



## **ObsEva R&D Day Showcases Multiple Women's Health Programs and Outlines Plans for Transition to Commercial Operations**

### ***Clinical Trial Data and Regulatory Progress on Lead Programs Targeting IVF, Endometriosis, and Uterine Fibroids to Transform Company in 2019***

**GENEVA, Switzerland and BOSTON, Mass. (December 7, 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 held an R&D Day in New York City.

At the event, company executives and women's health Key Opinion Leaders (KOLs) discussed recent clinical data, upcoming clinical milestones, and commercial potential of ObsEva R&D pipeline, including nolasiban, an oral oxytocin receptor antagonist for the improvement of IVF outcomes, and linzagolix, a novel, oral gonadotropin-releasing hormone (GnRH) receptor antagonist for the treatment of uterine fibroids and endometriosis. The company also outlined its recently initiated approach to commercial operations in preparation for potential European and U.S. regulatory approvals in 2021 and beyond.

"Today's meeting presents a major opportunity to underscore the tremendous unmet needs in our disease areas of focus in Women's Health and Fertility, and also demonstrate how ObsEva's compounds can provide significant value by helping physicians and patients address the current therapeutic shortcomings," said Ernest Loumaye, co-founder and Chief Executive Officer of ObsEva.

ObsEva's Chief Commercial Officer Wim Souverijns further commented, "I recently joined ObsEva because I was attracted by its impressive late-stage R&D pipeline. Today, I am able to share some initial perspectives on how our most advanced compound, nolasiban, can potentially transform the lives of couples experiencing infertility, starting in Europe."

Senior Executives from ObsEva's management team were joined by KOLs Hugh Taylor, MD, Professor and Chair, Department of Obstetrics Gynecology and Reproductive Sciences at Yale School of Medicine in New Haven, Conn.; Annette Lee, MD, Medical Director of Reproductive Endocrinology & Infertility at Abington Reproductive Medicine in Abington, Penn.; and Christophe Blockeel, MD, PhD, Medical Director of the Centre for Reproductive Medicine, University Hospitals Brussels in Belgium.

Highlights of the R&D day included:

- ObsEva outlined significant R&D program plans for 2019 and 2020 for its three potential best-in-class/first-in-class new chemical entities, including six Phase 3 trials and one Phase 2b trial. Cash on hand is now expected to be sufficient to fund operations to mid-2020, as opposed to into the first half of 2020 previously.

- The Phase 3 IMPLANT 4 trial with Nolasiban for improving IVF outcomes has been initiated and patients are being screened. The placebo-controlled, double-blind trial is being conducted at 51 clinical sites in 10 countries, primarily in Europe (n=43), Russia (n=4) and Canada (n=4), and will enroll approximately 800 patients who are undergoing single embryo (blastocyst) transfer (SET) on Day 5 post IVF. A successful IMPLANT 4 primary endpoint readout is expected to support the filing of a Marketing Authorization Application (MAA) in Europe in late 2019.
- The Nolasiban commercial strategy addresses two key areas of need in IVF, namely increasing success rates of embryo transfer and, in turn, reducing procedure and healthcare costs. Commercial planning is underway with the initial target geography of Europe having nearly 800,000 ART cycles performed annually, with growth of approximately 8% per year. The potential value of nolasiban is to deliver approximately one-third more babies to couples undergoing IVF, while at the same time providing cost benefits to both patients and payors via higher success rates and lower rates of double embryo transfer (DET) and subsequent multiple births. Given the high concentration of IVF clinics in both Europe (in EU5 ~900 clinics) and the U.S. (~500 clinics), ObsEva believes a small infrastructure will be sufficient to commercialize nolasiban in target markets.
- Patient enrollment has recently accelerated in the Phase 3 PRIMROSE 1 and PRIMROSE 2 trials of linzagolix for the treatment of heavy menstrual bleeding due to uterine fibroids. Six-month primary endpoint results are expected from these trials in the second half of 2019. ObsEva believes it is the only company with a Phase 3 development program for uterine fibroids that includes a non-hormonal add back therapy (ABT) dosing regimen.
- Following an end-of-Phase 2 meeting scheduled with the FDA prior to the end of 2018, in the first quarter of 2019 ObsEva plans to initiate Phase 3 trials with linzagolix for treating endometriosis-associated pelvic pain. This program will target two linzagolix doses, one without ABT (first line therapy) and one with low dose ABT, addressing clinician feedback that the majority of patients ultimately will prefer no ABT. The ABT option (second line) will be reserved to patients requiring full estrogen suppression hence having the need for ABT to protect bone.
- With the recent completion of Part A of the Phase 2a PROLONG trial of the oral and selective prostaglandin F2 alpha antagonist OBE022 for treating acute pre-term labor, the randomized placebo-controlled Part B of the trial is now underway. Preliminary efficacy data is expected in the first quarter of 2019 in approximately 30 patients and may support a go/no-go Phase 2b decision.

A live and archived webcast of the event including slides is available [here](#).

#### **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 [www.obseva.com](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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