



## Mithra reaches milestone in estetrol skin study

- Mithra achieves last patient randomized concluding recruitment phase of study to explore the various effects of estetrol (E4) on patients' skin to further demonstrate the beneficial effects of E4 beyond VMS in postmenopausal women
- Top-line results expected to be completed by the end of 2024 with the final clinical study report expected by Q2 2025

**Liege, Belgium, 08 April 2024 – 17:45 CEST** – Mithra (Euronext Brussels: MITRA), a company dedicated to women's health, today announces a significant milestone in its ongoing clinical program extension to explore treatments beyond vasomotor symptoms (VMS) in postmenopausal women. An update of this study was last provided on [28 February 2024](#). Mithra has achieved the last patient randomized (LPR) in this study, marking the culmination of the recruitment phase.

The study, titled "*Randomized, double-blind, placebo-controlled, pilot proof-of-concept study to evaluate the effect of estetrol (E4) on skin parameters in postmenopausal women with vasomotor symptoms*," was conducted at a single site in Germany. The study randomized a total of 66 postmenopausal women to receive either E4 or placebo over a duration of 6 months.

The primary endpoints of the study are skin elasticity and skin roughness, while key secondary endpoints included collagen content, skin hydration, skin thickness, skin dryness, and quality of life. In addition to dermatological efficacy endpoints, the study also collected gynecological/general safety data, such as treatment-emergent adverse events.

Collection of top-line results is expected to be completed by the end of 2024, with the final clinical study report (CSR) expected by Q2 2025.

"We are excited to have achieved this crucial milestone in our skin study," said **Graham Dixon, Chief Scientific Officer of Mithra**. "The completion of patient randomization signifies a significant step forward in our quest to evaluate the effects of estetrol on skin parameters in postmenopausal women with VMS. While no unexpected safety events have been reported thus far, we continue to prioritize the safety and well-being of our study participants, working closely with our medical monitor to ensure thorough oversight. We are optimistic about the potential impact of our findings as we look to further demonstrate the beneficial effects of E4 beyond VMS in postmenopausal women."

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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<sup>®</sup>, Mithra is now focusing on its second product DONESTA<sup>®</sup>, 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](http://www.mithra.com)*

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