



GEDEON RICHTER

Richter Announces Submission to European Medicines Agency for Type II Variation Application for RYEQO® for the Treatment of Endometriosis

Budapest, Hungary – 25 October 2022 – Gedeon Richter Plc. (“Richter”) today announced that it has submitted a Type II Variation application for RYEQO® (relugolix 40 mg, estradiol 1.0 mg, and norethindrone acetate 0.5 mg) to the European Medicines Agency (EMA) for the treatment of moderate to severe pain associated with endometriosis in adult women of reproductive age with a history of previous medical or surgical treatment for their endometriosis. RYEQO® is already approved by the EMA for the treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age since July 2021.

“Expanding the therapeutic reach of our core innovative products takes us further on the way of consolidating our leading role in addressing women’s health issues,” – said Gábor Orbán, CEO of Gedeon Richter. “If approved, this new therapy will offer a treatment of choice to many women suffering from endometriosis.”

This application is supported by two 24-week multi-national clinical studies (SPIRIT 1 and SPIRIT 2) in more than 1,200 women with moderate to severe pain associated with endometriosis, as well as the 80-week open-label extension study to assess longer-term use of RYEQO®. Together, these data represent up to two years of efficacy and safety information with RYEQO®.

About Endometriosis

Approximately 10% of women of reproductive age have endometriosis. Many women with endometriosis-associated pain are not able to manage their pain symptoms with current treatment options, underscoring the high unmet need for this disease.¹

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.

Initial treatment options for pain associated with endometriosis include oral contraceptives and progestins as well as non-prescription and prescription pain medications for acute pain. In more severe cases, GnRH agonists such as leuprorelin (leuprolide acetate) are used for short-term treatment.

¹ Becker CM, et al. *Fertil Steril*. 2017 Jul;108(1):125-136.

About RYEQO®

RYEQO® (relugolix 40 mg, estradiol 1.0 mg, and norethisterone 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 norethisterone acetate (a progestin) which is necessary when women with a uterus (womb) take estrogen. For full prescribing information and patient information, visit this link: https://www.ema.europa.eu/en/documents/product-information/ryeqo-epar-product-information_en.pdf

About Gedeon Richter

Gedeon Richter Plc. (www.gedeonrichter.com), headquartered in Budapest/Hungary, is a major pharmaceutical company in Central Eastern Europe, with an expanding direct presence in Western Europe, in China in Latin America and in Australia. Having reached a market capitalization of EUR 4.4 billion (USD 5.0 billion) by the end of 2021, Richter's consolidated sales were approximately EUR 1.8 billion (USD 2.1 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.

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