ISSN: 2475-6296

Short Communication

Journal of Clinical & Experimental Immunology

mAb Therapeutics Approved by FDA for Hematologic Malignancies (Mini Review)

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Submitted: 20 Jan 2023; **Accepted**: 25 Jan 2023; **Published**: 31 Jan 2023

Citation: Henry Hongrong Cai, MD* and Ayesha A. Pandit, MD MS (2023) mAb Therapeutics Approved by FDA for Hematologic Malignancies (Mini Review). *J Clin Exp Immunol*. 8(1); 530-532.

Monoclonal antibody (mAb) technique was created by Georges Köhler, César Milstein, and Niels Kaj Jerne in 1975 by using a mouse x mouse hybridoma. In 1984 they were awarded the Nobel Prize in Medicine for the discovery. Eight years later, in 1992 US FDA approved the first therapeutic mAb muromonab-CD3 (trade name Orthoclone OKT3) to reduce acute rejection in patients with organ transplants. In 1997 US FDA approved first therapeutic mAb rituximab (trade name RITUXAN) for treatment of NHL and CLL [1, 2]. Since then, as of December 15, 2022, FDA has approved 151 therapeutic mAbs, 58 were approved for cancer therapy, among them 20 targets at hematological malignancies, listed here [3-22].

Among 20 mAbs 18 therapeutics targeted at the cluster of differentiation (CD), including CD19 3; CD20 7; CD22 2; CD30 1; CD33 1; CD38 3; CD79b 1, another two mAbs targeted at SLAMF7 (Signaling Lymphocytic Activation Molecule Family member 7) protein and B-cell maturation antigen (BCMA). CD is used to identify and investigate cell surface molecules providing targets for immunophenotyping of cells, CD molecules can act in numerous ways, often acting as receptors or ligands important to the cell. A signal cascade (signaling pathway) is usually initiated, altering the behavior of the cell. Some CD proteins play a role in cell adhesion.

Monoclonal Antibodies Approved by FDA for Hematologic Malignancies

Aproval on	MAH	Drug Name	Active Ingredients	Target	Indication	MOA	AE	Warning
11/26/1997	Genen tech	RITUXAN	rituximab	CD 20	NHL; CLL	CDC; ADCC	febrile neutro penia	IRR; TLS
2/19/2002	Spec trump	ZEVALIN	ibritumomab tiuxetan	CD 20	NHL	Y-90 radicals	Cyto penia	IRR
11/1/2013	Genen tech	GAZYVA	obinutu zumab	CD 20	CLL; FL	ADCC; ADCP	IRR	HBV; PML
6/22/2017	Genen tech	RITUXAN HYCELA	rituximab +hyalu ronidase	CD 20	FL; DLBCL; CLL	permeability CDC; ADCC	neutro penia	SMR; HBV; PML
11/28/2018	Cell Trion	TRUXIMA	rituximab -abbs	CD 20	NHL; CLL	CDC; ADCC	fever	IRR; SMR HBV; PML
7/23/2019	Pfizer	RUXIENCE	rituximab -pvvr	CD 20	NHL; CLL	CDC; ADCC	fever	IRR; SMR HBV; PML
12/17/2020	Amgen	RIABNI	rituximab -arrx	CD 20	NHL; CLL	CDC; ADCC	fever	IRR; SMR HBV; PML
8/19/2011	Seattle Genetics	ADCETRIS	brentuximab vedotin	CD 30	HL; SALCL;	ADC MMAE	peripheral neuropathy	PML
11/30/2015	BMS	EMPLICITI	elotuzumab	SLAMF7	MM	ADCC	fatigue	IRR; SPM

9/1/2017	Wyeth	MYLOTARG	gemtuzumab ozogamicin	CD 33	AML	ADC	hemorrhage	Hepato toxicity
12/3/2014	Amgen	BLINCYTO	blinatumomab	CD19/CD3	ALL	T cell engager	Infection	CRS
7/31/2020	Morphosys	MONJUVI	tafasitamab -cxix	CD 19	DLBCL	ADCC; ADCP	neutropenia	IRR
4/23/2021	ADC Thera peutics	ZYNLONTA	loncastuximab tesirine-lpyl	CD 19	LBCL; DLBCL	ADC	neutropenia	IRR
11/16/2015	Janssen	DARZALEX	daratumumab	CD 38	MM	ADCC; ADCP	URI	IRR
3/2/2020	Sanofi	SARCLISA	isatuximab-irfc	CD 38	MM	ADCC; ADCP; CDC	IRR; SPM	Infection
5/1/2020	Janssen	DARZALEX FASPRO	daratumumab+ hyaluro nidase-fihj	CD 38	MM; Light Chain Amyloidosis	permeability ADCC; ADCP	URI	IRR
8/17/2017	Wyeth	BESPONSA	inotuzumab ozogamicin	CD 22	ALL	ADC	IRR	Hepato toxicity
9/13/2018	Innate	LUMOXITI	moxetumomab pasudotox-tdfk)	CD 22	HCL	ADC	IRR	CLS; HUS
6/10/2019	Genen tech	POLIVY	polatuzumab vedotin-piiq	CD 79b	DLBCL	ADC	IRR	Neutropenia
8/5/2020	GSK	BLENREP	belantamab mafodotin-blmf	BCMA	MM	ADC	nausea	vision loss

ADC Antibody-drug conjugate
ADCC Antibody dependent cell mediated cytotoxicity
ADCP Antibody dependent cellular phagocytosis
ALL Acute lymphoblastic leukemia
AML Acute Myeloid Leukemia
BCMA B-cell maturation antigen
CDC Complement dependent cytotoxicity
CLL Chronic Lymphocytic Leukemia
CLS Capillary Leak Syndrome
CRS Cytokine Release Syndrome
DLBCL Diffuse Large B-cell Lymphoma
FL Follicular Lymphoma
HBV Hepatitis B virus reactivation
HCL Hairy cell leukemia
HL Hodgkin Lymphoma
HUS Hemolytic Uremic Syndrome
IRR Infusion-related reactions
LBCL Large B-cell lymphoma
MM Multiple myeloma
MMAE Monomethyl auristatin E (tubulin inhibitor)
NHL Non-Hodgkin's Lymphoma
PML Progressive multifocal leukoencephalopathy
SALCL Systemic Anaplastic Large Cell Lymphoma
SLAMF7 signaling lymphocytic activation molecule family member 7 (CD319)
SMR Severe mucocutaneous reactions
SPM Second Primary Malignancies
TLS Tumor lysis syndrome
URI Upper respiratory infection

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