



The Antibody Society maintains a comprehensive table of approved antibody therapeutics and those in regulatory review in the European Union (EU) or United States (US). In the table below, candidates undergoing review are listed first, and approved products are listed in reverse chronological order by year of first approval. Products that were granted approvals but subsequently withdrawn from the market are included in the table. Approved antibody therapeutics that were not granted a first approval (i.e., first approval in any country for any indication) in either the EU or US are listed at the end of the table.

Therapeutic monoclonal antibodies approved or in review in the European Union or the United States

International non-proprietary name	Brand name	Target; Format	Indication first approved or reviewed	First EU approval year	First US approval year
Erenumab	(Pending)	CGRP receptor; Human IgG2	Migraine prevention	In review	In review
Ibalizumab	(Pending)	CD4; Humanized IgG4	HIV infection	NA	In review
Tildrakizumab	(Pending)	IL-23 p19; Humanized IgG1	Plaque psoriasis	In review	In review
Caplacizumab	(Pending)	von Willebrand factor; Humanized Nanobody	Acquired thrombotic thrombocytopenic purpura	In review	NA
Benralizumab	(Pending)	IL-5R α ; Humanized IgG1	Asthma	In review	In review
Burosumab	(Pending)	FGF23; Human IgG1	X-linked hypophosphatemia	In review	NA
Sirukumab	(Pending)	IL-6; Human IgG1	Rheumatoid arthritis	In review	In review
Romosozumab	EVENTITY	Sclerostin; Humanized IgG2	Osteoporosis in postmenopausal women at increased risk of fracture	NA	In review
(Pending)	Xilonix	IL-1 α ; Human IgG1	Advanced colorectal cancer	In review	NA
Guselkumab	TREMFYA	IL-23 p19; Human IgG1	Plaque psoriasis	In review	2017
Inotuzumab ozogamicin	BESPOUSA	CD22; Humanized IgG4; ADC	Acute lymphoblastic leukemia	2017	In review
Sarilumab	Kevzara	IL-6R; Human IgG1	Rheumatoid arthritis	2017	2017
Durvalumab	IMFINZI	PD-L1; Human IgG1	Bladder cancer	NA	2017
Dupilumab	Dupixent	IL-4R α ; Human IgG4	Atopic dermatitis	In review	2017
Ocrelizumab	OCREVUS	CD20; Humanized IgG1	Multiple sclerosis	In review	2017
Avelumab	Bavencio	PD-L1; Human IgG1	Merkel cell carcinoma	In review	2017
Brodalumab	Siliq, LUMICEF	IL-17R; Human IgG2	Plaque psoriasis	EC decision pending	2017
Atezolizumab	Tecentriq	PD-L1; Humanized IgG1	Bladder cancer	In review	2016
Bezlotoxumab	Zinplava	<i>Clostridium difficile</i> enterotoxin B; Human IgG1	Prevention of <i>Clostridium difficile</i> infection recurrence	2017	2016
Olaratumab	Lartruvo	PDGFR α ; Human IgG1	Soft tissue sarcoma	2016	2016

Reslizumab	Cinqaero, Cinqair	IL-5; Humanized IgG4	Asthma	2016	2016
Obiltoximab	Anthim	Protective antigen of B. anthracis exotoxin; Chimeric IgG1	Prevention of inhalational anthrax	NA	2016
Ixekizumab	Taltz	IL-17a; Humanized IgG4	Psoriasis	2016	2016
Daratumumab	Darzalex	CD38; Human IgG1	Multiple myeloma	2016	2015
Elotuzumab	Empliciti	SLAMF7; Humanized IgG1	Multiple myeloma	2016	2015
Necitumumab	Portrazza	EGFR; Human IgG1	Non-small cell lung cancer	2015	2015
Idarucizumab	Praxbind	Dabigatran; Humanized Fab	Reversal of dabigatran-induced anticoagulation	2015	2015
Mepolizumab	Nucala	IL-5; Humanized IgG1	Severe eosinophilic asthma	2015	2015
Alirocumab	Praluent	PCSK9; Human IgG1	High cholesterol	2015	2015
Evolocumab	Repatha	PCSK9; Human IgG2	High cholesterol	2015	2015
Dinutuximab	Unituxin	GD2; Chimeric IgG1	Neuroblastoma	2015	2015
Secukinumab	Cosentyx	IL-17a; Human IgG1	Psoriasis	2015	2015
Nivolumab	Opdivo	PD1; Human IgG4	Melanoma, non-small cell lung cancer	2015	2014
Blinatumomab	Blinicyto	CD19, CD3; Murine bispecific tandem scFv	Acute lymphoblastic leukemia	2015	2014
Pembrolizumab	Keytruda	PD1; Humanized IgG4	Melanoma	2015	2014
Ramucirumab	Cyramza	VEGFR2; Human IgG1	Gastric cancer	2014	2014
Vedolizumab	Entyvio	$\alpha4\beta7$ integrin; humanized IgG1	Ulcerative colitis, Crohn disease	2014	2014
Siltuximab	Sylvant	IL-6; Chimeric IgG1	Castleman disease	2014	2014
Obinutuzumab	Gazyva, Gazyvaro	CD20; Humanized IgG1; Glycoengineered	Chronic lymphocytic leukemia	2014	2013
Ado-trastuzumab emtansine	Kadcyla	HER2; humanized IgG1; ADC	Breast cancer	2013	2013
Raxibacumab	(Pending)	B. anthracis PA; Human IgG1	Anthrax infection	NA	2012
Pertuzumab	Perjeta	HER2; humanized IgG1	Breast Cancer	2013	2012
Brentuximab vedotin	Adcetris	CD30; Chimeric IgG1; ADC	Hodgkin lymphoma, systemic anaplastic large cell lymphoma	2012	2011
Belimumab	Benlysta	BLYS; Human IgG1	Systemic lupus erythematosus	2011	2011
Ipilimumab	Yervoy	CTLA-4; Human IgG1	Metastatic melanoma	2011	2011
Denosumab	Prolia	RANK-L; Human IgG2	Bone Loss	2010	2010
Tocilizumab	RoActemra, Actemra	IL-6R; Humanized IgG1	Rheumatoid arthritis	2009	2010
Ofatumumab	Arzerra	CD20; Human IgG1	Chronic lymphocytic leukemia	2010	2009
Canakinumab	Ilaris	IL-1 β ; Human IgG1	Muckle-Wells syndrome	2009	2009
Golimumab	Simponi	TNF; Human IgG1	Rheumatoid and psoriatic arthritis, ankylosing spondylitis	2009	2009

Ustekinumab	Stelara	IL-12/23; Human IgG1	Psoriasis	2009	2009
Certolizumab pegol	Cimzia	TNF; Humanized Fab, pegylated	Crohn disease	2009	2008
Catumaxomab	Removab	EPCAM/CD3;Rat/mouse bispecific mAb	Malignant ascites	2009#	NA
Eculizumab	Soliris	C5; Humanized IgG2/4	Paroxysmal nocturnal hemoglobinuria	2007	2007
Ranibizumab	Lucentis	VEGF; Humanized IgG1 Fab	Macular degeneration	2007	2006
Panitumumab	Vectibix	EGFR; Human IgG2	Colorectal cancer	2007	2006
Natalizumab	Tysabri	a4 integrin; Humanized IgG4	Multiple sclerosis	2006	2004
Bevacizumab	Avastin	VEGF; Humanized IgG1	Colorectal cancer	2005	2004
Cetuximab	Erbix	EGFR; Chimeric IgG1	Colorectal cancer	2004	2004
Efalizumab	Raptiva	CD11a; Humanized IgG1	Psoriasis	2004#	2003#
Omalizumab	Xolair	IgE; Humanized IgG1	Asthma	2005	2003
Tositumomab-I131	Bexxar	CD20; Murine IgG2a	Non-Hodgkin lymphoma	NA	2003#
Ibritumomab tiuxetan	Zevalin	CD20; Murine IgG1	Non-Hodgkin lymphoma	2004	2002
Adalimumab	Humira	TNF; Human IgG1	Rheumatoid arthritis	2003	2002
Alemtuzumab	Lemtrada; MabCampath, Campath-1H	CD52; Humanized IgG1	Multiple sclerosis; chronic myeloid leukemia#	2013; 2001#	2014; 2001#
Gemtuzumab ozogamicin	Mylotarg	CD33; Humanized IgG4; ADC	Acute myeloid leukemia	In review	In review; 2000#
Trastuzumab	Herceptin	HER2; Humanized IgG1	Breast cancer	2000	1998
Infliximab	Remicade	TNF; Chimeric IgG1	Crohn disease	1999	1998
Palivizumab	Synagis	RSV; Humanized IgG1	Prevention of respiratory syncytial virus infection	1999	1998
Basiliximab	Simulect	IL-2R; Chimeric IgG1	Prevention of kidney transplant rejection	1998	1998
Daclizumab	Zinbryta; Zenapax	IL-2R; Humanized IgG1	Multiple sclerosis; prevention of kidney transplant rejection#	2016; 1999#	2016; 1997#
Rituximab	MabThera, Rituxan	CD20; Chimeric IgG1	Non-Hodgkin lymphoma	1998	1997
Edrecolomab	Panorex	EpCAM; Murine IgG2a	Colon cancer	1995*#	NA
Abciximab	Reopro	GPIIb/IIIa; Chimeric IgG1 Fab	Prevention of blood clots in angioplasty	1995*	1994
Nebacumab	Centoxin	Endotoxin; Human IgM	Gram-negative sepsis	1991*#	NA
Muromonab-CD3	Orthoclone Okt3	CD3; Murine IgG2a	Reversal of kidney transplant rejection	1986*	1986#

Source: Janice M. Reichert, PhD, The Antibody Society; table updated July 13, 2017.

Table notes: *, Country-specific approval. #, Withdrawn or marketing discontinued for the first approved indication. NA, not approved or in review in the EU; not approved or information on review status not available in US.

Additional notes:

1. Of the antibody therapeutics listed in the table, the following products were not first approved in the EU or US: Sarilumab, first approved in Canada on January 12, 2017; Brodalumab, first approved in Japan on July 4, 2016; Secukinumab, first approved in Japan in December 2014; Cetuximab, first approved in Switzerland December 1, 2003.

2. Several antibody therapeutics are approved for marketing in regions other than the EU or US. These products include:

Nimotuzumab (TheraCIM[®], BIOMAB-EGFR[®]), humanized anti-EGFR IgG1 approved in numerous countries for various forms of solid tumors starting in the 2000s;
Mogamulizumab (POTELIGEO[®]), humanized anti-CCR4 IgG1 first approved in Japan on March 30, 2012 for relapsed or refractory CCR4-positive adult T-cell leukemia-lymphoma;
Itolizumab (Alzumab), humanized anti-CD6 IgG1 approved in India in January 2013 for psoriasis;
Rmab (RabiShield), human anti-rabies virus G glycoprotein IgG1 approved in India in 2016 for post-exposure prophylaxis of rabies.

References:

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