



## MITHRA PHARMACEUTICALS HOSTS ITS 2016 INVESTOR DAY AND REAFFIRMS ITS STRATEGY FOR THE UPCOMING YEARS

**Brussels, Belgium 29 June 2016** – Mithra Pharmaceuticals hosts its 2016 Investor Day today in Brussels. Through interviews with the CEO François Fornieri, members of the Executive Management and of the Scientific Committee, Mithra provides an update on its strategy and business model, as well as on its Research and Development projects one year after its Initial Public Offering.

### R&D projects highlights

#### Estetrol

- Mithra strengthens its intellectual property by obtaining two European patents related to its innovative Estetrol synthesis process. Those patents granted by the European Patent Office are part of a portfolio that includes already granted patents in USA, China, Singapore, Russia, South-Africa and New-Zealand.
- Mithra currently owns a portfolio of 25 patent families on Estetrol.
- Mithra will launch in Q4 2016 a Pharmacokinetic study of its Estetrol sublingual new formulation to compare with the oral form. 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 and bypasses the digestive system, avoiding the so-called “first pass liver effect”. The relevance of this project lies in the fact that on the one hand, Mithra would be able to start the development of a new project and on the other hand, Mithra would acquire a protection of its intellectual property on Estetrol on the longer term thanks to the patents previously mentioned.

#### Estelle® (E4/DRSP)

- Mithra submitted its Investigational New Drug (IND) to the FDA in the United States, as well as the CTA in Canada for the development of its Estetrol-based project Estelle® (E4/DRSP) in contraception. These steps are required by local agencies in order to get a green light for conducting clinical trials on these territories. Feedback from the agencies is expected before end 2016.
- Mithra has set up two Advisory Boards composed of international experts to support the last development steps of the Estetrol-based project Estelle®. The European and North American advisory boards respectively composed of 5 high-level Key Opinion Leaders, set up by Mithra and its scientific committee, are aimed at gathering impressions and recommendations from

the international experts in the contraception field. Both meetings were held in May and June 2016. The Key Opinion Leaders clearly considered Estetrol (combined with Drospirenone) as a major breakthrough in Contraception in Europe and the United States. They were also very impressed by the other potential indications such as vulvovaginal atrophy (VVA), neuroprotection or wound-healing (dermatology).

#### **Donesta® (E4)**

- According to regulatory notices from agencies, Mithra chose to add several biopsies to its Donesta® Phase II clinical trial protocol. Thanks to these biopsies, Mithra will be able to gather far more safety data, increasing valuation of the product.

#### **Myring**

- Technical batches of Myring are currently in production within the facilities of Macors in France. The validation and the bioequivalence batches of Myring will be produced in the Mithra CDMO as planned end 2016.

#### **Zoreline®**

- Mithra is currently waiting for the Clinical Study Report of the Pharmacodynamic study regarding the Zoreline® 3-month implant. These results are expected by end of 2016. The Pharmacokinetic studies are still ongoing. The report of both studies is expected end 2016.
- The pharmacokinetic study regarding the 1-month implant will be launched during H2 2016.

#### **Tibelia®**

- During the last few weeks, Mithra has received 4 new Marketing Authorisations for its Tibelia® product in Belgium, Hungary, Finland and the Netherlands. These are added to the MA Mithra received in April for the United Kingdom, Sweden and Norway. In total, Mithra has now 9 Marketing Authorisations for Tibelia®.
- Mithra already signed two contracts for the commercialization of Tibelia® in seven European countries. The first one with Mercury for the commercialization of Tibelia® in the United Kingdom, the second with Gedeon Richter for the commercialization of this product in Italy, Spain, Switzerland, Germany, Belgium and Luxembourg.
- The shelf life of the finished dosage form is currently 2 years and in line with the originator. Mithra is aiming to extend the shelf life up to 3 years, which will confer to the product a competitive advantage for Mithra's distribution partners.

## CDMO

- The Mithra CDMO will be inaugurated on September 30, 2016 in the presence of Mr Jean-Claude Marcourt, Minister for Economy, Industry and Innovation. The timing should be respected.

## **Operational Highlights**

- Mithra signed last week a Letter of Intent with the Women's Health market leader in Japan, Fuji Pharmaceuticals, to work towards a broad partnership on Estetrol in women's health in Japan and the ASEAN. This important partnership involves potential milestones in the double-digit million range and both parties intend to finalize their partnership in an agreement before the end of this year.
- Mithra also signed a few days ago a non-exclusive License and Supply Agreement with the Hungarian company Gedeon Richter for its product Tibelia®. Under the terms of this contract, Mithra grants Gedeon a non-exclusive license for the commercialization of Tibelia® in Italy, Switzerland, Spain, Germany, Belgium and Luxembourg. This contract follows the contract signed with Mercury for the commercialisation of Tibelia® in the United Kingdom, the fourth biggest potential of the global tibolone market. Altogether, these markets represent more than 59 million tablets, accounting for a total market of about EUR 24.6 million<sup>1</sup>.

For those who were unable to attend in person, the webcast and presentations of the meeting will be available on [investors.mithra.com](http://investors.mithra.com) on Thursday June, 30 2016 after market closing.

## **Pictures**

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

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

**For more information, please contact:**

## Press

### **Julie Dessart**

Chief Communication Officer

+32 4 349 28 22

+32 475 86 41 75

[press@mithra.com](mailto:press@mithra.com)

---

<sup>1</sup> Source : IMS 2015 Audited SU Value/Volume

## Investor Relations

**François Fornieri, CEO**

+32 4 349 28 22

[investorrelations@mithra.com](mailto:investorrelations@mithra.com)

## 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.*

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