

ObsEva Announces Corporate Updates

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

GENEVA, Switzerland – July 27, 2022 – ObsEva SA (NASDAQ: OBSV; SIX: OBSN), a biopharmaceutical company developing novel therapies for women's health, today announced that it plans to initiate a corporate restructuring and refocus the Company's development and commercialization strategy. ObsEva believes the changes are necessary due to the commercial landscape and potential additional capital needed to fund the completion of the linzagolix clinical development program, as the U.S. Food and Drug Administration (FDA) has notified the Company of review issues regarding deficiencies in the New Drug Application (NDA) for linzagolix for uterine fibroids. These review issues preclude discussion of labeling and post-marketing commitments at this time. While ObsEva continues to engage in communications with the FDA, including submission of documentation as well as a plan for the provision of additional data addressing the deficiencies, the Company believes that resolution of the identified review issues may not be feasible by the September 13, 2022 target action date under the Prescription Drug User Fee Act (PDUFA). The FDA's review of the NDA is still ongoing and ObsEva has not been informed of any final decision by the agency.

Based on this assessment, ObsEva's Board of Directors has decided to undertake the following actions:

- Termination of the license agreement with Kissei for linzagolix;
- Planned corporate restructuring to resize the Company to be able to meet ObsEva's other license obligations and assess strategic options with respect to pipeline development;
- Application to the Swiss court for a moratorium to facilitate the planned restructuring.

In consideration of the cost of ongoing development and the competitive impact of a potential delay in approval of linzagolix for uterine fibroids by the FDA, ObsEva has decided to terminate the license agreement with Kissei for linzagolix. Termination of the linzagolix license agreement will cause ObsEva's licensing agreement with Theramex for linzagolix to be assigned to Kissei. Linzagolix was granted marketing authorization for the management of moderate to severe symptoms of uterine fibroids in reproductive age women over 18 years old by each of the European Commission and the UK Medicines and Healthcare Products Regulatory Agency in June 2022.

ObsEva intends to restructure its operations to support existing license agreements, namely its global license agreement with Organon for the development and commercialization of ebopiprant and its sublicense agreement with Yuyuan BioScience for the development and commercialization of nolasiban in the People's Republic of China. In addition, ObsEva will assess strategic options with respect to pipeline development and the worldwide rights it holds for nolasiban, excluding China.

Based on an evaluation of the Company's current assets and liabilities and cash runway, ObsEva's Board of Directors has decided to apply to the competent court in Geneva, Switzerland, for a court-sanctioned moratorium. If granted, the moratorium will provide the Company with temporary protection against debt-enforcement and bankruptcy proceedings in Switzerland, with a view to make it possible for the Company to undertake restructuring measures under the supervision of one or more court-appointed administrators.



Consistent with ObsEva's plans to restructure its operations, ObsEva will initiate a mass dismissal process, pursuant to Swiss law. A final decision on the extent of the restructuring will be taken following a consultation process with the Company's employees.

Ebopiprant License Agreement with Organon

Under the license agreement with Organon for ebopiprant, ObsEva is entitled to receive tiered doubledigit royalties on commercial sales, up to \$90 million in development and regulatory milestone payments, and up to \$385 million in sales-based milestone payments. Upon execution of the agreement, ObsEva received a \$25 million upfront payment. Ebopiprant is an investigational, orally active, selective prostaglandin F2 α receptor antagonist being evaluated as a potential treatment for preterm labor by reducing inflammation and uterine contractions.

Nolasiban Sublicense Agreement with Yuyuan BioScience

Under the sublicense agreement with Yuyuan BioScience for nolasiban, ObsEva is entitled to receive aggregate milestone payments of up to \$17 million upon the achievement of specified development, regulatory, and first sales milestones, and aggregate milestone payments of up to \$115 million upon the achievement of additional, tiered sales milestones. In addition, Yuyuan BioScience has agreed to pay tiered royalties on net sales at percentages ranging from high-single digit to low-second digits. Nolasiban is a novel, oral oxytocin receptor antagonist being developed for improving clinical pregnancy and live birth rates in women undergoing in vitro fertilization.

About ObsEva

ObsEva is a biopharmaceutical company developing novel therapies to improve women's reproductive health and pregnancy. Through strategic in-licensing and disciplined drug development, ObsEva has established a clinical pipeline with development programs focused on new therapies for the treatment of preterm labor and improving clinical pregnancy and live birth rates in women undergoing in vitro fertilization. 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 <u>www.ObsEva.com</u>

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, including addressing deficiencies in the NDA for linzagolix, plans to submit additional data for the NDA for linzagolix, and the potential timing to address or resolve such deficiencies, the need for additional capital to fund the completion of the linzagolix clinical development program, potential benefits, if any, resulting from ObsEva's filing for a court-sanctioned moratorium and the effects of such moratorium, ObsEva's plans for, and ability to implement successfully, the restructuring of its operations and to refocus the Company's development and commercialization



strategy, the termination of ObsEva's license agreement with Kissei, the effects of such termination and the ability of ObsEva and Kissei to cooperate successfully on the completion of the extension studies currently underway 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 linzagolix and other product candidates to be commercially competitive, 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 Organon and Yuyuan BioScience, 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 in the outcome and potential impact of the courtsanctioned moratorium, including with respect to ObsEva's agreements with third parties, in ObsEva's ability to successfully restructure its operations and refocus the Company's development and commercialization strategy, and to cooperate with Kissei or other third parties on the completion of the linzagolix extension studies, 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 forwardlooking statements, whether as a result of new information, future events or otherwise.

For further information, please contact: CEO Administrative Contact Shauna Dillon shauna.dillon@obseva.ch +41 22 552 1550

Investor Contact Katja Buhrer <u>katja.buhrer@obseva.com</u> +1 (917) 969-3438

Media Contact Jeanene Timberlake RooneyPartners jtimberlake@rooneypartners.com +1 (646) 770-8858