



GREEN LIGHT FROM FDA FOR THE LAUNCH OF ESTELLE®(E4/DRSP) PHASE III STUDY IN THE UNITED STATES

- Mithra obtains FDA's approbation for its Investigational New Drug for the Phase III clinical trials of Estelle® (E4/DRSP).
- This green light paves the way for the clinical trial of Mithra's Estetrol-based product candidate in contraception in the United States and in Canada.

Liège, Belgium 22 July 2016 – Mithra announced today that the American Food and Drug Administration (FDA) approved its Investigational New Drug application following the review of the presented documents (quality data, clinical and non-clinical data that are available to date regarding its product candidate). This regulatory green light paves the way for the clinical trial of Mithra's Estetrol-based product candidate in contraception, Estelle® (E4/DRSP) in the United States and in Canada.

As a reminder, these Phase III clinical programs will evaluate the contraceptive efficacy of Estelle® (E4/DRSP) in adult women aged from 18 (16 for US and Canada) to 50 years. These trials are aimed at enrolling 1550 patients from 18 to 50 years in Europe/Russia and 2000 patients from 16 to 50 years in United States/Canada. These will receive Estelle® (E4/DRSP) during 12 months.

François Fornieri, CEO Mithra Pharmaceuticals : *"This is very positive news for Mithra, knowing that the Phase III study can now start in line with our objectives and program. We also have taken a significant regulatory step today, thanks to the dedicated work of our internal teams."*

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

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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