



## MITHRA COMPLETES RECRUITMENT FOR ESTELLE® PHASE III STUDY IN US & CANADA

- Estelle® Phase III study in US/Canada remains on track to report top line data in Q1 2019
- Study recruited 2148 women in total; 57% of subjects already completed over half the 13 treatment cycles
- First subject completed the 13 cycle treatment as well as the end of study visit in October

**Liège, Belgium, 30 October 2017** – Mithra (Euronext Brussels: MITRA), a company specialized in Women's Health, today announces the completion of recruitment in the *E4 Freedom* Phase III study of Estelle® in the US and Canada. Estelle® is Mithra's combined oral contraceptive (COC) candidate composed of 15 mg Estetrol (E4) and 3 mg drospirenone (DRSP). Top-line data, based on 13 cycles of treatment, remain on track to be reported in the first quarter of 2019.

The Phase III Estelle® study in the US & Canada is a multicenter open-label single arm study that has enrolled 2148 subjects aged 16-50 years, of whom 1940 subjects are aged 16-35 years.

Recruitment for the separate European/Russian Phase III study was completed in February 2017 and top line results from this study are expected in Q3 2018. A total of 1577 women were enrolled in this study, almost 8% of which already successfully completed 13 cycles of Estelle® as well as the end of study visit.

**François Fornieri, CEO of Mithra, commented:** *"Today's announcement marks another important step in the development of Estelle®. We are looking forward to the outcome of the Phase III trial in Q1 2019, which we hope will corroborate earlier studies indicating that Estelle® has the potential to exhibit a better safety and efficacy profile compared to currently-available COCs. Moreover, the fact that 57% of US study subjects already completed over half of the treatment cycles may indicate the good user acceptability profile of Estelle®. We believe that Estelle® has the potential to become a true 'next-generation' contraceptive option, including in North America, a market worth 35% of the USD 22bn worldwide contraceptive market.<sup>1</sup>"*

### About the *E4 Freedom* Estelle® Phase III study in US/Canada

The Phase III Estelle® study design in the US & Canada is an open-label single arm study that has enrolled 2148 subjects aged 16-50 years of whom 1940 subjects are aged 16-35 years. Estelle® is Mithra's combined oral contraceptive (COC) candidate composed of 15 mg Estetrol (E4) and 3 mg drospirenone (DRSP).

The study is taking place in approximately 77 centres across the US and Canada, and will involve subject treatment for a period of 12 months (13 cycles; 1 cycle = 28 days). The primary outcome

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<sup>1</sup> Transparency Market Research 2017

measures the number of pregnancies per 100 women per 12 months of exposure (Pearl Index; PI) in subjects aged 16 to 35 years old.

The secondary outcomes will measure the method failure PI in the primary population as well as the PI within the overall study population (16-50 years). Also, 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.

### **For more information, please contact:**

#### **Investor Relations**

##### **Sofie Van Gijssel, IRO**

+32 485 19 14 15

[investorrelations@mithra.com](mailto:investorrelations@mithra.com)

[svangijssel@mithra.com](mailto:svangijssel@mithra.com)

#### **Consilium Strategic Communication**

Jonathan Birt, Philippa Gardner, Ivar Milligan, Hendrik Thys

[mithra@consilium-comms.com](mailto:mithra@consilium-comms.com)

+44 2 037 095 700

#### **Press**

##### **Julie Dessart**

Chief Communication Officer

+32 4 349 28 22 / +32 475 86 41 75

[press@mithra.com](mailto:press@mithra.com)

### **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](http://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*

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