Obseva Announces U.S. FDA Acceptance of New Drug Application for Linzagolix

FDA Accepts NDA for Linzagolix for the Management of Heavy Menstrual Bleeding Associated with Uterine Fibroids

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

GENEVA, Switzerland November 22, 2021 – Obseva SA (NASDAQ: OBSV; SIX: OBSN), a biopharmaceutical company developing and commercializing novel therapies to improve women's reproductive health, today announced that the New Drug Application (NDA) for linzagolix for the management of heavy menstrual bleeding associated with uterine fibroids in premenopausal women has been accepted for review by the United States Food and Drug Administration (FDA). The submission is based on data from the two Phase 3 PRIMROSE trials. Linzagolix has a differentiated profile and if approved, would be the first and only GnRH receptor antagonist with flexible dosing options for uterine fibroids, including a low dose option to address the needs of women who cannot or do not want to take hormones.[1,4] The FDA set a target action date of September 13, 2022 for this NDA under the Prescription Drug User Fee Act (PDUFA).

"Today marks an important milestone not only in the linzagolix clinical development process, but for Obseva as a company, and most importantly, the millions of women living with uterine fibroids throughout the US. Linzagolix is a significant innovation in the field of women's health – an area that is consistently underinvested in – and we are incredibly excited about the potential of bringing this important treatment to market" said Brian O'Callaghan, CEO of Obseva. "We are encouraged by our positive Phase 3 PRIMROSE results. If approved, we believe linzagolix will address a significant unmet need in offering a more individualized treatment option for a broader range of women."

The Phase 3 PRIMROSE trials of linzagolix (PRIMROSE 1: US; n=574 and PRIMROSE 2: Europe and US; n=535) investigated the efficacy and safety of two dosing regimens, 100mg once daily and 200mg once daily, alone or 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. The NDA submission comprises positive 24-week treatment results from both studies, as well as supportive results from Week 52 and the 76-week post-treatment follow-up.

"Uterine fibroids can have a devastating impact on women's day-to-day life. With its unique dosing options, linzagolix has the potential to significantly advance medical options for women," stated Elizabeth Garner, MD, MPH, Chief Medical Officer of Obseva. "A dosing option without hormonal ABT would be welcomed by the significant number of women who either have contraindications to or a personal preference to avoid the use of estrogen-based therapies, while also providing a dosing option for women in whom hormonal ABT is indicated."

The linzagolix marketing authorization application (MAA) was validated by the European Medicine Agency (EMA) with an approval recommendation from the Committee for Medicinal Products for Human Use

(CHMP) expected in Q4 2021. Obseva announced previously that the company has entered into a partnership with Syneos Health to support commercialization of linzagolix in the US and EU.

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.

About Uterine Fibroids

Uterine fibroids are common benign tumors of the muscular tissue of the uterus which affect women of childbearing age and can vary in size from undetectable to large bulky masses. Few long-term medical treatments are available, and as a result, approximately 300,000 hysterectomies are performed for uterine fibroids every year in the US.

The symptoms of uterine fibroids are wide-ranging and include heavy menstrual bleeding, anemia, pelvic pressure and bloating, urinary frequency and pain that can be extremely debilitating with a significant impact on quality of life. These symptoms can also have an impact on mental health, creating the additional burden of anxiety and distress.

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 potential timing of and 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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