Myovant Sciences Presents Additional Data on Bone Mineral Density in Women with Uterine Fibroids from Phase 3 LIBERTY Program and from Prospective Observational Study

September 14, 2020

- *Relugolix combination therapy maintained bone mineral density through one year, consistent with bone mineral density changes observed in untreated women*
- *Findings presented at the American Society for Bone and Mineral Research (ASBMR) 2020 Annual Meeting Virtual Event*

BASEL, Switzerland, Sept. 14, 2020 (GLOBE NEWSWIRE) -- Myovant Sciences (NYSE: MYOV), a healthcare company focused on redefining care for women and for men, today announced the presentation of one-year data on bone mineral density (BMD) from the Phase 3 LIBERTY program evaluating the safety and efficacy of once-daily relugolix combination therapy (relugolix 40 mg plus estradiol 1.0 mg and norethindrone acetate 0.5 mg) in women with uterine fibroids. The BMD results from the LIBERTY program demonstrated maintenance of BMD through one year and were consistent with those observed in a separate prospective observational study of untreated, age-matched women with uterine fibroids. The findings were presented at the American Society for Bone and Mineral Research (ASBMR) 2020 Annual Meeting Virtual Event, held September 11-15, 2020.

“Uterine fibroids are a chronic condition, but the duration of use for existing treatment options has been limited by concerns about potential bone loss while on therapy,” said Michael McClung, M.D., founding director of the Oregon Osteoporosis Center. “These new data show relugolix combination therapy maintained bone mineral density over one year of treatment, consistent with that of untreated, age-matched women with uterine fibroids in a concurrent study.”

“We believe these findings add to the unique and growing evidence supporting relugolix combination tablet as a potential long-term treatment option for women with uterine fibroids,” said Juan Camilo Arjona Ferreira, M.D., chief medical officer of Myovant Sciences. “These data further support our vision of providing a one pill, once-a-day treatment that may provide substantial reductions in menstrual blood loss and symptom relief while maintaining bone health.”

Details of the presentations are as follows:

Relugolix Combination Therapy Preserves Bone Mass in Patients with Uterine Fibroids: Results from Phase 3 LIBERTY Program (Abstract # P-641)
The Phase 3 LIBERTY program evaluated the safety and efficacy of once-daily relugolix combination therapy in premenopausal women with heavy menstrual bleeding due to uterine fibroids. The program met its primary endpoints and demonstrated that relugolix combination therapy significantly reduced menstrual blood loss and pain. In this analysis, pooled data from 768 women in the LIBERTY 1 and LIBERTY 2 studies showed that mean changes in lumbar spine bone mineral density (LS BMD) were comparable for relugolix combination therapy and placebo (Week 12: -0.63% vs. 0.34%; Week 24: -0.23% vs. 0.18%, respectively).

Evaluation of Relugolix Combination Therapy to Maintain Bone Mass in Women with Uterine Fibroids Through 52 Weeks: LIBERTY Long-Term Extension Study (Abstract # P-639)
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 up to 52 weeks. In this analysis, data from 163 women who entered the extension study after receiving 24 weeks of relugolix combination therapy demonstrated maintenance of BMD through 52 weeks of treatment (Week 52: LS BMD -0.80%).

A Prospective Observational Study of Bone Mineral Density in Premenopausal Women with Uterine Fibroids (Abstract # P-552)
This prospective observational study was designed to characterize longitudinal BMD in 262 premenopausal women with uterine fibroids. Mean LS BMD showed minimal changes over the 52-week observational period (0% at Week 24 and -0.41% at Week 52).

Relugolix combination tablet is under review by the U.S. Food and Drug Administration (FDA) for the treatment of women with uterine fibroids, with a target action date of June 1, 2021. Myovant submitted a Marketing Authorization Application to the European Medicines Agency in March 2020 for relugolix combination tablet in uterine fibroids. Additionally, 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. 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 dates under the Prescription Drug User Fee Act (PDUFA) for Myovant's NDAs for the treatment of women with heavy menstrual bleeding associated with uterine fibroids; and for the treatment of men with advanced prostate cancer; the characterization of data from Myovant's clinical studies, including the LIBERTY program and the prospective observational study of relugolix combination therapy relating to bone mineral density; the statements and quotes regarding relugolix combination tablet as a potential long-term treatment option for women with uterine fibroids; and Myovant's vision of providing a one pill, once-a-day treatment that may provide substantial reductions in menstrual blood loss and symptom relief while maintaining bone health. 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.

Investor Contact:
Frank Karbe
President and Chief Financial Officer
Myovant Sciences, Inc.
investors@myovant.com

Media Contact:
Albert Liao
Director, Corporate Communications
Myovant Sciences, Inc.
media@myovant.com

Source: Myovant Sciences, Inc.