



## European Authorities Approve Advantageous Modifications to Myring™ Labelling

- Removal of requirement for special temperature storage for vaginal contraceptive ring Myring™
- Competitive advantage in terms of reduced costs and convenience for distributors, pharmacists and patients
- Similar labelling to be pursued in the United States

Liege, Belgium, 08 November 2019 – 7:30 CET – Mithra (Euronext Brussels: MITRA), a company dedicated to Women's Health today announces that the European Authorities has approved two noteworthy modifications relating to the change in the shelf-life and storage conditions of its vaginal contraceptive ring Myring™.

The shelf-life of Myring™ has been extended from 18 to 24 months, and the requirement for special storage conditions has been lifted. Previously, as the originator product, Myring™ needed to be refrigerated prior to the dispensing to the patient, at a temperature between 2 °C and 8 °C. This advantageous modification reduces the impact on transport and storage costs, suppressing the need for cold chain storage. Furthermore, it provides a more convenient option for the distributors, pharmacists and patients.

**François Fornieri, CEO Mithra Women's Health, commented:** *"We are very pleased that the European authorities have approved these significant amendments to the Myring™ label. The increased shelf-life, in addition to the removal of the requirement for special temperature storage, provides a clear advantage vis-à-vis competitor products. By eliminating the special temperature requirement, supply chain logistics of the product are greatly simplified, and costs reduced. Mithra will seek to obtain the same labeling in the US, where there is not yet any generic competition. This conservation benefit, which is highly anticipated by the market, should enable us to increase our sales volumes in Europe."*

\*\*\*\*\*

### For more information, please contact:

**Alexandra Deschner (IRO)** : +32 490 58 35 23 - [investorrelations@mithra.com](mailto:investorrelations@mithra.com)

**Maud Vanderthommen (Press)** : +32 473 58 61 04 – [press@mithra.com](mailto:press@mithra.com)

### About Mithra

*Mithra (Euronext: MITRA) is a Belgian biotech company dedicated to transforming Women's Health by offering new choices through innovation, with a particular focus on contraception and menopause. Mithra's goal is to develop products offering better efficacy, safety and convenience, meeting women's needs throughout their life span. Its three lead development candidates are built on Mithra's unique native estrogen platform, Estetrol (E4): Estelle®, a new era in oral contraception, PeriNesta®, the first complete oral treatment for perimenopause and*

*Donesta®*, the next-generation hormone therapy. Mithra also develops and manufactures complex therapeutics in the areas of contraception, menopause and hormone-dependent cancers. It offers partners a complete spectrum of research, development and specialist manufacturing at its technological platform Mithra CDMO. Active in more than 85 countries around the world, Mithra has an approximate headcount of 250 staff members and is headquartered in Liège, Belgium. [www.mithra.com](http://www.mithra.com)

### About Myring™

*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.*

To receive our press releases by email, please subscribe to our mailing list on [investors.mithra.com](http://investors.mithra.com)