

ObsEva Presents Clinical Data on Oral GnRH Antagonist Linzagolix for the Treatment of Uterine Fibroids at the 2022 ACOG Annual Clinical and Scientific Meeting

-Additional data from the PRIMROSE Phase 3 studies of linzagolix featured in four posters. Oral presentation took place on May 8, 2022 at 9:15am PT/12:15pm ET-

GENEVA, Switzerland May 9, 2022 – ObsEva SA (NASDAQ: OBSV; SIX: OBSD), a biopharmaceutical company developing and commercializing novel therapies for women's health, today announced the presentation of clinical data from the PRIMROSE (1 and 2) Phase 3 studies of linzagolix for the treatment of heavy menstrual bleeding associated with uterine fibroids at the American College of Obstetricians and Gynecologists (ACOG) Annual Clinical and Scientific Meeting (ACSM), which was held in San Diego, California from May 6-8, 2022.

"We are encouraged by these additional analyses and post-treatment data from the PRIMROSE Phase 3 study that continue to underscore linzagolix's clinical utility and differentiated profile," said Dr. Brandi Howard, Chief Clinical Officer of ObsEva. "The results demonstrate that linzagolix has the potential to balance safety, efficacy, and address the wide-ranging symptoms of uterine fibroids. Linzagolix shows promise in delivering sustained clinical benefit, and if approved, would be the only approved GnRH antagonist to provide flexible dosing options with and without hormonal add-back therapy to better address the individual needs of patients."

Details of the presentations, along with key conclusions, are included below. The full abstracts have also been published in the *Obstetrics & Gynecology* supplement.

Quality of Life Improvements in Women with Uterine Fibroids: Results of Two Phase 3 Trials with Linzagolix

Format: Oral Presentation, A107

Presenter: Linda Bradley, MD; Vice Chair of Cleveland Clinic's Women's Health Institute and Professor of Surgery at Case Western Reserve University Cleveland Clinic Lerner College of Medicine

Date and Time: Sunday, May 8, 2022, beginning at 9:15am PT/12:15pm ET

Congress Link: [Click Here](#)

Key Conclusions: Linzagolix treatment had substantial beneficial effects on health-related quality of life in women with uterine fibroids after 24 weeks of treatment. The positive changes were maintained at 52 weeks. At 64 weeks, 12 weeks after treatment termination, improvements decreased across treatment groups but did not return to baseline.

Incidence of Alopecia in Treatment of Women with Uterine Fibroids: Results of Two Phase 3 Trials of Linzagolix

Format: e-Poster, A104

Lead Author: Ayman Al-Hendy, MD; Professor of Obstetrics and Gynecology, University of Chicago

Date and Time: Friday, May 6, 2022, beginning at 1:00pm PT/4:00pm ET

Congress Link: [Click Here](#)

Key Conclusions: While alopecia was previously reported with other GnRH antagonists, it was rarely observed in the PRIMROSE trials of linzagolix for the treatment of uterine fibroids. Further, no subjects reported alopecia during the post-treatment follow-up period.

Title: Effects of the Oral GnRH Antagonist Linzagolix on Uterine Fibroid-Related Severe Anemia

Format: e-Poster, A105

Lead Author: Elizabeth Stewart, MD; Professor of Obstetrics and Gynecology, Mayo Clinic

Date and Time: Friday, May 6, 2022, beginning at 1:00pm PT/4:00pm ET

Congress Link: [Click Here](#)

Key Conclusions: Iron-deficiency anemia is common in women with uterine fibroid-related heavy menstrual bleeding. High and low doses of linzagolix-with and without hormonal add-back therapy (ABT), improved hemoglobin levels in patients with uterine fibroids suffering from severe anemia.

Incidence of Depression and Other Mood Disorders in Women with Uterine Fibroids Treated with Linzagolix: 52 Week Results from Two Phase 3 Trials

Format: e-Poster, A106

Lead Author: Erica Marsh, MD, MSCI, FACOG; Professor of Obstetrics and Gynecology, University of Michigan

Date and Time: Friday, May 6, 2022, beginning at 1:00pm PT/4:00pm ET

Congress Link: [Click Here](#)

Key Conclusions: There was a low incidence of depression and other mood disorder treatment emergent adverse events (TEAEs) in the 24-52 week treatment period with linzagolix.

Post-Treatment Efficacy and Safety Follow-Up in Women with Uterine Fibroids Treated for 52 Weeks with Linzagolix

Format: e-Poster, A108

Lead Author: Hugh Taylor, MD; Professor, Department of Obstetrics, Gynecology and Reproductive Sciences, Yale School of Medicine

Date and Time: Friday, May 6, 2022, beginning at 1:00pm PT/4:00pm ET

Congress Link: [Click Here](#)

Key Conclusions: Linzagolix effects persisted following the 52-week treatment period, although there was partial return to baseline for all measured efficacy endpoints. At 64 weeks, improvements in pain, hemoglobin, health-related quality of life, as well as uterine and fibroid volumes were diminished, but a beneficial difference from baseline was maintained. The return to menstruation was rapid, and at 76 weeks, study participants had full or partial recovery of lumbar spine bone mineral density across doses.

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 norethindrone 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 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 [here](#).

About Linzagolix

Linzagolix is a 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 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 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, 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