

First denosumab biosimilar debuts in the United States

Market Event Summary

Jubbonti is the first denosumab biosimilar in the U.S. market; more on the way

Background

Sandoz launches Jubbonti (denosumab-bbdz), the first biosimilar approved as interchangeable with Prolia, in the United States on **June 2, 2025**.

U.S. label specifications:

- Jubbonti is available as a single-dose prefilled syringe for **subcutaneous use (strength: 60 mg/mL)**, indicated for postmenopausal women at high risk of fracture, men with osteoporosis at high risk of fracture, and people with glucocorticoid-induced osteoporosis at high risk for fracture.

Key events in the major markets:

United States

- Sandoz's Jubbonti is the first biosimilar to receive approval as interchangeable with Prolia, in March 2024.
- Starting in 2025, several biosimilars referencing Prolia received approval in the United States:



Europe

- Jubbonti is the first biosimilar to receive approval in Europe in May 2024; launch is expected following Prolia's patent expiration in **November 2025**.
- Samsung Bioepis's Obodence and Celltrion's Stoboclo also received approval in February 2025.

Clarivate's takeaways

Clarivate expects progressive uptake of denosumab biosimilars

- Clarivate's primary market research highlights endocrinologists' strong preference for the reference brand due to its proven efficacy and safety, but its high-cost limits use. Key opinion leaders are increasingly interested in lower-cost denosumab biosimilars, indicating a shift toward more cost-effective options.
- We expect Jubbonti will benefit from being first to market, as well as U.S. prescribers' familiarity with the Sandoz brand. We forecast Jubbonti will garner a sizable patient share of 10% in the U.S. market in 2033.

The stage is set for intense competition in the major markets

- Following the launch of Sandoz's Jubbonti, the competitive landscape in the U.S. biosimilars market is set to intensify. A robust pipeline of denosumab biosimilars is advancing toward regulatory milestones, with several candidates expected to seek approval or launch in the near term. This influx of biosimilar candidates signals a period of heightened competition, with implications for pricing dynamics, market access strategies, and long-term biologics adoption across the United States and other major markets.

Commercial potential in the osteoporosis market

- With several denosumab biosimilars expected to launch in the U.S. and European markets over the coming years, the respective biosimilars markets are projected to reach **\$2.7 billion** and **\$347 million** in 2033. **Major-market biosimilar shares** are expected to reach **52%** in 2033.

About the author



Yashu Malhotra, M. Pharm.

**Senior Healthcare Research and Data Analyst,
Biosimilars**

Yashu Malhotra, M. Pharm., is senior analyst on the Biosimilars and Oncology teams at Clarivate. Previously, she was a senior analyst in the life sciences department at Course5 Intelligence. She also worked in competitive intelligence at WNS Global Services. Ms. Malhotra earned her master's degree in pharmacy (quality assurance) from India's Delhi Institute of Pharmaceutical Sciences and Research.

Yashu.Malhotra@Clarivate.com

Clarivate coverage of Biosimilars

- [Biosimilars | Market Events and Forecast | Endocrinology](#)
- [Biosimilars | Emerging Biosimilars | Global](#)
- [Biosimilars | Access & Reimbursement | Payer Insights | US/EU](#)
- [Biosimilars | Access & Reimbursement | Global Landscape](#)
- [Biosimilars | Corporate Strategies | Global](#)
- [Biosimilars | China-in Depth | China](#)



Think forward™

Have a question?

healthcare.support@clarivate.com
clarivate.com

+1 215 386 0100 (U.S.)

+44 (0) 20 7433 4000 (Europe)

About Clarivate

Clarivate is the leading global information services provider. We connect people and organizations to intelligence they can trust to transform their perspective, their work and our world. Our subscription and technology-based solutions are coupled with deep domain expertise and cover the areas of Academia & Government, Life Sciences & Healthcare and Intellectual Property. For more information, please visit [clarivate.com](https://www.clarivate.com)

© 2025 Clarivate. All rights reserved

Clarivate and its logo, as well as all other trademarks used herein are trademarks of their respective owners and used under license.