GEDEON RICHTER

Richter Announces Submission to European Medicines Agency for Biosimilar Denosumab in Multiple Indications

Budapest, 18 July 2024 – Gedeon Richter Plc. ("Richter") announces today that the European Medicines Agency (EMA) has accepted Richter's two marketing authorization applications (MAAs) for its proposed biosimilar to denosumab. Denosumab is indicated for treating osteoporosis in postmenopausal women, preventing skeletal-related complications in cancer that has spread to the bone, and treating unresectable giant cell tumor of the bone. Richter's two MAAs include all indications covered by the reference biologics.

Richter submitted a comprehensive analytical and clinical data package, which comprises data from a Phase I pharmacokinetic/pharmacodynamic (PK/PD) similarity study in healthy volunteers and a multicenter Phase III study. According to the data package, Richter's denosumab biosimilar matches the reference products in relation to PK, PD, efficacy, safety, and immunogenicity in the respective populations used in the studies. The data also contribute to the demonstration of similarity, which forms the basis for the biosimilar's use in all indications of the originator's products.

"Acceptance of our denosumab biosimilar for assessment by the EMA marks a very important milestone for Richter, it is the first biosimilar monoclonal antibody within the Company's broadening biosimilars portfolio" – said Dr Erik Bogsch, Head of the Biotechnology Business Unit at Richter. "When approved, this will increase patient access to this important biologic drug, strengthening Richter's future presence in the affordable medicines segment."

For additional prescribing information and patient information about the originator products, please visit the following links:

https://www.ema.europa.eu/en/documents/product-information/prolia-epar-product-information_en.pdf

https://www.ema.europa.eu/en/documents/product-information/xgeva-epar-product-information_en.pdf

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.

For further information:

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