



Myovant Sciences Announces Additional Positive Efficacy and Cardiovascular Safety Data from Phase 3 HERO Study of Once-Daily, Oral Relugolix in Advanced Prostate Cancer and Publication in the *New England Journal of Medicine*

May 29, 2020

- Phase 3 data presented in oral presentation during the [ASCO20 Virtual Scientific Program](#), with simultaneous publication in the [New England Journal of Medicine](#)
- Presentation expands on previous results demonstrating superiority of relugolix to leuprolide acetate, with additional data on testosterone suppression and recovery, prostate-specific antigen (PSA) response, and cardiovascular safety
- Relugolix treatment showed a 54% lower risk of major adverse cardiovascular events compared to leuprolide acetate
- Conference call and webcast to be held Monday, June 1 at 8:30 a.m. EDT / 5:30 a.m. PDT

BASEL, Switzerland, May 29, 2020 (GLOBE NEWSWIRE) -- Myovant Sciences (NYSE: MYOV), a healthcare company focused on redefining care for women and for men, today announced additional results from its Phase 3 HERO study of once-daily, oral relugolix (120 mg) in men with advanced prostate cancer in an oral presentation at the American Society of Clinical Oncology (ASCO)'s [ASCO20 Virtual Scientific Program](#) and simultaneous publication in the [New England Journal of Medicine \(NEJM\)](#). The data expand on earlier findings from the HERO study, demonstrating the superiority of relugolix to leuprolide acetate across multiple endpoints, and further show that treatment with relugolix was associated with a lower risk of major adverse cardiovascular events compared to leuprolide acetate.

Relugolix met the primary endpoint and demonstrated superiority to leuprolide acetate across six key secondary endpoints, all with p-values < 0.0001. In the primary endpoint responder analysis, 96.7% of men receiving once-daily, oral relugolix achieved sustained testosterone suppression to castrate levels (< 50 ng/dL) through 48 weeks, compared to 88.8% of men treated with leuprolide acetate.

Detailed secondary endpoint data, presented and published today, showed notable differences in the rapid and profound suppression of testosterone, PSA response, and testosterone recovery after discontinuation of treatment. In the relugolix group, testosterone suppression to less than 50 ng/dL was achieved in 56.0% of men by Day 4 and 98.7% by Day 15, compared to 0.0% by Day 4 and 12.1% by Day 15 for men in the leuprolide acetate group. Additionally, in the relugolix group, profound testosterone suppression to less than 20 ng/dL was achieved in 78.4% of men at Day 15, compared to 1.0% at Day 15 for men in the leuprolide acetate group. A higher proportion of men in the relugolix group achieved a 50% reduction in PSA by Day 15 and confirmed at Day 29 compared to those in the leuprolide acetate group (79.4% vs. 19.8%, respectively). Within 90 days of treatment discontinuation, 54% of men in the relugolix group achieved normal testosterone levels (\geq 280 ng/dL) with a mean testosterone level of 288.4 ng/dL, compared to 3% of men in the leuprolide acetate group with a mean testosterone level of 58.6 ng/dL.

"A faster effect in lowering testosterone for prostate cancer patients can be clinically significant – likewise, a more rapid testosterone recovery after stopping treatment, could potentially improve a patient's quality of life," said Neal Shore, M.D., medical director of the Carolina Urologic Research Center, HERO program steering committee member, presenter of the ASCO data, and lead author on the *NEJM* paper. "Both of these findings could make a meaningful difference in the treatment journey for men with advanced prostate cancer."

Men in the relugolix group had a 54% lower risk of major adverse cardiovascular events compared to men in the leuprolide acetate group (2.9% vs. 6.2%, respectively). Additionally, in men with a history of these events, the relugolix group had 80% fewer major adverse cardiovascular events reported compared to the leuprolide acetate group (3.6% vs. 17.8%, respectively). More than 90% of men in the HERO study had at least one cardiovascular risk factor, including lifestyle risk factors such as tobacco use and obesity, comorbidities such as diabetes and hypertension, and prior history of a major adverse cardiovascular event.

"Cardiovascular disease is the leading cause of death in men with prostate cancer," said Dr. Shore. "An oral therapeutic option with strong efficacy that also reduces cardiovascular risk compared to that of conventional GnRH agonist therapy would be a critical achievement for men with advanced prostate cancer."

As previously reported, the incidence of adverse events in the HERO study was comparable for relugolix and leuprolide acetate groups (92.9% vs. 93.5%, respectively). The most frequently reported adverse events, reported in at least 10% of men in the relugolix group, were hot flashes, fatigue, constipation, mild to moderate diarrhea, and arthralgia.

"Relugolix has the potential to be an important new treatment option for men with prostate cancer and would represent significant progress in our company's commitment to redefine care for men," said Lynn Seely, M.D., chief executive officer of Myovant Sciences. "We are grateful to have the opportunity to share these additional data through presentation and publication in such highly-respected venues as the American Society of Clinical Oncology and the *New England Journal of Medicine*. We have already submitted our New Drug Application to the FDA with the goal of bringing this oral, once-daily potential treatment to men with prostate cancer as expeditiously as possible, especially given the current environment with the COVID-19 pandemic and the difficulties and risks men face traveling to hospitals and clinics to receive injections."

Myovant submitted a New Drug Application (NDA) to the FDA for relugolix in April 2020, which, if approved, would be the first and only oral gonadotropin-releasing hormone (GnRH) receptor antagonist treatment for men with advanced prostate cancer.

The ASCO presentation (#5602), "[HERO phase III trial: Results comparing relugolix, an oral GnRH receptor antagonist, versus leuprolide acetate for advanced prostate cancer](#)," is available for on-demand viewing.

Conference Call

Myovant will hold a conference call to discuss these data on Monday, June 1, 2020 at 8:30 a.m. Eastern Time / 5:30 a.m. Pacific Time. Myovant management will be joined by Neal Shore, M.D. To participate in the live conference call, please dial 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 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 men with androgen-sensitive advanced prostate cancer who required at least one year of continuous androgen deprivation therapy. Men 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.

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. 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 receptor agonists, such as leuprolide acetate, or slow-release injections are 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 rise 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 200,000 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 production, a hormone known to stimulate the growth of prostate cancer, and ovarian estradiol production, 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. Sumitomo 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](https://twitter.com/Myovant) on Twitter and [LinkedIn](https://www.linkedin.com/company/myovant).

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 redefining care for women and for men; the characterizations of data from the HERO study; the timing and likelihood of any approvals by the FDA; the timing of data readout regarding the analysis of the secondary endpoint of castration resistance-free survival expected in the third quarter of 2020 and the commercial potential for once-daily, oral relugolix 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. 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' Annual 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, 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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