



## **ObsEva SA Reports Consistent Long-Term Findings from Phase 2b EDELWEISS trial of Linzagolix for Endometriosis-Associated Pain**

**Geneva, Switzerland and Boston, MA** – May 3, 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 a woman’s reproductive health and pregnancy, today reported follow-up results from the Phase 2b EDELWEISS clinical trial of its oral gonadotropin releasing hormone (GnRH) receptor antagonist, linzagolix, for the treatment of endometriosis-associated pelvic pain. These new data include 28-week extension study treatment (52 weeks of continuous treatment), as well as the 24-week post treatment follow-up (PTFU) results for patients who did not enter the extension study after completing the initial 24-week treatment period.

"We are pleased to report long-term data from the EDELWEISS trial of linzagolix, which show that in patients treated with linzagolix for 52 weeks, pelvic pain response rates are maintained with the 75mg or the 200mg dose. Bone mineral density remains within safe limits. Patients that were followed for 6 months after treatment completion continue to experience pain control, and showed BMD increase," said Ernest Loumaye, Co-Founder and Chief Executive Officer of ObsEva. "These data further support the long term therapeutic potential of linzagolix and support the currently starting Phase 3 program for the endometriosis indication, as we anticipate initial Phase 3 clinical results later this year from the trial in uterine fibroids."

### **Overall Pelvic Pain reduction sustained long-term**

After 52 weeks of treatment, responder rates for Overall Pelvic Pain (OPP)— defined as the proportion of patients experiencing an OPP score reduction >30% from baseline using a verbal rating scale— were 69% for the 75mg once daily dose and 82% for the 200mg/100mg once daily dose. This long-term linzagolix treatment also showed sustained reductions in dysmenorrhea, non-menstrual pelvic pain, dyspareunia, dyschesia and improvements in quality of life. These long-term responder rates are similar to those reported in the preceding 24-week treatment period (Table 1). At 12 weeks, after cessation of treatment within the limits of a small sample size, pelvic pain response rates seem to be maintained.

Table 1

<b>Overall Pelvic Pain Responder Rates (%)</b>		
<b><i>Dose Levels (once-daily dose)</i></b>	<b><i>75mg</i></b>	<b><i>200mg *</i></b>
24 weeks of treatment	70.8 (n=48)	77.3 (n=44)
52 weeks of treatment	69.2 (n=36)	82.4 (n=30)
24-week PTFU **	87.5 (n=7)	70.0 (n=10)

\* Subjects randomized to 200 mg received 100 mg from 24 weeks to 52 weeks

\*\*OPP recorded up to 12 weeks PTFU after the 24-week treatment period

For patients who received placebo up to week 12, OPP responder rates were 33.3% (n= 48).

#### **Bone Mineral Density (BMD) seen returning towards baseline**

Changes from BMD baseline to week 52, measured by dual-energy x-ray absorptiometry (DXA) scan, were consistent with the values observed at 24 weeks of treatment as per Table 2 below.

Table 2

<b>Patients Treated for 52 weeks: BMD at Spine (mean % change from baseline)</b>		
<b><i>Dose Levels (once-daily dose)</i></b>	<b><i>75mg</i></b>	<b><i>200mg *</i></b>
24 weeks of treatment	-0.798 %	-2.602 %
52 weeks of treatment	-1.139 %	-2.188 %

\* Subjects randomized to 200 mg received 100 mg from 24 weeks to 52 weeks

<b>Patients Treated for 24 weeks and 24 weeks PTFU: BMD at Spine (mean % change from baseline)</b>		
<b><i>Dose Levels (once-daily dose)</i></b>	<b><i>75mg</i></b>	<b><i>200mg *</i></b>
24 weeks of treatment	-0.798 %	-2.602 %
24-week PTFU	0.313 %	1.135 %

#### **Data support previous 75mg, 200 mg dose selection**

These data further support the dose selection for the Phase 3 program in women with endometriosis-associated pain i.e. linzagolix 75mg once daily dose without add- back hormonal therapy ABT, and 200mg once daily dose in combination with low-dose, ABT.

## **EDELWEISS data presentation at forthcoming medical conferences**

@ The American College of Obstetricians and Gynecologists Annual Meeting (ACOG May3-6 2019, Nashville, USA)

- The Effect of Linzagolix on Bone Mineral Density (BMD): Safety Results From a Dose-Ranging Trial , ePoster Session J - Sat 04 May 2019, 11:30am - 12:30pm

@ 5<sup>th</sup> Congress of the Society of Endometriosis and Uterine Disorders (SEUD 16-18May 2019, Montreal, CA)

- Linzagolix for Endometriosis-Associated Pain: Primary Efficacy and Safety in a Dose-Ranging Trial – Fri 17 May 2019, session 11
- Linzagolix for Endometriosis-Associated Pain: Secondary Endpoint Results From a Dose-Ranging Trial – Fri 17 May 2019, session 5
- The Effect of Linzagolix on Bone Mineral Density (BMD): Safety Results From a Dose-Ranging Trial – Fri 17 May 2019, session 17

Fifty two week treatment and PTFU data are expected to be presented at medical conference later this year.

### **About the EDELWEISS trial**

EDELWEISS is a Phase 2b, randomized, double blind, placebo controlled clinical trial designed to evaluate the safety and efficacy of multiple doses of linzagolix in 327 women with moderate-to-severe endometriosis-associated pain. Patients were randomized to receive either an oral once daily dose of linzagolix (50mg, 75mg, 100mg or 200mg) or placebo for up 12 weeks. Subsequently, patients on placebo received 100mg of linzagolix.

After 24 weeks of treatment, patient could choose between a 24 week post treatment follow-up (PTFU) period which included efficacy assessments up to 12 weeks and BMD assessment after 24 weeks, or to enter an extension part with 28 weeks of further linzagolix treatment. In this extension part, patients continued linzagolix doses they had received up to week 24 but subjects on 200mg switched to 100mg of linzagolix.

### **About LINZAGOLIX (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 pain associated with endometriosis and heavy menstrual bleeding associated with uterine fibroids. Linzagolix acts by binding to and blocking the GnRH receptor in the pituitary gland, resulting in a dose-dependent reduction in estrogen production by the ovaries. Given reported results from this class of drugs and sophisticated pharmacological modelling, linzagolix is being developed to potentially 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 OBE2109 from Kissei in 2015 and retains worldwide rights, excluding Asia.

To date, more than 1850 subjects have been exposed to 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 [www.ObsEva.com](http://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 ObsEva's product candidates and the timing of enrollment in and data from clinical trials. 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, clinical development and related interactions with regulators, ObsEva's reliance on third parties over which it may not always have full control, 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, 2018, 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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