

# Therapeutic monoclonal antibodies approved by FDA in 2015

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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 May 1, 2016, FDA has approved 62 therapeutic mAbs.<sup>1</sup> Among them, this year already approved 4, including ANTHIM (March 18, 2016),<sup>2</sup> TALTZ (March 22, 2016) [3 CINQAIR (March 23, 2016),<sup>4</sup> and INFLECTRA (April 5, 2016).<sup>5</sup> In 2015, FDA totally approved 10 therapeutic monoclonal antibodies, (Table 1 & 2),<sup>6-15</sup> It is historical high since first approval in 1992. This mini review focuses briefly on the characteristics of the antibodies approved in 2015 by FDA.

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**Table 1** Therapeutic Monoclonal Antibodies Approved by FDA in 2015

Drug Name	Active Ingredients	Company	Approval Date
Cosentyx	Secukinumab	Novartis Pharms Corp	1/21/2015
Opdivo	Nivolumab	Bristol Myers Squibb	3/4/2015
Unituxin	Dinutuximab	United Therap	3/10/2015
Praluent	Alirocumab	Sanofi Aventis	7/24/2015
Praxbind	Idarucizumab	Boehringer Ingelheim	10/16/2015
Repatha	Evolocumab	Amgen Inc	8/27/2015
Darzalex	Daratumumab	Janssen Biotech	11/16/2015
Nucala	Mepolizumab	Glaxosmithkline Llc	11/4/2015
Portrazza	Necitumumab	Eli Lilly Co	11/24/2015
Empliciti	Elotuzumab	Bristol Myers Squibb	11/30/2015

**Table 2** Some Characteristics of the Therapeutic Mab Approved by FDA in 2015

Drug Name	Indications and Usage	Warnings and Precautions	Mechanism of Action
Cosentyx	Moderate to severe plaque psoriasis	Infections Tuberculosis (TB) Crohn's Disease Hypersensitivity Reactions	IL-17A antagonist
Opdivo	Moderate to severe plaque psoriasis	Immune-mediated adverse reactions; Hypo-/ hyperthyroidism; Embryo fetal toxicity	A programmed death receptor-1 (PD-1) blocking antibody
Unituxin	Pediatric Neuroblastoma	Infusion reaction; Neuropathy	GD2 expressing cells ADCC and CDC
Praluent	Heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease	Allergic Reactions	PCSK9 (Proprotein Convertase Subtilisin Kexin Type 9) inhibitor
Praxbind	Reversal of the Anticoagulant effects of dabigatran (pradaxa®) for emergency	Thromboembolic Risk; Hypersensitivity reactions	A specific reversal agent
Repatha	HeFH or CVD, tolerated statin therapy	Allergic Reactions	Inhibiting the binding of PCSK9 to LDLR
Darzalex	Multiple Myeloma	Infusion reactions; interference with cross- matching	Inhibit the growth of CD38 expressing tumor cells by inducing apoptosis
Nucala	Severe Asthma	Hypersensitivity reactions	Interleukin-5 antagonist
Portrazza	Metastatic squamous NSCLC	Cardiopulmonary arrest and/or sudden death; Hypomagnesemia	Block the binding of EGFR to its ligands
Empliciti	Multiple myeloma who have received one to three prior therapies	Infusion reactions; Infections; Second Primary Malignancies; Hepatotoxicity	Target Signaling Lymphocytic Activation Molecule Family member 7

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