



## Myovant Sciences Submits Marketing Authorization Application to the European Medicines Agency for Relugolix Combination Tablet for the Treatment of Women with Uterine Fibroids

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- *If approved, relugolix combination tablet would offer a one pill, once-a-day treatment option for women with uterine fibroids*
- *New Drug Application to the U.S. Food and Drug Administration planned for submission in April 2020*

BASEL, Switzerland, March 09, 2020 (GLOBE NEWSWIRE) -- Myovant Sciences (NYSE: MYOV), a healthcare company focused on developing innovative treatments for women's health and prostate cancer, today announced the submission of a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for relugolix combination tablet (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg) for the treatment of women with moderate to severe symptoms associated with uterine fibroids. The two most common symptoms associated with uterine fibroids are heavy menstrual bleeding and pain.

"With this submission, we have achieved a significant milestone and are one step closer to providing a one pill, once-a-day potential new treatment option to women with uterine fibroids," said Juan Camilo Arjona Ferreira, M.D., chief medical officer of Myovant. "We look forward to further communication with the EMA and to additional regulatory submissions in the coming months, including an NDA for relugolix combination tablet for women with uterine fibroids planned for April."

The MAA is supported by efficacy and safety data from the Phase 3 LIBERTY program which consisted of two multinational, replicate pivotal clinical studies, LIBERTY 1 and 2, as well as data from a one-year open-label extension study of relugolix combination therapy. The EMA is expected to perform a technical validation of the MAA in March 2020 to ensure all essential regulatory elements required for scientific assessment are included in the application prior to the start of the procedure.

### **About the Phase 3 LIBERTY Program in Uterine Fibroids**

Myovant's Phase 3 clinical program for uterine fibroids consisted of two multinational, replicate pivotal clinical studies (LIBERTY 1 and LIBERTY 2) of relugolix combination therapy (relugolix 40 mg plus estradiol 1.0 mg and norethindrone acetate 0.5 mg) in women with heavy menstrual bleeding associated with uterine fibroids for 24 weeks. Eligible women who completed the LIBERTY 1 or LIBERTY 2 studies were offered the opportunity to enroll in an active treatment extension study in which all women received relugolix combination therapy for an additional 28-week period for a total treatment period of 52 weeks, designed to evaluate the safety and efficacy of longer-term treatment. Upon completion of this 52-week total treatment period, eligible women could elect to participate in a second 52-week randomized withdrawal study designed to provide two-year safety and efficacy data on relugolix combination therapy and to evaluate the need for maintenance therapy. Across studies, a response was defined as a menstrual blood loss volume of less than 80 mL and a 50% or greater reduction from baseline in menstrual blood loss volume during the last 35 days of treatment measured using the alkaline hematin method.

LIBERTY 1 and 2 met the primary endpoint ( $p < 0.0001$ ) with 73.4% and 71.2% of women receiving relugolix combination therapy achieving the responder criteria compared with 18.9% and 14.7% of women receiving placebo at 24 weeks, respectively. On average, women receiving relugolix combination therapy in both studies experienced an 84.3% reduction in menstrual blood loss from baseline ( $p < 0.0001$ ). Bone mineral density was comparable between the relugolix combination therapy and placebo groups in LIBERTY 1 and 2. The distribution of the change in bone mineral density, including outliers, was similar for the relugolix combination therapy and placebo groups at 24 weeks, as assessed by dual energy x-ray absorptiometry (DXA). The overall incidence of adverse events in the relugolix combination and placebo groups was comparable in both studies.

The open-label extension study also met the primary endpoint with relugolix combination therapy demonstrating an 87.7% response rate at one year, showing the durability of the response observed in LIBERTY 1 and 2. In addition, women experienced, on average, an 89.9% reduction in menstrual blood loss from baseline. Changes in bone mineral density through one year, as assessed by DXA every three months, were consistent with LIBERTY 1 and 2. Adverse events reported in more than 10% of women treated with relugolix combination therapy for one year and more than those reported in the placebo group after 6 months included only hot flush.

### **About Uterine Fibroids**

Uterine fibroids are noncancerous tumors that develop in or on the muscular walls of the uterus and are among the most common reproductive tract tumors in women. In addition to an individual's genetic predisposition, estrogens are well known to play an important role in the regulation of fibroid growth.

Although uterine fibroids are benign tumors, they can cause debilitating symptoms such as heavy menstrual bleeding (frequently resulting in anemia and fatigue), pain (including painful periods, abdominal pain, painful intercourse, backache), increased abdominal girth and bloating, urinary frequency or retention, constipation, pregnancy loss, and, in some cases, infertility. These symptoms can also lead to loss of productivity at work, limitations in normal activities of daily living, and social embarrassment.

An estimated five million women in the U.S. suffer from symptoms of uterine fibroids, and an estimated three million women are inadequately treated by current medical therapy and require further treatment.

### **About Relugolix**

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

## 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. Sumitovant Biopharma, Ltd., a wholly owned subsidiary of Sumitomo Dainippon Pharma, 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 become the leading healthcare company focused on innovative treatments for women's health and prostate cancer; the Company's plans and timing to file an NDA seeking approval of relugolix combination tablet for the treatment of heavy menstrual bleeding associated with uterine fibroids in the U.S.; the likelihood and timing of validation of the MAA and any approvals of the MAA or NDA in Europe and the U.S.; and the Company's expectations with respect to labeling and the duration of use of any approved product in Europe and the U.S.. 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.

## Investor Contact:

Frank Karbe  
President, Chief Financial Officer  
Myovant Sciences, Inc.  
[investors@myovant.com](mailto:investors@myovant.com)

## Media Contact:

Albert Liao  
Director, Corporate Communications  
Myovant Sciences, Inc.  
[media@myovant.com](mailto:media@myovant.com)



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