



## Mithra signs its first major partnership with the Japanese leader in Women Health Fuji Pharma to commercialize Estelle® in Japan and ASEAN<sup>1</sup>

- Mithra signs its first major partnership agreement for Estelle, in line with its strategy to partner out its lead Estetrol-based products earlier for territories outside of the EU and US
- Mithra's partner, Fuji Pharma, the leader in the Japanese contraception and dysmenorrhea market, obtains the rights to commercialize Estelle®, Mithra's oral contraceptive product candidate based on Estetrol, in Japan and ASEAN, representing a total market of EUR 330 million annual sales.
- The 20-year partnership agreements, which include exclusive supply by Mithra from its CDMO<sup>2</sup>, generate upfront milestones of up to EUR 26 million, of which EUR 10 million is paid at signature.

**Liège, Belgium 31 August 2016** – Mithra Pharmaceuticals, a company dedicated to Women's Health, is extremely pleased to announce it has signed its first major partnership agreement for Estelle®.

Only two months after the LOI between Mithra and Fuji, announced on 24 June 2016, Mithra today announces it has signed a 20-year exclusive license and supply agreement for Estelle® with Fuji Pharma, the Japanese leader in Women's Health and Japanese market leader in contraception and dysmenorrhea.

Under the terms of the agreements, Mithra will, depending on the progress of the development, receive a total down payment consideration of up to EUR 26 million of which EUR 10 million as an upfront signature milestone. In addition, the agreements comprise an exclusive supply obligation for the duration, which in the future will provide Mithra's CDMO with a steady flow of production work for Estetrol-based products, and Mithra with a source of revenue and margin over the entire term.

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<sup>1</sup> Association of Southeast Asian Nations : Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Phillipines, Singapore, Thailand and Vietnam

<sup>2</sup> The Mithra CDMO (Contract Development and Manufacturing Organization): this future cutting-edge technological platform of 15,000m<sup>2</sup> is a specialized and integrated R&D and manufacturing platform which will be inaugurated on 30th September 2016.

The total value of this deal should be between €250 and €600 million.

Furthermore, Fuji Pharma will undertake and fund the development of Estelle in Japan in the dysmenorrhea indication, which entails a significant investment and mark of confidence on their part, and which data can also strengthen the other developments of Estelle.

Mithra considered Japan as one of its priority target territories for partnering (outside of the “core” territories of EU and US, for which partnering is envisaged later), mainly due to the attractive market profile presented by the local contraception and dysmenorrhea market. This market is both large (the Japanese contraception and dysmenorrhea markets currently amount to over EUR 200 million) and attractively priced.

In addition, the ASEAN market comprises ten separate countries for which the total contraception market represents about EUR 130 million, with overall pricing (varying by country) roughly comparable to the EU.

**François Fornieri, CEO Mithra Pharmaceuticals:** “This deal confirms our strategy and our desire to partner-up with Women’s Health global leaders everywhere in the World. Japan is one of our priority “non-core” markets outside of our core markets of EU and US, as it is a high potential market in volume and value especially when considering the contraception and dysmenorrhea indications together, the latter indication offering attractive reimbursement rates. We are pleased to see that women’s health leaders around the world are prepared to engage with us at this stage of the development of Estelle which has just started Phase III. We believe this deal confirms that Mithra is able to attract the right partners with the unique potential of Estetrol and we are confident it opens the way for many more such partnerships in non-core territories in shorter time, and in our core territories in a later stage, a strategy which should create the highest value for our shareholders. »

## About Fuji Pharma

Fuji Pharma is a Tokyo based company founded in 1965, listed on the Tokyo Stock Exchange (4554:JP) with a 37bn JPY market capitalization and 2015 revenues of 31.68bn 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.

## Pictures

For pictures of François Fornieri, please click here on the following link:

<http://www.mithra.com/en/logo/>

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### **About Mithra**

Mithra Pharmaceuticals SA, founded in 1999 as a spin-off of the University of Liège by Mr. François Fornieri and Prof. dr. Jean-Michel Foidart, is a pharmaceutical company focused on Women's Health. Mithra's mission is to support and assist women at every stage of their life, thereby improving their overall quality of life. As such the Company aims to become a worldwide leader in women's health by developing, manufacturing and commercialising proprietary, innovative and differentiated drugs and complex therapeutical entities in four therapeutic fields of women's health, fertility and contraception, menopause and osteoporosis, vaginal infections and cancers.

Mithra has a total headcount of approximately 85 staff members and is headquartered in Liège, Belgium. Further information can be found at: [www.mithra.com](http://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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