

# ObsEva SA to Present Model-Based Analysis Supporting Clinical Use of Linzagolix at Doses Not Requiring Hormonal Add back Therapy

Once-daily oral Linzagolix doses of 75 mg and 100 mg without hormonal add-back therapy could lead to symptom relief of endometriosis-association pain and heavy bleeding from uterine fibroids while maintaining bone health

2019 American Conference on Pharmacometrics Quality Award Winning Abstract

**Geneva, Switzerland and Boston, MA – October 11, 2019** - ObsEva SA (NASDAQ: OBSV / SIX: OBSN), a clinical-stage biopharmaceutical company focused on the development and commercialization of novel therapeutics for serious conditions that compromise woman's reproductive health and pregnancy, today announced upcoming clinical data presentations on linzagolix at multiple medical meetings, including:

13th European Society of Gynecology (ESG) Congress: October 16-19 in Vienna, Austria.
 Oral Presentation, Thursday, October 17 at 11:45 a.m. CET

"Is hormonal add-back necessary? A model-based analysis to guide gonadotropin-releasing hormone (GnRH) receptor antagonist use for management of endometriosis and uterine fibroids"

10th American Conference on Pharmacometrics (ACoP) meeting: October 20-23 in Orlando, FL
 Poster Presentation, Tuesday, October 22 and Oral Presentation, Wednesday, October 23 at 9 a.m. EDT

"Model-based Dose Selection for a GnRH Receptor Antagonist in Endometriosis and Uterine Fibroids to Reduce Symptoms While Preventing Lumbar Spine Bone Mineral Density Loss"

Based on actual clinical data in 770 endometriosis patients and 198 healthy volunteers, this modelling and trial simulation analysis aimed to assess effective doses of the GnRH antagonist linzagolix for treatment of symptoms associated with endometriosis and uterine fibroids without the need for hormonal add-back therapy (ABT).

The model-based analysis showed that linzagolix doses ranging from 75 mg to 125 mg were efficacious and reached bone safety targets. These results support the potential use of linzagolix without ABT in premenopausal women with these conditions, avoiding the known risks of ABT while providing symptom relief and protection of bone.

Clinical efficacy and safety of linzagolix at 75mg and 100mg doses without hormonal ABT are being assessed in ObsEva's ongoing Phase 3 endometriosis (EDELWEISS 2/3) and uterine fibroid (PRIMROSE 1/2) trials.

## **About linzagolix (formerly OBE2109)**

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 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 ObsEva

ObsEva is a clinical-stage biopharmaceutical company focused on the clinical development and commercialization of novel therapeutics for serious conditions that compromise a woman'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 IVF outcomes. 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 <a href="https://www.ObsEva.com">www.ObsEva.com</a>.

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