

European Commission approves the commercialisation of RYEQO®

Budapest, Hungary – 20 July 2021 – Gedeon Richter Plc. ('Richter') announces that the European Commission ('EC') has granted approval for the marketing authorisation of RYEQO® a novel oral treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. This decision followed a positive opinion from the Committee for Medicinal Products for Human Use ('CHMP') of the European Medicines Agency ('EMA') on 21 May 2021 and is applicable for all Member States in the European Union.

'We are delighted to offer a novel, non-invasive treatment option for women suffering of debilitating symptoms of uterine fibroids,' – said Erik Bogsch, Chairman of Gedeon Richter Plc. "Richter strives to exploit additional therapeutic advantages promised by RYEQO® and remains committed to further expand its women's healthcare portfolio in order to improve overall quality of life for female population."

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.

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 4.7 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.

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