



Mithra Announces an Update on PeriNesta®

Liege, Belgium, 21 September 2021 –17:50 CEST – Mithra (Euronext Brussels: MITRA), a company dedicated to Women's Health, today announces an update on its Research & Development strategy regarding the PeriNesta® product candidate¹.

At inception, the PeriNesta® product candidate was intended to specifically target relief of hot flushes, and/or vasomotor symptoms (VMS), while providing effective contraception for women who are starting to exit the reproductive stage and are transitioning into postmenopause, a period called perimenopause. To do so, Mithra intended to conduct a safety study with a comparable formulation to E4 15 mg/DRSP 3 mg in women aged around 50 years of age affected by VMS².

Since no product has ever been approved for this specific indication, the Company held several discussions and meetings with the scientific community and the European and American regulatory agencies. As announced in March 2021, the Company also decided to work on alternative development strategies in addition to the initial scenario.

Following a strategic meeting held on September 20 & 21, 2021, the Board of Directors analyzed both regulatory agencies' feedback as for the initial development project of PeriNesta®, as well as the additional budget required to achieve this development in accordance with the regulatory expectations compared to the initial EUR 20 million. Accordingly, the Board decided that the initial PeriNesta® development project was no longer timely nor a priority for the Company and that alternative scenarios based on Estelle® and Donesta® could potentially target this perimenopausal market without incurring substantial development costs. Therefore, the targeted market authorization initially planned for 2023 is no longer achievable in this opportunistic development project.

After successfully launching earlier this year Estelle®, its first estetrol platform's product, the Company intends to make the enhancement of its second and major candidate product based on estetrol targeting menopause, Donesta®, an absolute priority. With this pipeline covering contraception and menopause, Mithra will explore in parallel the most judicious way to meet the specific needs of women during the transitional phase of perimenopause.

Graham Dixon, Chief Scientific Officer of Mithra Women's Health, commented: *"This specific period of women's lives remains completely unexplored. To date, there are no registered products to meet the needs of perimenopausal women. Yet, the needs associated with this period are real. The R&D development of such a product candidate therefore remains quite challenging, in particular from a regulatory perspective and feedback from agencies has convinced us to try and use one of our products for contraception and menopause in order to target this market. Our absolute priority is to further explore all the potentialities of estetrol in menopause within the Donesta® program, and to continue our investigations to develop innovative alternatives that will meet the unmet needs of women at every stage of their lives as well as improve, safely, their quality of life."*

¹ PeriNesta®, Estelle® and Donesta® are registered trademarks of Estetra SRL, an affiliate of Mithra Pharmaceuticals SA.

² [Press release Mithra_09/01/2019](#).

For more information, please contact:**Benoît Mathieu (IRO)** : +32 473 35 80 18 - investorrelations@mithra.com**Maud Vanderthommen (Press)** : +32 473 58 61 04 – 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. Mithra explores the potential of the unique native estrogen Estetrol in a wide range of applications in women health and beyond (Covid-19, neuroprotection...). 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 300 staff members and 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.

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](#)