



FULL ESTETROL (E4) PROGRAM UPDATE PROVIDED AT SCIENTIFIC ADVISORY BOARD MEETINGS

- **Scientific Advisory Boards consulted for the next stages of development and regulatory approval of Estelle® and Donesta® - Mithra's late stage contraceptive and menopause candidates**

Liège, Belgium, 19 November 2018 – Mithra (Euronext Brussels: MITRA), a company dedicated to Women's Health, announces that it held two scientific advisory board (SAB) meetings in New Orleans (LA) at the end of October to discuss the progress in the development plans for Estelle® and Donesta®, Mithra's key programs for contraception and menopause. The SABs, composed of American and Canadian experts in these fields, provided constructive feedback on the recently completed EU/Russia phase III trials for Estelle®. Guidance on the phase III clinical development plan for Donesta®, Mithra's next generation hormonal therapy, was also received.

The contraception advisory board meeting was moderated by Professor Mitchell Creinin, global expert in contraception at the University of California, Davis in Sacramento. Mithra presented top-line results from the Estelle EU/Russia pivotal phase III trial and discussed the interim US/Canadian pivotal phase III trial, which was completed on November 14, 2018. The study results were perceived as positive, promising and on-track with pre-trial projections. Topline results from the US/Canadian trial are expected in Q1 2019.

The experts provided constructive feedback regarding the data analyzed, the interpretation of study results, and preparation for regulatory filing in the US and Canada which is due to take place in 2019. The favourable hemostasis data from the phase II trials were also presented. Life-cycle management recommendations were shared that will further support the clinical differentiation of Estelle®.

Prof. Mitchell Creinin commented: *"The contraceptive safety, hemostatic, and metabolic profile for Estelle® is very promising. Both the Estelle® and Donesta® studies show that the mixed agonist/antagonist estrogenic activity of E4 supports its distinctive profile and the potential for clinical benefits over currently available treatment options in these fields."*

The menopause advisory board meeting was moderated by Professor Roger Lobo from Columbia University in New York. Participants reviewed and discussed the phase II dose-finding data set for the program. Based on the positive efficacy and safety data, the experts unanimously supported Mithra's plans to progress the candidate into phase III trials. Solid guidance on the phase III trial design was also provided and important strategic advice was given ahead of interactions with the FDA on the Phase III study plan, which is scheduled to take place in 2019.

Prof. Roger Lobo commented: *"The results of the Donesta® phase II clinical study look promising and show that E4 might be a very suitable post-menopausal treatment option since it appears to have some additional clinically relevant efficacy and safety benefits. If approved, Donesta® may offer a next-generation oral hormonal therapy, with an improved benefit/risk profile, to the many women suffering from menopausal symptoms worldwide."*

François Fornieri, CEO of Mithra Women's Health commented: *"We are extremely proud to work alongside so many Key Opinion Leaders to ensure our lead programs continue to address market needs. Their involvement demonstrates the level of interest among the scientific community in our E4 product"*

candidates. This expertise is invaluable to Mithra as we look to advance these two promising candidates through to regulatory approval and into the hands of patients for whom novel, safe treatment options are sorely lacking."

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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 a 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 Mithra CDMO. Mithra was founded in 1999 as a spin-off of the University of Liège by Mr. François Fornieri and Prof. Dr. Jean-Michel Foidart and is headquartered in Liège, Belgium. Further information can be found at: www.mithra.com

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