



MITHRA ANNOUNCES POSITIVE OUTCOME OF MYRING™ COMMERCIAL BATCH BIOEQUIVALENCE STUDY

- Bioequivalence study performed on commercial Myring™ batch produced at Mithra CDMO
- Data will form part of planned Myring™ FDA filing by US partner Mayne Pharma

Liège, Belgium, 17 November 2017 – Mithra (Euronext Brussels: MITRA), a company specialized in Women's Health, announces the successful outcome of a confirmatory bioequivalence study performed on a commercial batch of Myring™ produced at the Mithra CDMO¹. The study results reconfirm that Myring™ is bioequivalent to Nuvaring®, a combined hormonal contraceptive vaginal ring made of ethylene vinyl acetate copolymers (EVA).

The study was performed following the tech transfer of Myring™ to Mithra's CDMO facility in early 2017. Mayne Pharma, Mithra's US partner, is progressing regulatory preparations to ensure a timely submission to FDA in the next few months, and correspondingly efficient approval and commercial launch timelines for Myring™. As a reminder, in February 2017, Mithra closed a 10-year exclusive LSA with Mayne Pharma for an upfront of EUR 2.4 million, milestones of at least EUR 10 million following FDA approval and important revenues based on the minimal annual quantities and manufacturing forecasts at the Mithra CDMO. The global market for Nuvaring® amounts to approximately USD 970 million (CAGR: 7.1%), with nearly 80% of sales in the US², making this a key territory for Myring™.

These latest bioequivalence data will also be used to supplement the Myring™ European marketing approval application (MAA), which was already submitted to the European authorities in July 2017. In May 2017, Mithra received Good Manufacturing Practice (GMP) approval for the production line of Myring™ at the Mithra CDMO.

François Fornieri, CEO of Mithra, commented: *"We are very pleased with the results of the commercial production bioequivalence study, which confirms the previously generated bioequivalence data and demonstrates the expertise of our R&D and CDMO team. With today's results, our US partner Mayne Pharma can prepare for FDA submission based on a very extensive file, which may allow for a swift approval and market launch in this important territory."*

¹ Contract Development and Manufacturing Organization

² IMS Health Q2 2017

For more information, please contact:

Investor Relations

Sofie Van Gijssel, IRO

+32 485 19 14 15

investorrelations@mithra.com

svangijssel@mithra.com

Consilium Strategic Communications

Jonathan Birt, Philippa Gardner, Ivar Milligan, Hendrik Thys

mithra@consilium-comms.com

+44 2 037 095 700

Press

Julie Dessart

Chief Communication Officer

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

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 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

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.

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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