Myovant Sciences Announces 97% Response Rate in Positive Phase 3 HERO Study of Once-Daily, Oral Relugolix in Men with Advanced Prostate Cancer

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- *Primary efficacy endpoint met with 96.7% of men achieving sustained testosterone suppression to castrate levels (< 50 ng/dL) through 48 weeks*
- *Achieved all six key secondary endpoints, including superiority to leuprolide acetate on rapid suppression of testosterone and prostate-specific antigen (PSA), all with p-values < 0.0001*
- *New Drug Application (NDA) submission expected in the second quarter of 2020*
- *Conference call and webcast to be held today at 8:30 a.m. EST / 5:30 a.m. PST*

BASEL, Switzerland, Nov. 19, 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 the Phase 3 HERO study of once-daily, oral relugolix (120 mg) met its primary efficacy endpoint and all six key secondary endpoints in men with advanced prostate cancer. These results support a New Drug Application (NDA) submission to the U.S. Food and Drug Administration (FDA) in the second quarter of 2020 and future regulatory submissions in Europe and Japan.

“An oral gonadotropin-releasing hormone, or GnRH, antagonist for advanced prostate cancer has been an aspiration for many years,” said Neal Shore, M.D., Medical Director of the Carolina Urologic Research Center and HERO Program Steering Committee Member. “If approved, relugolix would become the first-of-its-kind oral option for men with advanced prostate cancer.”

In the primary endpoint responder analysis, 96.7% (95% CI: 94.9%, 97.9%) of men receiving once-daily, oral relugolix achieved sustained testosterone suppression to castrate levels. A responder was defined as achieving and maintaining testosterone suppression to less than or equal to 50 ng/dL from Week 5 through Week 48. For the study to be successful, the lower bound of the 95% confidence interval of the response rate had to be at least 90%.

Five key secondary endpoints demonstrated superiority to leuprolide acetate, including rapid suppression of testosterone at Day 4 and Day 15, profound suppression of testosterone at Day 15, rapid suppression of prostate-specific antigen (PSA) at Day 15, and suppression of follicle-stimulating hormone (FSH) at Week 24 (all p-values < 0.0001). In addition, relugolix demonstrated non-inferiority to leuprolide acetate on sustained testosterone suppression through 48 weeks (96.7% vs. 88.8%, respectively) with a between-group difference of 7.9% (95% CI: 4.1%,11.8%), the primary endpoint required for regulatory submissions outside of the U.S. In addition, the pharmacodynamic results showed no testosterone flare after initiation of relugolix and mean testosterone levels returned to normal levels within 90 days after treatment discontinuation.

“With the exciting results from the HERO study demonstrating the potential of relugolix to provide unique benefits compared to leuprolide, we look forward to submitting an NDA to the FDA,” said Lynn Seely, M.D., President and CEO of Myovant Sciences. “We are now closer to our goal of bringing a precision oral medicine to the broad spectrum of men with advanced prostate cancer.”

The overall incidence of adverse events in the relugolix and leuprolide acetate groups was comparable (92.9% vs. 93.5%, respectively). In the relugolix group, 3.5% of men discontinued the study early due to adverse events compared with 2.6% of men in the leuprolide acetate group. The most frequently reported adverse events, reported in at least 10% of men in the relugolix group, were hot flashes, fatigue, constipation, diarrhea, and arthralgia. Unadjudicated major adverse cardiovascular events were reported in 2.9% of men in the relugolix group versus 6.2% of men in the leuprolide acetate group. These events included non-fatal myocardial infarction, non-fatal stroke, and all-cause mortality.

Conference Call
Myovant will hold a conference call today, November 19, 2019 beginning at 8:30 a.m. EST / 5:30 a.m. PST. The dial-in numbers are 1-800-532-3746 for domestic callers and +1-470-495-9166 for international callers. A live webcast of the conference call will also be available on the investor relations page of Myovant’s website at investors.myovant.com and will remain archived on Myovant’s website for at least 30 days.

About the Phase 3 HERO Program
This randomized, open-label, parallel-group, multinational clinical study was designed to evaluate the safety and efficacy of relugolix in men with androgen-sensitive advanced prostate cancer who required at least one year of continuous androgen deprivation therapy. Patients enrolled in the study 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.

The primary efficacy endpoint of the study to support U.S. approval was the ability of relugolix to achieve and maintain testosterone suppression to castrate levels (< 50 ng/dL) through 48 weeks.

Approximately 1,100 patients are planned to be enrolled in this study, including approximately 430 patients with metastatic prostate cancer to support the analysis of a secondary endpoint of castration resistance-free survival, data which are expected in the third quarter of 2020, and 138 Chinese patients (enrolled in China and Taiwan) to support registration in China.

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. Approximately three million men in the U.S. are currently living with prostate cancer, and approximately 170,000 men are estimated to be newly diagnosed in 2019. 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. Treatment for advanced

prostate cancer typically involves androgen deprivation therapy, which reduces testosterone to very low levels, commonly referred to as castrate levels. GnRH agonists, such as leuprolide acetate, or slow-release injections are the current standard of care for medical castration. However, GnRH agonists may be associated with mechanism-of-action limitations, including the potentially detrimental initial rise in testosterone levels that can exacerbate clinical symptoms, which is known as clinical or hormonal flare, and delayed testosterone recovery if the drug is discontinued.

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

Earlier this year, Myovant announced positive top-line data from two Phase 3 studies, LIBERTY 1 and LIBERTY 2, evaluating relugolix combination therapy for uterine fibroids, as well as positive results from a separate bioequivalence study supporting a potential one tablet, once-daily dosing regimen. Myovant expects to submit an NDA to the FDA for uterine fibroids in April 2020. Myovant also expects to announce top-line results from two Phase 3 studies, SPIRIT 2 and SPIRIT 1, evaluating relugolix combination therapy for endometriosis-associated pain in the first and second quarters of 2020, respectively.

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, a subsidiary of Takeda Pharmaceutical Company Limited, 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 and quotes regarding Myovant Sciences' aspirations to become the leading healthcare company focused on innovative treatments for women's health and prostate cancer, the Company's plans and timing to file for approval of once-daily, oral relugolix for the treatment of men with advanced prostate cancer in the United States, Europe and Japan, the likelihood of any approvals, the timing of data readout regarding the analysis of the secondary endpoint of castration resistance-free survival expected in the third quarter of 2020, the commercial potential for once-daily, oral relugolix for the treatment of men with advanced prostate cancer, and the timing of Myovant's plans to submit a New Drug Application to the FDA for uterine fibroids in April 2020 and to announce top-line results from the SPIRIT 2 and SPIRIT 1 studies in the first and second quarters of 2020, respectively. 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 November 12, 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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