

# Therapeutic Monoclonal Antibodies Approved by FDA in 2020

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## ABSTRACT

This minireview summarizes the major characters of 13 therapeutic monoclonal antibody approved by FDA in year 2020.

**Key words:** FDA, therapeutic monoclonal antibody, target

## INTRODUCTION

In 1975, the monoclonal antibody (mAb) technique was created by Georges Köhler, César Milstein, and Niels Kaj Jerne using a mouse x mouse hybridoma. They shared

the Nobel Prize in Physiology of Medicine in 1984 for the discovery. Eight years later, in 1992, the 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, 2020,

**Table 1:** Therapeutic monoclonal antibodies approved by FDA in 2020

Drug name	Active ingredients	Company	Approval date
TEPEZZ	Teprotumumab-trb	HORIZON THERAPEUTICS	January 21, 2020
VYEPTI	Eptinezumab-jjmr	Lundbeck	February 21, 2020
SARCLISA	Isatuximab-irfc	SANOVI AVENTIS	March 2, 2020
TRODELVY	Sacituzumab govitecan-hziy	IMMUNOMEDICS	April 22, 2020
DARZALEX FASPRO	Daratumumab and hyaluronidase-fihj	JANSSEN	May 1, 2020
UPLIZNA	Inebilizumab-cdon	VIELA	June 11, 2020
PHESGO	Pertuzumab, trastuzumab, and hyaluronidase-zzxf	GENENTECH	June 29, 2020
BLENREP	Belantamab mafodotin-blmf	GLAXOSMITHKLINE	August 5, 2020
ENSPRYNG	Satralizumab-mwge	GENENTECH	August 14, 2020
INMAZEB	ATOLTIVIMAB +2	REGENERON	October 14, 2020
DANYELZA	NAXITAMAB-GQGK	Y-MABS THERAPEUTICS	November 25, 2020
MARGENZA	MARGETUXIMAB-CMKB	MACROGENICS	December 16, 2020
RIABNI	RITUXIMAB-ARRX	AMGEN	December 17, 2020

ATOLTIVIMAB +2 ATOLTIVIMAB; ODESIVIMAB; MAFTIVIMAB

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**Table 2: Some characteristics of the therapeutic Mab approved by FDA in 2020**

Drug name	Indications and usage	Warnings and precautions	Mechanism of action
TEPEZZ	Thyroid eye disease	IBD worsening; hyperglycemia	IGF-1R block
VYEPTI	Migraine	Hypersensitivity	CGRP block
SARCLISA	Multiple myeloma	Neutropenia; SPM	Anti-CD38, ADCC, CDC,
TRODELVY	mTNBC	Hypersensitivity, neutropenia	Anti-Trop-2; SN-38; ADC
DARZALEX FASPRO	Multiple myeloma	Hypersensitivity, Neutropenia	Anti-CD38, ADCC, CDC,
UPLIZNA	NMOSD (AQP4+)	Immune compromise	Anti-CD19
PHESGO	Breast cancer (HER2+)	Neutropenia	Anti-HER2; increases permeability
BLENREP	Multiple Myeloma	Thrombocytopenia	Anti-BCMA; microtubule inhibitor; ADC
ENSPRYNG	NMOSD (AQP4+)	Elevated liver enzymes	Anti-IL6 receptor
INMAZEB	Zaire ebolavirus infection.	Hypersensitivity	Zaire ebolavirus glycoprotein
DANYELZA	Neuroblastoma	Neurotoxicity; Hypertension	Anti-glycolipid GD2, CDC, ADCC
MARGENZA	Breast cancer	Left ventricular dysfunction	Anti-HER2, ADCC
RIABNI	NHL, CLL, GPA, MPA	IRR; TLS; PML	Anti-CD20, ADCC, CDC

IBD: Inflammatory bowel disease, IGF-1R: Insulin-like growth factor 1 (IGF-1) receptor, CGRP: Calcitonin gene-related peptide, SPM: Second primary malignancies, ADCC: Antibody-dependent cell-mediated cytotoxicity, CDC: Complement-dependent cytotoxicity, ADCP: Antibody-dependent cellular phagocytosis, mTNBC: Metastatic triple-negative breast cancer, SN-38: Topoisomerase I inhibitor, ADC: Antibody drug conjugate, NMOSD: Neuromyelitis optica spectrum disorder, AQP4+: Anti-aquaporin-4 antibody positive, NHL: Non-Hodgkin's lymphoma, CLL: Chronic lymphocytic leukemia, GPA: Granulomatosis with polyangiitis (Wegener's granulomatosis), MPA: Microscopic polyangiitis, IRR: Infusion-related reaction, TLS: Tumor lysis syndrome, PML: Progressive multifocal leukoencephalopathy

FDA has approved 119 therapeutic mAbs (including two diagnostic mAb).<sup>[1]</sup> Among them, in 2015, FDA approved 10 therapeutic monoclonal antibodies;<sup>[2]</sup> it was a historic high since the first approval in 1992. In 2016, once again FDA approved 10 therapeutic antibodies.<sup>[3]</sup> In 2017, FDA broke its record and approved 17 therapeutic antibodies.<sup>[4]</sup> In 2018, FDA approved 15 therapeutic antibodies.<sup>[5]</sup> In 2019, FDA approved 16 therapeutic antibodies.<sup>[6]</sup> In 2020, despite the impact of COVID 19 pandemic, FDA approved 13 therapeutic antibodies. This mini-review focuses briefly on the characteristics of 13 therapeutic antibodies approved in 2020 by FDA [Tables 1 and 2].<sup>[7-19]</sup>

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