**ObsEva Presents Clinical Data on Oral GnRH Antagonist Linzagolix for the Treatment of Uterine Fibroids at ASRM 2021 Scientific Congress & Expo**

*-Final results from pilot study of linzagolix for the treatment of severe adenomyosis to be presented in a second poster -*

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

**GENEVA, Switzerland October 20, 2021 – ObsEva SA (NASDAQ: OBSV; SIX: OBSN),** a biopharmaceutical company developing and commercializing novel therapies to improve women's reproductive health, today announced the presentation of clinical data from PRIMROSE (1 and 2) Phase 3 study of linzagolix for the treatment of uterine fibroids as well as final data from a pilot study of linzagolix for the treatment of severe adenomyosis at the American Society for Reproductive Medicine (ASRM) 2021 Scientific Congress & Expo, being held October 17-20, 2021.

"Enlarged uterine volume is an important driver of abnormal bleeding and pain associated with uterine fibroids; moreover, bulk and pressure symptoms may strongly impact women's quality of life," said Jacques Donnez, M.D., Ph.D., a key opinion leader in gynecologic therapeutics. "We are encouraged by the positive data and the robust responses that were observed at the full suppression dose of linzagolix, demonstrating the potential to promote meaningful reductions in uterine volume in addition to reduction in heavy menstrual bleeding. Linzagolix is the only GnRH antagonist to provide flexible dosing options to better address the individual needs of patients, and these results further underscore its differentiated profile and potential clinical utility."

**Linzagolix for the Treatment of Uterine Fibroids**

The abstract, titled "Administration of Hormonal Add-Back Therapy (ABT) Counteracts the Uterine Volume Reducing Effects of Oral GnRH Antagonist Therapy," is presented by Dr. Donnez in an ePoster and available on-demand through the ASRM conference portal.

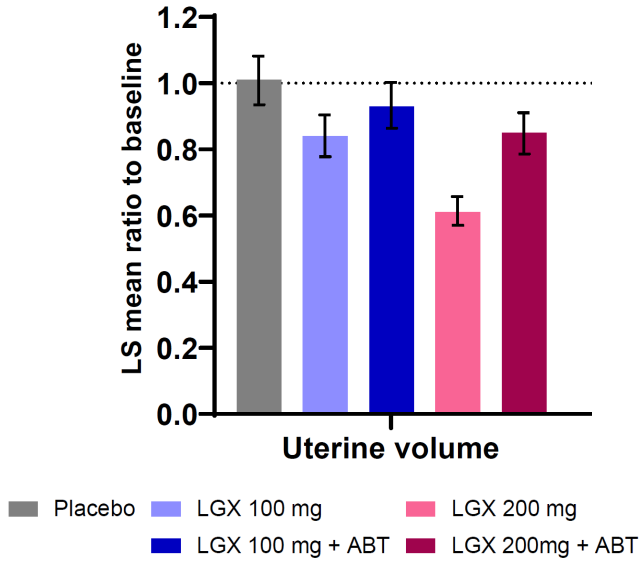
PRIMROSE 1 & 2 were randomized, parallel group, double-blind, placebo-controlled Phase 3 studies that investigated the efficacy and safety of two dosing regimens of linzagolix, 100 mg or 200 mg once daily, alone or in combination with hormonal ABT (1 mg estradiol and 0.5 mg norethisterone acetate) for 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 the United States and enrolled 535 women. Both trials comprised a 52-week treatment period. Women receiving linzagolix 200 mg alone or placebo were switched to linzagolix 200 mg + ABT after 24 weeks, except for a group of placebo subjects in one study who continued placebo until 52 weeks. Uterine volumes were measured using transvaginal ultrasound at baseline, 24 and 52 weeks. Change from baseline was analyzed using a mixed model with repeated measures. Serum estradiol (E2) levels were measured using a validated sensitive assay.

**Summary of the data**

**Key takeaway:** Once daily treatment of 200 mg linzagolix without ABT reduced uterine volume by 39% after 24 weeks. However, co-administration of hormonal ABT after 24 weeks counteracted the uterine volume reducing effects at 52 weeks.

In women who received linzagolix without ABT for 24 weeks and then changed to linzagolix 200 mg with ABT from 24 to 52 weeks:

- **Uterine volume at 24 weeks:** Mean ratio to baseline was 0.61 (95% CI 0.57, 0.65) corresponding to a 39% reduction
- **Fibroid volume at 24 weeks:** Mean ratio to baseline was 0.51 (95% CI 0.44, 0.58) corresponding to a 49% reduction
- **Estradiol levels at 24 weeks:** Median serum E2 was suppressed to 9 pg/mL
- **Uterine volume at 52 weeks:** Mean ratio to baseline increased to 0.79 (95% CI 0.73, 0.86) corresponding to a 21% reduction from baseline.
- **Estradiol levels at 52 weeks:** Median serum E2 increased to 43 pg/mL




**Linzagolix for the Treatment of Severe Adenomyosis**

The abstract, titled "Efficacy and Safety of Linzagolix for the Treatment of Severe Adenomyosis: Final Results from a Pilot Study," is presented by Dr. Donnez in an ePoster and available on-demand through the ASRM conference portal.

This single-center, open-label, exploratory study was designed to assess the efficacy and safety of linzagolix in the treatment of symptomatic adenomyosis. Premenopausal patients with MRI-confirmed adenomyosis, moderate-to-severe pain and abnormal uterine bleeding were treated with high-dose linzagolix (200 mg) for 12 weeks followed by low-dose (100 mg) for an additional 12 weeks. The primary measure of efficacy was the reduction in uterine volume assessed by MRI. Other endpoints included pelvic pain, bone mineral density (BMD) and quality of life.

**Summary of the data**

**Key takeaway**: A high dose of 200 mg linzagolix reduced uterine volume by 55% from baseline at 12 weeks and 32% from baseline at 24 weeks after continued treatment with 100 mg linzagolix. Pelvic pain was markedly reduced at 12 and 24 weeks with initial signs of reduction after 4 weeks. Overall, significant improvements in quality of life were reported.

- **Estradiol levels:** Median serum estradiol was suppressed to 12 pg/mL after four weeks and maintained up to 12 weeks. Median serum estradiol was partially suppressed (19 to 38 pg/mL) from 16 to 24 weeks.
- **Uterine volume:** Mean uterine volume decreased significantly and was 198 $cm^3$ ($p<0.0001$) after 12 weeks and 139 $cm^3$ ($p<0.006$) at 24 weeks, corresponding to a 55% reduction from baseline at 12 weeks and an additional 32% reduction from baseline at 24 weeks.
- **Pelvic pain:** Mean pelvic pain score (0-10 numeric rating scale) was reduced from 8.4 at baseline to 3.4 ($p=0.034$) at 4 weeks with continued decrease from baseline of 6.0 ($p=0.0035$) at 12 weeks and 7.8 ($p<0.0001$) at 24 weeks.
- **Safety and tolerability:** Hot flash and fatigue were the most common side effects. No serious adverse effects were reported.
- **BMD:** Bone mineral density was assessed at 24 weeks and the mean ± SD % decrease at the lumbar spine was 2.4 ± 3.6% and the mean z-score was -0.65 (range -1.6, 0.9). This was consistent with effects of estradiol suppression on BMD.
- **Quality of Life:** Significant improvements were observed in all of the EHP-30 domains at 12 and 24 weeks ($p<0.05$).

**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 heavy menstrual bleeding associated with 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.

**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 and commercialization plans for ObsEva's product candidates, including linzagolix, expectations regarding regulatory and development milestones, including the potential timing of regulatory submissions to the EMA and FDA and ObsEva's ability to obtain and maintain regulatory approvals for its product candidates, 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 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 filed with Securities and Exchange Commission (SEC) on March 5, 2021 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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