

ObsEva Initiates Phase 1 Clinical Program of OBE022, a First-in-Class Orally Active Prostaglandin F_{2α} Antagonist, for the Treatment of Preterm Labor

July 28, 2016 11:41 AM ET

Geneva, Switzerland, 28 July 2016 – ObsEva, a biopharmaceutical company innovating women's reproductive health and pregnancy therapeutics from conception to birth, announced today the initiation of a Phase 1 clinical program of OBE022, a novel, first-in-class, orally-active, small molecule prostaglandin F_{2α} (PGF_{2α}) receptor antagonist. OBE022 is being developed for the treatment of preterm labor. This program will evaluate in 70 healthy volunteers the safety and tolerability, pharmacokinetics and pharmacodynamics of single ascending and multiple ascending oral doses of OBE022 as well as the effect of food on the absorption of OBE022. ObsEva is developing OBE022 to safely control PGF_{2α} – mediated inflammation, uterine contractions, membrane rupture and cervical changes, which are the key features of preterm labor resulting in preterm birth.

Administration of broad prostaglandin synthesis inhibitors, including NSAIDs such as Indomethacin, has been shown to be effective in causing tocolysis (the postponement of preterm labor) (Haas, 2012). However, the use of prostaglandin synthesis inhibitors is strictly limited by severe adverse events which include premature closure of the fetal ductus arteriosus, fetal and neo-natal renal function impairment, and neo-natal necrotizing enterocolitis (Besinger, 1991, Sawdy, 2003, Hammers, 2015). In preclinical studies, OBE022 was shown to inhibit spontaneous uterine contractions in pregnant rats. Moreover, OBE022 was not observed to constrict the ductus arteriosus or impair the neo-natal renal function in this model, which is believed to be because of its specificity relating to the PGF_{2α} receptor. Altogether these observations support the potential of OBE022 as a tocolytic without the safety liability of NSAIDs.

"The first-in-human study program is an important step towards the development of our first-in-class, orally active, PGF_{2α} antagonist OBE022. This further strengthens our advanced clinical stage product pipeline. The program, designed for evaluating in healthy women, the safety, the tolerance and the pharmacokinetics properties of OBE022, will be essential for moving to Phase 2 in 2017," stated Jean-Pierre Gotteland, Chief Scientific Officer of ObsEva.

Oliver Pohl, Senior Director Non-Clinical Development and Phase 1 of ObsEva added: *"The role of prostaglandins in preterm labor and the dilemma of risks versus benefits for the fetus and the neonate, by broadly inhibiting prostaglandin synthesis, is well established. Within the family of prostaglandins, PGF_{2α} plays a central action in labor and OBE022 specificity to antagonize its action should provide a new modality for the treatment of preterm labor with an improved safety profile compared to NSAIDs."*

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About Preterm Labor

Preterm labor is a serious women's pregnancy health condition characterized by premature uterus contractions leading to birth before 37 weeks of gestation. The cause of preterm labor is often not known, although there are multiple risk factors associated with the onset of the condition such as inflammation, high blood pressure and/or diabetes, among others. According to the World Health Organization, 15 million babies are born before 37 weeks of gestation every year, which represents more than 1 in 10 babies. Over 1 million children die each year due to complications of preterm birth and many survivors are at greater risk for 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, and are associated with an immense financial impact to the global healthcare system. Currently, NSAIDs as pan-inhibitors of prostaglandin synthesis are commonly used therapies but are associated with severe safety risks for the fetus and the neonate.

About OBE022 and PGF_{2α}

OBE022 is a first-in-class, orally active small molecule prostaglandin F_{2α} (PGF_{2α}) receptor antagonist currently in Phase 1 clinical development for the treatment of preterm labor. PGF_{2α} contracts the myometrium, and causes metabolites to rise in amniotic fluid before and during labor. PGF_{2α} also upregulates enzymes causing cervix dilation and membrane rupture. ObsEva is developing OBE022 to safely control inflammation through a specific inhibition of the PGF_{2α} receptor, which has the potential not only to suppress uterine contractility but also to prevent cervical changes resulting from preterm labor. In preclinical studies, ObsEva has observed that OBE022 inhibits spontaneous uterine contractions in pregnant rats without causing the adverse effects seen with NSAIDs.

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 uterine fibroids, endometriosis, 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.

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