

A close-up profile of a woman with long, dark hair, wearing a traditional Indian sari with a pink and purple pattern. She is looking towards the left of the frame. The background is a soft, out-of-focus light blue and white.

**Obseva**  
nature meets nurture

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Focused on unmet needs in  
women's reproductive health

August 2020

Obseva

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# Obseva: focus on unmet needs in women's health

## LINZAGOLIX



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

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## 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	Status/NEXT MILESTONES
<b>YSELT<sup>®</sup></b> <b>(LINZAGOLIX)</b> Oral GnRH receptor antagonist	Uterine Fibroids – Ph3 PRIMROSE 2 EU & U.S.			Positive Ph3 24W Primary endpoint results for both PRIMROSE 1 & 2 PRIMROSE 1 52W data Q4:2020 MAA /NDA Q4:2020/1H:2021  Initiated Ph3 Q2 2019  Positive Phase 2b results 2018/19
	Uterine Fibroids – Ph3 PRIMROSE 1 U.S.			
	Endometriosis – Ph3 EDELWEISS 2 U.S.			
	Endometriosis – Ph3 EDELWEISS 3 EU & U.S.			
	Endometriosis – Ph2b EDELWEISS*			
<b>OBE022</b> Oral PGF <sub>2α</sub> receptor antagonist	Preterm Labor – Ph2a PROLONG		Phase 2a Part B results expected 4Q:20  Pre-clinical/Phase 1 complete	
	Preterm Labor – Ph1			
<b>NOLASIBAN</b> Oral oxytocin receptor antagonist	IVF – Ph3 IMPLANT 2/4 EU			Positive IMPLANT 2 Ph3 Results IMPLANT 4 Ph3 missed primary endpoint YuYuan BioScience : China IND submission 4Q:20
	IVF – Ph1/2 in China			

# Major upcoming catalysts

**Progressing from a pure development play to preparing commercialization**



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## First linzagolix regulatory filings

MAA/NDA Q4:20/1H:21

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## Linzagolix regional commercial partnerships

Active discussions ongoing

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## Phase 2a readout of OBE022 in preterm labor

Part B results in ~120 patients 4Q:20

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## Nolasiban development proceeding in China

Partner YuYuan Bioscience submitting IND 4Q:20

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nature meets nurture



## Phase 3 Trial Results PRIMROSE 1 and 2

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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 **U.S.** costs from direct costs, lost workdays and complications

**9** million

women in the **U.S.** 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 **U.S.**

**>4** million

women in the **U.S.** are treated annually for fibroids

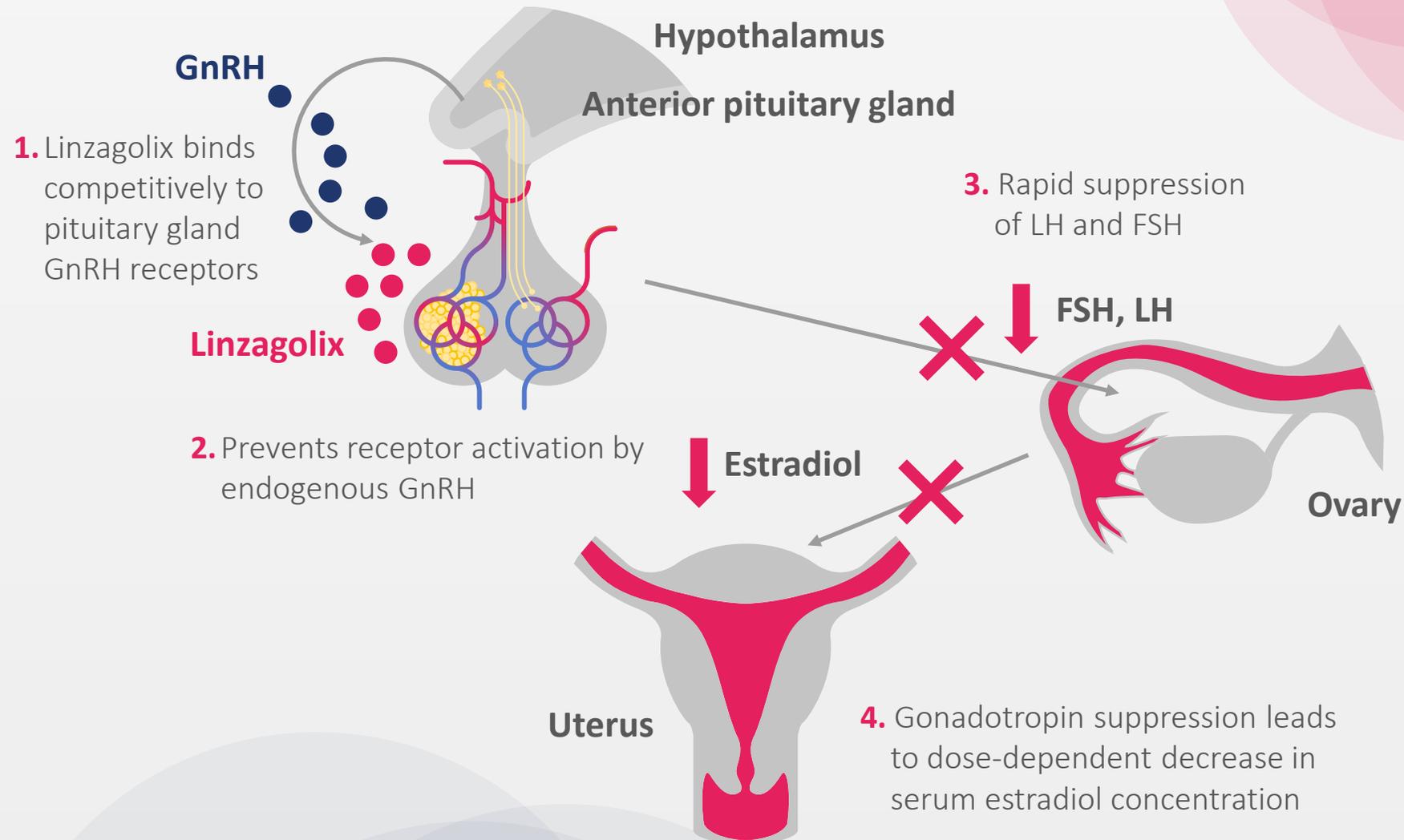
**300,000**

are because of uterine fibroids



# A potential new gold standard treatment for uterine fibroids

## Mechanism of action



# A potential new gold standard treatment for uterine fibroids

Unique PK/PD profile

Bioavailability  
> 80%

Half-life  
14-15 hours

Once daily  
dosing

1

## Reliable absorption

Predictable exposure/effect with each dose

2

## 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

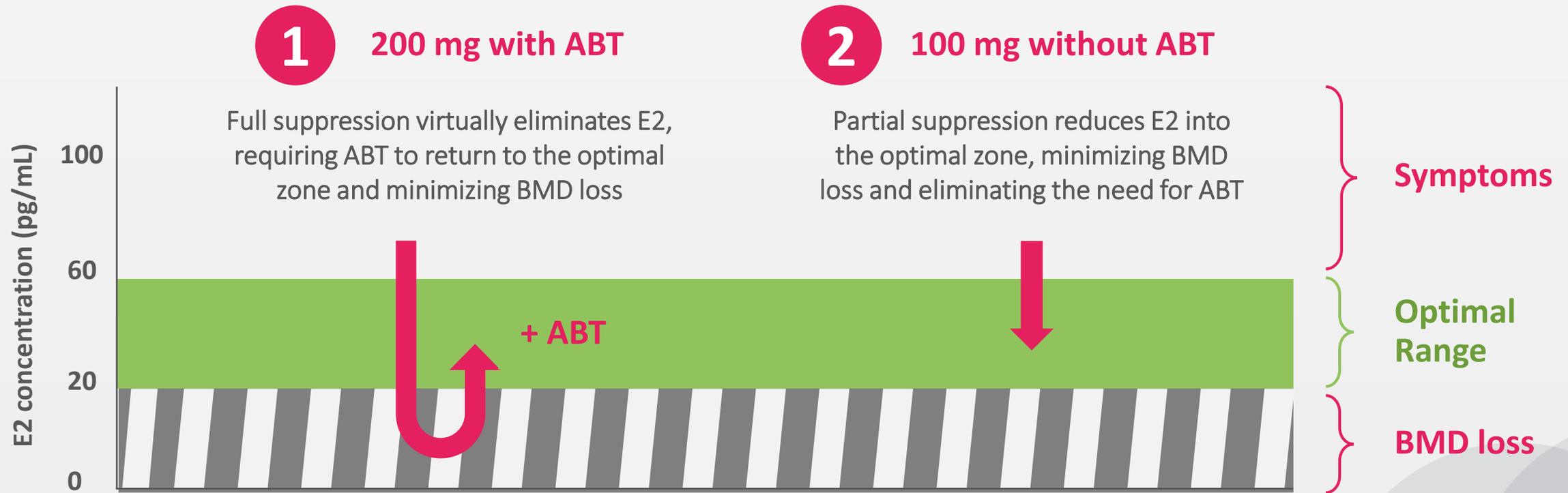
## "No hassle" administration profile

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

# The promise of the GnRH antagonists

## Dose dependent reduction of estradiol (E2)

**Linzagolix** is the only GnRH antagonist being developed to provide differentiated options for women suffering from uterine fibroids



# The only GnRH antagonist designed to treat more women

Because not every woman is the same, one size does not fit all

+/- 50%  
UF patients



Carole, 47 – Desires a long-term medical treatment to transition her to menopause\*

- Black woman, weighing 230 lbs
- Moderate hypertension, not well-controlled
- Worsening heavy bleeding and pain related to UF

100 mg linzagolix  ABT

+/- 50%  
UF patients



Jane, 32 – Strongly wishes to avoid surgery

- Healthy white woman, weighing 120 lbs
- Increasingly heavy bleeding and unpredictable flooding episodes that interfere with quality of life
- Multiple fibroids in the uterine cavity

200 mg linzagolix  ABT

Additional  
indications  
(adenomyosis,  
pre-surgery, ...)



Keisha, 42 – Needs a rapid & substantial reduction in uterine volume

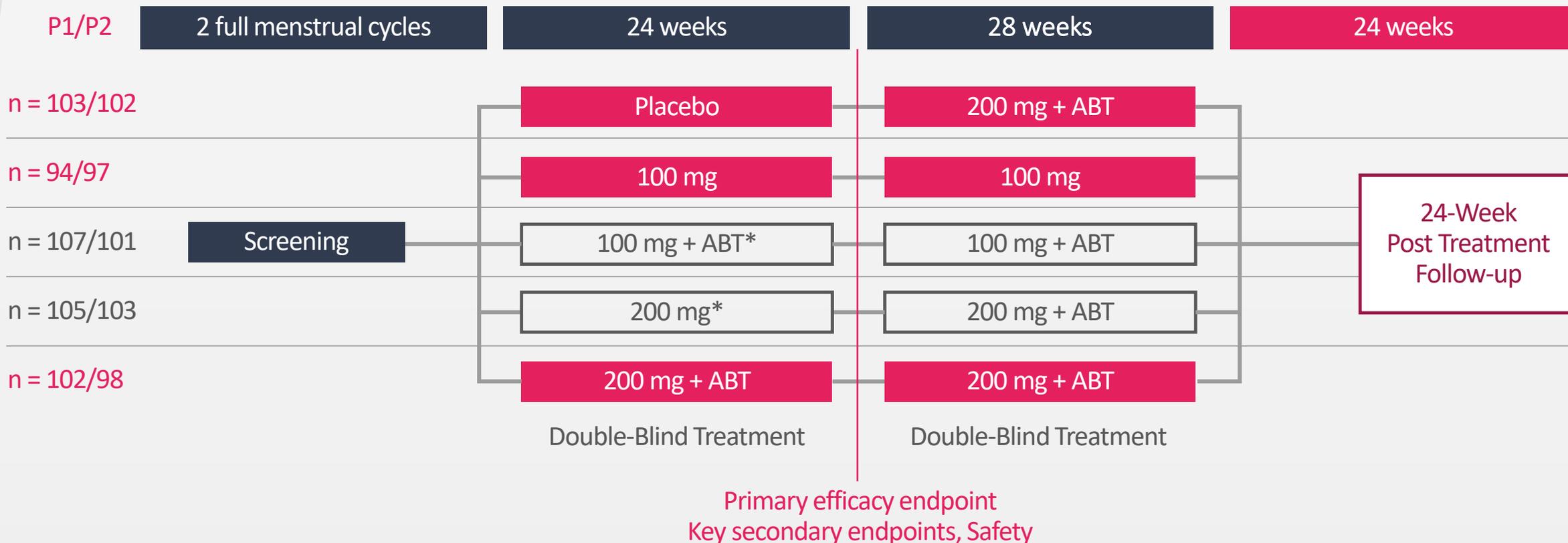
- Black woman with bulky 26-week-sized uterus and MRI suggestive of concomitant adenomyosis
- Increasing pelvic pressure and pain, urinary frequency and urgency, interfering with ability to go to work
- Hb level of 10.2 g/dL

200 mg linzagolix  ABT

For up to 6 months

# Phase 3 registration studies

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



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

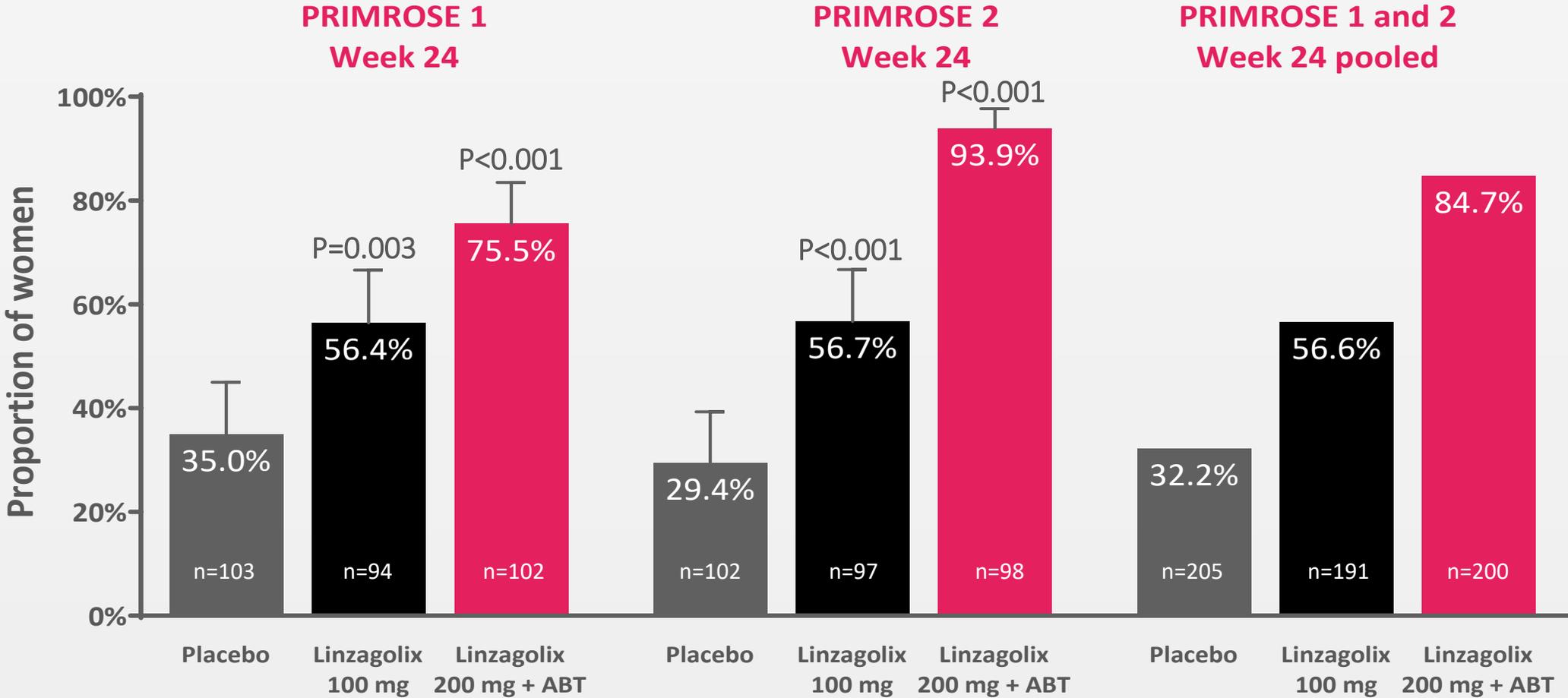
Patients in the studies received no Vitamin D or calcium supplementation

# Demographic and baseline characteristics

Full Analysis Set	PRIMROSE 1 – US study			PRIMROSE 2 – EU/US study		
	Placebo	Linzagolix 100 mg	Linzagolix 200 mg + ABT	Placebo	Linzagolix 100 mg	Linzagolix 200 mg + ABT
	n=103	n=94	n=102	n=102	n=97	n=98
Age (years) - mean (SD)	42.0 (5.7)	41.3 (5.9)	41.8 (5.9)	42.9 (5.3)	43.4 (5.4)	43.1 (4.8)
Proportion of Black women %	63	64	61	5	4	4
BMI (kg/m <sup>2</sup> ) - mean (SD)*	32.2 (6.8)	33.3 (7.4)	33.0 (7.3)	26.8 (5.4)	27.4 (5.7)	26.8 (5.5)
Weight (kg) - mean (SD)**	87.4 (18.9)	90.4 (22.4)	88.6 (20.2)	74.4 (16.0)	75.2 (15.6)	72.7 (15.2)
Hb < 10 g/dL - n (%)	26 (25.2)	31 (33.0)	31 (30.4)	14 (13.7)	21 (21.6)	24 (24.5)
Hb < 12 g/dL - n (%)***	76 (73.8)	68 (72.3)	72 (70.6)	51 (50.0)	61 (62.9)	56 (57.1)
MBL**** (mL) mean (SD)	195 (110)	197 (110)	195 (117)	218 (128)	247 (162)	213 (143)

# PRIMROSE 1 and 2 achieved primary endpoint for both doses

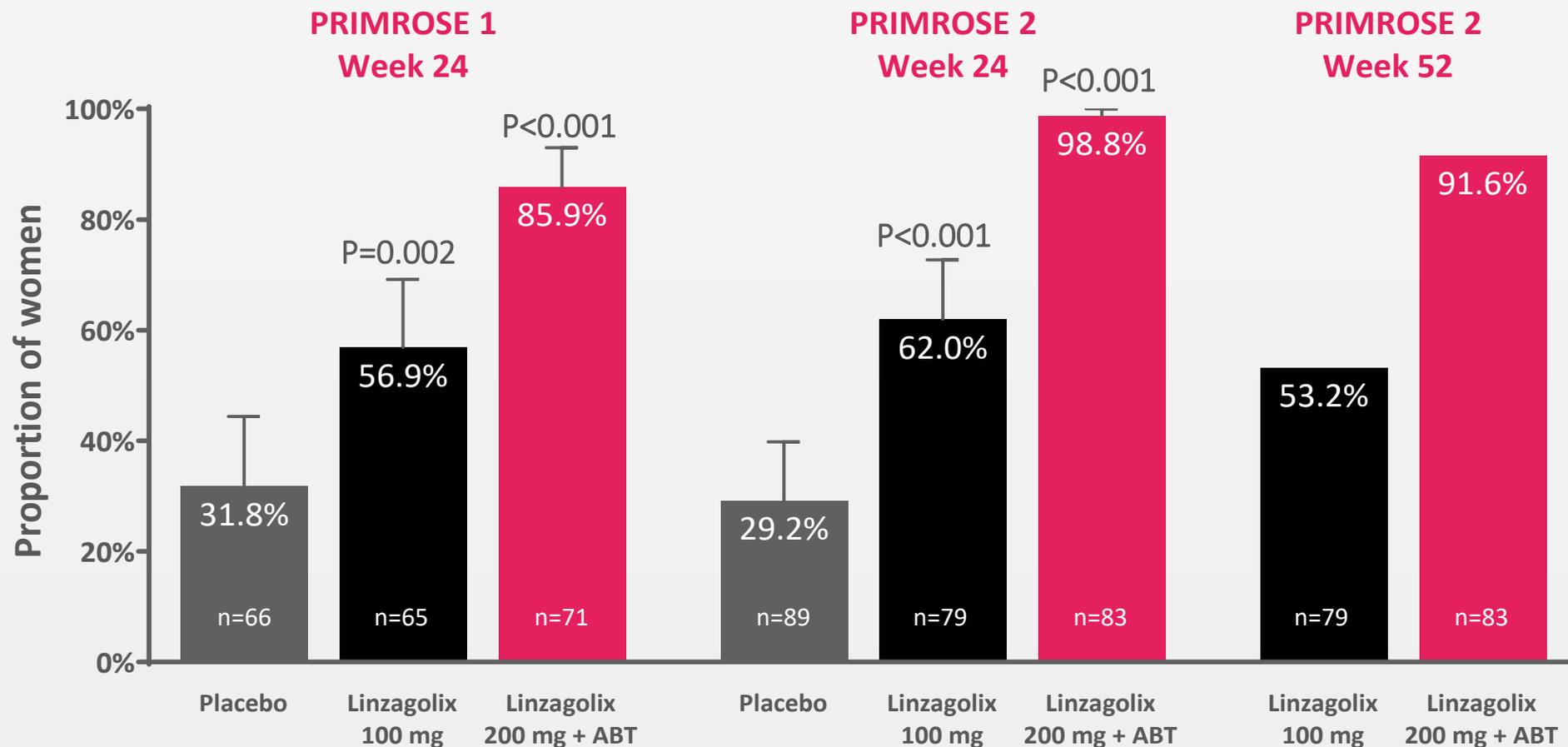
## Responder\* analysis



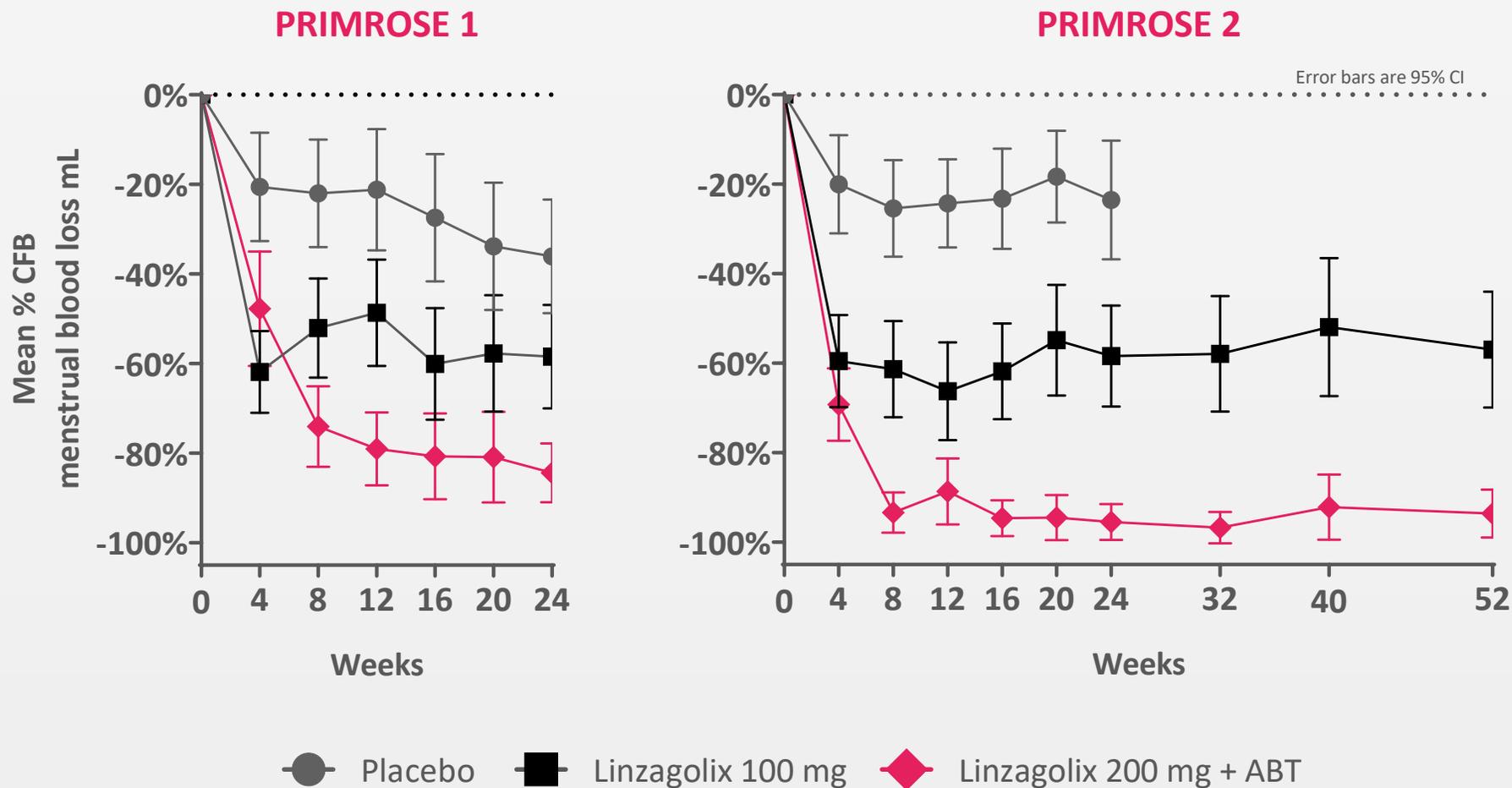
\*Proportion of women with menstrual blood loss ≤ 80 mL (by alkaline hematin method) and ≥ 50% reduction from baseline

Error bars are 95% CI

# Responder\* rate in patients completing treatment at week 24 sustained at week 52

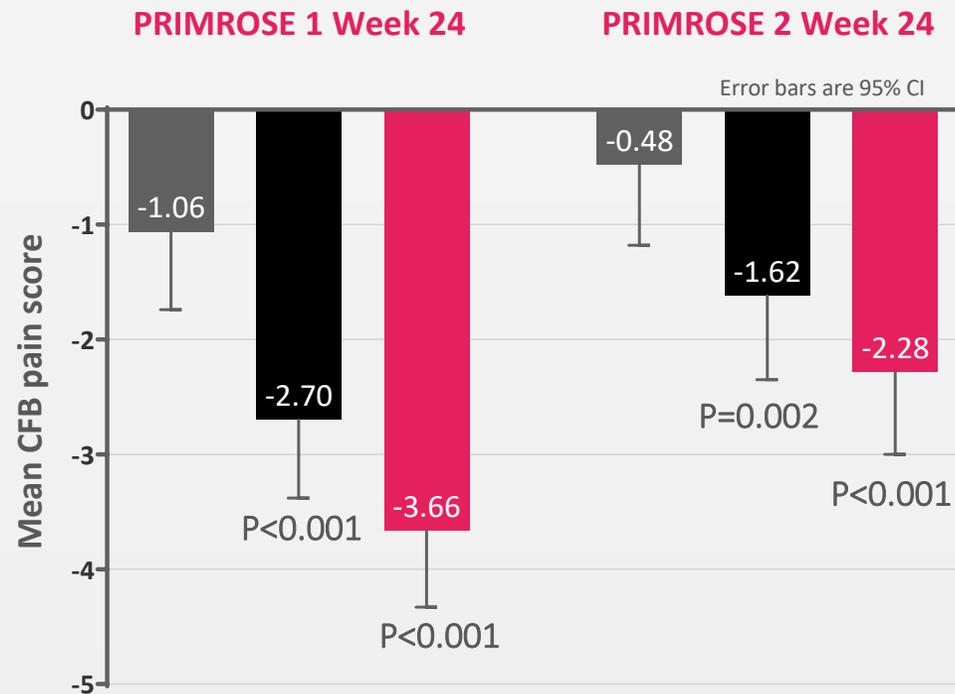


# Rapid onset and significant, sustained reduction in menstrual blood loss

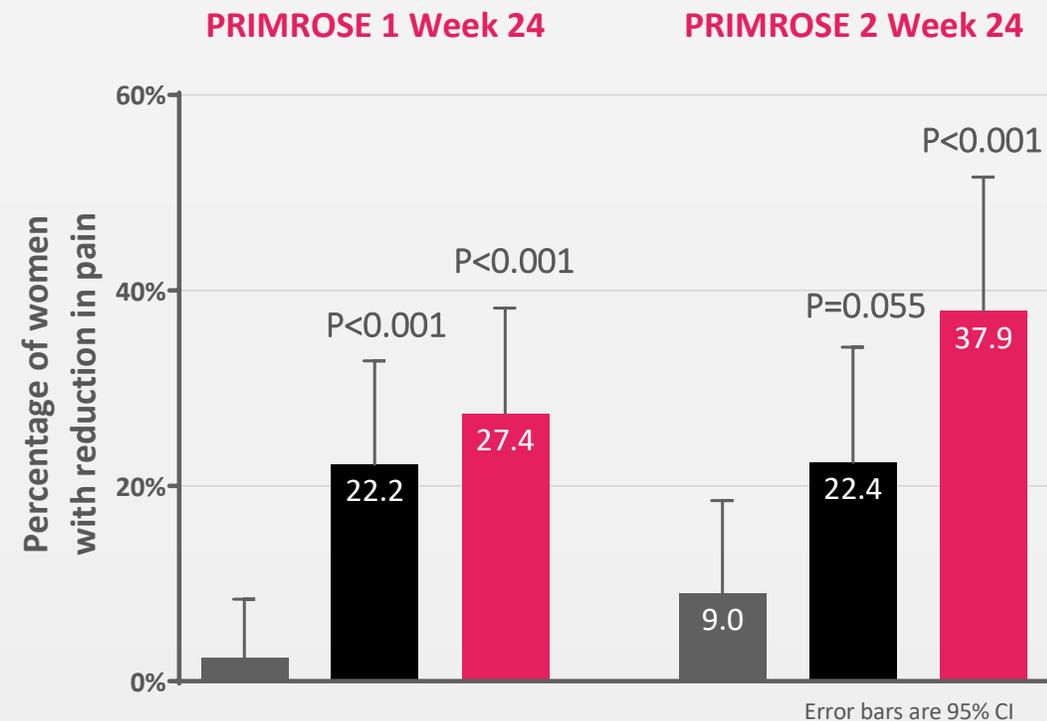


# Significant reduction or elimination of pain with both doses

Mean pain score reduction from baseline



Proportion of patients with a score of 1 or less at Week 24 out of those with a baseline score of at least 4



Placebo Linzagolix 100 mg

Linzagolix 200 mg + ABT

# Ranked and key secondary endpoints

Secondary Endpoints	100 mg		200 mg + ABT	
	P1	P2	P1	P2
<b>Reduction in menstrual blood loss*</b>				
• Time to reduced menstrual blood loss ( $\leq 80$ mL and $\geq 50\%$ reduction from baseline) up to Week 24	p = 0.002	p < 0.001	p < 0.001	p < 0.001
• Number of days of uterine bleeding for the last 28-day interval prior to Week 24	p = 0.001	p < 0.001	p < 0.001	p < 0.001
<b>Amenorrhea*</b>				
• Percentage at Week 24	p = 0.009	p < 0.001	p < 0.001	p < 0.001
• Time to amenorrhea up to Week 24	p = 0.007	p < 0.001	p < 0.001	p < 0.001
<b>Improvement in anemia*</b>				
• Hemoglobin level at week 24 in anemic subjects <sup>+</sup>	p = 0.019	p = 0.002	p < 0.001	p < 0.001
<b>Reduction in pain</b>				
• Change from baseline pain score at week 24	p < 0.001	p = 0.002	p < 0.001	p < 0.001
<b>Reduction in volume</b>				
• Fibroid volume change from baseline at Week 24	p = 0.149	p = 0.055	p = 0.671	p = 0.008
• Uterine volume change from baseline at Week 24	p = 0.014	p = 0.003	p = 0.223	p < 0.001
<b>Improvement in quality of life</b>				
• Change from baseline UFS-QoL <sup>++</sup> symptom severity score (LS mean)	p = 0.002	p = 0.004	p < 0.001	p < 0.001

# 24 week efficacy data support 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

	Linzagolix		
	PRIMROSE 1	PRIMROSE 2	Pooled Analysis
Dose Regimen	200mg + ABT Once daily		
Mean Age (y)	41.6	43.1	
Baseline MBL (mL per cycle)	197	212	
<b>Responder* Rate (RR) (%)</b>	<b>75.5</b>	<b>93.9</b>	<b>84.7</b>
Amenorrhea	✓	✓	
Pain	✓	✓	
Fibroid Volume	✗	✓	
Uterine Volume	✗	✓	
Menstrual Blood Loss	✓	✓	
Anemia	✓	✓	
Quality of Life	✓	✓	

Elagolix		
ELARIS 1	ELARIS 2	Pooled Analysis
300 mg + ABT Twice daily		
42.6	42.5	
238	229	
<b>68.5</b>	<b>76.5</b>	<b>72.2<sup>+</sup></b>
✓	✓	
NR	NR	
NR**	NR**	
NR**	NR**	
✓	✓	
✓	✓	
✓	✓	

Relugolix		
LIBERTY 1	LIBERTY 2	Pooled Analysis
40mg + ABT Once daily		
41.3	42.1	
229	247	
<b>73.4</b>	<b>71.2</b>	<b>72.3<sup>++</sup></b>
✓	✓	
✓	✓	
✗	✗	
✓	✓	
✓	✓	
✓	✓	

# Linzagolix safety profile

Day 1 to week 24

Number (%) of women	PRIMROSE 1			PRIMROSE 2		
	Placebo	Linzagolix 100 mg	Linzagolix 200 mg + ABT	Placebo	Linzagolix 100 mg	Linzagolix 200 mg + ABT
	n=104	n=100	n=107	n=105	n=99	n=101
Subject with at least one TEAE	56 (53.8)	66 (66.0)	61 (57.0)	47 (44.8)	50 (50.5)	52 (51.5)
TEAE leading to discontinuation	10 (9.6)	8 (8.0)	10 (9.3)	7 (6.7)	7 (7.1)	7 (6.9)
SAE related to linzagolix	0	0	0	0	1 (1.0)*	0
Adverse Events occurring in > 5% of women in 100 mg or 200 mg + ABT groups						
Hot flush	7 (6.7)	6 (6.0)	7 (6.5)	4 (3.8)	14 (14.1)	13 (12.9)
Headache	6 (5.8)	8 (8.0)	8 (7.5)	6 (5.7)	4 (4.0)	7 (6.9)
Anemia	4 (3.8)	1 (1.0)	4 (3.7)	11 (10.5)	19 (19.2)	9 (8.9)

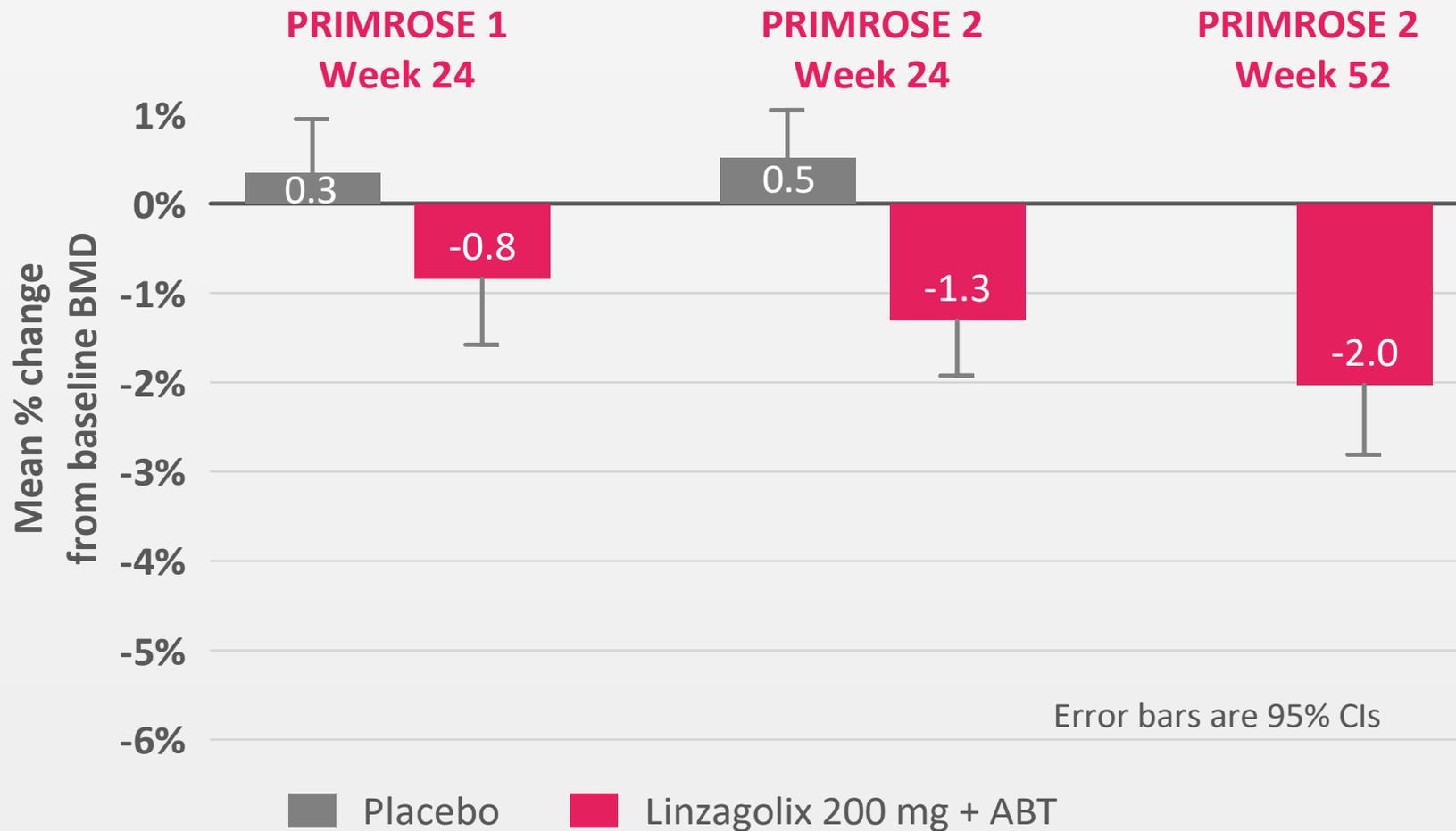
# Low rates of adverse events interest/pregnancy

Day 1 to week 24

Number (%) of women	PRIMROSE 1			PRIMROSE 2		
	Placebo	Linzagolix 100 mg	Linzagolix 200 mg + ABT	Placebo	Linzagolix 100 mg	Linzagolix 200 mg + ABT
	n=104	n=100	n=107	n=105	n=99	n=101
Suicidal ideation	0	0	0	0	0	0
Depression; depressed mood	0	1 (1.0)	0	0	0	1 (1.0)
Anxiety	1 (1.0)	0	0	0	0	2 (2.0)
Alopecia	2 (1.9)	0	2 (1.9)	0	1 (1.0)	0
Decreased libido	0	0	0	0	1 (1.0)	1 (1.0)
Pregnancy	0	0	0	0	0	0

# BMD: changes in lumbar spine at weeks 24 and 52

200 mg with ABT regimen



### BMD Advisory Board Feedback

- The margin of error on any individual DXA scan is in the order of 2-3%
- 2% of bone loss is marginal
- Treatment with glucocorticoids can cause patients to lose 5-15% of bone in the first year of use

Error bars are 95% CIs

■ Placebo   ■ Linzagolix 200 mg + ABT

Patients in the trial received no vitamin D or calcium supplementation

# BMD safety is at similar levels between all 3 GnRH antagonists

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

	Linzagolix		Elagolix		Relugolix	
	PRIMROSE 1 US	PRIMROSE 2 EU/US	ELARIS 1 US	ELARIS 2 US	LIBERTY 1 US/RoW	LIBERTY 2 US/RoW
	200 mg QD + ABT		300 mg BID + ABT		40 mg QD + ABT	
Black women %	61	4	67		48	
BMI, mean (kg/m <sup>2</sup> )	33.0	26.8	33.4	33.2	31.4	31.0
<b>BMD mean CBL Spine (%) @W24</b>	-0.84	-1.31	-0.76 <sup>+</sup>	-0.61 <sup>+</sup>	-0.36 <sup>++</sup>	-0.13 <sup>++</sup>
Patients (%) with BMD loss >3%	23.3	29.1	20	20	<23 <sup>*</sup>	<23 <sup>*</sup>
Patients (%) with BMD loss >8%	1.8 <sup>**</sup>	0	0	0	0	0
<b>BMD mean CBL Spine (%) @W52</b>	NA	-2.03	-1.5 <sup>+</sup>		ND	
Patients (%) with BMD loss >3%	NA	28.3	27.0		ND	
Patients (%) with BMD loss >8%	NA	1.7	1.7		ND	

# Linzagolix 100 mg – no ABT

Two key topics for discussion

## ABT

1

### ABT, a real issue/ opportunity

- Elagolix UF label was harsher than expected for ABT
- Up to 50% of US women may have a contraindication; Black/Hispanic women are disproportionately exposed to the serious potential risks of ABT
- Labeling has also created a liability issue for HCPs

## BMD

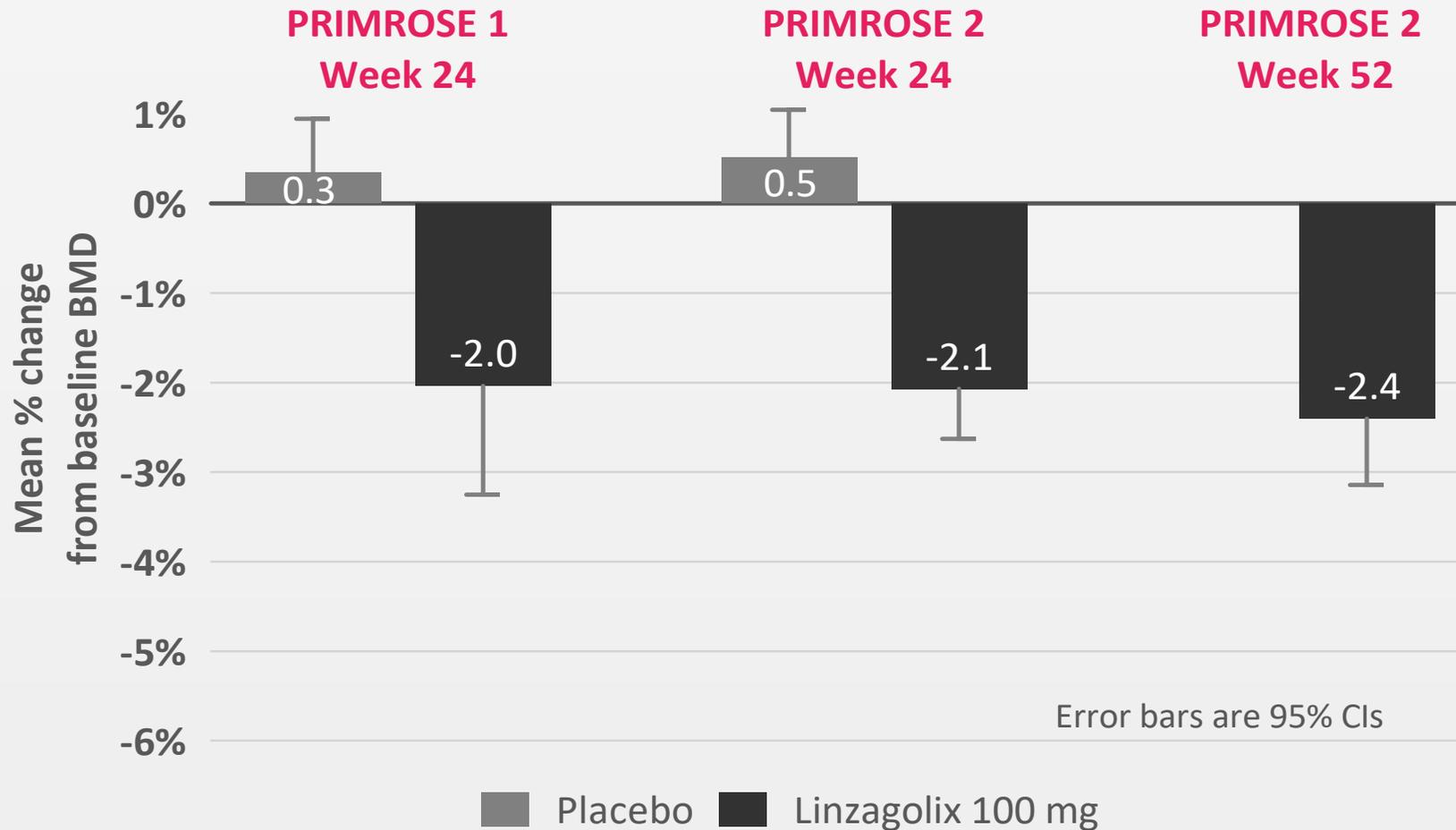
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### Minimal expected regulatory risk for 100mg dose

- BMD loss for 100 mg without ABT is minor and not considered an approval risk
- Based on historical benchmarks anticipated treatment duration limitation will be  $\geq 18$  months at the worst

# Changes in lumbar spine BMD at weeks 24 and 52

100 mg without ABT regimen



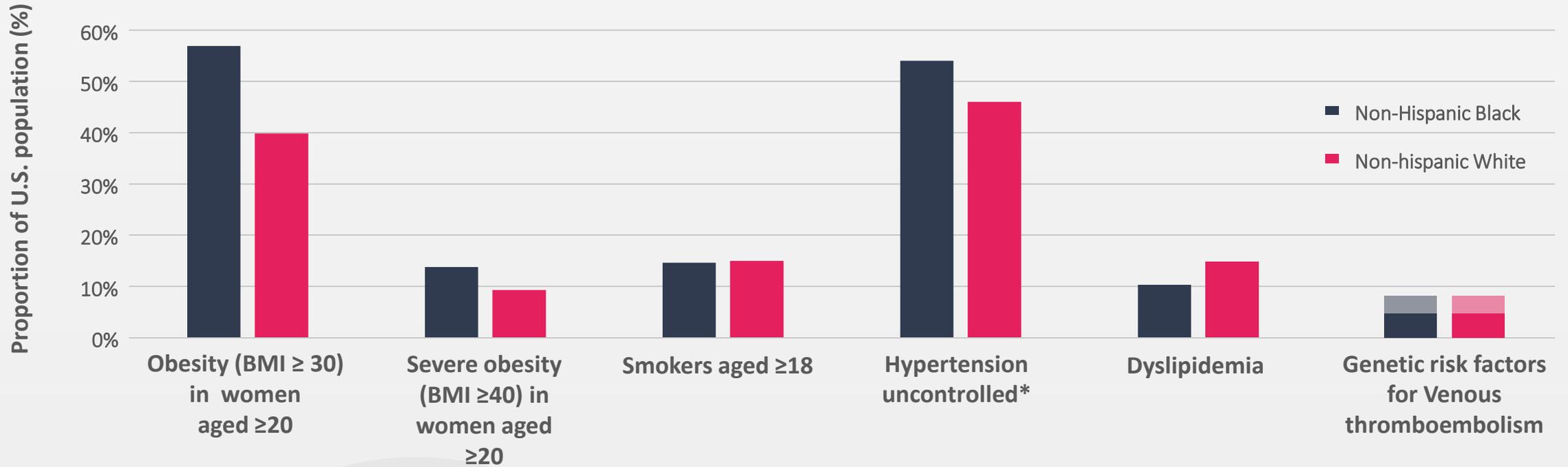
## BMD Advisory Board Feedback

- The margin of error on any individual DXA scan is in the order of 2-3%
- 2% of bone loss is marginal
- Treatment with glucocorticoids can cause patients to lose 5-15% of bone in the first year of use

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

Minorities are overrepresented

Proportion of U.S. population

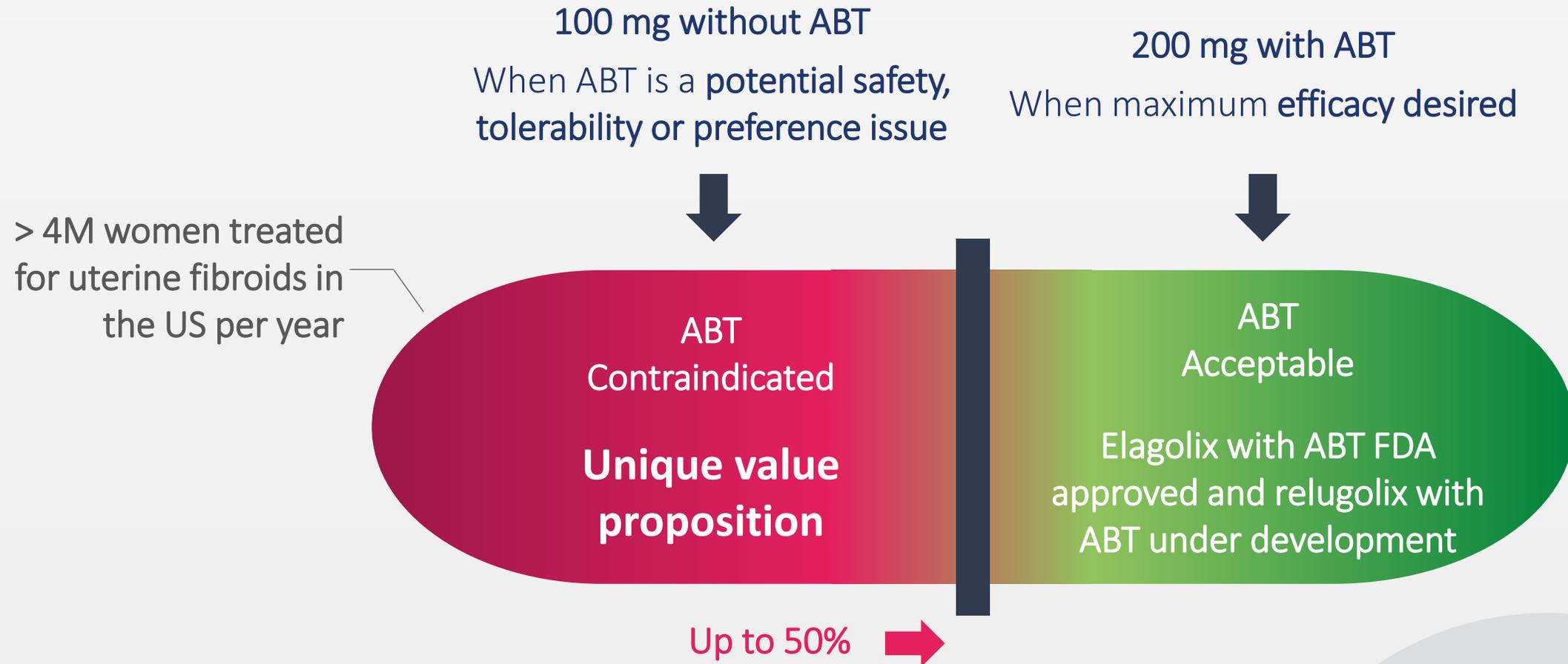


<https://www.cdc.gov/nchs/products/databriefs/db360.htm>: 2017-2018; <https://www.cdc.gov/nchs/products/databriefs/db360.htm>: 2017-2018; [https://www.cdc.gov/tobacco/data\\_statistics/fact\\_sheets/adult\\_data/cig\\_smoking/index.htm#nation](https://www.cdc.gov/tobacco/data_statistics/fact_sheets/adult_data/cig_smoking/index.htm#nation); <https://www.cdc.gov/2018>

\* Proportion of individuals with hypertension - Overall population Male vs Female: 47% vs 43%

# Yselty<sup>®</sup> designed to treat more women

Only non-ABT dosing option under development for treating uterine fibroids  
Potential best in class ABT containing regimen



# Elagolix (OriaHnn) US prescribing information

Contraindications, precautions and warnings – issued May 29, 2020 -

## HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use ORIAHNN safely and effectively. See full prescribing information for ORIAHNN.

ORIAHNN (elagolix, estradiol, and norethindrone acetate capsules; elagolix capsules), co-packaged for oral use  
Initial U.S. Approval: 2020

### WARNING: THROMBOEMBOLIC DISORDERS AND VASCULAR EVENTS

*See full prescribing information for complete boxed warning.*

- Estrogen and progestin combinations, including ORIAHNN, increase the risk of thrombotic or thromboembolic disorders, especially in women at increased risk for these events. (5.1)
- ORIAHNN is contraindicated in women with current or a history of thrombotic or thromboembolic disorders and in women at increased risk for these events including women over 35 years of age who smoke or women with uncontrolled hypertension. (4)

## 5 WARNINGS AND PRECAUTIONS

### 5.1 Thromboembolic Disorders and Vascular Events

ORIAHNN is contraindicated in women with current or history of thrombotic or thromboembolic disorders and in women at increased risk for these events [see *Contraindications (4)*]. In the Phase 3 clinical trials (Studies UF-1, UF-2, and UF-3), two thrombotic events occurred in 453 ORIAHNN-treated women (thrombosis in the calf and

pulmonary embolism) [see *Adverse Reactions (6.1) and Clinical Studies (14)*]. Estrogen and progestin combinations, including the estradiol/norethindrone acetate component of ORIAHNN, increase the risk of thrombotic or thromboembolic disorders, including pulmonary embolism, deep vein thrombosis, stroke, and myocardial infarction, especially in women at high risk for these events. In general, the risk is greatest among women over 35 years of age who smoke, and women with uncontrolled hypertension, dyslipidemia, vascular disease, or obesity.

The elagolix label in UF clearly highlights the liability of prescribing ABT in a significant portion of US women  
Ignoring or down-playing this warning for commercial or other purposes is unethical & legally risky

# Black and hispanic US women with UF are at highest risk

ABT

1

## Black women

- More prone to uterine fibroids, and present at an earlier age with more severe disease
- More frequently have risk factors for thromboembolic disease, hence more likely to be contraindicated for ABT<sup>1</sup>

2

## Hispanic women

- More frequently have risk factors for thromboembolic disease, hence more likely to be contraindicated for ABT<sup>2</sup>

Full suppression GnRH antagonist regimens with ABT are contraindicated for many of these women



## Long-term hormone therapy for perimenopausal and postmenopausal women (Review)

Marjoribanks J, Farquhar C, Roberts H, Lethaby A, Lee J , 2017

Women with intolerable menopausal symptoms may wish to weigh the benefits of symptom relief against the small absolute risk of harm arising from short-term use of low-dose HT, provided they do not have specific contraindications. HT may be unsuitable for some women, including those at increased risk of cardiovascular disease, increased risk of thromboembolic disease (such as those with obesity or a history of venous thrombosis) or increased risk of some types of cancer (such as breast cancer, in women with a uterus). The risk of endometrial cancer for women with a uterus who take oestrogen-only HT is well documented.

### Main results

We included 22 studies involving 43,637 women. We derived nearly 70% of the data from two well-conducted studies (HERS 1998; WHI 1998). Most participants were postmenopausal American women with at least some degree of comorbidity, and mean participant age in most studies was over 60 years. None of the studies focused on perimenopausal women.

## SUMMARY OF FINDINGS FOR THE MAIN COMPARISON *[Explanation]*

Combined continuous hormone therapy (HT) compared with placebo for perimenopausal and postmenopausal women

Population: relatively healthy postmenopausal women

Setting: community

Intervention: combined continuous HT (moderate-dose oestrogen) - CEE 0.625 mg + MPA 2.5 mg

Comparison: placebo

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No. of participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk*	Corresponding risk				
	Placebo	Combined continuous hormone therapy (HT)				
Coronary events (MI or cardiac death) Follow-up: mean/median 1 year	2 per 1000	4 per 1000 (3 to 7)	RR 1.89 (1.15 to 3.10)	20,993 (2 studies)	⊕⊕⊕○ Moderate <sup>a</sup>	
Stroke Follow-up: mean 3 years	6 per 1000	8 per 1000 (6 to 12)	RR 1.46 (1.02 to 2.09)	17,585 (2 studies)	⊕⊕⊕○ Moderate <sup>a</sup>	
Venous thromboembolism (DVT or PE) Follow-up: mean/median 1 year	2 per 1000	7 per 1000 (4 to 11)	RR 4.28 (2.49 to 7.34)	20,993 (2 studies)	⊕⊕⊕○ Moderate <sup>a</sup>	
Breast cancer Follow-up: median 5.6 years	19 per 1000	24 per 1000 (20 to 30)	RR 1.27 (1.03 to 1.56)	16,608 (1 study)	⊕⊕⊕○ Moderate <sup>a</sup>	

# CDC statistics on venous thromboembolism

1

## DVT/PE

- Precise number unknown, but as many as 900,000 people (1-2/1,000) could be affected each year in the US
- 5-8% of US population has genetic risk factors or ‘inherited thrombophilias’

2

## DVT/PE mortality

- 60-100,000 Americans die of DVT/PE per year  
10-30% die within 1 month of diagnosis
- Sudden death is the first symptom in 25% of people with a PE

3

## Long term complications

35-50% of people experiencing a DVT with have long term complications such as swelling, discoloration, pain and scaling in the affected limb

4

## Recurrence

1 out of 3 with a DVT/PE will have a recurrence within 10 years

# Why non-ABT options matter

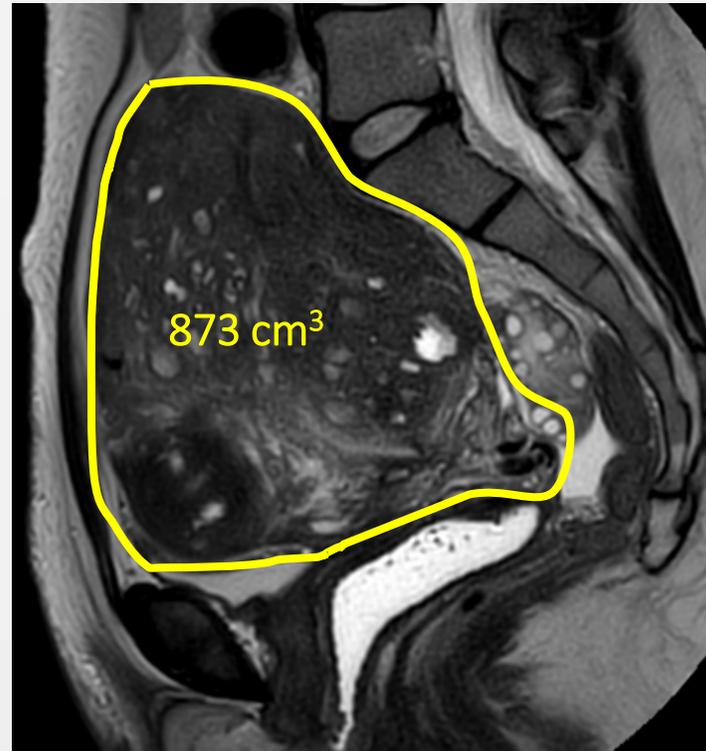
When uterus volume reduction is a priority, high dose GnRH antagonist without ABT is a relevant strategy

A potential therapeutic strategy for treating adenomyosis could be to initiate a patient on a full suppression dose (200 mg) without ABT to quickly reduce uterine volume

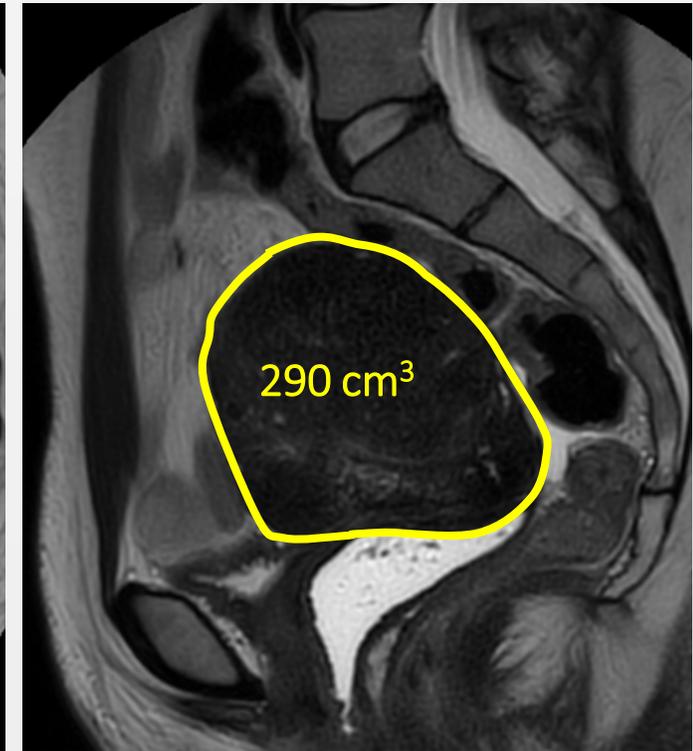
30%+

of women of reproductive age are affected by adenomyosis often co-existing with endometriosis or uterine fibroids

Magnetic resonance images showing an enlarged uterus with diffuse and disseminated adenomyosis in a 39 year old women



After more than 1 year without therapy, a very large uterus is seen, with multiple images typical of severe full-thickness adenomyosis



After 12 weeks of GnRH antagonist therapy (daily dose of 200 mg linzagolix), a significant reduction is observed

# Designed to treat more women

Excellent clinical data driving differentiated profile

Statistically significant & clinically meaningful



Primary and key secondary endpoints met in PRIMROSE 1 & 2

Durability of response



Sustained efficacy and continued safety at week 52 for PRIMROSE 2

Differentiated options for more women



Unique profile offers convenient, once daily dosing, with or without Add Back Therapy (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\*\*

# Next steps in uterine fibroids



**Yselty<sup>®</sup>** is the **only** GnRH antagonist being developed to provide **differentiated options for women** suffering from uterine fibroids

1

## Primrose 1

52 week results  
expected 4Q:20

2

## MAA regulatory submission

anticipated in  
4Q:20

3

## NDA regulatory submission

anticipated in  
1H:21

4

## Commercial partnerships

ongoing discussions

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## Designed to treat more women

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**Obseva**  
nature meets nurture



## EDELWEISS Phase 2b & Phase 3

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**DESIGNED TO TREAT MORE  
WOMEN SUFFERING FROM  
ENDOMETRIOSIS**

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.



# Endometriosis

An emotionally and physically painful condition

**\$22B**/yr

total U.S. 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

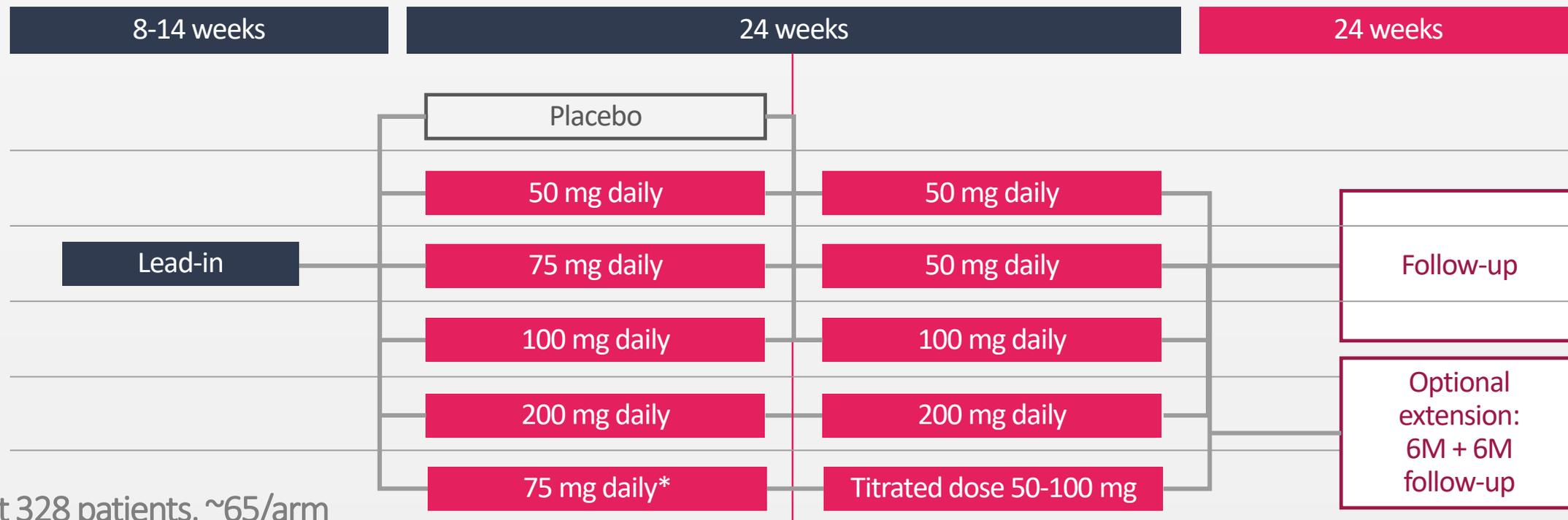
**60**%+ in patients with  
chronic pelvic pain

**5** million

women in the U.S.  
are treated annually  
for endometriosis



# Phase 2b EDELWEISS in endometriosis



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

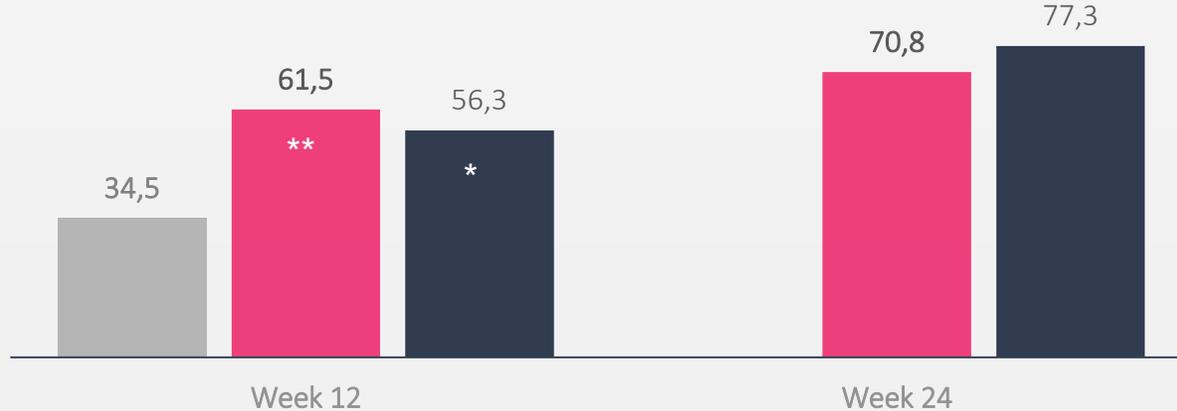
Primary efficacy endpoint: VRS PAIN SCORE RESPONDER RATE  
Secondary endpoint: BMD\*\*

# Phase 2b EDELWEISS in endometriosis

## Overall Pelvic Pain (%)

### Responder (0-3 VRS)

■ Plc ■ 75mg ■ 200mg

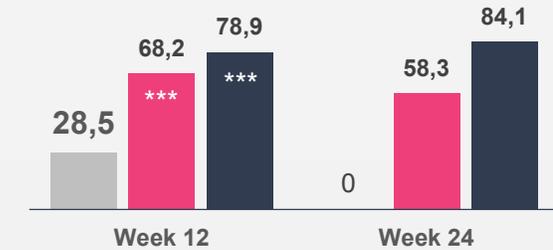


Potential point of differentiation as 75mg partial suppression dose is nearly as effective as 200mg full suppression dose

## Dysmenorrhea (%)

### Responder (0-3 VRS)

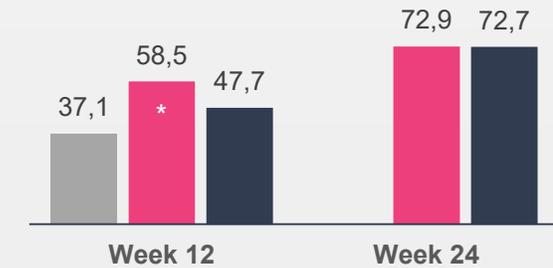
■ Plc ■ 75mg ■ 200mg



## Non-menstrual Pelvic Pain (%)

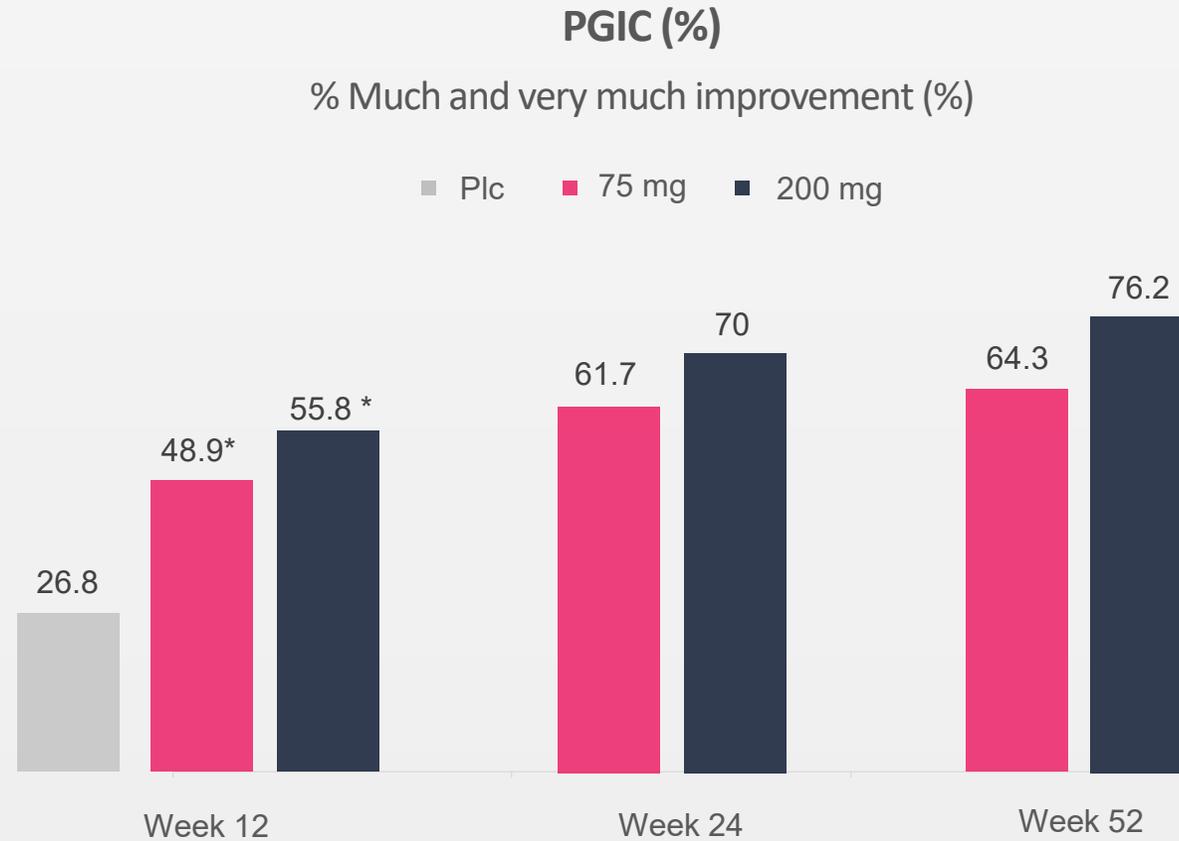
### Responder (0-3 VRS)

■ Plc ■ 75mg ■ 200mg



# Phase 2b EDELWEISS in endometriosis

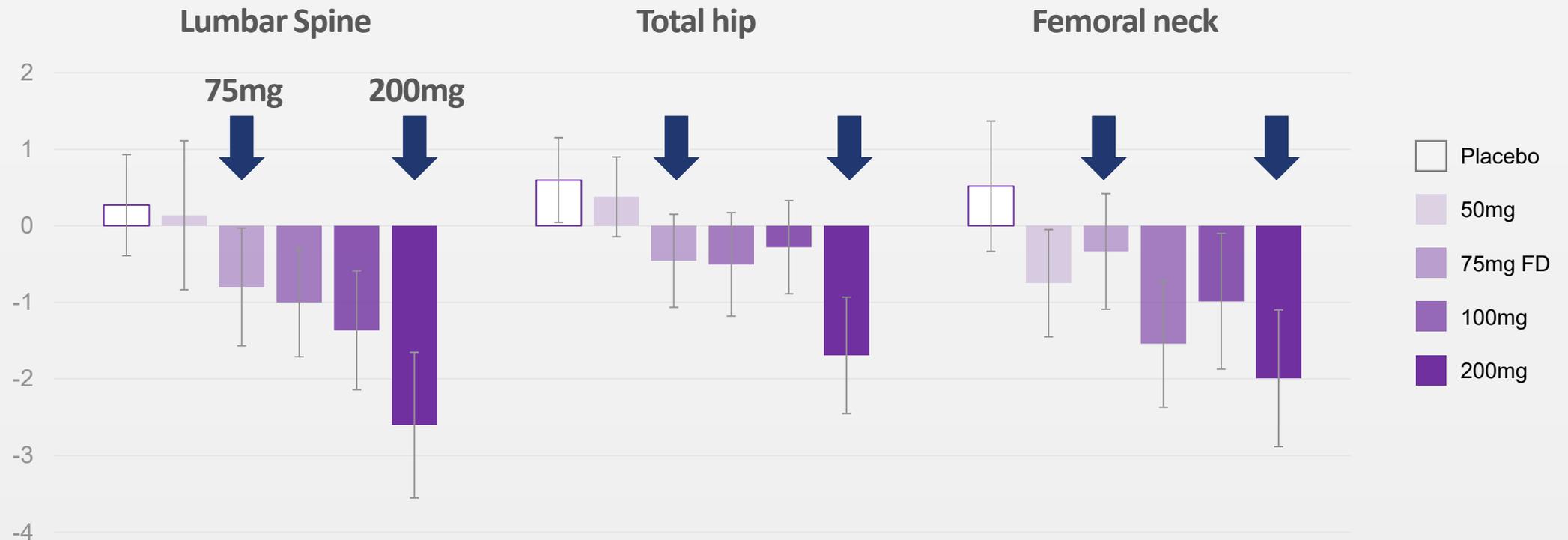
## Sustained improvement in overall endometriosis symptoms (PGIC)



# Phase 2b EDELWEISS in endometriosis

## 75 mg effective without significantly affecting BMD

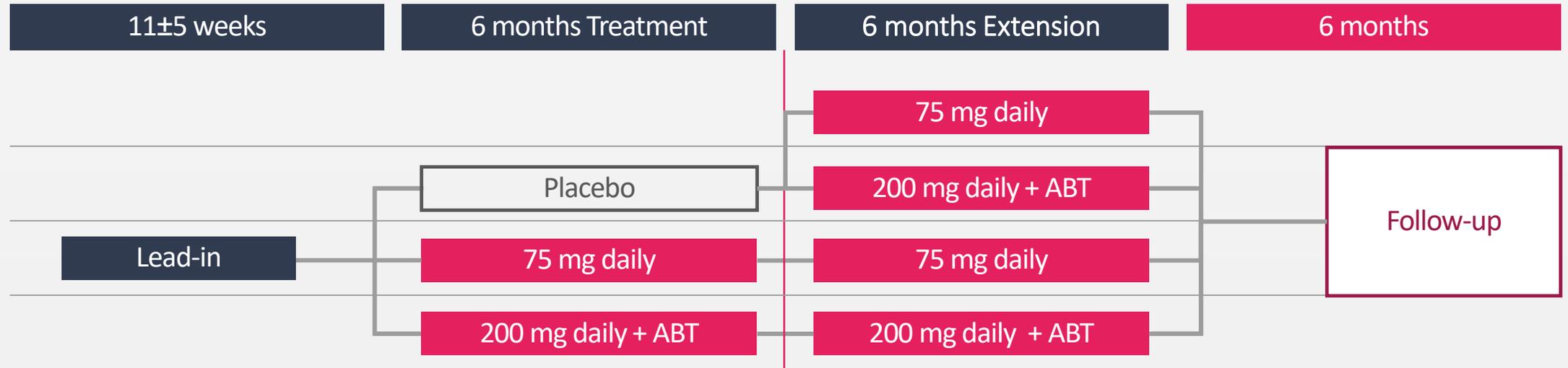
Mean % change in BMD from baseline to 24 weeks (12 weeks for placebo)



Error bars are 95% CIs

# Phase 3 endometriosis trials

## EDELWEISS 2 and 3



Co-Primary efficacy endpoint: DYS/NMPP Responder Analysis

Initiated 1H:19

## OBE-022

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**POTENTIAL TO DELAY  
PRETERM BIRTH TO  
IMPROVE NEWBORN  
HEALTH AND REDUCE  
MEDICAL COSTS**



# Preterm delivery

Life altering and costly

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

U.S. economic burden

**>1**

In 10 babies are born preterm

**1** million

preterm related deaths in 2015 in the U.S.

## LEADING

cause of death in children under age 5

Preterm birth, a costly burden per baby

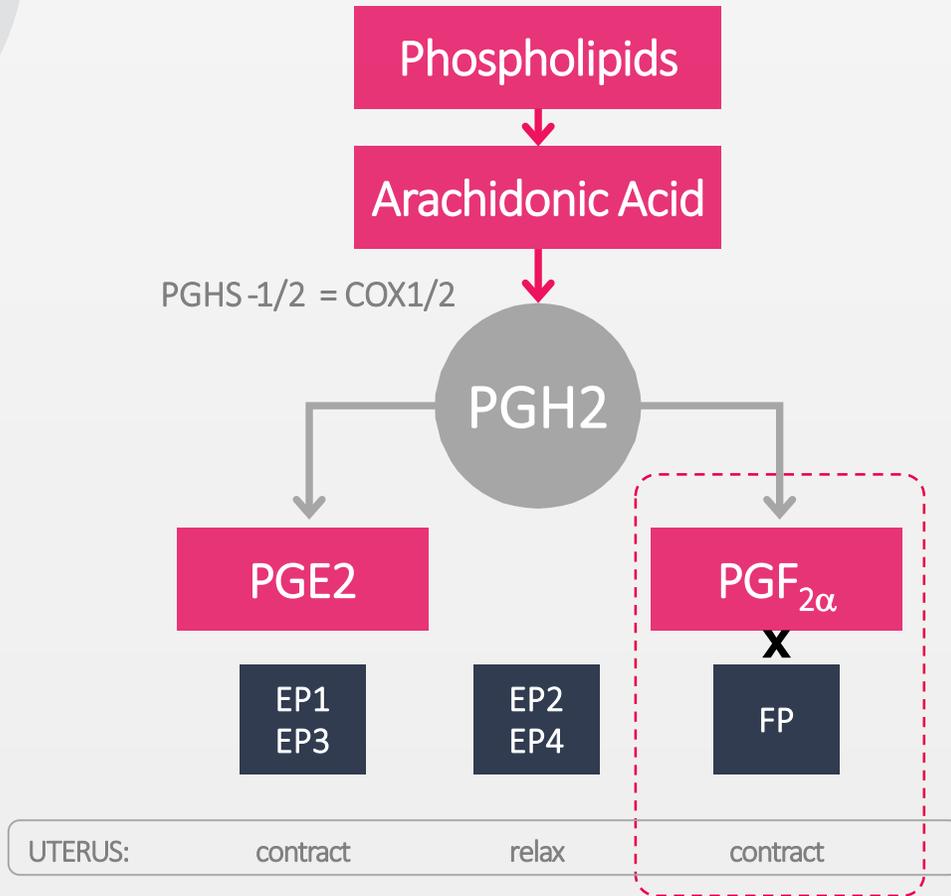
**\$16.9**<sub>B+</sub> U.S. infant medical costs

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

**\$50**<sub>K</sub> average U.S. cost for a preterm infant



# Mode of action of PGF<sub>2</sub> alpha receptor antagonist to control preterm labor



OBE-022

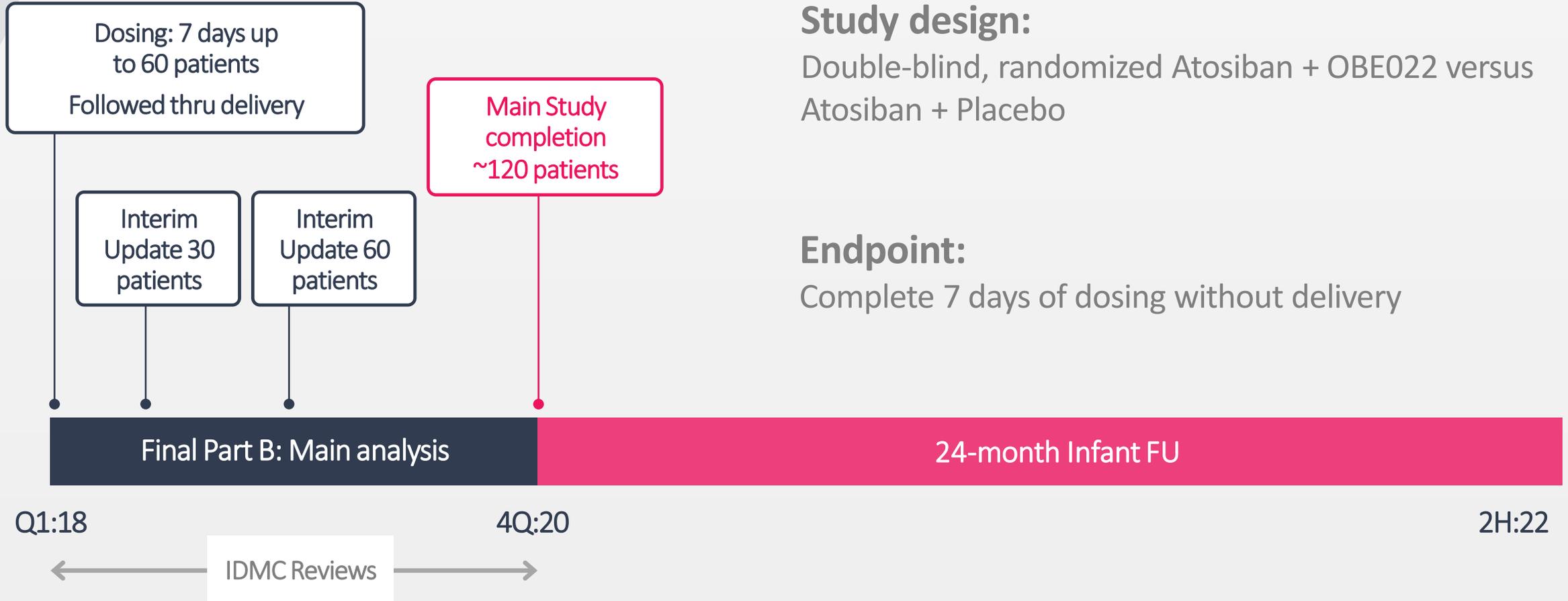
Selectively blocks the PGF<sub>2α</sub> receptor



Has the potential to treat preterm labor with improved safety over NSAIDs

# OBE-022 Phase 2a study part B

## PROLONG



### Study design:

Double-blind, randomized Atosiban + OBE022 versus Atosiban + Placebo

### Endpoint:

Complete 7 days of dosing without delivery



# Financials & Milestones

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**FOCUSED ON UNMET  
NEEDS IN WOMEN'S  
REPRODUCTIVE HEALTH**



# Financial outlook to achieve milestones and drive programs

June 30, 2020 cash  
**\$45 million**

Expected cash runway  
**Q1:21 excluding  
credit facility**

First commercial launch  
**Yselty EU Q1:22**

1

## **Linzagolix**

- Completion of PRIMROSE 1 and 2
- EU/US Uterine Fibroid regulatory filings
- Preparing commercialization through partnership(s)
- EDELWEISS 2 and 3 continuation

2

## **OBE-022**

- PROLONG readout
- Phase 2b initiation

3

## **Nolasiban**

- Phase 1 trial results in China
- Phase 2 initiation in China
- Reassess EU/U.S. development

# Thank you

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