



## MITHRA SIGNS EXCLUSIVE AGREEMENT FOR TIBELIA® IN CANADA

- **Tibelia® would be the first tibolone-based Hormone Therapy product available in Canada**
- **Marketing authorization process is ongoing**
- **Tibelia® already marketed in a number of countries through supply and license agreements**

**Liège, Belgium, 6 June 2017** – Mithra (Euronext Brussels: MITRA), a company specialized in Women's Health, announces that it has signed an exclusive License and Supply Agreement for Tibelia®, its generic version of tibolone for use in Hormone Therapy (HT), with an undisclosed Canadian partner. Tibelia® is a generic version of Livial®.

There are currently no tibolone-based products on the market in Canada for the relief of postmenopausal symptoms and prevention of osteoporosis in post-menopausal women. Subject to obtaining marketing approval from Health Canada, Tibelia® would therefore be launched as a new treatment option for these indications in Canada. The dossier seeking marketing approval has already been submitted.

The Canadian menopausal health market is currently valued at approximately EUR 80 million<sup>1</sup>, with further growth potential as new products are introduced, offering a promising opportunity for Tibelia®. Mithra intends to produce Tibelia® at its own research and production facility (Mithra CDMO<sup>2</sup>), so that this new agreement would not only generate milestone payments but also additional revenues through supply agreements.

**François Fornieri, CEO of Mithra, commented:** *"The Canadian market represents an important opportunity for Tibelia® and has the potential to offer women in Canada new options to safely address menopausal symptoms. This agreement follows the completion of the decentralized approval procedure for Tibelia® in Europe and demonstrates the increasing momentum and interest in Tibelia® in a growing number of markets. We look forward to establishing further partnerships for both our potentially game-changing E4-based pipeline, with Estelle® for contraception and Donesta® for menopause, and our Complex Therapeutics, such as Myring™ and Tibelia®."*

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<sup>1</sup> IMS Health 2016

<sup>2</sup> Contract Development & Manufacturing Organization.

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**About Tibelia®**

Tibelia® is a synthetic steroid (tibolone) intended to be used for Hormone Therapy (HT). 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. This includes the relief of postmenopausal symptoms, in addition to prevention of osteoporosis in postmenopausal women at high risk of future fractures who are intolerant of, or contraindicated for, other medicinal products. It has been demonstrated that tibolone has favorable effects on various tissues in the body, such as brain, vagina and bone.<sup>3</sup>

**About Mithra**

Mithra (Euronext: MITRA) is dedicated to providing innovation and choice in women's health, with a particular focus on fertility, contraception and menopause. Mithra's goal is to develop new and improved products that meet women's needs for better safety and convenience. Its two lead development candidates – a fifth generation oral contraceptive Estelle® and next-generation hormone therapy Donesta® - are built on Mithra's unique natural estrogen platform, E4 (Estetrol). Mithra also develops, manufactures and markets complex therapeutics and offers partners a complete spectrum of research, development and specialist manufacturing at its CDMO. Mithra was founded in 1999 as a spin-off from the University of Liège by Mr. François Fornieri and Prof. Dr. Jean-Michel Foidart. Mithra is headquartered in Liège, Belgium. Further information can be found at: [www.mithra.com](http://www.mithra.com)

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<sup>3</sup> Livial® Patient Information Leaflet.

## 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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