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Myovant Sciences and Pfizer Announce FDA Acceptance of Supplemental New Drug Application for MYFEMBREE®

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BASEL, Switzerland and NEW YORK, [June 2, 2022] (GLOBE NEWSWIRE) -- Myovant Sciences (NYSE: MYOV) and Pfizer Inc. (NYSE: PFE) announced today 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). The sNDA proposes updates to MYFEMBREE's United States Prescribing Information (USPI) based on safety and efficacy data from the Phase 3 LIBERTY randomized withdrawal study (RWS) of MYFEMBREE in premenopausal women with heavy menstrual bleeding associated with uterine fibroids for up to two years. The FDA set a target action date of January 29, 2023 for this sNDA under the Prescription Drug User Fee Act (PDUFA).

"Heavy menstrual bleeding is the most common symptom affecting women with uterine fibroids that can impact their daily life and activities over a long period of time," said Juan Camilo Arjona Ferreira, M.D., Chief Medical Officer of Myovant Sciences, Inc. "We are pleased to submit these study results to the FDA as they show the value MYFEMBREE can potentially have on treating women's uterine fibroid symptoms long term."

Patients who completed the 24-week pivotal LIBERTY 1 and 2 studies were offered the option to receive MYFEMBREE for an additional 28 weeks in an open-label extension study. After completion of the LIBERTY 1 or LIBERTY 2 and the open-label extension studies, women who met the definition of responder (menstrual blood loss < 80 mL and a reduction from pivotal study baseline > 50%) could participate in an additional 52-week randomized withdrawal study (N=229) designed to provide two-year safety and efficacy data on MYFEMBREE and to evaluate the need for maintenance therapy. Women who entered the RWS were re-randomized to either MYFEMBREE or placebo for 52 additional weeks (N = 229), with the primary endpoint at Week 76. The LIBERTY randomized withdrawal study met its primary endpoint with 78.4% of women who continued on MYFEMBREE achieving the sustained responder rate (menstrual blood loss < 80 mL) through Week 76 compared with 15.1% of women who discontinued treatment and initiated placebo at Week 52 ($p < 0.0001$). All three key secondary endpoints in the LIBERTY randomized withdrawal study were also achieved, including sustained responder rate through Week 104, time to relapse of heavy menstrual bleeding, and amenorrhea rate (all $p < 0.0001$).

Bone mineral density remained stable in women who received MYFEMBREE in the randomized withdrawal study. Additionally, bone mineral density was maintained through two years in the subset of women continuously treated with MYFEMBREE (N = 31). The incidence of adverse events over one additional year of treatment was consistent with those observed in prior studies, with no new safety signals observed.

"Data from the MYFEMBREE RWS supports our mission to improve care for women living with uterine fibroids," 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 the FDA's review of the

application and potential updates to the MYFEMBREE prescribing information based on these data."

MYFEMBREE was approved in the U.S. in 2021 for the management of heavy menstrual bleeding associated with uterine fibroids in premenopausal women with a treatment duration of up to 24 months.

About the Phase 3 LIBERTY Program in Uterine Fibroids
The Phase 3 clinical program for uterine fibroids consisted of two multi-national, replicate pivotal clinical studies (LIBERTY 1, N=388 and LIBERTY 2, N=382) of MYFEMBREE® in women with heavy menstrual bleeding associated with uterine fibroids for 24 weeks. Eligible women who completed the LIBERTY 1 or LIBERTY 2 studies were offered the opportunity to enroll in an active treatment, open-label extension study in which all women received MYFEMBREE for an additional 28-week period for a total treatment period of 52 weeks (N=477), designed to evaluate the safety and efficacy of longer-term treatment. After completion of the LIBERTY 1 or LIBERTY 2 and open-label extension studies, eligible women could elect to participate in an additional 52-week randomized withdrawal study (N=229) designed to provide two-year safety and efficacy data on MYFEMBREE and to evaluate the need for maintenance therapy. Across the LIBERTY 1, LIBERTY 2 and open-label extension studies, 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.

LIBERTY 1 and LIBERTY 2 met their primary endpoints ($p < 0.0001$) with 72.1% and 71.2% of women receiving MYFEMBREE achieving the responder criteria compared with 16.8% and 14.7% of women receiving placebo at 24 weeks, respectively. On average, women receiving MYFEMBREE in both studies experienced an 84.3% reduction in menstrual blood loss from baseline at Week 24 ($p < 0.0001$). The overall incidence of adverse events in the relugolix combination and placebo groups was comparable in both studies. The most common adverse reactions (incidence ? 3%) were hot flush, hyperhidrosis or night sweats, uterine bleeding, alopecia, and decreased libido.

In the open-label extension study, changes in bone mineral density through one year, as assessed by DXA every three months, were consistent with LIBERTY 1 and 2. The incidence of adverse events over one year was consistent with that observed in LIBERTY 1 and 2, with no new safety signals observed.

The LIBERTY randomized withdrawal study met its primary endpoint of maintaining sustained responder rate (menstrual blood loss < 80 mL). All three key secondary endpoints in the LIBERTY randomized withdrawal study were also achieved, including sustained responder rate at two years (Week 104), time to relapse of heavy menstrual bleeding, and amenorrhea rate (all $p < 0.0001$). Bone mineral density was maintained through two years in the subset of women continuously treated with MYFEMBREE (N = 31). The incidence of adverse events over one additional year of treatment was consistent with those observed in prior studies, with no new safety signals observed.

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,[i] and an estimated three million women are inadequately treated by current medical therapy.[ii]

About MYFEMBREE®
MYFEMBREE (relugolix, estradiol, and norethindrone acetate) is the first and only 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, 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, Myovant has executed five successful Phase 3 clinical trials across oncology and women’s health leading to two regulatory approvals by the U.S. Food and Drug Administration (FDA) for men with advanced prostate cancer and women with heavy menstrual bleeding associated with uterine fibroids, respectively. Myovant also has received regulatory approvals by the European Commission (EC) for women with symptomatic uterine fibroids and for men with advanced hormone-sensitive prostate cancer. Myovant has supplemental New Drug Applications under review with the FDA for endometriosis-associated pain, and for updates to the United States Prescribing Information (USPI) based on safety and efficacy data from the Phase 3 LIBERTY randomized withdrawal study (RWS) of MYFEMBREE in premenopausal women with heavy menstrual bleeding due to uterine fibroids for up to two years. Myovant also is conducting a Phase 3 study to evaluate the prevention of pregnancy in women with uterine fibroids or endometriosis. Myovant also is developing MVT-602, an investigational 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 Pharma Co., Ltd., is Myovant’s majority shareholder. For more information, please visit 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. 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. In this press release, forward-looking statements include, but are not limited to, the statements with respect to the value of MYFEMBREE on treating women's uterine fibroid symptoms, the potential updates to the MYFEMBREE USPI, and the potential outcome of FDA's review of the sNDA for MYFEMBREE.

For a further discussion of factors that could materially affect Myovant Sciences' operations and future prospects or which could cause actual results to differ materially from expectations, see 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, 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 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 June 2, 2022. 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), including a sNDA proposing updates to the United States Prescribing Information based on safety and efficacy data from the Phase 3 LIBERTY randomized withdrawal study (RWS) of MYFEMBREE in premenopausal women with heavy menstrual bleeding due to uterine fibroids for up to two years, 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 RWS study data or in any jurisdictions for any other potential indications for MYFEMBREE; 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, 2021 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.

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[i] Stewart E. Lancet. 2001. 357:293-298
[ii] Marjoribanks et al. Cochrane Database Syst. Rev. 2006.

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