



## **Focused on unmet needs in women's reproductive health**

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July 2021



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# About ObsEva

**ObsEva (NASDAQ: OBSV and SIX: OBSN) is a clinical-stage biopharmaceutical company developing and commercializing novel therapies to improve women's reproductive health.**

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

- Founded in 2012
- Headquarters: Geneva, Switzerland
- Employees: 47 total EU and US
- Listings: NASDAQ (OBSV) and SIX (OBSN)
- Collaborations with Kissei, Yuyuan Bioscience, Merck Serono





# Seasoned leadership team



**Brian O'Callaghan**  
Chief Executive Officer



**Elizabeth Garner MD, MPH**  
Chief Medical Officer



**David Renas**  
Chief Financial Officer



**Fabien de Ladonchamps**  
Chief Administrative Officer



**Jean-Pierre Gotteland, PhD**  
Chief Scientific Officer



**Clive Bertram**  
Chief Commercial Officer



# Board of Directors



Frank Verwiel, MD  
Chairperson



Ernest Loumaye,  
MD, PhD



Brian O'Callaghan



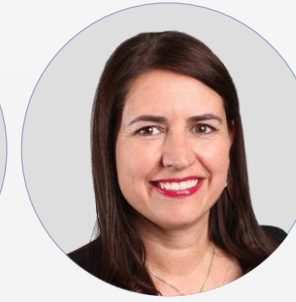
Annette Clancy, BSc  
(Hons)



Anne VanLent



Ed Mathers



Catarina Edfjäll  
PhD



Jacky Vonderscher,  
PhD



# Investor highlights

1

Pursuing large indications for conditions that compromise **women's reproductive health and beyond**

2

Yselyt<sup>®</sup> has potential **best in class efficacy, favorable tolerability, and unique flexible dosing options**

3

Ebopiprant is the only known product in development for preterm labor and has **positive Phase 2a data**

4

Business model built on strong **global partnerships and collaborations**

5

Seasoned **leadership team** with a track record for success

# Product overview

**YSELT<sup>®</sup>**  
**(LINZAGOLIX)**



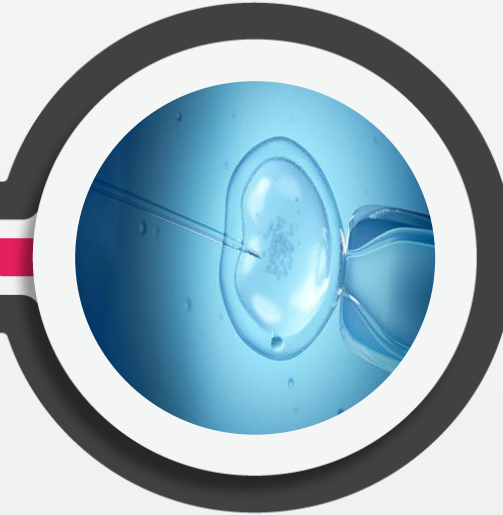
Potential to relieve symptoms of heavy menstrual bleeding due to uterine fibroids and pain associated with endometriosis

**EBOPIPRANT**  
**(OBE022)**



Potential to delay preterm birth to improve newborn health and reduce medical costs

**NOLASIBAN**



Potential to improve live birth rate following IVF & embryo transfer

# Multiple development programs drive value

	Phase 1	Phase 2	Phase 3	Next Milestones
<b>YSELT<sup>®</sup></b> <b>(LINZAGOLIX)</b> Oral GnRH receptor antagonist	Uterine Fibroids – Ph3 PRIMROSE 2 (EU & US)			NDA submission (Q3:21) MAA for uterine fibroids expected recommendation (Q4:21)
	Uterine Fibroids – Ph3 PRIMROSE 1 (US)			
	Endometriosis – Ph3 EDELWEISS 3 (EU & US)			EDELWEISS 3: Completed enrollment with primary endpoint readout expected (Q4:21)
<b>EBOPIPRANT</b> Oral PGF <sub>2α</sub> receptor antagonist	Preterm Labor – Ph2b (EU & Asia)			Initiation of Phase 2b dose ranging study (Q4:21)
<b>NOLASIBAN</b> Oral oxytocin receptor antagonist	IVF – Ph1/2 (China)			In development, partnership with Yuyuan BioScience Technology (PRC)





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**DESIGNED TO TREAT MORE  
WOMEN SUFFERING FROM  
UTERINE FIBROIDS**

Yselty®, our proposed trade name for linzagolix, is conditionally acceptable for the FDA. Linzagolix has not been approved by FDA for any indication for use. Linzagolix is an investigational drug.



# Uterine fibroids

A significant unmet need translating into a multibillion market

**\$34B**/yr

total **US** costs from direct costs, lost workdays and complications

**9** million

women in the **US** affected by fibroids

**70**%+

of women have fibroids by age 50

## Quality of Life

premenopausal women may experience heavy menstrual bleeding, anemia, bloating, infertility, pain and swelling

**600,000**

hysterectomies are performed annually in the **US**

**>4** million

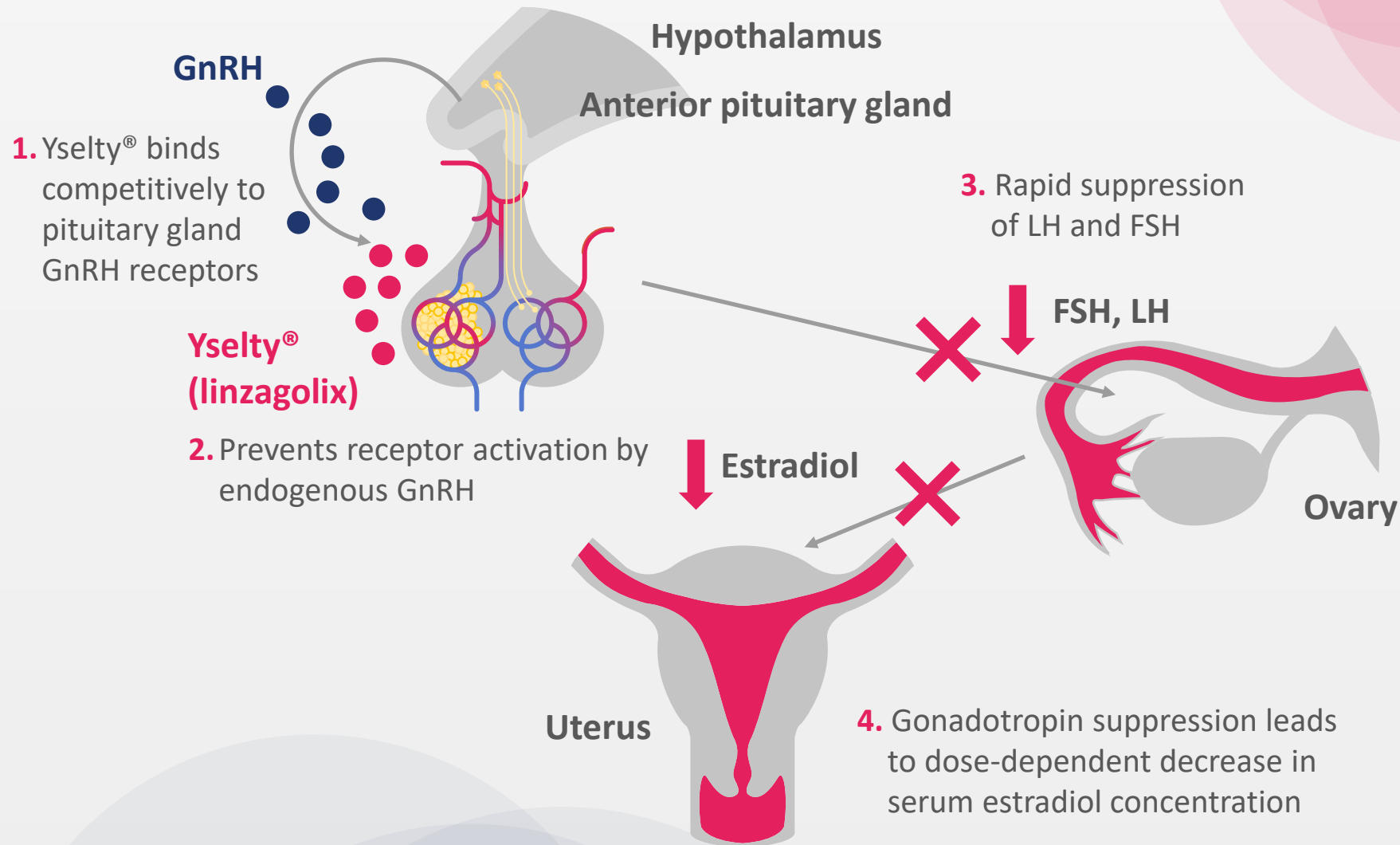
women in the **US** are treated annually for fibroids

**300,000**

are because of uterine fibroids



# GnRH antagonist mechanism of action



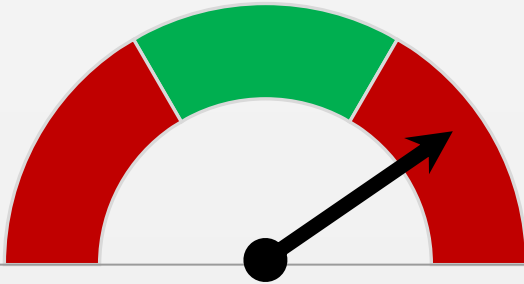


# Promise of GnRH antagonists

Dose dependent reduction of estradiol (E2)

Women with symptoms of uterine fibroids

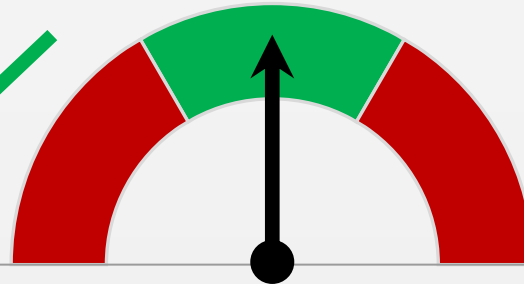
No estradiol suppression



**Disease Symptoms**

- Heavy menstrual bleeding/anemia
- Abdominal/pelvic pain and pressure

Target estradiol

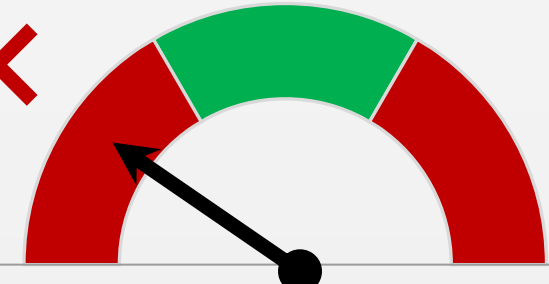


**Outcomes**

- Reduction in bleeding
- Minimal to no impact on BMD

**\*ABT not required**

Full estradiol suppression



**Symptoms/Safety Concerns**

- BMD loss
- Hot flashes

**\*ABT required for long term use (>6 months)**

\*ABT: 1mg estradiol/0.5 mg norethisterone acetate



# A potential new gold standard treatment for uterine fibroids

Differentiated PK/PD profile

1

**Bioavailability  
> 80%**

## **Reliable absorption**

Predictable exposure/effect with each dose

2

**Half-life  
14-15 hours**

## **Optimal balance for dosing and effectiveness**

- Convenient once-daily dosing that fits into women's busy lives
- Blood levels that last long enough to allow flexibility in dosing time

3

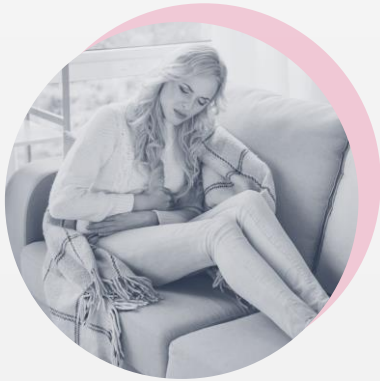
**No CYP3A4  
induction/food  
effect**

## **“No hassle” administration profile**

- Can be taken with or without food
- No relevant interactions with hormonal add-back therapy, oral iron, calcium or other common medications

# Uterine fibroids are ruining lives...

No two women are the same, but millions share a common problem: suffering the daily consequences of uterine fibroids



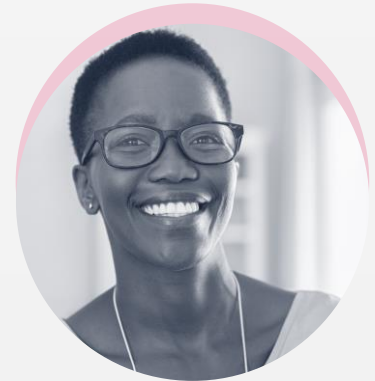
**Yselty® 200 mg once daily  
with concomitant ABT**

For long-term use for women  
for whom ABT is appropriate



**Yselty® 100 mg once  
daily without ABT**

For long-term use for women with  
a contraindication to or who prefer  
to avoid ABT



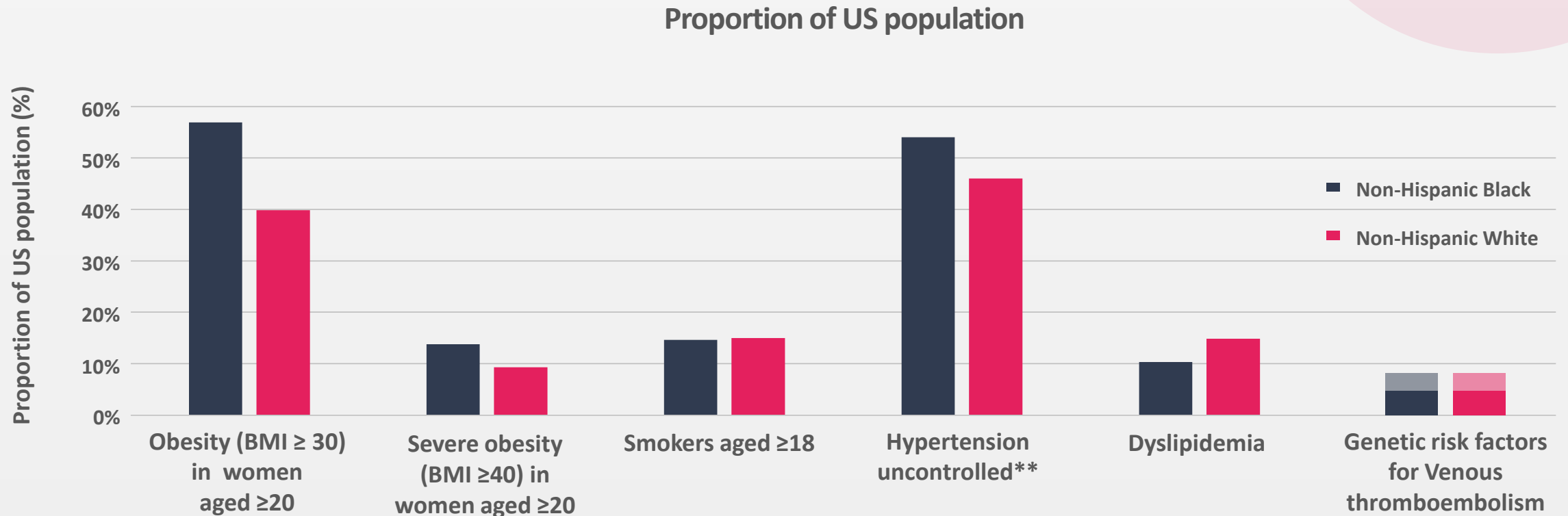
**Yselty® 200 mg once  
daily without ABT**

For short-term use (up to 6 months)  
when rapid reduction in fibroid and  
uterine volume is desired

**...Yselty®, designed to treat more women**

# Up to 50% of US women suffering from uterine fibroids may have a contraindication to hormonal ABT\*

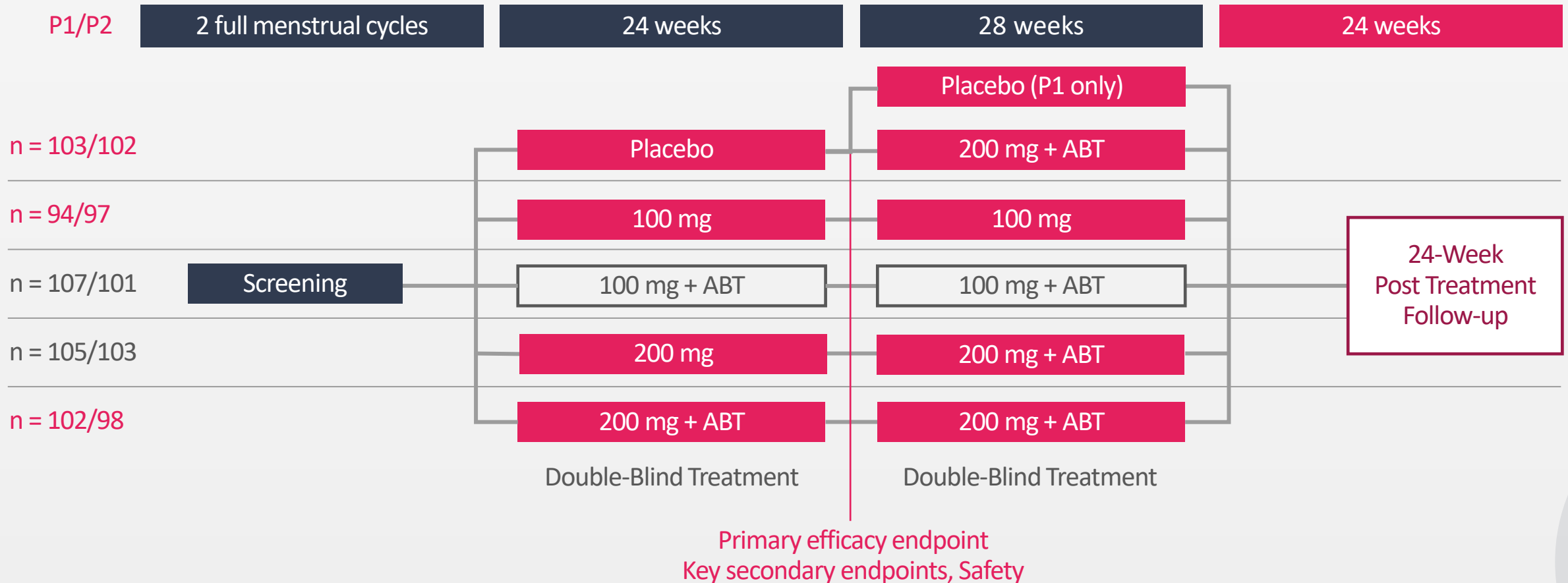
Black women are overrepresented



\*US FDA elagolix PI, section 4. Contraindications and section 5.1. Warnings and precautions – thromboembolic disorders and vascular events \*\* Proportion of individuals with hypertension - Overall population Male vs Female: 47% vs 43% \*\*Hales et al., Prevalence of obesity and severe obesity among adults: United States, 2017–2018. NCHS Data Brief, no 360

# Phase 3 registration studies

## PRIMROSE 1 (US) and PRIMROSE 2 (EU/US)



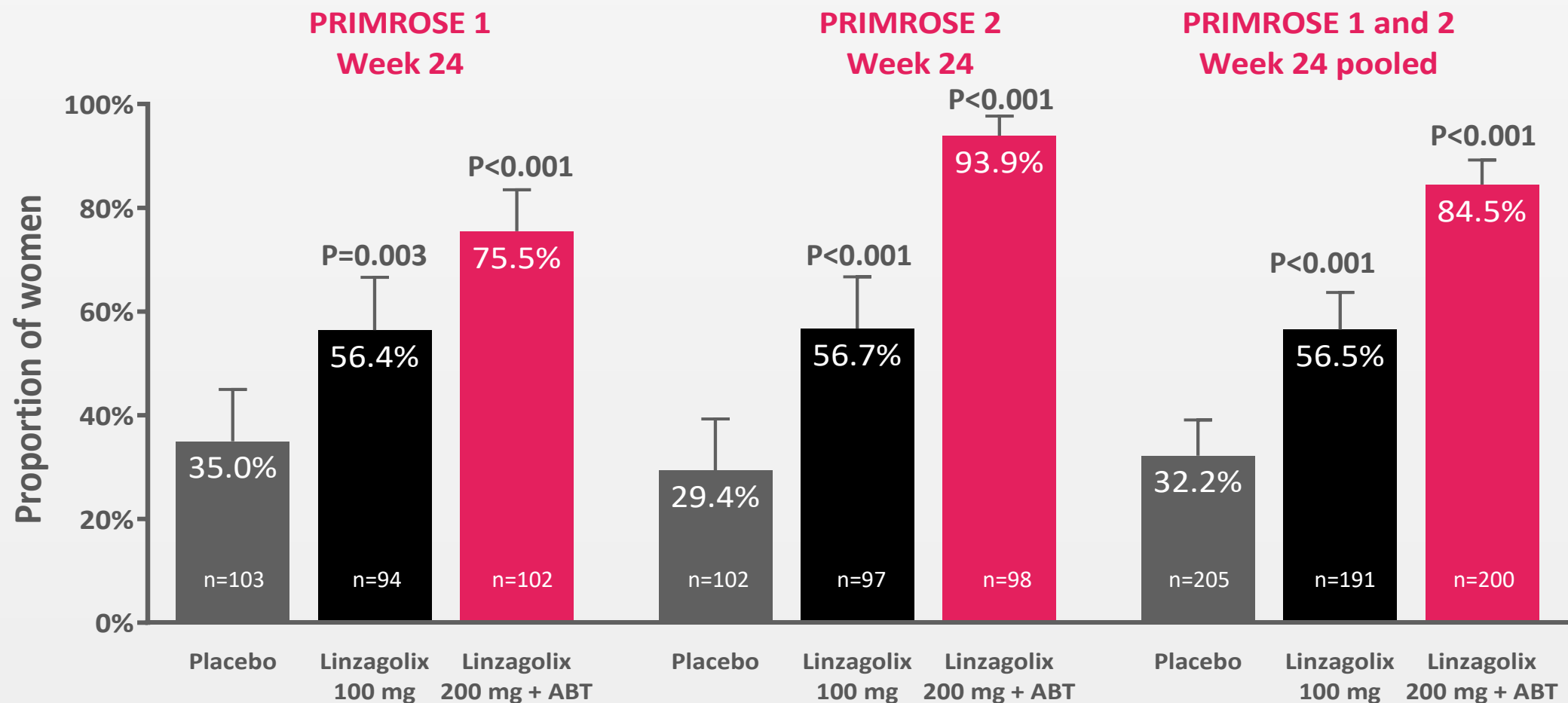
Primary efficacy endpoint: proportion of women with menstrual blood loss  $\leq 80$  mL (by alkaline hematin method) and  $\geq 50\%$  reduction from baseline

Patients in the studies received no Vitamin D or calcium supplementation  
ABT = Add Back Therapy (1mg estradiol + 0.5 mg norethindrone acetate)



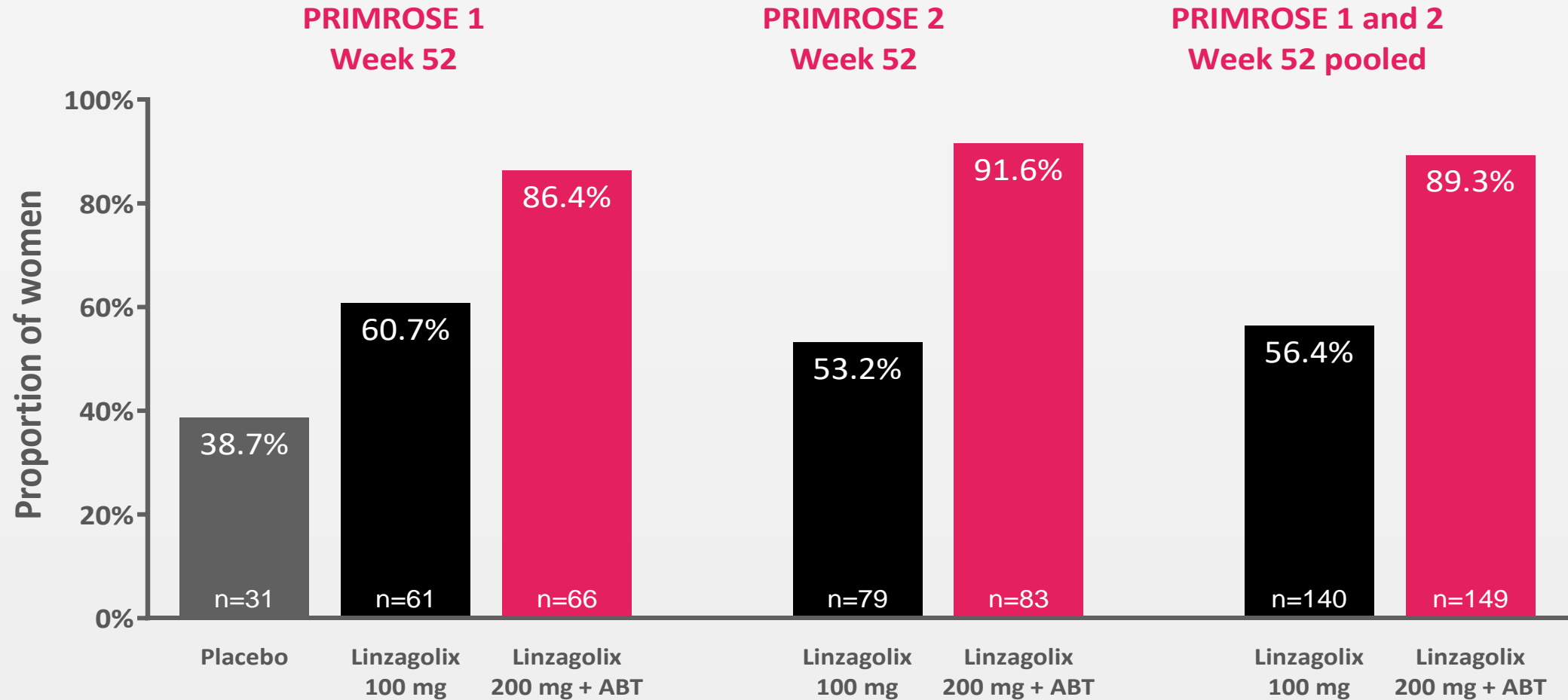
# PRIMROSE 1 and 2 achieved primary endpoint for both doses

## Responder\* analysis at week 24

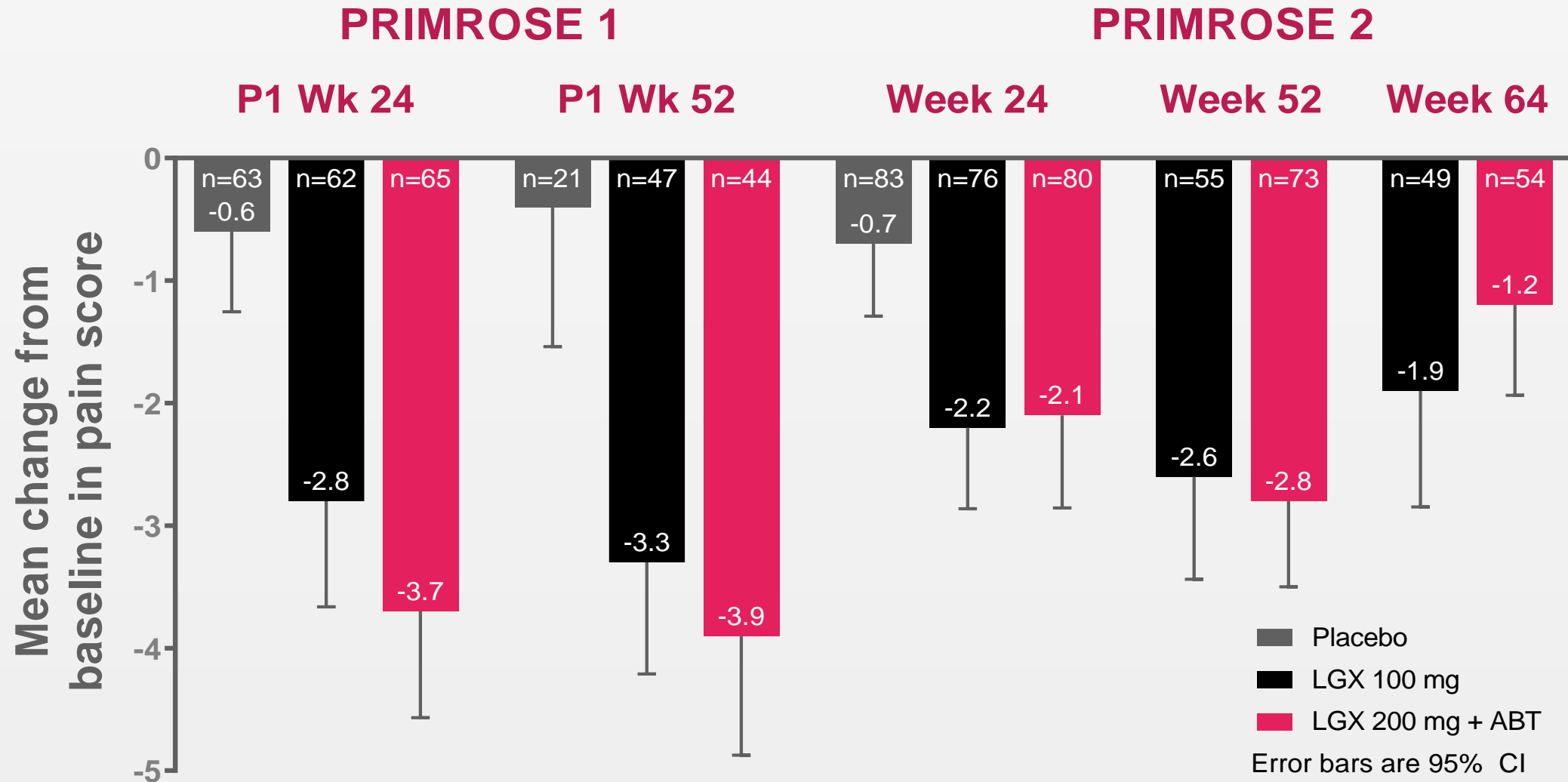


# PRIMROSE 1 and 2 achieved sustained reduction in MBL

## Responder\* analysis at week 52



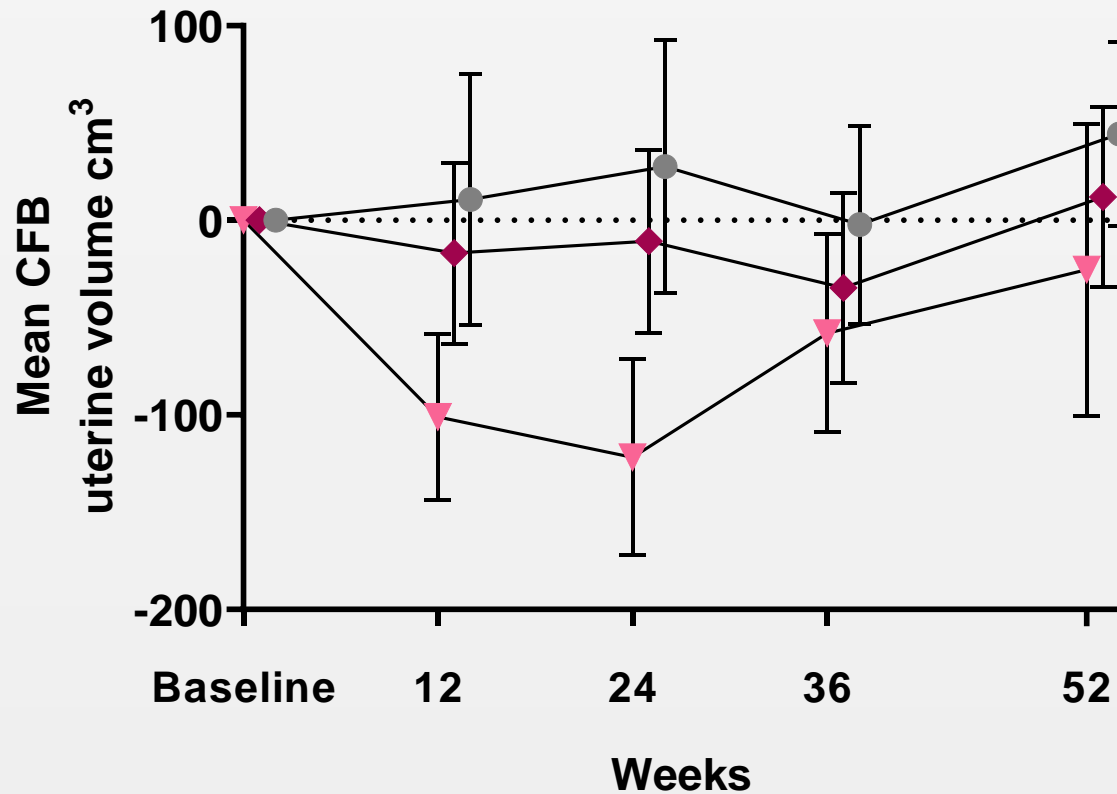
# Significant pain reduction maintained at weeks 52 and 64



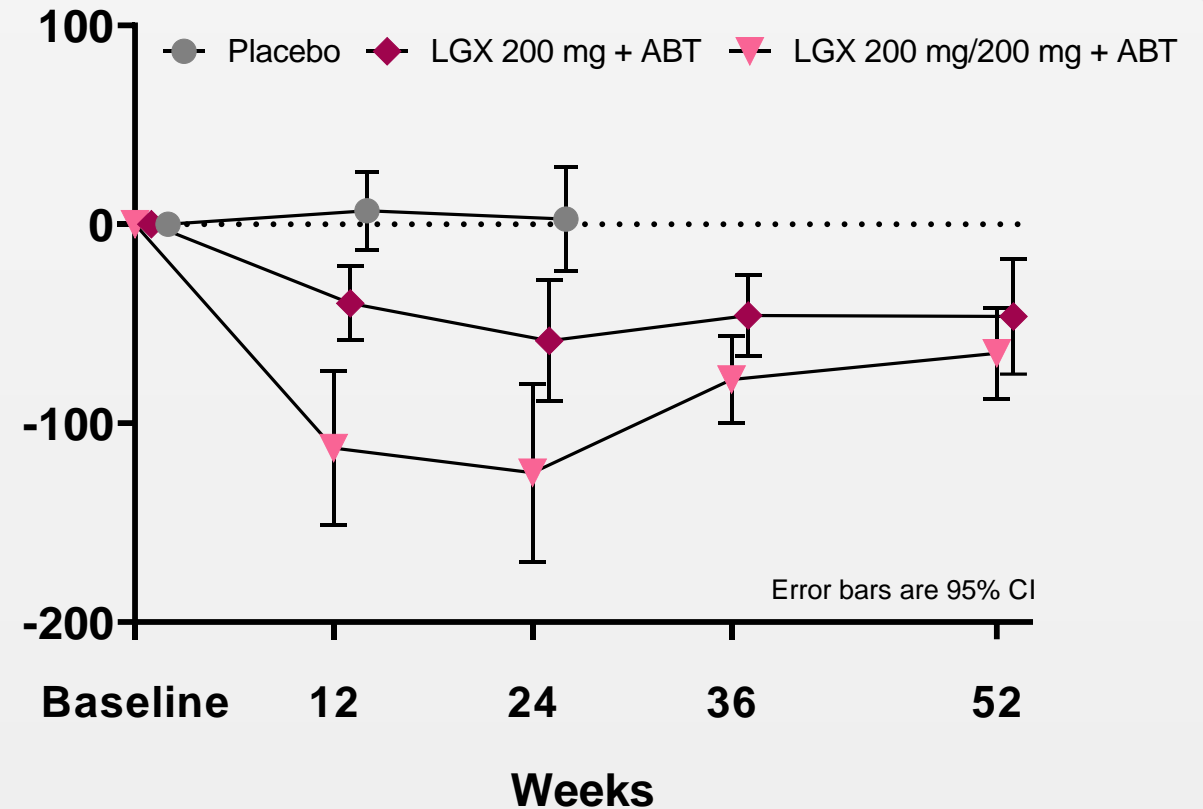
# LGX 200 mg without ABT significantly reduces uterine volume

Substantial reduction compared to placebo & LGX 200 mg with ABT at Week 24

PRIMROSE 1



PRIMROSE 2





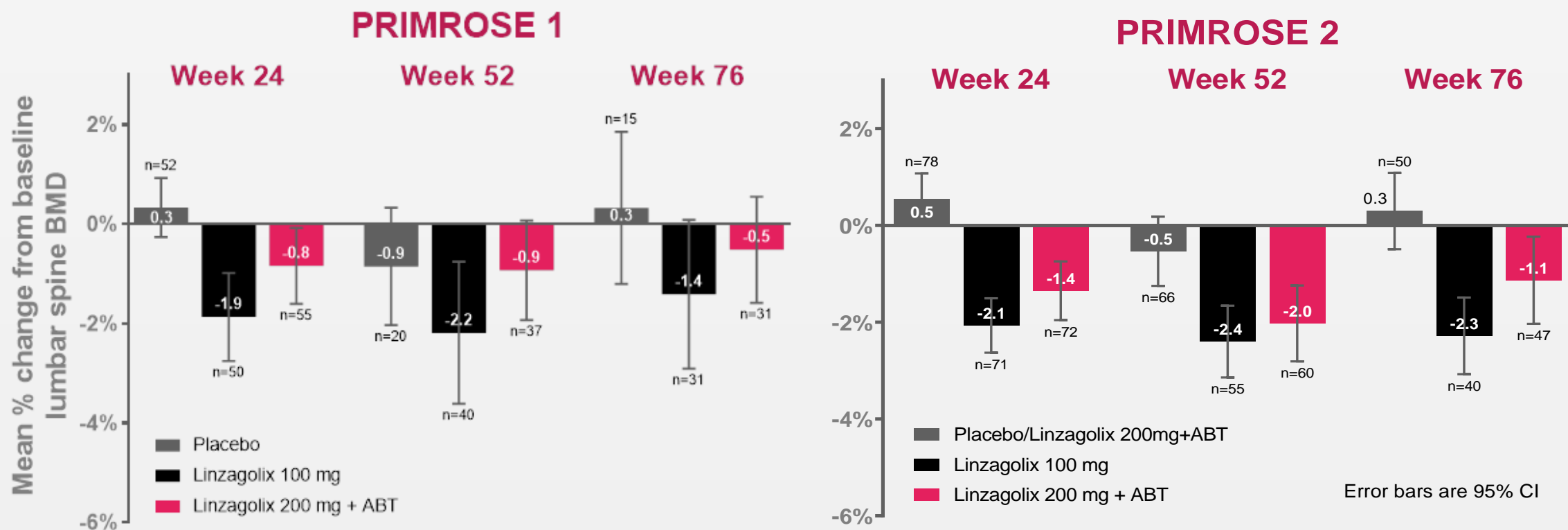
# 24-week efficacy data support Yselty® (linzagolix) as potential best-in-class GnRH antagonist

Caution advised when comparing across clinical trials. Below data are not head-to-head comparison, and no head-to-head trials have been completed, nor are underway

	Yselty® (Linzagolix)			Elagolix			Relugolix		
	PRIMROSE 1	PRIMROSE 2	Pooled Analysis	ELARIS 1	ELARIS 2	Pooled Analysis	LIBERTY 1	LIBERTY 2	Pooled Analysis
Dose Regimen	200mg + ABT Once daily			300 mg + ABT Twice daily			40mg + ABT Once daily		
Mean Age (y)	41.6	43.1		42.6	42.5		41.3	42.1	
Baseline MBL (mL per cycle)	197	212		238	229		229	247	
Responder* Rate (RR) (%)	75.5	93.9	84.7	68.5	76.5	72.2 <sup>+</sup>	73.4	71.2	72.3 <sup>++</sup>
Amenorrhea	✓	✓		✓	✓		✓	✓	
Pain	✓	✓		NR	NR		✓	✓	
Fibroid Volume	✗	✓		NR <sup>**</sup>	NR <sup>**</sup>		✗	✗	
Uterine Volume	✗	✓		NR <sup>**</sup>	NR <sup>**</sup>		✓	✓	
Menstrual Blood Loss	✓	✓		✓	✓		✓	✓	
Anemia	✓	✓		✓	✓		✓	✓	
Quality of Life	✓	✓		✓	✓		✓	✓	

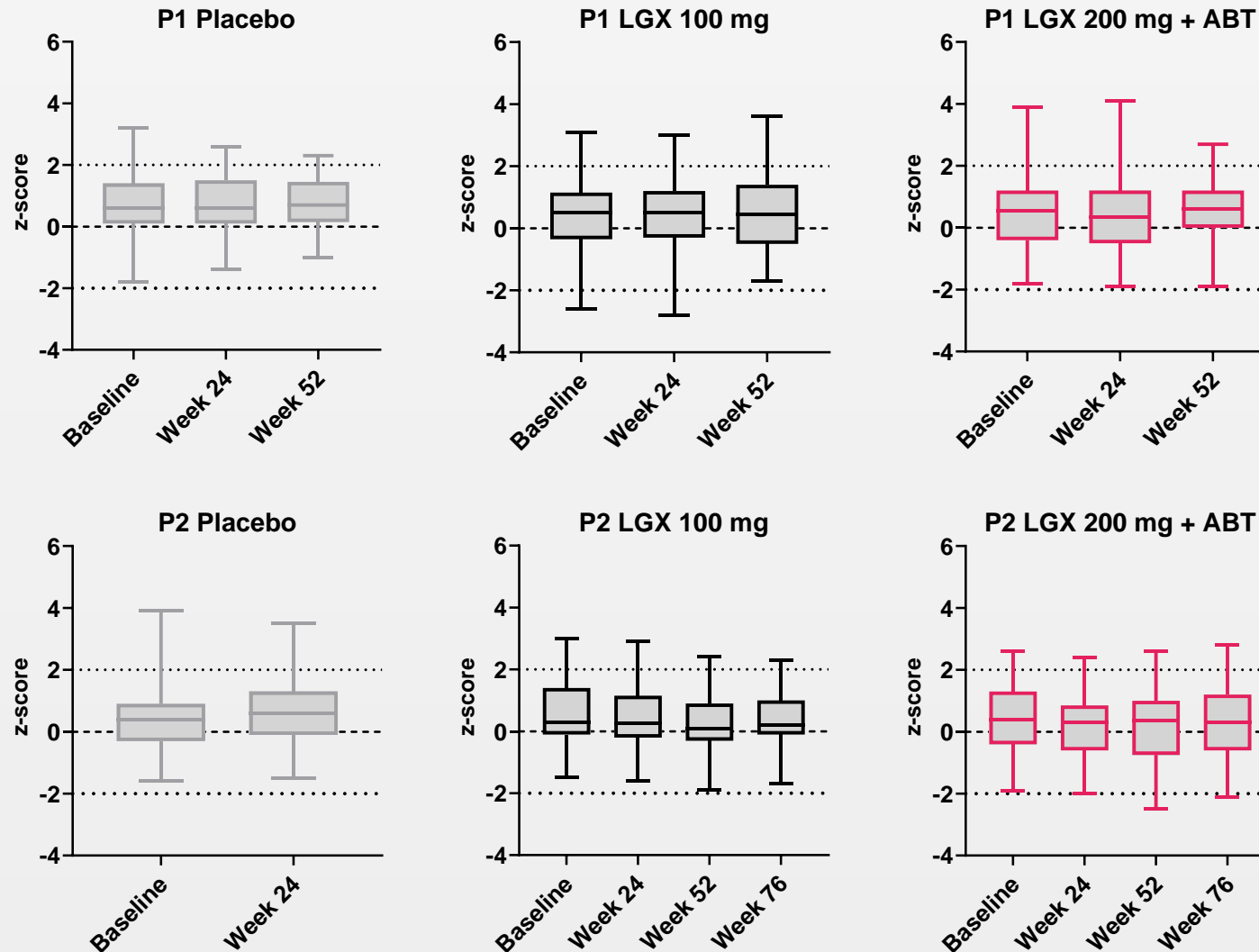
# Minimal BMD change with both doses, plateauing after week 24

Expected age-related BMD decline observed in placebo arm at Week 52



# Bone mineral density – no change in z-scores

Expected age-related BMD decline observed in placebo arm at Week 52



Z-score compares BMD to the average values of a person of the same age and gender. A score < -2 is a sign of less bone mass than expected

# Favorable tolerability profile

## Summary of adverse events—week 24 to 52

Number (%) of women	PRIMROSE 1			PRIMROSE 2	
	Placebo	Yselty® 100 mg	Yselty® 200 mg + ABT	Yselty® 100 mg	Yselty® 200 mg + ABT
	n=31	n=62	n=70	n=79	n=84
Subject with at least one TEAE	12 (38.7)	25 (40.3)	25 (35.7)	22 (27.8)	21 (25.0)
TEAE leading to discontinuation	1 (3.2)	2 (3.2)	1 (1.4)	7 (8.9)	1 (1.2)
SAE related to linzagolix	0	0	0	0	0
Occurrence after week 24 of most frequently reported AEs (> 5%) up to week 24					
Hot flush	0	1 (1.6)	0	2 (2.5)	3 (3.6)
Headache	1 (3.2)	3 (4.8)	0	1 (1.3)	1 (1.2)
Anemia	1 (3.2)	0	0	2 (2.5)	1 (1.2)





# Designed to treat more women

Excellent clinical data driving differentiated profile

**Potentially  
best-in-class**



- Unique PD/PK Profile
- Efficacy sustained up to 52 weeks for all dose regimens

**Favorable  
tolerability  
profile**



- No safety signal of concern
- BMD remains within normal ranges during and after treatment

**Unique set  
of treatment  
options**



- Unique low dose option without ABT
- Significant uterine volume reduction for 200 mg without ABT

**ABT-containing regimens may be contraindicated in up to 50% of US women with uterine fibroids based on the elagolix US label\* and analysis of CDC data\*\***

# Endometriosis

An emotionally and physically painful condition

**\$22B**/yr

total **US** costs

**176** million

women **worldwide**  
suffer from  
endometriosis

**60**%+

of women feel  
symptoms by  
age 16

## Quality of Life

premenopausal women  
may experience pelvic pain,  
pain during intercourse and  
defecation, infertility and  
emotional distress

Endometriosis  
affects up to

**10**%+ in the general  
population

**50**%+ in the fertile  
population

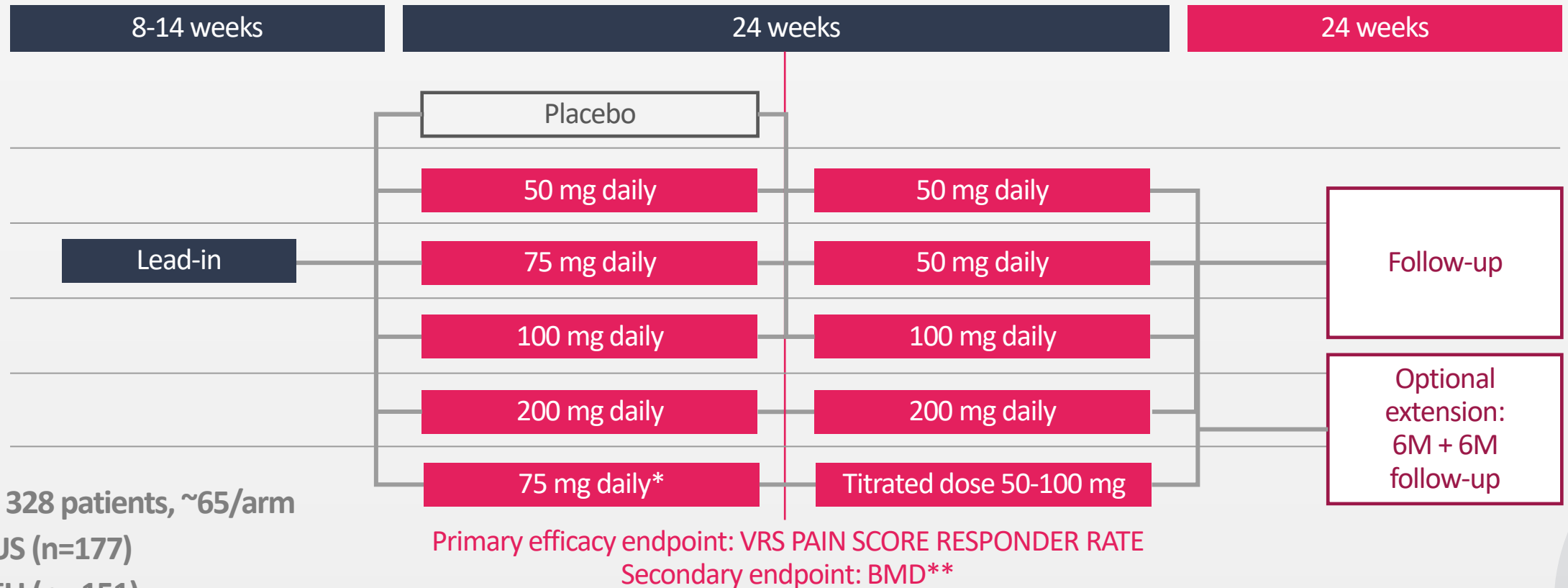
**60**%+ in patients with  
chronic pelvic pain

**5** million

women in the **US**  
are treated annually  
for endometriosis



# Phase 2b EDELWEISS in endometriosis



Enrollment 328 patients, ~65/arm  
50 sites in US (n=177)  
14 sites in EU (n= 151)

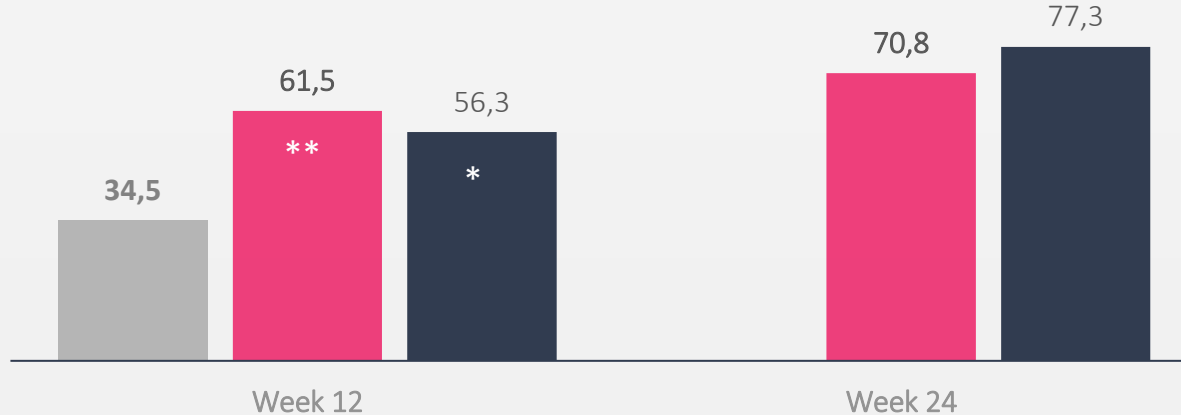
Patients were provided with Vitamin D and calcium

# Phase 2b EDELWEISS in endometriosis

## Overall Pelvic Pain (%)

Responder (0-3 VRS)

■ Plc ■ 75mg ■ 200mg

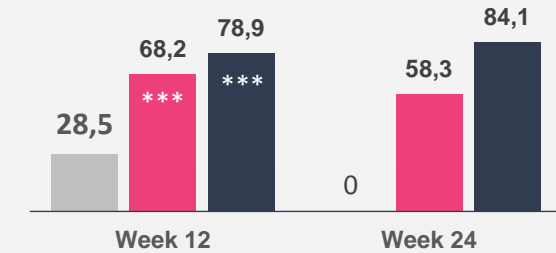


Potential point of differentiation as 75mg partial suppression dose is nearly as effective as 200mg full suppression dose

## Dysmenorrhea (%)

Responder (0-3 VRS)

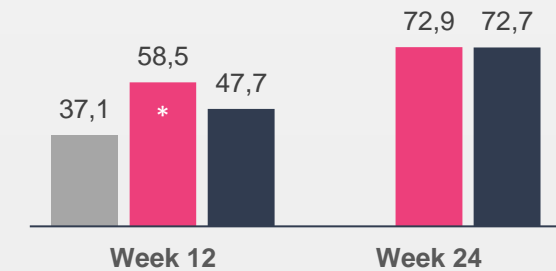
■ Plc ■ 75mg ■ 200mg



## Non-menstrual Pelvic Pain (%)

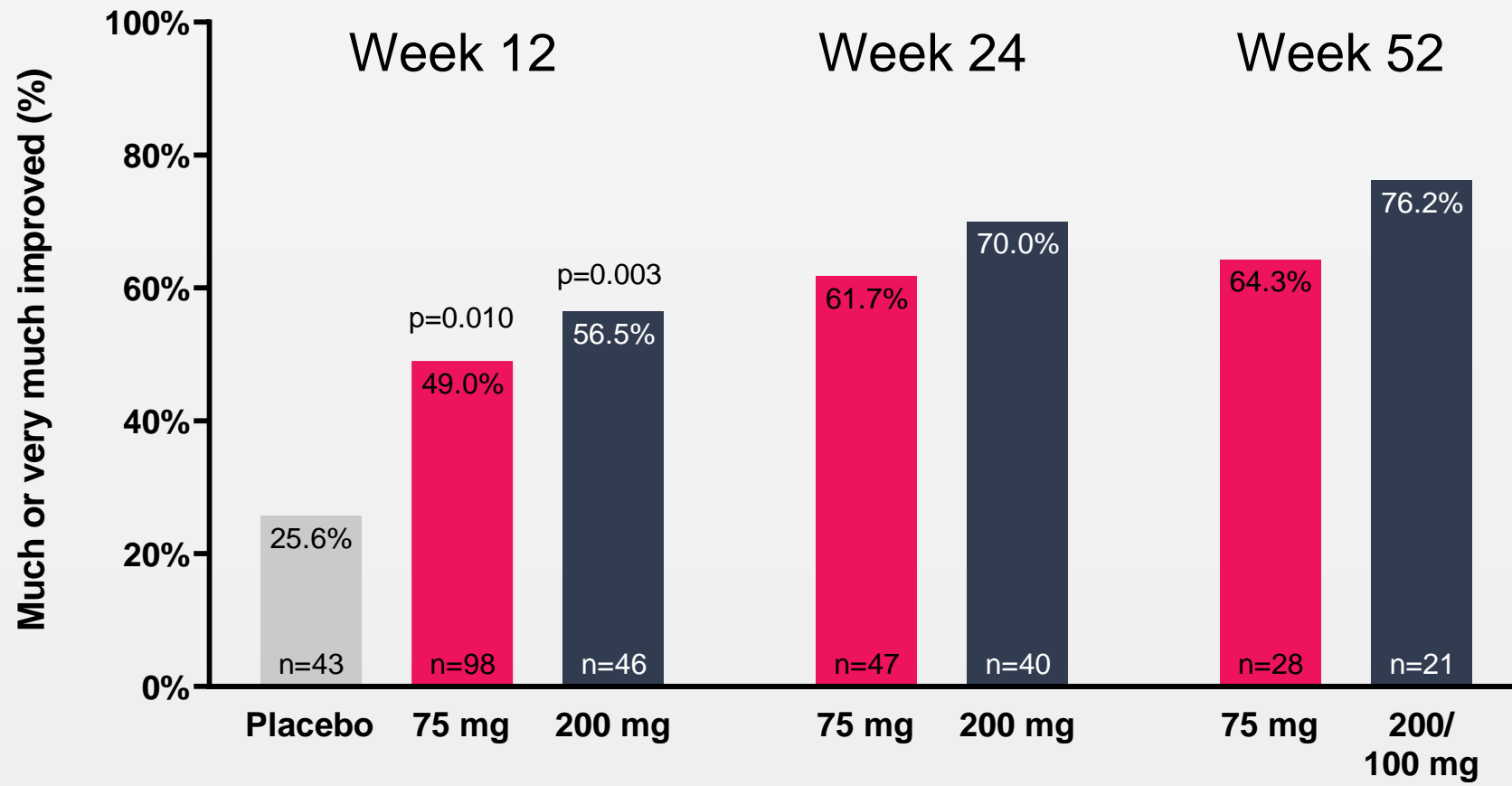
Responder (0-3 VRS)

■ Plc ■ 75mg ■ 200mg



# Phase 2b EDELWEISS in endometriosis

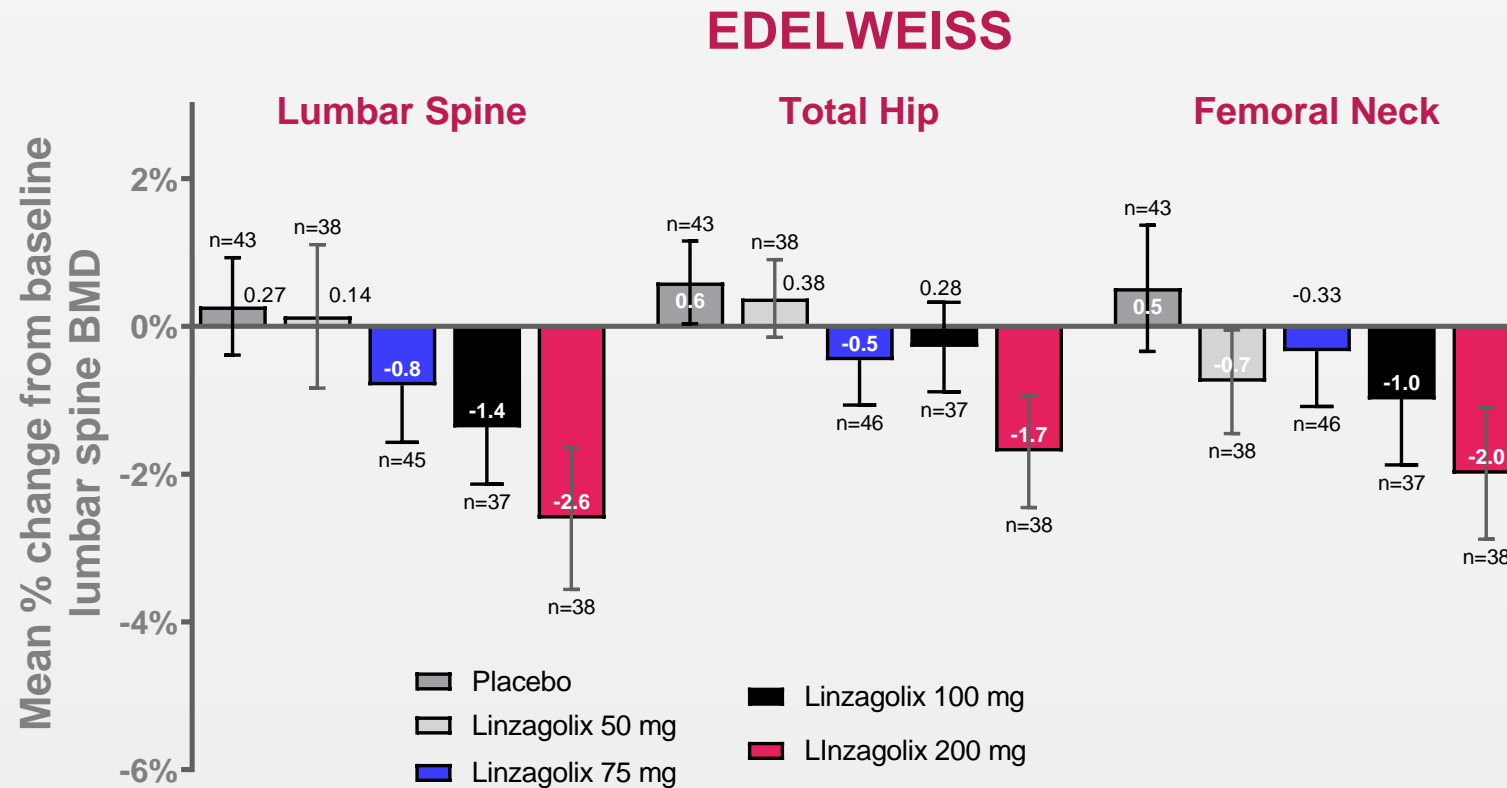
Sustained improvement in overall endometriosis symptoms (PGIC)



# Phase 2b EDELWEISS in endometriosis

75 mg effective without significantly affecting BMD

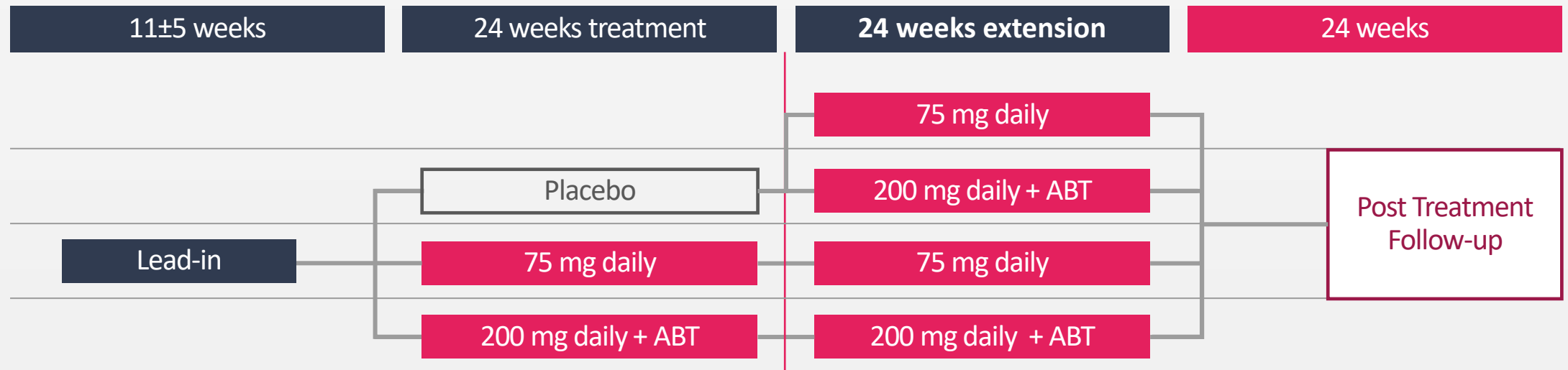
Mean % change in BMD from baseline to 24 weeks (12 weeks for placebo)





# Phase 3 endometriosis trial

EDELWEISS 3



Co-Primary efficacy endpoint: DYS/NMPP Responder Analysis

Patients are provided with Vitamin D and calcium

# Prostate cancer

The second most prevalent form of cancer in men and a leading cause of death due to cancer<sup>1</sup>

3.8%

Of all cancer deaths in men in 2018 due to prostate cancer<sup>2</sup>

1.3M

New cases of prostate cancer reported globally in 2018<sup>3</sup>

2X Mortality Rate

In African-American men compared to Caucasians; incidence rate of 158.3 new cases diagnosed per 100K African-American men<sup>4</sup>

~130K

Number of patients in the US treated with Lupron

\$600M

Total US sales for GnRH agonists

Lupron was the biggest product in the US with nearly \$350M in revenue

\$2.1B

Total global prostate cancer market for GnRH agonists in 2020<sup>5</sup>

Or over half of the total global GnRH agonist market<sup>6</sup>



# Advanced prostate cancer opportunity

## Current Standard of Care

Aims to reduce testosterone (T) to castration levels

## Limitations

Injectable GnRH agonists (leuprolide) most commonly used but associated with initial T level spike that can worsen symptoms and delay recovery upon drug discontinuation

## Benefit of GnRH antagonists

Evidence from pooled analyses suggest lower cardiovascular risk with GnRH antagonists versus GnRH agonists<sup>1</sup>

## Paradigm Change

Once-daily oral drugs that can safely and effectively suppress T levels would represent a paradigm change in chronic treatment of the disease

## Superiority of relugolix

Myovant's relugolix (Orgovyx™) demonstrated superiority in Phase 3 versus Lupron and launched in January 2021

# GnRH analogues in prostate cancer\*

Profile			Efficacy <sup>††</sup>				Safety		
GnRH analog	Delivery Route	Flare Effect <sup>†</sup>	Castration on Day 4 (%)	Castration on Day 15 (%)	Sustained T Level to 48 Weeks (%)	PSA Response at Day 15 (%)	MACE <sup>‡</sup> Overall/ Prior History (%)	Injection Site Reaction (%)	Hot Flush (%)
GnRH Agonist									
Leuprolide	Injection (Every 1-3 months)	Yes	0	12	89	20	6.2/17.8	14	51.6
Degarelix <sup>§</sup>	Injection (Monthly)	No	96	99	97	-	-	40	26.0
Relugolix	Oral	No	56	99	97	79	2.9/3.6	n/a	54.3

\*Phase 3 relugolix (HERO) results for leuprolide and Relugolix (Shore et al., NEJM. 2020; 382: 2187 -96 ; Degarelix package insert (PI)

†Flare effect = initial spike in T levels upon treatment initiation due to initial activation of GnRH receptor

††Responder = Testosterone levels <50 ng/dL (i.e., castration)

‡MACE=major cardiovascular event after 48 weeks of treatment; KM analysis showed 54% lower risk in relugolix group vs leuprolide group

§Degarelix PI: Day 3 and Day 14; sustained levels to Day 364 for 240/80mg dose; \*rate of hot flush for leuprolide in Degarelix studies was 21%

# ObsEva's linzagolix could potentially challenge the current standard of care as the best-in-class oral GnRH antagonist for advanced prostate cancer



Potentially best-in-class GnRH antagonist in uterine fibroids & endometriosis



ObsEva exploring development of linzagolix in combination with estrogen for the treatment of advanced prostate cancer



Potential improvement on GnRH antagonist-only regimen by further decreasing cardiovascular & bone loss risk, and mitigating hot flushes: Phase 3 results showed similar hot flush rates (>50%) for relugolix and leuprolide<sup>1</sup>



ObsEva has exclusive global rights (excluding Asia) to linzagolix for all indications



# EBOPIPRANT

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Potential To Delay  
Preterm Birth To  
Improve Newborn  
Health And Reduce  
Medical Costs





# Preterm birth is delivery before 37 weeks of pregnancy

Life altering & costly

**\$26B**<sub>/yr</sub>

US economic burden

**>1**

In 10 babies are born preterm

**1** million

preterm related deaths in 2015 WW<sup>1</sup>

## LEADING

cause of death in children under age 5

Babies surviving early birth face greater likelihood of lifelong disabilities

Preterm birth, a costly burden per baby

**\$16.9**<sub>B+</sub> US infant medical costs

**\$195**<sub>K+</sub> average cost per US survivor infant born 24-26 weeks

**\$50**<sub>K</sub> average US cost for a preterm infant



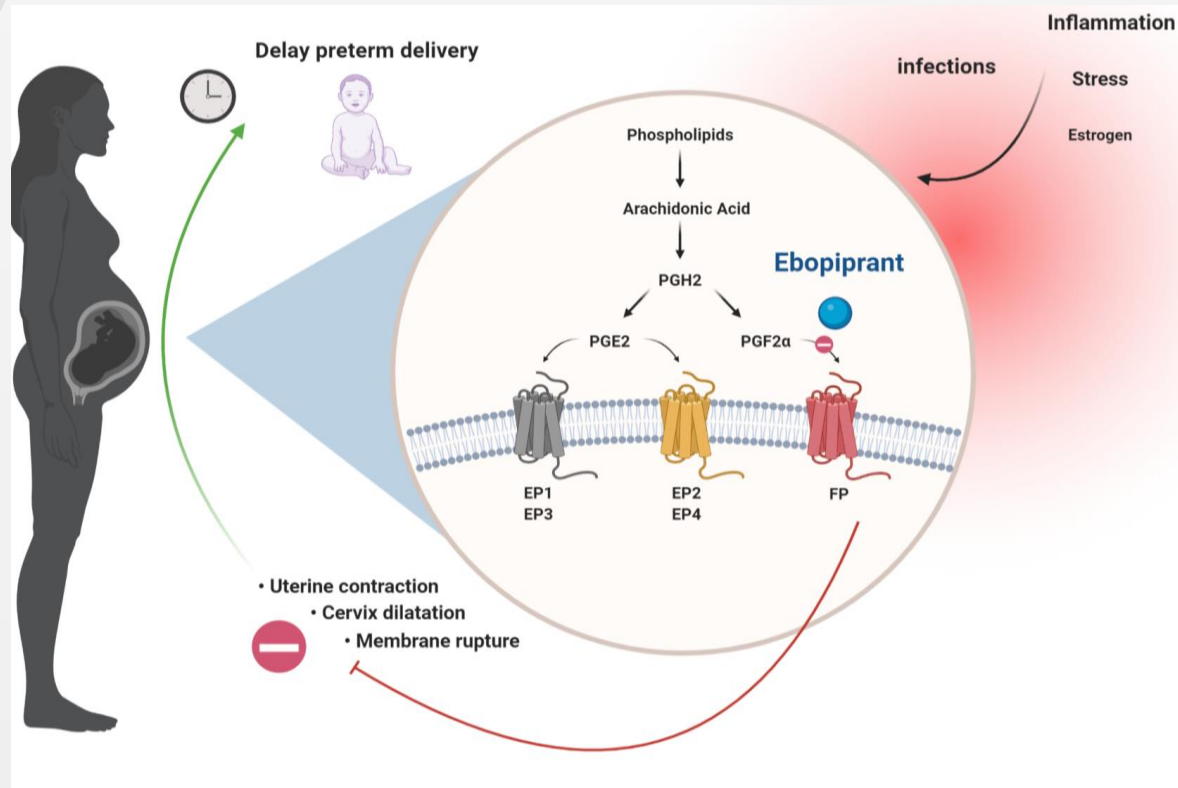
# Ebopiprant is designed to treat preterm labor (PTL)

	Treating Preterm Labor	Preventing Preterm Labor
Drug(s)	<p>No FDA–approved PTL treatment available in US</p> <p>Current treatment in US includes off-label use of non-selective prostaglandin (COX) inhibitors, Indomethacin, calcium channel blocker, beta-mimetics; all are associated with safety issues that limit use</p> <p>Atosiban (oxytocin receptor antagonist) approved in EU/some Asian countries</p>	<p>Makena approved for prevention of PTL in women with history of preterm birth</p> <p>Not approved for treatment of PTL</p> <p>Potential withdrawal from US market after failed confirmatory trial</p>
Use	<p>Use in setting of active preterm labor and threatened premature delivery</p>	<p>Use starts between 16 and 20 weeks of pregnancy</p>



# Ebopiprant: an advancement in treatment of preterm labor

Orally active, selective prostaglandin  $F_{2\alpha}$  ( $PGF_{2\alpha}$ ) receptor antagonist



## ebopiprant

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

Potential to treat preterm labor  
with improved safety over non-  
selective COX \*inhibitors  
(NSAIDS)

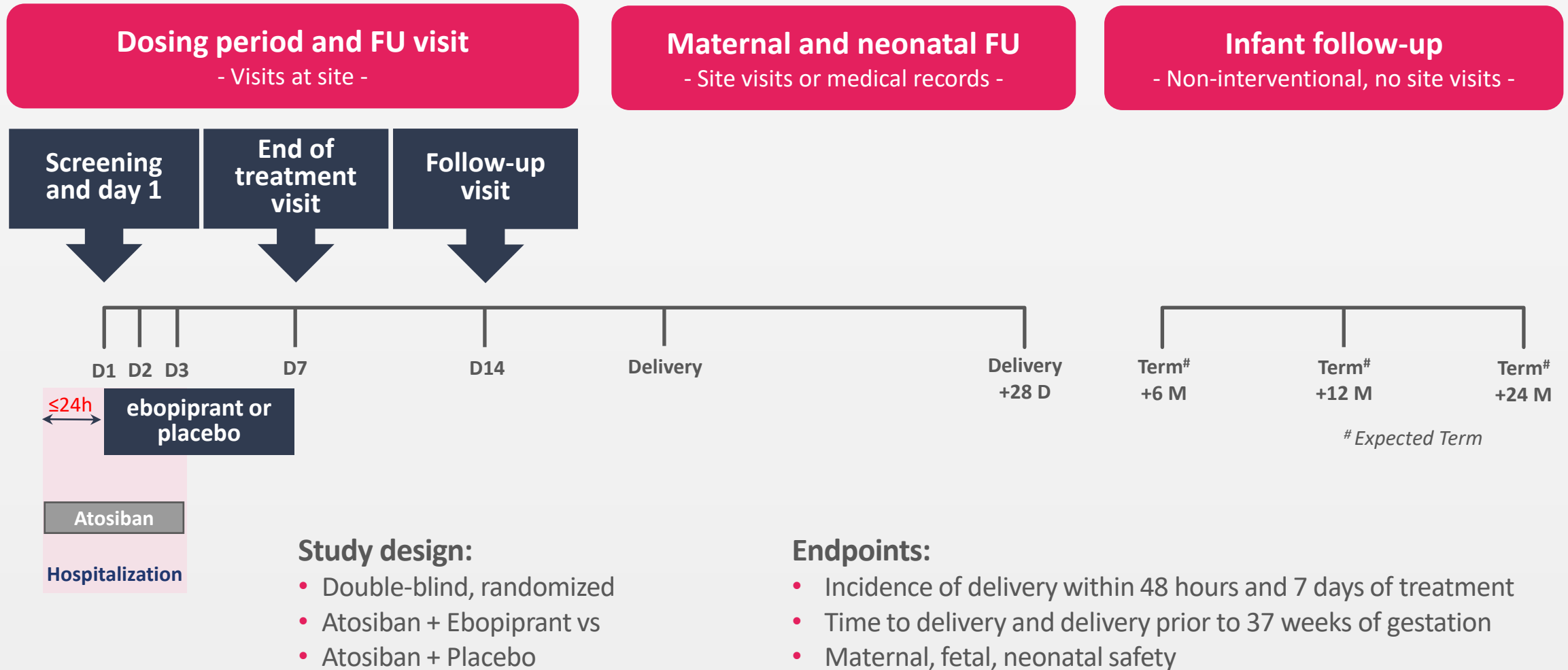
# Ebopiprant is designed to delay delivery by at least 48 hours

Short-term prolongation of pregnancy (*at least 48 hours*) provides a critical window for impact on neonatal outcomes:

- Allows full effect of corticosteroids on neonatal lung maturity
  - Prematurity associated with respiratory complications due to insufficient lung maturation
  - Corticosteroids used to speed up maturation process
  - Maximum effect occurs ~48+ hours after administration
- Allows patient transfer to centers with NICU\*



# Ebopirant Phase 2a PROLONG study



# Ebopiprant Phase 2a PROLONG study

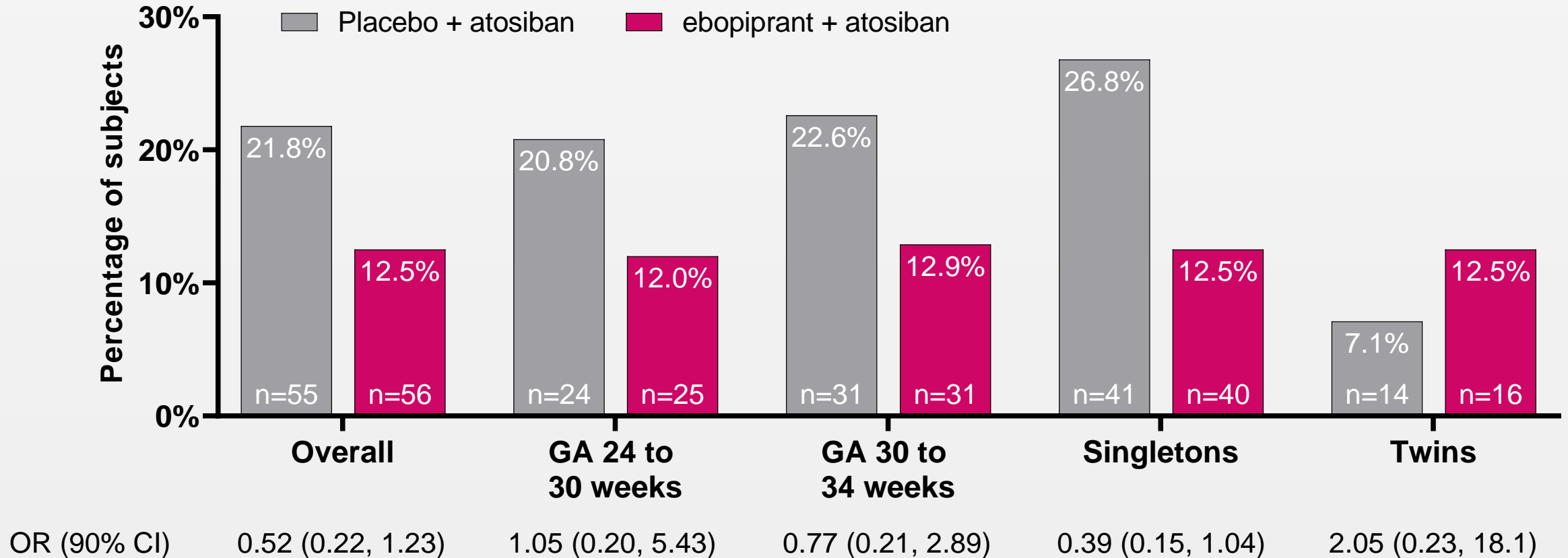
## Demographics and baseline characteristics

	Atosiban + Placebo	Atosiban + Ebopiprant
	n=55	n=58
Mean age – years (SD)	29.6 (5.1)	29.7 (5.7)
Race		
White – n (%)	39 (70.9%)	42 (72.4%)
Asian – n (%)	16 (29.1%)	14 (24.1%)
Mean (SD) gestational age – weeks	29 (3.0)	30.2 (2.6)
24 to 30 weeks – n (%)	23 (41.8%)	25 (43.1%)
30 to 34 weeks – n (%)	32 (58.2%)	33 (56.9%)
Singleton – n (%)	41 (74.5%)	42 (72.4%)
Twin – n (%)	14 (25.5%)	16 (27.6%)



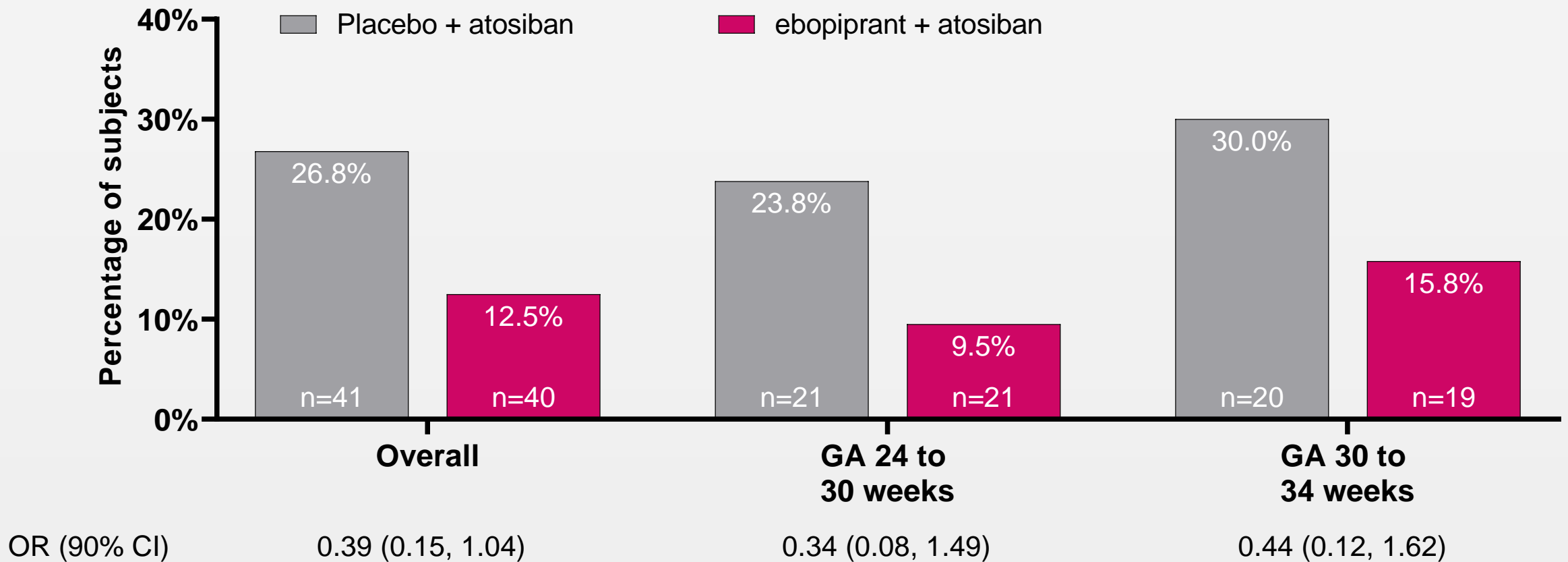
# Overall delivery rate within 48 hours reduced by >40%

Percentage of women delivering within 48 hours



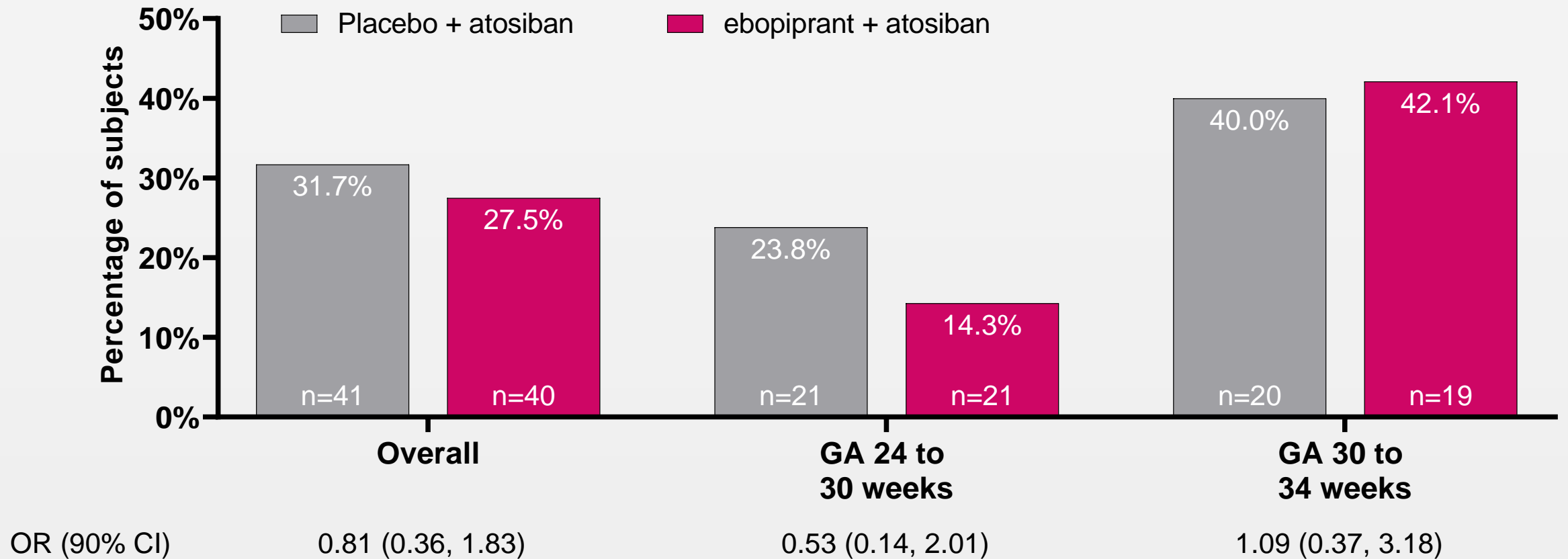
# Singleton delivery rate within 48 hours reduced by >50%

Percentage of women delivering within 48 hours



# Reduced Singleton 24- to 30-week delivery rate within 7 days

Percentage of women delivering within 7 days



# Ebopiprant Maternal and neonatal safety

	Atosiban + Placebo	Atosiban + Ebopiprant
Maternal & Fetal AEs until 7 days post treatment – n (%)	n=55	n=58
At least one TEAE	23 (41.8%)	24 (41.4%)
SAEs	0	0
Most common (constipation)	4 (7.3%)	4 (6.9%)
Neonatal AEs and prematurity related Events – n (%)	n=69	n=72
At least one TEAE or prematurity related event	41 (59.4%)	44 (61.1%)
SAEs	9 (13.0%)	10 (13.9%)
Most common (neonatal jaundice)	28 (40.6%)	22 (30.6%)
Neonatal outcomes – n (%) singletons	n=41	n=40
Duration of hospitalization in days – mean (SD)	18.0 (25.8)	13.7 (16.5)

# Ebopiprant Phase 2b dose ranging study

## Anticipated initiation Q4:21\*

### Study Design:

- Global (EU and Asia)
- Dose escalating
- Double-blind, randomized
- Atosiban + Ebopiprant
- Atosiban + Placebo

### Key Eligibility Criteria:

- Single gestation
- 24-34 weeks
- Confirmed preterm labor
- No contraindication to tocolysis

### Endpoints:

- Optimal dose
- Incidence of delivery within 48 hours and 7 days of treatment
- Time to delivery and delivery prior to 37 weeks of gestation
- Maternal, fetal, neonatal safety

# Ebopiprant development in the US

- FDA approved the beta-mimetic ritodrine (Yutopar) in 1980
  - Withdrawn from the market in 1995 due to cardiovascular complications
  - No subsequent US approvals for PTL treatment
- Discussions with FDA regarding clinical development program will be required
- Currently engaging with US KOLs/advocacy groups
- Potential approaches include:
  - Combination with non-registered standard of care
  - Comparison with non-registered standard of care
  - Open label single-arm study vs historical data
- Single Phase 3 study may be acceptable



# Ebopiprant, a potential breakthrough for preterm labor

**Over 50%  
reduction of  
singleton delivery  
within 48 hrs**



Enabling administration of  
critical drugs for neonatal  
protection

**Favorable  
maternal,  
fetal and  
neonatal safety**



Maternal, fetal and  
neonatal safety  
comparable to placebo

**Supports  
advancing  
ebopiprant  
into Phase 2b**



Phase 2b study will include higher  
doses to more fully define  
ebopiprant potential and the longer-  
term benefits for babies

**Ebopiprant has demonstrated proof of concept in delaying preterm birth**

# Investor highlights

1

Pursuing large indications for conditions that compromise **women's reproductive health and beyond**

2

Yselyt<sup>®</sup> has potential **best in class efficacy, favorable tolerability, and unique flexible dosing options**

3

Ebopiprant is the only known product in development for preterm labor and has **positive Phase 2a data**

4

Business model built on strong **global partnerships and collaborations**

5

Seasoned **leadership team** with a track record for success

# Thank you

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