EMA started the evaluation of Richter's marketing authorisation application for a novel combined oral contraceptive

Budapest, Hungary – 27 February 2020 – Gedeon Richter Plc. ("Richter") today announced that the European Medicines Agency (EMA) has accepted Richter's regulatory submission for a combined oral contraceptive, containing estetrol (E4) and drospirenone.

The product is considered a novel oral contraceptive with natural, native estrogen acting selectively in tissues. According to the relevant license agreement Richter is going to commercialize the product in Europe, Russia and other CIS countries.

About the compound

The novel oral contraceptive developed by Mithra is a product candidate composed of 15 mg estetrol (E4), a unique native estrogen and 3 mg drospirenone.

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 3.6 billion (USD 4.1 billion) by the end of 2019, Richter's consolidated sales were approximately EUR 1.6 billion (USD 1.7 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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