



MITHRA OBTAINS A MARKETING AUTHORISATION FOR ITS OWN PRODUCT TIBELIA® IN SPAIN FOR WHICH IT HAS TWO COMMERCIAL AGREEMENTS

- **Mithra obtains a Marketing Authorisation (MA) for its product Tibelia® in Spain.**
- **With this Marketing Authorisation, Mithra is able to move forward with two non-exclusive commercial agreements it had signed for the Spanish market, with Gedeon Richter and Procure Health.**
- **Mithra now has a total of 10 MAs of the 15 requested and should terminate the whole procedure by September 2016.**

Liège, Belgium 5 July 2016 – Mithra Pharmaceuticals announces today that it obtained a new Marketing Authorisation for the commercialization of its product Tibelia® (bioequivalent of Livial® developed by Mithra) in Spain.

In December 2015, Mithra has signed a non-exclusive Licence and Supply Agreement with the company Procure Health for the Spanish territory. This Marketing Authorisation allows Mithra to move forward in Spain with this contract, as well as with the contract it signed more recently with Gedeon Richter, as Spain is one of Gedeon's key markets.

The Spanish market ranks third of the global Tibolone markets in terms of volume, with more than 9.3 million tablets, accounting for a total market of 2.4 million euros¹.

This contract follows the one signed with Mercury covering the commercialisation of Tibelia® in the United Kingdom, the fourth biggest potential of the global tibolone market (14 million tablets) and another one signed with the Hungarian company Gedeon Richter under which Mithra grants Gedeon a non-exclusive license for the commercialization of Tibelia in Italy, Spain, Switzerland, Germany, Belgium and Luxembourg.

Altogether, these markets represent more than 59 million tablets, accounting for a total market of about EUR 24.6 million².

¹ Source : IMS 2015 Audited SU Value/Volume

² Source : IMS 2015 Audited SU Value/Volume

This Marketing Authorisation in Spain joins the Marketing Authorisations that Mithra previously received for Tibelia® in Belgium, Italy, Hungary, Finland, the Netherlands, the United Kingdom, Norway and Sweden. As of today, Mithra has obtained 10 Marketing Authorisations and should obtain the authorisations of Luxembourg, Germany, France, Portugal and Greece by September 2016.

A validation of Mithra's R&D and regulatory expertise

Tibelia®, which is set to be bioequivalent to Livial® on the European market, is indeed a “complex” generic, as tibolone (the active ingredient involved) is known as a particularly unstable active pharmaceutical ingredient, presenting many challenges for development. Additionally, the clinical guidelines for demonstrating bioequivalence for this product have evolved, becoming much more difficult to pass. Obtaining marketing authorisations for such a product is a significant validation for Mithra's development and regulatory expertise, which was previously demonstrated in the development of Mithra's first R&D projects developed in-house Xena® and Levosert®, and which will continue to serve it well as it continues to develop and prepare the regulatory pathway for its lead products based on Estetrol.

About Tibelia®

Tibelia® is a synthetic steroid (tibolone) intended to be used for hormone replacement therapy. Tibelia® is a bioequivalent of Livial® 2.5mg which is a product that mimics the activity of the female sex hormones in the body, and is used especially for the relief of symptoms occurring after menopause. In some countries, this product is also used for the prevention of osteoporosis. It has been demonstrated that tibolone has favourable effects on various tissues in the body, such as brain, vagina and bone.³

Pictures

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

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

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³ Livial® Patient Information Leaflet.

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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

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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