

## **ObsEva to Present Pharmacology Results Demonstrating OBE022 Exerts a Synergistic Effect in Combination with Standard of Care in Animal Model for Preterm Labor**

*- OBE022 is ObsEva's potential first-in-class, oral and selective PGF2 $\alpha$  receptor antagonist -*

**Geneva, Switzerland - 17 March 2017** – ObsEva SA (Nasdaq: OBSV), a Swiss 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 that OBE022 was observed to exert a synergistic effect in combination with nifedipine on the delay of delivery in an animal model for preterm labor. OBE022 is a potential first-in-class, once daily, oral and selective prostaglandin F<sub>2 $\alpha$</sub>  (PGF2 $\alpha$ ) receptor antagonist, which is in development for the treatment of preterm labor in weeks 24 to 34 of pregnancy. Nifedipine is a calcium channel blocker approved for the treatment of hypertension and used as standard of care in preterm labor. The results of this pharmacology study will be presented on March 18, 2017 at the Society for Reproductive Investigation's 64th Annual Scientific Meeting (Orlando, USA) <sup>(1)</sup>.

The study evaluated the effect of OBE022 and nifedipine, alone and in combination with each other, on an animal model of RU486-induced parturition in pregnant mouse. The induction of labor by the antiprogesterin RU486 results from inhibition of progesterone activation leading to the up-regulation of labor-associated proteins as seen in the case of idiopathic preterm labor.

Compared to the vehicle control, nifedipine (5mg/kg, taken orally), as well as OBE022 (100mg/kg, taken orally), alone demonstrated statistically significant delays in RU486-induced preterm labor. Combination treatment with OBE022 and nifedipine demonstrated a clear synergistic effect on the delay of delivery when compared to vehicle, nifedipine or OBE022 alone (p<0.001, p<0.001 and p<0.01, respectively).

Management of preterm labor remains an unmet medical need. Pan-prostaglandin inhibition with non-steroidal anti-inflammatory drugs (NSAID) is an effective treatment for preterm labor, but is limited due to severe and sometimes life-threatening adverse effects on the fetus. PGF2 $\alpha$  is a naturally occurring prostaglandin that acts to induce labor in pregnant women. Through specific antagonism of the PGF2 $\alpha$  receptor, OBE022 is designed to reduce PGF2 $\alpha$ -mediated inflammation, decrease uterine contractions and prevent membrane ruptures and cervical changes, which are the key features of preterm labor resulting in preterm birth.

Currently, though not approved for this indication, one of the commonly used preterm labor treatments is the oral calcium channel blocker nifedipine. Therefore, selectively targeting the PGF2 $\alpha$

receptor in combination with nifedipine may be an optimal strategy for preventing or delaying preterm delivery.

*“The results of this study constitute an important step towards the development of our potential first-in-class PGF2 $\alpha$  receptor antagonist, OBE022, in the treatment of preterm labor, as adding it to the standard of care will facilitate the clinical testing of OBE022 for the prevention of preterm birth, and more importantly may provide a winning therapeutic combination for that indication,”* said Jean-Pierre Gotteland, CSO of ObsEva.

(1) Oliver Pohl, Murielle Méen, Philippe Lluel, André Chollet and Jean-Pierre Gotteland, Effect of OBE022, an oral and selective non-prostanoid PGF2 $\alpha$  receptor antagonist in combination with nifedipine for preterm labor: a study on RU486-induced parturition of pregnant mice, Abstract # 321

## **About Preterm Labor**

Preterm labor, defined as the body commencing the birthing process prior to 37 weeks, is a serious women’s pregnancy health condition characterized by uterine contractions, cervical dilation and rupture of the fetal membranes that surround and protect the fetus during pregnancy. 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, preterm labor is a condition for which only treatments with limited efficacy or restrictive safety issues are available. In the United States, nifedipine, which is approved for the treatment of hypertension, is used off-label as a tocolytic to suppress uterine contractions and delay birth. Approved tocolytic treatments in Europe include intravenous infusions of atosiban (an oxytocin receptor antagonist) and beta-adrenergic agonists such as salbutamol and terbutaline sulfate, which carry severe maternal cardiovascular risks. While NSAIDs can also be effective for controlling preterm labor, use of such drugs is very 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 PGF2 $\alpha$**

ObsEva is advancing OBE022, a potential first-in-class, once daily, oral and selective PGF2 $\alpha$  receptor antagonist designed to control preterm labor by reducing inflammation, decreasing uterine contractions, and preventing cervical changes and fetal membrane ruptures. PGF2 $\alpha$  induces contraction of the myometrium and also upregulates enzymes causing cervix dilation and membrane rupture. In preclinical studies, ObsEva has observed that OBE022 markedly reduces spontaneous uterine contractions in pregnant rats without causing the adverse effects seen with NSAIDs.

## **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](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 similar expressions, and are based on ObsEva's current beliefs and expectations. These forward-looking statements include expectations regarding the pharmacology study of OBE022, the potential benefits of OBE022 and the potential clinical development plan for OBE022. 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 Registration Statement on Form F-1, as amended, declared effective by the Securities and Exchange Commission (SEC) on January 25, 2017, and other filings ObsEva makes with the SEC from time to time. 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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