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Celltrion Gains First Omalizumab Biosimilar Approval

👤 Stanton Mehr 📁 Uncategorized ⌚ March 11, 2025

On March 10, Celltrion announced [receiving US marketing authorization from the FDA](#) for its omalizumab biosimilar Omlyclo (omalizumab-igec). This is the first omalizumab biosimilar (reference product, Xolair) to receive US approval.

The FDA also granted Celltrion the interchangeability designation for Omlyclo. Omalizumab is an anti-IgE antibody.

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Amneal v. Genentech
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The approval was for all of the reference product's indications, including:

- Moderate-to-severe persistent asthma in adults and pediatric patients (≥ 6 yr) of age with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms
- Chronic rhinosinusitis with nasal polyps in patients ≥ 18 years of age as add-on maintenance treatment
- IgE-mediated food allergy in adult and pediatric patients (≥ 1 yr) for the reduction

of allergic reactions (Type I, including anaphylaxis), which may occur with accidental exposure to one or more foods

- Chronic spontaneous urticaria in patients ≥ 12 years of age who remain symptomatic despite H_1 antihistamine treatment

A spokesperson for Celltrion told *BR&R* that “In accordance with a settlement with Genentech, Omlyclo will be able to enter the US market as early as September 1, 2026.” Licensing agreements with other potential omalizumab biosimilar manufacturers have not been publicized, but Celltrion's potential competition (that is, publicly disclosed competition) in the omalizumab category seems a bit behind. Kashiv Biosciences completed its [phase 3 investigation](#) of ADL-018 in patients with urticaria in December 2024. Its marketing partner, Amneal Biosciences, also is anticipating a 2026 launch, [according to its website](#). Teva completed a phase 3 study in May 2024 but has not announced an FDA 351(k) filing. Aurobindo and Glenmark are also possible contenders, but neither have announced filings.

The food allergy indication, which was approved most recently for Xolair, [boosted its US net revenues by 16%](#), to \$2.7 billion in 2024.

March has gotten off to a very positive start for Celltrion, having already [received approval](#) on its denosumab biosimilars.

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(Editor's Note: This post was revised March 11, with information about the potential launch date for Omlyclo.)

Published by Stanton Mehr

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