Transcript Details
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A Once Daily Treatment Option for Heavy Menstrual Bleeding Due to Uterine Fibroids or Moderate to Severe Pain Due to Endometriosis in Premenopausal Women

Dr. Caudle:
This is *Advances in Women's Health* on ReachMD. I'm your host Dr. Jennifer Caudle, and joining me to discuss how an FDA-approved treatment option in premenopausal women could help address uterine fibroid-associated heavy menstrual bleeding or moderate to severe endometriosis pain is Dr. Rosanne Kho, Chair of the OB/GYN Department at the University of Arizona College of Medicine in Phoenix.

Welcome to the program, Dr. Kho.

Dr. Kho:
Thank you, so much for having me.

Dr. Caudle:
Dr. Kho, let's start off with uterine fibroids, which is a common and burdensome health concern for many premenopausal women. Can you tell us about the challenges associated with diagnosing and treating uterine fibroids?

Dr. Kho:
Thank you for that question,Uterine fibroids affect approximately 19 million women between the ages of 15 and 49 years in the U.S., with about five million patients experiencing symptoms severe enough to require treatment.[1,2] And unfortunately, patients are often dismissed when presenting with heavy or painful periods, so establishing a diagnosis requires us as providers to ask further questions and perform further evaluation, including imaging, as a next step.[3,4]

Heavy menstrual bleeding is the most commonly experienced symptom—affecting about one in three patients with uterine fibroids—and it can lead to anemia, fatigue, and dysmenorrhea.[2,5]

Dr. Caudle:
With that being said, Dr. Kho, how can we manage heavy menstrual bleeding for patients?

Dr. Kho:
Medical therapies, such as combined hormonal contraceptives, or CHCs, tranexamic acid, and levonorgestrel-containing intrauterine devices, or IUDs, are usually the first therapies considered for patients with heavy menstrual bleeding related to uterine fibroids.[3]

Gonadotropin-releasing hormone analogues, or GnRH analogues for short, are an approved treatment for use in patients with fibroids, and they have varying limitations on the duration of use.[6-8] Unfortunately, even for patients on treatment, as many as 50 percent report ongoing moderate to severe symptoms of pelvic pressure and heavy menstrual bleeding.

Announcer:
This data is based on a cross-sectional survey of 59,411 women, of whom 1025 were being treated for uterine fibroids.[9]

Dr. Kho:
Interestingly, in a survey of 968 patients with fibroids who were asked about their own preferences in treatment, 79 percent of patients did not want to undergo invasive surgery for fibroids.[10] So, for patients who either prefer to avoid invasive surgery, or who may not be good candidates for surgery, we can offer medical therapy as a treatment option.[3]

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Now, allow me to focus our discussion on a once daily treatment called Myfembree®, a combination of relugolix, estradiol, and norethindrone acetate, which is the first FDA-approved GnRH antagonist combination therapy that's dually indicated in premenopausal patients for the management of heavy menstrual bleeding associated with fibroids, as well as moderate to severe pain associated with endometriosis.[6] It's important to keep in mind that use of Myfembree should be limited to 24 months due to the risk of continued bone loss, which may not be reversible.[6]

Dr. Caudle:
And before we take a closer look at Myfembree, let's pause for a moment and review some Important Safety Information.

Announcer:
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 those at increased risk for these events, including women >35 years of age who smoke or with uncontrolled hypertension.

Please stay tuned to hear Important Safety Information continued throughout this program.

Please see full Prescribing Information, including BOXED WARNING, at the link below this video or tinyurl.com/MyfembreePI

Dr. Caudle:
And with that important safety information in mind, Dr. Kho, can you tell us a bit about the makeup and mechanism of action for this treatment option?

Dr. Kho:
Absolutely. So when we break down its components, Myfembree combines three key ingredients into a once daily pill to support an optimal estradiol range. This treatment consists of a GnRH antagonist, 40 milligrams of relugolix, with added hormonal therapy of one milligram of estradiol and 0.5 milligrams of norethindrone acetate. Each of these components of Myfembree has a very specific role.[6,11]

Relugolix is a non-peptide GnRH receptor antagonist that competitively binds to pituitary GnRH receptors, reducing the release of follicle-stimulating and luteinizing hormones, which then decreases downstream production of estradiol and progesterone. This aids in reducing the bleeding associated with uterine fibroids and pain associated with endometriosis.[6]It's important to note that with endogenous estradiol suppression, patients can experience hypoestrogenic effects, such as bone loss and vasomotor symptoms like hot flashes.[11]

That is why the exogenous estradiol component may reduce the increased bone resorption and the resultant bone loss that can occur from relugolix. [6] The norethindrone acetate may protect the uterus from the potential adverse endometrial effects of unopposed estrogen.[6]

So, by combining the three key ingredients, Myfembree is designed to maintain estradiol levels in an optimal midrange. It is intended to mitigate the hypoestrogenic effects of a low estradiol range, such as bone loss, while still helping to reduce the symptoms of heavy menstrual bleeding due to uterine fibroids or moderate to severe endometriosis pain from a high estradiol range.[11,12,13]

Dr. Caudle:
Well thank you for walking us through the mechanism of action and design rationale for Myfembree, Dr. Kho. I'd like to take a moment here to learn more Important Safety Information.

Announcer:
Important Safety Information, continued

CONTRAINDICATIONS
Myfembree is contraindicated in women with: high risk of arterial, venous thrombotic, or thromboembolic disorder; pregnancy; known osteoporosis; current or history of breast- or other hormone-sensitive cancers; known hepatic impairment or disease; undiagnosed abnormal uterine bleeding; known hypersensitivity to components of Myfembree.

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WARNINGS AND PRECAUTIONS

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

Bone Loss: Myfembree may decrease bone mineral density (BMD) in some patients, which may be greater with longer use and may not be completely reversible. Consider the benefits and risks in patients with a history of low trauma fracture or risk factors for osteoporosis or bone loss. Baseline dual-energy X-ray absorptiometry (DXA) is recommendedin all women. During treatment, DXA is recommended periodically for heavy menstrual bleeding due to uterine fibroids and annually for moderate to severe endometriosis pain.

Please stay tuned to hear Important Safety Information continued throughout this program.

Dr. Caudle:
Now as we return from that Important Safety Information message, Dr. Kho, could you tell us about the clinical trials that led to the approval of Myfembree for heavy menstrual bleeding due to uterine fibroids?

Dr. Kho
Sure. So Myfembree was evaluated in two replicate, 24-week, multinational, randomized, double-blinded, placebo-controlled clinical trials called LIBERTY 1 and 2. They enrolled a total of 768 premenopausal patients with heavy menstrual bleeding associated with fibroids. In these trials, heavy menstrual bleeding was defined as menstrual blood loss volume of 80 milliliters or more for two cycles or 160 milliliters or more for one cycle.[6]

The primary endpoint in LIBERTY 1 and 2 was the proportion of patients in the Myfembree group, compared with placebo, who achieved menstrual blood loss of less than 80 cc's as well as 50 percent or more reduction in menstrual blood loss volume from baseline over the last 35 days of treatment.

Announcer:
Women were randomized 1:1:1, with 253 to receive Myfembree, 256 to receive placebo, and 259 to receive 12 weeks of relugolix monotherapy followed by 12 weeks of Myfembree.[6]

Dr. Kho:
I will note here that the relugolix monotherapy treatment arm was included to compare its impact on hypoestrogenic effects, like bone mineral density, to combination treatment of relugolix plus hormone therapy. So, that data will not be reviewed here because relugolix monotherapy is not approved in the United States for heavy menstrual bleeding due to uterine fibroids.Patients who completed LIBERTY 1 and 2 were eligible to enroll in an open-label extension study. A total of 476 patients were treated with Myfembree in this 28-week extension study.[6]

Turning to the LIBERTY trials patient population, the clinical and demographic characteristics of the patients in the Myfembree and placebo arms were balanced in both trials. The median age was 43 years, with a range from 19 to 51 years, and mean body mass index was 31.6 kilograms per meters squared. Black patients made up 53 percent of the study participants, White patients were 41 percent, and 6 percent were of the other races.[6]

And looking at their baseline uterine fibroid-related characteristics, with a mean menstrual blood loss volume of 231 cc's and mean hemoglobin of 11.2 grams per deciliter, patients in the LIBERTY 1 and 2 studies were representative of patients with symptomatic fibroids in the general population based in other reports.[3,6,14,15,16]So now let's look at the pooled results, approximately 72 percent of patients taking Myfembree were responders, which means that their bleeding reduced by half or more and to less than 80 cc's over the last 35 days of their treatment, compared to about 16 percent of patients taking placebo.

Announcer:
Separately, the results for the LIBERTY trials were 72.1 percent and 71.2 percent for Myfembree in LIBERTY 1 and 2 versus 16.8 percent and 14.7 percent for placebo, respectively, with a P value less than 0.0001 for both.[16]

Dr. Kho:
In a pooled key secondary endpoint, there was a 50.8 percent reduction in menstrual blood loss volume by week four with Myfembree compared to 12.7 percent with placebo.[16] Please note, that the menstrual blood loss volume assessments at weeks four through 20 were prespecified but not adjusted for multiplicity.[12]By the end of the study, the pooled mean reduction in menstrual blood loss volume was 83.7 percent in the Myfembree group, compared to only 17.2 percent in the placebo group.

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Announcer:
For each trial, the results at Week 24 were 82.0 percent and 84.3 percent for Myfembree for LIBERTY 1 and 2 versus 19.1 percent and 15.1 percent for placebo, respectively, with a P value less than 0.0001 for both.[16]

Dr. Caudle:
And if we now focus on the safety data in the LIBERTY trials, what did they show?

Dr. Kho:
So first off, the LIBERTY studies had pre-specified safety endpoints that included:[13]

- adverse events;
- change in bone mineral density; and
- vasomotor symptoms.

Dr. Kho:
Serious adverse reactions were reported in 3.1 percent of Myfembree-treated patients compared with 2.3 percent of placebo-treated patients. These included uterine myoma expulsion and menorrhagia, uterine fibroid prolapse, cholecystitis, and pelvic pain.[6]

Also, discontinuation rates due to adverse events were similar between the two groups, at 3.9 percent for Myfembree and 4.3 percent for placebo. In the Myfembree arm, discontinuation was most commonly due to uterine bleeding events at 1.2 percent, with onset usually reported within the first three months of therapy.[6]The most common adverse reactions reported in at least three percent of patients treated with Myfembree, and at greater incidence than placebo, were:[6]

Announcer:

- vasomotor symptoms at 10.6 percent—including hot flush, hyperhidrosis, or night sweats;
- abnormal uterine bleeding at 6.3 percent —including menorrhagia, metrorrhagia, vaginal hemorrhage, polymenorrhea, and irregular menstruation;
- alopecia at 3.5 percent, and libido decreased and loss of libido at 3.1 percent. [6]

Dr. Kho:
A key prespecified safety endpoint was the percent change of bone mineral density as measured by dual-energy X-ray absorptiometry, or DXA for short, from baseline to weeks 12 and 24. Baseline and month 6 assessments included only those participants from LIBERTY 1 and 2 who participated in the LIBERTY open-label extension study.[12]

And in LIBERTY 1 and 2, the Myfembree group had a mean decrease of 0.23 percent and the placebo group had a mean increase of 0.18 percent in lumbar spine bone mineral density from baseline at month six.[6]Patients who continued on to a LIBERTY open-label extension study observed continued bone loss, with a total of 0.8 percent decline in lumbar spine bone mineral density by week 48.[12]

Please note here, again, that the use of Myfembree should be limited to 24 months due to the risk of continued bone loss, which may not be reversible. A baseline and periodic DXA are recommended for patients with heavy menstrual bleeding due to uterine fibroids. You may consider discontinuing Myfembree if the risk associated with bone loss exceeds that of the potential benefit of treatment in your patient. It's also important to take note that Myfembree is contraindicated in patients with known osteoporosis.[6]

Dr. Caudle:
Well, you've really helped us understand the data behind Myfembree for this indication, Dr. Kho, thank you so much for this. Let's take a moment to learn some more Important Safety Information.

Announcer:
WARNINGS AND PRECAUTIONS continued

Hormone-Sensitive Malignancies: Discontinue Myfembree if a hormone-sensitive malignancy is diagnosed. Breast exams and mammography are recommended. Use of estrogen alone or estrogen plus progestin has resulted in abnormal mammograms requiring further evaluation.

Suicidal Ideation and Mood Disorders (Including Depression): Evaluate patients with a history of suicidal ideation, depression, and mood disorders before starting treatment. Monitor for these symptoms including shortly after initiating treatment. Advise patients to seek medical care for new or worsening depression, anxiety, other mood changes, or suicidal ideation and behavior. Gonadotropin-releasing

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hormone receptor antagonists, including Myfembree, have been associated with mood disorders (including depression) and suicidal ideation.

Hepatic Impairment and Transaminase Elevations: Due to poor metabolism of steroid hormones, instruct these patients to promptly seek medical care for symptoms/signs of liver injury, e.g., jaundice or right upper abdominal pain. Acute liver test abnormalities may require discontinuing Myfembree until tests return to normal and Myfembree causation is excluded.

Gallbladder Disease or History of Cholestatic Jaundice: Discontinue Myfembree if signs/symptoms of gallbladder disease or jaundice occur. Studies among estrogen users suggest a small increased relative risk of developing gallbladder disease.

Please stay tuned to hear Important Safety Information continued throughout this program.

Dr. Caudle:
So, Dr. Kho, you've taken us through the LIBERTY trials data on Myfembree for heavy menstrual bleeding from uterine fibroids, but now let's shift over to its other clinical indication that you mentioned: moderate to severe pain due to endometriosis.

I'd like to hear more about the evidence supporting this indication. But first, can you tell us about the treatment challenges of endometriosis-associated pain for women and their healthcare providers?

Dr. Kho:
Thank you so much for this question. Endometriosis can have a significant burden on premenopausal patients. In 1 and 10 patients of reproductive age are thought to have the condition in the US[17,18] and many of them wait up to 4 to 11 years for a definitive diagnosis.[19,20] But despite this high prevalence, diagnosis continues to be a challenge. Unfortunately, about 75-80 percent of patients with endometriosis are symptomatic,[21] and these symptoms can have a significant impact on a patient's daily life, both physically and psychologically.[19]

The most common symptoms of endometriosis are dysmenorrhea, non-menstrual pelvic pain, dyschezia, dysuria, and dyspareunia.[17,21]Yet, despite being a chronic and systemic disease, there's no single curative treatment.[22,23] In my opinion, when uncontrolled endometriosis pain is a burden on our patients, a different approach to treatment may be needed, and shared decision-making is the best way to identify our patient's priorities and goals of care while reviewing risks and benefits together.

For a patient whom I'm suspicious for endometriosis, remember that imaging is an important next step in diagnosis. Imaging with MRI or transvaginal ultrasound is able to detect ovarian and deep endometriosis. So even if the imaging is negative, if my clinical suspicion remains high, then I would still pursue medication therapy for a presumptive diagnosis of endometriosis. However, because there's always a risk of adverse reactions for any particular medication, I would consider all appropriate treatment options for my patient – including switching medication treatments, adding non-pharmacological therapies, and surgical options, if suitable for it.

So let's take a look at each of the treatment approaches available in turn:

- Pharmacological treatments include CHCs and progestin -only formulations. GnRH analogues come into the picture if the decision is made not to pursue surgery. Some challenges of pharmacological options include side effects and limited duration of use for some therapies.[22,23]
- Also, over-the-counter pain medications and nonpharmacologic treatments such as physical therapy or alternative therapies can support symptom management. And while adjuvant therapies can help manage symptoms, they don't treat the underlying disease, and large randomized clinical trials are lacking in this area.[22-24]
- Surgical intervention may also be an option. While surgery can be helpful for some patients, recurrence may occur post-surgery, and patients may need pharmacologic management after surgery.[23]

So, earlier we mentioned that Myfembree is also approved in premenopausal patients for treating moderate to severe endometriosis-related pain. And just as we did with the heavy menstrual bleeding from fibroids indication, I would be happy to go through the safety and efficacy evidence supporting this indication for Myfembree.

Dr. Caudle:
Well thank you, I'd be very interested in taking a closer look at the data, Dr. Kho. But before we do, let's take a minute to review more Important Safety Information on Myfembree.

Announcer:
WARNINGS AND PRECAUTIONS continued

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

Change in Menstrual Bleeding Pattern and Reduced Ability to Recognize Pregnancy: Advise women to use nonhormonal contraception during and for one week after discontinuing Myfembree. Avoid use with hormonal contraceptives. Myfembree may delay recognition of pregnancy because it alters menstrual bleeding. Test for pregnancy if suspected and discontinue Myfembree if confirmed.

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

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

Alopecia: Alopecia, hair loss, and hair thinning were reported in phase 3 trials in women with heavy menstrual bleeding associated with uterine fibroids with Myfembree. Whether hair loss is reversible is unknown.

Please stay tuned to hear Important Safety Information continued throughout this program.

Dr. Caudle:
And now that we've heard this Important Safety Information, let's return to where we left off. So, how was the efficacy of Myfembree for moderate to severe endometriosis-related pain assessed in clinical trials?

Dr. Kho:
Myfembree's approval for moderate to severe pain associated with endometriosis was based on the SPIRIT trials. SPIRIT 1 and 2 were designed as two replicate, 24-week long, randomized, double-blinded, placebo-controlled, multinational clinical trials.[6]

Dr. Kho:
A total of 1,251 premenopausal patients with endometriosis-associated moderate to severe pain were randomized 1:1:1 to be treated with Myfembree, placebo, or 12 weeks of relugolix monotherapy followed by 12 weeks of Myfembree.[6] And just as in the LIBERTY trials, this relugolix monotherapy arm was included to compare the safety of relugolix monotherapy versus relugolix combined with hormone therapy.[6,13] So again, relugolix monotherapy *is not* FDA-approved for pain associated with endometriosis, so we won't review those results here.

Women who completed SPIRIT 1 and 2 were also eligible to enroll in an 80-week open-label extension trial, and 799 patients were treated with Myfembree in this extension trial.[13]

Now when we take a look into the patient population of the SPIRIT trials, we see in the baseline characteristics that the majority of patients enrolled experienced moderate to severe dysmenorrhea, non-menstrual pelvic pain, or NMPP for short, and dyspareunia from endometriosis at study entry, in part reflected by higher analgesic use, including opioids, for pain control.[16,25]

Announcer:
Dysmenorrhea, NMPP, and dyspareunia were evaluated daily using a zero to ten numerical rating scale that asked women to rate their pain severity during the prior 24 hours on a scale of zero or "no pain" to ten, or "pain as bad as you can imagine.[6]

Dr. Kho:
The co-primary endpoints of the SPIRIT studies were the proportions of patients with at least a 2.8-point reduction in dysmenorrhea score and those with at least a 2.1-point reduction in non-menstrual pelvic pain score from baseline over the last 35 days of treatment with no increase in analgesic use.[6]

Myfembree achieved a statistically significant response rate for both the dysmenorrhea and non-menstrual pain endpoints. Approximately 75 percent of patients on Myfembree achieved the dysmenorrhea endpoint, compared to only about 29 percent of placebo patients in pooled analysis of SPIRIT 1 and 2. And 62 percent of patients on Myfembree achieved the non-menstrual pelvic pain endpoint, compared to only 41 percent of placebo patients in pooled analysis of SPIRIT 1 and 2.

Announcer:
And for dysmenorrhea, the separate study results were 74.5 percent and 75.1 percent for Myfembree in SPIRIT 1 and 2 versus 26.9 percent and 30.5 percent for placebo, respectively, with a p value of less than or equal to 0.0001 for both. The results for each SPIRIT study for NMPP were 58.5 percent and 65.9 percent for Myfembree in SPIRIT 1 and 2 versus 39.6 percent and 42.5 percent for placebo, respectively, with the p value less than or equal to 0.0001 for both.[6,16]

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Dr. Caudle:
And turning to the safety data, what did we learn about Myfembree from the SPIRIT trials?

Dr. Kho:
First off, the prespecified safety endpoints of the SPIRIT trials were similar to those of the LIBERTY trials:[13]

- adverse events; and change in bone mineral density.

Dr. Kho:
The most common adverse reactions reported in at least three percent of the patients taking Myfembree, and at greater incidence than placebo, included:[6]

Announcer:

- headache at 33 percent;
- vasomotor symptoms at 13.2 percent — including hot flush, hyperhidrosis, night sweats, and flushing;
- mood disorders at 9.1 percent — including 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; and
- abnormal uterine bleeding at 6.7 percent — including menorrhagia, metrorrhagia, vaginal hemorrhage, uterine hemorrhage, polymenorrhea, and menstruation irregular.

The rest of the most common adverse reactions, again, at a greater incidence than placebo, were:

- nausea at 6.0 percent;
- toothache at 5.5 percent,
- back pain at 4.8 percent,
- decreased sexual desire and arousal at 4.3 percent — including libido decreased, libido disorder, and female sexual arousal disorder;
- arthralgia at 3.6 percent;
- fatigue at 3.1 percent; and
- dizziness at 3.1 percent.[6]

Dr. Kho
Serious adverse reactions included uterine hemorrhage, suicidal ideation, cholelithiasis, and cholecystitis. 2.9 percent of patients taking Myfembree experienced serious adverse reactions, compared to 2.2 percent of patients taking placebo.[6]

4.5 percent of patients taking Myfembree experienced adverse reactions leading to discontinuation of the drug compared to 2.9 percent of patients taking placebo.[6]The most common adverse reaction leading to discontinuation of Myfembree was mood-related disorders—including depression, mood swings, altered mood, affect lability, and suicidal ideation.[6]

Dr. Kho:
So just as in the LIBERTY trials, let's dig deeper into the prescribed safety endpoint of bone mineral density, defined as percentage change from baseline in bone mineral density.

Announcer:
Again, baseline and month 6 assessments included only those participants from SPIRIT 1 and 2 who participated in the SPIRIT open-label extension study.[13]

Dr. Kho:
In SPIRIT 1 and 2, the Myfembree group had a mean reduction of 0.72 percent and the placebo group had a mean increase of 0.12 percent in lumbar spine bone mineral density from baseline at month six.[6] For women who continued on to a SPIRIT open-label extension study, bone mineral density loss was observed with a mean total 0.81 percent decline in lumbar spine bone mineral density from baseline to 12 months of therapy with Myfembree.[6]

Do keep in mind that the context I mentioned when discussing the bone mineral density results for LIBERTY also apply here. One difference here is that for patients on Myfembree for the endometriosis indication, there's a recommendation for a baseline DXA when

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starting the treatment and annually thereafter to monitor for bone loss.[6]

Dr. Caudle:
Well thank you so much for walking us through the efficacy and safety data for Myfembree. And as we come to the end of our program, Dr. Kho, what are some key takeaways you would like to leave with our audience?

Dr. Kho:
I think it's important to remember that uncontrolled symptoms from uterine fibroids and endometriosis continue to be an extremely heavy burden for many premenopausal patients. And Myfembree is a treatment option that's FDA-approved in premenopausal patients for both heavy menstrual bleeding associated with uterine fibroids and also moderate to severe endometriosis pain.[6] In a once daily dose, its combination of a GnRH antagonist with hormone therapy is designed to support an optimal estradiol range intended to mitigate bone loss caused by relugolix alone while still reducing heavy menstrual bleeding due to fibroids or moderate to severe pain due to endometriosis.[6,11] This combination therapy has met multiple endpoints across four phase 3 trials in over 2,000 patients.[6] Now, due to the risk of potential irreversible bone loss, Myfembree use should be limited to 24 months.[6]

The last thought I'd like to leave with everyone is that for our patients who unfortunately continue to struggle with symptoms of heavy menstrual bleeding from uterine fibroids or moderate to severe pain associated with endometriosis, we can offer this FDA-approved treatment option as an additional choice.[3,6,23]

Dr. Caudle:
Well I would like to thank my guest, Dr. Rosanne Kho, for helping us better understand the design, the efficacy, and safety evidence supporting Myfembree. Dr. Kho, it was great speaking with you today.

Dr. Kho:
Thank you so much for having me.

Dr. Caudle:
I'm your host Dr. Jennifer Caudle.

And before we close, let's review some Important Safety Information.

Announcer:
WARNINGS AND PRECAUTIONS continued

Effects on Carbohydrate and Lipid Metabolism: More frequent monitoring in women with prediabetes and diabetes may be necessary. Myfembree may decrease glucose tolerance and increase blood glucose concentrations. Monitor lipid levels and consider discontinuing if hypercholesterolemia or hypertriglyceridemia worsens. In women with pre-existing hypertriglyceridemia, estrogen therapy may increase triglycerides levels leading to pancreatitis. 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. Combined estrogen and progestin may raise serum concentrations of binding proteins, which may reduce free thyroid or corticosteroid hormone levels. 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 (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.

LACTATION: Advise women not to breastfeed while taking Myfembree.

Please see full Prescribing Information, including BOXED WARNING, at the link below this video or at tinyurl.com/MyfembreePI

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