



## MITHRA RECEIVES GMP APPROVAL FOR MYRING™ PRODUCTION

- **On track to file for marketing approval of hormonal contraceptive Myring™ in EU and US in Q2 2017**
- **Approval ensures Mithra fully prepared to ship first commercial batches in Europe**

**Liege, Belgium 23 May 2017** – Mithra (Euronext Brussels: MITRA), a company specialized in Women's Health, is pleased to announce that the Mithra CDMO<sup>1</sup> has received Good Manufacturing Practice (GMP) approval for the production line of Myring™, a combined hormonal contraceptive vaginal ring made of ethylene vinyl acetate copolymers (EVA).

Following the GMP approval by AFMPS, the Belgian Federal Agency for Medicines and Health Products, Mithra will be able to ship its first commercial batches in the European Union once marketing approval has been received. The Company is on track to file for marketing approval in both Europe and the United States in Q2 2017.

Myring's™ originator product, Nuvaring™, will go off patent in April 2018, allowing other products, such as Myring™, to enter the US and European market. The vaginal ring market in Europe and the US is valued at EUR 143m and EUR 740m<sup>2</sup> respectively.

Mithra recently announced a 10-year license and supply agreement with Gynial GmbH, for the commercialization of Myring™ in Austria. This followed news in February of an exclusive long-term license and supply agreement with Mayne Pharma, a leading specialty pharmaceutical company, for the commercialization of Myring™ in the US.

**François Fornieri, CEO of Mithra, commented:** *"GMP approval of our manufacturing line is an important milestone for our vaginal contraceptive Myring™ as well as for Mithra's manufacturing and development capabilities at our dedicated CDMO. We already have an excellent partnership in the US with Mayne Pharma and recently announced a further licensing agreement for Myring™ in Austria. Today's GMP accreditation will further assist ongoing discussions with potential licensing and distribution partners in Europe and other key markets."*

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### Press

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<sup>1</sup> Contract Development & Manufacturing Organization

<sup>2</sup> Based on IMS Analytics 2016

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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® and next-generation hormone therapy Donesta® - 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. Mithra 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.*