



GEDEON RICHTER

## **Richter and Hikma receive FDA approval for denosumab biosimilars Enoby™ and Xtrenbo™, referencing Prolia® and Xgeva®, respectively**

**Budapest, Hungary and London, UK – 29 September 2025** – Gedeon Richter Plc. (“Richter”) and Hikma Pharmaceuticals Plc. along with its wholly owned subsidiary Hikma Pharmaceuticals USA Inc. (“Hikma”) announce today that the U.S. Food and Drug Administration (FDA) has granted approval for the Biologics License Applications (BLA) of their biosimilar denosumab products, Enoby™ (denosumab-qbde) and Xtrenbo™ (denosumab-qbde), referencing Prolia® and Xgeva®, respectively.

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 FDA approval of Enoby™, originally known as RGB-14-P and Xtrenbo™, originally known as RGB-14-X, was based on a comprehensive analytical, non-clinical, and clinical data package submitted by Hikma to the FDA. The content of the BLA demonstrated that Enoby™ and Xtrenbo™ have similar quality, efficacy, safety and immunogenicity as the reference denosumab products Prolia® and Xgeva®, respectively.

Hikma and Richter entered into a license and commercialization agreement for RGB-14 in December 2021. Under the terms of the agreement, Richter is responsible for the development and manufacture of the products, and Hikma is responsible for the FDA registration and exclusive commercialization in the U.S..

*“We are proud to be able to bring these biosimilar options to healthcare providers and patients, improving affordability and access to these important therapies,” said Dr. Bill Larkins, President of Hikma Injectables. “We are a top-three U.S. provider of sterile injectable medicines to U.S. hospitals and we will use our strong and well-established commercial capabilities to bring these products to patients.”*

*“The approvals of Enoby™ and Xtrenbo™ represent a significant milestone accomplishment for Richter, as our first FDA approved biosimilars. They are a testimony to Richter’s ambition in providing affordable biosimilar access in important therapies to patients across the globe and establishing Richter as a high quality biosimilar developer and manufacturer.” said Dr. Erik Bogsch, Head of Biotechnology Business Unit at Richter.*

### **About Enoby™ and Xtrenbo™ (denosumab-qbde)**

Both Enoby™ and Xtrenbo™ 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.

Chemical Works of Gedeon Richter Plc.

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### **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](http://www.gedeonrichter.com)

### **About Hikma Pharmaceuticals Plc.**

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](http://www.hikma.com)

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