Bevacizumab – Fact Sheet

Molecule

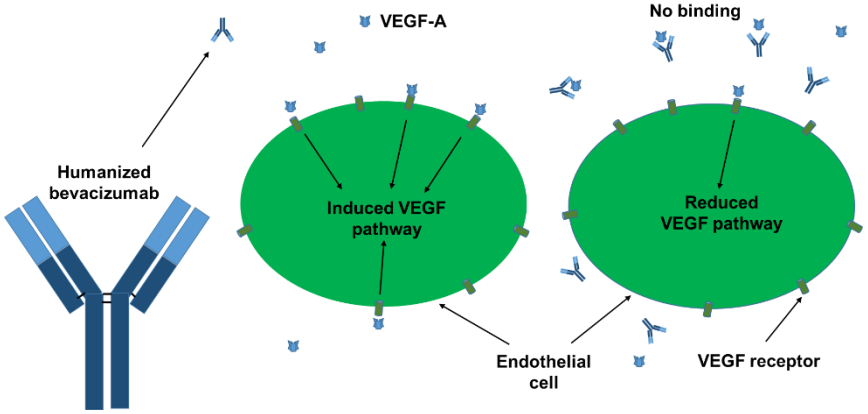
Bevacizumab (Avastin®) is a typical humanized monoclonal IgG1 / kappa antibody comprised of a tetramer of two heavy and two light chains with one N-glycosylation site per heavy chain.

Mode of Action

Bevacizumab inhibits angiogenesis (formation of new blood vessels) by blocking the interaction of Vascular Endothelial Growth Factor A (VEGF-A) with its receptors, VEGF receptor-1 or VEGF receptor-2. Bevacizumab can therefore also slow the growth of new blood vessels in tumors.

Indication

Bevacizumab is indicated for various cancers including metastatic colorectal cancer, non-squamous non-small cell lung cancer, metastatic renal cell carcinoma, recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer and also for a few glioblastomas.



Patent Situation

Bevacizumab patents expired in US (2019) and will expire in EU (2022) and there is no hint that these patents will not hold in EU. Roche as owner of the originator will defend these dates and all biosimilar developments in late stage will have to wait for market entry in EU until expiration of the patents.

Market and Competitive Field

The originator product, Roche's Avastin® was approved by FDA in 2004 and by EMA in 2005. Avastin® had sales of 6.17 and 6.70 billion in 2018 and 2019, respectively making it a popular target for biosimilar developers. Mvasi® from Amgen is already marketed and had in 2019 sales of 102 million €. Pfizer also started sales of Zirabev®. In developing countries, non-originator biologicals are marketed as well.

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VelaLabs Portfolio

		Bevacizumab
		Avastin®, Mvasi®. Zirabev®
	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)	n.a
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)	n.a.
Effector function	[1]**CDC** (Flow cytometry)	n.a.
Effector function	[2]**ADCC** (DELFIA, Fluorescence)	n.a.
Effector function	Additional **bioassays** (Luminescence, fluorescence)	Anti-proliferation
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

	Vela portfolio
	n.a. = not applicable

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