



## **MITHRA'S TIBELIA<sup>®</sup> GETS GREEN LIGHT FOR MARKET AUTHORIZATION IN 14 EUROPEAN COUNTRIES, REINFORCES ITS CDMO PRODUCTION PIPELINE AND DEMONSTRATES ITS DEVELOPMENT CAPABILITIES**

- After Xena<sup>®</sup> and Levosert<sup>®</sup>, Tibelia<sup>®</sup> becomes the third R&D project in which Mithra has been involved from research phase to approval from regulatory authorities, underlining the strength and expertise of its development and regulatory teams in tackling complex generic developments.
- This step allows Mithra to enter the worldwide tibolone market, a growing market of 131 Million euro, and means that Tibelia<sup>®</sup> looks set to provide Mithra with a source of near-term cash flow in terms of license payments and sales revenue
- Additionally, this approval reinforces the pipeline of products that Mithra can produce in-house at its CDMO in Flémalle.

**Liège, Belgium 10 March 2016 – Regulated information –** Mithra is proud to announce that today it received official confirmation of the successful closure of its decentralized procedures regarding its candidate product Tibelia<sup>®</sup> (a bioequivalent of Livial<sup>®</sup> it developed in-house). This successful closure means that Tibelia<sup>®</sup> can expect to quickly receive market authorization in the 14 European countries that were targeted by the decentralized procedures.

François Fornieri, CEO of Mithra Pharmaceuticals, comments: *“We are extremely pleased with this important milestone for Tibelia<sup>®</sup>, and the validation brings to the unique development and regulatory expertise of our team. This news means that Mithra can move forward confidently to address this attractive market, not only in the 14 relevant European countries, but also worldwide, as having an approved EU-standard regulatory file opens up possibilities for partnerships around the world. Last, but by no means least, it reinforces the product pipeline that could potentially be produced in our CDMO.”*

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

Tibelia<sup>®</sup>, which is set to be only the second Livial<sup>®</sup> bioequivalent product 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 regulatory approval for such a product is a significant validation for Mithra's development and regulatory expertise, which was previously demonstrated in the developments of Xena<sup>®</sup> and Levosert<sup>®</sup>, 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.

## A source of cash flow and an entry into an interesting worldwide market

The first indication which Tibelia<sup>®</sup> targets is the treatment of oestrogen deficiency symptoms in postmenopausal women, more than one year after menopause. A second indication is prevention of osteoporosis in postmenopausal women at high risk of future fractures who are intolerant of, or contraindicated for, other medicinal products approved for the prevention of osteoporosis.

These indications represent an interesting and growing market of 131 million euro (IMS Q3/2015), showing a growth in value of 4.3%. In terms of volume, this means 315 million tablets, growing at a rate of 2.0%.

## About Tibelia<sup>®</sup>

Tibelia<sup>®</sup> is a synthetic steroid (tibolone) intended to be used for hormone replacement therapy. Tibelia<sup>®</sup> is a bioequivalent of Livial<sup>®</sup> 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.<sup>1</sup>

## Pictures

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

<http://www.mithra.com/logo-et-charte-graphique/>

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<sup>1</sup> Livial<sup>®</sup> Patient Information Leaflet.

## 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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