



GEDEON RICHTER

Richter and Mithra sign binding Head of Terms to commercialize estetrol containing products in China

Budapest, Hungary – 4 December 2023 – Gedeon Richter Plc. (“Richter”) announces today that it expanded its partnership with Mithra Pharmaceuticals SA (“Mithra”) with a binding Head of Terms (HoT) agreement for the development and commercialization of the first estetrol-based combined oral contraceptive (15 mg estetrol (E4) / 3 mg drospirenone) and the mono estetrol (E4) investigational product for the treatment of the symptoms of menopause in China.

Upon the finalization of the license agreements, Richter will have the exclusive commercialization rights for both products in China. Richter will perform and fund the clinical studies required to obtain marketing approvals in China.

Upon the finalization of the license agreements Richter will pay to Mithra a down 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 EUR 8.5 million in sales-related milestones, as well as a low-double-digit share of cumulative net sales (royalties) after launch.

China is a major Asian market and pivotal for 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 an annual CAGR of 15% over five years while the addressable market for menopause is valued at EUR 87 million with a CAGR of 10% during the next five years¹.

Erik Bogsch, Chairman of the Board of Richter, commented: “We strongly believe that Richter will address Chinese 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 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.”

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 Chinese women 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.”

The first E4-based product composed of 15 mg estetrol and 3 mg drospirenone (DRSP), is commercialized as a combined oral contraceptive in Europe by Richter as DROVELIS[®]. DONESTA[®] is Mithra’s next generation orally administered estetrol-based hormone therapy product candidate.

¹ IQVIA AL – Moving Annual Total Q2/2023

About 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.

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

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

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