Myovant Sciences Announces Results of Additional Secondary Endpoint of Castration Resistance-Free Survival from Phase 3 HERO Study of Relugolix in Advanced Prostate Cancer

September 29, 2020

- *Relugolix had a similar rate of castration resistance-free survival in the subgroup of men with metastatic disease compared to leuprolide acetate (74% vs. 75%, respectively) and did not achieve statistical superiority (p = 0.84)*
- *Relugolix is under Priority Review with an FDA target action date of December 20, 2020, supported by positive Phase 3 HERO study results including a 97% responder rate and six positive key secondary endpoints*

BASEL, Switzerland, Sept. 29, 2020 (GLOBE NEWSWIRE) -- Myovant Sciences (NYSE: MYOV), a healthcare company focused on redefining care for women and for men, today announced results of an additional secondary endpoint from the Phase 3 HERO study evaluating relugolix in men with advanced prostate cancer. Relugolix did not achieve statistical superiority for castration resistance-free survival compared to leuprolide acetate in men with metastatic disease through 48 weeks.

“These new data from the Phase 3 HERO study show that three out of four men with metastatic prostate cancer remained castration resistance-free through 48 weeks while on oral relugolix, in-line with leuprolide acetate injections, the current standard of care,” said Dan George, M.D., a professor of medicine and surgery at the Duke University School of Medicine and HERO program steering committee member. “I continue to be excited by relugolix as a potential new and differentiated treatment option for men with prostate cancer given its robust clinical and safety data, including the lower risk of major adverse cardiovascular events compared to leuprolide acetate.”

Castration-resistant prostate cancer is defined by disease progression despite achieving testosterone suppression to castrate levels (< 50 ng/dL). In the subgroup of men with metastatic disease treated with relugolix, 74% were castration-resistance free through 48 weeks compared to 75% men treated with leuprolide acetate (HR = 1.03 [95% CI: 0.68-1.57]; p = 0.84). In the secondary endpoint analysis, castration resistance-free survival was defined as the time from first dose to prostate-specific antigen (PSA) progression per the Prostate Cancer Clinical Trials Working Group 3 (PCWG3) criteria or death from any cause. PSA progression was defined as a PSA increase ≥ 25% and ≥ 2 ng/mL above the nadir, and confirmed by a second PSA value ≥ 3 weeks later.

“We believe the totality of data – including previously reported data from the Phase 3 HERO program, published in the *New England Journal of Medicine* – presents compelling evidence for the potential use of relugolix in men with advanced prostate cancer,” said Lynn Seely, M.D., chief executive officer of Myovant Sciences. “With our New Drug Application under Priority Review by the FDA, we look forward to our target action date in December 2020 and hope to advance our commitment to redefining care by bringing once-daily, oral relugolix to men with prostate cancer.”

The incidence of adverse events in the subgroup of men with metastatic disease was consistent with that observed in primary analysis of HERO with no new safety signals observed.

Relugolix (120 mg) is under Priority Review by the FDA for the treatment of men with advanced prostate cancer, with a target action date of December 20, 2020. In the Phase 3 HERO study, 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 six key secondary endpoints, demonstrating 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).

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.

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 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. Relugolix monotherapy tablet (120 mg) is under regulatory review in the U.S. for men with advanced prostate cancer. Relugolix combination tablet (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg) is under regulatory review in Europe and the U.S. for women with uterine fibroids and is under development for women with endometriosis.

About Myovant Sciences

Myovant Sciences aspires to redefine care for women and for men through purpose-driven science, empowering medicines, and transformative advocacy. Our lead product candidate, relugolix, is a once-daily, oral GnRH receptor antagonist. Relugolix monotherapy tablet (120 mg) is under regulatory review in the U.S. for men with advanced prostate cancer. Relugolix combination tablet (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg) 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. 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 characterizations of the data from the HERO study, including the results of additional secondary endpoint of castration resistance-free survival; and the FDA target action date of December 20, 2020 under the Prescription Drug User Fee Act (PDUFA) for Myovant's NDA for the treatment of men with advanced prostate cancer. 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. 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 11, 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. 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.