

Focused on unmet needs in women's reproductive health

November 2020



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

Key updates today

YSELTY® (LINZAGOLIX)

**EBOPIPRANT (OBE022)** 

**NOLASIBAN** 







Potential to relieve symptoms from 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

Potential to improve live birth rate following IVF & embryo transfer

- MAA filing 4Q:20 on track
- Commercial partnership discussions ongoing

- Positive results PROLONG
   Proof-of-Concept Phase 2a
- Initiation Phase 2b

 Submission of IND in China by YuYuan



# Multiple development programs drive value

	Phase 1	Phase 2	Phase 3	Status/NEXT MILESTONES		
YSELTY® (LINZAGOLIX) Oral GnRH receptor antagonist	Uterine Fibroids – Ph3 PRIMROSE 2 EU & U.S.			Positive Ph3 24W results for both PRIMROSE 1 & 2 PRIMROSE 1 52W data Q4:2020 MAA/NDA Q4:2020/1H:2021		
	Uterine Fibroids – Ph3 PRIMROSE 1 U.S.					
	Endometriosis – Ph3 EDELWEISS 2 U.S.			Phase 3 trials ongoing		
	Endometriosis – Ph3 EDELWEISS 3 EU & U.S.					
	Endometriosis – Ph2b	EDELWEISS		Positive Phase 2b results 2018/19		
EBOPIPRANT Oral $PGF_{2\alpha}$ receptor antagonist	Preterm Labor – Ph2a Preterm Labor – Ph1	PROLONG		Positive PoC - Phase 2a study. Moving to Phase2b Dose Ranging study Pre-clinical/Phase 1 complete		
NOLASIBAN Oral oxytocin receptor antagonist	IVF – Ph3 IMPLANT 2/4 IVF – Ph1/2 in China	ł EU		Positive IMPLANT 2 Ph3 Results IMPLANT 4 Ph3 missed primary endpoint YuYuan BioScience: China IND submission 4Q 2020		



Preterm birth is delivery before 37 weeks of pregnancy Life altering and costly

\$26B/yr

In 10 babies are born preterm

1 million preterm related deaths in 2015 WW \*

### **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

 $$16.9_{\text{B+}}$$  U.S. infant medical costs

\$195K+ average cost per U.S. survivor infant born 24-26 weeks

average U.S. cost for a preterm infant

WHO 'Born Too Soon: The Global Action Report on Preterm Birth' (2012); Kissin et al. NEJM, 2014 Behrman et al., National Academies Press, 2007

\* WHO: 15 million babies born preterm each year worldwide, and number is rising.

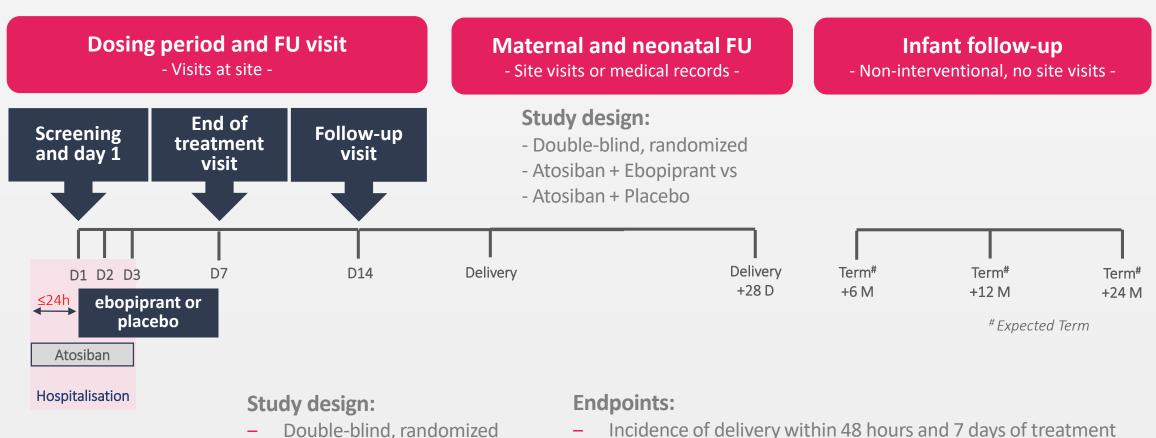




Atosiban + Ebopiprant vs

Atosiban + Placebo

The objective of a PTL treatment is to delay delivery by at least 48 hours to allow transfer of women to a center with neonatal intensive care facilities, and to allow corticosteroids administration to the mother to have maximal effectiveness for the baby





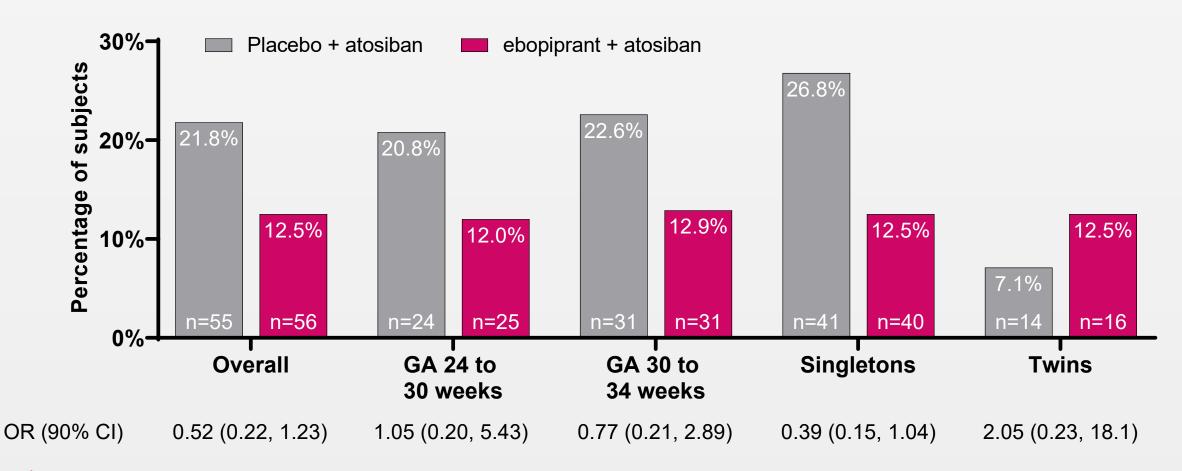
- Incidence of delivery within 48 hours and 7 days of treatment
- Time to delivery and delivery prior to 37 weeks of gestation
- Maternal, fetal, neonatal safety

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%)
Mean (SD) contractions /30 mins	3.19 (2.93)	3.37 (2.97)

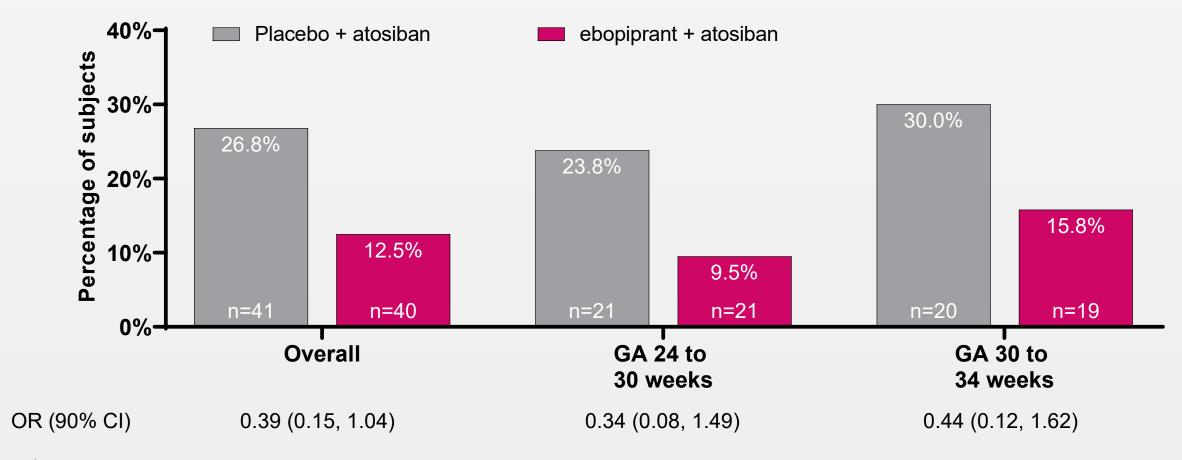


Percentage of subjects delivering within 48 hours



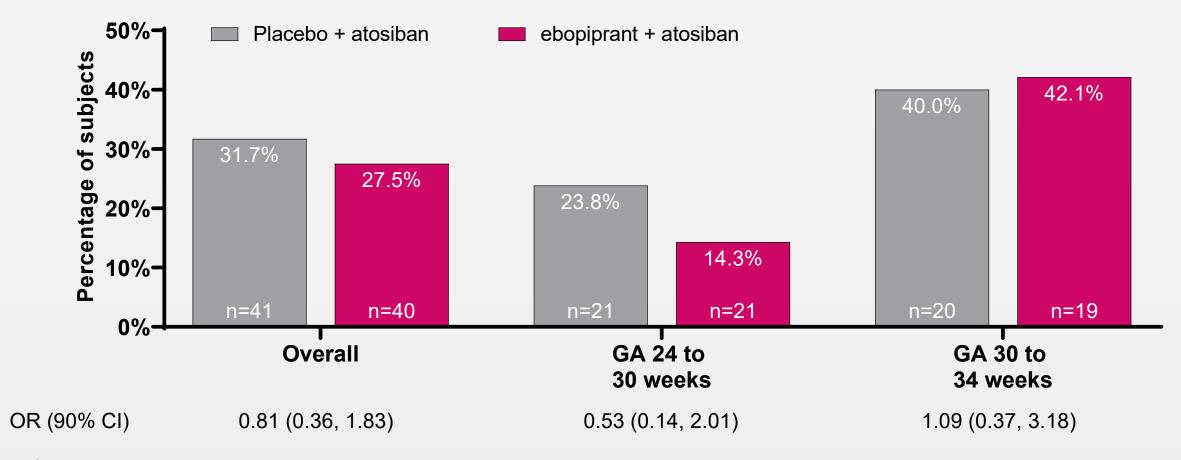


Percentage of singleton pregnancies delivering within 48 hours





Percentage of singleton pregnancies delivering within 7 days





#### Conclusions

Over 50% reduction of premature delivery within 48 hrs

Enabling administration of critical drugs for neonatal protection



Maternal, fetal and neonatal safety comparable to placebo



Phase 2b dose range finding 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, enabling ObsEva to plan its further development



### Uterine fibroids

A significant unmet need translating into a multibillion market

\$34B/vr

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

 $9_{\mathsf{million}}$ 

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.

300,000

are because of uterine fibroids

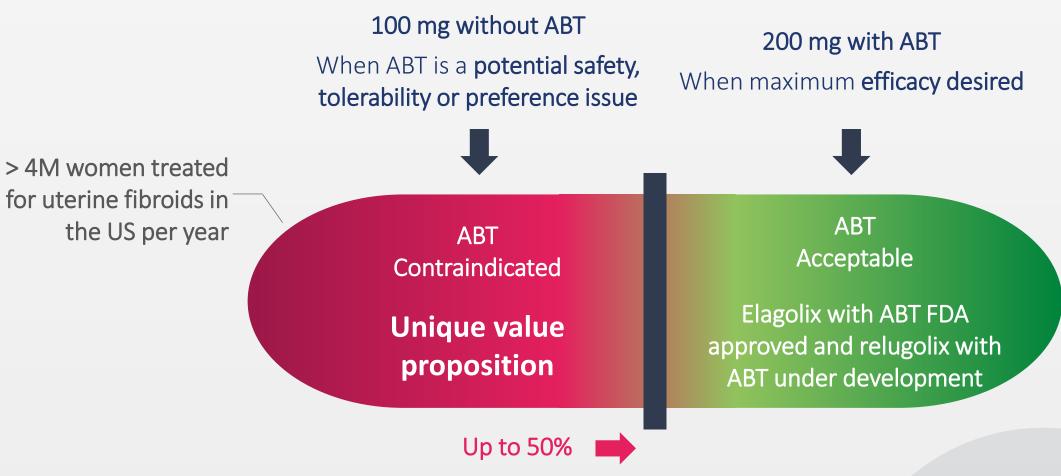
>4million

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



## Yselty® designed to treat more women

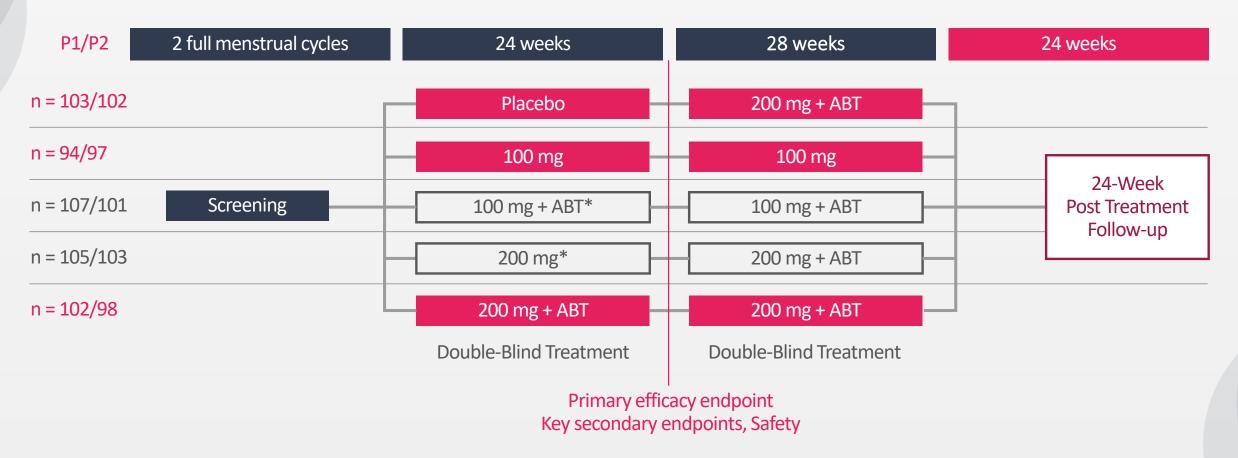
Only non-ABT dosing option under development for treating uterine fibroids Potential best-in-class ABT containing regimen





# Phase 3 registration studies

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



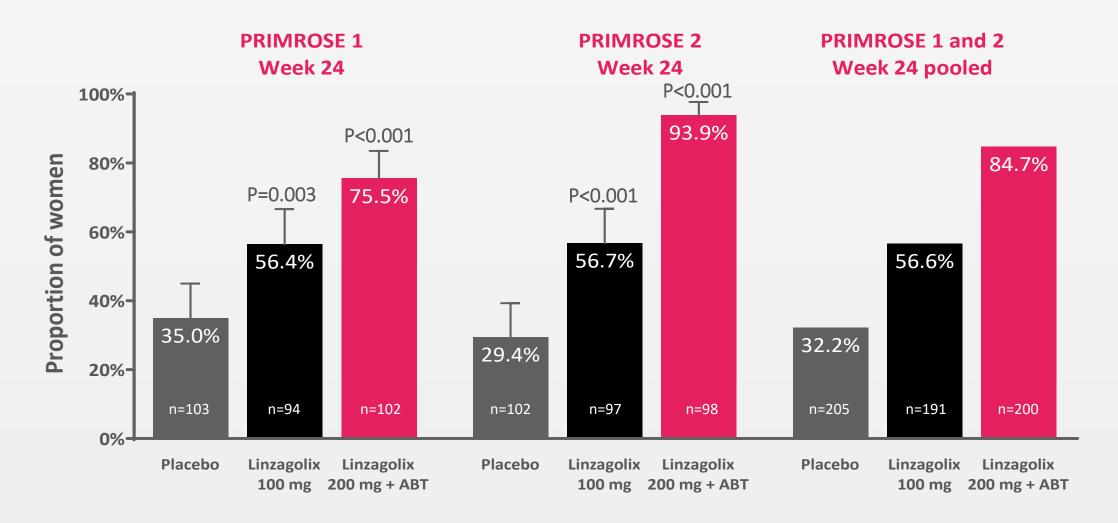
Primary efficacy endpoint is proportion of women with menstrual blood loss  $\leq$  80 mL (by alkaline hematin method) and  $\geq$  50% reduction from baseline

Patients in the studies received no Vitamin D or calcium supplementation



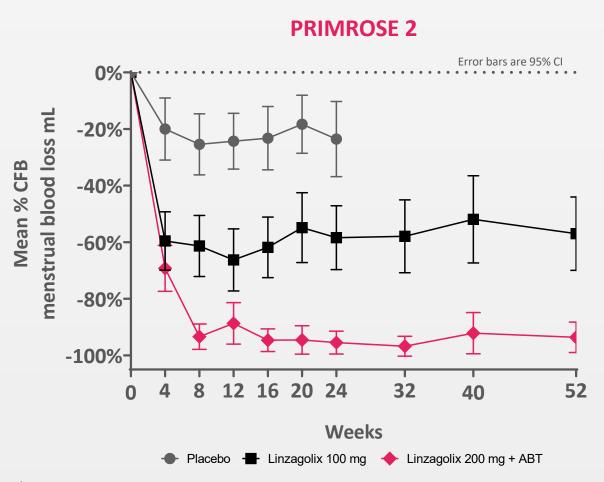
# PRIMROSE 1 and 2 achieved primary endpoint for both doses

Responder\* analysis

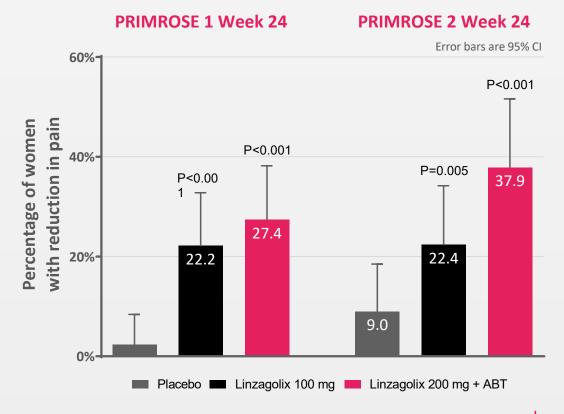




# Rapid onset and significant, sustained reduction in menstrual blood loss, as well as reduction or elimination of pain



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





# Linzagolix safety profile Day 1 to week 24

	PRIMROSE 1			PRIMROSE 2			
Number (%) of women	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)	



## Safety: Minimal BMD change

	PRIMROSE 1 US		PRIMROSE 2 EU/US	
	Linzagolix 100mg	Linzagolix 200 mg + ABT	Linzagolix 100mg	Linzagolix 200 mg + ABT
Black women %	63	61	4	4
BMI, mean (kg/m²)	33.0	33.0	27.4	26.8
BMD mean CBL Spine (%) @W24	-2.04	-0.84	-2.07	-1.31
Patients (%, n) with BMD loss >3%	38.0 (19)	23.2 (13)	35.7 (25)	29.2 (21)
Patients (%, n) with BMD loss >8%	4.0 (2)	1.8 (1)	1.4 (1)	0
BMD mean CBL Spine (%) @W52	-	-	-2.40	-2.03
Patients (%, n) with BMD loss >3%	-	-	36.4 (20)	30.0 (18)
Patients (%, n) with BMD loss >8%	-	-	1.8 (1)	1.7 (1)

"2% of bone loss is marginal. Treatment with glucocorticoids can cause patients to lose 5-15% of bone in the first year of use!"

BMD Expert

Patients in the studies received no Vitamin D or calcium supplementation

ABT = add-back therapy (E2 1 mg/NETA 0.5 mg), once a day concomitant administration





# Designed to treat more women Excellent clinical data driving differentiated profile

Statistically significant & clinically meaningful efficacy

Primary and key secondary endpoints met in PRIMROSE 1 & 2



Sustained efficacy and continued safety at week 52 for PRIMROSE 2



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



## Financial outlook to achieve milestones and drive programs

September 30 2020 cash

Expected cash runway

First commercial launch

\$50.6 million

Q2 2021 ex credit facility and warrants

Yselty® EU Q1:22



## Major upcoming catalysts

Evolving from pure development to a commercial company



## Linzagolix PRIMROSE 1 - 52 Weeks data

Q4:20

#### First linzagolix regulatory filings

MAA/NDA Q4:20/1H:21

### Linzagolix regional commercial partnerships

Active discussions ongoing

### Nolasiban development proceeding in China

Partner YuYuan Bioscience submitted IND

### Initiation Phase 2b Ebopiprant in preterm labor

Anticipated 2H:21

# Thank you

