Mithra Receives Positive DSMB Opinion on DONESTA® European Phase 3 Trial

- The DSMB recommends continuing the phase 3 trial in Europe following regular safety assessment
- The menopause phase 3 program has previously reported positive top-line data; extension to Europe trial ongoing
- Additional endometrial data analyses ongoing for inclusion in regulatory submissions
- Mithra plans to submit DONESTA® for approval by U.S. and European regulators in Q4 2024

Liege, Belgium, 18 December 2023 – 7:00 CET – Mithra (Euronext Brussels: MITRA), a company dedicated to Women's Health, today announces it has received a positive review from the independent Data and Safety Monitoring Board (DSMB) on its phase 3 program for DONESTA®, its investigational, next generation hormone therapy medicine containing estetrol (E4) for the treatment of the symptoms of menopause.

All clinical investigations involving greater than minimal risk to participants are, at a minimum, required to develop a data and safety monitoring plan to assure the safety and welfare of the participants. The DSMB experts completed their latest regular safety assessment of the randomized, multicentred and double-blind phase 3 trial of DONESTA® in Europe (C301), which has recruited 300 additional menopausal non-hysterectomised women, and recommended to continue the study extension. The last patient-out is expected in Q1 2024. Positive efficacy top line results have been previously reported from the menopause phase 3 program, including the European trial. Top level safety conclusions were reported as well from the US trial (C302). Mithra plans to submit DONESTA® for the treatment on menopause symptoms for approval by regulators in the U.S. and Europe in Q4 2024.

Graham Dixon, Chief Scientific Officer of Mithra, commented, "This DSMB recommendation allows us to continue the extension of the DONESTA® phase 3 trial in Europe, which will generate important data for our marketing authorization applications. The role of the DSMB is to review the safety profile of a treatment during the clinical study, and to independently safeguard the interests of study participants. The DSMB review general safety data and endometrial safety data across the studies at regular, pre-defined intervals while the clinical studies are ongoing. The DSMB's decision is a testament to the safety of DONESTA®— our next generation orally administrated E4-based hormone therapy product candidate— which offers a potential long-term solution for treating various symptoms of menopause."

E4 is the first native and selective estrogen, present in developing human fetuses and is manufactured from a plant-based source. It acts differently from classical estrogens and its

unique metabolism results in a low impact on haemostasis and breast tissue with an expected improvement in the benefit-to-risk profile.

In early 2022, Mithra announced positive top-line efficacy results of the DONESTA® phase 3 program, which demonstrated a meaningful reduction in vasomotor symptoms of menopause (VMS) from baseline and compared to placebo with all co-primary efficacy endpoints statistically met. Data also showed improved quality of life and reduction of genito-urinary symptoms of menopause, as secondary efficacy endpoints. Promising top-line safety results from the phase 3 trial in North America (C302) were announced in 2023, and primary safety data from the European trial are expected in H1 2024.

Mithra has agreed with the US Food and Drug Administration (FDA) that it will conduct additional endometrial data analyses, due to a variation observed by Mithra in the endometrial biopsy diagnoses, which could have resulted in a limited addressable market for DONESTA®. The US new drug application (NDA), including the complementary data, is expected in Q4 2024. This additional safety data is foreseen to be included in the European Medicines Agency (EMA) and FDA submissions, planned within the same time frame.

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About Mithra

Mithra Pharmaceuticals SA (Euronext: MITRA) is a Belgian biopharmaceutical 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. Mithra explores the potential of the unique native estrogen estetrol in a wide range of applications in women health and beyond. After having successfully launched the first estetrol-based product in 2021, the contraceptive pill ESTELLE®, Mithra is now focusing on its second product DONESTA®, the next-generation hormone therapy. Mithra also offers partners a complete spectrum of solutions from early drug development, clinical batches and commercial manufacturing of complex polymeric products (vaginal ring, implants) and complex liquid injectables and biologicals (vials, pre-filled syringes or cartridges) at its technological platform Mithra CDMO. Active in more than 100 countries around the world, is headquartered in Liège, Belgium. www.mithra.com

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