

## **ObsEva Announces the Initiation of a Pivotal Phase 2 Study to Evaluate OBE001 for Improving Embryo Implantation and Clinical Pregnancy Rate in Women Undergoing IVF/ICSI**

November 18, 2014 3:42 PM ET

**Geneva, Switzerland, 18 November 2014** – ObsEva, a Swiss biopharmaceutical company dedicated to the development and commercialization of innovative drugs for women's reproductive medicine, announced today the initiation of a Phase 3-enabling, Phase 2 study of its lead compound, OBE001, a novel orally active oxytocin receptor antagonist. The IMPLANT study is designed to assess the safety and efficacy of a range of doses of OBE001 compared to placebo in women undergoing embryo transfer after IVF/ICSI. The primary objective of this study is to assess the increase in clinical pregnancy rate.

*"Initiation of this study is an important milestone for our young company and demonstrates ObsEva's expertise and operational capabilities as we continue to execute our product development plan"* stated Ernest Loumaye, CEO and Co-Founder of ObsEva.

The study is a prospective, dose-finding randomised, parallel group, double-blind, placebo-controlled study. It is planned to recruit 240 patients at 30 specialist IVF centres across 6 European countries including Belgium, Czech Republic, Denmark, Poland, Spain and UK.

*"The study will recruit women who are at risk of embryo implantation failure due to the presence of uterine contractions at the time of embryo transfer"* added Andrew Humberstone, Head of Clinical Operations of ObsEva. *"They will be administered a single, oral dose of OBE001 or placebo before embryo transfer"*.

The specialist IVF centre at Brussels Hospital University (UZB) in Belgium has been the first site to be initiated on November 17, 2014. Professor Herman Tournaye is the principal investigator for the IMPLANT study at that site.

*"Implantation is a key to success in ART, however, it largely remains a black box. Given the fact that uterine contractions may have a negative impact on this process, as a clinician, I am glad to have the opportunity to participate to the IMPLANT study which assesses the potential of this new compound to inhibit uterine contractions and improve success rates in ART"* said Pr. Herman Tournaye, Head of the Centre for Reproductive Medicine, Brussels Hospital University (UZB), Belgium.

More information on the trial is available at [www.clinicaltrials.gov](http://www.clinicaltrials.gov)

– ends –

### **About Assisted Reproductive Technology (ART) and About OBE001**

Infertility affects about 10% of reproductive-aged couples. Every year, worldwide, about 1.6 million of ART/IVF treatments are performed of which 176'000 are in the USA and 588'000 in the EU. The success rate of such treatment is highly dependent of the age of the woman and is on average 20-25% *Take Home Baby* rate per treatment cycle. The cost of one ART/IVF cycle varies between USD 8'000-15'000 in the USA, EUR 2'000-10'000 in the EU and USD 2'000-6'000 in Japan. There is good evidence that uterine contractile activity at the time of embryo transfer could expel embryos from the uterus. It is estimated that about 30% of patients undergoing embryo transfer have pronounced uterine contractions. OBE001 is a new generation of oxytocin antagonist with the potential to inhibit uterine contractions at the time of embryo transfer, thereby enhancing embryo implantation during ART and increase ART *Take Home Baby* rates.

### **About ObsEva**

ObsEva SA is a clinical stage, Swiss biopharmaceutical company dedicated to the development and commercialization of innovative drugs for women's reproductive medicine. ObsEva was founded in November 2012, by Ernest Loumaye MD,

PhD and André Chollet PhD. Ernest Loumaye is a specialist in female reproductive medicine with 20 years of experience in the biopharmaceutical industry. Ernest Loumaye was previously Co-Founder and CEO of PregLem SA, a successful biopharmaceutical company which was acquired by Gedeon Richter in 2010. André Chollet is specialist in medicinal and pharmaceutical chemistry with more than 30 years of experience in various positions in the biopharmaceutical industry. André Chollet was responsible for the preterm labor program at Serono before the acquisition of the company by Merck KGaA.

ObsEva's founding assets are innovative products at early stages of clinical development addressing preterm labor 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:

Delphine Renaud

Tel: +41 22 552 1550

Email: [delphine.renaud@obseva.ch](mailto:delphine.renaud@obseva.ch)