



Alvotech Announces Approval of AVT03, a Biosimilar to Prolia® and Xgeva® (denosumab) in the European Economic Area

November 24, 2025

REYKJAVIK, Iceland, Nov. 24, 2025 (GLOBE NEWSWIRE) -- Alvotech (NASDAQ: ALVO), a global biotech company specializing in the development and manufacture of biosimilar medicines for patients worldwide, today announced that the European Commission (EC) has approved AVT03 as a biosimilar to Prolia® and Xgeva® (denosumab).

The European denosumab market is currently valued at approximately US\$1.2 billion across all indications, based on originator sales in the last 12 months including the second quarter of 2025^[1]. Denosumab is widely used to manage osteoporosis and to prevent skeletal related events in patients with certain cancers. A biosimilar option can help broaden access to these established treatments in Europe.

AVT03 is approved in two presentations: as a biosimilar to Prolia® 60 mg/mL single use pre-filled syringe for the treatment of osteoporosis and bone loss; and as a biosimilar to Xgeva® 70 mg/mL single use vial for the prevention of skeletal related events in adults with advanced malignancies involving bone.

"We welcome the European Commission's approval of AVT03, which demonstrates the continued strength of our end-to-end platform and our ability to deliver high quality biosimilars at scale. This milestone reflects not only the dedication and expertise of our teams, but also the strong partnerships we have built to bring affordable medicines to patients across Europe. Working together, we can help broaden access to essential osteoporosis and oncology supportive care treatments and strengthen the resilience of supply in key markets," said Robert Wessman, Chairman and Chief Executive Officer of Alvotech.

The EC decision represents continued progress across Alvotech's biosimilar portfolio and underscores the company's role as a longer term partner to health systems across Europe.

In Europe, disabilities due to osteoporosis are greater than those caused by common cancers (with the exception of lung cancer) and comparable to those caused by chronic noncommunicable diseases, such as rheumatoid arthritis, asthma and high blood pressure. Fragility fractures represent a significant economic burden, with incident and prior fragility fractures estimated at €57 billion in 2019^[2].

Biosimilars play an important role in supporting sustainable healthcare budgets across Europe by offering cost-effective treatment options.

In Europe, AVT03 will be commercialised in partnerships with STADA and Dr. Reddy's, where each partner holds semi-exclusive rights in the EEA, Switzerland and the UK. STADA will market AVT03 as Kefdensis®, biosimilar to Prolia® and as Zvogra®, biosimilar to Xgeva®. Dr. Reddy's will market AVT03 as Acvybra®, biosimilar to Prolia® and as Xbonzy®, biosimilar to Xgeva®.

The European Commission's approval of AVT03 as a biosimilar to Prolia and Xgeva was based on a totality of evidence that included comparative analytical, pharmacokinetic and pharmacodynamic data, and data from a confirmatory clinical study. The clinical data package included the PK similarity study AVT03-GL-P01^[3] in healthy adult males (ClinicalTrials.gov identifier [NCT05126784](#)) and the comparative efficacy study AVT03-GL-C01^[4] in post menopausal women with osteoporosis (ClinicalTrials.gov identifier [NCT05395091](#)) with Prolia used as the reference product in both clinical studies. The results of the clinical studies demonstrate equivalent pharmacokinetics and efficacy, and comparable safety and immunogenicity to the reference product and were reported in peer reviewed publications^[3,4]. Analytical similarity studies also compared AVT03 with both Prolia and Xgeva.

About AVT03 (denosumab)

AVT03 is a human monoclonal antibody and a biosimilar to Prolia® (denosumab 60 mg/mL single use pre-filled syringe) and Xgeva® (denosumab 70 mg/mL single use vial), that has been approved for marketing in the EEA and Japan. Denosumab targets and binds with high affinity and specificity to the RANK ligand membrane protein, preventing the RANK ligand/RANK interaction from occurring, resulting in reduced osteoclast numbers and function, thereby decreasing bone resorption and cancer-induced bone destruction^[5].

Use of trademarks

Prolia® and Xgeva® are registered trademarks of Amgen Inc. Kefdensis® and Zvogra® are registered trademarks of STADA Arzneimittel. Acvybra® and Xbonzy® are registered trademarks of Dr. Reddy's Laboratories SA.

References

[1] IQVIA

[2] [Osteoporosis in Europe: a compendium of country-specific reports | Archives of Osteoporosis](#)

[3] [Expert Opinion on Investigational Drugs Vol. 34, 2025 – Issue 6](#)

[4] [Expert Opinion on Biological Therapy, Vol. 25, 2025 – Issue 8](#)

[5] [Prolia product information, EMA](#)

About Alvotech

Alvotech is a biotech company, founded by Robert Wessman, focused solely on the development and manufacture of biosimilar medicines for patients worldwide. Alvotech seeks to be a global leader in the biosimilar space by delivering high quality, cost-effective products, and services, enabled by a fully integrated approach and broad in-house capabilities. Two biosimilars, to Humira® (adalimumab) and Stelara® (ustekinumab), are already approved and marketed in multiple global markets. The current development pipeline includes nine disclosed biosimilar candidates aimed at treating autoimmune disorders, eye disorders, osteoporosis, respiratory disease, and cancer.

Alvotech has established a network of strategic commercial partnerships to provide global reach and leverage local expertise in markets that include the United States, Europe, Japan, China, and other Asian countries and large parts of South America, Africa and the Middle East. Alvotech's commercial partners include Teva Pharmaceuticals, a US affiliate of Teva Pharmaceutical Industries Ltd. (US), STADA Arzneimittel AG (EU), Fuji Pharma Co., Ltd (Japan), Advanz Pharma (EEA, UK, Switzerland, Canada, Australia and New Zealand), Dr. Reddy's (EEA, UK and US), Biogaran (FR), Cipla/Cipla Gulf/Cipla Med Pro (Australia, New Zealand, South Africa/Africa), JAMP Pharma Corporation (Canada), Yangtze River Pharmaceutical (Group) Co., Ltd. (China), DKSH (Taiwan, Hong Kong, Cambodia, Malaysia, Singapore, Indonesia, India, Bangladesh and Pakistan), YAS Holding LLC (Middle East and North Africa), Abdi Ibrahim (Turkey), Kamada Ltd. (Israel), Mega Labs, Stein, Libbs, Tuteur and Saval (Latin America) and Lotus Pharmaceuticals Co., Ltd. (Thailand, Vietnam, Philippines, and South Korea). Each commercial partnership covers a unique set of product(s) and territories. Except as specifically set forth therein, Alvotech disclaims responsibility for the content of periodic filings, disclosures and other reports made available by its partners. For more information, please visit <https://www.alvotech.com>. None of the information on the Alvotech website shall be deemed part of this press release.

Forward Looking Statements

Alvotech Forward Looking Statements

Certain statements in this communication may be considered "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements include, for example, Alvotech's expectations regarding competitive advantages, business prospects and opportunities including pipeline product development, future plans and intentions, regulatory submissions, review and interactions, the potential approval and commercial launch of its product candidates, the timing of regulatory approval, market launches and financial projections. Such forward-looking statements are subject to risks, uncertainties, and other factors which could cause actual results to differ materially from those expressed or implied by such forward-looking statements. These forward-looking statements are based upon estimates and assumptions that, while considered reasonable by Alvotech and its management, are inherently uncertain and are inherently subject to risks, variability, and contingencies, many of which are beyond Alvotech's control. Factors that may cause actual results to differ materially from current expectations include, but are not limited to factors set forth in the sections entitled "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements" in documents that Alvotech may from time-to-time file or furnish with the SEC. There may be additional risks that Alvotech does not presently know or that Alvotech currently believes are immaterial that could also cause actual results to differ from those contained in the forward-looking statements. These forward-looking statements are provided for illustrative purposes only and are not intended to serve as, and must not be relied on by an investor as, a guarantee, assurance, prediction or definitive statement of a fact or probability. Alvotech does not undertake any duty to update these forward-looking statements or to inform the recipient of any matters of which any of them becomes aware of which may affect any matter referred to in this communication. Alvotech disclaims any and all liability for any loss or damage (whether foreseeable or not) suffered or incurred by any person or entity as a result of anything contained or omitted from this communication and such liability is expressly disclaimed.

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