



GEDEON RICHTER

Richter receives positive opinion from CHMP for marketing authorisation for Junod® and Yaxwer®, its biosimilar denosumab products for bone disease and osteoporosis

Budapest, 25 April 2025 – Gedeon Richter Plc. ("Richter") announces today that it received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) recommending that marketing authorization be granted in Europe for Junod® and Yaxwer®, its biosimilar denosumab products, for all indications of the reference medicines Prolia® and Xgeva® of Amgen.

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.

"The positive CHMP opinion for Junod® and Yaxwer® paves the way for EU marketing authorisation of these vital medicines, marking Richter's first monoclonal antibody biosimilar approval and a significant milestone in our commitment to expanding access to high-quality, affordable biologic therapies for patients across Europe. Junod® and Yaxwer® enhance our bone health portfolio, joining Terrosa®, our marketed teriparatide biosimilar product addressing the considerable burden of bone loss and cancer-related skeletal complications and improving patients' lives." said Dr. Erik Bogesch, Head of the Biotechnology Business Unit at Richter.

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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