PRESS RELEASE

MITHRA OBTAINS THREE MARKETING AUTHORISATIONS FOR ITS PRODUCT TIBELIA ®, ONE OF WHICH IN THE UNITED KINGDOM WHERE IT SIGNED A FIRST LICENSE AND SUPPLY AGREEMENT

- **Mithra already obtained three Marketing Authorisations for its product Tibelia® in United Kingdom, Norway and Sweden.**
- **These MA's occur just a few weeks after the successful closure of the two decentralized procedures providing a green light in 14 European countries. Still 11 Marketing Authorisations to come in the next few weeks and months.**
- **Mithra already signed an exclusive License and Supply Agreement with Mercury in the United Kingdom, the fourth biggest potential of the global tibolone market in terms of volume (nearly 14 million tablets in 2015).**
- **Tibelia should be available on the UK market in the next few months.**

Liège, Belgium 13 April 2016 – Mithra Pharmaceuticals announces today that it obtained three Markering Authorisations for the commercialisation of its product Tibelia® (a product which is bioequivalent to Livial® and developed in-house) in the territories of United Kingdom, Norway and Sweden. These authorisations occur just a few weeks after the successful closure of the two decentralized procedures providing a green light in 14 European countries. There are thus still 11 Marketing Authorisations to come in the next few weeks and months.

Mithra is now able to enter the worldwide tibolone market, a growing market of EUR 131 million[1], as Mithra already signed an exclusive License and Supply Agreement with Mercury, a growing international pharmaceutical company, for the distribution of Tibolone in the United Kingdom. The United Kingdom is indeed the fourth biggest potential of the global tibolone market in terms of volume with nearly 14 million tablets[2]. Tibelia should be available on the UK market in the next few months.

[1] Source : IMS Q3/2015

[2] Source : IMS Q3/2015

Norway and Sweden respectively represent a market of 1,112,594 tablets and 743,265 tablets of tibolone[3].

Tibelia® looks set to provide Mithra with a source of near-term cash flow in terms of license payments and sales revenue.

François Fornieri, CEO of Mithra Pharmaceuticals, comments: "*Obtaining Marketing Authorisations for a product candidate is a real recognition for the development and regulatory expertise of our dedicated teams. These mean that Mithra can move forward confidently to address the attractive market of Tibolone, full of possibilities for partnerships around the world.*"

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.

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

The first indication which Tibelia® 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, showing a growth in value of 4.3%. In terms of volume, this means 315 million tablets, growing at a rate of 2.0%[4].

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.[5]

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[3] Source : IMS Q3/2015

[4] Source : IMS Q3/2015

[5] Livial® Patient Information Leaflet.

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

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.