



Mithra and the University of Liège Secure Proof-of-Concept for Novel Manufacturing Process of Estetrol

Collaboration demonstrates Mithra's commitment to innovation and sustainable drug supply in Women's Health

Liege, Belgium, 04 May 2023 – 7:30 CEST – Mithra (Euronext Brussels: MITRA), a company dedicated to Women's Health, today announces that through a collaboration with researchers from the University of Liège's Center for Integrated Technology and Organic Synthesis (CiTOS), proof-of-concept has been demonstrated for a novel manufacturing process of a key estetrol intermediate.

Estetrol (E4), Mithra's core asset, is a natural estrogen with potential applications across multiple therapeutic fields including Women's Health (contraception and menopause). After successfully launching the first estetrol-based product in 2021, the contraceptive pill Estelle®, Mithra continued to work towards innovation in manufacturing aimed at reducing cost of goods and potential environmental impact through the removal of a metal catalyst in the production process.

The Mithra and CiTOS teams have developed a novel, intensified manufacturing methodology to improve robustness and productivity while ensuring a limited environmental footprint. The new metal-free process is based on the thermolysis of a key sulfoxide derivative of estrone. Early proof of concept for this novel methodology was published in the peer-reviewed industry journal *Reaction Chemistry & Engineering* earlier this year [here](#).

Mithra and CiTOS will continue their development work, with initial commercial production by a CDMO using the enhanced manufacturing process expected in 2026/27.

David H Solomon, Chief Executive Officer of Mithra, commented: « *Mithra's collaboration with CiTOS demonstrates our commitment to innovation and sustainable drug supply in women's health. With the mass production of estetrol integral to our daily activities, we are always looking at ways we can enhance the manufacturing process. This particular method allows us to produce estetrol at scale to meet increased demand while also delivering reduced cost of goods.* »

Jean-Christophe Monbaliu, Professor of Organic Chemistry at the University of Liège, added: « *With this novel methodology we are able to yield about 1kg of the estetrol intermediate every three hours in just our pilot setup. If we applied these metrics to an industrial estetrol production setup, a forecast of several tons, is achievable with minimal global footprint.* »

For more information, please contact:

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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. 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, Mithra has an approximate headcount of 230 staff members and is headquartered in Liège, Belgium. www.mithra.com

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