PRESS RELEASE

# MITHRA ANNOUNCES VERY PROMISING HEMOSTASIS RESULTS FOR ESTELLE®

- **Results point to minimal changes in markers of coagulation and fibrinolysis, which is key to further delineate unique safety potential of Estelle®**
- **Detailed results available in coming weeks, with presentations at scientific conferences planned in Q1/Q2**

**Liège, Belgium, 08 February 2018** – Mithra (Euronext Brussels: MITRA), a company specialized in Women's Health, today announces that the company obtained promising results for its Phase II hemostasis study of Estelle®, Mithra's combined oral contraceptive (COC) candidate composed of 15 mg Estetrol (E4) and 3 mg drospirenone (DRSP).

The Phase II study[1], which is a substudy running in parallel with the ongoing pivotal Phase III studies for Estelle®, analyzes an extensive series of hemostatic, endocrine function and metabolic control parameters, in compliance with regulatory guidelines.[2] The results are very important to further define the unique safety potential of Estelle® and in particular its biological impact on hemostasis: the parameters analyzed are widely accepted as surrogate markers of coagulation (blood clotting) and fibrinolysis (breakdown of clots). Hence, an analysis of these markers is key to help determine the risk profile of a novel COC for deep vein thrombosis (DVT) and pulmonary embolism, which are well-documented side effects of certain contraceptive pills. Therefore, the results are closely studied by the regulatory bodies and keenly awaited by clinicians and (potential) commercialization partners for Estelle®.

Given their importance, Mithra plans to present the hemostasis data at the following highly regarded scientific conferences:

- **ISGE –** Gynaecological Endocrinology Conference (Florence, March 7-10, 2018)
- **ESC –** Congress of the European Society of Contraception & Reproductive Health (Budapest, May 9-12, 2018)

**François Fornieri, CEO Mithra Pharmaceuticals, commented**: *"We are pleased with the results from the hemostasis study, which are very promising indeed. With our Phase III trials in Europe/Russia and US/Canada well underway, the results of the hemostasis study corroborate earlier findings that Estelle® may present a unique benefit/risk profile, offering the potential of a true 'next generation' contraceptive option for women."*

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[1] ClinicalTrials.gov identifier NCT02957630; study number: MIT-Es0001-C201

[2] The study analyses data for 100 subjects, divided over three treatment groups: 15 mg E4/3 mg DRSP (or Estelle®), 30 mcg EE/150 mcg LNG (as requested by the regulatory agencies), and 20 mcg EE/3 mg DRSP

## For more information, please contact:

**Investor Relations**

**Sofie Van Gijsel, IRO**
+32 485 19 14 15
investorrelations@mithra.com
svangijsel@mithra.com

**Press**

**Julie Dessart**
Chief Communication Officer
+32 4 349 28 22 / +32 475 86 41 75
press@mithra.com

## About Estelle®

Estelle® is Mithra's novel oral contraceptive product candidate composed of 15 mg Estetrol (E4), its unique native estrogen, and 3 mg DRSP. Currently, pivotal Phase III Estelle® trials (*E4 Freedom*) are ongoing in Europe and Russia as well as in the US and Canada, with top line results expected in Q3 2018 and Q1 2019, respectively. The *E4 Freedom* studies are open-label single arm trials to assess the safety and efficacy of Estelle® in over 1,550 participants in Europe/Russia and approximately 2,000 participants in the US/Canada, over a period of 13 cycles.

## 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

## 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*

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