Myovant Sciences Announces Priority Review and FDA Acceptance of New Drug Application for Once-Daily, Oral Relugolix for Advanced Prostate Cancer

June 22, 2020

- *Priority Review status expected to accelerate review, with a target FDA action date of December 20, 2020*

BASEL, Switzerland, June 22, 2020 (GLOBE NEWSWIRE) -- Myovant Sciences (NYSE: MYOV), a healthcare company focused on redefining care for women and for men, today announced that its New Drug Application (NDA) for once-daily, oral relugolix (120 mg) for the treatment of men with advanced prostate cancer has been accepted for Priority Review by the U.S. Food and Drug Administration (FDA).

"We are delighted that the FDA has accepted for Priority Review our New Drug Application for relugolix, bringing us one step closer to providing a one pill, once a day potential new treatment option to men with advanced prostate cancer," said Lynn Seely, M.D., chief executive officer of Myovant Sciences. "As recently published in the *New England Journal of Medicine*, relugolix demonstrated superior efficacy and a 54% lower risk of major adverse cardiovascular events compared to the current standard of care, leuprolide acetate injections, in the Phase 3 HERO study."

The FDA grants Priority Review to applications for potential therapies that, if approved, would be significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications. The FDA has set a target action date of December 20, 2020 under the Prescription Drug User Fee Act (PDUFA). In its acceptance letter, the FDA also stated that it is currently not planning to hold an advisory committee meeting for this application. If approved, relugolix would be the first and only oral gonadotropin-releasing hormone (GnRH) receptor antagonist treatment for men with advanced prostate cancer.

In May 2020, Myovant submitted a separate NDA for once-daily, oral relugolix combination tablet (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg) for women with heavy menstrual bleeding associated with uterine fibroids. A Marketing Authorization Application for relugolix combination tablet in women with moderate to severe symptoms associated with uterine fibroids is also under review by the European Medicines Agency.

About the Phase 3 HERO Program in Advanced Prostate Cancer
Myovant's Phase 3 clinical program for advanced prostate cancer consisted of a randomized, open-label, parallel-group, multinational clinical study designed to evaluate the safety and efficacy of relugolix in over 900 men with androgen-sensitive advanced prostate cancer who required at least one year of continuous androgen deprivation therapy. Men were randomized 2:1 to receive a single loading dose of relugolix 360 mg followed by relugolix 120 mg once daily, or to treatment with leuprolide acetate 3-month depot injection, respectively.

Relugolix met the primary efficacy endpoint, with 96.7% of men treated with relugolix achieving sustained testosterone suppression to castrate levels (< 50 ng/dL) through 48 weeks versus 88.8% of men treated with leuprolide acetate. Relugolix also met all six key secondary endpoints, demonstrating superiority to leuprolide acetate in rapid and profound suppression of testosterone and PSA response, in addition to improved testosterone recovery after discontinuation of treatment. Men in the relugolix group had a 54% lower risk of major adverse cardiovascular events (MACE) compared to men in the leuprolide acetate group (2.9% vs. 6.2%, respectively). In men with a reported history of MACE, the relugolix group had 80% fewer MACE events reported compared to the leuprolide acetate group (3.6% vs. 17.8%, respectively). The overall incidence of adverse events in the relugolix and leuprolide acetate groups was comparable (92.9% vs. 93.5%, respectively).

Data from an additional key secondary endpoint, castration resistance-free survival, are expected in the third quarter of 2020.

About Prostate Cancer
Prostate cancer is the second most prevalent form of cancer in men and the second leading cause of death due to cancer in men in the U.S. Cardiovascular mortality is the leading cause of death in men with prostate cancer and accounts for 34% of deaths in men with prostate cancer in the U.S. More than three million men in the U.S. are currently living with prostate cancer, and approximately 190,000 men are estimated to be newly diagnosed in 2020. Advanced prostate cancer is prostate cancer that has spread or come back after treatment and may include men with biochemical recurrence (rising PSA in the absence of metastatic disease on imaging), locally advanced disease, or metastatic disease. Front-line medical therapy for advanced prostate cancer typically involves androgen deprivation therapy, which reduces testosterone to very low levels, commonly referred to as castrate levels. GnRH receptor agonists, such as leuprolide acetate, are depot injections and the current standard of care for androgen deprivation therapy. However, GnRH receptor agonists may be associated with mechanism-of-action limitations, including the potentially detrimental initial surge in testosterone levels that can exacerbate clinical symptoms, which is known as clinical or hormonal flare, and delayed testosterone recovery after the drug is discontinued. Approximately 210,000 men are treated with androgen deprivation therapy with a GnRH agonist or antagonist each year.

About Relugolix
Relugolix is a once-daily, oral gonadotropin-releasing hormone (GnRH) receptor antagonist that reduces production of testicular testosterone, a hormone known to stimulate the growth of prostate cancer, and ovarian estradiol, a hormone known to stimulate the growth of uterine fibroids and endometriosis. Myovant is developing relugolix as a monotherapy tablet (120 mg once daily) for men with advanced prostate cancer. Myovant is also 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.

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 redefine care for women and for men; the FDA's target action date of December 20, 2020 under the Prescription Drug User Fee Act (PDUFA); the FDA's statement that it is currently not planning to hold an advisory committee meeting for this application; the expectation that relugolix would be the first and only oral gonadotropin-releasing hormone (GnRH) receptor antagonist treatment for men with advanced prostate cancer; the timing of data from an additional key secondary endpoint, castration resistance-free survival, expected in the third quarter of 2020; any expectations regarding the approval of relugolix in any indication and the timing of any approval; and any anticipated market size for relugolix in any indication. 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-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.

Investor Contact:
Frank Karbe
President and Chief Financial Officer
Myovant Sciences, Inc.
investors@myovant.com

Media Contact:
Albert Liao
Director, Corporate Communications
Myovant Sciences, Inc.
media@myovant.com

Source: Myovant Sciences, Inc.