

## ObsEva Provides Business Outlook for 2021

**GENEVA, Switzerland and BOSTON, MA (February 10, 2021) – ObsEva SA (NASDAQ: OBSV; SIX: OBSN)**, a biopharmaceutical company developing and commercializing novel therapies to improve women’s reproductive health, today provided a corporate update, including its roadmap for advancing its clinical programs in 2021.

“We made significant progress across all aspects of the company in 2020, most significantly preparing Yselty® for uterine fibroids for regulatory approval with a filed and validated European marketing authorization application and an upcoming planned new drug application in the US,” said Brian O’Callaghan, CEO of ObsEva. “Meanwhile our other pipeline programs have continued to advance through development as evidenced by the recent exciting topline results from the PROLONG Phase 2a proof-of concept study of ebopiprant which, to our knowledge, is the only candidate drug in active development that has the potential to delay delivery in women with spontaneous preterm labor.”

“While we remain committed to advancing our clinical development programs in women’s health, we are equally excited about our potential to extend into new indications that address important unmet needs in other therapeutic areas,” continued Mr. O’Callaghan. “As an example, we believe that linzagolix in combination with estrogen could potentially challenge the current standard of care as the best-in-class oral GnRH antagonist for the treatment of advanced prostate cancer. Recent M&A and partnering activity in the women’s reproductive health and prostate cancer landscape underscores the potential of these currently underserved patient populations as well as the importance of retaining, rather than relinquishing, the inherent value of our assets. As we approach multiple catalysts in 2021, we will continue to seek opportunities and partnerships that preserve our control and maximize the value of our pipeline candidates.”

### Key 2021 Objectives

- **Yselty® for uterine fibroids:** NDA submission (Q2:21); MAA approval (Q4:21)
- **Yselty® for endometriosis:** Phase 3 EDELWEISS 3 primary endpoint readout (Q4:21)
- **Ebopiprant for treatment of preterm labor:** Phase 2b dose ranging study initiation in EU/Asia (Q4:21)

### Clinical Development Details

#### Yselty® for Uterine Fibroids

ObsEva is developing Yselty®, an oral GnRH receptor antagonist with the potential to treat more women thanks to its potential best-in-class efficacy, a favorable tolerability profile and unique, flexible dosing options for the treatment of uterine fibroids. Following the European Medicine Agency’s (EMA) recent validation of the marketing authorization application (MAA), a major milestone toward making Yselty® available in the E.U., the Company will continue to work closely with the EMA to achieve marketing approval, projected in Q4:2021.

The second key objective for 2021 will be to submit a U.S. New Drug Application (NDA), projected in Q2:2021, that will include the Week 76 post-treatment follow-up results from the Phase 3 PRIMROSE 1

(US only; n=574) and PRIMROSE 2 (Europe and US; n=535) clinical studies. In both studies, patients with heavy menstrual bleeding (HMB) associated with uterine fibroids were administered Yselyt doses of 100 mg or 200 mg, with and without hormonal add-back-therapy (ABT; 1 mg estradiol(E2)/0.5 mg norethisterone acetate (NETA) or placebo. Additional information about these studies can be found [here](#).

“Uterine fibroids impact an estimated 9 million women in the U.S. However, as the medical needs of each woman vary, we need more individualized treatment options,” said Ayman Al-Hendy, M.D., Ph.D., Distinguished Professor of Obstetrics and Gynecology at the University of Chicago Division of the Biological Sciences. “Of the millions of women with symptomatic uterine fibroids, the majority are African American, a population with higher risk of contraindications to hormonal add-back-therapy (ABT). According to the CDC, approximately 57% of non-Hispanic African American women have obesity, which is specified in oral GnRH antagonist labeling as a risk factor for venous thromboembolism when used with add-back therapy for treatment of fibroids. In addition, when preparing for surgical intervention in women with the most severe fibroids, there is often a need for rapid uterine and fibroid volume reduction, which is best achieved using short-term high-dose treatment without ABT. The PRIMROSE studies demonstrated the potential of Yselyt®’s unique non-ABT options (100 mg and 200 mg without ABT) to address these needs. Furthermore, the strong results on the full suppression dose (200 mg) with ABT showed that Yselyt® could potentially offer best-in-class efficacy. ObsEva’s dedication to addressing the unique needs of the diverse uterine fibroids population is welcomed and encouraging.”

### **Yselyt® for Endometriosis**

The EDELWEISS 3 trial in the EU is progressing as planned, with primary endpoint data expected in Q4: 2021. The ongoing Phase 3 EDELWEISS 3 study (Europe and US) was designed to enroll approximately 450 patients with endometriosis-associated pain, with a co-primary endpoint of response on both dysmenorrhea (menstrual pain) and non-menstrual pelvic pain. The study includes a 75 mg once-daily dose without hormonal ABT, and a 200 mg once-daily dose in combination with hormonal ABT (1 mg E2 / 0.5mg NETA). Subjects who completed the initial six-month treatment period will have the option to enter a six-month treatment extension. Additional information about this study can be found [here](#).

[As previously announced](#), the EDELWEISS 2 (US-only) study was recently discontinued due to challenges with screening and enrollment. ObsEva remains strongly committed to developing linzagolix for endometriosis, for which better long-term treatments are still needed. The Company plans to conduct a new Phase 3 endometriosis study with a number of design and operational adjustments to facilitate faster enrollment, with a goal to maintain the original MAA and NDA filing timelines for this important indication.

### **Ebopiprant (OBE022) for Treatment of Preterm Labor**

A key objective for 2021 will be to initiate the Phase 2b program, which will build on the [recently announced](#) positive topline data from the PROLONG Phase 2a proof-of-concept study by initiating a late-stage clinical development program. Based on the unmet need, ebopiprant’s innovative mechanism of action and positive topline data regarding early clinical efficacy and safety in pregnant women with spontaneous preterm labor, and with no other known compound under development for this indication, the Company plans to discuss with European regulators a possible accelerated registration program based on a Phase 2b/3 adaptively designed trial. ObsEva is also engaging with key opinion leaders and plan to meet with the FDA in 1H2021 to discuss the development program in the US.

As previously described, delaying delivery by at least 48 hours in women with active preterm labor is critical for new treatments, as it allows for the maximum effect of corticosteroids administered to the mother for neonatal lung maturation and buys time for the mother to be transferred to a hospital with neonatal intensive care facilities with the expertise to manage the baby in case preterm delivery occurs.

In the PROLONG study, ebopirant plus atosiban substantially reduced delivery at 48 hours after initiation of dosing by 43% compared to atosiban alone, with 12.5% of women (including women with twin gestations) receiving ebopirant plus atosiban delivering within 48 hours of starting treatment, compared to 21.8% receiving atosiban alone (OR 90% CI: 0.52 (0.22, 1.23)). In singleton pregnancies, 12.5% of women receiving ebopirant plus atosiban delivered within 48 hours compared to 26.8% receiving atosiban only (OR 90% CI: 0.39 (0.15, 1.04)). A modest overall effect on delivery at seven days was observed in singletons; however, there was a more pronounced effect in 24-to-30-week gestations, with 23.8% versus 14.3% of women delivering within 7 days in the atosiban alone and ebopirant plus atosiban arms, respectively (OR 90% CI: 0.53 (0.14, 2.01)). The incidence of maternal, fetal, and neonatal adverse events was comparable between the ebopirant group and placebo groups. Additional information about this study can be found [here](#).

“Preterm birth rates are on the rise, yet there is no available FDA-approved treatment for preterm labor in the US. Women continue to face treatment options with limited efficacy or restrictive safety issues, and in this context the results from the Phase 2 ObsEva PROLONG study are very encouraging,” said George Saade, M.D., Professor of Obstetrics and Gynecology, Director of the Maternal-Fetal Medicine Division, as well as the Chief of Obstetrics at the University of Texas Medical Branch in Galveston. “The recently announced positive Phase 2a data demonstrated ebopirant’s ability to reduce premature delivery within the critical timepoint of 48 hours, while potentially avoiding the serious maternal and fetal side effects associated with non-specific prostaglandin synthesis inhibitors and other medications currently used in women with preterm labor. I commend the company for taking a leadership role in addressing this longstanding serious unmet need.”

### **Nolasiban for In Vitro Fertilization**

ObsEva is also developing nolasiban, an oral oxytocin receptor antagonist, to improve live birth rates in women undergoing *in vitro* fertilization. Additional information about this study can be found [here](#).

### **Business Update and Financial Guidance**

The Company plans to report its fourth quarter and full-year 2020 financial results in March.

David Renas, CFO of ObsEva, commented, “Since joining ObsEva, I can confirm that our team has been highly focused on maximizing the value of the company’s existing portfolio, including leveraging external assistance and securing new sources of funding, both equity and non-dilutive. Though our upcoming development and commercialization initiatives will require a variety of external support and financial resources, we are optimistic that the company’s unique product pipeline and a high level of talent will present a winning combination as we focus on this year’s objectives and beyond.”

### **About Yselty®**

Yselty® (linzagolix, previously known as OBE2109) is a novel, oral, once daily, GnRH receptor antagonist with a potentially best-in-class profile. Yselty is currently in late-stage clinical development for the treatment of heavy menstrual bleeding associated with uterine fibroids and pain associated with

endometriosis. ObsEva licensed Yselty from Kissei in late 2015 and retains worldwide commercial rights, excluding Asia, for the product. Yselty® is a registered trademark owned by Kissei for use by ObsEva. Yselty® is not yet approved for use anywhere in the world.

### **About Ebopiprant and PGF<sub>2α</sub>**

ObsEva is developing ebopiprant, a potential first-in-class, once daily, oral and selective prostaglandin F<sub>2α</sub> receptor antagonist, which is designed to control preterm labor by reducing inflammation, decreasing uterine contractions, preventing cervical changes and fetal membrane rupture without causing the potentially serious side effects to the fetus seen with non-specific prostaglandin synthesis inhibitors (NSAIDs). PGF<sub>2α</sub> is believed to induce contractions of the myometrium and also upregulate enzymes causing cervix dilation and membrane rupture. In nonclinical studies, ObsEva has observed that ebopiprant markedly reduces spontaneous and induced uterine contractions in pregnant rats without causing the fetal side effects seen with non-specific prostaglandin inhibitors such as indomethacin.

Ebopiprant (OBE022) was licensed from Merck KGaA, Darmstadt, Germany, in 2015. ObsEva retains worldwide, exclusive, commercial rights.

### **About Nolasiban**

Nolasiban (previously known as OBE001), is an oral oxytocin receptor antagonist which was licensed from Merck KGaA, Darmstadt, Germany, in 2013. ObsEva retains worldwide, exclusive, commercial rights (ex China).

### **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 treating endometriosis, uterine fibroids and preterm labor. ObsEva is listed on the Nasdaq Global Select Market and is trading under the ticker symbol "OBSV" and on the SIX Swiss Exchange where it is trading under the ticker symbol "OBSN". For more information, please visit [www.ObsEva.com](http://www.ObsEva.com).

### **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 other similar expressions, and are based on ObsEva's current beliefs and expectations. These forward-looking statements include expectations regarding the potential therapeutic benefits and the clinical development of ObsEva's product candidates, the potential for new indications for any of ObsEva's product candidates, the timing of enrollment in and data from clinical trials, expectations regarding regulatory and development milestones, including the potential timing of regulatory submissions to the EMA and FDA, the timing of and ObsEva's ability to obtain and maintain regulatory approvals for its product candidates and the results of interactions with regulatory authorities. 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, ObsEva's reliance on third parties over which it may not always have full control, the impact of the 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, 2019, the Risk Factors disclosed in ObsEva's Report on Form 6-K filed with the Securities and Exchange Commission (SEC) on November 5, 2020 and other filings ObsEva makes with the SEC. These documents are available on the Investors page of ObsEva's website at <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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