



## Richter and Mithra Receive Positive CHMP Opinion for Estelle®

**Budapest, Hungary – Liege, Belgium – 26 March 2021 – 13:15 CET** – 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 Bogesch, Executive 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 physicians and patients in Europe.”*

*“After Estelle® first approval granted 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 colors. 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 an 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.*

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## About Estelle®

*Estelle® is Mithra's novel combined oral contraceptive (COC) product based on Estetrol (E4)15 mg and drospirenone (DRSP) 3 mg. E4 is a native estrogen that is produced by the human fetus during pregnancy. In two phase III clinical studies conducted in nearly 3,800 women, Estelle® showed positive top-line results against primary efficacy and safety endpoints and achieved positive secondary endpoints including good bleeding profile, cycle control, and tolerability. Mithra has signed 15 licensing deals for Estelle® with a number of leading women's health companies covering more than 100 countries in the world.*

## About Richter

*Gedeon Richter Plc. ([www.richter.hu](http://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](http://www.mithra.com)*

## Important information

*The contents of this announcement include statements that are, or may be deemed to be, "forward-looking statements". These forward-looking statements can be identified by the use of forward-looking terminology, including the words "believes", "estimates," "anticipates", "expects", "intends", "may", "will", "plans", "continue", "ongoing", "potential", "predict", "project", "target", "seek" or "should", and include statements the Company makes concerning the intended results of its strategy. By their nature, forward-looking statements involve risks and uncertainties and readers are cautioned that any such forward-looking statements are not guarantees of future performance. The Company's actual results may differ materially from those predicted by the forward-looking statements. The Company undertakes no obligation to publicly update or revise forward-looking statements, except as may be required by law.*

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