

Therapeutic monoclonal antibodies approved by FDA in 2017

Introduction

In 1975, Monoclonal antibody (mAb) technique was created by Georges Köhler, César Milstein, and Niels Kaj Jerne by using mouse x mouse hybridoma; they shared the Nobel Prize in Physiology or Medicine in 1984 for the discovery. 8 years later, in 1992 FDA approved first therapeutic mAb Muromonab-CD3 (trade name Orthoclone OKT3) to reduce acute rejection in patients with organ transplants, since then, as of May 10, 2018, FDA has approved 80 therapeutic mAbs.¹ Among them, in 2015, FDA totally approved 10 therapeutic monoclonal antibodies,² it is historical high since first approval in 1992; in 2016, once again FDA approved 10 therapeutic antibodies.³ In 2017 FDA broken the record and approved 17 therapeutic antibodies. This mini review focuses briefly on the

Volume 6 Issue 3 - 2018

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Received: May 18, 2018 | **Published:** May 23, 2018

characteristics of the antibodies approved in 2017 by FDA (Table1) (Table 2).⁴⁻²⁰

Table 1 Therapeutic monoclonal antibodies approved by FDA in 2017

Drug name	Active ingredients	Company	Approval date
SILIQ	BRODALUMAB	VALEANT LUXEMBOURG	2/15/2017
BAVENCIO	AVELUMAB	EMD SERONO INC	3/23/2017
OCREVUS	OCRELIZUMAB	GENENTECH INC	3/28/2017
DUPIXENT	DUPIXUMAB	REGENERON PHARMACEUTICALS	3/28/2017
RENFLEXIS	INFLIXIMAB-ABDA	SAMSUNG BIOEPSIS CO LTD	4/21/2017
IMFINZI	DURVALUMAB	ASTRAZENECA UK LTD	05-01-17
BAVENCIO	AVELUMAB	EMD SERONO INC	05-09-17
KEVZARA	SARILUMAB	SANOFI SYNTHELABO	5/22/2017
RITUXAN HYCELA	HYALURONIDASE;RITUXIMAB	GENENTECH INC	6/22/2017
TREMFYA	GUSELKUMAB	JANSSEN BIOTECH	7/13/2017
BENLYSTA	BELIMUMAB	GLAXOSMITHKLINE LLC	7/20/2017
CYLTEZO	ADALIMUMAB-ADBIM	BOEHRINGER INGELHEIM	8/25/2017
MYLOTARG	GEMTUZUMAB OZOGAMICIN	WYETH PHARMS INC	09-01-17
MVASI	BEVACIZUMAB-AWWB	AMGEN INC	9/14/2017
FASENRA	BENRALIZUMAB	ASTRAZENECA AB	11/14/2017
HEMLIBRA	EMICIZUMAB	GENENTECH INC	11/16/2017
OGIVRI	TRASTUZUMAB-DKST	MYLAN GMBH	12-01-17

Table 2 Some characteristics of the therapeutic Mab approved by FDA in 2017

Drug name	Indications and usage	Warnings and precautions	Mechanism of action
SILIQ	moderate to severe plaque psoriasis	SUICIDAL IDEATION AND BEHAVIOR; Infection	IL-17RA antagonist
BAVENCIO	metastatic Merkel cell carcinoma (MCC).	Immune-mediated diseases	a programmed death ligand-1 (PD-L1) blocking antibody
OCREVUS	relapsing or primary progressive forms of multiple sclerosis	Infusion reactions; Infection; Malignancies	a CD20-directed cytolytic antibody
DUPIXENT	moderate-to-severe atopic dermatitis	Hypersensitivity; Conjunctivitis and Keratitis; Comorbid Asthma	interleukin-4 receptor alpha antagonist
RENFLEXIS	Crohn's Disease; Ulcerative Colitis; Rheumatoid Arthritis; Ankylosing Spondylitis; Psoriatic Arthritis	Increased risk of serious infections	tumor necrosis factor (TNF) blocker
IMFINZI	Locally advanced or metastatic urothelial carcinoma	Immune-mediated diseases	programmed death-ligand 1 (PD-L1) blocking antibody

Table Continued

Drug name	Indications and usage	Warnings and precautions	Mechanism of action
BAVENCIO	metastatic Merkel cell carcinoma (MCC); locally advanced or metastatic urothelial carcinoma (UC)	Immune-mediated diseases	a programmed death ligand-1 (PD-L1) blocking antibody
KEVZARA	moderately to severely active rheumatoid arthritis	Serious Infections; Neutropenia; Gastrointestinal (GI) Perforation	interleukin-6 (IL-6) receptor antagonist
RITUXAN HYCELA	Follicular Lymphoma (FL); Diffuse Large B-cell Lymphoma (DLBCL); Chronic Lymphocytic Leukemia (CLL)	Severe mucocutaneous reactions; Tumor lysis syndrome; Hepatitis B virus reactivation; Progressive multifocal leukoencephalopathy resulting in death	CD20-directed cytolytic antibody, and hyaluronidase human, an endoglycosidase
TREMFYA	moderate-to-severe plaque psoriasis	Infections; Tuberculosis (TB)	interleukin-23 blocker
BENLYSTA	active, autoantibody-positive, systemic lupus erythematosus	Serious Infections; Progressive Multifocal Leukoencephalopathy (PML)	B-lymphocyte stimulator (BLyS)-specific inhibitor
CYLTEZO	Rheumatoid Arthritis (RA); Ankylosing Spondylitis (AS); Adult Crohn's Disease (CD); Ulcerative Colitis (UC); Plaque Psoriasis (Ps)	Serious infections; Malignancies	biosimilar to HUMIRA (adalimumab TNF blocker)
MYLOTARG	newly-diagnosed CD33-positive acute myeloid leukemia (AML)	Hepatotoxicity; Hemorrhage; Embryo-fetal toxicity	CD33-directed antibody-drug conjugate
MVASI	Metastatic colorectal cancer; Non-squamous non-small cell lung cancer; Glioblastoma; Metastatic renal cell carcinoma; Cervical cancer	Perforation or Fistula; Hemorrhage	biosimilar to AVASTIN (bevacizumab, VEGF blocker)
FASENRA	maintenance treatment of patients with severe asthma aged 12 years and older	Hypersensitivity reactions; Reduction in Corticosteroid Dosage	interleukin-5 receptor alpha-directed mAb
HEMLIBRA	hemophilia A (congenital factor VIII deficiency) with factor VIII inhibitors	thrombotic microangiopathy and thrombotic events; Laboratory Coagulation Test Interference	bispecific factor IXa- and factor X-directed antibody
OGIVRI	HER2-overexpressing breast cancer; HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma	Cardiomyopathy; Infusion Reactions; Pulmonary Toxicity; Embryo-Fetal Toxicity; Exacerbation of Chemotherapy-Induced Neutropenia	biosimilar to HERCEPTIN (trastuzumab, HER2/neu receptor antagonist)

Acknowledgements

None.

Conflict of interest

The author declares that there is no conflict of interest.

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