

## **ObsEva SA reports additional positive Phase 3 results of IMPLANT 2 trial showing significant increase of Live Birth Rate (LBR) following IVF with Single Embryo Transfer (SET)**

- ***Phase 3 IMPLANT 2 trial results showed Live Birth Rate increased by up to 35% with Nolasiban treatment***
- ***Nolasiban safety profile not different from placebo in IMPLANT 2***
- ***European MAA submission confirmed to be targeted for 4Q:19, commercial planning underway***
- ***Nolasiban is a novel therapy and the first therapy of its kind to improve clinical pregnancy and live birth rates in women undergoing IVF***

**Geneva, Switzerland and Boston, MA – October 3, 2018** - ObsEva SA (NASDAQ: OBSV / SIX: OBSN), a Swiss 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 positive Phase 3 data from the IMPLANT 2 trial of its oral, oxytocin receptor antagonist, Nolasiban in patients undergoing IVF procedures, as well as future development plans following receipt of EU regulatory feedback. Data from the IMPLANT 2 trial showed that Nolasiban significantly increased live birth rate following IVF treatment.

Live birth rate (LBR), also called "Take Home Baby" rate is a key secondary endpoint in IMPLANT 2 trial of Nolasiban in IVF, and these new results show a clinically and statistically significant benefit in favor of Nolasiban. In the primary population, combined Day 3 and Day 5 embryo transfer (ET), treatment with Nolasiban as a single 900mg oral dose 4h prior ET resulted in a live birth rate of 34.8% vs. 27.7% for patients receiving placebo, a 25% relative increase (p=0.025). The live birth rate in women undergoing Day 5 ET was 44.8% for those receiving Nolasiban, vs 33.2% for those receiving placebo, a 35% relative increase (p value=0.025). LBR is an important endpoint as live birth is the ultimate goal of couples who undergo IVF treatment. These data are very consistent with the 10-week pregnancy rate of 35.6% for Nolasiban vs. 28.5% for placebo (p=0.031) that were reported in February 2018.

"We are very pleased by the results of the Phase 3. IMPLANT 2 trial of Nolasiban that showed a very significant improvement in live birth rate. We believe these exciting results represent a major advance in our efforts to offer an improved standard of care for women undergoing IVF treatment. We are working with health authorities to plan the next steps and make this treatment available to women as soon as

possible” said Dr. Ernest Loumaye, Co-Founder and CEO of ObsEva. “Too many transfers of apparently healthy embryos are still failing, resulting in many patients going home with no baby after a physically, emotionally and economically demanding ART procedure”.

ObsEva has received feedback from two European regulatory authorities on the development path forward to support potential future product registration. Pending positive outcome of an additional Phase 3 trial, both regulatory bodies have agreed to a proposed Marketing Authorization Application (MAA) that will include the complete IMPLANT 1 Phase 2 and IMPLANT 2 Phase 3 clinical trial results (which will include new-born follow-up for up to 6 months after birth), as well as the primary endpoint results from the additional Phase 3 clinical trial. This Phase 3 trial is expected to begin prior to the end of 2018, and is anticipated to generate the primary endpoint, 10-week ongoing pregnancy data, in approximately 12 months, allowing for a planned MAA submission of Nolasiban by the end of 2019. This clinical trial of Nolasiban is planned to randomize approximately 1,000 patients. Patients will be randomized to receive either a single, oral dose of 900 mg Nolasiban or placebo four hours prior to ET. All patients will undergo Day 5 ET with a single embryo.

For the U.S., ObsEva is awaiting feedback from the FDA on future development plans and registration requirements, which it expects to receive prior to the end of this month.

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

IMPLANT 2 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 is ongoing pregnancy at 10 weeks after ET. Women with confirmed pregnancies are 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 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, 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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