



CANADA APPROVES CLINICAL TRIAL APPLICATION FOR ESTELLE® (E4/DRSP) PHASE III STUDY

Liège, Belgium 20 July 2016 – Mithra announces today that the Canadian authorities approved its Clinical Trial Application (CTA) for the Phase III study for Estelle® (E4/DRSP), the Estetrol-based product candidate in contraception developed by Mithra. This great news has been received a few weeks after the enrolment of the first patient in the Phase III study in Europe. Mithra should receive a feedback from the American Food and Drug Administration (FDA) in the next few days, as well as ethic committees, representing the last step before the launch of the Phase III study in the United States and in Canada.

As a reminder, Mithra submitted its Investigational New Drug (IND) to the FDA in the United States, as well as the CTA in Canada for the development of its Estetrol-based project Estelle® (E4/DRSP). These steps are required by local agencies in order to get a green light for conducting clinical trials on these territories.

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.

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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