



Presentation of Estelle® Phase III results at the 13th Meeting of the European Society of Gynecology

Liege, Belgium, 16 October 2019 – 7:30 CEST – Mithra (Euronext Brussels: MITRA), a company dedicated to Women’s Health today announces that its Phase III results for Estelle® will be presented at the 13th Annual Meeting of the European Society of Gynecology (ESG) taking place from 16-19 October 2019 in Vienna, Austria.

Estelle® is Mithra’s novel combined oral contraceptive (COC) product candidate based on Estetrol (E4) 15 mg and drospirenone (DRSP) 3 mg, with a unique benefit/risk profile. Positive top-line results for the Phase III studies in Europe/Russia and U.S./Canada were announced in August 2018 and in January 2019, respectively. A total of 3,725 women were included in the studies and these positive results confirm the outstanding safety profile of Estelle® as a novel, next-generation combined oral contraceptive.

Mithra will open the ESG Conference with its presentation addressing the complete Estelle® positive Phase III data entitled “*Estetrol: 4 reasons to believe in a new era in oral contraception*” on 16th October 2019 from 15:30-17:00. An additional oral presentation will review the Phase III sound efficacy and stable bleeding pattern results on Friday during a session dedicated to contraception from 11:45-13:15. Three poster presentations are also scheduled¹.

A selection of these presentation will be made available in the coming days in the [investors section](#) of the company’s website.

Graham Dixon, CSO of Mithra Women’s Health, commented: « *We are very pleased to present the results of the Phase III which support Estelle®, the first and only E4-based contraceptive to be developed for better Women’s Health. This is the first high profile conference where our compelling data is presented. Preparations are underway to file Estelle® for a market introduction anticipated by the end of 2020, early 2021.*”

Mitchell Creinin, Director of Family Planning at the University of California, Davis, commented: « *Estelle® has great potential based on the Phase II and III data which shows less effects on liver metabolism, lipids, and the coagulation profile as compared to contraceptives using ethinyl estradiol. The overall efficacy, safety and excellent cycle control demonstrated in the studies confirms that Estelle® is paving the way towards a new era in oral contraception.*”

¹ “Estetrol 15 mg combined with drospirenone 3 mg is an effective oral contraceptive: results from the E4Freedom EU/RU phase 3 trial” - Abstract Id 9027; “Excellent cycle control of an estetrol 15 mg and drospirenone 3 mg combined oral contraceptive in the E4Freedom EU/RU phase 3 trial” - Abstract Id 9033; “E4Relief: a phase 2b study with Estetrol (E4), the next generation hormone therapy for menopausal symptoms” - Abstracts Id 9049.

For more information, please contact:

Alexandra Deschner (IRO) : +32 490 58 35 23 - investorrelations@mithra.com

Maud Vanderthommen (Press) : +32 473 58 61 04 – press@mithra.com

About Mithra

Mithra (Euronext: MITRA) is dedicated to providing innovation and choice in Women's Health, with a particular focus on contraception and menopause. Mithra's goal is to develop new and improved products that meet women's needs for better safety and convenience. Its three lead development candidates – a fifth generation oral contraceptive Estelle®, the first complete oral treatment for perimenopause PeriNesta™ and next-generation hormone therapy Donesta® - are built on Mithra's unique native estrogen platform, E4 (Estetrol). Mithra also develops and manufactures 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 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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