



## MITHRA AGREES EXCLUSIVE LONG-TERM LICENSE AND SUPPLY AGREEMENT WITH MAYNE PHARMA TO COMMERCIALIZE MYRING™ IN THE US

- Mithra grants its first exclusive license for its vaginal contraception ring, Myring™, to Mayne Pharma (ASX: MYX), the second-largest supplier of oral contraceptives in the US market, covering commercialization in the United States
- As part of the agreement, Mayne Pharma will pay milestones of at least EUR 10.0m following approval by the US FDA
- Mithra will produce Myring™ for Mayne Pharma at its Research, Development and Manufacturing facility (Mithra CDMO)

**Liège, Belgium, 27 February 2017** – Mithra Pharmaceuticals, a company dedicated to Women's Health, is pleased to announce an exclusive long-term license and supply agreement that extends beyond 10 years with Mayne Pharma, a leading specialty pharmaceutical company, for the commercialization in the United States of Myring™, Mithra's combined hormonal contraceptive vaginal ring made of ethylene vinyl acetate copolymers (EVA). Mayne Pharma is the second largest supplier of oral contraceptive products in the US market.

Under the terms of the agreement, Mithra will receive EUR 2.4m upon signature, as well as significant milestone payments on ANDA approval (market approval by the FDA) and on the commercial launch of the product. As a part of Mayne Pharma's long-term exclusive sourcing commitment, Mithra is considering the expansion of its production capacity for Myring™.

Currently, the US market for biocompatible contraceptive rings is worth EUR 740m<sup>1</sup>, which represents approximately 30% of the total global market by volume and over 75% by value, making this a key territory for the commercialization of Myring™.

Mithra is anticipating important financial contributions from this product post-commercial launch, aligned with the market potential and Mayne Pharma's commitment to the oral contraceptive market.

**François Fornieri, CEO Mithra Pharmaceuticals:** *"This agreement with Mayne Pharma further demonstrates Mithra's attractiveness for partnerships, exemplifying our strategy to seek specialist partners around the world. It also underlines our expertise in polymers and proves the confidence that key US companies have in our know-how and the research and manufacturing capabilities of Mithra's CDMO. Furthermore, the attractive deal terms validate Mithra's acquisition of the remainder of Novalon in December 2015. Through the acquisition of a portfolio of 42 pharmaceutical products from*

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<sup>1</sup> As determined by Mayne Pharma, based on IMS Health for the 12 months ending 31 December 2016.

*Teva last year, Mayne Pharma became a top 25 retail generic pharmaceutical company with an extensive portfolio of women's health products. Hence, we strongly believe that we have the best partner at our side to market our vaginal ring, Myring™, in the key US market."*

## **About Mayne Pharma**

Mayne Pharma is a publicly traded specialty pharmaceutical company listed on the Australian Securities Exchange (ASX: MYX). The company develops and manufactures branded and generic products globally — either directly or through distribution partners — while applying its drug-delivery expertise for contract development and manufacturing services. Mayne Pharma has a 30-year track record of innovation and success in developing new oral drug delivery systems, and its technologies have been successfully commercialized in products marketed around the world. Mayne Pharma has drug development and manufacturing facilities in Greenville, North Carolina, USA, and Salisbury, Australia, and offers expertise in formulating complex oral dose forms including highly potent compounds, controlled substances, and modified release products. In the United States, Mayne Pharma's operations consist of U.S. Generic Products, U.S. Specialty Brands, and Metrics Contract Services.

## **About Myring™**

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 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. 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.

## **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 pharmaceutical company focused on Women's Health. Mithra's mission is to support and assist women at every stage of their life, thereby improving their overall quality of life. 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 entities in four therapeutic fields of women's health, fertility and contraception, menopause and osteoporosis, vaginal infections and cancers.

Mithra has a total headcount of approximately 85 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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