Press Release

Hikma and Richter announce FDA submission acceptance for Denosumab biosimilar products

Budapest, Hungary and London, UK, 12 December 2024 – Gedeon Richter Plc. ("Richter") and Hikma Pharmaceuticals PLC ("Hikma") today announced that the U.S. Food and Drug Administration (FDA) had accepted for review the Biologics License Applications (BLA) for RGB-14, a Denosumab biosimilar candidate comprising two biosimilar products referencing Prolia® and Xgeva® ("Products"), a human monoclonal antibody for the treatment of osteoporosis and fractures due to bone metastasis.

In December 2021, Hikma entered an exclusive license agreement to commercialise Richter's denosumab in the United States ("US"). According to the agreement, Richter has been responsible for the development of the Products (including both Phase 1 and Phase 3 global clinical studies) and will supply finished commercial Products for the US market. Hikma is responsible for FDA registration and has exclusive rights to commercialise them in the US upon FDA approval.

The FDA submission underscores Hikma's commitment to improving access to high quality injectable products for US patients and highlights Richter's commitment to develop its biosimilar programmes for global markets with strong focus on the United States.

"We are pleased FDA has accepted for review our application for Denosumab, an important biosimilar needed by a growing number of patients across the US, and we look forward to adding this product to our large and growing US portfolio of essential injectable medicines," said Dr. Bill Larkins, President of Hikma Injectables. "We are especially pleased to be partnering on this product with the highly talented team at Gedeon Richter."

"The FDA submission of our denosumab biosimilar product is a significant milestone, which strengthens our partnership with Hikma, a highly respected company having strong US presence, enabling Richter to reach patients across the globe with our biosimilar programmes." said Erik Bogsch, Head of the Biotechnology Business Unit at Richter.

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About Hikma
(LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY) (rated BBB-/stable S&P and BBB-/positive Fitch)

Hikma helps put better health within reach every day for millions of people around the world. For more than 45 years, we've been creating high-quality medicines and making them accessible to the people who need them. Headquartered in the UK, we are a global company with a local presence across North America, the Middle East

and North Africa (MENA) and Europe, and we use our unique insight and expertise to transform cutting-edge science into innovative solutions that transform people's lives. We're committed to our customers, and the people they care for, and by thinking creatively and acting practically, we provide them with a broad range of branded and non-branded generic medicines. Together, our 9,100 colleagues are helping to shape a healthier world that enriches all our communities. We are a leading licensing partner, and through our venture capital arm, are helping bring innovative health technologies to people around the world. For more information, please visit: www.hikma.com

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.