



GEDEON RICHTER

Richter and Mithra received positive CHMP opinion for a novel estetrol and drospirenone containing oral contraceptive

Budapest, Hungary – Liège, Belgium – 26 March 2021 – Gedeon Richter Plc. (“Richter”) and Mithra Pharmaceuticals (“Mithra”) today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion for a novel combined oral contraceptive containing 15 mg estetrol (E4) and 3 mg drospirenone (DRSP). Subject to approval by the European Commission, the marketing authorization valid for all European Union Member States is expected to be granted by the end of the second quarter 2021. The product will be marketed in Europe by Richter under the brand name Drovelis®.

“Richter is dedicated to bring to market innovative, treatment like Drovelis® that will widen the selection of products within the female contraception solutions,” – said Erik Bogsch, Chairman of Gedeon Richter Plc. “We are encouraged by this positive opinion from the CHMP and we shall do our best to make Drovelis® available to women in Europe.”

“After first approval in Canada early this month, we are very pleased with this positive opinion given by the European Medicines Agency,” – said Leon Van Rompay, CEO of Mithra. “Being able to offer the result of so many years of work to women is a huge achievement for a biotech such as Mithra. It demonstrates the resilience of our teams which, despite of the turbulences caused by COVID-19, managed to take up the challenge with flying colours. We are pleased to collaborate on this exciting project with our long-standing partner Gedeon Richter as this further strengthens our successful partnership.”

Prof Jean-Michel Foidart, Permanent Secretary of the Royal Academy of Medicine of Belgium, added: “We’ve been working on Estetrol, a native hormone produced by the human body during pregnancy, for more than ten years to develop a new generation contraceptive pill with a clear benefit/risk aiming to improve women’s quality of life. This product promises to be a major breakthrough in a space where there hasn’t been any innovation in decades.”

“This new product has a unique profile, significantly supports reproductive health preservation and conscious family planning. Estetrol combined with drospirenone represents a major innovation breakthrough in reproductive health and sets a new horizon for women around the world,” – stated Professor Emeritus György Bártfai, the Chairman of the Egon and Ann Diczfalusy Foundation, founded in 2007 to preserve and forward professor’s spirit and legacy for the next generations.

About Drovelis®

Drovelis® is Richter’s brand name for a novel oral contraceptive product candidate 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. The product licensed out by Mithra to other commercial partners was already granted marketing authorization in Canada earlier this month and it expects further MA in the US by the end of the first half of 2021.

[Chemical Works of Gedeon Richter Plc.](#)

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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.

About Mithra

Mithra (Euronext: MITRA) is a Belgian biotech company dedicated to transforming Women's Health by offering new choices through innovation, with a particular focus on contraception and menopause. Mithra's goal is to develop products offering better efficacy, safety and convenience, meeting women's needs throughout their life span. Mithra explores the potential of the unique native estrogen estetrol in a wide range of applications in women health and beyond (Covid-19, neuroprotection). Mithra also develops and manufactures complex therapeutics in the areas of contraception, menopause and hormone-dependent cancers. It offers partners a complete spectrum of research, development and specialist manufacturing at its technological platform Mithra CDMO. Active in more than 100 countries around the world, Mithra has an approximate headcount of 300 staff members and is headquartered in Liège, Belgium. www.mithra.com

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