First Stelara biosimilars debut in Europe and Japan, with a U.S. launch on the horizon

Market Event Summary

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Stelara biosimilars launch

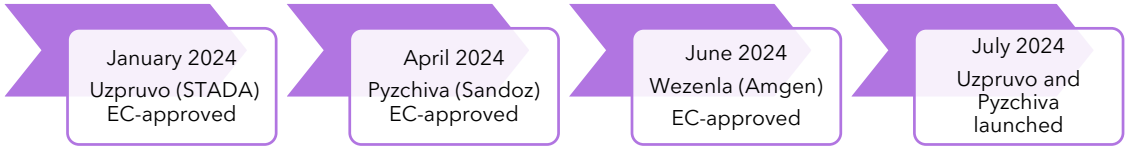
Background

- Johnson and Johnson's (J&J's) blockbuster drug Stelara (INN: ustekinumab) is an IL-12/IL-23 inhibitor used to treat autoimmune conditions such as plaque psoriasis, pediatric plaque psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis.
- Stelara is available as a 45 mg and 90 mg PFS for subcutaneous use.
- In 2023, Stelara reported annual sales of $10 billion worldwide.

Key events in Europe

- In January 2024, Alvotech and Stada's Uzpruvo became the first ustekinumab biosimilar to receive EC approval, followed by Samsung Bioepis and Sandoz's Pyzchiva in April 2024.
- Following **Stelara's EU patent expiration in July 2024**, **Uzpruvo and Pyzchiva** became the **first ustekinumab biosimilars to launch across Europe**; marketed by **STADA** and **Sandoz,** respectively.
- **Amgen's** ustekinumab biosimilar, **Wezenla**, received EC approval in June 2024 and is **expected to launch in Europe later this year**.

Stelara biosimilar approval and launch timelines in the EU market



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Market outlook in Europe

- **First-to-market advantage:** Starting in 2025, up to nine biosimilars are expected to enter the EU market, intensifying competition. Uzpruvo and Pyzchiva, with their first-to-launch advantage, may secure a competitive edge in this crowded landscape.
- **Price implications:** According to Clarivate's primary market research (PMR) data for 2024, lower costs compared with the originator biologic are a key driver of biosimilar uptake. Uzpruvo entered the German and U.K. market with approximately a 10% list price discount to Stelara, while Pyzchiva launched with discounts to Stelara of 33% in Germany and 10% in the United Kingdom. Pyzchiva's steeper discount could provide a competitive advantage, particularly in Germany. However, Uzpruvo is the only ustekinumab biosimilar available in France, where it launched with a 32% discount to Stelara.
- **Biosimilar uptake:** Clarivate's 2024 PMR data highlight Stelara's strong preference among dermatologists due to its proven efficacy and safety; however, its high cost limits wider use. Key opinion leaders expect increased interest in lower-cost ustekinumab biosimilars, signaling a shift toward more-cost-effective options. As European-based companies with established supply chains and strong prescriber recognition, Stada and Sandoz are also well positioned to boost the uptake of Uzpruvo and Pyzchiva, respectively, in Europe.

Stelara biosimilars launch

Key events in the United States and Japan

- Stelara lost market exclusivity in Japan in November 2021 and in the United States in September 2023.
- In May 2024, Alvotech, in partnership with **Fuji Pharma**, **launched Ustekinumab BS SC Injection 45 mg Syringe "F,"** the first Stelara biosimilar in **Japan**.
- In the United States, J&J used patent thickets to delay the entry of Stelara biosimilars until 2025. The company successfully negotiated settlements with multiple biosimilar manufacturers, paving the way for ustekinumab biosimilars to enter the U.S. market.
- **Amgen's Wezlana is expected to be the first Stelara biosimilar to launch in the U.S. in January 2025.**

Stelara patent litigation- United States

- Stelara has six patents listed in the Purple Book, with its key composition patent expiring on September 25, 2023. However, J&J leveraged patent 307, which covers methods of treating colitis with ustekinumab and expires on September 25, 2039, to delay biosimilar competition.
- To overcome J&J's patent strategy, several biosimilar manufacturers entered into settlement agreements with the company, allowing J&J to postpone the U.S. market launch of Stelara biosimilars from late 2023 to early 2025.

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Potential implications in other major markets

- **United States:**
  - The launch of up to eight ustekinumab biosimilars in the United States starting January 2025 may mirror the market dynamics seen with Humira biosimilars, which had eight launches in July 2023 and two more since.
  - Clarivate's research highlights key barriers to biosimilar adoption in the United States, including unfamiliarity with biosimilars and concerns about switching treatments midcourse—challenges that also arose with Humira biosimilars in 2023. Manufacturers may need to focus on early physician education to drive biosimilar uptake.
  - Ustekinumab biosimilars may face additional market challenges in the United States due to Stelara's 66% price reduction under Medicare negotiations through the Inflation Reduction Act (IRA). This increased pricing pressure may push biosimilar manufacturers to stay competitive by adopting innovative pricing strategies, offering value-added services, and providing patient support programs.
- **Japan:**
  - In Japan we expect ustekinumab biosimilars to achieve a market share of 64% by 2032.

About the author

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Archana Prasad Variyar is a healthcare research & data analyst on the Biosimilars team at Clarivate. Previously, she was a market access analyst at Qlaar Solutions Pvt Ltd. She has also worked in digital health product development at HumanFractal.AI. She earned her master's degree in pharmacy (pharmaceutical chemistry) from the National Institute of Pharmaceutical Education and Research (NIPER), Hyderabad, and her master's in business administration from Mumbai University.

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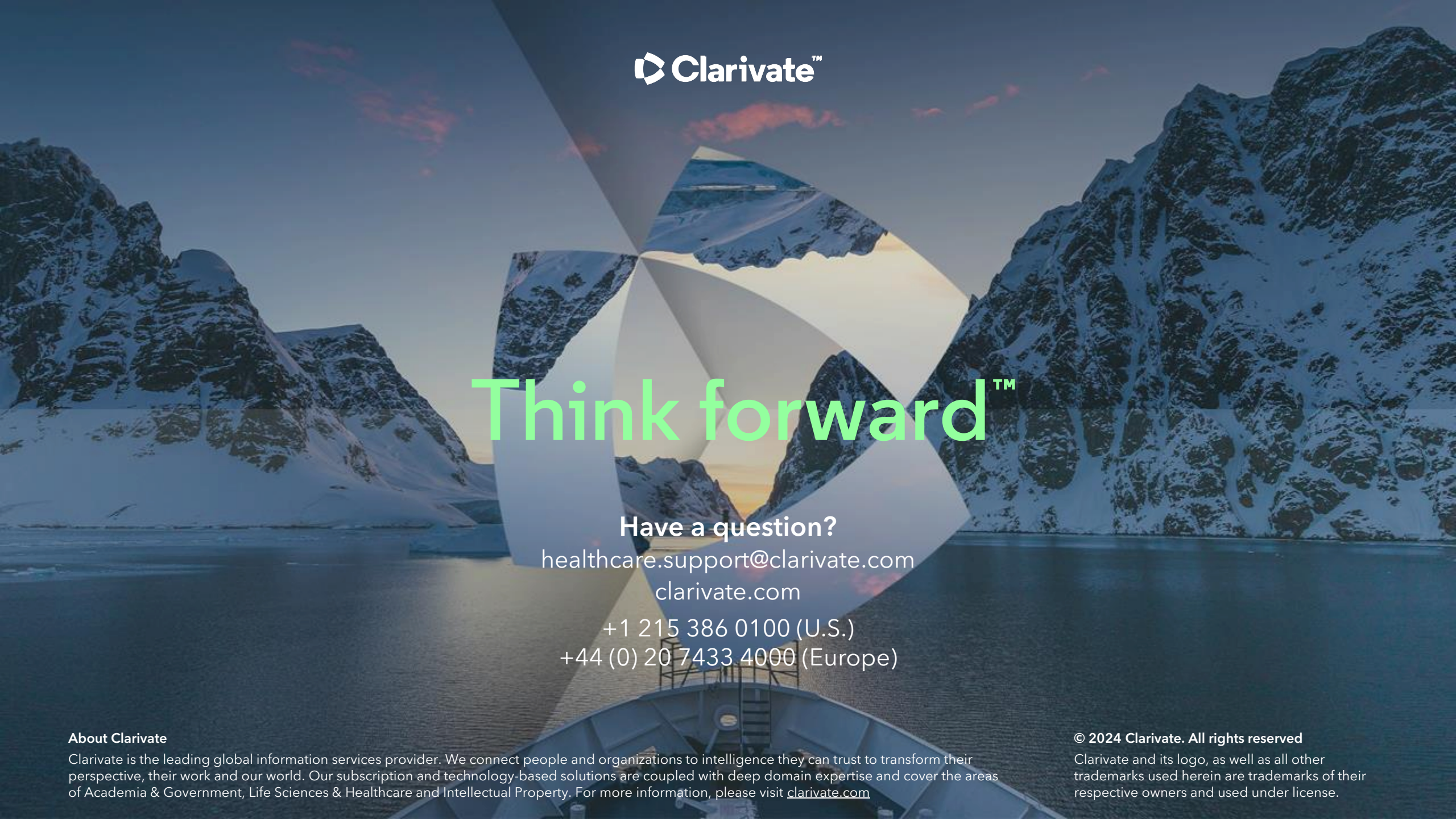

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