ObsEva Announces Completion of Phase 1 First-in-Women Study of OBE022 for the Treatment of Preterm Labor

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- First-in-class orally active prostaglandin F2α receptor antagonist designed to safely control inflammation, uterine contractions, membrane ruptures and cervical changes that can result in preterm birth -

Geneva, Switzerland, 13 January 2017 – ObsEva, a biopharmaceutical company focused on the development and commercialization of novel therapeutics for serious conditions that impact a woman's reproductive health and pregnancy, announced today the completion of a Phase 1 single and multiple ascending dose study of OBE022, a potential first-in-class, once daily, oral and selective prostaglandin F2α, or PGF2α, receptor antagonist for the treatment of preterm labor in weeks 24 to 34 of pregnancy. ObsEva is developing OBE022 to safely control PGF2α–mediated inflammation, decreasing uterine contractions and preventing membrane ruptures and cervical changes, which are the key features of preterm labor resulting in preterm birth. The study evaluated the safety, tolerability and pharmacokinetics of OBE022 in healthy post-menopausal female volunteers after single doses of 10 to 1,300 mg and multiple doses between 100 and 1,000 mg/day over 7 consecutive days.

Based on preliminary data from the single and multiple doses administered in the Phase 1 study, OBE022 was observed to be readily absorbed and converted into the active stable metabolite OBE002. Exposure to OBE002 increased with dose of OBE022 and reached clinically meaningful exposure levels within an hour after administration, which is an important feature for orally administered preterm labor treatments. Median OBE002 half-lives were observed to be between 7 and 15 hours, which ObsEva believes is an adequate half-life for OBE022 to have once or twice daily dosing. Single and multiple administrations of OBE022 were well tolerated at all doses. There were no serious adverse events and no clinically relevant changes in safety parameters.

Jean-Pierre Gotteland, CSO of ObsEva stated: "The successful completion of the OBE022 Phase 1 first-in-women study is paving the way for the further evaluation of OBE022 in a Phase 2 study in 2017 to assess its safety and efficacy to delay birth after oral administration in pregnant women who face preterm labor and potentially preterm delivery in weeks 24 to 34 of pregnancy."

About Preterm Labor

Preterm labor, defined as the body commencing the birthing process prior to 37 weeks, is a serious women's pregnancy health condition characterized by uterine contractions, cervical dilation and rupture of the fetal membranes that surround and protect the fetus during pregnancy. According to a study published in the Lancet in 2012, approximately 15 million babies are born before 37 weeks of gestation in 2010, accounting for 11.1% of all live births worldwide. Over 1 million children under the age of five died in 2013 worldwide due to preterm birth complications, and many infants who survive preterm birth may have lifelong health problems such as cerebral palsy, delays in development, hearing and vision issues, and often face a lifetime of disability. The rates of preterm births are rising in almost all countries with reliable data for preterm birth, and are associated with an immense financial impact to the global healthcare system.About OBE022 and PGF2αOBE022 is a first-in-class, once daily, oral and selective prostaglandin F2α (PGF2α) receptor antagonist currently in Phase 1 clinical development for the treatment of preterm labor. PGF2α induces contraction of the myometrium and also upregulates enzymes causing cervix dilation and membrane rupture. ObsEva is developing OBE022 to safely control inflammation through specific inhibition of the PGF2α receptor, which has the potential to decrease uterine contractions and prevent cervical changes and membrane ruptures resulting from preterm labor. In preclinical studies, ObsEva has observed that OBE022 markedly reduces spontaneous uterine contractions in pregnant rats without causing the adverse effects seen with the NSAID indomethacin.

About ObsEva

ObsEva is a biopharmaceutical company innovating women's reproductive health and pregnancy therapeutics from

conception to birth. Between the ages of 15 and 49, millions of women worldwide suffer from reproductive health conditions that affect their quality of life or their ability to conceive and 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 clinical-stage pipeline with multiple development programs focused on treating the symptoms associated with uterine fibroids and endometriosis, improving clinical pregnancy and live birth rates in women undergoing in vitro fertilization, and treating preterm labor. For more information, please visit www.ObsEva.com.

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