Myovant Sciences Announces European Medicines Agency Validation of Marketing Authorization Application for RELUGOLIX for the Treatment of Advanced Prostate Cancer

•If approved, relugolix would be the first and only oral androgen deprivation therapy for advanced prostate cancer in Europe

•Relugolix is FDA-approved and currently available in the U.S. under the trade name ORGOVYX™

•Pfizer has an exclusive option to commercialize relugolix in oncology outside of the U.S. and Canada, excluding certain Asian countries, with a decision expected in the first half of 2021

BASEL, Switzerland, March 29, 2021 (GLOBE NEWSWIRE) — Myovant Sciences (NYSE: MYOV), a healthcare company focused on redefining care for women and for men, today announced the European Medicines Agency (EMA) has validated the Marketing Authorization Application (MAA) for relugolix for the treatment of advanced prostate cancer. The validation of the application confirms the submission is sufficiently complete for the EMA to begin the formal review process.

“We are delighted that the Marketing Authorization Application for relugolix has been accepted for review by the European Medicines Agency. This is an important milestone in bringing a potential oral treatment option to men with advanced prostate cancer in Europe,” said David Marek, Chief Executive Officer of Myovant Sciences, Inc. “Following our recent FDA approval and launch in the U.S., we believe relugolix has the potential to transform the standard of care for men with advanced prostate cancer requiring androgen deprivation therapy. We look forward to making this potential treatment available to more men around the world.”

Under the terms of the collaboration between Myovant and Pfizer to develop and commercialize relugolix, Pfizer has an exclusive option to commercialize relugolix in oncology outside of the U.S. and Canada, excluding certain Asian countries. If Pfizer exercises this option, Myovant will receive $50 million and be eligible to receive double-digit royalties on net sales from these markets. Pfizer’s decision to exercise this option is expected in the first half of calendar year 2021.

The MAA is supported by efficacy and safety data from the Phase 3 HERO study, a randomized, open-label, parallel-group, multinational clinical study evaluating the safety and efficacy of relugolix in over 1,000 men with androgen-sensitive advanced prostate cancer who required at least one year of continuous androgen deprivation therapy. Relugolix received U.S. Food and Drug Administration (FDA) approval in December 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 diagnosed with prostate cancer are alive in the U.S., and approximately 250,000 men are estimated to be newly diagnosed in 2021.

Prostate cancer is considered advanced when it has spread or come back after initial treatment and may include biochemical recurrence (rising prostate-specific antigen 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 (< 50 ng/dL). Luteinizing hormone-releasing hormone (LHRH) receptor agonists, such as leuprolide acetate, are depot injections and the current standard of care for androgen deprivation therapy. However, LHRH 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 300,000 men are treated with androgen deprivation therapy each year in the U.S.

About Myovant Sciences
Myovant Sciences aspires to redefine care for women and for men through purpose-driven science, empowering medicines, and transformative advocacy. We have one FDA-approved medicine, ORGOVYX™ (relugolix), for

adult patients with advanced prostate cancer. Our lead product candidate, relugolix combination tablet (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5mg), is under regulatory review in Europe and the U.S. for women with uterine fibroids and is under development for women with endometriosis. We are also developing MVT-602, an oligopeptide kisspeptin-1 receptor agonist, which has completed a Phase 2a study for female infertility as part of assisted reproduction. Sumitovant Biopharma, Ltd., a wholly owned subsidiary of Sumitomo Dainippon Pharma Co., Ltd., is our majority shareholder. For more information, please visit our 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. In this press release, forward-looking statements include, but are not limited to, all statements and quotes reflecting Myovant Sciences' expectations regarding the MAA for advanced prostate cancer and Pfizer's exclusive option to commercialize relugolix in oncology outside the U.S. and Canada. 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, including uncertainties regarding whether Pfizer will exercise its exclusive option and the timing of its decision; any regulatory approval dates and/or launch dates in Europe; the risk that clinical trial data are subject to differing interpretations and assessments by different regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from the clinical studies; whether and when the MAA and whether and when other regulatory authorities may approve any other applications that may be filed for relugolix in other jurisdictions, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether relugolix will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of relugolix; and unforeseen circumstances or other disruptions to normal business operations arising from or related to the COVID-19 pandemic. Myovant Sciences cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur. 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 February 11, 2021, 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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