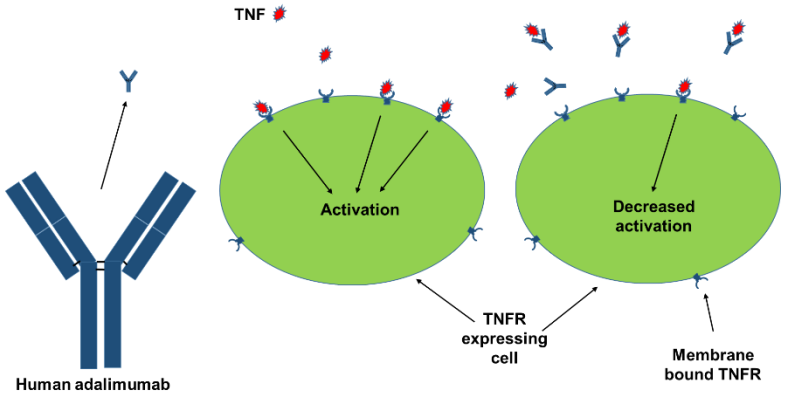
Adalimumab – Fact Sheet

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 has secured 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 will pursue litigation to try keeping biosimilars off the US market until January 2023. In Europe launch was possible in October 2018.

Market and Competitive Field

In 2018, AbbVie's Humira® generated 17.2 billion € and was the top-selling drug globally. Biosimilars Amjevita™, Amgevita™, and Solymbic® from Amgen are already approved by EMA and FDA, but launch is on hold due to patent litigation. Cyltexo™ from Boehringer Ingelheim is also approved. Furthermore, a large number of other biosimilars are either approved, submitted for approval, or in late phase III.

VelaLabs GmbH
Brunner Straße 69 / Obj. 3, A-1230 Vienna / Austria
Phone: +43 1 890 5979 11, Fax: +43 1 890 5979 10
E-Mail: office@vela-labs.at

		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

VelaLabs GmbH
Brunner Straße 69 / Obj. 3, A-1230 Vienna / Austria
Phone: +43 1 890 5979 11, Fax: +43 1 890 5979 10
E-Mail: office@vela-labs.at