

ObsEva Presents PROLONG Phase 2a Proof-of-Concept Data on Ebopiprant (OBE022) for the Treatment of Spontaneous Preterm Labor at the RCOG Virtual World Congress 2021

-PROLONG data demonstrating ebopiprant was well tolerated and showed early evidence of efficacy selected for presentation-

- Phase 2b/3 adaptive dose-ranging study planned to initiate in Q4:21-

GENEVA, Switzerland and BOSTON, MA – June 10, 2021 – ObsEva SA (NASDAQ: OBSV) (SIX: OBSN), a biopharmaceutical company developing and commercializing novel therapies to improve women's reproductive health, today announced the presentation of clinical data from the PROLONG Phase 2a proof-of-concept study of ebopiprant for the treatment of spontaneous preterm labor at the Royal College of Obstetricians and Gynecologists (RCOG) Virtual World Congress 2021. As previously disclosed, the PROLONG data demonstrated that ebopiprant was well tolerated and showed early evidence of efficacy in pregnant women with spontaneous preterm labor and supports the advancement into a Phase 2b/3 adaptive study.

"We are encouraged by the positive data generated to date, highlighting the unique mechanism of action and the potential clinical benefit of ebopiprant for the treatment of preterm labor to reduce the incidence of preterm birth," said Ben Mol, Ph.D., M.D., Professor of Obstetrics and Gynaecology, Monash Medical Centre, Melbourne Australia and a leading Key Opinion Leader in preterm labor therapeutics. "A key objective in the treatment of preterm labor is to delay delivery for at least 48 hours, as this allows for the transfer of women to centers with neonatal intensive care facilities and for the peak effect of corticosteroids given to accelerate fetal lung maturation. Building on the effects seen at 48 hours and in earlier gestations at 7 days, the next clinical study will explore a range of doses to fully define and optimize the full therapeutic potential of ebopiprant. We look forward to leveraging important learnings from PROLONG in this next phase of development."

"These positive data play a critical role in our development plans for ebopiprant, and we are excited to build on this momentum," said Brian O'Callaghan, CEO of ObsEva. "Preparations are ongoing to initiate a Phase 2b/3 clinical study in Q4:21. We believe this adaptive study has the potential to support an accelerated registration program in Europe, and we look forward to providing additional updates on our progress later this year. We also plan to engage the FDA in discussions regarding the US clinical program for ebopiprant. With no other known compounds under development for the treatment of preterm labor, ebopiprant has the potential to be an important advancement in the prevention of preterm birth."

The abstract, titled "A Randomised, Placebo-Controlled, Proof-of-Concept Trial of Ebopiprant for Spontaneous Preterm Labor (PROLONG)," will be presented today during an oral session by Dr. Ben Mol (Abstract #601).



Summary of the data:

- Ebopiprant, when administered with atosiban infusion to women with preterm labor, reduced delivery in singleton pregnancies at 48 hours after the start of dosing by over 50% compared to atosiban alone.
- Overall, 7/56 (12.5%) of women receiving ebopiprant on top of atosiban delivered within 48 hours of starting treatment compared to 12/55 (21.8%) receiving atosiban plus placebo (OR 90% CI: 0.52 (0.22, 1.23)).
- In singleton pregnancies, 5/40 (12.5%) of women receiving ebopiprant plus atosiban delivered within 48 hours compared to 11/41 (26.8%) receiving atosiban plus placebo (OR 90% CI: 0.39 (0.15, 1.04)).
- This difference was observed for singletons (12.5% vs 26.8%) but not for twins (12.5% vs 7.1%).
- The treatment effect for the overall population was more modest at 7 days, however in younger gestational ages, the percentage of women who delivered within 7 days was lower in women receiving ebopiprant on top of atosiban (23.8%) compared to women who received placebo plus atosiban (14.3%) (OR 90% CI: 0.53 (0.14, 2.01)).
- The incidence of maternal, fetal and neonatal adverse events was comparable between the treatment groups.

The presentation is available through the RCOG conference portal, and the link to the session is also available under the "Events Calendar" in the Investors section of ObsEva's website at <u>www.ObsEva.com</u>

About PROLONG

The randomized, double-blind, placebo-controlled, parallel-group trial was designed to assess the efficacy, safety and pharmacokinetics of ebopiprant. In this study, 113 women (83 singletons, 30 twins) with spontaneous preterm labor (gestational age between 24 and 34 weeks) were randomized and treated with atosiban (ex-U.S. standard of care) plus ebopiprant or atosiban plus placebo for 7 days. There were 83 (73%) women with singleton pregnancies and 30 (27%) with twin pregnancies. One hundred and forty-one neonates were born. Ebopiprant or placebo was administered orally, with 1000 mg as a starting dose (within 24 hours after starting the atosiban infusion), then 500 mg twice a day for 7 days. Women were assessed up to 14 days (unless delivery occurred sooner) and then again at delivery and up to 28 days after delivery. Follow-up of infants at 6, 12 and 24 months after birth. The efficacy endpoints assessed were delivery within 48 hours of starting treatment, delivery within 7 days of starting treatment, delivery before 37 weeks of gestation, and time to delivery. Safety assessments included maternal, fetal and neonatal safety. Infants are being followed-up at 6, 12 and 24 months. For additional information on this trial (NCT03369262), please visit www.clinicaltrials.gov.

About Ebopiprant and $PGF_{2\alpha}$

ObsEva is developing ebopiprant, a potential first-in-class, once daily, oral and selective prostaglandin $F_{2\alpha}$ 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_{2α} 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 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 "OBSV".

About RCOG

The RCOG is a medical charity that champions the provision of high-quality women's healthcare in the UK and beyond. It is dedicated to encouraging the study and advancing the science and practice of obstetrics and gynaecology. It does this through postgraduate medical education and training and the publication of clinical guidelines and reports on aspects of the specialty and service provision. If you would like to request a Press pass to the congress please email pressoffice@rcog.org.uk.

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 clinical development of and commercialization plans for ObsEva's product candidates, 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, 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 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 other filings ObsEva makes with the SEC. These



documents are available on the Investors page of ObsEva's website at <u>http://www.ObsEva.com</u>. 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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