



## MITHRA ENROLS ITS FIRST 5 PATIENTS FOR THE DONESTA® PHASE II CLINICAL STUDY MIT-DO0001-C201

**Liège, Belgium 13 May 2016** – Mithra Pharmaceuticals, a company dedicated to Women’s Health, announces today the enrolment of its first 5 patients in Poland for its Phase II clinical trial MIT-Do0001-C201 (E4Relief) for Donesta®, its Estetrol-based product candidate in the menopause indication. This enrolment is in line with the envisaged timing and objectives, as it was planned for H2 2016, as already announced in Mithra’s IPO Prospectus.

**Bernard Cornet, Estetrol Development Programs Director of Mithra Pharmaceuticals** : *“We are extremely pleased with the quick launch of this study. The clinical centers involved in this trial all around Europe are particularly enthusiastic. The start of enrolment is in line with our timing and objectives.”*

Donesta® is a new generation Hormonal Replacement Therapy (HRT) in development for vasomotor menopausal symptoms which consists of the oral administration of Estetrol.

The main objective of these Phase II clinical trials regarding the Donesta product candidate® is to define the minimum effective dose to treat vasomotor menopausal symptoms, namely hot flashes. In total, 5 doses will be tested in this blinded study, among which one placebo. These doses will be tested on a panel of 225 women for 12 weeks of treatment.

The secondary objectives of these clinical trials are to evaluate the effects of Estetrol on other menopausal symptoms and more particularly vulvo-vaginal atrophy (VVA), lipids and glucose metabolism, haemostasis or bone density loss.

The innocuity profile of Donesta® will be evaluated by the monitoring of patients and of their endometrial condition (proliferation or bleeding).

Chiltern has been chosen as Clinical Research Organization (CRO) for this study. Chiltern has been working on the study since September 2015 with a project management team based in Germany. Clinical monitors are also present on each of the 5 countries involved, working actively on investigation sites and ensuring a quick enrolment of patients.

The progress of clinical trials regarding Donesta® remains in line with objectives and schedule.

### 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](http://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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