PRESS RELEASE

ESTELLE® PHASE IIB RESULTS ON WELL-BEING AND BODY WEIGHT PUBLISHED IN LEADING PEER-REVIEWED JOURNAL

- ***European Journal Of Contraception and Reproductive Health Care*** **publishes article on Phase IIb results of Estelle®, Mithra's combined oral contraceptive candidate**
- **Article reports on Estelle's® high acceptability, user satisfaction and general well-being in addition to favorable body weight control**
- **Estelle® is currently being tested in two large-scale Phase III studies, with top-line results expected in Q3 2018-Q1 2019**

Liège, Belgium, 26 June 2017 – Mithra (Euronext Brussels: MITRA), a company specialized in Women's Health, announces that the *European Journal of Contraception and Reproductive Health Care*, one of the most prestigious peer-reviewed journals in the field, has published an article[1] detailing the acceptability, user satisfaction, well-being and body weight control of Estelle® in the Phase IIb FIESTA study. Estelle® is Mithra's combined oral contraceptive (COC) candidate, composed of 15 mg Estetrol (E4) and 3 mg drospirenone (DRSP). Estelle® is currently being tested in two Phase III trials in Europe/Russia and in the US/Canada, the results of which should be available in Q3 2018 and Q1 2019, respectively.

The article reports on a number of secondary endpoints of the FIESTA study, which are key to the eventual user acceptability of Estelle®. User satisfaction and well-being were evaluated by a self-reported Subject Satisfaction and Health-related Questionnaire, which assessed parameters including the effect of the study medication on mood, sexual life and pre-menstrual symptoms. Estelle® (15 mg E4/DRSP) reported the highest treatment satisfaction, above both E4/levonorgestrel (LNG) doses, the 20 mg E4/DRSP dose and the Qlaira® reference group. Well-being was significantly higher for the E4/DRSP doses compared to E4/LNG, and was comparable to Qlaira®. Estelle® had the lowest drop-out rate of the five treatment groups.

With regard to body weight, the proportion of women with weight loss of 2 kg or more after 3 and 6 cycles was highest in the Estelle® group. Weight gain is considered an important and common reason for treatment discontinuation of COCs[2]. Therefore, the favorable weight control profile observed in the FIESTA study could potentially be an important advantage of Estelle®, as it could play a role in treatment compliance and continuation.

François Fornieri, CEO of Mithra, commented: "*We are very pleased that the positive results from the FIESTA study with our novel compound Estelle® have been published in a well-respected, peer-reviewed*

[1] Article available online at http://www.tandfonline.com/doi/full/10.1080/13625187.2017.1336532

[2] Bitzer J, Paoletti AM. 2009. Clin Drug Investig.; 29(2):73-8.

journal. The data highlight that Estelle® could offer women a number of advantages over current COCs. Furthermore, the article reinforces the need for an innovative, improved COC for women and is validation of the scientific community's support for Estelle's® potential. We are looking forward to the results of the Phase III trials of Estelle®: we expect continued demonstration that Estelle® is strongly differentiated from current COCs, as it has the potential to combine an improved safety profile with high user acceptance, satisfaction, and good body weight control."

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About the FIESTA study

The FIESTA study was an open-label, multi-center, dose-finding, six-cycle Phase IIb study. 396 healthy women of reproductive age were randomized into five treatment groups: 15 mg or 20 mg E4 combined with either 3 mg drospirenone (DRSP) or 150 µg levonorgestrel (LNG), and Qlaira® as reference (estradiol valerate (E2V) combined with dienogest (DNG)). The primary endpoint of the FIESTA Phase IIb study was the bleeding pattern and cycle control of oral contraceptives containing E4 combined with either DRSP or LNG[3].

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

[3] Apter et al. 2016. *Contraception*. 94(4):366-73

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 has an approximate headcount of 140 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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