Myovant Sciences Announces Positive Results from Second Phase 3 Study Evaluating Once-Daily Relugolix Combination Therapy in Women with Uterine Fibroids and Positive Results from Bioequivalence Study

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- Primary efficacy endpoint met with 71.2% response rate ($p < 0.0001$); women experienced, on average, an 84.3% reduction in menstrual blood loss ($p < 0.0001$)
- Achieved six key secondary endpoints including reduction in pain, with a well-tolerated safety profile including low incidence of hot flashes and bone mineral density maintained comparable to placebo
- Single-tablet relugolix combination therapy met all required FDA bioequivalence criteria in a separate bioequivalence study supporting a potential one-pill, once-daily dosing regimen
- New Drug Application (NDA) submission expected in fourth quarter 2019
- Conference call and webcast to be held today at 8:30 a.m. EDT / 5:30 a.m. PDT

BRISBANE, Calif. and BASEL, Switzerland, July 23, 2019 (GLOBE NEWSWIRE) -- Myovant Sciences (NYSE: MYOV), a clinical-stage healthcare company focused on developing and commercializing innovative therapies for women's health and prostate cancer, today announced that LIBERTY 2, the second of two Phase 3 studies of once-daily relugolix combination therapy, met its primary efficacy endpoint and six key secondary endpoints in women with uterine fibroids. In addition, relugolix combination therapy maintained bone mineral density at levels comparable to placebo over 24 weeks and was generally well- tolerated. These results confirm the previously announced data from the Phase 3 LIBERTY 1 study and enable an NDA submission to the U.S. Food and Drug Administration (FDA) by the end of this year.

Myovant Sciences also announced that a separate clinical study of single-tablet relugolix combination therapy met all required and pre-specified FDA criteria for bioequivalence, providing critical data necessary to include the once-daily, single-tablet regimen in the NDA submission for approval of the treatment for uterine fibroids. The single-tablet regimen is the formulation intended to be offered to women should relugolix combination therapy receive FDA approval.

"Millions of women suffer from heavy bleeding, pain, anemia, lost productivity, or pregnancy complications resulting from uterine fibroids," said Andrea Lukes, MD, MHSc, Founder of the Carolina Women's Research and Wellness Center and LIBERTY Program Steering Committee Member. "The data from the two pivotal LIBERTY studies suggest we have a medicine that could offer meaningful improvement in symptoms without sacrificing safety and tolerability. Relugolix combination therapy has the potential to transform the treatment paradigm for women by offering them a well-tolerated, elegant oral alternative to the surgical or less effective treatment options available today."

"Myovant Sciences has now clearly demonstrated in two, large, late-stage studies and a separate, positive bioequivalence study that relugolix combination therapy has a distinctive constellation of attributes, including substantial symptom relief with a well-tolerated safety profile, all in a single pill that can be taken once a day. No one else has achieved this for women with uterine fibroids," said Lynn Seely, MD, President and CEO of Myovant Sciences. "With these results, our team is focused on submitting the NDA by the end of the year and continuing to build the organization and capabilities to efficiently and successfully deliver this treatment to women in need."

In the primary endpoint analysis of LIBERTY 2, 71.2% of women receiving once-daily relugolix combination therapy achieved the responder criteria compared with 14.7% of women receiving placebo ($p < 0.0001$). 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. On average, women receiving relugolix combination therapy experienced a highly significant 84.3% reduction in menstrual blood loss from baseline ($p < 0.0001$). In addition, a significantly greater proportion of women suffering from moderate-to-severe pain from uterine fibroids at baseline experienced no pain or minimal pain during the last 35 days of treatment with relugolix combination therapy compared with women on placebo ($p < 0.0001$).

Changes in bone mineral density were comparable between the relugolix combination and placebo groups at the end of treatment. 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).

Six key secondary endpoints achieved statistical significance compared to placebo, consisting of mean change in menstrual blood loss from baseline to week 24, reduction in pain in women with pain at baseline, improvement in quality of life, amenorrhea, defined as no or negligible blood loss, improvement in anemia in those women with anemia at baseline (all p-values < 0.0001), and reduction in uterine volume ($p = 0.008$).

The overall incidence of adverse events in the relugolix combination and placebo groups was comparable (60.3% vs. 58.9%). In the relugolix combination therapy group, 1.6% of women discontinued treatment early due to adverse events compared with 4.7% in the placebo group. There were no adverse events in the relugolix combination group reported by at least 10% of women and more frequently than in the placebo group. The incidence of hot flashes in the relugolix combination group was similar to placebo (5.6% versus 3.9%). There were no pregnancies in the relugolix combination group and one in the placebo group.

Conference Call
Myovant Sciences will hold a conference call today, July 23, 2019 beginning at 8:30 a.m. EDT / 5:30 a.m. PDT. The dial-in numbers are 1-800-532-3746 for domestic callers and 1-470-495-9166 for international callers. A live webcast of the conference call will also be available on the investor relations page of Myovant Sciences' website at investors.myovant.com. After the live webcast, the event will remain archived on Myovant

Sciences' website for at least 30 days.

Phase 3 LIBERTY Program in Uterine Fibroids
Myovant Sciences' 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 uterine fibroids and heavy menstrual bleeding. Women in the LIBERTY 1 and LIBERTY 2 studies underwent a screening period requiring up to two menstrual cycles to document heavy menstrual bleeding and were randomized in a 1:1:1 ratio to one of three groups. 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.

Myovant Sciences enrolled 388 women in LIBERTY 1 and 382 women in LIBERTY 2. To be enrolled, women must have had a monthly menstrual blood loss volume of at least 80 mL in two consecutive cycles or 160 mL in one cycle, measured by the alkaline hematin method, a quantitative measure of menstrual blood loss from an assessment of collected menstrual products.

In LIBERTY 1, 73.4% of women receiving once daily oral relugolix combination therapy achieved the responder criteria compared with 18.9% of women receiving placebo ($p < 0.0001$). On average, women receiving relugolix combination therapy experienced an 84.3% reduction in menstrual blood loss from baseline ($p < 0.0001$) as well as a significant improvement in pain ($p < 0.0001$) and measures of quality of life ($p < 0.0001$). In LIBERTY 1, the safety profile observed with relugolix combination therapy was generally similar to placebo including comparable changes in bone mineral density between the relugolix combination and placebo groups.

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 receive 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 can elect to participate in a second 52-week randomized withdrawal study designed to provide two-year safety and efficacy data on relugolix combination therapy, to evaluate the need for maintenance therapy.

Bioequivalence Study
The bioequivalence study was conducted to establish the bioequivalence of a single tablet containing relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg with the co-administered regimen used in the LIBERTY clinical program (one relugolix 40 mg tablet and one tablet containing estradiol 1.0 mg and norethindrone acetate 0.5 mg).

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 5 million women in the U.S. suffer from symptoms of uterine fibroids, and an estimated 3 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.

Myovant is also studying relugolix combination therapy (relugolix 40 mg plus 1.0 mg estradiol with 0.5 mg norethindrone acetate) in two Phase 3 clinical studies (SPIRIT 1 and SPIRIT 2) evaluating endometriosis-associated pain. Relugolix monotherapy, 120 mg once daily, is also being evaluated in a Phase 3 HERO study in 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. Myovant's lead product candidate is relugolix, an oral once-daily small molecule that acts as a GnRH receptor antagonist. Myovant has three late-stage clinical programs for relugolix ongoing in uterine fibroids, endometriosis and prostate cancer. Myovant 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 granted Myovant 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. Over time, Myovant intends to expand its development pipeline to include other potential treatments for women's health and prostate cancer. For more information, please visit Myovant's website at www.myovant.com. Follow @Myovant on Twitter and LinkedIn (https://www.linkedin.com/company/myovant-sciences).

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 that are not historical statements of fact and statements regarding the Company's intent, belief, or expectations and can be identified by words such as "aspire, "anticipate," "believe," "can," "could," "expect," "intend," "likely," "may," "might," "plan," "potential," "project," "should," "will," "would," or the negative or plural of these words, although not all forward-looking statements contain these identifying words. In this press release, forward-looking statements include, but are not limited to, statements regarding the Company's aspirations to become the leading healthcare company focused on innovative treatments for women's health and prostate cancer, the Company's intentions to expand its development pipeline to include other potential treatments for women's health and prostate cancer, the Company's plans to file for approval of relugolix combination therapy, including with a once daily single tablet, and for long-term use, the timing of such filing, the likelihood of approval, and the commercial potential for relugolix, including market size.

The Company's 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 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 the Company's 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 the Company's filings with the United States Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in the Company's Annual Report on Form 10-K filed with the SEC on May 24, 2019, as such risk factors may be amended, supplemented or superseded from time to time by other reports the Company files with the SEC. These risks are not exhaustive. New risk factors emerge from time to time and it is not possible for the Company's management to predict all risk factors, nor can Myovant 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, the Company undertakes no obligation to update these forward-looking statements to reflect events or circumstances after the date of such statements.

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