

## **MITHRA PHARMACEUTICALS SELECTS CHILTERN AS CRO FOR THE PHASE II CLINICAL TRIALS OF ITS PRODUCT CANDIDATE DONESTA®**

**Liège, Belgium 21 October 2015** – Mithra Pharmaceuticals SA/NV announced that it has signed an agreement with Chiltern for the Phase II dose-finding study of its Estetrol-base product candidate Donesta®, a hormonal replacement therapy for menopausal women. This study called E4Relief is expected to start H1 2016 and to be finished end 2016. This contract amounts to EUR 4,5 million.

The Phase II dose-finding study will be conducted to select the minimal effective dose of E4 necessary for vasomotor symptoms (hot flushes) in menopausal women. 5 different doses of E4 alone will be evaluated on 225 women during a treatment period of 12 weeks.

As a secondary objective, this study will also evaluate the effects of Estetrol on vulvovaginal atrophy (VVA), lipid and carbohydrate metabolism, markers of coagulation and bone density loss.

The innocuity profile of Donesta® will also be assessed by a follow-up evaluation of patients and particularly of their endometrium (bleedings and proliferation).

*« The launch of this Phase II study for Donesta® is happening in the timeframe we expected », explained Valérie Gordenne, Chief Scientific Officer de Mithra Pharmaceuticals. « We could not be more enthusiastic about this collaboration with Chiltern. »*

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## About Chiltern

Chiltern is a contract research organization (CRO) gathering more than 30 years of expertise in clinical trials development for pharma and biotech companies. Recently, Chiltern has acquired Theorem Clinical Research, reinforcing its position as bigger middle-sized clinical trial services supplier. Chiltern currently works with 3,700 people across 47 countries.

## 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](http://www.mithra.com)

To subscribe to Mithra's newsletter, visit [investors.mithra.com](http://investors.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.*