



MITHRA SIGNS EXCLUSIVE LICENSE AND SUPPLY AGREEMENT WITH FUJI PHARMA FOR DONESTA® IN JAPAN AND ASEAN

- **Fuji Pharma obtains rights to commercialize Donesta®, Mithra's Hormone Therapy (HT) product candidate based on Estetrol (E4), in Japan and ASEAN¹**
- **20-year agreement to generate low double digit million development, regulatory and commercialization milestones plus long-term supply revenues**
- **Exclusive License and Supply agreement follows binding term sheet announced in March 2017**

Liège, Belgium, 28 June 2017 – Mithra (Euronext Brussels: MITRA), a company specialized in Women's Health, announces that it has signed an exclusive License and Supply Agreement (LSA) with Fuji Pharma, the leader in Women's Health in Japan, for the commercialization of Donesta® in Japan and ASEAN territories. Donesta® is Mithra's next generation Hormone Therapy (HT) candidate for which a dose-finding Phase II study is currently ongoing, with top-line results expected late Q1 2018.

Under the terms of the agreement, Mithra is entitled to EUR 1 million upon signature as well as future low double digit million development, regulatory and commercialization milestones. Fuji Pharma and Mithra or one of its partners will undertake and equally fund the development of Donesta® Phase III in Japanese subjects in the HT indication. Furthermore, based on the annual minimum order quantities agreed upon, the exclusive supply agreement will provide Mithra's CDMO² with a steady flow of production work, and will be a source of recurring revenue for Mithra for the duration of the contract.

The Donesta® LSA follows the binding term sheet announced in March 2017. Mithra and Fuji Pharma already have an exclusive LSA in place, agreed in August 2016, for Estelle®, Mithra's combined oral contraceptive candidate which is also based on the E4 platform and is currently in Phase III studies.

The Japanese and ASEAN HT markets are valued at approximately EUR 42.6 million³. Fuji Pharma is fully committed to expanding the current market with Donesta®, given the potentially improved safety profile of E4 versus currently available HTs, including a lower VTE risk profile and a reduced risk of drug-drug interactions^{4,5}.

¹ Association of Southeast Asian Nations: Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand and Vietnam

² Contract Development and Manufacturing Organization

³ IMS Health 2016; data based on Japan and 6 ASEAN countries (no data available for Cambodia, Laos, Myanmar, and Brunei)

⁴ Kluft et al. 2017. *Contraception* 95(2) : 140-7

⁵ Visser et al. 2012. *Oncotarget* 6(19): 17621-36

François Fornieri, CEO of Mithra: *“We are very pleased to sign this agreement with Fuji Pharma for Donesta® in Japan and ASEAN, and signing as early as Phase II highlights Fuji Pharma’s commitment to the program. As the leader in Women’s Health in Japan and our existing partner for Estelle® in these territories, Fuji Pharma is our partner of choice for the commercialization of Donesta®. Partnering our lead E4-based products in territories outside of Europe and the US is also a key part of our strategy and we look forward to creating additional partnerships with Women’s Health players for both Donesta® and Estelle®. These innovative product candidates could provide women with potentially safer alternatives to currently marketed hormone-based menopause and contraception products.”*

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, Sue Stuart, Philippa Gardner, Hendrik Thys, Cameron Standage

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 Donesta®

Donesta®, the Company’s next-generation hormone therapy (HT) with oral administration of E4, entered into a Phase II dose-ranging study in Europe. In total, the study will recruit 225 patients in Czech Republic, Poland, Belgium, the Netherlands and the UK, for a treatment period of 12 weeks. The main objective of the Phase II clinical trial is to identify the minimum dose required to effectively treat vasomotor menopausal symptoms (VMS), or hot flashes. In total five doses will be tested in this blinded study, including placebo.

About Fuji Pharma

Fuji Pharma is a Tokyo based company founded in 1965, listed on the Tokyo Stock Exchange (4554:JP) with a 61.3bn JPY market capitalization and 2016 revenues of 34.23bn JPY. It specializes in development, manufacture, and marketing of pharmaceutical products, such as injection agents, internal drugs, drugs for external use, and diagnostic products. Their products and services are focused on medical care for women, in vitro diagnostics, acute medical care products and curative medicine (injection agents), and information regarding pharmaceuticals and health.

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

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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