PRESS RELEASE

MITHRA COMPLETES RECRUITMENT FOR ADDITIONAL ESTELLE® SAFETY STUDY

- **Safety study is part of the development of Estelle®, Mithra's combined oral contraceptive candidate**
- **Aim of the study is to analyze a broad range of safety parameters for Estelle®, including hemostatic, endocrine and metabolic markers**

Liège, Belgium, 21 June 2017 – Mithra (Euronext Brussels: MITRA), a company specialized in Women's Health, announces that it has completed recruitment into a safety study to evaluate the effect of Estelle® on endocrine function (thyroid, adrenal), metabolic control (lipid and carbohydrate metabolism) as well as on a broad panel of hemostasic markers[1]. Estelle® is Mithra's combined oral contraceptive (COC) candidate, composed of 15 mg Estetrol (E4) and 3 mg drospirenone (DRSP). Estelle® is currently being tested in two Phase III trials in Europe/Russia and in the US/Canada, the results of which are expected in Q3 2018 and Q1 2019, respectively.

This study, which is part of EMA's[2] regulatory requirements for a novel COC, is a single center, randomized, open-label, controlled, three-arm trial. As comparators, the study will also analyze[3] COCs containing either 30 µg ethinylestradiol (EE)/150 µg levonorgestrel (LNG) or 20 µg EE/3 mg DRSP. A total of 101 subjects have been enrolled for six 28-day treatment cycles, and results are expected towards the end of H1 2018.

The Phase III Estelle® studies, *E4 Freedom*, are open-label single arm trials to assess the safety and efficacy of Estelle® in approximately 1,550 participants in Europe/Russia and 2,000 participants in the US/Canada over a period of 12 months. Patient enrolment in the Europe/Russia study is complete with enrolment in the US/Canada study ongoing. The US/Canada arm of the trial is making good progress with over 90% of the sites now actively recruiting.

François Fornieri, CEO of Mithra, commented: "*We are pleased to confirm that we have finalized the recruitment for this additional safety study for Estelle®, and we expect that the study will corroborate earlier findings that indicate the potentially improved safety profile of Estelle® compared to current COCs. We look forward to the full results of the Estelle® Phase III studies, which are on track to report in Q3 2018 for Europe/Russia and in Q1 2019 for US/Canada.*"

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[1] Study reference MIT-Es0001-C201

[2] European Medicines Agency ; see *"Guideline on Clinical Investigation of Steroid Contraceptives in Women"*

[3] EE/LNG is a comparator required by the agencies. EE/DRSP is currently marketed as Yaz®.

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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 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 CDMO.

Mithra was founded in 1999 as a spin-off from the University of Liège by Mr. François Fornieri and Prof. Dr. Jean-Michel Foidart. Mithra is headquartered in Liège, Belgium. Further information can be found at: **www.mithra.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.