Mithra Completes Pediatric Study of ESTELLE® in Adolescent Patients

- Important milestone for Mithra's commitment to bring benefits of ESTELLE® to more women
- Potential EMA approval in pediatric population could lead to six-month extension of the Supplementary Protection Certificate (SPC)[1] and hence extended patent exclusivity
- Study recruited more than 100 adolescents, with primary aim to evaluate safety profile
- Last subject, last visit now completed, with data expected in Q2 2024

Liege, Belgium, 20 December 2023 – 17:45 CET – Mithra (Euronext Brussels: MITRA), a company dedicated to Women's Health, today announces the completion of a pediatric study of its marketed contraceptive ESTELLE® in adolescent women.

The study (MIT-Es001-C303, ClinicalTrials.gov: NCT04792385, EudraCT: 2019-003002-27) evaluates the safety, compliance, and pharmacokinetic profile of ESTELLE® in more than 100 participants aged 12 to 17 years old. The primary endpoint of the study, which is being conducted in Estonia, Finland, Georgia, Latvia, Poland and Sweden, is to evaluate the safety of ESTELLE® in post-menarchal subjects. Recruitment was completed in April 2023 and the last subject and last visit has now been held, with data expected to be available in Q2 2024.

Graham Dixon, Chief Scientific Officer of Mithra, commented, "The completion of this pediatric study on schedule is another important milestone for Mithra. It underlines our commitment to bringing the benefits of ESTELLE® to a broader patient population, as we continue to work to demonstrate its differentiated safety profile. With results from this study expected in Q2 2024, we are taking another step towards potentially offering ESTELLE®'s differentiated efficacy, safety, and convenience to additional female populations, effectively expanding our reach."

Combined oral contraceptives such as ESTELLE®, Mithra's first product based on estetrol (E4) naturally-occuring estrogen, are the most popular hormonal contraceptives[2] in the adolescent population. Adolescents are more likely than adult women to use these products for health purposes other than birth control such as cycle and bleeding control[3]. Despite widespread use in adolescents, clinical data from this population is limited.

Mithra is undertaking this study under a Pediatric Investigation Plan (PIP) agreed with the European Medicines Agency (EMA). Medicines which are authorized by the EMA, with the application include results from studies conducted under a PIP, are eligible for an extension of their SPC by six months.

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[1] Supplementary protection certificates (SPCs) are an intellectual property right that serve as an extension to a patent right

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

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

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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

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.