DONESTA® safety study for menopause completes treatment phase and advances to data management & reporting phase

- Mithra on-track for completion of Phase 3 study for DONESTA® to treat vasomotor symptoms (VMS) in menopause
- Mithra begins patient recruitment for the three proof-of-concept studies to explore treatment of symptoms beyond VMS

Liege, Belgium, 28 February 2024 – 17:45 CET – Mithra (Euronext Brussels: MITRA), a company dedicated to women's health, announces an achievement in its clinical research efforts in menopause and the C301 Endometrial Safety Study. The last patient-out milestone was reached on 08 February 2024, marking the completion of patient treatments and the initiation of the data management/reporting phase.

The C301 study assessing the therapeutic value of estetrol (E4) in post-menopause is a crucial component for the company's submissions in both the United States and the European Union. The positive progress and timely completion of this phase reinforce the company's commitment to meeting its final Clinical Study Report (CSR) timeline. All indicators currently signal green, further reinforcing the company's optimism in receiving positive top line results and completing the CSR later this year. Mithra is on track to submit DONESTA® for the treatment of vasomotor symptoms of menopause in the U.S. and Europe in Q4 2024.

Mithra remains dedicated to pioneering medical advancements, and the positive developments in the C301 study underscore our commitment to delivering innovative solutions that address critical healthcare needs.

In addition to the success of the C301 study, Mithra also announces the approval of the competent authorities and ethics committees for all protocols for its clinical program extension to explore treatments beyond VMS in post-menopausal women. The clinical program extension encompasses various studies focusing on dermatological and reproductive health, including the following:

- Skin Study - A single-centered, randomized, double-blind, placebo-controlled proof of concept study in Germany is currently in progress, evaluating the effect of estetrol on skin parameters (skin roughness and skin elasticity) in post-menopausal women. The recruitment of the 60 participants is ongoing. Top-line results are anticipated by the end of 2024.

- Hair Study - A single-centered randomized, double blind, placebo-controlled proof of concept study in Germany is currently underway. This study will assess the effect of estetrol on various hair growth parameters in postmenopausal women with female pattern hair loss. Top-line results for this study are expected by Q1 2025.
- FSAD Study - A multicentric, randomized, double-blind, placebo-controlled proof-of-concept study conducted in the United States to evaluate the efficacy of estetrol in postmenopausal women with Female Sexual Arousal Disorder (FSAD). This study has reached a significant milestone, with the first patient screened at the end of January 2024. Recruitment is ongoing, and top-line results are anticipated by Q2 2025.

Graham Dixon, Chief Scientific Officer of Mithra, commented, "These projects highlight Mithra's commitment to demonstrate beneficial effects of E4 on other bothersome symptoms of menopause beyond VMS. The European study (C301) should reinforce the differentiated safety profile of E4, supporting further the broad therapeutic potential of this molecule. As Mithra manages its business challenges, the R&D team remains focused on supporting our estetrol platform to ensure that patients have access to our differentiated therapeutics. The advancements announced today showcase Mithra's resilience and determination in navigating the complex landscape of clinical research, further solidifying its position as a leader in Women's Health."

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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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