FDA approves first medication to help reduce allergic reactions to multiple foods

Xolair is not approved for the immediate emergency treatment of allergic reactions, including anaphylaxis. Xolair received Priority Review and Breakthrough Therapy designations for this indication.

Xolair is a drug (in the class of drugs called monoclonal antibodies) that binds to immunoglobulin E (IgE)

The U.S. Food and Drug Administration (USFDA) approved Xolair (omalizumab) injection for immunoglobulin E-mediated food allergy in certain adults and children 1 year or older for the reduction of allergic reactions (Type I), including reducing the risk of anaphylaxis, that may occur with accidental exposure to one or more foods.

According to a press statement, patients who take Xolair must continue to avoid foods they are allergic to. Xolair is intended for repeated use to reduce the risk of allergic reactions and is not approved for the immediate emergency treatment of allergic reactions, including anaphylaxis.

Xolair was originally approved in 2003 for the treatment of moderate to severe persistent allergic asthma in certain patients. Xolair is also approved to treat chronic spontaneous urticaria and chronic rhinosinusitis with nasal polyps in certain patients.

“This newly approved use for Xolair will provide a treatment option to reduce the risk of harmful allergic reactions among certain patients with IgE-mediated food allergies,” said Kelly Stone, M.D., Ph.D., associate director of the Division of Pulmonology, Allergy, and Critical Care in the FDA’s Center for Drug Evaluation and Research. “While it will not eliminate food allergies or allow patients to consume food allergens freely, its repeated use will help reduce the health impact if accidental exposure occurs.”

According to the Centers for Disease Control and Prevention, almost 6% of people in the United States in 2021 had a food allergy and exposure to the particular food(s) to which they are allergic can lead to potentially life-threatening allergic reactions (i.e., anaphylaxis). There is currently no cure for food allergy. Current treatment requires strict avoidance of the food(s) the patient is allergic to, and prompt administration of epinephrine to treat anaphylaxis should accidental exposures occur. Palforzia (peanut allergen powder) is an oral immunotherapy product approved in patients 4-17 years of age for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut, but its benefits are restricted to peanut allergy. Xolair is the first FDA-approved medication to reduce allergic reactions to more than one type of food after accidental exposure.

Xolair is a drug (in the class of drugs called monoclonal antibodies) that binds to immunoglobulin E (IgE), the antibody type that triggers allergic reactions, and blocks IgE from binding to its receptors.

The most common side effects of Xolair observed included injection site reactions and fever. Xolair comes with certain warnings and precautions, such as anaphylaxis, malignancy, fever, joint pain, rash, parasitic (worm) infection and abnormal laboratory tests.

In addition, Xolair comes with a boxed warning for anaphylaxis, which can be life threatening, based on pre-marketing and post-marketing reports of anaphylaxis that occurred after Xolair administration. Anaphylaxis has occurred after the first dose of Xolair, but also has occurred beyond one year after beginning treatment. Xolair should only be started in a healthcare setting equipped to manage anaphylaxis. For selected patients who tolerate initial Xolair treatments in a healthcare setting without anaphylaxis, self-administration (or administration by a caregiver) may be appropriate and should be discussed with a healthcare provider.

Patients should not receive Xolair if they have a history of known severe hypersensitivity to Xolair or any of its components, USFDA warned.

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