



MITHRA ANNOUNCES FIRST SUBJECT COMPLETES ESTELLE® PHASE III STUDY

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

Liège, Belgium, 18 August 2017 – Mithra (Euronext Brussels: MITRA), a company specialized in Women's Health, today announces that the first European study subject has successfully completed 13 cycles of Estelle® and the end of study physician visit in the *E4 Freedom* Phase III study program. 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 announced in February 2017 that recruitment was completed in Europe and Russia and top line data remain on track to be reported during Q3 2018. For the Phase III study in the US and Canada, which was initiated in September 2016, all sites are now actively recruiting subjects, with completion of recruitment expected in the near future and top line data expected during Q1 2019.

François Fornieri, CEO of Mithra, commented: *"Today's news is another positive step in the development of Estelle® which remains on track to report top line results in Q3 2018 for Europe/Russia and in Q1 2019 for US/Canada. The first woman successfully completing 13 cycles with Estelle® and others nearing completion provides an encouraging indication of the user acceptance and well-being of subjects using our novel COC product candidate. We look forward to reporting the Phase III results, which we believe will show that Estelle® offers women a convenient and potentially safer contraceptive alternative to currently available treatments."*

European Phase III study design (Estelle®)

The European Phase III Estelle® study design is an open-label single arm study that enrolled 1577 subjects aged 18-50 years of whom 1350 treated subjects are aged 18-35 years. The objectives of the study 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 aged 18-50 years old.

The study is taking place in 69 centres across Europe and Russia, and involves subject participation for a period of minimum 12 months (13 cycles, 1 cycle = 28 days). The primary outcome is contraceptive efficacy in the 18-35 year old group based on the Pearl Index, which measures the number of pregnancies per 100 women per 12 months of exposure.

Secondary outcomes include cycle control and bleeding profile, safety and tolerability, general wellbeing of the subjects (measured by two questionnaires) and any adverse impact on the endometrium. This last parameter will be evaluated based on approximately 170 subjects out of the 1577 enrolled.

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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.

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