Obseva
nature meets nurture

PROLONG

A phase 2a, double-blind, parallel group, randomised, placebo controlled, proof of concept study to assess the efficacy, safety and pharmacokinetics of EBOPIPRANT (OBE022) added-on to atosiban, after oral administration in pregnant women with spontaneous preterm labour.

MAIN STUDY RESULTS

NOVEMBER 2020

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Preterm birth is delivery before 37 weeks of pregnancy

Life altering and costly

$26B/yr
U.S. economic burden

>1
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

$16.9B+ U.S. infant medical costs

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

$50K average U.S. cost for a preterm infant

Obseva

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

Professor Ben Mol, MD, PhD

Professor of Obstetrics and Gynecology, Monash University, Australia

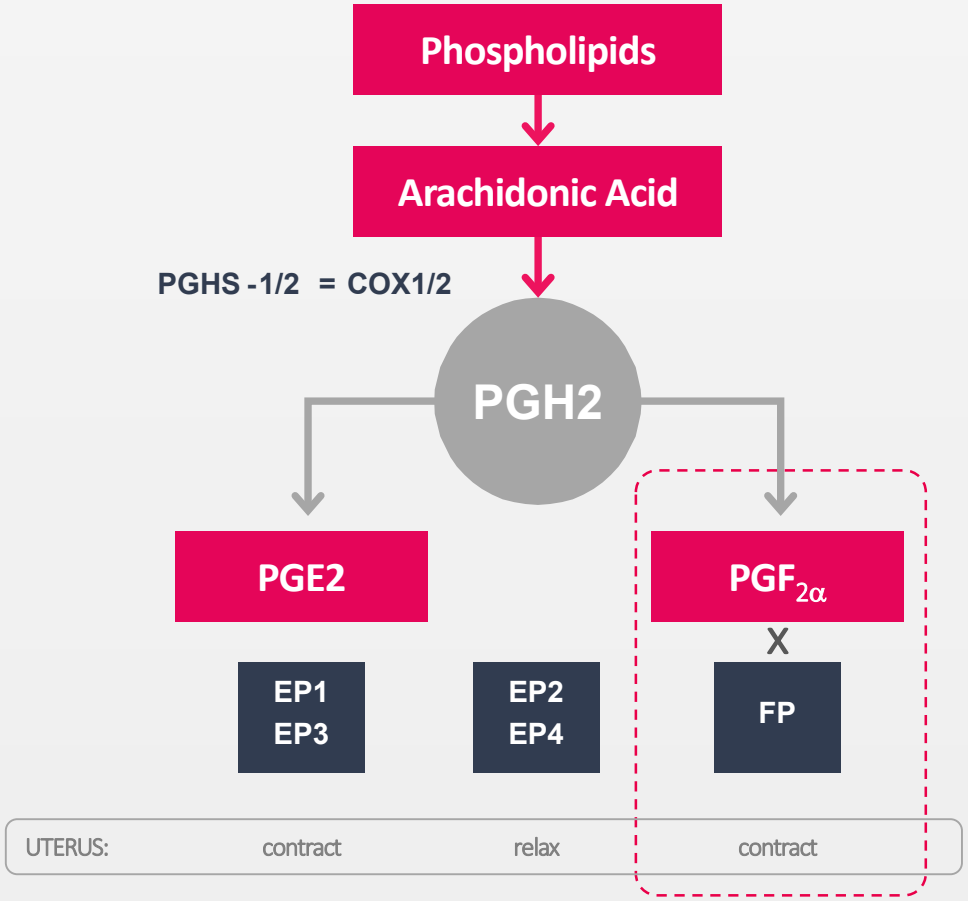
"We desperately need new medical treatments for preterm labor to reduce the incidence of preterm birth, which accounts for about 10% of all births."

"A delay of delivery by 48 hours is extremely important as this allows transfer of women to a center with neonatal intensive care facilities, and it allows corticosteroids administered to the mother to have maximal effectiveness for the baby"

"The development of ebopiprant is exciting and the results of PROLONG are promising"

Melbourne, November 2020

Mode of action of $PGF_{2\alpha}$ receptor antagonist to control preterm labor



EBOPIPRANT (OBE022)

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

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

*NSAID's are pan-inhibitor of PG synthesis (e.g. Indomethacin) that are effective for controlling pre-term labor, but which are associated with severe adverse effects for the neonates such as premature closure of ductus arteriosus, necrotizing entero-colitis, renal insufficiency, platelet aggregation inhibition. (ref)

Ebopiprant Phase 2a study

Study design

Randomized, double-blind, placebo-controlled, trial in 113 patients (recruited Jan 2019 to Mar 2020)

Patients

- Gestational age 24-34 weeks
- Singleton or twin pregnancy
- ≥ 4 contractions/30 min
- Cervical dilation 1-4 cm
- One other sign of labor
- Rx atosiban infusion
- Contraindication to delayed birth excluded

Treatments

- Atosiban infusion for 48 h
- Oral ebopiprant/placebo 1000 mg then 500 mg twice daily for 7 days
  - ✓ First dose given within 24 h after starting atosiban infusion
- Parenteral MgSO4 for neuroprotection and beta/dexamethasone permitted

Efficacy Outcomes

- Delivery within 2 days
- Delivery within 7 days
- Delivery before 37 weeks
- Time to delivery
- Uterine Contractions
- Ebopiprant Pharmacokinetics

Safety Outcomes

- Maternal – AEs, labs, VS
- Fetal AEs
- Neonatal – AEs, VS, Apgar score, weight, head circumference, specific neonatal morbidities
- Infant development – ASQ-3 at 6, 12 and 24 months (ongoing)

Ebopiprant Phase 2a study

Study schedule

Dosing period and F/U visit
- Visits at site -

Maternal and neonatal F/U
- Site visits or medical records -

Infant F/U
- Non-interventional, no site visits -

Expected Term

Endpoints:

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

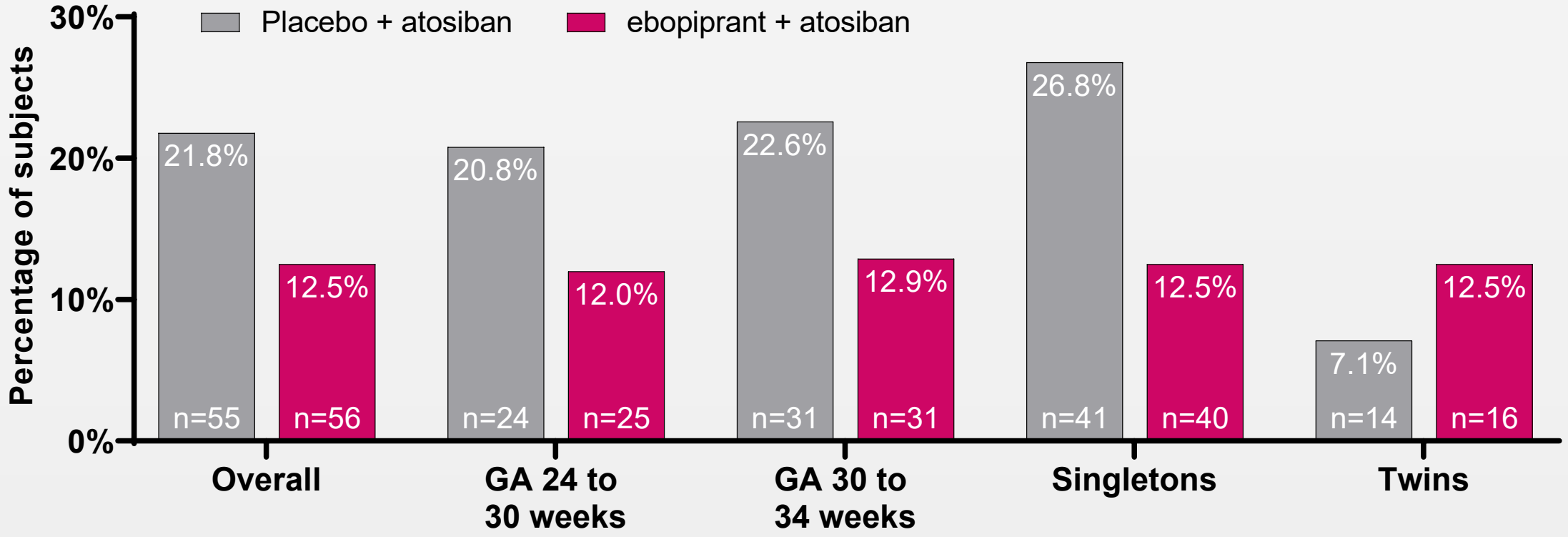
Ebopiprant Phase 2a study

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)

Ebopiprant Phase 2a study

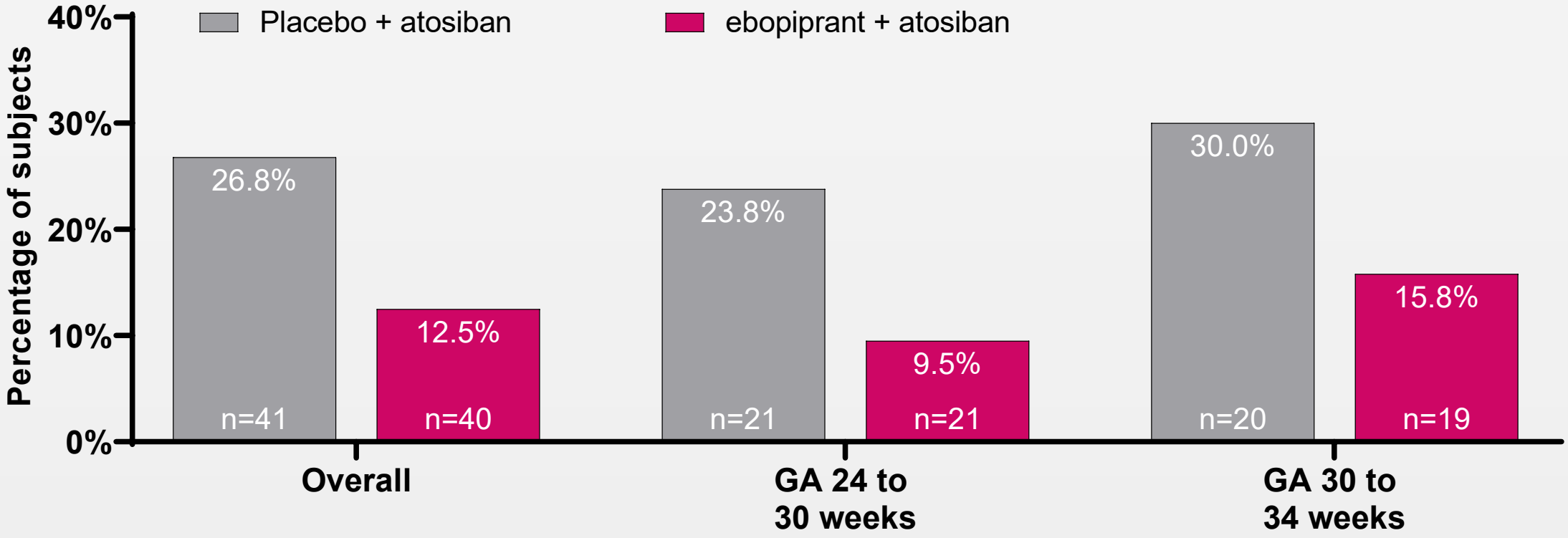
Percentage of subjects delivering within 48 hours



	Overall	GA 24 to 30 weeks	GA 30 to 34 weeks	Singletons	Twins
OR (90% CI)	0.52 (0.22, 1.23)	1.05 (0.20, 5.43)	0.77 (0.21, 2.89)	0.39 (0.15, 1.04)	2.05 (0.23, 18.1)

Ebopiprant Phase 2a study

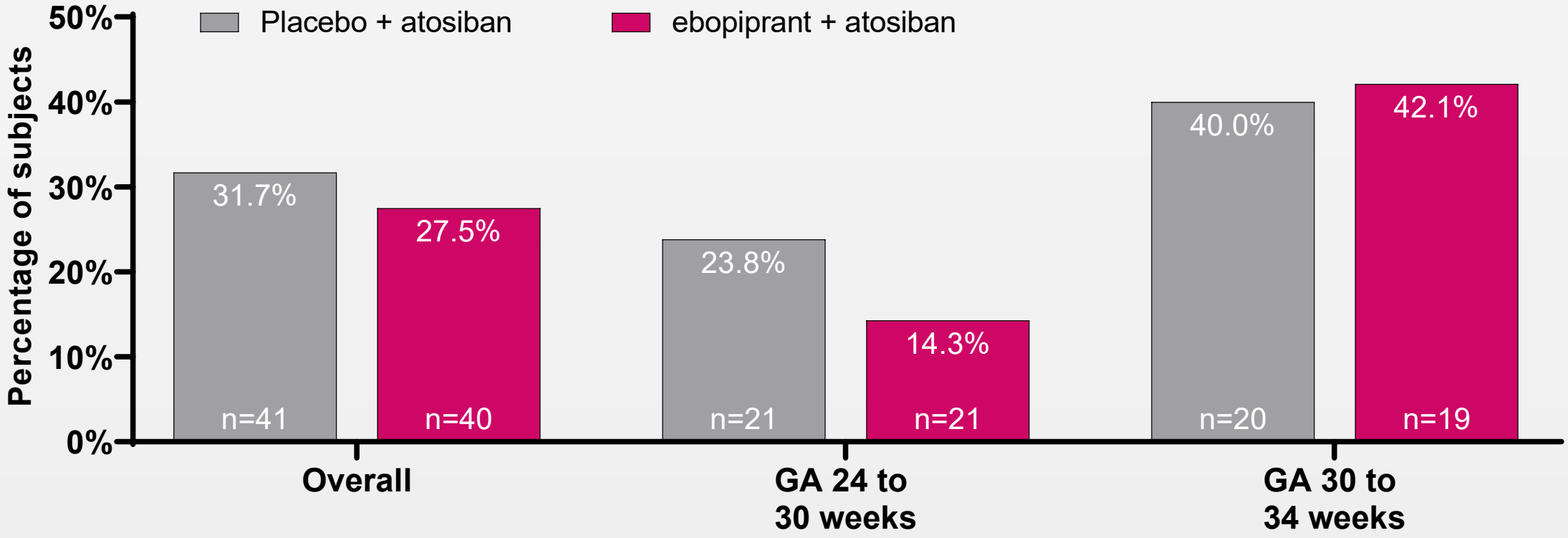
Percentage of singleton pregnancies delivering within 48 hours



OR (90% CI)	0.39 (0.15, 1.04)	0.34 (0.08, 1.49)	0.44 (0.12, 1.62)

Ebopiprant Phase 2a study

Percentage of singleton pregnancies delivering within 7 days

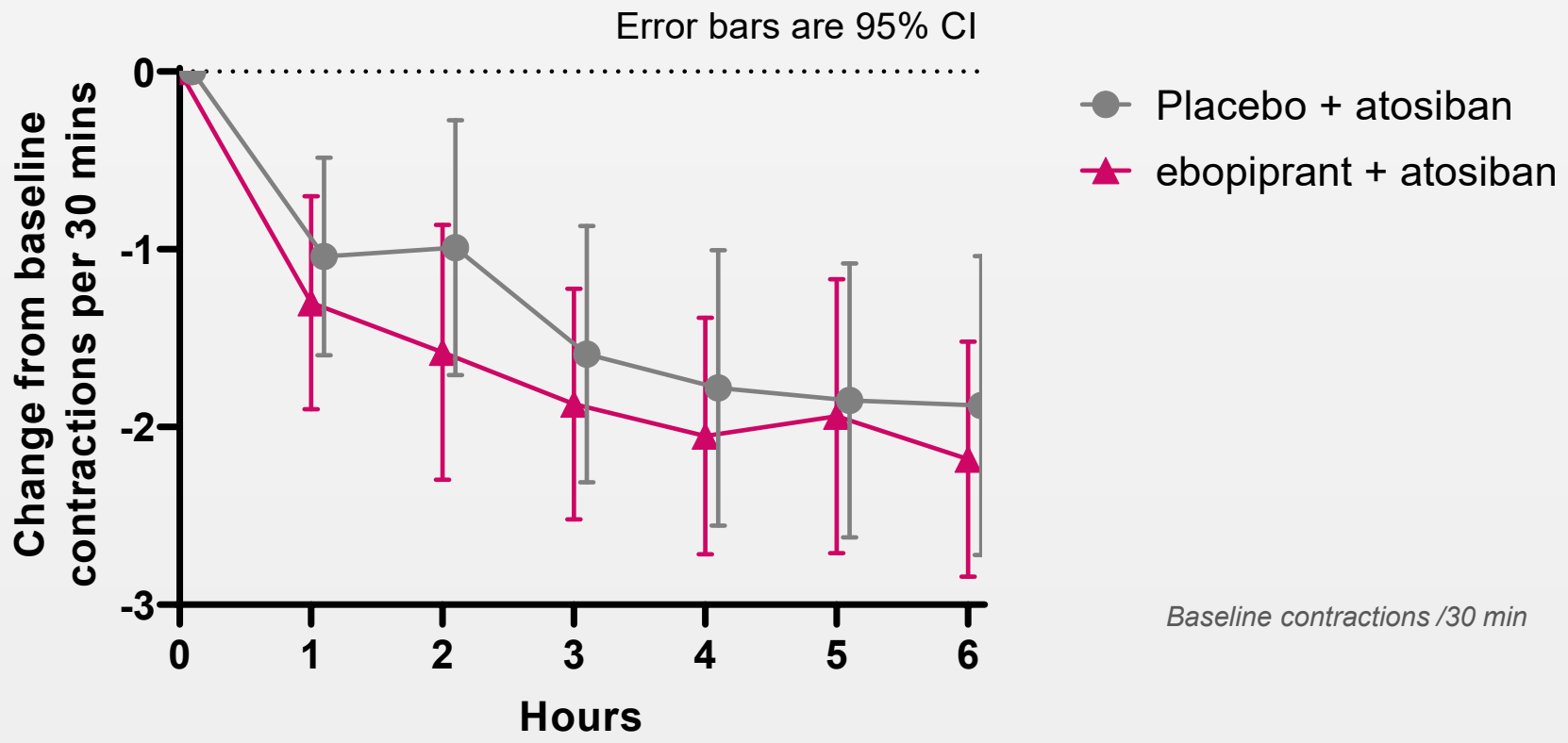


OR (90% CI)	0.81 (0.36, 1.83)	0.53 (0.14, 2.01)	1.09 (0.37, 3.18)

Ebopiprant Phase 2a study

Efficacy outcomes

Change from baseline in uterine contractions per 30 minutes



	Placebo + atosiban	*ebopiprant + atosiban*
Baseline contractions /30 min	*3.19 (2.93)*	*3.37 (2.97)*

Ebopiprant Phase 2a study

Maternal/Fetal safety prior to delivery until 7 days post treatment

Maternal & Fetal TEAEs – n (%)	Atosiban + Placebo	Atosiban + Ebopiprant
	n=55	n=58
At least one TEAE	23 (41.8%)	24 (41.4%)
SAEs	0	0
Severe	1*	0
Leading to IMP discontinuation	0	1** (1.7%)
AEs (>5% in any group)		
Constipation	4 (7.3%)	4 (6.9%)
Diarrhea	3 (5.5%)	0
Flatulence	0	3 (5.2%)

*Fetal growth restriction; ** Gastralgia

Ebopiprant Phase 2a study

Neonatal safety*

AEs of Special Interest (related to NSAIDs) – n (%)	Atosiban + Placebo	Atosiban + Ebopiprant
	n=69	n=72
Any AEs of special interest	7 (10.1%)	5 (6.9%)
Ductus arteriosus	4 (5.8%)	5 (6.9%)
Necrotizing enterocolitis	1 (1.4%)	0
CNS lesions	2 (2.9%)	0
Intraventricular hemorrhagia	4 (5.8%)	1 (1.4%)
Renal Impairment	1 (1.4%)	0

* Presented data are limited to specific AE's for which frequency has been reported to be increased following administration of NSAIDs. This list does not encompass all AE's reported In PROLONG neonates

Ebopiprant Phase 2a study

Conclusions

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