



## MITHRA PLANS TO SUBMIT MYRING FOR US AND EU APPROVAL IN Q2 2017

Planned submissions follow successful trials demonstrating bioequivalence to NuvaRing®

**Liège, Belgium, 24 January 2017** – Mithra Pharmaceuticals (Euronext Brussels: MITRA), a company focused on women’s health, today announces that it intends to submit its combined hormonal contraceptive vaginal ring, Myring, for marketing approval in both Europe and the United States in Q2 2017.

This follows the completion of two successful studies in Europe and the US demonstrating that Myring is bioequivalent to the branded versions of NuvaRing®, sold in both markets.

**Valérie Gordenne, CSO of Mithra Pharmaceuticals, said:** *“Following completion of successful bioequivalence studies in both Europe and the United States, we are on track to submit Myring for regulatory approval in both markets in the second quarter of 2017. We are also working on submissions in other markets.”*

**François Fornieri, CEO of Mithra Pharmaceuticals, said:** *“This is yet another important step in the development of Myring and we believe that we are on track to sign a commercialisation deal in 2017, both in the US, as well as in other territories. Additionally, this is great news for Mithra’s CDMO, our integrated R&D and manufacturing platform, where we will be producing Myring. This fundamental step shows that Mithra is successful in developing complex therapeutic solutions alongside Estetrol (E4), which recently also reported positive results.”*

Mithra has conducted two studies of bioequivalence involving 42 subjects. The studies are required to confirm the effectiveness and the safety of the product with a view to completion of the marketing authorization applications in Europe and the U.S.

### About Myring

Myring is developed to be similar to Nuvaring® vaginal ring, still under patent protection up to April 2018 both in US and in EU.

Myring (etonogestrel/ethinyl estradiol vaginal ring) is a non-biodegradable, flexible, transparent, combination contraceptive vaginal ring, with an outer diameter of 54 mm and a cross-sectional diameter of 4 mm. It is made of ethylene vinylacetate copolymers, and contains 11.7 mg etonogestrel and 2.7 mg ethinyl estradiol. When placed in the vagina, each ring releases in line with the originator (Nuvaring®) on average 0.120 mg/day of etonogestrel and 0.015 mg/day of ethinyl estradiol over a three-week period of use.

### Pictures

For pictures of François Fornieri, please click here on the following link:  
<http://www.mithra.com/en/logo/>

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## About Mithra

Mithra Pharmaceuticals SA, founded in 1999 as a spin-off of the University of Liège by Mr. François Fornieri and Prof. Dr. Jean-Michel Foidart, is a Euronext listed pharmaceutical company (MITRA) focused on Women's Health. Mithra's mission is to improve every stage of women's life with innovative and accessible pharmaceutical solutions. As such the Company aims to become a worldwide leader in women's health by developing, manufacturing and commercialising proprietary, innovative and differentiated drugs and complex therapeutical solutions in four therapeutic fields of women's health: fertility and contraception, menopause and osteoporosis, gynecological infections and female cancers.

Mithra has an approximate headcount of 141 staff members 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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