PRESS RELEASE

FDA FEEDBACK ON SPA ESTELLE®: A NEW STEP CLOSER TO THE LAUNCH OF ESTELLE® PHASE III PIVOTAL CLINICAL STUDIES

- **Mithra received feedback on the SPA (Special Protocol Assessment) of the FDA (Food and Drug Administration) regarding its Estelle® Phase III Protocol.**
- **At the clinical protocol level, only minor recommendations and requests for clarification were expressed by the FDA.**
- **This feedback is comforting and in line with objectives and remains on Estelle® Phase III schedule.**

Liège, Belgium 05 April 2016 – After receiving encouraging news from the different European countries regarding the Estelle® Phase III pivotal clinical studies under approval, Mithra Pharmaceuticals announces today that the FDA (Food and Drug Administration) also gave encouraging feedback regarding the Estelle® Phase III pivotal clinical study protocol in the United States. Mithra already has the answers at its disposal and will provide them through the IND (Investigational New Drug) submission as planned in the course of June 2016. At the clinical level, only minor recommendations and requests for clarification were expressed by the FDA.

Bernard Cornet, Estetrol Development Programs Director Mithra Pharmaceuticals : *« The FDA feedback was a significant step in the European protocol finalization, as we want both clinical study protocols (US-EU) to be similar in order to combine datasets ».*

François Fornieri, CEO Mithra Pharmaceuticals : *" This is very positive news for Mithra, since the Phase III study will begin in line with our objectives and agenda. This is a new step closer to the launch on time of Estelle® Phase III pivotal clinical study in Europe and the United States.*

The Phase III clinical study will evaluate the contraceptive efficacy of Estelle in women aged between 18 and 35 years. This is done by measuring the Pearl Index[1] (PI). During the trial 1550 patients in Europe and 2000 patients in the United States will receive Estelle® for up to one year.

Mithra is expected to enroll its first Phase III subjects in H2 2016.

[1] The Pearl Index (PI) is the standardized measurement of combined hormonal contraceptives calculated as the number of contraceptive failures per 100 women divided by the years of exposure.

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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