

Therapeutic monoclonal antibodies approved by FDA in 2016

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Mini review

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 January 11, 2017, FDA has approved 68 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. This mini review focuses briefly on the characteristics of the antibodies approved in 2016 by FDA,³⁻¹² (Table 1&2).

Table 1 Therapeutic Monoclonal Antibodies Approved by FDA in 2016

Drug Name	Active Ingredients	Company	Approval Date
Anthim	Obiltoximab	Elusys Therapeutics Inc	#####
Taltz	Ixekizumab	Eli Lilly and Co	#####
Cinqair	Reslizumab	Teva Respiratory Llc	#####
Tecentriq	Atezolizumab	Genentech Inc	#####
Zinbryta	Daclizumab	Biogen	#####
Amjevita	Adalimumab-Atto	Amgen Inc	#####
Stelara	Ustekinumab	Janssen Biotech	#####
Tecentriq	Atezolizumab	Genentech Inc	#####
Lartruvo	Olaratumab	Eli Lilly and Co	#####
Zinplava	Bezlotoxumab	Merck Sharp Dohme	#####

Table 2 Some Characteristics of the Therapeutic Mab Approved by FDA in 2016

Drug Name	Indications and Usage	Warnings and Precautions	Mechanism of Action
Anthim	Inhalational anthrax due to B. anthracis	Hypersensitivity reactions, including anaphylaxis	Against the protective antigen of Bacillus anthracis
Taltz	Moderate to severe plaque psoriasis	Infection; Tuberculosis (TB); Hypersensitivity; Inflammatory Bowel Disease	Interleukin-17A antagonist
Cinqair	Add-on maintenance treatment of patients with severe asthma	Anaphylaxis	Interleukin-5 antagonist
Tecentriq	Locally advanced or metastatic urothelial carcinoma	Immune-related disorders	Programmed death- ligand 1 PD-L1 blocking
Zinbryta	Relapsing forms of multiple sclerosis (MS)	Hepatic injury and Other Immune-Mediated Disorders	Interleukin-2 receptor blocking
Amjevita	Rheumatoid Arthritis (RA) Juvenile Idiopathic Arthritis (JIA); Psoriatic Arthritis (PsA); Ankylosing Spondylitis (AS); Adult Crohn's Disease (CD); Ulcerative Colitis (UC); Plaque Psoriasis (Ps)	Serious infection and malignancy	Tumor necrosis factor (TNF) blocker
Stelara	Moderate to severe plaque psoriasis (Ps); active psoriatic arthritis (PsA); active Crohn's disease (CD)	Serious infection and malignancy Reversible Posterior Leukoencephalopathy Syndrome (RPLS)	Interleukin-12 and -23 antagonist
Tecentriq	Locally advanced or metastatic urothelial carcinoma; Metastatic non-small cell lung cancer	Immune-related disorders	Programmed death-ligand 1 (PD-L1) blocking

Table Continued...

Drug Name	Indications and Usage	Warnings and Precautions	Mechanism of Action
Lartruvo	Soft tissue sarcoma (STS)	Infusion-Related Reactions; Embryo-Fetal Toxicity	Platelet-derived growth factor receptor alpha (PDGFR- α) blocking
Zinplava	Reduce recurrence of Clostridium difficile infection (CDI)	Heart Failure	Binding Clostridium difficile toxin B

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Conflicts of interest

Author declares there are no conflicts of interest.

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