

## Therapeutic Monoclonal Antibodies Approved by FDA in 2022

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### Introduction

Compared with the annual record high, 17 therapeutic monoclonal antibodies (mAb) approved in 2017, this year total 16 therapeutic mAb were approved by FDA, interestingly 4 of them targeted at VEGF (Vascular Endothelial Growth Factor), two indicated for solid tumor, two for Neovascular (Wet) Age-Related Macular Degeneration [1]. Monoclonal antibody 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. Since then, genetic engineering technique was developed and used into preparation of humanized mAb. As of December 31, 2022, FDA has approved 153 therapeutic mAbs (not including two diagnostic mAb). Among them 59 were approved for cancer therapy (20 for hematological cancer and 39 for solid tumor), they are reviewed in separated articles. In this mini review focuses briefly on the characteristics of 16 therapeutic antibodies approved in 2022 by FDA (Table) [2-17].

Therapeutic monoclonal antibodies approved by FDA in 2022

Approval Date	MAH	Drug Name	Active Ingredients	Target	Indication	MOA	Warning	AE
01/28/2022	GENENTECH	VABYSMO	FARICIMAB-SVOA	VEGF; Ang-2	nAMD; DME	Antagonist	EP; RD; ATE	IIP; CH
2/4/2022	BIOVERATIV	ENJAYMO	SUTIMLIMAB-JOME	CP	CAD	Antagonist	SI; IRR; RoAD	diarrhea dyspepsia cough
3/18/2022	BMS	OPDUALAG	NIVOLUMAB; RELATLIMAB-RMBW	PD-1; LAG-3	melanoma	Antagonist	IMAR; IRR	MP; fatigue; rash
4/13/2022	AMNEAL	ALYMSYS	BEVACIZUMAB-MALY	VEGF	mCRC	Antagonist	GIPF; WHC; Hemorrhage	epistaxis; headache; hypertension
6/16/2022	ABBVIE	SKYRIZI	RISANKIZUMAB-RZAA	IL-23	PP; APA; ACD	Antagonist	HR; SI; TB	URI
8/2/2022	COHERUS	CIMERLI	RANIBIZUMAB-EQRN	VEGF	nAMD; RVO; DME; DR; mCNV	Antagonist	RD; IIP; ATE	CR; eye pain
9/1/2022	BOEHRINGER	SPEVIGO	SPESOLIMAB-SBZO	IL-36R	GPPF	Antagonist	SI; TB; IRR	asthenia; nausea and vomiting
9/27/2022	CELLTRION	VEGZELMA	BEVACIZUMAB-ADCD	VEGF	mCRC; NSCLC; RG; mRCC; mCC; EFP	Antagonist	GIPF; WHC; Hemorrhage	epistaxis; headache; hypertension

10/21/2022	ASTRA ZENECA	IMJUDO BLA 761289	TREMELIMUMAB-ACTL	CTLA-4	uHCC	Antagnist	IMAR; IRR; EFT	rash; diarrhea; fatigue
10/25/2022	JANSSEN	TECVAYLI	TECLISTAMAB-CQYV	BCMA; CD3	MM	T-cell engager	CRS; NT; Hepato toxicity	pyrexia; CRS; MP
11/10/2022	ASTRAZENECA	IMJUDO BLA 761270	TREMELIMUMAB-ACTL	CTLA-4	uHCC; NSCLC	Antagnist	IMAR; IRR; EFT	rash; diarrhea; fatigue
11/14/2022	IMMUNOGEN	ELAHERE	MIRVETUXIMAB SORAVTANSINE-GYNX	FR $\alpha$ -DM4	EFP	ADC	severe ocular toxicities	vision impairment; fatigue
11/17/2022	PROVENTION	TZIELD	TEPLIZUMAB-MZWV	CD3	type 1 diabetes	Antagnist	CRS; SI; ymphopenia	ymphopenia; rash
12/13/2022	FRESENIUS	IDACIO	ADALIMUMAB-AACF	TNF	RA JIA PsA AS CD UC Ps	Antagnist	TB SPM	URI; ISR
12/22/2022	GENENTECH	LUNSUMIO	MOSUNETUZUMAB-AXGB	CD20; CD3	FL	T-cell engager	CRS; ICANS	fatigue; rash; pyrexia
12/28/2022	TG	BRIUMV	UBLITUXIMAB-XIY	CD20	MS	ADCC; CDC	IRR; SI; RiI	IRR; URI

ACD Active Crohn's Disease  
ADC antibody-drug conjugate  
ADCC antibody-dependent cellular cytotoxicity  
Ang-2 Angiopoietin-2  
APA Active Psoriatic Arthritis  
AS Ankylosing Spondylitis  
ATE Arterial Thromboembolic Events  
BCMA B-cell maturation antigen  
CAD Cold agglutinin disease  
CD Crohn's Disease  
CDC complement-dependent cytotoxicity  
CH conjunctival hemorrhage  
CP complement pathway  
CRS Cytokine release syndrome  
CTLA-4 cytotoxic T-lymphocyte-associated antigen 4  
DM4 microtubule inhibitor  
DME Diabetic Macular Edema  
DR Diabetic Retinopathy  
EFP Epithelial ovarian, fallopian tube, or primary peritoneal cancer  
EFT Embryo-Fetal Toxicity  
EP Endophthalmitis  
FL follicular lymphoma  
FR $\alpha$  folate receptor alpha  
GIPF Gastrointestinal Perforations and Fistula  
GPPF Generalized Pustular Psoriasis Flares  
HR Hypersensitivity Reactions  
ICANS Immune Effector Cell-Associated Neurotoxicity Syndrome  
IIP Increasing Intraocular Pressure  
IL-23 Interleukin-23  
IL-36R Interleukin-36 Receptor

IMAR Immune-Mediated Adverse Reactions  
IRR - Infusion-Related Reactions  
ISR injection site reactions  
JIA Juvenile Idiopathic Arthritis  
LAG-3 Lymphocyte Activation Gene-3  
mCC - metastatic cervical cancer  
mCNV - Myopic Choroidal Neovascularization  
mCRC - Metastatic Colorectal Cancer  
MM - multiple myeloma  
MP - Musculoskeletal Pain  
mRCC - Metastatic renal cell carcinoma  
MS f multiple sclerosis  
nAMD - Neovascular (Wet) Age-Related Macular Degeneration  
NSCLC - non-squamous non-small cell lung cancer  
NT - Neurologic toxicity  
PD-1 a Programmed Death receptor-1  
PP - Plaque Psoriasis  
PS - Plaque Psoriasis  
PsA - Psoriatic Arthritis  
RA - Rheumatoid Arthritis  
RD - Retinal Detachments  
RG - Recurrent glioblastoma  
RiI - Reduction in Immunoglobulins  
RoAD - Risk of Autoimmune Disease  
RVO - Retinal Vein Occlusion  
SI - Serious Infections  
SPM - Secodary Primary Malignancy  
TB - Tuberculosis  
TNF - tumor necrosis factor  
UC - Ulcerative Colitis  
uHCC - unresectable hepatocellular carcinoma  
URI - Upper Respiratory Infection

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VEGF - Vascular Endothelial Growth Factor  
WHC - Wound Healing Complications

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