Obseva

nature meets nurture

Overview – July 2023

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OUR COMPANY

ObsEva is a clinical-stage biopharmaceutical company developing novel therapies to improve women's reproductive health.

Through strategic in-licensing and disciplined drug development, ObsEva has established a clinical pipeline with development programs focused on treating infertility and preterm labor.

- Founded in 2012
- Headquarters: Geneva, Switzerland
- Listing on the SIX Swiss Exchange (OBSN) since July 2018

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MULTIPLE DEVELOPMENT PROGRAMS

	PHASE 1	PHASE 2	PHASE 3	
NOLASIBAN Oral oxytocin receptor antagonist	Obseva ✓ Ph1 (EU) Preparing Ph2 / Ph3 Enabling Multiple Dose Study	✓ Ph2 IMPLANT (EU)	✓ Ph3 IMPLANT 2 (EU) × Ph3 IMPLANT 4 (EU)	Worldwide Rights
EBOPIPRANT Oral $PGF_{2\alpha}$ receptor antagonist	Obseva ✓ Ph1 (EU) Organon IND Request	✓ Ph2a (EU) Add On Atosiban		Global license to Organon acquired by Xoma ➢ up to $113 million in upfront and milestone payments

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NOLASIBAN

First-in-class, Blockbuster Potential

for Improving Clinical Pregnancy and Live Birth Rates
in Women Undergoing In-Vitro Fertilization (“IVF”)
in Assisted Reproductive Technology (“ART”)

INFERTILITY: A HUGE GLOBAL MEDICAL NEED

With No Innovation in the Last 25 Years

Infertility – a health & societal issue

- Approx. **17.5% of people affected globally** in 2022 [1]
- Ageing population problematic
- Globally, **> 3.0MM ART/IVF cycles/year** [2]

Too few healthy babies

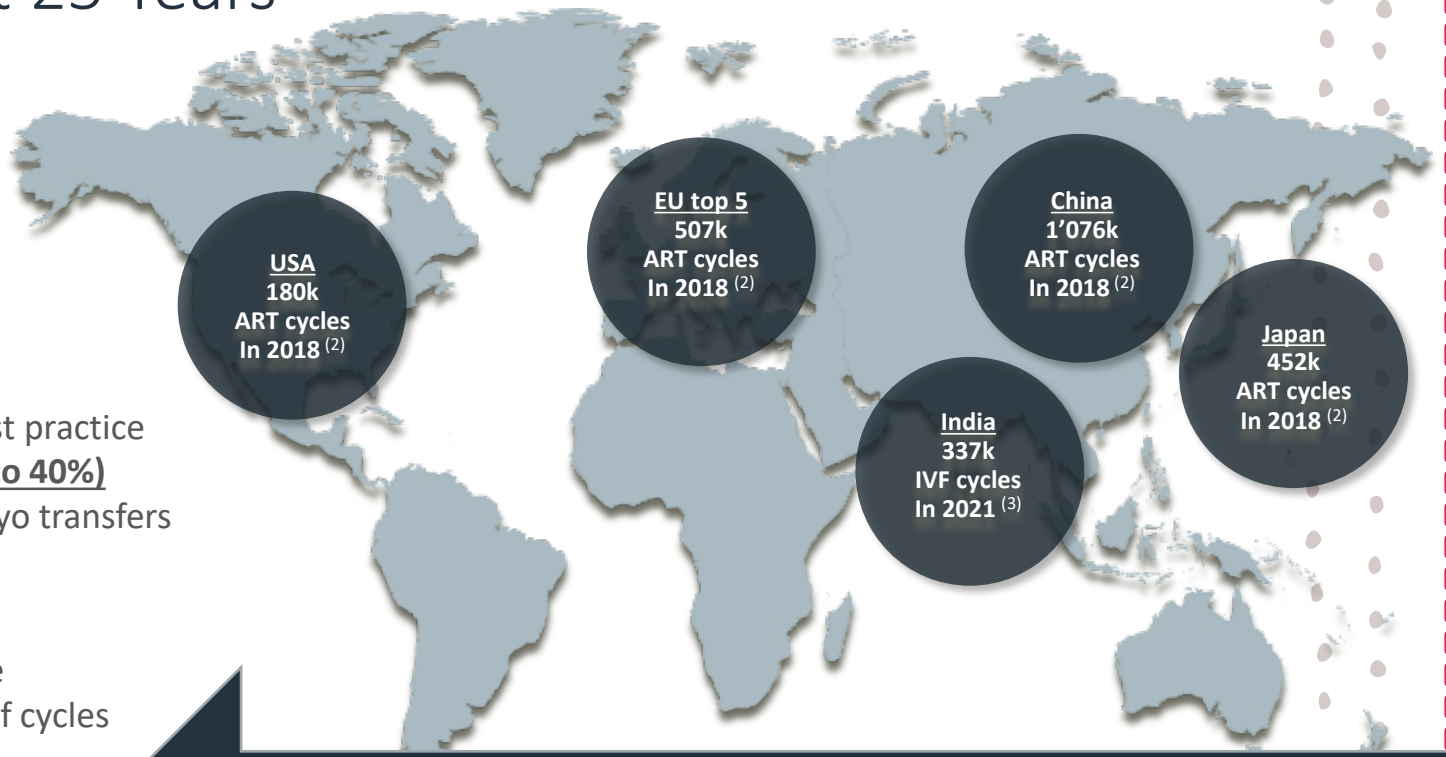
- Despite good quality embryos (blastocysts) & using best practice transfer techniques, **IVF success rate not optimal (30 to 40%)**
- Multiple pregnancy risk associated with multiple embryo transfers

The number of IVF/ART cycles continues to increase

- China a dominant player with 1/3rd of cycles worldwide
- India emerging as a future key contributor in number of cycles

Frozen Thawed ET (FET) becoming the dominant practice

- US: 80.6% of ET were FET in 2020 (69.4% in 2017) [5]
- EU: 38% of ET were FET in 2019 (25% in 2014) [6]



Infertility affects millions of people of reproductive age worldwide – and has an impact on their families and communities. Approximately one in six people have experienced infertility at some stage in their lives, globally. [1]

1. WHO infertility report, April 2023.
2. ICMART preliminary world report 2018: https://www.icmartivf.org/wp-content/uploads/ICMART-ESHRE-WR2018-Preliminary-Report.pdf
3. https://health.economictimes.indiatimes.com/news/industry/indian-fertility-industry-to-witness-huge-growth-in-coming-years/91487508
4. CDC report.
5. ESHRE.

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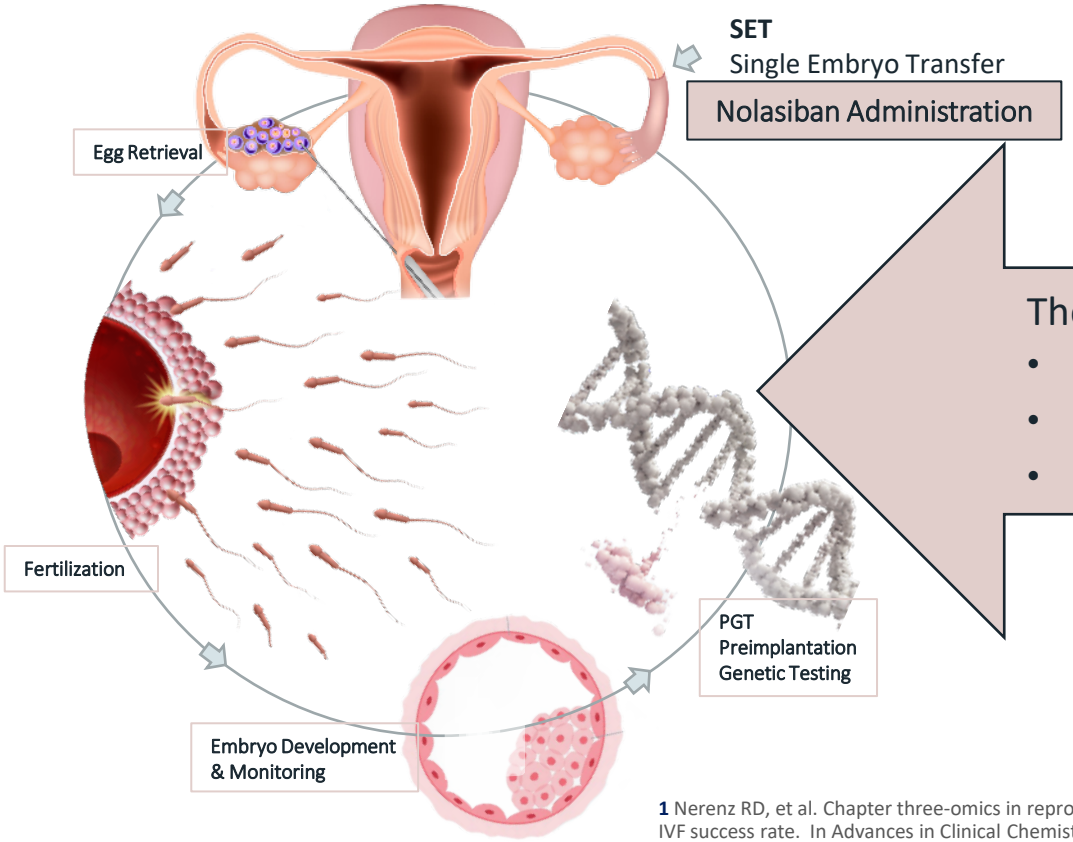
PREDICTORS FOR SUCCESS OF EMBRYO TRANSFER

Uterine Receptivity: an Unaddressed Key Parameter



3-6 Day Window for Uterine/Endometrial Receptivity

The Most Important Predictors for Success of Embryo Transfer are[1,2,3]:

- The Transfer Technique
- Embryo Quality
- **Uterine Receptivity** » **NOLASIBAN IMPACT**

NOLASIBAN INNOVATION

↓

UNIQUE OPPORTUNITY TO IMPROVE UTERINE RECEPTIVITY

1 Nerenz RD, et al. Chapter three-omics in reproductive medicine application of novel technologies to improve the IVF success rate. In Advances in Clinical Chemistry (ed. Makowski GS). 55-95 (Elsevier, Amsterdam, 2016).
2 Tomas C, et al. Human Reprod 2002;17(10:2632-2635.
3 Decleer W, et al. The role of oxytocin antagonists in repeated implantation-failure. Facts Views Vis ObGyn 2012;4:227-229.

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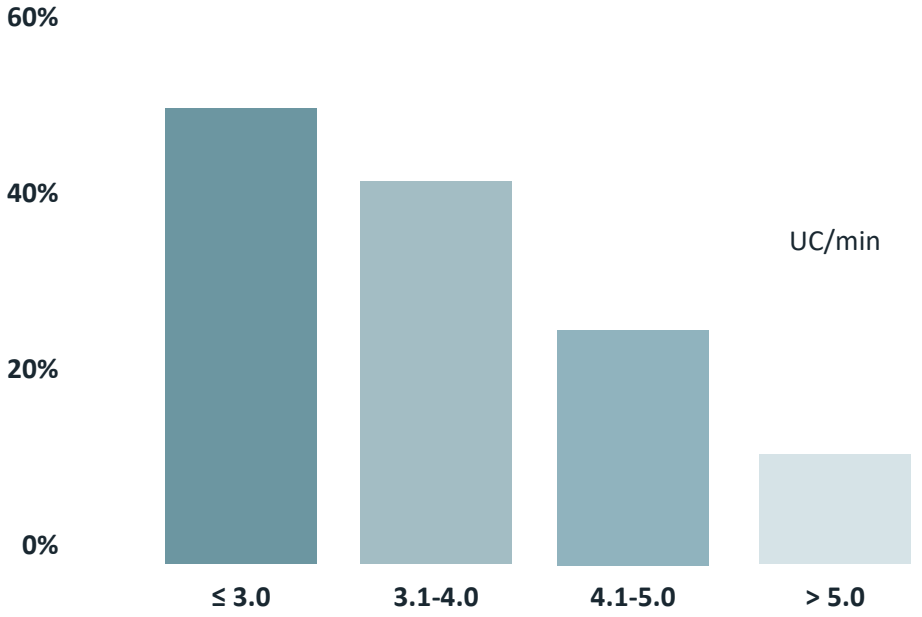
OXYTOCIN RECEPTORS

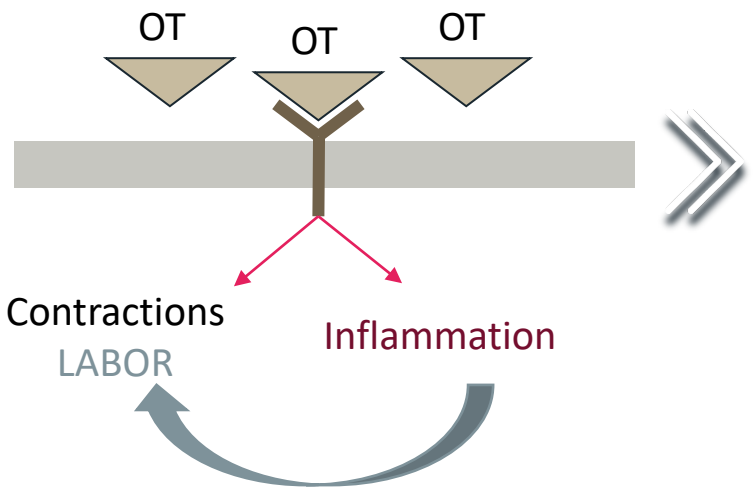
The Right Target to Address Uterine Receptivity

Uterine contractile activity at the time of embryo transfer could expel embryos from the uterus. It is estimated that approx. 30% of patients undergoing embryo transfer have pronounced uterine contractions. Success rates of IVF/ET treatment were 16% versus 53% of clinical pregnancies in patients with “silent” uterus

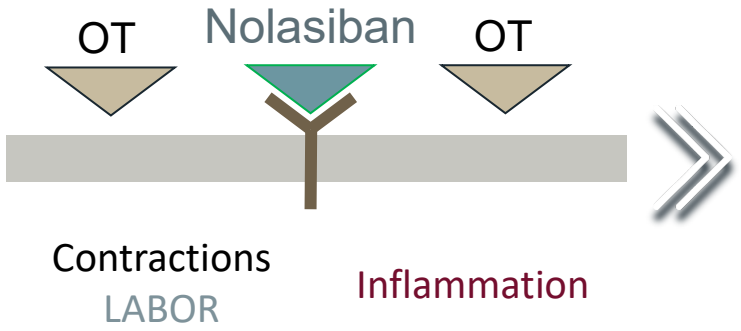
Uterine contractions at the time of embryo transfer alter pregnancy rates after in-vitro fertilization.
Fanchin et al. Human Reprod. 1998



Stepwise decrease in clinical pregnancy rates from the lowest to the highest uterine contraction (UC) frequency groups (P , 0.001; ANOVA).



Oxytocin activates labor directly through contractions and indirectly through activating inflammation.



***Nolasiban**, an Oxytocin Receptor Antagonist, inhibits contractions and inflammation*

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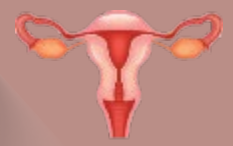
NOLASIBAN

A Potent and Specific Oxytocin Receptor (OTR) Antagonist
to increase embryo implantation rate and life birth rate following embryo transfer

CLINICAL PROFILE

- ✓ Oral administration
- ✓ t_{max} at 2-4h; $t_{1/2}$= 12h
- ✓ High bioavailability
- ✓ IC50: 50 nMol
- ✓ So far developed as a single 900 mg oral dose, 4 hours prior to fresh ET
- ✓ Up to 2400 mg daily dose evaluated in HV

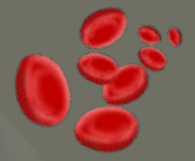
1



Reduced uterine contractions[2,1]

Uterine contraction frequency reduced over 24-hour measurement period

2



Increased endometrium blood flow[3,1]

Improved perfusion (flow and vascularity) in the endometrium

3

Increased endometrium receptivity[4,1]

In vitro changes consistent with improved receptivity[4] and in vivo changes in gene expression potentially relevant for uterine receptivity[1]

1 Pierzyński P et al, Reproductive BioMedicine Online, 2021 Aug, Volume 43, Issue 2, Pages 184-192 - The mechanism of action of oxytocin antagonist nolasiban in ART in healthy female volunteers.
2 Lan V et al, Reprod BioMedicine Online, 2012 Sep, Volume 25, Issue 3, Pages 254-260 - Atosiban improves implantation and pregnancy rates in patients with repeated implantation failure.
3 Kalmantis K et al., Arch Gynecol Obstet 2012; 285:265-270 - Three-Dimensional Power Doppler evaluation of human endometrium after administration of oxytocine receptor antagonist (OTRa) in an IVF program.
4 Sztachelska M et al., RBMO, 2019 - Oxytocin antagonism reverses the effects of high estrogen levels and oxytocin on decidualization and cyclooxygenase activity in endometrial tissues.

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WEALTH OF CLINICAL DATA: COMPLETED STUDIES

Phase 1	Single Ascending Dose/SAD 26414	**Design:** 30, 90, 180, 300, 600, 900,1200 or 1500 mg, single dose oral (liquid-filled capsule)	**Purpose:** Safety and PK	
	Multiple Ascending Dose/MAD 27334	**Design:** 90 mg, 300 mg, 600 mg or 900 mg/day for 7 days (liquid-filled capsule)	**Purpose:** Safety and PK, assess the effect of food on PK of nolasiban	
	Human absorption, metabolism & excretion /hAME	**Design:** 900mg single dose, fasted/oral solution or suspension (po, iv)	**Purpose:** Mass balance – therapeutic dose Routes/rates of elimination / Metabolite profiling / Metabolite identification	
	PK/PD 18-OBE001-004	**Design:** 900 mg, 1800 mg, 2400 mg single dose oral	**Purpose:** Safety, PK and pharmacodynamics endpoints on uterine perfusion and uterine contractions	
Phase 2	IMPLANT 1 NCT02310802 DEC 2014*	**Design:** 100/300/900 mg, placebo R, DB, parallel group, dose-ranging study, N=240	**Purpose:** Dose-ranging study in women undergoing D3 SET or DET following IVF or ICSI	**Key Findings:** 900 mg dose supported highest clinical/ongoing pregnancy rates
Phase 3	IMPLANT 2 NCT03081208 MAR 2017*	**Design:** 900 mg, placebo R, DB, parallel group, Phase 3 study, N=760	**Purpose:** Assess the safety and efficacy of a single oral administration of nolasiban 900 mg in D3 or D5 SET.	
	IMPLANT 4 NCT03758885 NOV 2018*	**Design:** 900 mg, placebo R, DB, parallel group, Phase 3 study, N=820	**Purpose:** Assess the safety and efficacy of a single oral administration of nolasiban 900 mg in D5 SET.	

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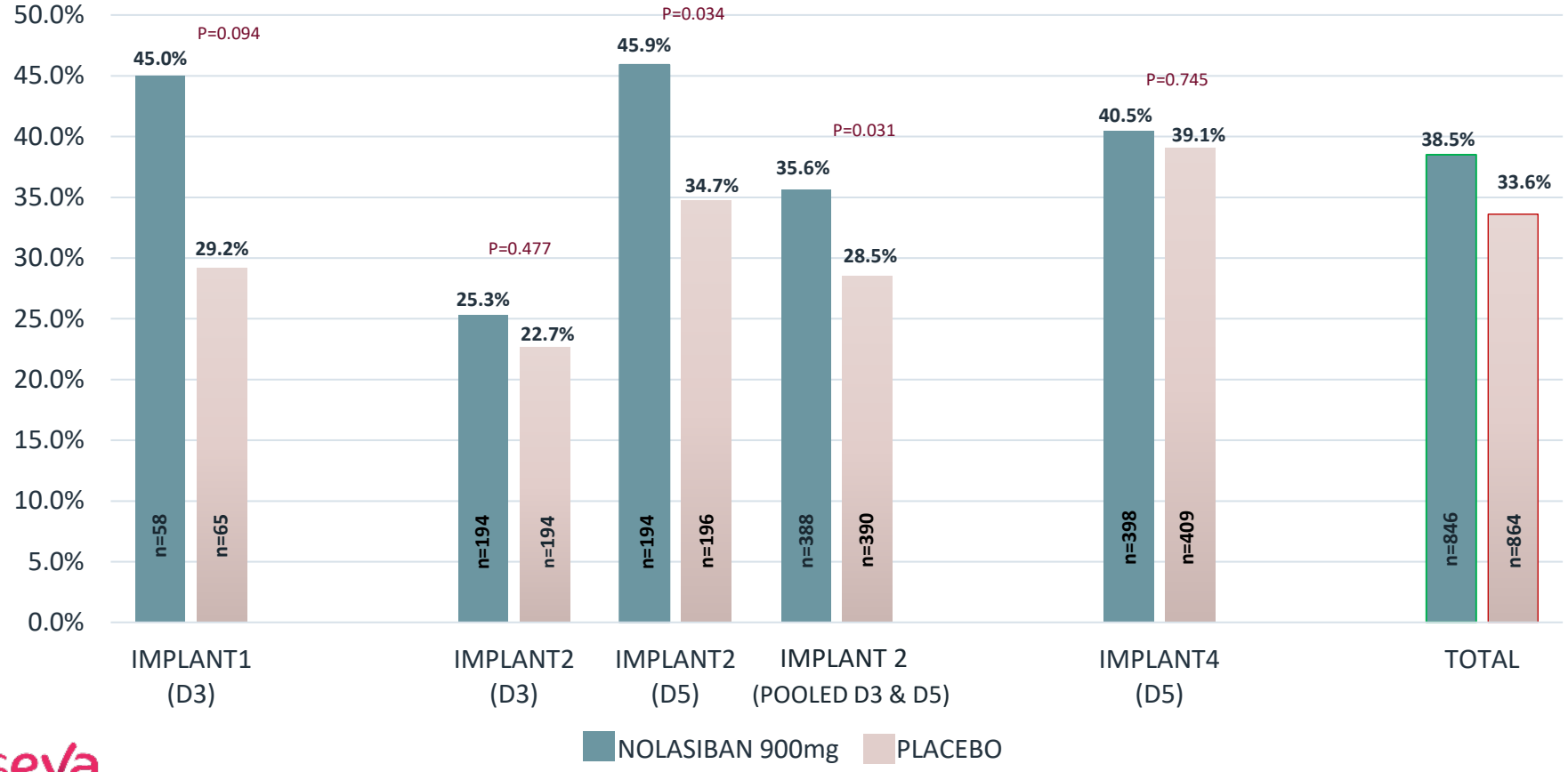
*First patient in

EFFICACY RESULTS

In Phase 2 and Phase 3 “IMPLANT” Clinical Trials of Nolasiban

Ongoing Pregnancy Rate (%) at 10 Weeks



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DRUG SAFETY

Nolasiban well tolerated in > 1100 subjects exposed

Pregnancy and Live Birth

- ✓ Lower or no increase in miscarriage rate
- ✓ No increase in ectopic pregnancy
- ✓ No increase in congenital malformations

28-day Neonatal Follow-up

- ✓ No difference in ICU admissions
- ✓ No difference in reported neonatal morbidity

6-month Infant follow-up

- ✓ No treatment related SAE's identified
- ✓ Median ASQ-3 scores comparable for individual domains*

* IMPLANT 4 : mean and median total scores were slightly higher in the placebo group

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EBOPIPRANT

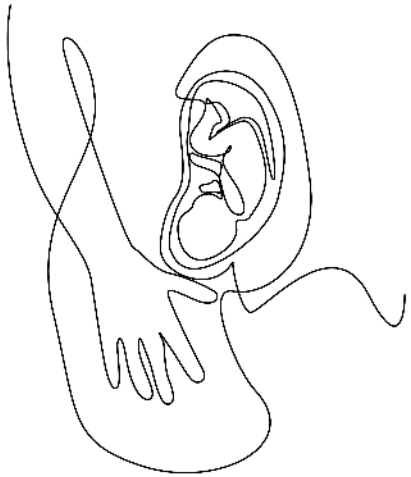
EBOPIPRANT

…..What is Ebopiprant?

ebopiprant

Selectively blocks the $PGF2_{2\alpha}$ receptor

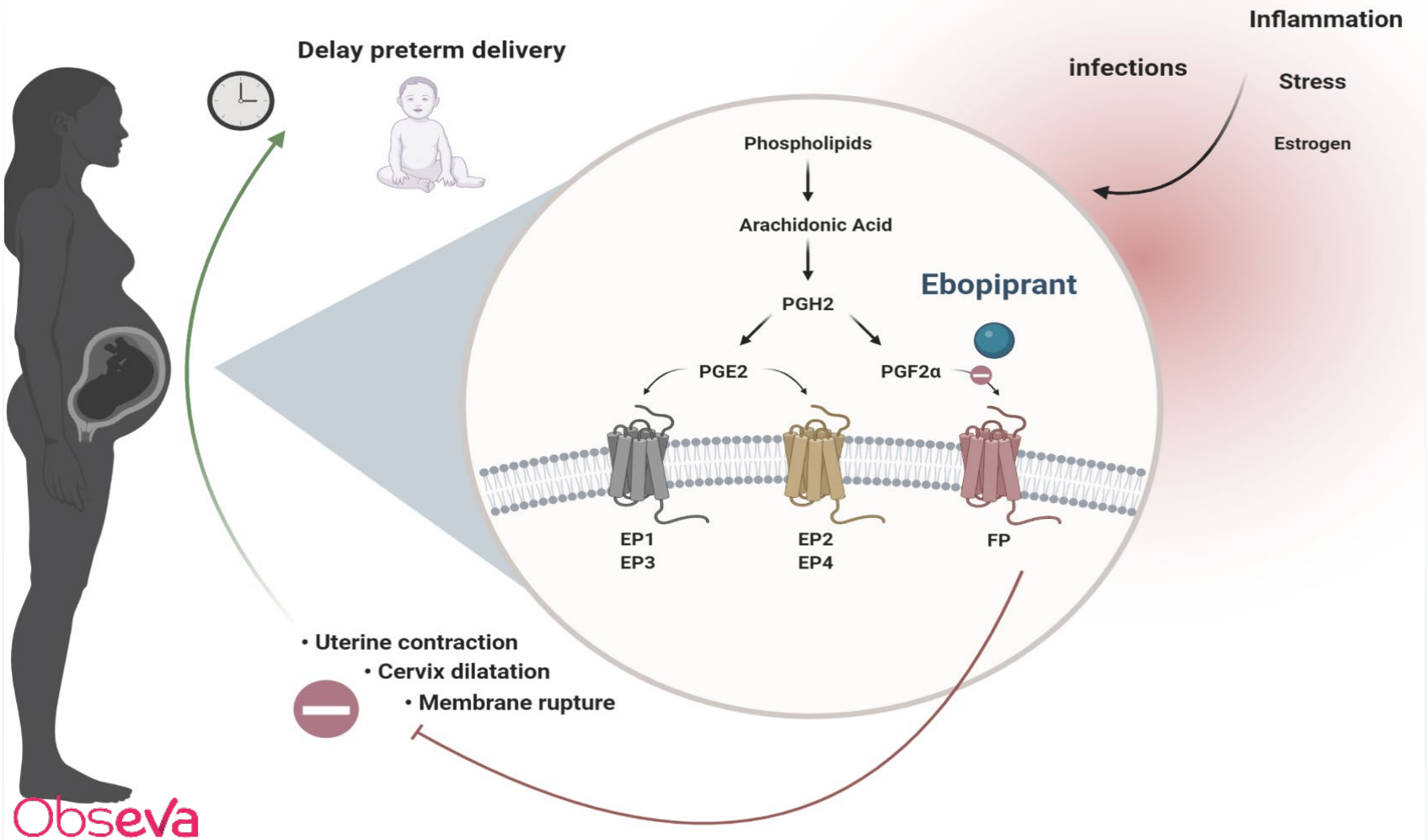
Ebopiprant is a novel, orally available, small molecule, potent prostaglandin F2α (PGF2α or FP) receptor antagonist in development for the treatment of spontaneous preterm labour by reducing inflammation and uterine contractions.



- Ebopiprant was developed by Obseva from preclinical stage to phase 2a, with positive results
- Ebopiprant was in-licenced from Merck KGaA, Darmstadt, Germany, in 2015
- Global development, manufacturing and commercial rights to ebopiprant (OBE022) were licenced to Organon in July 2021, generating an upfront payment of $25 million
- November 2022, ObsEva sold the ebopiprant License Agreement to XOMA for up to $113 Million which included an upfront payment of $15 million and future milestone payments of up to $98 million

EBOPIPRANT

Mechanism of Action



ebopiprant

Selectively blocks the $PGF2_{2\alpha}$ receptor

Ebopiprant:
a potential breakthrough for preterm labor

with improved safety over non-selective COX* inhibitors (NSAIDS)

*COX: cyclooxygenase

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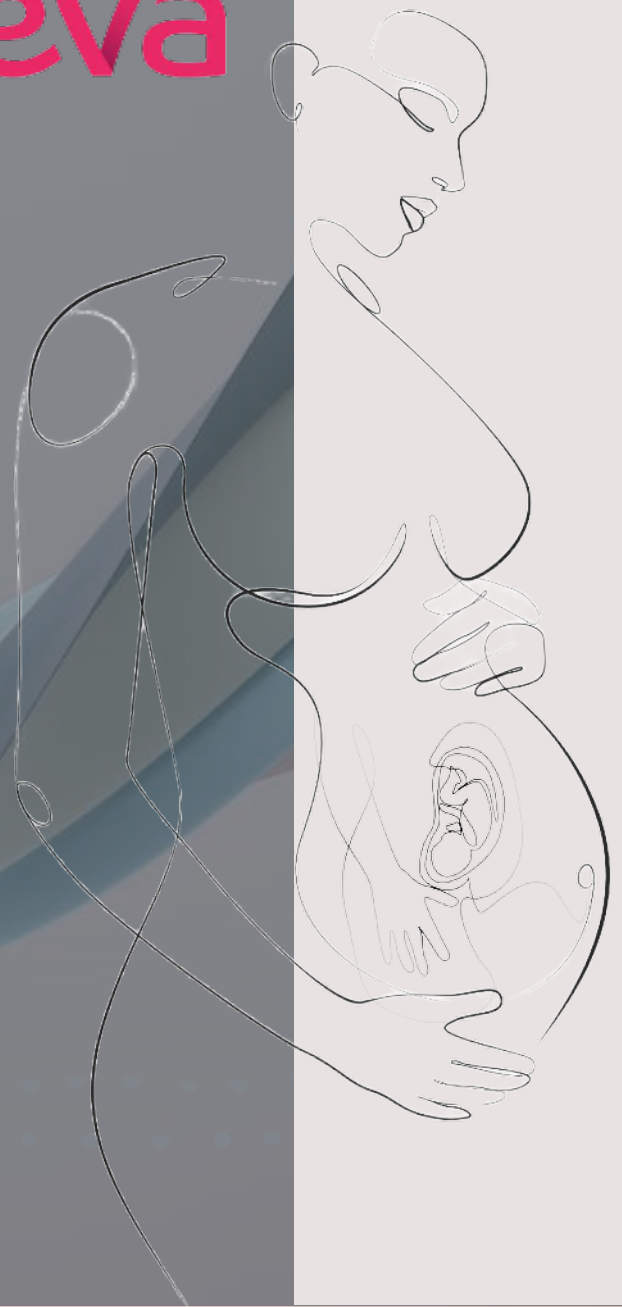

Focused on Unmet Needs in Women’s Reproductive Health