MITHRA ANNOUNCES MYRING™ UPDATE

- **Mithra's US partner Mayne Pharma receives complete response letter for Myring™**
- **Increased manufacturing capacity to meet market demand following licensing deals with market leaders in the US, Austria, Czech Republic, Chile, Denmark, Russia, Australia and New Zealand**
- **Launch of Myring™ EU production in January 2019**

Liège, Belgium, 14 December 2018, 17:45 CET – Mithra (Euronext Brussels: MITRA), a company dedicated to Women's Health, today announced that its US commercial partner Mayne Pharma LLC[1] has received a Complete Response Letter from the US Food & Drug Administration (FDA) related to the abbreviated new drug application (ANDA) for Myring™, the vaginal ring made of ethylene vinyl acetate copolymers (EVA).

In the letter, the FDA stated that additional bioequivalence data would be required to support the ANDA[2], including the manufacture of new test batches .

As a consequence, there is expected to be a delay in US commercial launch into 2020. The overall 10 year business plan is not expected to be impacted as the competitive landscape has evolved reflecting the complexity of the ring development. There are currently no generic NuvaRing® competitors in the US. NuvaRing remains the largest contraceptive sold in the US with sales of more than US$900m[3]. The Company still believes Myring™ could be among the first few generic NuvaRing® products in the U.S. market.

To meet expected increased market demand, Mithra has acquired new manufacturing equipment to triple its capacity. The upgraded equipment will be used to support the U.S. filing and significantly augment the production output to sustain commercial demand. It should also improve profitability and strengthen the manufacturing process in order to avoid later tech transfer and variations.

Manufacturing operations for Myring™ are planned to begin in January 2019 and nine batches will be produced at Mithra's CDMO which received EU GMP approval in 2017. This is an important milestone for Mithra's new production facility which will be processing its first commercial order. It will also allow Mithra CDMO to ramp up its manufacturing process including serialization of its finished products. This is also an important development as the Company is currently addressing demands for innovative Ring development and manufacturing projects.

François Fornieri, CEO of Mithra Women's Health, commented: "*We are working closely with our partner Mayne Pharma to address the issues raised by US regulators as quickly as possible. Although this will lead to a delay in our prospective launch plans for Myring in the US, we believe the competitive and market conditions for the product remain highly favourable. We also continue to advance plans*

[1] In February 2017, Mithra agreed an Exclusive long term license and supply agreement with Mayne Pharma to commercialize Myring in the US

[2] Abbreviated New Drug Application

[3] IQVIA 2018

for Myring™ in Europe and other major markets. Myring™ has already received marketing approval in six European countries and will be launched in early 2019. The increase in capacity will also allow us to address additional demands for ring development projects."

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About Myring™

Myring™ is developed to be a generic of NuvaRing® vaginal ring. NuvaRing®'s patent expired in April 2018 both in the US and in EU. Myring™ (etonogestrel/ethinyl estradiol vaginal ring) is a nonbiodegradable, 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.

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 native 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

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