



Mithra Announces European Approval of Estelle®

Liege, Belgium, 20 May 2021 – 18:45 CEST – Mithra (Euronext Brussels: MITRA), a company dedicated to Women's Health, is very pleased to announce that the European Commission has accepted the registration application for the novel combined oral contraceptive Estelle®. This decision follows the adoption of a positive opinion by the Committee for Medicinal Products for Human Use ("CHMP") of the European Medicines Agency ("EMA") on 26 March 2021 and is valid for all Member States of the European Union.

Developed by Mithra, Estelle® is composed of 15 mg estetrol (E4), a unique native estrogen and 3 mg drospirenone. E4 is produced by the human fetus, passing the maternal blood at relatively high levels during pregnancy. 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.

The product will be marketed in whole Europe by Richter under the brand name Drovelis® and in Belgium and Luxemburg by Ceres Pharma under the brand name Lydisilka®. The commercial launch of Estelle® in Europe will be phased during the second half of the year, starting with Germany, Austria and Poland. Once launched, Estelle® will be the first new estrogen in a COC in the European market in over half a century. Currently, the total European contraceptives market is valued at approximately EUR 2.4 billion annually. As a result of receiving European approval for Estelle®, Gedeon Richter will pay Mithra EUR 15 million in cash.

"After Estelle® approval granted in the US and in Canada, we are very pleased with this third approval given by the European Commission", said Leon Van Rompay, CEO of Mithra. "It is a great pride for all our teams to offer the result of so many years of research available to women around the world. "

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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 Estelle®

Developed by Mithra, Estelle® is a novel patent protected combined oral contraceptive pill containing 3 mg drospirenone (DRSP) and 15 mg estetrol (E4). E4 is a naturally produced estrogen during pregnancy, which can now be made from a plant source. In two phase 3 clinical studies conducted in 3,725 women, Estelle® was shown to be both safe and effective and met its primary efficacy endpoint of pregnancy prevention. It also delivered excellent results on a variety of secondary endpoints that demonstrated outstanding cycle control, bleeding control, safety, 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.

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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