



Mithra and Gedeon Richter sign binding Head of Terms to commercialize ESTELLE[®] and DONESTA[®] in China

- Mithra signs binding Head of Terms for a twenty-year partnership with Gedeon-Richter for the development and commercialization of ESTELLE[®] and DONESTA[®] in China
- Mithra to receive EUR 4.5 million in combined milestone payments at signature of the license agreements with additional combined regulatory milestones of EUR 1.2 million
- Mithra eligible to receive a combined total of EUR 8.5 million sales related milestones and additional high-single-digit to low-double-digit percent tiered royalties after launch
- ESTELLE[®] to target an addressable contraceptive market in China valued at EUR 104 million annually (with a 5-year CAGR ~15%)¹
- DONESTA[®] to target an addressable menopause market in China valued at EUR 87 million annually (with a 5-year CAGR at ~10%)¹

Liege, Belgium, 04 December 2023 – 07:00 CET – Mithra (Euronext Brussels: MITRA), a company dedicated to Women's Health, today announces the signing of a binding Head of Terms (HoT) with Gedeon Richter Plc. related to an agreement for the development and commercialization of ESTELLE[®] and DONESTA[®] in China. ESTELLE[®] is the first estetrol-based combined oral contraceptive (15 mg estetrol (E4) / 3 mg drospirenone) and DONESTA[®] is Mithra's investigational, next generation hormone therapy medicine containing estetrol (E4) for the treatment of the symptoms of menopause.

Upon the finalization of the license agreements, Gedeon Richter will have the exclusive commercial rights for both ESTELLE[®] and DONESTA[®] in China. Gedeon Richter will perform and fund the clinical studies required to obtain marketing approvals in China.

Upon the closing of the two licencing agreements, Mithra will receive a combined milestone payment of EUR 4.5 million. The deal also foresees a total of EUR 1.2 million in payments for

the achievement of regulatory milestones for both products, and a EUR 8.5 million in sales-related milestones, as well as a high-single-digit to low-double-digit percent share of cumulative net sales (royalties) after launch.

China is a major Asian market and pivotal for Gedeon Richter to enable it to better serve women's needs in the Asia Pacific region. According to recent data, the 2023 addressable market for contraceptives in China stands at EUR 104 million annually with a compound annual growth rate (CAGR) of around 15% over the past five years while the addressable market for menopause is valued at EUR 87 million with a CAGR of around 10% during the last five years¹.

David Horn Solomon, CEO of Mithra stated, "We are excited to sign this agreement with our valued partner Gedeon Richter. Both ESTELLE® and DONESTA® will enable us to offer differentiated efficacy, safety, and convenience to millions of women across China. Oral contraceptives are commonly used by women in China and there is a major demand for menopause medication in this growing market, which counts an impressive 660 million women across all ages. We are convinced that our offering will make an active difference to their lives. We look forward to working closely with our partner to support their drive for success there."

Erik Bogsch, Chairman of the Board of Gedeon Richter commented, "We strongly believe that Gedeon Richter will address women's increasing health needs and meet a growing demand for innovative therapies with both E4-containing products. We look forward to working together with Mithra throughout our market entry process. With Mithra's innovation engine and Gedeon Richter's commercialization capabilities, we will be able to offer this market a next generation solution that will have a positive impact on millions of women's lives across this vast market."

ESTELLE®, Mithra's first E4-based product is commercialized as a combined oral contraceptive in the US and Canada under the brand name NEXTSTELLIS® and in Europe by Gedeon Richter as DROVELIS®. DONESTA® is Mithra's next generation orally administered E4-based hormone therapy product candidate.

For more information, please contact:

Mithra Pharmaceuticals SA

Alex Sokolowski, PhD
Head of IR & Communications
investorrelations@mithra.com
+32 (0)4 349 28 22

Frédérique Depraetere
Communications Director
info@mithra.com
+32 (0)4 349 28 22

¹ IQVIA Analytics Link – Moving Annual Total Q2/2023

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[®], Mithra is now focusing on its second product DONESTA[®], 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

ESTELLE[®], DONESTA[®] and NEXTSTELLIS[®] are registered trademarks of Mithra Pharmaceuticals or one of its affiliates.

DROVELIS[®] is a registered trademark of Richter Gedeon Nyrt.

About Gedeon Richter

Gedeon Richter Plc. (www.gedeonrichter.com), headquartered in Budapest/Hungary, is a major pharmaceutical company in Central Eastern Europe, with an expanding direct presence in Western Europe, China, Latin America, and Australia. Having reached a market capitalization of EUR 3.9 billion (USD 4.1 billion) by the end of 2022, Richter's consolidated sales were approximately EUR 2.0 billion (USD 2.1 billion) during the same year. The product portfolio of Richter covers many important therapeutic areas, including Women's Healthcare, Central Nervous System, and Cardiovascular areas. Having the largest R&D unit in Central Eastern Europe, Richter's original research activity focuses on CNS disorders. With its widely acknowledged steroid chemistry expertise, Richter is a significant player in the Women's Healthcare field worldwide. Richter is also active in biosimilar product development.

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.



News
Alerts

Subscribe to our mailing list on investors.mithra.com to receive press releases by email or follow us on social media:

[Linkedin](#) • [X](#) • [Facebook](#)