



Richter and Mithra sign a licence agreement for the commercialisation of Donesta[®], the first Estetrol-based hormone therapy

15 February 2023, 7:30 CET, Budapest, Hungary and Liege, Belgium – Gedeon Richter Plc. ("Richter") and Mithra Pharmaceuticals ("Mithra") today announced that they signed a licence agreement for the commercialisation of Donesta[®], a novel product candidate for the treatment of post-menopausal symptoms.

The completion of the agreement follows the signing of the Binding Term Sheet by the parties on 20 December 2022. The territories covered by the agreement are geographical Europe, the CIS countries, Latin America, Australia and New Zealand.

Donesta[®] is Mithra's next generation orally-administrated estetrol (E4)-based hormone therapy product candidate offering a potential long-term solution for treating the different symptoms of menopause. Estetrol (E4), the first native estrogen from human fetal origin. E4 acts differently from classical estrogens. Its selective activation of nuclear Estrogen receptors and its unique metabolism result in a low impact on haemostasis and breast with an improved benefit/safety profile. 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 (improved quality of life and reduction of genito-urinary symptoms of menopause).

Hormone therapy (HT) is the most effective treatment for the relief of vasomotor symptoms and the genitourinary syndrome, while slowing osteoporosis and fracture risk. It contributes to maintain glucose homeostasis and epidemiological studies point to a 2/3 decreased risk of all cause dementias of menopause while slowing bone loss and demonstrating fracture prevention. Estetrol (E4) clinical results to date point towards the biggest advance in post-menopausal hormone therapy in the past decades. Upon study completion and approval it will offer clinicians and women a novel treatment option to strengthen practitioners and women confidence in the benefits of hormone therapy to address most effectively the challenges of the menopause confidence in the benefits of menopause treatment.

Under the terms of the licence agreement, Mithra is eligible to receive EUR 55 million in upfront payment – EUR 5 million was paid upon signature of the binding term sheet in December 2022 and EUR 50 million upon signature of this license agreement –, as well as EUR 15 million in additional milestone payments subject to specific regulatory achievements and tiered double-digit royalties depending on net sales' evolution during the 20-year term contract. Richter will be in charge of the supply and the production of the product for all its territories.

We are pleased to capitalise on our well established cooperation with Mithra and we are looking forward to further expand the therapeutic reach of our niche Women's Healthcare business by adding a meaningful product to our existing Hormone replacement therapy portfolio" – said Erik Bogsch, Chairman of the Board. "We consider that serving women of all age groups is of paramount importance in Europe, which is

characterised by aging population. We are convinced that the current transaction is a perfect fit for our specialty strategy."

Leon Van Rompay, CEO Mithra Women's Health, commented: *"We are very pleased to announce the closing of this agreement with Gedeon Richter, our long-standing partner for the commercialisation of the contraceptive pill Drovelis® in Europe, the UK and Russia. Together we will be able to deliver an innovative product to menopausal women, a market that has been underserved for decades and where women today are actively looking for solutions. Recent media attention around the globe demonstrates a clear shift towards Hormone Therapy. Building further upon our product lifecycle development plan, we remain confident to sign a future partnership for Donesta® in the US, representing 57% of the menopause market in value¹."*

For more information, please contact:

Richter:

Investors:

Katalin Ördög: **+36 1 431 5680**

Media:

Zsuzsa Beke: **+36 1 431 4888**

Mithra

Benoît Mathieu (IRO): +32 473 35 80 18 – investorrelations@mithra.com

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.

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

¹ IQVIA MAT Q3 2022 (hormonal menopausal treatment based on ATC class G3C, G3F and G2F)

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 300 staff members and is headquartered in Liège, Belgium. www.mithra.com

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

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.

A circular icon with a teal background and white text that reads "News Alerts".

News
Alerts

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

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