# ObsEva Announces Publication of Data Showing Efficacy of Linzagolix in a Potential New Indication for Treatment of Adenomyosis

**GENEVA, Switzerland and BOSTON, MA (June 4, 2020) – ObsEva SA (NASDAQ: OBSV) (SIX: OBSN)**, a biopharmaceutical company developing and commercializing novel therapies to improve women's reproductive health, today reported publication in the journal *Fertility and Sterility* of **"Gonadotropin-releasing Hormone Antagonist (linzagolix): a New Therapy for Uterine Adenomyosis,"** a case report from a pilot study assessing the use of linzagolix for the treatment of uterine adenomyosis.

Adenomyosis is an estrogen-driven condition in which endometrial tissue (inner uterine lining) is present within the myometrium (muscular uterine wall), resulting in uterine enlargement, heavy menstrual bleeding, dysmenorrhea (painful menses) and infertility. Adenomyosis affects between 20 and 35% of reproductive-aged women, and may co-exist with endometriosis and/or uterine fibroids. The only definitive treatment for adenomyosis is hysterectomy, which is used in the minority of patients (<10%) because it ends fertility and may have long-term adverse impact. A clear unmet need exists for effective long-term medical therapies.

The pilot study is a single-center, open-label study in women (n=9) with symptomatic adenomyosis confirmed by Magnetic Resonance Imaging (MRI). Patients are treated once daily with 200 mg linzagolix for 12 weeks, followed by 12 weeks of 100 mg linzagolix, both without hormonal add-back therapy (ABT). The primary measure of efficacy is the reduction in uterine volume as measured by MRI.

The patient described in the case report presented with pelvic pain, heavy menstrual bleeding, anemia and infertility. MRI showed an enlarged uterus (875 $cm^3$) with severe adenomyosis. By week 12 of treatment with 200 mg linzagolix, the patient was amenorrheic (cessation of bleeding), her pelvic pain was substantially improved, anemia was resolved, and MRI showed marked shrinkage in uterine volume (to 290 $cm^3$) with regression of adenomyotic lesions. During the subsequent 12-week course with 100 mg linzagolix, she remained amenorrheic and reported continued alleviation of symptoms. Persistence of linzagolix effect was observed at 8 weeks following completion of treatment.

The patient's bone mineral density by Dual Energy X-ray Absorptiometry at 24 weeks of treatment showed no change from baseline in lumbar spine and femoral neck T- and Z-scores. Expected hypoestrogenic side effects of hot flushes and vaginal dryness on the 200 mg linzagolix dose resolved following the dose adjustment to the 100 mg dose.

"These new clinical results showing a dramatic effect of linzagolix in a patient with severe adenomyosis are promising for women and clinicians who have struggled for decades to treat this challenging and painful condition," said Dr. Jacques Donnez, a prominent European gynecologist and co-author on the paper. "The data also suggest that starting with a course of high dose of linzagolix without ABT, followed by low-dose maintenance therapy may be a highly effective approach to adenomyosis treatment."

Pending confirmation of the results in additional patients, ObsEva may pursue additional studies to support supplemental labeling for the use of linzagolix in the treatment of adenomyosis in reproductive-age women.

Please click here to access the publication.

**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.

**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 potential use of linzagolix for the treatment of adenomyosis, including the dosing regimen, potential additional studies to support additional labeling for the use of linzagolix, as well as statements regarding ObsEva's 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, 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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