



MITHRA LAUNCHES ITS PRODUCT TIBELIA¹ ON THE GLOBAL MARKET

- Mithra Pharmaceuticals received 14 Marketing Authorizations (MA) in 12 European countries for its product based on tibolone.
- Mithra should receive shortly 3 more authorizations for France, Italy and Greece.
- Tibelia received 24 months shelf-life and should be able to extend this one in 36 months in 2017, what would give the product a unique advantage on the market and would make it more competitive than its competitors.
- In 2016, Mithra signed 8 License and Supply Agreements.
- Mithra expects to sign other agreements with Ukraine, Russia, Chile, Singapore, France and Switzerland.
- Mithra estimates, according to the sales forecasts of his distributors, incomes in double digit for the next five years.

Liège, Belgium, 22 December 2016 – Mithra Pharmaceuticals, a company focused on Women’s Health, announces today that it obtained 14 Marketing Authorizations for the commercialization of its product Tibelia in the United Kingdom, Belgium, Holland, Luxembourg, Spain, Portugal, Germany, Hungary, Poland, Norway, Sweden and Finland. Mithra is still waiting for 3 MA in France, Greece and Italy that should be received by the beginning of 2017.

The product based on tibolone developed by Mithra will be more competitive due to its extended shelf-life.

Valérie Gordenne, CSO Mithra Pharmaceuticals: *“At this stage, we believe we can justify a shelf-life of 36 months versus 24 months for the competitors. Currently, data are available on 24 months for the pilot batches. Trends show a possible stability extension. The results are confirmed on the first industrial batch (18 months). The best stability of the active ingredient in the formulation is linked to specific components of this formulation, for which a patent has been applied.”*

In 2016, Mithra signed 8 License and Supply Agreements in the United Kingdom, Spain, Switzerland, Germany, Benelux, Australia, South Africa, Canada and Finland for a total amount in double digit, down payments included. In 2017, Mithra expects to sign other agreements with Ukraine, Russia, Chile, Singapore and France

In United Kingdom, marketing is already effective, as well as it will be effective in Spain and Holland in January 2017.

¹ Code name for the product based on Tibolone developed by Mithra. Every distributor is free to choose the name he wishes to commercialize locally.

François Fornieri CEO Mithra Pharmaceuticals: *“Obtaining a Marketing Authorization for a product candidate is a real recognition of the unique expertise of our team in terms of development and regulatory affairs. Tibelia is set to be a competitor on the European market. It is indeed a ‘complex’ therapeutical solution as tibolone, the active ingredient involved, is known as a particularly unstable active ingredient, presenting many challenges in terms of development. 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 the past, 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.”*

The global market of tibolone is an attractive and growing market of EUR 131 million², accounting for an increase of 4.3% in value³. In terms of volume, this market represents 315 million tablets, up 2%⁴.

About Tibelia

Tibelia is a synthetic steroid (tibolone) intended to be used for hormone replacement therapy. Tibelia 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 bone⁵.

Pictures

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

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

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² Source : IMS Q3/2015

³ Source : IMS Q3/2015

⁴ Source : IMS Q3/2015

⁵ 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 Euronext listed pharmaceutical company (MITRA) focused on Women's Health. Mithra's mission is to improve every stage of women's life with innovative and accessible pharmaceutical solutions. 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 solutions in four therapeutic fields of women's health: fertility and contraception, menopause and osteoporosis, gynecological infections and female cancers.

Mithra has an approximate headcount of 141 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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