



MITHRA COMPLETES RECRUITMENT FOR EUROPEAN PHASE III ESTELLE® STUDY

Liège, Belgium, 07 February 2017 – Mithra Pharmaceuticals (Euronext Brussels: MITRA), a company focused on women’s health, today announces that it has completed recruitment into the Phase III study of its product candidate Estelle®, a combined oral contraceptive based on Estetrol (E4) and Drospirenone (DRSP), in Europe and Russia.

As of 6 February 2017, 1709 patients have been screened, of which it is expected that at least 1550 will qualify for enrollment into the study which is designed to assess the safety and efficacy of Estelle® over the course of 12 months. Results of the European study are expected in H2 2018. A second Phase III study in the US and Canada started enrollment in September 2016.

Francois Fornieri, CEO of Mithra Pharmaceuticals, said: *“We are pleased to confirm the completion of patient enrollment into one of two pivotal studies for Estelle®. Initial studies have shown the potential advantages of Estetrol including a reduction in side effects such as the risk of venous thromboembolism, an increase in body weight and undesired bleeding whilst on the pill. We are on track to complete the trial in 2018 and hope to be able to provide women globally with a novel contraceptive option with a better safety and efficacy profile compared 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 is expected to enroll at least 1550 patients aged 18-50 years of whom 1350 patients 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 15mg estetrol (E4) and 3mg DRSP combination oral contraceptive pill in healthy women aged 18-50 years old.

The study is taking place in approximately 69 centres across Europe and Russia, and will involve patient enrollment for a period of 12 months (13 cycles, 1 cycle = 28 days). The primary outcome measures will be the number of pregnancies per 100 women per 12 months of exposure in patients aged 18 to 35 years old.

The secondary outcomes will measure the on-treatment pregnancies within the overall study population (18-50 years), bleeding profile, safety and tolerability, general wellbeing of the patients (measured by two questionnaires) and any adverse impact on the endometrium. This last parameter will be evaluated based on 167 patients out of the expected 1550 enrolled.

ENDS

Pictures

For pictures of François Fornieri, please click here on the following link:

<http://www.mithra.com/en/logo/>

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About Mithra

Mithra Pharmaceuticals SA, founded in 1999 as a spin-off of the University of Liège by Mr. François Fornieri and Prof. Dr. Jean-Michel Foidart, is a Euronext listed pharmaceutical company (MITRA) focused on Women's Health. Mithra's mission is to improve every stage of women's life with innovative and accessible pharmaceutical solutions. As such the Company aims to become a worldwide leader in women's health by developing, manufacturing and commercialising proprietary, innovative and differentiated drugs and complex therapeutical solutions in four therapeutic fields of women's health: fertility and contraception, menopause and osteoporosis, gynecological infections and female cancers. Mithra has an approximate headcount of 141 staff members 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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