



## Mithra Announces Donesta® Phase III Clinical Program Update

**Liege, Belgium, 01 April 2020 – 17:45 CEST** – Mithra (Euronext Brussels: MITRA), a company dedicated to Women's Health today announces an update on the Donesta® Phase III Clinical Program called "E4 Comfort", which aims at enrolling approximately 2200 menopausal women (40-65 years) and includes two pivotal studies: in North America (United States/Canada) launched in October 2019<sup>1</sup>, and in Europe, Russia and South America launched in December 2019<sup>2</sup>. For each pivotal study, women will be recruited in about 120 sites in the concerned areas.

In light of the current global covid-19 crisis, Mithra confirms that E4 Comfort studies are still ongoing at this time, but that current patient recruitment has been delayed or put on hold in some countries. As the evolution of the health crisis cannot be predicted at present, it is possible that the global recruitment stage of the studies be further delayed compared to the initial schedule. Mithra however intends to make every effort to recover any potential delay endured during this crisis and has already put in place a safety management plan at all its active sites, in accordance with the guidelines of the respective competent health authorities.

**Graham Dixon, CSO Mithra Women's Health, commented:** *"From the beginning of this crisis triggered by covid-19, Mithra has taken all the necessary measures to pursue its R&D program, in strict compliance with the worldwide guidelines of Health Agencies. Our top priority is above all the safety of all people involved in our Donesta® Clinical Program, not only the patients, but also the nurses and physicians. We have implemented all of the recommended measures taken by country-and local governments, particularly in terms of social distancing (e.g. use of phone/video calls with patients, use of postal services to send follow-up materials to patients,...). We continue to monitor the situation closely and will take the necessary measures to ensure the safety of the patient and to preserve the validity of the study. It is our responsibility to support without fail the decisions of our authorities, while pursuing as far as possible our scientific mission to develop innovative products."*

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### About Mithra

*Mithra (Euronext: MITRA) is a Belgian biotech company dedicated to transforming Women's Health by offering new choices through innovation, with a particular focus on contraception and menopause. Mithra's goal is to*

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<sup>1</sup> [Press release Mithra](#), 09/10/2019

<sup>2</sup> [Press release Mithra](#), 30/12/2019

develop products offering better efficacy, safety and convenience, meeting women's needs throughout their life span. Its three lead development candidates are built on Mithra's unique native estrogen platform, Estetrol (E4): Estelle<sup>®</sup>, a new era in oral contraception, PeriNesta<sup>®</sup>, the first complete oral treatment for perimenopause and Donesta<sup>®</sup>, the next-generation hormone therapy. Mithra also develops and manufactures complex therapeutics in the areas of contraception, menopause and hormone-dependent cancers. It offers partners a complete spectrum of research, development and specialist manufacturing at its technological platform Mithra CDMO. Active in more than 85 countries around the world, Mithra has an approximate headcount of 250 staff members and is headquartered in Liège, Belgium. [www.mithra.com](http://www.mithra.com)

### About E4 Comfort Phase III Program

The Donesta<sup>®</sup> Phase III study program includes 2 studies which design is a worldwide randomized, multicenter, double-blind, placebo-controlled trial. The studies primary objective is to measure the effect of treatment with different E4 doses (15mg and 20 mg) compared to placebo on frequency and severity of moderate to severe VMS in menopausal women at 4 and 12 weeks. Secondary objectives include the evaluation of the effect of the treatment on a series of additional key efficacy and safety parameters. The North American study (United States/Canada) is aimed at enrolling 1000 menopausal women between 40 and 65 years. The second pivotal study will be conducted in 12 countries (Europe, Russia, South America) with about 1200 menopausal women. For each pivotal study, women will be recruited at about 120 sites in the concerned areas. For more information about the E4 Comfort Phase III program, please visit [www.clinicaltrials.gov](http://www.clinicaltrials.gov)

### 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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