



Myovant Sciences and Gedeon Richter Enter into Exclusive License Agreement to Commercialize Relugolix Combination Tablet for Uterine Fibroids and Endometriosis in Certain Territories Outside the U.S.

March 31, 2020

- *Gedeon Richter to commercialize relugolix combination tablet for uterine fibroids and endometriosis in Europe, Russia - CIS, Latin America, Australia, and New Zealand*
- *Myovant to receive an upfront payment of \$40 million, up to \$147.5 million in regulatory and sales milestones, and tiered royalties on net sales*

BASEL, Switzerland and BUDAPEST, Hungary, March 31, 2020 (GLOBE NEWSWIRE) -- Myovant Sciences (NYSE: MYOV), a healthcare company focused on developing innovative treatments for women's health and prostate cancer, and Gedeon Richter Plc., a major pharmaceutical company in Central Eastern Europe focused on women's health, today announced that they have entered into an exclusive license agreement for Gedeon Richter to commercialize relugolix combination tablet (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg) for uterine fibroids and endometriosis in Europe, the Commonwealth of Independent States including Russia, Latin America, Australia, and New Zealand. Under the agreement, Myovant will receive an upfront payment of \$40 million and is eligible to receive up to \$40 million in regulatory milestones and \$107.5 million in sales-related milestones, and tiered royalties on net sales following regulatory approval. Myovant retains all rights to relugolix combination tablet in the U.S., as well as rights to relugolix in other therapeutic areas outside of women's health.

[TWEET THIS](#): "We are delighted to be joining forces with Gedeon Richter, a company with a leading market position in women's health in more than 38 countries, to accelerate the potential global launch of one pill, once a day relugolix combination tablet for women with uterine fibroids and endometriosis," said Frank Karbe, president and chief financial officer of Myovant. "In addition, this agreement further strengthens Myovant's financial position and focus as we continue to advance the development of relugolix and prepare for multiple potential upcoming launches in the U.S."

Under the terms of the agreement, Myovant will continue to lead the global development of relugolix combination tablet. Gedeon Richter will be responsible for local clinical development, manufacturing, and all commercialization for its territories. Myovant has also granted Gedeon Richter an option to collaborate on relugolix combination tablet for future indications in women's health other than fertility.

"Adding innovative products to our core women's healthcare portfolio has been the focus of our strategy," said Erik Bogsch, chairman of Gedeon Richter. "Through this license agreement with Myovant, we have a unique opportunity to make a meaningful difference in the lives of millions of women suffering from uterine fibroids and endometriosis."

Myovant submitted a Marketing Authorization Application to the European Medicines Agency (EMA) for relugolix combination tablet for the treatment of women with moderate to severe symptoms associated with uterine fibroids in March 2020. The application has completed validation and is now under evaluation by the EMA. Myovant expects top-line data from the Phase 3 SPIRIT 2 and SPIRIT 1 studies in women with pain associated with endometriosis in April and the second quarter of 2020, respectively.

About Uterine Fibroids

Affecting over 25% of women of reproductive age, 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 Endometriosis

Affecting approximately 10% of women of reproductive age, endometriosis is a disease in which tissue similar to the uterine lining is found outside the uterine cavity, commonly in the lower abdomen or pelvis, on ovaries, the bladder, and the colon. This endometrial-like tissue outside the uterus results in chronic inflammation and can cause scarring and adhesions.

The symptoms associated with endometriosis include painful periods and chronic pelvic pain, painful ovulation, pain during or after sexual intercourse, heavy bleeding, fatigue, and infertility. Endometriosis can also impact general physical, mental, and social well-being.

For pain associated with endometriosis, initial treatment options include oral contraceptives and over-the-counter pain medications. In more severe cases, GnRH agonists such as leuprolide acetate are used for short-term 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, 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. Follow [@Myovant](https://twitter.com/Myovant) on Twitter and [LinkedIn](https://www.linkedin.com/company/myovant).

About Gedeon Richter

Gedeon Richter Plc. (www.richter.hu), headquartered in Budapest/Hungary, is a major pharmaceutical company in Central Eastern Europe, with an expanding direct presence in Western Europe, in China and in Latin America. Having reached a market capitalization of EUR 3.6 billion (USD 4.1 billion) by the end of 2019, Richter's consolidated sales were approximately EUR 1.6 billion (USD 1.7 billion) during the same year. The product portfolio of Richter covers many important therapeutic areas, including Women's Healthcare, Central Nervous System and Cardiovascular areas. Having the largest R&D unit in Central Eastern Europe, Richter's original research activity focuses on CNS disorders. With its widely acknowledged steroid chemistry expertise, Richter is a significant player in the Women's Healthcare field worldwide. Richter is also active in biosimilar product development.

Myovant Sciences' 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 payment to Myovant of an upfront payment; Myovant's potential receipt of regulatory and sales milestones, as well as royalties on sales of relugolix combination tablet; the clinical, therapeutic and commercial potential of relugolix; the belief that agreement will accelerate the potential global launch of relugolix combination tablet; the retention of certain rights to relugolix by Myovant; the likelihood and timing of validation of the MAA and any filings and approvals of the MAA or NDA in Europe and the U.S.; and the expected timing of the announcement of top-line data from the SPIRIT clinical studies. 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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