



Therapeutic Monoclonal Antibodies Approved by FDA in 2021

Henry Hongrong Cai* and Ayesha Pandit

Premier Research, 3800 Paramount Parkway, Morrisville, NC, USA

***Corresponding Author:** Henry Hongrong Cai, Premier Research, 3800 Paramount Parkway, Morrisville, NC, USA.**DOI:** 10.31080/ASMI.2022.05.1166**Received:** November 30, 2020**Published:** October 19, 2022© All rights are reserved by **Henry Hongrong Cai and Ayesha Pandit**.

AMD: Age-Related Macular Degeneration; ANGPTL3: Angiotensin-like 3; ARIA: Amyloid Related Imaging Abnormalities; AS: Ankylosing Spondylitis; ATE f: Arterial Thromboembolic Even; CD: Crohn's Disease; CR: Cutaneous Reactions; DAE: Dermatologic Adverse Reactions; DLBCL: Diffuse Large B-cell Lymphoma; dMMR EC: Mismatch Repair Deficient Endometrial Cancer; EE: Effusion and Edema; EFT: Embryo-Fetal Toxicity; EGFR: Epidermal Growth Factor Receptor; ERD: Endophthalmitis and Retinal Detachment; HoFH: Homozygous Familial Hypercholesterolemia (HoFH); HR: Hypersensitivity Reactions; (I)INFR: Type I Interferon Receptor; IOP: Increases in Intraocular Pressure; ILD: Interstitial Lung Disease; ILI: Influenza-like Illness; IMAE: Immune-mediated Adverse Reactions; IRR: Infusion-related Reactions; JIA: Juvenile Idiopathic Arthritis; LBCL: Large B-cell Lymphoma; LDL-C: Low-Density Lipoprotein-Cholesterol; mCNV: Myopic Choroidal Neovascularization; MET: Receptor MET Also Known as Hepatocyte Growth Factor Receptor; MS: Myelosuppression; NSCLC: Non-Small Cell Lung Cancer; OT: Ocular Toxicity; PD-1: Programmed Death Receptor-1; PN: Peripheral Neuropathy; Ps: Plaque Psoriasis; PsA: Psoriatic Arthritis; RA: Rheumatoid Arthritis; RVO: Retinal Vein Occlusion; SHR: Serious Hypersensitivity Reactions; SI:

Serious Infections; SLE: Systemic Lupus Erythematosus; TNF: Tumor Necrosis Factor; TSLP: Thymic Stromal Lymphopoietin; URTI: Upper Respiratory Tract Infections; UC: Ulcerative Colitis; VEGF: Vascular Endothelial Growth Factor

Introduction

Despite the impact of covid-19, FDA approved 13 therapeutic monoclonal antibodies, compared with the annual record high, 17 therapeutic antibodies approved in 2017. 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. Since then, as of December 31, 2021, FDA has approved 136 therapeutic mAbs (not including two diagnostic mAb) [1]. Among them 50 were approved for cancer therapy (18 for hematological cancer and 32 for solid tumor), there are reviewed in separated articles. In this mini review focuses briefly on the characteristics of 13 therapeutic antibodies approved in 2021 by FDA (Table 1) [2-14].

Therapeutic monoclonal antibodies approved by FDA in 2021								
Approval on	MAH	Drug Name	Active Ingredients	Target	Pay-load	Indication	Warning	Adverse Events (1 st five)
2/11/2021	REGENERON	EVKEEZA	Evinacu-mab-dgnb	ANG-PTL3		HoFH LDL-C	SHR; EFT	Nasopharyngitis, ILI, dizziness, rhinorrhea, nausea
4/22/2021	GSK	JEMPERLI	Dostarlimab-gxly	PD-1		dMMR EC	IMAE; IRR; EFT	Fatigue/asthenia, nausea, diarrhea, anemia, constipation

4/23/2021	ADC	ZYNLON-TA	Loncastuximab-tesirine-lpyl	CD19	Alkylating agent	LBCL; DLBCL	EE; MS; Infection; CR; EFT	Neutropenia, anemia, hyperglycemia, transaminase elevation
5/21/2021	JANSSEN	RYBREVANT	Amivantamab-vmjw	EGFR MET Receptor		NSCLC	IRR, ILD, DAE, OT, EFT	Rash, IRR, paronychia, musculoskeletal pain, dyspnea, nausea, fatigue
6/7/2021	BIOGEN	ADUHELM	Aducanumab-avwa	Amyloid beta		Alzheimer's disease	ARIA, HR	ARIA-Edema, headache, ARIA-H microhemorrhage, ARIA-H superficial siderosis, and fall
7/30/2021	ASTRA-ZENECA	SAPHNELO	Anifrolumab-fnia	(I)IFNR		SLE	SI, HR, Malignancy	Nasopharyngitis, URTI, bronchitis, infusion related reactions, herpes zoster and cough
8/17/2021	GSK	JEMPERLI	Dostarlimab-gxly	PD-1		dMMR EC, Solid tumor	IMAE; IRR; EFT	Fatigue/asthenia, anemia, diarrhea, and nausea
9/17/2021	SAMSUNG	BYOOVIZ	Ranibizumab-nuna	VEGF		AMD, RVO, mCNV	ERD, IOP, ATE	Conjunctival hemorrhage, eye pain, vitreous floaters, IOP
9/20/2021	SEAGEN	TIVDAK	Tisotumab vedotin-tftv	Tissue Factor	MMAE	Cervical cancer	PN, Hemorrhage Pneumonitis EFT	Fatigue, nausea, peripheral neuropathy, alopecia, epistaxis
10/22/2021	GENENTECH	SUSVIMO	Ranibizumab	VEGF		AMD	Boxed endophthalmitis	Conjunctival hemorrhage (72%), conjunctival hyperemia (26%), iritis (23%) and eye pain
12/17/2021	COHERUS	YUSIMRY	Adalimumab-aqvh	TNF		RA	Boxed SI, Malignancy	Infections (e.g., upper respiratory, sinusitis), injection site reactions, headache
12/17/2021	ASTRA ZENECA	TEZSPIRE	Tezepelumab-ekko	TSLP		Severe asthma	HS, Helminth Infection, EFT	Pharyngitis, arthralgia, and back pain.
12/27/2021	LEO	ADBRY	Tralokinumab-ldrm	IL-13		Eczema	hypersensitivity	Hypersensitivity

Bibliography

1. <https://asclepiusopen.com/clinical-research-in-immunology/volume-4-issue-1/1.pdf>
2. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761181s000lbl.pdf
3. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761174s000lbl.pdf
4. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761196s000lbl.pdf
5. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761210s001lbl.pdf
6. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761178s003lbl.pdf
7. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761123s000lbl.pdf
8. https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761223s000lbl.pdf
9. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761202s000lbl.pdf
10. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761208Orig1s000bledt.pdf
11. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761197s000lbl.pdf
12. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761216s000lbl.pdf
13. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761224s000lbl.pdf
14. Label for ADBRY not available yet.