



E4/DRSP, a Novel Combined Oral Contraceptive, submitted to Brazilian regulatory authorities

Liege, Belgium, 17 November 2020 – 7:30 CET – Mithra (Euronext Brussels: MITRA), a company dedicated to Women's Health, today announced that the regulatory submission for E4/DRSP, a combined oral contraceptive containing estetrol (E4) and drospirenone (DRSP), has been submitted to the National Sanitary Surveillance Agency (ANVISA) by Mithra's commercial partner, Libbs, the Women's Health leader in Brazil.

Developed by Mithra, the product candidate is composed of 15 mg estetrol, a unique native estrogen and 3 mg drospirenone. E4 is produced by the human fetus, passing the maternal blood at relatively high levels during pregnancy. In two phase III clinical studies conducted in 3,725 women, E4/DRSP showed positive top-line results against primary efficacy and safety endpoints and achieved positive secondary endpoints including good bleeding profile, cycle control, and tolerability.

Graham Dixon, Chief Scientific Officer of Mithra Women's Health, commented: *"The submission to ANVISA completes the global regulatory submission process for Estelle® prior to the first expected approvals in H1 2021. With this submission, Libbs is on-track for potential market authorization in Brazil in H2 2022. To date, Estelle®'s submission has been accepted by the FDA, EMA and Health Canada, where we expect market authorization in H1 2021. We are excited by the upcoming arrival of Estelle® on the market, providing women with a new choice in oral contraception, combining efficacy with a much improved safety profile. Estelle® promises to be a major breakthrough in a space where there hasn't been any innovation in decades."*

For more information, please contact:

Alexandra Deschner (IRO - Mithra) : +32 490 58 35 23 – investorrelations@mithra.com

Carole Kousis (Press - Mithra) : +32 4 348 28 22 – press@mithra.com

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. Its three lead development candidates are built on Mithra's unique native estrogen platform, Estetrol (E4): Estelle®, a new era in oral contraception, PeriNesta®, the first complete oral treatment targeting perimenopause and Donesta®, the next-generation hormone therapy. Mithra also develops and manufactures complex therapeutics in the areas of contraception, menopause and hormone-dependent cancers. It offers partners a complete spectrum of research, development and specialist manufacturing at its technological platform Mithra CDMO. Active in more than 100 countries around the world, Mithra has an approximate headcount of 250 staff members and is headquartered in Liège, Belgium. www.mithra.com

About Estelle®

Estelle® is Mithra's novel combined oral contraceptive (COC) product candidate based on Estetrol (E4) 15 mg and drospirenone (DRSP) 3 mg. E4 is a native estrogen that is produced by the human fetus, passing the maternal blood at relatively high levels during pregnancy. In two phase III clinical studies conducted in 3,725 women, E4/DRSP showed positive top-line results against primary efficacy and safety endpoints and achieved positive secondary endpoints including good bleeding profile, cycle control, and tolerability. Mithra has signed 11 licensing deals for Estelle® with a number of leading women's health companies covering United States, Canada, Europe, Russia, Australia, Japan, South Korea, ASEAN, Brazil, Middle East, North Africa and Southern Africa.

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.

A circular icon with a teal background and white text that reads "News Alerts".

News
Alerts

Subscribe to our mailing list on investors.mithra.com to receive our press releases by email or follow us on our social media :

[Linkedin](#) • [Twitter](#) • [Facebook](#)