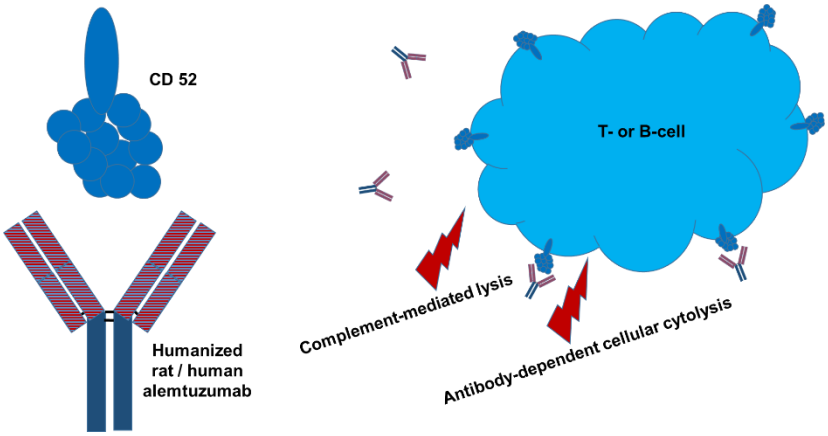
# Alemtuzumab – Fact Sheet

## 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 are 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 Then it was withdrawn from markets in the US and EU in 2012 to prepare for a higher-priced relaunch of Lemtrada® indicated for multiple sclerosis. In 2017, Genzyme / Sanofi had sales of 474 Mio. Euro for Lemtrada®.

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

| | | 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 |

**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