



Mithra's exclusivity on Estetrol applications extended to 2036 in Europe

Thanks to a new patent relating to Estetrol applications, Mithra secures its future results. A similar process is underway for the US market.

Liège, Belgique, 30 novembre 2020 – 7:30 CET – Mithra (Euronext Brussels: MITRA), a company dedicated to Women's Health, today announces that it has been granted a new patent by the European Patent Office (EPO) relating to various pharmaceutical compositions containing Estetrol (E4) and their manufacturing process. In doing so, Mithra consolidates its exclusivity for the use of E4 in a wide range of indications such as the treatment of hormone-dependent cancers (breast and prostate in particular), dermatology, neuroprotection, dysmenorrhea and emergency contraception.

Since its creation, Mithra's ambition has been to transform the women's health sector by developing innovative products offering better efficacy, safety and convenience, meeting women's needs throughout their life span.

Following fruitful research, Mithra identified the health benefits of E4 and its countless potential applications, particularly in contraception and menopause treatment. Thanks to its unique mode of action, this native estrogen, recently recognized as New Active Substance (NAS) by EMA¹, is distinguished by a significant reduction of side effects that women suffer with conventional estrogens. Thanks to the exploitation of Estetrol, Mithra is developing two particularly innovative product candidates: Estelle®, a new era in combined oral contraception, and Donesta®, a new-generation hormonal treatment for vasomotor symptoms of menopause.

Based on the various results of preclinical and clinical research conducted to date, which confirm the efficacy of E4 in various therapeutic indications, Mithra has implemented an intellectual property strategy aimed at regularly patenting the various applications of E4 as well as the synthesis process of the molecule. The stakes are high: the world contraception market is worth €22 billion and it is estimated that 30% of women do not take the pill because they do not tolerate its side effects²; the menopause market is valued at nearly €13 billion and less than 10% of women resort to treatment for fear of side effects.

Falling within this strategy the recent decision of the European Patent Office (EPO) to grant Mithra a new patent related to Estetrol, extends and reinforces the 35 patent-family portfolio filed by the Belgian biotech company worldwide. Concretely, this decision guarantees Mithra effective exclusivity of Estelle® and Donesta® product candidates until 2036 in Europe. As far as the United States is concerned, a similar patent application has been filed by Mithra and is currently being examined by the United States Patent & Trademark Office (USPTO). In doing so, Mithra secures and strengthens the earnings prospects of its various Estetrol related products once they are approved for sale.

¹ [Mithra Press Release, 25/11/2020](#)

² K. Daniels et al., National Health Statistics report n° 62, 2013

François Fornieri, CEO of Mithra Women's Health, commented: *"The approval of this new patent by the European Patent Office is another important step in the commercialization strategy of our products. With a total of 35 patent families filed worldwide, 14 more families than at IPO, we have strong intellectual property protection around Estelle® and more broadly around our portfolio of Estetrol-based products. In parallel with the steps linked to their market launch, it is imperative to work towards their effective protection. By protecting our innovations from any possible competition, this protection is the best guarantee we can have of our future ability to generate results that meet our expectations."*

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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

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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