

European Commission Approves the Commercialisation of RYEQO® for the Symptomatic Treatment of Endometriosis

BUDAPEST, Hungary and BASEL, Switzerland and CAMBRIDGE, Mass , Nov. 2, 2023 [/PRNewswire/](#) -- Gedeon Richter Plc. ('Richter') together with Sumitomo Pharma America, Inc. ('SMPA') and Sumitomo Pharma Switzerland, GmbH ('SMPS') today announce that the European Commission ('EC') has granted approval of a Type II Variation application for RYEQO® (relugolix 40 mg, estradiol 1.0 mg, and norethisterone acetate 0.5 mg) for the symptomatic treatment of endometriosis in women with a history of previous medical or surgical treatment for their endometriosis. This decision followed a positive opinion from the Committee for Medicinal Products for Human Use ('CHMP') of the European Medicines Agency ('EMA') on 15 September 2023 and is applicable for all Member States in the European Union.

RYEQO® was initially approved by the EMA in July 2021 for the treatment of moderate-to-severe symptoms of uterine fibroids in adult women of reproductive age.

"We are delighted that this approval has opened the way to offer a viable symptomatic treatment option for many women living with endometriosis" - said Dr. Peter Turek, Global Head of Women's Health at Gedeon Richter. "As we aim to become a leading pharmaceutical company in the field of Women's Healthcare, a sustained broadening of the therapeutic reach of our core innovative products is of utmost importance for us."

"Approximately 14 million women in the European Union are living with endometriosis, a chronic condition whose painful symptoms can impact a woman's ability to engage in certain daily activities. We are pleased that as a result of this decision women in the EU living with endometriosis now have another safe and effective symptomatic treatment option," said Adele Gulfo, Chief Executive Officer, Biopharma Commercial Unit at SMPA.

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.

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 the 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.

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 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, China, Latin America, and Australia. Having reached a market capitalization of EUR 3.9 billion (USD 4.1 billion) by the end of 2022, Richter's consolidated sales were approximately EUR 2.0 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.

About Sumitomo Pharma

Sumitomo Pharma Co., Ltd. is a global pharmaceutical company based in Japan with key operations in the U.S. (Sumitomo Pharma America, Inc.), Canada (Sumitomo Pharma Canada, Inc.) and Europe (Sumitomo Pharma Switzerland GmbH) focused on addressing patient needs in psychiatry & neurology, oncology, urology, women's health, rare disease, and cell & gene therapies. With several marketed products in the U.S., Canada, and Europe, a diverse pipeline of early- to late-stage assets, and in-house advanced technology capabilities, we aim to accelerate discovery, research, and development to bring novel therapies to patients sooner. For more information, please visit <https://www.us.sumitomo-pharma.com> and [LinkedIn](#) to follow us.

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