First Xolair biosimilar enters Europe

Market Event Summary

Prabal Singh; Yashu Malhotra | October 2025

Omlyclo sets a new benchmark

Background

- Celltrion launched Omlyclo (CT-P39) in France in September 2025; it is the first and only approved biosimilar referencing Xolair.
- Omlyclo was approved in the United States in March 2025; we expect it to launch in September 2026.

EMA label specifications

- Omlyclo is available as a 75 mg and 150 mg prefilled syringe (PFS). The product is indicated for the treatment of patients with allergic asthma, chronic rhinosinusitis with nasal polyps (CRSwNP), and chronic spontaneous urticaria (CSU), aligning with the reference product's label.

Clinical evidence supporting approval

- The approval is supported by a robust multicenter, double-blind, Phase 3 trial (NCT ID: NCT04426890; EudraCT ID: 2020-000952-36) conducted in patients with CSU who remained symptomatic despite H1 antihistamine treatment.
- The study confirmed therapeutic equivalence between Omlyclo and its reference product. The 95% confidence interval for the difference in mean change from baseline in Itch Severity Score (ISS7) at Week 12 fell within the predefined equivalence margin of -2.0 to 2.0. Safety profiles were comparable, with most treatment-emergent adverse events being mild to moderate (grade 1 or 2), and no deaths were reported through Week 12.

Clarivate's takeaways

First-to-market advantage

- As the first biosimilar to launch in Europe, we expect it to secure over 20% of the omalizumab market share in that region in 2033. This growth will be driven by its early entry, Celltrion's strong presence in the European market, and the planned introduction of an autoinjector formulation.
- The availability of Omlyclo in PFS form will accelerate uptake, mirroring the success of Xolair's PFS. Omlyclo will be positioned ahead of future biosimilar entrants that launch in powder form, offering a competitive edge in convenience of administration.

Market outlook

- Following the launch of Omlyclo, we expect several competitors to enter the market, including Teva's TEV-45779 and CuraTeq/Aurobindo's BP11 in 2026, followed by Alvotech's AVT23/ADL018 in 2027, and Glenmark Pharmaceuticals' GBR 310 in 2029, setting the stage for intense competition.
- With multiple biosimilars expected over the next 10 years, Clarivate forecasts the European biosimilar omalizumab market to surpass $120 million in 2033, representing over half of total omalizumab sales across the EU5 as multiple biosimilars enter the market.

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Prabal Singh, B.Pharm., works as an Associate Healthcare Research & Data Analyst, contributing to the Biosimilars and Oncology teams at Clarivate. Before joining Clarivate, Mr. Singh served as an associate analyst at DelveInsight Business Research, where he specialized in forecasting, competitive intelligence, and primary and secondary research, particularly in the fields of oncology and immunology. He also gained experience in SAS programming during his internship as a clinical data engineer at Parexel. Mr. Singh holds a bachelor's degree in pharmacy from Bundelkhand University in Jhansi.

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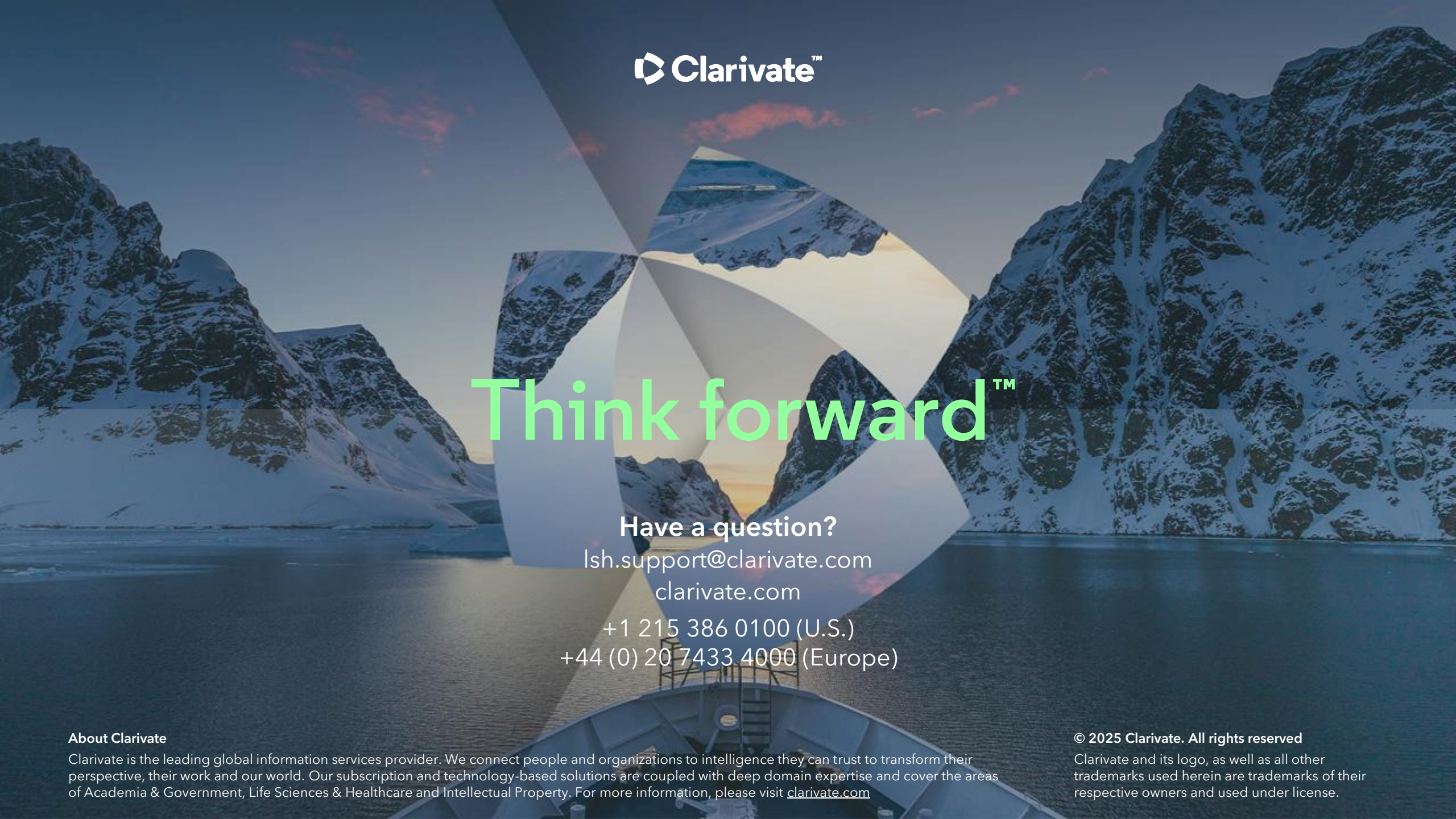

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