

# ObsEva Reports New Clinical Evidence of Nolasiban Mechanism of Action, Supporting Its Potential to Increase Live Birth Rate Following Embryo Transfer in IVF

Results show decreased uterine contractions, increased endometrial blood flow and gene expression relevant for uterine receptivity to implantation

4Q:19 Read-out confirmed for Phase 3 IMPLANT 4 trial of ObsEva's novel oxytocin receptor antagonist nolasiban

Geneva, Switzerland and Boston, MA – September 03, 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 reported results from a mechanism of action (MoA) trial of its oral oxytocin receptor antagonist, nolasiban. The trial assessed the effect of nolasiban on uterine contractions and endometrial blood flow, both of which are known to be associated with uterine receptivity and embryo implantation, and ultimately pregnancy and live birth following IVF. The effect of nolasiban administration on endometrial gene expression was also investigated.

The randomized, double blind trial was conducted in 42 healthy female volunteers, aged 18 to 37 years, who had been pre-treated with a hormonal preparation identical to that used in women undergoing frozen-thawed embryo transfer. On the day corresponding to a Day 5 embryo transfer, subjects received a single, oral administration of the clinical dose of 900 mg nolasiban, a supra-therapeutic dose of 1800 mg nolasiban, or matching placebo. Pharmacodynamic (PD) assessments up to 24 hours after treatment included measurements of uterine contraction frequency by ultrasound and uterine perfusion by 3D-power Doppler. Endometrial biopsy was obtained following PD assessments, and tissue samples analyzed for differential mRNA expression.

A single oral dose of nolasiban produced measurable and durable effects, with a reduction in the frequency of uterine contractions and a marked and sustained increase in endometrial blood flow. Within 24 hours of nolasiban administration, statistically significant changes were observed in the expression of a set of endometrial genes that have been described as potentially important in endometrial receptivity and embryonic implantation.

These nolasiban trial results represent the first in vivo demonstration of the effect of oxytocin receptor inhibition on endometrial blood flow and receptivity-related gene expression. These important new MoA

findings support the potential for nolasiban to increase live birth rates following IVF. The trial results are scheduled to be presented at an upcoming international OB/GYN conference.

"These highly unique and informative new data substantially expand our understanding of the potential mechanism of action of nolasiban in increasing the success of embryo implantation, a critical process in the achievement of pregnancy following IVF, which has not seen significant advances despite other notable achievements in the field. We are extremely pleased to have observed the positive effects of nolasiban in reducing uterine contraction frequency, increasing endometrial blood flow, and driving specific changes in gene expression, which all support the potential to increase live birth rates following embryo transfer. These data are timely as we look forward to the upcoming results of our second nolasiban phase 3 trial, IMPLANT 4, and a submission of a Marketing Authorization Application (MAA) in Europe expected by the end of this year," said Ernest Loumaye, CEO and co-Founder of ObsEva.

# About Assisted Reproductive Technology (ART)

Infertility affects approximately 10% of reproductive-aged couples, with more than 2 million ART treatments (including IVF and ICSI) performed worldwide each year. Currently in the United States, 62% of fresh embryo transfers are performed on Day 5 and 30% on Day 3 (CDC report, 2016 data).

While the success of ART depends on multiple factors such as embryo quality and ET procedures, successful embryo implantation and subsequent pregnancy ultimately hinge on endometrial receptivity, which may be reduced by excessive uterine contractions and suboptimal blood flow to the uterus at the time of embryo transfer.

## **About Nolasiban**

Nolasiban (previously known as OBE001), is an oral oxytocin receptor antagonist which has been shown in an IMPLANT2 phase 3 trial to increase ongoing pregnancy rate and live birth rate in patients undergoing single embryo transfer. 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.

# **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 statements regarding the potential for nolasiban to increase live birth rates following embryo transfer, expectations regarding the clinical development of nolasiban, data from clinical trials and the Company's regulatory plans regarding nolasiban. 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 and clinical development and related regulatory reviews and approvals, including the risk that the results of earlier clinical trials may not be predictive of the results of later-stage 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, 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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