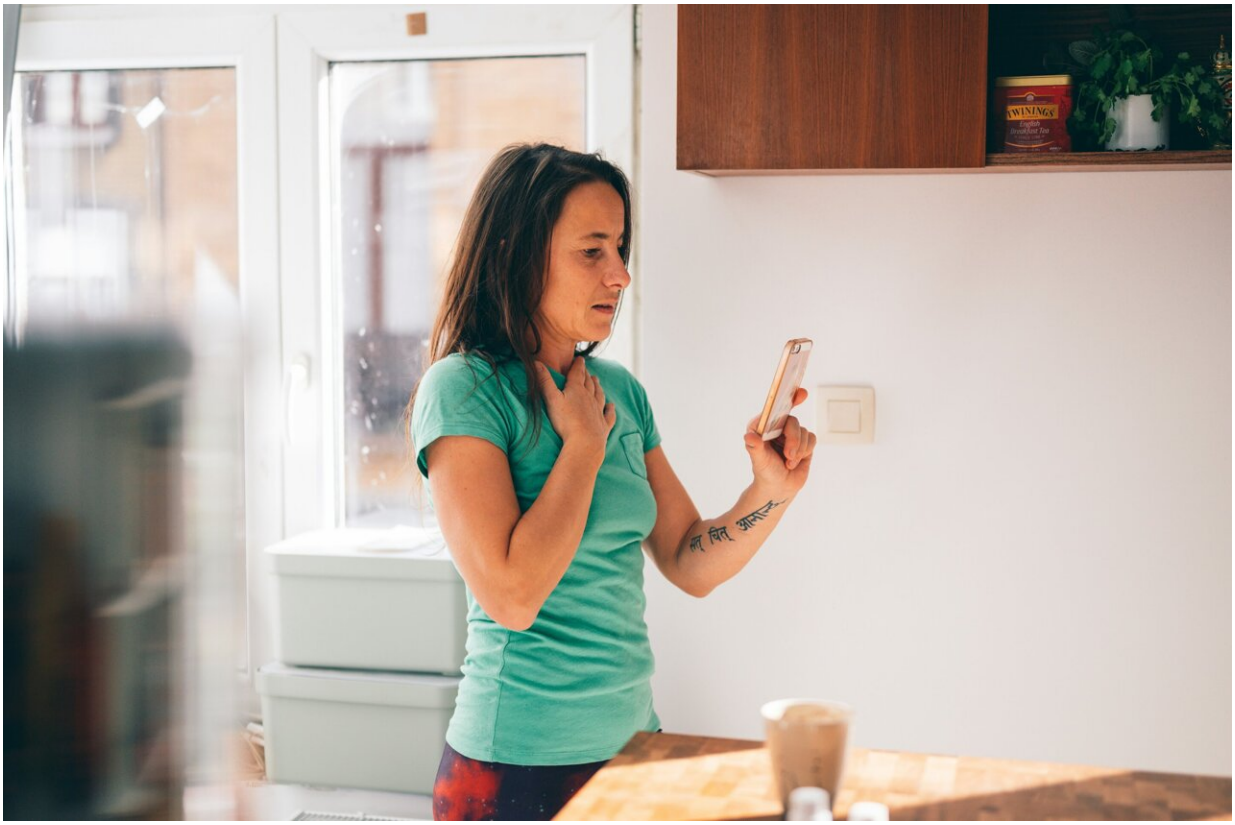
Trial data underpins FDA approval of omalizumab for food allergy

February 16 2024



Credit: Unsplash/CC0 Public Domain

Today's Food and Drug Administration approval of a supplemental biologics license for the monoclonal antibody omalizumab (Xolair) highlights the vital role of the National Institutes of Health-supported

research that underpins the FDA decision.

FDA has approved omalizumab for the reduction of allergic reactions, including anaphylaxis, that may occur with accidental exposure to one or more foods in adults and children aged 1 year and older with food allergies. People taking omalizumab still need to avoid exposure to foods to which they are allergic. Omalizumab previously received FDA approval for three other indications, including the treatment of moderate-to-severe persistent allergic asthma in certain patients.

The new FDA approval is based on data from a planned interim analysis of a Phase 3 clinical trial sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), part of NIH. The trial is called Omalizumab as Monotherapy and as Adjunct Therapy to Multi-Allergen OIT in Food Allergic Children and Adults, or OUtMATCH. Investigators in the Consortium for Food Allergy Research conducted the trial.

Detailed final results from the first stage of the trial will be presented at the American Academy of Allergy, Asthma & Immunology Annual Meeting in Washington, D.C., during a late-breaking symposium titled, "Omalizumab for the Treatment of Food Allergy: The OUtMATCH Study" on Sunday, Feb. 25, 2024, at 1:45 pm ET. An online supplement of the *Journal of Allergy and Clinical Immunology* published an abstract outlining the final results on Feb. 5, 2024.

More information: Robert Wood et al, Omalizumab for the Treatment of Multiple Food Allergy (OUtMATCH), *Journal of Allergy and Clinical Immunology* (2024). DOI: 10.1016/j.jaci.2023.11.909

Provided by NIH/National Institute of Allergy and Infectious Diseases