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obstetrics & beyond

Linzagolix Phase 3 PRIMROSE 2 Trial Results

Heavy Menstrual Bleeding due to Uterine Fibroids

December 9, 2019

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FOCUSED ON UNMET NEEDS IN WOMEN'S REPRODUCTIVE HEALTH

LINZAGOLIX

Potential best-in-class to relieve symptoms for the millions of women suffering from heavy menstrual bleeding (HMB) due to uterine fibroids

POSITIVE PHASE 3 RESULTS – PRIMROSE 2

1 Primary endpoint* achieved for both doses (p<0.001)

- **200mg with ABT** **93.9%** responder rate
- **100 mg without ABT** **56.7%** responder rate
- **Placebo** **29.4%** responder rate

2 Key secondary endpoints achieved for both doses

- High **amenorrhea** rate (p<0.001) and reduction in **bleeding days** (p<0.001)
- Reduction in **pain** (p<0.001) and **uterine volume** (p<0.001)
- Reduction in **uterine fibroid volume** for 200mg dose with ABT (p<0.008)
- Improvement in **hemoglobin levels** (p<0.001) and quality of life (p<0.001)

3 Generally well tolerated

- AE's >5%: headache, hot flush, anemia
- Mean percentage change from baseline in BMD consistent with expectations

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

ABT = add-back therapy, estradiol 1.0 mg and norethindrone acetate 0.5 mg

BMD = Bone Mineral Density

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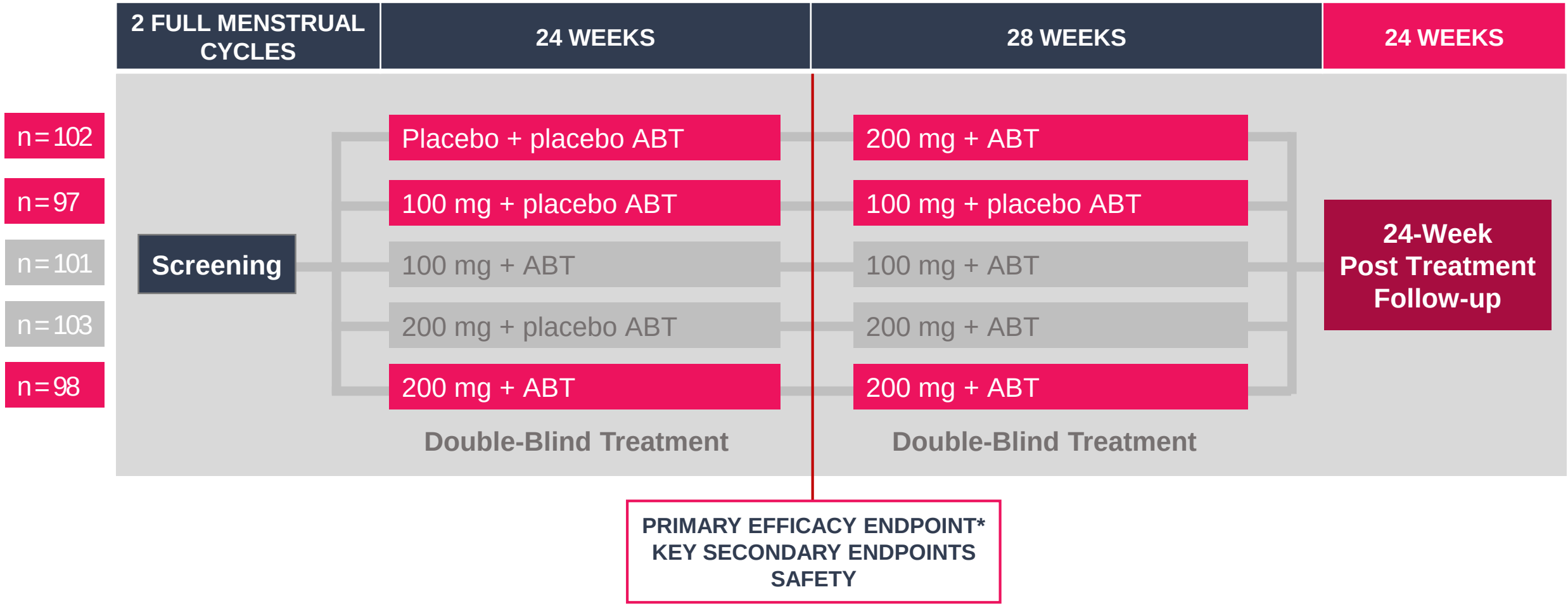
EU/US PHASE 3 PRIMROSE 2 TRIAL: DESIGNED FOR DUAL LABEL



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

ABT = add-back therapy, estradiol 1.0 mg and norethindrone acetate 0.5 mg

Patients in the trial received no Vitamin D or calcium supplementation

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DEMOGRAPHIC AND BASELINE CHARACTERISTICS

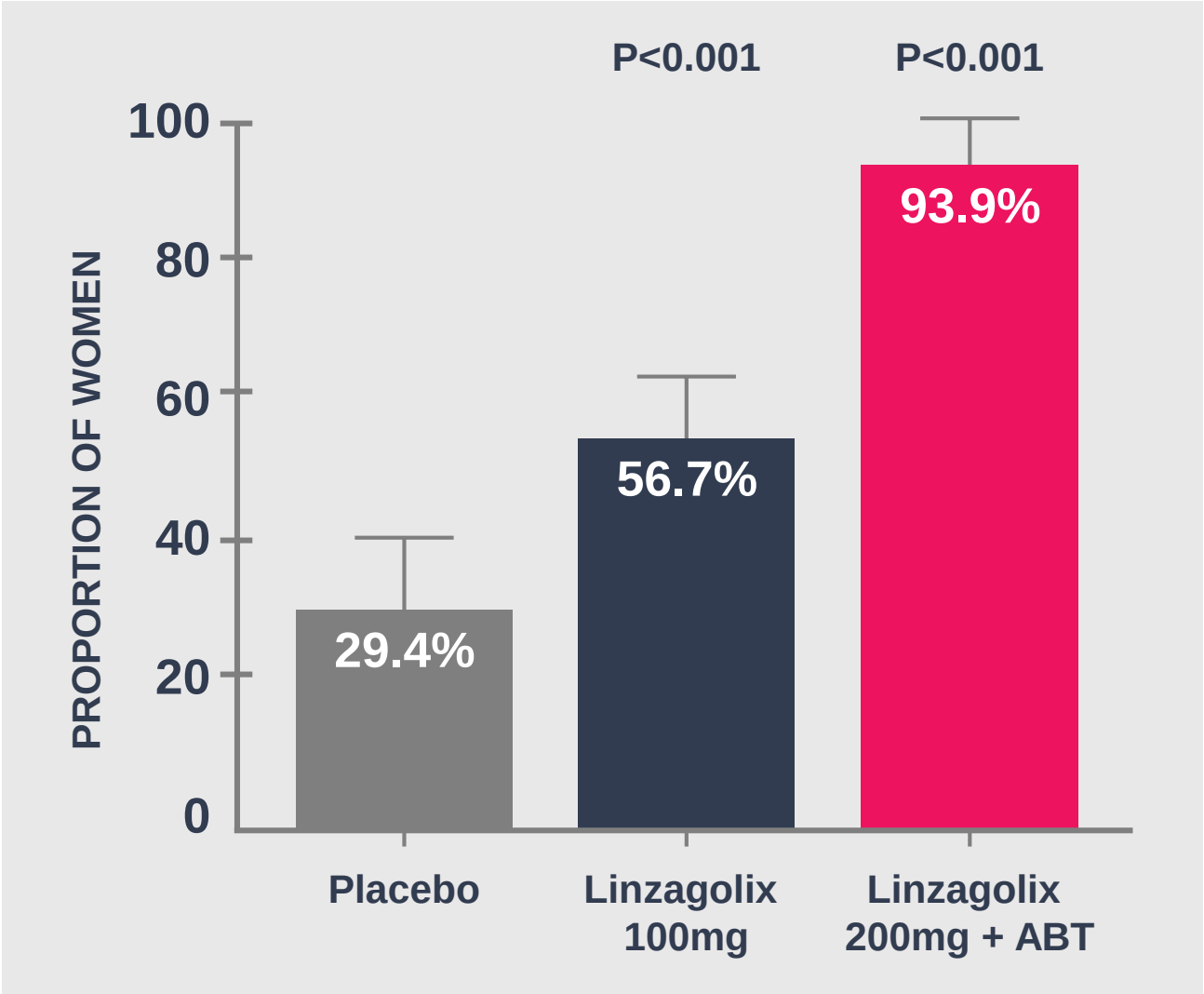
FULL ANALYSIS SET	Placebo N=102	Linzagolix 100 mg N=97	Linzagolix 100 mg + ABT N=101	Linzagolix 200 mg N=103	Linzagolix 200 mg + ABT N=98	Total N=501
Age (years) - mean (SD)	42.9 (5.3)	43.4 (5.4)	42.5 (5.1)	42.7 (5.8)	43.1 (4.8)	42.9 (5.3)
BMI (kg/m^2) - mean (SD)	26.83 (5.42)	27.44 (5.67)	27.22 (5.82)	26.82 (5.55)	26.80 (5.47)	27.02 (5.57)
Hb < 10 g/dL – n(%)	14 (13.7)	21 (21.6)	16 (15.8)	18 (17.5)	24 (24.5)	93 (18.6)
Hb < 12 g/dL – n(%)*	51 (50.0)	61 (62.9)	59 (58.4)	57 (55.3)	56 (57.1)	284 (56.7)
MBL** (mL) at baseline mean (SD)	218 (128)	246 (161)	193 (92)	219 (136)	212 (142)	218 (134)

95% Caucasian / 5% Black

* Anemia is diagnosed when a blood test shows a hemoglobin value of less than less than 12.0 g/dL in a woman
** MBL: Menstrual Blood Loss

PRIMARY ENDPOINT ACHIEVED FOR BOTH TARGET 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

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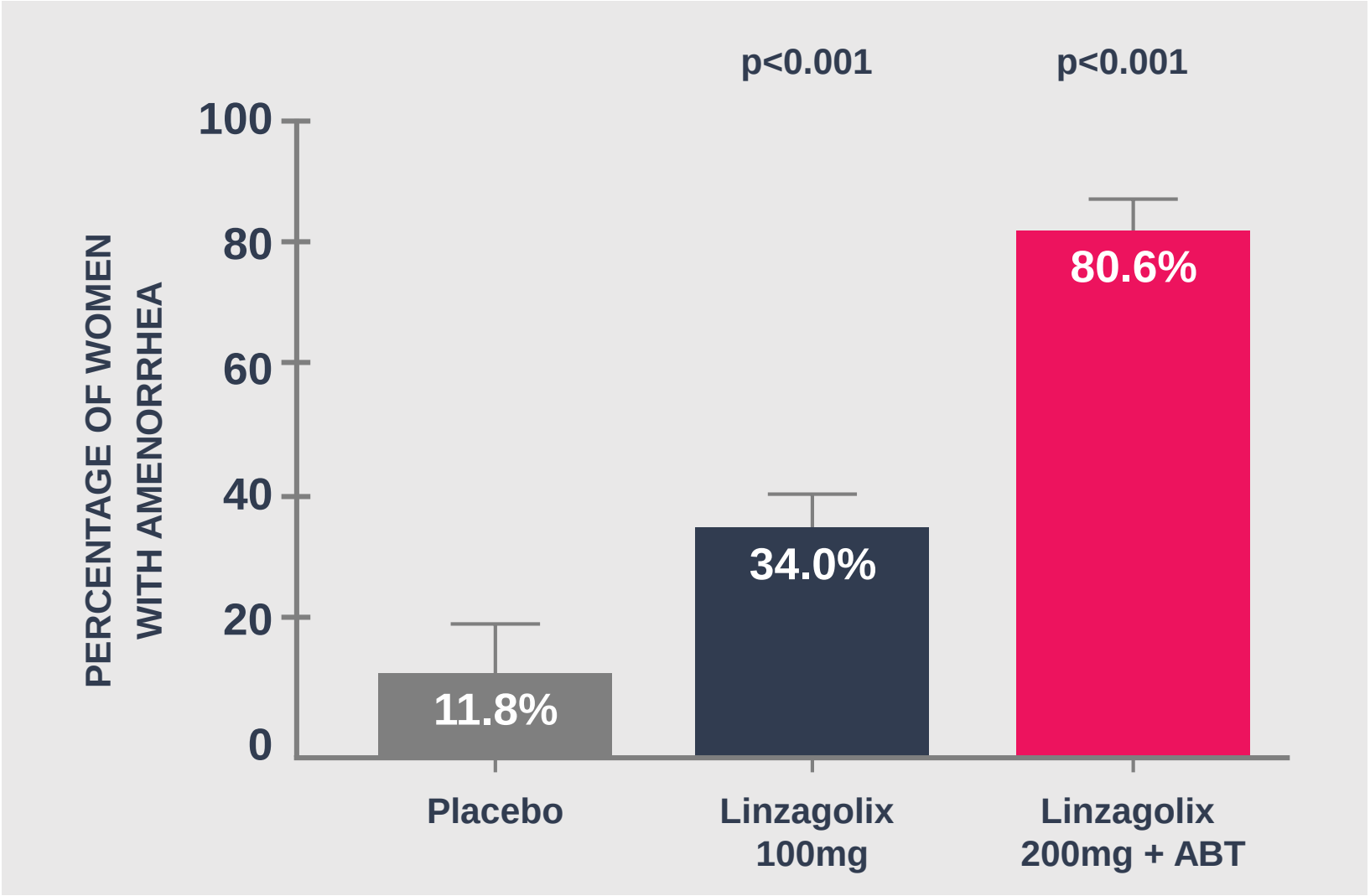
SIGNIFICANT AMENORRHEA RESPONSE FOR BOTH TARGET DOSES



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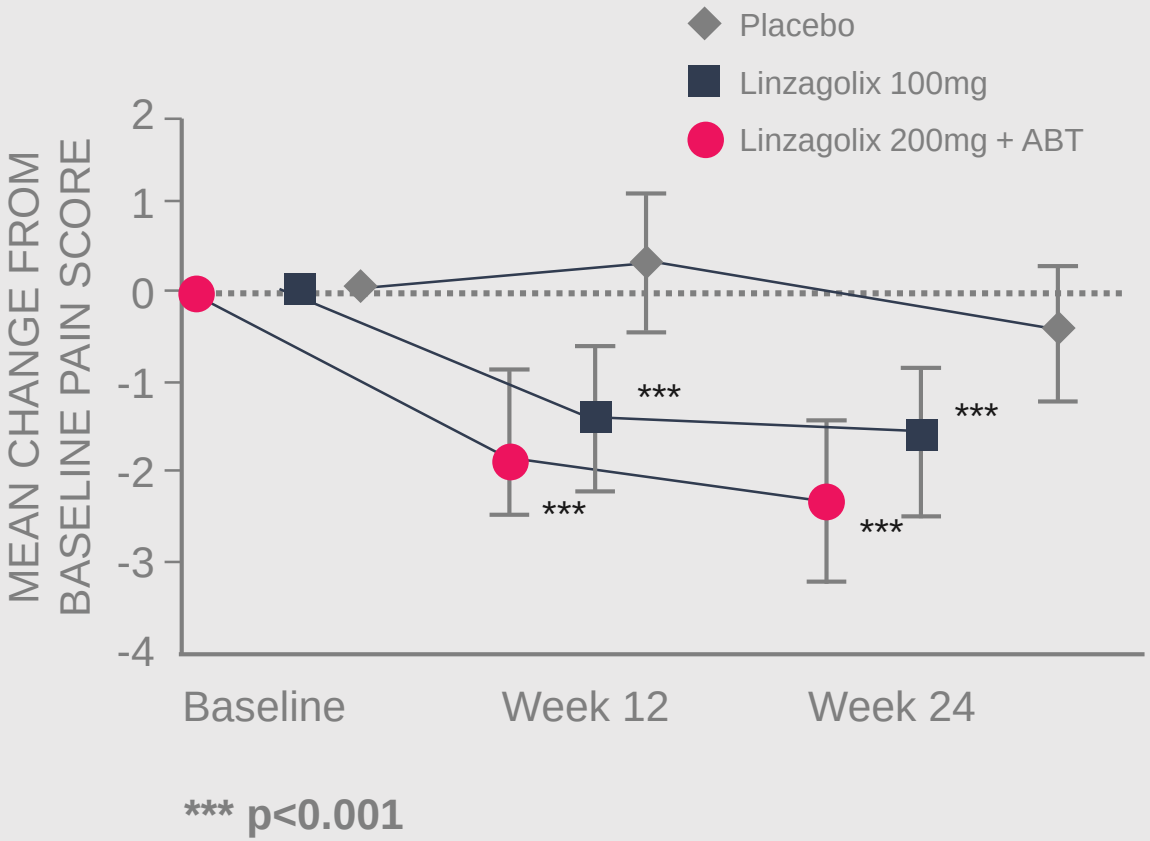
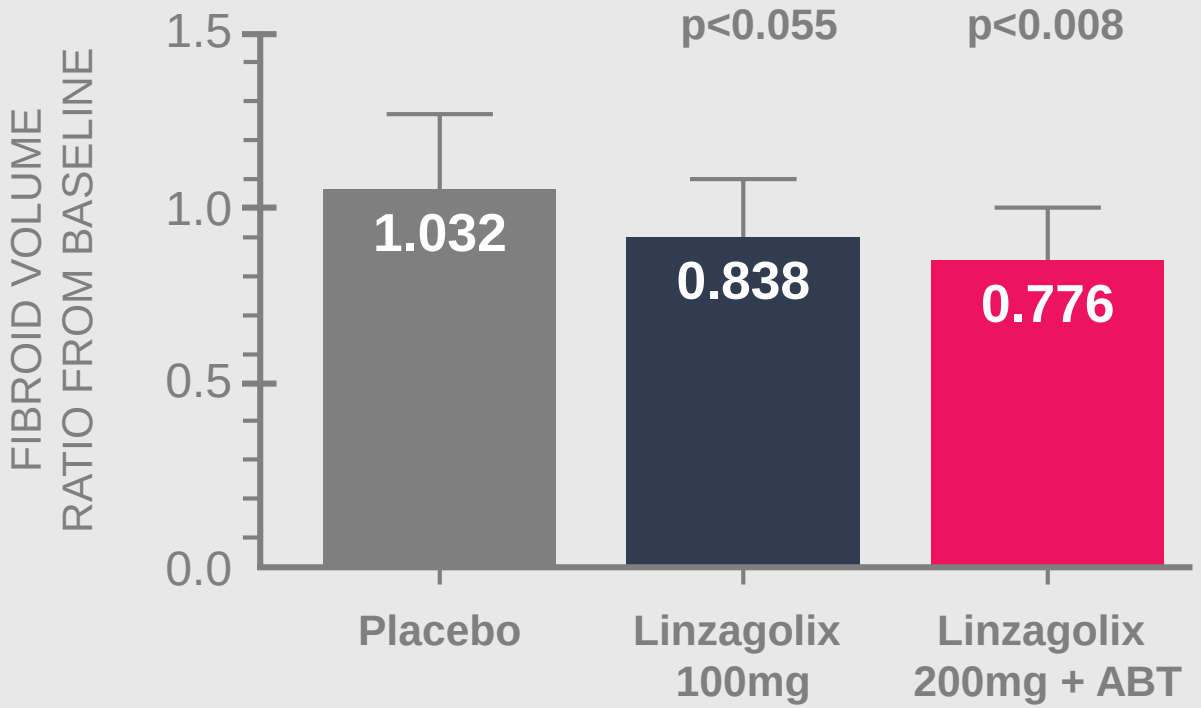
PAIN AND FIBROID VOLUME REDUCTION FOR BOTH TARGET DOSES



*** p<0.001



Error bars are 95% CI

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KEY SECONDARY ENDPOINTS ACHIEVED

Key Secondary Endpoints	Measurement	p-value
Reduction in menstrual blood loss	• Time to reduced menstrual blood loss (i.e., ≤80 mL and ≥50% reduction from baseline) up to Week 24 • Number of days of uterine bleeding for the last 28-day interval prior to Week 24	p < 0.001 p < 0.001
Amenorrhea	• Percentage at Week 24 • Time to amenorrhea up to Week 24	p < 0.001 p < 0.001
Improvement in anemia	• Hemoglobin level at week 24 in anemic subjects (defined as subjects with Hb < 12 g/dL at baseline)	p < 0.001
Reduction in pain	• Change from baseline pain score at week 24	p < 0.001
Reduction in volume	• Fibroid volume change from baseline at Week 24 for 100mg without ABT and 200mg with ABT • Uterine volume change from baseline at Week 24	p < 0.055/0.008 p < 0.001
Improvement in quality of life	• Change from baseline health-related quality of life (UFS-QoL*) at Week 24	p < 0.001

* UFS-QoL = Uterine Fibroids Symptoms and Health-Related Quality of Life questionnaire

SUMMARY OF ADVERSE EVENTS

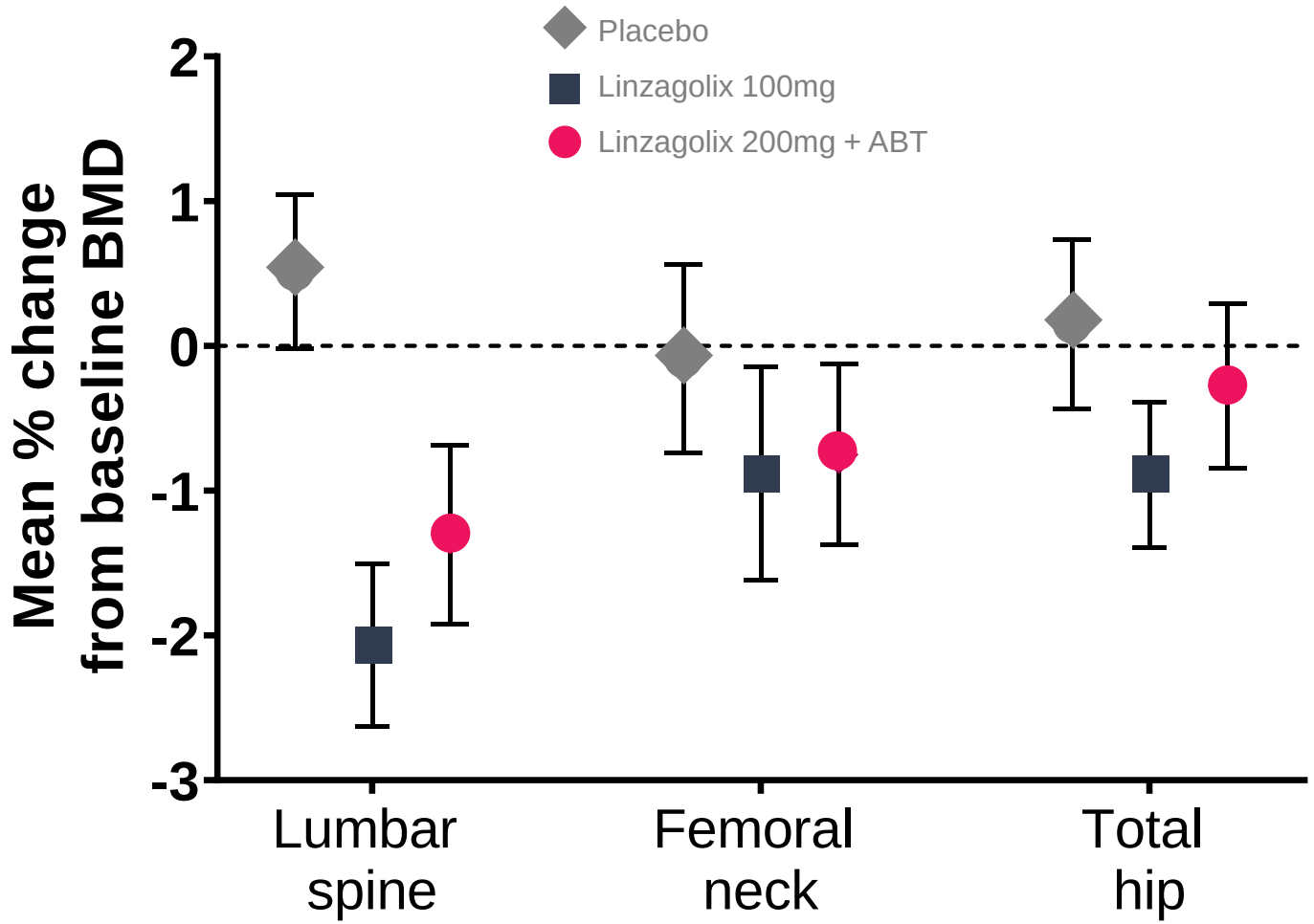
Treatment emergent adverse events, n (%)	Placebo n=105	Linzagolix 100 mg n=99	Linzagolix 100 mg + ABT n=102	Linzagolix 200 mg n=104	Linzagolix 200 mg + ABT n=101	Total n=511
Subjects with at least one TEAE	**47 (44.8)**	**50 (50.5)**	45 (44.1)	62 (59.6)	**51 (50.5)**	**255 (49.9)**
Vascular disorders*	**6 (5.7)**	**15 (15.2)**	12 (11.8)	36 (34.6)	**14 (13.9)**	**83 (16.2)**

* Vascular disorders include hot flushes, hypertension, flushing, varicose veins

- Severe AEs (4.7%)
- Serious AEs (2.0%)

- Most common TEAEs (>5%)
  - Hot flushes (13.9%)
  - Anemia (10.4%)
  - Headache (6.8%)

BMD % CHANGE FROM BASELINE TO WEEK 24



- Across all treatment groups, only 2.5% of women (9/367 with BMD data for all anatomic sites), had a >8% BMD decrease, an important FDA threshold
- In the non-ABT group, BMD loss inversely related to BMI

Patients in the trial received no Vitamin D or calcium supplementation

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RECENT TRIALS WITH GNRH ANTAGONISTS IN UTERINE FIBROIDS

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	Relugolix		Elagolix	
	PRIMROSE 2	LIBERTY 1	LIBERTY 2	ELARIS 1	ELARIS 2
Dose	200mg + ABT	40mg + ABT		300mg + ABT	
Regimen	Once daily	Once daily		Twice daily	
Responder* Rate (%)	**93.9**	**73.4**	**71.3**	**68.5**	**76.5**
Amenorrhea (%)	**80.6**	**52.3**	**50.4**	**48.1**	**52.9**
Pain	✓	✓	✓	**NR****	**NR**
Fibroid volume	✓	✘	✘	**NR**	**NR**
Uterine volume	✓	✓	✓	**NR**	**NR**
Menstrual blood loss	✓	✓	✓	✓	✓
Anemia	✓	✓	✓	✓	✓
Quality of life	✓	✓	✓	✓	✓
BMD Loss (%, Spine)	**-1.31**	**-0.36**	**-0.13**	**-0.76**	**-0.61**

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

** NR = not reported

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UTERINE FIBROIDS: A MULTIBILLION MARKET WITH SIGNIFICANT UNMET NEED

Total U.S. costs estimated at up to

$34B/yr

from direct costs, lost workdays and complications

19 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

10 million

women in the U.S. are suffering from 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; 2017; Stewart et al. NEJM, 2015; Flynn et al., Am J Obstet Gynecol 2006; Truven Health, Fibroid Foundation website

PRIMROSE 2 KEY TAKE AWAYS

LINZAGOLIX is the only GnRH antagonist intended to be developed as two different SIMPLE & WELL TOLERATED regimens of administration for fibroids

1

Potentially best-in class full suppression option

- 200mg with ABT, once daily oral
- 94% response in controlling HMB
- 80% in complete suppression of bleeding (amenorrhea)

2

Potentially unique partial suppression option

- 100mg without ABT, once daily oral
- Only option under development for women who cannot or don’t want to take ABT

3

Optimal administration

- Once a day – no food interaction – no DDI

LINZAGOLIX UTERINE FIBROIDS: NEXT STEPS

LINZAGOLIX is the only GnRH antagonist intended to be developed as two different SIMPLE & WELL TOLERATED regimens of administration for fibroids

1. **PRIMROSE 2 – Primary endpoint met Q4:19** ✓
2. **PRIMROSE 1 – Primary endpoint results expected Q2:20**
3. **PRIMROSE 2 – 12-month results expected mid-2020**
4. **MAA/NDA regulatory submissions – anticipated in Q4:20 / Q1:21**

OBSEVA: MULTIPLE DEVELOPMENT PROGRAMS DRIVE VALUE

	PHASE 1	PHASE 2	PHASE 3	MARKET SIZE	NEXT MILESTONES
LINZAGOLIX (OBE2109) Oral GnRH receptor antagonist	Uterine Fibroids – Ph3 PRIMROSE 2 EU & U.S.			4M diagnosed and treated in U.S.	Positive Ph3 24W Primary endpoint Results
	Uterine Fibroids – Ph3 PRIMROSE 1 U.S.				24W Primary endpoint data Q2 2020 MAA /NDA Q4:2020/Q1:2021
	Endometriosis – Ph3 EDELWEISS 2 U.S.			2.5M diagnosed and treated in U.S. ~2.5M potentially undiagnosed	Initiated Ph3 Q2 2019
	Endometriosis – Ph3 EDELWEISS 3 EU & U.S.				
	Endometriosis – Ph2b EDELWEISS*				Positive Phase 2b results 2018/19
OBE022 Oral $PGF_{2\alpha}$ receptor antagonist	Preterm Labor – Ph2a PROLONG			500,000 annual cases in each of U.S and Europe	Interim update in 60 patients Q4 2019
	Preterm Labor – Ph1				Pre-clinical/Phase 1 complete
NOLASIBAN Oral oxytocin receptor antagonist	IVF – Ph3 IMPLANT 2/4 EU			Evaluating potential re-positioning	Positive IMPLANT 2 Ph3 Results IMPLANT 4 Ph3 missed primary endpoint

* Primary and secondary endpoints met

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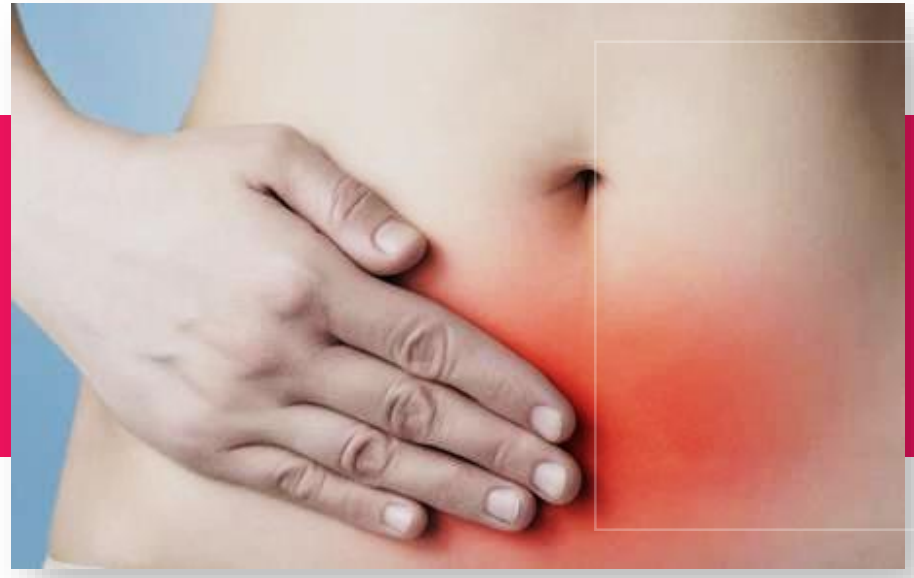
LINZAGOLIX



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THANK YOU