



## MITHRA ANNOUNCES PRESENTATION OF DONESTA® RESULTS AT THE INTERNATIONAL MENOPAUSE SOCIETY'S 16<sup>TH</sup> WORLD CONGRESS

**Liège, Belgium, 8 June 2018** – Mithra (Euronext Brussels: MITRA), a company specialized in Women's Health, today presents its Phase IIb results for Donesta® at the International Menopause Society's 16<sup>th</sup> World Congress on menopause (Vancouver, Canada).

Donesta® is Mithra's next-generation hormone therapy (HT) product candidate with oral administration of Estetrol (E4) for the treatment of Vasomotor Symptoms (VMS), and in particular hot flushes relief, in post-menopausal women. Mithra recently announced positive top-line results, showing a significant improvement on the frequency and severity of hot flushes, as well as on secondary menopausal symptoms such as VVA, while indicating a beneficial safety profile.

The following key notes lectures will be presented at a dedicated Symposium titled *Estetrol (E4) development update: a new horizon for post-menopausal women?* :

- Prof. J.-M. Foidart: *Introducing the first NEST in menopause (native estrogen with selective tissue activity)*
- Prof. Roger Lobo (University of Columbia, New York): *Estetrol: Towards the development of a new generation of hormonal therapy: update on clinical development*

Mithra also presents a poster titled *Estetrol, the Next Generation of Hormone Therapy: Update on Clinical Development*. The poster and presentations will be made available in the Investor section of the Company's website at [investors.mithra.com](http://investors.mithra.com).

**Prof. Jean-Michel Foidart, MD, Perpetual Secretary of the Royal Academy of Medicine of Belgium:** *"The results of the Donesta® study are promising indeed. The 15 mg E4 dose significantly reduces the frequency and severity of hot flushes as well as bothersome secondary symptoms such as VVA. Moreover, the detailed statistical analyses further reinforce the robustness of the results.*

*The safety profile with regard to hemostatic and metabolic factors is very encouraging and coherent with the previous Phase II data findings in contraception (Estelle®). Both the Estelle® and Donesta® studies show that E4's mixed agonist/antagonist estrogenic activity supports its distinctive profile and added clinical benefits.*

*Hence, we are fully aligned with our advisors and KOLs in the recommendation to pursue the development of Donesta®, and to move the product candidate into Phase III trials to further confirm these promising results. If approved, Donesta® may offer a next-generation hormonal therapy, with an improved benefit/risk profile, to women suffering from menopausal symptoms worldwide."*

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Donesta® is a next generation orally-administered hormone therapy based on E4 for vasomotor menopausal symptoms (VMS). In May 2016, Donesta® entered into a European Phase II dose-ranging study, *E4 Relief* (MIT-Do0001-C201) in 257 women aged 40-65 in the Czech Republic, Poland, Belgium, Ireland and the UK, 200 of whom completed a treatment period of 12 weeks. Four doses of E4 (2.5 mg, 5 mg, 10 mg and 15 mg) compared to placebo were tested to establish the minimum effective dose. For non-hysterectomized women, E4 therapy is followed by a progestin therapy (Dydrogesterone 10 mg) for 2 weeks as a protective measure to curb any endometrial growth.

The primary endpoint is an evaluation of the changes in frequency and severity of moderate to severe VMS (vasomotor symptoms or hot flashes). Secondary outcomes include: (1) evaluation of the effects of different doses on vulvovaginal atrophy, on vaginal maturation index and on vaginal pH; (2) evaluation of additional secondary endpoints, including bone parameters, lipid & glucose metabolism, hemostatic laboratory variables, PK and women satisfaction; (3) a safety assessment, with most importantly a measurement by transvaginal ultrasonography of the change in endometrial thickness at each study visit.

**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](http://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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