ObsEva SA Announces Initiation of Phase 3 IMPLANT 4 Trial of Nolasiban in Europe, Canada and Russia for Improving IVF Outcomes

Geneva, Switzerland and Boston, MA – November 28, 2018 – 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 initiation of the IMPLANT 4 Phase 3 clinical trial of its oral oxytocin receptor antagonist, nolasiban, for the improvement of rates of pregnancy and live birth in patients undergoing assisted reproduction technology (ART), or in-vitro fertilization (IVF).

“We are very pleased by the initiation of the IMPLANT 4 trial, as this represents an important step toward bringing nolasiban to patients undergoing IVF, for improving their chances to take home a baby after undergoing this demanding procedure,” said Ernest Loumaye, co-founder and Chief Executive Officer of ObsEva. “With a successful IMPLANT 4 outcome, we are planning a MAA submission in Europe prior to the end of 2019, a key step in ObsEva’s evolution into a commercial company with a unique and innovative product that may not only help patients, but has the potential to lower associated health care costs.”

IMPLANT 4 trial is a placebo-controlled, double blind Phase 3 trial conducted in 49 clinical sites in 10 countries primarily in Europe, as well as in Canada and Russia. Planned enrollment is approximately 800 patients who are undergoing an IVF cycle with a Day 5 single embryo transfer (SET). Eligible women will be randomized in a 1:1 ratio, to receive either a single oral 900 mg dose of nolasiban or placebo four hours prior to embryo transfer (ET). The primary endpoint of the IMPLANT 4 trial is the proportion of patients successfully achieving ongoing pregnancy 10 weeks post ET. Live birth rate (LBR) is a secondary endpoint of the trial, and follow-up will include 28-day neonatal assessment, as well as infant development assessment at 6 and 12 months post-birth. A successful IMPLANT 4 study will support a Marketing Authorization Application in Europe, Canada, Russia and other countries such as Switzerland.

About Assisted Reproductive Technology (ART)

Infertility affects about 10 percent of reproductive-aged couples, with more than 2 million ART treatments (including IVF and ICSI) 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 such as 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 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.

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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