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FDA approves Sanofi / Regeneron's Dupixent for chronic spontaneous urticaria

Market Event Summary

Colleen Albacker, Ph.D. | May 2025

FDA approval of Dupixent for CSU marks the first targeted therapy available in over a decade

Background

- Sanofi / Regeneron's Dupixent (dupilumab) is a first-in-class IL-4/IL-13 inhibitor. It was first approved by the FDA for moderate to severe atopic dermatitis in 2017 and has subsequently expanded its U.S. label to include asthma, chronic rhinosinusitis with nasal polyps, eosinophilic esophagitis, prurigo nodularis, and COPD.
- Patients with chronic spontaneous urticaria (CSU) develop symptoms such as itching, wheals, and angioedema that last for more than six weeks at a time without a known trigger. With Roche / Novartis's Xolair (omalizumab) as the only targeted therapy, this market needed additional, effective treatments for antihistamine-refractory patients.

Event

- On April 18, 2025, the FDA approved Dupixent for CSU (its seventh indication), making it the first targeted therapy approved in the United States for CSU in 11 years.
- Dupixent's FDA approval was based on the LIBERTY-CSU CUPID Phase 3 program, in which the drug demonstrated a 4.7-point improvement in the itch severity score (ISS7) and an 8.5-point improvement in the urticaria activity score (UAS7) in biologic-naive CSU patients.
- The drug is administered via subcutaneous injection every 2 weeks.

Clarivate's takeaways

Fitting into the CSU treatment algorithm

- In the LIBERTY-CSU CUPID trials, Dupixent was efficacious in biologic-naive, antihistamine-refractory patients but was found to lack efficacy in omalizumab-refractory patients; these results should position the drug as a first-line biologic, competing directly with omalizumab. Many dermatologists are familiar with Dupixent from its use for atopic dermatitis, and some interviewed KOLs are eager to start prescribing the drug for CSU, especially those in dermatology clinics that are not equipped to administer omalizumab.
- Omalizumab will remain a formidable competitor. Specialists have had more than a decade of experience with this agent, and some interviewed KOLs have expressed that they have no plans to change their preferred first-line biologic. Dupixent will struggle with these prescribers, since the drug did not show efficacy as a second-line biologic to omalizumab. In addition, the March 2025 approval of an interchangeable biosimilar of omalizumab will keep costs in check.

Commercial potential

- Dupixent was already being used off-label for chronic urticaria, and this approval will boost its sales. We forecast to Dupixent to exceed $400 M in annual G7 sales by 2033 in the CSU subpopulation.
- A Phase 3 trial was conducted to determine the efficacy and safety of Dupixent in chronic inducible cold urticaria patients, but development has not moved forward; studies such as this could help Dupixent expand its urticaria footprint, increasing its sales potential.

About the author

Colleen Albacker, Ph.D.

Director, Healthcare Research & Data Analytics, Immune and Inflammation

Colleen Albacker, Ph.D., leads a team of analysts and managers generating syndicated market research content on respiratory, rheumatology, dermatology, and gastrointestinal indications. She has authored market research reports analyzing physician, payer, and market trends across various autoimmune indications. Previously, Dr. Albacker conducted her graduate research on chromatin-modifying factors in zebrafish cancer and hematopoietic development at Harvard Medical School and Boston Children's Hospital. She also gained experience with market research through a fellowship with the Harvard Office of Technology Development. Dr. Albacker holds a Ph.D. in genetics from Harvard University and a B.S. in biology with honors from the Pennsylvania State University.

Colleen.Albacker@clarivate.com

Clarivate coverage of chronic urticaria

- Disease Landscape & Forecast: Chronic Urticaria (G7), providing comprehensive market insights
- Epidemiology: Total and diagnosed prevalence data for various population segments of chronic urticaria across the mature markets
- Treatment Algorithms: Claims Data Analysis (US): Explores the current treatment journey of chronic spontaneous urticaria through longitudinal patient claims data
- Treatment Algorithms: Claims Data Analysis (US): Explores the current treatment journey of chronic inducible urticaria through longitudinal patient claims data
- Unmet Need: Chronic urticaria (encompassing both chronic spontaneous urticaria and chronic inducible urticaria) (US / EU), including an Excel-based target product profile simulator

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