ObsEva Announces Positive CHMP Opinion for Linzagolix, an Oral GnRH Antagonist, for the Treatment of Uterine Fibroids

-European Commission Decision Anticipated in Q1 2022-

-CHMP recommendation follows the recent acceptance of the linzagolix uterine fibroids NDA by the U.S. Food and Drug Administration-

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

GENEVA, Switzerland December 17, 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 Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion recommending approval of linzagolix, an oral GnRH antagonist for the management of moderate to severe symptoms of uterine fibroids (UF) in adult women of reproductive age.

ObsEva's Marketing Authorisation Application submission was based on positive data from the Company's two Phase 3 PRIMROSE trials. If approved, linzagolix would be the first and only approved GnRH receptor antagonist with a non-hormonal option to address the needs of women who cannot or do not want to take hormones.

"The positive CHMP opinion is an important milestone for millions of women in the EU living with UF to address the diverse medical needs of the women who suffer from this condition," said Brian O'Callaghan, CEO of ObsEva. "We will continue our productive, ongoing dialogue with EMA toward potential marketing authorization in the EU, and in parallel, continue to work with the FDA to advance linzagolix through the U.S. regulatory process."

Jacques Donnez, M.D., Ph.D., a key opinion leader in gynecologic therapeutics commented, "While GnRH antagonists offer an exciting new, non-invasive alternative for the treatment of uterine fibroids, there is still the need for more individualized treatment options for the millions of women who may have a higher risk of contraindications to hormonal add-back therapy or ABT. If approved, linzagolix would be the only approved GnRH antagonist to provide flexible dosing options with and without hormonal ABTs to better address the individual needs of patients. Results from the PRIMROSE studies further underscore linzagolix's differentiated profile and potential clinical utility. Additionally, the strong results on the full suppression dose (200 mg) with ABT showed that linzagolix could potentially offer best-in-class efficacy."

The positive opinion adopted by the CHMP is based on 52-week treatment results from the Phase 3 PRIMROSE 1 (U.S. only; n=574) and PRIMROSE 2 (Europe and U.S.; n=535) clinical studies as well as supportive results from the 76-week post-treatment follow-up periods of both trials. Both studies evaluated full suppression (200 mg once daily) and partial suppression (100 mg once daily) doses of linzagolix, with and without hormonal add-back therapy (ABT).

PRIMROSE 1 and 2 successfully met their primary endpoints, with all doses showing statistically significant and clinically relevant reductions in heavy menstrual bleeding (HMB) compared to placebo. A number of important secondary endpoints were also met, including reduction in pain, rates of amenorrhea, time to

reduced HMB and amenorrhea, and for the high dose without ABT, reductions in uterine and fibroid volume.

A final marketing authorization decision from the EC is anticipated within two months. The CHMP's positive opinion follows the recent FDA acceptance for review of the uterine fibroids New Drug Application (NDA) (PDUFA date of September 13, 2022).

About Linzagolix

Linzagolix is a novel, once daily, oral GnRH receptor antagonist with a potentially best-in-class profile[1,2,3]. Linzagolix has completed clinical trial development 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. Uterine fibroids affect women of childbearing age and can vary in size from undetectable to large bulky masses. Few long-term medical treatments are available.

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 developing and commercializing novel therapies to improve women'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 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. 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 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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