MINI REVIEW ARTICLE

Therapeutic Monoclonal Antibodies Approved by FDA in 2019 (Mini Review)

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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, 2019, FDA has approved 106 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.[4] In 2018, FDA approved 15 therapeutic antibodies.[5] This mini-review focuses briefly on the characteristics of 16 therapeutic antibodies approved in 2019 by FDA [Tables 1 and 2].[6-21]

Table 1: Therapeutic monoclonal antibodies approved by FDA in 2019

Drug name	Active ingredients	Company	Approval date
Ontruzant	Trastuzumab-dttb	Samsung Bioepis	1/18/2019
Cablivi	Caplacizumab-yhdp	Ablynx NV	2/6/2019
Herceptin hylecta	Trastuzumab; hyaluronidase-oysk	Genentech	2/28/2019
Trazimera	Trastuzumab-qyyp	Pfizer	3/11/2019
Evenity	Romosozumab-aqqg	Amgen	4/9/2019
Skyrizi	Risankizumab-rzaa	Abbvie	4/23/2019
Nucala	Mepolizumab	Glaxosmithkline	6/6/2019
Polivy	Polatuzumab vedotin-piiq	Genentech	6/10/2019
Kanjinti	Trastuzumab-anns	Amgen	6/13/2019
Zirabev	Bevacizumab-bvzr	Pfizer	6/27/2019
Hadlima	Adalimumab-bwwd	Samsung Bioepis	7/23/2019
Beovu	Brolucizumab-dbll	Novartis	10/7/2019
Abrilada	Adalimumab-afzb	Pfizer	11/15/2019
Adakveo	Crizanlizumab-tmca	Novartis	11/15/2019
Avsola	Infliximab-axxq	Amgen	12/6/2019
Enhertu	Fam-trastuzumab deruxtecan-nxki	Daiichi Sankyo	12/20/2019

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Table 2: Some characteristics of the therapeutic mAb approved by FDA in 2019

Drug name	Indications and usage	Warnings and precautions	Mechanism of action
Ontruzant	Breast and Gastric Cancer*	Neutropenia, CMP, IR, PT, EFT	Anti-HER2, ADCC
Cablivi	aTTP	Bleeding	Anti-A1-domain of vWF
Herceptin hylecta	HER2+ Breast Cancer	Neutropenia, CMP, IR, PT, EFT	Absorbsion^ anti-HER2, ADCC
Trazimera	Breast and Gastric Cancer*	Neutropenia, CMP, IR, PT, EFT	Anti-HER2, ADCC
Evenity	Osteoporosis	MI, stoke, CVD	Anti-sclerostin
Skyriz	Plaque psoriasis	Infections, tuberculosis	Anti-interleukin 23
Nucala	Asthma, EGPA	Hypersensitivity	Anti-IL-5
Polivy	RDLBL	IRR, Infection, TLS	Anti-mitotic agent+CD79b mAb
Kanjinti	Breast and Gastric Cancer*	Neutropenia, CMP, IR, PT, EFT	Anti-HER2, ADCC
Zirabev	Metastatic colorectal cancer	Fistula, hemorrhage, IRR, EFT	Anti-VEGF
Hadlima	RA JIA PsA AS CD UC Ps	Infection, malignancy	Anti-tumor necrosis factor
Beovu	Wet AMD	ERD IOP ATE	Anti-VEGF
Abrilada	RA JIA PsA AS CD UC Ps	Infection, malignancy	Anti-tumor necrosis factor
Adakveo	VOC in SCD	Platelet clumping	Anti-P-selectin
Avsola	CD PCD UC RA PsA	Infection, malignancy	Anti-tumor necrosis factor
Enhertu	HER2+breast cancer	Neutropenia, left ventricular dysfunction	Anti-HER2, topoisomerase inhibitor, apoptosis

*HER2-overexpressing breast cancer; HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma. CMP: Cardiomyopathy, IR: Infusion reaction, PT: Pulmonary toxicity, EFT: Embryofetal toxicity, ADCC: Antibody-dependent cellular cytotoxicity, aTTP: Acquired thrombotic thrombocytopenic purpura, vWF: von Willebrand factor. ^Absorption increase by hyaluronidase. EGPA: Eosinophilic granulomatosis polyangiitis, RDLBL: Relapsed or refractory diffuse large B-cell lymphoma, PN: Peripheral neuropathy, IRR: Infusion-R elated reactions, TLS: Tumor lysis syndrome, VEGF: Vascular endothelial growth factor, RA: Rheumatoid arthritis, JIA: Juvenile idiopathic arthritis, PsA: Psoriatic arthritis, AS: Ankylosing spondylitis, CD: Crohn's disease, UC: Ulcerative colitis, Ps: Plaque psoriasis. Wet AMD f Neovascular (Wet) age-related macular degeneration. ERD: Endophthalmitis and retinal detachment, IOP: Increases in intraocular pressure, ATE: Arterial thromboembolic eve. To reduce the frequency of VOCs in patients with SCD. PCD: Pediatric Crohn's disease, VOC: Vaso-occlusive crises, SCD: Sickle cell disease

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