



## Top-Line Results:

- Phase 3 Endometriosis SPIRIT 2 Study
- Ovulation Inhibition Study

April 22, 2020



*Redefining Care*

# Forward-looking Statements

This presentation contains forward-looking statements, including without limitation, statements related to: statements and quotes regarding Myovant Sciences' aspirations to become the leading healthcare company focused on redefining care for women's health and prostate cancer; statements summarizing and characterizing data from the SPIRIT 2 and ovulation inhibition studies; the expected timing of results from the second Phase 3 study in endometriosis (SPIRIT 1); Myovant's vision of a one dose, one pill, once a day treatment that balances clinically meaningful symptom relief with a well-tolerated safety profile for women suffering from endometriosis and uterine fibroids; the estimated market size for endometriosis and commercial potential for relugolix combination tablet for the treatment of women with endometriosis; the timing and success of Myovant's regulatory filings and potential approvals; Myovant's business strategies, financial condition and trends, competitive position, potential growth opportunities, the effects of competition and expectations or probabilities for success. Forward-looking statements can be identified by "anticipate," "believe," "can," "continue," "could," "estimate," "expect," "intend," "likely," "may," "might," "objective," "ongoing," "plan," "potential," "predict," "project," "should," "to be," "will," "would," or the negative or plural of these words or other similar expressions or variations, although not all forward-looking statements contain these identifying words. Myovant cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur and actual results could differ materially from those expressed or implied by these forward-looking statements. Forward-looking statements are subject to a number of risks, uncertainties, assumptions and other factors known and unknown that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, risks relating to those discussed under the heading "Risk Factors" in Myovant Sciences' Quarterly Report on Form 10-Q filed on February 10, 2020, and other filings that Myovant makes with the SEC from time to time. These risks are not exhaustive. New risk factors emerge from time to time and it is not possible for its management to predict all risk factors, nor can Myovant assess the impact of all factors on its business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. These statements are inherently uncertain, and investors are cautioned not to unduly rely upon these statements. Except as required by law, Myovant undertakes no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.



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*Redefining Care*



# Redefining Care. For Women. For Men. For You.



Phase 3 LIBERTY 1 Study  
in Uterine Fibroids



Phase 3 HERO Study  
in Prostate Cancer



Phase 3 LIBERTY 2 Study  
in Uterine Fibroids



NDA Submission in  
Prostate Cancer

“ *It feels like I’m constantly being stabbed on the inside... I don’t want to move, because every time I move it feels like my insides are ripping themselves apart.* ”

## Redefining **care for women.**

“ *When I am in pain, I want to either stay at home on a couch or stay in bed and don’t really want to be around anybody.* ”



# Millions of Women In Need of Better Medicines for **Endometriosis**

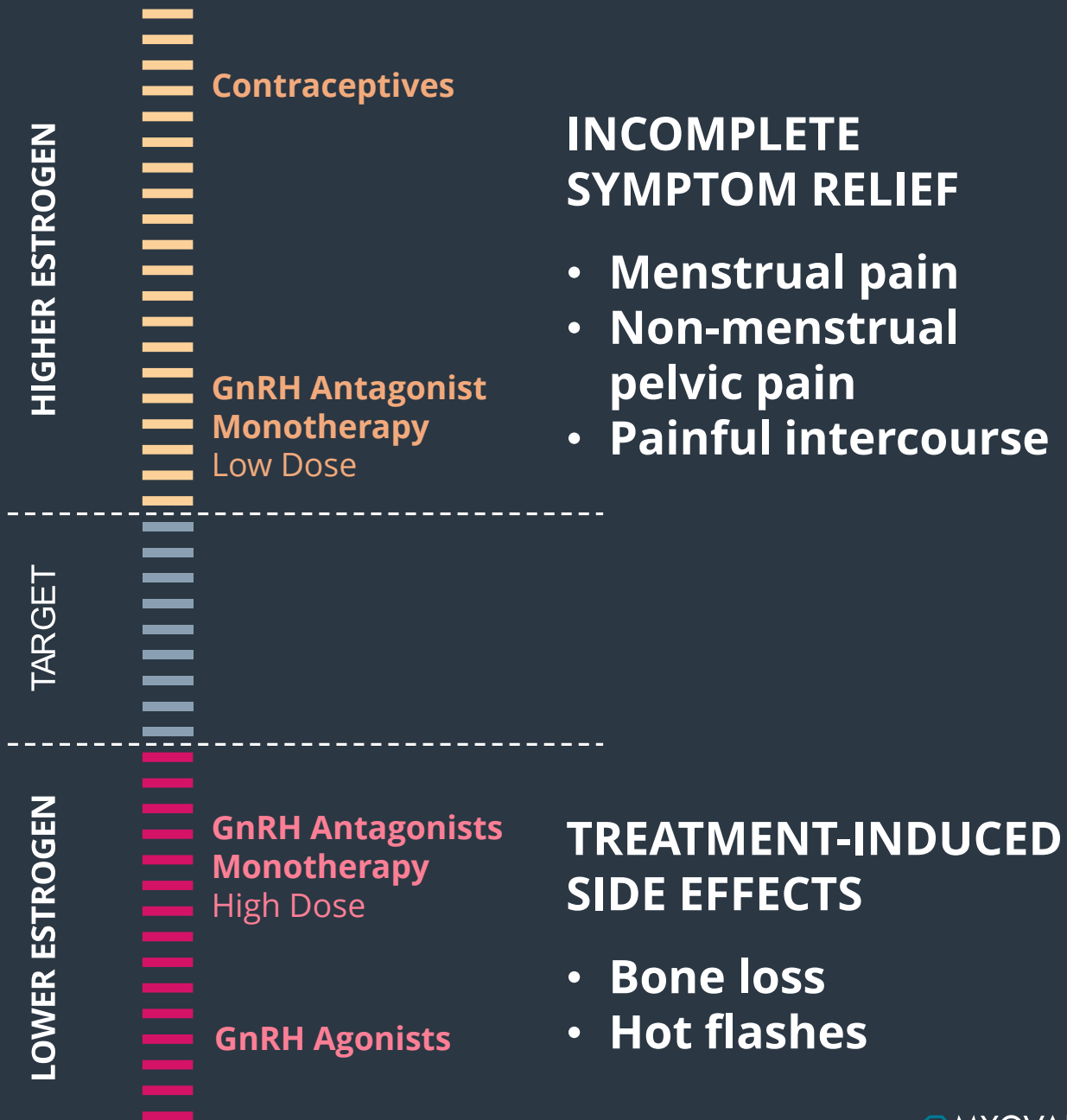
**~1M women**  
remain symptomatic  
on first-line  
therapy in U.S.

**~100,000**  
hysterectomies  
each year  
in U.S.

**>\$70B**  
**per year**  
annual societal  
cost

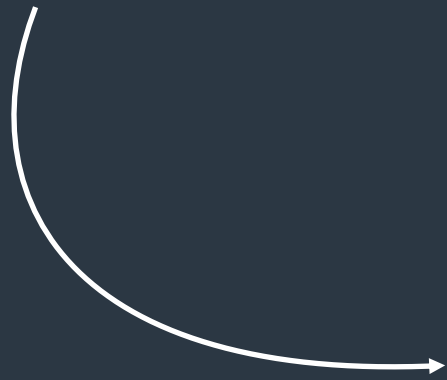
Bulletti et al. J Assist Reprod Genet. 2010; Quaas et al. Fertil Steril. 2015;  
Simoens et al. Human Reproduction. 2012; Wright et al. Obstet Gynecol. 2013;  
Cohen et al. Obstet Gynecol. 2017.

# A Clearly Defined Gap in Treatment in Endometriosis



# Relugolix Combination Vision

Intentionally  
Designed to Fill  
Treatment Gap



**HIGHER ESTROGEN**

Contraceptives

GnRH Antagonist Monotherapy Low Dose

**TARGET**

**RELUGOLIX COMBINATION VISION**

- Reduction in pain
- Well-tolerated with bone health maintained
- One dose, one pill, once a day

**LOWER ESTROGEN**

GnRH Antagonist Monotherapy High Dose

GnRH Agonists

**INCOMPLETE SYMPTOM RELIEF**

- Menstrual pain
- Non-menstrual pelvic pain
- Painful intercourse

**TREATMENT-INDUCED SIDE EFFECTS**

- Bone loss
- Hot flashes

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



# Positive Study Results

## SPIRIT 2 STUDY

- ✔ Co-primary endpoints achieved with significant pain reduction ( $p < 0.0001$ )  
Dysmenorrhea responders: **75.2%**  
Non-menstrual pelvic pain responders: **66.0%**
- ✔ 75.1% reduction on NRS for menstrual pain from 7.2 (severe) to 1.7 (mild)
- ✔ Six key secondary endpoints achieved
- ✔ Generally well-tolerated including minimal bone mineral density loss

## OVULATION INHIBITION STUDY

- ✔ 100% ovulation inhibition & 100% return to ovulation or menses

NRS = Numerical Rating Scale

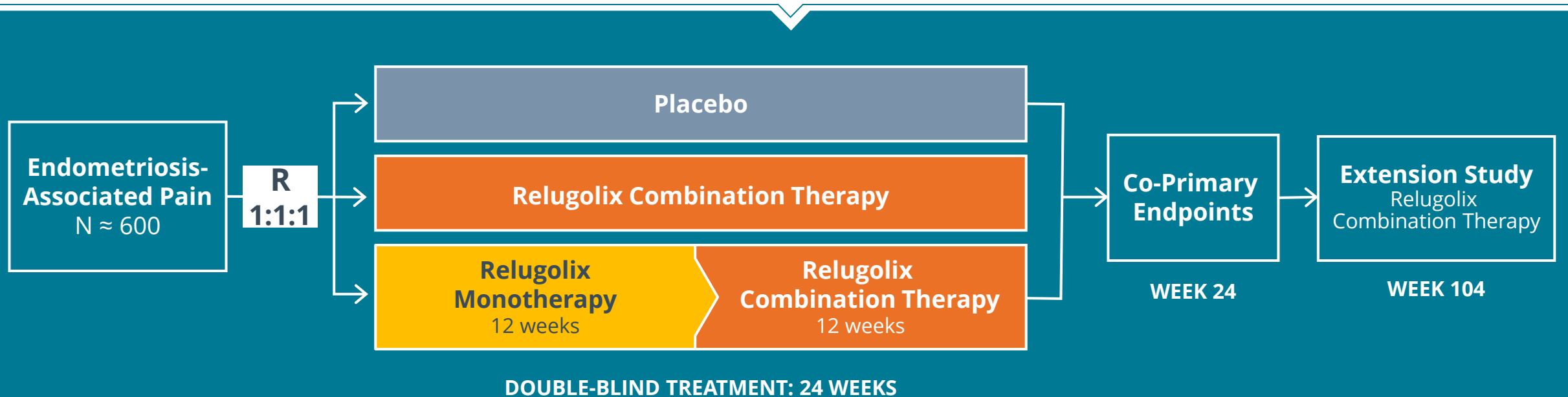
# Phase 3 Study Design – SPIRIT 2

## Inclusion Criteria

Moderate-to-severe pain in women with a surgical diagnosis of endometriosis in the last 10 years

## Co-Primary Endpoints

Proportion of women with a clinically-meaningful reduction in dysmenorrhea (menstrual pain) and non-menstrual pelvic pain as assessed using the Numerical Rating Scale (NRS)



# Primary Endpoint Assessment

Numerical Rating Scale by Daily Electronic Diary

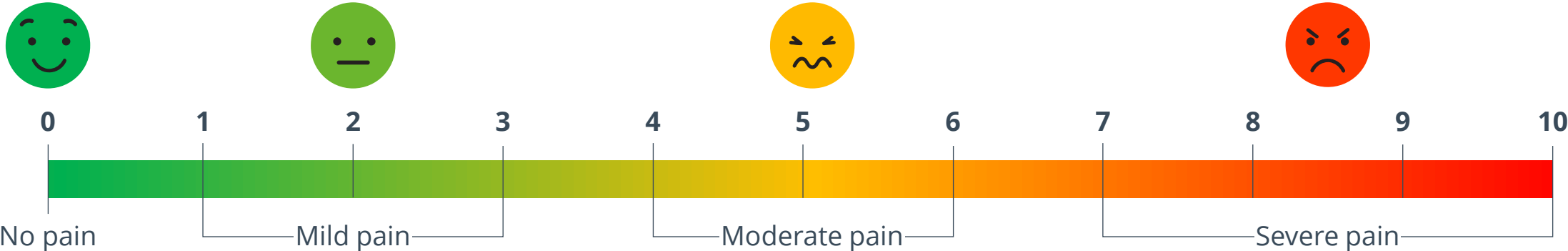
**Primary Endpoint #1**

**Primary Endpoint #2**

Clinically-meaningful reduction  
in **dysmenorrhea score**

Clinically-meaningful reduction  
in **non-menstrual pelvic pain score**

## Numerical Rating Scale (NRS)



Description is illustrative; face icons not part of instrument. Women selected individual integers in SPIRIT 2.

# Baseline Demographics Balanced Across Groups



Placebo  
(N = 204)



Relugolix  
Combination Therapy  
(N = 206)



Relugolix → Relugolix  
Combination Therapy  
(N = 206)

SPIRIT 2 Demographics	Placebo (N = 204)	Relugolix Combination Therapy (N = 206)	Relugolix → Relugolix Combination Therapy (N = 206)
Age (Median, Range In Years)	34 (18-50)	34 (20-49)	34 (18-49)
Geographic Region (Number, %)			
North America	49 (24%)	50 (24%)	50 (24%)
Rest Of World	155 (76%)	156 (76%)	156 (76%)
Race (Number, %)			
White	183 (90%)	186 (90%)	188 (91%)
Black	12 (6%)	14 (7%)	10 (5%)
Other	9 (4%)	6 (3%)	8 (4%)
Body Mass Index (Mean, SD In kg/m <sup>2</sup> )	25.8 (6.0)	26.1 (6.5)	26.2 (5.9)

SD = standard deviation

# Baseline Characteristics Balanced Across Groups



Placebo  
(N = 204)



Relugolix  
Combination Therapy  
(N = 206)

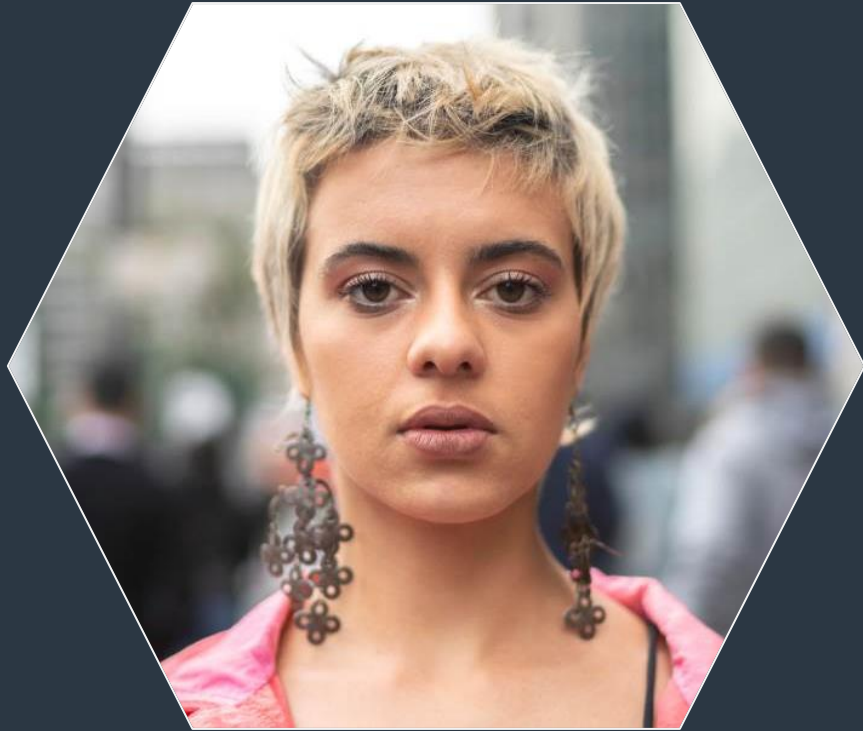


Relugolix → Relugolix  
Combination Therapy  
(N = 206)

SPIRIT 2 Characteristics	Placebo (N = 204)	Relugolix Combination Therapy (N = 206)	Relugolix → Relugolix Combination Therapy (N = 206)
Time Since Surgical Diagnosis (Mean, SD in Years)	3.8 (3.0)	4.1 (3.5)	4.2 (3.5)
Dysmenorrhea NRS score (Mean, SD)	7.0 (1.6)	7.1 (1.6)	6.9 (1.5)
Non-Menstrual Pelvic Pain NRS Score (Mean, SD)	5.5 (1.9)	5.8 (1.9)	5.5 (1.9)
EHP-30 Pain domain (Mean, SD)	55.0 (16.2)	56.2 (17.1)	55.5 (15.2)

NRS = Numerical Rating Scale. EHP-30 = Endometriosis Health Profile-30, ranges 0-100 with 100 = incapacitation.

# Before Treatment: Women in SPIRIT 2

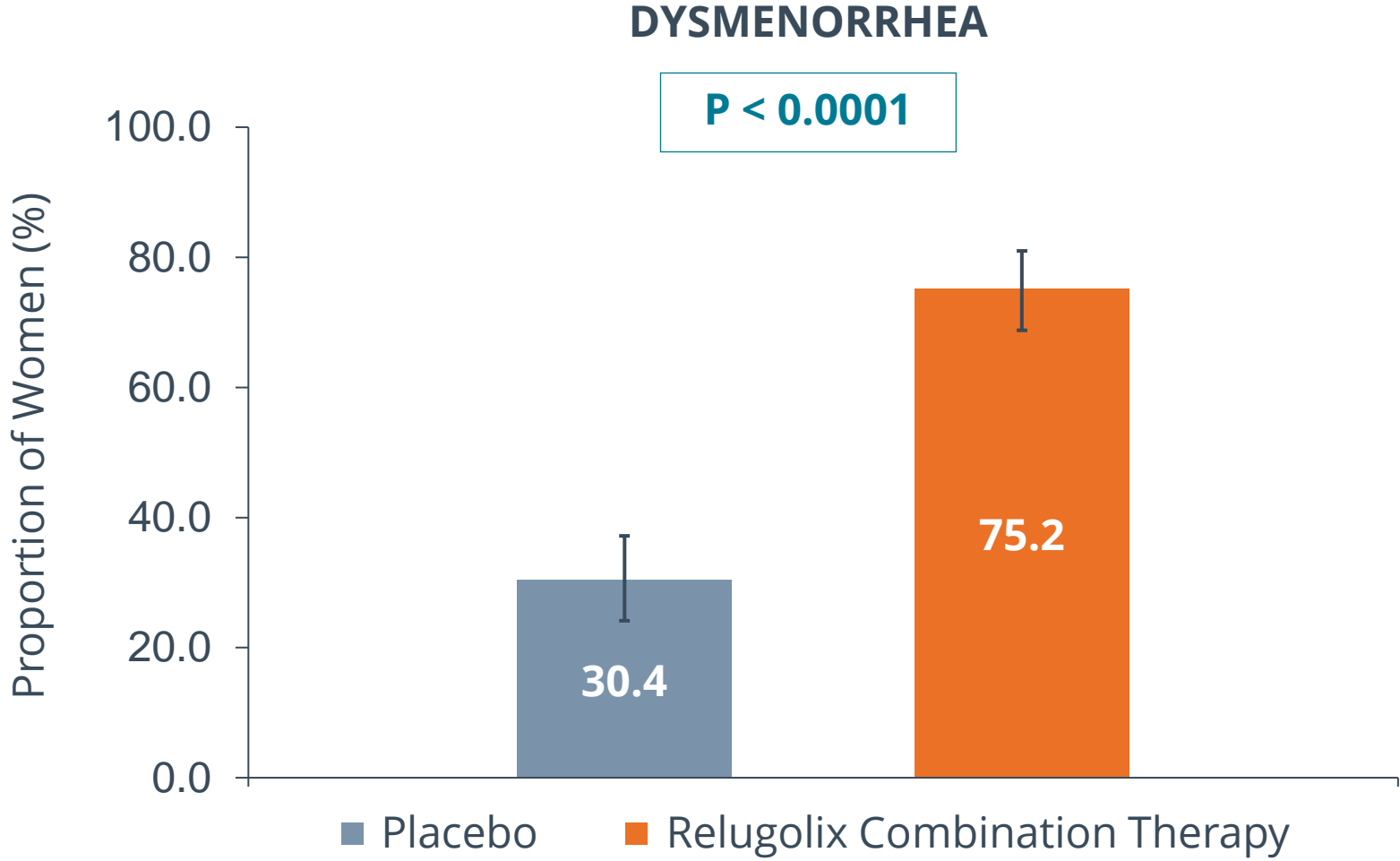


**54%** of women had severe dysmenorrhea on the NRS ( $\geq 7$ )

**48%** of women taking opioids

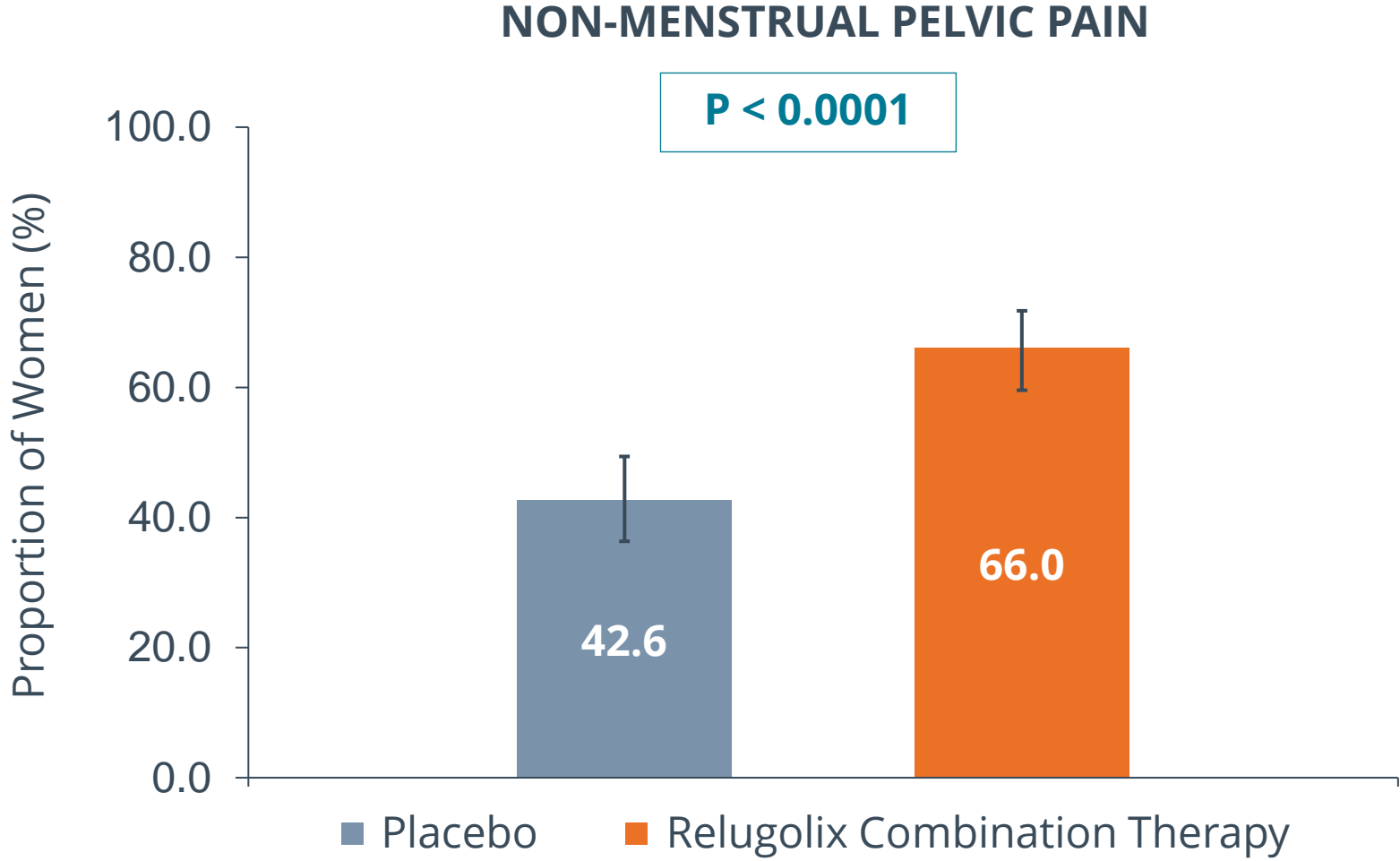
**92%** of women reported moderate, significant, or very significant impact on their daily activities

# SPIRIT 2: Achieved Co-Primary Endpoints



Error bars denote 95% confidence interval

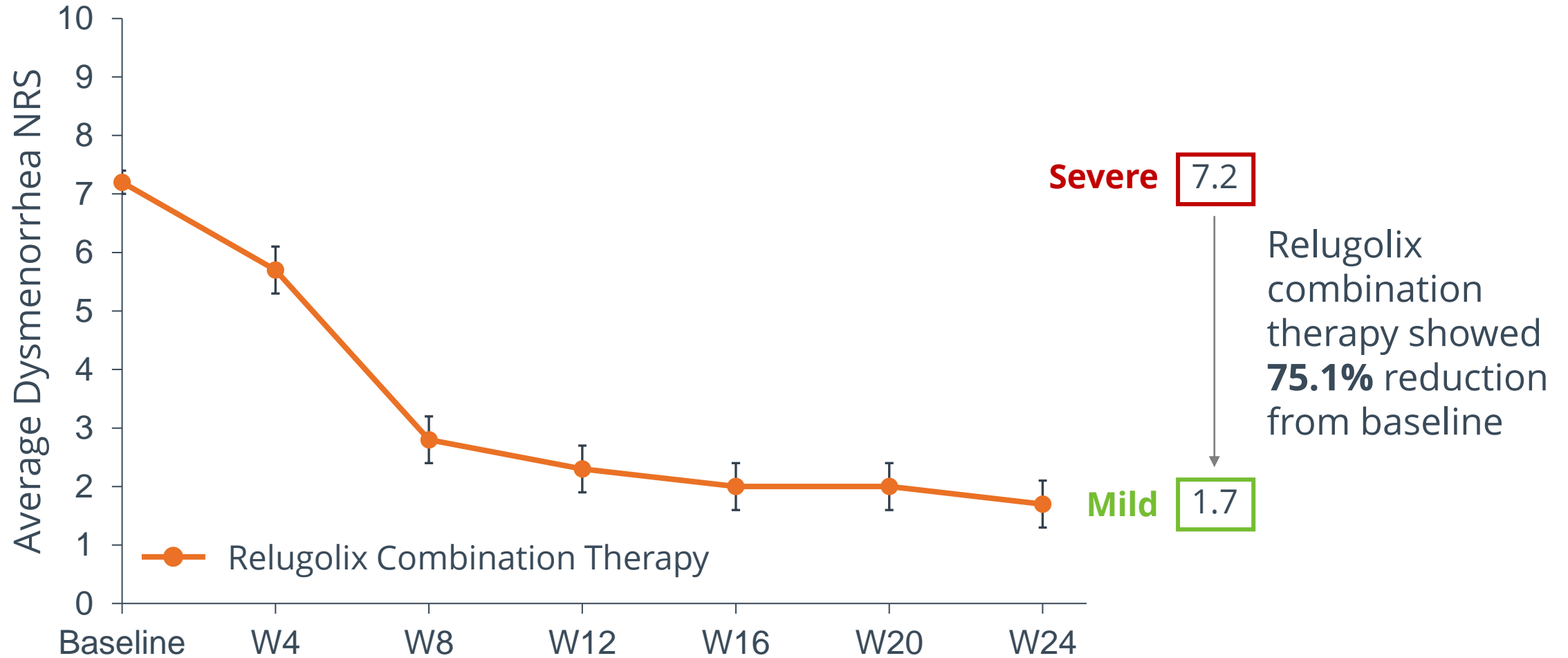
# SPIRIT 2: Achieved Co-Primary Endpoints



Error bars denote 95% confidence interval



# Average Menstrual Pain NRS Score Through Week 24



Error bars denote 95% confidence interval. NRS = Numerical Rating Scale.

PROPRIETARY

Relugolix Combination Therapy = relugolix 40 mg + estradiol 1.0 mg and norethindrone acetate 0.5 mg

# Six Key Secondary Endpoints Achieved

Key Secondary Endpoints (SPIRIT 2)	p-value
<b>Reduction in Menstrual Pain</b>	Change in dysmenorrhea NRS from baseline to Week 24
<b>Reduction in Overall Pelvic Pain</b>	Change in pelvic pain NRS from baseline to Week 24
<b>Improvement in Daily Activities</b>	Change in EHP-30 Pain Domain from baseline to Week 24
<b>Reduction in Opioid Use</b>	Proportion of women not using opioids for endometriosis-associated pain at Week 24
<b>Reduction in Non-menstrual Pelvic Pain</b>	Change in non-menstrual pelvic pain NRS from baseline to Week 24
<b>Reduction in Pain During Intercourse</b>	Change in dyspareunia NRS from baseline to Week 24
<b>Reduction in Analgesic Use</b>	Change in analgesic use from baseline to Week 24

**p < 0.0001**




**P = 0.0012**

**p = 0.0489**

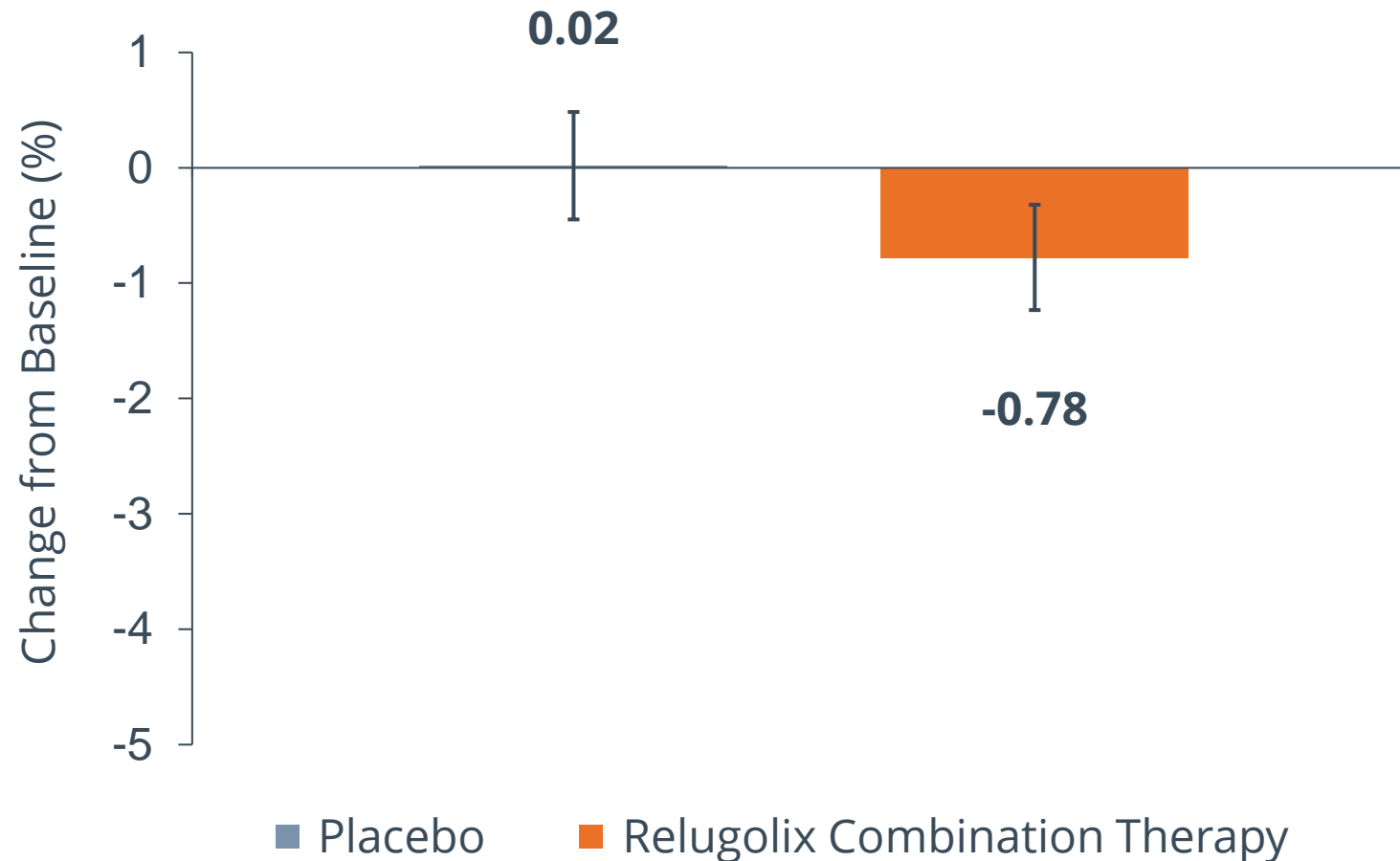
**p = 0.114\***

NRS = Numerical Rating Scale. \* = not statistically significant.

# Summary of Adverse Events

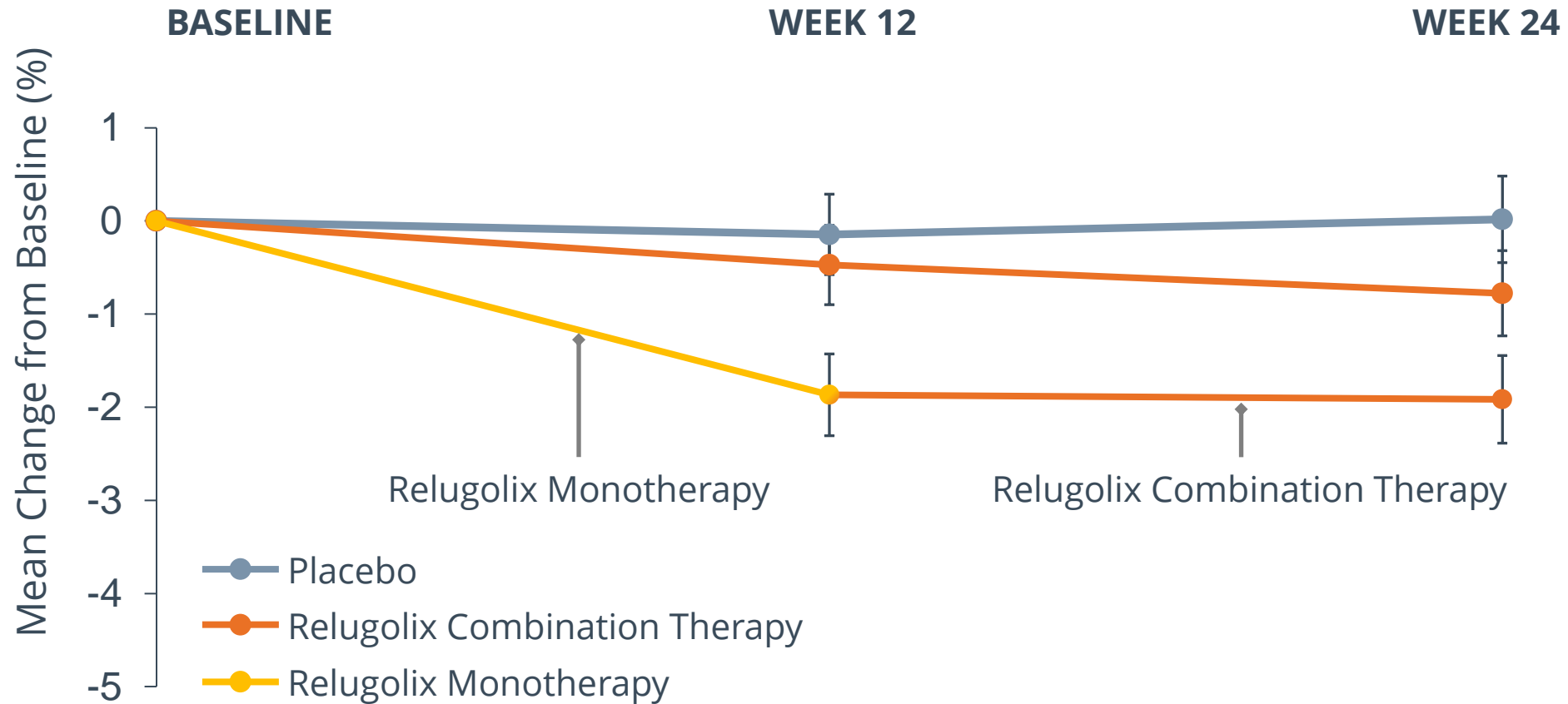
	 Placebo (N = 204)	 Relugolix Combination Therapy (N = 206)	 Relugolix → Relugolix Combination Therapy (N = 206)
Number (%) of Women			
At least one adverse event	153 (75.0%)	166 (80.6%)	168 (81.6%)
Adverse event leading to study discontinuation	8 (3.9%)	11 (5.3%)	15 (7.3%)
Serious adverse event related to study drug	1 (0.5%)	5 (2.4%)	2 (1.0%)
Pregnancy	5 (2.4%)	3 (1.4%)	0 (0.0%)
<b>Adverse Events Occurring in <math>\geq 10\%</math> Women <u>in Any Group</u></b>			
Headache	64 (31.4%)	81 (39.3%)	79 (38.3%)
Nasopharyngitis	17 (8.3%)	29 (14.1%)	14 (6.8%)
Hot flashes	7 (3.4%)	28 (13.6%)	72 (35.0%)

# Minimal Bone Mineral Density Loss at Week 24 (Lumbar Spine)



Error bars denote 95% confidence interval

# Minimal Bone Mineral Density Loss Through Week 24 (Lumbar Spine)



Error bars denote 95% confidence interval



# SPIRIT 2 Key Takeaways

- ✓ Achieved co-primary endpoints
- ✓ 75.1% reduction in menstrual pain
- ✓ Met six key secondary endpoints
- ✓ Minimal bone mineral density loss
- ✓ Generally well-tolerated

# Ovulation Inhibition Study

Primary Endpoint – proportion of women who achieved inhibition of ovulation based on the Hoogland-Skouby assessment scale (score of < 5)



67 healthy women on relugolix combination therapy evaluated during an 84-day treatment period

- Baseline cycle confirmed ovulation
- 3 cycles determined impact of relugolix combination therapy on ovulation
- Follow up determined time to return of ovulation

# Ovulation Inhibition Study

**100%**  
ovulation  
inhibition

No women ovulated during  
treatment

All women resumed ovulation  
after treatment

Avg time of return to ovulation  
**23.5 days**

Well-tolerated

**100%**  
return to  
ovulation or  
menses



# Relugolix Combination Vision: One Dose, Two Diseases

## RELUGOLIX COMBINATION TABLET\*

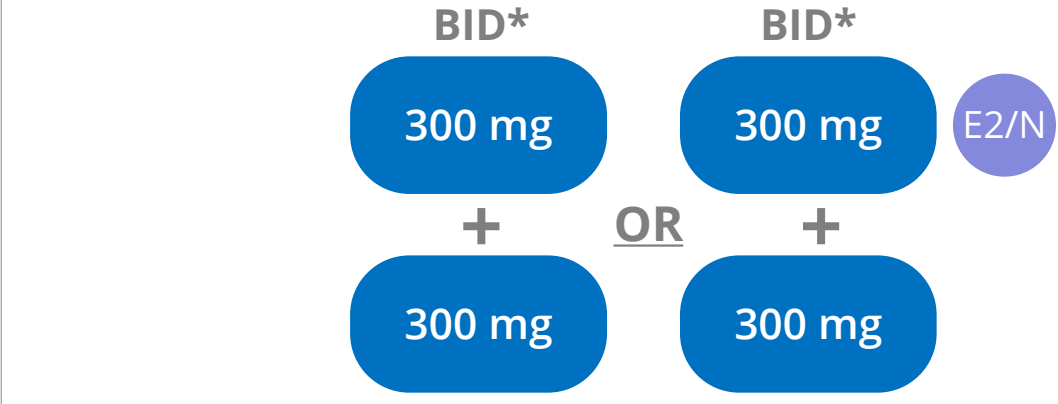
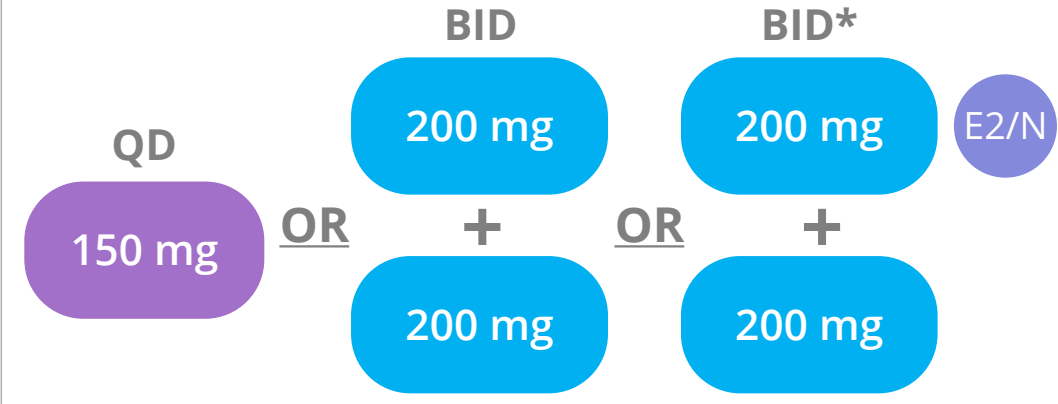
ENDOMETRIOSIS

One pill, once a day



UTERINE FIBROIDS

## OTHER



Pills and tablets to scale (except 300 mg; size is unknown)  
E2/N = estradiol and norethindrone acetate

\*In late-stage clinical development

# GnRH Antagonists for Endometriosis: Recent Studies

No direct head-to-head data available – caution advised when comparing clinical studies with different assessment measures

	Relugolix Combination Therapy 40 mg QD	Elagolix Monotherapy Week 24*			
		150 mg QD		200 mg BID	
	SPiRiT 2	Elaris EM-1	Elaris EM-2	Elaris EM-1	Elaris EM-2
<b>Responder Rate (placebo)</b>					
<b>Dysmenorrhea</b>	<b>75.2%</b> (30.4%)	<b>42.1%</b> (23.1%)	<b>46.2%</b> (25.4%)	<b>75.3%</b> (23.1%)	<b>76.9%</b> (25.4%)
<b>Non-Menstrual Pelvic Pain</b>	<b>66.0%</b> (42.6%)	<b>45.7%</b> (34.9%)	<b>51.6%</b> (40.6%)	<b>62.1%</b> (34.9%)	<b>62.2%</b> (40.6%)
<b>Bone Mineral Density Loss, Lumbar Spine (placebo)</b>	<b>-0.78%</b> (0.02%)	<b>-0.32%</b> (0.47%)	<b>-0.72%</b> (0.56%)	<b>-2.61%</b> (0.47%)	<b>-2.49%</b> (0.56%)

## Ovulation Inhibition Study Results

<b>Ovulation Inhibition</b>	100%	48%	68%
<b>Ovulation or Menses Return at 100%</b>	✓	?	?

Taylor et al. New England Journal of Medicine. 2017; Chiu et al. Reproductive Sciences. 2017.



## **Linda Giudice, MD, PhD**

The Robert B. Jaffe, MD Endowed Professor  
in the Reproductive Sciences at the  
University of California, San Francisco

SPIRIT Steering Committee Chair

Financial Disclosures: AbbVie, Merck, Forendo Pharma

# Upcoming Milestones



## Uterine Fibroids

NDA submission in  
**May 2020**




## Endometriosis

Phase 3 SPIRIT 1 study  
results in **Q2 2020**



## Prostate Cancer

 NDA submitted in  
**April 2020**

Castration resistance-free  
survival data in **Q3 2020**



**Linda Giudice, MD, PhD**  
Ob/Gyn, Professor (UCSF)



**Lynn Seely, MD**  
Chief Executive Officer



**Frank Karbe**  
President and  
Chief Financial Officer



**Kim Sablich**  
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*Redefining Care.  
For women. For men. For you.*

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