Mithra Announces Positive DSMB Safety Review and Continuation of its Phase III Clinical Program Donesta® in menopause

- **Independent Data Safety Monitoring Board (DSMB) confirms the acceptable safety profile of Donesta® and recommends to continue the Phase III Clinical Program as planned**
- **On track to target marketing authorization in 2023**
- **Consolidation of business development strategy of Donesta® by successful major funding transactions in 2020**

Liege, Belgium, 16 December 2020 – 7:30 CET – Mithra (Euronext Brussels: MITRA), a company dedicated to Women's Health today announces that its independent Data and Safety Monitoring Board (DSMB) completed its end-of-year safety assessment of the Phase III Clinical Program of Donesta®, a next generation orally-administered E4-based hormone therapy product candidate for the relief of menopausal vasomotor symptoms (VMS).

The independent board of experts confirmed an expected pharmacological profile during the trial from initiation until the safety evaluation of 1.369 patients treated, and recommended to continue the studies without modification. As per study protocol, the DSMB meets quarterly to review the safety data of the Phase III Donesta® Study and issues recommendations on the conduct of the study.

Graham Dixon, CSO Mithra Women's Health, commented: *"This positive recommendation from our independent board of experts confirms the safety profile of Estetrol in addition to the data already obtained on Estelle® contraceptive. Since the beginning of the Covid pandemic, we have put in place a safety management plan for our active sites and have made every effort to ensure patient safety, trial integrity and good progress of the studies in the different regions. The conclusion of the DSMB allows us to continue our clinical program as planned, with results expected in the first half of 2022. We remain confident in the promising potential of Donesta® as a next generation alternative addressing the unmet needs of menopausal women."*

Launched in late 2019, the Donesta® Phase III clinical program called "E4 Comfort" aims to recruit approximately 2,200 postmenopausal women (40-65 years) and includes two pivotal studies: one in North America (United States/Canada); one in 14 countries in Europe, Russia and America. Both studies 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 flushes), 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.

Depending on the evolution of the Covid-19 situation and regulatory approvals, Mithra believes it could achieve marketing authorization for Donesta® in 2023. Thanks to the recent consolidation of Mithra's Estetrol patent portfolio[1], Donesta® is protected until 2036 in Europe, with a similar patent application filed in the United States.

[1] Press release Mithra, 30/11/2020

Furthermore, major funding transactions in 2020 for a total of EUR 260 million[2] reinforces Mithra's business development strategy for Donesta®, targeting major global partners in women's health while generating more data in the Phase III trial. The global menopause market currently stands at nearly USD 13 billion, which is expected to grow to approximately USD 16 billion by 2025[3].

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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 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®, a new era in oral contraception, PeriNesta®, the first complete oral treatment targeting perimenopause and Donesta®, 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 100 countries around the world, Mithra has an approximate headcount of 250 staff members and is headquartered in Liège, Belgium. 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.

[2] Press release Mithra, 24/09/2020 and 10/12/2020

[3] Transparency Market Research 2017