# Obseva nature meets nurture

Focused on unmet needs in women's reproductive health

August 2021



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### Investor highlights

- 1 Pursuing large indications for conditions that compromise women's reproductive health and beyond
- Linzagolix has potential best in class efficacy, favorable tolerability, and unique flexible dosing options
- Global licensing agreement with Organon to develop and commercialize ebopiprant, the only known product in development for preterm labor
- Business model built on strong global partnerships and collaborations
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#### **Product overview**



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

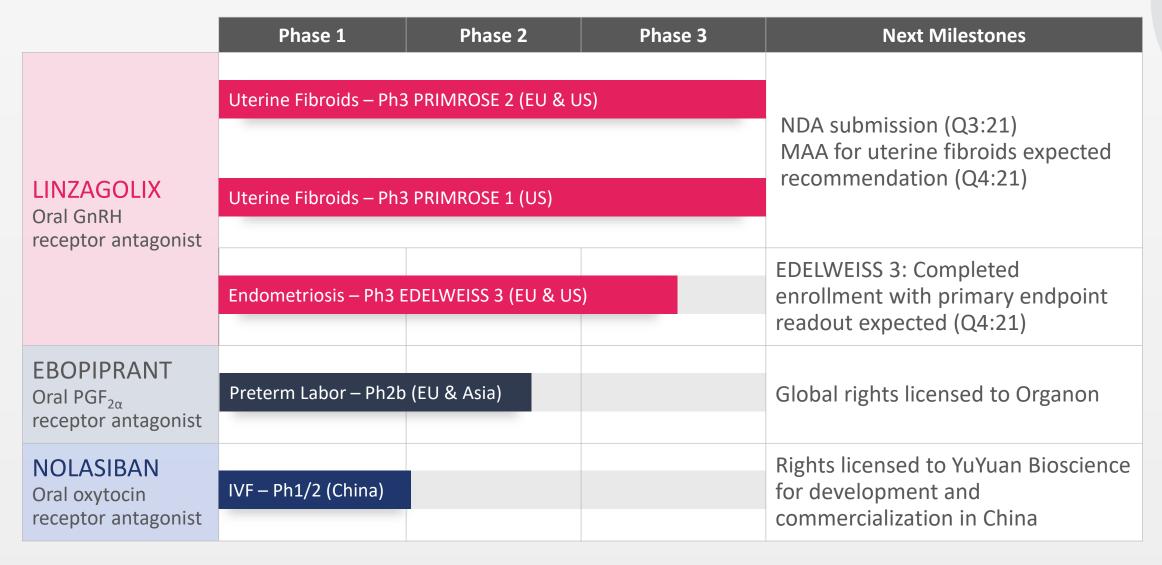
Potential to delay preterm birth to improve newborn health and reduce medical costs<sup>1</sup>

Potential to improve live birth rate following IVF & embryo transfer



<sup>&</sup>lt;sup>1</sup>The global development, manufacturing and commercial rights of ebopiprant is licensed to Organon

#### Multiple development programs drive value









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

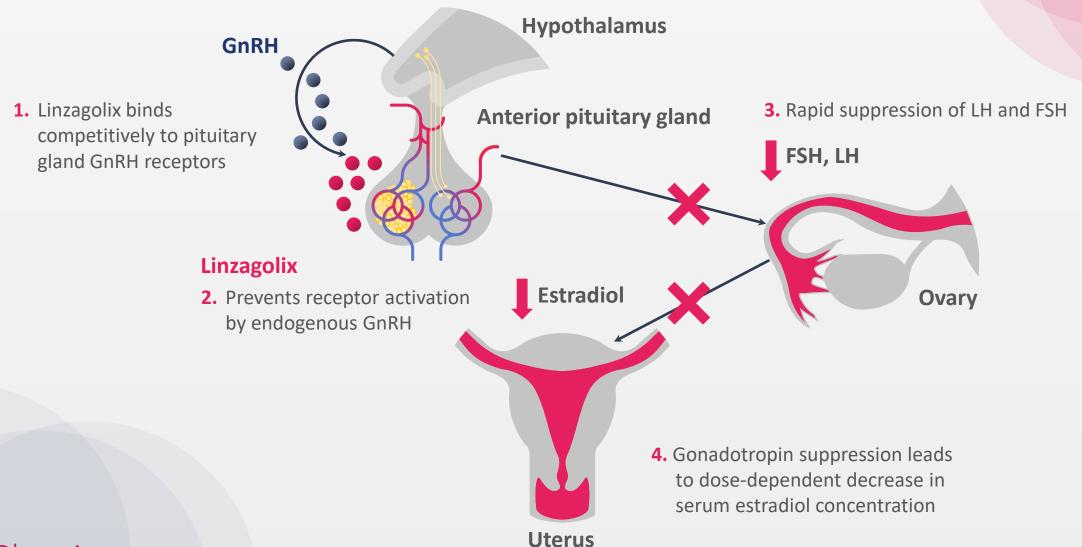
300,000

are because of uterine fibroids

>4 million
women in the US
are treated annually
for fibroids



#### GnRH antagonist mechanism of action





#### A potential new gold standard treatment for uterine fibroids

#### Differentiated PK/PD profile







#### **Reliable absorption**

Predictable exposure/effect with each dose

## 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

## "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



#### 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 flushes

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



#### Uterine fibroids are ruining lives...

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



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



Linzagolix 200 mg once daily with concomitant ABT



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



Linzagolix 100 mg once daily without ABT



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

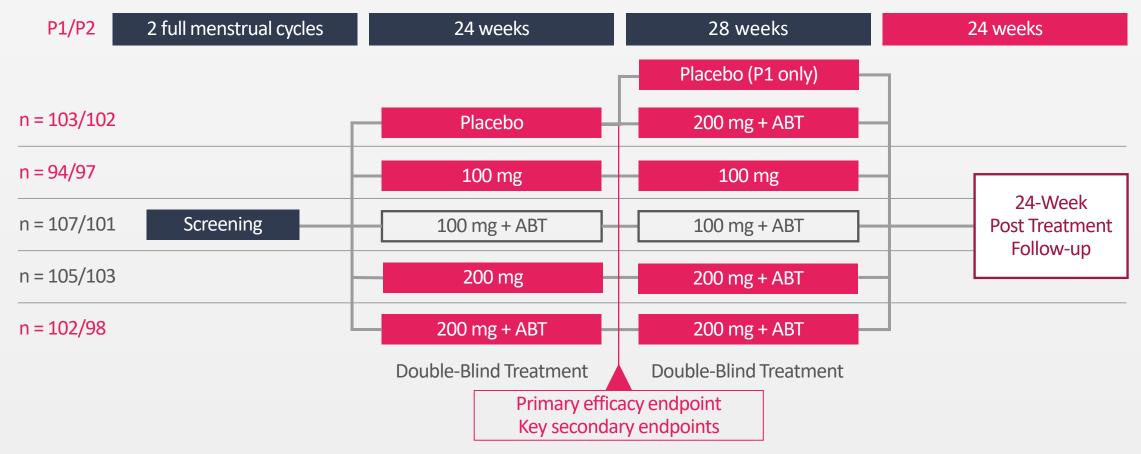


Linzagolix 200 mg once daily without ABT

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\*\*

#### Phase 3 registration studies

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



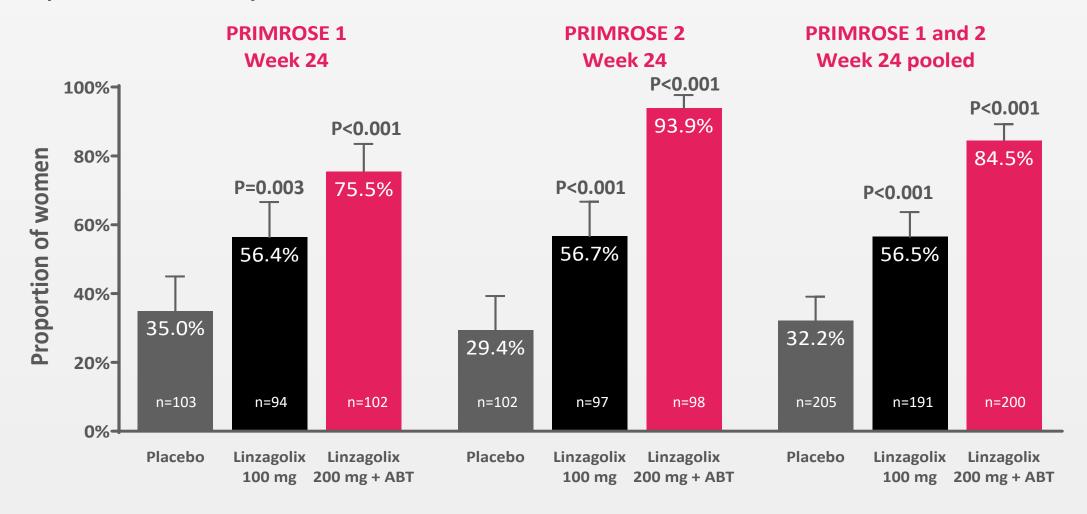
Primary efficacy endpoint: proportion of women with menstrual blood loss ≤ 80 mL (by alkaline hematin method) and ≥ 50% reduction from baseline

Patients in the studies received no Vitamin D or calcium supplementation



### PRIMROSE 1 and 2 achieved primary endpoint for both doses

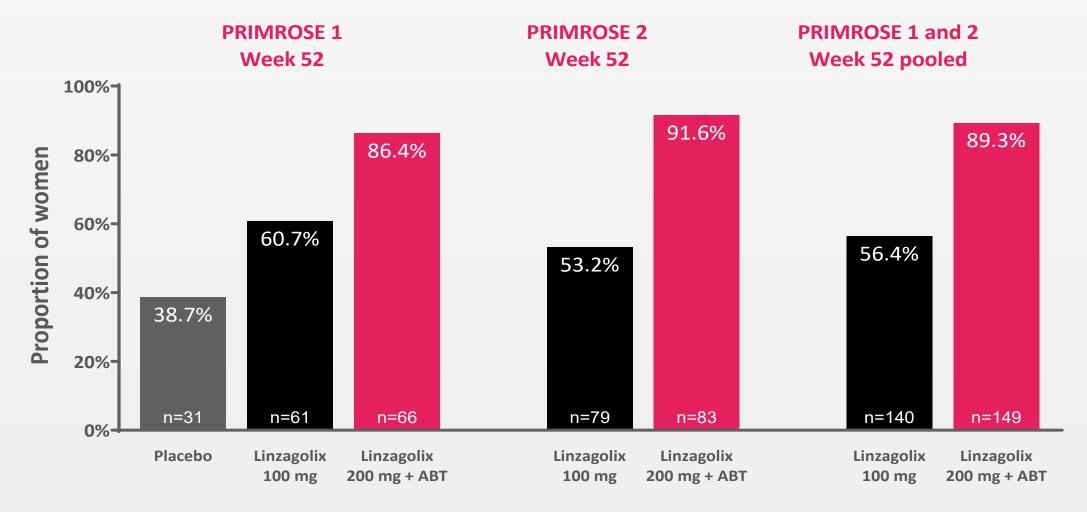
Responder\* analysis at week 24





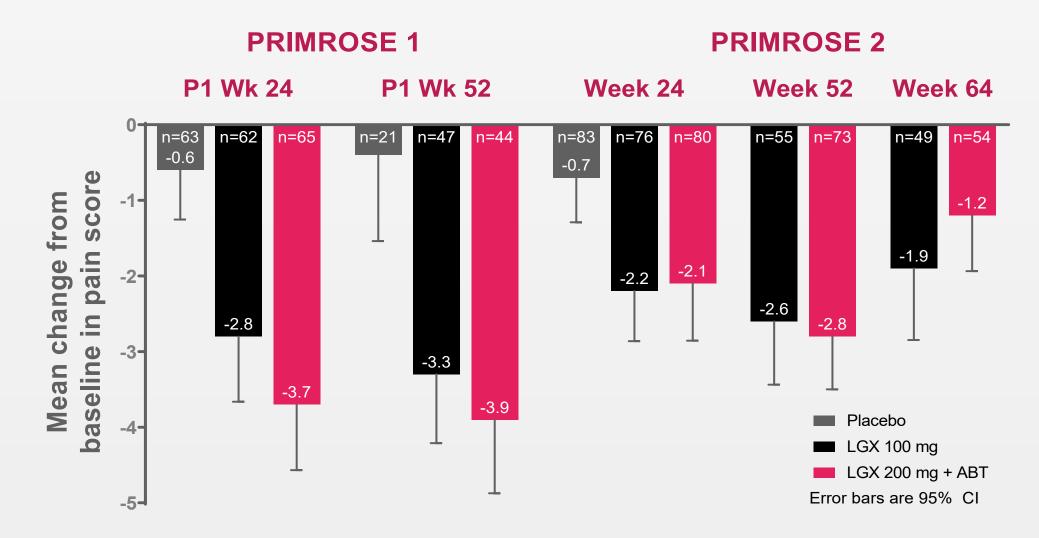
#### PRIMROSE 1 and 2 achieved sustained reduction in MBL

Responder\* analysis at week 52





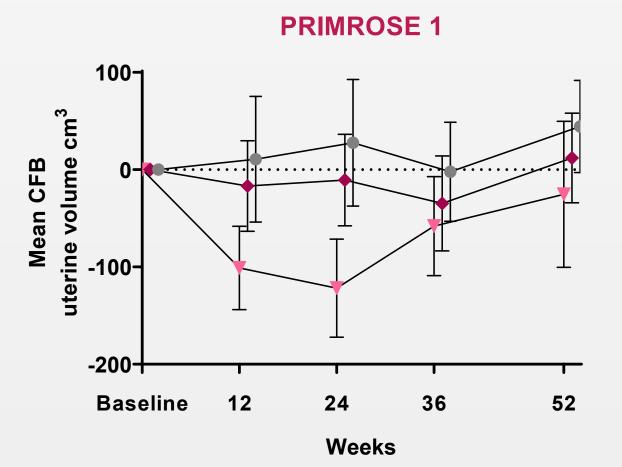
### Significant pain reduction maintained at weeks 52 and 64



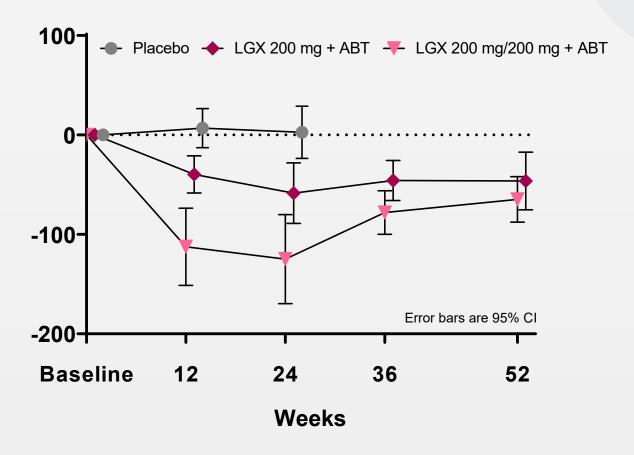


### LGX 200 mg without ABT significantly reduces uterine volume

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



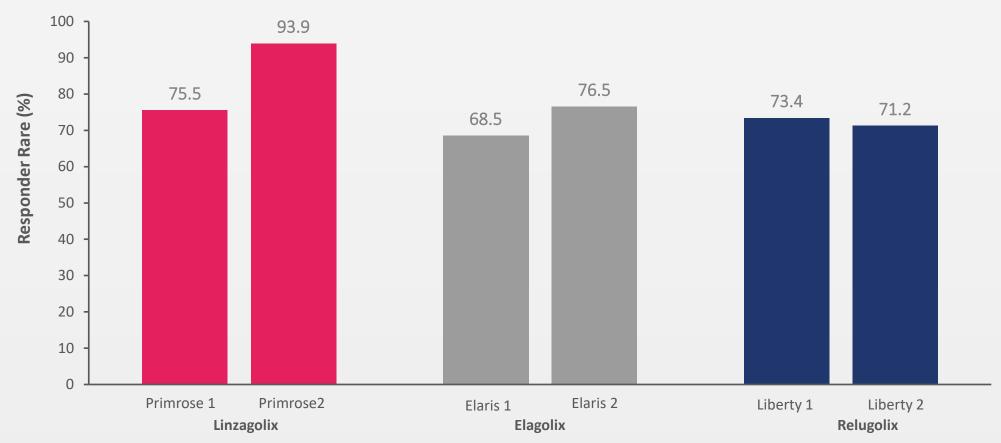
#### **PRIMROSE 2**

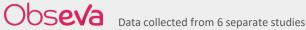




## 24-week efficacy data support linzagolix as potential best-in-class GnRH antagonist

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





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	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		
Responder* Rate (RR) (%)	75.5	93.9	84.7	
Amenorrhea	✓	✓		
Pain	✓	✓		
Fibroid Volume	x	✓		
Uterine Volume	x	✓		
Menstrual Blood Loss	✓	✓		
Anemia	✓	✓		
Quality of Life	✓	✓		

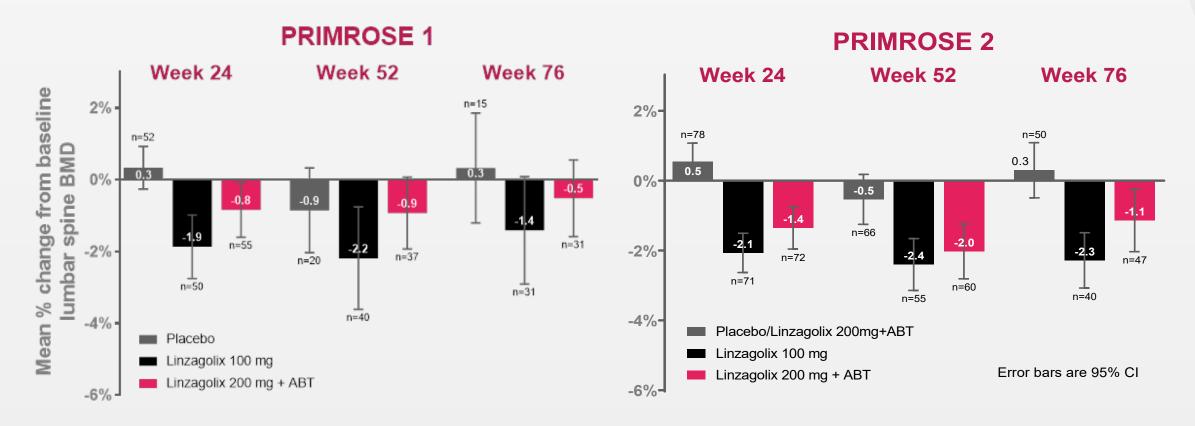
Elagolix					
ELARIS 1	ELARIS 2	Pooled Analysis			
;	300 mg + ABT Twice daily				
42.6	42.5				
238	229				
68.5	76.5	72.2+			
✓	✓				
NR	NR				
NR**	NR**				
NR**	NR**				
✓	✓				
✓	✓				
✓	✓				

Relugolix				
LIBERTY 1	LIBERTY 2	Pooled Analysis		
	40mg + ABT Once daily			
41.3	42.1			
229	247			
73.4	71.2	72.3++		
✓	✓			
✓	✓			
×	×			
✓	✓			
✓	✓			
✓	✓			
✓	✓			



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

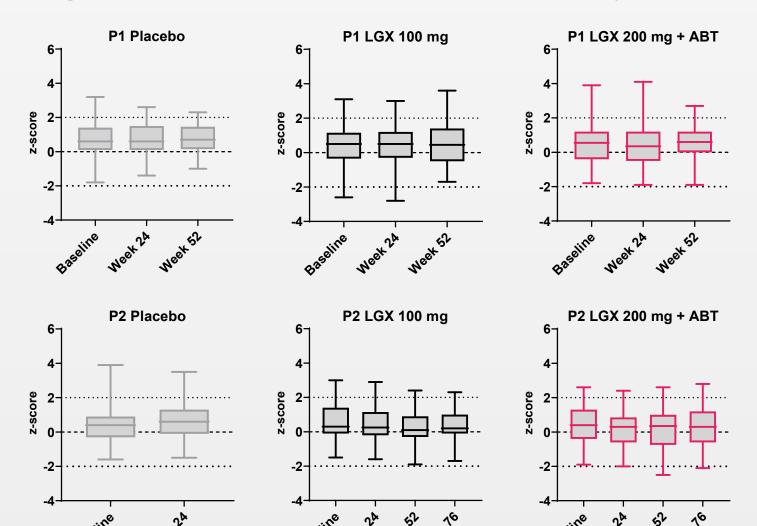
Expected age-related BMD decline observed in placebo arm at Week 52





### 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

		PRIMROSE 1		PRIME	OSE 2
	Placebo	Linzagolix 100 mg	Linzagolix 200 mg + ABT	Linzagolix 100 mg	Linzagolix 200 mg + ABT
Number (%) of women	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 mos	st frequently repor	ted 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)



#### Linzagolix, designed to treat more women...

Robust clinical data driving differentiated profile











Linzagolix 200 mg once daily with concomitant ABT

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

Linzagolix 100 mg once daily without ABT

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

Linzagolix 200 mg once daily without ABT

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

Potentially best-in-class, only GnRH antagonist to address the non-ABT market

Favorable efficacy rates and tolerability profile compared to other GnRH antagonists for the ABT regimen

Unique set of treatment options and complementary solution for uterine fibroids surgeons for pre-op



## Linzagolix: Potentially "best-in-class" GnRH antagonist

	Linzagolix	Elagolix	Relugolix
Flexible dosing to allow dose dependent reduction of estradiol (E2)	٧	X	X
For long-term use for women for whom ABT is appropriate*	84%	72.2%+	72.3%++
For long-term use for women with a contraindication to or who prefer to avoid ABT	56%	X	X
Significant reduction in pain	٧	X (NR)	٧
Once a day dosing	٧	X	٧
Favorable bioavailability	>80%	30-50%	11%
No food effect**	٧	X	X
Favorable tolerability profile	٧	٧	٧
Minimal BMD change	٧	٧	٧

Source: Company information Note: NR = Not reported. ABT=add-back therapy

Note: The data on this page are not from head-to-head comparisons.



<sup>\*</sup>Primary endpoint: Proportion of women with menstrual blood loss ≤ 80 mL (by alkaline hematin method) and ≥ 50% reduction from baseline

<sup>\*\*</sup> In a dedicated food effect study using a single 200 mg dose of elagolix, there was a decrease of 24% and 36% in AUC and Cmax, respectively, under high-fat meal conditions; however, labeling states elagolix can be taken without regard to meals; in a food effect study of relugolix, AUC and Cmax decreased by 38% and 55% respectively, after administration following consumption of a high-fat, high-calorie meal; however, labeling states the decrease in exposure is not clinically meaningful and relugolix can be taken without regard to meals.

<sup>+</sup>Simon et al, Obstet Gynecol 135, 1313-1326 2020

<sup>++</sup> Venturella R et al. ESHRE 2020 abstract.

#### **Endometriosis**

An emotionally and physically painful condition

\$22B/yr

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

in the general population

in the fertile population

60%+ in patients with chronic pelvic pain

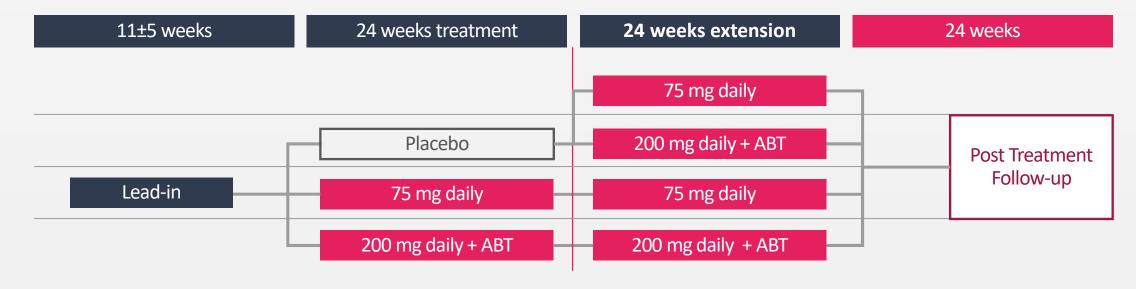
5 million

women in the US are treated annually for endometriosis



#### Phase 3 endometriosis trial

#### **EDELWEISS 3**



**Co-Primary efficacy endpoint: DYS/NMPP Responder Analysis** 

Patients are provided with Vitamin D and calcium



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## Thank you

