



## Mithra Signs LSA for Commercialization of Myring™ in Germany, the biggest market in Europe

- Mithra grants exclusive license to Hormosan for commercialization of vaginal contraceptive ring in Germany
- Germany is the largest European market in terms of volumes, with 3 million vaginal rings sold per year
- Agreement follows licensing deals for Myring™ with market leaders in the U.S., Europe, Russia, Australia, Middle East, Latin and South America

Liege, Belgium, 28 May 2019 - 7 :30 CEST – Mithra (Euronext Brussels: MITRA), a company dedicated to Women’s Health today announces that it has entered into an exclusive license and supply agreement with Hormosan for the commercialization of its hormonal contraceptive ring Myring™, bioequivalent to Nuvaring®<sup>1</sup>, in Germany. Hormosan is a subsidiary of the innovation-driven pharmaceutical company Lupin Group, offering low-cost generics in Germany that offer added value relevant to therapy.

Under the terms of this 5-year agreement, Hormosan will distribute Myring™ in Germany, which is the largest European market in terms of volume. With 3 million vaginal rings sold per year, the German contraceptive rings market is worth EUR 27 million per year<sup>2</sup>. Mithra will receive an upfront payment and will be eligible to receive milestone payments and recurring revenues based on minimum annual quantities (MAQ). Moreover, Mithra will manufacture the product at its Contract Development and Manufacturing Organization (CDMO) facility in Belgium. Globally, this agreement could generate revenues of at least EUR 2.5 million for Mithra.

To date, Mithra has licensed Myring™ to industry leaders in ten international markets, including the United States, Austria, Czech Republic, Russia, Denmark, Chile, Australia/New Zealand, the MENA territories<sup>3</sup>, the Argentinean/Uruguay/Dominican Republic zone and Germany. All these contracts provide for the production of Myring™ at the Mithra CDMO, which has tripled its production capacity to meet the expected market increase. The commercial manufacturing process has been successfully launched in early 2019 and will continue in the second half of the year for the commercial batches for the European market.

In Europe, Mithra has already eight Marketing Authorizations (MA’s) for Myring™, including the United Kingdom, Latvia, Hungary, Croatia, Czech Republic, Poland, Slovakia and Slovenia. Mithra is expected to obtain 15 additional MA’s for the European market, mainly in Western Europe, in the second half of the year.

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<sup>1</sup> Registered trademark of Merck

<sup>2</sup> IQVIA Q4 2018

<sup>3</sup> Middle East and North Africa

**François Fornieri, CEO Mithra Women's Health, comments:** *"We are pleased to have formed a partnership with Hormosan and Lupin for the commercialization of Myring™ in Germany, the largest contraceptive vaginal rings market in Europe in terms of sales volumes. Myring™ will be a new option for women as the first Q1/Q2 bioequivalent generic of the originator to be launched in this key market. Thanks to the 15 additional marketing authorizations for European countries planned for the second half of this year, we should significantly strengthen our presence in the whole of Europe. After the successful launch of our commercial manufacturing process earlier this year, we look forward to producing Myring™ for our international partners at our Mithra CDMO."*

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#### **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.*

#### **About Mithra**

*Mithra (Euronext: MITRA) is dedicated to providing innovation and choice in Women's Health, with a particular focus on contraception and menopause. Mithra's goal is to develop new and improved products that meet women's needs for better safety and convenience. Its three lead development candidates – a fifth generation oral contraceptive Estelle®, the first complete oral treatment for perimenopause PeriNesta™ and next-generation hormone therapy Donesta® - are built on Mithra's unique native estrogen platform, E4 (Estetrol). Mithra also develops and manufactures 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 François Fornieri and Prof. Dr. Jean-Michel Foidart. Mithra is headquartered in Liège, Belgium. Further information can be found at [www.mithra.com](http://www.mithra.com)*

#### **About Hormosan**

*Hormosan is the German subsidiary of the Indian pharmaceutical company Lupin. Lupin is an innovation led transnational pharmaceutical company developing and delivering a wide range of branded and generic formulations, biosimilar products and APIs globally. The Company is a significant player in the Cardiovascular, Diabetology, Asthma, Pediatric, CNS, GI, Anti-Infective and NSAID space and holds global leadership position in the Anti-TB segment. Lupin is the 8<sup>th</sup> largest generics pharmaceutical company by revenues (31<sup>st</sup> Dec 2018, Bloomberg LTM). The Company is the 3<sup>rd</sup> largest pharmaceutical player in the US by prescriptions (IQVIA MAT Mar 2019); 3<sup>rd</sup> largest Indian pharmaceutical company by global revenues (31<sup>st</sup> Dec 2018, Bloomberg LTM); 5<sup>th</sup> largest company in the Indian Pharmaceutical Market and 6<sup>th</sup> largest generic pharmaceutical player in Japan (IQVIA MAT Mar 2019). Please visit [www.hormosan.de](http://www.hormosan.de) or [www.lupin.com](http://www.lupin.com) for more information.*

**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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