GEDEON RICHTER

Approval for Alyssa® combination tablets (FSN-013), an Estetrol-based drug in Japan

Budapest, 24 September 2024 - Gedeon Richter Plc. ("Richter") announces today that its partner, Fuji Pharma Co., Ltd. ("Fuji") has received marketing approval of Alyssa® combination tablets (Development code: FSN-013), developed in Japan, to the Ministry of Health, Labour and Welfare ("MHLW") for the scheduled indication of dysmenorrhea. The approval triggers a milestone payment of EUR 10mn to Estetra SRL, a 100% subsidiary of Richter, under the agreement whereby Fuji holds development and commercialization rights for Alyssa® in Japan and the ASEAN region.

Alyssa® combination tablets is a dysmenorrhea treatment containing drospirenone and Estetrol (E4), a natural estrogen in-licensed by Fuji from Estetra SRL. Estetrol (E4) is a new active ingredient in Japan and has been confirmed to selectively act on estrogen receptors, and this selectivity is expected to provide a variety of benefits for patients.

Fuji is preparing for the launch FSN-013 combination tablets with tradename Alyssa® to provide a new treatment option for dysmenorrhea patients and help more women live healthier and more energetic lives.

About Gedeon Richter Plc.

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 4.3bn (USD 4.7bn) by the end of 2023, Richter's consolidated sales were approximately EUR 2.1bn (USD 2.3bn) 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, manufacture and commercialization.

For further information:

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