Pfizer Logo

Myovant Sciences and Pfizer Receive FDA Approval for MYFEMBREE®, the First Once-Daily Treatment for Heavy Menstrual Bleeding Associated With Uterine Fibroids

Wednesday, May 26, 2021 - 04:15pm

- *In the Phase 3 LIBERTY 1 and LIBERTY 2 studies, MYFEMBREE demonstrated 72.1% and 71.2% response rates in menstrual blood loss (MBL) at Week 24, with MBL reductions of 82.0% and 84.3% from baseline*
- *Myovant and Pfizer will jointly commercialize MYFEMBREE, with product availability expected in June*
- *Myovant to host conference call and webcast on Friday, May 28, 2021 at 8:30 a.m. Eastern Time / 5:30 a.m. Pacific Time*

BASEL, Switzerland and NEW YORK, May 26, 2021 (GLOBE NEWSWIRE) -- Myovant Sciences (NYSE: MYOV) and Pfizer Inc. (NYSE: PFE) today announced that the U.S. Food and Drug Administration (FDA) has approved MYFEMBREE® (relugolix 40 mg, estradiol 1 mg, and norethindrone acetate 0.5 mg), the first once-daily treatment for the management of heavy menstrual bleeding associated with uterine fibroids in premenopausal women, with a treatment duration of up to 24 months. The approval is supported by efficacy and safety data from the Phase 3 LIBERTY 1 and LIBERTY 2 studies, which were published in the *New England Journal of Medicine*. Under the terms of their previously announced collaboration, Myovant and Pfizer will jointly commercialize MYFEMBREE in the U.S. MYFEMBREE is expected to be available in June 2021.

“With MYFEMBREE, we can offer women with uterine fibroids a non-invasive treatment that provides clinically meaningful symptom relief for heavy menstrual bleeding with one pill, once-a-day,” said Ayman Al-Hendy, M.D., Ph.D., Professor of Obstetrics and Gynecology, University of Chicago, and LIBERTY Program Steering Committee Member. “The FDA approval of MYFEMBREE represents a significant milestone in expanding treatment options for uterine fibroids, a chronic and debilitating disease for many women in the U.S.”

“Uterine fibroids affect millions of women in the U.S. and account for over 250,000 hysterectomies each year, with heavy menstrual bleeding being one of the most bothersome symptoms,” said David Marek, Chief Executive Officer of Myovant Sciences, Inc. “The approval of MYFEMBREE represents the second FDA product approval for Myovant in less than one year. This is an important step forward as we seek to redefine care for women and for men, not only through new medicines but through continued collaboration with the community.”

“MYFEMBREE’s approval is a testament to the shared commitment between Myovant and Pfizer to support women living with uterine fibroids,” said Nick Lagunowich, Global President, Internal Medicine at Pfizer. “We

are excited to offer this new treatment option which will help provide much needed symptom relief with the convenience of an oral, once-daily tablet."

The Phase 3 LIBERTY studies each met the primary endpoint, with 72.1% and 71.2% of women in the MYFEMBREE groups achieving the responder criteria compared with 16.8% and 14.7% women in the placebo groups at Week 24, respectively (both $p < 0.0001$). A response was defined as a menstrual blood loss volume of less than 80 mL and a 50% or greater reduction from baseline in menstrual blood loss volume during the last 35 days of treatment measured using the alkaline hematin method. Women receiving MYFEMBREE experienced reductions of 82.0% and 84.3% in menstrual blood loss from baselines, respectively (both $p < 0.0001$ compared to placebo). Adverse reactions occurring in at least 3% of women treated with MYFEMBREE and at a greater incidence than placebo were hot flush, abnormal uterine bleeding, alopecia, and decreased libido. There were no pregnancies reported in the MYFEMBREE groups in either study.

Myovant and Pfizer are committed to supporting women in the U.S. who are prescribed MYFEMBREE throughout their treatment journeys. The MYFEMBREE Support Program provides services, including insurance benefits checks, prior authorization support, co-pay support for commercially insured patients, and patient assistance for qualifying uninsured patients. Program terms and conditions apply. For more information and additional resources, please contact 833-MYFEMBREE (833-693-3627), 8 a.m.–8 p.m. Eastern Time, Monday–Friday.

Myovant Conference Call and Webcast
Myovant will hold a conference call on Friday, May 28, 2021 at 8:30 a.m. Eastern Time / 5:30 a.m. Pacific Time to discuss the FDA approval of MYFEMBREE®. Investors and the general public may access a live webcast of the call by visiting the investor relations page of Myovant's website at investors.myovant.com. Investors and analysts may also participate in the conference call by dialing 1-800-532-3746 in the U.S. or +1-470-495-9166 from outside the U.S. A replay of the webcast will be archived on Myovant's investor relations website.

About Uterine Fibroids
Uterine fibroids are noncancerous tumors that develop in or on the muscular walls of the uterus and are among the most common reproductive tract tumors in women. In addition to an individual's genetic predisposition, estrogens are well known to play an important role in the regulation of fibroid growth.

Although uterine fibroids are benign tumors, they can cause debilitating symptoms such as heavy menstrual bleeding (frequently resulting in anemia and fatigue), pain (including painful periods, abdominal pain, painful intercourse, backache), increased abdominal girth and bloating, urinary frequency or retention, constipation, pregnancy loss, and, in some cases, infertility. These symptoms can also lead to loss of productivity at work, limitations in normal activities of daily living, and social embarrassment.

An estimated five million women in the U.S. suffer from symptoms of uterine fibroids, and an estimated three million women are inadequately treated by current medical therapy and require further treatment.

About MYFEMBREE®
MYFEMBREE (relugolix 40 mg, estradiol 1 mg, and norethindrone acetate 0.5 mg) is the first once-daily treatment of heavy menstrual bleeding associated with uterine fibroids in premenopausal women approved by the U.S. Food and Drug Administration, with a treatment duration of up to 24 months. MYFEMBREE contains relugolix, which reduces the amount of estrogen (and other hormones) produced by ovaries, estradiol (an estrogen) which may reduce the risk of bone loss, and norethindrone acetate (a progestin) which is necessary when women with a uterus (womb) take estrogen.

For full prescribing information including Boxed Warning and patient information, please click here.

Indications and Usage

MYFEMBREE is indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women. 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 and periodically thereafter. 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.

Depression, Mood Disorders, and Suicidal Ideation: Promptly evaluate patients with mood changes and depressive symptoms including shortly after initiating treatment, to determine whether the risks of continued therapy 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.

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 hot flush/hyperhidrosis/night sweats, abnormal uterine bleeding, alopecia, and decreased libido. 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.

About Myovant Sciences
Myovant Sciences aspires to redefine care for women and for men through purpose-driven science, empowering medicines, and transformative advocacy. ORGOVYX™ (relugolix) was approved by the U.S. Food and Drug Administration in 2020 as the first and only oral gonadotropin-releasing hormone (GnRH) receptor antagonist for the treatment of adult patients with advanced prostate cancer, and relugolix is also under regulatory review in Europe for men with advanced prostate cancer. MYFEMBREE® (relugolix 40 mg, estradiol 1 mg, and norethindrone acetate 0.5 mg) was approved in the U.S. in 2021 as the first once-daily treatment for the management of heavy menstrual bleeding associated with uterine fibroids in premenopausal women. Relugolix combination tablet (relugolix 40 mg, estradiol 1 mg, and norethindrone acetate 0.5 mg) is under regulatory review in Europe for women with uterine fibroids, has completed Phase 3 registration-enabling studies for women with endometriosis, and is being assessed for contraceptive efficacy in healthy women ages 18-35 years who are at risk for pregnancy. We are also developing MVT-602, an oligopeptide kisspeptin-1 receptor agonist, which has completed a Phase 2a study for female infertility as part of assisted reproduction. Sumitovant Biopharma, Ltd., a wholly owned subsidiary of Sumitomo Dainippon Pharma Co., Ltd., is our majority shareholder. For more information, please visit our website at www.myovant.com. Follow @Myovant on Twitter and LinkedIn.

About Pfizer: Breakthroughs That Change Patients' Lives
At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 170 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.Pfizer.com. In addition, to learn more, please visit us on www.Pfizer.com and follow us on Twitter at @Pfizer and @Pfizer News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

Myovant Sciences Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. In this press release, forward-looking statements include, but are not limited to, all statements reflecting Myovant Sciences' expectations, including: statements regarding Myovant's aspiration to redefine care for women and for men; Myovant's expectations regarding the potential benefits of MYFEMBREE; Myovant's expectations regarding the potential commercial launch of MYFEMBREE by Myovant and Pfizer in the United States; Myovant's expectation that MYFEMBREE will become available in June 2021; the plan to offer a MYFEMBREE support program for patients; and the features of such program.

Myovant Sciences' forward-looking statements are based on management's current expectations and beliefs and 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, including unforeseen circumstances or other disruptions to normal business operations arising from or related to the COVID-19 pandemic. Myovant Sciences 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. Factors that could materially affect Myovant Sciences' operations and future prospects or which could cause actual results to differ materially from expectations include, but are not limited to the risks and uncertainties listed in Myovant Sciences' filings with the United States Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in Myovant Sciences' Annual Report on Form 10-K filed on May 11, 2021, 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 Myovant Sciences' management to predict all risk factors, nor can Myovant Sciences 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. You should not place undue reliance on the forward-looking statements in this press release, which speak only as of the date hereof, and, except as required by law, Myovant Sciences undertakes no obligation to update these forward-looking statements to reflect events or circumstances after the date of such statements.

Pfizer Disclosure Notice

The information contained in this release is as of May 26, 2021. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about MYFEMBREE® (relugolix 40 mg, estradiol 1 mg, and norethindrone acetate 0.5 mg) for the treatment of heavy menstrual bleeding associated with uterine fibroids in premenopausal women, and a collaboration between Pfizer and Myovant Sciences to develop and commercialize relugolix in advanced prostate cancer and women's health, including their potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, uncertainties regarding the commercial success of MYFEMBREE; the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from the clinical studies; whether and when applications for MYFEMBREE may be filed in any other jurisdictions for any potential indications for MYFEMBREE; whether and when regulatory authorities in any other jurisdictions may approve any such applications for MYFEMBREE that may be pending or filed, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether MYFEMBREE will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of MYFEMBREE; whether our collaboration with Myovant Sciences will be successful; uncertainties regarding the impact of COVID-19 on Pfizer's business, operations and financial results; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2020 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future

Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

Pfizer Media Contact:

Steve Danehy
+1 (212) 733-1538
Steven.Danehy@Pfizer.com

Pfizer Investor Contact:

Chuck Triano
+1 (212) 733-3901
Charles.E.Triano@Pfizer.com

Myovant Sciences Media Contact:

Albert Liao
+1 (650) 410-3055
media@myovant.com

Myovant Sciences Investor Contact:

Ryan Crowe
+1 (650) 781-9106
investors@myovant.com