GEDEON RICHTER

Gedeon Richter and Sumitomo Pharma Receive Positive CHMP Opinion for RYEQO® for Treatment of Endometriosis

Budapest, Hungary – Basel, Switzerland / Cambridge, Mass., USA – 15 September 2023 – Gedeon Richter Plc. ('Richter') together with Sumitomo Pharma America, Inc. ('SMPA') and Sumitomo Pharma Switzerland ('SMPS') today announce that the Committee for Medicinal Products for Human Use ("CHMP") of the European Medicines Agency ("EMA") has adopted a positive opinion recommending the 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. The European Commission ("EC") will review the CHMP recommendation and a final decision on the Marketing Authorization Application is expected to be available in the coming months. The decision will be applicable to all member states of the European Economic Area.

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.

"Broadening the therapeutic reach of our core innovative products demonstrates our tireless pursuit of becoming a leading pharmaceutical company to address women's health issues," said Dr Peter Turek, Global Head of Women's Health at Gedeon Richter. "Once fully approved by the EC, this new therapy could offer a viable treatment option for many women living with endometriosis."

"Endometriosis can impact general physical, mental, and social well-being. Women often go many years before receiving their endometriosis diagnosis. Some will undergo multiple surgeries in an effort to manage their pain, but many have their symptoms continue or return. This recommendation in the EU serves as an important next step towards making this medicine available for more women living with this condition globally," said Adele Gulfo, Chief Executive Officer, Biopharma Commercial Unit at Sumitomo Pharma America.

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.

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

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