



## Mithra announces completion of recruitment in pediatric study of Estelle in adolescent patients

Trial designed to address limited clinical data in this population despite widespread use of Combined Oral Contraceptives (COC) in adolescents

**Liege, Belgium, 11 May 2023 – 7:30 CEST** – Mithra (Euronext Brussels: MITRA), a company dedicated to Women's Health, today announces that the pediatric study of Estelle® in adolescent patients has completed recruitment. Data from the study is expected to be available in H1 2024.

Developed by Mithra, Estelle is the first and only contraceptive pill containing Estetrol (E4), the only estrogen native to human pregnancy. The objective of the pediatric study (MIT-Es001-C303, ClinicalTrials.gov: NCT04792385, EudraCT: 2019-003002-27) is to evaluate the safety, compliance, and pharmacokinetics profile of Estelle (estetrol monohydrate 15 mg and drospirenone 3 mg) in 100 participants aged 12 to 17 years old, as agreed with regulatory authorities. The study is being conducted in a number of European countries (Estonia, Finland, Georgia, Latvia, Poland, Sweden).

**Graham Dixon, Chief Scientific Officer of Mithra**, commented: « *The completion of recruitment for this pediatric study represents an important milestone in our commitment to bringing Estelle to a wider patient population. We look forward to reporting data from this trial in 2024 and expanding the body of scientific data available to clinicians to support their decision-making.* »

**Professor Kristina Gemzell-Danielsson, Chair of Obstetrics and Gynecology and Head of the Department of Women's and Children's Health, Karolinska Institutet, and Karolinska University Hospital, Stockholm, Sweden**, commented: « *Combined Oral Contraceptives such as Estelle are the most popular hormonal contraceptives<sup>1</sup> in the adolescent population, and adolescents are more likely than adult women to use these products for health purposes other than birth control such as cycle and bleeding control<sup>2</sup>. Despite widespread use in adolescents, clinical data from this population is limited. Studies such as this one are needed in order to bring safe and effective contraceptives to those that need it most.* »

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1. [Todd N and Black A Contraception for Adolescents J Clin Res Pediatr Endocrinol 2020;12\(Suppl 1\):28-40](#)

2. [Jones RK. Beyond birth control: the overlooked benefits of oral contraceptive pills. New York, NY: Guttmacher Institute; 2011](#)

**For more information, please contact:**

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### **About Estelle®**

*Developed by Mithra, Estelle® is a novel patent protected combined oral contraceptive pill containing 3 mg drospirenone (DRSP) and 15 mg estetrol (E4). E4 is a naturally produced estrogen during pregnancy, which can now be made from a plant source. In two phase 3 clinical studies conducted in 3,725 women, Estelle® was shown to be both safe and effective and met its primary efficacy endpoint of pregnancy prevention. It also delivered excellent results on a variety of secondary endpoints that demonstrated outstanding cycle control, bleeding control, safety, and tolerability. Mithra has signed 15 licensing deals for Estelle® with a number of leading women's health companies covering more than 100 countries in the world.*

*The product is marketed in Belgium by Gedeon Richter under the brand name Drovelis® and by Ceres Pharma under the brand name Lydisilka®.*

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

*ESTELLE®, DONESTA® and MYRING® are registered trademarks of Mithra Pharmaceuticals or one of its affiliates.*

### Important information

*The contents of this announcement include statements that are, or may be deemed to be, "forward-looking statements". These forward-looking statements can be identified by the use of forward-looking terminology, including the words "believes", "estimates," "anticipates", "expects", "intends", "may", "will", "plans", "continue", "ongoing", "potential", "predict", "project", "target", "seek" or "should", and include statements the Company makes concerning the intended results of its strategy. By their nature, forward-looking statements involve risks and uncertainties and readers are cautioned that any such forward-looking statements are not guarantees of future performance. The Company's actual results may differ materially from those predicted by the forward-looking statements. The Company undertakes no obligation to publicly update or revise forward-looking statements, except as may be required by law.*

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