

International non-proprietary name, US product identifier	Brand name	Target; Format	Indication first approved or reviewed	First EU approval year	First US approval year	Estimated PDUFA date or FDA action
Abciximab	Reopro	GP1Ib/IIIa; Chimeric IgG1 Fab	Prevention of blood clots in angioplasty	1995*	1994	
Rituximab	MabThera, Rituxan	CD20; Chimeric IgG1	Non-Hodgkin lymphoma	1998	1997	
Trastuzumab	Herceptin	HER2; Humanized IgG1	Breast cancer	2000	1998	
Basiliximab	Simulect	IL-2R; Chimeric IgG1	Prevention of kidney transplant rejection	1998	1998	
Palivizumab	Synagis	RSV; Humanized IgG1	Prevention of respiratory syncytial virus infection	1999	1998	
Infliximab	Remicade	TNF; Chimeric IgG1	Crohn disease	1999	1998	
Ibritumomab tiuxetan	Zevalin	CD20; Murine IgG1	Non-Hodgkin lymphoma	2004	2002	
Adalimumab	Humira	TNF; Human IgG1	Rheumatoid arthritis	2003	2002	
Omalizumab	Xolair	IgE; Humanized IgG1	Asthma	2005	2003	
Natalizumab	Tysabri	α 4 integrin; Humanized IgG4	Multiple sclerosis	2006	2004	
Cetuximab	Erbitux	EGFR; Chimeric IgG1	Colorectal cancer	2004	2004	
Bevacizumab	Avastin	VEGF; Humanized IgG1	Colorectal cancer	2005	2004	
Panitumumab	Vectibix	EGFR; Human IgG2	Colorectal cancer	2007	2006	
Ranibizumab	Lucentis	VEGF; Humanized IgG1 Fab	Macular degeneration	2007	2006	
Eculizumab	Soliris	C5; Humanized IgG2/4	Paroxysmal nocturnal hemoglobinuria	2007	2007	
Certolizumab pegol	Cimzia	TNF; Humanized Fab, pegylated	Crohn disease	2009	2008	
Ofatumumab	Arzerra	CD20; Human IgG1	Chronic lymphocytic leukemia	2010#	2009	
Ustekinumab	Stelara	IL-12/23; Human IgG1	Psoriasis	2009	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	
Tocilizumab	RoActemra, Actemra	IL-6R; Humanized IgG1	Rheumatoid arthritis	2009	2010	
Denosumab	Prolia	RANK-L; Human IgG2	Bone Loss	2010	2010	
Belimumab	Benlysta	BLyS; Human IgG1	Systemic lupus erythematosus	2011	2011	
Brentuximab vedotin	Adcetris	CD30; Chimeric IgG1; ADC	Hodgkin lymphoma, systemic anaplastic large cell lymphoma	2012	2011	
Ipilimumab	Yervoy	CTLA-4; Human IgG1	Metastatic melanoma	2011	2011	
Raxibacumab	(Pending)	<i>B. anthraxis</i> PA; Human IgG1	Anthrax infection	NA	2012	
Pertuzumab	Perjeta	HER2; humanized IgG1	Breast Cancer	2013	2012	
Ado-trastuzumab emtansine	Kadcyla	HER2; humanized IgG1; ADC	Breast cancer	2013	2012	
Obinutuzumab	Gazyva, Gazyvaro	CD20; Humanized IgG1 Glycoengineered	Chronic lymphocytic leukemia	2014	2013	
Blinatumomab	Blinicyto	CD19, CD3; Murine bispecific tandem scFv	Acute lymphoblastic leukemia	2015	2014	
Siltuximab	Sylvant	IL-6; Chimeric IgG1	Castleman disease	2014	2014	
Nivolumab	Opdivo	PD1; Human IgG4	Melanoma, non-small cell lung cancer	2015	2014	
Pembrolizumab	Keytruda	PD1; Humanized IgG4	Melanoma	2015	2014	
Ramucirumab	Cyramza	VEGFR2; Human IgG1	Gastric cancer	2014	2014	
Vedolizumab	Entyvio	α 4 β 7 integrin; humanized IgG1	Ulcerative colitis, Crohn disease	2014	2014	
Daratumumab	Darzalex	CD38; Human IgG1	Multiple myeloma	2016	2015	
Idarucizumab	Praxbind	Dabigatran; Humanized Fab	Reversal of dabigatran-induced anticoagulation	2015	2015	
Necitumumab	Portrazza	EGFR; Human IgG1	Non-small cell lung cancer	2015	2015	
Dinutuximab	Qarziba; Unituxin	GD2; Chimeric IgG1	Neuroblastoma	2017; 2015#	2015	
Secukinumab	Cosentyx	IL-17a; Human IgG1	Psoriasis	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	
Elotuzumab	Empliciti	SLAMF7; Humanized IgG1	Multiple myeloma	2016	2015	
Obiltoxaximab	Anthim	<i>B. anthraxis</i> PA; Chimeric IgG1	Prevention of inhalational anthrax	2020	2016	
Bezlotoxumab	Zinplava	<i>Clostridium difficile</i> enterotoxin B; Human IgG1	Prevention of <i>Clostridium difficile</i> infection recurrence	2017	2016	
Ixekizumab	Taltz	IL-17a; Humanized IgG4	Psoriasis	2016	2016	
Reslizumab	Cinqair, Cinqair	IL-5; Humanized IgG4	Asthma	2016	2016	

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Atezolizumab	Tecentriq	PD-L1; Humanized IgG1	Bladder cancer	2017	2016	
Ocrelizumab	OCREVUS	CD20; Humanized IgG1	Multiple sclerosis	2018	2017	
Inotuzumab ozogamicin	BESPONSA	CD22; Humanized IgG4; ADC	Acute lymphoblastic leukemia	2017	2017	
Emicizumab	Hemlibra	Factor IXa, X; Humanized IgG4, bispecific	Hemophilia A	2018	2017	
Brodalumab	Siliq, LUMICEF	IL-17R; Human IgG2	Plaque psoriasis	2017	2017	
Guselkumab	TREMFYA	IL-23 p19; Human IgG1	Plaque psoriasis	2017	2017	
Dupilumab	Dupixent	IL-4R α ; Human IgG4	Atopic dermatitis	2017	2017	
Benralizumab	Fasenra	IL-5R α ; Humanized IgG1	Asthma	2018	2017	
Sarilumab	Kevzara	IL-6R; Human IgG1	Rheumatoid arthritis	2017	2017	
Avelumab	Bavencio	PD-L1; Human IgG1	Merkel cell carcinoma	2017	2017	
Durvalumab	IMFINZI	PD-L1; Human IgG1	Bladder cancer	2018	2017	
Ravulizumab, ravulizumab-cwvz	Ultomiris	C5; Humanized IgG2/4	Paroxysmal nocturnal hemoglobinuria	2019	2018	
Mogamulizumab, mogamulizumab-kpkc	Poteligeo	CCR4; Humanized IgG1	Mycosis fungoides or Sézary syndrome	2018	2018	
Moxetumomab pasudotox, moxetumomab pasudotox-tdfk	Lumoxiti	CD22; Murine IgG1 dsFv immunotoxin	Hairy cell leukemia	2021	2018	
Ibalizumab, ibalizumab-uiyk	Trogarzo	CD4; Humanized IgG4	HIV infection	2019	2018	
Erenumab, erenumab-aooe	Aimovig	CGRP receptor; Human IgG2	Migraine prevention	2018	2018	
Fremanezumab, fremanezumab-vfrm	Ajovy	CGRP; Humanized IgG2	Migraine prevention	2019	2018	
Galcanezumab, galcanezumab-gnlm	Emgality	CGRP; Humanized IgG4	Migraine prevention	2018	2018	
Burosumab, burosumab-twza	Crysvita	FGF23; Human IgG1	X-linked hypophosphatemia	2018	2018	
Emapalumab, emapalumab-lzsg	Gamifant	IFN γ ; Human IgG1	Primary hemophagocytic lymphohistiocytosis	NA	2018	
Tildrakizumab, tildrakizumab-asmn	Ilumya	IL-23 p19; Humanized IgG1	Plaque psoriasis	2018	2018	
Cemiplimab, cemiplimab-rwlc	Libtayo	PD-1; Human mAb IgG4	Cutaneous squamous cell carcinoma	2019	2018	
Lanadelumab, lanadelumab-flyo	Takhzyro	Plasma kallikrein; Human IgG1	Hereditary angioedema attacks	2018	2018	
Crizanlizumab, crizanlizumab-tmca	Adakveo	CD62 (aka P-selectin); Humanized IgG2	Sickle cell disease	2020	2019	
Polatuzumab vedotin, polatuzumab vedotin-piiq	Polivy	CD79b; Humanized IgG1 ADC	Diffuse large B-cell lymphoma	2020	2019	
[fam-]trastuzumab deruxtecan, fam-trastuzumab deruxtecan-nxki	Enhertu	HER2; Humanized IgG1 ADC	HER2+ metastatic breast cancer	2021	2019	
Risankizumab, risankizumab-rzaa	Skyrizi	IL-23 p19; Humanized IgG1	Plaque psoriasis	2019	2019	
Enfortumab vedotin, enfortumab vedotin-ejfv	Padcev	Nectin-4; Human IgG1 ADC	Urothelial cancer	2022	2019	
Romosozumab, romosozumab-aqqg	Evenity	Sclerostin; Humanized IgG2	Osteoporosis in postmenopausal women at increased risk of fracture	2019	2019	
Brolucizumab, brolucizumab-dbli	Beovu	VEGF-A; Humanized scFv	Neovascular age-related macular degeneration	2020	2019	
Caplacizumab, caplacizumab-yhdp	Cablivi	von Willebrand factor; Humanized Nanobody	Acquired thrombotic thrombocytopenic purpura	2018	2019	
Ansuvimab-zykl	Ebanga	Ebola virus glycoprotein; Human IgG1	Ebola virus infection	NA	2020	
Belantamab mafodotin, belantamab mafodotin-blmf	BLENREP	B-cell maturation antigen; Humanized IgG1 ADC	Multiple myeloma	2020	2020	

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Tafasitamab, tafasitamab-cxix	Monjuvi, Minjuvi	CD19; Humanized IgG1	Diffuse large B-cell lymphoma	2021	2020	
Inebilizumab, inebilizumab-cdon	Uplizna	CD19; Humanized IgG1	Neuromyelitis optica spectrum disorders	2022	2020	
Isatuximab, isatuximab-irfc	Sarclisa	CD38; Chimeric IgG1	Multiple myeloma	2020	2020	
Eptinezumab, eptinezumab-jjmr	VYEPTI	CGRP; Humanized IgG1	Migraine prevention	2022	2020	
Atoltivimab, maftivimab, and odesivimab-ebgn	Inmazeb	Ebola virus; mixture of 3 human IgG1	Ebola virus infection	NA	2020	
Naxitamab-gqgk	DANYELZA	GD2; Humanized IgG1	High-risk neuroblastoma and refractory osteomedullary disease	NA	2020	
Margetuximab-cmkb	MARGENZA	HER2; Chimeric IgG1	HER2+ metastatic breast cancer	NA	2020	
Teprotumumab, teprotumumab-trbw	Tepezza	IGF-1R; Human IgG1	Thyroid eye disease	NA	2020	
Satralizumab, satralizumab-mwge	Enspryng	IL-6R; Humanized IgG2	Neuromyelitis optica spectrum disorder	2021	2020	
Sacituzumab govitecan; sacituzumab govitecan-hziy	TRODELVY	TROP-2; Humanized IgG1 ADC	Triple-neg. breast cancer	2021	2020	
Aducanumab, aducanumab	Aduhelm	Amyloid beta; Human IgG1	Alzheimer's disease	Application withdrawn	2021	
Evinacumab	Evkeeza	Angiopoietin-like 3; Human IgG4	Homozygous familial hypercholesterolemia	2021	2021	
Loncastuximab tesirine, loncastuximab tesirine-lpyl	Zynlonta	CD19; Humanized IgG1 ADC	Diffuse large B-cell lymphoma	In review	2021	
Amivantamab, amivantamab-vmjw	Rybrevant	EGFR, cMET; Human bispecific IgG1	NSCLC w/ EGFR exon 20 insertion mutations	2021	2021	
Anifrolumab, anifrolumab-fnia	SAPHNELO	IFNAR1; human IgG1	Systemic lupus erythematosus	2022	2021	
Tralokinumab, tralokinumab-ldrm	Adtralza	IL-13; Human IgG4	Atopic dermatitis	2021	2021	
Dostarlimab, dostarlimab-gxly	Jemperli	PD-1; Humanized IgG4	Endometrial cancer	2021	2021	
Tezepelumab, tezepelumab-ekko	Tezspire	Thymic stromal lymphopoietin; Human IgG2	Severe asthma	In review	2021	
Tisotumab vedotin, tisotumab vedotin-tftv	TIVDAK	Tissue factor; Human IgG1 ADC	Cervical cancer	NA	2021	
Sutimlimab, sutimlimab-jome	Enjaymo	C1s; Humanized IgG4	Cold agglutinin disease	In review	2022	
Tebentafusp, tebentafusp-tebn	KIMMTRAK®	gp100, CD3; Bispecific immunoconjugate	Metastatic uveal melanoma	2022	2022	
Relatlimab	Opdualag	LAG-3; Human IgG4	Melanoma	In review	2022	
Faricimab, faricimab-svoa	Vabysmo	VEGF-A, Ang-2; Human/humanized IgG1 kappa/lambda bispecific, with domain crossover	Neovascular, age-related macular degeneration, diabetic macular edema	In review	2022	
Muromonab- CD3	Orthoclone Okt3	CD3; Murine IgG2a	Reversal of kidney transplant rejection	1986*	1986#	
Efalizumab	Raptiva	CD11a; Humanized IgG1	Psoriasis	2004#	2003#	
Tositumomab-I131	Bexxar	CD20; Murine IgG2a	Non-Hodgkin lymphoma	NA	2003#	
Alemtuzumab	Lemtrada; MabCampath, Campath-1H	CD52; Humanized IgG1	Multiple sclerosis; chronic myeloid leukemia#	2013; 2001#	2014; 2001#	
Olaratumab	Lartruvo	PDGFRα; Human IgG1	Soft tissue sarcoma	2016#	2016#	
Daclizumab	Zinbryta; Zenapax	IL-2R; Humanized IgG1	prevention of kidney transplant rejection#	2016#; 1999#	2016#; 1997#	

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Gemtuzumab ozogamicin	Mylotarg	CD33; Humanized IgG4; ADC	Acute myeloid leukemia	2018	2017; 2000#	
Sotrovimab	Xevudy	SARS-CoV-2; Human IgG1	COVID-19	2021	2021 EUA	
Tixagevimab, cilgavimab	Evusheld	SARS-CoV-2; Human IgG1	COVID-19	2022	2022 EUA	
Omburtamab	(Pending)	B7-H3; Murine IgG1	CNS/leptomeningeal metastasis from neuroblastoma	In review	In review	November 30, 2022; FDA is planning to hold an advisory committee meeting in October 2022 to discuss the application.
Mosunetuzumab	Lunsumio	CD20, CD3; Humanized IgG1 bispecific	Follicular lymphoma	2022	In review	12/29/2022 PDUFA date
Lecanemab	(Pending)	Amyloid beta protofibrils; Humanized IgG1	Alzheimer's disease	NA	In review	January 6, 2023 PDUFA date
Donanemab	(Pending)	Amyloid beta, N3pG (N-terminal truncated); Humanized IgG1	Alzheimer's disease	NA	In review	
Teclistamab	(Pending)	B-cell maturation antigen, CD3; Humanized/human bispecific IgG4	Multiple myeloma	In review	In review	
Ublituximab	(Pending)	CD20; Chimeric IgG1	Multiple sclerosis	In review	In review	BLA for MS: PDUFA date December 28, 2022.
Inolimomb	(Pending)	CD25; Muine IgG1	Graft vs. host disease	NA	In review	NA; Real-Time Oncology Review
Teplizumab	(Pending)	CD3; Humanized IgG1	Type 1 diabetes	NA	In review	BLA resubmitted in Feb 2022; CR letter issued July 2021
Tremelimumab	(Pending)	CTLA-4; Human IgG2	Antineoplastic; liver cancer	In review	In review	Q4 2022
Oportuzumab monatox	Vysyrium	EpCAM; Humanized scFv immunotoxin	Bladder cancer	NA	In review	CR letter issued Aug 2021
Mirvetuximab soravtansine	(Pending)	Folate receptor alpha; Humanized IgG1 ADC	Ovarian cancer	NA	In review	November 28, 2022 PDUFA date
Trastuzumab duocarmazine	(Pending)	HER2; Humanized IgG1 ADC	Breast cancer	NA	In review	May 12, 2023 PDUFA date
Bimekizumab	Bimzelx	IL-17A, F; Humanized IgG1	Psoriasis	2021	In review	CR letter issued May 2022
Mirikizumab	(Pending)	IL-23p19; Humanized IgG4	Ulcerative colitis	In review	In review	
Spesolimab	(Pending)	IL-36 receptor; Humanized IgG1	Generalized pustular psoriasis	In review	In review	Priority review granted ~Dec 15, 2021
Narsoplimab	(Pending)	MASP-2; Human IgG4	Hematopoietic stem cell transplant-associated thrombotic microangiopathies	NA	In review	CR letter issued Oct 2021
Sintilimab	(Pending)	PD-1; Human IgG4	Non-small cell lung cancer	NA	In review	CR letter issued Mar 2022
Penpulimab	(Pending)	PD-1; Humanized IgG1	Metastatic nasopharyngeal carcinoma	NA	In review	NA; Real-Time Oncology Review
Tislelizumab	(Pending)	PD-1; Humanized IgG4	Esophageal squamous cell carcinoma	In review	In review	7/12/2022
Toripalimab	Tuoyi	PD-1; Humanized IgG4	Nasopharyngeal carcinoma	NA	In review	December 23, 2022 PDUFA date; BLA resubmission in June 2022; CR letter issued Apr 2022
Retifanlimab	(Pending)	PD-1; Humanized IgG4	Carcinoma of the anal canal	Application withdrawn	In review	CR letter issued July 2021
Casirivimab + imdevimab	REGEN-COV2, Ronapreve	SARS-CoV-2; Human IgG1	COVID-19	2021	In review	7/13/2022
Glofitamab	(Pending)	CD20, CD3e; Bispecific 2+1 IgG1 CrossMab	Diffuse large B-cell lymphoma	In review	NA	
Nirsevimab	(Pending)	RSV; Human IgG1	RSV infection	In review	NA	
Nebacumab	Centoxin	Endotoxin; Human IgM	Gram-negative sepsis	1991*#	NA	
Catumaxomab	Removab	EpCAM/CD3; Rat/mouse bispecific mAb	Malignant ascites	2009#	NA	
Edrecolomab	Panorex	EpCAM; Murine IgG2a	Colon cancer	1995*#	NA	
Regdanvimab	Regkirona	SARS-CoV-2; Human IgG1	COVID-19	2021	NA	

Source: Janice M. Reichert, PhD, The Antibody Society, Inc.

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

Additional notes:

Of the antibody therapeutics listed in the table, the following products were not first approved in the EU or US:

Satralizumab (Enspryng), anti-IL-6R approved in Canada in May 2020 for neuromyelitis optica spectrum disorder.

Risankizumab, first approved in Japan in March 2019;

Romosozumab, first approved in Japan;

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;

Mogamulizumab, first approved in Japan in March 2012;

Tocilizumab, first approved in Japan in 2005;

Cetuximab, first approved in Switzerland December 1, 2003.

Antibody therapeutics that are approved for marketing in regions other than the EU or US include:

Nimotuzumab (TheraCIM®, BIOMAB-EGFR®), humanized anti-EGFR IgG1 approved in numerous countries for various forms of solid tumors starting in the 2000s;

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;

RabiMabs (Twinrab TM), mixture of 2 anti-rabies virus mAbs approved in India in 2019;

Sintilimab (Tyvyt), human IgG4 anti-PD-1 mAb approved in China in December 2018 for Hodgkin's lymphoma;

Toripalimab (Tuoyi), humanized anti-PD-1 mAb approved in China in December 2018 for melanoma;

Camrelizumab, humanized anti-PD-1 mAb approved in China in 2019 for Hodgkin's lymphoma;

Tislelizumab, humanized anti-PD-1 mAb, approved in China in December 2019 as a treatment for classical Hodgkin's lymphoma;

Disitamab vedotin (Aidixi), anti-HER2 humanized ADC approved in China in June 2021 as a treatment for gastric cancer;

Penpulimab, anti-PD-1 humanized mAb approved in China in August 2021 for Hodgkin's lymphoma;

Zimberelimab, anti-PD-1 human mAb approved in China in August 2021 for Hodgkin's lymphoma

Netakimab (Efleira), anti-IL-17 mAb approved in Russia in 2019 for plaque psoriasis;

Prolgolimab (Forteca), anti-PD-1 mAb approved in Russia in 2020 for melanoma.

Olokizumab (Artlegia), anti-IL-6 humanized IgG4 approved in Russia in 2020 for rheumatoid arthritis.

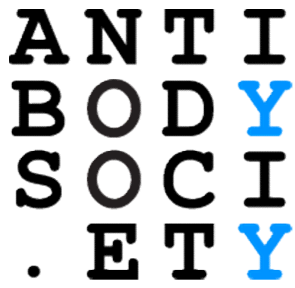
Levilimab (Ilsira) anti-IL-6R human mAb approved in Russia in 2020 for COVID-19.
Cetuximab saratolacan sodium, anti-EGFR mAb approved in Japan in September 2020 for head and neck cancer;
Pabinafusp alfa (IZCARO), anti-transferrin receptor immunoconjugate approved in Japan in March 2021 for Hunter syndrome;
Sotrovimab, anti-SARS-CoV-2 antibody approved in Japan in July 2021.
Casirivimab and imdevimab (Ronapreve), anti-SARS-CoV-2 antibody approved in Australia in Oct 2021.
Regdanvimab, anti-SARS-CoV-2 antibody approved in the Republic of Korea in September 2021.

The antibody therapeutic vaccine Vaxira® (racotumomab, 1 E 10; murine IgG1 kappa) is approved in Argentina and Cuba. It is an anti-idiotypic monoclonal antibody that induces an immune response against glycolylated gangliosides (NeuGcGM3) present in tumor cells. Originally developed in Cuba at the Center of Molecular Immunology, Vaxira® is marketed in Argentina and Cuba for the treatment of recurrent or advanced non-small cell lung cancer (NSCLC), or NSCLC independent of the disease stage when no other standard therapy can be administered for lung cancer.

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 Information about the cell lines used to produce the products can be found at:
www.antibodyociety.org/antibody-therapeutics-product-data/

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The Antibody Society is an international, non-profit representing individuals and organizations involved in antibody-related research and development.

The Society has a variety of initiatives and working groups focused on improving the antibody field.

The Society:

- Creates opportunities for education and networking;
- Monitors and reports advances in the commercial pipeline for antibody and CAR-T therapeutics;
- Creates standards for characterizing antibody and T-cell receptor repertoires, and engaging this field;
- Engages government and international agencies on matters concerning the antibody community.

Questions or comments? Please contact us at info@antibodysociety.org or contact Jan Reichert at janice.reichert@antibodysociety.org

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