



## Mithra and Rafa Laboratories sign binding Head of Terms to commercialize DONESTA<sup>®</sup> in Israel

- Rafa Laboratories to receive the exclusive commercial rights for DONESTA<sup>®</sup> in Israel on the signing of the final license and supply agreement
- Mithra is eligible to receive a total of EUR 2.05 million sales-related milestones, along with tiered double-digit royalties on annual net sales and payments at signature of the license agreement and for regulatory milestones
- DONESTA<sup>®</sup> to target an addressable menopause market in Israel of ~900,000 women aged between 45 and 64<sup>1</sup>

**Liege, Belgium, 21 December 2023 – 17:45 CET** – Mithra (Euronext Brussels: MITRA), a company dedicated to Women's Health, today announces the signing of a binding Head of Terms (HoT) agreement for the commercialization of DONESTA<sup>®</sup> in Israel with Rafa Laboratories LTD, an Israeli pharmaceutical company. DONESTA<sup>®</sup> is Mithra's investigational, next generation hormone therapy medicine containing estetrol (E4) for the treatment of the symptoms of menopause.

Rafa Laboratories will have the exclusive commercial rights for DONESTA<sup>®</sup> in Israel and the Palestinian Territories on the signing of the final license and supply agreement – planned in Q1 2024.

Mithra is eligible to receive a total of EUR 2.05 million sales-related milestones, along with tiered double-digit royalties on annual net sales.

David Horn Solomon, CEO of Mithra stated, "We are thrilled that Mithra and Rafa Laboratories will work together to offer DONESTA<sup>®</sup> to women who suffer from the symptoms of menopause. We look forward to working closely with Rafa Laboratories to support its success in delivering differentiated efficacy, safety, and convenience to a market of hundreds of thousands of women."

Amir Levin, CEO of Rafa, commented, "We are excited to cooperate with Mithra on this new product which will enable Rafa Laboratories to add to its Women's Health portfolio. We are pleased to offer this next generation, orally administered estetrol-based hormone therapy

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<sup>1</sup> World Health Organization data, 2021

product candidate to the Israeli market. It's innovative nature and the prospect it offers to women suffering from the symptoms of menopause can be a game-changer."

#### For more information, please contact:

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#### About Mithra

*Mithra Pharmaceuticals SA (Euronext: MITRA) is a Belgian biopharmaceutical 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. Mithra explores the potential of the unique native estrogen estetrol in a wide range of applications in women health and beyond. After having successfully launched the first estetrol-based product in 2021, the contraceptive pill ESTELLE<sup>®</sup>, Mithra is now focusing on its second product DONESTA<sup>®</sup>, the next-generation hormone therapy. Mithra also offers partners a complete spectrum of solutions from early drug development, clinical batches and commercial manufacturing of complex polymeric products (vaginal ring, implants) and complex liquid injectables and biologicals (vials, pre-filled syringes or cartridges) at its technological platform Mithra CDMO. Active in more than 100 countries around the world, is headquartered in Liège, Belgium. [www.mithra.com](http://www.mithra.com)*

ESTELLE<sup>®</sup> and DONESTA<sup>®</sup> are registered trademarks of Mithra Pharmaceuticals or one of its affiliates.

#### 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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