



GEDEON RICHTER

Richter receives European Commission approval for Junod® and Yaxwer®, its biosimilar denosumab products for bone disease and osteoporosis

Budapest, 1 July 2025 – Gedeon Richter Plc. ("Richter") announces today that the European Commission (EC) granted marketing authorization for Junod® and Yaxwer®, its biosimilar denosumab products. The EC decision follows the positive opinion adopted on 25 April 2025 by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA). This approval marks a significant milestone as Richter's monoclonal antibody biosimilars receive EC authorization.

Junod® and Yaxwer® are approved for all indications of the reference medicines Prolia® and Xgeva® (Amgen), including the treatment of osteoporosis in postmenopausal women, prevention of skeletal-related events in patients with bone metastases from solid tumors, and treatment of unresectable giant cell tumor of bone.

The EC approval is based on a comprehensive development program demonstrating biosimilarity to the reference products in terms of quality, safety, and efficacy.

About Junod® and Yaxwer®

Both Junod® and Yaxwer® contain denosumab, a human monoclonal antibody (IgG2) that targets and binds with high affinity to RANKL, inhibiting its interaction with the RANK receptor on osteoclasts and their precursors. This mechanism prevents osteoclast formation, function, and survival, thereby reducing bone resorption in both cortical and trabecular bone. The products are administered subcutaneously, with dosing regimens and presentations identical to those of the reference medicines.

About Gedeon Richter Plc.

Richter aspires to be a global innovator in some key scientific fields, while dedicated to making medicines more accessible worldwide. Founded in 1901, headquartered in Hungary, with a market capitalization of EUR 4.7bn and sales of EUR 2.2bn in 2024, it operates Central Europe's largest R&D hub. Its research drives breakthroughs in Neuropsychiatry and Women's Healthcare, while Biotechnology and General Medicines strengthen its affordable treatment portfolio. Committed to sustainable growth, Richter invests in R&D, manufacturing excellence, and digitalization to advance medical innovation. Learn more at www.gedeonrichter.com

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