Myovant Sciences Presents Additional Data on Relugolix Combination Therapy from Phase 3 LIBERTY Studies in Women with Uterine Fibroids and from Ovulation Inhibition Study

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- *Data from Phase 3 LIBERTY program show improvement in patient-reported outcomes in addition to improvement in hemoglobin levels in anemic women*
- *Detailed data from ovulation inhibition study demonstrate 100% ovulation inhibition and 100% return of ovulation upon treatment discontinuation*
- *Findings presented during European Society of Human Reproduction and Embryology (ESHRE) virtual 36th Annual Meeting taking place July 5-8, 2020*

BASEL, Switzerland, July 06, 2020 (GLOBE NEWSWIRE) -- Myovant Sciences (NYSE: MYOV), a healthcare company focused on redefining care for women and for men, today announced the presentation of additional data from clinical studies of its once-daily 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. The data were presented in virtual oral and poster sessions during the European Society of Human Reproduction and Embryology (ESHRE) virtual 36th Annual Meeting.

"The additional data being presented at the European Society of Human Reproduction and Embryology Annual Meeting reinforce the potential of relugolix combination therapy to offer women suffering from uterine fibroids meaningful reduction in distress due to bleeding, passing blood clots, and pelvic pressure, as well as improvement in anemia," said Juan Camilo Arjona Ferreira, M.D., chief medical officer of Myovant Sciences. "Furthermore, the data from our ovulation inhibition study showed inhibition in 100% of women on treatment as well as rapid return after stopping treatment, potentially offering women the ability to control their ovulation and fertility goals."

Details of the presentations are as follows:

Relugolix combination therapy reduced patient-reported distress from bleeding and pelvic symptoms and improved daily activities in patients with uterine fibroids in the LIBERTY program (oral presentation, O-024)

In the Phase 3 LIBERTY program, women were asked to provide feedback (between 0 and 100) on the Bleeding and Pelvic Discomfort (BPD) scale, which assesses distress due to heavy menstrual bleeding, passing blot clots, and pelvic pressure/tightness, and the Revised Activities (RA) scale (between 0 and 100), which assesses physical and social activities.

- Reductions in distress on the BPD scale from baseline to Week 24 were significantly greater for women taking relugolix combination therapy (48.4 point reduction) than placebo (17.4 point reduction) ($p < 0.0001$).
- Improvements in physical and social activities on the RA scale from baseline to Week 24 were significantly greater for women taking relugolix combination therapy (45.1 point increase) than placebo (15.8 point increase) ($p < 0.0001$).
- Responder rates (women reporting at least a 20-point change from baseline to Week 24) were significantly higher for women taking relugolix combination therapy (62.5% on BPD, 61.7% on RA) than placebo (28.1% on BPD, 34.0% on RA) (all $p < 0.0001$).

Relugolix combination therapy improves hemoglobin levels in anemic women with heavy menstrual bleeding due to uterine fibroids: results from the LIBERTY Phase 3 program (oral presentation, O-023)

In the Phase 3 LIBERTY program, approximately one-third of women had anemia (hemoglobin ≤ 10.5 g/dL) at baseline. These women were more likely to be Black/African American (65.2% versus 51.2% in overall study population) and their baseline menstrual blood volume was higher (mean: 285.5 mL versus 228.8 mL in overall study population), where menstrual blood volume > 80 mL in a cycle is defined as heavy menstrual bleeding.

- The percentage of women with a clinically-meaningful increase in hemoglobin levels (> 2 g/dL) from baseline to Week 24 was higher for women taking relugolix combination therapy (55.7%) than placebo (11.7%) ($p < 0.0001$).
- The mean percentage increase in hemoglobin concentration from baseline to Week 24 was significantly greater in women taking relugolix combination therapy (23.0%) than placebo (6.4%) ($p < 0.0001$).

Suppression of ovarian activity during co-administration of the oral gonadotropin-releasing hormone receptor antagonist relugolix, estradiol, and norethindrone acetate in healthy female volunteers (poster presentation, P-287)

In a Phase 1 open-label, single-arm ovulation inhibition study, 67 healthy premenopausal women were evaluated over an 84-day treatment period (three cycles) to assess the effects of relugolix combination therapy on ovulation inhibition, per the Hoogland-Skouby assessment scale (score < 5). A post-treatment follow-up period assessed time to the return of ovulation.

- Once-daily dosing with relugolix combination therapy resulted in suppression of ovarian activity and inhibition of ovulation in 100% of women during the treatment period.
- Mean and median estradiol levels were between 30 and 44 pg/mL during treatment.

- Ovarian activity resumed after treatment discontinuation, with ovulation occurring a mean of 23.5 days after the last treatment day.
- Relugolix combination therapy was generally well-tolerated.

Myovant submitted a Marketing Authorization Application to the European Medicines Agency in March 2020 and a New Drug Application to the U.S. Food and Drug Administration in May 2020 for relugolix combination tablet (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg) for the treatment of women with uterine fibroids. Myovant also recently reported positive data from its second Phase 3 SPIRIT trial 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 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's health and prostate cancer; the statements and characterizations of data from the LIBERTY and ovulation inhibition clinical studies; the potential of relugolix combination therapy to offer women suffering from uterine fibroids meaningful benefit in reduced distress due to bleeding, passing blood clots, and pelvic pressure, as well as improvement in anemia; the Company's regulatory strategies; and the timing of any potential regulatory filings and approvals in any indication. 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. 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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