

# Innovation in Women's Health & Prostate Cancer



Cowen Health Care Conference  
March 4, 2020



# Forward-Looking Statements

This presentation contains forward-looking statements, including without limitation, statements related to: Myovant's focus on developing and commercializing innovative therapies for the treatment of women's health and endocrine diseases; Myovant's ability to advance the clinical development of relugolix through the LIBERTY, SPIRIT and HERO clinical trials and MVT-602 through its clinical trials; 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 in the section titled "Risk Factors" set forth in Part I, Item 1A of Myovant's Annual Report on Form 10-K filed with the United States Securities and Exchange Commission, or the SEC, on May 24, 2019, 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.



Improve the lives of millions of women and men, many impacted by diseases during their most productive years of life.





# A Unique Investment Opportunity

## 2019 Positive Phase 3 Data:

- Uterine Fibroids
- Prostate Cancer

## 2020 Endometriosis:

- Phase 3 Data

### Uterine Fibroids:

- 1-Year Data
- NDA Submission
- MAA Submission

### Prostate Cancer:

- NDA Submission
- Castration Resistance-Free Survival Data

~\$400M

Cash and committed funding

## RIGHTS

Wholly-owned U.S. and EU rights for all indications

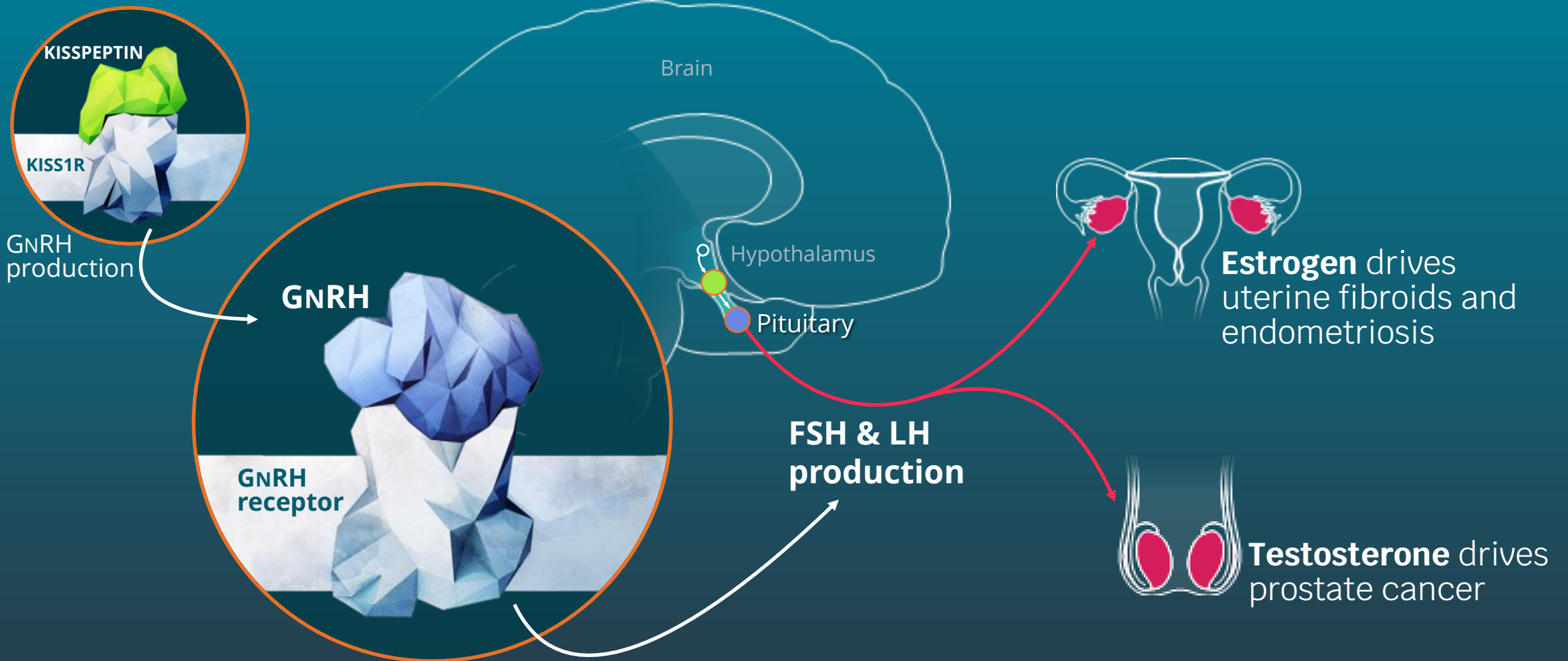
# Myovant's Late-Stage Pipeline

|  | PHASE 1 | PHASE 2        | PHASE 3 | ANTICIPATED MILESTONES  |
|--|---------|----------------|---------|---|
| <b>Relugolix</b>   |         |                |         |   |
| <b>COMBINATION THERAPY</b><br>Symptoms of Uterine Fibroids |         | <b>LIBERTY</b> |         | <ul style="list-style-type: none"> <li>• <b>NDA Submission (April 2020)</b></li> <li>• MAA Submission (Q1 2020)</li> <li>• 1-Year Extension Data (Q1 2020)</li> </ul> |
| <b>COMBINATION THERAPY</b><br>Symptoms of Endometriosis    |         | <b>SPIRIT</b>  |         | <ul style="list-style-type: none"> <li>• Phase 3 Data SPIRIT 2 (April 2020)</li> <li>• SPIRIT 1 (Q2 2020)</li> </ul>  |
| <b>MONOTHERAPY</b><br>Advanced Prostate Cancer             |         | <b>HERO</b>    |         | <ul style="list-style-type: none"> <li>• <b>NDA Submission (Q2 2020)</b></li> <li>• Castration Resistance-Free Survival Data (Q3 2020)</li> </ul>                     |
| <b>MVT-602</b> kisspeptin agonist                          |         |                |         |   |
| Female Infertility as Part of Assisted Reproduction        |         |                |         | <ul style="list-style-type: none"> <li>• Phase 2 Development</li> </ul>   |

MAA = Marketing Authorisation Application for European Medicines Agency

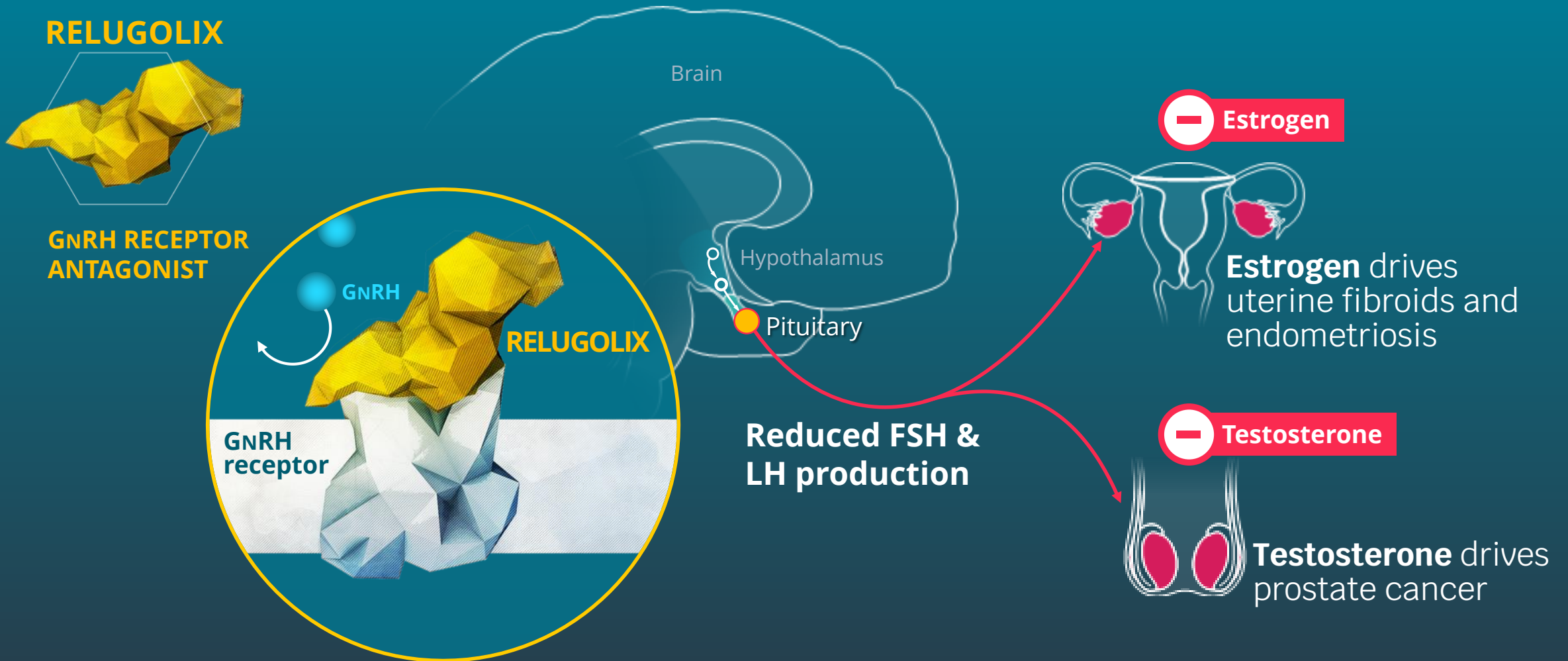
# GnRH Pathway

Shared Across Women's Health and Prostate Cancer



Definition: Follicle-Stimulating Hormone (FSH); Luteinizing Hormone (LH)

# Relugolix Mechanism of Action



Definition: Follicle-Stimulating Hormone (FSH); Luteinizing Hormone (LH)

# One Pill, Once A Day

## Two Distinct Therapeutic Candidates

### WOMEN'S HEALTH



Relugolix 40 mg  
+ estradiol 1.0 mg  
+ norethindrone acetate 0.5 mg

#### RELUGOLIX COMBINATION TABLET

Designed for the treatment of women with symptomatic uterine fibroids or endometriosis as an alternative to surgery or other invasive procedures.

### PROSTATE CANCER



Relugolix 120 mg  
(following single 360 mg loading dose)

#### RELUGOLIX MONOTHERAPY TABLET

Designed with the potential to be the first and only oral androgen deprivation therapy for men with advanced prostate cancer.



# Relugolix for Women's Health







# Millions of Women In Need of Better Medicines for **Uterine Fibroids**

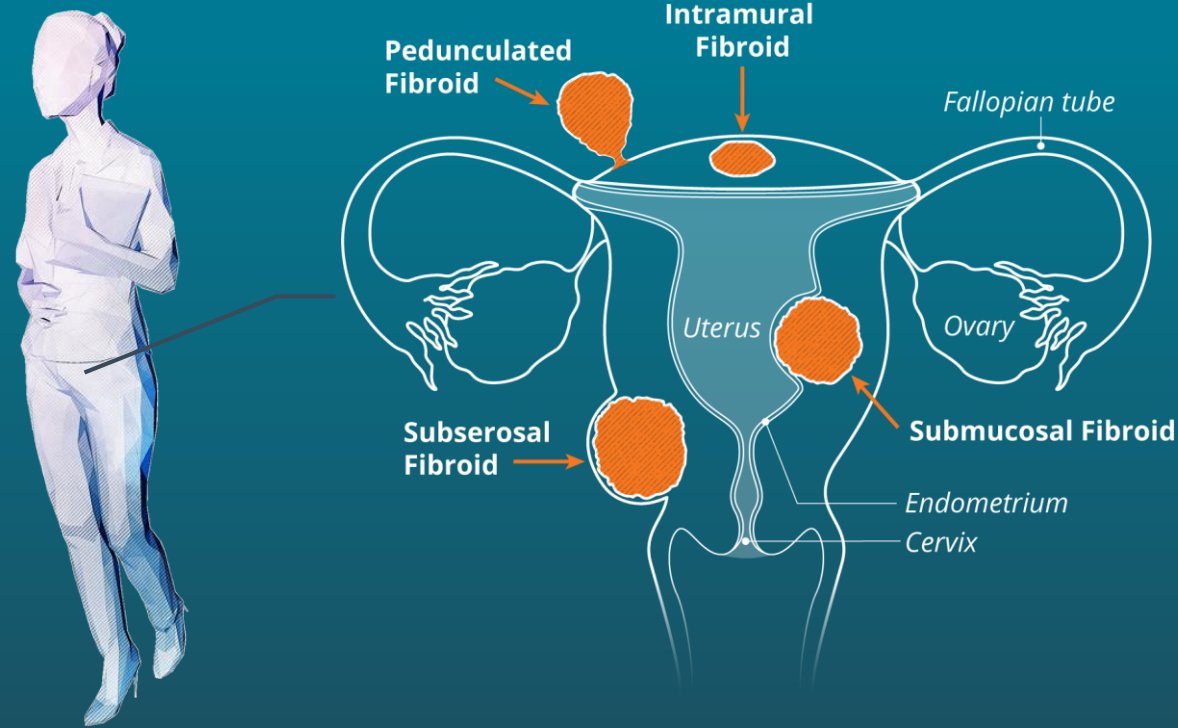
**~5M women**  
with symptoms  
in U.S.

**~250,000**  
hysterectomies  
each year  
in U.S.

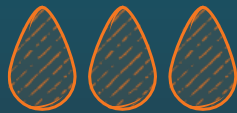
**>\$34B**  
**per year**  
annual societal  
cost

Stewart. NEJM. 2015; Stewart. Lancet. 2001  
Majoribanks et al. Cochrane Database Syst. Rev. 2006. Cardozo et al. Am J Obstet Gynecol. 2012;  
Wright et al. Obstet Gynecol. 2013; Cohen et al. Obstet Gynecol. 2017.

# Uterine Fibroids: A Common, Debilitating Disease



## EFFECTS



Heavy Bleeding



Anemia



Pelvic Pain



Urinary Symptoms



Pregnancy Complications





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

**~6M women**  
with symptoms  
in U.S.

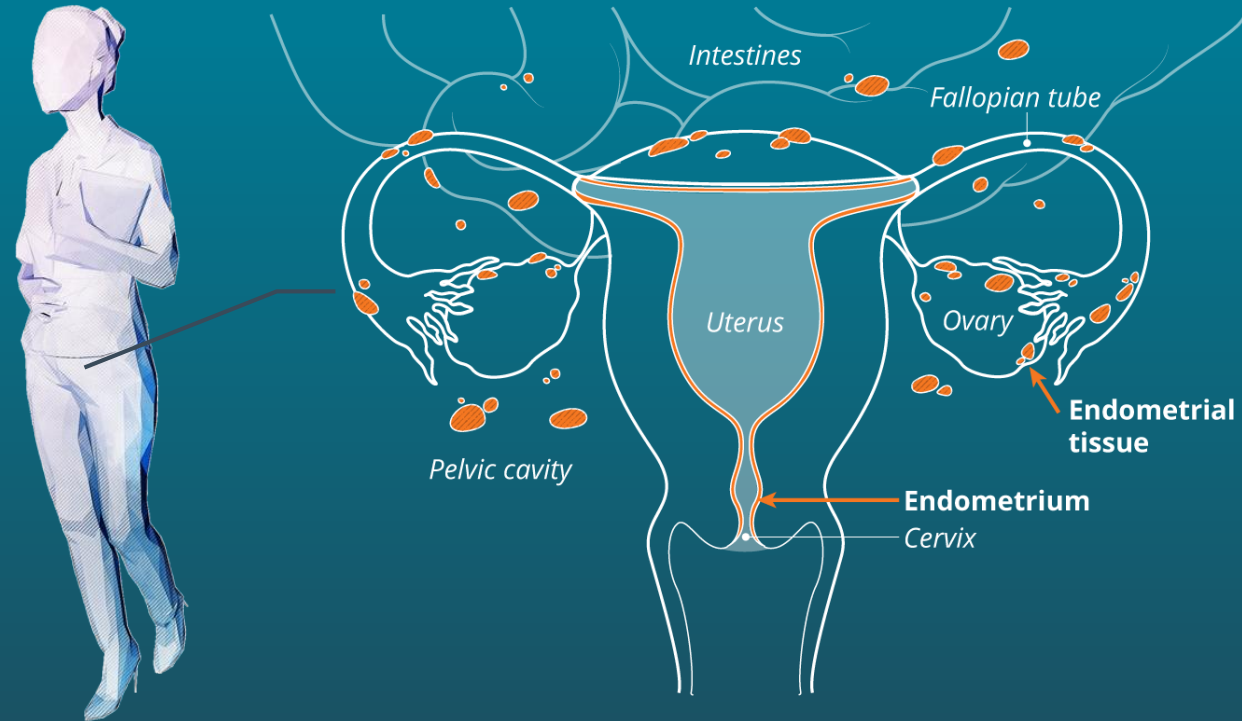
**~100,000**  
hysterectomies  
each year  
in U.S.

**>\$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.



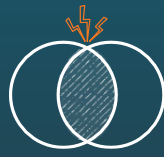
# Endometriosis: A Common, Debilitating Disease



## EFFECTS



Pelvic Pain



Painful Intercourse



Infertility



Fatigue

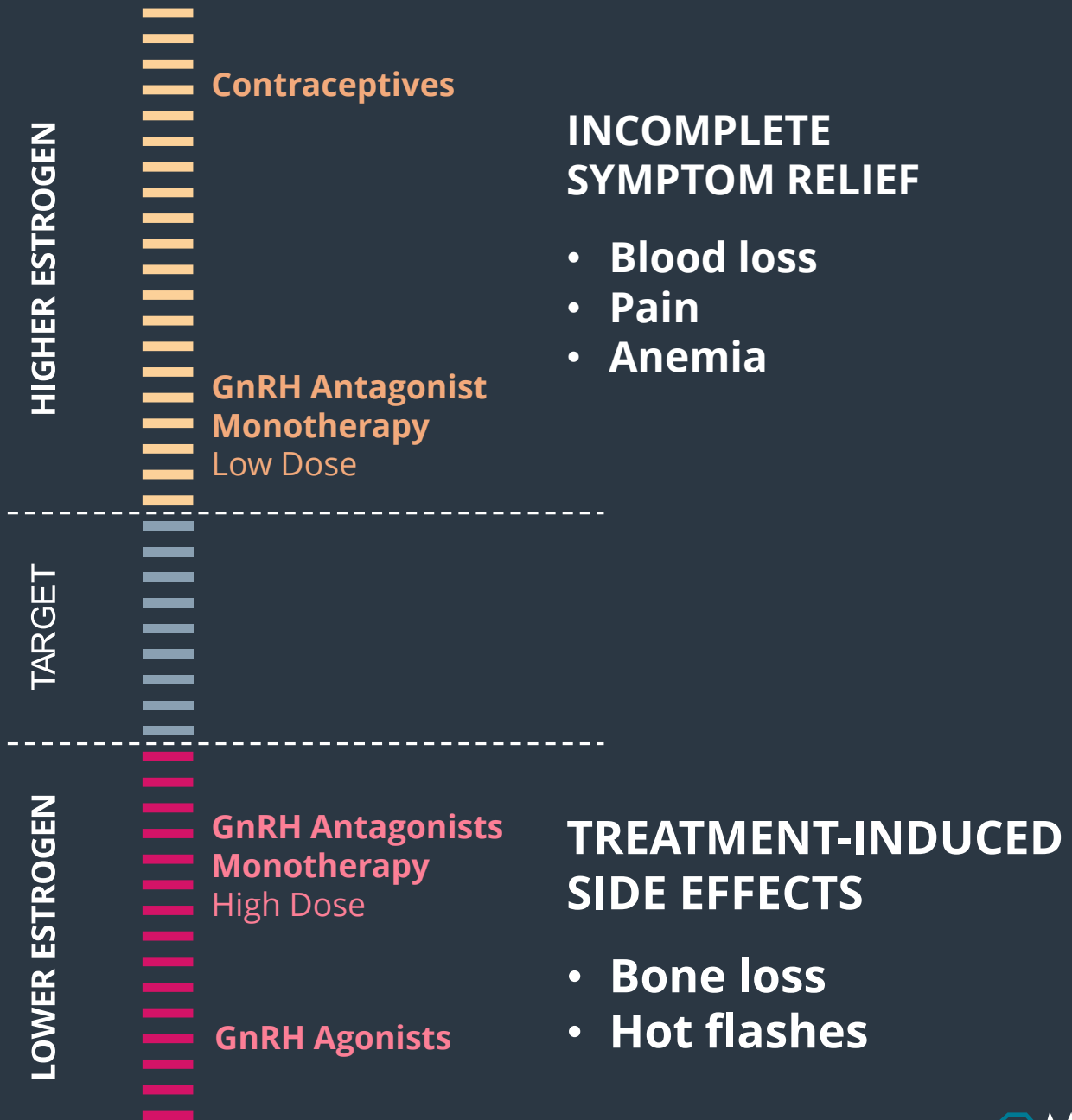


Bowel Symptoms



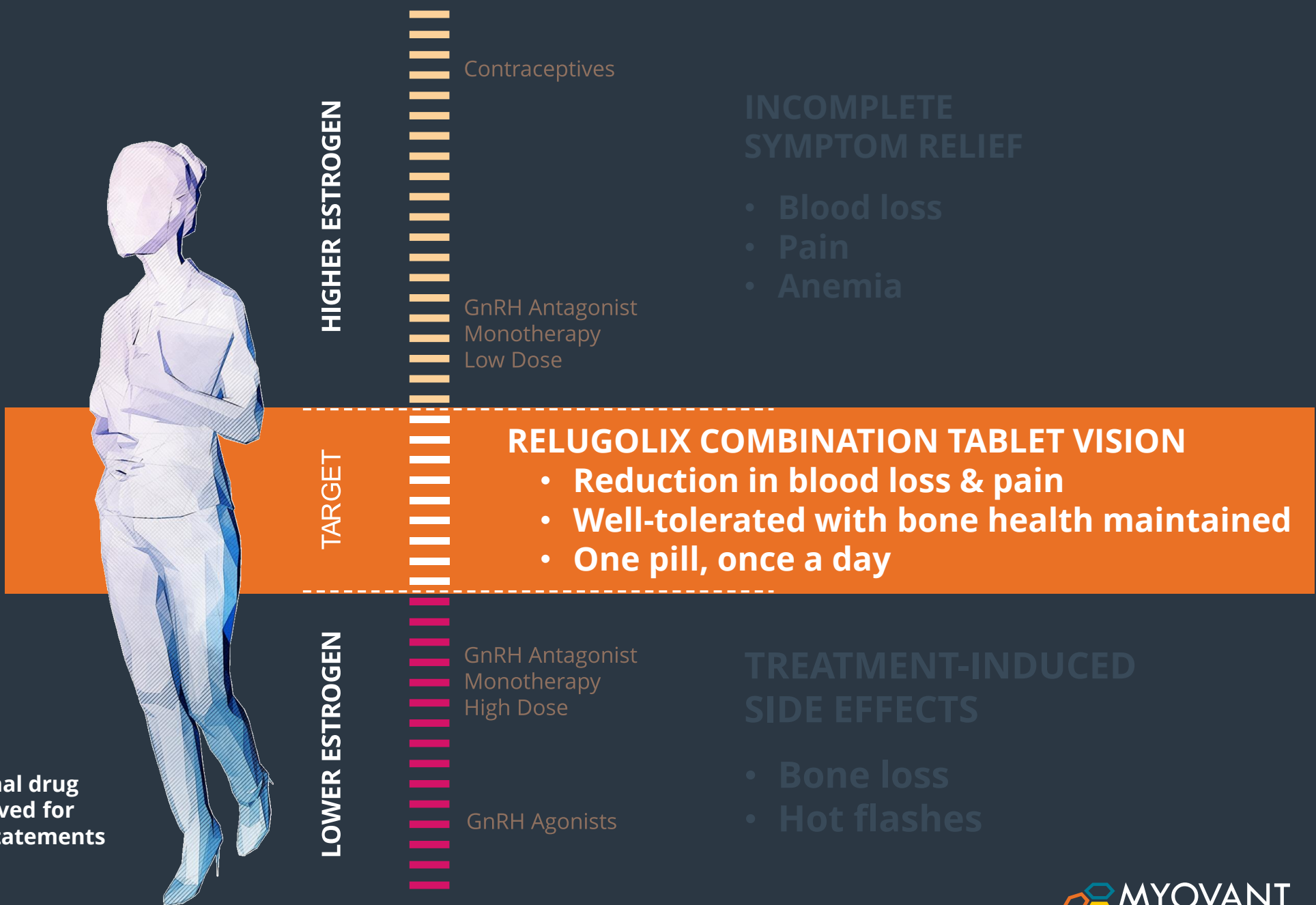
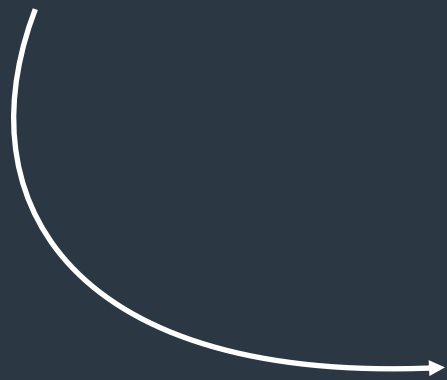
Despite the significant burden of uterine fibroids and endometriosis, women do not have the options they deserve and need.

# A Clearly Defined Gap in Treatment in Uterine Fibroids and Endometriosis



# Relugolix Combination Vision

Intentionally  
Designed to Fill  
Treatment Gap



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



# Relugolix Combination Tablet Vision: One Dose, Two Diseases

RELUGOLIX COMBINATION TABLET\*

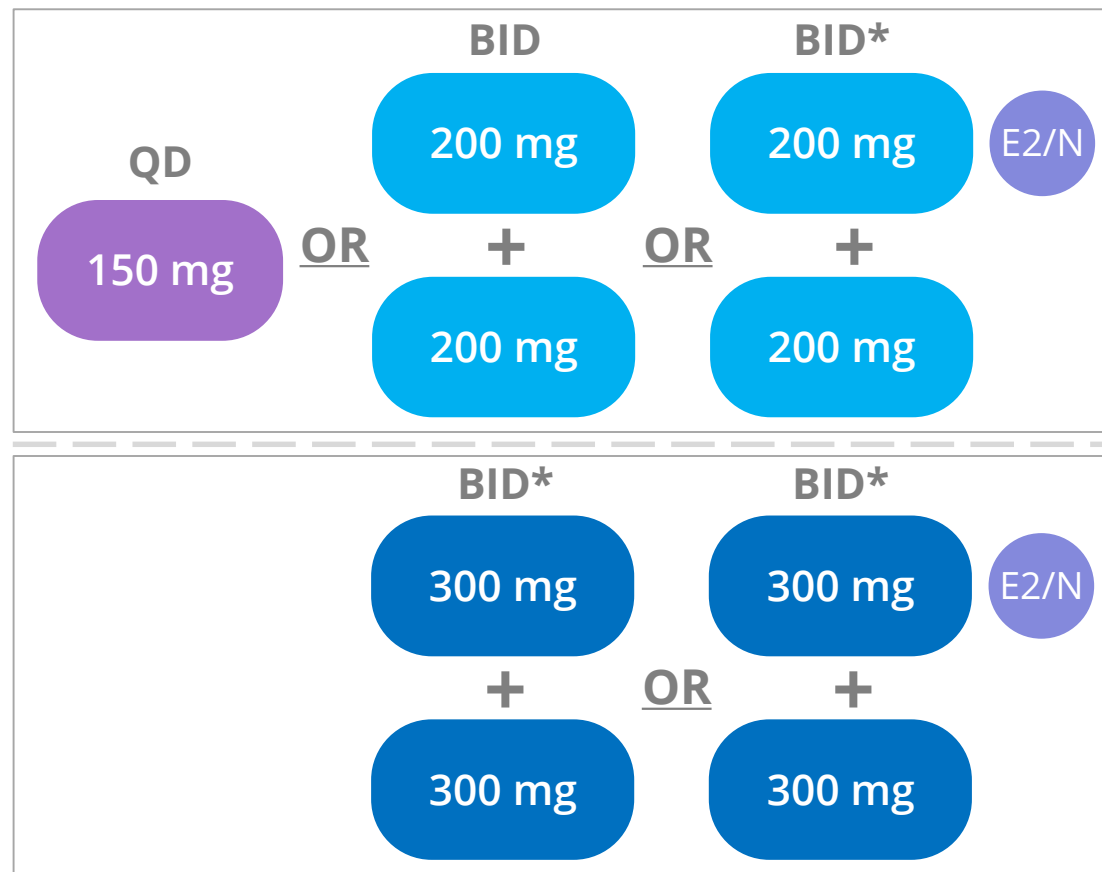
ENDOMETRIOSIS

One pill, once a day



UTERINE FIBROIDS

OTHER

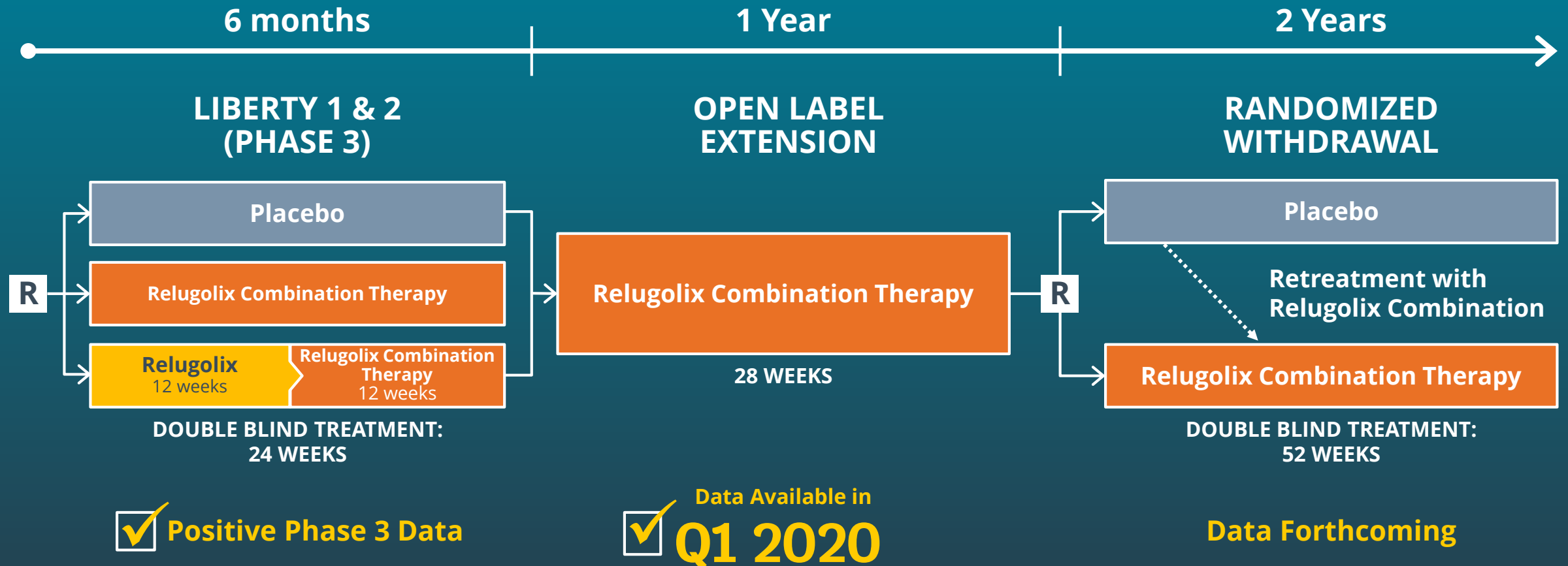


Pills and tablets to scale (except 300 mg; size is unknown)  
E2/N = estradiol and norethindrone acetate

\*In late-stage clinical development

\*Relugolix is an investigational drug that has not been FDA approved for use

# LIBERTY Development Program: Long-Term Data





# Relugolix Combination: **LIBERTY Clinical Data Insights**

\*Relugolix is an investigational drug  
that has not been FDA approved for use

1

**84.3% Reduction in  
Menstrual Blood Loss**

2

**Reduction in Pain**

3

**Bone Mineral Density  
Comparable to Placebo**

4

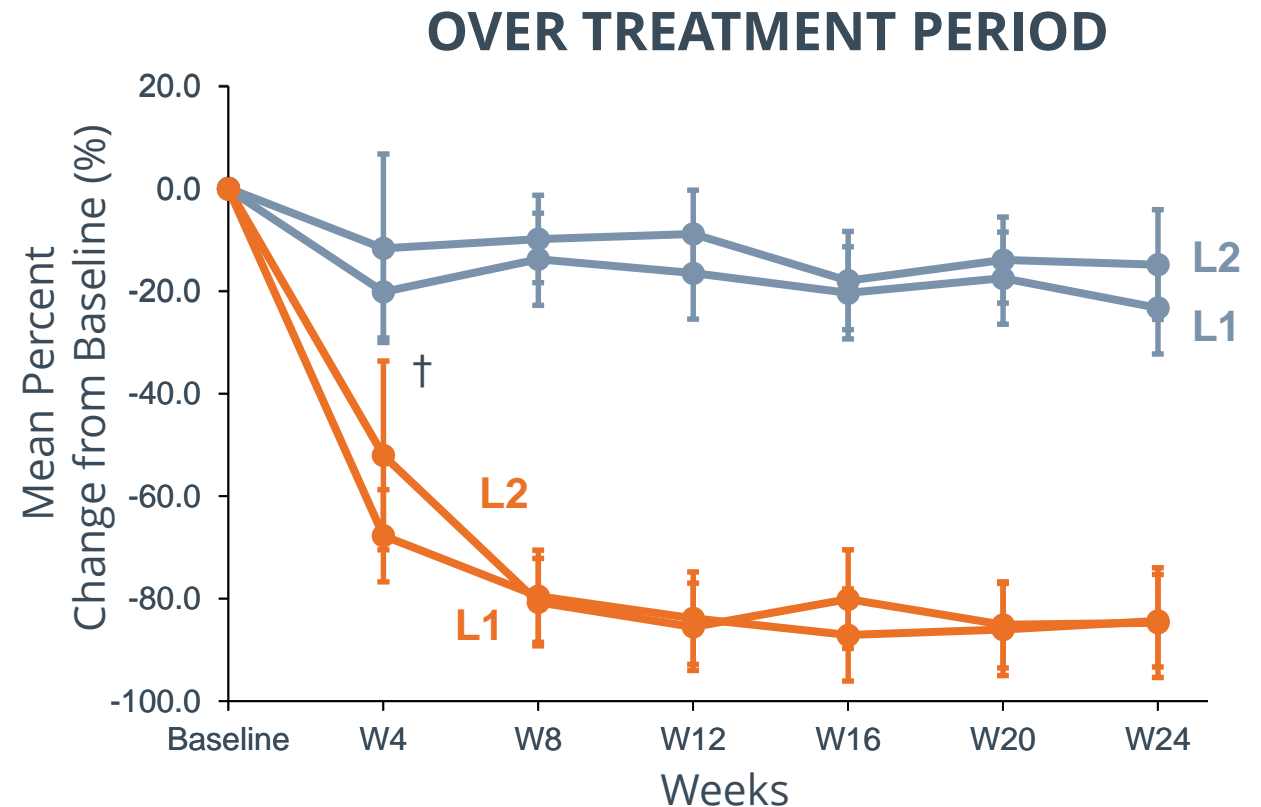
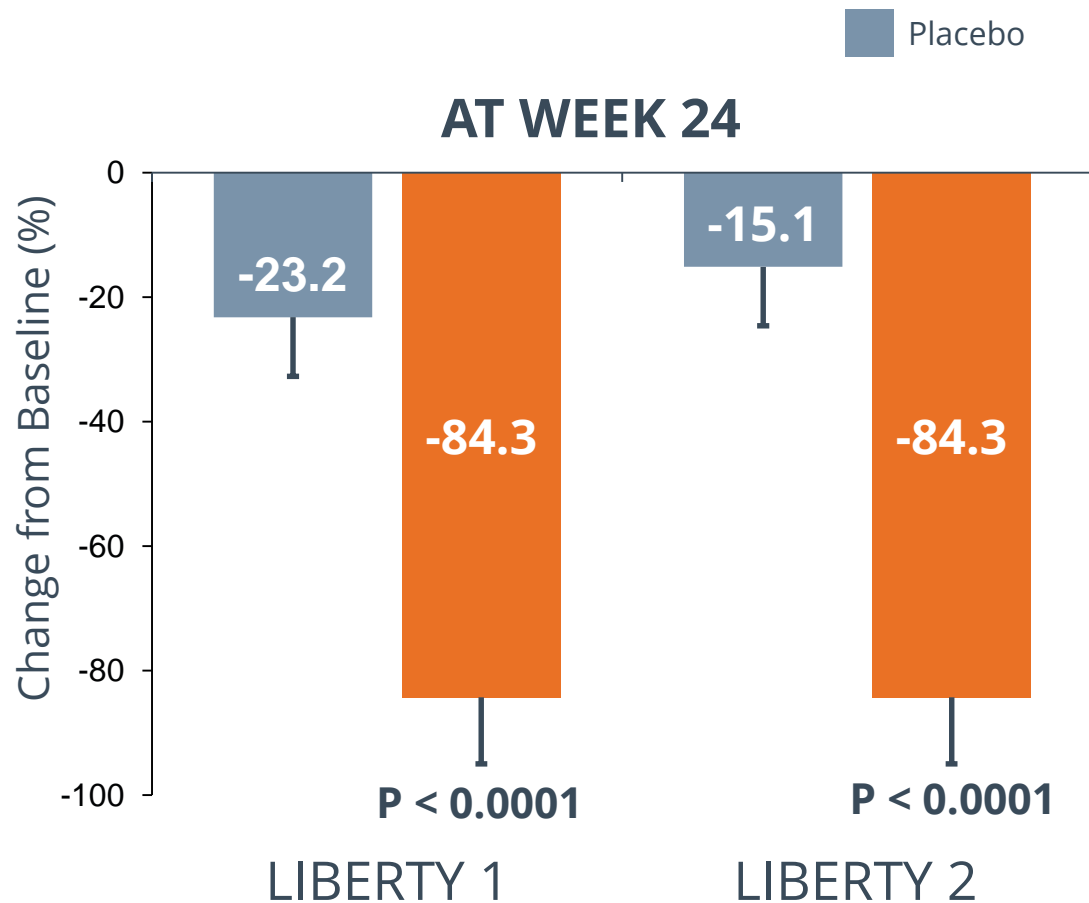
**Well-Tolerated with  
Adverse Event Rates  
Comparable to Placebo**

5

**One Dose, Once a Day**



# Reduction in Menstrual Blood Loss Volume with Relugolix Combination Therapy

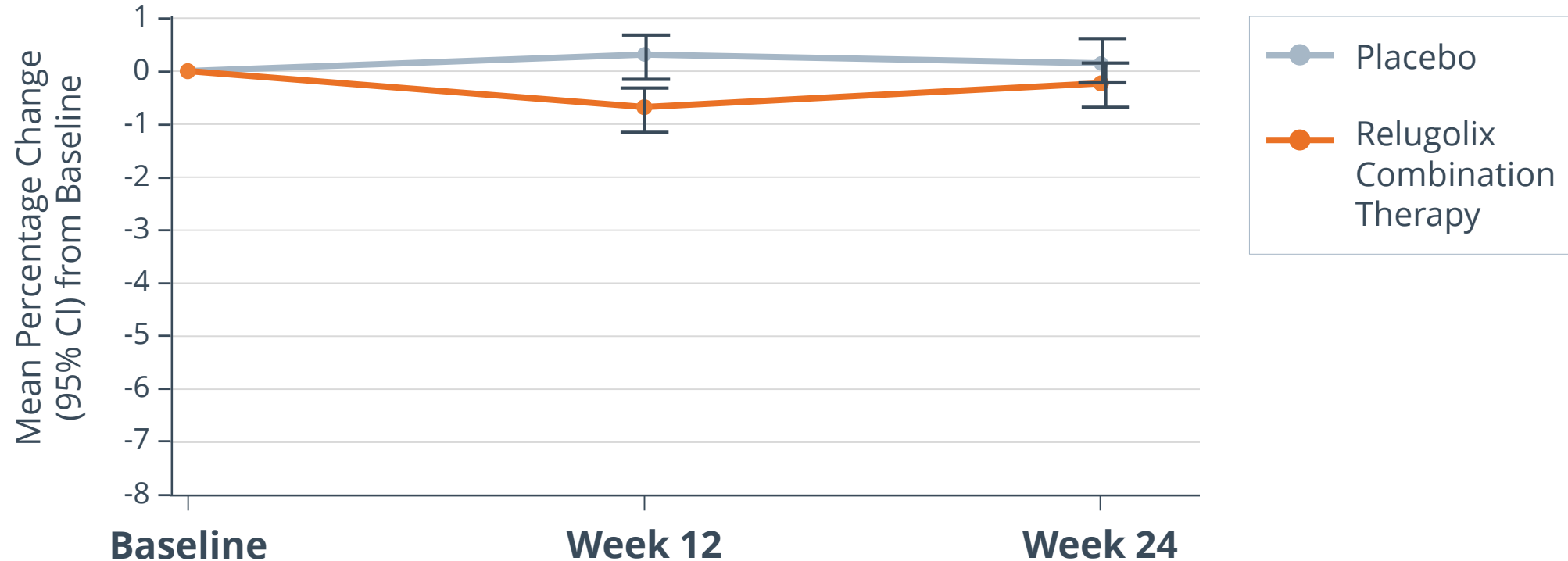


Data Presented at American Society for Reproductive Medicine (ASRM), October, 2019.

†A patient with MBL volume of 2710.3 mL at Week 4 was excluded from the analysis.  
L1 = LIBERTY 1; L2 = LIBERTY 2

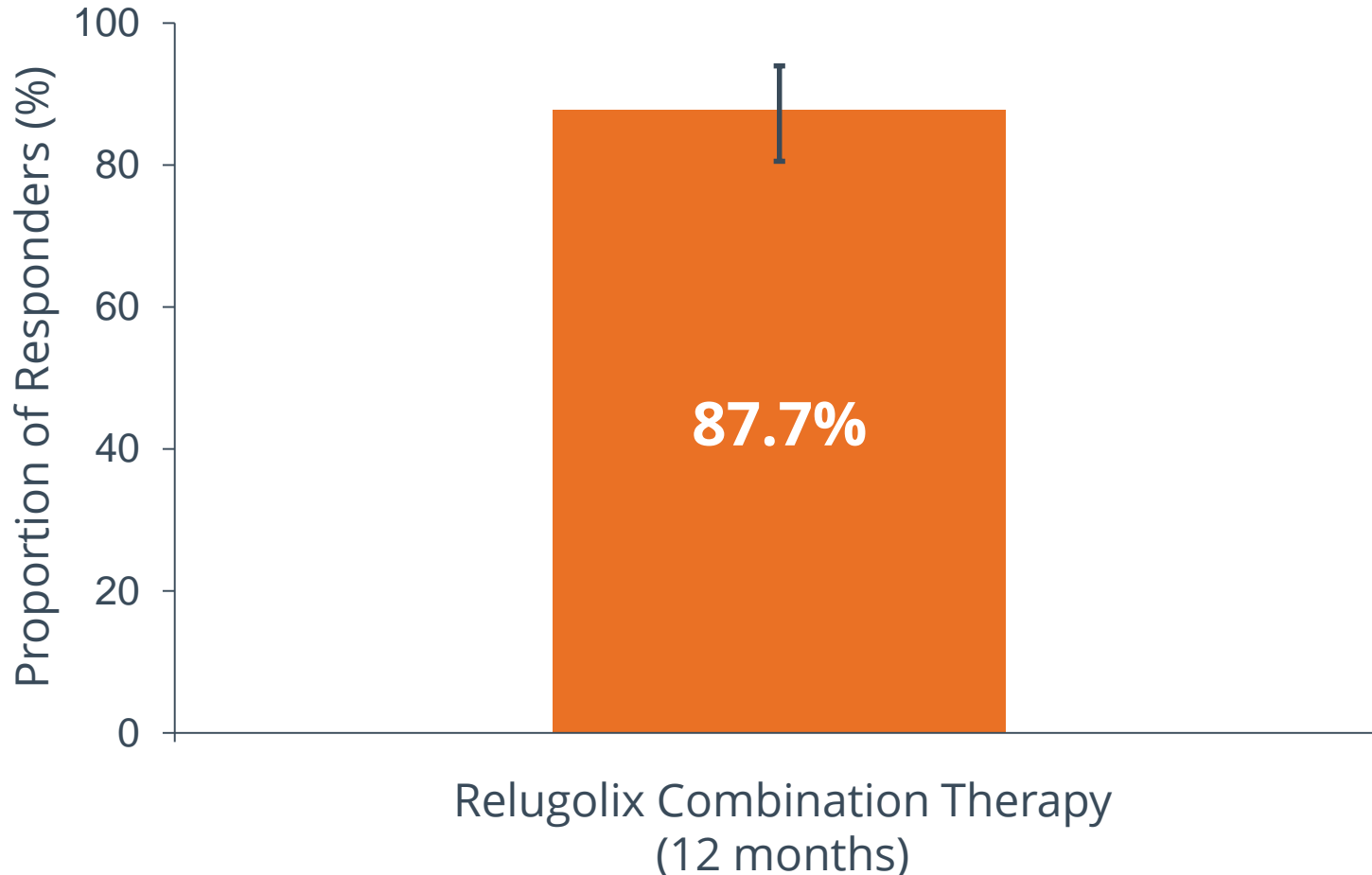


# Bone Health Maintained Across LIBERTY Studies (Lumbar Spine)



# LIBERTY Primary Endpoint at One Year

Proportion of responders with < 80 mL menstrual blood loss/cycle and at least a 50% reduction in menstrual blood loss by alkaline hematin method



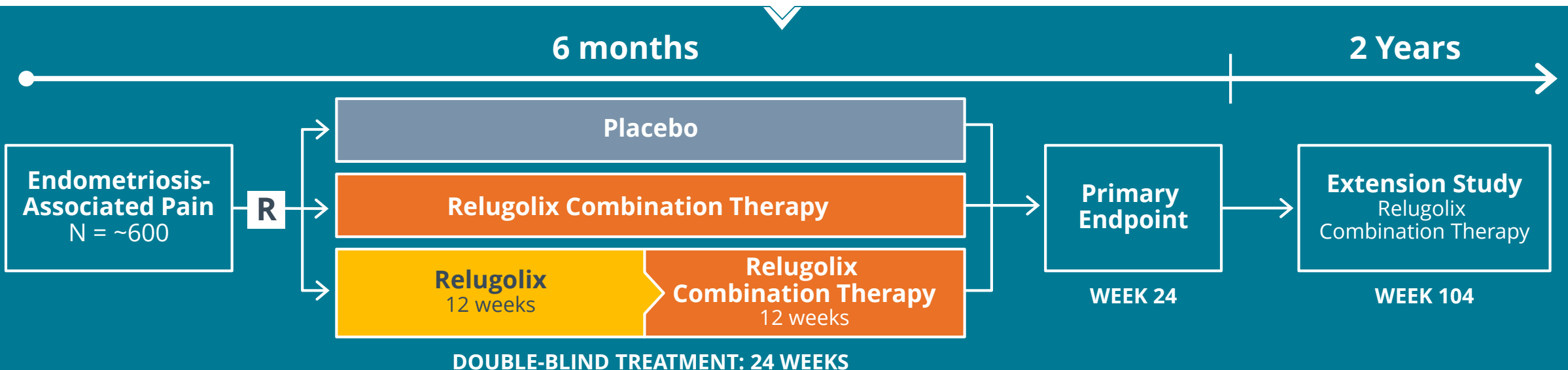
- Average reduction in menstrual blood loss per cycle of 90% at one year
- Bone mineral density at one-year consistent with data at 6 months

# Endometriosis Phase 3 Study Design

Results expected for SPIRIT 2 in April and for SPIRIT 1 in Q2 2020

## CO-PRIMARY ENDPOINTS

Reduction in dysmenorrhea (painful periods) and non-menstrual pelvic pain as assessed using the Symptoms of Endometriosis Scale (a daily questionnaire for the assessment of endometriosis-associated pain) scored using the Numerical Rating Scale





# Relugolix for Advanced Prostate Cancer

The First and Only Oral  
GnRH Receptor Antagonist  
in Development for  
Prostate Cancer





# Prostate Cancer

the 2nd Most Common Cancer Affecting Men

Androgen Deprivation Therapy (ADT) is the Foundational Treatment

**>200,000 men**  
treated with ADT each year

**30% men**  
with prostate cancer have cardiovascular disease

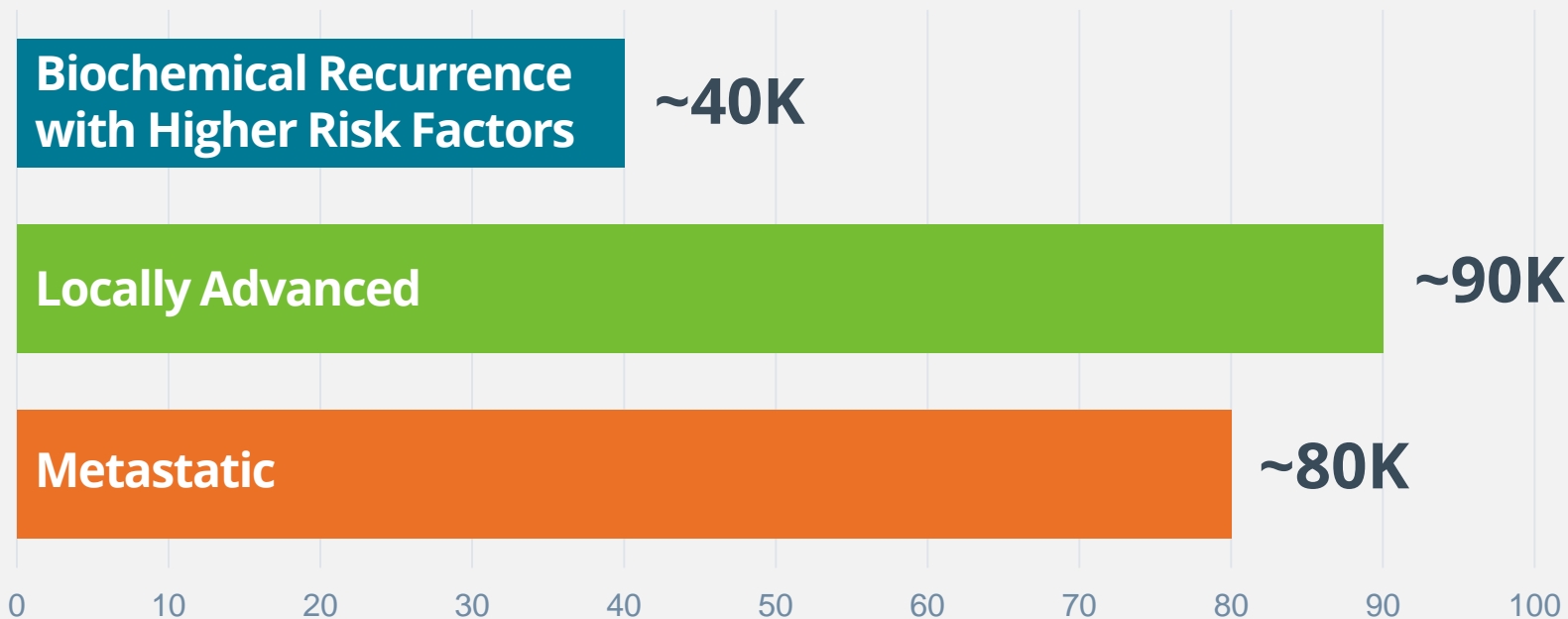
**~3M men**  
diagnosed with prostate cancer alive in the U.S.

National Cancer Institute; PharmaPoint Prostate Cancer 2017; Litwin et al. *JAMA*, 2017; Sartor et al. *NEJM*, 2018. Datamonitor Prostate Cancer Forecast 2018. SEER 21 Database; American College of Surgeons National Cancer Database; Albertsen et al. *Eur Urol*. 2014.



# Relugolix Has Potential to Benefit Broad Spectrum of Men with Advanced Prostate Cancer

## 2018 Prevalence of Prostate Cancer Patients Treated with Androgen Deprivation Therapy



### Current Standard of Care



Injectable

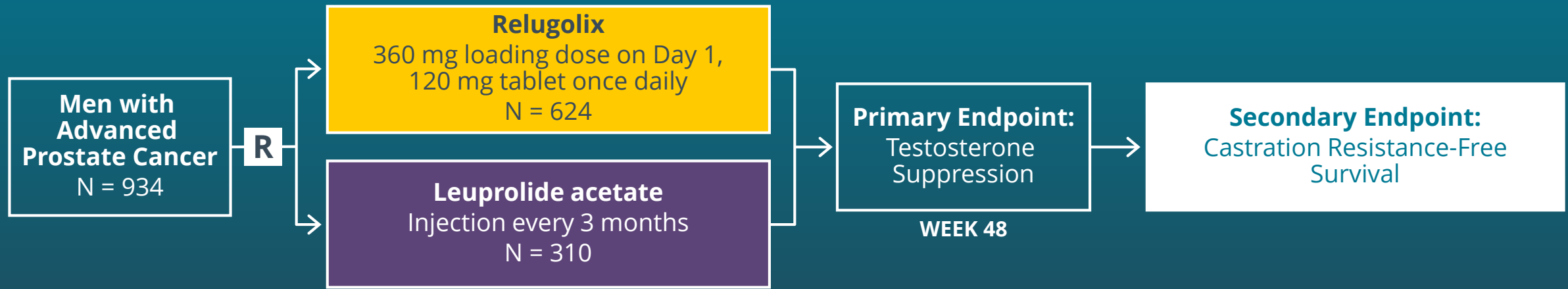


Clinical Flare



Weeks to reduce PSA; Months for testosterone recovery

# HERO: Phase 3 Study Design in Advanced Prostate Cancer



 **Positive Phase 3 Data**

Data Available in  
**Q3 2020**





# The Relugolix Difference: HERO Clinical Data Insights

\*Relugolix is an investigational drug that has not been FDA approved for use

1

**Testosterone Suppression Without Clinical Flare**

2

**Testosterone Recovery Within 90 Days**

3

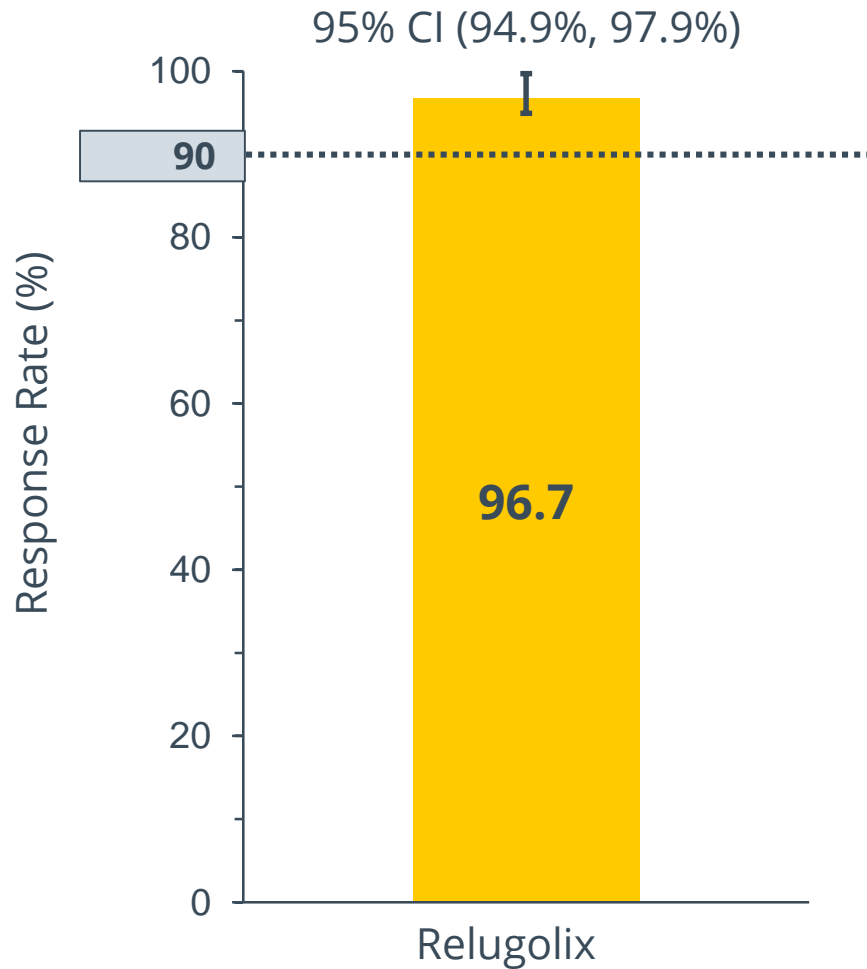
**50% Fewer Major Adverse Cardiovascular Events as Compared to Leuprolide**

4

**One Pill, Once A Day**



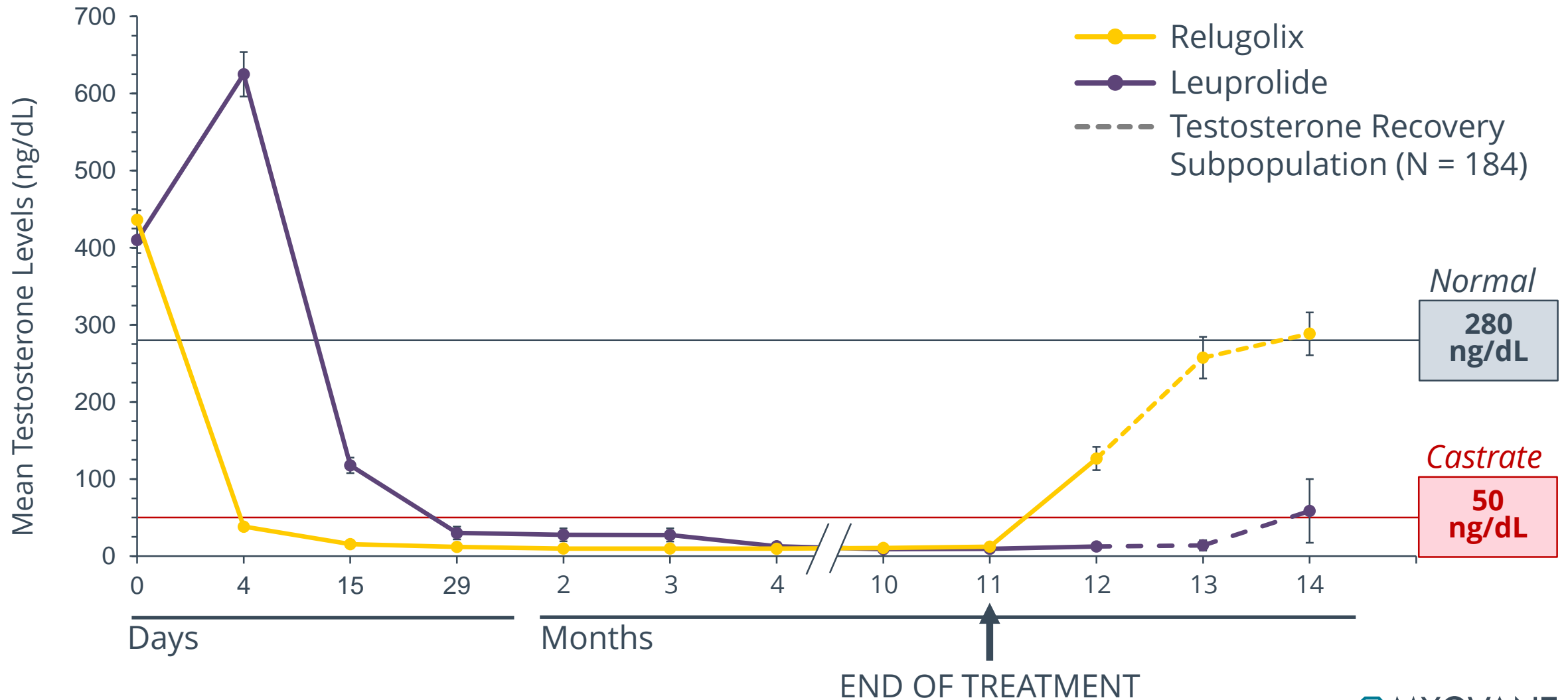
# Achieved U.S. Primary Endpoint



**96.7% of men  
responded to treatment**

**Sustained testosterone suppression  
to castrate levels (< 50 ng/dl) with  
lower bound of 95% CI > 90%**

# Relugolix Achieved Faster Onset & Recovery than Leuprolide



# Superior to Leuprolide in Five Key Secondary Endpoints

| Key Secondary Endpoints  | Definitions   | P-Value           |
|--------------------------|---|-------------------|
| Testosterone Suppression | Testosterone suppression to castrate levels (< 50 ng/dL) at Day 4           | <i>P</i> < 0.0001 |
|                          | Testosterone suppression to castrate levels (< 50 ng/dL) at Day 15          |                   |
|                          | Testosterone suppression to profound castrate levels (< 20 ng/dL) at Day 15 |                   |
| PSA Response             | Confirmed PSA response rate (> 50% reduction from baseline at Day 15)       |                   |
| FSH Level                | Mean FSH level (IU/L) at Week 24  |                   |

PSA = Prostate-Specific Antigen; FSH = Follicle-Stimulating Hormone



# Summary of Adverse Events

| Number of patients, %                         | Relugolix, N = 622 | Leuprolide, N = 308 |
|---|--------------------|---------------------|
| Study discontinuation due to an adverse event | 3.5%               | 2.6%                |
| Patients reporting at least 1 adverse event:  | 92.9%              | 93.5%               |
| Related to study drug                         | 73.6%              | 68.8%               |
| Grade 3 or above                              | 18.0%              | 20.5%               |
| Serious                                       | 12.2%              | 15.3%               |
| Major Adverse Cardiovascular Events (MACE)    | 2.9%               | 6.2%                |
| Fatal outcome                                 | 1.1%               | 2.9%                |

MACE = non-fatal myocardial infarction + non-fatal stroke + all-cause mortality



# Launch Readiness



Hiring of Commercial and Medical Affairs Teams



Advisory Boards and KOL Engagement



Presentations and Publications



Brand Strategies and Tactics



Building Commercial Operations and Medical Affairs Infrastructure



## Focused and Efficient Field Team



### WOMEN'S HEALTH

Millions of women with uterine fibroids and endometriosis are treated primarily by  
**~36K OB/GYNs in the U.S.**



### PROSTATE CANCER

Men with prostate cancer are primarily treated by  
**~18K Urologists and Oncologists in the U.S.**





# A Unique Investment Opportunity

## 2019 Positive Phase 3 Data:

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- Prostate Cancer

## 2020 Endometriosis:

- Phase 3 Data

### Uterine Fibroids:

- 1-Year Data
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- MAA Submission

### Prostate Cancer:

- NDA Submission
- Castration Resistance-Free Survival Data

~\$400M

Cash and committed funding

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**Thank You!**



**Contact Email:**  
[investors@myovant.com](mailto:investors@myovant.com)

