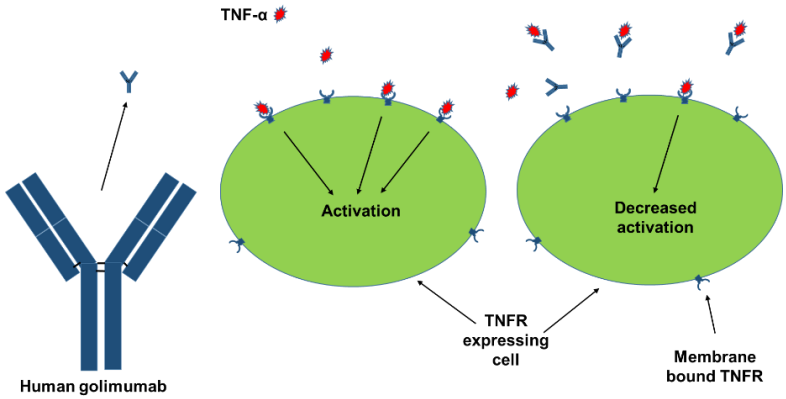
Golimumab – Fact Sheet

Molecule

Golimumab (Simponi®) is a fully human anti-tumor necrosis factor (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.

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 2021: 2.13 billion €). In Europe, Russia, and Turkey, Simponi® is distributed by MSD and in 2021 sales were 763 million €. Note: Mitsubishi Tanabe has distribution rights in Asian countries.

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		Golimumab
		Simponi®
	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

If you are interested in the full version including patent and originator data please contact us: velabd@vela-labs.at

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