



## Mithra Receives EUR 1.25 Million Milestone Payment from Fuji Pharma under Estelle® Licensing Agreement

- *Relates to completion of the interim clinical study reports of Phase 3 trials in patients with dysmenorrhea or endometriosis*
- *Marks strong progress in 2016 agreement and further boosts Mithra cash position*
- *Additional EUR 12.5 million milestone payments scheduled prior to commercialization*
- *Mithra eligible for revenue from supply of the manufactured product post-commercialization*

**Liege, Belgium, 3 August 2023 – 07:30 CEST** – Mithra (Euronext Brussels: MITRA), a company dedicated to Women's Health, today announces it has received a milestone payment of EUR 1.25 million from its partner Fuji Pharma, the Japanese leader in women's health, under a license and supply agreement for its Estetrol (E4) native estrogen-based product Estelle® in Japan and ASEAN territories.

The payment was triggered by completion of the interim clinical study reports of Phase 3 trials investigating Estelle® for the treatment of Japanese patients with dysmenorrhea or endometriosis. Fuji announced positive top-line results from the double-blind, placebo-controlled studies in February 2023, showing the first trial met its primary endpoint by demonstrating a statistically significant difference for the change in the total dysmenorrhea score when compared to placebo. The second trial in patients with endometriosis also met its primary endpoint by demonstrating a statistically significant difference for the change in the Visual Analog Scale for the most severe pelvic pain when compared to placebo.

It is the second milestone payment received by Mithra under this agreement with Fuji, which was signed in 2016. The first milestone of EUR 1.25 million was received by Mithra upon completion of Phase 3 trials in Europe and the United States. Mithra remains eligible to receive a further EUR 12.5 million in total milestones prior to commercialization and to receive revenue from supply of the manufactured product post-commercialization.

**David Horn Solomon, Chief Executive Officer of Mithra, commented:** "We are pleased with the strong progress made by our partner Fuji Pharma with Estelle®. This EUR 1.25 million milestone payment marks strong Phase 3 results, which indicate that this could be an excellent treatment for patients with dysmenorrhea and endometriosis, and will further boost Mithra's balance sheet, as we pursue our aim of becoming a global leader in women's health. We are looking forward to continuing our close cooperation with Fuji as we work to bring Estelle® to patients in Japan and ASEAN territories."

Estelle®, Mithra's first E4-based product composed of 15 mg Estetrol (E4) and 3 mg Drospirenone (DRSP), is commercialized as a combined oral contraceptive in the US (NEXTSTELLIS®), Canada (NEXTSTELLIS®), and Europe (DROVELIS® and LYDISILKA®).

Mithra's core asset Estetrol (E4) is a native estrogen produced by the human fetus during pregnancy, passing into maternal blood at relatively high levels. Because of its unique mode of action and safety profile, Estetrol could represent a major breakthrough in various therapeutic fields of women's health and beyond.

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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, Mithra has an approximate headcount of 230 staff members and is headquartered in Liège, Belgium. [www.mithra.com](http://www.mithra.com)*

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*DROVELIS<sup>®</sup> is a registered trademark of Richter Gedeon Nyrt.*

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