# ObsEva Announces Publication of Abstracts from Phase 2b EDELWEISS Trial of Linzagolix in Endometriosis

- Significant improvement in quality of life outcomes maintained or increased after 52 weeks of treatment with linzagolix
- Small, expected, non-clinically relevant increases in serum lipids observed at 12 weeks generally stable at 52 weeks

**GENEVA, Switzerland and BOSTON, MA (April 22, 2020) – ObsEva SA (NASDAQ: OBSV) (SIX: OBSN)**, a biopharmaceutical company developing and commercializing novel therapies to improve women's reproductive health, today reported that there will be an online publication of two abstracts in *Obstetrics and Gynecology (The Green Journal)*, the official journal of the American College of Obstetricians and Gynecologists, on Thursday 23rd April at 5pm ET.

The abstracts, titled **"Quality of Life Results After 52 Weeks of Treatment with Linzagolix for Endometriosis-Associated Pain"** and **"Linzagolix for Endometriosis-Associated Pain: Lipid Changes After 52 Weeks of Treatment"** are based on 52-week data from the EDELWEISS trial, a Phase 2b randomized, double-blind, placebo-controlled, dose-ranging trial conducted in the US and Europe to assess the safety and tolerability of a range of daily oral linzagolix doses (50 to 200 mg) in women with moderate to severe endometriosis-associated pain. Subjects receiving the 200 mg dose were switched to 100 mg after 24 weeks of treatment. No hormonal add-back therapy (ABT) was used in this trial.

Quality of life (QoL) is critically important for women suffering from endometriosis-associated pain. In the trial, several QoL endpoints were assessed, including the difficulty of doing daily activities, the Patient Global Impression of Change (PGIC), and the Endometriosis Health Profile-30 (EHP-30). On all endpoints linzagolix demonstrated significant improvements versus placebo at 12 weeks:

- ***Difficulty of doing daily activities*** was significantly decreased compared to placebo at week 12 at doses of 75 mg and higher and these decreases were maintained or further improved up to 52 weeks.
- At 52 weeks, 64.3% and 76.2% of subjects treated with the 75 and 200/100 mg doses, respectively, reported much or very much improved endometriosis symptoms on the ***PGIC***.
- Subjects at all linzagolix doses reported improvements on the ***EHP-30 questionnaire***, which were maintained at week 52.

As treatments that modulate estrogen levels may impact serum lipids, changes in serum LDL-cholesterol (C), HDL-C, LDL-C/HDL-C ratio and triglycerides were assessed.

- Once daily doses of linzagolix for 52 weeks resulted in expected small percentage increases of HDL-C and LDL-C (≤ 10%) after 12 weeks, which generally did not increase

further up to 52 weeks of treatment. In the 200/100 mg arm, serum triglycerides increased by 32% compared to 20% in the placebo arm; of note, other than at baseline, fasting was not required for blood sampling.

- Across treatment groups, the percentages of women with LDL cholesterol > 160 mg/dL or triglycerides > 200 mg/dL at 24 and 52 weeks were less than 10% at most time points, and the overall proportions were similar to baseline levels. Overall, these findings support non-clinically relevant changes in serum lipids with long-term linzagolix treatment.

These data add to the favorable safety and efficacy profile of linzagolix in the treatment of women with endometriosis-associated pain. Together with mean lumbar spine BMD loss results of 1.14% and 2.19% at 52 weeks for the 75 mg and 200/100 mg doses, respectively (ASRM Poster, Oct 2019), the overall data are supportive of potential long-term use of the 75 mg dose of linzagolix without the need for ABT in this patient population. The 75 mg and 200 mg + ABT doses are currently being studied in the Phase 3 EDELWEISS endometriosis trials.

**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, preterm labor, and improving ET outcomes following IVF. 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/linzagolix is a new chemical entity discovered by Kissei R&D and currently in development in Japan by Kissei.

**About Linzagolix**

Linzagolix is a novel, orally administered GnRH receptor antagonist with a potentially best-in-class profile in late-stage clinical development for the treatment of heavy menstrual bleeding associated with uterine fibroids and pain associated with endometriosis. Linzagolix acts by binding to and blocking the GnRH receptor in the pituitary gland, ultimately inducing a dose dependent reduction of estrogen production by the ovaries. It has been established that maintaining estradiol within a specific target range provides the optimal balance between reducing symptoms while mitigating bone density loss associated with excessive estradiol suppression. Linzagolix is being developed to provide two regimens of administration, one targeting partial suppression of estradiol that may not necessitate add-

back therapy (ABT) in the majority of patients, and one targeting full or near full estradiol suppression that would require the administration of ABT, with the goal of providing appropriate treatment to the broadest possible proportion of the endometriosis and uterine fibroid patient populations. ObsEva licensed linzagolix from Kissei in late 2015 and retains worldwide commercial rights, excluding Asia, for linzagolix.

**About the EDELWEISS Study**

The EDELWEISS trial was a Phase 2b, double-blind, randomized, placebo-controlled, multicenter, dose-ranging trial in USA and Europe to assess the effects of a range of doses of linzagolix (50, 75, 100 and 200 mg) given orally once a day for 52 weeks on EAP and to assess safety and tolerability including effects on serum lipids. Participants were women with surgically confirmed endometriosis and moderate to severe EAP. Patients were randomized to one of 6 treatment groups: 50, 75 (fixed dose; FD), 75 (titrated dose; TD), 100 and 200 mg linzagolix or placebo for 24 weeks. Patients on placebo were switched to 100 mg at week 12. In the 75 mg titrated dose group, the dose after 12 weeks was 50, 75 or 100 mg depending on the mean serum E2 being < 20, 20 to 50 or > 50 pg/mL at 4 and 8 weeks. Following 24 weeks of treatment, subjects were invited to continue treatment up to 52 weeks at the same dose. Those receiving 200 mg were swapped to 100 mg.

**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 ObsEva's product candidates, the timing of enrollment in and data from clinical trials 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 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, 2019, 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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