



## Tibelia<sup>®</sup>, First Tibolone-Based Hormone Therapy Approved in Canada

- The Canadian Health authorities have granted the Marketing Authorization for Tibelia<sup>®</sup>, the company's tibolone-based product for use in Hormone Therapy (HT).
- First tibolone-based hormone treatment to be available in Canada, offering a true new option for women with a proven efficacy, tolerability and safety profile
- The introduction of Tibelia<sup>®</sup> in Canada plays a crucial role in the international commercial expansion strategy in key attractive markets like the United States

Liege, Belgium, 15 May 2019 – 7 :30 CEST – Mithra (Euronext Brussels: MITRA), a company dedicated to Women's Health today announces that Health Canada, the Canadian Health authorities, has approved Tibelia<sup>®</sup> (tibolone), indicated for the short-term treatment of vasomotor symptoms due to estrogen deficiency in postmenopausal women, more than one year after menopause. Developed by Mithra as bioequivalent version of Livial<sup>®1</sup>, Tibelia<sup>®</sup> is a synthetic steroid that relieves postmenopausal symptoms and prevents osteoporosis in postmenopausal women at high risk of future fractures who are intolerant of, or contraindicated for, other medicinal products.

### New treatment option for postmenopausal women in North America

There are currently no tibolone-based products on the market in Canada (originator and generic included) for the relief of postmenopausal symptoms and prevention of osteoporosis in postmenopausal women. With this go-ahead of Health Canada, Tibelia<sup>®</sup> will be launched as a new treatment option for these indications in Canada.

**Dr. Robert Reid, MD, Gynaecologist and Adjunct Professor at the Department of Obstetrics and Gynaecology, Queen's University, commented:** *"Available hormonal treatment options for menopausal vasomotor symptoms while generally effective are often accompanied by side effects related to combination therapies that add a progestational agent to estrogen therapy as a protection against endometrial neoplasia. As a result, many women discontinue therapy and seek help from complementary and alternative medicines that are mostly unregulated, unproven and lacking safety information. Tibolone has unique properties that allow it to be used alone without the need for progestin co-therapy. It has been in use in Europe for treatment of menopausal symptoms for many years and has a proven efficacy, tolerability and safety profile."*<sup>2</sup>

### First tibolone-based product on the Canadian market

Mithra has already signed an exclusive license and supply agreement for the commercialization of Tibelia<sup>®</sup> in Canada with BioSyent Pharma Inc (TSX Venture Exchange : RX)<sup>3</sup>. The Canadian menopausal

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<sup>1</sup> Registered trademark of Merck.

<sup>2</sup> [Press Release - May 13th, 2019 - BioSyent Announces Health Canada Approval of New Women's Health Product](#)

<sup>3</sup> Tibelia<sup>®</sup> will be marketed under the name Tibella<sup>®</sup>

health market is currently valued at approximately CAD \$200 million (EUR 132 million)<sup>4</sup>, with further growth potential as new products are introduced, offering a promising opportunity for Tibelia®. Mithra will produce Tibelia® for the Canadian market at its own research and production facility, the Mithra CDMO<sup>5</sup>. The agreement with BioSyent Pharma Inc will generate milestone payments and additional revenues through supply agreements.

To date, Mithra has entered licensing agreements for Tibelia® in ten countries. The introduction on the North American continent plays a crucial role to support the international commercial expansion strategy in key attractive markets like the United States. As in Canada, there are currently no tibolone-based products available on the U.S., where the menopausal market is worth USD 2,9 billion (EUR 2,5 billion)<sup>6</sup>.

**François Fornieri, CEO Mithra Women's Health, commented:** « *We are very pleased to offer Canadian women a new option to safely address menopausal symptoms. The introduction of Tibelia® in Canada marks the first tibolone-based product launch in the whole of North America. This green light from the Canadian Health authorities is a very positive signal that could open the doors to the crucial U.S. market.* »

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**About Mithra**

*Mithra (Euronext: MITRA) is dedicated to providing innovation and choice in Women's Health, with a particular focus on contraception and menopause. Mithra's goal is to develop new and improved products that meet women's needs for better safety and convenience. Its three lead development candidates – a fifth generation oral contraceptive Estelle®, the first complete oral treatment for perimenopause PeriNesta™ and next-generation hormone therapy Donesta® - are built on Mithra's unique native estrogen platform, E4 (Estetrol). Mithra also develops and manufactures 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 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)*

**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.<sup>7</sup>*

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<sup>4</sup> IQVIA market data for the 12 months ending December 2018

<sup>5</sup> Contract Development & Manufacturing Organization.

<sup>6</sup> IQVIA market data for the 12 months ending December 2018

<sup>7</sup> Livial® Patient Information Leaflet.

**About BioSyent Inc.**

*Listed on the TSX Venture Exchange under the trading symbol "RX", BioSyent is a profitable growth-oriented specialty pharmaceutical company focused on in-licensing or acquiring innovative pharmaceutical and other healthcare products that have been successfully developed, are safe and effective, and have a proven track record of improving the lives of patients. BioSyent supports the healthcare professionals that treat these patients by marketing its products through its community, hospital and international business units.*

**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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