ObsEva Announces Submission of New Drug Application to U.S. FDA for Linzagolix for the Treatment of Uterine Fibroids

-If approved, linzagolix will be the only GnRH antagonist with flexible dose regimen options to address the clinical needs of more women with uterine fibroids-

-NDA submission includes positive data from Phase 3 PRIMROSE trials up to 52 weeks on treatment and 24 weeks post-treatment follow-up results-

-EU MAA CHMP recommendation anticipated in Q4 2021-

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

GENEVA, Switzerland– September 15, 2021 – ObsEva SA (NASDAQ: OBSV) (SIX: OBSN), a biopharmaceutical company developing and commercializing novel therapies to improve women's reproductive health, today announced that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for linzagolix for the treatment of uterine fibroids. Linzagolix is an oral GnRH receptor antagonist with potential best-in-class efficacy, favorable tolerability profile, and unique and flexible dosing options. Further, if approved, linzagolix will be the only GnRH antagonist in uterine fibroids with a low dose non-add-back therapy (ABT) option.

The NDA submission includes the positive 52-week on treatment results from the Phase 3 PRIMROSE 1 (US only; n=574) and PRIMROSE 2 (Europe and US; n=535) clinical studies as well as supportive results from the 76-week post-treatment follow-up study. In both studies, patients with heavy menstrual bleeding (HMB) associated with uterine fibroids were administered linzagolix doses of 100 mg or 200 mg, with and without hormonal add-back-therapy (ABT; 1 mg estradiol/0.5 mg norethindrone acetate), or placebo. PRIMROSE 1 and 2 successfully met their primary endpoints, with all doses showing statistically significant and clinically relevant reductions in HMB compared to placebo.

"The NDA submission is a major milestone in making linzagolix available in the U.S., and an important step toward addressing the diverse medical needs that exist for women with uterine fibroids," said Brian O'Callaghan, CEO of ObsEva. "Our positive Phase 3 PRIMROSE results underscore linzagolix's clinical utility and well-known differentiated profile. If approved, linzagolix will be the first oral GnRH antagonist to offer treatment options for women who cannot or do not want to take hormones, as well as for women who are able to take additional hormone therapy. We look forward to overcoming existing challenges in the treatment of uterine fibroids -- with linzagolix's unique low-dose option (100 mg without ABT) and high dose option (200 mg with ABT) -- and will work with the FDA through the regulatory process as we prepare for commercialization."

Concurrently, ObsEva is also working closely with the European Medicine Agency's (EMA) to achieve marketing approval. Linzagolix previously received validation of the marketing authorization application (MAA) with an approval recommendation from the Committee for Medicinal Products for Human Use (CHMP) expected in Q4 2021.

About Linzagolix

Linzagolix is a novel, once daily, oral GnRH receptor antagonist with a potentially best-in-class profile. Linzagolix is currently in late-stage clinical development for the treatment of heavy menstrual bleeding associated with uterine fibroids and 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.

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, 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 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.

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 other similar expressions, and are based on ObsEva's current beliefs and expectations. These forward-looking statements include expectations regarding the clinical development of and commercialization plans for ObsEva's product candidates, ObsEva's ability to generate value, expectations regarding regulatory and development milestones, including the potential timing of regulatory submissions to the EMA and FDA 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, the impact of the 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 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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