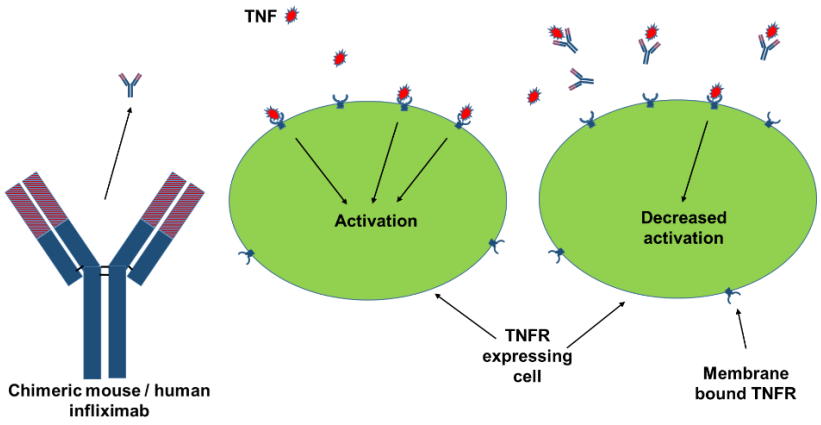
Infliximab – Fact Sheet

Molecule

Infliximab (Remicade®) is a chimeric (mouse / human) monoclonal IgG1 / kappa antibody. Like etanercept and adalimumab, infliximab is also a TNF-α blocker. It is composed of human constant and murine variable regions with a molecular weight of approximately 144 kD. 25% of the polypeptide chain are murine derived (binding epitope for TNF), 75% are human (IgG fragment).

Mode of Action

TNF is a cytokine produced primarily by activated macrophages and T-cells. It normally binds to TNF-α receptors (TNFRs), leading to an inflammatory response of autoimmune diseases. By binding to TNF, infliximab is reducing this particular inflammatory response triggered via TNFR signaling pathways.



Indication

Remicade® is indicated for treatment of Crohn's Disease, Psoriatic Arthritis, Ulcerative Colitis, Psoriasis, Ankylosing Spondylitis, and Rheumatoid Arthritis used together with methotrexate.

Patent Situation

The main patent of Remicade® expired in 2015 (EU) and in US in 2018. J&J (Janssen Biotech), the owner of the originator molecule is trying to delay the market entry of biosimilars with additional patents, however, is struggling to defend their validity at court.

Market and Competitive Field

J&Js sells Remicade® in US, Mitsubishi Tanabe in Japan and parts of Asia, Xian Janssen in China, and MSD in Europe and in ROW. Total worldwide sales of J&J in 2018 were 4.68 billion €. About 2/3 of the market was owned by J&J, but biosimilars are already on the market, i.e. Flixabi®, Inflectra®, Renflexis™, Remsima®.

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		Infliximab Remicade® Flixabi®, Infimab™, Inflectra®, Ixifi™ Renflexis™, Remsima®, Zessly™
	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)	c.l.d.
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)	c.l.d.
Effector function	[1]**CDC** (Flow cytometry)	c.l.d.
Effector function	[2]**ADCC** (DELFIA, Fluorescence)	c.l.d.
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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