

# ObsEva SA Announces the Completion of Patient Recruitment in the EDELWEISS Phase 2b Clinical Trial of OBE2109 for the Treatment of Endometriosis

**Geneva, Switzerland and Boston, MA – November 7, 2017** – ObsEva SA (NASDAQ: OBSV), 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 reported completion of patient recruitment of its Phase 2b EDELWEISS clinical trial of OBE2109, its oral gonadotropin releasing hormone (GnRH) receptor antagonist, for the treatment of pain associated with endometriosis.

"The completion of patient recruitment in our Phase2b EDELWEISS clinical trial is a testament to our clinical research and operations teams, and underscores ObsEva's commitment to bringing new treatment alternatives to women suffering from debilitating diseases such as endometriosis," said Ernest Loumaye, MD, PhD, OB/GYN, CEO and Co-Founder of ObsEva.

Approximately 330 patients are expected to be randomized in the EDELWEISS clinical trial, and primary endpoint efficacy results continue to be anticipated in mid-2018.

### **About the EDELWEISS Clinical Trial**

EDELWEISS is a Phase 2b, randomized, double blind clinical trial assessing multiple dosages of OBE2109 compared to placebo for the treatment of pain associated with endometriosis. The primary endpoint is patient response following 12 weeks of treatment, defined as at least 30% improvement in combined menstrual and non-menstrual pain as measured by a four point verbal rating scale (VRS). The goal of this trial is to set the foundation for ObsEva's OBE2109 Phase 3 program in endometriosis by aiding the validation of the pain scoring system, as well as identifying the optimal doses that address pain symptoms while potentially not necessitating full estrogen suppression and hormonal add back therapy (ABT).

# **About Endometriosis**

Endometriosis is a disease in which the endometrium (tissue lining the inside of the uterus) grows outside of the uterus, where it induces a chronic inflammatory reaction in the abdomen that may result in scar tissue. It is primarily found on the pelvic peritoneum, on the ovaries, in the rectovaginal septum, on the bladder and in the bowels. The most common symptom of endometriosis is pelvic pain, which often correlates to the menstrual cycle. Patients may also experience painful ovulation, pain during or after sexual intercourse, heavy bleeding, chronic pelvic pain, fatigue and infertility. For many,

endometriosis pain can be so severe and debilitating that it impacts day-to-day activities and has a negative effect on general physical, mental and social well-being.

The World Endometriosis Research Foundation's EndoCost study estimated the aggregate annual cost of endometriosis to be approximately \$80 billion in the United States and approximately \$60 billion in Germany, the UK, France and Italy in 2012.

#### **About OBE2109**

OBE2109 is a novel, orally administered GnRH receptor antagonist with a potentially best-in-class profile in late-stage clinical development for the treatment of pain associated with endometriosis and heavy menstrual bleeding associated with uterine fibroids. OBE2109 acts by binding to and blocking the GnRH receptor in the pituitary gland, ultimately reducing estrogen production by the ovaries. Through previously reported results from this class of drugs 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 OBE2109 from Kissei in late 2015 and retains worldwide commercial rights, excluding Asia, for OBE2109.

#### **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 is a new chemical entity discovered by Kissei R&D.

# **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 ART outcomes. ObsEva is listed on The NASDAQ Global Select Market and is trading under the ticker symbol "OBSV". For more information, please visit <a href="https://www.ObsEva.com">www.ObsEva.com</a>.

# **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 and the timing of reporting of data from clinical trials, including the EDELWEISS clinical trial. 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, 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, 2016, 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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# **Media Contact:**

Liz Bryan
Spectrum Science
Ibryan@spectrumscience.com
+1 202-955-6222 x2526

# **Company Contact:**

CEO Office contact
Delphine Renaud
delphine.renaud@obseva.ch
+41 22-552-1550

Investor Contact
Mario Corso
Senior Director, Investor Relations
mario.corso@obseva.com
+1 781-366-5726