ObsEva Hosts Symposium and Presents Clinical Data on Oral GnRH Antagonist Linzagolix at SEUD Congress 2021

-Symposium on oral GnRH antagonists and personalized therapeutic approaches for women with uterine fibroids to be hosted Friday, December 10 at 1 p.m. CET-

-52-Week Data from the Phase 3 PRIMROSE studies of linzagolix for the treatment of uterine fibroids demonstrating sustained safety and efficacy results at 52 weeks to be presented orally-

-Long-term follow-up data from Phase 2b EDELWEISS study of linzagolix for the treatment of endometriosis demonstrating bone mineral density recovery to be presented orally-

Ad hoc announcement pursuant to Art. 53 LR of the SIX Swiss Exchange

GENEVA, Switzerland December 10, 2021 – ObsEva SA (NASDAQ: OBSV; SIX: OBSN), a biopharmaceutical company developing and commercializing novel therapies to improve women's reproductive health, today announced upcoming presentations of its linzagolix clinical development program at the 7th Society of Endometriosis and Uterine Disorders (SEUD) Congress being held virtually and in Stockholm, Sweden as a hybrid event from December 9-11, 2021. ObsEva will also be hosting a symposium on Friday, December 10, 2021, at 1 p.m. CET, which will highlight the importance of more personalized therapeutic approaches and the potential of oral GnRH antagonists in uterine fibroid management.

"The encouraging data presented at SEUD highlights the differentiated therapeutic potential of linzagolix, which, if approved, would be the only GnRH antagonist that would provide flexible dosing options to better address the individual needs of women with uterine fibroids," said Jacques Donnez, M.D., Ph.D., a key opinion leader in gynecologic therapeutics. "We are encouraged by the sustained results observed at 24-weeks and 52-weeks at both high and low doses of linzagolix, as well as with and without hormonal add-back therapy. The bone-mineral-density (BMD) changes in this patient population are consistent with the dose-dependent suppression of serum estradiol as well as the presence of hormonal add-back therapy. In the endometriosis indication, the long-term results from the Phase 2b study showing BMD recovery are encouraging. Together, these results build upon a compelling foundation that underscores, if approved, the potential clinical utility of linzagolix and the opportunity to offer unique dosing options that could balance efficacy and safety across indications."

Details on the data presentations are provided below.

Linzagolix for the Treatment of Uterine Fibroids

The presentation titled "Long Term Efficacy of Linzagolix for Treatment of Heavy Menstrual Bleeding (HMB) due to Uterine Fibroids (UF): 52-Week Results from Two Placebo-Controlled, Randomized, Phase 3 Trials," is being presented by Dr. Hugh Taylor.

Summary of the data and key takeaway: Once daily doses of linzagolix 100 and 200 mg with and without ABT improved heavy menstrual bleeding (HMB) and other symptoms of uterine fibroids, including pain and Quality of Life, compared to placebo at 24 weeks and these improvements were maintained at 52 weeks.

HMB: Reductions observed at 24 weeks in all active treatment groups compared to placebo (p≤0.003).
Responder rates for menstrual blood loss (MBL):

	Placebo	100 mg	100 mg +ABT	200 mg	200 mg + ABT
MBL P1 at 24 weeks	35%	56%	67%	71%	75%
MBL P2 at 24 weeks	29%	57%	77%	78%	94%
MBL P1 at 52 weeks	39%	61%	91%	76%	86%
MBL P2 at 52 weeks	NA	53%	91%	85%	92%

Mean pain scores at 52 weeks: Reductions in mean pain scores of 2-4 were observed in all linzagolix groups compared to <1 in the placebo groups (p≤0.002).
Uterine volume at 52 weeks: Uterine volume was substantially decreased at 24 weeks by approximately 40% in the linzagolix 200 mg without ABT group but not in the other groups. Furthermore, after the addition of ABT in this group, uterine volumes increased again by 52 weeks.

The presentation titled "Long Term Safety and Tolerability of Linzagolix for Treatment of Heavy Menstrual Bleeding (HMB) due to Uterine Fibroids (UF): 52-Week Results from Two Placebo-Controlled, Randomized, Phase 3 Trials," is being presented by Dr. Jacques Donnez.

Summary of the data and key takeaway: Effects on safety and tolerability including hot flushes, BMD changes, serum lipid and liver transaminase increases, were consistent with the dose dependent suppression of serum estradiol and the presence or not of hormonal ABT.
Serum estradiol: Levels were suppressed below 20 pg/mL in the linzagolix 200 mg without ABT group and maintained between 20-60 pg/mL in the other linzagolix groups.

Mean lumbar spine percent BMD change from baseline: At 24 weeks BMD change ranged from 0–2% in all active treatment groups except 200 mg linzagolix (3–4%). At 52 weeks BMD change was 3.6% in P1 and 2.4% in P2 with linzagolix 100 mg; 1.3 in P1 and 2.0% in P2 with linzagolix 200 mg + ABT compared to 2.3% with placebo (P1 only).
Lipids and liver transaminases: There were minor elevations in lipids and rare increases in liver transaminases in the linzagolix groups; no specific signal for potential of drug-induced liver injury was identified.

Adverse Events (AE): The most common AE up to 52 weeks, were hot flushes, which was reported in 22% of subjects in the 200mg group and between 6% to 12% in the other linzagolix arms, compared to 8% in placebo subjects.

Linzagolix for the Treatment of Endometriosis

The presentation titled "Recovery of Bone Mineral Density (BMD) after Long Term Treatment with Linzagolix in Women with Endometriosis: Results from a Phase 2b Dose-Ranging Trial," is being presented by Dr. Jacques Donnez.

Summary of the data and key takeaway: Subjects remained within the age normalized range during and after treatment. Bone safety was demonstrated in the vast majority of subjects across all doses of linzagolix.

Mean lumbar spine percent BMD change from baseline: Once daily linzagolix for 52 weeks in patients with endometriosis was associated with dose-dependent changes in bone mineral density (BMD) of the lumbar spine at doses of 75 mg and above. Mean changes ranged from about -1% at 75mg to more than -2% at 200/100 mg and were reversed 6 months after stopping treatment.

	50 mg	75 mg	100 mg	200 mg
BMD at 24 weeks	0.14%	-0.8%	-1.4%	-2.6%
BMD at 52 weeks	0.14%	-1.1%	-1.4%	-2.2%
BMD after 6 months	1.3%	1.2%	0.2%	0%

At 52 weeks, the proportion of subjects with a BMD decrease >3% was 50% in the high dose group and <20% in the low dose groups (75 and 100 mg) and no subjects in any group had a BMD decrease >8%.

About Linzagolix

Linzagolix is a novel, once daily, oral GnRH receptor antagonist with a potentially best-in-class profile[1,2,3]. Linzagolix is the subject of submitted marketing authorization applications for the treatment of heavy menstrual bleeding associated with uterine fibroids and is currently in late-stage clinical development for the treatment of pain associated with endometriosis. Obseva licensed linzagolix from Kissei in late 2015 and retains worldwide commercial rights, excluding Asia, for the product. Linzagolix is not currently approved anywhere in the world.

About the Phase 3 PRIMROSE Program in Uterine Fibroids

PRIMROSE 1 & 2 were prospective, randomized, parallel group, double-blind, placebo-controlled Phase 3 studies that investigated the efficacy and safety of two dosing regimens of linzagolix, 100 mg and 200 mg once daily, alone and in combination with hormonal ABT (1 mg estradiol and 0.5 mg norethisterone acetate) for the treatment of heavy menstrual bleeding associated with uterine fibroids. PRIMROSE 1 was conducted in the United States and enrolled 574 women. PRIMROSE 2 was conducted in Europe and the United States and enrolled 535 women. Both trials comprised a 52-week treatment period followed by a 6-month post treatment follow-up period. Additional information can be found here. The primary efficacy endpoint was reduced MBL at 24 weeks (MBL ≤ 80 mL and ≥ 50% reduction from baseline). Other efficacy assessments included amenorrhea, hemoglobin, pain (0–10 numerical rating scale), uterine and fibroid volume, and quality of life. For additional information on this trial see clinicaltrials.gov [NCT03070899, NCT03070951]

About EDELWEISS

EDELWEISS, a Phase 2b, randomized, double blind, placebo controlled clinical trial was 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. Subjects originally randomized to placebo were switched to 100mg at 12 weeks and subjects randomized to 200mg were switched to 100mg at 24 weeks. Bone mineral density (BMD) was assessed using Dual Energy X-ray Absorptiometry (DXA) at baseline, after 24 and 52 weeks of treatment and 24 after stopping treatment. For additional information on this trial see clinicaltrials.gov [NCT02778399].

About Obseva

Obseva is a biopharmaceutical company built to address some of the most challenging unmet needs in women's health – an under-researched, under-invested field of medicine. With deep expertise in clinical development, Obseva is passionate about the pursuit of advances that benefit women and their health and the importance of delivering truly meaningful innovation in this space. Through strategic in-licensing and disciplined drug development, Obseva has established a late-stage clinical pipeline with development programs focused on new therapies for the treatment of uterine fibroids, endometriosis, and preterm labor. Obseva is listed on the Nasdaq Global Select Market and is traded under the ticker symbol "OBSV" and on the SIX Swiss Exchange where it is traded 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 is a new chemical entity discovered by Kissei R&D.

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 and potential therapeutic and clinical benefits of and commercialization plans for Obseva's product candidates, including linzagolix, expectations regarding regulatory and development milestones, including the Obseva's ability to obtain and maintain regulatory approvals for its product candidates, and the results of interactions with regulatory authorities, including the FDA and EMA. 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 that FDA's review of the linzagolix NDA may determine that the existing clinical data is insufficient to support approval or that significant labeling limitations would be required, 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, and the capabilities of such third parties; the impact of the ongoing 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, 2020 filed with Securities and Exchange Commission (SEC) on March 5, 2021 and in the Report on Form 6-K filed with the SEC on November 4, 2021, and other filings ObsEva makes with the SEC. These documents are available on the Investors page of Obseva's website at 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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