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FDA Approves Groundbreaking Drug Xolair to Prevent Severe Food Allergic Reactions



In a historic move, the U.S. Food and Drug Administration (FDA) has granted approval for Xolair, **the first-ever drug designed to treat individuals with life-threatening food allergies**. Xolair, also known by its generic name omalizumab, is administered through injections and is now accessible to **both adults and children aged one** and above, with the primary aim of reducing the risk of severe allergic reactions to various foods.

Unlike immediate emergency treatments, Xolair is positioned as a preventive measure against accidental exposures to allergens, providing an additional layer of safety for those vulnerable to severe food allergies. Approximately 6% of the U.S. population experienced food allergies in 2021, as estimated by the Centers for Disease Control and Prevention, exposing millions to potential life-threatening reactions.

Xolair falls under the category of monoclonal antibodies and works by binding to immunoglobulin E (IgE), an antibody responsible for triggering allergic reactions. By blocking this process, **Xolair aims to prevent the body from initiating severe allergic responses**. Genentech, in collaboration with Novartis, developed and secured FDA approval for Xolair, offering hope to the estimated 3.4 million children and 13.6 million adults diagnosed with IgE-mediated food allergies.

Advocates for individuals with serious food allergies have welcomed this development, emphasizing that it broadens the limited treatment options available to manage the potentially fatal condition. Erin Malawer, founder and executive director of the national nonprofit AllergyStrong, expressed enthusiasm, stating, “We’ve literally overnight doubled the amount of options we have to manage this disease.”

While there is currently no cure for food allergies, patients typically manage the condition by avoiding allergenic foods. Xolair, however, represents a breakthrough as the first FDA-approved medication to reduce allergic reactions to multiple types of food following accidental exposure. This includes allergies to common triggers such as milk, egg, wheat, or nuts.

Dr. Kelly Stone, associate director of pulmonology, allergy, and critical care in FDA’s Center for Drug Evaluation and Research, emphasized that while Xolair won’t eliminate food allergies, its repeated use can help mitigate the health impact in case of accidental exposure. The drug’s success in recent clinical trials, where participants could tolerate small doses of allergenic foods without severe symptoms, played a crucial role in the FDA’s decision.

It’s worth noting that Xolair comes with a **price tag of up to \$5,000 per month for adults, with a lower cost for children**. Genentech assured that most insured patients would pay less out of pocket. However, advocates stress the importance of making Xolair accessible and affordable, particularly for low-income individuals, to prevent costly emergency room visits resulting from allergic reactions.

Xolair initially received FDA approval in 2003 for the treatment of allergic asthma and has since been approved for chronic hives and rhinosinusitis with nasal polyps. Despite its potential benefits, concerns exist about the need for indefinite usage and possible side effects, including injection site reactions, fever, and a boxed warning for anaphylaxis. The FDA recommends starting Xolair in a healthcare setting to manage associated risks.

Source: <https://www.fda.gov/news-events/press-announcements/fda-approves-first-medication-help-reduce-allergic-reactions-multiple-foods-after-accidental#:~:text=Today%2C%20the%20U.S.%20Food%20and,accidental%20exposure%20to%20one%20or>

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