



Mithra obtains crucial additional Estelle® patent in Japan

- **Estelle®**, Mithra's oral contraceptive product candidate, has been granted a key patent for the dysmenorrhea indication in Japan, a four times larger market than the contraceptive one.
- Important milestone for the commercialization of Estelle® by Fuji Pharma in Japan and ASEAN¹, representing a total attractively priced market of EUR 400 million annual sales.
- Thanks to a solid Intellectual Property strategy, Estelle® will be protected from any generic competitor on the Japanese market until 2037 with a potential patent term extension of a maximum of 5 years.

Liege, Belgium, 8 August 2019 – 7 :30 CEST – Mithra (Euronext Brussels: MITRA), a company dedicated to Women's Health today announces that it has received an additional patent for Estelle® in Japan in the dysmenorrhea² indication. Estelle® is Mithra's combined oral contraceptive (COC) candidate, composed of 15 mg Estetrol (E4) and 3 mg drospirenone (DRSP).

Mithra considers Japan as one of its priority target territories for Estelle®, mainly due to the attractively priced and quite large market profile. This additional patent opens the door for the dysmenorrhea market, which is four times larger than the contraceptive market, particularly thanks to the attractive reimbursement rate. Together, the contraception and dysmenorrhea markets in Japan account for at least EUR 270 million a year³.

Mithra has already a business partner for the commercialization of Estelle® in Japan, but also in ASEAN where the contraception market represents about EUR 130 million a year. In August 2016, the Company has signed a 20-year exclusive license and supply agreement with Fuji Pharma, the Japanese leader in Women's Health. The terms of the agreement include a down payment, milestone payments, recurring revenues based on minimum annual quantities (MAQ) and further sales-related royalties. This agreement represents a potential deal value of EUR 450 million over the period.

Consolidation of the IP Strategy

The issuance of this patent covering the management of dysmenorrhea extends Estelle's IP protection in Japan until 2037. In addition, Mithra will apply for a patent term extension based on its marketing authorization for Estelle® in Japan, which should extend the patent lifetime for a maximum of 5 years. This patent application covering dysmenorrhea has also been filed in about 20 countries, mainly in Asia and Latin America where the dysmenorrhea market is particularly attractive in terms of sales volume and pricing.

¹ Association of Southeast Asian Nations (Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand and Vietnam)

² Dysmenorrhea refers to the symptom of painful menstruation.

³ IQVIA 2017

Mithra is continuously expanding and consolidating its Intellectual Property portfolio to further strengthen and extend the E4 intellectual property estate. This now contains 31 patent families filed across the world, ranging from the synthesis of Estetrol to its use in a wide range of indications, including among others, menopause, cancer treatment and neuroprotection.

François Fornieri, CEO Mithra Women's Health, comments: « *This new patent in Japan is crucial for the Estelle's commercialization strategy in this high potential market in volume and value, especially when considering the contraception and dysmenorrhea indications together. With our 31 patent families, we have built a very strong Intellectual Property protection around Estelle® and more broadly our portfolio of Estetrol-based products, securing our innovations from potential competitors in a large majority of countries around the world.* »

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About Mithra

Mithra (Euronext: MITRA) is dedicated to providing innovation and choice in Women's Health, with a particular focus on contraception and menopause. Mithra's goal is to develop new and improved products that meet women's needs for better safety and convenience. Its three lead development candidates – a fifth generation oral contraceptive Estelle®, the first complete oral treatment for perimenopause PeriNesta® and next-generation hormone therapy Donesta® - are built on Mithra's unique native estrogen platform, E4 (Estetrol). Mithra also develops and manufactures complex therapeutics and offers partners a complete spectrum of research, development and specialist manufacturing at its CDMO. Mithra was founded in 1999 as a spin-off from the University of Liège by François Fornieri and Prof. Dr. Jean-Michel Foidart. Mithra is headquartered in Liège, Belgium. Further information can be found at 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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