



ObsEva Announces Two Cornerstone Publications Describing Clinical Trials of Nolasiban for Improving Pregnancy and Live Birth Outcomes Following IVF

- A Combined Analysis of Pregnancy and Live Birth in more than 1800 IVF Patients Across Three Randomized, Placebo-Controlled Clinical Trials Published in the Journal of Human Reproduction-

-A Mechanism of Action Trial Assessing the Effect of Nolasiban on Contractions, Blood Flow and Gene Expression in the Uterus Published in the Journal of Reproductive BioMedicine Online-

Geneva, Switzerland and Boston, MA – August 4, 2021 – ObsEva SA (NASDAQ: OBSV / SIX: OBSN), a biopharmaceutical company developing and commercializing novel therapies to improve women’s reproductive health, today announced the publication of two peer-reviewed papers on nolasiban, an oxytocin receptor antagonist in development for improving live birth rates in women undergoing embryo transfer following in-vitro fertilization (IVF).

The first paper, entitled “[Effect of the oxytocin receptor antagonist nolasiban on pregnancy rates in women undergoing embryo transfer following IVF: analysis of three randomized clinical trials](#)” (Griesinger et al), was published in the *Journal of Human Reproduction*. The study reports the results from a meta-analysis of three randomized, placebo-controlled trials showing that nolasiban increased the likelihood of live birth following IVF. Participants were administered a single oral dose of nolasiban 900 mg (n=846) or placebo (n=864) and assigned to one of three trials (IMPLANT 1, IMPLANT 2 and IMPLANT 4) conducted in Europe and Canada between 2015 and 2019. Key outcomes of the study were as follows:

- The Phase 2 IMPLANT1 and Phase 3 IMPLANT 2 trials both demonstrated that administration of a single 900 mg dose of nolasiban administered before fresh single embryo transfer (SET) increased live birth rates compared to placebo. These results were not confirmed in a third trial, IMPLANT 4.
- A patient-level combined analysis of the three studies showed a 5% absolute increase (15% relative increase) in ongoing pregnancy rate, with an odds ratio for nolasiban versus placebo of 1.25 that was statistically significant (p=0.029).
- The analyses also showed that the effect size for nolasiban was similar for ongoing pregnancy rate and live birth rate.
- Population pharmacokinetic analyses indicated that higher exposures of nolasiban were associated with a higher probability of pregnancy.
- Nolasiban was well tolerated at a dose of 900 mg and there were few differences in maternal, obstetric and neonatal outcomes between the nolasiban and placebo treatment groups.

“This very important paper summarizes the comprehensive clinical development program of nolasiban to date, and the positive impact in an individual patient-level meta-analysis such as this is very

encouraging,” said Professor Georg Griesinger, first author and Principal Investigator at the Women and Children’s Hospital in Lubeck, Germany. “In the context of the substantial physical, emotional and financial impact of an unsuccessful IVF cycle and the less than 40% chance of success still seen today, these results give us confidence that with optimizing dosing and trial design, further clinical studies may demonstrate how nolasiban can help us achieve higher live birth rates in IVF.”

The second paper, “[The mechanism of action of oxytocin antagonist nolasiban in ART in healthy female volunteers](#)” (Pierzynski et al), was published in *Reproductive BioMedicine Online*[®], and describes the results of a prospective mechanism of action study of nolasiban. In the randomized, double-blind study, forty-five healthy, premenopausal women were treated with nolasiban 900 mg (n=14), 1800 mg (n=16) or placebo (n=15) on the day corresponding to blastocyst transfer. The study focused on nolasiban’s impact on uterine contractions, endometrial perfusion and endometrial mRNA expression. Key outcomes of the study were as follows:

- Both doses of nolasiban showed trends of decreased contraction frequency and increased endometrial perfusion.
- At 1800 mg, 10 endometrial genes were significantly differentially expressed, including three genes (DPP4, CXCL12 and IDO2) believed to be associated with decidualization and endometrial receptivity.
- Nolasiban was well tolerated, supporting testing at higher doses in IVF patients.

“The data from this study underscore the clinical utility of nolasiban, its potential to increase pregnancy rates after embryo transfer and further advance ART techniques,” said Piotr Pierzynski, M.D., Ph.D., first author and Investigator in the study. “We showed that nolasiban at doses of 900 and 1800 mg decreased uterine contractions, increased endometrial perfusion and affected expression of genes associated with implantation, decidualization and endometrial receptivity. The observed effects of nolasiban on these important factors for the success of ART support its potential use in patients undergoing fertility treatment.”

“We are excited that the meta-analysis and mechanism of action data support the potential for blockade of the oxytocin receptor with nolasiban to translate into a treatment that improves the probability of pregnancy and live birth following embryo transfer, and that increased exposure via higher doses and/or longer dose regimens may provide an even better treatment effect,” said Elizabeth Garner, M.D., MPH, ObsEva’s Chief Medical Officer. “Improving IVF outcomes following embryo transfer would be a meaningful contribution toward helping women with infertility realize their dream of having a baby, and we are exploring options for the further development of nolasiban in this important indication.”

About ObsEva

ObsEva is a biopharmaceutical company developing and commercializing novel therapies to improve women’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 new therapies for the treatment of uterine fibroids, endometriosis, and preterm labor. ObsEva is listed on the Nasdaq Global Select Market and is traded under the ticker symbol “OBSV” and on the SIX Swiss Exchange where it is traded under the ticker symbol “OBSN”. For more information, please visit www.ObsEva.com.

About Nolasiban

Nolasiban (previously known as OBE001), is an oral oxytocin receptor antagonist which was licensed from Merck KGaA, Darmstadt, Germany, in 2013. ObsEva retains worldwide, exclusive, commercial rights (ex-China).

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 other similar expressions, and are based on ObsEva's current beliefs and expectations. These forward-looking statements include expectations regarding the clinical development of and commercialization plans for ObsEva's product candidates, expectations regarding regulatory and development milestones, including the potential timing of regulatory submissions to the EMA and FDA and ObsEva's ability to obtain and maintain regulatory approvals for its product candidates, 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 and clinical development, including the risk that the results of earlier clinical trials may not be predictive of the results of later stage clinical trials, related interactions with regulators, ObsEva's reliance on third parties over which it may not always have full control, the impact of the novel coronavirus outbreak, 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, 2020 filed with Securities and Exchange Commission (SEC) on March 5, 2021 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.

For further information, please contact:

CEO Office contact

Shauna Dillon

Shauna.dillon@obseva.ch

+41 22 552 1550

Investor Contact:

Joyce Allaire

jallaire@lifesciadvisors.com

+1 (617)-435-6602