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MITHRA PHARMACEUTICALS SA/NV RECEIVES AUTHORISATION TO CARRY OUT ITS FOOD EFFECT STUDY MIT-ES0001-C101

- **The approval of the study by the competent authorities has been received in a short time of approximately 1 month (instead of 2 at most).**
- **The progress of Estelle clinical studies is in line with objectives and remains on schedule to enrol its first subjects for Phase III in H2 2016.**
- **MIT-ES-0001-C101 is a crucial study within the process prior to the launch of the Phase III study for the product candidate Estelle in the United States.**

Liège, Belgium 14 Augustus 2015 – Mithra Pharmaceuticals announced today that it received the authorisation from the Bulgarian Drug Agency and the Ethics Committee at MC Comac Medical Ltd to carry out the food effect study MIT-Es0001-C101 in Bulgaria for its product candidate Estelle®, a combined oral contraceptive (COC), composed of 15 mg of Estetrol (E4) and 3 mg Drospirenone (DRSP).

This study will be conducted in order to evaluate the potential modifications induced by the intake of food on the pharmacokinetic profile of Estelle®. This is a typical study to determine the interaction of a product candidate when taken with a meal.

the results of this food effect study will allow us to adapt accordingly the protocol for the phase III US study.

Valérie Gordenne, CSO of Mithra Pharmaceuticals, said “ We are approaching the launch of our Phase III clinical study for Estelle® and remain on schedule to enrol our first subjects in H2 2016. The approbation of Bulgarian competent authorities is a very positive sign for the implementation of our clinical development plan”.

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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 generic products 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.