



## MITHRA AND MAYNE PHARMA'S VAGINAL CONTRACEPTIVE RING ACCEPTED FOR FILING BY FDA

- **Filing acceptance is a key regulatory milestone, confirming time line towards potential launch in the US by Mayne Pharma in H1 201**
- **Pending FDA approval, Mithra is eligible for down payment and milestone payments totaling at least EUR 10 million**
- **Mithra to produce Myring™<sup>1</sup> for Mayne Pharma at its CDMO<sup>2</sup>, with substantial annual revenues expected**

**Liège, Belgium, 20 March 2018** – Mithra (Euronext Brussels: MITRA), a company dedicated to Women's Health, is pleased to announce that the Abbreviated New Drug Application (ANDA) for its vaginal ring for contraception has been accepted for filing by the US Food and Drug Administration (FDA). The ANDA has been submitted by Mithra's partner for the US commercialization of the vaginal ring, Mayne Pharma (ASX: MYX). The acceptance by the FDA is an important regulatory step, as it reconfirms the pathway towards launch of the product candidate in H1 2019.

The vaginal ring product candidate, Myring™<sup>1</sup>, 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>3</sup>. The US market represents over 75% of the annual global sales of Nuvaring®, making this a key territory for the product. Nuvaring® will go off patent in April 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 next to a EUR 2.4 million down payment received, Mithra is eligible for further milestones of at least EUR 7.6 million from approval by the US FDA through to commercial launch of the product. Following launch, Mithra is anticipating important financial contributions from the production of the vaginal ring at the Mithra CDMO.

In 2017 and early 2018, Mithra also closed European contracts for its vaginal contraception ring with Gynial, Adamed and Alvogen for the Austrian, Czech and Russian market, respectively.

**François Fornieri, CEO Mithra Women's Health:** *"We are very pleased that our partner Mayne Pharma has received filing acceptance from the FDA for our vaginal ring. This important regulatory milestone underlines the dedication and know-how of the Mayne Pharma team to bring the ring to market."*

---

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

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

<sup>3</sup> According to IQVIA, as provided by Mayne Pharma

*Mayne Pharma remains on track to launch the ring in H1 2019, and we expect the production of the ring to contribute significantly to our revenues at the level of the Mithra CDMO”.*

## **About Myring™<sup>1</sup>**

Myring™ is developed to be a generic of Nuvaring® vaginal ring, still under patent protection up to April 2018 both in the US and in the 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, as originator product Nuvaring®, on average 0.120 mg/day of etonogestrel and 0.015 mg/day of ethinyl estradiol over a three-week period of use. The ring is to remain in place continuously for three weeks. It is removed for a one-week break, during which a withdrawal bleed usually occurs. A new ring is inserted one week after the last ring was removed.

## **About Mayne Pharma**

Mayne Pharma is an ASX-listed specialty pharmaceutical company focused on applying its drug delivery expertise to commercialise branded and generic pharmaceuticals. Mayne Pharma also provides contract development and manufacturing services to more than 100 clients worldwide.

Mayne Pharma has a 30-year track record of innovation and success in developing new oral drug delivery systems and these technologies have been successfully commercialised in numerous products that have been marketed around the world.

Mayne Pharma has two product development and manufacturing facilities based in Salisbury, Australia and Greenville, USA with expertise in formulation of complex oral dose forms including highly potent compounds, controlled substances, modified release products and inherently unstable compounds.

## **For more information, please contact:**

### **Investor Relations**

#### **Sofie Van Gijzel**

Investor Relations Officer

+32 485 19 14 15

[investorrelations@mithra.com](mailto:investorrelations@mithra.com)

### **Press**

#### **Julie Dessart**

Chief Communication Officer

+32 4 349 28 22 / +32 475 86 41 75

[press@mithra.com](mailto:press@mithra.com)

## **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 a 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 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.*

To subscribe to Mithra's newsletter, visit [investors.mithra.com](http://investors.mithra.com)