



## **ObsEva SA Achieves Primary and Secondary Endpoints for EDELWEISS Phase 2b Clinical Trial of Linzagolix (OBE2109) in Women with Endometriosis**

***Partial suppression of estradiol with moderate dose (75mg) of linzagolix demonstrated highly significant reduction of pain and improvement of patient well-being***

***High dose (200mg) of linzagolix achieves full estradiol suppression and highly significant efficacy***

***Excellent safety profile demonstrated***

**Geneva, Switzerland and Boston, MA – June 18, 2018** – ObsEva SA (NASDAQ: OBSV), 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 positive 12-week results from the EDELWEISS Phase 2b clinical trial of linzagolix, its oral GnRH receptor antagonist, for the treatment of endometriosis-associated pain. The company is also identifying the two doses of linzagolix intended to be studied in the upcoming Phase 3 program, one for full estradiol (E2) suppression and one targeting partial suppression.

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 recruited from 64 gynecological clinics across the U.S. and Europe. Following a lead-in phase of two menstrual cycles to establish baseline pain level, patients were randomized to receive either an oral once daily dose of linzagolix (50mg, 75mg, 100mg or 200mg) or placebo for up 12 weeks.

The primary endpoint of the EDELWEISS clinical trial was a responder analysis, with responses defined as a reduction of at least 30%<sup>1</sup> in combined menstrual and non-menstrual pelvic pain, recorded daily and assessed via electronic diary over the last 28 days of treatment on a verbal rating scale (VRS) of 0 (no pain) through 3 (severe pain).

Demographics and baseline characteristics were comparable between groups with a mean baseline overall pain VRS of 1.7, menstrual pain VRS of 2.1 and non-menstrual pain VRS of 1.6.

**Primary Endpoint Results:**

- The study primary endpoint was achieved for the three top doses, and patients receiving a 75mg dose had the highest responder rate of 61.5% compared to the placebo at 34.5%.

Dose	Placebo	50mg (n=49)	75mg (n=114)*	100mg (n=51)	200mg (n=56)
<b>Responder Rate</b>	34.5%	49.4%	61.5%	56.4%	56.3%
<b>P-Value</b>	—	0.155	0.003	0.039	0.034

\*as per protocol

**Secondary Endpoint Results:**

- With respect to the menstrual pain VRS, patients receiving a 200mg dose reported the highest responder rate at 78.9%, compared to a placebo responder rate of 28.5%.

Dose	Placebo	50mg	75mg	100mg	200mg
<b>Responder Rate</b>	28.5%	43.3%	68.2%	68.6%	78.9%
<b>P-Value</b>	—	0.141	<0.001	<0.001	<0.001

- Responder rates for the non-menstrual pain VRS endpoint were statistically significant for the 75mg dose and the 100mg dose and both doses showed comparable responder rates at 58.5% and 61.5% respectively.

Dose	Placebo	50mg	75mg	100mg	200mg*
<b>Responder Rate</b>	37.1%	46.2%	58.5%	61.5%	47.7%
<b>P-Value</b>	—	0.380	0.017	0.022	0.297

\*200mg at week 8: responder rate 57.0% (p=0.022)

In addition, doses of linzagolix from 75mg to 200mg significantly and consistently improved dyschezia and patient well-being as assessed by Endometriosis Health Profile-30 score, Patient Global Impression of Change scale (PGIC), Patient Global Impression of Severity (PGIS), the activity impairment score and the modified Biberoglu & Behrman score. Dyspareunia was also improved for all doses and reached statistical significance at the 200mg dose.

Serum Estradiol median levels at week 12 were 12 pg/ml for the 200mg dose and 48 pg/ml for the 75mg dose, which indicates full suppression at the higher dose and partial suppression at the 75mg dose.

<sup>1</sup> Recommended by the International Association for the Study of Pain, Farrar et al. 2001 and Vincent et al. 2010.

Linzagolix was observed to be safe and well tolerated. In line with the therapeutic class and mechanism of action, a moderate proportion of patients reported at least one hot flush as an adverse event (which is a side effect of suppression of E2 levels). The incidence of hot flush in the most effective 75mg dose cohort was 18.4%, versus the placebo arm of 10.9%. Additionally, the incidence of hot flush in the 200mg dose cohort was 42.1%, which is expected for a full E2 suppression dose.

"We are very pleased by the EDELWEISS results reported today. We believe that these data strongly support the therapeutic potential of linzagolix for improving the condition and well-being of patients suffering from endometriosis. In addition, we believe these data further confirm ObsEva's vision and product development strategy that a significant proportion of patients will not require full E2 suppression which mandates add-back hormone replacement therapy. With these data, we reiterate our intention to move to Phase 3 by the end of the year with two doses of linzagolix," said Ernest Loumaye, MD, PhD, OB/GYN, CEO and Co-Founder of ObsEva.

Dr. Hugh Taylor, Chair of Obstetrics, Gynecology and Reproductive Sciences, Yale School of Medicine, and Chief of Obstetrics and Gynecology, Yale-New Haven Hospital commented, "Given the tremendous need for new therapies that can treat the large and diverse population of women with endometriosis, it is encouraging to see that linzagolix may be able to offer a range of effective dosing alternatives to suit individual patient needs."

Currently, patients in the EDELWEISS trial continue to receive linzagolix for an additional 12 weeks. Twenty-four-week data, including the bone mineral density (BMD) assessment, is expected to be available in the fourth quarter of 2018. ObsEva subsequently intends to seek feedback from regulatory authorities on the design of a Phase 3 clinical trial program by the end of 2018.

### **Conference Call Information**

ObsEva will host a conference call and audio webcast today at 8 a.m. Eastern Time/2 p.m. Central European Time, to discuss EDELWEISS top-line results and review the company's strategic development plans. To participate in the conference call, please dial +1(844) 419-1772 for U.S. callers and +1(213) 660-0921 for international callers, and refer to conference ID 9839439. The webcast can be accessed under the "Investors" section of ObsEva's website [www.obseva.com](http://www.obseva.com).

### **About Endometriosis**

Endometriosis is associated with a multitude of symptoms, most common is severe pain during menstruation as well as chronic pelvic pain throughout the menstrual cycle or during intercourse. In addition, endometriosis is a leading cause of infertility. The World Endometriosis Research Foundation estimates that endometriosis affects one in ten women during their reproductive years, representing approximately 176 million women worldwide. The World Endometriosis Research Foundation's EndoCost study estimated the aggregate annual cost of endometriosis to be approximately \$80 billion in the United States and approximately \$60 billion in Germany, the U.K., France and Italy in 2012 based on current exchange rates.

Endometriosis is a disease in which the endometrium (tissue lining the inside of the uterus) is found outside the uterus, where it induces a chronic inflammatory reaction that may result in scar tissue. It is primarily found on the pelvic endometrium, on the ovaries, in the rectovaginal septum, on the bladder and bowel. The most common symptom of endometriosis is pelvic pain, which often correlates

to the menstrual cycle. Patients may also experience painful ovulation, pain during or after sexual intercourse, dyschezia (difficult or painful defecation), heavy bleeding, chronic pelvic pain, fatigue and infertility. Endometriosis pain can be so severe and debilitating that it affects day-to-day activities and has a negative impact on general, physical, mental and social well-being. Endometriosis treatments aim first to alleviate pain, then to remove or decrease the size and number of endometrial lesions, and possibly improve fertility. Oral contraceptives, progestins and NSAIDs are generally first-line treatments for women experiencing pain. Following the failure of first-line therapies, current treatment options are limited to intra-muscular or subcutaneous GnRH agonist injections, GnRH agonists nasal spray pumps or surgery (including hysterectomy) for the most symptomatic cases.

### **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, ultimately reducing 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 1500 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.

### **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". 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 as well as the feedback from and clinical requirements of relevant 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, including that past results may differ from future results in the EDELWEISS clinical trial or any future clinical trials, ObsEva's reliance on third parties over which it may not always have full control, feedback from relevant regulatory authorities, 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, 2017 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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