



## MITHRA SUBMITS MYRING™ FOR EUROPEAN MARKETING APPROVAL

- **Myring™ regulatory approvals in Europe and the US expected in 2018**
- **Regulatory submission follows recent European GMP approval for Myring™ production at Mithra CDMO**

**Liège, Belgium, 17 July 2017** – Mithra (Euronext Brussels: MITRA), a company specialized in Women's Health, announces that it has filed Myring™ for marketing approval in Europe. Myring™ is Mithra's version of Nuvaring™, a combined hormonal contraceptive vaginal ring made of ethylene vinyl acetate copolymers (EVA). The global market for Nuvaring™ amounts to approximately USD 960 million, with over 75% of sales in the US.<sup>1</sup>

In May 2017 Mithra received Good Manufacturing Practice (GMP) approval for the production line of Myring™ at its Mithra CDMO<sup>2</sup>. This followed a license and supply agreement with Mayne Pharma for the commercialization of Myring™ in the US. Mithra has also signed its first European commercialization agreement, with Gynial in Austria, and is in discussions with other companies for additional geographies.

Pending regulatory approval, Myring™ is on track to be launched in Europe from Q2 2018, following Nuvaring's™ patent expiration in April 2018. Mayne Pharma is expected to submit the US marketing authorization application for Myring™ in Q4 2017, with US approval expected in H2 2018 and launch shortly thereafter.

**François Fornieri, CEO of Mithra, commented:** *"The filing of Myring™ for commercial approval in Europe is another key step in bringing this additional contraceptive option to market, and we also look forward to our partner Mayne Pharma seeking approval in the US later this year. Building on the partnerships announced to date, we are in discussions with potential partners in a number of*

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<sup>1</sup> IMS Health 2016. The US market is worth approximately USD 760 million, while the European market stands at approximately USD 160 million.

<sup>2</sup> Contract Development & Manufacturing Organization

*additional territories, which should provide an important source of revenue for the Company following the anticipated launch and roll out of Myring™ from 2018.”*

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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 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](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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