

# MITHRA AND RICHTER SIGN LICENSE AND SUPPLY AGREEMENT FOR COMMERCIALIZATION OF ESTELLE®, A NOVEL ORAL CONTRACEPTIVE

Liège, Belgium - 12 September 2018, 7:30 CEST - Mithra Pharmaceuticals (hereinafter: "Mithra") and Gedeon Richter Plc. (hereinafter: "Richter") today announced that they have entered into a license and supply agreement to commercialize Estelle®, a combined oral contraceptive (COC), containing 15 mg Estetrol (E4) / 3 mg drospirenone (DRSP), in Europe and Russia. Richter will commercialize the product under a different brand name. The product is a novel combined oral contraceptive with natural, native estrogen acting selectively in tissues combined with drospirenone's non-contraceptive benefits.

Under the terms of the agreement Richter will make, upon signature of the contract, an upfront payment totaling EUR 35 million. Additional milestone payments amounting to EUR 20 million will be made depending on the progress of the regulatory process of the product. Further sales-related royalties will be payable to Mithra subsequent to the launch of the product. Moreover, Mithra will receive guaranteed annual recurring revenues based on minimum annual quantities (MAQ), in addition to tiered royalties on net sales.

François Fornieri, CEO of Mithra Women's Health commented: "We are very pleased to have agreed terms with Richter for the commercialization of our next generation oral contraceptive product candidate Estelle® in Europe and Russia. This is by far the biggest contract in Mithra's history. As an undisputed leader in Women's Health, with a rapidly expanding direct presence in Western Europe, we are confident that Richter is the best possible partner for Estelle® in this important geography. We are looking forward to a fruitful and long-term collaboration with the Richter team. Today's news further reinforces our confidence in our ability to sign a future partnership for Estelle® in the US, where the oral contraceptive market is valued at twice the size of the European market."

Gábor Orbán, CEO of Gedeon Richter Plc, added : "Broadening our core Women's Healthcare portfolio remains a paramount objective of Richter's strategy aiming towards the improvement of the quality of life of the female population in all age groups. This agreement fits into this endeavour and we look forward to a successful cooperation with Mithra in the commercialization of a novel oral contraceptive."

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#### **About Estelle®**

Estelle® is Mithra's novel oral contraceptive product candidate composed of 15 mg Estetrol (E4), its unique native estrogen, and 3 mg drospirenone (DRSP). The E4 Freedom studies are open-label single arm trials to assess the safety and efficacy of Estelle® in over 1,550 participants in Europe/Russia and approximately 2,000 participants in the US/Canada, over a period of 13 cycles. Mithra recently announced positive top-line results for its pivotal EU/Russia Phase III study, with the top-line results of the US/Canada study to follow in Q1 2019.

## Regulated information / Inside Information PRESS RELEASE

#### **About Mithra**

Mithra (Euronext: MITRA) is dedicated to providing innovation and choice in Women's Health, with a particular focus on fertility, contraception and menopause. Mithra's goal is to develop new and improved products that meet women's needs for better safety and convenience. Its two lead development candidates – a fifth generation oral contraceptive Estelle® and next-generation hormone therapy Donesta® - are built on Mithra's unique natural estrogen platform, E4 (Estetrol). Mithra also develops, manufactures and markets complex therapeutics and offers partners a complete spectrum of research, development and specialist manufacturing at its CDMO. Mithra was founded in 1999 as a spin-off from the University of Liège by Mr. François Fornieri and Prof. Dr. Jean-Michel Foidart. Mithra is headquartered in Liège, Belgium. Further information can be found at: www.mithra.com

#### **About Richter**

Gedeon Richter Plc. (www.richter.hu), headquartered in Budapest/Hungary, is a major pharmaceutical company in Central Eastern Europe, with an expanding direct presence in Western Europe, in China and in Latin America. Having reached a market capitalisation of EUR 4.1 billion (USD 4.9 billion) by the end of 2017, Richter's consolidated sales were approximately EUR 1.4 billion (USD 1.6 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.

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### Important information

The contents of this announcement include statements that are, or may be deemed to be, "forwardlooking 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.

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