PRESS RELEASE

Mithra Signs a Binding Term Sheet with the Japanese Leader in Women's Health Fuji Pharma to Commercialize Donesta® in Japan and ASEAN[1]

- **Mithra signs a binding term sheet for Donesta® with Fuji Pharma, in line with its strategy to partner out its lead Estetrol-based products**
- **Fuji Pharma, the Women's Health leader in Japan, obtains the rights to commercialize Donesta®, Mithra's Hormonal Treatment (HT) product candidate based on Estetrol, in Japan and ASEAN. Fuji Pharma intend to extend the actual market of menopause in Japan which represents EUR 42.6 million, thanks to the potential advantages of Estetrol use in menopause.**
- **The 20-year partnership agreement, which includes an exclusive supply agreement by Mithra's CDMO[2], should generate single-digit upfront milestones. More details on the deal will be communicated when the full and complete LSA is finalized.**
- **Mithra also provides an update on its Phase II program for Donesta®. Following discussions with the regulatory agencies and recommendations of its international scientific committees, Mithra has decided to extend the protocol of its Phase II study, and top line results are now expected in Q1 2018.**
- **Mithra will accelerate its business development efforts for Donesta®, and plans to identify global partners its Phase III program, as it now does with Fuji.**
- **The term sheet with Fuji underlines the strategy adopted, while also demonstrating the value of the reinforced Phase II study for the further development and commercialization of Donesta®.**

Liège, Belgium, 01 March 2017 – Mithra Pharmaceuticals, a company dedicated to Women's Health, is pleased to announce it has signed a binding term sheet for Donesta®**,** its Hormonal Treatment (HT) product candidate.

Six months after Mithra announced the signing of 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, Fuji has now signed a term sheet for its product candidate in menopause, Donesta®, as well.

Under the terms of the agreements, Mithra will, depending on the progress of the development,

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

[2] The Mithra CDMO (Contract Development and Manufacturing Organization): this future cutting-edge technological platform of 15,000m² is a specialized and integrated R&D and manufacturing platform.

receive single digit milestones. The term sheet comprises an exclusive supply obligation for the duration of the contract, which would provide Mithra's CDMO with a steady flow of production work for its Estetrol-based products, and hence represent a source of revenue for Mithra over the entire term.

Furthermore, Fuji Pharma and Mithra Pharmaceuticals or one of its partners will undertake and equally fund the development of Donesta® Phase III in Japan in the HT indication.

Mithra also provides an update on its ongoing Phase II study for Donesta®:

Following discussions with regulatory agencies as well as recommendations from its international clinical advisory boards, the Company has decided to expand the protocol for the study and amend patient exclusion criteria. Regulatory approval of the new protocol is expected towards the end of Q1 2017. The Phase II study is now expected to be completed in Q1 2018, and topline results of the Phase II study should be available late Q1 2018.

The amended study protocols are expected to generate additional safety and efficacy data and provide a much stronger platform for the Phase III program.

Mithra's recent scientific advisory boards in both Europe and North America provided further support for the amended Phase II study protocol, stressing that the stringent inclusion criteria and deep assessment of secondary data put the company in a strong position for further development and commercialization of Donesta®.

François Fornieri, CEO of Mithra Pharmaceuticals: *"First of all, this agreement further confirms our strategy and will to create partnerships with global leaders worldwide in the field of Women's Health.*

Moreover, our Japanese partners' enthusiasm regarding Donesta® shows they are ready to commit with us at this stage of development. Based on recommendations of the Agency, but also emanating from our scientific advisory boards in Europe and North America, composed by experts in the field of menopause, we chose to strengthen our Phase II study protocol. These amendments, even if they cause a delay, are an opportunity to build a stronger file that provides us with a real advantage on the growing market of menopause.

The menopause market is indeed not only bursting out, but it also significantly differs from the contraception market and varies according to the different regions worldwide. That is the reason why Mithra chose to reinforce its file with a more qualitative Phase II that could be suitable for all global markets. Donesta® Phase II will allow Mithra to find reliable partners that would develop their own Phase III, in accordance with regulatory and commercial requirements on the markets they target.

Today, thanks to this term sheet, we are more than ever convinced that our Donesta® file is far more attractive to seek future partners."

The recent scientific advisory boards held in Europe and in North America support this statement and underline the advantages of Phase II reinforcement: *"The Donesta® Phase II study protocol is a high-quality clinical study, especially challenging on the efficacy and safety parameters. We are convinced that the additional data that will be generated by the revised protocol will strengthen the safety assessment for patients during the study, will provide with additional criteria that will help evaluating the efficacy, as well as offering a platform that is far more stronger for the Phase III program."*

About Donesta Project

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 flushes. 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 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 Euronext listed pharmaceutical company (MITRA) focused on Women's Health. Mithra's mission is to improve every stage of women's life with innovative and accessible pharmaceutical solutions. 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 therapeutic solutions in four therapeutic fields of women's health: fertility and contraception, menopause and osteoporosis, gynecological infections and female cancers. Mithra has an approximate headcount of 141 staff members and 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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