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Myovant Sciences and Pfizer Announce FDA Acceptance of Supplemental New Drug Application for MYFEMBREE® for the Management of Moderate to Severe Pain Associated With Endometriosis

Thursday, September 09, 2021 - 06:58am

- *Filing in endometriosis is supported by data from the Phase 3 SPIRIT program*
- *FDA PDUFA target action date is May 6, 2022*

BASEL, Switzerland and NEW YORK, September 9, 2021 (GLOBE NEWSWIRE) -- Myovant Sciences (NYSE: MYOV) and Pfizer Inc. (NYSE: PFE) today announced that the U.S. Food and Drug Administration (FDA) accepted for review a supplemental New Drug Application (sNDA) for MYFEMBREE® (relugolix 40 mg, estradiol 1 mg, and norethindrone acetate 0.5 mg) for the management of moderate to severe pain associated with endometriosis. The FDA set a target action date of May 6, 2022 for this sNDA under the Prescription Drug User Fee Act (PDUFA).

“Women with endometriosis often experience debilitating symptoms that impact their daily lives – and unfortunately, many of them do not find relief with the medical options that are currently available,” said Juan Camilo Arjona Ferreira, M.D., Chief Medical Officer of Myovant Sciences, Inc. “If approved for this indication, we believe MYFEMBREE has the potential to redefine care for women with endometriosis as an effective, one pill, once-a-day treatment option.”

The sNDA submission in endometriosis is supported by results from the Phase 3 SPIRIT program, which included two multinational, replicate pivotal clinical studies (SPIRIT 1 and SPIRIT 2) in over 1,200 women with pain associated with endometriosis for 24 weeks, and an open-label extension study for eligible women who completed either SPIRIT 1 or SPIRIT 2 through one year.

“The submission of the sNDA for MYFEMBREE to treat endometriosis pain reflects our commitment to addressing areas of significant unmet need in women’s health,” said James Rusnak, M.D., Ph.D., Senior Vice President, Chief Development Officer, Internal Medicine and Hospital, Global Product Development at Pfizer. “We look forward to potentially bringing this important new treatment option to women with endometriosis.”

In the U.S., MYFEMBREE is currently available for the management of heavy menstrual bleeding associated with uterine fibroids in premenopausal women, with a treatment duration of up to 24 months. The FDA approved MYFEMBREE for this indication on May 26, 2021, based on data from the Phase 3 LIBERTY program. Myovant and Pfizer are jointly developing and commercializing MYFEMBREE in the U.S.

About Endometriosis
Endometriosis is an estrogen-dependent, inflammatory disease in which tissue similar to the uterine lining is found outside the uterine cavity, commonly in the lower abdomen or pelvis, on ovaries, the bladder, and the colon. This endometrial-like tissue outside the uterus results in chronic inflammation and can cause scarring and adhesions.

The symptoms associated with endometriosis include painful periods and chronic pelvic pain, painful ovulation, pain during or after sexual intercourse, heavy bleeding, fatigue, and infertility. Endometriosis can also impact general physical, mental, and social well-being, requiring a multi-disciplinary approach to care.

For endometriosis-associated pain, per current guidelines, initial treatment options include hormonal contraceptives and over-the-counter pain medications. In more severe cases, LHRH agonists such as leuprolide acetate are used for short-term treatment. An estimated six million women in the U.S. suffer from symptoms of endometriosis, and an estimated one million women are inadequately treated by current medical therapy and require further treatment. Almost 200 million women are affected globally.

About MYFEMBREE®
MYFEMBREE (relugolix 40 mg, estradiol 1 mg, and norethindrone acetate 0.5 mg) is the first once-daily oral treatment for 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. Founded in 2016, we have two FDA-approved products. 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. Relugolix combination tablet (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg) was approved in 2021 in the U.S. as MYFEMBREE® as the first once-daily treatment for the management of heavy menstrual bleeding associated with uterine fibroids in premenopausal women, and by the European Commission as RYEQO® for the treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. The therapy has also completed Phase 3 registration-enabling studies for women with

endometriosis and is being assessed for the prevention of 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 for the management of moderate to severe pain associated with endometriosis; and Myovant's expectations regarding the development and commercialization of MYFEMBREE by Myovant and Pfizer in the United States.

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' Quarterly Report on Form 10-Q filed on July 28, 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 September 9, 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 management of moderate to severe pain associated with endometriosis, including its 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 may be filed in any additional jurisdictions for MYFEMBREE for the management of moderate to severe pain associated with endometriosis or in any jurisdictions for any other potential indications for MYFEMBREE; whether and when the FDA may approve the supplemental new drug application for the management of moderate to severe pain associated with endometriosis and whether and when regulatory authorities in any jurisdictions may approve any such other 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.

Myovant Sciences Contacts
Ryan Crowe, Investors
+1 (650) 781-9106
investors@myovant.com

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

Pfizer Contacts
Media Relations
Steve Danehy
+1 (212) 733-1538
PfizerMediaRelations@pfizer.com

Investor Relations
Bryan Dunn

+1 (212) 733-8917
Bryan.Dunn@Pfizer.com