



## **ObsEva SA Reports Further Infant Follow-up Data from IMPLANT2 Trial Echoing Favorable Safety Profile of Nolasiban in IVF**

**Geneva, Switzerland and Boston, MA – April 29 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 additional neonatal and infant follow-up results from the IMPLANT2 Phase 3 trial of its oral, oxytocin receptor antagonist, nolasiban, in patients undergoing IVF procedures. These additional data, resulting from additional follow-up extending to 6 months beyond delivery for the neonates and infants, are consistent with the favorable safety profile of nolasiban observed during pregnancy and within the first month following birth.

“We are very pleased by the results from the follow-up of the babies born in the IMPLANT2 trial, which is consistent with prior pre-clinical and clinical data indicating that the safety of nolasiban administered at the time of embryo transfer is no different from placebo,” said Dr. Ernest Loumaye, Co-Founder and Chief Executive Officer of ObsEva. “Following these important results, ObsEva’s final anticipated step leading to a planned MAA filing is the read-out of the second Phase 3 trial in Europe, IMPLANT4, which we continue to expect in Q4 2019.”

Previously reported data from the IMPLANT2 trial showed a live birth rate (LBR) of 34.8% and 27.7% ( $p=0.025$ ) in the nolasiban and placebo groups, respectively, a relative 25% increase. In the subgroup of patients receiving a single embryo transfer (SET) on Day 5, LBR was 44.8% and 33.2% in the nolasiban and placebo groups, respectively, a relative 35% increase. There were 108 deliveries resulting in 109 infants in the placebo group and 131 deliveries resulting in 136 infants in the nolasiban group.

Safety follow-up in the IMPLANT2 trial included neonatal outcomes assessed up to 28 days following birth, and infant development assessed using the Ages and Stages Questionnaires®-3 (ASQ®-3) completed 6 months following birth. Reported maternal, obstetrical, and neonatal outcomes up to 28 days post-delivery were very similar between the nolasiban and placebo groups. These measures included incidence and type of congenital malformations (reported in 5 [4%] infants in the nolasiban group and 4 [4%] infants in the placebo group), as well as the incidence of intrauterine growth restriction.

At 6-months post birth, infant follow-up and developmental outcomes showed no notable differences between the nolasiban and placebo groups in terms of ASQ-3 domain score (mean  $\pm$  SD total ASQ-3 scores were  $208.7 \pm 38.8$  in the placebo group and  $208.51 \pm 44.7$  in the nolasiban group), total score, or percentage of infants with at least one domain score below the respective cut-off value.

Overall, Phase 3 IMPLANT2 trial results demonstrated that nolasiban increased rates of ongoing pregnancy and live birth following SET, with no safety concerns identified in either mothers or infants. ObsEva plans to present full safety results from the IMPLANT2 trial at a scientific conference in 2019.

### **About the IMPLANT2 Clinical Trial**

IMPLANT2 is a Phase 3, randomized, double blind, clinical trial assessing nolasiban compared to placebo for improving the rate of pregnancy in patients undergoing IVF or ICSI due to low fertility. Following ovarian stimulation, egg retrieval and fertilization, eligible women are randomized to receive either a single, oral dose of 900 mg nolasiban or placebo 4 hours before D3 or D5 fresh, single ET. The primary endpoint was ongoing pregnancy at 10 weeks after ET. Women with confirmed pregnancies were monitored until delivery and the infants for up to 6 months following birth.

### **About Assisted Reproductive Technology (ART)**

Infertility affects about 10 percent of reproductive-aged couples, with more than 2 million ART treatments (most being IVF) performed worldwide each year. Currently 59% of fresh embryo transfers are performed on D5 and 31% on D3 in the United States (CDC report, 2015 data).

While the success of ART depends on multiple factors including ovarian response, fertilization, embryo quality and ET procedure, a successful pregnancy ultimately hinges on the receptivity of the uterus to accept embryo implantation. Uterine contractions at the time of ET, as well as suboptimal thickness of the uterine wall and insufficient blood flow to the uterus, may impair the implantation of the embryo.

### **About Ages and Stages Questionnaire-3 (ASQ-3)**

The Ages and Stages Questionnaires<sup>®</sup>, Third Edition (ASQ<sup>®</sup>-3) is a Patient-reported outcome measure to evaluate infant developmental outcome at 6 months after birth. ASQ-3 includes 6 questions in each of the following domains: Communication, Gross motor, Fine motor, Problem solving, Personal-social

### **About Nolasiban**

Nolasiban (previously known as OBE001), 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, all of which may increase the chance of successful pregnancy and live-birth among patients undergoing ART. ObsEva licensed nolasiban from Merck KGaA, Darmstadt, Germany, in 2013 and retains worldwide, exclusive, commercial rights.

## **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](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 clinical development of ObsEva's product candidates and the timing of enrollment in and data from clinical trials. 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, 2018, 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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