ObsEva SA Announces the Completion of a Phase 1 PK/PD Clinical Trial Evaluating Different Doses of OBE2109 and Add-Back Therapy

- OBE2109 is a GnRH receptor antagonist currently in development as both a stand-alone treatment and with add-back therapy designed to address the needs of endometriosis and uterine fibroid patients -

Geneva, Switzerland and Boston, MA – 07 June 2017 – ObsEva SA (Nasdaq: OBSV), a Swiss 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 the completion of a Phase 1 clinical trial aimed at evaluating the PK/PD relationship of OBE2109 combined with different doses of add-back therapy.

OBE2109 is a novel, oral GnRH receptor antagonist that is currently in a Phase 2b clinical trial for the treatment of pain associated with endometriosis (EM) and in Phase 3 clinical trials for the treatment of heavy menstrual bleeding (HMB) associated with uterine fibroids (UF) in pre-menopausal women. Although estrogen (E2) suppression is a well-validated strategy for alleviating symptoms of UF and EM, therapeutic benefit can be compromised by hypo-estrogenic effects, principally bone mineral density (BMD) loss. This often necessitates administration of add-back therapy (ABT) to patients, which delivers estrogen/progestogens to counteract the deleterious effects of BMD. The ongoing OBE2109 development program is investigating two complementary approaches to achieving what ObsEva believes is the optimal estrogen level to find a balance between efficacy and side effects. The first approach is to use a "low" dose of OBE2109 that targets an E2 range of 20 to 60 pg/mL, without the addition of add-back therapy. The second approach targets maximal E2 suppression with a "high" dose of OBE2109, combined with add-back therapy to bring exogenous E2 back to the desired level that is intended to aid BMD safety.

"*We are very pleased by the results of this important PK/PD study in which we observed in Caucasian subjects the rapid onset and effectiveness of OBE2109 to reduce E2 levels that was previously reported in Japanese subjects,"* said Ernest Loumaye, MD, PhD, OB&GYN, CEO and Co-Founder of ObsEva. *"We believe there are several important observations from this study that support our ongoing development strategy for OBE2109 as a treatment for EM and UF. First, the OBE2109 dosages of 100 mg and 200 mg being tested in our ongoing PRIMROSE 1 and PRIMROSE 2 Phase 3 clinical trials, as well as add-back therapy of 1mg/0.5 E2/*norethindrone acetate (NETA)*, appear to be doses that balance the intended therapeutic effect with deleterious side effects. Second, as demonstrated by the median E2 level of 18 pg/mL following six weeks of dosing with 100 mg of OBE2109, upwards of 50% of patients may not require add-back therapy. And third, the addition of add-back therapy intended to counteract BMD reduction appears to significantly moderate the potential benefit of GnRH antagonism, in terms of bleeding control as measured by rates of amenorrhea and spotting. Therefore, we continue to believe that development of two regimens of administration for OBE2109 (with and without ABT) may best address the needs of the EM and UF populations.*"

The present Phase 1 clinical trial reported herein aimed to evaluate the pharmacodynamics, safety, tolerability and pharmacokinetics of the oral GnRH receptor antagonist OBE2109 alone or co-administered with E2/NETA add-back therapy. This was a prospective, randomized, parallel group study involving 76 healthy, Caucasian women of child-bearing potential. Subjects were randomized to one of five arms for a period of six weeks to receive either 100 mg of OBE2109 alone or with one of two ABT doses (E2/NETA: 0.5mg/0.1mg or 1mg/0.5mg), or 200 mg of OBE2109 alone or with the standard dose of ABT (E2/NETA: 1mg/0.5mg).

ObsEva observed that OBE2109 at 100 mg and 200 mg doses rapidly reduced E2 to levels that are expected to treat symptoms of UF and EM (see Table 1 below). The marked E2 reduction seen with standalone dosing supports the need for ABT to minimize BMD loss in the 200 mg group, and potentially in some subjects treated with 100 mg. The addition of ABT doses in the study to subjects treated with 100 mg and 200 mg of OBE2109 restored E2 levels to the target range that ObsEva believes would minimize BMD loss. As for the other metric in this clinical trial, the bleeding pattern during the final four weeks of treatment, results were as expected; the vast majority of patients achieved amenorrhea when treated with OBE2109 alone. Notably, the majority of patients in each treatment arm achieved a status of either ”amenorrhea,” or bleeding characterized as “spotting only,” which ObsEva believes demonstrates the benefit of combined OBE2109/ABT (see Table 2 below). However, the rates of bleeding control were lower in treatment arms that included ABT.

Table 1: Median (IQR: 25 – 75%) E2 level after week 1 and 6 of treatment

OBE2109 daily dose	100 mg (n=14)	100 mg (n=14)	100 mg (n=15)	200 mg (n=14)	200 mg (n=15)
Add-Back E2/NETA	-	0.5mg/0.1mg	1mg/0.5mg	-	1mg/0.5mg
E2 Week 1 [pg/mL]	12 (9-18)	25 (18-30)	35 (26-45)	5 (4-7)	27 (22-38)
E2 Week 6 [pg/mL]	18 (9-27)	40 (31-50)	34 (26-47)	3 (2-3)	25 (21-34)

Table 2: Bleeding pattern during the last four weeks of treatment

OBE2109 daily dose	100 mg (n=14)	100 mg (n=14)	100 mg (n=15)	200 mg (n=15)	200 mg (n=15)
Add-Back E2/NETA	-	0.5mg/0.1mg	1mg/0.5mg	-	1mg/0.5mg
Amenorrhea (no bleeding)	86%	21%	53%	87%	33%
Amenorrhea + spotting only	93%	57%	93%	100%	60%

From a safety standpoint, all regimens were well-tolerated and no safety signal emerged. OBE2109 has now been dosed in more than seven hundred (700) women. ObsEva plans to submit detailed results for presentation at a future scientific conference.

About Uterine Fibroids

Uterine fibroids are common non-cancerous tumors that grow within the muscular wall of the uterus.

They can vary in size and number and when symptomatic, are most often accompanied by heavy menstrual bleeding, anemia, abdominal pressure and pain, bloating, increased urinary frequency and reproductive dysfunction. Uterine fibroids are associated with an increased risk of pregnancy complications such as infertility, miscarriage, placental abruption and early onset of labor. According to a study published in the American Journal of Obstetrics & Gynecology in 2003, uterine fibroids affect an estimated 20 to 40 percent of women over the age of 30 in the United States based on clinical cases and women who undergo treatment.

For the millions of women with symptomatic uterine fibroids seeking treatment options, selection is driven by symptom severity, the woman's age, and her desire to have children now or in the future. While medical, surgical and minimally invasive treatments are available, the standard of care for symptomatic uterine fibroids is a hysterectomy or, in women who wish to preserve their fertility, surgical removal of the fibroid(s).

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 do day-to-day activities and has a negative effect on general physical, mental and social well-being.

Endometriosis treatments aim first to alleviate pain, then to remove or decrease the size and number of endometrial lesions, and possibly improve fertility. Oral contraceptives, progestins and NSAIDs are generally first-line treatments for women experiencing pain. Following the failure of first-line therapies, current treatment options are limited to intra-muscular or subcutaneous GnRH agonist injections, GnRH agonists nasal spray pumps or surgery (including hysterectomy) for the most symptomatic cases.

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 based on current exchange rates.

About OBE2109 and GnRH

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 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 OBE2109, including its safety, tolerability and potential for efficacy. 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 and related interactions with regulatory bodies, 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 from time to time. 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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