Final results of ObsEva SA Phase 2b EDELWEISS trial of Linzagolix show sustained efficacy and Bone Mineral Density safety, for the treatment of endometriosis-associated pain

- ***Linzagolix overall efficacy and safety maintained or improved at week 24***
- ***Linzagolix 75mg once daily showed no clinically significant impact on Bone Mineral Density (BMD), supporting further development with no need for add back therapy (ABT)***
- ***Linzagolix 200mg once daily results support further development with low dose add back therapy (ABT)***
- ***Initiation of Phase 3 endometriosis trials expected in early 2019***

Geneva, Switzerland and Boston, MA – September 28, 2018 - ObsEva SA (NASDAQ: OBSV / SIX: OBSN), a Swiss 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 announced additional positive results from the EDELWEISS clinical trial of its oral GnRH receptor antagonist, linzagolix, for the treatment of endometriosis-associated pain.

In the EDELWEISS trial, hallmark pain symptoms of endometriosis, dysmenorrhea (DYS) and non-menstrual pelvic pain (NMPP), showed sustained reduction or further improvement after 24 weeks of treatment, as compared to the positive 12-week results that were announced in June 2018. Sustained efficacy was also seen in additional endpoints such as dyspareunia and dyschezia, as well as in the assessments of patient well-being, most notably the Patient Global Impression of Change (PGIC) and Endometriosis Health Profile-30 (EHP-30) questionnaire.

The main pain efficacy endpoints of the EDELWEISS clinical trial were reported as a responder analysis, with responses defined as a reduction of at least 30% in pain, recorded daily via electronic diary using a verbal rating scale (VRS) of 0 (no pain) through 3 (severe pain).

"We are very pleased with these favorable results that further demonstrate the differentiated therapeutic potential of linzagolix for alleviating the severe, painful and chronic symptoms of endometriosis. These data strongly validate ObsEva's development strategy for linzagolix as a potential best in class oral GnRH antagonist," said Dr. Loumaye, co-founder and Chief Executive Officer of ObsEva.

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Study Top-Line Results

Overall pelvic pain responder analysis @ week 12 and week 24 (0-3 VRS)

Dose (once daily) **n=FAS***	Placebo (53)	50mg (49)	75mg (114)	100mg (51)	200mg (56)
Responder Rate @ Week 12	34.5%	49.4%	61.5%	56.4%	56.3%
P-Value vs Placebo @ Week 12	—	0.155	0.003	0.039	0.034
Responder Rate @ Week 24	N/A	52.5%	70.8%**	66.7%	77.3%

*FAS = Full Analysis Set

**sub-group randomized to fixed dose 75mg for 24 weeks (n=56)

Non-menstrual pelvic pain responder analysis @ week 12 and week 24 (0-3 VRS)

Dose (once daily) **n=FAS***	Placebo (n=53)	50mg (49)	75mg (114)	100mg (51)	200mg (56)
Responder Rate @ Week 12	37.1%	46.2%	58.5%	61.5%	47.7%
P-Value vs Placebo@ Week 12	—	0.380	0.017	0.022	0.297
Responder Rate @ Week 24	N/A	50.0%	72.9%**	64.1%	72.7%

*FAS = Full Analysis Set

**sub-group randomized to fixed dose 75mg for 24 weeks (n=56)

Dysmenorrhea pain responder analysis @ week 12 and week 24 (0-3 VRS)

Dose (once daily) **n FAS***	Placebo (53)	50mg (49)	75mg (114)	100mg (51)	200mg (56)
Responder Rate @ Week 12	28.5%	43.3%	68.2%	68.6%	78.9%
P-Value vs Placebo @ Week 12	—	0.141	<0.001	<0.001	<0.001
Responder Rate @ Week 24	N/A	47.5%	58.3%**	82.1%	84.1%

*FAS = Full Analysis Set

**sub-group randomized to fixed dose 75mg for 24 weeks (n=56)

Overall linzagolix safety and tolerability were shown not to be different from placebo, except as expected for a dose-dependent increase in hot flushes (placebo at week 12: 10.9% of subjects reporting at least one hot flush; linzagolix 75mg at week 24: 19.0%; linzagolix 200mg at week 24: 45.6%).

In addition, changes from baseline to week 24 in BMD, as measured by dual-energy x-ray absorptiometry (DXA) scan are reported in the table below. Partial estradiol (E2) suppression with linzagolix 75mg allows the lower boundary of the confidence interval of BMD reduction from baseline to be comfortably better than -2.2%, the cut-off limit for clinically significant BMD loss, while achieving improvement of the conditions in the majority of patients. As expected, full E2 suppression with linzagolix 200mg was observed to reduce lumbar spine BMD by more than 2.0%, which we believe will indicate the need for a low dose ABT when used beyond 6 months.

Mean Percent BMD change from baseline to week 24 (mean, 95% CI, p value)

Dose (once daily)	50mg	75mg	100mg	200mg
Femoral Neck	-0.749% (-1.45, -0.05) 0.037	-0.334% (-1.08, 0.42) 0.375	-0.986% (-1.88, -0.10) 0.031	-1.992% (-2.88, -1.10) <0.001
Total Hip	0.378% (-0.15, 0.90) 0.154	-0.457% (-1.06, 0.15) 0.136	-0.278% (-0.88, 0.33) 0.359	-1.690% (-2.45, -0.93) <0.001
Lumbar Spine	0.137% (-0.83, 1.11) 0.777	-0.798% (-1.57, -0.03) 0.042	-1.365% (-2.14, -0.59) <0.001	-2.602% (-3.56, -1.65) <0.001

Overall, we believe these data strongly support the planned development of a 75mg once daily dose (without ABT), and a 200mg once daily dose in combination with low dose ABT. Offering dual therapeutic options, is the cornerstone of ObsEva's strategy to address the needs of the large and diverse endometriosis patient population. In that context, we believe that if successful in Phase 3 trials and approved, the 75mg dose has the potential to become first line therapy (i.e. without ABT), as ABT may change the risk benefit ratio of the treatment. We believe this is further supported by the preference for dose flexibility among U.S. gynecologists.

ObsEva plans to provide additional details from the EDELWEISS trial at a later date, including presentation at a future medical conference. Following End-of-Phase 2 regulatory discussions, expected later this year, ObsEva intends to initiate the Phase 3 program of linzagolix for the treatment of endometriosis-associated pain in early 2019.

About Endometriosis

The World Endometriosis Research Foundation estimates that endometriosis affects one in ten women during their reproductive years, representing approximately 176 million women worldwide between the ages of 15 and 49. 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 peritoneum, 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 (dyspareunia), dyschezia (difficult or painful defecation), heavy bleeding, 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 will not necessitate add-back therapy (ABT) in the majority of patients (a potential preferred, first line treatment), and one targeting full or near full estradiol suppression that would require the administration of a low 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 1,500 subjects have been exposed to linzagolix in clinical trials and linzagolix has been generally well tolerated.

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 continued their treatment as initially randomized up to 24 weeks but subjects on placebo received 100mg of linzagolix and half of the subjects on 75 mg were titrated according to their estradiol levels to either 50mg, 75mg or 100mg of 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.

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, 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, 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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