



## PRESENTATION OF DONESTA® PHIB RESULTS AT THE 2018 ANNUAL MEETING OF THE NORTH AMERICAN MENOPAUSE SOCIETY

**Liège, Belgium, October 3<sup>rd</sup> 2018** – Mithra (Euronext Brussels: MITRA), a company specialized in Women's Health, today announces its Phase IIb results for Donesta® will be presented at the 29<sup>th</sup> Annual Meeting of the North American Menopause Society (NAMS), being held on 3-6 October 2018 in San Diego, CA.

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 relief from hot flushes in post-menopausal women. In May, Mithra 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 VulvoVaginal Atrophy (VVA), while indicating a beneficial safety profile.

There will be an oral presentation covering the Donesta® PhIIb data entitled "*Estetrol, the Next Generation of Hormone Therapy: Results of a Phase IIb Dose-finding Study in Postmenopausal Women (E4 Relief)*" on 5<sup>th</sup> October 2018 at 4:30 pm.

**Maud Jost, E4 Program Director, commented:** "*The presentation of data from the E4 Relief trial provides further evidence of the potential of Estetrol in the treatment of menopausal symptoms. This is the second high profile conference where our compelling data from our promising Donesta® program is presented. Preparations are already underway to progress Donesta® into Phase III trials, which if approved could provide an innovative alternative to the millions of women seeking a treatment with an improved benefit and risk profile.*"

The presentation will be made available on Monday in the Investor section of the company's website at [investors.mithra.com](http://investors.mithra.com).

\*\*\*\*\*

### For more information, please contact:

#### Investor Relations & Press

**François Fornieri (CEO):** +32 4 349 28 22

**Jean-Manuel Fontaine (PRO):** +32 (0)476 96 54 59

[investorrelations@mithra.com](mailto:investorrelations@mithra.com)

### About the *E4 Relief* Donesta® Phase II study

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 flushes). 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.*

To subscribe to Mithra's mailing list, visit [investors.mithra.com](http://investors.mithra.com)