Myovant Sciences Receives Positive CHMP Opinion for RYEQO® (Relugolix Combination Tablet) for the Treatment of Women With Uterine Fibroids

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- *CHMP opinion recommending approval based on data from the Phase 3 LIBERTY program in women with uterine fibroids*
- *Gedeon Richter will commercialize RYEQO for uterine fibroids, if approved, in Europe*
- *Relugolix combination tablet for uterine fibroids is also under U.S. FDA review with a target action date of June 1, 2021*

BASEL, Switzerland, May 21, 2021 (GLOBE NEWSWIRE) -- Myovant Sciences (NYSE: MYOV) today announced the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency has adopted a positive opinion recommending the approval of RYEQO® (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg) for the treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. The European Commission will review the CHMP recommendation, and a final decision on the Marketing Authorization Application is expected to be available in approximately two months. The decision will be applicable to all 27 European Union member states plus Iceland, Norway, and Liechtenstein.

“Over 25% of women of reproductive age develop uterine fibroids. This chronic disease can cause debilitating symptoms that have a significant impact on quality of life and require long-term treatment, yet there are currently limited treatment options in Europe and many women are faced with the decision to undergo surgery to alleviate symptoms,” said Roberta Venturella, M.D., Ph.D., Associate Professor, Magna Græcia University of Catanzaro and investigator in the LIBERTY program. “The CHMP’s positive opinion further validates RYEQO’s potential to effectively address heavy menstrual bleeding and pain associated with uterine fibroids and serve as an important new treatment option for patients and physicians.”

“This positive CHMP opinion represents an important step in advancing our mission to redefine care for women living with uterine fibroids,” said David Marek, Chief Executive Officer of Myovant Sciences, Inc. “We look forward to Gedeon Richter’s launch of RYEQO, if approved, as a new treatment option for uterine fibroids.”

The positive opinion recommending approval is based on safety and efficacy data from the Phase 3 LIBERTY program, which consisted of two replicate, 24-week, multinational clinical studies (LIBERTY 1 and LIBERTY 2), a one-year extension study, and a randomized withdrawal study assessing the safety and efficacy for up to two years of relugolix combination therapy (relugolix 40 mg plus estradiol 1.0 mg and norethindrone acetate 0.5 mg). Results from the LIBERTY 1 and LIBERTY 2 studies were published in the *New England Journal of Medicine* in February 2021.

In March 2020, Myovant and Gedeon Richter entered into an exclusive license agreement for Gedeon Richter to commercialize relugolix combination tablet for uterine fibroids and endometriosis in Europe, the Commonwealth of Independent States including Russia, Latin America, Australia, and New Zealand. Under the terms of the agreement, Myovant continues to lead the global development of relugolix combination tablet while Gedeon Richter is responsible for local clinical development, manufacturing, and all commercialization for its territories.

Relugolix combination tablet for the treatment of uterine fibroids is also under review by the U.S. Food and Drug Administration, with a target action date of June 1, 2021.

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.

About RYEQO®
RYEQO (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg) is being evaluated for the treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. RYEQO contains relugolix, which reduces the amount of estrogen (and other hormones) produced by ovaries, estradiol (an estrogen), which may reduce the risk of bone loss, and norethindrone acetate (a progestin), which is necessary when women with a uterus (womb) take estrogen.

RYEQO is not approved for any indication in any geography.

About Myovant Sciences
Myovant Sciences aspires to redefine care for women and for men through purpose-driven science, empowering medicines, and transformative advocacy. ORGOVYX™ (relugolix) was approved by the U.S. Food and Drug Administration in 2020 as the first and only oral gonadotropin-releasing hormone (GnRH) receptor antagonist for the treatment of adult patients with advanced prostate cancer, and relugolix is also under regulatory review in Europe for men with advanced prostate cancer. Our lead product candidate, relugolix combination tablet (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg), is under regulatory review in the U.S. and Europe for women with uterine fibroids, has completed Phase 3 registration-enabling studies for women with endometriosis, and is being assessed for contraceptive efficacy in healthy women ages 18-35 years who are at risk for pregnancy. 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. In this press release, forward-looking statements include, but are not limited to, all statements reflecting Myovant Sciences' expectations, including: statements regarding Myovant's aspiration to redefine care for women and for men; the expectations of commercialization and launch of RYEQO ® for uterine fibroids in Europe by Gedeon Richter, if approved; the expectations of the European Commission's review of the CHMP recommendation and the timeline of its final decision on the Marketing Authorization Application and the application of such decision in the European Union; and Myovant's expectations regarding the potential benefits of RYEQO® and it serving as an important new treatment option for uterine fibroids, if approved.

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, including unforeseen circumstances or other disruptions to normal business operations arising from or related to the COVID-19 pandemic. 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 11, 2021, 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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