



MITHRA RECOGNIZED BY THE SCIENTIFIC COMMUNITY: THE CONTRACEPTION JOURNAL PUBLISHES A SCIENTIFIC ARTICLE ABOUT E4 (ESTETROL) FIESTA PHASE II STUDY

- Mithra Pharmaceuticals announces today the publication of a scientific article based on the results of the E4 FIESTA Phase II study of its estetrol-based product candidate Estelle[®], a combined oral contraceptive composed of 15 mg Estetrol (E4) and 3 mg Drospirenone (DRSP).
- The article describes the bleeding pattern and cycle control observed with different E4 combinations.
- The published results are very interesting for the scientific community as they demonstrate the good bleeding profile of the estetrol-based product candidate Estelle[®], which will be confirmed in the coming phase 3 studies.

Liège, Belgium, 4 May 2016 – Mithra Pharmaceuticals announces today that an article has been published in the peer-reviewed Contraception Journal. The published results of the E4 FIESTA Phase II study are particularly encouraging for the imminent launch of the Phase III studies.

The scientific article is entitled *Bleeding pattern and cycle control with estetrol-containing combined oral contraceptives: results from a phase II, randomised, dose-finding study (FIESTA)* and concerns the bleeding pattern and cycle control seen with E4 combinations.

This article is available on the Contraception Journal's website: <http://contraceptionjournal.org>

About the article entitled “Bleeding pattern and cycle control with estetrol-containing combined oral contraceptives: results from a phase II, randomised, dose-finding study (FIESTA)”

Objectives: This study assesses the vaginal bleeding patterns and cycle control of oral contraceptives containing estetrol (E4) combined with either drospirenone (DRSP) or levonorgestrel (LNG).

Study design: This was an open-label, multi-centre, randomised, dose-finding study lasting six cycles and conducted in healthy women aged 18–35 years. Four treatments (15 mg or 20 mg E4, combined with either 3 mg DRSP or 150 µg LNG) were administered in a 24/4-day regimen (24 days of active tablets intake followed by 4 days of placebo tablet intake). A marketed combined oral contraceptive containing estradiol valerate and dienogest (E2V/DNG) served as reference, since it contains (like E4) a natural estrogen.

Results: A total of 396 women were randomised, of whom 389 received study medication, and 316 completed the study. By cycle 6, the frequencies of unscheduled bleeding and/or spotting, and absence of withdrawal bleeding were the lowest in the 15 mg E4/DRSP group (33.8% and 3.5%, respectively). In the E2V/DNG reference group these frequencies were 47.8% and 27.1%, respectively. By cycle 6, the frequency of women with absence of withdrawal bleeding was <20% for

all E4-treatment groups: 3.5–3.8% combined with DRSP and 14.0–18.5% combined with LNG. By cycle 6, unscheduled intracyclic bleeding was reported by <20% of women in the 20 mg E4/LNG group (18.9%) and in the 15 mg E4/DRSP group (16.9%).

Conclusion: This study showed that of the four treatment modalities investigated, the 15 mg E4/DRSP combination has the most favourable bleeding pattern and cycle control.

Implications: Due to its favourable bleeding pattern and cycle control, the 15 mg E4/DRSP combination is the preferred combination for further phase III clinical development.

About the Contraception Journal

The journal Contraception wishes to advance reproductive health through the rapid publication of the best and most interesting new scholarship regarding contraception and related fields such as abortion. The journal welcomes manuscripts from investigators working in the laboratory, clinical and social sciences, as well as public health and health professions education.

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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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