

ObsEva Progressing Toward U.S. Phase 3 Trial for Nolasiban in IVF Following Recent FDA Meeting

Geneva, Switzerland and Boston, MA – June 19, 2019 – ObsEva SA (NASDAQ: OBSV / SIX: OBSN), a clinicalstage 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 that the Company's recent End-of-Phase 2 (EOP2) meeting with the U.S. Food and Drug Administration (FDA) provided clarification on a number of key development issues for its oral oxytocin receptor antagonist nolasiban. The Company anticipates beginning its U.S. Phase 3 clinical trial (IMPLANT 3) in the fourth quarter of this year or early 2020.

The EOP2 meeting addressed a range of issues important to the trial design of nolasiban for increasing the rate of live births in women undergoing single blastocyst transfer (Day 5 SET) following in vitro fertilization (IVF). The official meeting minutes, reflect alignment between the Company and FDA on many issues, and useful dialogue on topics that are the subject of ongoing discussions. Based on the meeting, ObsEva anticipates working with FDA regarding certain issues, including timing of randomization and number of previous IVF failures. We expect to submit the IMPLANT 3 trial protocol with an updated IND in the third quarter of 2019.

"We had a very constructive dialogue with the FDA and are pleased by the important clarifications we received on the development path for nolasiban in the U.S.," said Dr. Ernest Loumaye, co-founder and Chief Executive Officer of ObsEva. "We look forward to assessing the potential benefit of nolasiban for U.S. patients undergoing embryo transfer following IVF, as we put in place the building blocks for regulatory filings in critical geographies. Our first filing, anticipated for later this year, will be a marketing authorization application (MAA) in Europe based on IMPLANT 2 and IMPLANT 4 trial results."

Nolasiban Development Overview

IMPLANT 4 is an ongoing European-based placebo-controlled trial evaluating the impact of nolasiban on rates of pregnancy and live birth in approximately 820 women undergoing single embryo transfer on Day 5 following IVF. On June 4, 2019, ObsEva announced completion of patient recruitment in the trial; primary end point results are anticipated in the fourth quarter of 2019. Subject to a positive outcome of this trial, ObsEva expects to submit an MAA in Europe.

Positive primary endpoint results from the Company's completed Phase 3 IMPLANT 2 trial were released in 2018, showing that nolasiban treatment resulted in an improvement in live birth rate that was both statistically and clinically significant. Treatment with a single nolasiban 900 mg oral dose four hours prior to single embryo transfer (ET) on Day 3 or Day 5 resulted in a live birth rate of 34.8%. This compared with a 27.7% live birth rate for patients receiving placebo (p=0.025), a 26% relative increase. The live birth rate



in the subgroup of women undergoing Day 5 ET was 44.8% for those receiving nolasiban vs. 33.2% for those receiving placebo (p value = 0.025), a 35% relative increase.

About Assisted Reproductive Technology (ART)

Infertility affects about 10% of reproductive-aged couples, with more than 2 million assisted reproductive technology (ART) treatments (including IVF/ICSI) performed worldwide each year. Currently 62% of fresh ETs are performed on Day 5 and 30% on Day 3 in the United States (CDC report, 2016 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 and preterm labor, and on 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 <u>www.obseva.com</u>.

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, 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.

For further information, please contact:

Media Contact Switzerland and Europe: Christophe Lamps Dynamics Group <u>cla@dynamicsgroup.ch</u> +41 22 308 6220 Office +41 79 476 26 87 Mobile

Media Contact U.S.: Marion Janic RooneyPartners LLC mjanic@rooneyco.com +1 212 223 4047 Office +1 646 537 5649 Mobile

CEO Office Contact: Shauna Dillon Shauna.dillon@obseva.ch +41 22 552 1550

Investor Contact: Mario Corso Senior Director, Investor Relations <u>mario.corso@obseva.com</u> +1 857 972 9347 Office +1 781 366 5726 Mobile