



## Scientific community convinced of Estetrol's potential for women's health

- At the 19th ISGE Congress, Mithra and Gedeon Richter presented the clinical results of Estelle® to an international scientific audience
- While Estetrol (E4) has recently been designated as a "New Active Substance" by the European Medicines Agency (EMA)<sup>1</sup>, doctors there have confirmed their strong interest in the use of E4 in contraception.

**Liege, Belgium, 3 December, 2020 – 7:30 CET** – Mithra (Euronext Brussels: MITRA), a company dedicated to Women's Health today announces that physicians at the 19th Congress of the International Society of Gynecologic Endocrinology (ISGE) expressed a strong interest in the clinical results of Estelle®, Mithra's novel combined oral contraceptive (COC) candidate.

At this Scientific Congress, Mithra and its partner Gedeon Richter held a symposium entitled "*E4: it is time for a Renaissance in Oral Contraception*". During this conference, the clinical results of Estelle® and the advances it makes possible both in terms of comfort and safety for women's health were presented to an audience of international specialists.

Mithra's participation is part of the valorisation strategy put in place by the Belgian biotech company in view of the market entry of the product candidate Estelle® once its commercialization is authorized by the European Medicines Agency. This scientific meeting also aims to identify with the medical community the future developments of E4 in the field of healthcare.

While the conclusions of the European Medicines Agency (EMA) are expected at the beginning of 2021, this meeting with the scientific community was a unique opportunity for Mithra and Gedeon Richter to promote the applications of E4 in the field of contraception and to identify as closely as possible the level of interest and expectations of the scientific community for its forthcoming availability. At the end of this meeting, the international specialists present expressed their expectation of the new E4 pill and confirmed the importance of the nature of estrogen in the pill.

Recently accepted as a "New Active Substance" by the European Medicines Agency, the E4 contained in the Estelle® product candidate is characterized in particular by its contraceptive efficacy associated with greater protection of women's health.

During the ISGE Congress, Mithra also presented 3 posters detailing some of the clinical results of Estelle® to the scientific community:

- Estetrol 15 mg combined with drospirenone 3 mg is an effective oral contraceptive: results from the E4Freedom EU/RU phase 3 trial (Author(s) Creinin M, Bastidas A, Mawet M, Ledant S, Jost M, Foidart J)
- Cycle control of an estetrol 15 mg and drospirenone 3 mg combined oral contraceptive in the E4Freedom EU/RU phase 3 trial (Author(s) Creinin M, Bastidas A, Mawet M, Ledant S, Jost M, Foidart J)

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<sup>1</sup> [Communiqué de presse Mithra, 25/11/2020](#)

- A Phase 3 Protocol to assess the Efficacy and Safety of Estetrol (E4), a Promising New Treatment for Menopausal Vasomotor Symptoms (Author(s) Wulf H. Utian, Adriana Bastidas, Mélanie Taziaux, Maud Jost, Ulysse Gaspard, and Jean-Michel Foidart, Rogerio A. Lobo)

**Professor Mitchell Creinin, MD, Director of Family Planning at the University of California, Davis,** commented: "Estelle® Phase 2 and 3 clinical results demonstrate high contraceptive efficacy and desirable bleeding patterns while showing a lower impact on liver metabolism, lipids, and the coagulation profile as compared to contraceptives using ethinyl estradiol. I am looking forward to having a combined oral contraceptive with the novel estrogen, Estetrol, available for our patients in 2021."

**Prof. Jonathan Douxfils, PhD, PharmD, Namur Thrombosis and Hemostasis Center, University of Namur,** Belgium, commented: "Estelle® Phase 2 investigations on hemostasis markers further delineate the distinct profile of Estetrol (E4) on the liver compared to ethinylestradiol (EE). These exciting data include a test that was shown to stratify the risk VTE according to the contraceptive combination and demonstrate the favorable hemostatic profile of E4/DRSP compared to EE-containing products. These observations confirm that this is the choice of the estrogen that modulates the impact on coagulation".

**Graham Dixon, CSO of Mithra Women's Health, comments:** "We are very pleased to have participated in the 19th ISGE conference. Additional results on our product candidate Estelle®, including Phase III data, were presented there. Marketing approval of the first and only E4-based contraceptive is expected in 2021 in the European Union, Canada and the United States and should provide women with a truly novel alternative to oral contraception".

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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. 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 targeting 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 100 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)*

### Important information

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