

Therapeutic Monoclonal Antibodies Approved by FDA in 2023

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1. Introduction

Compared with the annual record high, 17 therapeutic monoclonal antibodies (mAb) approved in 2017, this year new record was set, total 20 therapeutic mAb were approved by FDA, interestingly 4 of them are bispecific engager, Ag + CD3, Which significantly increases the efficacy. 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 muromonabCD3 (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, 2023, FDA has approved 173 therapeutic mAbs (not including two diagnostic mAb). Among them 65 were approved for cancer therapy (24 for hematological cancer and 41 for solid tumor) [1], they are reviewed in separated articles. In this mini review focuses briefly on the characteristics of 20 therapeutic antibodies approved in 2023 by FDA (Table) [2-21].

Approval Date	MAH	Drug Name	Active Ingredients	Target	Indication	MOA	Warning	AE
1/6/2023	EISAI	LEQEMBI	LECANEM-AB-IRMB	Amyloid b	Alzheimer's	antagnist	ARIA	ARIA IRR
3/22/2023	INCYTE	ZYNYZ	RETIFAN-LIMAB-DLWR	PD-1	MCC	antagnist	IMAR	Fatigue
5/19/2023	GENMAB	EPKINLY	EPCORITAM-AB-BYSP	CD20+CD3	DLBCL	engager	CRS ICANS	CRS, Fatigue
5/23/2023	CELLTRION	YUFLYMA	ADALIMUM-AB-AATY	TNF	auto-i	antagnist	TB SPM	infection
6/15/2023	Genetech	COLUMVI	GLOFITAM-AB-GXBM	CD20+CD3	DLBCL	engager	CRS	CRS
6/26/2023	UCB	RYSTIGGO	ROZANOLIXI-ZUMAB-NOLI	Fc receptor	gMG	antagnist	infection	headache
7/17/2023	AZ	BEYFOR-TUS	NIRSE-VIMAB-ALIP	RSV-F	RLRTD	antagnist	Anaphylaxis	rash
8/9/2023	JANSSEN	TALVEY	TALQUETAM-AB-TGVS	GPRC-5D+CD3	MM	engager	CRS ICANS	pyrexia
8/14/2023	PFIZER	ELREXFIO	ELRANATAM-AB	BCMA+CD3	MM	engager	CRS ICANS	fatigue
8/18/2023	REGENERON	VEOPOZ	PO-ZELIMAB-BBFG	C5 Inhibitor	PLE	antagnist	infection	infection
8/24/2023	SANDOZ	TYRUKO	NATALIZUM-AB-SZTN	integrin	MS CD	antagnist	infection	headache
9/27/2023	TAKEDA	ENTYVIO	VEDOLIZUMAB	integrin receptor	UC CD	antagnist	IRR infection	headache
9/29/2023	BIOGEN	TOFIDENCE	TOCILIZUM-AB-BAVI	IL-6R	RA PJIA SJIA	antagnist	Serious infection	infection
10/6/2023	NOVARTIS	COSENTYX	SECUKINUMAB	IL-17A	psoriasis	antagnist	infection	infection
10/17/2023	UCB	BIMZELX	BIMEKIZUM-AB-BKZX	IL-17A and F	psoriasis	antagnist	SI/B, TB, IBD	Infection

10/20/2023	CELLTRION	ZYMFEN-TRA	INFLIX-IMAB-DYYB	TNF	UC CD	antagnist	Serious infection	covid-19
10/26/2023	ELI LILLY	OMVOH	MIRIKIZUM-AB-MRKZ	IL-23	UC	antagnist	infection	URTI
10/27/2023	COHERUS	LOQTORZI	TORI-PALIMAB-TPZI	PD-1	NPC	antagnist	IMAR IRR	nausea
10/31/2023	AMGEN	WEZLANA	USTEKINUM-AB-AUUB	IL-12, -23	Ps PsA CD UC	antagnist	infection	URTI
12/6/2023	BIO-THERA Solutions	AVZIVI	BEVACIZUM-AB-TNJV	VEGF	mCRC NSCLC GB RCC OC	antagnist	GP/F SWHC PRES	Epistaxis

ARIA amyloid related imaging abnormalities
 auto-I auto-immune disease RA, PA, Ankylosing Spondylitis
 CD Crohn's disease
 CRS Cytokine release syndrome
 DLBCL diffuse large B-cell lymphoma
 GB glioblastoma
 GB/F Gastrointestinal Perforations and Fistula
 gMG generalized myasthenia gravis
 IBD Inflammatory Bowel Disease
 ICANS Immune Effector Cell-Associated Neurotoxicity Syndrome
 IMAR Immune-Mediated Adverse Reactions
 IRR : infusion-related reactions
 MCC Merkel cell carcinoma
 mCRC Metastatic colorectal cancer
 MS Multiple Sclerosis
 NPC nasopharyngeal carcinoma
 NSCLC non-small cell lung cancer
 OC Ovarian cancer

PD-1 Programmed cell death protein 1
 PLE Protein Losing Enteropathy
 PJIA Polyarticular Juvenile Idiopathic Arthritis
 PRES Posterior Reversible Encephalopathy Syndrome
 Ps Psoriasis
 PsA Psoriatic arthritis
 RA Rheumatoid Arthritis
 RCC Renal cell carcinoma
 RLRTD RSV lower respiratory tract disease
 RSV-F respiratory syncytial virus F protein
 SI/B Suicidal Ideation and Behavior
 SJIA Systemic Juvenile Idiopathic Arthritis
 SPM Secondary primary malignancy
 SWHC Surgery and Wound Healing Complications
 TB Tuberculosis
 TNF Tumor necrosis factor
 UC ulcerative colitis
 URTI upper respiratory tract infections

Reference

- Cai, H., Pandit, A., (2023). Therapeutic monoclonal antibodies approved by FDA in 2022 (mini review). J Clin Exp Immunol. 8(1); 533-535.
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