Myovant Sciences Completes Patient Recruitment for Phase 3 SPIRIT 1 Study Evaluating Relugolix Combination Therapy in Women with Endometriosis

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- Top-line results for SPIRIT 2 and SPIRIT 1 expected in the first and second quarters of 2020, respectively
- Studies support potential regulatory submission for a single tablet, once-daily treatment of moderate-to-severe endometriosis-associated pain

BRISBANE, Calif. and BASEL, Switzerland, Oct. 21, 2019 (GLOBE NEWSWIRE) -- Myovant Sciences (NYSE: MYOV), a healthcare company focused on developing innovative treatments for women's health and prostate cancer, today announced that it has completed patient recruitment for its SPIRIT 1 study, the second of two Phase 3 replicate studies evaluating relugolix combination therapy in women with endometriosis-associated pain.

“The completion of recruitment for the SPIRIT program marks another important step in achieving our goal to bring a best-in-class, non-invasive treatment option to women suffering from endometriosis, that has predictable efficacy and tolerability and is potentially suitable for long-term use,” said Juan Camilo Arjona Ferreira, M.D., Chief Medical Officer of Myovant Sciences. “We are extremely appreciative of the physicians and patients who participate in our clinical trials and have helped us reach this important milestone. We look forward to sharing the top-line results in the first and second quarters of 2020.”

About the Phase 3 SPIRIT Program
Myovant Sciences’ 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 women with endometriosis-associated pain. Each of the SPIRIT studies was designed to enroll approximately 600 women 18 to 50 years of age with a diagnosis of endometriosis confirmed by laparoscopy or laparotomy. Eligible women have been randomized to one of three groups: relugolix combination therapy for 24 weeks, relugolix 40 mg monotherapy for 12 weeks followed by relugolix combination therapy for an additional 12 weeks, or placebo for a period of 24 weeks.

The co-primary endpoints evaluate the impact of treatment on menstrual pelvic pain, or dysmenorrhea, and non-menstrual pelvic pain. Safety outcomes, including bone mineral density changes as measured by dual-energy x-ray absorptiometry, are also being assessed.

Eligible patients completing the initial 24-week blinded assessment will be offered an active treatment extension with relugolix combination therapy for an additional 80-week period, resulting in a total treatment period of up to 104 weeks, to evaluate the safety of longer-term treatment.

About Endometriosis
Endometriosis is a 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.

For endometriosis-associated pain, initial treatment options include oral 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.

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. Myovant Sciences is developing a relugolix combination tablet (relugolix 40 mg plus estradiol 1.0 mg and norethindrone acetate 0.5 mg) for women with heavy menstrual bleeding associated with uterine fibroids and for women with endometriosis-associated pain. Myovant is also evaluating relugolix monotherapy (120 mg once daily) 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. 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 granted the company 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. 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 regarding Myovant Sciences’ aspirations to become the leading healthcare company focused on innovative treatments for women’s health and prostate cancer, the expected timing for announcing top-line results for SPIRIT 2 and SPIRIT 1 and whether the studies will

support regulatory submission for a single tablet, once-daily treatment of moderate-to-severe endometriosis-associated pain. 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' Quarterly Report on Form 10-Q filed on August 6, 2019, 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, nor can Myovant Sciences 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, 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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