

## **ObsEva Receives Clearance from US FDA to Initiate Phase 2b Study EDELWEISS with OBE2109, a Potentially Best-in-Class Oral GnRH Antagonist, for the Treatment of Endometriosis**

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**Geneva, Switzerland, 06 July, 2016** – [ObsEva](#), a Swiss biopharmaceutical company innovating women's reproductive health and pregnancy therapeutics, today announced that its Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) for OBE2109 has been cleared and the company is authorized to begin enrolling patients in the Phase 2b clinical study (EDELWEISS) with OBE2109 for the treatment of endometriosis. OBE2109 is a novel, orally active, gonadotropin-releasing hormone (GnRH) antagonist with a potentially best-in-class profile that has been successfully tested in more than 140 Japanese patients with endometriosis. In those studies, conducted by Kissei Pharmaceutical Co., Ltd., treatment with OBE2109 demonstrated a dose-dependent reduction in serum luteinizing hormone and estradiol within the optimal target range, resulting in a reduction of endometriosis-related pain, analgesic use and bleeding days.

*"Endometriosis is a painful, debilitating condition that affects more than 170 million women worldwide and is a leading cause of infertility. There has been little innovation in the field to treat this chronic condition over the last thirty years and the currently available drugs have significant limitations," said Ernest Loumaye, CEO and Co-Founder of ObsEva. "The design of the EDELWEISS study supports the differentiated profile of OBE2109 as OBE2109's low PK/PD variability is particularly suitable to consistently maintain estradiol levels within an optimal range. We believe that OBE2109 has significant market potential and could emerge as the best-in-class GnRH antagonist, uniquely positioned to address a high unmet need in this women's reproductive health condition."*

ObsEva's EDELWEISS clinical trial is a Phase 2b, randomized, double-blind, placebo-controlled, dose-ranging study to assess the efficacy and safety of OBE2109 in patients with endometriosis-associated pelvic pain. The study will be conducted in North America and Europe, with approximately 50 centers located in the US and 15 centers located in Europe. ObsEva expects to enroll approximately 330 endometriosis patients who will be treated daily for a period of up to 24 weeks. The goal is to provide an optimal dosing regimen which could treat a wide range of women living with endometriosis. For more information on the EDELWEISS study, please visit [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

*"OBE2109 open IND enables us to proceed with our EDELWEISS study in endometriosis, which represents a major step forward in our clinical development strategy for OBE2109 and brings us one step closer to providing a therapeutic solution for women suffering from this condition,"* stated Elke Bestel, M.D., Chief Medical Officer of ObsEva. Dr. Bestel added that patient screening for the EDELWEISS trial will begin in the coming months.

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### **About Endometriosis**

Endometriosis affects an estimated 1 in 10 women during their reproductive years, which is approximately 176 million women in the world.<sup>(1)</sup> Endometriosis is a disease in which tissue similar to the lining inside the uterus (called "the endometrium") is found outside the uterus, where it induces a chronic inflammatory reaction 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 bowel.<sup>(2)</sup> The symptoms of endometriosis include painful periods, painful ovulation, pain during or after sexual intercourse, heavy bleeding, chronic pelvic pain, fatigue and infertility, and can impact on general physical, mental, and social well-being.<sup>(3)</sup> The World Endometriosis Research Foundation (WERF) EndoCost study, the first ever prospective study of the actual cost of endometriosis, estimated the annual cost of endometriosis at EUR 70.9 billion in the US and EUR 58.8 billion in Germany, UK, France and Italy.<sup>(4)</sup>

## **About OBE2109 and GnRH**

OBE2109 is a novel, orally active GnRH antagonist with a potentially best-in-class profile in late-stage clinical development for the treatment of challenging women's reproductive health conditions like uterine fibroids and endometriosis. OBE2109 acts by preventing the endogenous gonadotropin releasing hormone (GnRH) from activating its pituitary receptors, ultimately reducing estrogen production by the ovaries. Through previously reported results from this class of drugs and sophisticated pharmacological modelling, it is established that maintaining estradiol within a specific target range is essential to inhibit disease progression and alleviate symptoms whilst avoiding significant bone mineral density loss.<sup>(5)</sup> Phase 2a studies conducted in Japan demonstrated that OBE2109 resulted in a reduction of endometriosis-associated pain, analgesic use and bleeding days. ObsEva licensed OBE2109 from Kissei Pharmaceuticals in late 2015 and retains worldwide commercial rights, excluding Asia.

## **About Kissei**

Kissei is a Japanese pharmaceutical company with approximately 70 years of history, specialized in the field of obstetrics/gynecology, renal dialysis, urology, metabolism and ophthalmology. 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 which contributes to Kissei's obstetrics/gynecology franchise.

## **About ObsEva**

ObsEva is a biopharmaceutical company innovating women's reproductive health and pregnancy therapeutics from conception to birth. Between the ages of 20 and 50, millions of women worldwide suffer from reproductive health conditions that affect their quality of life and their ability to conceive or may lead to complications during pregnancy. ObsEva aims to improve upon the current treatment landscape with the development of novel, oral medicines with potentially best-in-class safety and efficacy profiles. Through strategic in-licensing and disciplined drug development, ObsEva has established a late-stage clinical pipeline with multiple development programs focused on treating endometriosis, uterine fibroids, Assisted Reproductive Technology and preterm labor. ObsEva is supported by top-tier investors and a globally recognized board and is well-positioned to establish a leadership position in women's reproductive therapeutics. For more information, please visit [www.ObsEva.com](http://www.ObsEva.com).

(1) The World Endometriosis Research Foundation

(2) <http://www.mayoclinic.org/diseases-conditions/endometriosis/basics/definition/con-20013968>

(3) <http://www.acog.org/Patients/FAQs/Endometriosis>

(4) Simoens S, et al. The burden of endometriosis: costs and quality of life of women with endometriosis and treated in referral centres. Hum Reprod 2012.

(5) CPT: Pharmacometrics & Systems Pharmacology (2012) 1, e11; [www.nature.com](http://www.nature.com)

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