



LIBERTY 1 PHASE 3 UTERINE FIBROID STUDY RESULTS

May 14, 2019

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LIBERTY 1 PHASE 3 UTERINE FIBROID STUDY RESULTS

May 14, 2019

LIBERTY 1: POSITIVE EFFICACY & SAFETY RESULTS

- ✓ **Primary endpoint achieved ($p < 0.0001$)**
 - Relugolix combination therapy: 73.4%
 - Placebo: 18.9%
- ✓ **Six key secondary endpoints achieved with statistical significance**
- ✓ **Bone density comparable to placebo**
- ✓ **Generally well tolerated with adverse event rates comparable to placebo**

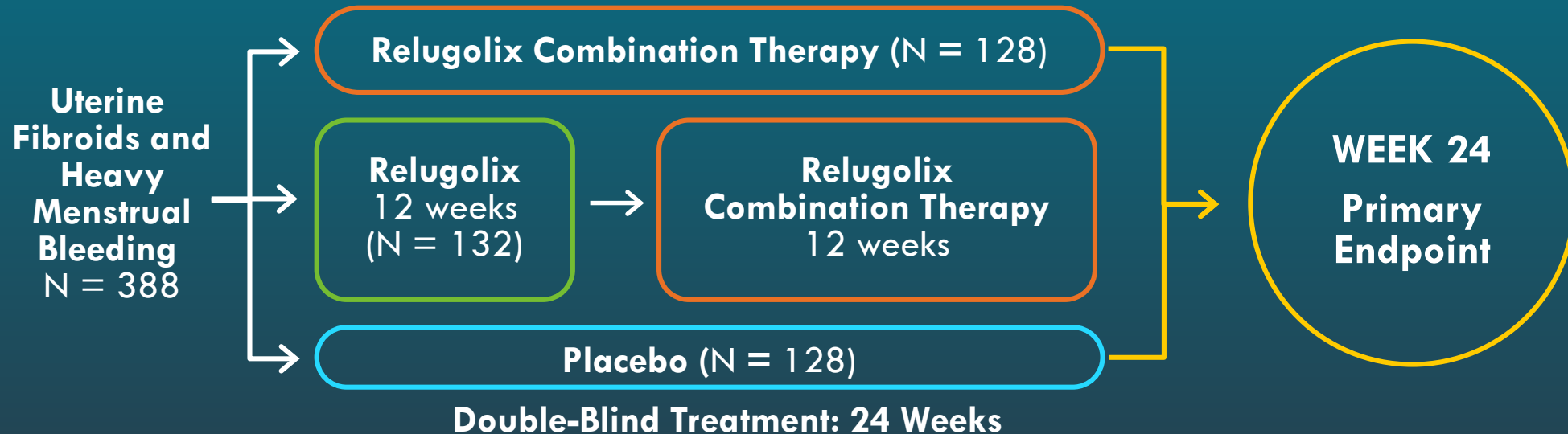
LIBERTY 1: PHASE 3 STUDY DESIGN

INCLUSION CRITERIA

Uterine fibroids and heavy menstrual bleeding: At least 160 mL during one cycle or at least 80 mL during each of two consecutive cycles

PRIMARY ENDPOINT

Proportion of women with < 80 mL menstrual blood loss/cycle and $\geq 50\%$ reduction in menstrual blood loss by alkaline hematin method



Relugolix combination therapy = relugolix 40 mg + estradiol 1.0 mg and norethindrone acetate 0.5 mg

BASELINE CHARACTERISTICS AND DEMOGRAPHICS WERE WELL-BALANCED ACROSS GROUPS

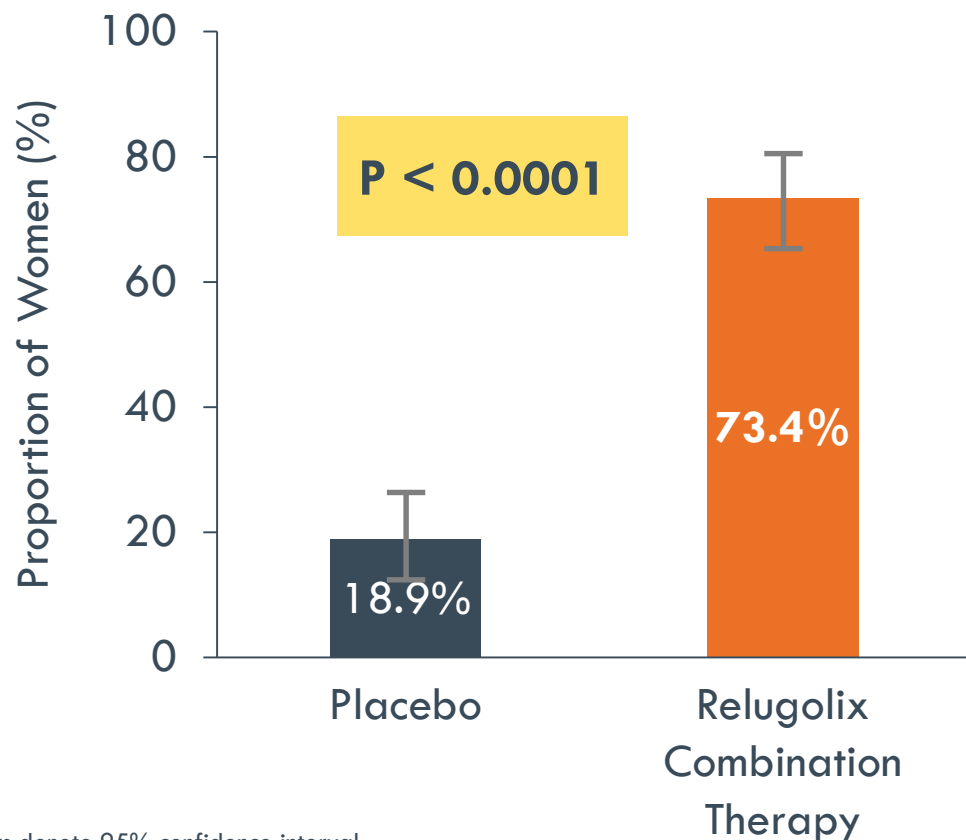
LIBERTY 1 Demographics and Baseline Characteristics	Relugolix Combination Therapy (N = 128)	Relugolix → Relugolix Combination Therapy (N = 132)	Placebo (N = 127)
Age (mean, SD in years)	42.5 (5.0)	41.3 (5.4)	42.2 (5.4)
Geographic Region (number, %)			
North America	98 (77%)	101 (76%)	98 (77%)
Rest of World	30 (23%)	31 (24%)	29 (23%)
Race (number, %)			
White	64 (50%)	53 (40%)	56 (44%)
Black	59 (46%)	67 (51%)	65 (51%)
Other	5 (4%)	12 (9%)	6 (5%)
Body Mass Index (mean, SD in kg/m ²)	31.4 (7.6)	31.4 (7.3)	32.3 (7.5)
Menstrual Blood Loss (mean, SD in mL)	239 (180)	229 (160)	219 (125)

Note: Patient numbers represent safety population (i.e., number of patients dosed)
SD = standard deviation

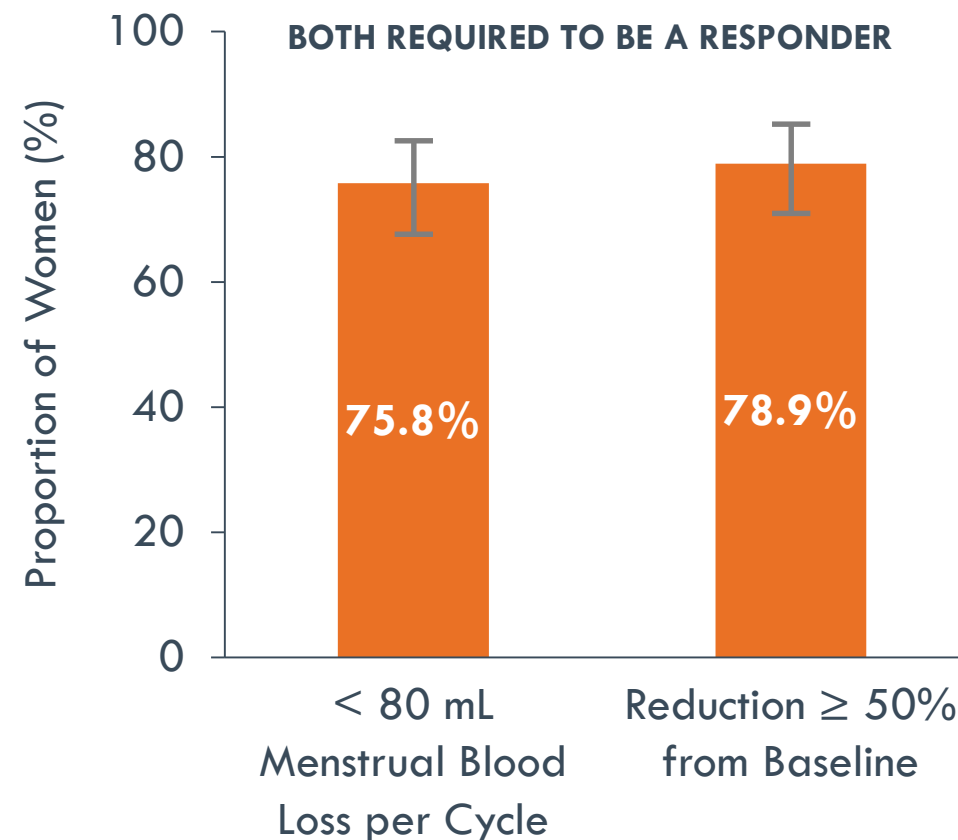
LIBERTY 1 ACHIEVED PRIMARY ENDPOINT

RESPONDER ANALYSIS

PRIMARY ENDPOINT



COMPONENTS OF PRIMARY ENDPOINT

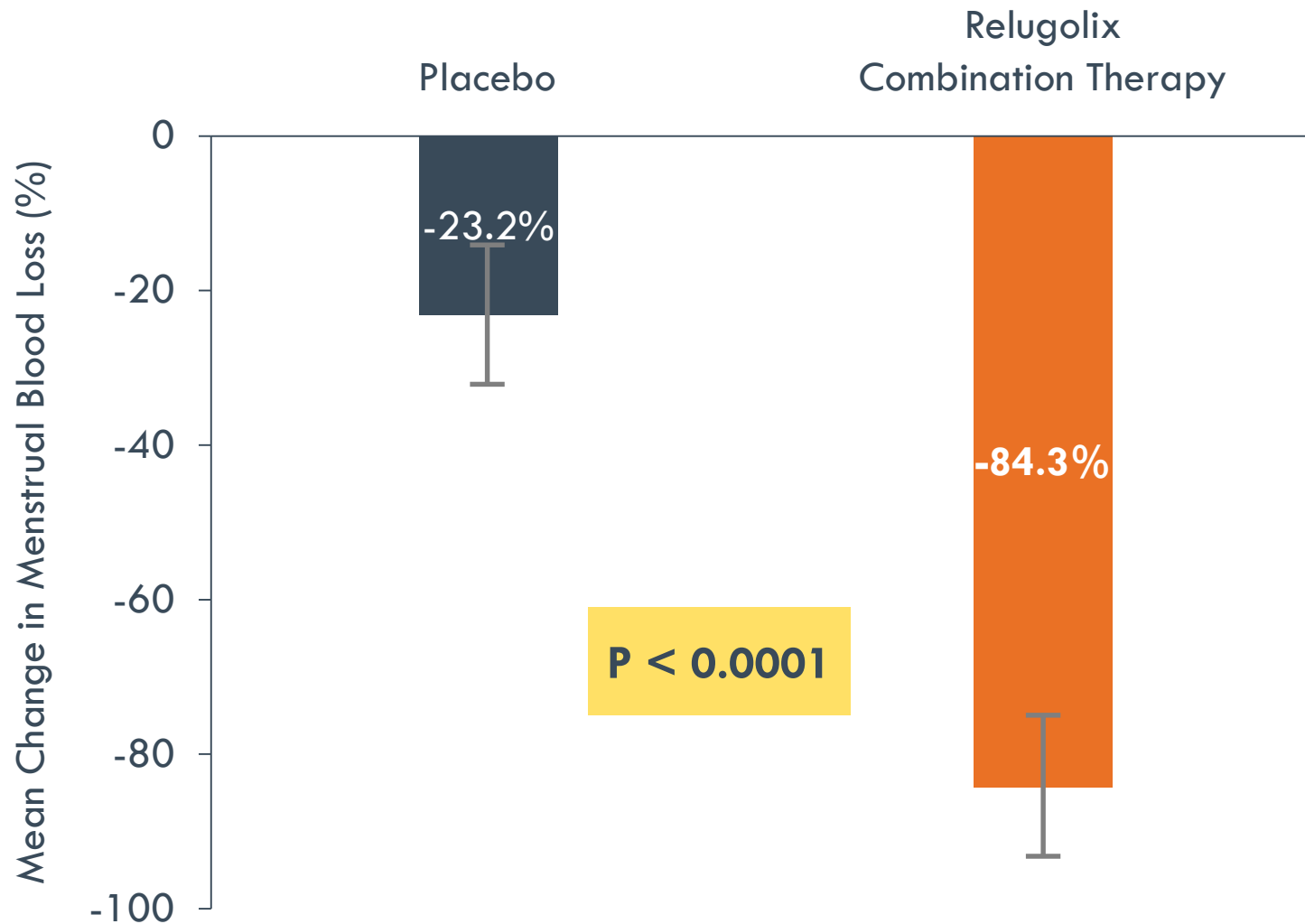


Error bars denote 95% confidence interval

Relugolix combination therapy = relugolix 40 mg + estradiol 1.0 mg and norethindrone acetate 0.5 mg

ON AVERAGE, 84.3% REDUCTION IN MENSTRUAL BLOOD LOSS AT WEEK 24

SIGNIFICANT IMPROVEMENT IN SYMPTOM MOST RELEVANT TO WOMEN



Error bars denote 95% confidence interval

Relugolix combination therapy = relugolix 40 mg + estradiol 1.0 mg and norethindrone acetate 0.5 mg

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SIX KEY SECONDARY ENDPOINTS ACHIEVED BY RELUGOLIX COMBINATION

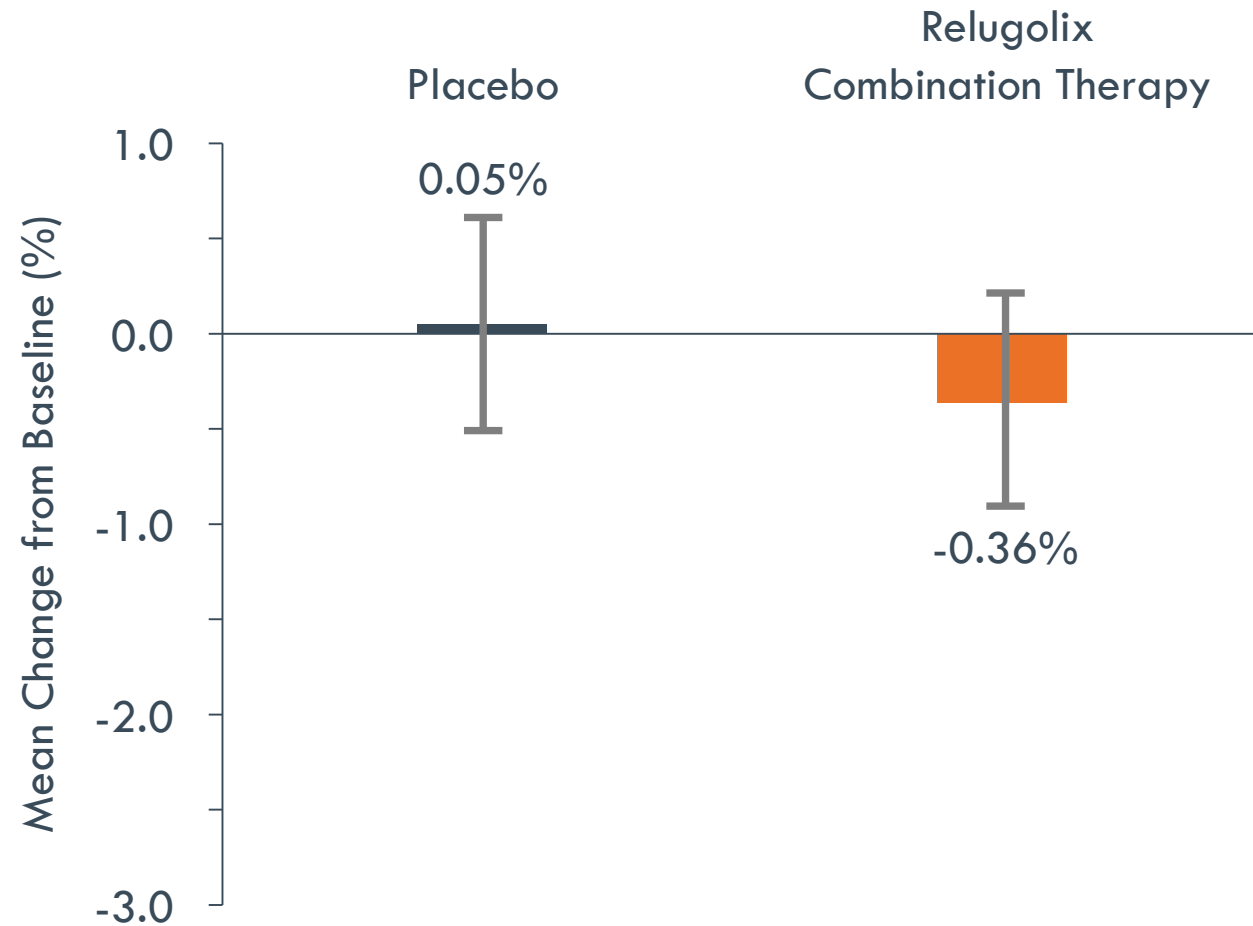
KEY SECONDARY ENDPOINTS		p-value
REDUCTION IN MENSTRUAL BLOOD LOSS	Percent mean change in menstrual blood loss from baseline to Week 24	p < 0.0001
AMENORRHEA	Proportion of women who achieve amenorrhea	p < 0.0001
REDUCTION IN PAIN	Proportion of women with a reduction in pain defined using the Numerical Rating Scale score (at least 4 at baseline; no more than 1 during the last 35 days of the study)	p < 0.0001
IMPROVEMENT IN QUALITY OF LIFE	Change in the UFS-QoL bleeding and pelvic discomfort scale score from baseline to Week 24	p < 0.0001
IMPROVEMENT IN ANEMIA	Proportion of women with improvement in anemia defined as a hemoglobin below 10.5 g/dL at study entry who achieve an increase of ≥ 2 g/dL from baseline to Week 24	p < 0.05
REDUCTION IN VOLUME	Percent change in uterine volume from baseline to Week 24	p = 0.0002
	Percent change in uterine fibroid volume from baseline to Week 24	p = 0.09*

* Not statistically significant

UFS-QoL = Uterine Fibroid Symptom Health-Related Quality of Life Questionnaire

MEAN % CHANGE FROM BASELINE TO WEEK 24 IN BONE MINERAL DENSITY (LUMBAR SPINE)

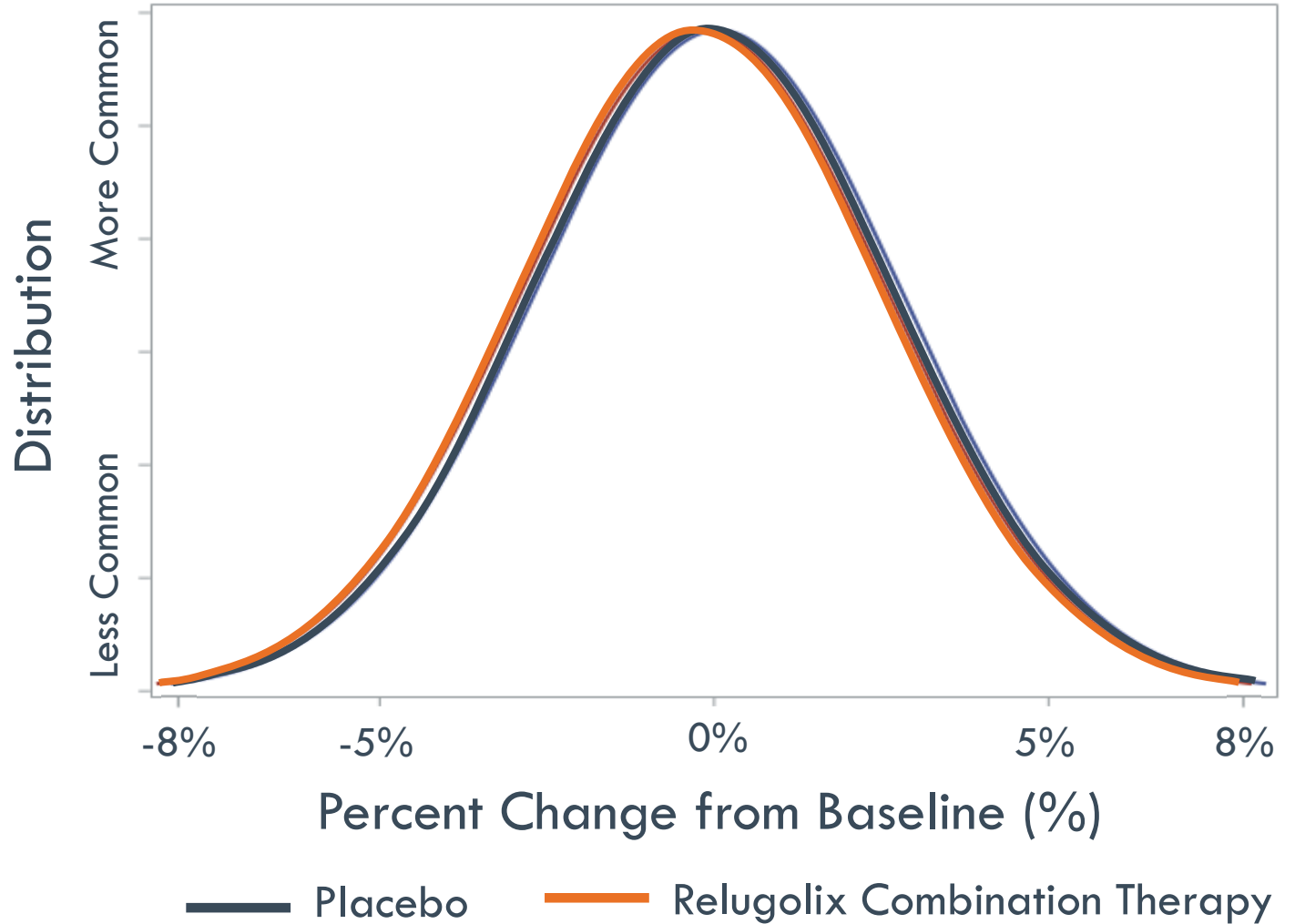
CHANGE IN
BONE DENSITY
COMPARABLE
TO PLACEBO



Error bars denote 95% confidence interval
Relugolix combination therapy = relugolix 40 mg + estradiol 1.0 mg and norethindrone acetate 0.5 mg

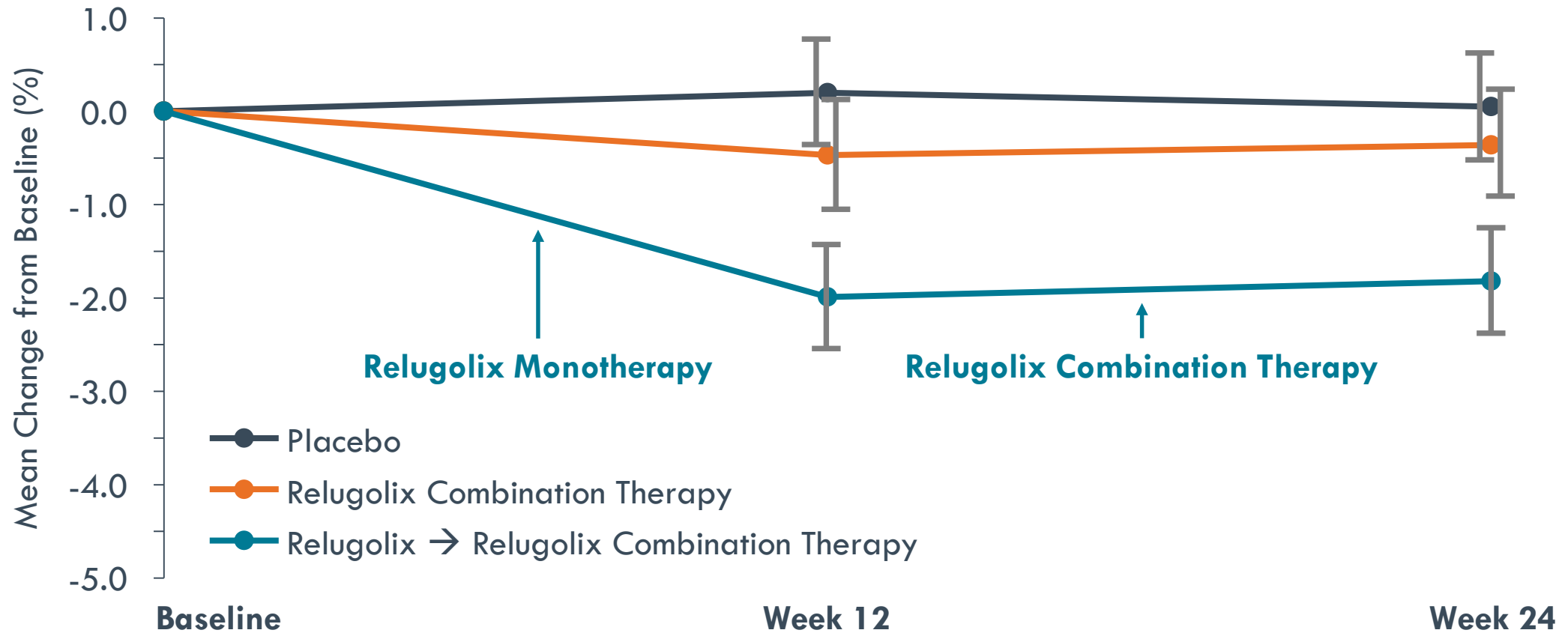
DISTRIBUTION OF CHANGE IN BONE DENSITY COMPARABLE TO PLACEBO

DISTRIBUTION OF CHANGE IN BONE MINERAL DENSITY AT WEEK 24 (LUMBAR SPINE)



Relugolix combination therapy = relugolix 40 mg + estradiol 1.0 mg and norethindrone acetate 0.5 mg

COMBINATION APPROACH MAINTAINED BONE DENSITY THROUGH 24 WEEKS (LUMBAR SPINE)



SUMMARY OF ADVERSE EVENTS

Number (%) of Women	Relugolix Combination Therapy (N = 128)	Relugolix → Relugolix Combination Therapy (N = 132)	Placebo (N = 127)
At least one adverse event	79 (62%)	96 (73%)	84 (66%)
Adverse event leading to study discontinuation	7 (5%)	16 (12%)	5 (4%)
Serious adverse event related to study drug	2 (2%)*	0	0
Pregnancy	0	0	1 (1%)
Adverse Events Occurring in ≥ 10% of Women in Any Group			
Hot flush	14 (11%)	47 (36%)	10 (8%)
Headache	14 (11%)	14 (11%)	19 (15%)

* 1 fibroid expulsion, 1 pelvic pain

Note: Patient numbers represent safety population (i.e., number of patients dosed)

Relugolix combination therapy = relugolix 40 mg + estradiol 1.0 mg and norethindrone acetate 0.5 mg

RELUGOLIX COMBINATION:

LIBERTY 1 KEY TAKEAWAYS AND NEXT STEPS

Achieved primary endpoint: 73.4% of women met responder criteria ($P < 0.0001$)

Key secondary endpoints showed benefits in pain, quality of life, and anemia, in addition to a marked reduction in bleeding

Bone mineral density comparable to placebo

Generally well-tolerated; protected women from side effects of monotherapy

Phase 3 LIBERTY 2 study results expected in Q3 2019

NDA filing planned for Q4 2019; on track to launch with single pill, once daily regimen for relugolix combination

Data to be submitted for presentation and publication in 2019

UTERINE FIBROIDS IS A DEBILITATING DISEASE

PREVALENCE

Occurs in up to **70-80%** of women by age 50; more prevalent in black women

SYMPTOMS

- 1 in 4** women experience decreased quality of life
- Heavy menstrual bleeding and anemia
 - Pain, urinary frequency, constipation
 - Pregnancy-related complications

SURGERY

~250,000 hysterectomies per year (US)
Hysterectomies account for **~70%** of fibroid procedures

HOSPITALIZATION

Responsible for **30%** of gynecologic hospitalizations among women aged 15-54

COSTS

Annual societal cost is estimated to be up to **\$34 BILLION** in the US alone, more than breast and ovarian cancers combined

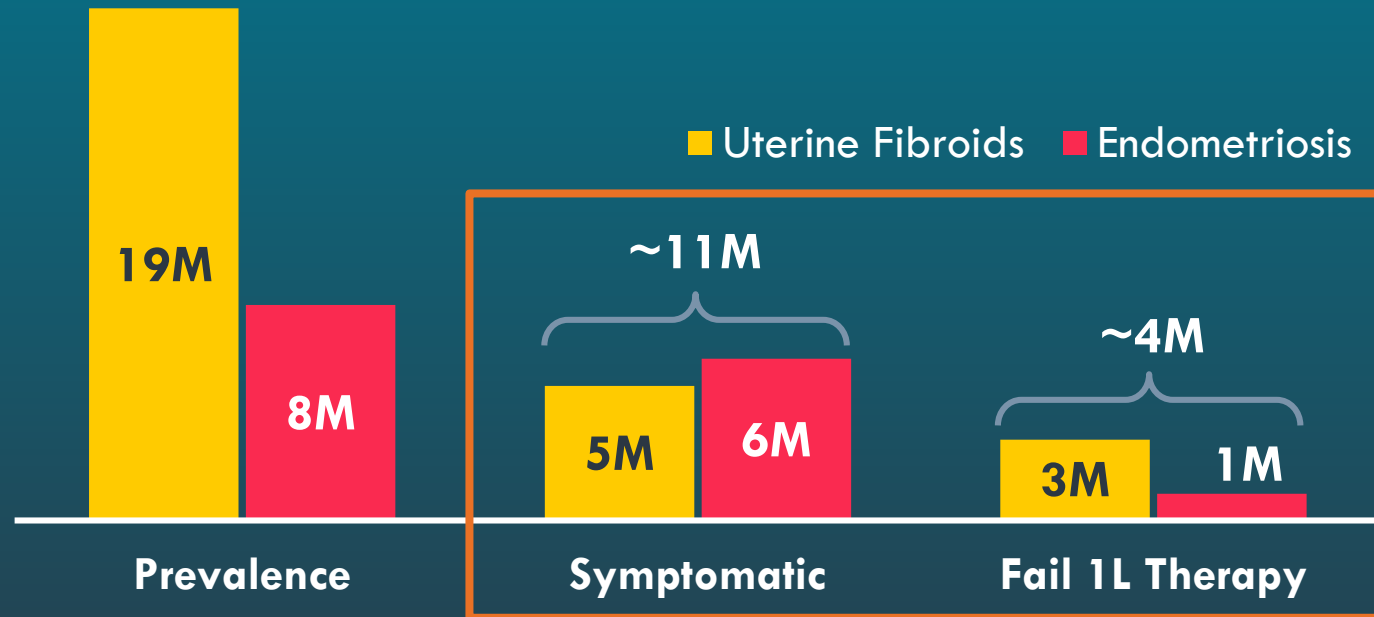
Baird, *Am J Obstet Gynecol*, 2003; Buletti *J Assist Reprod Genet*. 2010; Bulun *New Engl J Med*, 2013; Cohen, *Obstet Gynec*. 2017; Wright, *Obstet Gynec*. 2013; Barrett, Agency for Healthcare Research and Quality, 2016; Stewart, *NEJM*. 2015; Stewart *J Women's Health*, 2013; Cardozo, *Am J Obstet Gynecol* 2012

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GREAT NEED IN UTERINE FIBROIDS AND ENDOMETRIOSIS

US WOMEN AGES 15 – 49



A MULTI-BILLION DOLLAR OPPORTUNITY

Endometriosis Foundation, American College of OB/Gyn; Bulletti et al. *J Assist Reprod Genet.* 2010; Quaas et al. *Fertil Steril.* 2015; Stewart. *NEJM.* 2015; Stewart. *Lancet.* 2001; Majoribanks et al. *Cochrane Database Syst. Rev.* 2006.

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WHAT DO WOMEN AND OBGYNs WANT?



WOMEN

Pain &
Bleeding

“I want a future where I can do things and **not be controlled by the pain and bleeding**”

Safe For
Chronic Use

“Would love to find a **SAFE treatment**”

Non-Surgical
Option

“The ideal treatment would be **non-invasive**”

Convenient &
Easy to Use

“It would be **easy to take** every day”



OBGYNs

“Looking for a **reduction in bleeding** and subsequent **anemia**”

“To be able to help my patients and give them the best possible treatment with the **least harmful side effects**”

“Patients often **don't want surgery** and available medical options aren't great”

“**Convenient** so the patient will follow through with their treatment”

VISION FOR RELUGOLIX COMBINATION THERAPY

RELUGOLIX 40 MG +
ESTRADIOL AND PROGESTIN



COMBINATION THERAPY
DESIGNED TO OPTIMIZE
ESTRADIOL LEVELS

**ONE PILL
ONCE A DAY
DESIGNED
FOR WOMEN**

Provide predictable efficacy: bleeding, pain, anemia, quality of life

Maintain bone health and mitigate hot flashes

Enable long-term use

Improve patient adherence and therapeutic effect

Minimize spotting and breakthrough bleeding

Prevent ovulation to minimize risk of pregnancy on therapy

Relugolix is an investigational drug that has not been approved for use; these are aspirational statements

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RECENT STUDIES INVESTIGATING ORAL GnRH ANTAGONISTS FOR UTERINE FIBROIDS

NOTE: No direct head-to-head data available - Caution advised when comparing information across clinical studies

	LIBERTY 1	ELARIS UF-1	ELARIS UF-2
Dosing	Once Daily	Twice Daily	
	Same dose for Endometriosis	Different doses for Endometriosis	
Responder Rate: Heavy Menstrual Bleeding	73.4%	68.5%	76.2%
Bone Mineral Density Loss at 24 Weeks (Lumbar Spine)	-0.36%	-0.75%	-0.61%
Key Secondary Endpoints Achieved	<ul style="list-style-type: none"> ✓ Pain ✓ Uterine volume ✓ Menstrual blood loss ✓ Amenorrhea ✓ Anemia ✓ Quality of life 	<ul style="list-style-type: none"> ✗ Not reported ✗ Not reported ✓ Menstrual blood loss ✓ Amenorrhea ✓ Anemia ✓ Quality of life 	

MYOVANT'S LATE-STAGE PIPELINE

