

## Mithra Signs Partnership Agreement With Itrom for Commercialization of Estelle® in the Middle East

- Mithra strengthens its presence in the Middle East with a third partnership with UAE<sup>1</sup>-based ITROM Pharmaceutical Group for the combined oral contraceptive Estelle®
- Following the publication of the positive top-line results of the Estelle® Phase III study, Mithra is intensifying its business development strategy of its potential contraceptive blockbuster in key international markets
- Agreement follows licensing deals for Estelle® with market leaders in Europe, Russia, Canada, Brazil, Japan, South Africa and South Korea

Liege, Belgium, 28 February 2019 - 7:30 CET - Mithra (Euronext Brussels: MITRA), a company dedicated to Women's Health, announces that it has signed a 20-year binding Head of Terms agreement with ITROM Pharmaceutical Group (ITROM) for the commercialization of Estelle® in the Middle East. Estelle® is Mithra's novel combined oral contraceptive (COC) product candidate, containing 15 mg Estetrol (E4) and 3 mg drospirenone (DRSP).

ITROM is a UAE-based pharmaceutical group specializing in breakthrough healthcare, with women's health placed at the forefront of its activities. The aim is to bring innovative and safe alternatives to women in the areas of fertility, contraception, Hormonal Therapy (HT) and personal care.

Under the terms of the agreement, ITROM will distribute Estelle® in MENA<sup>2</sup> territories (Saudi Arabia, United Arab Emirates, Bahrain, Kuwait, Qatar, Oman, Lebanon and Jordan) where the COC market is estimated at EUR 30 million a year3. This agreement represents a deal worth up to EUR 55 million over the period.

This third contract between Mithra and ITROM strengthens the partnership which began in December 2018. At that time, a licensing agreement was signed for two other Mithra products, the hormonal treatment Tibelia® and the contraceptive pill Daphne Continu4. In February 2019, Mithra signed a second deal for the commercialization of its combined hormonal contraceptive vaginal ring Myring™. Together, these agreements will generate at least EUR 69 million of value to Mithra and emphasizes ITROM's confidence in Mithra's portfolio of innovative products and its expertise in the development of new therapeutic solutions for women.

The agreement in the Gulf countries follows a number of licensing deals for Estelle® with key commercial partners in leading markets. In 2018, Mithra signed an exclusive long-term license and supply agreement with Gedeon Richter for the commercialization of Estelle® in Europe and Russia, as

<sup>2</sup> Middle East and North Africa

<sup>&</sup>lt;sup>1</sup> UAE: United Arab Emirates

<sup>&</sup>lt;sup>3</sup> IQVIA Q3 2017: KSA, UAE, Lebanon, Jordan, Kuwait

<sup>&</sup>lt;sup>4</sup> Daphne Continu (21 + 7)

well as further agreements with Fuji Pharma, Libbs, Searchlight Pharma, Adcock Ingram, and Hyundai Pharm in Japan and ASEAN, Brazil, Canada, South Africa and South Korea respectively.

François Fornieri, CEO Mithra Women's Health, commented: "We are very pleased to have finalized these three significant partnership with ITROM within the last two months, which shows their confidence in our innovative products and our know-how. The recent publication of the positive topline results of Estelle® Phase III clearly confirmed the novel efficacy and safety profile of Estelle® and its status as 5<sup>th</sup> generation oral contraceptive, bringing our future potential blockbuster closer to the market. In parallel with the filing submission to the regulatory agencies, we are intensifying our business development strategy for Estelle® and continuing our negotiations with leading markets."

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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 two lead development candidates - a fifth generation oral contraceptive Estelle® and next-generation hormone therapy Donesta® - are built on Mithra's unique native estrogen platform, E4 (Estetrol). Mithra also develops, manufactures and markets 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 Mr. 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, "forwardlooking 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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