

# LIBERTY 2 PHASE 3 UTERINE FIBROID AND BIOEQUIVALENCE STUDY RESULTS

July 23, 2019

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# LIBERTY 2 PHASE 3 UTERINE FIBROID AND BIOEQUIVALENCE STUDY RESULTS

July 23, 2019

### MILLIONS OF WOMEN ARE SUFFERING

"I feel trapped and betrayed by my own body, suffering from a disease that robs me of days each month"





### UNIQUE CONSTELLATION OF ATTRIBUTES

## VISION FOR RELUGOLIX COMBINATION THERAPY

DESIGNED TO MEET
THE NEEDS OF WOMEN
AND OBGYNs

Substantial and predictable symptom relief Well-One dose, tolerated, one pill, safe for once-a-day long-term use

#### Easy to use — similar to oral contraceptive

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



## POSITIVE STUDY RESULTS

NDA SUBMISSION WITH SINGLE-TABLET ON TRACK FOR Q4 2019

#### **POSITIVE STUDY RESULTS FOR LIBERTY 2**



Primary endpoint achieved (p < 0.0001)

- Relugolix combination therapy: 71.2%
- Placebo: 14.7%



- Significant reduction in menstrual blood loss: 84.3%
- Significant reduction in pain
- Bone density comparable to placebo
- Generally well-tolerated with adverse event rates comparable to placebo

SINGLE-TABLET RELUGOLIX COMBINATION THERAPY ACHIEVED BIOEQUIVALENCE





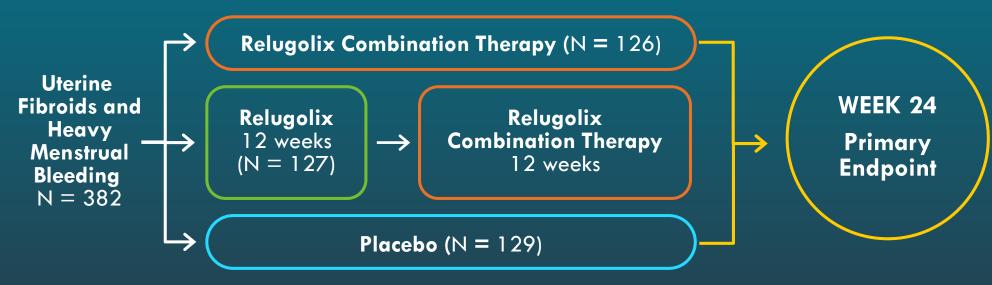
## **LIBERTY 2: PHASE 3 STUDY DESIGN**

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 per cycle and ≥ 50% reduction in menstrual blood loss by alkaline hematin method



**Double-Blind Treatment: 24 Weeks** 

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 2 Demographics and Baseline Characteristics	Placebo (N = 129)	Relugolix Combination Therapy (N = 125)	Relugolix → Relugolix Combination Therapy (N = 127)
Age (mean, SD in years)	41.8 (5.3)	42.4 (5.4)	42.1 (5.3)
Geographic Region (number, %) North America Rest of World	96 (74%) 33 (26%)	93 (74%) 32 (26%)	94 (74%) 33 (26%)
Race (number, %) White Black Other	49 (38%) 74 (57%) 6 (5%)	58 (46%) 62 (50%) 5 (4%)	50 (39%) 66 (52%) 11 (9%)
Body Mass Index (mean, SD in kg/m²)	32.1 (7.6)	31.0 (6.6)	30.8 (5.7)
Menstrual Blood Loss (mean, SD in mL)	212 (130)	247 (186)	227 (134)

8 MYOVANT SCIENCES

## BURDEN OF UTERINE FIBROIDS

LIBERTY 2
AT BASELINE

- 77% of women considered their symptoms moderately severe, very severe, or extremely severe
- On average, women had menstrual blood loss of
   200 mL per cycle, with some up to 1 liter
   (<80 mL is normal)</li>
- 74% of women had moderate or severe pain
- 67% of women reported daily function that was moderately, quite a bit, or extremely limited

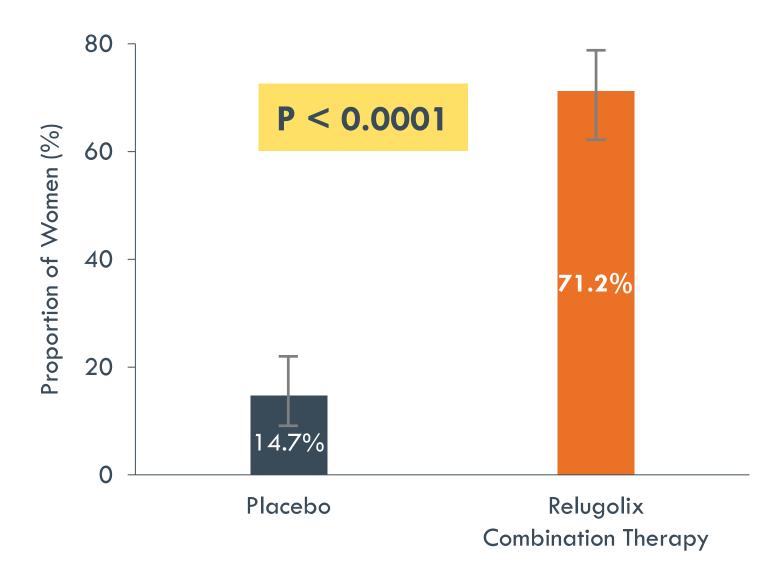




#### 71.2% OF WOMEN MET RESPONDER CRITERIA

## ACHIEVED PRIMARY ENDPOINT

LIBERTY 2

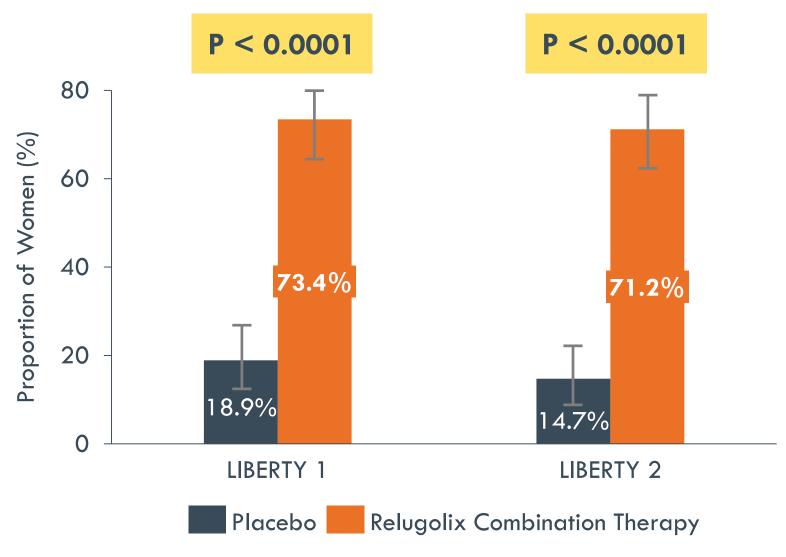






#### **CONSISTENT RESULTS ON PRIMARY ENDPOINT**

## LIBERTY PROGRAM WITH TWO POSITIVE STUDIES

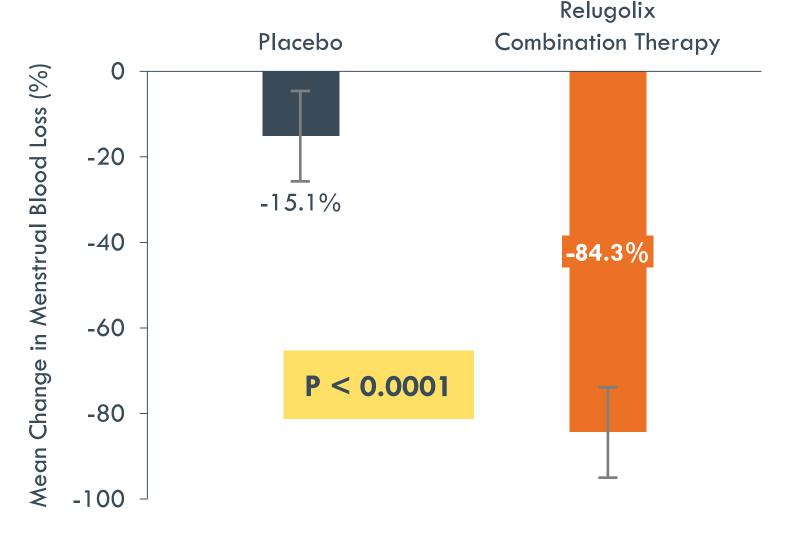






## ON AVERAGE, 84.3% REDUCTION IN MENSTRUAL BLOOD LOSS AT WEEK 24

SIGNIFICANT IMPROVEMENT IN SYMPTOM MOST BOTHERSOME TO WOMEN





LIBERTY 2



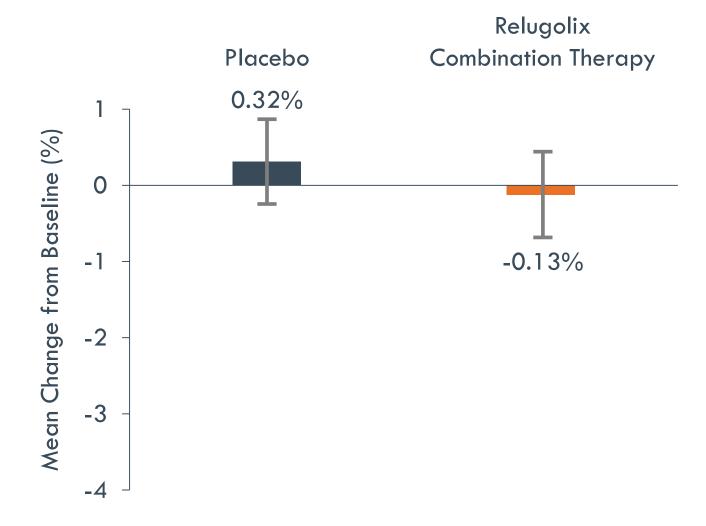
## SIX KEY SECONDARY ENDPOINTS ACHIEVED BY RELUGOLIX COMBINATION

KEY SECONDARY ENDPOINTS (LIBERTY 2)		p-value
REDUCTION IN MENSTRUAL BLOOD LOSS	Percent mean change in menstrual blood loss from baseline to Week 24	
AMENORRHEA	Proportion of women who achieve amenorrhea	
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	
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 $\geq 2$ g/dL from baseline to Week 24	
REDUCTION	Percent change in uterine volume from baseline to Week 24	p = 0.008
IN VOLUME	Percent change in uterine fibroid volume from baseline to Week 24	p = 0.21*



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

## CHANGE IN BONE DENSITY COMPARABLE TO PLACEBO



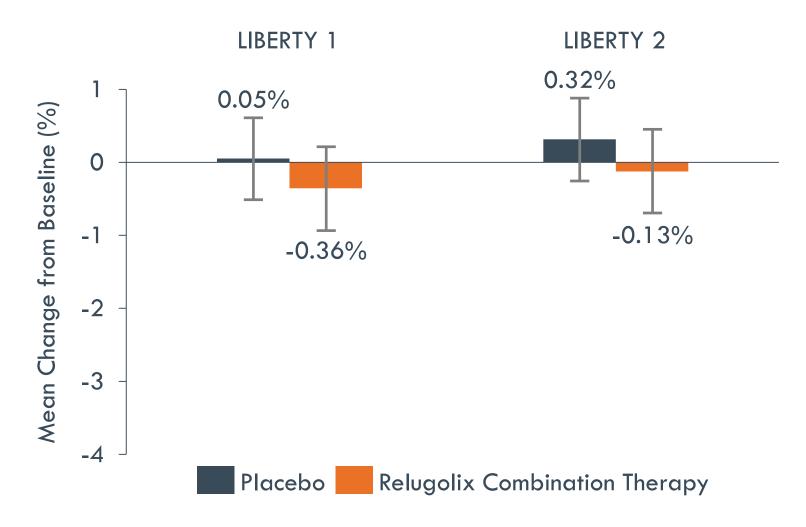


LIBERTY 2



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

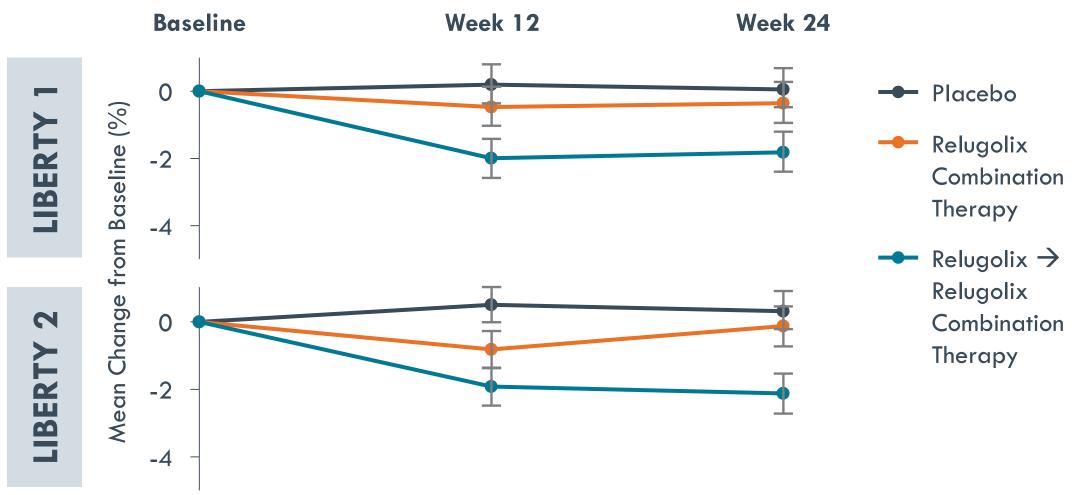
## BONE HEALTH MAINTAINED IN BOTH LIBERTY STUDIES







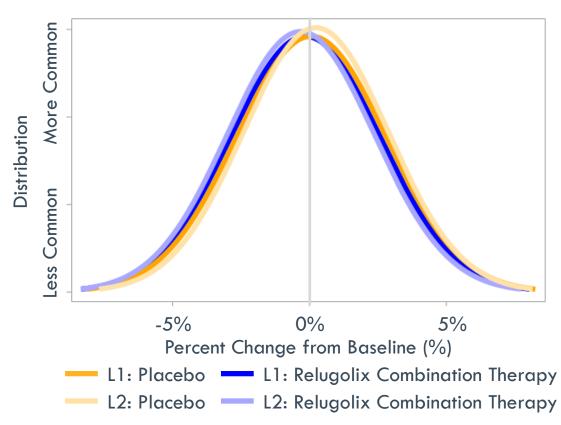
## COMBINATION APPROACH MAINTAINED BONE DENSITY THROUGH 24 WEEKS (LUMBAR SPINE)

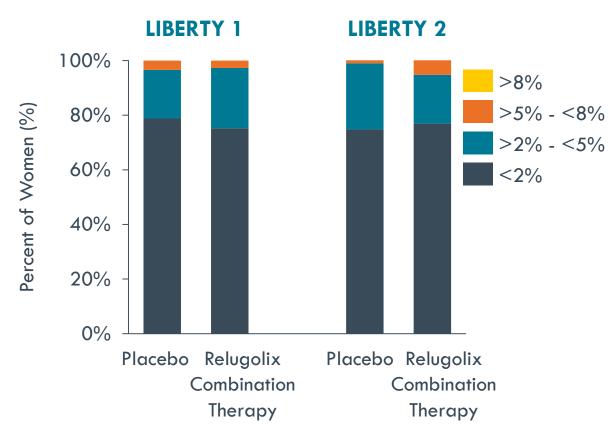




## BONE DENSITY DISTRIBUTION COMPARABLE TO PLACEBO IN BOTH STUDIES

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



## **SUMMARY OF ADVERSE EVENTS**

LIBERTY 2 Number (%) of Women	Placebo (N = 129)	Relugolix Combination Therapy (N = 126)	Relugolix → Relugolix Combination Therapy (N = 126)			
At least one adverse event	76 (59%)	76 (60%)	90 (71%)			
Adverse event leading to study discontinuation	6 (5%)	3 (2%)	14 (11%)			
Serious adverse event related to study drug	0	0	0			
Pregnancy	1 (1%)	0	0			
Adverse Events Reported for ≥ 10% of Women in Any Group						
Hot flash	5 (4%)	7 (6%)	44 (35%)			
Headache	15 (12%)	11 (9%)	28 (22%)			

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



## SUCCESSFUL BIOEQUIVALENCE STUDY

## **GOAL:** ESTABLISH THAT RELUGOLIX COMBINATION THERAPY CAN BE DELIVERED AS A SINGLE-TABLET

#### STUDY COMPARED PHARMACOKINETICS OF:

- Single-tablet relugolix combination therapy
- Co-administered regimen used in the LIBERTY studies

**ANALYSIS INCLUDED >20,000 BLOOD SAMPLES** 

FDA REQUIRED 8 PRIMARY & 8 SECONDARY ENDPOINTS

MET REQUIREMENTS LAID OUT BY FDA
FOR ALL 16 ENDPOINTS



## MILLIONS OF WOMEN IN NEED OF BETTER MEDICINES

### **UTERINE FIBROIDS** (Prevalence 19M)

Symptomatic women

5M **3M** 

Still symptomatic on therapy

### **ENDOMETRIOSIS** (Prevalence 8M)

Symptomatic women



Still symptomatic on therapy

**1**M

Prevalence data includes US women ages 15-49.

Endometriosis Foundation, American College of OBGYNs; 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. Cardozo ER et al.. Am J Obstet Gynecol 2012.

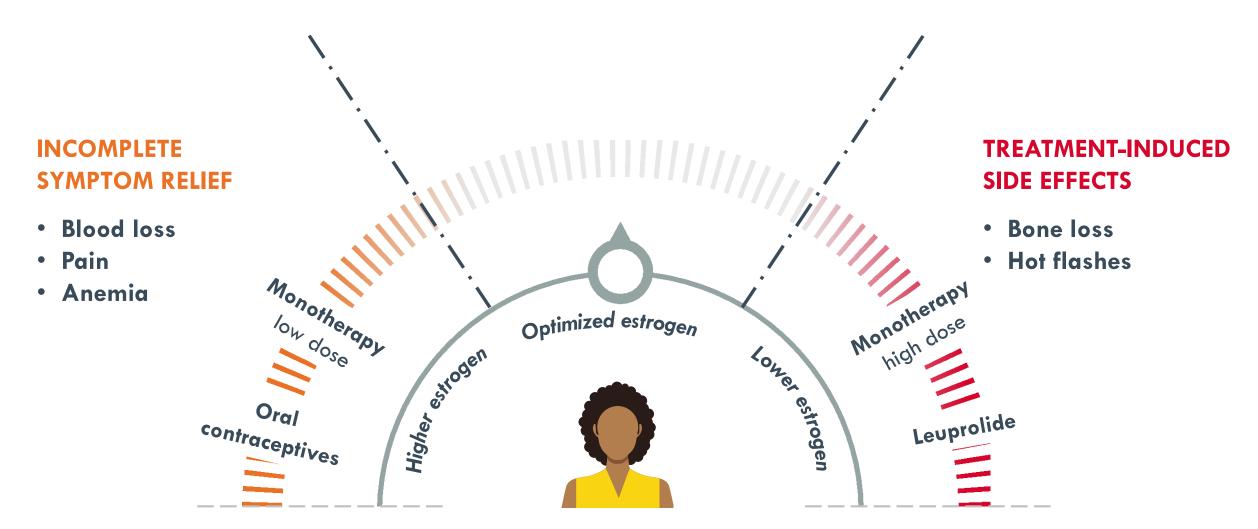


**Combined Annual** 

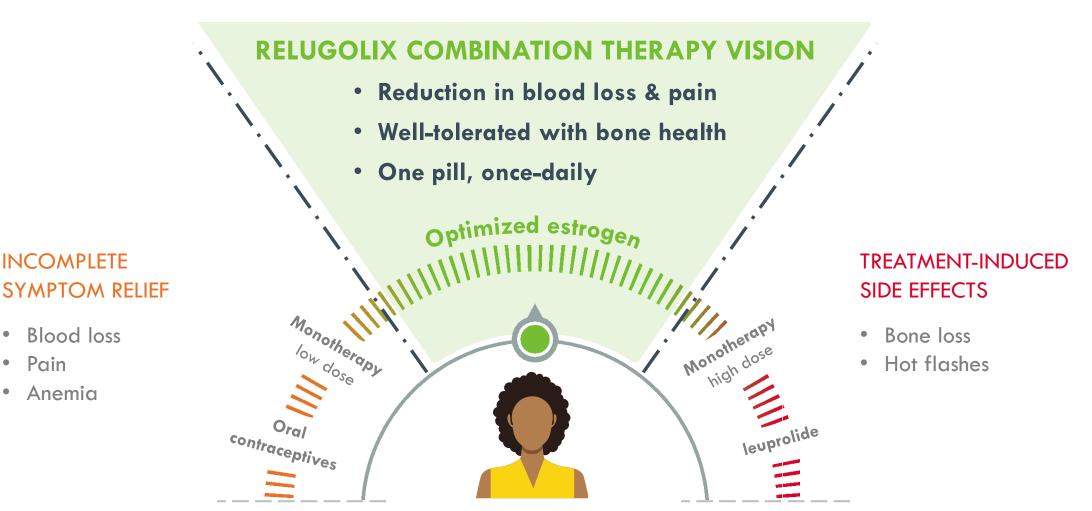
Societal Cost:

>\$100B per year

## A CLEARLY DEFINED GAP IN TREATMENT



## RELUGOLIX COMBINATION INTENTIONALLY DESIGNED TO FILL TREATMENT GAP



**INCOMPLETE** 

Blood loss

Pain

Anemia

## THE RELUGOLIX COMBINATION DIFFERENCE



- Combination therapy from the start
  - Achieved symptom reduction; well-tolerated
- 2 Significant pain reduction
  - Only medicine in class to demonstrate
- Bone health maintained
  - Bone mineral density comparable to placebo
- 4 Simplicity
  - One dose, one pill, once-a-day



## RELUGOLIX COMBINATION SIMPLICITY VISION

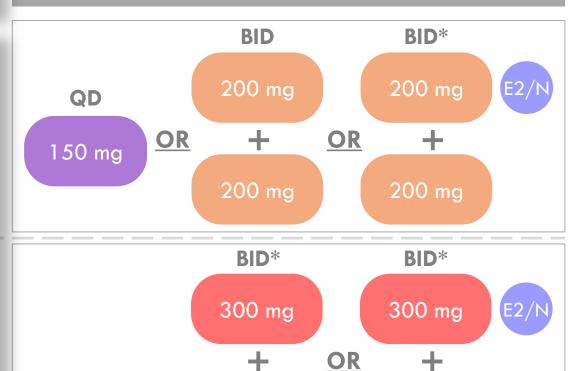
#### **RELUGOLIX COMBINATION THERAPY\***

**OTHER** 

**Endometriosis** 

**Uterine Fibroids** 





300 mg



300 mg

## STRONG ENTHUSIASM FOR RELUGOLIX COMBINATION PROFILE

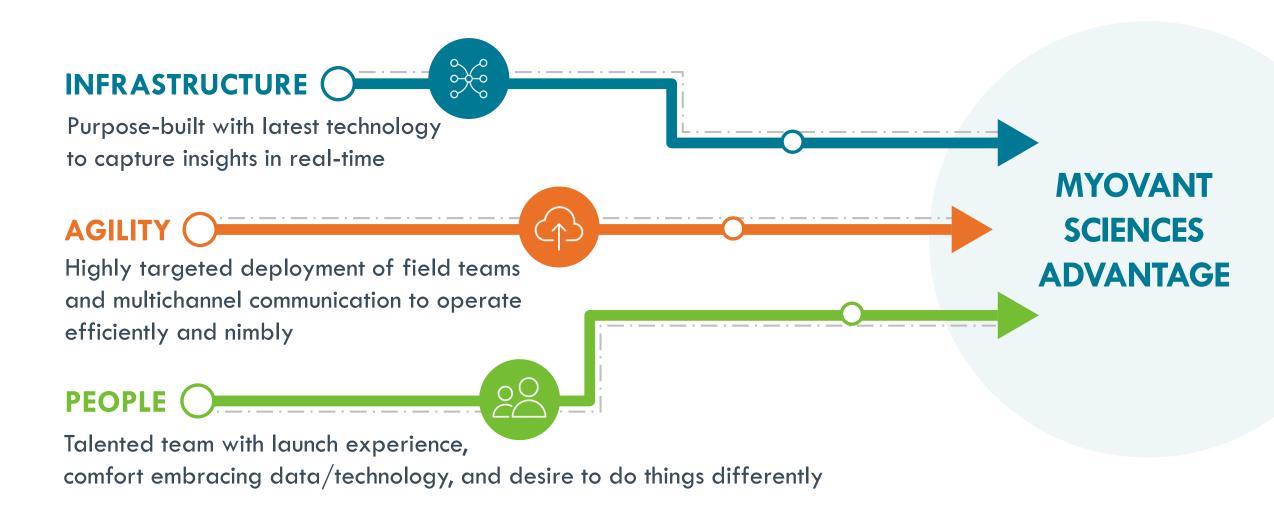
Myovant Sciences research showed

95%

of OBGYNs are very likely (70%) or likely (25%) to prescribe relugolix combination therapy

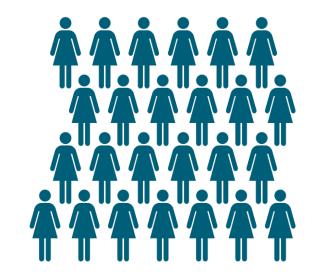


## **BUILDING FIT-FOR-PURPOSE CAPABILITIES**



## PLAN TO LAUNCH WITH FOCUSED FIELD TEAM

Millions of women suffering from uterine fibroids and endometriosis



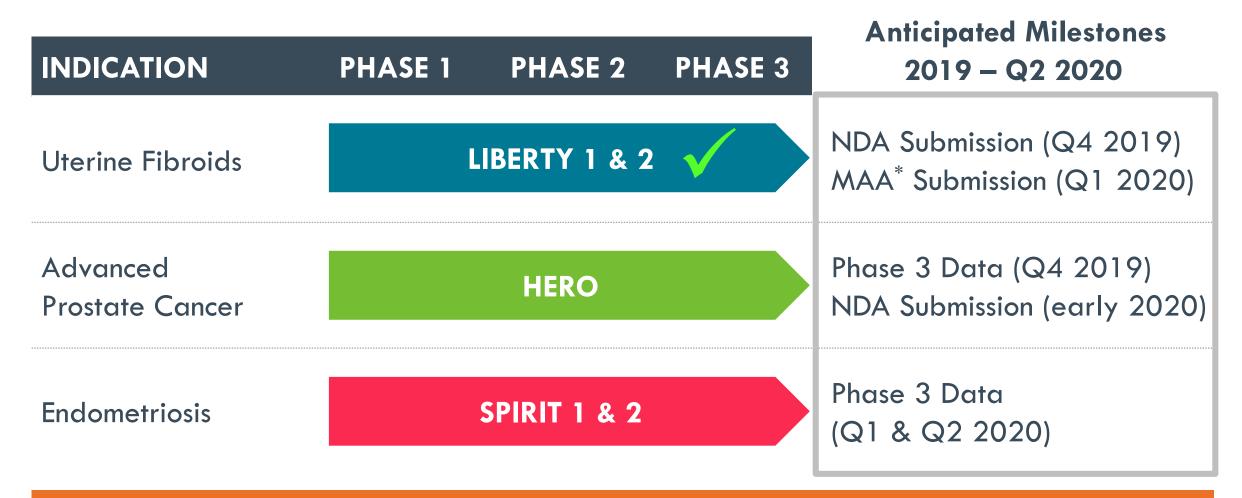
Treated primarily by OBGYNs, of which there are only 36K in the U.S.\*



COMMERCIAL TEAM SIZE: ~150 TO 200



## **MYOVANT SCIENCES' UPCOMING MILESTONES**



#### HOLD EXCLUSIVE RIGHTS IN THE US AND EUROPE FOR ALL INDICATIONS



## TAKEAWAYS: MAJOR STEPS FORWARD

Positive study results for LIBERTY 2 with significant symptom relief across multiple endpoints

Well-tolerated safety profile; maintained bone health

Relugolix single-tablet combination therapy achieved bioequivalence

NDA submission with single-tablet on track for Q4 2019

LIBERTY data to be submitted for presentation and publication this year

Launch preparations well underway



