

**ObsEva Announces UK MHRA 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-*

*-Approval by MHRA follows the European Commission's marketing authorization, granted in June 2022-*

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

**GENEVA, Switzerland – June 28, 2022 – ObsEva SA (NASDAQ: OBSV; SIX: OBSN)**, a biopharmaceutical company developing and commercializing novel therapies for women's health, today announced that the UK Medicines and Healthcare Products Regulatory Agency (MHRA) 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. Yselty® is the only approved oral GnRH antagonist to offer flexible dosing options, with and without additional hormonal therapy, for women suffering from UF.

The MHRA approval follows the granting of marketing authorization by the European Commission earlier in June 2022.

Yselty® offers a potentially best-in-class efficacy rate<sup>1,2,3</sup> and favorable tolerability profile for women with UF for whom hormonal add-back therapy (ABT, estradiol 1 mg and norethisterone acetate 0.5 mg) is appropriate. 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.

"We are pleased to announce our second regulatory approval for Yselty®. As the first and only approved GnRH antagonist to offer flexible dosing options with and without additional hormonal therapy, we hope to redefine care for women suffering from uterine fibroids. We are excited to commercialize Yselty® in Great Britain and advance medical options for women suffering from this chronic and debilitating disease with our partner Theramex, a global leader in women's health," said Brian O'Callaghan, CEO of ObsEva.

Consistent with the EU approval, Yselty® is approved in Great Britain 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

In February 2022, ObsEva entered into a strategic licensing agreement with Theramex to support the commercialization and market introduction of linzagolix across international markets outside of the U.S., Canada, and Asia.

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<sup>1,2,3</sup>. 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 and Great Britain. 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 favorable 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 and Great Britain. 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 and Great Britain. 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](http://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](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, 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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