

ObsEva Announces European Commission Marketing Authorization for Yselty® (linzagolix), an Oral GnRH Antagonist, for the Treatment of Uterine Fibroids

-Yselty® (linzagolix) is the first and only approved GnRH antagonist to provide flexible dosing options with and without hormonal add-back therapy-

-Theramex to commercialize Yselty®; ObsEva to receive royalties on commercial sales, as well as development, commercial, and sales-based milestone payments-

-In the United States, the New Drug Application (NDA) 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-

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

GENEVA, Switzerland – June 17, 2022 – ObsEva SA (NASDAQ: OBSV; SIX: OBSN), a biopharmaceutical company developing and commercializing novel therapies for women’s health, today announced that the European Commission (EC) has granted marketing authorization for Yselty® (linzagolix), an oral GnRH antagonist, for the management of moderate to severe symptoms of uterine fibroids (UF) in adult women (over 18 years of age) of reproductive age.

The EC decision follows confirmation of a positive opinion from the Committee for Medicinal Products for Human Use of the European Medicines Agency in April 2022, and is valid in all 27 European Union Member States, as well as Iceland, Norway, and Liechtenstein.

Yselty® is the only approved oral GnRH antagonist to offer flexible dosing options, with and without additional hormonal therapy, for women suffering from UF. For women with UF for whom hormonal add-back therapy (ABT, estradiol 1 mg and norethisterone acetate 0.5 mg) is appropriate, Yselty® offers a potentially best-in-class efficacy rate^{1,2,3} and favourable tolerability profile. For women with UF who cannot or do not want to take hormones, Yselty® is the first and only approved oral GnRH antagonist with a non-hormonal dosing option. Yselty® is approved in the EU at the following doses:

- 100 mg or 200 mg once daily with hormonal ABT, with no limitation in treatment duration
- 100 mg once daily for women in whom ABT is not recommended or who prefer to avoid hormonal therapy, with no limitation in treatment duration
- 200 mg once daily for short-term use (< 6 months) in clinical situations when reduction of uterine and fibroid volume is desired

The approval is based on positive data from the Company’s two Phase 3 PRIMROSE trials. The pooled week 24 data from these studies support a potentially best-in-class profile, with a responder rate of 84.5% in women receiving linzagolix 200 mg with hormonal ABT, and 56.5% in women receiving linzagolix 100 mg without ABT.

“As the first and only approved GnRH antagonist to provide flexible dosing options with and without hormonal add-back therapy, Yselty® has the potential to transform the treatment paradigm and significantly advance medical options for women in the EU with uterine fibroids,” said Dr. Brandi Howard, Chief Clinical Officer of ObsEva. “We are pleased to be the first to provide women and doctors with a non-hormonal dosing option for the millions of women who either have contraindications to or a personal

preference to avoid the use of hormonal add-back therapy, while also providing dosing options for women for whom hormonal add-back therapy is appropriate.”

Brian O’Callaghan, CEO of ObsEva, commented, “Our first approval marks a major milestone for ObsEva and further validates our work to address one of the most challenging unmet needs facing women. As we transition to a commercial stage company, our agreement with Theramex provides a strong foundation to realize the potential for linzagolix across key markets, and we look forward to commercial launch in Europe.”

In February 2022, ObsEva entered into a strategic licensing agreement with Theramex, a global leader in women’s health, to support the commercialization and market introduction of linzagolix across international markets outside of the U.S., Canada, and Asia. Under the terms of the agreement, ObsEva is entitled to receive royalties of a mid-thirties percentage on commercial sales, which includes the cost of goods sold to Theramex. Furthermore, the agreement contains up to EUR72.75 million in upfront and milestone payments, including up to EUR13.75 million in development and commercial milestones and up to EUR54 million in sales-based milestones.

The NDA for linzagolix in the U.S. is currently under review by the FDA, with a PDUFA target action date of September 13, 2022.

About Yselty® (linzagolix)

Linzagolix is a novel, once daily, oral GnRH receptor antagonist with a potentially best-in-class profile^{1,2,3}. Linzagolix was developed to offer flexible dosing options with and without hormonal add-back therapy to women suffering from uterine fibroids, and is approved in the EU. 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 favourable tolerability profile. For women with uterine fibroids who cannot or do not want to take hormones, linzagolix is the first and only approved oral GnRH antagonist with a non-hormonal dosing option in the EU. ObsEva licensed linzagolix from Kissei in late 2015 and retains worldwide commercial rights, excluding Asia, for the product. Linzagolix is currently under review by the FDA, with a PDUFA target action date of September 13, 2022.

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 United States.

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. The Company’s first, just recently approved drug is Yselty®

(linzagolix), a once daily, oral GnRH receptor antagonist that was developed to offer flexible dosing options to women suffering from uterine fibroids, and is approved in the EU. 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 Kissei

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 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, expectations regarding commercial launch of linzagolix, the success of the Company's partnerships with third parties and the amount of potential payments the Company may earn pursuant to such partnerships, including with Theramex, 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 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 geopolitical events, 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, in the Report on Form 6-K filed with the SEC on May 17, 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, except as required by law, 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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