

ObsEva SA

Developing advanced therapeutics for endometriosis, uterine fibroids, preterm labor, and IVF (In Vitro Fertilization) / ICSI (Intracytoplasmic Sperm Injection)

www.obseva.com

ObsEva SA
Chenin des Aulx, 12
Plan-les-Ouates, 1228
SWITZERLAND

Founded in: 2012
CEO: Ernest Loumaye M.D. Ph.D.
No. of employees: 30
Type of Ownership: Public
Stock exchange: OBSV (NASDAQ)

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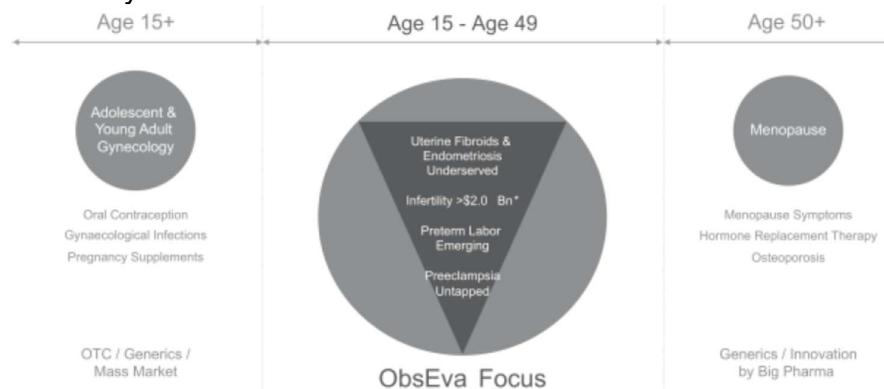
ObsEva is specialized in reenergizing women's reproductive and pregnancy therapeutics that have been overlooked and underserved for years. Venture Valuation (VV) interviewed Dr. Ernest Loumaye, co-founder and CEO.



VV: ObsEva is expert in reproductive health and pregnancy therapeutics.

Loumaye: Millions of women in the world suffer from reproductive health conditions that significantly impact their quality of life, ability to conceive, and potential complications in pregnancy. Compared to younger and older women who have access to various treatment options for women's health issues, the efficacy of current treatment options is limited for patients suffering from uterine fibroids, endometriosis, infertility, and preterm labor.

ObsEva is committed to developing leading-edge therapeutics to serve those patients who have been overlooked, underdiagnosed and underserved for years.



VV: Since ObsEva has been established in 2012, all products in its pipeline are already in clinical phases (chart below). What is your business strategy?

Loumaye: We strategically look for and select compounds to in-license, develop and potentially commercialize. Product OBE2109 for endometriosis and uterine fibroids was acquired from Kissei Pharmaceuticals. Three Phase 2a studies have already been completed in endometriosis in Japan. We have the exclusive rights to develop and commercialize OBE2109 worldwide excluding Asia.

Products OBE001 for IVF and ICSI, and OBE022 for preterm labor were in-licensed from Merck Serono. We own the exclusive rights to develop and commercialize those products worldwide.

Product Candidate	Preclinical	Phase 1	Phase 2	Next Milestone	Commercial Rights
OBE2109 Oral GnRH receptor antagonist	Endometriosis			US/EU Phase 2b data 1H 2018	Worldwide ex-Asia
	Uterine Fibroids			Initiate two US/EU Phase 3 1H 2017	
OBE001 (nolasiban) Oral oxytocin receptor antagonist	IVF			Initiate European Phase 3 1H 2017	Worldwide
OBE022 Oral PGF _{2α} receptor antagonist	Preterm Labor			DDI data 1H 2017	Worldwide

VV: OBE2109, oral GnRH (Gonadotropin-releasing hormone) antagonist, is for a dual indication: endometriosis and uterine fibroids. Is it possible that the new GnRH antagonist approach represented by OBE2109 may take over from the GnRH agonist drugs available on the market?

Loumaye: GnRH agonists were originally designed for the treatment of prostate cancer, targeting the pituitary gland to ultimately shut down testosterone in males and oestrogen production in females. For treating endometriosis, their therapeutic limitations are an initial worsening of symptoms, administration by injection only, risk of substantial bone loss, and other adverse effects.

OBE2109 is a novel orally administrable GnRH antagonist. Its consistent PK/PD (pharmacokinetic/pharmacodynamic) profile potentially allows for personalized dosing aiming to maintain estradiol levels within an acceptable range to relieve symptoms while mitigating patient bone density loss. Furthermore, OBE2109's PK/PD profile may be favorable to other GnRH antagonists in development such as Elagolix (by Neurocrine and AbbVie) and Relugolix (by Myovant).

Six months ago, we announced the initiation of a phase 2b clinical study aiming at the randomization of approximately 330 patients. This study

(EDELWEISS) is being conducted in 46 centers in the U.S. and 15 in Central and Eastern Europe.¹

It is worth mentioning that in a subgroup of endometriosis patients enrolled in a phase2a study in Japan, who also had uterine fibroids, around 85% of women taking a 200 mg dose of OBE2109 reported rapid control of bleeding within the first month of treatment and correction of anemia within three.

Uterine fibroids affect 20% to 40% of women over the age of 30. The patients represent an underserved and large market due to the absence of satisfactory medical treatments. Endometriosis affects one in 10 women during their reproductive years, which is approximately 176 million women worldwide. It is a major cause of infertility. Yet current treatment options are not adequate enough to control endometriosis-related symptoms.

VV: OBE001, an orally available small molecule, next generation oxytocin receptor antagonist, aims to improve embryo implantation during ART. What is the development stage?

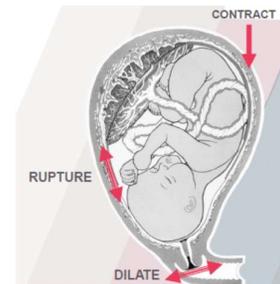
Loumaye: OBE001 has been assessed in a Phase 2 clinical study. Based on the results of the Phase 2 clinical study, we believe OBE001 can enhance uterine receptivity at the time of embryo transfer, and embryo implantation during ART. In consequence, OBE001 was observed to increase clinical pregnancy rates and live birth rates following IVF compared to placebo.

Infertility affects about 11% of reproductive-aged couples. Approximately 1.6 million ART treatments are performed worldwide each year. We believe OBE001 has the potential to contribute to support successful ART treatments.

VV: OBE022, an orally available small molecule, PGF2 α receptor antagonist for preterm labor (24 to 34 weeks), is now in a Phase 1 study which is scheduled to be completed by Q2 2017.

Loumaye: OBE022 has the potential to be a first-in-class oral medication on the market. It has the potential to suppress uterine contractions and prevent membrane rupture and cervical changes resulting in preterm birth.

Different from currently approved treatments which are given by intravenous infusion, OBE022 oral medication may provide a new therapeutic approach to control preterm labor and delay birth.



¹ <http://www.obseva.com/news/obseva-randomizes-first-patient-phase-2b-edelweiss-study-obe2109-treatment-endometriosis/>



Preterm labor treatment requires serious medical attention. According to World Health Organization², around 15 million babies worldwide (more than one in 10) are born too soon every year (before week 37 of pregnancy). Since 2014 preterm birth has been the world's number one cause of neonatal death (death in the first 28 days of life).

VV Comments after the interview:

"There has been little innovation in the field to treat this chronic condition (endometriosis) over the last thirty years and currently available drugs have significant limitations." mentioned Dr. Hugh S. Taylor, Chair of the Department of Obstetrics Gynecology and Reproductive Sciences at Yale School of Medicine.³ One may wonder why the women's reproductive health and pregnancy therapeutics has been overlooked for so long a time.

Yet the commercial opportunity is not trivial. The global market for endometriosis treatment is estimated to achieve 1.92 billion USD in 2020, and to expand from 2016 to 2026.⁴

According to the EndoCost Study by World Endometriosis Research Foundation⁵, endometriosis causes loss of productivity due to pain and a consequent decrease in quality of life. An average loss of productivity is estimated to 11 hours a week in women with endometriosis. By offering advanced treatment solutions, ObsEva will make a substantial impact on women's socioeconomic progress and empowerment.

Contact **Mariko Hirano**, m.hirano (at) venturevaluation.com

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² http://www.who.int/pmnch/media/news/2012/201204_borntoosoon-report.pdf

³ <http://www.obseva.com/news/obseva-randomizes-first-patient-phase-2b-edelweiss-study-obe2109-treatment-endometriosis/>

⁴ <http://www.pnewswire.com/news-releases/endometriosis-drug-forecasts-and-rd-2016-2026-300300268.html>

⁵ <http://endometriosisfoundation.org/news/article/werf-endocost-study-shows-loss-of-productivity-is-higher-than-direct-healthcare-costs/>