respectively, compared to more than 90% reduction in MBL in the linzagolix responder groups.

The presentation titled “Linzagolix for Endometriosis-Associated Pain: Efficacy Results from EDELWEISS 3, A Phase 3 Randomized, Double-Blind, Placebo-Controlled Trial” was presented by Dr. Hugh Taylor, MD, Yale School of Medicine.

Summary of the data and key takeaway: At 12 weeks, once-daily treatment with linzagolix 200 mg with hormonal ABT significantly improved dysmenorrhea (DYS), non-menstrual pelvic pain (NMPP), and other symptoms of endometriosis, including dyschezia and ability to do daily activities. Treatment with linzagolix 75 mg significantly improved DYS but not NMPP, yet there was evidence of improvement in other symptoms which supports the further clinical development of a partial suppression dose for the treatment of endometriosis-associated pain.

Details on the ISGE data presentation are provided below.

The poster titled “Efficacy and Safety of Linzagolix (LGX) for the Treatment of Heavy Menstrual Bleeding (HMB) Due to Uterine Fibroids (UF): Results from Two Phase 3 Randomized Clinical Trials” was presented by Dr. Kristina Gemzell-Danielsson, MD, Karolinska Institutet.

Summary of the data and key takeaway: Once-daily doses of linzagolix (100 mg, 100 mg + ABT, 200 mg, and 200 mg + ABT) met the primary endpoint of significantly reduced HMB ($\geq 50\%$ from baseline) at 24 weeks in all active treatment groups compare to placebo (PRIMROSE 1, $p \leq 0.003$; PRIMROSE 2, $p \leq 0.001$). The most common adverse event up to 52 weeks were hot flushes, which was reported in 32-35% of subjects in the 200mg group without ABT and less than 15% in the other linzagolix arms.

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 linzagolix, 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 HMB associated with uterine fibroids. PRIMROSE 1 was conducted in the United States and enrolled 574 women. PRIMROSE 2 was conducted in Europe and in 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. Additional information can be found on ObsEva’s website.

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 endometriosis-associated pain (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 add-back therapy (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. Additional data from the post-treatment follow-up of the Phase 3 EDELWEISS 3 trial as well as data from the long-term treatment in the extension study are expected in mid-2022, and from the post-treatment follow-up of the extension study in early 2023. Additional information about this study can be found on ObsEva’s website.

About Linzagolix

Linzagolix is an investigational novel, once daily, oral GnRH receptor antagonist with a potentially best-in-class profile^{1,2,3}. Linzagolix was developed to offer flexibility and choice to women suffering from uterine fibroids, with proposed dosing regimens alone and in combination with hormonal add-back therapy. For women with uterine fibroids for whom hormonal add-back therapy is appropriate, linzagolix has the potential to offer a best-in-class efficacy rate and tolerability profile. For women with uterine fibroids who cannot or do not want to take hormones, linzagolix has the potential to be the first and only approved oral GnRH antagonist with a non-hormonal dosing option. 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 health. 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.

Linzagolix has been discovered by Central Research Laboratories of 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 potential approval of linzagolix by regulatory authorities, including the European Commission and the U.S. Food and Drug Administration (FDA), and the timing of such approval and subsequent transition of ObsEva to a commercial-stage company, the timing or results of interactions with regulatory authorities, clinical development of ObsEva's product candidates, including the timing, advancement of, and potential therapeutic benefits of such product candidates, including linzagolix, the potential for linzagolix and other product candidates to be commercially competitive, the success of the Company's partnerships with third parties, expectations regarding regulatory and development milestones, including anticipated timing of data from ObsEva's clinical trials, 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, including interactions with the European Medicines Agency during the marketing authorization application process and with the FDA during the New Drug Application process for linzagolix, 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 geopolitical events, 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, in the Report on Form 6-K filed with the SEC on May 17, 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, except as required by law, 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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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