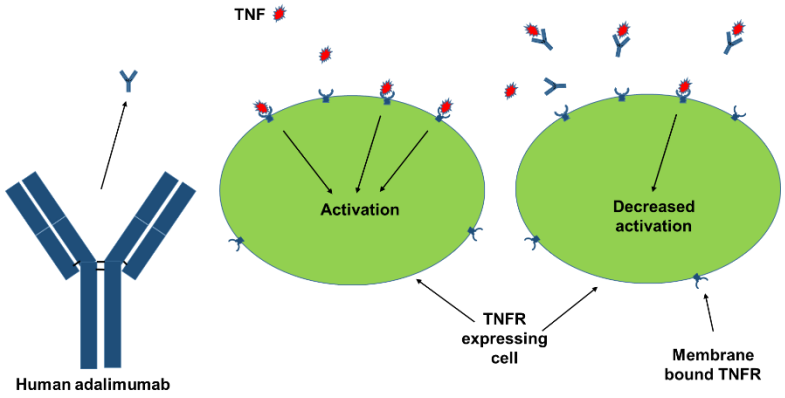
Adalimumab – Fact Sheet

Molecule

Adalimumab (Humira®) is a human monoclonal IgG1 / kappa antibody. Humira® was the third tumor necrosis factor TNF-α inhibitor on the market, but the first fully human antibody directed towards this target. Adalimumab consists of a tetramer of two heavy and two light chains with one N-glycosylation site per heavy chain.

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 the inflammatory response of autoimmune diseases. By binding to TNF, adalimumab is reducing the inflammatory response triggered via TNFR signaling pathways.



Indication

Indicated for treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, moderate to severe chronic psoriasis, moderate to severe hidradenitis suppurativa, and juvenile idiopathic arthritis.

Patent Situation

The patents of Humira® owned by AbbVie expired in 2016 in US and in EU in 2018. In the last years, AbbVie filed about 70 (US) patents covering Humira® formulations, manufacturing techniques and methods to treat multiple diseases. These additional patents expire between 2022 and 2034 and AbbVie pursued litigation to keep biosimilars off the US market until January 2023. All competitors accepted licenses. In Europe, launch was possible in October 2018.

Market and Competitive Field

In 2020, AbbVie's Humira® generated 16.4 billion € (2019: 17.4 billion €) and was still the top-selling drug globally. Several biosimilars were already approved by EMA and FDA but marketed only outside US. Due to competition (e.g., sales of Amgevita® from Amgen 273 million € and of Imraldi® of Samsung 179 million €) revenues of Humira® are decreasing outside of USA. Also, other biosimilars are approved, submitted for approval, or in late phase of development.

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		Adalimumab
		Humira®
		Adfrar™, Amjevita™, Amgevita™, CinnoRA®, Cyltezo™, Exemptia™, Hadlima™, Halimatoz™, Hefiya™, Hulio™, Hyrimoz™, Imraldi®, Mabura, Solymbic®
	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

	VelaLabs portfolio
	c.l.d. = cell line dependent
	In development

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