



## MITHRA LAUNCHES MANUFACTURING OF MYRING FIRST TECHNICAL AND CLINICAL BATCHES

**Liège, Belgium 10 May 2016** – Mithra announces that the production of the first technical and clinical batches of Myring, a combined hormonal contraceptive vaginal ring made of ethylene vinyl acetate copolymers (EVA), has started within its external CMO (Macors). These clinical batches will be used in the bioequivalence study.

The manufacturing of the first batches starts today and is expected to be finalized end June 2016.

**François Fornieri, CEO Mithra Pharmaceuticals** : « *This is a significant step in the development process of this product candidate. We expect the Bioequivalence study to be finalized by the end of 2016. As such, the Myring dossier submission is expected for February 2017 in Europe and in US. The decision on the approval is expected around one year later and should then be on time for launch after patent expiry of the original Nuvaring®. We are one of the very few development companies in the world working on this product within the expected timelines and as such attractive to partner up with pharma companies around the world.* »

The batches manufacturing will consist of several stages:

1/ The production of transfer batches aimed at initiating a first trial (non-GMP) and ensuring a proper transfer of the manufacturing process, as well as the proper settlement of equipments within the CMO facilities.

2/ The production of the clinical batch that will be used as reference batch for the bioequivalence studies (EU and US). This will also be used as reference batch for the further process validation within the Mithra CDMO facilities.

3/ The production of the first and second stability batches aimed at generating stability data required for the registration dossier submission of Myring.

As soon as Mithra has received the GMP approvals expected Q4 2016 for its CDMO, all equipments and technology developed by Mithra will be transferred to Mithra's proper R&D and production platform in Flemalle as from October 2016.

### 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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