



ALREADY 4 EUROPEAN COUNTRIES FULLY APPROVED PROTOCOL OF MIT-ES001-C301 ESTELLE PHASE III CLINICAL STUDY

- Czech Republic, Sweden, Poland and Norway authorities give green light to start the Phase III clinical studies on their territories.
- The progress of the clinical program regarding the Estetrol-based contraceptive product candidate is in line with objectives and remains on schedule.
- In parallel, the MIT-ES001-C302 study will be conducted in the United States and in Canada.
- Mithra set up an International European Advisory Board about the development of its Estetrol-based contraceptive product candidate to meet market needs.

Liège, Belgium 24 March 2016 – On the 9 countries selected to host Phase III clinical trials for Mithra's contraceptive product candidate based on Estetrol (Estelle®) in Europe, 4 already fully approved the clinical trials protocol. Competent Authorities and Central Ethic Committees of Czech Republic, Sweden, Poland and Norway gave their green light to start the final study of one of Mithra's lead R&D projects on their territory.

Bernard Cornet, Estetrol Development Programs Director of Mithra Pharmaceuticals: *"This is a significant milestone for the Company since this is the first pivotal study with Estelle, one of Mithra's lead R&D Projects. A combined product candidate developed for Oral Contraception that contains our proprietary molecule Estetrol (with Drospirenone) that is a natural oestrogen with a unique mode of action. Estetrol is also developed in several other indications including Hormone Replacement Therapy in menopause".*

This approbation of European local authorities is the last regulatory step before the effective launch of the Phase III clinical trials.

The progress of the clinical program regarding the Estetrol-based contraceptive product candidate is in line with objectives and remains on schedule to enrol its first Phase III subjects in H2 2016.

The MIT-ES001-C301 trial will assess the efficacy and safety of the Estetrol-based contraceptive product candidate in 1550 subjects in Europe (Czech Republic, Sweden, Poland, Norway and the remaining countries to approve are Belgium, Finland, Germany, Hungary and Russia). Another Phase III trial (MIT-ES001-C302) will also be started soon in 2000 subjects at multiple centers across the United States and Canada.

In order to prepare the launch of this product, Mithra set up an International European Advisory Board. This board composed of 6 international experts in gynecology will advise the Company on the product development and on the use of Estetrol in contraception. These Key Opinion Leaders will collaborate with Mithra in order to identify the market needs and help Mithra align its

developments to them. The next board is scheduled on May 4 in Basel, Switzerland during the ESC Congress (European Society of Contraception and Reproductive Health) and will be moderated by Mitchell Creinin, a worldwide expert in contraception.

About MIT-Es001-C302 and MIT-Es001-C301 Phase III trials

The main objective of these trials is to evaluate the contraceptive efficacy of the Estetrol-based product candidate in women aged between 18 and 35 years. This is done by measuring the overall Pearl Index (PI) (i.e. standardised measurement of contraceptive methods calculated as the number of contraceptive failures per 100 women divided by the years of exposure).

The secondary objectives are to evaluate the contraceptive efficacy among the entire population (18 to 50 years old) and to evaluate the safety of this Estetrol-based product candidate. Endometrial safety will be assessed in a subset of women by performing endometrial biopsies before and at the end of the study.

Pictures

For pictures of François Fornieri, please click here on the following link:

<http://www.mithra.com/logo-et-charte-graphique/>

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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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