Myfembree®
(relugolix, estradiol, and norethindrone acetate) tablets
40 mg, 1 mg, 0.5 mg

You're invited to attend a **Myfembree** live event!

The Emerging Paradigm of Endometriosis-Associated Pain Management

Date: Thursday, April 13, 2023

Event ID: 1089

Time: 6:30 PM ET

WHAM/Host: Rich Joesting at

Location: Eddie Merlot's
10808 Montgomery Road
Cincinnati, OH 45242

Presented By:

Samir Ahuja, MD
University Hospitals of Cleveland
Cleveland, OH

Please RSVP for this event by registering here:

WWW.MYOVANTPROGRAMS.COM/REGISTRATION/EVENT/MYFEMBREE

Or call 866-825-8821 to speak to a program representative

This is a promotional program sponsored by Myovant Sciences Inc. CE/CME credit will not be available for this session. This program is not eligible for AMA PRA Category 1 Credits™. Attendance at this educational program is limited to healthcare professionals. If made available, food and beverage costs and any other transfers of value provided to applicable healthcare providers will be reported under any/all state and federal laws. In accordance with OIG and PhRMA Guidelines, Myovant will not provide alcohol at this program.

INDICATIONS

Myfembree is indicated in premenopausal women for the management of:
- Heavy menstrual bleeding associated with uterine leiomyomas (fibroids)
- Moderate to severe pain associated with endometriosis

Limitations of Use: Use of Myfembree should be limited to 24 months due to the risk of continued bone loss which may not be reversible.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: THROMBOEMBOLIC DISORDERS AND VASCULAR EVENTS

- **Estrogen and progestin combination products, including Myfembree, increase the risk of thrombotic or thromboembolic disorders including pulmonary embolism, deep vein thrombosis, stroke and myocardial infarction, especially in women at increased risk for these events.**
- **Myfembree is contraindicated in women with current or a history of thrombotic or thromboembolic disorders and in women at increased risk for these events, including women over 35 years of age who smoke or women with uncontrolled hypertension.**

CONTRAINDICATIONS

Myfembree is contraindicated in women with any of the following: 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

Thromboembolic Disorders: Discontinue immediately if an arterial or venous thrombotic, cardiovascular, or cerebrovascular event occurs or is suspected. Discontinue at least 4 to 6 weeks before surgery associated with an increased risk of thromboembolism, or during periods of prolonged immobilization, if feasible. Discontinue immediately if there is sudden unexplained partial or complete loss of vision, proptosis, diplopia, papilledema, or retinal vascular lesions and evaluate for retinal vein thrombosis as these have been reported with estrogens and progestins.

Bone Loss: Myfembree may cause a decrease in bone mineral density (BMD) in some patients, which may be greater with increasing duration of use and may not be completely reversible after stopping treatment. Consider the benefits and risks in patients with a history of low trauma fracture or risk factors for osteoporosis or bone loss, including medications that may decrease BMD. Assessment of BMD by dual-energy X-ray absorptiometry (DXA) is recommended at baseline in all women. During treatment, periodic DXA is recommended for women with heavy menstrual bleeding due to uterine fibroids; in those with moderate to severe endometriosis pain, annual DXA is recommended. Consider discontinuing Myfembree if the risk of bone loss exceeds the potential benefit.

Hormone-Sensitive Malignancies: Discontinue Myfembree if a hormone-sensitive malignancy is diagnosed. Surveillance measures in accordance with standard of care, such as breast examinations and mammography are recommended. Use of estrogen alone or estrogen plus progestin has resulted in abnormal mammograms requiring further evaluation.

Please see Important Safety Information continued on next page and accompanying full Prescribing Information, including BOXED WARNING

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IMPORTANT SAFETY INFORMATION (cont.)

Suicidal Ideation and Mood Disorders (Including Depression): Evaluate patients with a history of suicidal ideation, depression, and mood disorders prior to initiating treatment. Monitor patients for mood changes and depressive symptoms including shortly after initiating treatment, to determine whether the risks of continuing therapy with Myfembree outweigh the benefits. Patients with new or worsening depression, anxiety, or other mood changes should be referred to a mental health professional, as appropriate. Advise patients to seek immediate medical attention for suicidal ideation and behavior and reevaluate the benefits and risks of continuing Myfembree. Gonadotropin-releasing hormone receptor antagonists, including Myfembree, have been associated with mood disorders (including depression) and suicidal ideation.

Hepatic Impairment and Transaminase Elevations: Steroid hormones may be poorly metabolized in these patients. Instruct women to promptly seek medical attention for symptoms or signs that may reflect liver injury, such as jaundice or right upper abdominal pain. Acute liver test abnormalities may necessitate the discontinuation of Myfembree use until the liver tests return to normal and Myfembree causation has been excluded.

Gallbladder Disease or History of Cholestatic Jaundice: Discontinue Myfembree if signs or symptoms of gallbladder disease or jaundice occur. For women with a history of cholestatic jaundice associated with past estrogen use or with pregnancy, assess the risk-benefit of continuing therapy. Studies among estrogen users suggest a small increased relative risk of developing gallbladder disease.

Elevated Blood Pressure: For women with well-controlled hypertension, monitor blood pressure and stop Myfembree if blood pressure rises significantly.

Change in Menstrual Bleeding Pattern and Reduced Ability to Recognize Pregnancy: Advise women to use non-hormonal contraception during treatment and for one week after discontinuing Myfembree. Avoid concomitant use of hormonal contraceptives. Myfembree may delay the ability to recognize pregnancy because it alters menstrual bleeding. Perform testing if pregnancy is suspected and discontinue Myfembree if pregnancy is confirmed.

Risk of Early Pregnancy Loss: Myfembree can cause early pregnancy loss. Exclude pregnancy before initiating and advise women to use effective non-hormonal contraception.

Uterine Fibroid Prolapse or Expulsion: Advise women with known or suspected submucosal uterine fibroids about the possibility of uterine fibroid prolapse or expulsion and instruct them to contact their physician if severe bleeding and/or cramping occurs.

Alopecia: Alopecia, hair loss, and hair thinning were reported in phase 3 trials with Myfembree. Consider discontinuing Myfembree if hair loss becomes a concern. Whether the hair loss is reversible is unknown.

Effects on Carbohydrate and Lipid Metabolism: More frequent monitoring in Myfembree-treated women with prediabetes and diabetes may be necessary. Myfembree may decrease glucose tolerance and result in increased blood glucose concentrations. Monitor lipid levels and consider discontinuing if hypercholesterolemia or hypertriglyceridemia worsens. In women with pre-existing hypertriglyceridemia, estrogen therapy may be associated with elevations in triglycerides levels leading to pancreatitis. Use of Myfembree is associated with increases in total cholesterol and LDL-C.

Effect on Other Laboratory Results: Patients with hypothyroidism and hypoadrenalism may require higher doses of thyroid hormone or cortisol replacement therapy. Use of estrogen and progestin combinations may raise serum concentrations of binding proteins (e.g., thyroid-binding globulin, corticosteroid-binding globulin), which may reduce free thyroid or corticosteroid hormone levels. Use of estrogen and progestin may also affect the levels of sex hormone-binding globulin, and coagulation factors.

Hypersensitivity Reactions: Immediately discontinue Myfembree if a hypersensitivity reaction occurs.

ADVERSE REACTIONS: Most common adverse reactions for Myfembree (incidence ≥3% and greater than placebo) were:

- Heavy menstrual bleeding associated with uterine fibroids: vasomotor symptoms, abnormal uterine bleeding, alopecia, and decreased libido.
- Moderate to severe pain associated with endometriosis: headache, vasomotor symptoms, mood disorders, abnormal uterine bleeding, nausea, toothache, back pain, decreased sexual desire and arousal, arthralgia, fatigue, and dizziness.

These are not all the possible side effects of Myfembree.

DRUG INTERACTIONS: P-gp Inhibitors: Avoid use of Myfembree with oral P-gp inhibitors. If use is unavoidable, take Myfembree first, separate dosing by at least 6 hours, and monitor patients for adverse reactions. **Combined P-gp and Strong CYP3A Inducers**: Avoid use of Myfembree with combined P-gp and strong CYP3A inducers.

LACTATION: Advise women not to breastfeed while taking Myfembree.

Please see accompanying full Prescribing Information, including BOXED WARNING

Notice: This event is conducted in accordance with the PhRMA Code on Interactions with Health Care Professionals (HCPs) and is limited to appropriate attendees. Guests or spouses may not attend a Myovant speaker program unless the individual independently qualifies as an appropriate attendee. Before providing an RSVP or attending a program, please confirm with your Myovant representative that you meet the requirements to attend.

State and Federal Employees: State and ederal laws and regulations may carry additional restrictions. By attending this event, you confirm that you have obtained any necessary approvals from your employer.

Public Disclosures: If a meal is provided to U.S. HCPs, the cost of the meal is subject to Myovant's national public disclosure policy as well as applicable state and federal law such as the National Physician Payment Transparency Program (otherwise known as "Sunshine"). Myovant's disclosure allocates the cost of meals equally across all attendees who have not opted out of receiving a meal or have consumed a meal regardless of opt-out status.

State Law Restrictions:

Minnesota: Regardless of where you practice or reside, if you are a Minnesota-licensed practitioner with prescribing privileges, then you may not consume any food or beverage associated with this event.

Vermont: Regardless of where you practice or reside, if you are a Vermont-licensed HCP, you may not consume any food or beverage associated with this event. Additionally, if you are an employee/agent of a Vermont HCP (e.g., PAs, non-prescribing nurses, etc.), regardless of where you practice or reside, you may not consume any food or beverage associated with this event.