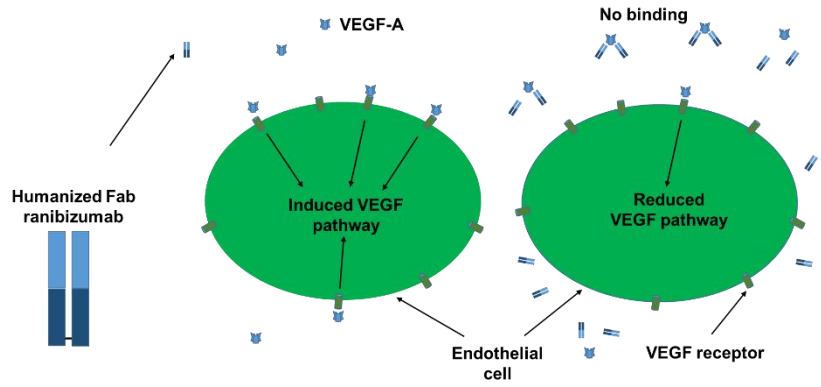
Ranibizumab – Fact Sheet

Molecule

Ranibizumab (Lucentis®) is a humanized monoclonal truncated antibody (Fab-fragment) created from the same parent mouse antibody as bevacizumab. It has a molecular weight of approximately 48 kDa and its effectiveness is very similar to that of bevacizumab.

Mode of Action

Ranibizumab binds to the receptor binding site of active forms of vascular endothelial growth factor A (VEGF-A), including the biologically active, cleaved form of this molecule, VEGF110. The binding of ranibizumab to VEGF-A prevents the interaction of VEGF-A with its receptors (VEGFR1 and VEGFR2) on the surface of endothelial cells, reducing endothelial cell proliferation, vascular leakage, and new blood vessel formation.



Indication

Lucentis® is indicated for the treatment of neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema, diabetic retinopathy, and myopic choroidal neovascularization.

Patent Situation

Relevant patents for Lucentis® will expire in US in 2020 and in EU in 2022, however, there are still uncertainties about patent term extensions.

Market and Competitive Field

Ranibizumab was developed by Genentech (Roche) and is marketed in the US by Genentech and elsewhere by Novartis under the brand name Lucentis®. The originator product was first approved by FDA in 2006 and by EMA in 2007. In 2017, Lucentis® had global sales of 1.6 billion € (Novartis), and 1,26 billion € (Genentech / Roche). Several ranibizumab biosimilars are in development, one product is already marketed in India.

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		Ranibizumab Lucentis® Razumab®
	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)	neg. assay
Effector function	**Affinity** to recombinant Fc-receptors (SPR-BIACORE)	n.a.
Effector function	Reporter gene assays, [2]**ADCC surrogate** (Luminescence)	n.a.
Effector function	[1]**CDC** (Flow cytometry)	n.a.
Effector function	[2]**ADCC** (DELFIA, Fluorescence)	n.a.
Effector function	Additional **bioassays** (Luminescence, fluorescence)	
Gly	Glyco-pattern with **Lectin Microarray** (45 different lectins)	n.a.
	(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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