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nature meets nurture

Yselty® for Uterine Fibroids Clinical Results

PRIMROSE 1 up to Week 52
PRIMROSE 2 up to Week 76

10 DEC 2020

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Uterine fibroids are ruining lives …

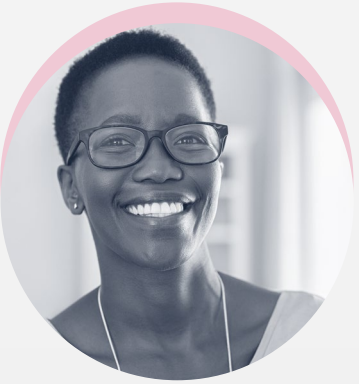
No two women are the same. But millions share a common problem: suffering the daily consequences of uterine fibroids

Yselty® 200 mg once daily with concomitant ABT

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

Yselty® 100 mg once daily without ABT

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



Yselty® 200 mg once daily without ABT

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

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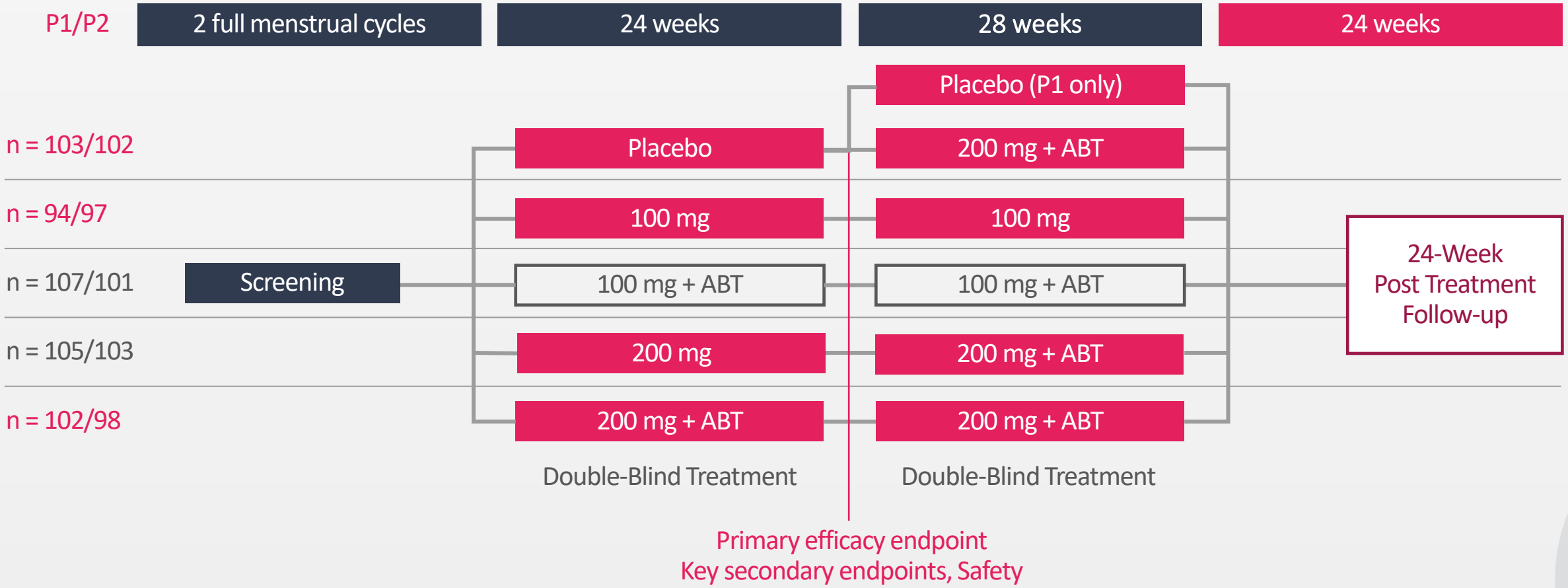
… Yselty®, designed to treat more women

Phase 3 registration studies

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



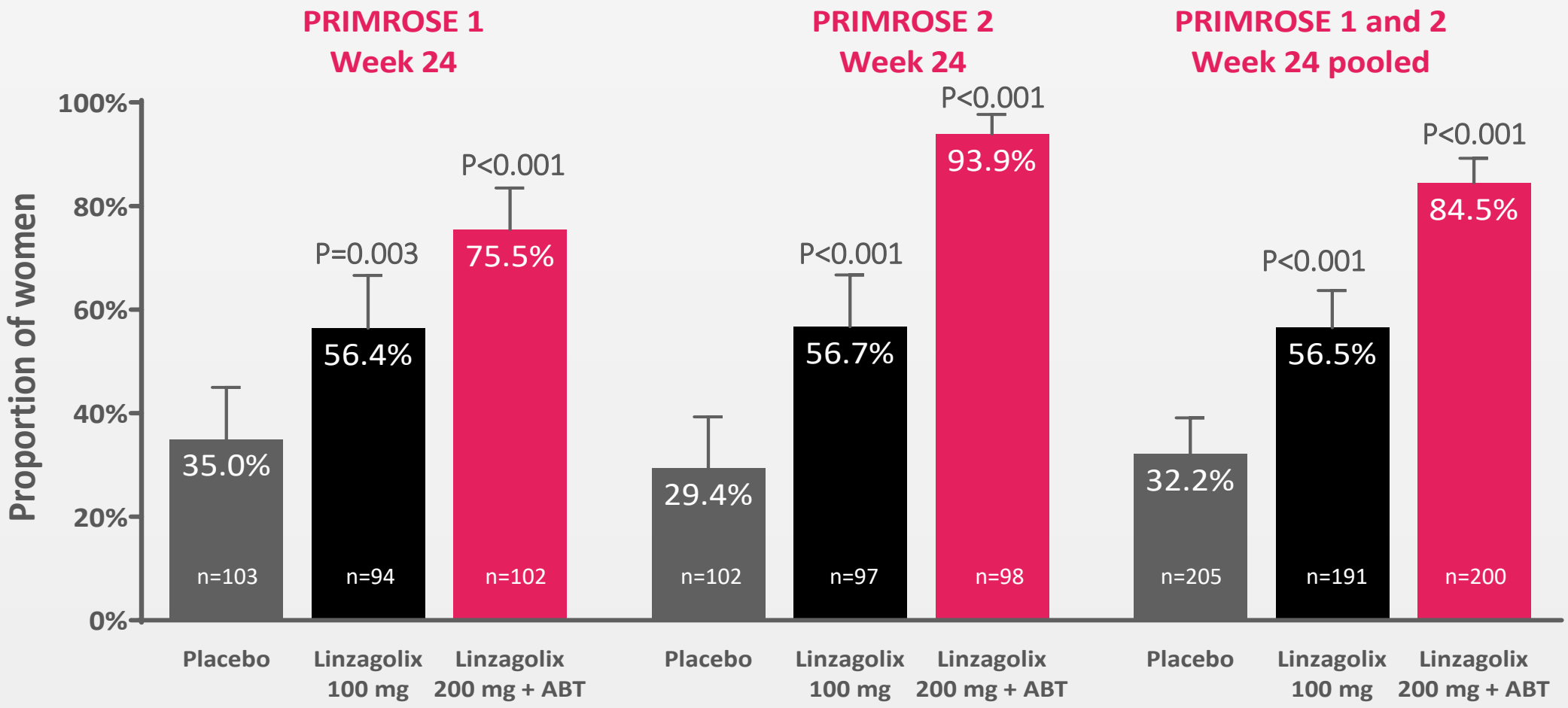
Primary efficacy endpoint is proportion of women with menstrual blood loss ≤ 80 mL (by alkaline hematin method) and ≥ 50% reduction from baseline

Patients in the studies received no Vitamin D or calcium supplementation

ABT = Add Back Therapy (1mg estradiol + 0.5 mg norethindrone acetate)

PRIMROSE 1 and 2 achieved primary endpoint for both doses

Responder* analysis at Week 24

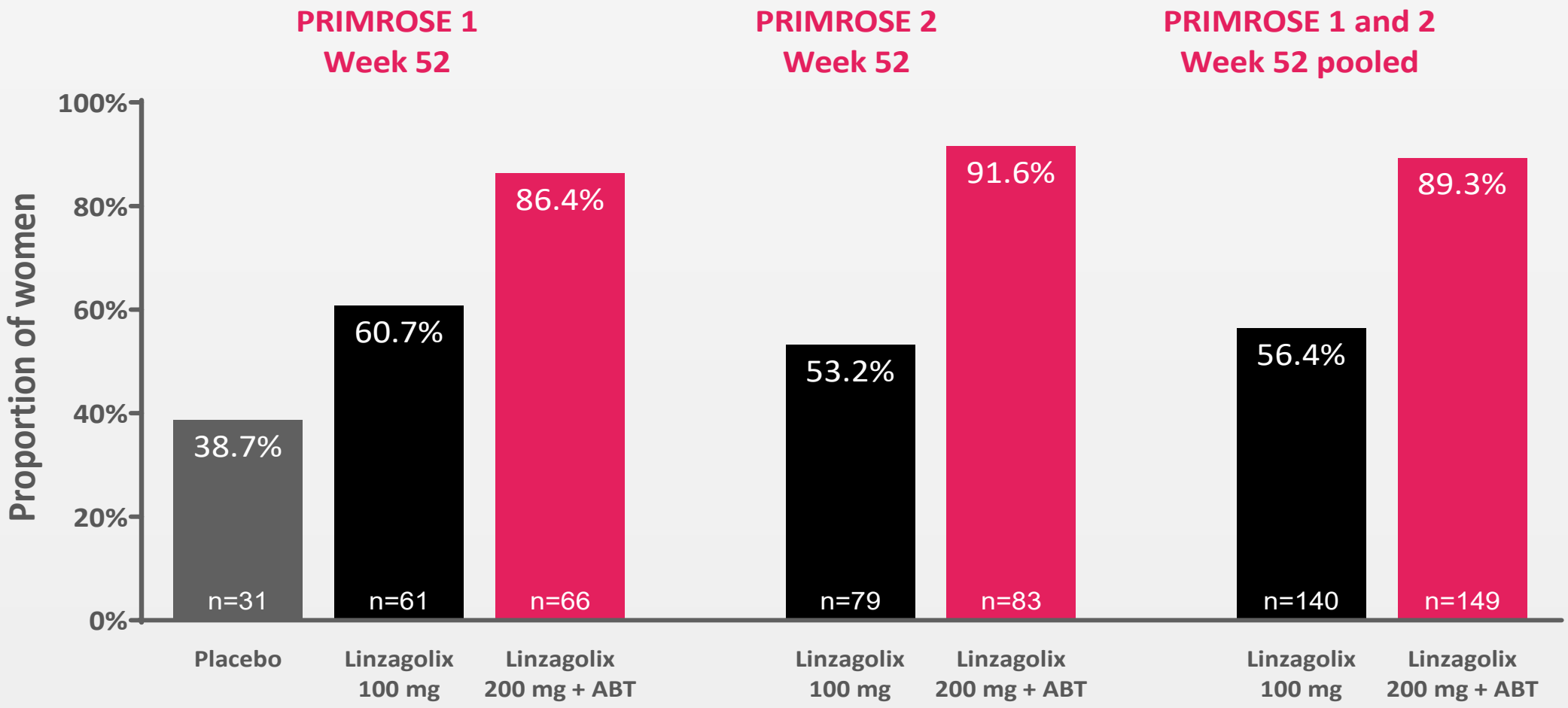


*Proportion of women with menstrual blood loss ≤ 80 mL (by alkaline hematin method) and ≥ 50% reduction from baseline

Error bars are 95% CI

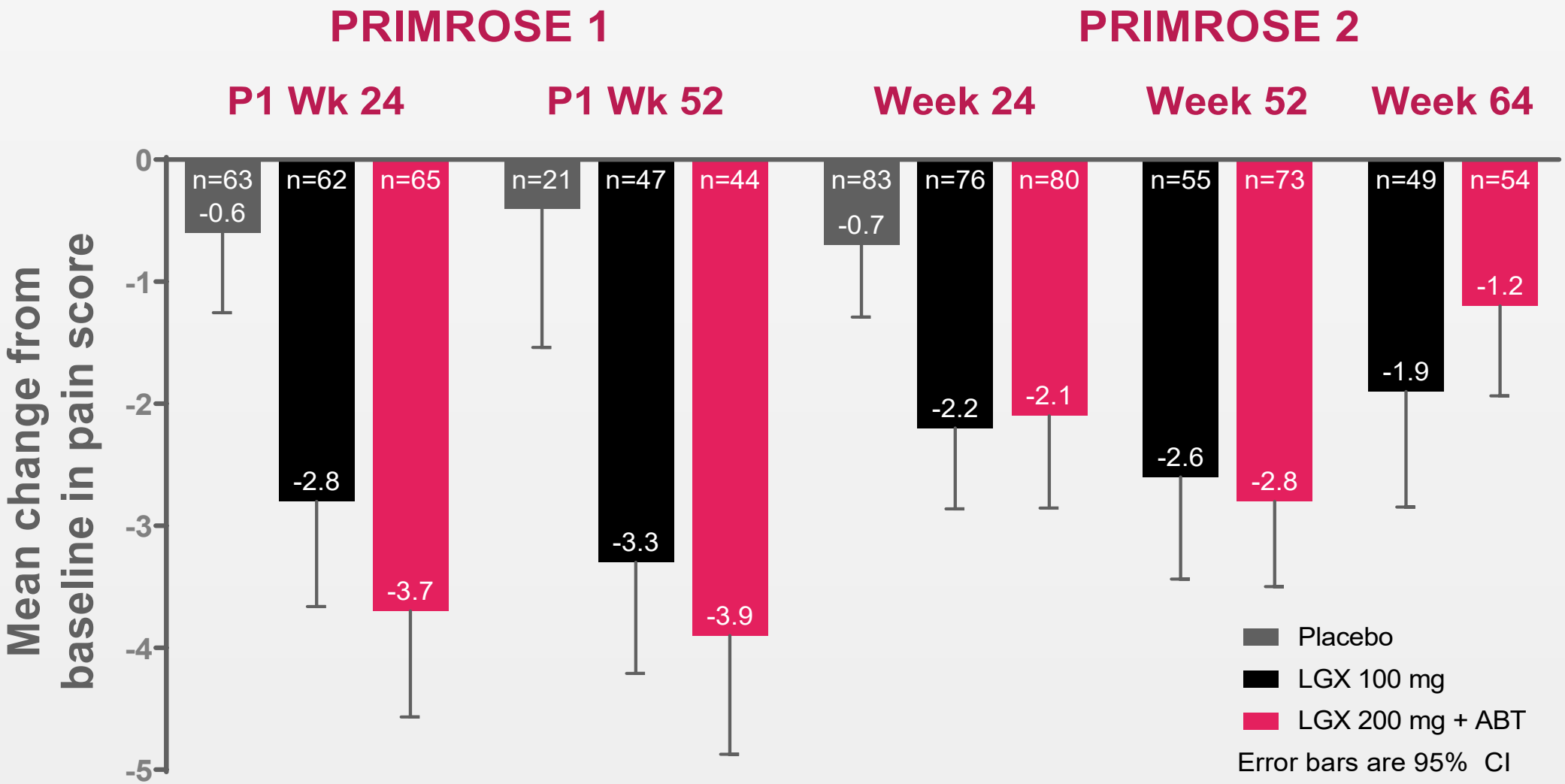
PRIMROSE 1 and 2 achieved sustained reduction in MBL

Responder* analysis at Week 52



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

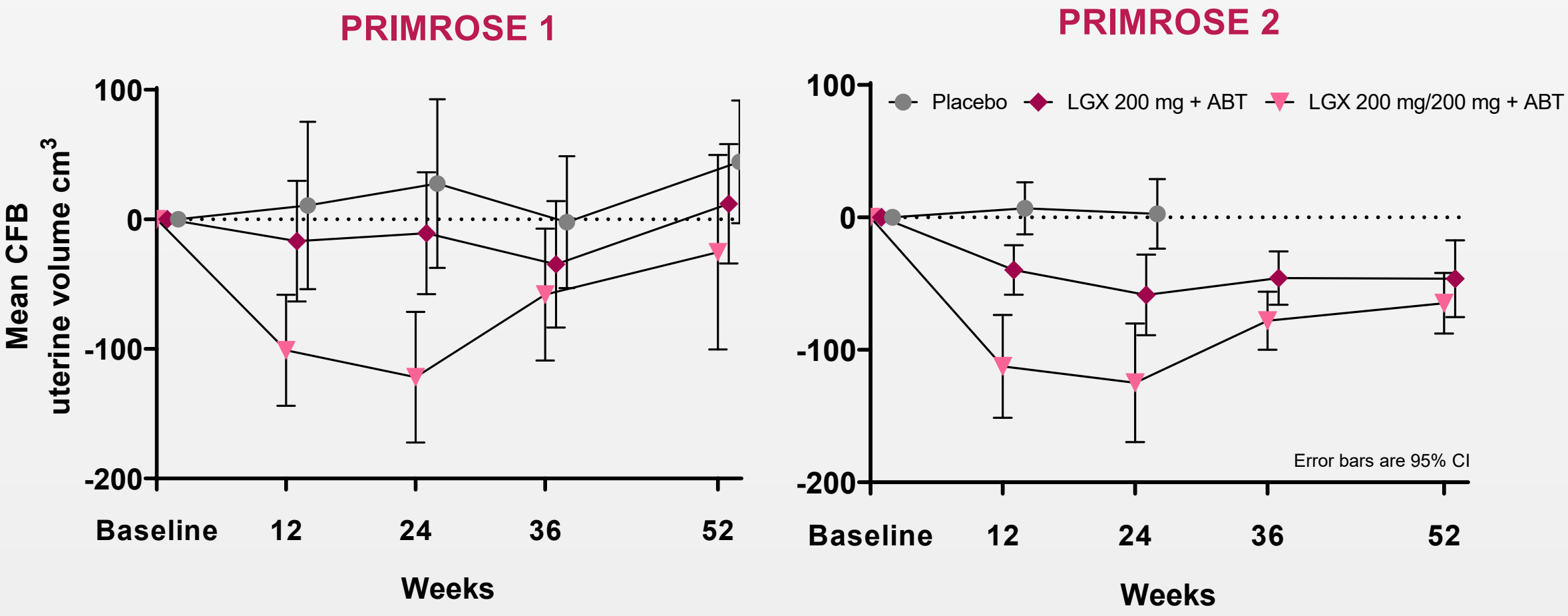
Significant pain reduction maintained at Weeks 52 and 64



Pain assessed on Numerical Rating Scale: 0-10

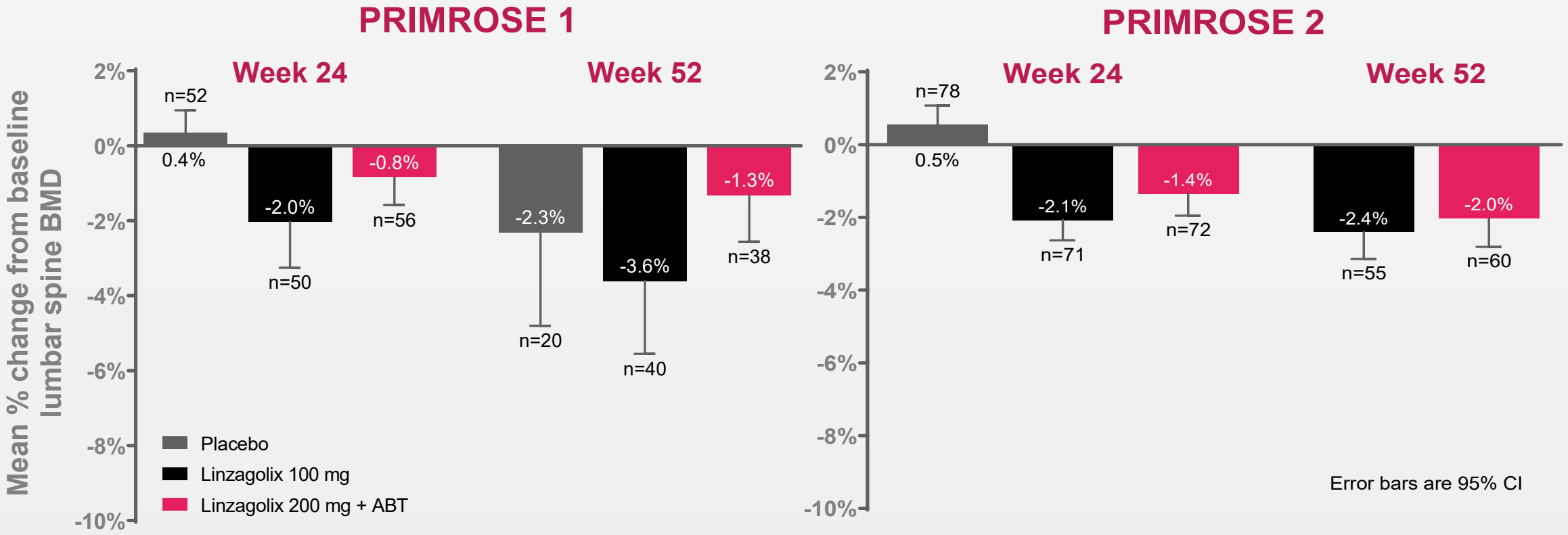
LGX 200 mg without ABT significantly reduces uterine volume

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



Minimal BMD change with both doses, plateauing after Week 24

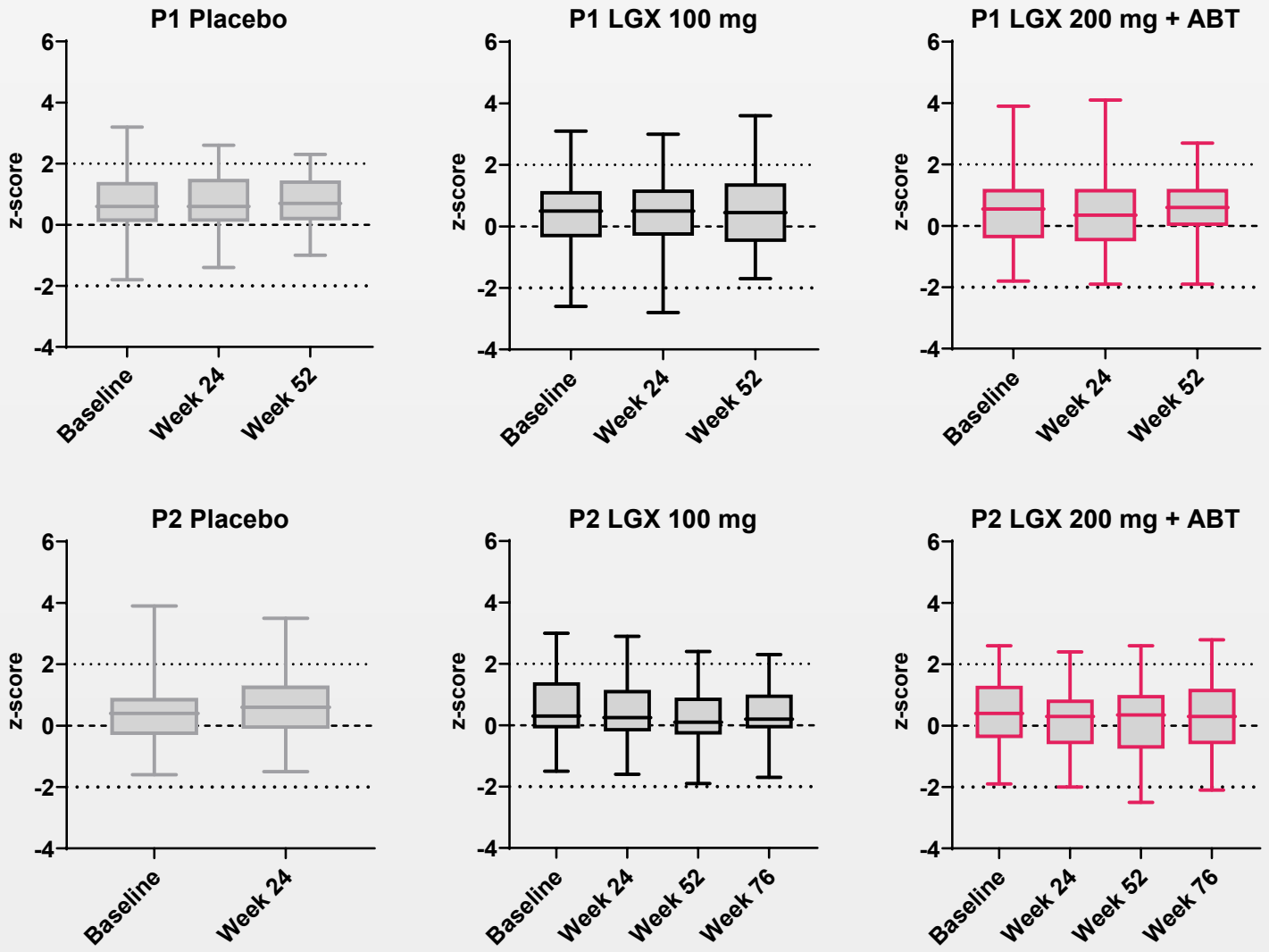
Expected age-related BMD decline observed in placebo arm at Week 52



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

Summary of adverse events – week 24 to 52

Confirmed good safety & tolerability

Number (%) of women	PRIMROSE 1			PRIMROSE 2	
	Placebo	Linzagolix 100 mg	Linzagolix 200 mg + ABT	Linzagolix 100 mg	Linzagolix 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)

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* Hypertension in an obese subject

Adverse events of interest/pregnancy – week 24 to 52

No signal related to adverse events of interest*

Number (%) of women	PRIMROSE 1			PRIMROSE 2	
	Placebo	Linzagolix 100 mg	Linzagolix 200 mg + ABT	Linzagolix 100 mg	Linzagolix 200 mg + ABT
	n=31	n=62	n=70	n=79	n=84
Suicidal ideation	0	0	0	0	0
Depression; depressed mood	0	0	0	0	0
Anxiety	0	0	0	0	0
Alopecia	0	0	0	0	1 (1.2)
Decreased libido	0	0	0	0	1 (1.2)
Pregnancy	0	0	0	1 (1.3)	0

* Adverse events of interest are AEs that are potentially related to suppression of estradiol and have been reported with Oriahnn treatment

PRIMROSE 1 & PRIMROSE 2 results

Conclusions

1

Potential best-in-class efficacy

- Efficacy sustained up to 52 weeks for all dose regimens
- Potentially best-in-class symptom control for 200 mg with ABT

2

Unique set of treatment options

- Clinically meaningful & sustained efficacy of the 100 mg without ABT
- Significant uterine volume reduction for 200 mg without ABT

3

Favorable tolerability profile

- No safety signal of concern for any of the linzagolix regimens
- BMD remains within age-matched normal ranges during and after treatment

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Thank you