



## Mithra successfully renegotiates the earnouts relating to its Complex Therapeutics and acquires full licensing and distribution rights for Zoreline®

- Strengthening of Mithra's development strategy with the complete buyout of all remaining contingent payments obligation (earnouts) linked to Myring® and Zoreline®
- Full global licensing and distribution rights for the Zoreline® implant indicated for the treatment of breast, prostate cancer and certain gynecological disorders
- Zoreline® represents an attractive business opportunity in a market exclusively dominated by one brand product recording worldwide sales higher than EUR 700 million with a 4,5 % growth<sup>1</sup>

**Liege, Belgium, 24 June 2021 – 17:45 CEST** – Mithra (Euronext Brussels: MITRA), a company dedicated to Women's Health, is pleased to announce today the successful renegotiation of the earnouts linked to two products of its Complex Therapeutic portfolio: the Zoreline® implant and the Myring® contraceptive hormonal ring

In line with the strategy of renegotiating the Estelle® earnouts in 2019<sup>2</sup>, Mithra succeeds to further reduce the fair value of its contingent payments obligation reported under "Other financial liabilities" on its balance sheet, with the complete buyout of all earnouts linked to Myring® and Zoreline®. Mithra also becomes sole owner of all rights related to its Complex Therapeutics product, Zoreline®.

The 2020 various funding transactions achieved for an amount of EUR 260 million and the current significant cash lines (capital commitment line with LDA Capital Ltd and bank loan) still unused, show Mithra's strong cash position. Mithra current financials allow the company to pursue its evolution towards a biopharmaceutical structure with commercial stage assets like Estelle® combine oral contraceptive, and finance the parallel development of its E4 portfolio and Complex Therapeutics.

Under the terms of this agreement signed with SVR Invest BV<sup>3</sup>, Mithra buys back all contingent payments linked to Myring® and Zoreline® for an amount of EUR 8.5 million compared to the EUR 8.8 million booked as at fair value on December 2020<sup>4</sup>. This amount of EUR 8.5 million shall be paid upon closing of the agreement.

Mithra also acquires, for an additional amount of EUR 8.5 million (spread over the next four years), the full licensing and distribution rights on Zoreline® held by SVR invest<sup>5</sup>, including important territories such as China, Canada and Australia, that should represent more than 70% of market opportunity by 2025. Prior to this purchase Mithra only held 50 % of worldwide commercial licensing territorial rights (situation "as is"). Under the new agreement, Mithra holds 100 % of worldwide licensing territorial rights which allows Mithra to significantly increase its margin in some of the most attractive geographies outside of Mithra's former territorial scope.

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<sup>1</sup> IQVIA 2020

<sup>2</sup> [Press release Mithra 01/10/2019](#)

<sup>3</sup> Following assignment of the rights from Generic Specialty Pharma Ltd (GSP) to SVR Invest BVBA. Related party transaction pursuant to article 7:97 of the Code of companies and association applies to the present deal (see details below).

<sup>4</sup> In our annual report 2020, contingent payment considerations for Myring® and Zoreline® are reported as Other Financial liabilities on the balance sheet (see section 9.17.4) with a fair value of respectively at EUR 5.7 million and EUR 3.1 million.

<sup>5</sup> Except in the UK.

As confirmed by a group of independent experts, this agreement holds significantly more value for Mithra than remaining in the as-is scenario, balanced by the earn-outs extinction and the positive return on investment expected for Zoreline® on a global scale.

### Significant business opportunity

Mithra CDMO has extensive expertise in the development and production of complex and innovative products using medical polymer technology, enabling a drug's active pharmaceutical ingredient to be distributed at a predetermined rate over a period of time with a controlled drug delivery. After the Tibelia® tablet and the Myring® vaginal ring, already commercialized, the Zoreline® implant is Mithra's next priority project based on this worldwide unique expertise. This biodegradable subcutaneous implant based on goserelin (3.6 mg for 1 month/10.8 mg for 3 months formulation) is used to treat prostate cancer, breast cancer and gynaecological indications (endometriosis, uterine fibroids). Mithra also has proprietary technology offering improved product delivery and operator safety features.

Zoreline® represents a significant business opportunity in a market dominated by the branded Zoladex®<sup>6</sup>, with annual worldwide revenues of nearly EUR 733 million (4.22 million in volume). Zoladex® has been off patent for around 20 years and no generic version has been approved to date, except in a few Eastern European countries, which demonstrates the complexity of the development of such a drug.

**Jean-Manuel Fontaine, Chief Business Officer of Mithra, commented:** *"We are very pleased with this renegotiation which enables Mithra to extinguish all contingent payments and to own the full commercial rights of Zoreline® for key countries that should represent the majority of the global market opportunity by 2025, in particular China which is worth more than 33% of the market opportunity."*

### Zoreline® Scientific Program

Two formulations (1 month/3 months) of Zoreline® are currently being manufactured to be tested in an animal PK/PD<sup>7</sup> comparative study, with first results expected by the end of 2021. Mithra expect to launch the clinical studies in H1 2022, with a potential commercial launch in 2025. This R&D Oncology Program is supported by the Walloon Region through recoverable cash advances of about EUR 10 million.

**Graham Dixon, Chief Scientific Officer of Mithra, commented:** *"The development of long-acting hormonal products has been at the heart of Mithra's expertise since the beginning. We were the first and the only one to succeed in developing a generic of the IUD Mirena®, before developing successfully the Tibelia® tablet and the Myring® contraceptive ring. In the past two years, we have made significant progress in the development of both formulations of Zoreline® and we strongly believe in the capacity of our teams to bring Zoreline® to the worldwide market as first generic."*

### Additional information regarding related party transaction

The following information is provided pursuant to Article 7:97 of the Belgian Companies and Associations Code. The present transaction took place between Novalon SA (a fully owned subsidiary of Mithra) and SVR Invest BVBA which is a related party to Mithra as SVR Invest BV is controlled by Mr Stijn Van Rompay, co-founder of Novalon and Company's CEO's son. The transaction was closed on the 23 June 2021 for an aggregate value of seventeen million euros.

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<sup>6</sup> Zoladex® is a trademark of AstraZeneca UK Limited

<sup>7</sup> Pharmacokinetics (PK); Pharmacodynamic (PD)

Pursuant the Article 7:97 of the Belgian Companies and Association Code, a committee of three independent directors of the Company has assessed the above transaction with the assistance of an independent expert mandated by them to review the Company's financial models and assumptions with respect to the transaction and provide their opinion regarding Mithra's interest in renegotiating this deal. The independent expert concluded that the renegotiation of the initial contracts would generate much more value for Mithra than the scenario " as-is" , with a significant difference between both scenario.

Following this positive recommendation, the committee of three independent directors has issued a written substantial opinion to Mithra's Board of Directors in which the committee deems the transaction to be in the interest of the Company and recommended to the Board of Directors to approve the renegotiation of the original contracts. This committee namely endorsed the conclusions of the independent experts and considered that the renegotiation price to be paid was significantly balanced by the earn-outs extinction and the return on investment to be expected in the key countries where Zoreline® could be distributed pending clinical development and regulatory approval. The Board of Directors followed unanimously the favourable opinion of the independents committee and approved the renegotiation.

The statutory auditor's assessment of the committee's opinion and the minutes of the board meeting is as follows: " *Based on our assessment, the financial and accounting data included in the minutes of the Board of Directors and in the opinion of the committee do not contain any significant inconsistencies in comparison with the information available to us in the context of our engagement.*"

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#### About Mithra

*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. Mithra explores the potential of the unique native estrogen Estetrol in a wide range of applications in women health and beyond (Covid-19, neuroprotection...). 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 300 staff members and is headquartered in Liège, Belgium.*

[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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