ObsEva SA Reports Positive Topline Results of the PROLONG Proof-of-Concept Trial of Ebopiprant (OBE022) for Treatment of Preterm Labor

- Over 50% reduction of pre-term delivery within 48hrs of treatment in singleton pregnancy
- Maternal, fetal and neonatal safety comparable to placebo
- Data supports advancement of ebopiprant to Phase 2b dose range finding

Geneva, Switzerland and Boston, MA – 16 November 2020 – ObsEva SA (NASDAQ: OBSV / SIX: OBSN), a clinical-stage biopharmaceutical company developing and commercializing novel therapies to improve women's reproductive health today announced the positive topline results of PROLONG, the Phase 2a proof-of-concept, randomized, double-blind, placebo-controlled trial of ebopiprant in preterm labor. Ebopiprant is a new, first in class, orally active, selective prostaglandin $F_{2\alpha}$ ($PGF_{2\alpha}$), receptor antagonist designed to treat preterm labor by reducing uterine contractions and cervical maturation while avoiding the adverse neonatal side-effects associated with non-specific prostaglandin inhibitors such as Indomethacin.

One of the key objectives in reducing the mortality and morbidity associated with preterm birth is delaying delivery for at least 48 hours thereby allowing for the administration and the full effect of critical drugs that induce lung maturation and neural protection for the neonate

"Assessing the therapeutic potential of a new chemical entity in pregnant women is a major challenge and I would like to thank the participating patients and congratulate our team for successfully completing this unique study. Today, no approved options are available in the United States for treatment of women with preterm labor. The encouraging PROLONG results offer new hope for these women and their babies. Furthermore, the results support the potential for improving the standard of care in Europe and Asia." said Ernest Loumaye, co-founder and Chief Executive Officer of ObsEva. "*Building on the strong effect seen at 48 hours, the Phase 2b dose range finding, including testing of higher doses, will allow us to more fully define this product's potential and the longer-term benefits for babies."*

In this study, 113 women 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.

In the PROLONG study, ebopiprant reduced delivery in singleton pregnancies at 48 hours after the start of dosing by 55% compared to atosiban alone. Overall, 7/56 (12.5%) of women receiving ebopiprant delivered within 48 hours of starting treatment compared to 12/55 (21.8%) receiving placebo (OR 90% CI: 0.52 (0.22, 1.23)). In singleton pregnancies, 5/40 (12.5%) of women receiving ebopiprant delivered

within 48 hours compared to 11/41 (26.8%) receiving placebo (OR 90% CI: 0.39 (0.15, 1.04)). A modest effect on delivery at 7 days was seen in the singletons.

The incidence of maternal, fetal and neonatal adverse events were comparable between subjects in the ebopiprant group and the placebo group.

"We desperately need new medical treatments for preterm labor to reduce the incidence of preterm birth, which accounts for about 10% of all births." said Professor Ben Mol, Professor of Obstetrics and Gynecology, Monash University, Australia. *"The development of ebopiprant is exciting and the results of PROLONG are promising. A delay of delivery by 48 hours is extremely important as this allows transfer of women to a center with neonatal intensive care facilities, and it allows corticosteroids administered to the mother to have maximal effectiveness for the baby."*

About PROLONG

PROLONG is a proof-of-concept Phase 2a clinical trial conducted in two parts: Part A and Part B.

Part A was an open-label single arm trial of ebopiprant administered orally for 7 days to pregnant women with nine subjects enrolled. Ebopiprant was well tolerated by the mothers and their fetuses and the pharmacokinetics of ebopiprant were similar to those previously observed in non-pregnant women.

Today we are reporting results from PROLONG Part B, which is a randomized, double-blind, placebo-controlled, parallel-group trial to assess the efficacy, safety and pharmacokinetics of ebopiprant. Subjects were pregnant women presenting with spontaneous threatened preterm labor between gestational ages of 24 to 34 weeks. To be enrolled, women had to have at least 4 uterine contractions over 30 minutes, and cervical dilatation of 1 to 4 cm, and at least one other symptom of preterm labor from cervical length ≤ 25 mm, or progressive cervical change, or a positive test of preterm labor (e.g. fetal fibronectin). Furthermore, they had to have been prescribed the standard-of-care therapy for preterm labor, atosiban infusion for 48 hours.

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. The 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 is continuing and results will be available in 2021 and 2022. The efficacy endpoints were delivery within 48 h 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.

To access the PROLONG presentation directly, please click [here].
To access the investor presentation section of the Company's website, please click [here].

About Preterm Labor

Preterm labor, defined as the birthing process starting prior to 37 weeks of gestation, is a serious condition characterized by uterine contractions, cervical dilation and rupture of the fetal membranes that can lead to preterm birth. According to a study published in the Lancet in 2012, approximately 15

million babies were born before 37 weeks of gestation in 2010, accounting for 11.1% of all live births worldwide. Over 1 million children under the age of five die each year worldwide due to preterm birth complications, and many infants who survive preterm birth are at greater risk for cerebral palsy, delays in development, hearing and vision issues, and often face a lifetime of disability. The rates of preterm births are rising in almost all countries with reliable data for preterm birth, and are associated with an immense financial impact to the global healthcare system. Until now, no universal treatment is available to stop or delay preterm birth.

To date, only treatments with limited efficacy or restrictive safety issues are available to treat preterm labor. In the United States, no drugs are approved for acute treatment of PTL and recommended off-label tocolytic treatments (medications that inhibit labor) include beta-adrenergic receptor agonists, calcium channel blockers, or NSAIDs, which are used for short-term prolongation of pregnancy (up to 48 hours) to allow for the administration of antenatal steroids (e.g. betamethasone). Magnesium sulfate, used for fetal neuroprotection can also be used (up to 48 hours) to inhibit acute preterm labor. Approved tocolytic treatments in Europe include beta-adrenergic agonists, which carry severe maternal cardiovascular risks, and intravenous infusions of atosiban (an oxytocin receptor antagonist).

While non-specific prostaglandin inhibitors (NSAIDs) have been shown to be effective for inhibiting preterm labor, use of such drugs is limited, due to the threat of serious and sometimes life-threatening side effects in the fetus. Such side effects may include kidney function impairment, premature constriction of the blood vessel connecting the pulmonary artery and the descending aorta in a developing fetus (ductus arteriosus), and higher risk of thrombosis of the intestinal arteries (a condition called necrotizing enterocolitis).

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). $PGF_{2\alpha}$ 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, preterm labor, and improving embryo transfer outcomes following in vitro fertilization. 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.

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 potential therapeutic benefits and the clinical development of ebopiprant. 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, results of earlier preclinical studies and clinical trials not being predictive of results of future preclinical studies or clinical trials, clinical development and related interactions with regulators, ObsEva’s ability to develop and eventually commercialize one or more product candidates, 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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