Myovant Sciences Completes Patient Recruitment for Phase 3 SPIRIT 2 Study Evaluating Relugolix Combination Therapy in Women with Endometriosis

August 20, 2019

- Top-line data for SPIRIT 2 expected in first quarter of 2020

- Company on track to announce top-line results from SPIRIT 1 in second quarter of 2020

BRISBANE, Calif., and BASEL, Switzerland, Aug. 20, 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 it has completed patient recruitment for its SPIRIT 2 study, the first of two Phase 3 replicate studies evaluating relugolix combination therapy in women with endometriosis-associated pain. The SPIRIT 2 study is part of an international clinical development program designed to gain regulatory approval of relugolix for the treatment of moderate-to-severe endometriosis-associated pain.

"One in ten premenopausal women have endometriosis, a condition often associated with debilitating pain, that is particularly severe during menstruation, and infertility. Currently, the standard of care for women with moderate to severe endometriosis is invasive procedures and pain medicines, including opioids, which have significant limitations. We are developing relugolix combination therapy as a single pill taken once a day with the goal of offering patients a well-tolerated and effective alternative," said Juan Camilo Arjona Ferreira, M.D., Chief Medical Officer of Myovant Sciences. "With the completion of recruitment, we are on track to report top-line data for SPIRIT 2 in the first quarter of 2020, and data from our replicate study, SPIRIT 1, in the second quarter."

About Myovant's Phase 3 Program for Endometriosis

Myovant is currently conducting a Phase 3 clinical program consisting of two international, replicate pivotal clinical studies (SPIRIT 1 and SPIRIT 2) of relugolix combination therapy in women with endometriosis-associated pain. Each of the SPIRIT studies is enrolling approximately 600 women 18 to 50 years of age with a diagnosis of endometriosis confirmed by laparoscopy or laparotomy. Eligible women are randomized to one of three groups: relugolix combination therapy (relugolix 40 mg plus estradiol 1.0 mg and norethindrone acetate 0.5 mg) 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 are evaluating the impact of treatment on menstrual pelvic pain or dysmenorrhea and on 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 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 developing relugolix combination therapy (relugolix 40 mg plus 1.0 mg estradiol with 0.5 mg norethindrone acetate) for women with heavy menstrual bleeding associated with uterine fibroids and for endometriosis-associated pain.

Myovant announced results from two successful Phase 3 clinical studies evaluating relugolix combination therapy in women with heavy menstrual bleeding and uterine fibroids. The company expects to submit a New Drug Application (NDA) to the FDA in the fourth quarter of 2019 for this indication. Top-line results from Myovant's two Phase 3 studies evaluating women with endometriosis-associated pain are expected in the first and second quarters of 2020.

Relugolix monotherapy, 120 mg once daily, lowers testosterone in men and is being evaluated in a Phase 3 HERO study in men with advanced prostate cancer. Top-line results from the HERO study are expected in the fourth quarter of 2019.

About Myovant Sciences

Myovant Sciences aspires to be the leading healthcare company focused on innovative treatments for women's health and prostate cancer. Myovant Sciences' lead product candidate is relugolix, an oral, once-a-day small molecule that acts as a GnRH receptor antagonist. Myovant Sciences has three late-stage clinical programs for relugolix ongoing in uterine fibroids, endometriosis and prostate cancer. Myovant Sciences 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 Sciences 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 Sciences intends to expand its development pipeline to include other potential treatments for women's health and prostate cancer. For more information, please visit Myovant Sciences' website at www.myovant.com. Follow @Myovant on Twitter and LinkedIn (https://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 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, Myovant Sciences' intentions to expand its development pipeline to include other potential treatments for women's health and prostate cancer and Myovant Sciences' plans to report the results from its two Phase 3 endometriosis studies in the first and second quarters of calendar year 2020.

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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