

## PRESS RELEASE



### MITHRA'S MARKETING AUTHORIZATION APPLICATION FOR TIBELIA® ACCEPTED BY HEALTH CANADA

- Tibelia® would be the first tibolone-based Hormone Therapy product available in Canada
- Marketing Authorization (MA) decision in Canada expected as of Q4 2018
- Mithra's Canadian partner preparing for potential launch shortly thereafter

**Liège, Belgium, 10 October 2017** – Mithra (Euronext Brussels: MITRA), a company specialized in Women's Health, today announces that Health Canada has accepted the Marketing Authorization Application for its complex therapeutic Tibelia®, the company's tibolone-based product for use in Hormone Therapy (HT).

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. If approved, Tibelia® would therefore be launched as a new treatment option for these indications in Canada. With the acceptance of the MAA by Health Canada, Mithra is on track to receive potential Tibelia® approval as of Q4 2018. In June 2017, Mithra announced an exclusive License and Supply Agreement for Tibelia® with an undisclosed Canadian partner.

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®.

**François Fournier, CEO of Mithra, commented:** “We are very pleased to see Tibelia®, which could offer women new options to safely address menopausal symptoms, continue to advance globally. Today’s news reconfirms that we are on track for a marketing authorization decision in Canada as of late 2018, and we look forward to launching Tibelia® on the Canadian market with our distribution partner. With Tibelia® on the market in three countries already, and launches in Sweden and Finland planned this year, we expect that Canada will be an important contributor to the growing revenues of this product.”

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<sup>1</sup> IMS Health Q2 2017

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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 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)

**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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