

Richter signed binding Heads of Terms with Mithra for the commercialization of Donesta®

Budapest, Hungary – 20 December 2022 – Gedeon Richter Plc. (“Richter”) today announced it has signed a Binding Term Sheet (BTS) with Mithra Pharmaceuticals (“Mithra”) for the commercialisation of Donesta®, an estetrol-based product candidate for Hormone Replacement Therapy in postmenopausal women. The territories covered by the BTS are geographical Europe, including Russia and CIS countries, Latin America, Australia and New Zealand. The parties intend to finalise their partnership in an agreement during the first quarter 2023.

Donesta® is Mithra’s next generation orally-administrated estetrol (E4)-based hormone therapy product candidate offering a potential long-term solution for treating different symptoms of menopause. Early 2022, Mithra announced positive top-line efficacy results of Donesta® Phase 3 Program, which demonstrated a meaningful reduction in vasomotor symptoms (VMS) from baseline and compared to placebo with all co-primary efficacy endpoints statistically met.

Under the terms of the agreement, Mithra is eligible to receive EUR 55 million in upfront payment – EUR 5 million upon signature of the binding Head of Terms and EUR 50 million upon signature of the License and Supply Agreement – as well as EUR 15 million in additional milestone payments subject to specific regulatory achievements and tiered low double-digit royalties depending on net sales’ evolution throughout time. Richter will be responsible for the commercialization of Donesta® in about 90 territories through an exclusive license in Europe, Russia, CIS, Latin America, Australia and New Zealand.

“We are honored to materialize a second agreement with Mithra to develop further the Estetrol (E4) native estrogen platform discovered by Egon Diczfalusy at Karolinska Institute and being developed by Mithra Research,” - said Erik Bogch, Chairman of the Board of Richter. “Richter is a leading company in Women’s Health and second largest in Europe with affiliates in more than 90 countries including LATAM, Australia and New Zealand. In the Territory we are reaching out to over 70 % of the Gynecologists universe.”

“Drovelis®, Ryeqo®, Bemfola® and Evra® all helped to strengthen Richter’s innovative Women’s Healthcare pipeline covering almost all age groups of the female population. The Estetrol containing product for the management of menopause will assist millions of women in demand of better treatment options,” - added Gábor Orbán, CEO of Richter.

Leon Van Rompay, CEO Mithra Women’s Health, commented: “We are very pleased to announce this new agreement with Gedeon Richter, our long-standing partner for the commercialisation of our contraceptive pill Drovelis® in Europe and Russia. This agreement is perfectly in line with our successful collaboration on this first estetrol-based product. We are convinced that they are the best possible partner for the commercialization of Donesta® in these territories and they will deploy the necessary resources to unlock Donesta®’s tremendous potential and to become market leader.”

VMS, characterized by hot flushes and/or night sweats, are common symptoms of menopause and can have a disruptive impact on women's daily activities and overall quality of life.^{1,2} Worldwide, more than 50% of women 40 to 64 years of age experience VMS, with 55% having moderate to severe VMS.^{3,4} Menopause symptoms are severely impacting menopausal women with 83% of women highlighting menopause negatively affected their work with nearly one in two women considering to retire or taking a break from work.⁵

Professor Wulf H. Utian, founder of the North American Menopause Society (NAMS), commented: 'The North American Menopause Society recent guidelines reinforced hormone therapy as the most effective treatment for vasomotor symptoms and the genitourinary syndrome of menopause while slowing bone loss and demonstrating fracture prevention. Estetrol (E4) clinical results to date point towards the biggest advance in post-menopausal estrogen development in almost 100 years. Upon study completion and approval it should add a novel and natural treatment option for clinicians and women to address estrogen deficiency consequences related to the menopause.'

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, in China, in Latin America and in Australia. Having reached a market capitalization of EUR 4.4 billion (USD 5.0 billion) by the end of 2021, Richter's consolidated sales were approximately EUR 1.8 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.

¹ Utian WH. Psychosocial and socioeconomic burden of vasomotor symptoms in menopause: a comprehensive review. *Health Qual Life Outcomes*. 2005;3:47.

² Jones RE, Lopez KH, eds. *Human Reproductive Biology*. 4th ed. Waltham, Mass.: Elsevier; 2014.

³ Makara-Studzinska MT, Krysz-Noszczyk KM, Jakiel G. Epidemiology of the symptoms of menopause - an intercontinental review. *Przegl Menopauzalny [Menopause Rev]*. 2014;13:203-211.

⁴ Yu Q, Chae H-D, Hsiao S-M, et al. Prevalence, severity, and associated factors in women in East Asia with moderate-to-severe vasomotor symptoms associated with menopause. *Menopause*. 2022;29(5):553-563.

⁵ Circle In's Research 2021 with the Support of the Victorian Women's Trust : "Driving the Change: menopause and the workplace."

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. 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 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

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