Myovant Sciences Announces Positive Phase 3 Results from LIBERTY 1 Study Evaluating Once Daily Relugolix Combination Therapy in Women with Uterine Fibroids

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- Phase 3 study met primary efficacy endpoint with highly statistically significant 73.4% response rate ($p < 0.0001$); women experienced, on average, an 84.3% reduction in menstrual blood loss
- Achieved six key secondary endpoints including reduction in menstrual blood loss ($p < 0.0001$), reduction in pain ($p < 0.0001$), and improvement in quality of life ($p < 0.0001$)
- Bone mineral density maintained at levels comparable to placebo
- Conference call and webcast to be held today at 8:30 a.m. EDT / 5:30 a.m. PDT

BASEL, Switzerland, May 14, 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 1, the first 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. Relugolix combination therapy maintained bone mineral density at levels comparable to placebo over 24 weeks and was generally well tolerated.

In the primary endpoint analysis, 73.4% of women receiving once daily oral relugolix combination therapy achieved the responder criteria compared with 18.9% of women receiving placebo ($p < 0.0001$). A response was defined as a menstrual blood loss volume of less than 80 mL and a 50 percent or greater reduction from baseline in menstrual blood loss volume during the last 35 days of the 24-week treatment period measured using the alkaline hematin method. On average, women receiving relugolix combination therapy experienced an 84.3% reduction in menstrual blood loss from baseline, a clinically relevant key secondary endpoint.

Bone mineral density was comparable between the relugolix combination and placebo groups. 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).

"We are incredibly pleased with the positive results of this first Phase 3 study demonstrating a clinically meaningful response in a high proportion of women while maintaining bone health," said Lynn Seely, M.D., President and Chief Executive Officer of Myovant. "These results substantiate our once daily oral combination therapy approach. The improvements in symptoms most relevant to women, such as reduction in menstrual blood loss and pain, and improvement in quality of life are particularly exciting. We look forward to the possibility of bringing a new treatment option, suitable for long-term use, to the millions of women suffering from this debilitating disease."

"Women with uterine fibroids have limited medical treatment options and suffer from heavy menstrual bleeding, pain, anemia, and other symptoms that can significantly decrease their quality of life," said Ayman Al-Hendy, M.D., Ph.D., Professor and Director, Translational Research, University of Illinois College of Medicine. "These results highlight the potential of a once daily oral medicine to become an important option to help women with uterine fibroids manage symptoms without invasive procedures or major surgery such as hysterectomy."

The 24-week study achieved six key secondary endpoints with statistical significance compared to placebo including 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, and reduction in uterine volume.

The overall incidence of adverse events in the relugolix combination and placebo groups was comparable (62% vs. 66%). In the relugolix combination therapy group 5% of women discontinued treatment early due to adverse events compared with 4% in the placebo group. The only adverse event in the relugolix combination arm occurring in at least 10% of women and more frequently than in the placebo arm was hot flush (11% versus 8%). There were no pregnancies in the relugolix combination group and one in the placebo group.

Myovant expects data from LIBERTY 2, the replicate Phase 3 study evaluating once daily relugolix combination therapy in women with uterine fibroids and heavy menstrual bleeding, in the third quarter of 2019 and, provided the LIBERTY 2 study is successful, plans to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration in the fourth quarter of 2019.

Conference Call
Myovant will hold a conference call today, Tuesday, May 14, 2019 beginning at 8:30 a.m. EDT / 5:30 a.m. PDT to discuss results of the clinical study. The dial in numbers are 1-866-807-9684 for domestic callers and 1-412-317-5415 for international callers. A live webcast of the conference call will also be available on the investor relations page of Myovant's website at investors.myovant.com. After the live webcast, the event will remain archived on Myovant's website for at least 30 days.

Phase 3 LIBERTY Program in Uterine Fibroids
Myovant's ongoing Phase 3 clinical program for uterine fibroids consists 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 40 mg once daily in combination with 1.0 mg estradiol and 0.5 mg norethindrone acetate (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 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.

Eligible women completing the LIBERTY 1 or LIBERTY 2 studies are 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.

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 of whom 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. Roivant Sciences is the majority owner of Myovant. 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/myovantsciences).

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 "anticipate," "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 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 expected timelines for announcing additional top-line safety and efficacy data for relugolix in 2019, the Company's plans to file for approval of relugolix, the timing of such filing, the likelihood of approval, including for long-term use 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 Quarterly Report on Form 10-Q filed with the SEC on February 7, 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 its 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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