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

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- *Co-primary endpoints met with response rates of 74.5% for dysmenorrhea (menstrual pain) and 58.5% for non-menstrual pelvic pain (p-values < 0.0001)*
- *Women receiving relugolix combination therapy, on average, had a 73.3% reduction on the Numerical Rating Scale for dysmenorrhea from 7.3 (severe pain) to 1.8 (mild pain)*
- *Achieved all seven key secondary endpoints, including dyspareunia (painful intercourse) and a greater proportion of women not using opioids, with a generally well-tolerated safety profile including minimal bone mineral density loss*
- *Conference call and webcast to be held today at 8:30 a.m. EDT / 5:30 a.m. PDT*

BASEL, Switzerland, June 23, 2020 (GLOBE NEWSWIRE) -- Myovant Sciences (NYSE: MYOV), a healthcare company focused on redefining care for women and for men, today announced top-line results from SPIRIT 1, the second of two Phase 3 studies of once-daily relugolix combination therapy (relugolix 40 mg plus estradiol 1.0 mg and norethindrone acetate 0.5 mg) in women with pain associated with endometriosis. Relugolix combination therapy met its co-primary efficacy endpoints and all seven key secondary endpoints in the SPIRIT 1 study. In addition, relugolix combination therapy was generally well-tolerated and resulted in minimal bone mineral density loss over 24 weeks.

“An estimated six million women in the U.S. suffer from symptoms and effects of endometriosis, which can include severe pain and significant impact on well-being, as seen by the women who participated in the SPIRIT studies,” said Eric L. Brown, M.D., a practicing obstetrician-gynecologist and coordinating investigator in the SPIRIT program. “Women need and deserve treatment options beyond surgery, and these data indicate relugolix combination therapy has the potential to substantially reduce pain while improving function and activities of daily living and decreasing the proportion of women on opioids, all with a well-tolerated safety profile.”

Consistent with the previously announced SPIRIT 2 study, relugolix combination therapy achieved both co-primary endpoints by demonstrating clinically-meaningful pain reductions for 74.5% of women with dysmenorrhea (menstrual pain) and 58.5% of women with non-menstrual pelvic pain, compared to 26.9% and 39.6% of women in the placebo group, respectively (p-values < 0.0001). On average, women receiving relugolix combination therapy had a 73.3% reduction on the 11-point (0 to 10) Numerical Rating Scale for dysmenorrhea from 7.3 (severe pain) to 1.8 (mild pain).

All seven key secondary endpoints measured at Week 24 and compared to placebo achieved statistical significance, including changes in mean dysmenorrhea and overall pelvic pain, impact of pain on daily activities as measured by the Endometriosis Health Profile-30 (EHP-30) pain domain, greater proportions of women not using analgesics (p-values < 0.0001), changes in mean non-menstrual pelvic pain (p = 0.0002), greater proportions of women not using opioids (p = 0.0005), and changes in mean dyspareunia (painful intercourse) (p = 0.0149).

Relugolix combination therapy was generally well-tolerated with minimal bone mineral density loss over 24 weeks. The overall incidence of adverse events in the relugolix combination and placebo groups was similar (71.2% vs. 66.0%). In the relugolix combination therapy group, 3.8% of women had adverse events leading to discontinuation of treatment versus 1.9% in the placebo group. The only reported adverse events in at least 10% of women in the relugolix combination group were headache and hot flashes. There was one pregnancy in the relugolix combination group and three in the placebo group.

“Relugolix has now achieved positive results in five Phase 3 studies across three indications, demonstrating its potential to benefit women with pain from endometriosis and women with heavy menstrual bleeding from uterine fibroids as well as men with advanced prostate cancer,” said Juan Camilo Arjona Ferreira, M.D., chief medical officer of Myovant Sciences. “We look forward to sharing the one-year data from the SPIRIT extension study and submitting a New Drug Application to the FDA for this one dose, one pill, once a day potential treatment for women with endometriosis, which would be our third NDA submission in short succession.”

Eligible women who completed the SPIRIT 1 or SPIRIT 2 studies were offered the opportunity to enroll in an extension study and receive relugolix combination therapy for an additional 80-week period, resulting in a total treatment period of up to 104 weeks. The one-year results of this extension study, expected in the first quarter of 2021, will form the basis of the New Drug Application (NDA) together with the efficacy and safety data from the SPIRIT 1 and SPIRIT 2 studies.

Conference Call
Myovant will hold a conference call today, Tuesday, June 23, 2020 beginning at 8:30 a.m. EDT / 5:30 a.m. PDT to discuss results of the SPIRIT 1 Phase 3 study. 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’s website at investors.myovant.com. After the live webcast, the event will remain archived on Myovant’s website for at least 30 days.

About the Phase 3 SPIRIT Program in Endometriosis
Myovant’s Phase 3 clinical program for endometriosis consists of two multinational, replicate pivotal clinical studies (SPIRIT 1 and SPIRIT 2) of relugolix combination therapy (relugolix 40 mg plus estradiol 1.0 mg and norethindrone acetate 0.5 mg) in over 1,200 women with pain associated with endometriosis. 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 SPIRIT 1 or SPIRIT 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 80-week period, resulting in a total treatment period of up to 104 weeks, designed to evaluate the safety

and sustained efficacy of longer-term treatment.

About Endometriosis
Endometriosis is an estrogen-dependent, inflammatory disease in which tissue similar to the uterine lining is found outside the uterine cavity, commonly in the lower abdomen or pelvis, on ovaries, the bladder, and the colon. This endometrial-like tissue outside the uterus results in chronic inflammation and can cause scarring and adhesions.

The symptoms associated with endometriosis include painful periods and chronic pelvic pain, painful ovulation, pain during or after sexual intercourse, heavy bleeding, fatigue, and infertility. Endometriosis can also impact general physical, mental, and social well-being, requiring a multi-disciplinary approach to care.

For endometriosis-associated pain, initial treatment options include hormonal contraceptives and over-the-counter pain medications. In more severe cases, GnRH agonists such as leuprolide acetate are used for short-term treatment. An estimated six million women in the U.S. suffer from symptoms of endometriosis, and an estimated one million women are inadequately treated by current medical therapy and require further treatment. Almost 200 million women are affected globally.

About Relugolix
Relugolix is a once-daily, oral gonadotropin-releasing hormone (GnRH) receptor antagonist that reduces production of 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. 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 relugolix as a 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 become the leading healthcare company focused on redefining care for women and for men; statements summarizing and characterizing data from the SPIRIT 1 and SPIRIT 2 studies; the expected timing of results from the extension study and the timing of any NDA filing; Myovant's vision of a one dose, one pill, once a day treatment for women suffering from endometriosis and uterine fibroids; and the estimated market size for endometriosis and commercial potential for relugolix combination tablet for the treatment of women with endometriosis. 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 and it is not possible for Myovant Sciences' management to predict all risk factors. 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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