OBSEVA

obstetrics & beyond

April 2019

Innovating Women's Reproductive Health and Pregnancy Therapeutics

DISCLAIMER

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OBSEVA IS A CLINICAL STAGE BIOPHARMA COMPANY DEDICATED TO WOMEN'S HEALTH

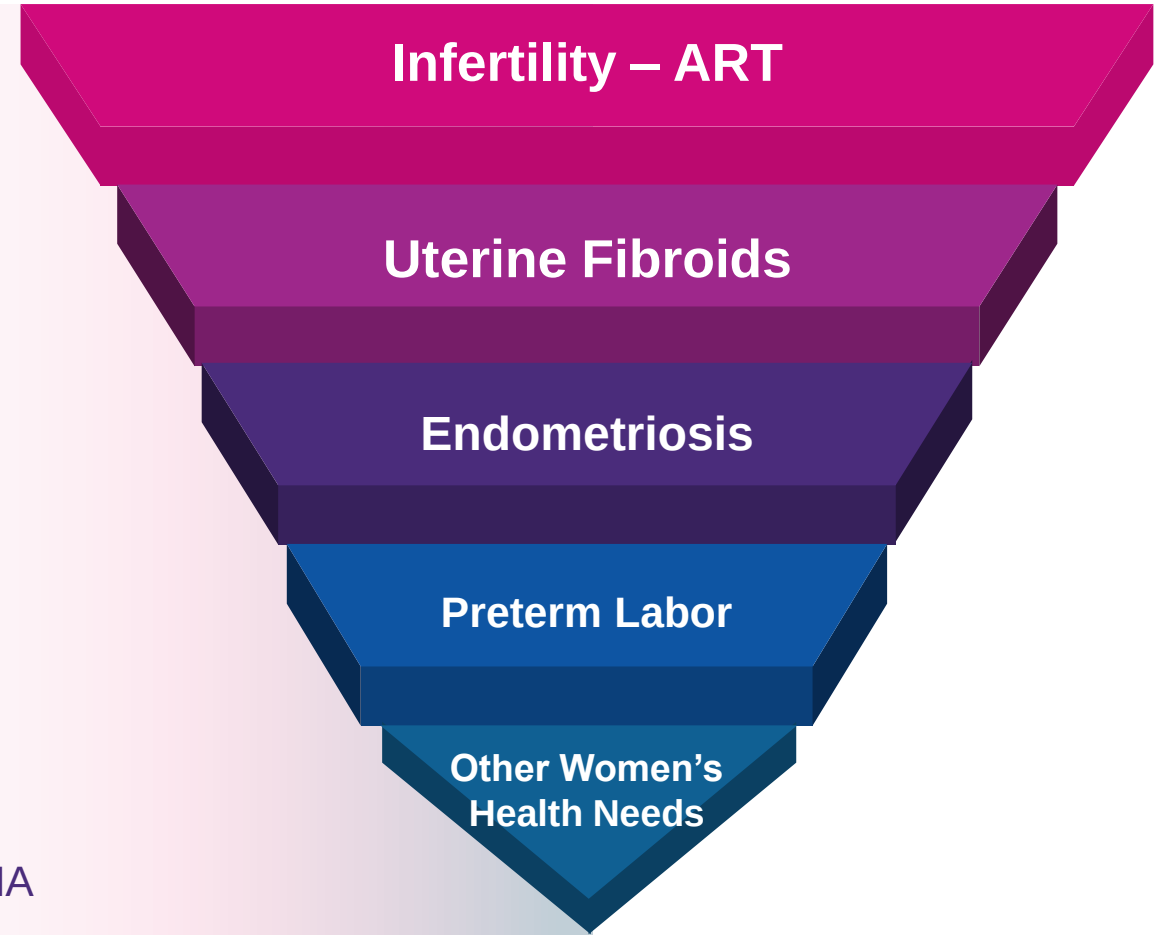
We are passionately focused to innovate for addressing serious, quality-of-life impacting conditions and reproductive challenges faced by women around the world.

Our **lead candidate Nolasiban** has the potential to be the first-in-class to increase rate of live birth after IVF

Our **second product candidate Linzagolix** has the potential to be best-in-class in treating endometriosis and uterine fibroids

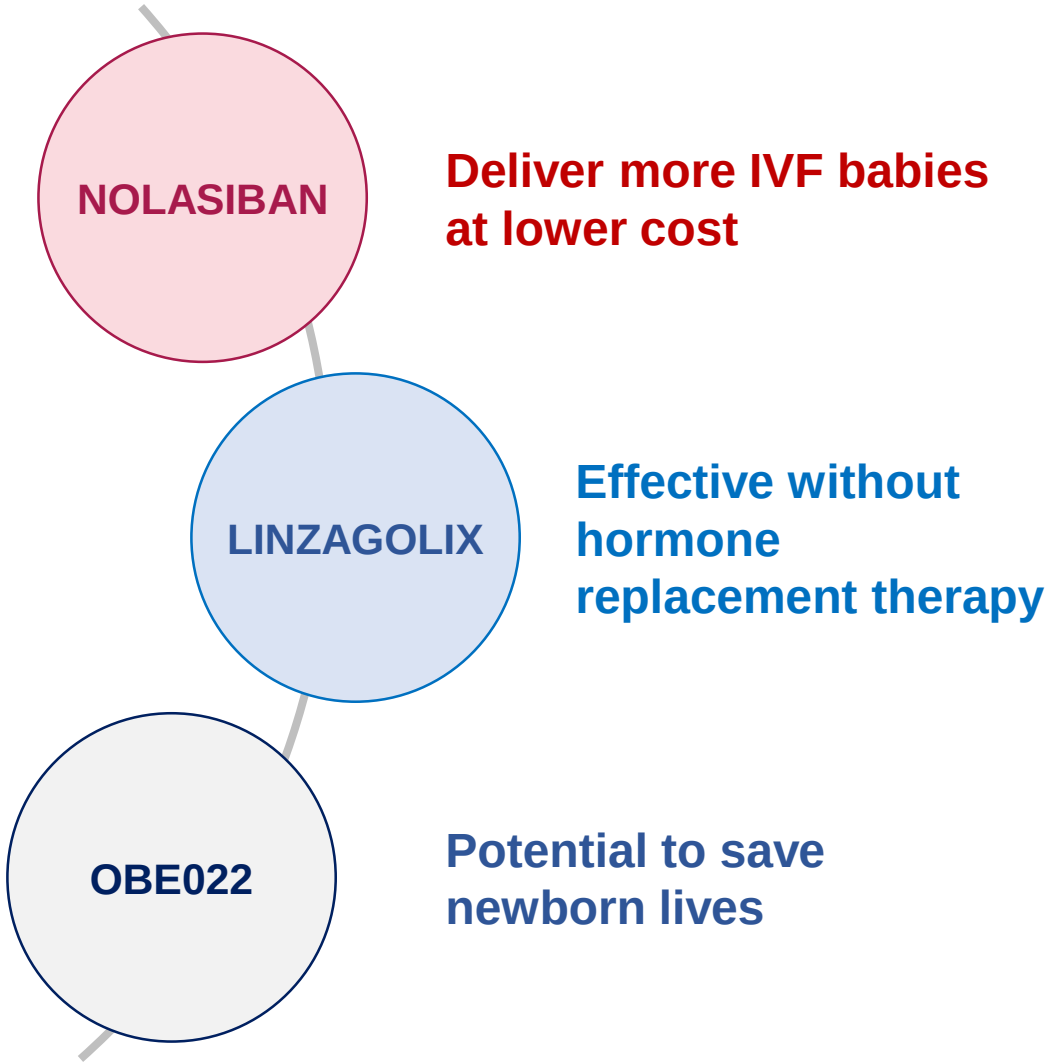
Strategic Focus

(Women ages 15 - 49)



Tickers: OBSV (NASDAQ) - OBSN (SIX)
Headquarters: Geneva, Switzerland U.S. office: Boston, MA
Employees: 47

OBSEVA – A UNIQUE INVESTMENT OPPORTUNITY



- **Multibillion USD opportunity**
  - ✓ 3 Product candidates in 4 large indications
  - ✓ Wholly-owned **exclusive WW rights***
  - ✓ **IP ≥ mid-2030** for all 3 product candidates
- **Major catalysts in 2019**
  - ✓ Nolasiban IMPLANT 4 IVF Ph3 readout and MAA filing
  - ✓ Linzagolix PRIMROSE Fibroid Ph3 readout
  - ✓ OBE022 PROLONG PTL Ph2a readout
- **NOLASIBAN – Expected first launch in EU** (1Q 2021)

* Except for linzagolix Asia rights own by KISSEI

SEASONED LEADERSHIP TEAM

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

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

Tim Adams
Chief Financial Officer

demandware
athenahealth
Constitution Medical Investors

Jean-Pierre Gotteland, PhD
Chief Scientific Officer

Pierre Fabre
serono biotech & beyond
preglem reproductive medicine

Wim Souverijns
Chief Commercial Officer

AMGEN
Celgene

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OBSEVA PIPELINE

PRODUCT CANDIDATE	PRECLINICAL / PHASE 1 / PHASE 2 / PHASE 3	NEXT MILESTONES	COMMERCIAL RIGHTS
NOLASIBAN Oral oxytocin receptor antagonist	IVF – Ph3 IMPLANT 2 EU *	Primary endpoint data IMPLANT 4 Q4 2019	Exclusive Worldwide
	IVF – Ph3 IMPLANT 4 EU **	EU MAA filing planned late 2019	
	IVF – Ph3 IMPLANT 3 US	FDA feedback expected in 2019 for potential US IMPLANT 3 Initiation 2H 2019	
	IVF – Ph3 IMPLANT 5 CHINA		
LINZAGOLIX (OBE2109) Oral GnRH receptor antagonist	Endometriosis – Ph2b EDELWEISS ***	52W extension data 1H 2019	Exclusive Worldwide (ex-Asia)
	Endometriosis – Ph3 EDELWEISS 2 US	EoP2 meeting completed	
	Endometriosis – Ph3 EDELWEISS 3 EU & US	Commencing Phase 3 Q1 2019	
	Uterine Fibroids – Ph3 PRIMROSE 1 US	Phase 3 PRIMROSE 1 & 2 Enrolling	
	Uterine Fibroids – Ph3 PRIMROSE 2 EU & US	24W Primary Endpoint Data Q4 2019-Q1 2020	
		NDA targeted end of 2020	
OBE022 Oral $PGF_{2\alpha}$ receptor antagonist	Preterm Labor – Ph2a PROLONG	EU Phase 2a PROLONG Interim Efficacy 1H 2019	Exclusive Worldwide

* Week 10 ongoing pregnancy primary endpoint met – Live Birth Rate secondary endpoint met

** Second Phase 3 study (EU/Canada/Russia) initiated *** Primary and secondary endpoints met

NOLASIBAN (OBE001)

IVF: Deliver more IVF babies at lower cost

NOLASIBAN (OBE001) – FIRST-IN-CLASS ORAL OXYTOCIN RECEPTOR ANTAGONIST TO IMPROVE IVF OUTCOMES

NOLASIBAN

Well-characterized profile; Positive Phase 3 EU trial results

At a Glance

- Oxytocin Receptor Antagonist
- MOA uterine contractions/ blood flow, endometrium receptivity
- Exclusive worldwide license from Merck Serono
- IP Protection to ≥ 2035 - 2036

Dosing Profile

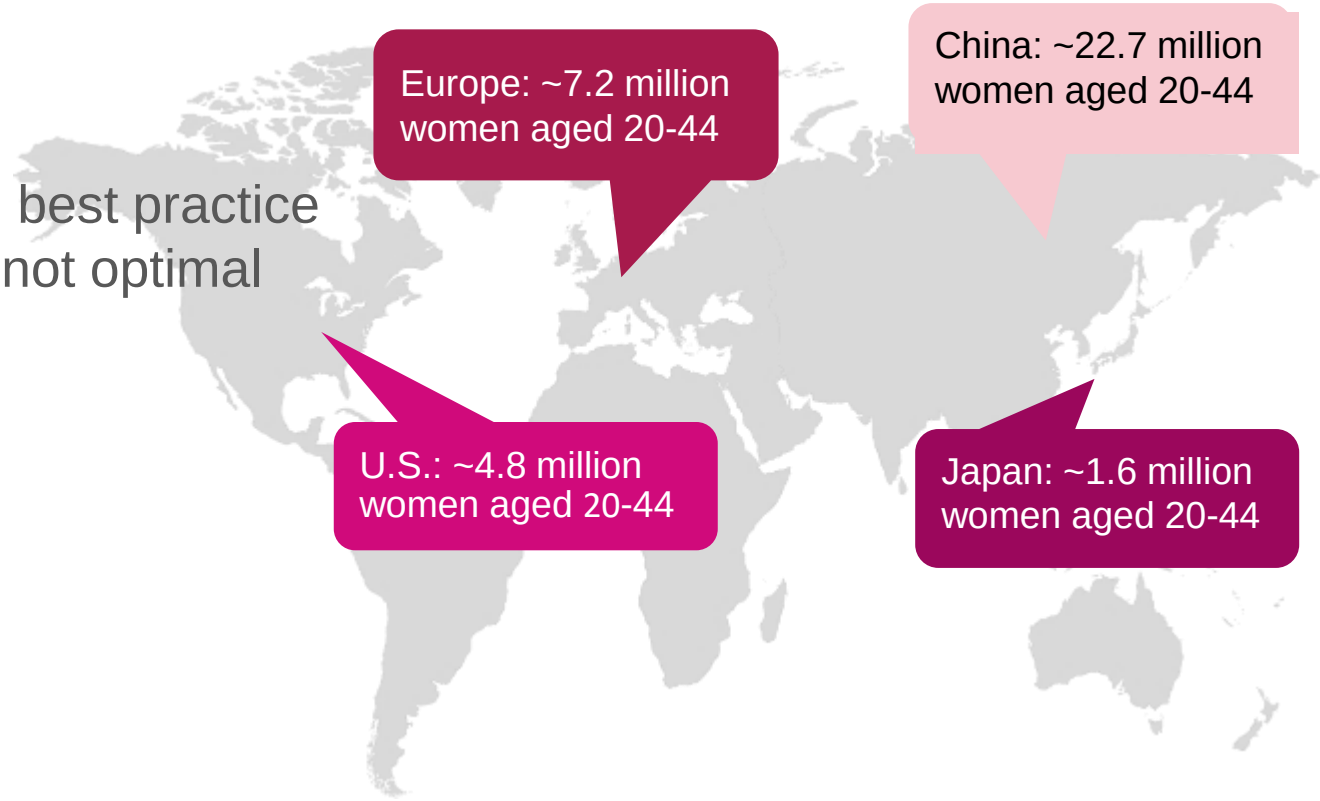
- Single oral 900mg dose +/- 4 hours prior to embryo transfer
- t^{max} at 2-4h; $t^{1/2}$= 12h
- High bioavailability
- >650 subjects exposed – well tolerated

Target Markets

- >2.0M ART/IVF cycles/year globally
- >800K cycles in Europe and China
- ~230K cycles in US in 2015
- ART cycle cost: $10-20K+ in the US, € 4-10K in the EU/China

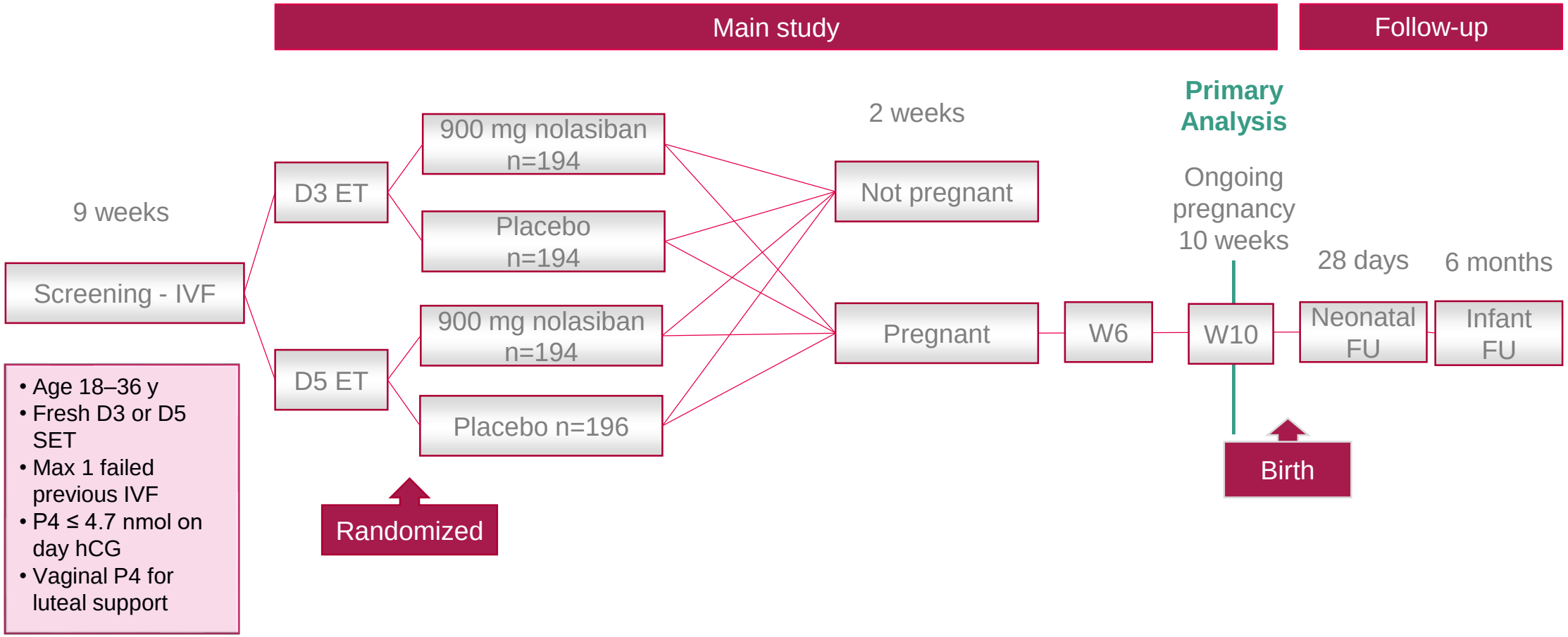
INFERTILITY – A GLOBAL PUBLIC HEALTH ISSUE[1], BUT IVF IS COSTLY AND NOT EFFICIENT ENOUGH

- **Infertility – a health & societal issue**
  - ✓ 9% of women 20-44 affected globally
  - ✓ Ageing population problematic
- **Too few healthy babies**
  - ✓ Despite good quality embryos & using best practice transfer techniques, IVF success rate not optimal
- **IVF comes with a significant cost**
  - ✓ Couples often self fund
  - ✓ Payers see an unacceptably high multiple pregnancy rate
  - ✓ Society pays a higher cost per healthy baby



[1] WHO infertility website, April 2018. – http://www.who.int/reproductivehealth/topics/infertility/perspective/en/

NOLASIBAN
IMPLANT2 PHASE 3 CLINICAL TRIAL PROTOCOL



778 Patients enrolled – Trial conducted in 41 fertility centers in 9 European countries

FPI Mar 2017 – Recruitment completed Aug 2017 – Positive top Line Results Feb 2018

IMPLANT 2 – PRIMARY EFFICACY ENDPOINT

POOLED DAY 3 & DAY 5 SET – 25% INCREASE VS PLACEBO

	Pooled D3 and D5		
	Placebo	Nolasiban 900 mg	p
N	390	388	
Ongoing pregnancy rate at 10 weeks	28.5%	35.6%	0.031
Live birth rate	27.7%	34.8% *	0.025

- ***Absolute 7.1% increase and 25% relative increase compared to placebo**
- "*A 5 per cent increase in live birth rate represents a real clinically meaningful difference for IVF specialists*" Prof Peter Brinsden, former president of The British Fertility Society

IMPLANT 2 – SECONDARY EFFICACY ENDPOINT

SUBGROUP EFFICACY ANALYSES – D5 SET 35% INCREASE

	D3			D5		
	Placebo	Nolasiban 900 mg	p-value	Placebo	Nolasiban 900 mg	p-value
N	194	194		196	194	
Ongoing pregnancy rate at 10 weeks	22.7%	25.3%	0.477	34.7%	45.9%	0.034
Live birth rate	22.2%	24.7%	0.552	33.2%	44.8% *	0.025

- *** Live Birth Rate increased by 35% after SET at day 5**

PREGNANCY OUTCOMES & SAFETY IN IVF PATIENTS

CUMULATIVE DATA FROM 2 PLACEBO-CONTROLLED RANDOMIZED TRIALS

	Nolasiban (n=570)	Placebo (n=455)
Positive pregnancy test (Day 14 post-OPU)	**274 (48.1%)**	**188 (41.3%)**
Pregnancy loss (≤ week 10)	61 (22.3%*)	53 (28.2%*)
Ectopic pregnancy	3 (1.1%*)	5 (2.7%*)
Ongoing pregnancy at week 10 post-ET	**213 (37.4%)**	**130 (28.6%)**
Pregnancy loss (week 10 to 24)	6 (2.8%**)	3 (2.3%**)
Fetus/neonate with Serious Adverse Event	15 (7.0%**)	9 (6.9%**)
Congenital malformations	11 (5.2%**)	7 (5.4%**)

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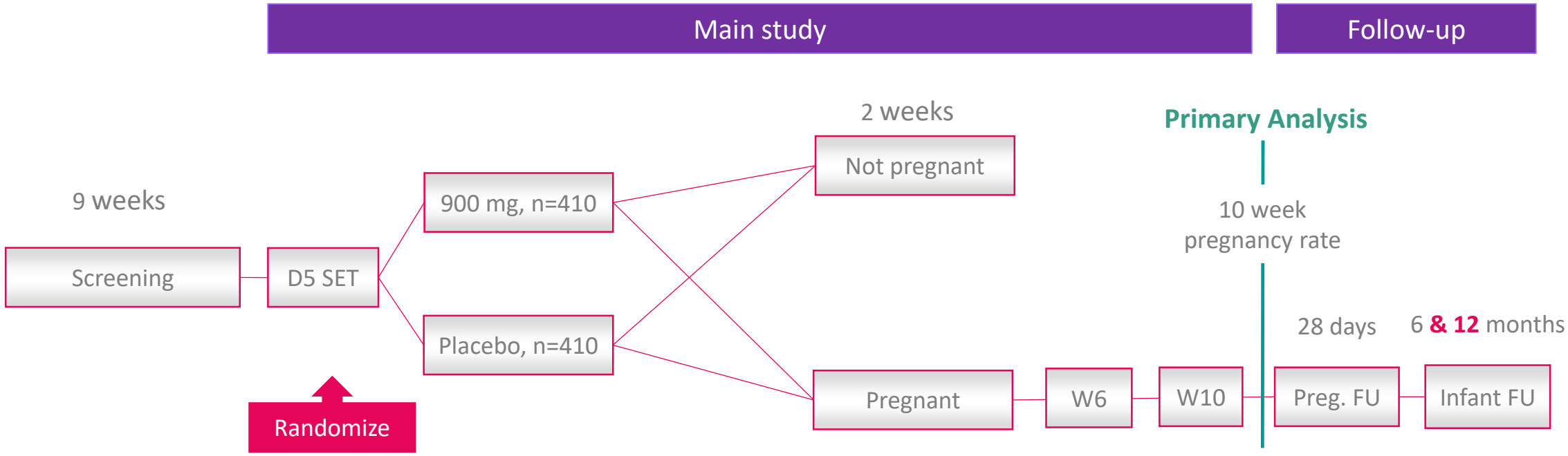
* % of positive pregnancy test at 14 days post-OPU ** % of ongoing pregnancy at week 10

IMPLANT 4 STUDY OVERVIEW



Sample Size Total (per arm)	Endpoint			Study Power
		Placebo	Active	
820 (420)	On going pregnancy	34.7%	45.9%	90%

2019 NOLASIBAN DEVELOPMENT PLAN

IMPLANT4 Trial initiated 4Q18 – MAA filing 4Q19

- ✓ 800 patients, 40 centers in Europe, Russia, Canada
- ✓ Day 5, Fresh SET
- ✓ Primary endpoint 10 week ongoing pregnancy

Targeting U.S. Ph3 program start

- ✓ FDA interactions Q2:19 on study design
- ✓ Finalize protocol, trial start 2H:19

Getting started in China

- ✓ Assessing development and commercial strategic options

A LEAN OPERATION TO COMMERCIALIZE NOLASIBAN

1. Highly concentrated
2. Sophisticated B2B market

# ART Centers	105	134	354	231	82	~ 500

Less than 100 FTEs to drive a blockbuster business

LINZAGOLIX (OBE2109)

Endometriosis and Uterine Fibroids: **Effective without hormone replacement therapy**

LINZAGOLIX, A POTENTIAL BEST-IN-CLASS, ORAL, GnRH RECEPTOR ANTAGONIST

LINZAGOLIX

Validated MOA, Ph3 Trials ongoing targeting large populations

At a Glance

- Oral GnRH receptor antagonist
- Licensed from Kissei (WW rights, excludes Asia)
- IP protection to ≥ 2036

Dosing Profile

- 15h $t^{1/2}$ for once daily dosing
- High bioavailability, low volume of distribution
- No interaction with food, CYP3A, OATP1
- > 1,850 female subjects exposed

Target Markets

- Uterine Fibroids for heavy menstrual bleeding
  - ~ 4 million women diagnosed and treated
  - ~ 200,000 surgeries/year
- Endometriosis for menstrual and non menstrual pelvic pain
  - ~ 2.5 million women diagnosed and treated

UNMET MEDICAL NEED – STANDARD OF CARE CALLS FOR NEW IMPROVED THERAPIES

1st Line

- **Oral Contraceptives**
  - ✓ Reduce bleeding in UF and treat menstrual pain in EM
  - ✓ Limited efficacy
- **NSAID's/opioids**
  - ✓ Treat pain in UF and EM
  - ✓ Incomplete response/abuse liability

2nd Line

- **LUPRON® Injections (GnRH agonist)**
  - ✓ Administered in office
  - ✓ Not ideal for younger, chronic population
  - ✓ Associated with initial symptom flares
  - ✓ Full estrogen suppression, ABT[1] mandatory > 6 months
  - ✓ Used as bridge to surgery or to reduce surgical bleeding

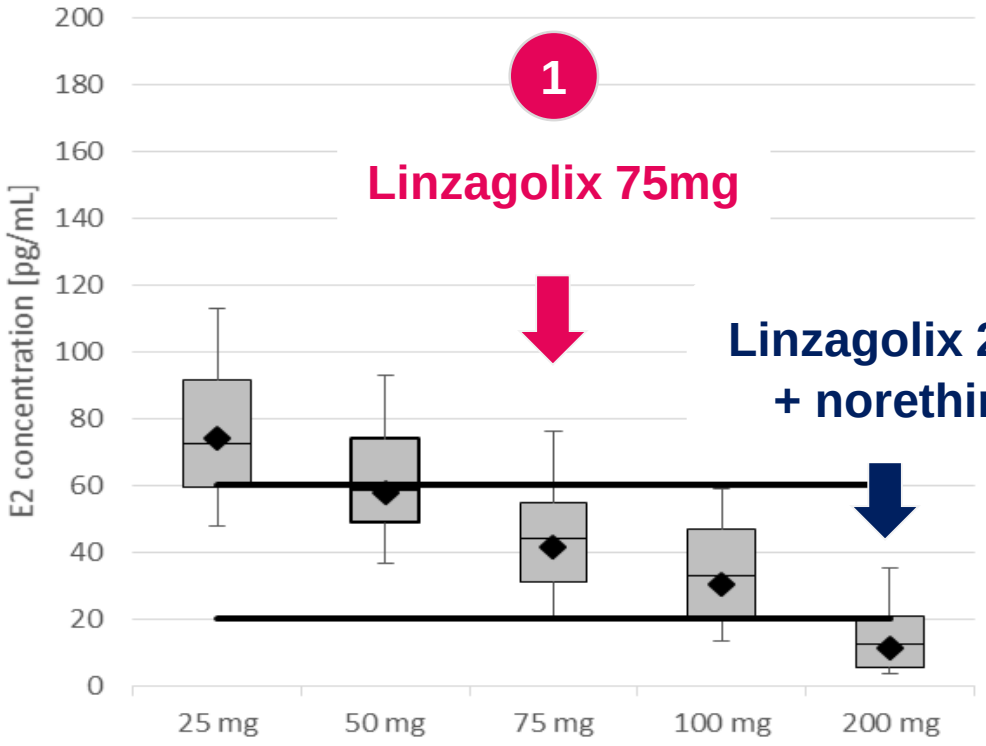
Last Line

- **Surgery**
  - ✓ Invasive, costly and often not curative
  - ✓ Hysterectomy ends fertility for younger women
  - ✓ High rate of recurrence following myomectomy

[1] Low dose Add Back Therapy (ABT) = estradiol/norethindrone acetate - tablet 1.0 mg/ 0.5 mg

OUR AIM – PROVIDING THE MOST CONVENIENT, EFFECTIVE AND SAFEST, LONG TERM TREATMENT

Week 24 Modelled E2 Data
(whiskers represent 10%/90% percentile)



Linzagolix Daily Dose (mg) for 24 Weeks

1 **Linzagolix 75mg**

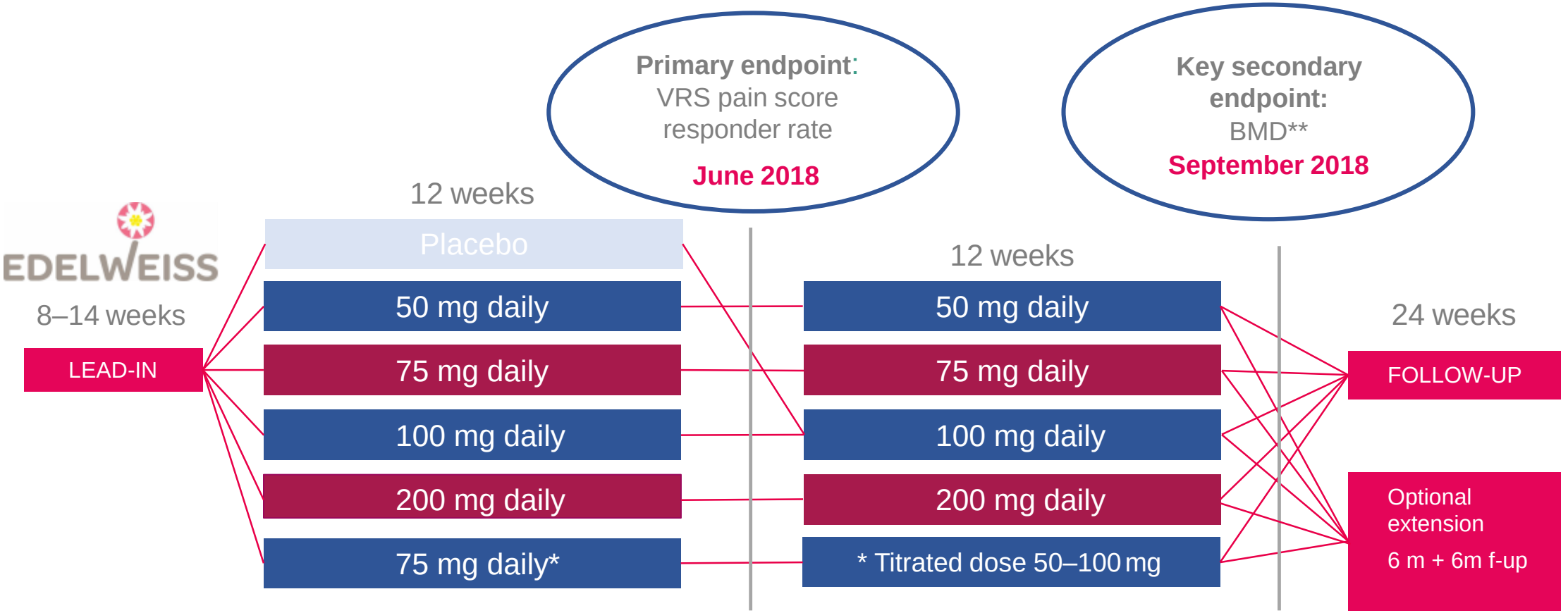
2 **Linzagolix 200mg + estradiol + norethindrone acetate***

1 **Preferred first line option**

2 If needed, higher dose option with ABT available

* Add Back Therapy (ABT) Activella™

PHASE 2B EDELWEISS CLINICAL TRIAL
ENDOMETRIOSIS PATIENTS

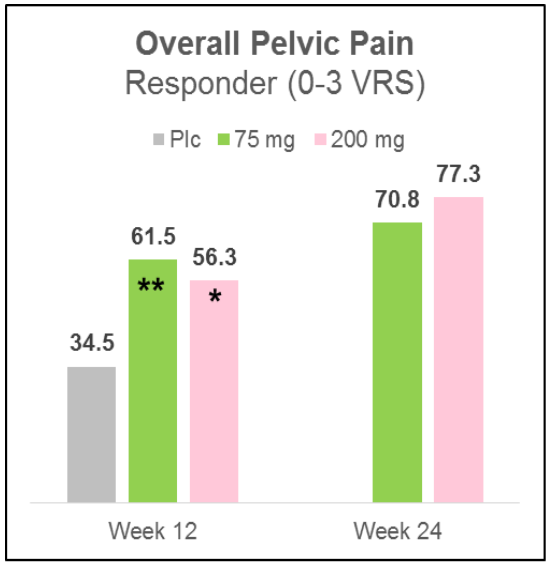


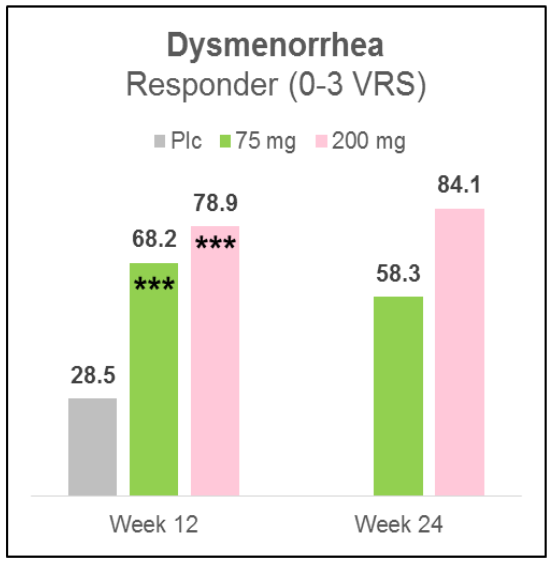
* *Titration after 12 weeks based on E2 serum level at weeks 4 and 8*

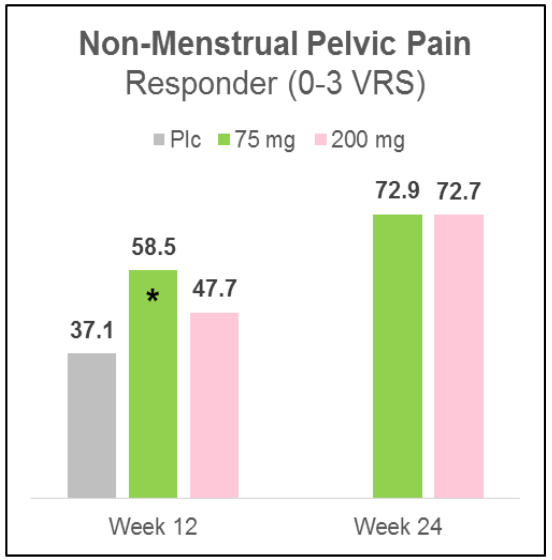
Enrollment 328 patients • 50 sites in US (n=177) • 14 sites in EU (n= 151)

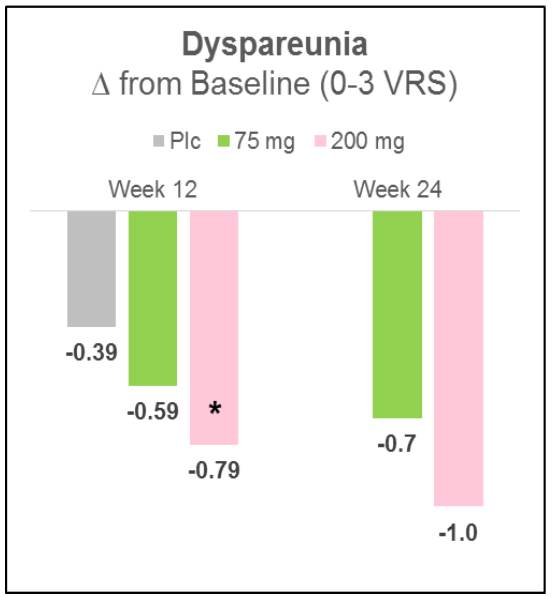
**BMD: Bone Mineral Density

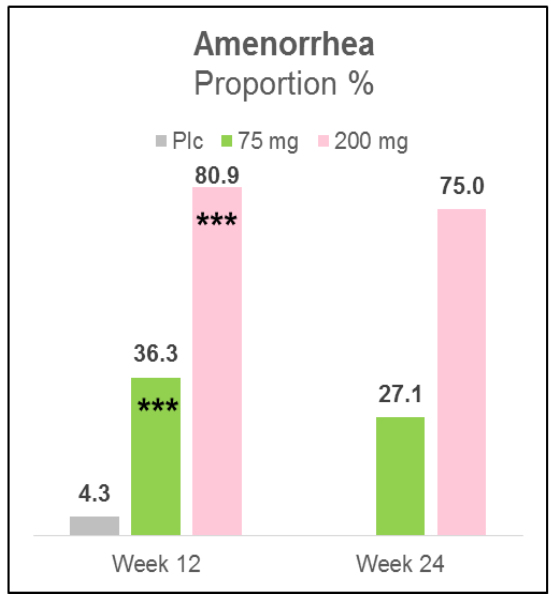
EDELWEISS PRIMARY AND SECONDARY ENDPOINTS

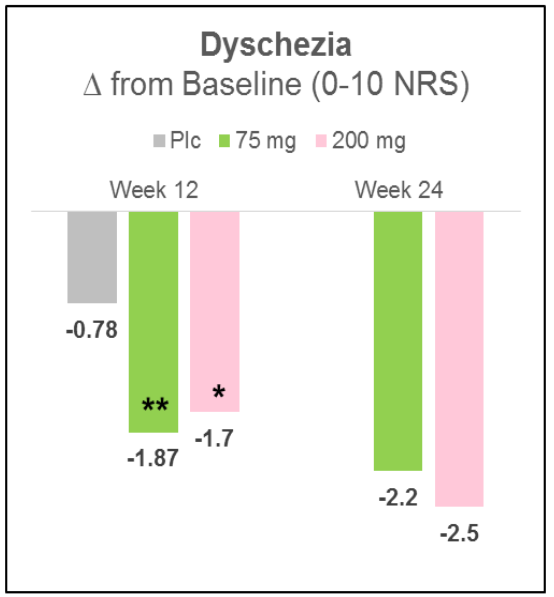












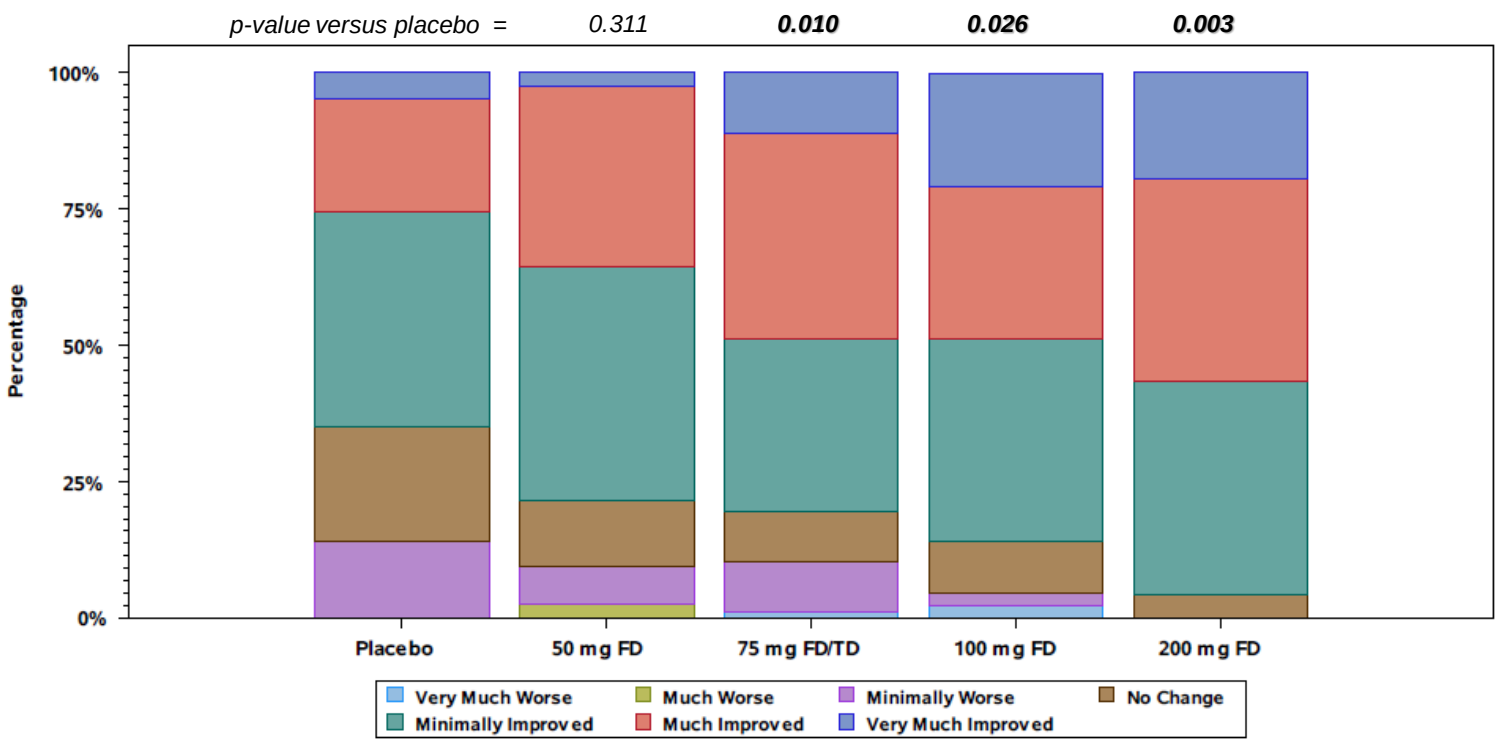
* = p value <0.05, ** = p value <0.01, *** = p value <0.001, for linzagolix doses compared to placebo

EDELWEISS ADDITIONAL OUTCOMES

75mg TO 200MG SIGNIFICANTLY AND CONSISTENTLY IMPROVED ASSOCIATED SYMPTOMS

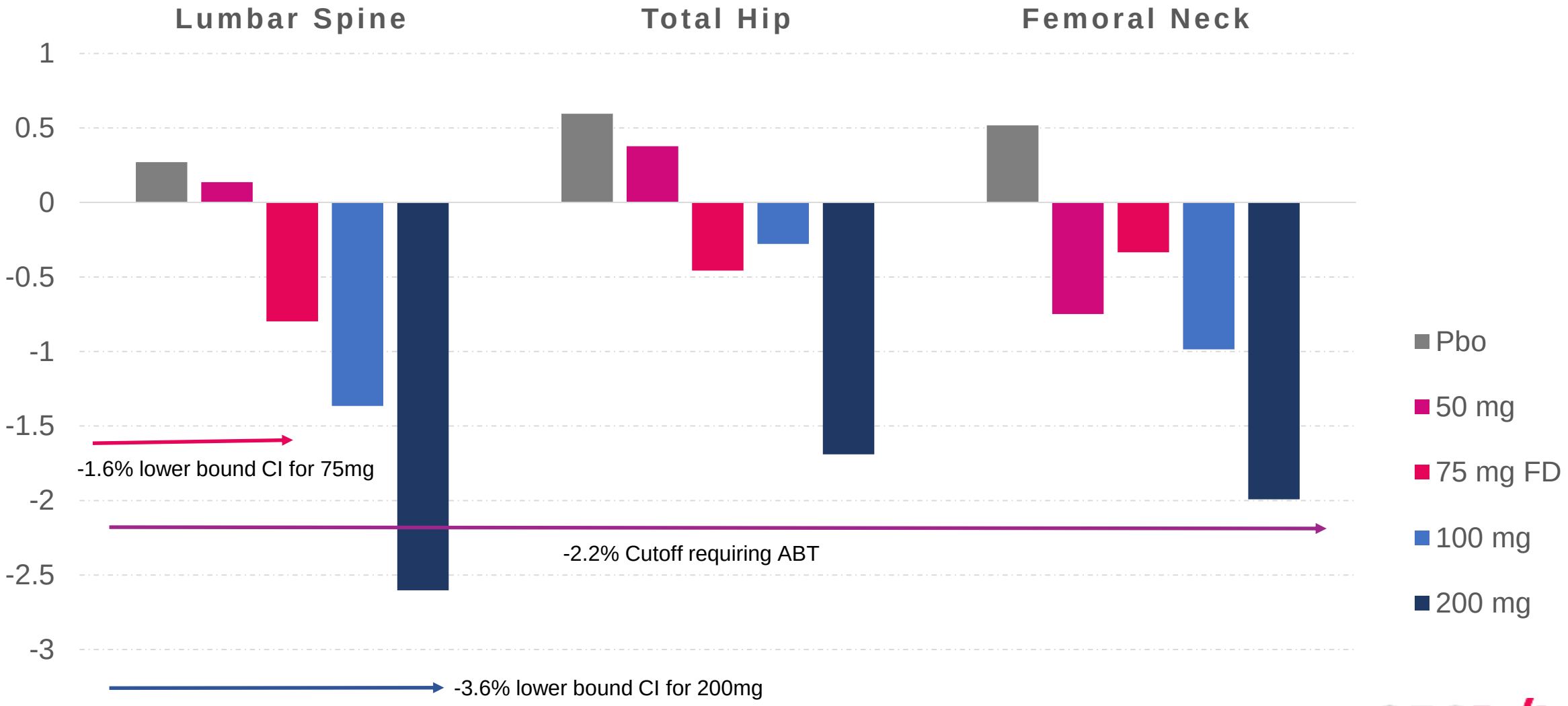
Confirmed Efficacy on Patient Well Being assessed by the following:

- Significant reduction of dyspareunia and dyschezia
- **Patient Global Impression of Change scale (PGIC)**
- Endometriosis Health Profile-30 score
- Patient Global Impression of Severity (PGIS)
- Activity impairment score
- Modified Biberoglu & Behrman score



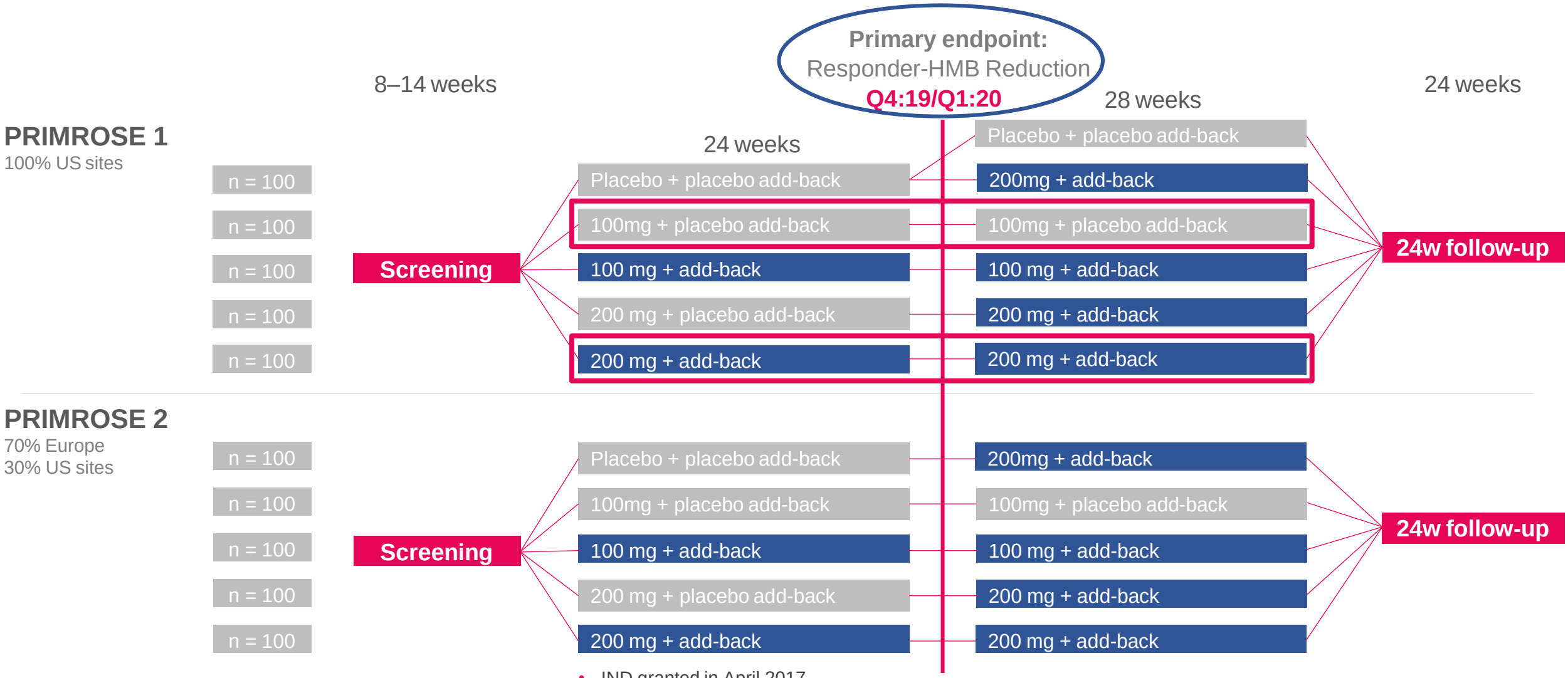
EDELWEISS BONE MINERAL DENSITY CHANGE

MEAN % CHANGE FROM BASELINE TO MONTH 6



PRIMROSE 1 & 2

PHASE 3 CLINICAL TRIALS FOR THE TREATMENT OF UTERINE FIBROIDS



- IND granted in April 2017
- Currently recruiting • Aiming at supporting the registration of two regimens of administration

"ABT OR NO ABT, THAT IS THE QUESTION"

DIFFERENTIATING BY NO ABT

1. Gynecologist survey in US shows ***high preference of no ABT as first line therapy***
2. Preferred dosing is to ***start low and go higher as needed***
3. Trend toward ***patients preferring avoidance of hormone therapy*** vs. endogenous estrogen management
4. ABT comes with HRT ***safety boxed warning****

Quintiles IMS Survey (2017)
30 US Gynecologists

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]	[28 out of 30 respondents]
7% respondents preferred Product 1	93% respondents preferred Product 2
Reasons • No time to try different dosages in severe patients • Convenient option	**Reasons** • More flexibility with addback therapy

* Activella US FDA Label: cardiovascular disorders, breast cancer, endometrial cancer, and probable dementia

LINZAGOLIX, BEST-IN-CLASS POTENTIAL

EFFICACY WITHOUT COMPROMISING SAFETY

1. ***Reliable Efficacy*** — ***Uterine fibroids*** / ***Endometriosis***: Majority of patients experiencing prompt & sustained symptom relief – heavy menstrual bleeding & pain
2. ***Uncompromising on Safety***: Avoiding bone loss without having to combine with two additional drugs (ABT)
3. ***With the Patient in Mind***: Single pill, one active ingredient, once daily without interaction with food & co-medications

OBE022

Preterm Labor: Potential to save newborn lives

OBE022, FIRST-IN-CLASS
ORAL AND SELECTIVE PGF_{2A} RECEPTOR ANTAGONIST FOR PRETERM LABOR (PTL)

OBE022

Well-characterized MOA, Strong pre-clinical/Phase 1 safety

At a Glance

- Prostaglandin F2α (FP) receptor antagonist
- Licensed from Merck Serono
- Composition of matter protection through 2037 with PTE

Dosing Profile

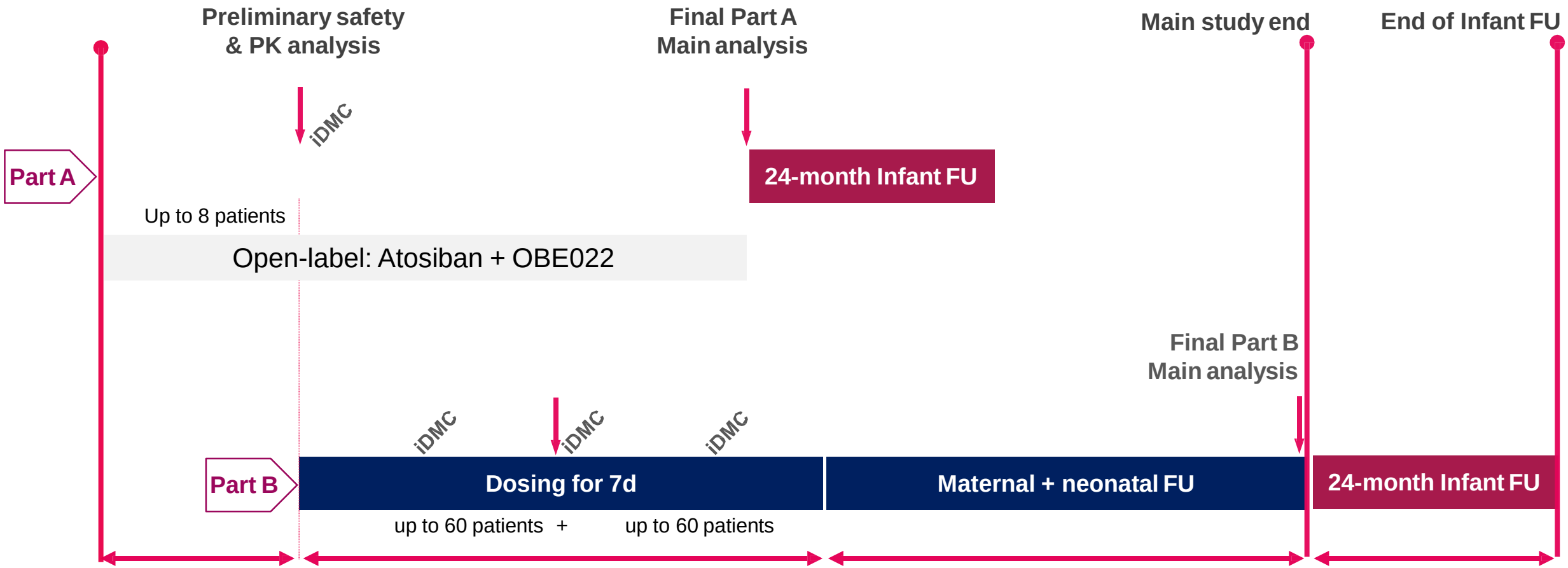
- Targeting myometrium contractions, cervix dilation, membrane rupture, inflammatory processes
- Current treatments limited efficacy & restrictive safety
- Goal to delay labor by 2-7 days to treat fetus for organ protection

Target Markets

- Preterm labor (GA 24-34 weeks) incidence
  - US ~ 500K
  - EU ~ 500K
  - Asia ~ 6.9M[1]
- Economic burden for premature infants in the US ~$26B ($16.9B in infant medical care)

[1] WHO 'Born Too Soon: The Global Action Report on Preterm Birth' (2012)

OBE022
PROLONG PH2A STUDY (PARTS A AND B)



- Double-blind: Atosiban + OBE022 vs Atosiban + PLACEBO
- Part A completed
- Part B began Q4:18

2019 FINANCIAL OUTLOOK

December 31, 2018 Cash	$139 million
Projected 2019 Cash Use	~$100 million
Expected Cash Runway	Mid-2020

2019 Investment Includes as many as 6 Phase 3 trials enrolling

- Phase 3 data readouts for linzagolix and nolasiban
- Getting started with nolasiban in U.S. and China
- Phase 2 decision for OBE022
- Pre-commercial nolasiban in EU

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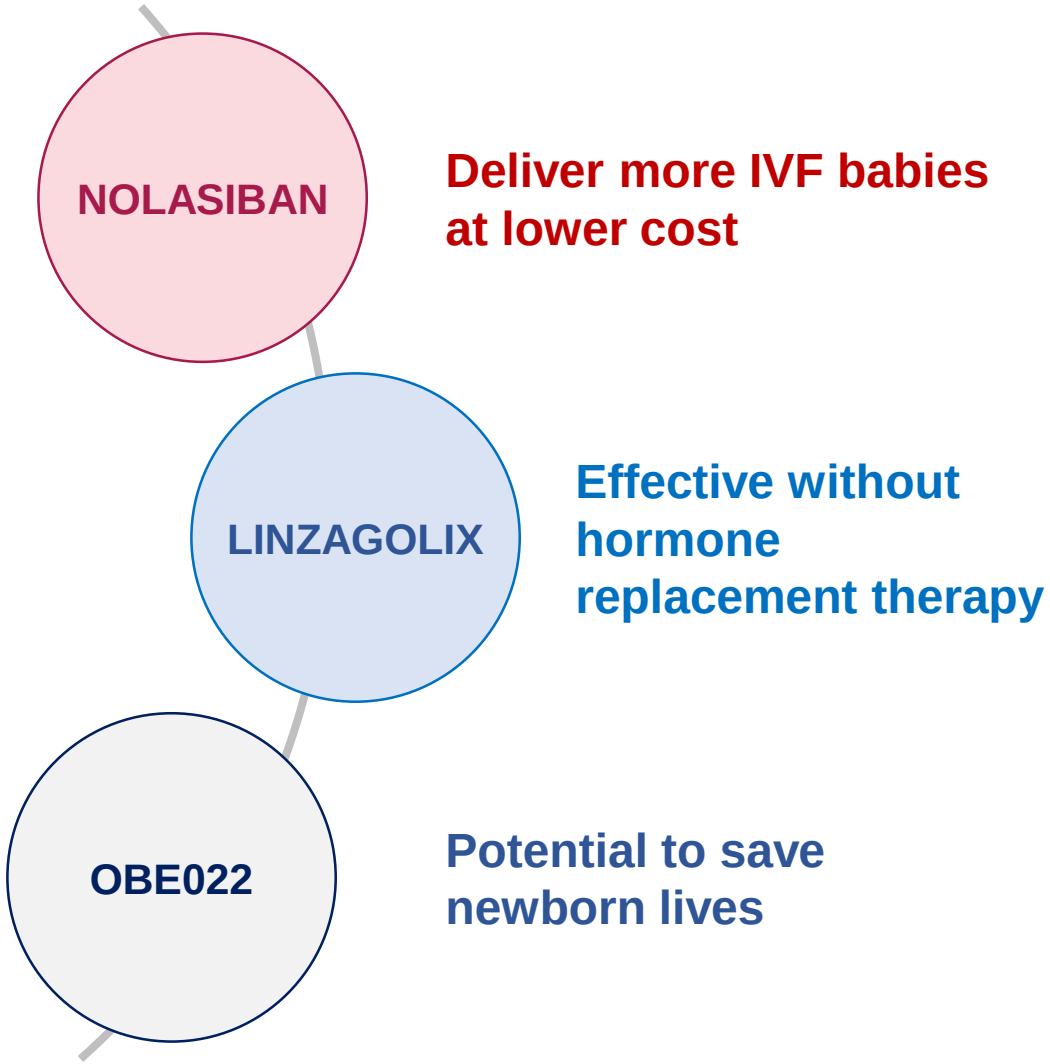

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THANK YOU

April 2019

NASDAQ:OBSV | SIX:OBSN