



MITHRA TO INITIATE PK STUDY FOR ESTELLE®

- **First step toward bringing Estelle® to the Japanese and ASEAN markets with partner Fuji Pharma**
- **Bridging study aims to characterize and compare the pharmacokinetic (PK) profile of Estetrol (E4) and its combination with Drospirenone (DRSP) in Japanese and Caucasian subjects**

Liège, Belgium May 12, 2017 – Mithra, a company dedicated to Women’s Health, announces that the Company received IRB¹ approval for the launch of a PK ethnobridging study for Estelle®. Estelle® is Mithra’s novel oral contraceptive product candidate composed of 15 mg E4, its unique native estrogen, and 3 mg DRSP. Currently, pivotal Phase III Estelle® trials are ongoing in the US and Canada as well as in Europe and Russia.

Mithra announced its partnership with Fuji Pharma for the development of Estelle® in Japan and ASEAN in August 2016. Top line results of the study are expected between Q4 2017 and Q1 2018.

The study is a single-center, double-blind, placebo-controlled, randomized trial to compare the pharmacokinetic (PK) profile of different dosages of E4 combined with DRSP or E4 alone between Japanese and Caucasian subjects. In total, 96 participants will be recruited, 48 of which will be Japanese and 48 Caucasian. The women will be randomized over four treatment groups².

The primary objective is to determine and compare the PK profile after a single oral dose, by charting differences in drug exposure and elimination. Additionally, safety and tolerability of E4 and DRSP, and of E4 alone, will be evaluated in the study population.

François Fornieri, CEO Mithra Pharmaceuticals: *“We are pleased to start the bridging study with our partner, Fuji Pharma. Progressing development to this stage highlights the constructive collaboration with Fuji Pharma, as well as their commitment to the Estelle® program. Moreover, this is an essential first step towards bringing Estelle to the Japanese market, and to potentially offer a safer contraceptive alternative to millions of Japanese women.”*

¹ International Review Board, powered by the FDA to approve planned research and clinical trials

²Treatment groups in the study: 5 mg E4/3mg DRSP or placebo, 15 mg E4/3mg DRSP or placebo, 20 mg E4/3 mg DRSP or placebo and 15 mg E4 or placebo

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About Fuji Pharma

Fuji Pharma is a Tokyo based company founded in 1965, listed on the Tokyo Stock Exchange (4554:JP) with a 55bn JPY market capitalization and 2016 revenues of 34.23bn JPY. It specializes in development, manufacture, and marketing of pharmaceutical products, such as injection agents, internal drugs, drugs for external use, and diagnostic products. Their products and services are focused on medical care for women, in vitro diagnostics, acute medical care products and curative medicine (injection agents), and information regarding pharmaceuticals and health.

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 and markets complex therapeutics and offers partners a complete spectrum of research, development and specialist manufacturing at its CDMO centre.

Mithra was founded in 1999 as a spin-off of 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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