Myovant Sciences Announces European Commission Approval for RYEQO® for the Treatment of Women With Uterine Fibroids

July 20, 2021

- *RYEQO is the first and only once-daily long-term treatment for uterine fibroids in Europe*
- *Indication has no limitation for duration of use, as supported by safety and efficacy data from the Phase 3 LIBERTY program*
- *Gedeon Richter to commercialize RYEQO, starting in the second half of 2021; Myovant to receive a regulatory milestone payment and is eligible to receive tiered royalties on net sales as well as sales milestone payments*
- *Marketing authorization application for RYEQO for endometriosis-associated pain on track for submission this calendar year*

BASEL, Switzerland, July 20, 2021 (GLOBE NEWSWIRE) -- Myovant Sciences (NYSE: MYOV), a healthcare company focused on redefining care for women and for men, today announced the European Commission (EC) has approved the marketing authorization application for 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, with no limitation for duration of use. The EC decision is valid in all 27 member states of the European Union, as well as Iceland, Norway, and Liechtenstein.

“Data from the Phase 3 LIBERTY program, which supported the approval of RYEQO, showed that RYEQO improved symptoms most relevant to women living with uterine fibroids, namely heavy menstrual bleeding and pain, while maintaining a well-tolerated safety profile,” said Roberta Venturella, M.D., Ph.D., Associate Professor, Magna Græcia University of Catanzaro and investigator in the LIBERTY program. “With this approval, women and doctors finally have a long-term treatment option, which is important for the management of this condition.”

“Today’s approval of RYEQO, the first and only once-daily long-term treatment for women with uterine fibroids in Europe, marks a major milestone in expanding non-invasive treatment options for this common and potentially debilitating disease,” said David Marek, Chief Executive Officer of Myovant Sciences, Inc. “Through our partnership with Gedeon Richter, we look forward to supporting even more women suffering from uterine fibroids.”

The 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 supportive bone mineral density data from a randomized withdrawal study. 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 agreement, Myovant received an upfront payment of $40 million and is eligible to receive up to $40 million in regulatory milestones and $107.5 million in sales milestones for a total of $147.5 million, and tiered royalties on net sales following regulatory approval. Gedeon Richter will be responsible for local clinical development, manufacturing, and all commercialization for its territories. Myovant and Gedeon Richter will also continue to collaborate on the marketing authorization application for endometriosis, which is expected to be submitted in the second half of calendar year 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 approved 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.

About Myovant Sciences
Myovant Sciences aspires to redefine care for women and for men through purpose-driven science, empowering medicines, and transformative advocacy. Founded in 2016, we have two FDA-approved products. 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. Relugolix combination tablet (relugolix 40 mg, estradiol 1 mg, and norethindrone acetate 0.5 mg) was approved in 2021 in the EU as RYEQO® for the treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age, and in the U.S. as MYFEMBREE® as the first once-daily treatment for the management of heavy menstrual bleeding associated with uterine fibroids in premenopausal women. The therapy has also 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 of RYEQO for uterine fibroids in Europe by Gedeon Richter; the submission of the marketing authorization application for RYEQO for endometriosis-associated pain; Myovant's expectations regarding the potential benefits of RYEQO and it serving as a long-term treatment option for managing heavy menstrual bleeding and pain associated with uterine fibroids; and Myovant's expectations regarding Myovant and Gedeon Richter's responsibilities and continued efforts to collaborate on the marketing authorization application for endometriosis.

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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