Gedeon Richter and Myovant Sciences Receive Positive CHMP Opinion for RYEQO® (Relugolix Combination Tablet) for the Treatment of Uterine Fibroids

Budapest, Hungary – 21 May 2021 – Gedeon Richter Plc. ("Richter") announces that the Committee for Medicinal Products for Human Use ("CHMP") of the European Medicines Agency ("EMA") has adopted a positive opinion recommending approval of RYEQO® (relugolix 40 mg, estradiol 1.0 mg, and norethisterone acetate 0.5 mg) for the treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. The European Commission ("EC") 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 member states of the European Economic Area.

"As one of the leading companies in Women's Healthcare, we are pleased with the receipt of the positive opinion from the CHMP," – said Erik Bogsch, Chairman of Gedeon Richter Plc. "This opinion underscores the potential of RYEQO® which sets new levels to the standards of care for women with uterine fibroids."

"Over 25 percent 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., PhD, 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."

About RYEQO®

RYEQO® (relugolix 40 mg, estradiol 1.0 mg, and norethisterone 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 norethisterone acetate (a progestin) which is necessary when women with a uterus (womb) take estrogen.

About uterine fibroids
Uterine fibroids are noncancerous tumours that develop in or on the muscular walls of the uterus and are among the most common reproductive tract tumours 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 tumours, they can cause debilitating symptoms such as heavy menstrual bleeding (frequently resulting in anaemia 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 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 3.8 billion (USD 4.5 billion) by the end of 2020, Richter's consolidated sales were approximately EUR 1.6 billion (USD 1.8 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.

About Myovant
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 norethisterone 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.

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For details of the decision please visit:
https://www.ema.europa.eu/en/medicines/human/summaries-opinion/ryeqo