



## MITHRA APPLIES FOR ADDITIONAL ESTELLE® PATENT BASED ON POSITIVE HEMOSTASIS DATA

- Patent will strengthen and extend the existing Estelle® and E4 intellectual property estate
- Positive hemostasis data differentiate Estelle® from commonly prescribed combined oral contraceptives

**Liège, Belgium, 28 March 2018** – Mithra (Euronext Brussels: MITRA), a company dedicated to Women's Health, today announces that it has filed an additional patent application in Europe based on the data generated in the Estelle® hemostasis Phase II substudy. Estelle® is Mithra's combined oral contraceptive (COC) candidate, composed of 15 mg Estetrol (E4) and 3 mg drospirenone (DRSP), and is currently being tested in two Phase III trials in Europe/Russia and in the US/Canada.

The hemostasis substudy is running in parallel with the ongoing Phase III pivotal trials for Estelle® in EU/Russia and the US/Canada, the results of which are expected in Q3 2018 and Q1 2019, respectively. Data from the hemostasis substudy were recently presented at the Gynaecological Endocrinology Conference (ISGE) in Florence, demonstrating the favorable hemostatic profile of Estelle®. This included minimal changes to key parameters widely accepted as surrogate markers of coagulation (blood clotting) and fibrinolysis (breakdown of clots). These help to determine the risk for deep vein thrombosis (DVT) and pulmonary embolism, which are well-documented side effects of certain commonly prescribed contraceptive pills.

Data from the hemostasis substudy demonstrate that, for a number of key parameters, Estelle® is comparable to the safest 2nd generation levonogestrel (LNG)-based COC (Melleva®), a key benchmark for regulators. Estelle® was also found to compare favourably to a 4th generation COC, Yaz®. The Yaz® family<sup>1</sup> is currently the best-selling contraceptive pill and contains DRSP, which has been linked to elevated risk of DVT relative to LNG-based products<sup>2</sup>.

Based on the favourable hemostatic profile, the aim is to patent the differentiation of Estelle® versus other currently commercialized COCs, and especially versus EE/DRSP based pills. If granted, the patent would extend the existing E4 intellectual property estate, which comprises patents relating to the E4 synthesis process (until 2032) and E4 as a potential new emergency contraception option.

**François Fornieri, CEO Mithra Women's Health:** *"We are pleased that the very promising results from our hemostasis study can be used to further extend and strengthen the intellectual property estate for Estelle®, as well as to differentiate Estelle® from the benchmark product Yaz®. We plan to make further applications in additional regions in the future based on the favourable Estelle® hemostatic data. We look forward to reporting top-line results in Q3 2018 for Europe/Russia and in Q1 2019 for US/Canada. We continue to believe that Estelle® has the potential to become a true 'next generation' contraceptive, offering a beneficial risk/benefit profile to women worldwide."*

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<sup>1</sup> Yaz and generic versions : USD 1.3bn; IMS Health Q3 2017

<sup>2</sup> Lidegard et al 2011. *BMJ* 2011;343:d6423

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**About Mithra**

Mithra (Euronext: MITRA) is dedicated to providing innovation and choice in women's health, with a particular focus on fertility, contraception and menopause. Mithra's goal is to develop new and improved products that meet women's needs for better safety and convenience. Its two lead development candidates - a fifth generation oral contraceptive, Estelle®, and a next generation hormone therapy, Donesta®- are built on Mithra's unique natural estrogen platform, E4 (Estetrol). Mithra also develops, manufactures and markets complex therapeutics and offers partners a complete spectrum of research, development and specialist manufacturing at its Mithra CDMO. Mithra was founded in 1999 as a spin-off of the University of Liège by Mr. François Fornieri and Prof. Dr. Jean-Michel Foidart and is headquartered in Liège, Belgium. Further information can be found at: [www.mithra.com](http://www.mithra.com)

**Important information**

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