



3 OUT OF 5 EUROPEAN COUNTRIES SELECTED HAVE FULLY APPROVED PROTOCOL OF PHASE II CLINICAL STUDY DONESTA®-MIT-DO001-C201

8 OUT OF 9 EUROPEAN COUNTRIES SELECTED HAVE FULLY APPROVED PROTOCOL OF PHASE III CLINICAL STUDIES ESTELLE®- MIT-ES001-C301

- **The authorities of 3 out of 5 countries give green light to start the Phase II clinical study of the Estetrol-based product candidate dedicated to vasomotor menopausal symptoms (VMS) treatment on menopausal women (Donesta®) on their territories.**
- **In parallel, Mithra announces: 8 out of 9 countries selected to host Phase III clinical trials for Mithra's contraceptive product candidate based on Estetrol (Estelle®) in Europe have already fully approved the clinical trials protocol.**
- **The progress of the clinical programs regarding the Estetrol-based products candidate (Donesta® and Estelle®) are in line with objectives and remains on Mithra's schedule.**

Liège, Belgium 29 April 2016 – On the 5 countries selected to host Phase II clinical trial for Mithra's HRT (Hormone Treatment Therapy) candidate based on Estetrol (Donesta®) in Europe, 3 already fully approved the clinical trial protocol. Competent Authorities and Central Ethic Committees of Poland, Belgium and The Netherlands gave their green light to start the study of one of Mithra's lead R&D projects on their territory. The remaining countries to approve are Czech Republic and United Kingdom.

Bernard Cornet, Estetrol Development Programs Director of Mithra Pharmaceuticals: *“This approbation of European local authorities is the last regulatory step before the effective launch of clinical trials. This Phase II trial is crucial in the progress of one of Mithra's lead R&D Projects.”*

The Phase II study (MIT-Do001-C201) trial will be assessed in 225 women in Europe (across 5 selected countries: Poland, Belgium, The Netherlands, Czech Republic and United Kingdom). The objectives are to define the minimum effective dose by evaluating changes in frequency and in severity of moderate to severe vasomotor symptoms (hot flushes), to evaluate effects of different doses of Estetrol on vulvovaginal atrophy (VVA), on vaginal maturation index, on vaginal pH and to evaluate safety, included change in endometrial thickness for menopausal women.

The progress of Donesta® clinical program is in line with objectives and remains on schedule to enrol the first Phase II subject in the next weeks.

In Parallel, further to the communication of the 24th of March 2016, Mithra announces that on the 9 countries selected to host Phase III clinical trials for Mithra's contraceptive product candidate based on Estetrol (Estelle®) in Europe, 8 already fully approved the clinical trials protocol. Competent

Authorities and Central Ethic Committees of Czech Republic, Sweden, Poland, Norway, Belgium, Finland, Hungary and Russia gave their green light to start the fundamental pivotal study for the product registration. The remaining country to approve is Germany for which the regulatory green light is obtained and the ethic committee green light is attended before end of June.

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 Another Phase III trial (MIT-ES001-C302) will also be started soon in 2000 subjects at multiple centers across the United States and Canada.

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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