Myovant Sciences Submits New Drug Application (NDA) to the FDA for Once-Daily Relugolix Combination Tablet for the Treatment of Women with Uterine Fibroids

June 1, 2020

- *NDA is supported by positive data from two Phase 3 studies and a long-term extension study, demonstrating sustained reduction in heavy menstrual bleeding while maintaining bone health through one year*
- *If approved, relugolix combination tablet would be the first once-daily, oral treatment for women with heavy menstrual bleeding associated with uterine fibroids in the U.S.*

BASEL, Switzerland, June 01, 2020 (GLOBE NEWSWIRE) -- Myovant Sciences (NYSE: MYOV), a healthcare company focused on redefining care for women and for men, today announced that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for its once-daily 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.

“An estimated five million women in the U.S. suffer from symptoms of uterine fibroids, which may include heavy menstrual bleeding, pain, and anemia – yet effective non-invasive treatment options are very limited,” said Lynn Seely, M.D., chief executive officer of Myovant Sciences. “If approved, we hope to redefine care for these women with relugolix combination tablet, a potential new treatment that demonstrated a predictable and clinically-meaningful reduction in menstrual blood loss while maintaining bone health in the Phase 3 LIBERTY program.”

The NDA submission in uterine fibroids is supported by positive results from the Phase 3 LIBERTY program, which included two multinational replicate studies and an open-label extension study through one year. The NDA is the third regulatory application Myovant has submitted this year, following a Marketing Authorization Application to the European Medicines Agency in uterine fibroids and an NDA in advanced prostate cancer. Myovant is also advancing the Phase 3 SPIRIT program, evaluating relugolix combination therapy (relugolix 40 mg plus estradiol 1.0 mg and norethindrone acetate 0.5 mg) in women with pain associated with endometriosis, with data from a second Phase 3 study expected this quarter. SPIRIT 2, the first of the two Phase 3 studies of once-daily relugolix combination therapy in women with pain associated with endometriosis, met its co-primary efficacy endpoints and six key secondary endpoints. In addition, relugolix combination therapy was generally well-tolerated including minimal bone mineral density loss over 24 weeks.

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 their primary endpoints ($p < 0.0001$) 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 at Week 24 ($p < 0.0001$). 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 its 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 at Week 52. 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 production, a hormone known to stimulate the growth of uterine fibroids and endometriosis, and testicular testosterone production, a hormone known to stimulate the growth of prostate cancer. Myovant is developing a relugolix combination tablet (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg) for women with uterine fibroids and for women with endometriosis. Myovant is also developing a relugolix monotherapy tablet (120 mg once daily) for men with advanced prostate cancer.

About Myovant Sciences
Myovant Sciences aspires to be the leading healthcare company focused on redefining care for women and for men. The company's lead product candidate is relugolix, a once-daily, oral GnRH receptor antagonist. The company has three late-stage clinical programs for relugolix in uterine fibroids, endometriosis, and prostate cancer. The company is also developing MVT-602, an oligopeptide kisspeptin-1 receptor agonist, that has completed a Phase 2a study for the treatment of female infertility as part of assisted reproduction. Takeda Pharmaceuticals International AG, a subsidiary of Takeda Pharmaceutical Company Limited, the originator of relugolix, previously granted the company a worldwide license to develop and commercialize relugolix (excluding Japan and certain other Asian countries) and an exclusive license to develop and commercialize MVT-602 in all countries worldwide. Sumitovant Biopharma, Ltd., a wholly owned subsidiary of Sumitomo Dainippon Pharma Co., Ltd., is the majority shareholder of Myovant. For more information, please visit the company's 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 men; the potential of relugolix combination tablet, if approved, to be the first once-daily, oral treatment for women with heavy menstrual bleeding associated with uterine fibroids in the U.S., redefine care for women and achieve a predictable and clinically-meaningful reduction in menstrual blood loss while maintaining bone health; any expectations regarding the approval of relugolix combination tablet and the timing of any approval; any anticipated market size; and the expected timing of data for the second Phase 3 study in women with endometriosis. 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. 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 18, 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 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.

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