Myovant Sciences Announces FDA Acceptance of New Drug Application for Once-Daily Relugolix Combination Tablet for Uterine Fibroids

August 17, 2020

- *FDA sets target action date of June 1, 2021*

BASEL, Switzerland, Aug. 17, 2020 (GLOBE NEWSWIRE) -- Myovant Sciences (NYSE: MYOV), a healthcare company focused on redefining care for women and for men, today announced that its New Drug Application (NDA) for once-daily, oral relugolix combination tablet (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg) for the treatment of women with heavy menstrual bleeding associated with uterine fibroids has been accepted for review by the U.S. Food and Drug Administration (FDA).

“Relugolix is now under FDA review for two distinct potential new treatment options in uterine fibroids and advanced prostate cancer, indications with high unmet need where we have the opportunity to elevate the standard of care for women and for men,” said Lynn Seely, M.D., chief executive officer of Myovant Sciences. “An estimated five million women in the U.S. suffer from symptomatic uterine fibroids, which may include heavy menstrual bleeding, pain, and anemia. Non-invasive treatment options are limited, and we believe women deserve an alternative to surgery that delivers a predictable and clinically-meaningful reduction in menstrual blood loss while maintaining bone health as demonstrated by relugolix combination therapy in the LIBERTY program.”

The FDA has set a target action date of June 1, 2021 under the Prescription Drug User Fee Act (PDUFA). In its acceptance letter, the FDA also stated that it is currently not planning to hold an advisory committee meeting for this application.

Relugolix (120 mg) is under Priority Review by the FDA for the treatment of men with advanced prostate cancer, with a target action date of December 20, 2020. Additionally, Myovant submitted a Marketing Authorization Application to the European Medicines Agency in March 2020 for relugolix combination tablet for the treatment of women with uterine fibroids. Myovant has also reported positive data from two replicate Phase 3 studies evaluating relugolix combination therapy in women with endometriosis.

About the Phase 3 LIBERTY Program in Uterine Fibroids
Myovant’s Phase 3 clinical program for uterine fibroids consisted of two multinational, replicate pivotal clinical studies (LIBERTY 1 and LIBERTY 2) of relugolix combination therapy (relugolix 40 mg plus estradiol 1.0 mg and norethindrone acetate 0.5 mg) 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 extension study in which all women received relugolix combination therapy for an additional 28-week period for a total treatment period of 52 weeks, designed to evaluate the safety and efficacy of longer-term treatment. Upon completion of this 52-week total treatment period, eligible women could elect to participate in a second 52-week randomized withdrawal study designed to provide two-year safety and efficacy data on relugolix combination therapy and to evaluate the need for maintenance therapy. Across 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 2 met the primary endpoint ($p < 0.0001$) with 73.4% and 71.2% of women receiving relugolix combination therapy achieving the responder criteria compared with 18.9% and 14.7% of women receiving placebo at 24 weeks, respectively. On average, women receiving relugolix combination therapy in both studies experienced an 84.3% reduction in menstrual blood loss from baseline ($p < 0.0001$). Bone mineral density was comparable between the relugolix combination therapy and placebo groups in LIBERTY 1 and 2. The distribution of the change in bone mineral density, including outliers, was similar for the relugolix combination therapy and placebo groups at 24 weeks, as assessed by dual energy x-ray absorptiometry (DXA). The overall incidence of adverse events in the relugolix combination and placebo groups was comparable in both studies.

The open-label extension study also met the primary endpoint with relugolix combination therapy demonstrating an 87.7% response rate at one year, showing the durability of the response observed in LIBERTY 1 and 2. In addition, women experienced, on average, an 89.9% reduction in menstrual blood loss from baseline. 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.

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 Relugolix
Relugolix is a once-daily, oral gonadotropin-releasing hormone (GnRH) receptor antagonist that reduces ovarian estradiol, a hormone known to stimulate the growth of uterine fibroids and endometriosis, and testicular testosterone, a hormone known to stimulate the growth of prostate cancer. Relugolix combination tablet (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg) is under regulatory review in Europe and the U.S. for women with uterine fibroids and is under development for women with endometriosis. Relugolix monotherapy tablet (120 mg) is under regulatory review in the U.S. for men with advanced prostate cancer.

About Myovant Sciences
Myovant Sciences aspires to redefine care for women and for men through purpose-driven science, empowering medicines, and transformative advocacy. Our lead product candidate, relugolix, is a once-daily, oral GnRH receptor antagonist. Relugolix combination tablet (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg) is under regulatory review in Europe and the U.S. for women with uterine fibroids and is under development for women with endometriosis. Relugolix monotherapy tablet (120 mg) is under regulatory review in the U.S. for men with advanced prostate cancer. 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.

Forward-Looking Statements
This press-release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include all statements regarding Myovant Sciences' intent, belief, or expectations regarding future events or results and can be identified by words such as "anticipate," "aspire," "believe," "can," "continue," "could," "estimate," "expect," "intend," "likely," "may," "might," "objective," "ongoing," "plan," "potential," "predict," "project," "should," "to be," "will," "would," or the negative or plural of these words or other similar expressions or variations, although not all forward-looking statements contain these identifying words. In this press release, forward-looking statements include, but are not limited to, statements and quotes regarding Myovant Sciences' aspirations to redefine care for women and for men; the FDA target action date of June 1, 2021 under the Prescription Drug User Fee Act (PDUFA) for Myovant's NDA for the treatment of women with heavy menstrual bleeding associated with uterine fibroids; whether or not the FDA will hold an advisory committee meeting for the uterine fibroids NDA; the FDA target action date of December 20, 2020 under the PDUFA for Myovant's NDA for the treatment of men with advanced prostate cancer; the characterization of relugolix combination tablet as showing predictable and clinically-meaningful reduction in menstrual blood loss while maintaining bone health in the LIBERTY program and whether relugolix combination tablet could provide women a deserved alternative to surgery. 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. 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 August 11, 2020, 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. 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.

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