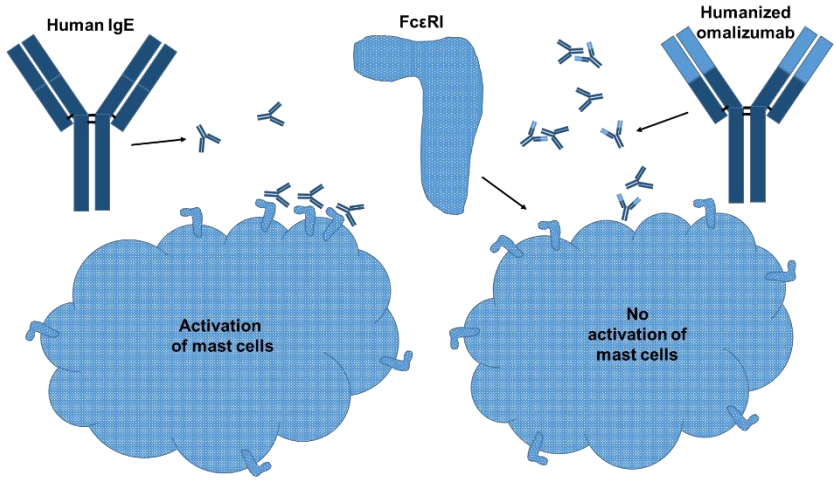
Omalizumab – Fact Sheet

Molecule

Omalizumab (Xolair®) is a recombinant humanized IgG1 kappa monoclonal antibody, which binds to free human immunoglobulin E (IgE) and to membrane-bound form of IgE (mIgE) on the surface of mIgE-expressing B lymphocytes. The molecular weight of omalizumab is 145 kDa.

Mode of Action

A typical anti-IgE antibody binds to IgE already bound to high affinity IgE receptor (FcεRI) on the surface of mast cells, basophils, and antigen-presenting dendritic cells. FcεRI-bound IgE is cross-linked and FcεRI is aggregated, which leads to activation of mast cells. Omalizumab inhibits binding of IgE to high affinity IgE receptor (FcεRI) by binding to an antigenic epitope on IgE, which overlaps with the binding site of FcεRI. The antigenic epitope on IgE is sterically hindered and thus anaphylactic effects of an ordinary anti-IgE antibody are averted. In addition, omalizumab decreases expression of FcεRI.



Indication

Xolair® is indicated for moderate to severe persistent asthma and for chronic idiopathic urticaria in patients who remain symptomatic despite H1 antihistamine treatment.

Patent Situation

Key patents on Xolair® already expired in 2017.

Market and Competitive Field

Xolair® was developed by Genentech (Roche) in collaboration with Novartis. It was approved in US in 2003 and in EU in 2005. Sales in 2020 were 1.05 billion € for Novartis (outside US) and for Roche 1.75 billion € (in US).

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VelaLabs Portfolio

		Omalizumab
		Xolair®
	Clone selection/ comparability	
HPLC	Separation based on **size** (SE-HPLC)	
HPLC	Separation based on **hydrophobicity** (RP-HPLC)	
HPLC	Detection of **charge variants** (CEX-HPLC)	
Binding	Binding to **cell surface** expressed target (Flow cytometry)	n.a.
Binding	Binding to **soluble target** (ELISA)	
Binding	Binding to specific **antibody or antigen** (SPR-BIACORE, ELISA)	
Binding	**Affinity/ kinetic** to recombinant target (SPR-BIACORE)	
Effector function	Binding to C1q, [1]**CDC surrogate** (ELISA)	
Effector function	**Affinity** to recombinant Fc-receptors (SPR-BIACORE)	
Effector function	Reporter gene assays, [2]**ADCC surrogate** (Luminescence)	
Effector function	[1]**CDC** (Flow cytometry)	
Effector function	[2]**ADCC** (DELFIA, Fluorescence)	
Effector function	Additional **bioassays** (Luminescence, fluorescence)	
Gly	Glyco-pattern with **Lectin Microarray** (45 different lectins)	
	(Pre)clinical application	
Clinics	Pharmacokinetics – **PK** (ECL, ELISA)	
Clinics	Pharmacodynamics – **PD** (ECL, ELISA, flow cytometry, bioassay)	
Clinics	Immunogenicity - [3]**ADAs** (ECL, Biacore, ELISA, neutr. assay)	

[1]CDC = Complement Dependent Cytotoxicity
[2]ADCC = Antibody Dependent Cellular Cytotoxicity
[3]ADA = Anti-Drug-Antibody

	Vela portfolio
	Vela planned
	c.l.d. = cell line dependent
	n.a. = not applicable
	In development

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