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

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

GENEVA, Switzerland – April 25, 2022 – **ObsEva SA (NASDAQ: OBSV; SIX: OBSN),** a biopharmaceutical company developing and commercializing novel therapies for women's health, today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has confirmed its previously adopted positive opinion, recommending approval of linzagolix for the treatment of uterine fibroids (UF).

The positive CHMP opinion, which was initially adopted on December 16, 2021, was confirmed at the April 2022 CHMP meeting following further review of the linzagolix marketing authorization application. The European Commission (EC) will now review the CHMP recommendation. If approved by the EC, linzagolix will be the only approved oral GnRH antagonist to offer flexibility and choice for women suffering from UF, including the first and only approved non-hormonal dosing option to address the needs of millions of women with UF who cannot or do not want to take hormones. European Commission decisions are valid in the European Union Member States, as well as Iceland, Norway, and Liechtenstein.

ObsEva has entered into a licensing agreement with Theramex to support the commercialization and market introduction of linzagolix in Europe. Theramex's extensive women's health commercial infrastructure includes a dedicated sales force of more than 180 experienced representatives across Europe, Brazil, and Australia, alongside third-party distributors across approximately 60 countries in Europe, the Middle East and Africa, Asia-Pacific, and Latin America.

"European launch preparations are firmly underway as we look ahead to the anticipated approval of linzagolix. Theramex is a proven global leader in women's health with a track record of successful new product launches, making it ideally positioned to execute the launch of linzagolix in Europe. In parallel, preparations for the commercialization of linzagolix in the United States are advancing through our relationship with Syneos Health as we approach our PDUFA target action date in September. Together, these agreements are expected to maximize the market opportunity for linzagolix, which has the potential to be the first and only approved GnRH receptor antagonist for uterine fibroids with a dosing option free of hormonal add-back therapy," said Brian O'Callaghan, CEO of ObsEva.

In the United States, the New Drug Application for linzagolix is currently under review by the Food and Drug Administration (FDA), with a Prescription Drug User Fee Act (PDUFA) target action date of September 13, 2022. In October 2021, ObsEva announced a strategic relationship with Syneos Health to commercialize linzagolix within the United States.

About Linzagolix

Linzagolix is an investigational novel, once daily, oral GnRH receptor antagonist with a potentially best-in-class profile[1,2,3]. Linzagolix was developed to offer flexibility and choice to women suffering from uterine fibroids, with proposed dosing regimens alone and in combination with hormonal add-back therapy. For women with uterine fibroids for whom hormonal add-back therapy is appropriate, linzagolix has the potential to offer a best-in-class efficacy rate and tolerability profile. For women with uterine fibroids who

cannot or do not want to take hormones, linzagolix has the potential to be the first and only approved oral GnRH antagonist with a non-hormonal dosing option. Linzagolix has completed clinical trial development for the treatment of 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 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 Theramex

Theramex is a leading global speciality pharmaceutical company dedicated to women and their health. Theramex supports women at every stage of their lives by providing a broad portfolio of innovative and established brands covering contraception, fertility, menopause and osteoporosis. Theramex's commitment is to listen to and understand its patients, serve their needs and offer healthcare solutions to help improve their lives. Theramex's vision is to be a lifetime partner for women and the healthcare professionals who treat them by providing patient-focused and effective solutions that care for and support women through every stage of life.

About Syneos Health

Syneos Health® (Nasdaq: SYNH) is the only fully integrated biopharmaceutical solutions organization. The Company, including a Contract Research Organization (CRO) and Contract Commercial Organization (CCO), is purpose-built to accelerate customer performance to address modern market realities. Syneos Health brings together approximately 27,000 clinical and commercial minds with the ability to support customers in more than 110 countries. Together it shares insights, uses the latest technologies and applies advanced business practices to speed its customers' delivery of important therapies to patients. To learn more about how Syneos Health is **Shortening the distance from lab to life®**, visit syneoshealth.com or subscribe to its podcast.

About Kissei Pharmaceutical Co., Ltd.

Linzagolix has been discovered by Central Research Laboratories of Kissei Pharmaceutical Co., Ltd. Kissei is a Japanese pharmaceutical company based on the management philosophy "contributing to society through high-quality, innovative pharmaceutical products" and "serving society through our employees." As a strong R&D-oriented corporation, it concentrates on providing innovative pharmaceuticals to patients worldwide in the focus fields of urology, nephrology/dialysis, gynecology and rare/intractable diseases.

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 "anticipate", "believe", "continue", "could",

“estimate”, “expect”, “intend”, “may”, “might”, “ongoing”, “objective”, “plan”, “potential”, “predict”, “should”, “will”, “would”, or the negative of these and similar expressions, and are based on ObsEva’s current beliefs and expectations. These forward-looking statements include expectations regarding the potential approval of linzagolix by regulatory authorities, including the European Commission and the FDA, and the timing of such approval, the timing or results of interactions with regulatory authorities, clinical development of ObsEva’s product candidates, including the timing, advancement of, and potential therapeutic benefits of such product candidates, including linzagolix, the potential for linzagolix and other product candidates to be commercially competitive, the success of the Company’s partnerships with third parties, including Theramex and Syneos Health, expectations regarding regulatory and development milestones and ObsEva’s ability to obtain and maintain regulatory approvals for its product candidates. 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, including interactions with the EMA during the marketing authorization application process and with the FDA during the New Drug Application process for linzagolix, 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, 2021 filed with Securities and Exchange Commission (SEC) on March 10, 2022, 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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1. Stewart E, ASRM 2020; Late-breaker abstract P-930
2. Al-Hendy A, NEJM 2021; 384:630-42
3. Schlaff W, NEJM 2020; 382:328-40