



## MITHRA FILES PATENT APPLICATIONS FOR ITS SUBLINGUAL FORM BASED ON ESTETROL THEREBY EXTENDING ITS IP POSITION TO SUBLINGUAL FORMULATIONS IN CONTRACEPTION AND MENOPAUSE UNTIL 2036

- Mithra files patent applications for its sublingual form based on Estetrol, an alternative formulation which could be used in menopause and contraception, including emergency contraception, offering potential protection for these indications until 2036.
- Mithra initiates galenic formulation of its sublingual form based on Estetrol with Pharmavize, as well as a collaboration with University College London to optimize the organoleptic characteristics of this formulation.
- Mithra hopes to obtain grant of its patents on the synthesis of Estetrol in Europe by July 2016.

**Liège, Belgium, 28 April 2016** – Mithra Pharmaceuticals announces filing patent applications on sublingual forms based on Estetrol, formulations which could be used in menopause and contraception, including emergency contraception. The patents on these formulations could offer a protection period running until 2036.

**François Fornieri, CEO Mithra Pharmaceuticals** : *“We are very pleased to announce that these patent applications on the sublingual form in the contraception and menopause indications would allow us to extend our IP protection regarding Estetrol. For us, the sublingual form offers a future avenue for the current development projects of Mithra based on Estetrol.”*

In parallel, Mithra initiates development of its sublingual form in collaboration with Pharmavize and University College London.

Pharmavize, located in Ghent, has specific expertise in the development of “orodispersible” forms (including sublingual delivery) and the University College London (School of Pharmacy) is specialized in determining the taste of new chemical entities using innovative *in vitro* techniques.

The form currently under development consists of a tablet to be placed under the tongue that quickly breaks apart when in direct contact with saliva.

Sublingual administration of an estrogen offers the advantage of bypassing the digestive system and avoiding the so-called “first pass liver effect”. The sublingual route of administration allows the active ingredient to directly enter the blood through the sublingual mucous membrane. This limits the exposure to the liver. Additionally, this route permits a more rapid targeting of relevant tissues.

Development will entail several stages : selection of excipients, development of formulation of tablets (taking care specifically to minimize the disintegration temperature while maintaining acceptable physical characteristics), optimization of taste and texture of the formulation.

This development project for a sublingual administration pathway for Estetrol is the subject of a European project named "SEPTIME" (Safety and Efficiency of Pulsed Treatment with Estetrol: an innovation for the treatment of Menopause).

SEPTIME has been selected by an international jury of European experts in a highly competitive procedure among a large number of project proposals for the Eureka Network<sup>1</sup> (Eurostars<sup>2</sup>). This European fund which has, over the past 30 years, been financing innovating R&D programs conducted by small and medium companies. It involves intensive international collaboration between academia and industry.

Within the framework of SEPTIME, the INSERM U1048-I2MC- Equipe 9 (Prof. J.F. Arnal) of Toulouse, the University of Liège (Prof. A. Noel-C. Péqueux) and UROSPHERE, a French company specialized in preclinical studies in urology, gastroenterology and oncology, will be working together with Mithra to optimize the sublingual Estetrol formulation and to evaluate in preclinical models, its efficacy and safety on the endometrium, as well as on urogenital and vascular targets in comparison to an oral administration.

## **Pictures**

For pictures of François Fornieri, please click here on the following link:

<http://www.mithra.com/en/logo/>

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<sup>1</sup> A Europe-wide network for industrial research and development, strengthening European competitiveness by promoting 'market-driven' collaborative RTD <http://www.eurekanetwork.org/about-eureka>

<sup>2</sup> Eurostars is a joint programme between EUREKA and the European Commission and is the first European financing and support programme specifically dedicated to SMEs active in R&D. Eurostars stimulates these companies to take up international collaboration projects in research and development .

## 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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