ObsEva SA Reports Initial Good Safety of OBE022 in Pregnant Women with Preterm Labour and Announces Start of Part B of the PROLONG Trial

Geneva, Switzerland and Boston, MA – January 23, 2019 – ObsEva SA (NASDAQ: OBSV / SIX: OBSN), a clinical-stage biopharmaceutical company focused on the development and commercialization of novel therapeutics for serious conditions that compromise a woman's reproductive health and pregnancy, today announced the completion of Part A of the PROLONG trial in preterm labor. In this trial, OBE022 was administered daily for 7 days, to pregnant women, who were already receiving standard of care therapy for preterm labour, atosiban infusion for 48 hours. The goal was to assess the safety and pharmacokinetics of OBE022 in patients.

"The Part A of the PROLONG trial was the first time that OBE022 was administered to pregnant women with preterm labor, which is an extremely important step in the development of OBE022 to treat preterm labor" said Ernest Loumaye, co-founder and Chief Executive Officer of ObsEva. *"OBE022 was very well tolerated by the mothers and their fetuses and we were able to demonstrate that the pharmacokinetics of OBE022 were similar to those previously observed in non-pregnant women. These very encouraging results allow us to initiate Part B of the study with the planned dose and dosage regimen."*

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

Part A was an open-label trial of OBE022 administered orally, with a loading dose of 1000 mg, then 500 mg twice a day for 7 days to pregnant women with threatened preterm labor. The nine women in Part A were between 28 and 34 weeks of gestation and were receiving a standard-of-care therapy for threatened preterm labor, atosiban infusion for 48 hours. OBE022 pharmacokinetics and maternal, fetal and infant safety were assessed. Fetal cardiac safety was monitored using Doppler ultrasound. Time to delivery was also measured. Eight of the nine patients did not deliver within the 7 days of OBE022 treatment and one patient delivered the day after starting OBE022. OBE022 was well absorbed from Day 1 to Day 7 and steady-state serum concentrations and pharmacokinetics were comparable to those observed previously in non-pregnant women. Two serious adverse events were reported in one infant but were not related to study drug. There were 22 non-serious adverse events, all mild or moderate, of which one (fatigue), was considered as related to study drug. There were no adverse events reported for the fetuses, and no clinically significant abnormal findings on the Doppler ultrasound including no constrictive effect on the ductus arteriosus. The results will be presented at the 66th Annual Scientific Meeting of the Society for Reproductive Investigation 12 to 16 Mar 2019 in Paris, France.

Part B, is a randomized, double-blind, placebo-controlled, parallel-group trial to assess the efficacy, safety and pharmacokinetics of OBE022. It is planned to recruit 120 patients with preterm labor at a gestational age of 24 to 34 weeks. As in Part A, OBE022 or placebo will be administered orally, with 1000 mg as a starting dose, then 500 mg twice a day for 7 days to women already receiving atosiban infusion for 48 hours.

Part A of the study was conducted in Finland and Spain. Part B has been initiated in Spain, Finland, Czech Republic and Vietnam and further trial sites are planned in Russia and Israel. The first patient in Part B has been enrolled in Czech Republic.

About Preterm Labour

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 died in 2013 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.

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 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 OBE022 and PGF2alpha

ObsEva is developing OBE022, a potential first-in-class, once daily, oral and selective prostaglandin F2alpha 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). PGF2alpha 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 OBE022 markedly reduces spontaneous and induced uterine contractions in pregnant rats without causing the fetal side effects seen with prostaglandin inhibitors such as indomethacin.

About ObsEva

ObsEva is a clinical-stage biopharmaceutical company focused on the clinical development and commercialization of novel therapeutics for serious conditions that compromise a woman'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 IVF outcomes. 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 clinical development of ObsEva’s product candidates, the timing of enrollment in and data from clinical trials 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, clinical development and related interactions with regulators, ObsEva’s reliance on third parties over which it may not always have full control, 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, 2017, 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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