



## Early data from Mithra's ESTELLE® pediatric study to be presented at two upcoming congresses

- Abstracts accepted to the ESC Bilbao and EURAPAG Thessaloniki congresses
- The study provides insights into safety, compliance, and bleeding profiles of ESTELLE® contraceptive use in post-menarchal adolescents, raising no new safety concerns

**Liege, Belgium, 16 April 2024 – 17:45 CEST** – Mithra (Euronext Brussels: MITRA), a company dedicated to women's health is proud to announce the acceptance of an abstract presenting the design and findings of a pediatric study involving ESTELLE®, Mithra's first product based on estetrol (E4), at two renowned congresses.

ESTELLE®, Mithra's first E4-based product is commercialized as a combined oral contraceptive in the US and Canada under the brand name NEXTSTELLIS® and in Europe by Gedeon Richter as DROVELIS®.

The abstract, showcasing the pediatric study conducted in adolescents, has been accepted for oral presentation at both the ESC Bilbao (1-4 May 2024) and EURAPAG Thessaloniki (5-8 June 2024) congresses. The presenting authors are esteemed experts in the field: Prof. Kristina Gemzell-Danielsson will present at ESC Bilbao, while Prof. Dan Apter will present at EURAPAG Thessaloniki.

Combined oral contraceptives (COCs) such as ESTELLE® are widely used among adolescents for contraception<sup>1</sup>, as well as cycle and bleeding control. However, despite their popularity<sup>2</sup>, clinical data specific to this age group remains limited.

To address this gap, Mithra undertook this study under a Pediatric Investigation Plan (PIP) agreed with the European Medicines Agency (EMA) to conduct a phase 3, open-label, single-arm study across 23 centers in Europe (MIT-Es001-C303, ClinicalTrials.gov: NCT04792385, EudraCT: 2019-003002-27). The study aimed to assess the safety and tolerability of ESTELLE® in healthy post-menarchal females aged 12 to 17 years over six cycles.

Out of 145 initially screened participants, 112 were enrolled, with 89 completing the study. The last subject's last visit was concluded in November 2023. The mean age of participants

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<sup>1</sup> Jones RK. *Beyond birth control: the overlooked benefits of oral contraceptive pills*. New York, NY : Guttmacher Institute; 2011

<sup>2</sup> Todd N and Black A *Contraception for Adolescents J Clin Res Pediatr Endocrinol 2020;12(Suppl 1):28-40*

was 15.2 years, with most being first-time users of oral contraceptives and/or experiencing dysmenorrhea.

The study provides valuable insights into the safety, compliance, and bleeding profiles of ESTELLE® in post-menarchal adolescents. Importantly, no new safety signals were observed.

"We are very pleased to share the findings of our pediatric study at these prestigious congresses," said Graham Dixon, Chief Scientific Officer of Mithra, "This research underscores our commitment to advancing the understanding of women's health and ensuring the safety and efficacy of our products for all age groups."

Additionally, medicines authorized across the EU with results from a PIP included in the product information are eligible for a six-month extension of their supplementary protection certificate.

### For more information, please contact:

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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](http://www.mithra.com)*

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