# Obseva nature meets nurture

Focused on unmet needs in women's reproductive health

January 2021

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# Investor highlights

Pursuing promising large indications for serious conditions that compromise women's reproductive health and beyond, with the potential to extend into other indications including prostate cancer



Ebopiprant, the only oral PGF<sub>2 $\alpha$ </sub> receptor antagonist in development, has positive phase 2 data and favorable safety that support a Phase 2b dose ranging study (initiation in EU/Asia planned in 2H:21)



Yselty<sup>®</sup> has potential **best in class efficacy**, a favorable tolerability profile, and unique flexible dosing **options**; multiple value-generating milestones in the next year, including:

- Phase 3 uterine fibroids PRIMROSE 76 W data (1Q:21); NDA submission (1H:21); MAA approval for uterine fibroids and regional commercial partnerships pending
- Phase 3 endometriosis EDELWEISS 3 primary endpoint readout (4Q:21)



Strong global partnerships and collaborations support ObsEva approach



Seasoned leadership team with a track record for success to drive meaningful patient data

# **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 Potential to improve live birth rate following IVF & embryo transfer

# Multiple development programs drive value

|  | Phase 1               | Phase 2                | Phase 3   | Next Milestones   |  |
|--|-----------------------|------------------------|---|---|--|
| YSELTY®<br>(LINZAGOLIX)  | Uterine Fibroids – Ph | 3 PRIMROSE 2 (EU & U.: | <ul> <li>PRIMROSE 1: 76W data (1Q:21)</li> <li>NDA submission (2Q:21)</li> <li>Regional commercial partnerships (111:21)</li> </ul> |   |  |
|  | Uterine Fibroids – Ph | 3 PRIMROSE 1 (U.S)     |   | <ul> <li>MAA for uterine fibroids expected approval<br/>(4Q:21)</li> </ul>            |  |
| Oral GnRH<br>receptor antagonist   | Endometriosis – Ph3   | EDELWEISS 3 EU & U.S.  |   | <ul> <li>EDELWEISS 3: Primary endpoint readout expected (4Q:21)</li> </ul>            |  |
| <b>EBOPIPRANT</b><br>Oral PGF <sub>2<math>\alpha</math></sub><br>receptor antagonist | Preterm Labor – Ph2l  | 0                      |   | <ul> <li>Initiation Phase 2b dose ranging study in EU<br/>and Asia (4Q:21)</li> </ul> |  |
| NOLASIBAN<br>Oral oxytocin<br>receptor antagonist                                    | IVF – Ph1/2 in China  |                        |   | • Nolasiban Phase 1 in China (1H:21)  |  |



# EBOPIPRANT

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

| \$2         | 6      | <b>B</b> /yr |
|-------------|--------|--------------|
| U.S. econom | nic bu | urden        |



In 10 babies are born preterm



WW \*

Preterm birth, a costly burden per baby

cause of death in children under age 5

LEADING

Babies surviving early birth face greater likelihood of lifelong disabilities

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

\$195<sub>K+</sub>

**\$50**к

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.



## **Ebopiprant: an advancement in treatment of preterm labor** Orally active, selective prostaglandin $F_{2\alpha}$ (PGF<sub>2</sub>) receptor antagonist





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

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8

# Ebopiprant represents an evolution of therapy for preterm labor (PTL)

- No FDA-approved PTL treatment available in the US\*
  - Treatment includes off-label use of COX (non-selective prostaglandin inhibitors), calcium channel blockers, beta-mimetics
  - Current treatments associated with safety issues that limit use
- Atosiban (intravenous oxytocin receptor antagonist) approved in EU and some Asian countries
- Ebopiprant is an oral selective prostaglandin inhibitor
  - Potential for similar efficacy with improved safety



#### \*Makena is a progestin used for the *prevention* of PTL in women with a prior history of preterm birth; it is not approved for the treatment of PTL

# 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\*



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

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

Percentage of women delivering within 48 hours



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

Percentage of women delivering within 48 hours



# Singleton 24-30wk delivery rate within 7 days reduced by 40%

Percentage of women delivering within 7 days



# Ebopiprant, a potential breakthrough for preterm labor

Over 50% reduction of premature 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 longerterm benefits for babies

Ebopiprant has demonstrated proof of concept in delaying preterm birth, enabling ObsEva to plan its further development





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

Yselty<sup>®</sup>, 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



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

>4 million

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

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Cardozo et al., Am J Obstet Gynecol 2012; Stewart et al. NEJM, 2015; Flynn et al., Am J Obstet Gynecol 2006; Truven Health, Fibroid Foundation website; Epidemiology of women's health, Jones & Bartlett Learning, Ruby T. Senie, 2014

### The promise of the GnRH antagonists Dose dependent reduction of estradiol (E2)

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



# 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<sup>®</sup> 200 mg once daily with concomitant ABT

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

### Yselty<sup>®</sup> 100 mg once daily without ABT

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

### Yselty<sup>®</sup> 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

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The hypothetical patients represented on this slide are for illustrative purposes only as no strength of linzagolix has been approved nor is there FDA-approved Prescribing Information to guide clinical decisions

# 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 at week 24



## PRIMROSE 1 and 2 achieved sustained reduction in MBL Responder\* analysis at week 52



\*Proportion of women with menstrual blood loss  $\leq$  80 mL (by alkaline hematin method) and  $\geq$  50% reduction from baseline 23

# Significant pain reduction maintained at weeks 52 and 64



Pain assessed on Numerical Rating Scale: 0-10

## 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<sup>®</sup> (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 <sup>®</sup> (Linzagolix) |                           |                    | Elagolix |                             |                    | Relugolix             |                          |                    |
|-----------------------------|----------------------------------|---------------------------|--------------------|----------|-----------------------------|--------------------|-----------------------|--------------------------|--------------------|
|                             | PRIMROSE 1                       | PRIMROSE 2                | Pooled<br>Analysis | ELARIS 1 | ELARIS 2                    | Pooled<br>Analysis | LIBERTY 1             | LIBERTY 2                | Pooled<br>Analysis |
| Dose Regimen                |                                  | 200mg + ABT<br>Once daily |                    |          | 300 mg + ABT<br>Twice daily | ſ                  |                       | 40mg + ABT<br>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+              | 73.4                  | 71.2                     | 72.3++             |
| Amenorrhea                  | ✓                                | ✓                         |                    | <b>√</b> | ✓                           |                    | ✓                     | ✓                        |                    |
| Pain                        | ✓                                | ✓                         |                    | NR       | NR                          |                    | ✓                     | ✓                        |                    |
| Fibroid Volume              | ×                                | ✓                         |                    | NR**     | NR**                        |                    | ×                     | ×                        |                    |
| Uterine Volume              | ×                                | ✓                         |                    | NR**     | NR**                        |                    | <ul> <li>✓</li> </ul> | ✓                        |                    |
| Menstrual Blood Loss        | ✓                                | ✓                         |                    | ✓        | <ul> <li>✓</li> </ul>       |                    |                       | ✓                        |                    |
| Anemia                      | ✓                                | ✓                         |                    | ✓        | <ul> <li>✓</li> </ul>       |                    | <ul> <li>✓</li> </ul> | ✓                        |                    |
| Quality of Life             | ✓                                | ✓                         |                    | ✓        | ✓                           |                    | <ul> <li>✓</li> </ul> | ✓                        |                    |

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Source: Company information Note: NR = Not reported. \*Primary endpoint: Proportion of women with menstrual blood loss  $\leq$  80 mL (by alkaline hematin method) and  $\geq$  50% reduction from baseline \*\* P-value not reported + Simon et al, Obstet Gynecol 135, 1313-1326 2020 ++ Venturella R et al, ESHRE 2020 abstract.

26

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

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



PRIMROSE 1

**PRIMROSE 2** 

Recovery at 6 months post-treatment (in subjects with a decrease at Week 52): Median % BMD increase: LGX 100 mg about 0.8%, LGX 200 mg + ABT about 1.2%

# Bone mineral density – no change in z-scores

BMD remains well within age-matched normal ranges during and after treatment for both doses



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 | PRIMROSE 2                              |  |                                      |  |  |  |  |
|---|---|------------|---|--|--------------------------------------|--|--|--|--|
| Number (%) of women   | Yselty <sup>®</sup><br>Placebo (Linzagolix)<br>100 mg |            | Yselty®<br>(Linzagolix)<br>200 mg + ABT | Yselty <sup>®</sup> (Linzagolix)<br>100 mg | Yselty® (Linzagolix)<br>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)                              |  |  |  |  |



- Unique PD/PK Profile
- Efficacy sustained up to 52 weeks for all dose regimens
- Potentially best-in-class symptom control for 200 mg with ABT
- No safety signal of concern for any of the Yselty<sup>®</sup> regimens
- BMD remains within age-matched normal ranges during and after treatment



• Significant uterine volume reduction for 200 mg without ABT

30

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\*\*

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# Thank you



