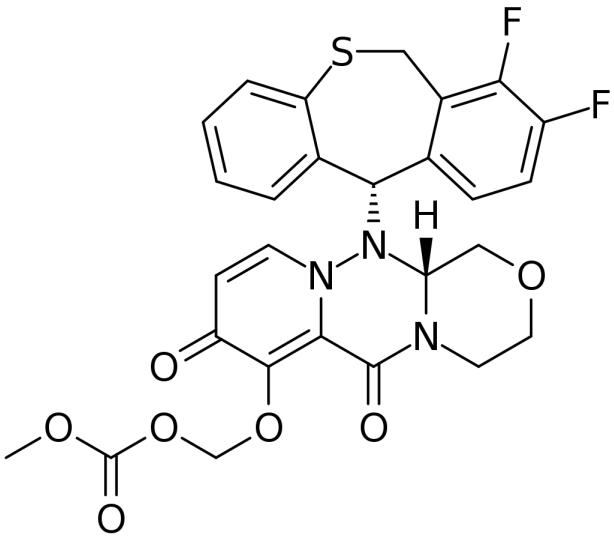
Brand Name: Xofluza
Generic: oseltamivir
Type: small molecule
Year Accepted/Phase: 2003

Mechanism:

Omalizumab is an anti-IgE antibody. It works by binding to immunoglobulin E (IgE), a substance in the body that can trigger allergic reactions and asthma symptoms. By binding to IgE, omalizumab prevents it from attaching to mast cells and basophils, reducing the release of inflammatory mediators that cause asthma symptoms and allergic reactions.

Chemical Structure:



Indication:

Xolair is indicated for the treatment of moderate to severe persistent asthma in patients aged 6 years and older whose symptoms are not controlled with inhaled corticosteroids and who have a positive skin test or in vitro reactivity to a perennial aeroallergen. It is also indicated for the treatment of chronic idiopathic urticaria in patients aged 12 years and older who remain symptomatic despite antihistamine treatment.

Clinical trials:

INNOVATE Trial (Phase III)
Purpose: Evaluate the efficacy and safety of omalizumab in patients with moderate to severe persistent asthma.
Dates: Conducted from 1999 to 2001.
Results: The INNOVATE trial showed that omalizumab significantly reduced the number of asthma exacerbations and improved asthma control in patients with moderate to severe persistent asthma. Patients receiving omalizumab experienced fewer exacerbations and had better overall asthma control compared to those receiving placebo.
Impact: These results led to the FDA approval of omalizumab for the treatment of moderate to severe persistent asthma in June 2003.

EXTRA Trial (Phase III)
Pubmed: https://pubmed.ncbi.nlm.nih.gov/10697061/
Purpose: Assess the long-term safety and efficacy of omalizumab in patients with severe allergic asthma.
Dates: Conducted from 2001 to 2003.
Results: The EXTRA trial demonstrated that omalizumab significantly reduced asthma exacerbations and improved asthma control over a two-year period.
Impact: Supported the use of omalizumab as a long-term treatment option for patients with severe allergic asthma.

ASTERIA I Trial (Phase III)
Pubmed: https://pubmed.ncbi.nlm.nih.gov/25046337/
Purpose: Assess the efficacy and safety of omalizumab in patients with CIU who remained symptomatic despite antihistamine treatment.
Dates: Conducted from 2011 to 2013.
Results: The ASTERIA I trial showed that omalizumab significantly reduced itch severity and hives compared to placebo. Patients treated with omalizumab had a higher rate of complete symptom control.
Impact: This trial contributed to the FDA approval of omalizumab for the treatment of CIU in March 2014.

ASTERIA II Trial (Phase III)
Pubmed: https://pubmed.ncbi.nlm.nih.gov/25046337/
Purpose: Similar to ASTERIA I, evaluate the efficacy and safety of omalizumab in CIU patients unresponsive to antihistamines.
Dates: Conducted from 2011 to 2014.
Results: The ASTERIA II trial confirmed the efficacy of omalizumab in reducing CIU symptoms, with significant improvements in itch severity and hives.

Impact: Reinforced the approval of omalizumab for CIU treatment, providing robust data on its effectiveness.

GLACIAL Trial (Phase III)
Pubmed: https://pubmed.ncbi.nlm.nih.gov/25046337/
Purpose: Evaluate the efficacy and safety of omalizumab in CIU patients who remained symptomatic despite high doses of antihistamines.
Dates: Conducted from 2012 to 2014.
Results: The GLACIAL trial demonstrated that omalizumab significantly reduced the symptoms of CIU, with marked improvements in quality of life for patients.
Impact: Supported the expanded use of omalizumab for severe cases of CIU unresponsive to other treatments.

Pediatric Asthma Trial (Phase III)
Pubmed:
Purpose: Evaluate the safety and efficacy of omalizumab in children aged 6 to 12 years with moderate to severe persistent asthma.
Dates: Conducted from 2004 to 2006.
Results: The trial showed that omalizumab was effective in reducing the number of asthma exacerbations in children and improved overall asthma control.
Impact: Led to the FDA approval of omalizumab for pediatric patients with moderate to severe persistent asthma in 2016.