

## **ObsEva Provides Update on EU Marketing Authorisation Process 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 – February 4, 2022 – ObsEva SA (NASDAQ: OBSV; SIX: OBSN)**, a biopharmaceutical company developing and commercializing novel therapies for women’s health, today announced that based on ongoing communications with the European Medicines Agency (EMA), further questions on the marketing authorisation application for linzagolix may be forthcoming, thereby extending the application timeline. ObsEva is in dialogue with the EMA to understand areas that may require further clarification and is committed to promptly addressing any questions that could arise.

In the United States, the New Drug Application for linzagolix for the treatment of uterine fibroids has been accepted for review by the United States Food and Drug Administration (FDA), with a PDUFA target action date of September 13, 2022.

### **About Linzagolix**

Linzagolix is a novel, once daily, oral GnRH receptor antagonist with a potentially best-in-class profile<sup>1,2,3</sup>. 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](http://www.ObsEva.com)

### **About 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 “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 extension of the application timeline with

the EMA for linzagolix, the timing or results of interactions with regulatory authorities, the FDA target action date for linzagolix, clinical development of ObsEva's product candidates, including the timing, advancement of, and potential therapeutic benefits of such product candidates, the potential for such product candidates to be commercially competitive, 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. 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, 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](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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