



### **MYFEMBREE**®

(relugolix, estradiol, and norethindrone acetate)
Moderate to Severe Pain Associated with Endometriosis
FDA Approval Conference Call

August 8, 2022



### Introduction

## **Uneek Mehra Chief Financial and Business Officer**

Myovant Sciences, Inc.



### Forward-Looking Statements

This presentation contains forward-looking statements, including without limitation, statements related to: Myovant's aspiration to redefine care for women and for men; the expectations that MYFEMBREE's approval in the U.S. for use by patients with endometriosis would contribute to significant growth opportunities; the timeline and expectations regarding the launch of MYFEMBREE for the management of moderate to severe pain associated with endometriosis by Myovant and Pfizer in the U.S.; the anticipated timeline of commercial coverage for MYFEMBREE endometriosis patients; the expectations of extending support for endometriosis patients; as well as statements related to Myovant's financial position, commercial execution success, market leadership, patient impact, and targeted pipeline investments and focus of new pipeline programs; Myovant's position for its corporate and business development opportunities; the timing and expectations of potential regulatory submissions, including the timing and expectation of submitting the MYFEMBREE sNDA to FDA based on 2-year data in endometriosis; commercial launches by Myovant and/or its partners; anticipated regulatory review results; and Myovant's business strategies, financial condition and trends, competitive position, potential growth opportunities, and expectations or probabilities for success. Forward-looking statements can be identified by the use of words such as "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 result expressed or implied by the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those risks discussed under the heading "Risk Factors" in Myovant's Quarterly Report on Form 10-Q filed on July 27, 2022, as such risk factors may be amended, supplemented or superseded 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.



## **Opening Remarks**

**Dave Marek Chief Executive Officer** 

Myovant Sciences, Inc.



# MYFEMBREE Now Approved in the U.S. for Use By Patients with Endometriosis



#### MYFEMBREE is the first and only once-daily oral treatment indicated for both:

The management of heavy menstrual bleeding associated with uterine fibroids

#### **AND**

• The management of moderate to severe pain associated with **endometriosis** 



## **Expanding Our Impact to More Women in Need**





<sup>(1)</sup> Stewart. Uterine Fibroids. New England Journal of Medicine. 2015;372(17):1646-1655.

<sup>(2) 2020</sup> US Census data.

<sup>(3)</sup> Marjoribanks, et al. Surgery versus medical therapy for heavy menstrual bleeding. *Cochrane Database Syst Rev.* 2006;19(2):CD003855. (4) Louis, et al. Incidence of endometriosis by study population and diagnostic method: the ENDO Study. *Fertil Steril.* 2011;96(2):360-365.

<sup>(5)</sup> Quaas, et al. On-label and off-label drug use in the treatment of endometriosis. Fertil Steril. 2015.103(3):612-625.

# Approval Contributes to Significant Growth Opportunity in 2022 and Beyond



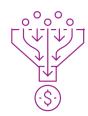
MYFEMBREE brings both significant efficacy and a well characterized safety profile for long-term<sup>1</sup> use, in a convenient **one-pill, once-daily dose** 



New indication creates promotional synergies across uterine fibroids and endometriosis leading to a highly efficient launch, starting later this month



Approval triggers \$100M milestone payment from Pfizer



Approval further enables MYOVANT's ability to achieve **significant growth**, while building our pipeline



# Review of U.S. Prescribing Information and Clinical Data

Juan Camilo Arjona, MD Chief Medical Officer

Myovant Sciences, Inc.



## **Endometriosis: A Significant Quality of Life Impact**

### 3 in 4

women with endometriosis experience symptoms<sup>1</sup>

#### MOST COMMON SYMPTOMS REPORTED BY WOMEN<sup>2</sup>



Menstrual pain & cramping (dysmenorrhea)



Non-menstrual Pelvic Pain



Painful Intercourse (dyspareunia)



#### **UNMET NEEDS IN ENDOMETRIOSIS<sup>3</sup>**

- Effective treatments that deliver relief from the pain associated with endometriosis
- Medical treatment options that reduce repeated surgical procedures
- Treatments with manageable tolerability profiles
- Less reliance on prescription medications to manage pain associated with endometriosis
- Affordable and easy to access treatment options



### Overview of U.S. Prescribing Information for MYFEMBREE

#### **INDICATION**

Management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women

## Management of moderate to severe pain associated with endometriosis in premenopausal women

• Use of MYFEMBREE should be limited to 24 months due to the risk of continued bone loss which may not be reversible

#### **DOSING**

One tablet taken orally once daily, at approximately the same time each day, with or without food

#### DOSAGE FORM AND STRENGTH

Tablet containing a fixed-dose combination of relugolix 40 mg, estradiol 1 mg, and norethindrone acetate 0.5 mg



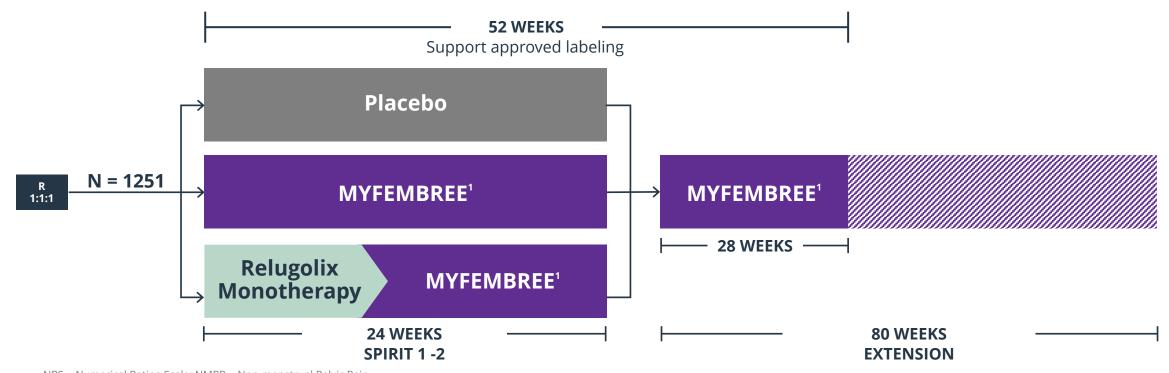


### Phase 3 SPIRIT Clinical Program

Two replicate, 24-week, multinational, double-blind trials involving women with moderate to severe pain associated with endometriosis randomized 1:1:1 to receive once-daily placebo, MYFEMBREE<sup>1</sup>, or delayed<sup>2</sup> MYFEMBREE<sup>1</sup> followed by optional open-label 80-week extension study

#### **Co-Primary Endpoints:**

- Proportion of women with a reduction from baseline of at least 2.8 points on the NRS for dysmenorrhea
- Proportion of women with a reduction from baseline of at least 2.1 points on the NRS for NMPP

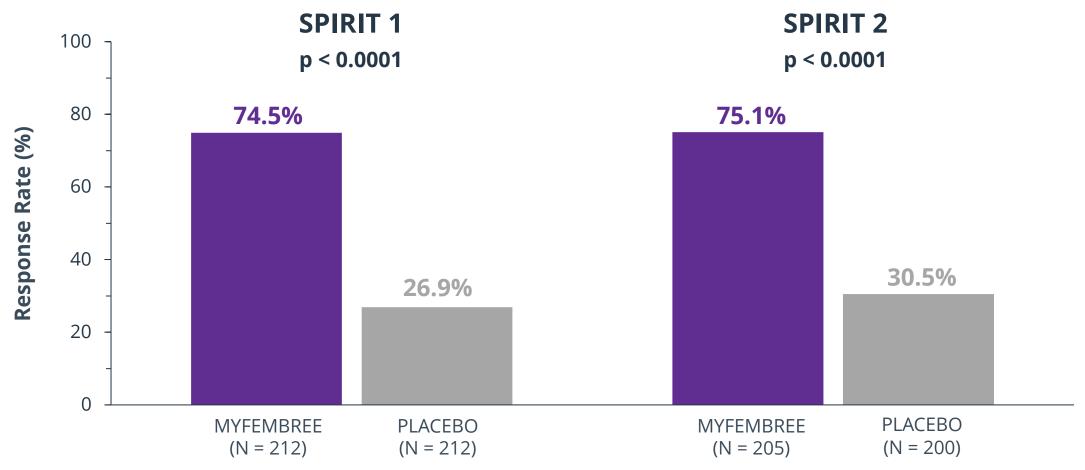




NRS = Numerical Rating Scale; NMPP = Non-menstrual Pelvic Pain

(1) In the SPIRIT 1 and 2 studies, women randomized to receive MYFEMBREE were dosed with a once daily relugality 40 mg tablet plus an

# MYFEMBREE Achieved Significant Response Rates for Dysmenorrhea in SPIRIT 1 and 2

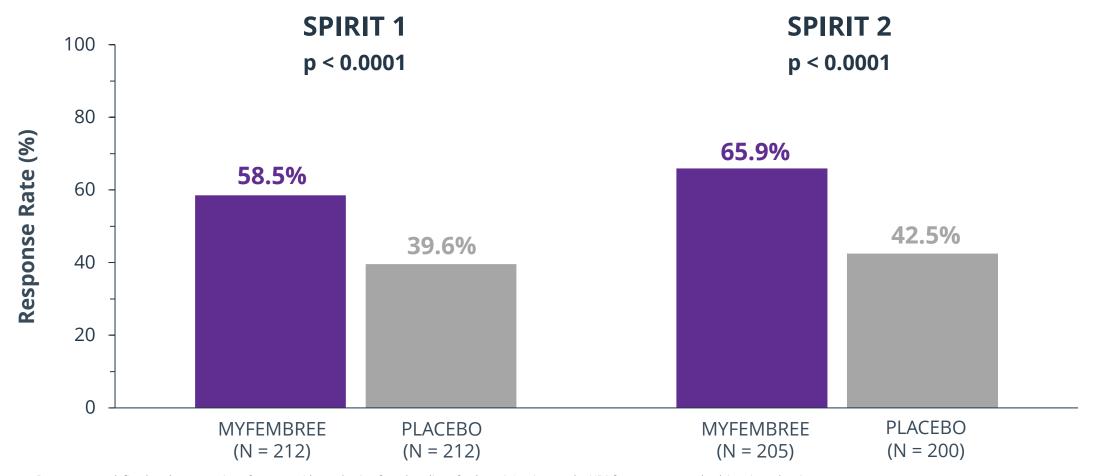


<sup>(1)</sup> Response rate defined as the proportion of women with a reduction from baseline of at least 2.8 points on the NRS for dysmenorrhea and no increase in analgesic use over the last 35 days of treatment at Week 24/EOT.





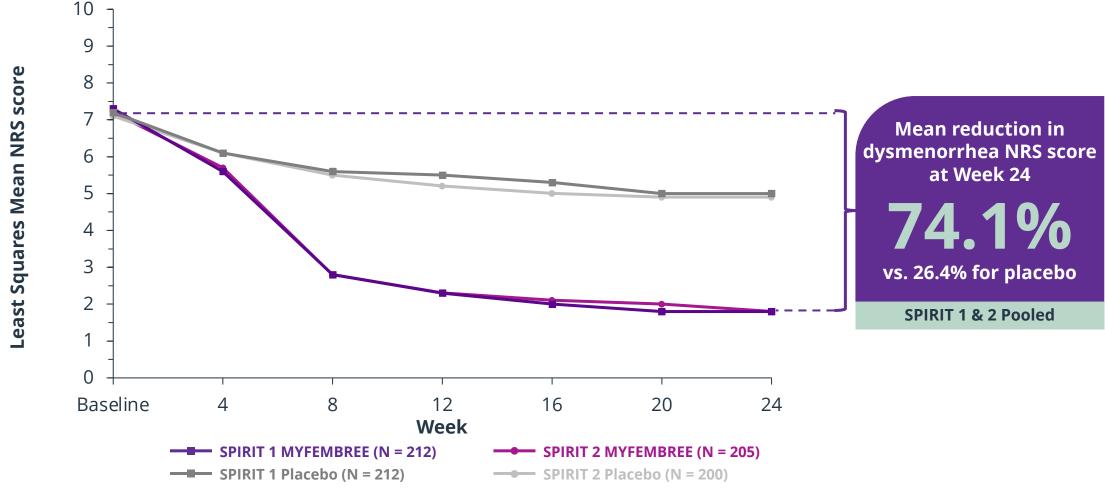
# MYFEMBREE Achieved Significant Response Rates for Non-menstrual Pelvic Pain in SPIRIT 1 and 2



<sup>(1)</sup> Response rate defined as the proportion of women with a reduction from baseline of at least 2.1 points on the NRS for non-menstrual pelvic pain and no increase in analgesic use over the last 35 days of treatment at Week 24/EOT.



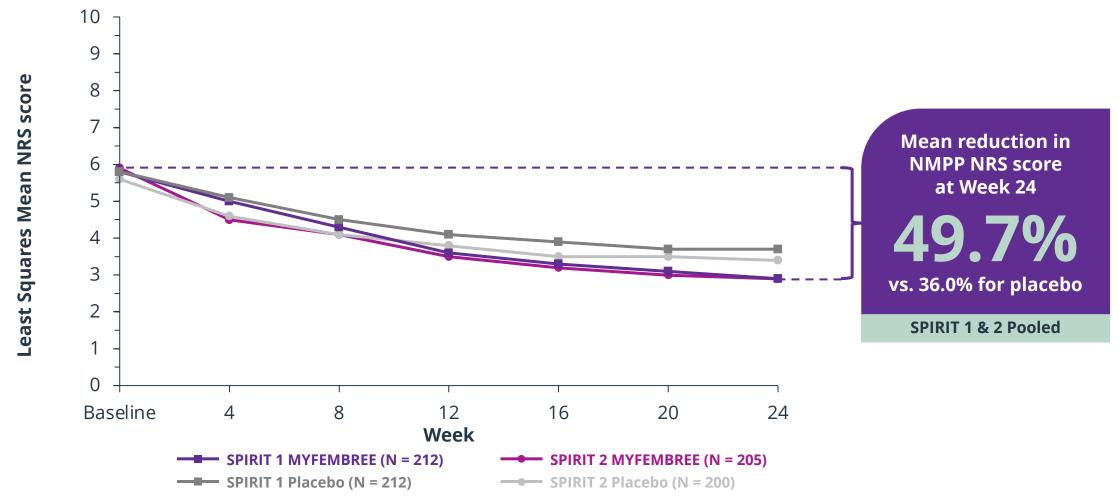
# MYFEMBREE Achieved Sustained Reductions in Dysmenorrhea NRS Scores<sup>1</sup>





MYOVANT SCIENCES

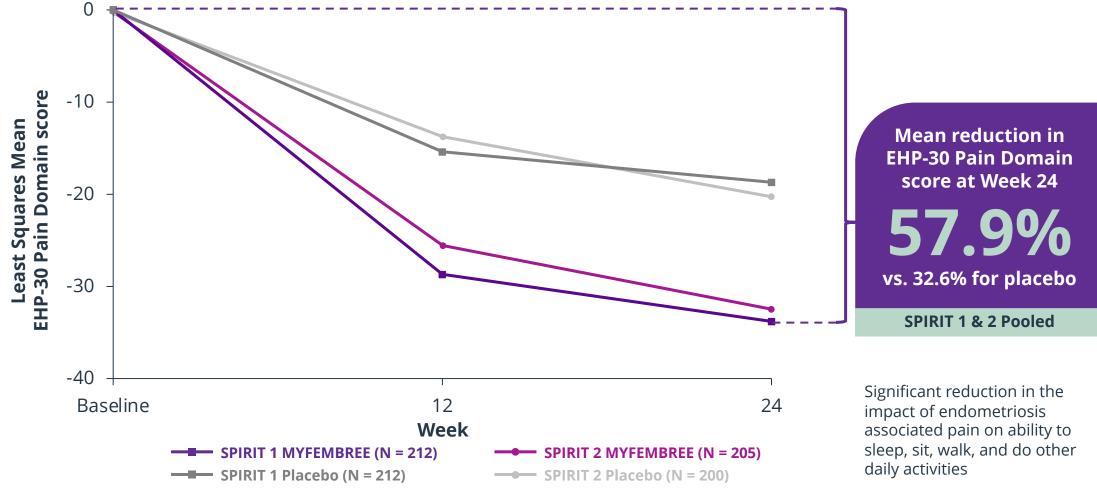
## MYFEMBREE Achieved Sustained Reductions in Non-Menstrual Pelvic Pain NRS Scores<sup>1</sup>





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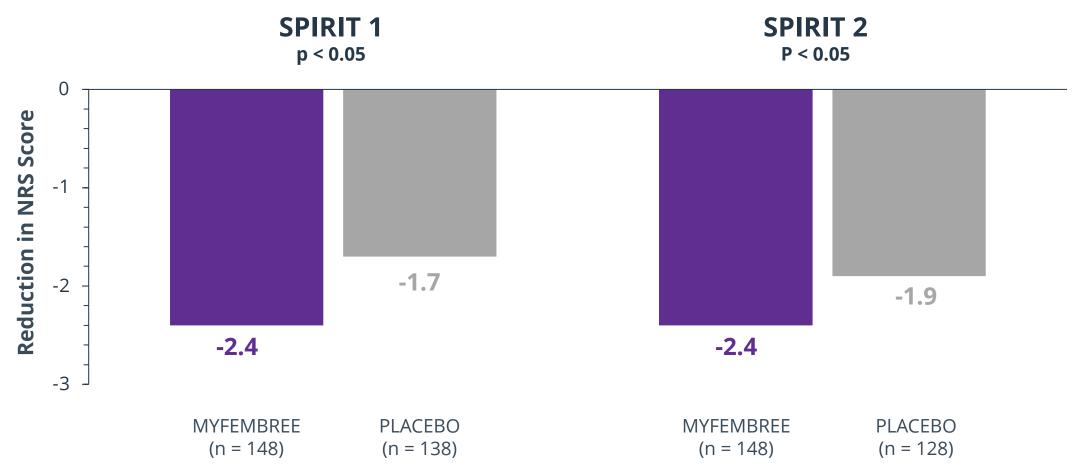
## MYFEMBREE Reduced the Impact of Pain on Activities as Shown By EHP-30 Pain Domain<sup>1</sup>





(1) Up to week 24.

# MYFEMBREE Improved Dyspareunia in Women Who Had Pain with Sexual Intercourse at Baseline

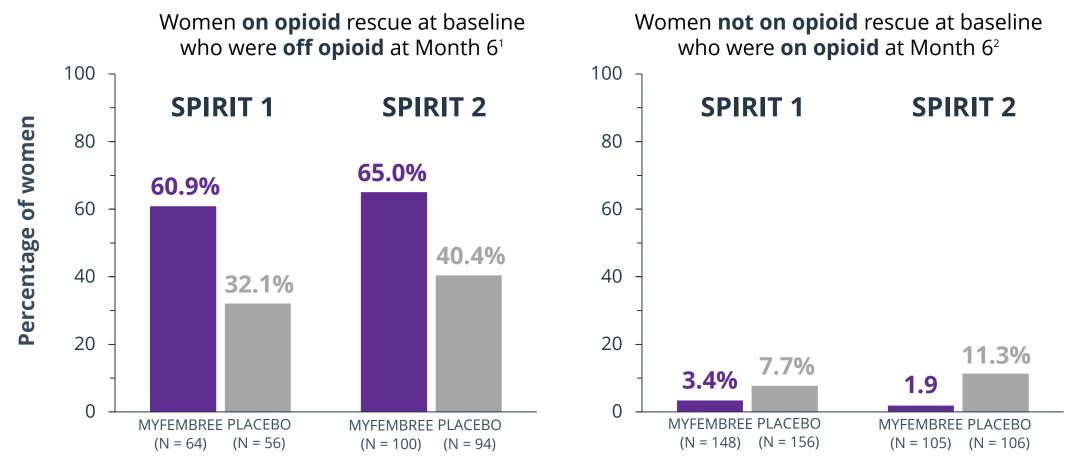


n = Subset of women who reported dyspareunia at baseline and who engaged in sexual activity with vaginal intercourse at baseline and during treatment; Dyspareunia = Pain with sexual intercourse (1) Assessed at Week 24/EOT



<sup>(2)</sup> Dyspareunia (pain during sexual intercourse) was assessed daily using an 11-point Numerical Rating Scale (NRS) ranging from 0 ("no pain") to 10 ("pain as bad as you can imagine") Full prescribing information for MYFEMBREE, including **Black Box Warning**, is available at <a href="https://www.myovant.com/myfembree-prescribing-information.pdf">www.myovant.com/myfembree-prescribing-information.pdf</a> **NOT FOR PROMOTION.** 

## Majority of Women Treated with MYFEMBREE Who Used Opioids at Baseline Were Opioid-free at Week 24







<sup>(2)</sup> Denominator is the number of subjects off opioid rescue analgesics at baseline Full prescribing information for MYFEMBREE, including **Black Box Warning**, is available at <a href="https://www.myovant.com/myfembree-prescribing-information.pdf">www.myovant.com/myfembree-prescribing-information.pdf</a> **NOT FOR PROMOTION.** 

### **MYFEMBREE Safety Highlights**

#### **BOXED WARNING: THROMBOEMBOLIC DISORDERS AND VASCULAR EVENTS**

#### **CONTRAINDICATIONS**

- High risk of arterial, venous thrombotic, or thromboembolic disorder
- Pregnancy
- Known osteoporosis
- Current or history of breast cancer or other hormone-sensitive malignancies
- Known hepatic impairment or disease
- Undiagnosed abnormal uterine bleeding
- Known hypersensitivity to components of MYFEMBREE

#### WARNINGS AND PRECAUTIONS

Bone loss; Suicidal ideation and mood disorders (including depression); Hepatic impairment and transaminase elevations; Elevated blood pressure; Change in menstrual bleeding pattern and reduced ability to recognize pregnancy; Risk of early pregnancy loss; Uterine fibroid prolapse or expulsion; Hypersensitivity reactions



## Adverse Reactions (≥ 3% of Women) Treated with MYFEMBREE and at a Greater Incidence Than Placebo

	MYFEMBREE (N = 418), %	Placebo (N = 416), %
Headache	33.0	26.4
Vasomotor symptoms <sup>1</sup>	13.2	7.2
Mood disorders <sup>2</sup>	9.1	7.2
Abnormal uterine bleeding <sup>3</sup>	6.7	4.6
Nausea	6.0	4.1
Toothache	5.5	2.4
Back pain	4.8	2.9
Decreased sexual desire and arousal <sup>4</sup>	4.3	1.2
Arthralgia	3.6	2.2
Fatigue	3.1	2.4
Dizziness	3.1	1.2

Adverse reactions most commonly reported in the SPIRIT extension study were similar to those in the placebo-controlled SPIRIT 1 and 2 studies.

NOTE: Table includes data from SPIRITY 1 and 2 studies pooled only. Does not include extension study. (1) Includes hot flush, hyperhidrosis, night sweats, and flushing.

Full prescribing information for MYFEMBREE, including **Black Box Warning**, is available at <u>www.myovant.com/myfembree-prescribing-information.pdf</u> **NOT FOR PROMOTION**.



<sup>(2)</sup> Includes affect lability, affective disorder, anxiety, depressed mood, depression, emotional distress, generalized anxiety disorder, irritability, mixed anxiety and depressive disorder, mood altered, mood swings, and suicidal ideation.
(3) Includes menorrhagia, metrorrhagia, vaginal hemorrhage, uterine hemorrhage, polymenorrhea, and menstruation irregular.

<sup>(4)</sup> Includes libido decreased, libido disorder, and female sexual arousal disorder.

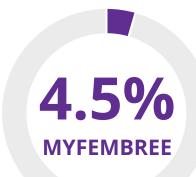
## MYFEMBREE Serious Adverse Reactions and Adverse Reactions Leading to Study Discontinuation Similar to Placebo

Proportion of women in which serious adverse reactions were reported





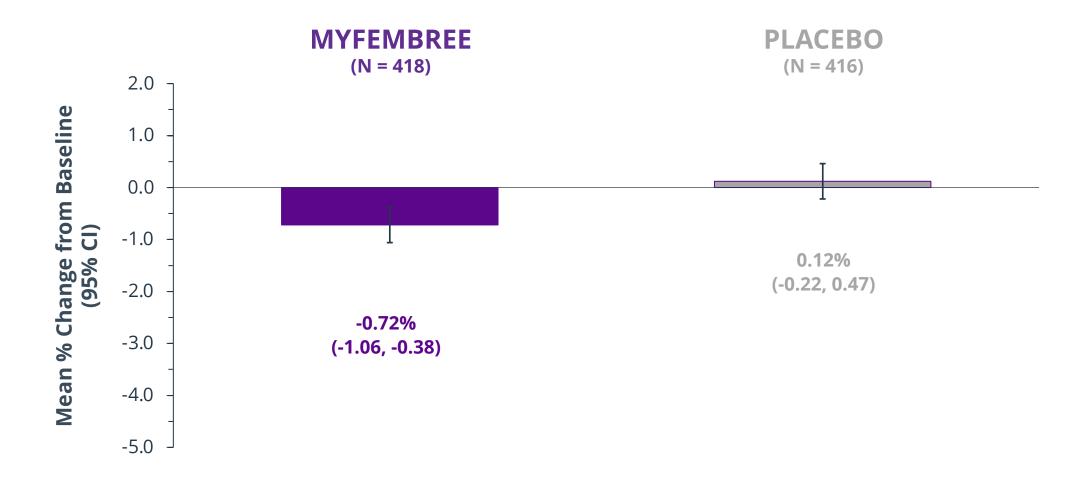
Proportion of women in which adverse reactions led to discontinuation







## Change from Baseline in Lumbar Spine BMD at Month 6 in Pooled Data from SPIRIT 1 and 2 Studies





## Change from Baseline in Lumbar Spine BMD at Month 6 and Month 12

Natural History Observational Study<sup>1</sup> (N = 452)



SPIRIT
Open-Label
Extension Study
(N = 277)



BMD = Bone mineral density; CI = Confidence interval



<sup>(1)</sup> A separate concurrent prospective observational study enrolled 452 women with endometriosis who were age-matched to participants of the SPIRIT 1 and 2 studies. These women did not receive treatment for endometriosis and underwent DXA scans at Month 6 and Month 12 to monitor for changes in BMD. Full prescribing information for MYFEMBREE, including **Black Box Warning**, is available at <a href="https://www.myovant.com/myfembree-prescribing-information.pdf">www.myovant.com/myfembree-prescribing-information.pdf</a> **NOT FOR PROMOTION.** 

#### **MYFEMBREE** for Pain Associated with Endometriosis

CLINICAL PROFILE	MYFEMBREE® (placebo)	
Dose and Dosing Regimen	40 mg once-daily	
<b>Duration of treatment</b>	2 years	
EFFICACY	SPIRIT 1	SPIRIT 2
• Dysmenorrhea	<b>74.5%</b> (26.9%)	<b>75.1%</b> (30.5%)
• Non-Menstrual Pelvic Pain	<b>58.5%</b> (39.6%)	<b>65.9%</b> (42.6%)
• Dyspareunia	$\otimes$	$\bigotimes$
EHP 30	$\otimes$	$\otimes$
Vasomotor Symptoms <sup>1</sup>	13.2% (7.2%)	
Bone Mineral Density Loss, Lumbar Spine <i>(placebo)</i>	-0.70% (0.12%)	

- Best in class results for dysmenorrhea, NMPP, and dyspareunia for a product approved with 2 years duration of use
- Demonstrated improvement in the impact of pain on daily function
- Vasomotor symptoms, were infrequent, mild to moderate in severity, and unlikely to lead to discontinuation
- Less than 1% BMD loss over 1 year



### **MYFEMBREE Launch Readiness Update**

## **Lauren Merendino Chief Commercial Officer**

Myovant Sciences, Inc.



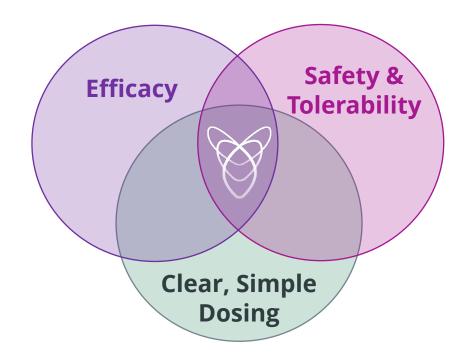
### Only MYFEMBREE Delivers Meaningful Pain Relief and Tolerability in One Simple Pill for Up to 2 Years





#### **REDUCTION IN MOST COMMON SYMPTOMS<sup>1</sup>:**

- Dysmenorrhea
- Non-menstrual pelvic pain
- Dyspareunia
- **REDUCED IMPACT OF PAIN:** 58% improvement in composite pain score<sup>1</sup>
- **DEMINISHED PAIN MEDICATION USE:** >60% women stopped opioid and analgesic use1





- **BONE MINERAL DENSITY:** Mean change in lumbar spine bone mineral density of <1% at 1 year
- **USE FOR UP TO 2 YEARS**







<sup>(2)</sup> Includes hot flush, hyperhidrosis, night sweats or flushing.

# Driving Launch Success Through Focus on Providers, Payers and Patients





Position MYFEMBREE as an effective, well-tolerated and simple treatment option for women with endometriosis whose oral contraceptive failed to provide meaningful relief



Rapidly establish high-quality coverage for endometriosis



Ensure positive initial experience for patients

MYFEMBREE's market opportunity approximately doubles with endometriosis approval



# Highly Efficient Launch By Established Team with Existing Relationships







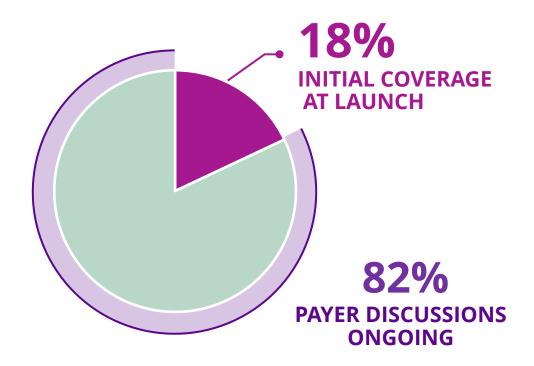
- Myovant & Pfizer teams prepared for launch in August
- Rapid engagement strategy for priority endometriosis targets
- Existing relationships with vast majority of endometriosis prescribers
- Dual indication calls for vast majority of customers
- Additional efficiencies in speaker programs, conferences and non-personal promotions



### 18% of Commercial Lives Covered for Endometriosis at Launch



Estimated Commercial Lives Covered August 2022



Preliminary discussions with payers began pre-launch

Goal of achieving broad commercial coverage within 6 months of launch



## **Extending Support for Endometriosis Patients to Deliver Positive First Experience**



**Benefits Investigation** 

Starter and **Bridge Programs** 

**Patient Assistance Program for Eligible Uninsured Patients** 

**Copay Support** for Commercially **Insured Patients** 



- Works with practices to support efforts in obtaining coverage
- Identifies support services for eligible patients

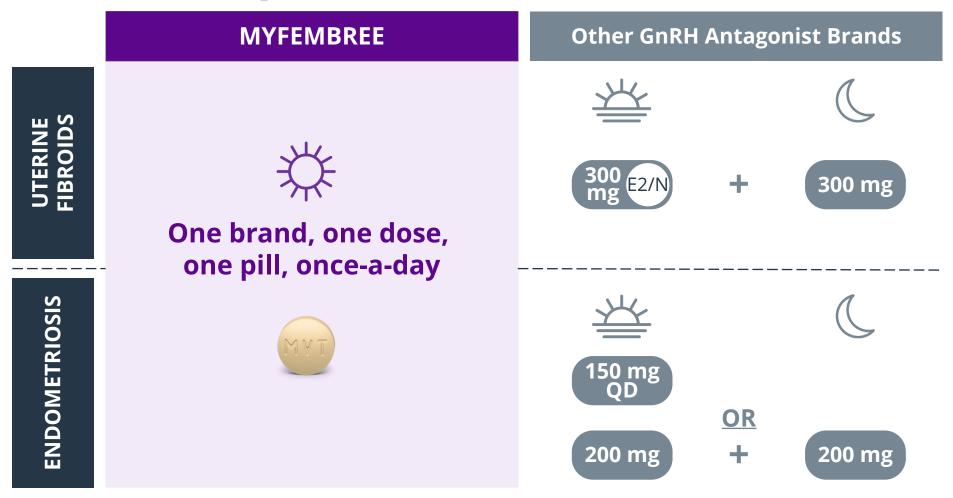


**Prior Authorization** 

& Appeals Support

# Simplicity Across Indications Sets MYFEMBREE Apart









## Positioned to Deliver on Key Growth Drivers

#### Delivering for Today

**ORGOVYX** – drive continued growth across patient types and treatment settings towards establishing a new standard of care

MYFEMBREE – leverage clinical profile and one-brand, one-pill, once-daily advantage to expand market share while growing the class¹ for both uterine fibroids and endometriosis

Leverage **strategic partnerships** to expand our patient impact globally

Strong **financial position** fuels successful commercial execution and targeted pipeline investments

#### While Building for Tomorrow

**EMA submission** for endometriosis by Gedeon Richter in 2022<sup>2</sup>

**New Drug Submission** to Health Canada for ORGOVYX and MYFEMBREE in 2022<sup>2</sup>

**ORGOVYX commercial launch** in Europe by Accord expected in 2022<sup>2</sup>

Support FDA's review of the accepted **MYFEMBREE sNDA** based on 2-year data in uterine fibroids; PDUFA January 29, 2023

Submit **MYFEMBREE sNDA** to FDA based on 2-year data in endometriosis in first half of 2023<sup>2</sup>

Details on **new pipeline programs** focused on women's health and hormone-sensitive oncology in FY2022



(1) GnRH antagonist class

### **Q&A Panel**

**Myovant Sciences, Inc.** 



**Dave Marek**Chief Executive Officer

**Uneek Mehra**Chief Financial & Business Officer

**Lauren Merendino**Chief Commercial Officer

Juan Camilo Arjona Ferreira, MD

Chief Medical Officer





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

investors@myovant.com