Omlyclo® (omalizumab-igec) – New first-time interchangeable biosimilar approval

- On March 9, 2025, Celltrion announced the FDA approval of Omlyclo (omalizumab-igec), biosimilar and *interchangeable* to Novartis/Genentech's Xolair (omalizumab).
    - Omlyclo is the first FDA-approved biosimilar to Xolair.
- Omlyclo and Xolair share the following indications:
    - Moderate to severe persistent asthma in adults and pediatric patients 6 years of age and older with a positive skin test or *in vitro* reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids
    - Chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients 18 years of age and older with inadequate response to nasal corticosteroids, as add-on maintenance treatment
    - IgE-mediated food allergy in adult and pediatric patients aged 1 year and older for the reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods. Omlyclo and Xolair be used in conjunction with food allergen avoidance.
    - Chronic spontaneous urticaria (CSU) in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment.
- The approval of Omlyclo is based on review of a comprehensive data package and totality of evidence demonstrating a high degree of similarity to its reference product, Xolair.
- Evidence also demonstrated that Omlyclo met the other legal requirements to be *interchangeable* with Xolair at the pharmacy level.
- Like Xolair, Omlyclo carries a boxed warning for anaphylaxis.
- Warnings and precautions for Omlyclo include malignancy; acute asthma symptoms and deteriorating disease; corticosteroid reduction; eosinophilic conditions; fever, arthralgia, and rash; parasitic (helminth) infection; laboratory tests; and potential medication error related to emergency.
- The most common adverse reactions (≥ 1%) with Omlyclo use in clinical studies of asthma with adult and adolescent patients ≥ 12 years of age were arthralgia, pain (general), leg pain, fatigue, dizziness, fracture, arm pain, pruritus, dermatitis, and earache. The most common adverse reactions (≥ 3%) in clinical studies with pediatric patients 6 to < 12 years of age were nasopharyngitis, headache, pyrexia, upper abdominal pain, streptococcal pharyngitis, otitis media, viral gastroenteritis, arthropod bites, and epistaxis.
- The most common adverse reactions (≥ 3%) with Omlyclo use in clinical studies of CRSwNP with adult patients were headache, injection site reaction, arthralgia, upper abdominal pain, and dizziness.
- The most common adverse reactions (≥ 3%) with Omlyclo use in IgE-mediated food allergy were injection site reactions and pyrexia.
- The most common adverse reactions (≥ 2%) with Omlyclo use in CSU were nausea, nasopharyngitis, sinusitis, upper respiratory tract infection, viral upper respiratory tract infection, arthralgia, headache, and cough.

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- The recommended dosage of Omlyclo for asthma is 75 mg to 375 mg by subcutaneous (SC) injection every 2 or 4 weeks based on serum total IgE level (IU/mL) measured before the start of treatment and by body weight.
- The recommended dosage of Omlyclo for CRSwNP and IgE-mediated food allergy is 75 mg to 600 mg by SC injection every 2 or 4 weeks based on serum total IgE level (IU/mL) measure before the start of treatment and by body weight.
- The recommended dosage of Omlyclo for CSU is 150 mg or 300 mg by SC injection every 4 weeks.
- Omlyclo is intended for use under the guidance of a healthcare provider. Therapy should be initiated in a healthcare setting and once therapy has been safely established, the healthcare provider may determine whether self-administration of Omlyclo prefilled syringe by the patient or caregiver is appropriate, based on careful assessment of risk for anaphylaxis and mitigation strategies.
- Celltrion's launch plans for Omlyclo are pending. Omlyclo will be available as a 75 mg/0.5 mL and 150 mg/mL solution in a single-dose prefilled syringe.

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