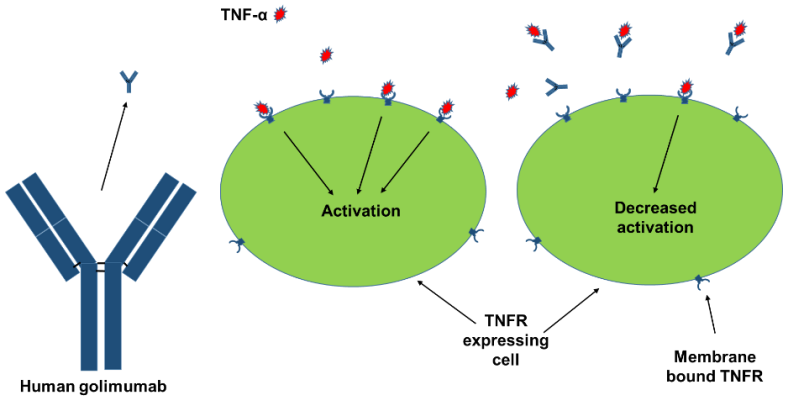
Golimumab – Fact Sheet

Molecule

Golimumab (Simponi®) is a fully human anti-TNF-α IgG1κ monoclonal antibody. It was developed by immunizing genetically engineered mice with human TNF-α, has a molecular mass of approximately 150 kDa, and exhibits multiple glyco-variants (isoforms).

Mode of Action

Golimumab is an anti-TNF antibody with affinity for both soluble and transmembrane TNF. 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, golimumab is reducing the inflammatory response triggered via TNFR signaling pathways.



Indication

Simponi® is indicated in adults as an adjunct to methotrexate treatment for rheumatoid arthritis, alone or as an adjunct to methotrexate treatment for active psoriatic arthritis and as a single agent for active ankylosing spondylitis and ulcerative colitis.

Patent Situation

Patents for Simponi® will expire in 2024 in US as well as in EU. In 2011, Bayer accused Centocor of infringing a patent titled “Human Anti-TNF Antibodies", but this action was not successful.

Market and Competitive Field

Starting from 2009, EMA and FDA have approved golimumab for its first indication under the trade name Simponi®. Simponi® was developed by J&J (Janssen/ Centocor). This company markets the product in North and South America, the Middle East, Africa and Asia Pacific (sales 2017: 1.54 billion €). In Europe, Russia and Turkey, Simponi® is distributed by Schering-Plough (Merck & Co) and in 2017 sales were 689 million €. Note: Mitsubishi Tanabe has distribution rights in Asian countries.

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		Golimumab
		Symponi®
	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)	
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
	VelaLabs planned
	c.l.d. = cell line dependent
	n.a. = not applicable
	In development

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