



## UPDATE ON MITHRA AND MAYNE PHARMA'S VAGINAL CONTRACEPTIVE RING OPPORTUNITY

**Liège, Belgium, 28 May 2018** – Mithra (Euronext Brussels: MITRA), a company specialized in Women's Health, today provides an update on the progress made with its vaginal contraception ring, Myring™<sup>1</sup>, for the US market.

The Abbreviated New Drug Application (ANDA) was submitted by Mithra's partner for the US commercialization of the vaginal ring, Mayne Pharma (ASX: MYX), and the FDA site visit is taking place as planned in Q2 2018.

Mithra believes the planned launch of the product candidate remains on track for H1 2019, pending necessary regulatory authorization, with the potential for approval as early as Q4 2018.

The vaginal ring product candidate, Myring™, is an intra-vaginal hormonal contraceptive delivery device combining etonogestrel and ethinyl estradiol over a 3-week period, and is developed to be fully bioequivalent to Merck's Nuvaring®. NuvaRing® had total US sales of approximately USD 830 million for the 12 months ending 31 January 2018<sup>2</sup>. The US market represents over 75% of the annual global sales of Nuvaring®, making this a key territory for the product. Nuvaring® went off patent on April 9 2018, and no generic version has been approved in the US to date.

The exclusive long-term license and supply agreement with Mayne Pharma was announced in 2017, and in addition to a EUR 2.4 million down payment already received, Mithra is eligible for further milestones totalling at least EUR 7.6 million following approval by the US FDA and through to commercial launch of the product. Based on recent market intelligence, Mayne Pharma now seems to be well placed to be one of the first, if not the first, to enter the US market, which would potentially entitle Mithra to an additional milestone payment. In addition, should Myring come to market as one of the first bioequivalent products, Mithra would expect financial contributions from the production of the vaginal ring at the Mithra CDMO<sup>3</sup> in Belgium to increase accordingly.

Mithra has separately signed distribution contracts for its vaginal contraception ring with Gynial, Adamed and Alvogen for Austria, the Czech Republic and Russia, respectively. Marketing authorization in Europe is expected in Q2/Q3 2018.

**François Fornieri, CEO of Mithra Women's Health:** *"The progress of the ANDA application in the US and the evolution in the competitive space is encouraging. Mithra is optimistic that its contraceptive ring will be one of the first fully bioequivalent products for NuvaRing® in the key US market, which would lead to increased milestone payments and boost the revenues for the Myring® production at the Mithra CDMO. We are currently investing in additional capacity at our CDMO facility to meet anticipated demand for the product once it is approved."*

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<sup>1</sup> Mayne Pharma will market Myring™ under a different trademark name in the US

<sup>2</sup> According to IQVIA, as provided by Mayne Pharma

<sup>3</sup> Contract Development and Manufacturing Organization

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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 fertility, 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<sup>®</sup>, and a next generation hormone therapy, Donesta<sup>®</sup>- are built on Mithra's unique natural 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 Mithra CDMO. Mithra was founded in 1999 as a spin-off of the University of Liège by Mr. François Fornieri and Prof. Dr. Jean-Michel Foidart and is headquartered in Liège, Belgium. Further information can be found at: [www.mithra.com](http://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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