



## Mithra Announces Commercial Launch of Tibelia® in Canada

- First tibolone-based hormone treatment available in Canada, offering a new treatment option for menopausal women
- Mithra's product commercialized by BioSyent Pharma for a growing annual market value of EUR 132 million
- Canadian launch generates additional revenues for Mithra through sales related milestones

**Liege, Belgium, 30 July 2020 – 7:30 CEST** – Mithra (Euronext Brussels: MITRA), a company dedicated to Women's Health, today announces the commercial launch of tibolone-based product Tibelia® in Canada. Developed by Mithra as the bioequivalent version of Livial®<sup>1</sup>, Tibelia® is a synthetic steroid that relieves postmenopausal symptoms and prevents osteoporosis in postmenopausal women at high risk of future fractures who are intolerant of other medicinal products. Mithra's product is marketed by BioSyent Pharma Inc. (TSX Venture Exchange: RX) in Canada under the trademark name Tibella®.

Mithra's product is the first tibolone-based product provided to menopausal Canadian women, offering an innovative solution with a proven safety profile. *"Available hormonal treatment options for menopausal vasomotor symptoms, while generally effective, are often accompanied by side effects. As a result, many women discontinue therapy. 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 the treatment of menopausal symptoms for many years and has a proven efficacy, tolerability and safety profile"*, commented Dr. Robert Reid, MD, Gynaecologist and Professor Emeritus at the Department of Obstetrics and Gynaecology, Queen's University.

In Canada, almost 4 million women between the ages of 45 and 59 have gone through or will soon go through menopause<sup>2</sup>. The Canadian menopausal health market is currently valued at approximately CAD \$200 million (EUR 132 million) per year<sup>3</sup>, with further growth potential as new products are introduced, offering a promising opportunity for Tibelia®. The agreement with BioSyent Pharma Inc. will generate additional revenues for Mithra through sales related milestone payments.

Already commercialized in about 30 countries, Tibelia® is now present for the first time on the North American continent, which should facilitate access to the major U.S. market. 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) per year<sup>4</sup>.

**François Fornieri, CEO Mithra Women's Health, commented:** *"We are delighted to provide Canadian physicians and women with a new treatment option to safely and effectively address menopausal symptoms. Our product is already present in many countries around the world, but its introduction on the North American continent was eagerly awaited and should now make it easier for us to enter the crucial U.S. market."*

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

<sup>2</sup> [Statistics Canada](#) 2019

<sup>3,4</sup> IQVIA market data for the 12 months ending December 2018

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*Mithra (Euronext: MITRA) is a Belgian biotech company dedicated to transforming Women's Health by offering new choices through innovation, with a particular focus on contraception and menopause. Mithra's goal is to develop products offering better efficacy, safety and convenience, meeting women's needs throughout their life span. Its three lead development candidates are built on Mithra's unique native estrogen platform, Estetrol (E4): Estelle<sup>®</sup>, a new era in oral contraception, PeriNesta<sup>®</sup>, the first complete oral treatment targeting perimenopause and Donesta<sup>®</sup>, the next-generation hormone therapy. Mithra also develops and manufactures complex therapeutics in the areas of contraception, menopause and hormone-dependent cancers. It offers partners a complete spectrum of research, development and specialist manufacturing at its technological platform Mithra CDMO. Active in more than 100 countries around the world, Mithra has an approximate headcount of 250 staff members and is headquartered in Liège, Belgium. [www.mithra.com](http://www.mithra.com)*

**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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