Myovant Sciences Announces 88% One-Year Response Rate in Positive Phase 3 LIBERTY Extension Study of Once-Daily Relugolix Combination Therapy in Women with Uterine Fibroids

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- *Primary efficacy endpoint met with 87.7% response rate at one year; women experienced, on average, an 89.9% reduction in menstrual blood loss*
- *Bone mineral density maintained through one year, with no new safety signals*
- *Data further strengthen the New Drug Application (NDA) expected to be submitted in April 2020*

BASEL, Switzerland, Feb. 10, 2020 (GLOBE NEWSWIRE) -- Myovant Sciences (NYSE: MYOV), a healthcare company focused on developing innovative treatments for women's health and prostate cancer, today announced that the Phase 3 LIBERTY open-label extension study of once-daily, oral relugolix combination therapy (relugolix 40 mg plus estradiol 1.0 mg and norethindrone acetate 0.5 mg) demonstrated an 87.7% response rate at one year while maintaining bone mineral density. Myovant expects to include the extension data in its New Drug Application (NDA) submission for heavy menstrual bleeding associated with uterine fibroids anticipated in April 2020.

“With an estimated quarter of a million U.S. women undergoing hysterectomies each year due to fibroids, there is an urgent need to rethink how we approach the condition and associated symptoms which can be debilitating and recurrent for many women,” said Ayman Al-Hendy, M.D., Ph.D., professor of obstetrics and gynecology and director of Translational Research, University of Illinois College of Medicine. “A non-invasive treatment option that could provide long-term symptom improvement and ease of use would be a game-changer for physicians and millions of women who suffer from this common condition.”

In the primary endpoint analysis, 87.7% of women achieved the responder criteria 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. The one-year primary endpoint result in the LIBERTY open-label extension study demonstrated 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 one year.

“We are very pleased to see that at one year both the safety and efficacy data for relugolix combination therapy are consistent with our prior data demonstrating a predictable and clinically-meaningful reduction in menstrual blood loss while maintaining bone health,” said Lynn Seely. M.D., CEO of Myovant. “We look forward to submitting applications to the regulatory agencies in Europe and the U.S. in the coming months to seek approval for our one pill, once-a-day potential new treatment for women with uterine fibroids.”

Changes in bone mineral density through one year, as assessed by dual energy x-ray absorptiometry (DXA) every three months, were consistent with those in 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. Adverse events reported in more than 10% of women treated with relugolix combination therapy for one year and more frequent than those reported in the placebo group after 6 months included only hot flash. There were no pregnancies reported in the relugolix combination therapy group.

Complete results from the LIBERTY open-label extension study will be submitted for presentation at a future scientific meeting and publication in a medical journal.

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. Women received treatment either with relugolix combination therapy for 24 weeks, relugolix 40 mg once daily monotherapy for 12 weeks followed by relugolix combination therapy once daily for an additional 12 weeks, or placebo once daily 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 sustained 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.

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 abnormal uterine bleeding, heavy or painful periods, anemia, abdominal pain, backache, increased abdominal girth and bloating, urinary frequency or retention, constipation or painful defecation, pregnancy loss, painful intercourse 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 plus estradiol 1.0 mg and norethindrone acetate 0.5 mg) for women with heavy menstrual bleeding with associated uterine fibroids and for women with pain associated 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 innovative treatments for women's health and prostate cancer. 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, granted the company an exclusive, 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, 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 become the leading healthcare company focused on innovative treatments for women's health and prostate cancer; the Company's plans and timing to file for approval of relugolix combination tablet for the treatment of heavy menstrual bleeding associated with uterine fibroids in the U.S. and Europe; the likelihood and timing of any approvals; and the Company's expectations with respect to the duration of use and labelling of any approved product. 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' Quarterly Report on Form 10-Q filed on November 12, 2019, 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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