

# ObsEva SA Announces Initiation of Phase 3 EDELWEISS 2 and 3 Trials of Linzagolix for Endometriosis Associated Pain in U.S., Canada and Europe

**Geneva, Switzerland and Boston, MA – May 9, 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 initiation of the Phase 3 development program of its orally administered, gonadotropinreleasing hormone (GnRH) receptor antagonist, linzagolix, for the treatment of endometriosis-associated pain, which includes the EDELWEISS 2 and EDELWEISS 3 clinical trials.

"We are very pleased to announce the initiation of pivotal Phase 3 trials for linzagolix in endometriosis associated pain which, if successful, will form the basis for our registration in the U.S. and Europe for that indication. We believe that linzagolix has the potential to be a best in class oral GnRH antagonist providing women with dosing options both with and without ABT to manage their condition ," said Dr. Loumaye, co-founder and Chief Executive Officer of ObsEva.

EDELWEISS 2 and 3 are randomized placebo-controlled, double blind, pivotal Phase 3 trials for 6 months, which will assess the efficacy and safety of linzagolix in patients with moderate to severe endometriosisassociated pain. Upon completion of the trials, eligible patients may enter a randomized 6 months extension trial in which they will receive only linzagolix followed by a 6 months post-treatment follow-up. Both trials are of identical design and are testing two dosing options: a 75mg single dose of linzagolix without low dose hormonal Add Back Therapy (ABT) and a 200mg single dose of linzagolix with ABT. Approximately 900 patients in total are expected to participate in the two trials. The EDELWEISS 2 study is being conducted in the U.S. and Canada, while EDELWEISS 3 is running in the U.S. and Europe.

## About linzagolix (formerly OBE2109)

Linzagolix is a novel, orally administered GnRH receptor antagonist with a potentially best-in-class profile in late-stage clinical development for the treatment of heavy menstrual bleeding associated with uterine fibroids and pain associated with endometriosis. Linzagolix acts by binding to and blocking the GnRH receptor in the pituitary gland, ultimately resulting in a dose-dependent reduction of the estrogen production by the ovaries. Through previously reported results from linzagolix and sophisticated pharmacological modelling, it has been established that maintaining estradiol within a specific target range provides the optimal balance between reducing symptoms while mitigating bone density loss associated with excessive estradiol suppression. ObsEva licensed linzagolix from Kissei in late 2015 and retains worldwide commercial rights, excluding Asia, for linzagolix.

#### About Kissei

Kissei is a Japanese pharmaceutical company with approximately 70 years of history, specialized in the field of urology, kidney-dialysis and unmet medical needs. Silodosin is a Kissei product for the treatment of the signs and symptoms of benign prostatic hyperplasia which is sold worldwide through its licensees. KLH-2109/OBE2109/linzagolix is a new chemical entity discovered by Kissei R&D and currently in development in Japan by Kissei.

## 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 "OBSV".

## **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.

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