

## **ObsEva Reports Positive Phase 1 Results for the First Orally Active Oxytocin Antagonist OBE001 to Treat Preterm Labour – Positive Safety, Rapid Absorption and Absence of Interaction with Betamethasone is Basis for Phase 2 Study –**

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**Geneva, Switzerland, 26 February 2015** – ObsEva, a Swiss biopharmaceutical company developing a novel generation of drugs addressing serious conditions compromising pregnancy from conception to birth, announced today the results of a Phase 1 drug interaction study for its lead compound, OBE001. OBE001 is a novel orally active oxytocin receptor antagonist, which ObsEva is developing for the treatment of preterm labour. The study was designed to assess the safety, tolerability and pharmacokinetics of OBE001 and betamethasone when co-administered to healthy non-pregnant women. Betamethasone is a corticosteroid systematically administered to prevent respiratory distress syndrome in threatened preterm labour patients. The results of this phase 1 study have been published today in the Journal of Clinical Pharmacy and Therapeutics and are available on the [journal website](#).

*“Demonstrating rapid absorption of the drug and absence of clinically relevant drug interactions with standard of care for this condition is essential. The results of this phase 1 study constitute an important step towards the development of OBE001 in preterm labour patients. Preterm labour is a second indication for OBE001, the lead indication being improvement of embryo implantation and clinical pregnancy rate in women undergoing IVF/ ICSI for which patient recruitment is ongoing in a Phase 3 enabling Phase 2 study”* stated Ernest Loumaye, CEO and Co-Founder of ObsEva.

The study was an open-label, randomised, 3-way crossover design and was performed in 12 healthy women. It showed that after oral administration OBE001 is rapidly absorbed with targeted therapeutic plasma levels reached within thirty minutes and maximal serum concentrations reached in a couple of hours. Moreover, co-administration of OBE001 and betamethasone did not adversely impact their respective pharmacokinetics. Both drugs, either alone or in combination, were well tolerated.

*“In clinics, it will thus be feasible to administer betamethasone in patient treated with OBE001 for threatened preterm labour and this will not require any specific precaution or administration adaptation”* added Oliver Pohl, Senior Director Non-Clinical Development and Phase 1 of ObsEva.

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### **About Preterm Labour and About OBE001**

According to The Global Action Report on Preterm Birth edited by WHO in 2012 “Born Too Soon”, 15 million babies are born too soon (born before 37 weeks of gestation) every year. This represents more than 1 in 10 babies. Over 1 million children die each year due to complications of preterm birth and many survivors face a lifetime of disability. The rates of preterm births are rising in almost all countries. These significant facts are associated with an important financial burden to the society, with an annual cost of preterm births which was estimated in 2005 at around 27 billion USD in the USA. Costs after the neonatal period for lifetime medical & special services reach more than 500K USD per premature/handicapped child. Preterm labour is characterized by premature uterus contractions leading to birth before 37 weeks and for which only products with limited efficacy or limiting safety are available.

OBE001 is a new generation oxytocin antagonist. Oxytocin antagonists are potent inhibitors of uterine contractions. OBE001 is a compound for oral treatment of preterm labour.

OBE001 is also currently assessed in a Phase 3 enabling Phase 2 study for improving embryo implantation and clinical pregnancy rate in women undergoing IVF/ICSI. For additional information about Assisted Reproductive Technology (ART) and about OBE001, please visit [www.obseva.com](http://www.obseva.com) and see the Press release dated November 18<sup>th</sup>, 2014.

## **About ObsEva**

ObsEva SA is a Swiss biopharmaceutical company developing a novel generation of drugs addressing serious conditions compromising pregnancy from conception to birth.

ObsEva's assets are innovative products in clinical development addressing preterm labour and infertility treatment as well as additional indications in reproductive medicine.

For more information, please visit [www.obseva.com](http://www.obseva.com)

For further information, please contact ObsEva CEO Office: