Building a Leader by Innovating Women's Reproductive Health and Pregnancy Therapeutics

April 2018

OBSEVA
obstetrics & beyond

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Strategic Focus:
Large populations with high unmet medical need & limited competition

Age 15+

Adolescent & Young Adult Gynecology

Oral Contraception

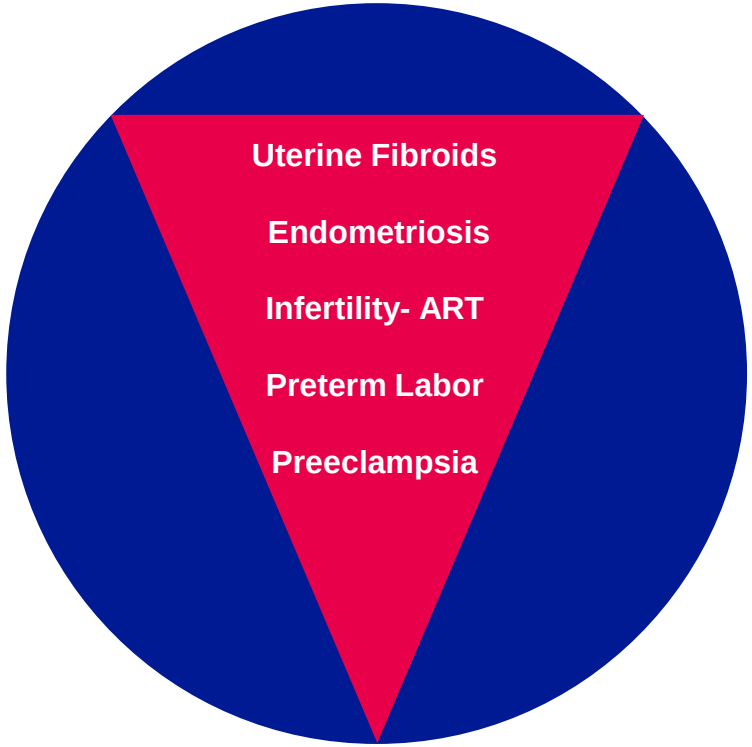
Anti-Infectives

Pregnancy Supplements

OTC / Generics

Age 15 - Age 49

ObsEva Focus



Age 50+

Menopause

Menopause Symptoms

Hormone Replacement Therapy

Osteoporosis

Generics / Innovation by Big Pharma

Unique mix of clinical and operational experience provides in-depth understanding of patient & physician needs

Ernest Loumaye, MD, PhD, OB/GYN
CEO and Co-founder

serono biotech & beyond
IPSEN Innovation for patient care
preglem reproductive medicine

Tim Adams
CFO

demandware
athenahealth
Constitution Medical Investing

Jean-Pierre Gotteland, PhD
CSO

Pierre Fabre
serono biotech & beyond
preglem reproductive medicine

Elke Bestel, MD
CMO

GALDERMA
preglem reproductive medicine

Ben T.G. Tan, MSc
VP Commercial & BD

Organon
NOVARTIS
Roche

A team of 35+ based in Geneva and Boston, with successful experience in world-wide development and commercialization of women health products

SOFINNOVA PARTNERS
SOFINNOVA VENTURES
NEA
MS Ventures
HBM Healthcare Investments
ROCK SPRINGS CAPITAL
OrbiMed Healthcare Fund Management
medicxi
venrock
NEW LEAF VENTURE PARTNERS
FIRST MANHATTAN CO.
OMEGA FUNDS
AISLING CAPITAL

ObsEva is listed on The NASDAQ Global Select Market and trades under the ticker symbol "OBSV"

OBSEVA

Robust late-stage pipeline for women's reproductive health & pregnancy

PRODUCT CANDIDATE	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	STATUS & NEXT MILESTONE	COMMERCIAL RIGHTS
OBE2109* Oral GnRH receptor antagonist			**Endometriosis: EDELWEISS** **		US/EU Phase 2b **Data mid-2018**	Worldwide ex-Asia
				Uterine Fibroids: PRIMROSE1 & 2	US/EU Phase 3 Primary Endpoint **Data 2H 2019**	
NOLASIBAN Oral oxytocin receptor antagonist				**IVF: IMPLANT2 EU** ***	EU Phase 3 **Live birth 4Q 2018**	Worldwide
				IVF: IMPLANT3 US	US Phase 3 **Initiation 4Q 2018**	
OBE022 Oral $PGF_{2\alpha}$ receptor antagonist			**Preterm Labor: PROLONG**		EU Phase 2a **Interim Data Late 2018**	Worldwide

* Kissei developing for Asia

** Patient recruitment completed

*** Week10 pregnancy, primary endpoint met in Feb 2018

2017 Accomplishments and 2018-19 Expected Milestones

Milestone	Timing
OBE2109 (Endometriosis): Completed EDELWEISS trial EU/US patient enrollment	4Q 2017 ✓
NOLASIBAN (IVF): Completed IMPLANT2 trial recruitment	3Q 2017 ✓
OBE022 (Preterm labor): Initiate Phase 2a PROLONG proof-of-concept clinical trial	4Q 2017 ✓
NOLASIBAN (IVF): IMPLANT2 Phase 3 primary endpoint data	1Q 2018 ✓
OBE2109 (Endometriosis): Phase 2b EDELWEISS 12 week primary endpoint data (pain)	**Mid-2018**
NOLASIBAN (IVF): Live birth rate (LBR) results from IMPLANT2 trial	4Q 2018
NOLASIBAN (IVF): Initiation of IMPLANT3 Trial in the U.S.	4Q 2018
OBE2109 (Endometriosis): Phase 2b EDELWEISS 24 week BMD safety results	**4Q 2018**
OBE2109 (Uterine Fibroids): Enrollment completion in Phase 3 PRIMROSE 1 and 2 trials	**4Q 2018**
OBE022 (Preterm labor): Phase 2a PROLONG interim data	Late 2018
OBE2109 (Endometriosis): Initiation of Phase 3 Clinical Trial Program	**Late 2018/early 2019**
NOLASIBAN (IVF): 6 month baby follow-up from IMPLANT2 trial	2Q 2019
OBE2109 (Uterine Fibroids): Phase 3 PRIMROSE 1 and 2 , 24 week primary endpoint data	**2H 2019**
US Phase 3 IMPLANT3 primary endpoint data (Ongoing Clinical Pregnancy 10 weeks)	4Q 2019
NOLASIBAN (IVF): Target EU MAA regulatory submission	2H 2019

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OBE2109 for Endometriosis and Uterine Fibroids

OBE2109: Potential best-in-class, oral, GnRH receptor antagonist

OBE2109 AT-A-GLANCE

- GnRH Receptor Antagonist
- OBE2109 (KLH-2109)
- Licensed from Kissei (WW rights, excludesAsia)
- IP Protection* to 2036 (COM 2032)
- **> 1400 female subjects exposed to date**

OBE2109 INDICATIONS

- **Uterine Fibroids**
  - Symptoms: **Heavy menstrual bleeding** and abdominal pain
  - Primary goal is to reduce/eliminate bleeding
- **Endometriosis**
  - Symptoms: **pain** and infertility
  - Primary goal is to alleviate pain

Landscape

Standard of Care:
Lupron,
oral contraceptives, surgery

Esmya/Fibristal®
SPRM approved in EU/Canada for uterine fibroids, U.S. NDA submitted

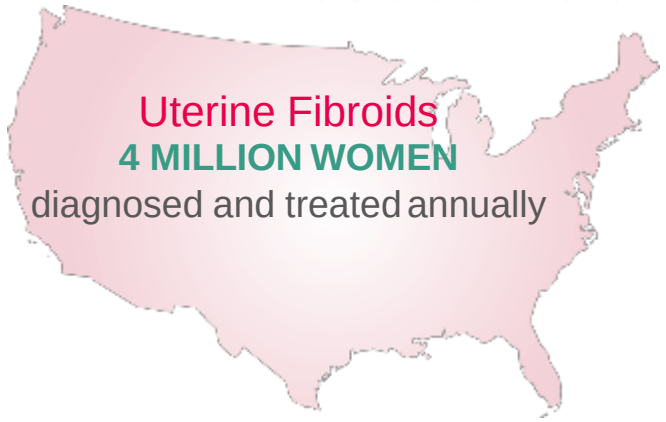
Elagolix
(AbbVie/Neurocrine) in Phase 3 Development for fibroids, U.S. NDA submitted for endometriosis

Relugolix
(Myovant/Takeda) in Phase 3 Development

* Including PTA/PTE (Patent Term Adjustment / Patent Term Extension)

Unmet medical need in endometriosis & uterine fibroids therapy

LARGE U.S. MARKET SIZE



Uterine Fibroids
4 MILLION WOMEN
diagnosed and treated annually

~200K Surgeries (Hysterectomy) Annually

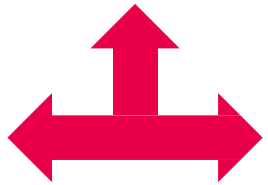
Endometriosis
2.5 MILLION WOMEN diagnosed and treated annually

Seeking to unlock
Another 2.5 MILLION Undiagnosed due to non-specific symptoms and invasive laparoscopy

OLDER, SUBOPTIMAL EXISTING TREATMENTS

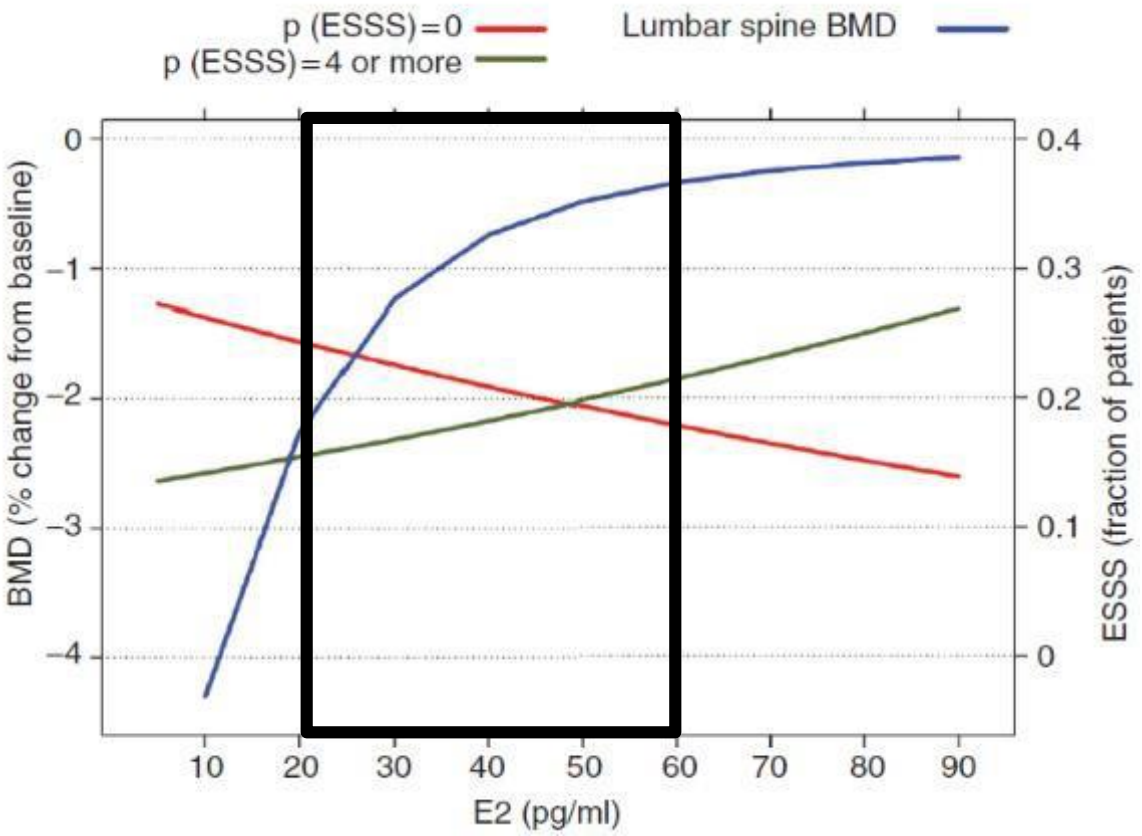
LUPRON® INJECTIONS cause flares, initial worsening of symptoms, no titration possible, prolonged and variable reversibility time

ORAL CONTRACEPTIVE and progestin, only partially effective, safety risks



SURGICAL INTERVENTIONS costly, invasive, side effects

GnRH antagonist MoA: Finding a balance between level of estradiol suppression, associated symptoms, and BMD protection



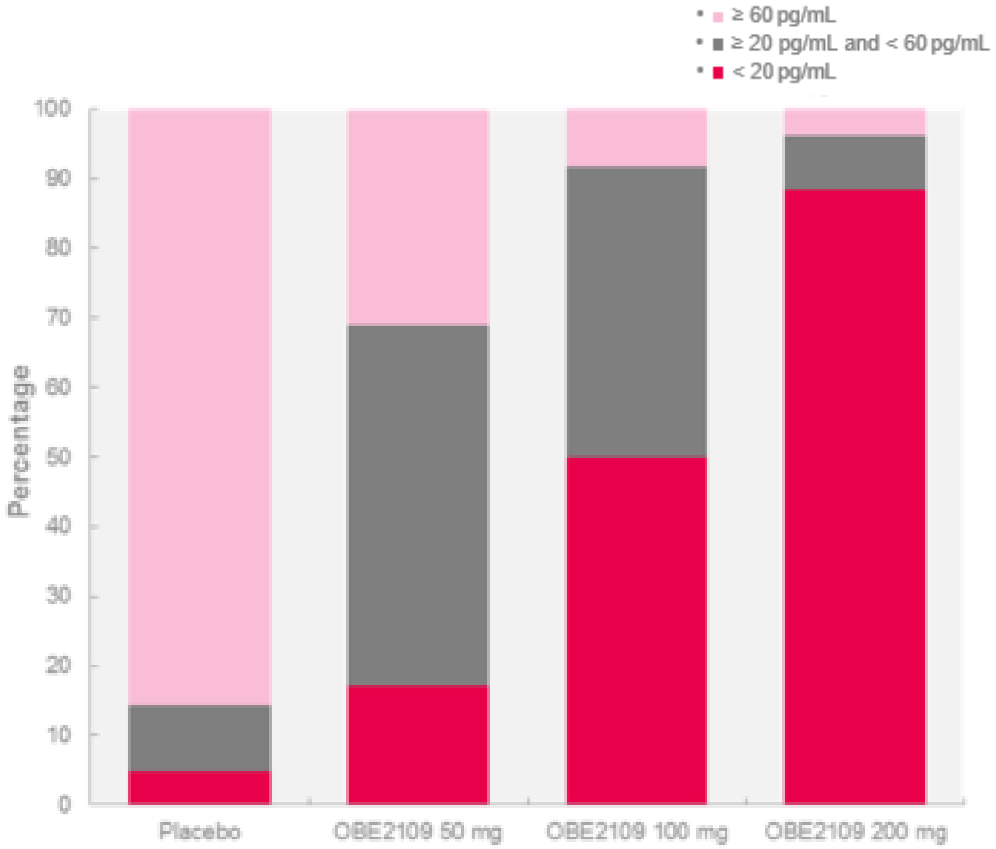
BMD: Bone mineral density
ESSS: Endometriosis symptom severity score

- Estradiol measured at 1-2 months after treatment initiation was shown to be a reliable predictor of 6-month BMD change.
- Estradiol range between 20 and 60 pg/mL targets optimal treatment of endometrial pain while minimizing BMD effects.
- This treatment approach will require use of add-back hormone replacement therapy only as needed.

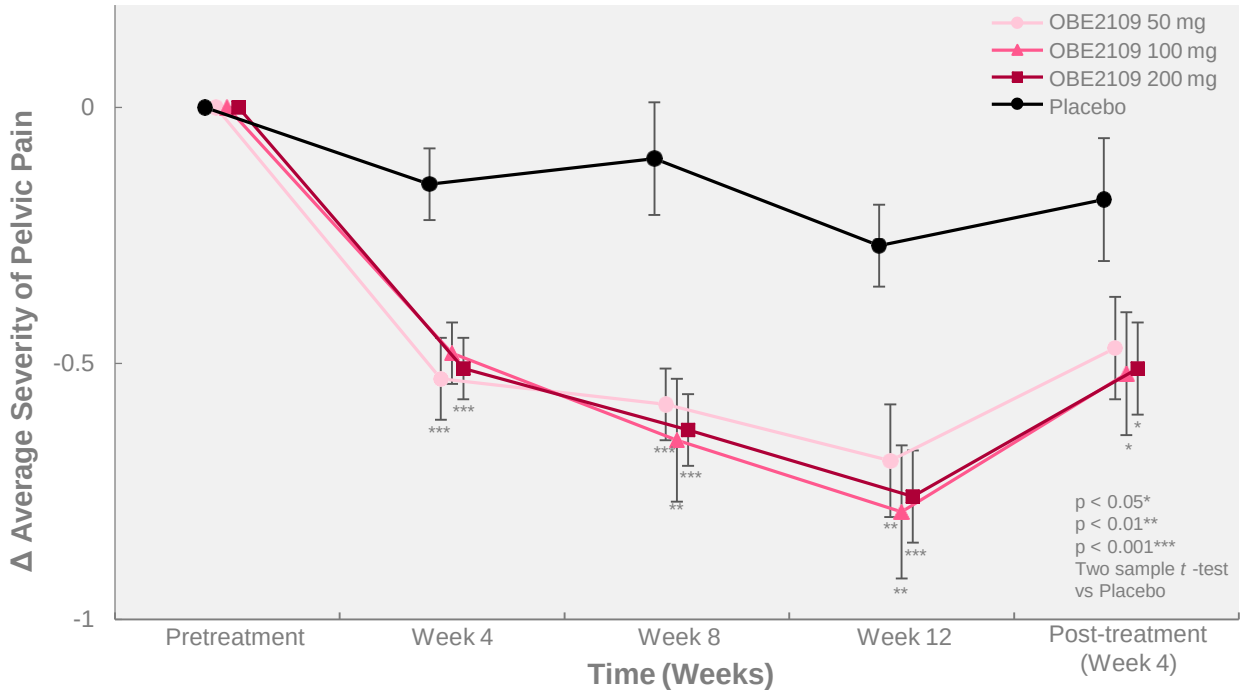
Integrated Pharmacometrics and Systems Pharmacology Model-Based Analyses to Guide GnRH Receptor Modulator Development for Management of Endometriosis
Riggs MM et al. 2012 CPT: Pharmacometrics & Systems Pharmacology 1, e11.

OBE2109 suppressed estradiol levels to the target range and reduced endometriosis-related pelvic pain severity across the three Phase 2 clinical trials (no add back)

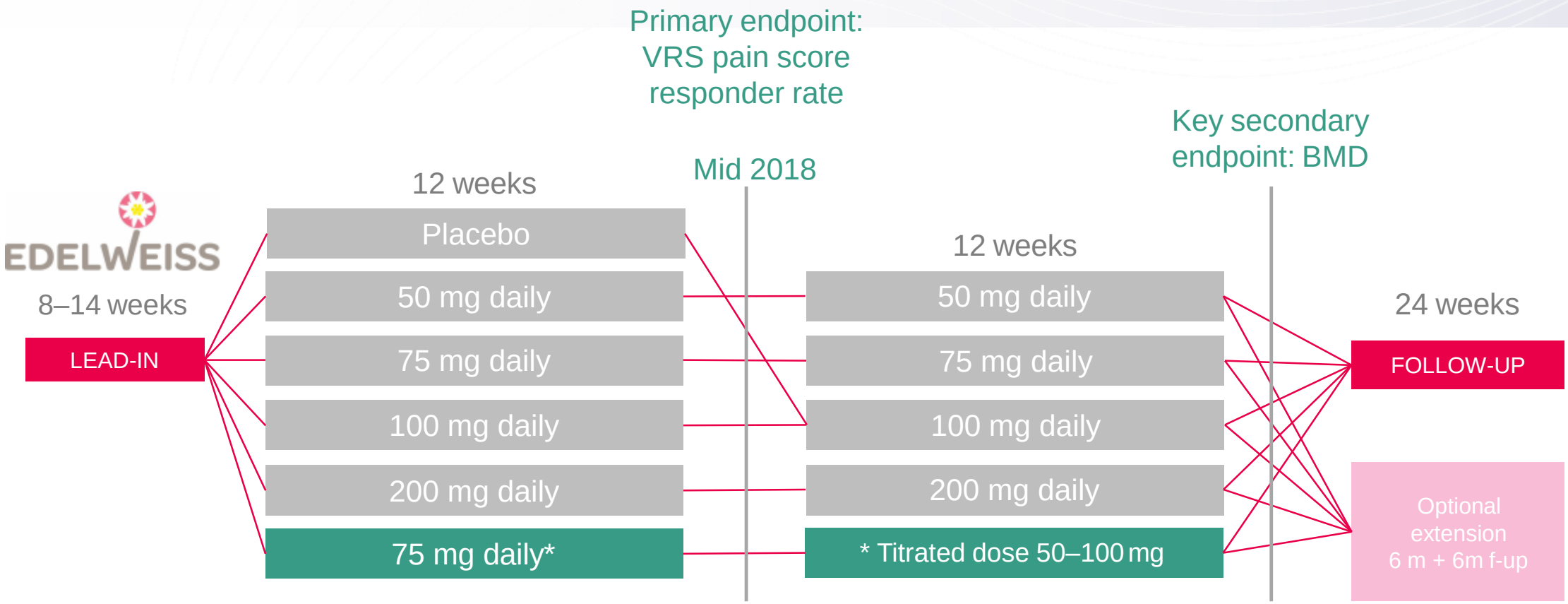
KLH1202 TRIAL: % OF PATIENTS AT VARIOUS ESTRADIOL LEVELS IN KLH1202 TRIAL AT WEEK 12



KLH1202 TRIAL: AVERAGE CHANGE IN SEVERITY OF PELVIC PAIN OVER TIME (MENSTRUAL AND NON-MENSTRUAL PAIN COMBINED)



OBE2109 Phase 2b clinical trial (EDELWEISS) in endometriosis patients



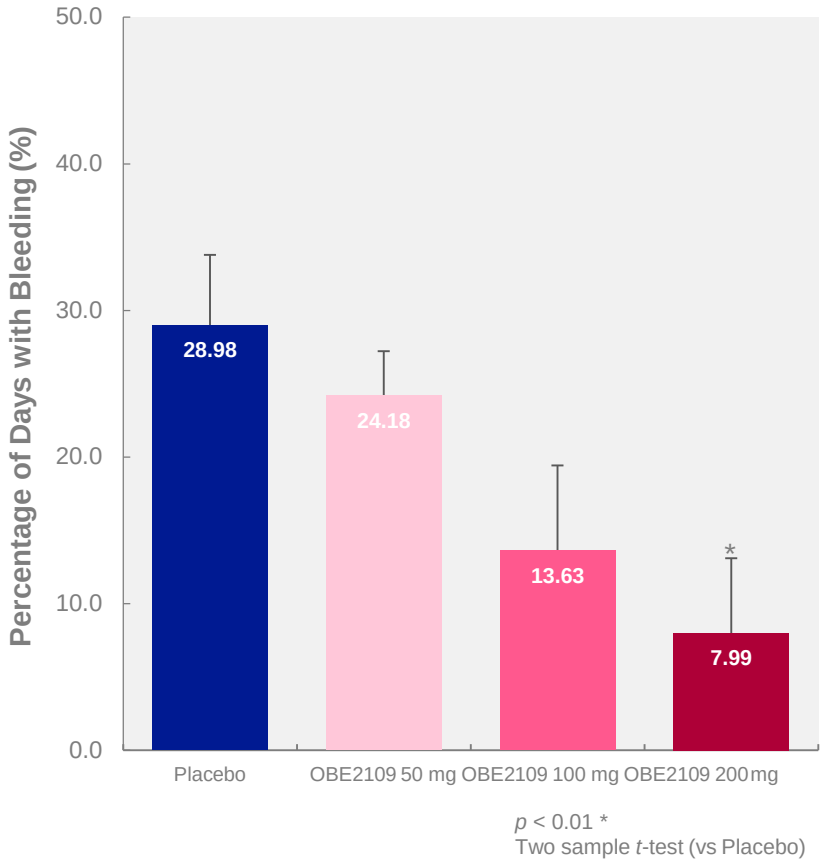
* Titration after 12 weeks based on E2 serum level at weeks 4 and 8

Target enrollment of 330 patients • ~70 sites in US (>50% of patients) • 15 sites in EU

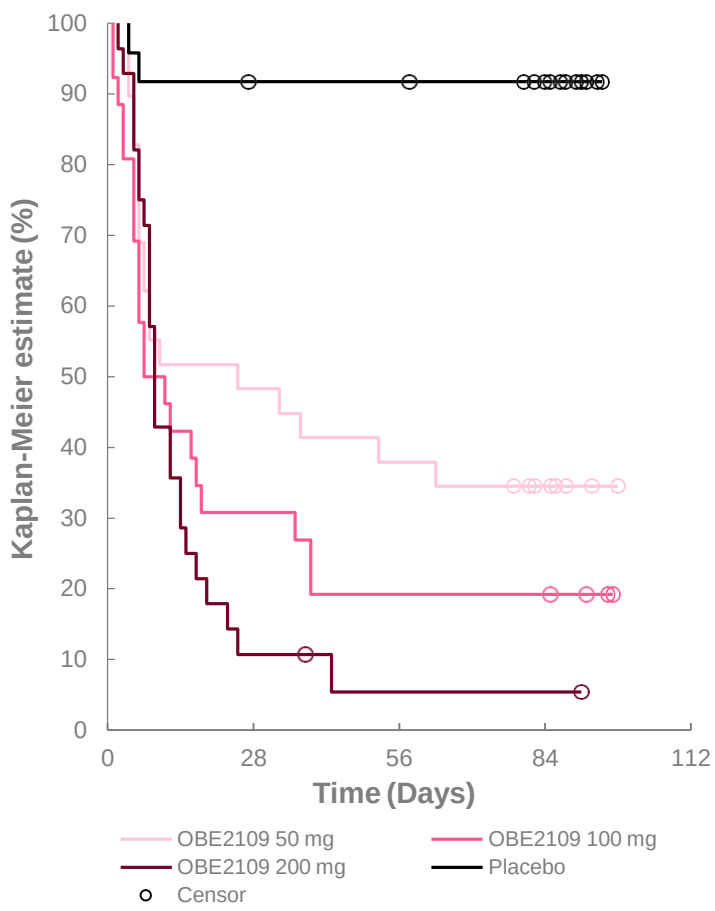
Recruitment completed November 2017

OBE2109 reduced menstrual bleeding and uterine volume in uterine fibroids (no add back)

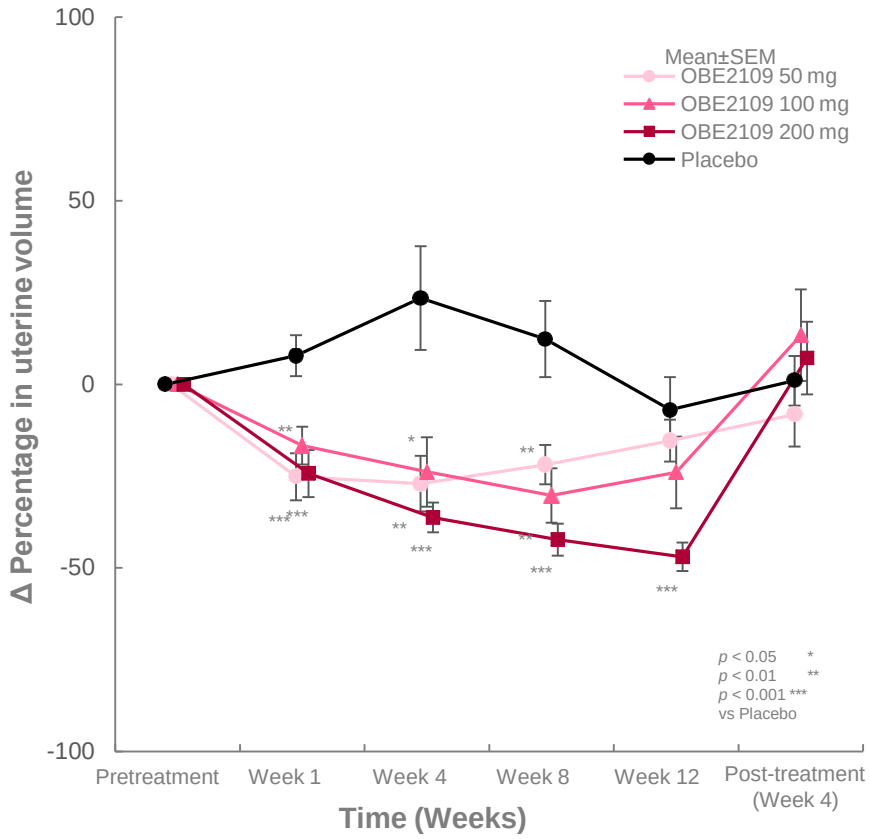
KLH1202 TRIAL: % OF DAYS WITH BLEEDING DURING 12-WEEK TREATMENT PERIOD



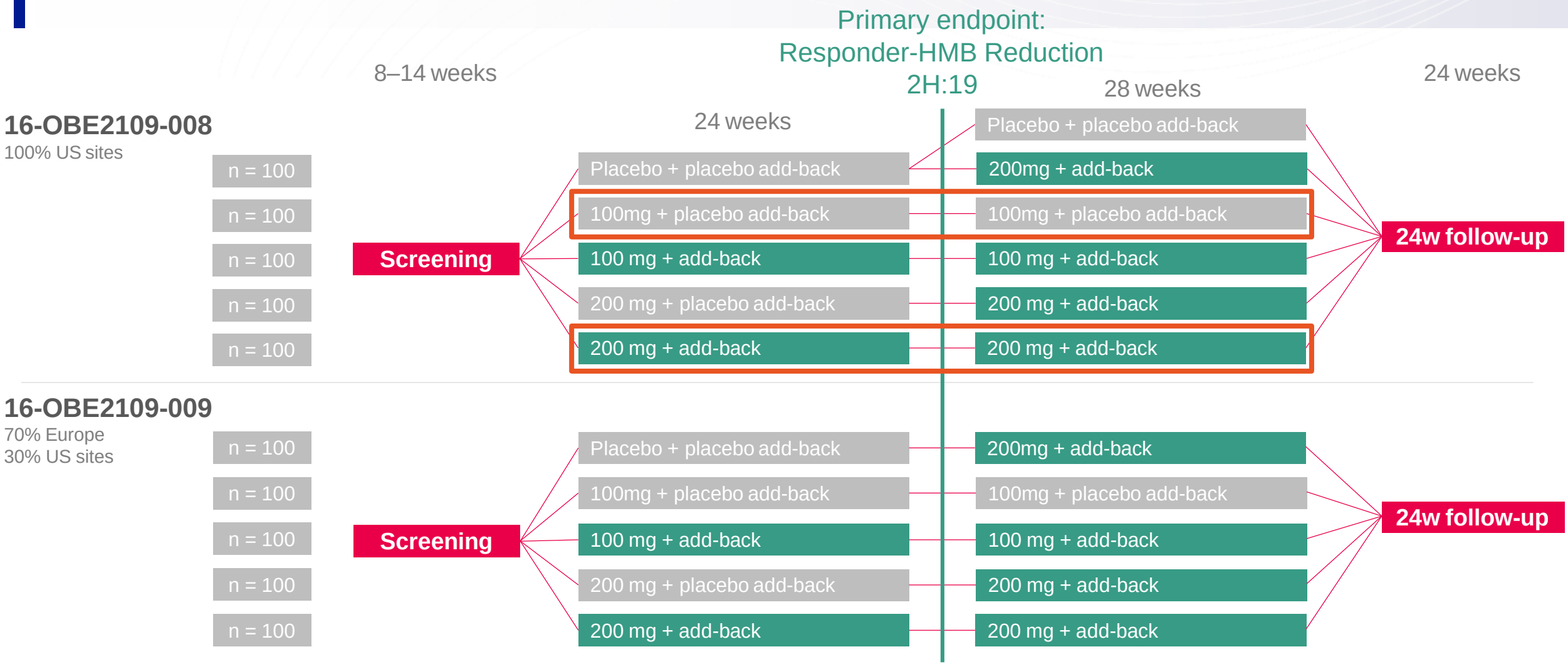
KLH1202 TRIAL: TIME TO NO BLEEDING FOR UTERINE FIBROIDS PATIENTS



KLH1202 TRIAL: CHANGE IN UTERINE VOLUME OVER TIME



OBE2109 Phase 3 clinical trials (PRIMROSE) in uterine fibroid patients



IND granted in April 2017

Currently recruiting • Aiming at supporting the registration of two regimens of administration

OBE2109 potential Best in Class GnRH antagonist

OBE2109 potential best in class based upon PK/PD profile

	OBE2109	*ELAGOLIX**	*RELUGOLIX**
Half-Life	14-15 hours	2-6 hours	37-42 hours
Bioavailability	> 80%	30 – 50 %	11%
Active transport limiting absorption (P-gP)	No	Inhibitor & Saturable substrate	Substrate
Volume of distribution *(unadjusted for bioavailability)*	11 L	>2,000 L	>20,000 L
Partition into fat	No	Yes	Yes
Food Effect	No	Yes	Yes
CYP3A4 induction (possible adverse impact on ABT)	No	Yes	No

OBE2109 potential best in class based upon dosing options

	OBE2109	*ELAGOLIX**	*RELUGOLIX**
Endometriosis	Moderate dose without ABT High dose with ABT	Moderate dose without ABT (150mg) High dose with ABT (200mg bid)	High dose with ABT (40mg) same dose 3 months only w/o ABT
Uterine Fibroids	Moderate dose without ABT High dose with ABT	High dose with ABT(300mg bid)	High dose with ABT (40mg) same dose 3 months only w/o ABT
Treatment duration	Placebo control for 12 months	Placebo control for 6/12 months	Placebo control for 6 months

ABT May Not be Appropriate for All Patients:
Exogenous vs endogenous estrogens

Add-back draw backs

- ✓Reduced bleeding control (spotting and/or breakthrough bleeding): > 50%
- ✓Study and post marketing side effects: breast pain (24%)[1], mood, libido, water retention
- ✓Reduction in anti-fibroid efficacy: approximately 10%
- ✓Contra-indication (estrogen dependent neoplasia, history/risk of thrombo-embolic disease, liver dysfunction)[1]: 5 %

Data from OBE2109 PK/PD study[3]

OBE2109 Daily Dose	100 mg (n=14)	100 mg (n=14)	100 mg (n=15)	200 mg (n=15)	200 mg (n=15)
Add-Back E2/NETA	-	0.5mg/0.1mg	1mg/0.5mg	-	1mg/0.5mg
Amenorrhea (no bleeding)	86%	21%	53%	87%	33%
Amenorrhea + (spotting only)	93%	57%	93%	100%	60%

Leuprolide Acetate (LA) discontinuation rate (within 6 months) in endometriosis patients[2]

- ✓ LA alone: 59.6%
- ✓ LA + ABT: 37.9% - 40.2%

[1] Activella US FDA label
[2] Soliman A.M. et al., J Manag Care Spec Pharm 2016; 22 (5):573-87
[3] Pohl O. et al., J Clin Endocrinol Metab 2018; 103(2): 497-504

OBE2109 Profile Testing – US Gynecologists prefer a “low dose without ABT” as first line therapy

- Product preference

Qualitative Market Research Quintiles-IMS for ObsEva - October 2017.

30 US Gynecologists took part in this qualitative study.

Neutral scenario

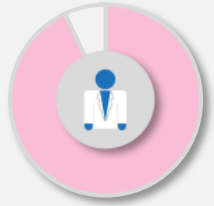
PRODUCT 1:	PRODUCT 2:
1. **High dose** of oral GnRH antagonist **with mandatory add-back (as the only option)**	1. **High dose** of oral GnRH antagonist **with mandatory add-back** **OR** 2. **Low dose** of oral GnRH antagonist **without add-back**

[2 out of 30 respondents]

7% respondents preferred Product 1

Reasons
- No time to try different dosages in severe patients
- Convenient option

[28 out of 30 respondents]



93% respondents preferred Product 2

Reasons
- More flexibility with addback therapy

After showing OBE2109

PRODUCT 1:	PRODUCT 2 (OBE2109):
1. **High dose** of oral GnRH antagonist with mandatory add-back **(as the only option)**	1. **OBE2109** oral tablet **200mg** given once per day, **with mandatory add-back** **OR** 2. **OBE2109** oral tablet **75mg** given once per day, **without add-back**

[1 out of 30 respondents]

3% respondents preferred product 1

Reasons
- No time to try different dosages in severe patients

[29 out of 30 respondents]

97% respondents preferred product 2

Reasons
- Dose flexibility
- Low dose so considered to have lesser side effects

Base (N) = 30

GnRH antagonist market takeaways

1. Large patient populations at 2.5 – 4+ million for each indication
2. Ample room for multiple market entrants
3. Patients not “one size fits all” – Availability of dosing options preferred by US Gynecologists
4. OBE2109 potential Best in Class:
   - Once-a-day, no adverse impact of food intake and no metabolic impact on ABT
   - Availability of two dosing options for both indications (ABT & No ABT)
5. Time to market: AbbVie leading and investing in early market development

NOLASIBAN to Improve IVF Outcomes

NOLASIBAN (OBE001):
Oral oxytocin receptor antagonist to improve IVF outcomes

NOLASIBAN AT-A-GLANCE

- Oxytocin Receptor Antagonist
- Licensed from Merck Serono
- IP Protection to 2035-2036
  - (COM 2027 with PTE)

NOLASIBAN INDICATIONS

- In Vitro Fertilization (IVF)
  - Market size: ~2.1-2.4 million ART cycles/year globally in 2013* (~230K in US in 2015, ~800K in Europe in 2014 and ~420K in Japan in 2015)
  - ART cycle cost: $8-15K in the US, EUR 2-10K in the EU and $3-6k in Japan
  - Estimated global sales of fertility drugs > 2 bn USD**

LANDSCAPE

Atosiban (Tractocile®)
approved ex-US for Preterm labor

I.V. peptide
No label for IVF use

NOLASIBAN: Well-characterized profile, Phase 2 clinical trial completed, EU Phase 3 primary endpoint completed

- ✓ >650 subjects exposed
- ✓ Orally active - Well tolerated
- ✓ tmax at 2h; t1/2= 12h; High bioavailability
- ✓ Single oral 900mg optimal dose

* Source: ICMART 2013 estimate; **IMS Health Incorporated estimate as of 2015.

ART: Day 5 ET preferred option

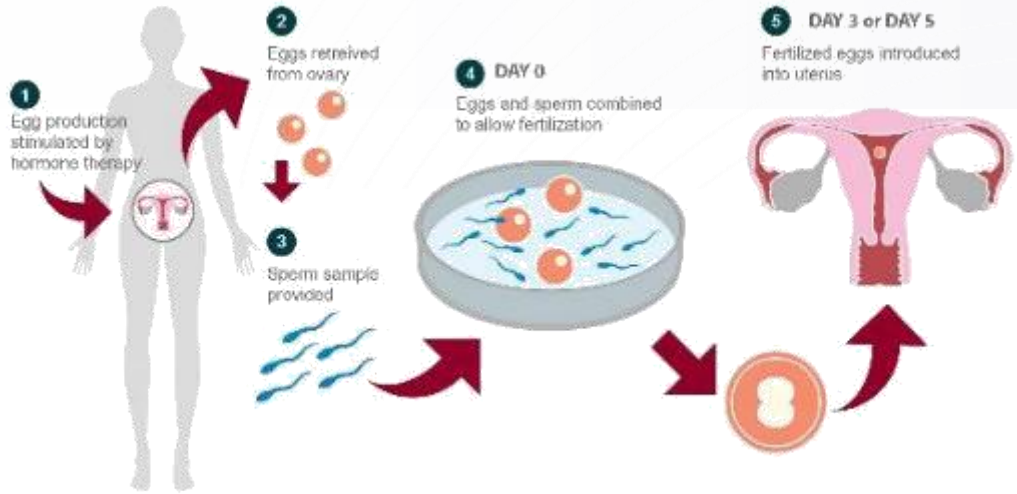
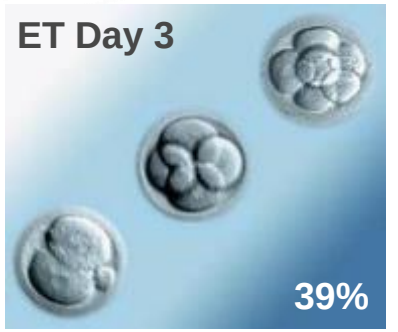


Table 2. Rates of Pregnancy and Delivery after the Transfer of Single Blastocyst-Stage and Cleavage-Stage Embryos.

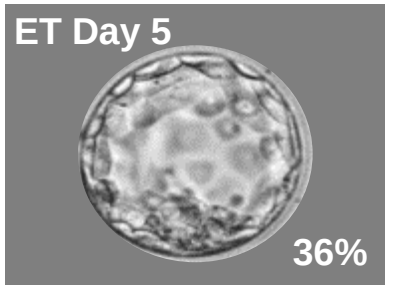
Variable	Single Blastocyst-Stage Embryo Transferred (N=175)	Single Cleavage-Stage Embryo Transferred (N=176)	Relative Risk (95% CI)*	P Value
	% (no.)			
Rate/patient randomly assigned to treatment				
Pregnancy†	41.7 (73)	33.5 (59)	1.23 (0.95–1.63)	0.11
Clinical pregnancy	33.1 (58)	23.3 (41)	1.42 (1.01–2.00)	0.04
Ongoing pregnancy	33.1 (58)	21.6 (38)	1.54 (1.08–2.18)	0.02
Delivery	32.0 (56)	21.6 (38)	1.48 (1.04–2.11)	0.03

N Engl J Med 2006;354:1139-46.

Fresh Embryo Transfer (Europe%)



US% 19%

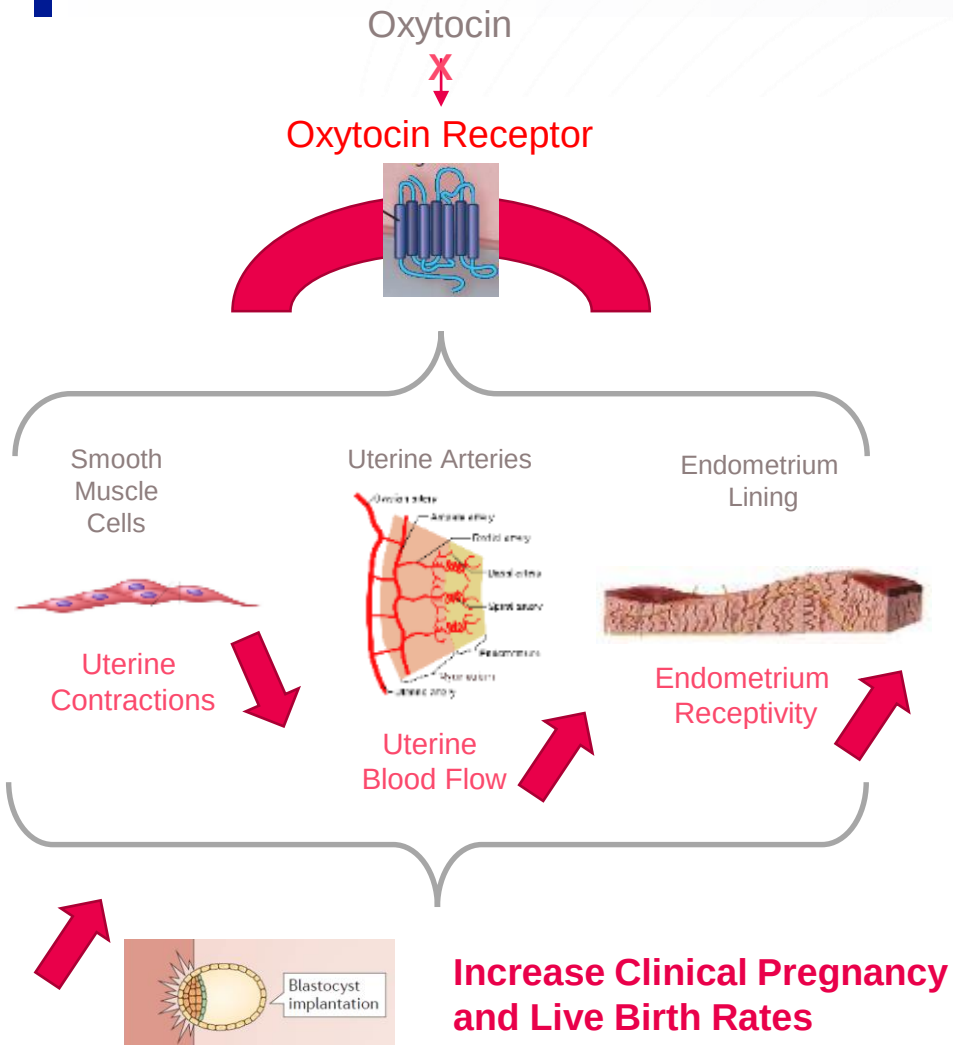


38%

Frozen Embryo for FET

43%

Blocking the oxytocin receptor is a potential target for improving pregnancy & live birth rates in ART



Comparative, randomized trials on the use of Atosiban (IV infusion) prior to ET in ART

Meta-analysis * (Huang et al. 2017)

Clinical Pregnancy Rate (6 studies; n = 1754)

Atosiban	**51.2%**
Control	**40.7%**

$p < 0.001$

Live Birth Rate (3 studies; n = 1190)

Atosiban	**38.6%**
Control	**30.8%**

$p < 0.083$

* No of embryos transfered: 1–4

Nolasiban Phase 2 Efficacy Results

As per protocol, all ET were performed on day 3 in the trial

FULL ANALYSIS RESULTS

	PLACEBO	Nolasiban 100 mg	Nolasiban 300 mg	Nolasiban 900 mg	Nolasiban All doses	TREND TEST
Number of subjects	65	62	60	60	182	
Clinical pregnancy rate at 6 weeks after ET day	33.8%	46.8%	35.0%	46.7%	42.9%	p=0.33
Ongoing pregnancy rate at 10 weeks after OPU day	29.2%	43.5%*	35.0%	45.0%*	41.2%	p=0.15
Live birth rate (baby born alive ≥ 24 weeks gestation)	29.2%	40.3%	35.0%	43.3%	39.6%	p=0.20
Relative change in uterine contractions	0.0%	-8.7%	-4.0%	-13.3%**		

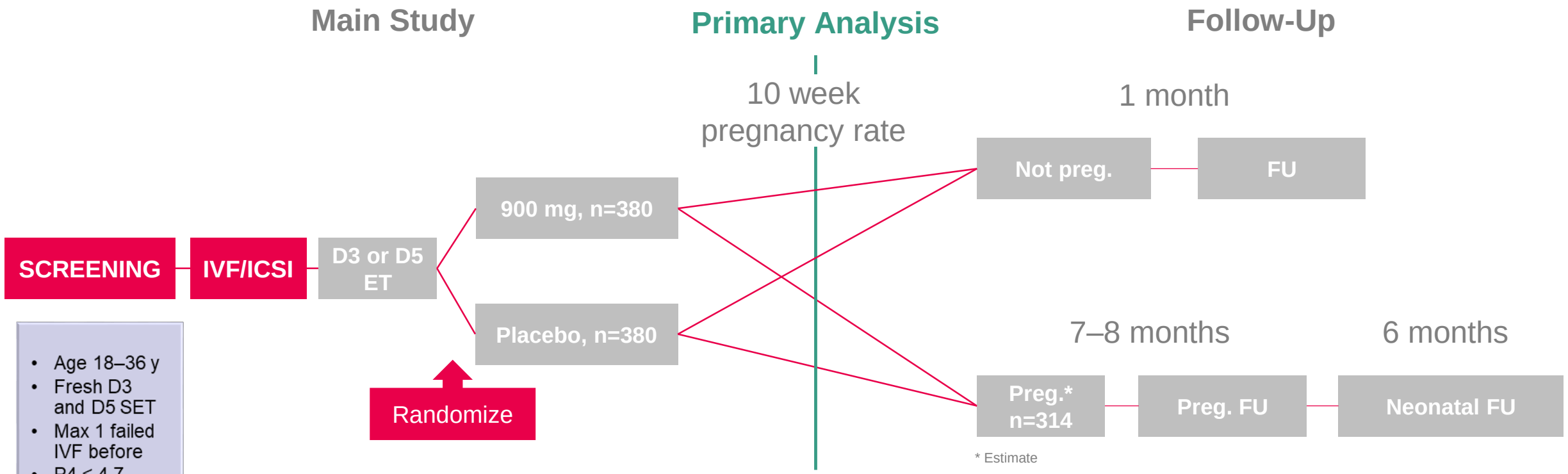
*p≤0.10 **p≤0.05, Nolasiban vs Placebo

IMPLANT2

A phase 3, double-blind, placebo-controlled study to assess the safety and efficacy of a single oral administration of nolasiban to improve pregnancy rates following IVF or ICSI in Day 3 and Day 5 Fresh Embryo Transfer cycles.

NOLASIBAN Phase 3 clinical trial protocol (IMPLANT2)

41 fertility centers in 9 European countries



- Age 18–36 y
- Fresh D3 and D5 SET
- Max 1 failed IVF before
- P4 ≤ 4.7 nmol/L on day of hCG.
- Vaginal progesterone for luteal support

Target enrollment of 760 patients • Trial conducted in Europe

FPI March 2017 – Recruitment completed August 2017 –Top Line Results February 2018

Note: N=760 gives 90% power to show significant difference if the true effect size is 11-12%. It will still show a significant effect if the observed size is about 6-7%.

Results: Demographics and baseline characteristics

		D3		D5		Pooled D3/D5	
Mean (SD)	Unit	Placebo	Nolasiban 900 mg	Placebo	Nolasiban 900 mg	Placebo	Nolasiban 900 mg
Number of subjects	n	**194**	**194**	**196**	**194**	**390**	**388**
Age	years	31.4 (3.3)	31.1 (3.2)	31.3 (3.2)	31.1 (3.3)	31.4 (3.2)	31.1 (3.3)
BMI	kg/m^2	23.94 (4.12)	24.11 (4.09)	23.67 (4.46)	23.80 (4.65)	23.80 (4.29)	23.95 (4.38)
Oocytes retrieved	n	9.0 (4.6)	8.6 (4.2)	9.8 (4.1)	10.9 (4.2)	9.4 (4.4)	9.7 (4.3)
Good quality embryos	n	2.7 (2.2)	2.5 (1.9)	2.3 (1.6)	2.7 (2.0)	2.5 (2.0)	2.6 (2.0)
P4 hCG day	nmol/L	2.0 (1.3)	1.8 (1.0)	1.9 (1.0)	1.9 (1.0)	2.0 (1.2)	1.9 (1.0)
P4 ET day	nmol/L	316 (233)	295 (130)	393 (189)	409 (191)	355 (215)	352 (173)

Results: Efficacy

Primary endpoint: Pooled D3 and D5

	Pooled D3 and D5			
	Placebo	Nolasiban 900 mg	Increase	p
n	390	388		
Ongoing pregnancy rate at 10 weeks	28.5%	35.6%	7.1%	0.031

Absolute 7.1% increase compared to placebo

Relative 25% increase compared to placebo

Results: Efficacy

Secondary endpoints: Individual D3 and D5

	D3				D5			
	Placebo	Nolasiban 900 mg	Delta	p	Placebo	Nolasiban 900 mg	Delta	p
n	194	194			196	194		
Ongoing pregnancy rate at 10 weeks	22.2%	25.3%	3.1%	0.477	34.7%	45.9%	11.2%	0.034
Clinical pregnancy rate at 6 weeks*	22.7%	27.3%	4.6%	0.290	35.7%	47.4%	11.7%	0.022
Positive pregnancy test at 14 days	33.5%	35.6%	2.1%	0.666	45.9%	54.6%	8.7%	0.112

*

* Nolasiban increases the relative ongoing pregnancy rate by 32% following single embryo transfer at Day5

Results: Safety
Summary of Treatment Emergent AEs: no safety concern

Parameter	ET D3		ET D5		Pooled D3 / D5	
	Placebo N=195 Subjects n (%)	Nolasiban N=193 Subjects n (%)	Placebo N=196 Subjects n (%)	Nolasiban N=194 Subjects n (%)	Placebo N=391 Subjects n (%)	Nolasiban N=387 Subjects n (%)
Any TEAE	44 (23)	34 (18)	55 (28)	51 (26)	99(25)	85(22)
TEAE related to IMP	0	2 (1)*	0	2 (1)**	0	4 (1)
Serious TEAE	2 (1)	2 (1)	7 (4)	2 (1)	9 (2)	4 (1)
Serious TEAE related to IMP	0	0	0	0	0	0
Fatal TEAE	0	0	0	0	0	0

Preliminary note:

- Congenital malformation: Placebo: 1; Nolasiban: 1
- Ectopic pregnancy: Placebo: 4; Nolasiban: 1

TEAE related to IMP (all mild):

* Feeling hot; Urticaria
** Dizziness; Headache

Conclusions: Nolasiban has the potential to increase clinical pregnancy rate w/o increasing multiple pregnancy rate

- Nolasiban significantly increased ongoing pregnancy rate at 10 weeks: Pooled D3/D5 (primary): Placebo 28.5%, Nolasiban 35.6%, p=0.03 (7.1% absolute increase, 25% relative increase).
- The largest increase in ongoing pregnancy rate was seen with D5 ET, Placebo 34.7%, Nolasiban 45.9%, p=0.03 (11.2% absolute increase, 32% relative increase).
- Nolasiban very well tolerated with a safety profile not different from placebo.
- Potential of nolasiban primarily as an agent to increase IVF efficacy, but also to increase the safety of IVF by supporting SET, hence dramatically reducing multiple pregnancies (from 25 - 40% to ≈ 5%).
- As Standard of Care increasingly moves to D5 ET, US IMPLANT3 trial will focus on D5 ET.

OBE022 for Preterm Labor

OBE022: Potential first-in-class, oral and selective PGF2α receptor antagonist for preterm labor (PTL)

OBE022 AT-A-GLANCE

- Prostaglandin F2α (FP) receptor antagonist
- Licensed from Merck Serono
- IP Protection through 2037
  - (COM 2037 with PTE)

OBE022 INDICATIONS

- Preterm labor (GA 24-34 week)
  - Incidence: USA: 500,000; EU: 500,000; Asia: 6,900,000*
  - Economic burden for premature infants: ~$26 billion in the U.S. ($16.9 billion in infant medical care)

COMPETITION

No drug approved for acute use in the US; atosiban used in the EU;

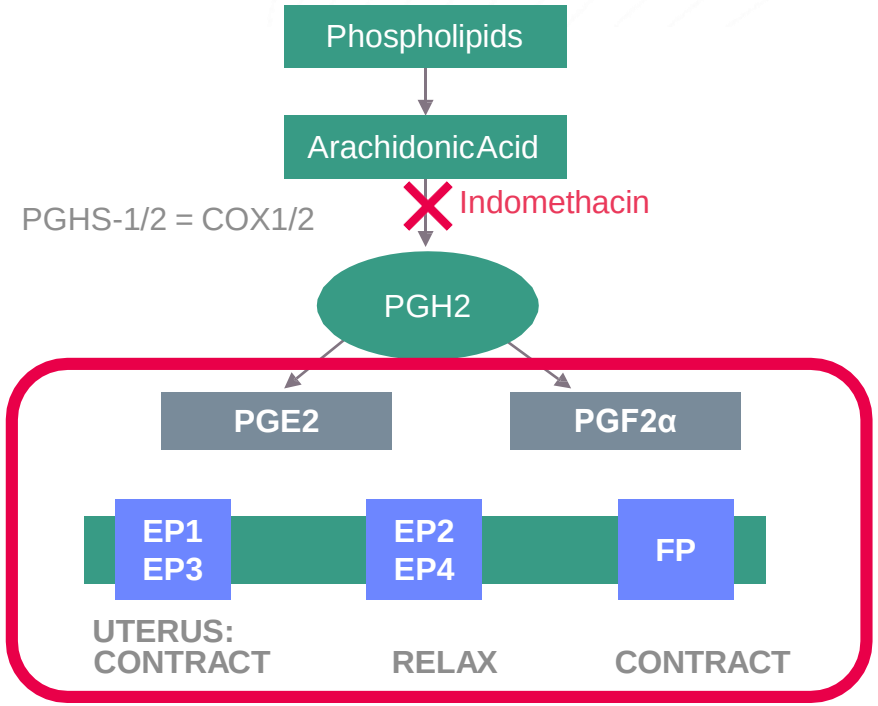
Progesterone indicated for prevention in a sub-population in the US

Phase 1 & DDI clinical trials completed

- Oral administration
- Favorable preclinical study outcomes

** WHO 'Born Too Soon: The Global Action Report on Preterm Birth' 2012)*

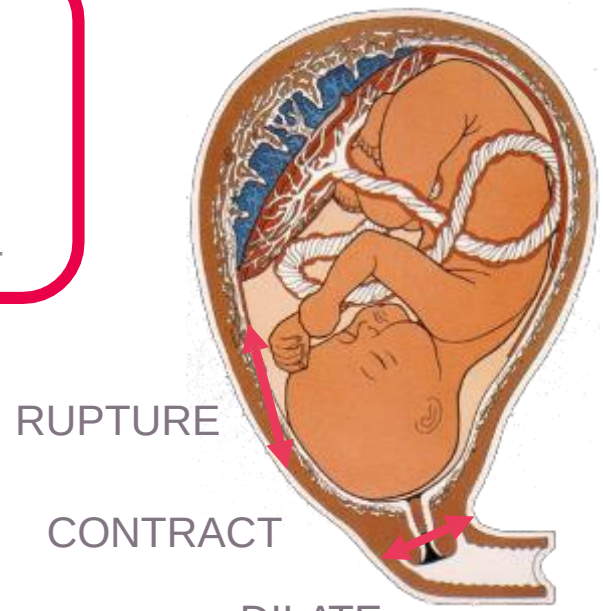
Blocking PGF2α receptor has potential to treat PTL with improved safety over NSAIDs

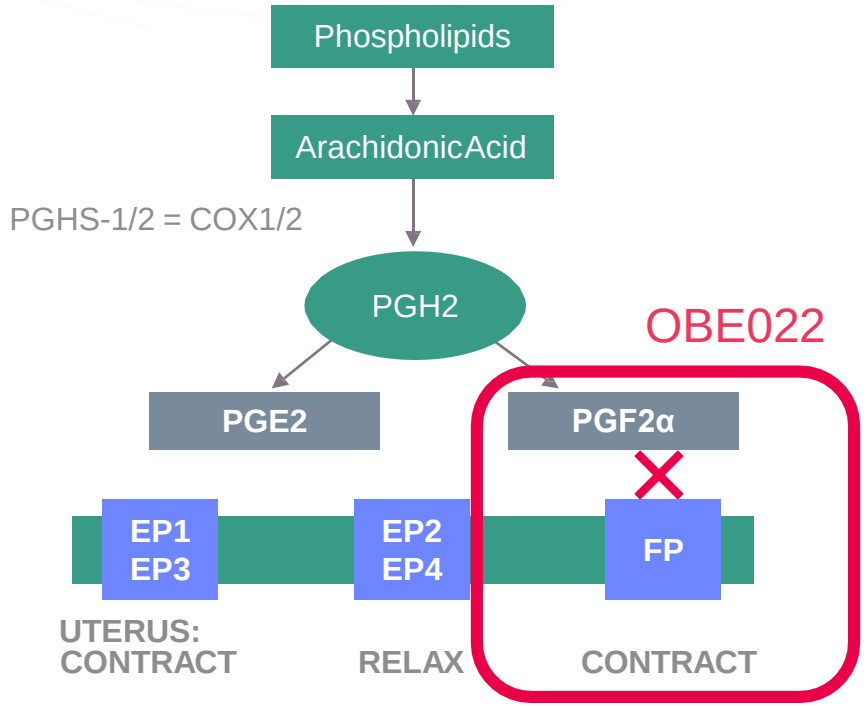


kidney, brain, vascular smooth muscle

Vasoconstriction of ductus arteriosus, renal and mesenteric arteries
Platelet aggregation inhibition

‘Inflammation’
Prostaglandins
Cytokines
Chemokines

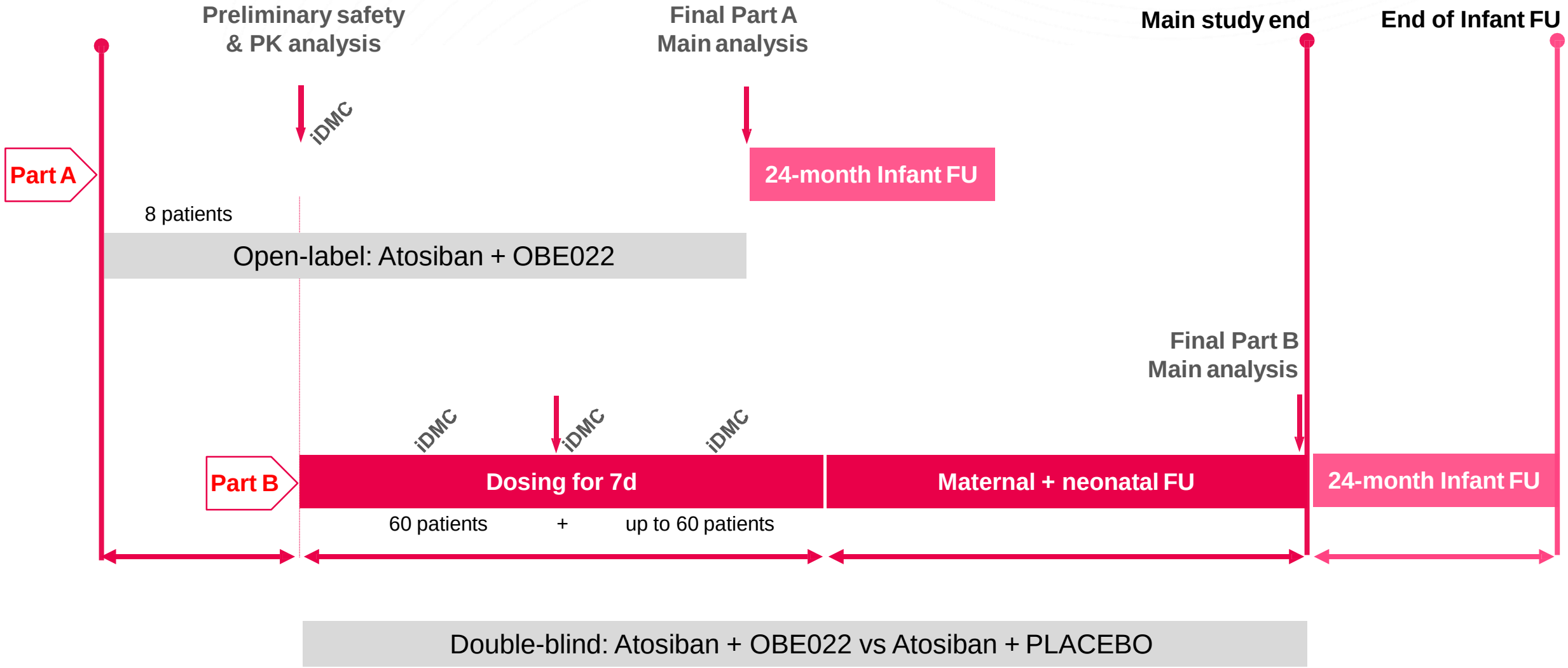




PGF2α contracts the myometrium and PGF2α metabolites rise in amniotic fluid before and during labor

PGF2α upregulates enzymes causing cervix dilatation and membrane rupture

PROLONG Ph2a Study (Parts A and B)



Thank You

OBSEVA
obstetrics & beyond