



MITHRA ANNOUNCES COMPLETION OF ESTELLE® CYCLES REQUIRED IN PHASE III CONTRACEPTION STUDIES

- **Estelle® Phase III studies remain on track to report top-line results in Q3 2018 from Europe/Russia and Q1 2019 from US/Canada**

Liège, Belgium, 23 March 2018 – Mithra (Euronext Brussels: MITRA), a company dedicated to Women's Health, today announces that the minimum number of female cycles required by regulators in both of the pivotal Phase III Estelle® studies have now been successfully completed. 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.

Mithra has now completed the minimum 10,000 cycles of Estelle® required in the US/Canada study and has already completed more than 12,000 cycles of Estelle® in the European/Russian study. It has now also fulfilled regulatory requirements for a minimum total of 20,000 cycles, of which 50% have to be from North America. Moreover, regulatory guidance regarding the required number of subjects completing a full year of treatment (13 cycles) has already been reached in each trial.

As previously announced, Mithra completed recruitment of 1,577 women in the Europe/Russia study in February 2017 and 2,148 women into the US/Canada study in October 2017. Top-line results continue to be expected in Q3 2018 for the Europe/Russia study and in Q1 2019 for the US/Canada trial.

François Fornieri, CEO Mithra Women's Health: *"The Phase III Estelle® program continues to make good progress and we are pleased to have achieved another important milestone, ensuring our studies satisfy key regulatory requirements. We remain encouraged by the number of women completing a full year with Estelle®, providing an indication of user acceptance and well-being of subjects using our novel COC product candidate. 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."*

About the E4 Freedom Estelle® Phase III program

The *E4 Freedom* Phase III program consists of two open-label, single arm studies. The European/Russian Phase III Estelle® study has enrolled 1,577 subjects aged 18-50 years of whom 1,350 subjects are aged 18-35 years. The study is taking place in 69 centers across Europe and Russia. The Phase III Estelle® study design in the US & Canada has enrolled 2,148 subjects aged 16-50 years of whom 1,940 subjects are aged 16-35 years. The study is taking place in approximately 77 centers across the US and Canada. Estelle® is Mithra's combined oral contraceptive (COC) candidate composed of 15 mg Estetrol (E4) and 3 mg drospirenone (DRSP).

The objectives of both studies are to evaluate the contraceptive's efficacy, cycle control, and the general safety and acceptability of the 15 mg Estetrol (E4) and 3 mg DRSP combination oral contraceptive pill in healthy women, and involves subject participation for a period of minimum 12 months (13 cycles, 1 cycle = 28 days).

The primary outcome is contraceptive efficacy measured by the number of pregnancies per 100 women per 12 months of exposure (Pearl Index; PI) in the primary population. In Europe/Russia this is in subjects aged 18-35 years old and in the US/Canada in subjects aged 16 to 35 years old.

Secondary outcomes include the method failure PI in the primary population as well as the PI within the overall study population. Also, cycle control, bleeding profile, safety and tolerability, and general wellbeing of the subjects (measured by two questionnaires) are analyzed. A pharmacokinetic (PK) substudy will assess the effect of various individual characteristics/covariates (such as race and BMI) on the PKs of 15 mg E4/3 mg DRSP.

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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

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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