ObsEva Initiates PROLONG, the Phase 2a Clinical Trial of OBE022 in Preterm Labor

OBE022 is a first-in-class, oral and selective PGF2α receptor antagonist for the potential treatment of preterm labor to delay or prevent preterm birth

Geneva, Switzerland and Boston, MA – December 5, 2017 – ObsEva SA (NASDAQ: OBSV), 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 initiation of its international Phase 2a Proof-of-Concept clinical trial, PROLONG.

The PROLONG trial is the first clinical trial of OBE022 in pregnant women presenting with spontaneous preterm labor at gestational ages between 24 and 34 weeks. OBE022 will be administered orally for 7 days together with standard-of-care tocolytic therapy, 48 hour intravenous infusion of atosiban.

“According to a recent United Nations Report, in 2016, 7,000 babies died every day in the first 28 days of life, despite a steady decrease in under-five mortality. Preterm birth complications and complications during labor or child birth caused 30% of newborn deaths in 2016,” said Ernest Loumaye, MD, PhD, OBGYN, CEO and Co-Founder of ObsEva. “OBE022 is a selective PGF2α receptor antagonist that we believe could be a promising new treatment for delaying or preventing preterm birth. The initiation of the PROLONG trial is an important milestone for ObsEva, as OBE022 is now our third compound in Phase 2 or later clinical development, and we are very pleased to be collaborating with the experienced research teams at some of the largest maternity hospitals”.

The PROLONG trial will be conducted in two parts: In Part A, at least 8 patients will receive OBE022 open-label to assess pharmacokinetics and safety before commencing Part B. Part B is planned to include 120 patients who will be randomized to OBE022 or placebo in a double-blind fashion. Beyond safety, the efficacy endpoints in the main part of the trial will include the proportion of patients who have delivered at 2 or 7 days after starting OBE022, at 37 weeks of gestation, and the time to delivery. In both parts of the trial, patients will be monitored until delivery. After birth, mothers and babies will be monitored for an initial 28 days, with subsequent 24 month infant follow-up. ObsEva expects to announce preliminary results from 60 patients in Part B in late 2018.

Part A of the PROLONG trial is being conducted in Finland at the Helsinki University Women’s Hospital, one of the largest maternity hospitals in Europe, under the supervision of Professor Seppo Heinonen, the Director of Obstetrics and Gynaecology. “We are very pleased to be conducting the PROLONG trial at the Helsinki University Women’s Hospital,” said Professor Heinonen. “There is a major need for new treatments for preterm labor and we are very excited to be testing the first compound in this promising new class.”
The PROLONG trial is also planned to be conducted at maternity hospitals in additional countries, including Spain, Israel and Vietnam.

**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 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 worldwide, 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, recommended first-line tocolytic treatments (medications that inhibit labor) include calcium channel blockers, non-specific inhibitors of prostaglandin synthesis, commonly named Nonsteroidal Anti-Inflammatory Drugs or NSAIDs, or beta-adrenergic receptor agonists, 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 NSAIDs are believed 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 to 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, 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, oral and selective prostaglandin F2α (PGF2α) receptor antagonist, which is designed to impact 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 NSAIDs. PGF2α 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 NSAIDs 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 ART outcomes. ObsEva is listed on The NASDAQ Global Select Market and is trading under the ticker symbol "OBSV". 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 and the timing of enrollment in and reporting of data from clinical trials, including the PROLONG clinical trial. 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, 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, 2016, 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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