



Mithra Announces Estelle® Approval in Russia

Liege, Belgium, 16 September 2021 – 7:30 CEST – Mithra (Euronext Brussels: MITRA), a company dedicated to Women's Health, is pleased to announce that the Russian Medicines Agency (Roszdravnadzor) has approved the registration application for the novel combined oral contraceptive Estelle® containing 15mg estetrol (E4) and 3 mg drospirenone (DRSP).

Developed by Mithra, Estelle® is the first and only pill containing estetrol (E4), a naturally occurring native estrogen produced in the human body during pregnancy. Synthesized from plant-based sources, E4 has a unique mechanism of action that displays tissue selective activity. In two phase III clinical studies conducted in 3,725 women, E4/DRSP showed positive top-line results against primary efficacy and safety endpoints and achieved positive secondary endpoints including good bleeding profile, cycle control, and tolerability. Recognized as a New Active Substance (NAS) by the European Medicines Agency, estetrol will be the first native estrogen available in any contraceptive in Russia.

The product will be marketed in Russia by Gedeon Richter under the brand name Esteretta®. Currently, the Russian contraceptives market is valued at approximately EUR 190 million annually with an average growth of 3% per year¹. Russia represents the third largest market in Europe, after Italy and Germany.

Leon Van Rompay, CEO Mithra Women's Health, commented: *"After Canada, the United States and Europe, we are delighted to obtain an additional market authorization for our first Estetrol-based product, Estelle®. Within a few months, we succeeded in obtaining marketing authorizations covering more than 80% of the contraceptive global market. It's pretty exciting for a biotech to see its product get its marketing approvals on time and make it available to women around the world."*

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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,

¹ IQVIA, Full Year 2020, CAGR 3% (2016-2020)

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 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

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.

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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