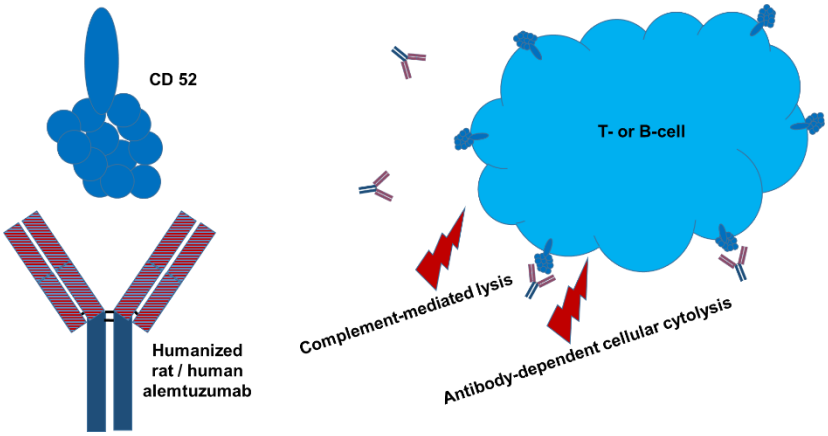
Alemtuzumab – Fact Sheet

Molecule

Alemtuzumab (Lemtrada®) is a humanized monoclonal antibody from the IgG1 kappa type with human variable framework and constant regions, and complementarity-determining regions from a rat monoclonal antibody.

Mode of Action

Alemtuzumab depletes circulating T- and B-cells through antibody-dependent cellular cytolysis and complement-mediated lysis. It is directed against the 21–28 kDa cell surface glycoprotein cluster of differentiation (CD)-52 present on the surface of mature lymphocytes, but not on the stem cells from which these lymphocytes are derived. A therapy with alemtuzumab increases the risk for opportunistic infections.



Indication

Alemtuzumab was originally indicated for second-line treatment of chronic lymphocytic leukemia (CLL), cutaneous T-cell lymphoma (CTCL) and normal T-cell lymphoma under trade names Campath®, MabCampath® and Campath-1H®. Currently it is indicated for the treatment of multiple sclerosis as Lemtrada®. It is also applied for some conditioning regimens for bone marrow transplantation, kidney transplantation, and islet cell transplantation.

Patent Situation

Basic patents for Lemtrada® already expired in 2017. New patents for treatment of multiple sclerosis were not granted.

Market and Competitive Field

Bayer HealthCare, which started the development of alemtuzumab, retains an option to co-promote alemtuzumab in multiple sclerosis. MabCampath® was originally approved for CLL in 2007 by Genzyme / Sanofi. Then it was withdrawn from markets in the US and EU in 2012 to prepare for a higher-priced relaunch of Lemtrada® indicated for multiple sclerosis. Sales of Genzyme / Sanofi for Lemtrada® are constantly decreasing, in 2020 only 113 million € were generated and in 2021 the drug is not listed anymore in the top ten of Sanofi.

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		Alemtuzumab
		Lemtrada®
	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)	Kit dependent
Binding	Binding to **soluble target** (ELISA)	Kit dependent
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)	
Effector function	[1]**CDC** (Flow cytometry)	
Effector function	[2]**ADCC** (DELFIA, Fluorescence)	n.a.
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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