



## Myovant Sciences Submits New Drug Application (NDA) to the FDA for Once-Daily, Oral Relugolix for the Treatment of Men with Advanced Prostate Cancer

April 21, 2020

- *Positive Phase 3 results with 96.7% response rate in men with advanced prostate cancer form the basis of the submission*
- *Myovant expects to submit a second NDA for relugolix combination tablet for women with uterine fibroids in May 2020*

BASEL, Switzerland, April 21, 2020 (GLOBE NEWSWIRE) -- Myovant Sciences (NYSE: MYOV), a healthcare company focused on redefining care for women's health and prostate cancer, today announced that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for once-daily, oral relugolix (120 mg) for the treatment of men with advanced prostate cancer. Myovant also announced that it expects to submit its 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 in May 2020.

**TWEET THIS:** "The submission of our NDA for prostate cancer is a major step towards providing a one pill, once a day potential new treatment option for men with advanced prostate cancer," said Lynn Seely, M.D., chief executive officer of Myovant Sciences. "Based on the robust efficacy and safety data from the Phase 3 HERO study, we believe relugolix, if approved, could provide men an important oral alternative to leuprolide injections, the current standard of care."

The NDA submission is supported by positive results from the Phase 3 HERO study, a randomized pivotal study comparing relugolix versus leuprolide acetate. Relugolix met the primary efficacy endpoint with 96.7% of men achieving sustained testosterone suppression to castrate levels (< 50 ng/dL) through 48 weeks. Six key secondary endpoints demonstrated superiority to leuprolide acetate, including sustained testosterone suppression to castrate levels through 48 weeks, rapid suppression of testosterone at Day 4 and at Day 15, profound suppression of testosterone (< 20 ng/dL) 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). The overall incidence of adverse events in the relugolix and leuprolide acetate groups was comparable (92.9% vs. 93.5%, respectively). 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.

"We made the decision to prioritize this NDA submission and potentially accelerate the availability of an oral treatment option for men with advanced prostate cancer," said Juan Camilo Arjona, M.D., chief medical officer of Myovant Sciences. "This is of particular importance in the current environment and for the foreseeable future due to COVID-19 and the need for men with advanced prostate cancer to go to a clinic to receive injections in person."

### 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.

Approximately 1,100 men are planned to be enrolled in this study, including approximately 430 men 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 90 Chinese men (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. 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.

### 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'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, 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](http://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 redefine care for women's health and prostate cancer; the potential of relugolix, if approved, to change the standard of care from injections to a once- daily pill for men with advanced prostate cancer; any expectations regarding the approval of relugolix in any indication and the timing of any approval; any anticipated market size; and the expected timing of filing the NDA for relugolix combination tablet for women with uterine fibroids. 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 February 10, 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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