

European Commission approves the commercialization of the novel estetrol and drospirenone containing oral contraceptive

Budapest, Hungary – 20 May 2021 – Gedeon Richter Plc. (“Richter”) announces that the European Commission (“EC”) has granted approval for the marketing authorization of the novel combined oral contraceptive containing 15 mg estetrol (“E4”) and 3 mg drospirenone (“DRSP”). This decision followed a positive opinion from the Committee for Medicinal Products for Human Use (“CHMP”) of the European Medicines Agency (“EMA”) on 26 March 2021 and is applicable for all Member States in the European Union. The product will be marketed in Europe by Richter under the brand name Drovelis®.

“We are delighted with this significant step forward for Drovelis®, as it means more choice for women in need of highly effective and convenient medical therapy for family planning”, – said Erik Bogsch, Chairman of Gedeon Richter Plc. “We remain committed to the development of female healthcare products, which improve quality of life for the female population in all age groups.”

About Drovelis®

Drovelis® is Richter’s brand name for a novel oral contraceptive product composed of 15 mg estetrol (E4), its unique native estrogen acting selectively in tissues and 3 mg drospirenone. The E4 Freedom studies were open-label single arm trials and they were aimed to assess the safety and efficacy of the product in over 1,550 participants in Europe/Russia and approximately 2,150 participants in the US/Canada, over a period of 13 cycles.

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.

For further information:

Investors:

Katalin Ördög: +36 1 431 5680

Media:

Zsuzsa Beke: +36 1 431 4888