



## Mithra Receives Acceptance of Marketing Authorization Application (MAA) to Market Estelle® in Belgium and Luxembourg

**Liege, Belgium, 03 March 2020 – 7:30 CET** – Mithra (Euronext Brussels: MITRA), a company dedicated to Women’s Health, today announces that the European Medicines Agency (EMA) has accepted its regulatory submission to market Estelle® in Belgium and Luxembourg. Estelle® is Mithra’s novel combined oral contraceptive (COC) product candidate, containing 15 mg Estetrol (E4) and 3 mg drospirenone (DRSP).

As per the license and supply agreement signed in July 2018, Ceres Pharma will be responsible for commercializing Estelle® in BeLux<sup>1</sup>. In its agreement with Ceres Pharma, Mithra received an immediate payment of EUR 20 million, with a potential additional EUR 20 million in earn-outs over the period 2019-2023, pending certain sales milestones. Ceres Pharma's sales and marketing teams are already actively preparing for the potential commercialisation of Mithra's first blockbuster candidate scheduled for the first half of 2021.

**François Fornieri, CEO Mithra Women’s Health, commented:** *“After the successful launch in February of our Myring™ contraceptive ring by Ceres Pharma in Belgium, we are delighted to have crossed another important milestone with the potential commercialization of our Estelle® contraceptive pill in BeLux, in the first semester of 2021. We are already actively preparing the global commercial launch, with all of our partners, and look forward to making the results of our research available to women.”*

**Mario Debel, CEO Ceres Pharma, confirms:** *“We are very happy that we will be able to add the potential commercialization of this great innovation to our contraception portfolio and re-inforce our number 1 position as Belgian partner in women’s health to Gynecologists, GP’s and women in BeLux.”*

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### About Estelle®

*Estelle® is Mithra’s novel combined oral contraceptive (COC) product candidate based on Estetrol (E4)15 mg and drospirenone (DRSP) 3 mg. E4 is a native estrogen that 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. Mithra has signed 11 licensing*

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<sup>1</sup> [Press release Mithra, 30 July 2018](#)

deals for Estelle® with a number of leading women's health companies covering Europe, Japan, South Korea, ASEAN, Russia, Brazil, Canada, Middle East, North Africa, Southern Africa and United States.

### 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. Its three lead development candidates are built on Mithra's unique native estrogen platform, Estetrol (E4): Estelle®, a new era in oral contraception, PeriNesta®, the first complete oral treatment for perimenopause and Donesta®, the next-generation hormone therapy. 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 85 countries around the world, Mithra has an approximate headcount of 250 staff members and is headquartered in Liège, Belgium. [www.mithra.com](http://www.mithra.com)

### About Ceres

Ceres Pharma is a young and dynamic Belgian pharmaceutical company founded by the investment company Alychlo and CEO Mario Debel. The ambition of Ceres Pharma is to grow the company by developing its own portfolio and through acquisitions. Ceres Pharma is active in the development, production and distribution of drugs, medical products, cosmetics, high-quality food supplements and pharmaceutical compounding in the BeLux, Spain, Central and Eastern Europe. [www.ceres-pharma.com](http://www.ceres-pharma.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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