

Mithra and Gedeon Richter Sign Supply Agreement for Production of API for Estelle[®] and Donesta[®]

- Gedeon Richter will manufacture and supply Estetrol (E4) for production of Estelle[®], Donesta[®]
- Strengthens Mithra's supply chain with commercially attractive source for Estetrol

Liege, Belgium and Budapest, Hungary 8 August 2023 – 07:30 CEST – Mithra (Euronext Brussels: MITRA), a company dedicated to Women's Health, and Gedeon Richter Plc. today announce they have signed a binding supply agreement for the active pharmaceutical ingredient (API) for the combined oral contraceptive Estelle[®] and Donesta[®], a novel product candidate for the treatment of post-menopausal symptoms.

The agreement specifies that Gedeon Richter will manufacture and supply the Estetrol (E4) native estrogen for Mithra's Estelle[®] and Donesta[®].

David Horn Solomon, Chief Executive Officer of Mithra, commented: "This agreement marks a deepening of our strong cooperation with Gedeon Richter and provides for expansion and improvement of our manufacturing capabilities for Estelle® as sales continue to grow. Our existing marketing agreements are progressing well and will all benefit from Gedeon Richter's strong experience in women's health. This new agreement affords us and our distribution partners with a commercially attractive source for our unique active pharmaceutical ingredient; it ensures both profitability as well as prudent redundancy in our supply chain, securing regular and reliable delivery of Estetrol to produce Estelle[®] and Donesta[®]."

Erik Bogsch, Chairman of the Board of Gedeon Richter, commented: "Gedeon Richter is deeply committed to the development and commercialization of products to improve quality of life for women across all age groups. In this spirit, we are pleased to expand our collaboration with Mithra through this agreement, which aims to capitalize on our well established steroid chemistry knowledge and active pharmaceutical ingredient manufacturing and supply capabilities."

Mithra and Gedeon Richter have a license and supply agreement for Estelle[®], concluded for Europe and CIS countries in 2018 and extended it to cover key markets in Latin America in 2020. Under the terms of the European agreement, Mithra received an upfront payment of EUR 35 million and EUR 20 million in regulatory milestones and is eligible for additional tiered sales-related royalties and commercial milestones. Mithra received an undisclosed upfront payment under the Latin America agreement and is eligible for regulatory- and sales-related milestones plus tiered royalties on sales.

Mithra and Gedeon Richter have a 20-year licensing agreement for Donesta[®] in Europe, Latin America, Australia and New Zealand. Under the terms of that agreement, signed in February 2023, Mithra received EUR 55 million in upfront payments and is eligible to receive EUR 15 million in additional milestone payments and tiered double-digit royalties on sales. Gedeon Richter is responsible for supply and production of the product for all its territories.

Estelle[®], Mithra's first E4-based product composed of 15 mg Estetrol and 3 mg Drospirenone (DRSP), is commercialized as a combined oral contraceptive in the US and Canada under the brand name NEXTSTELLIS[®] and in Europe as DROVELIS[®] and LYDISILKA[®]. Donesta[®] is Mithra's next generation orally administered Estetrol-based hormone therapy product candidate.

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[®], 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, Mithra has an approximate headcount of 230 staff members and is headquartered in Liège, Belgium. www.mithra.com

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DROVELIS® is a registered trademark of Richter Gedeon Nyrt.

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