ObsEva Announces Results of the IMPLANT Phase 2 Trial of OBE001 (nolasiban) for the Improvement of Pregnancy and Live Birth Rates Following IVF/ICSI

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Trial shows meaningful increase in pregnancy and live birth rates in patients treated with OBE001

ObsEva to proceed with a Phase 3 clinical trial in Europe

Geneva, Switzerland, 24 October 2016 – ObsEva SA, a Swiss biopharmaceutical company focused on the development and commercialization of novel therapeutics for serious conditions that impact a woman's reproductive health and pregnancy, announced today the results of its IMPLANT clinical trial, a Phase 2 clinical trial of OBE001 (nolasiban) for the improvement of clinical pregnancy and live birth rates in women undergoing embryo transfer (ET) following in vitro fertilization (IVF)/intracytoplasmic sperm injection (ICSI). The trial was designed to assess the safety and efficacy of a range of doses of OBE001, an oral oxytocin receptor antagonist, compared to placebo.

In the trial population of 247 patients, the percentage of women with a clinical pregnancy (defined as an intra-uterine pregnancy with positive embryo heart beat at six weeks after ET) was increased by over an absolute 9 percent and live birth rates were increased by 10.4 percent (actual live birth rates were 39.6 percent and 29.2 percent for patients treated with OBE001 and patients who received placebo, respectively). While the trial did not achieve its pre-defined primary endpoint of a statistically significant dose-response trend on the percentage of women with clinical pregnancy (powered at 80 percent to detect an absolute difference of 20 percent between placebo and ascending doses of OBE001), ObsEva believes the results were clinically meaningful and equivalent to a 26 percent increase relative to placebo.

The lack of a statistically significant dose-response appears to be primarily due to an imbalance in the 300 mg dose group, in the number of the patients who had a high progesterone level at baseline relative to the other arms. ObsEva believes that high progesterone levels can be a possible negative predictive factor for live birth. In a post-hoc analysis that excluded patients with a progesterone level in the top quartile of the patient pool, a statistically significant relationship between the dose of OBE001 and the ongoing clinical pregnancy at week 10 (trend test p-value = 0.035) and live birth rates was identified (trend test p-value = 0.025). In addition, a live birth rate of 51.0 percent was recorded in patients who received a 900 mg dose of OBE001 compared to 30.6 percent in the placebo group. This was the highest observed live birth rate in the trial and equivalent to a 67 percent increase relative to placebo. OBE001 was well tolerated in all dose groups.

"We are encouraged by the meaningful increase in pregnancy and live birth rates observed in patients treated with OBE001, particularly in women with normal progesterone levels at the time of embryo transfer," said Ernest Loumaye, MD, PhD and CEO and co-Founder of ObsEva. "We believe that if confirmed in larger trials, this would represent a major breakthrough for improving the success rate of IVF, a procedure more and more frequently used to address the need of the growing number of couples seeking treatment for infertility."

The IMPLANT trial was a prospective, dose ranging, randomized, double-blind, placebo-controlled trial, which enrolled 247 patients across 26 specialist IVF centers in five European countries including Belgium, Czech Republic, Denmark, Poland and Spain. Patients received a single oral dose of OBE001 (100 mg, 300 mg or 900 mg) approximately four hours before a Day 3 fresh embryo transfer and were evaluated for up to 10 weeks. Pregnancies, births and infant health were monitored up to six months after birth.

Based on the results of the IMPLANT trial, ObsEva intends to initiate in Europe a Phase 3 clinical trial in women undergoing IVF. The European Phase 3 trial, which ObsEva will refer to as IMPLANT-2, is planned to start in the first half of 2017.

About IVF and OBE001 (nolasiban)

Infertility affects about 11 percent of reproductive-aged women in the United States. Every year, approximately 1.6 million IVF/ICSI treatments are performed globally. In the United States, approximately 210,000 IVF/ICSI treatments

were performed in 2014, in the EU, approximately 620,000 IVF/ICSI treatments were performed in 2012 and in Japan, approximately 325,000 IVF/ICSI treatments were performed in 2012. The success rate, or live birth rate, of such treatments is highly dependent on the quality of the embryo, the transfer procedure and ultimately the receptivity of the uterus. The cost of one IVF/ICSI cycle varies between $8,000 to$15,000 in the United States, €2,000 to €10,000 in the EU and $2,000 to $6,000 in Japan. OBE001 (nolasiban) is an oral oxytocin receptor antagonist with the potential to decrease uterine contractions, improve uterine blood flow and enhance the receptivity of the endometrium to embryo implantation, thereby enhancing clinical pregnancy and live birth rates following IVF/ICSI.

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. ObsEva is focused on providing therapeutic solutions for women between the ages of 15 and 49 who suffer from reproductive health conditions that affect their quality of life and ability to conceive or that may lead to complications during pregnancy. ObsEva's goal is to build a leading women's reproductive health and pregnancy company focused on conditions where current treatment options are limited and significant unmet need exists. Through strategic in-licensing and disciplined drug development, ObsEva has established a clinical-stage pipeline with development programs focused on treating the symptoms associated with endometriosis and uterine fibroids, improving clinical pregnancy and live birth rates in women undergoing in vitro fertilization, and treating preterm labor. ObsEva is supported by leading healthcare investors and a globally recognized board and is well-positioned to establish a leadership position in women's reproductive therapeutics. For more information, please visit www.ObsEva.com.

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