



First patient recruited for Donesta® Phase III Clinical Study in Europe

- **Recruitment of the first patient for the second pivotal Donesta® Phase III study conducted in 12 countries in Europe, Russia and South America**
- **“E4 Comfort” Phase III Clinical Program for Donesta® successfully launched in October 2019 with recruitment of first patient for North American study**
- **Phase III Program aimed at enrolling approximately 2200 menopausal women with vasomotor symptoms**

Liege, Belgium, 31 December 2019 – 7:30 CET – Mithra (Euronext Brussels: MITRA), a company dedicated to Women’s Health, today announces the recruitment of the first patient for the second pivotal Phase III Donesta® clinical study. Donesta® is a next generation orally-administered E4-based hormone therapy product candidate for the relief of menopausal vasomotor symptoms (VMS).

The Donesta® Phase III study program called “E4 Comfort” includes two pivotal studies: in North America (United States/Canada) launched in October 2019¹, and in Europe, Russia and South America, which just began. E4 Comfort are worldwide randomized, multicenter, double-blind, placebo-controlled trials. The studies’ primary objective is to measure the effect of treatment on frequency and severity of moderate to severe VMS (i.e. hot flashes), with different doses of E4 (15mg and 20 mg), in menopausal women at 4 and 12 weeks of treatment. 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 approximately 1000 menopausal women between 40 and 65 years. The second pivotal study (Europe/Russia/South America) will be conducted with about 1200 menopausal women. For each pivotal study, women will be recruited at about 120 sites in the concerned areas. The Phase III Program, entirely funded by Mithra, should be completed over a period of two years.

Depending on the study results and regulatory approvals, Mithra believes that marketing authorization for Donesta® could be granted in 2023. Ongoing patent applications would protect Donesta® intellectual property rights until 2039. Furthermore, Mithra remains focused on establishing the best commercial partnerships for this product. The global menopause market currently stands at USD 12.6 billion and is expected to grow to approximately USD 16 billion by 2025².

For more information about the E4 Comfort Phase III program, please visit www.clinicaltrials.gov (North American study online [NCT04090957](https://clinicaltrials.gov/ct2/show/study/NCT04090957) - Europe/Russia/South America study available in the coming weeks).

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

² Transparency Market Research 2017

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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 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 (Esetrol). 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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