

Therapeutic Monoclonal Antibodies Approved by Food and Drug Administration in 2018

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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, 2018, FDA has approved 90 therapeutic mAbs (including two diagnostic mAb).^[1] Among them, in 2015, FDA approved 10 therapeutic monoclonal antibodies;^[2] It was a historic high since the first approval in 1992. In 2016, once again FDA approved 10 therapeutic antibodies.^[3] In 2017, FDA broke its record and approved 17 therapeutic antibodies. This mini-review focuses briefly on the characteristics

Table 1: Therapeutic monoclonal antibodies approved by FDA in 2018

Drug name	Active ingredients	Company	Approval date
TROGARZO	IBALIZUMAB-UIYK	TAIMED BIO	March 6, 2018
ILUMYA	TILDRAKIZUMAB-ASMN	SUN PHARMA	March 20, 2018
CRYSVITA	BUROSUMAB-TWZA	ULTRAGENYX	April 17, 2018
AIMOVIG	ERENUMAB-AOOE	AMGEN	May 17, 2018
POTELIGEO	MOGAMULIZUMAB-KPKC	KYOWA KIRIN	August 8, 2018
TAKHZYRO	LANADELUMAB (SHP643)	DYAX	August 23, 2018
LUMOXITI	MOXETUMOMAB PASUDOTOX-TDFK	ASTRA ZENECA	September 13, 2018
AJOVY	FREMANEZUMAB-VFRM	TEVA	September 14, 2018
EMGALITY	GALCANEZUMAB-GNLM	ELI LILLY	September 27, 2018
LIBTAYO	CEMPIIMAB-RWLC	REGENERON	September 28, 2018
HYRIMOZ	ADALIMUMAB-ADAZ	SANDOZ	October 30, 2018
GAMIFANT	EMAPALUMAB-LZSG	NOVIMMUNE S.A.	November 20, 2018
TRUXIMA	RITUXIMAB-ABBS	CELLTRION INC	November 28, 2018
HERZUMA	TRASTUZUMAB-PKRB	CELLTRION INC	December 14, 2018
ULTOMIRIS	RAVULIZUMAB-CWVZ	ALEXION PHARM	December 21, 2018

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Table 2: Some characteristics of the therapeutic mAb approved by FDA in 2018

Drug name	Indications and usage	Warnings and precautions	Mechanism of action
TROGARZO	Multidrug-resistant HIV-1	IRIS	CD4 Blocking
ILUMYA	Psoriasis	Hypersensitivity, infection, TB	IL-23 blocking
CRYSVITA	XLH	FGF23 blocking	
AIMOVIG	Migraine	Injection site response	CGRPR blocking
POTELIGEO	Mycosis fungoides	Dermatologic toxicity, infection	CCR4 blocking
TAKHZYRO	HAE	Hypersensitivity	Kallikrein blocking
LUMOXITI	HCL	Renal toxicity	CD22-directed cytotoxin
AJOVY	Migraine	Hypersensitivity	CGRPR blocking
EMGALITY	Migraine	Hypersensitivity	CGRPR blocking
LIBTAYO	CSCC	Severe immune-mediated AE	PD-1 blocking
HYRIMOZ	RA JIA PsA AS CD UC Ps	Infection, malignancy	TNF blocking
GAMIFANT	HLH	Infection	IFN-gamma blocking
TRUXIMA	NHL	Infection	CD22-directed cytotoxin
HERZUMA	Breast cancer	Cardiomyopathy	HER2-directed ab
ULTOMIRIS	PNH	Infection	Complement inhibitor

IRIS - Immune reconstitution inflammatory syndrome

XLH - X-linked hypophosphatemia

FGF23 - Fibroblast growth factor 23

CGRPR - Calcitonin gene-related peptide receptor

CCR4, a G protein-coupled receptor for CC chemokines

HAE - Hereditary angioedema

HCL - Hairy cell leukemia

HPRN - Hyperphosphatemia and risk of nephrocalcinosis

CSCC - Cutaneous squamous cell carcinoma

PD-1 programmed death receptor-1

TNF - Tumor necrosis factor

RA - Rheumatoid arthritis

JIA - Juvenile idiopathic arthritis

PsA - Psoriatic Arthritis

AS - Ankylosing spondylitis

CD - Adult Crohn's disease

UC - Ulcerative colitis

Ps - Plaque psoriasis

HLH - Hemophagocytic lymphohistiocytosis

NHL - Non-Hodgkin's lymphoma

PNH - Paroxysmal nocturnal hemoglobinuria

of 15 therapeutic antibodies approved in 2018 by FDA (Tables 1 and 2).^[4-19]

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