wellcome

iavi

Expanding access to monoclonal antibody-based products:
A global call to action

—

Appendix

Stakeholders

Academic and public research institutions	Indian Institute of Technology (IIT), India
	Translational Health Science and Technology Institute (THSTI), India
	Institute of Chemical Technology (ICT), India
	Centre for the AIDS Programme of Research in South Africa (CAPRISA), South Africa
	KEMRI – Wellcome Trust, Initiative to Develop African Research Leaders (IDeAL), Kenya
	Massachusetts Institute of Technology (MIT), MA (BioAccess Global Health Initiative), US
	St. George's, University of London, UK
	University of Zambia School of Medicine, Zambia
	Indian Institute of Technology, India
	National Institute of Immunology (NII), India
	University of Delhi, India
	Indian Institute of Science (IISc), Bangalore, India
	Jawaharlal Nehru Centre for Advanced Scientific Research (JNCASR), India
	Council of Scientific & Industrial Research—Central Drug Research Institute (CSIR-CDRI), India
	Regional Centre for Biotechnology, India
	Institute of Microbial Technology (IMTECH), Chandigarh, India
	Centre for Cellular and Molecular Platforms (C-CAMP), India
	ICAP at Columbia University, US
Biopharmaceutical	Adimab, US
	Gennova Biopharmaceuticals, India
	Kymab, UK
	Mapp Biopharmaceutical, US
	Anthem Biosciences, India
	Syngene International, India
	Serum Institute of India, Pvt. Ltd (SIIPL), India
	Johnson & Johnson, US
	GSK, UK
	Merck, US

(table continues on next page)

Biopharmaceutical *(continued)*	Novartis, Switzerland
	Pfizer, US
	Regeneron, US
	Roche, Switzerland
	Sanofi, France
	Takeda, Japan
	Cipla, India
	Lupin, India
	Cadila Pharmaceuticals, India
	Biocon, India
	Clonz Biotech, India
	International Health Management Associates, India
Government agency / funder	Biotechnology Industry Research Assistance Council (BIRAC), India
	U.S. President's Emergency Plan for AIDS Relief (PEPFAR), US
	National AIDS & STI Control Programme (NASCOP), Kenya
	National Hospital Insurance Fund (NHIF), Kenya
	Department of Biotechnology, Government of India, India
	Defense Advanced Research Projects Agency (DARPA), US
	Kenya Ministry of Health Pharmacy and Poisons Board, Kenya
	United States Agency for International Development (USAID), US
Multilateral / United Nations / global health organisations	Gavi, The Vaccine Alliance, Switzerland
	Medicines for Malaria Venture (MMV), Switzerland
	Unitaid, Switzerland
	The Global Fund to Fight AIDS, Tuberculosis and Malaria, Switzerland
	Access to Medicines Foundation (AMF), Netherlands
	Joint United Nations Programme on HIV/AIDS (UNAIDS), Switzerland
	Medicines Patent Pool (MPP), Switzerland
	United Nations International Children's Fund (UNICEF), US
	World Health Organization (WHO), Switzerland
Non-governmental organisations / civil society	Campaigning for Cancer, South Africa
	Southern African Generic Medicines Association (SAGMA), South Africa
	Treatment Action Group (TAG), US
	Southern African Programme on Access to Medicines (SAPAM), South Africa
	Southern African Development Community (SADC), Botswana

(table continues on next page)

Non-profit product developer / product development partnerships	Butantan Institute & Foundation, Brazil
	Utrecht Centre for Affordable Biologics (UCAB), Netherlands
	PATH, US
	IAVI, US
Philanthropic foundations	Bill & Melinda Gates Foundation (BMGF), US
	Clinton Health Access Initiative (CHAI), US
	Wellcome (UK)
Regulatory agency / institution	African Vaccine Manufacturing Initiative (AVMI), South Africa
	European Medicines Agency (EMA), EU
	U.S. Food and Drug Administration (USFDA), US

Monoclonal antibody products approved or under review in the European Union and United States

International non-proprietary name	Brand name	Target; format	Indication first approved or reviewed	First EU approval year	First US approval year
Muromonab-CD3 Okt3	Orthoclone	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's lymphoma	n/a	2003#
Edrecolomab	Panorex	EpCAM; Murine IgG2a	Colon cancer	1995*#	n/a
Catumaxomab	Removab	EPCAM/CD3; rat/mouse bispecific mAb	Malignant ascites	2009#	n/a
Daclizumab	Zinbryta; Zenapax	IL-2R; Humanized IgG1	Multiple sclerosis#; prevention of kidney transplant rejection#	2016# 1999#	2016# 1997#
Abciximab	Reopro	GPIIb/IIIa; Chimeric IgG1 Fab	Prevention of blood clots in angioplasty	1995*	1994
Rituximab	MabThera; Rituxan	CD20; Chimeric IgG1	Non-Hodgkin's lymphoma	1998	1997
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's disease	1999	1998
Trastuzumab	Herceptin	HER2; Humanized IgG1	Breast cancer	2000	1998
Adalimumab	Humira	TNF; Human IgG1	Rheumatoid arthritis	2003	2002
Ibritumomab tiuxetan	Zevalin	CD20; Murine IgG1	Non-Hodgkin's lymphoma	2004	2002
Omalizumab	Xolair	IgE; Humanized IgG1	Asthma	2005	2003
Cetuximab	Erbitux	EGFR; Chimeric IgG1	Colorectal cancer	2004	2004

(table continues on next page)

Monoclonal antibody products approved or under review in the European Union and United States (continued)

International non-proprietary name	Brand name	Target; format	Indication first approved or reviewed	First EU approval year	First US approval year
Bevacizumab	Avastin	VEGF; Humanized IgG1	Colorectal cancer	2005	2004
Natalizumab	Tysabri	α4 integrin; Humanized IgG4	Multiple sclerosis	2006	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's disease	2009	2008
Ustekinumab	Stelara	IL-12/23; Human IgG1	Psoriasis	2009	2009
Canakinumab	Ilaris	IL-1β; Human IgG1	Muckle-Wells syndrome	2009	2009
Golimumab	Simponi	TNF; Human IgG1	Rheumatoid and psoriatic arthritis; ankylosing spondylitis	2009	2009
Ofatumumab	Arzerra	CD20; Human IgG1	Chronic lymphocytic leukemia	2010	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
Ipilimumab	Yervoy	CTLA-4; Human IgG1	Metastatic melanoma	2011	2011
Brentuximab vedotin	Adcetris	CD30 Chimeric IgG1; ADC	Hodgkin's lymphoma; systemic anaplastic large cell lymphoma	2012	2011
Pertuzumab	Perjeta	HER2; humanized IgG1	Breast cancer	2013	2012
Ado-trastuzumab emtansine	Kadcyla	HER2; humanized IgG1; ADC	Breast cancer	2013	2012
Raxibacumab	*(Pending)*	B. anthrasis PA; Human IgG1	Anthrax infection	n/a	2012

(table continues on next page)

Monoclonal antibody products approved or under review
in the European Union and United States (continued)

International non-proprietary name	Brand name	Target; format	Indication first approved or reviewed	First EU approval year	First US approval year
Obinutuzumab	Gazyva; Gazyvaro	CD20; Humanized IgG1 Glycoengineered	Chronic lymphocytic leukemia	2014	2013
Siltuximab	Sylvant	IL-6; Chimeric IgG1	Castleman disease	2014	2014
Ramucirumab	Cyramza	VEGFR2; Human IgG1	Gastric cancer	2014	2014
Vedolizumab	Entyvio	$\alpha4\beta7$ integrin; humanized IgG1	Ulcerative colitis; Crohn's disease	2014	2014
Nivolumab	Opdivo	PD1; Human IgG4	Melanoma; non-small cell lung cancer	2015	2014
Pembrolizumab	Keytruda	PD1; Humanized IgG4	Melanoma	2015	2014
Blinatumomab	Blincyto	CD19, CD3; Murine bispecific tandem scFv	Acute lymphoblastic leukemia	2015	2014
Alemtuzumab	Lemtrada; MabCampath; Campath-1H	CD52; Humanized IgG1	Multiple sclerosis; chronic myeloid leukemia[#]	2013 2001[#]	2014 2001[#]
Evolocumab	Repatha	PCSK9; Human IgG2	High cholesterol	2015	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	Unituxin	GD2; Chimeric IgG1	Neuroblastoma	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
Daratumumab	Darzalex	CD38; Human IgG1	Multiple myeloma	2016	2015
Elotuzumab	Empliciti	SLAMF7; Humanized IgG1	Multiple myeloma	2016	2015
Ixekizumab	Taltz	IL-17a; Humanized IgG4	Psoriasis	2016	2016
Reslizumab	Cinqaero; Cinqair	IL-5; Humanized IgG4	Asthma	2016	2016

(table continues on next page)

Monoclonal antibody products approved or under review in the European Union and United States (continued)

International non-proprietary name	Brand name	Target; format	Indication first approved or reviewed	First EU approval year	First US approval year
Olaratumab	Lartruvo	PDGFRα; Human IgG1	Soft tissue sarcoma	2016	2016
Bezlotoxumab	Zinplava	*Clostridium difficile* enterotoxin B; Human IgG1	Prevention of *Clostridium difficile* infection recurrence	2017	2016
Atezolizumab	Tecentriq	PD-L1; Humanized IgG1	Bladder cancer	2017	2016
Obiltoxaximab	Anthim	*B. anthrasis* PA; Chimeric IgG1	Prevention of inhalational anthrax	*In review*	2016
Brodalumab	Siliq; LUMICEF	IL-17R; Human IgG2	Plaque psoriasis	2017	2017
Dupilumab	Dupixent	IL-4R α; Human IgG4	Atopic dermatitis	2017	2017
Inotuzumab ozogamicin	BESPONSA	CD22; Humanized IgG4; ADC	Acute lymphoblastic leukemia	2017	2017
Guselkumab	TREMFYA	IL-23 p19; Human IgG1	Plaque psoriasis	2017	2017
Sarilumab	Kevzara	IL-6R; Human IgG1	Rheumatoid arthritis	2017	2017
Avelumab	Bavencio	PD-L1; Human IgG1	Merkel cell carcinoma	2017	2017
Emicizumab	Hemlibra	Factor Ixa, X; Humanized IgG4, bispecific	Hemophilia A	2018	2017
Ocrelizumab	OCREVUS	CD20; Humanized IgG1	Multiple sclerosis	2018	2017
Benralizumab	Fasenra	IL-5R α; Humanized IgG1	Asthma	2018	2017
Durvalumab	IMFINZI	PD-L1; Human IgG1	Bladder cancer	2018	2017
Gemtuzumab ozogamicin	Mylotarg	CD33; Humanized IgG4; ADC	Acute myeloid leukemia	2018	2017; 2000#
Erenumab	Aimovig	CGRP receptor; Human IgG2	Migraine prevention	2018	2018
Galcanezumab	Emgality	CGRP; Humanized IgG4	Migraine prevention	2018	2018
Burosumab	Crysvita	FGF23; Human IgG1	X-linked hypophosphatemia	2018	2018
Lanadelumab	Takhzyro	Plasma kallikrelin; Human IgG1	Hereditary angioedema attacks	2018	2018

(table continues on next page)

Monoclonal antibody products approved or under review in the European Union and United States (continued)

International non-proprietary name	Brand name	Target; format	Indication first approved or reviewed	First EU approval year	First US approval year
Mogamulizumab	Poteligeo	CCR4; Humanized IgG1	Mycosis fungoides or Sézary syndrome	2018	2018
Tildrakizumab	Ilumya	IL-23 p19; Humanized IgG1	Plaque psoriasis	2018	2018
Fremanezumab	Ajovy	CGRP; Humanized IgG2	Migraine prevention	2019	2018
Ravulizumab (ALXN1210)	Ultomiris	C5; Humanized IgG2/4	Paroxysmal nocturnal hemoglobinuria	2019	2018
Cemiplimab	Libtayo	PD-1; Human mAb	Cutaneous squamous cell carcinoma	2019	2018
Ibalizumab; ibalizumab-uiyk	Trogarzo	CD4; Humanized IgG4	HIV infection	2019	2018
Emapalumab; emapalumab-lzsg	Gamifant	IFNγ; Human IgG1	Primary hemophagocytic lymphohistiocytosis	*In review*	2018
Moxetumomab pasudotox	Lumoxiti	CD22; Murine IgG1 dsFv immunotoxin	Hairy cell leukemia	*In review*	2018
Caplacizumab	Cablivi	von Willebrand factor; Humanized Nanobody	Acquired thrombotic thrombocytopenic purpura	2018	2019
Risankizumab	Skyrizi	IL-23 p19; Humanized IgG1	Plaque psoriasis	2019	2019
Polatuzumab vedotin	Polivy	CD79b; Humanized IgG1 ADC	Diffuse large B-cell lymphoma	2020	2019
Romosozumab	Evenity	Sclerostin; Humanized IgG2	Osteoporosis in postmenopausal women at increased risk of fracture	2019	2019
Brolucizumab; brolucizumab-dbll	Beovu	VEGF-A; Humanized scFv	Neovascular age-related macular degeneration	2020	2019
Crizanlizumab	Adakveo	CD62 (aka P-selectin); Humanized IgG2	Sickle cell disease	*In review*	2019
Enfortumab vedotin	Padcev	Nectin-4; Human IgG1 ADC	Urothelial cancer	n/a	2019
[fam-]trastuzumab deruxtecan	Enhertu	HER2; Humanized IgG1 ADC	HER2+ metastatic breast cancer	n/a	2019
Teprotumumab	Tepezza	IGF-1R; Human IgG1	Thyroid eye disease	n/a	2020
Eptinezumab	VYEPTI	CGRP; Humanized IgG1	Migraine prevention	n/a	2020

(table continues on next page)

Monoclonal antibody products approved or under review
in the European Union and United States (continued)

International non-proprietary name	Brand name	Target; format	Indication first approved or reviewed	First EU approval year	First US approval year
Isatuximab	Sarclisa	CD38; Chimeric IgG1	Multiple myeloma	*EC decision pending*	2020
Unavailable	Rabishield	G glycoprotein; Humanized IgG1	Rabies	2017 *(India)*	*In review*
Unavailable	Twinrab	G glycoprotein; Murine IgG1; IgG2b	Rabies	2019 *(India)*	
Inebilizumab	*(Pending)*	CD19; Humanized IgG1	Neuromyelitis optica and neuromyelitis optica spectrum disorders	n/a	*In review*
Leronlimab	*(Pending)*	CCR5; Humanized IgG4	HIV infection	n/a	*In review*
Sacituzumab govitecan	*(Pending)*	TROP-2; Humanized IgG1 ADC	Triple-negative breast cancer	n/a	*In review*
Satralizumab	*(Pending)*	IL-6R; Humanized IgG2	Neuromyelitis optica spectrum disorder	*In review*	*In review*
Narsoplimab	*(Pending)*	MASP-2; Human IgG4	Hematopoietic stem cell transplant-associated thrombotic microangiopathies	n/a	*In review*
Tafasitamab	*(Pending)*	CD19; Humanized IgG1	Diffuse large B-cell lymphoma	n/a	*In review*
REGNEB3	*(Pending)*	Ebola virus; mixture of 3 human IgG1	Ebola virus infection	n/a	*In review*
Naxitamab	*(Pending)*	GD2; Humanized IgG1	High-risk neuroblastoma and refractory osteomedullary disease	n/a	*In review*
Oportuzumab monatox	(Pending)	EpCAM; Humanized scFv immunotoxin	Bladder cancer	n/a	*In review*
Belantamab mafodotin	*(Pending)*	B-cell maturation antigen; Humanized IgG1 ADC	Multiple myeloma	*In review*	*In review*
Margetuximab	*(Pending)*	HER2; Chimeric IgG1	HER2+ metastatic breast cancer	n/a	*In review*
Tanezumab	*(Pending)*	Nerve growth factor; Humanized IgG2	Pain due to osteoarthritis of knee or hip	*In review*	*In review*
Dostarlimab (TSR-042)	*(Pending)*	PD-1; Humanized IgG4	Endometrial cancer	*In review*	*In review*
Teplizumab	*(Pending)*	CD3; Humanized IgG1	Type 1 diabetes	n/a	*In review*

*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

Source: Janice M. Reichert, PhD, The Antibody Society. https://www.antibodysociety.org/resources/

Trastuzumab biosimilars

Company	Product name	Status	Date approved
Biocon/Mylan (India, US)	CanMab® Hertraz® Hercules® Ogivri® Zedora®	India approved	November 2013
		Russia approved	January 2016
		Brazil approved	December 2017
		USFDA approved	December 2017
		EMA approved	October 2018
		Philippines, Pakistan, Nigeria, Zimbabwe approved	Unavailable
		Peru, Romania, Serbia, Russia, South Africa, Slovakia, Thailand, Turkey, Ukraine phase III trial completed	n/a
Biocad* (Russia)	HERtiCAD®	Russia approved	February 2016
		Sri Lanka approved	March 2016
		Belarus, India, Russia, Ukraine phase III trial completed	n/a
Samsung Bioepis* Merck (South Korea, US)	Ontruzant® Samfenet®	EMA approved	November 2017
		USFDA approved	January 2019
		South Korea approved	March 2018
		Bulgaria, Czechia, Romania, Russia, Ukraine phase III trial ongoing	n/a
Celltrion*/ Teva Pharmaceuticals (South Korea)	Herzuma®	South Korea approved	2017
		EMA approved	February 2018
		Japan approved	August 2018
		Mexico phase III trial ongoing	n/a
Allergan* and Amgen (US)	Kanjinti®	EMA approved	March 2018
		USFDA approved	June 2019
		Brazil, Bulgaria, Mexico, Romania, Russia, Serbia, South Africa, Ukraine phase III trials completed	n/a
Pfizer (US)	Trazimera®	EMA approved	July 2018
		USFDA approved	March 2019
		Brazil, Czechia, India, Mexico, Peru, Philippines, Romania, Russia, South Africa, Thailand, Turkey, Ukraine phase III trial ongoing	n/a
Reliance Life Sciences* (India)	TrastuRel®	India approved	Unavailable

(table continues on next page)

Trastuzumab biosimilars (continued)

Company	Product name	Status	Date approved
AryoGen Pharmed (Iran)	AryoTrust®	Iran phase III trial ongoing	n/a
Apobiologix (Canada)	Unavailable	Canada preclinical	n/a
BioXpress Therapeutics (Switzerland)	Unavailable	Switzerland preclinical	n/a
EirGenix (Taiwan)	Unavailable	Belarus, Colombia, Georgia, India, Russia, South Africa, Ukraine phase III trial ongoing	n/a
Hanwha Chemical (South Korea)	Unavailable	Belarus, Bulgaria, Georgia, Malaysia, Russia, Thailand, Ukraine phase III trial ongoing	n/a
Outlook Therapeutics (US)	Unavailable	US phase I trial planned	n/a
PlantForm (Canada)	Unavailable	South Africa preclinical	n/a
Prestige Biopharma (Singapore)	Unavailable	EU, US, Belarus, Bulgaria, Georgia, Malaysia, Russia, Thailand, Ukraine phase III trial ongoing	n/a
Shanghai CP Guojian Pharmaceutical (China)	Unavailable	China undisclosed	n/a
Shanghai Henlius Biotech (China)	Unavailable	China, Ukraine phase III trial ongoing	n/a
Stada Arzneimittel/ Gedeon Richter (Germany/Hungary)	Unavailable	EU undisclosed	n/a

*Marketed products

n/a = Not applicable

Data is as of 2019

Source: IAVI pipeline analysis

Pipeline of monoclonal antibodies for emerging, neglected and endemic infectious diseases and pathogens

Target	Organisation	Antibody	Highest phase	Reference
Acinetobacter baumannii	Biological Anti-infective Medicines	BioAIM1	Preclinical	NIH grant 5R42AI106375-04
	University at Buffalo, State University of New York	n/a	Preclinical	1
	Adidis Pharmaceuticals	AR-401	Preclinical	Organisation website
	Achaogen	n/a	Preclinical	Organisation website
	Vaxdyn	VXD-003	Preclinical	Organisation website
	B Spellberg	C8 and 39	Preclinical	NIH grant R01AI130060
Acinetobacter baumannii; Pseudomonas aeruginosa; Klebsiella pneumoniae	Trellis Bioscience	TRL1068	Preclinical	Organisation website
Adenovirus	Beijing Institute of Biotechnology	10G12	Preclinical	2
Adenovirus type 3	The Affiliated First Hospital of Guangzhou Medical University	3D7	Preclinical	3
Astrovirus	University of California, Santa Cruz	PL-2	Preclinical	4
Broad-Spectrum antibiotic resistance	Trellis Bioscience	TRL1068	Preclinical	Organisation website
Campylobacter	Humabs BioMed	n/a	Preclinical	Organisation website
Chikungunya	Integrated BioTherapeutics	Alphavirus Antibodies	Preclinical	Organisation website
	Moderna	mRNA-1944	Phase I	NCT03829384
	St George's University of London	n/a	Preclinical	Organisation website
	Inovivo	n/a	Preclinical	Organisation website

(table continues on next page)

Note: References that begin with "NCT" are https://clinicaltrials.gov trial identifiers.

Pipeline of monoclonal antibodies for emerging, neglected and endemic infectious diseases and pathogens (continued)

Target	Organisation	Antibody	Highest phase	Reference
Chikungunya	Macrogenics	n/a	Preclinical	Organisation website
Cholera	Chonbuk National University Medical School	24RA, 46RA, 47RA and 50RA	Preclinical	5
	Dartmouth	mAb 72.1	Preclinical	6
Clostridium Difficile	Immuron Limited	IMM-529	Phase I/II	NCT03065374
	Fzata,	FZ001	Preclinical	NIH grant R01AI132207
	Integrated BioTherapeutics	ISTAb	Preclinical	Organisation website
Clostridium difficile; cholera; *E. coli*; *Salmonella*; *Shigella*; and norovirus	OstriGen	n/a	Preclinical	AdisInsight Drugs
Crimean Congo hemorrhagic fever	Mapp Biopharmaceutical	n/a	Preclinical	Organisation website
	University of Texas, Galveston	n/a	Preclinical	NIH grant 1R01AI132246-01
	United States Army Medical Research Institute of Infectious Diseases	mAb-13G8	Preclinical	7
	University of Natural Resources and Applied Life Sciences, Vienna, Austria	CHIKV	Preclinical	8
Cytomegalovirus	Theraclone Sciences	TCN-202	Phase I	NCT01594437
	Novartis	CSJ148, LJP538 and LJP539	Phase II	NCT02268526
	Genentech	RG7667, MCMV3068A, MCMV5322A	Phase II	NCT01753167
	NCRR; NIAID; Facet Biotech; Johns Hopkins Bloomberg	MSL-109, Serivumab	Phase II/III	NCT00000135, NCT00002268, NCT00004642, NCT00000836, NCT00001061
	AIMM Therapeutics	n/a	Preclinical	Organization website
	Agenus	4Ab-028	Preclinical	9
	Trellis Bioscience	TRL345	Preclinical	Organisation website
	Medical University of Vienna, Vienna, Austria	gB/CD3 bispecific BiTE antibody	Preclinical	10

(table continues on next page)

Note: References that begin with "NCT" are https://clinicaltrials.gov trial identifiers.

Pipeline of monoclonal antibodies for emerging, neglected and endemic infectious diseases and pathogens (continued)

Target	Organisation	Antibody	Highest phase	Reference
Cytomegalovirus	University of Texas Health Science Center at Houston	n/a	Preclinical	11
Dengue	Serum Institute of India Pvt. Ltd.	Dengushield	Phase I	NCT03883620
	Visterra, Serum Institute of India Pvt. Ltd.	VIS513	Phase I planned	Organisation website
	State Key Laboratory of Antibody Medicine and Targeting Therapy, Shanghai, China.	n/a	Preclinical	12
	Florida Gulf Coast University	n/a	Preclinical	NIH grant 4R01AI099210-04
	Humabs BioMed	DV87 and DV22	Preclinical	Organisation website
	Washington University	Hu-E16	Preclinical	NIH grant 5U01AI077955-04
	Inovivo	n/a	Preclinical	Organisation website
	University of North Carolina at Chapel Hill	EDE1-binding antibodies	Preclinical	13
	Macrogenics	n/a	Preclinical	Organisation website
Ebola	Gamaleya Research Institute of Epidemiology and Microbiology, Health Ministry of the Russian Federation	GamEMab	Phase I	NCT03428347
	National Institute of Allergy and Infectious Diseases	VRC-EBOMAB092-00-AB (MAb114)	Phase II/III	NCT03719586;
	Mapp Biopharmaceutical	Zmapp	Phase II/III expanded access	Organisation website
	Mapp Biopharmaceutical	MBP134AF	Preclinical	14
	Hokkaido University	6D6	Preclinical	15
	Mapp; Public Health Agency of Canada; Chinese Academy of Sciences	MIL77E	Preclinical	16
	Scripps Research Institute	n/a	Preclinical	NIH grant 5U19AI109762-05
	Regeneron	REGN3470-3471-3479	Submitted for approval to USFDA	NCT03576690
Ebola and Marburg	Mapp Biopharmaceutical	MBP091 (MR191) and MR78, MR78	Preclinical	Organisation website

(table continues on next page)

Note: References that begin with "NCT" are https://clinicaltrials.gov trial identifiers.

Pipeline of monoclonal antibodies for emerging, neglected and endemic infectious diseases and pathogens (continued)

Target	Organisation	Antibody	Highest phase	Reference
Ebola and Marburg	University of Texas Medical Branch	BDBV223	Preclinical	17
Ebola, Sudan, and Bundibugyo	Albert Einstein College of Medicine	6E3 and 3F21	Preclinical	18
	United States Army Medical Research Institute of Infectious Diseases	MBP134AF	Preclinical	19
Ebola, Sudan, and Marburg	Integrated BioTherapeutics	m21D10	Preclinical	Organisation website
Enterobacter	University of Rochester	Stx1e-1, Stx1e-2, Stx1e-3, Stx1e-4	Preclinical	20
Enterococcus faecium	none in development			
Enterovirus	A*STAR/Cytos Biotechnology	n/a	Preclinical	AdisInsight Drugs
Enterovirus 71 (EV71) and coxsackievirus A16 (CA16)	National Institute of Diagnostics and Vaccine Development in Infectious Diseases	n/a	Preclinical	21
Escherichia coli	Humabs BioMed	n/a	Preclinical	Organisation website
	Teijin America	Urtoxazumab	Phase I	Organisation website
	Alexion Pharmaceuticals	Soliris eculizumab	Phase II	Organisation website
	Taro (Sun Pharm)	Shigamab cαStx1 and cαStx2	Phase II	NCT01252199
	Bravos Biosciences	ASN-4	Preclinical	Organisation website
	Arsanis Inc.	ASN200	Preclinical	Organisation website
Helicobacter pylori	none in development			
Hepatitis A	National Laboratory of Macromolecules, Institute of Biophysics, Chinese Academy of Science, Beijing	R10	Preclinical	22
Hepatitis B virus	Baylor College of Medicine	HBsAg/CD3-bispecific	Preclinical	23
Hepatitis E	National University of Singapore	8G12	Preclinical	24
HIV	University of Pennsylvania	3BNC117, 10-1074	Phase I	NCT03588715

(table continues on next page)

Note: References that begin with "NCT" are https://clinicaltrials.gov trial identifiers.

Pipeline of monoclonal antibodies for emerging, neglected and endemic infectious diseases and pathogens (continued)

Target	Organisation	Antibody	Highest phase	Reference
HIV	NIAID	3BNC117 and 10-1074	Phase I	NCT03571204 NCT03526848
	NIAID	VRC01; VRC01LS; VRC07-523LS	Phase I	NCT02256631
	NIAID	10E8VLS; VRC07-523LS	Phase I	NCT03565315
	NIAID	AAV8-VRC07	Phase I	NCT03374202
	CAPRISA	VRC07-523LS and PGT121	Phase I	PACTR2018089192-97244
	Rockefeller University	3BNC117-LS	Phase I	NCT03254277
	IAVI; Ragon Institute of MGH, MIT and Harvard	PGDM1400; PGDM1400 + PGT121	Phase I	NCT03205917
	IAVI; Ragon Institute of MGH, MIT and Harvard	PGT121	Phase I	NCT02960581
	Sanofi	SAR441236	Phase I	NCT03705169
	Aaron Diamond AIDS Research Center	iMab/10e8v2.0	Phase I	NCT03875209
	NIAID	PGT121.414.LS VRC07-523LS	Phase I	NCT04212091
	NIAID	VRC01; 10-1074	Phase I	NCT03831945
	NIAID	PGT121; PGDM1400;, 10-1074; VRC07-523LS	Phase I	NCT03928821
	NIAID	VRC01LS and VRC07-523LS	Phase I	NCT02840474
	NIAID	N6LS	Phase I	NCT03538626
	Rockefeller University	10-1074-LS; 3BNC117-LS	Phase I/II	NCT03554408 NCT04250636 NCT04173819
	IAVI; VRC; NIH	PGT121 + VRC07-523LS, PGT121 + VRC07-523LS + PGDM1400	Phase I/II	NCT03721510
	Rockefeller University; University of Aarhus	3BNC117	Phase II	NCT02850016 NCT03041012
	Frontier Biotechnologies	3BNC117	Phase II	NCT03719664

(table continues on next page)

Note: References that begin with "NCT" are https://clinicaltrials.gov trial identifiers.

Pipeline of monoclonal antibodies for emerging, neglected and endemic infectious diseases and pathogens (continued)

Target	Organisation	Antibody	Highest phase	Reference
HIV	University of Aarhus	3BNC117; 10-1074	Phase II	NCT03837756
	NIAID ViiV	VRC07-523LS	Phase II	NCT03739996
	NIAID	VRC01	Phase IIB	NCT02716675 NCT02568215
	CAPRISA	CAP256-LS	Phase I planned	
Influenza	Functional Genetics Inc; United States Department of Defense	FGI-101-1A6	Phase I	NCT01299142
	Crucell; NIAID	CR6261 2	Phase I	NCT01406418
	VIR	VIR-2482	Phase I	NCT04033406
	AIMM, Crucell Holland BV Retroscreen Virology Ltd.	CR8020	Phase II	NCT01756950; NCT01992276; NCT01938352
	MedImmune	MEDI8852	Phase II	NCT03903718, NCT02603952, NCT02350751
	Genentech, Inc.	MHAA4549A	Phase II	NCT02293863; NCT02623322
	Genentech, Inc.	MHAA549A	Phase II	NCT01980966
	Theraclone Sciences	TCN-032	Phase II	Ph 2 NCT01719874; Ph 1 NCT01390025
	NIAID	CR6261	Phase II	NCT02371668
	Visterra	VIS410	Phase II	NCT02045472
	Celltrion	CT-P27	Phase II	NCT03511066, NCT02071914
	Wistar Institute; Inovio	n/a	Preclinical	25
	Shanghai Institute of Biological Products	anti-neuraminidase monoclonal antibodies against H7N9	Preclinical	26
	Vanderbilt	n/a	Preclinical	27
	Chang Gung University	n/a	Preclinical	28
	Center for Biologics Evaluation and Research; USFDA	n/a	Preclinical	29
	Chinese Academy of Sciences	n/a	Preclinical	30
	Medical Biotechnology Center, Technologiepark, VIB	Flu Bite—bispecific	Preclinical	31

(table continues on next page)

Note: References that begin with "NCT" are https://clinicaltrials.gov trial identifiers.

**Pipeline of monoclonal antibodies for emerging, neglected
and endemic infectious diseases and pathogens** (continued)

Target	Organisation	Antibody	Highest phase	Reference
Influenza	Scripps Research; Janssen	MD3606 multispecific	Preclinical	32
	CureVac	n/a	Preclinical	33
	Shiraz University	n/a	Preclinical	34
	AIMM Therapeutics	BiFlu—bispecific	Preclinical	35
	Zhejiang University, Hangzhou, People's Republic of China	n/a	Preclinical	36
	BioSNTR	n/a	Preclinical	37
	PlantForm Corporation	KPF1-Antx hMAb	Preclinical	37
	University of Pennsylvania	n/a	Preclinical	38
	ContraFect	CF-404	Preclinical	Organisation website
	Vanderbilt	FluA-20	Preclinical	39
Junin Virus	Mapp Biopharmaceutical	n/a	Preclinical	Organisation website
Klebsiella pneumoniae	MedImmune	MrkA	Preclinical	40
	BioNTech	n/a	Preclinical	Organisation website
	Arsanis, Inc.	ASN300	Preclinical	Organisation website
Lassa	Zalgen Lab	n/a	Preclinical	41
	Tulane University	n/a	Preclinical	NIH grant 1R01AI132223-01
Malaria	PATH; CMC Biologics	n/a	Preclinical	Organisation website
	VRC	CIS43	Preclinical	42
	PATH; University of Washington; Just Biotherapeutics	n/a	Preclinical	43
	Visterra	n/a	Preclinical	Organisation website
	Scripps Research	n/a	Preclinical	44
Marburg	University of Guelph	n/a	Preclinical	American Society of Gene & Cell Therapy 2019 conference

(table continues on next page)

Note: References that begin with "NCT" are https://clinicaltrials.gov trial identifiers.

Pipeline of monoclonal antibodies for emerging, neglected and endemic infectious diseases and pathogens (continued)

Target	Organisation	Antibody	Highest phase	Reference
Meningococcal disease	University of Amsterdam	MASP-2-specific monoclonal	Preclinical	45
	Diana Hospital, Bad Bevensen, Germany	TEPC-15	Preclinical	46
	Ludwig Maximilians University	C5-specific monoclonal	Preclinical	120
MERS	Regeneron Pharmaceuticals	REGN3048; REGN3051	Phase I	NCT03301090
	SAB Biotherapeutics Inc	SAB-301	Phase I	NCT02788188
	Juntendo University	2F9 and YS110	Preclinical	47
	Dana Farber Institute	3B11; 1F8; 3A1; 80R	Preclinical	47
	Humabs Biomed SA	LCA60	Preclinical	47
	National Cancer Institute, NIH	M336; M337; M338	Preclinical	47
	Tsinghua University, Beijing, China	MERS-4; MERS-27	Preclinical	47
	New York Blood Center	Mersmab1	Preclinical	47
	Chinese Center for Disease Control and Prevention	MERS-GD2	Preclinical	48
	Chulalongkorn University, Bangkok, Thailand	n/a	Preclinical	49
	International Vaccine Institute	RBD-14F8 and RBD-43E4	Preclinical	50
	Shanghai Medical College, Fudan University, Shanghai	bispecific	Preclinical	51
	Osong Medical Innovation Foundation	n/a	Preclinical	52
	Tsinghua University+H277	7D10	Preclinical	53
	Hallym University	492-1G10E4E2	Preclinical	54
	NIAID	m336	Preclinical	NIH reporter 1ZIAAI001181-04
Monkeypox	USAMRIID	mAb 69-126-3-7	Preclinical	55
	USAMRIID	c7D11 and c8A	Preclinical	56
Morganella spp.	none in development			
Mycobacterium tuberculosis	National University Hospital, Singapore	Pascolizumab	Phase II	NCT01638520
	AbCellera	n/a	Preclinical	Organisation website

(table continues on next page)

Note: References that begin with "NCT" are https://clinicaltrials.gov trial identifiers.

Pipeline of monoclonal antibodies for emerging, neglected and endemic infectious diseases and pathogens (continued)

Target	Organisation	Antibody	Highest phase	Reference
Nipah	Harvard Medical School	anti-G	Preclinical	NIH reporter 5U54AI057159-08
	University of Oxford	mAb66	Preclinical	57
	Queensland Department of Health; the National Health and Medical Research Council; the National Hendra Virus Research Program; Indian Council of Medical Research	M 102.4	Phase I	58
Nipah virus and Hendra virus	Uniformed Services University of the Health Sciences	h5B3.1	Preclinical	59
	University of Washington	n/a	Preclinical	60
	Science Applications International Corp	n/a	Preclinical	NIH reporter 272201100023I-0-27200006-1
Norovirus	Humabs BioMed	GII.4 blockade antibody	Preclinical	AdisInsight drugs
Plague	Israel Institute for Biological Research	n/a	Preclinical	61
	University of Exeter	mAb7.3, mAb29.3, mAb46.3, mAb12.3 and mAb36.3,	Preclinical	62
	Stony Brook University	n/a	Preclinical	63
	NIH	m252, m253, m254	Preclinical	64
	The University of Texas at Austin	n/a	Preclinical	65
Proteus	none in development			
Providencia spp.	none in development			
Pseudomonas Aeruginosa	Humanigen	KB001	Discontinued phase I/II	NCT00638365; NCT00691587
	Kenta Biotech Ltd	AERUMAB 11 KBPA-101	Phase I/II	NCT00851435; EUCTR2007-000442-12-FR
	MedImmune	MEDI3902	Phase II	NCT02696902
	Aridis Pharmaceuticals, Inc.	Panobacumab AR-101	Phase II	Organisation website
	Inovio; Wistar	n/a	Preclinical	66
	Visterra	VIS705—conjugate	Preclinical	Organisation website

(table continues on next page)

Note: References that begin with "NCT" are https://clinicaltrials.gov trial identifiers.

Pipeline of monoclonal antibodies for emerging, neglected and endemic infectious diseases and pathogens (continued)

Target	Organisation	Antibody	Highest phase	Reference
Pseudomonas aeruginosa	Sorrento Therapeutics	anti-OpfF/I mAbs	Preclinical	NIH reporter 5R41AI114252-02
	Aridis Pharmaceuticals, Inc.	aerubumab AR-105 C15	Phase II	NCT03027609
Rabies	Zydus Cadila (collaboration WHO)	Twinrabs	Approved in India	67
	Molecular Targeting Technologies; North China Pharmaceutical Group Corporation	Human AntiRabies Mab	Phase II	68
	Crucell J&J	CL184	Phase II	SRCTN18660493 SRCTN12693237 NCT00656097 NCT01228383 NCT00708084
	Synermore Biologics Co., Ltd.	SYN023	Phase IIB	NCT03961555
	Humabs BioMed	RVC20; RVC58	Preclinical	Organisation website
	Mapp Biopharmaceutical	Raivir	Preclinical	68
Rift Valley fever	Institute of Novel and Emerging Infectious Diseases, Friedrich-Loeffler-Institut, Greifswald-Insel Riems, Germany	Gn3 and Gn32	Preclinical	69
	University of Chinese Academy of Sciences	n/a	Preclinical	70
	Scripps Research	RVFV Gn	Preclinical	71
Rotavirus	International Centre for Diarrhoeal Disease Research, Bangladesh	VHH batch 203027	Phase II	NCT01259765
	University of Tokyo	MucoRice-ARP1	Preclinical	72
	Universidad Politécnica de Valencia	hIgA_2A1	Preclinical	73
RSV	Ablynx	ALX-0171	Phase II	NCT02979431; NCT03418571
	Medimmune	MEDI-8897	Phase II	NCT02878330; NCT02290340; NCT02114268
	Merck	MK-1654	Phase II	NCT03524118
	Regeneron Pharmaceuticals	REGN2222; suptavumab	Phase III	NCT02325791
	Trellis Bioscience	TRL3D3	Preclinical	Organisation website

(table continues on next page)

Note: References that begin with "NCT" are https://clinicaltrials.gov trial identifiers.

Pipeline of monoclonal antibodies for emerging, neglected and endemic infectious diseases and pathogens (continued)

Target	Organisation	Antibody	Highest phase	Reference
RSV	Humabs BioMed	MPE8	Preclinical	Organisation website
	Pontificia Universidad Catolica de Chile	n/a	Preclinical	74
	UCAB; mAbXience	Palivizumab biosimilar	Preclinical	Organisation website
	Arsanis, Inc.; Adimab	ASN500	Pre-phase I	Organisation website
	bioXPRESS Therapeutic	Palivizumab biosimilar	n/a	Organisation website
	WHO; University of Utrecht; UCAB and mAbxience (Libbs, Medigen and Spimaco)	Palivizumab biosimilar	Preclinical	75
	iBio	Palivizumab biosimilar	Preclinical	Organisation website
Salmonella Typhi	Kymab	n/a	Preclinical	Organisation website
SARS	Dana-Farber Cancer Institute	mAb 80R	Preclinical	NIH reporter 5R01AI085524-03
	Wuhan Institute of Virology, Chinese Academy of Sciences, Wuhan	n/a	Preclinical	76
	University of Washington, Seattle	n/a	Preclinical	77
	George S. Wise Faculty of Life Sciences, Tel Aviv University, Tel Aviv	n/a	Preclinical	78
SARS-CoV-2	Eli Lilly; AbCellera Biologics	LY-CoV555	Phase I	NCT04411628
	Eli Lilly; Junshi	JS016	Phase I	NCT04441918
	Tychan	TY027	Phase I	NCT04429529
	Bio-Thera Solutions	BAT2020	Phase I	NCT04432766
	Regeneron Pharmaceutical	REGN10933 + REGN10987	Phase III	NCT04425629 NCT04426695
	Vir Biotechnology; GlaxoSmithKline	VIR-7831 and VIR-7832	Preclinical	Organisation website
	AstraZeneca	Antibody	Preclinical	Organisation website
	Celltrion	Library of antibodies	Preclinical	Organisation website
	Amgen; Adaptive	n/a	Preclinical	Organisation website

(table continues on next page)

Note: References that begin with "NCT" are https://clinicaltrials.gov trial identifiers.

Pipeline of monoclonal antibodies for emerging, neglected and endemic infectious diseases and pathogens (continued)

Target	Organisation	Antibody	Highest phase	Reference
SARS-CoV-2	SORRENTO; Mabpharm	ACE-MAB	Preclinical	Organisation website
	Vanderbilt University	n/a	Preclinical	79
	University of Amsterdam	n/a	Preclinical	80
	VRC; University of Washington	n/a	Preclinical	81
	Vir Biotechnology (Humabs Biomed)	S309	Preclinical	82
	Vir Biotechnology, partnering with Generation Bio	AAV vectored delivery of Vir's mabs	Preclinical	Organisation website
	Takeda Pharmaceutical	TAK-888	Preclinical	Organisation website
	Beroni Group; Tianjin University	Antibody	Preclinical	Organisation website
	Distributed Bio	n/a	Preclinical	Organisation website
	Emergent BioSolutions	n/a	Preclinical	Organisation website
	Eutilex	n/a	Preclinical	83
	GC Pharma	n/a	Preclinical	Organisation website
	GigaGen	CIG	Preclinical	Organisation website
	Harbour BioMed; Mount Sinai; Thomas Moran	n/a	Preclinical	Organisation website
	ImmunoPrecise Antibodies; EVQLV	n/a	Preclinical	Organisation website
	Kamada	n/a	Preclinical	Organisation website
	Medicago; Laval University	n/a	Preclinical	Organisation website
	Zhang Linqi at Tsinghua University in Beijing partnering with Brii Bioscience	n/a	Preclinical	84
	Utrecht University	47D11	Preclinical	85
	MOE/NHC/CAMS Key, Shanghai Medical College, Fudan University, Biomissile Corporation	n/a	Preclinical	86

(table continues on next page)

Note: References that begin with "NCT" are https://clinicaltrials.gov trial identifiers.

Pipeline of monoclonal antibodies for emerging, neglected and endemic infectious diseases and pathogens (continued)

Target	Organisation	Antibody	Highest phase	Reference
SARS-CoV-2	MOE/NHC/CAMS Key Laboratory of Medical Molecular Virology, School of Basic Medical Sciences, Shanghai Medical College, Fudan University, Shanghai, China	CR3022	Preclinical	87
	Singapore Immunology Network, Agency of Science, Technology and Research	n/a	Preclinical	88
	National University of Singapore	2B2; 1A9; 4B12 and 1G10	Preclinical	89
	VIB-UGent Center University of Texas; Ghent University in Belgium	n/a	Preclinical	90
	Antibody Therapy Against Coronavirus consortium	n/a	Preclinical	Organisation website
	Karolinska Institutet	n/a	Preclinical	Organisation website
	Harbour Antibodies BV (NL)	n/a	Preclinical	Organisation website
	The COVID-19 Therapeutics Accelerator	n/a	Preclinical	Organisation website
	La Jolla Institute for Immunology; Carterra Inc	n/a	Preclinical	Organisation website
	Aqualung Therapeutic	ALT-100	Preclinical	Organisation website
	Dyadic International Inc.; The Israel Institute for Biological Research	n/a	Preclinical	Organisation website
	Mateon	n/a	Preclinical	Organisation website
	Proteona Pte. Ltd.	n/a	Preclinical	Organisation website
	SAB Biotherapeutics	n/a	Preclinical	Organisation website
	Immunemed; Seoul National University Hospital	chVSF; HzVSF; hzVSF-v13	Preclinical	Organisation website
	XBiotech and BioBridge Global	n/a	Preclinical	Organisation website
	Octapharma; CSL Behring; Takeda Pharmaceutical Company	n/a	Preclinical	Organisation website

(table continues on next page)

Note: References that begin with "NCT" are https://clinicaltrials.gov trial identifiers.

Pipeline of monoclonal antibodies for emerging, neglected and endemic infectious diseases and pathogens (continued)

Target	Organisation	Antibody	Highest phase	Reference
SARS-CoV-2	Macromoltek	n/a	Preclinical	Organisation website
	Scripps Research Institute, HKU-Pasteur Research Pole, (Ian Wilson)	n/a	Preclinical	91
	Neurimmune Therapeutics AG and Ethris GmbH	n/a	Preclinical	83
	NHC Key Laboratory of Systems Biology of Pathogens, Institute of Pathogen Biology, Chinese Academy of Medical Sciences and Peking Union Medical College, Beijing, China	1E2; 2F2; 3F11; 4D8 and 5F8	Preclinical	92
	Twist Biosciences	n/a	Preclinical	Organisation website
	Shenzhen Key Laboratory of Pathogen and Immunity, Shenzhen Third People's Hospital, Shenzhen, China	B5; B38; H2 and H4	Preclinical	93
	Institute of Immunology, PLA, Chongqing China	311mab-31B5; 311mab-32D4 and 311mab-31B9	Preclinical	94
	IAVI	n/a	Preclinical	95
Serratia spp	None in development			
Severe fever with thrombocytopenia syndrome	None in development			
Smallpox	Ghent University	VACV-66; VACV-138; VACV-304	Preclinical	96
	University of Texas Health Science Center	anti-L1 monoclonal antibodies	Preclinical	97
	Pune University	n/a	Preclinical	98
	Kangwon National University	VC34; VC212	Preclinical	99
Smallpox and monkeypox	Vanderbilt	n/a	Preclinical	10
	La Jolla Institute for Allergy and Immunology	n/a	Preclinical	101
Staphylococcal enterotoxin B	Mapp Biopharmaceutical	n/a	Preclinical	Organisation website

(table continues on next page)

Note: References that begin with "NCT" are https://clinicaltrials.gov trial identifiers.

Pipeline of monoclonal antibodies for emerging, neglected and endemic infectious diseases and pathogens (continued)

Target	Organisation	Antibody	Highest phase	Reference
Staphylococcus Aureus	Bristol-Myers Squibb	Aurexis (tefibazumab)	Phase II	NCT00198289; NCT00198302
	Arsanis	ASN100	Phase II	NCT02940626
	Aridis	KBSA301 AR-301 Salvecin	Phase III	NCT03816956; NCT01589185
	MedImmune	LC10 (MEDI4893*)	Preclinical	102
	Genetech	DSTA4637S	Phase I	NCT03162250 NCT02596399
	XBiotech, Inc.	514G3	Phase I/II	NCT02357966
	MedImmune	Suvratoxumab (MEDI4893)	Phase II	NCT02296320; NCT01769417
	Genetech	DSTA4637A	Preclinical	103
	AIMM	rF1	Preclinical	Organisation website
Streptococcus pneumoniae	Arsanis	ASN400	Preclinical	Organisation website
	Boston Medical Center	n/a	Preclinical	5R21DC014323-02
Sudan virus	Celdara Medical	n/a	Preclinical	1R44AI136273-01A1
Tularemia	University of Nevada	n/a	Preclinical	104
	Boston University School of Medicine	Ft OAg IgG2a MAbs; N203; N77; N24	Preclinical	105
Typhoid	Alabama State University	SH6.11; WB60.4	Preclincal	121
	Universiti Sains Malaysia	Anti-Hemolysin E (HlyE)	Preclinical	122
Undisclosed bacterial infections	Sanofi	SAR279356 anti-PNAG mAB F 598	Phase II	Organisation website
	Achaogen	n/a	Preclinical	Organisation website
Yellow fever	Tysana Pte Ltd	TY014	Phase I	NCT03776786
	National Institute for Viral Disease Control and Prevention, Chinese Center for Disease Control and Prevention, Beijing	5A	Preclinical	106
	Nagasaki University	8H3; 3F4	Preclinical	107
	Colorado State University	2C9-cIgG	Preclinical	108

(table continues on next page)

Note: References that begin with "NCT" are https://clinicaltrials.gov trial identifiers.

Pipeline of monoclonal antibodies for emerging, neglected and endemic infectious diseases and pathogens (continued)

Target	Organisation	Antibody	Highest phase	Reference
Zika	University of Pennsylvania; Inovio Pharmaceuticals	dMAb-ZK190	Phase I	NCT03831503
	The J. Craig Venter Institute	ac10	Preclinical	109
	Howard Hughes Medical Institute, The Rockefeller University,	Z004; Z021	Preclinical	110
	CAS Key Laboratory of Molecular Virology & Immunology, Institut Pasteur of Shanghai, Center for Biosafety Mega-Science, Chinese Academy of Sciences, University of Chinese Academy of Sciences, Shanghai	5F8	Preclinical	111
	CAMS-Oxford University International Center for Translational Immunology, Chinese Academy of Medical Sciences and Peking Union Medical College, Beijing	n/a	Preclinical	112
	Tychan Pte	Tyzivumab	Phase I	NCT03443830; NCT03776695
	Humabs BioMed	FIT-1	Preclinical	113
	Mahidol University, Bangkok, Thailand	n/a	Preclinical	114
	Academia	2A10G6	Preclinical	115
	NIH	ZIKV-117* lead candidate	Preclinical	116
	Humabs BioMed	ZKA190	Preclinical	Organisation website
	Tsinghua University	ZK2B10	Preclinical	117
	Purdue University	ZIKV-195	Preclinical	118
	First Affiliated Hospital of Guangzhou Medical University	mAbs 7B3; 1C11; 6A6	Preclinical	119

* Estimated based on public information sources. Some mAbs may not be in active commercial programs. Preclinical programs are counted as one mAb in accompanying graphs. Note: References that begin with "NCT" are https://clinicaltrials.gov trial identifiers. n/a = not available

References

1. Wang-Lin SX, et al. (2019) Antibody Dependent Enhancement of Acinetobacter baumannii Infection in a Mouse Pneumonia Model. J Pharmacol Exp Ther 368(3): 475-89. https://doi.org/10.1124/jpet.118.253617

2. Wang R, et al. (2019) A Murine Monoclonal Antibody With Potent Neutralization Ability Against Human Adenovirus 7. Frontiers in Cellular and Infection Microbiology 9: 417.

3. Tian X, et al. (2015) Mapping the epitope of neutralizing monoclonal antibodies against human adenovirus type 3. Virus Res 208: 66-72. https://doi.org/10.1016/j.virusres.2015.06.002

4. Bogdanoff WA, et al. (2018) Structural Basis for Escape of Human Astrovirus from Antibody Neutralization: Broad Implications for Rational Vaccine Design. J Virol 92(1). https://doi.org/10.1128/jvi.01546-17

5. Lee TH, et al. (2016) Cross-protection against Vibrio cholerae infection by monoclonal antibodies against Vibrio vulnificus RtxA1/MARTX(Vv). Microbiol Immunol 60(11): 793-800. https://doi.org/10.1111/1348-0421.12449

6. Dharmasena MN, et al. (2009) Characterization of a novel protective monoclonal antibody that recognizes an epitope common to Vibrio cholerae Ogawa and Inaba serotypes. Microbiology 155(Pt 7): 2353-64. https://doi.org/10.1099/mic.0.025726-0

7. Golden JW, et al. (2019) GP38-targeting monoclonal antibodies protect adult mice against lethal Crimean-Congo hemorrhagic fever virus infection. Science Advances 5(7): eaaw9535. https://doi.org/10.1126/sciadv.aaw9535

8. Hurtado J, et al. (2020) In vitro and in vivo efficacy of anti-chikungunya virus monoclonal antibodies produced in wild-type and glycoengineered Nicotiana benthamiana plants. Plant Biotechnology Journal 18(1): 266-73. https://doi.org/10.1111/pbi.13194

9. Ohlin M, Söderberg-Nauclér C. (2015) Human antibody technology and the development of antibodies against cytomegalovirus. Mol Immunol 67(2 Pt A): 153-70. https://doi.org/10.1016/j.molimm.2015.02.026

10. Brey CU, et al. (2018) A gB/CD3 bispecific BiTE antibody construct for targeting Human Cytomegalovirus-infected cells. Scientific Reports 8(1): 17453. https://doi.org/10.1038/s41598-018-36055-2

11. Meng W, et al. (2018) Targeting Human-Cytomegalovirus-Infected Cells by Redirecting T Cells Using an Anti-CD3/Anti-Glycoprotein B Bispecific Antibody. Antimicrobial Agents and Chemotherapy 62(1): e01719-17. https://doi.org/10.1128/aac.01719-17

12. Shi X, et al. (2016) A bispecific antibody effectively neutralizes all four serotypes of dengue virus by simultaneous blocking virus attachment and fusion. mAbs 8(3): 574-84. https://doi.org/10.1080/19420862.2016.1148850

13. Swanstrom JA, et al. (2016) Dengue Virus Envelope Dimer Epitope Monoclonal Antibodies Isolated from Dengue Patients Are Protective against Zika Virus. mBio 7(4). https://doi.org/10.1128/mBio.01123-16

14. Wec AZ, et al. (2019) Development of a Human Antibody Cocktail that Deploys Multiple Functions to Confer Pan-Ebolavirus Protection. Cell Host Microbe 25(1): 39-48.e5. https://doi.org/10.1016/j.chom.2018.12.004

15. Furuyama W, et al. (2016) Discovery of an antibody for pan-ebolavirus therapy. Sci Rep 6: 20514. https://doi.org/10.1038/srep20514

16. Qiu X, et al. (2016) Two-mAb cocktail protects macaques against the Makona variant of Ebola virus. Sci Transl Med 8(329): 329ra33. https://doi.org/10.1126/scitranslmed.aad9875

17. Ilinykh PA, et al. (2018) Ebolavirus Chimerization for the Development of a Mouse Model for Screening of Bundibugyo-Specific Antibodies. The Journal of infectious diseases 218(suppl_5): S418-S22. https://doi.org/10.1093/infdis/jiy423

18. Wec AZ, et al. (2019) Development of a Human Antibody Cocktail that Deploys Multiple Functions to Confer Pan-Ebolavirus Protection. Cell host & microbe 25(1): 39-48.e5. https://doi.org/10.1016/j.chom.2018.12.004

19. Herbert AS, et al. (2020) Development of an antibody cocktail for treatment of Sudan virus infection. Proc Natl Acad Sci U S A 117(7): 3768-78. https://doi.org/10.1073/pnas.1914985117

20. Skinner C, et al. (2016) New Monoclonal Antibodies against a Novel Subtype of Shiga Toxin 1 Produced by Enterobacter cloacae and Their Use in Analysis of Human Serum. mSphere 1(1): e00099-15. https://doi.org/10.1128/mSphere.00099-15

21. Zhou B, et al. (2019) A bispecific broadly neutralizing antibody against enterovirus 71 and coxsackievirus A16 with therapeutic potential. Antiviral Res 161: 28-35. https://doi.org/10.1016/j.antiviral.2018.11.001

22. Wang X, et al. (2017) Potent neutralization of hepatitis A virus reveals a receptor mimic mechanism and the receptor recognition site. Proceedings of the National Academy of Sciences 114(4): 770-5. https://doi.org/10.1073/pnas.1616502114

23. Kruse RL, et al. (2017) In Situ Liver Expression of HBsAg/CD3-Bispecific Antibodies for HBV Immunotherapy. Molecular Therapy - Methods & Clinical Development 7: 32-41. https://doi.org/10.1016/j.omtm.2017.08.006

24. Gu Y, et al. (2015) Structural basis for the neutralization of hepatitis E virus by a cross-genotype antibody. Cell Res 25(5): 604-20. https://doi.org/10.1038/cr.2015.34

25. Wise MC, et al. (2019) In vivo delivery of synthetic DNA-encoded antibodies induces broad HIV-1-neutralizing activity. J Clin Invest. https://doi.org/10.1172/JCI132779

26. Xiong FF, et al. (2020) Protective efficacy of anti-neuraminidase monoclonal antibodies against H7N9 influenza virus infection. Emerg Microbes Infect 9(1): 78-87. https://doi.org/10.1080/22221751.2019.1708214

27. Gilchuk IM, et al. (2019) Influenza H7N9 Virus Neuraminidase-Specific Human Monoclonal Antibodies Inhibit Viral Egress and Protect from Lethal Influenza Infection in Mice. Cell Host Microbe 26(6): 715-28.e8. https://doi.org/10.1016/j.chom.2019.10.003

28. Rijal P, et al. (2020) Broadly Inhibiting Antineuraminidase Monoclonal Antibodies Induced by Trivalent Influenza Vaccine and H7N9 Infection in Humans. J Virol 94(4). https://doi.org/10.1128/jvi.01182-19

29. Wang W, et al. (2019) Generation of a protective murine monoclonal antibody against the stem of influenza hemagglutinins from group 1 viruses and identification of resistance mutations against it. PLoS One 14(9): e0222436. https://doi.org/10.1371/journal.pone.0222436

30. Li J, et al. (2019) Rapid isolation of a potent human antibody against H7N9 influenza virus from an infected patient. Antiviral Res 170: 104564. https://doi.org/10.1016/j.antiviral.2019.104564

31. Pendzialek J, et al. (2017) Bispecific T cell engaging antibody constructs targeting a universally conserved part of the viral M2 ectodomain cure and prevent influenza A virus infection. Antiviral Research 141: 155-64. https://doi.org/https://doi.org/10.1016/j.antiviral.2017.02.016

32. Laursen NS, et al. (2018) Universal protection against influenza infection by a multidomain antibody to influenza hemagglutinin. Science (New York, NY) 362(6414): 598-602. https://doi.org/10.1126/science.aaq0620

33. Thran M, et al. (2017) mRNA mediates passive vaccination against infectious agents, toxins, and tumors. EMBO Mol Med 9(10): 1434-47. https://doi.org/10.15252/emmm.201707678

34. Poursiami M, et al. (2019) Isolation of Neutralizing Human Single Chain Antibodies Against Conserved Hemagglutinin Epitopes of Influenza a Virus H3N2 Strain. Rep Biochem Mol Biol 8(3): 301-9.

35. Wagner K, et al. (2014) Bispecific antibody generated with sortase and click chemistry has broad antiinfluenza virus activity. Proceedings of the National Academy of Sciences 111(47): 16820-5. https://doi.org/10.1073/pnas.1408605111

35. Yang F, et al. (2020) Generation of neutralizing and non-neutralizing monoclonal antibodies against H7N9 influenza virus. Emerg Microbes Infect 9(1): 664-75. https://doi.org/10.1080/22221751.2020.1742076

37. Park JG, et al. (2020) A Broad and Potent H1-Specific Human Monoclonal Antibody Produced in Plants Prevents Influenza Virus Infection and Transmission in Guinea Pigs. Viruses 12(2). https://doi.org/10.3390/v12020167

38. Adam VS, et al. (2014) Adeno-associated virus 9-mediated airway expression of antibody protects old and immunodeficient mice against influenza virus. Clin Vaccine Immunol 21(11): 1528-33. https://doi.org/10.1128/cvi.00572-14

39. Bangaru S, et al. (2019) A Site of Vulnerability on the Influenza Virus Hemagglutinin Head Domain Trimer Interface. Cell 177(5): 1136-52.e18. https://doi.org/10.1016/j.cell.2019.04.011

40. Wang Q, et al. (2016) Target-Agnostic Identification of Functional Monoclonal Antibodies Against Klebsiella pneumoniae Multimeric MrkA Fimbrial Subunit. J Infect Dis 213(11): 1800-8. https://doi.org/10.1093/infdis/jiw021

41. Cross RW, et al. (2019) Antibody therapy for Lassa fever. Curr Opin Virol 37: 97-104. https://doi.org/10.1016/j.coviro.2019.07.003

42. Kisalu NK, et al. (2018) A human monoclonal antibody prevents malaria infection by targeting a new site of vulnerability on the parasite. Nature Medicine 24(4): 408-16. https://doi.org/10.1038/nm.4512

43. Sack BK, et al. (2017) Humoral protection against mosquito bite-transmitted Plasmodium falciparum infection in humanized mice. NPJ vaccines 2: 27-. https://doi.org/10.1038/s41541-017-0028-2

44. Tan J, et al. (2018) A public antibody lineage that potently inhibits malaria infection through dual binding to the circumsporozoite protein. Nature Medicine 24(4): 401-7. https://doi.org/10.1038/nm.4513

45. Kasanmoentalib ES, et al. (2017) Mannose-binding lectin-associated serine protease 2 (MASP-2) contributes to poor disease outcome in humans and mice with pneumococcal meningitis. Journal of Neuroinflammation 14(1): 2. https://doi.org/10.1186/s12974-016-0770-9

46. Gerber J, et al. (2012) Intrathecal Treatment with the Anti-Phosphorylcholine Monoclonal Antibody TEPC-15 Decreases Neuronal Damage in Experimental Pneumococcal Meningitis. Chemotherapy 58(3): 212-6. https://doi.org/10.1159/000337287

47. Uyeki TM, et al. (2016) Development of Medical Countermeasures to Middle East Respiratory Syndrome Coronavirus. Emerg Infect Dis 22(7). https://doi.org/10.3201/eid2207.160022

48. Niu P, et al. (2018) A novel human mAb (MERS-GD27) provides prophylactic and postexposure efficacy in MERS-CoV susceptible mice. Sci China Life Sci 61(10): 1280-2. https://doi.org/10.1007/s11427-018-9343-8

49. Shanmugaraj B, et al. (2020) Perspectives on monoclonal antibody therapy as potential therapeutic intervention for Coronavirus disease-19 (COVID-19). Asian Pac J Allergy Immunol 38(1): 10-8. https://doi.org/10.12932/ap-200220-0773

50. Goo J, et al. (2020) Characterization of novel monoclonal antibodies against MERS-coronavirus spike protein. Virus Research 278: 197863. https://doi.org/10.1016/j.virusres.2020.197863

51. Wang L, et al. (2019) Engineering a Novel Antibody-Peptide Bispecific Fusion Protein Against MERS-CoV. Antibodies (Basel, Switzerland) 8(4): 53. https://doi.org/10.3390/antib8040053

52. Kim Y, et al. (2019) Selection and Characterization of Monoclonal Antibodies Targeting Middle East Respiratory Syndrome Coronavirus through a Human Synthetic Fab Phage Display Library Panning. Antibodies (Basel) 8(3). https://doi.org/10.3390/antib8030042

53. Zhou H, et al. (2019) Structural definition of a neutralization epitope on the N-terminal domain of MERS-CoV spike glycoprotein. Nature Communications 10(1): 3068. https://doi.org/10.1038/s41467-019-10897-4

54. Park BK, et al. (2019) Generation and characterization of a monoclonal antibody against MERS-CoV targeting the spike protein using a synthetic peptide epitope-CpG-DNA-liposome complex. BMB Rep 52(6): 397-402. https://doi.org/10.5483/BMBRep.2019.52.6.185

55. Hughes LJ, et al. (2014) A highly specific monoclonal antibody against monkeypox virus detects the heparin binding domain of A27. Virology 464-465: 264-73. https://doi.org/10.1016/j.virol.2014.06.039

56. Mucker EM, et al. (2018) Intranasal monkeypox marmoset model: Prophylactic antibody treatment provides benefit against severe monkeypox virus disease. PLoS Negl Trop Dis 12(6): e0006581. https://doi.org/10.1371/journal.pntd.0006581

57. Avanzato VA, et al. (2019) A structural basis for antibody-mediated neutralization of Nipah virus reveals a site of vulnerability at the fusion glycoprotein apex. Proc Natl Acad Sci U S A 116(50): 25057-67. https://doi.org/10.1073/pnas.1912503116

58. Mudur G. Deal on Nipah compassionate response. The Telegraph 7 June 2019. Accessed 6/11/19 from https://www.telegraphindia.com/health/deal-on-nipah-compassionate-response/cid/1691941

59. Mire CE, et al. (2020) A Cross-Reactive Humanized Monoclonal Antibody Targeting Fusion Glycoprotein Function Protects Ferrets Against Lethal Nipah Virus and Hendra Virus Infection. J Infect Dis 221(Supplement_4): S471-s9. https://doi.org/10.1093/infdis/jiz515

60. Dang HV, et al. (2019) An antibody against the F glycoprotein inhibits Nipah and Hendra virus infections. Nat Struct Mol Biol 26(10): 980-7. https://doi.org/10.1038/s41594-019-0308-9

61. Sittner A, et al. (2018) Improved production of monoclonal antibodies against the LcrV antigen of Yersinia pestis using FACS-aided hybridoma selection. J Biol Methods 5(4): e100. https://doi.org/10.14440/jbm.2018.257

62. Read T, et al. (2015) Kinetic epitope mapping of monoclonal antibodies raised against the Yersinia pestis virulence factor LcrV. Biosens Bioelectron 65: 47-53. https://doi.org/10.1016/j.bios.2014.09.090

63. Ivanov MI, et al. (2014) Direct neutralization of type III effector translocation by the variable region of a monoclonal antibody to Yersinia pestis LcrV. Clin Vaccine Immunol 21(5): 667-73. https://doi.org/10.1128/cvi.00013-14

64. Xiao X, et al. (2010) Human anti-plague monoclonal antibodies protect mice from Yersinia pestis in a bubonic plague model. PLoS One 5(10): e13047. https://doi.org/10.1371/journal.pone.0013047

65. Van Blarcom TJ, et al. (2010) Affinity maturation of an anti-V antigen IgG expressed in situ through adenovirus gene delivery confers enhanced protection against Yersinia pestis challenge. Gene Ther 17(7): 913-21. https://doi.org/10.1038/gt.2010.42

66. Patel A, et al. (2017) An engineered bispecific DNA-encoded IgG antibody protects against Pseudomonas aeruginosa in a pneumonia challenge model. Nat Commun 8(1): 637. https://doi.org/10.1038/s41467-017-00576-7

67. Zydus Cadila. Zydus to launch novel biologic for rabies, Twinrab. 3 September 2019. Accessed 27/10/19 from https://zyduscadila.com/public/pdf/pressrelease/Zydus%20to%20launch%20novel%20biologic%20for%20rabies_WHO.pdf

68. WHO. Report: WHO Meeting on monoclonal antibodies against rabies and evaluation of mechanisms to improve access to other blood-derived immunoglobulins. 18 July 2017. Accessed 15/9/19 from https://www.who.int/immunization/research/meetings_workshops/Report_mAbs_access_immunoglobulins_18July2017.pdf

69. Gutjahr B, et al. (2020) Two monoclonal antibodies against glycoprotein Gn protect mice from Rift Valley Fever challenge by cooperative effects. PLoS Negl Trop Dis 14(3): e0008143. https://doi.org/10.1371/journal.pntd.0008143

70. Wang Q, et al. (2019) Neutralization mechanism of human monoclonal antibodies against Rift Valley fever virus. Nat Microbiol 4(7): 1231-41. https://doi.org/10.1038/s41564-019-0411-z

71. Allen ER, et al. (2018) A Protective Monoclonal Antibody Targets a Site of Vulnerability on the Surface of Rift Valley Fever Virus. Cell Rep 25(13): 3750-8.e4. https://doi.org/10.1016/j.celrep.2018.12.001

72. Tokuhara D, et al. (2013) Rice-based oral antibody fragment prophylaxis and therapy against rotavirus infection. J Clin Invest 123(9): 3829-38. https://doi.org/10.1172/jci70266

73. Juárez P, et al. (2012) Neutralizing antibodies against rotavirus produced in transgenically labelled purple tomatoes. Plant Biotechnol J 10(3): 341-52. https://doi.org/10.1111/j.1467-7652.2011.00666.x

74. Duenas-Gonzalez A, Gonzalez-Fierro A. (2019) Barriers for Pharmaceutical Innovation With Focus in Cancer Drugs, the Case of Mexico. Therapeutic Innovation & Regulatory Science: 2168479019839015. https://doi.org/10.1177/2168479019839015

75. Utrecht Centre for Affordable Biotherapeutics. Biosimilar palivizumab. Accessed 12/8/19 from https://www.uu.nl/en/organisation/utrecht-centre-for-affordable-biotherapeutics/projects/biosimilar-palivizumab

76. Zeng LP, et al. (2017) Cross-neutralization of SARS coronavirus-specific antibodies against bat SARS-like coronaviruses. Sci China Life Sci 60(12): 1399-402. https://doi.org/10.1007/s11427-017-9189-3

77. Walls AC, et al. (2019) Unexpected Receptor Functional Mimicry Elucidates Activation of Coronavirus Fusion. Cell 176(5): 1026-39.e15. https://doi.org/10.1016/j.cell.2018.12.028

78. Freund NT, et al. (2015) Reconstitution of the receptor-binding motif of the SARS coronavirus. Protein Eng Des Sel 28(12): 567-75. https://doi.org/10.1093/protein/gzv052

79. Zost SJ, et al. (2020) Rapid isolation and profiling of a diverse panel of human monoclonal antibodies targeting the SARS-CoV-2 spike protein. bioRxiv: the preprint server for biology: 2020.05.12.091462. https://doi.org/10.1101/2020.05.12.091462

80. Brouwer PJM, et al. (2020) Potent neutralizing antibodies from COVID-19 patients define multiple targets of vulnerability. Science: eabc5902. https://doi.org/10.1126/science.abc5902

81. Seydoux E, et al. (2020) Characterization of neutralizing antibodies from a SARS-CoV-2 infected individual. bioRxiv: the preprint server for biology: 2020.05.12.091298. https://doi.org/10.1101/2020.05.12.091298

82. Pinto D, et al. (2020) Structural and functional analysis of a potent sarbecovirus neutralizing antibody. bioRxiv: the preprint server for biology: 2020.04.07.023903. https://doi.org/10.1101/2020.04.07.023903

83. Biocentury. COVID-19 therapies and vaccines. From https://www.biocentury.com/clinical-vaccines-and-therapies

84. Ju B, et al. (2020) Human neutralizing antibodies elicited by SARS-CoV-2 infection. Nature. https://doi.org/10.1038/s41586-020-2380-z

85. Wang C, et al. (2020) A human monoclonal antibody blocking SARS-CoV-2 infection. Nature Communications 11(1): 2251. https://doi.org/10.1038/s41467-020-16256-y

86. Wu Y, et al. (2020) Identification of Human Single-Domain Antibodies against SARS-CoV-2. Cell host & microbe 27(6): 891-8.e5. https://doi.org/10.1016/j.chom.2020.04.023

87. Tian X, et al. (2020) Potent binding of 2019 novel coronavirus spike protein by a SARS coronavirus-specific human monoclonal antibody. Emerging Microbes & Infections 9(1): 382-5. https://doi.org/10.1080/22221751.2020.1729069

88. Poh CM, et al. (2020) Two linear epitopes on the SARS-CoV-2 spike protein that elicit neutralising antibodies in COVID-19 patients. Nature Communications 11(1): 2806. https://doi.org/10.1038/s41467-020-16638-2

89. Zheng Z, et al. (2020). Monoclonal antibodies for the S2 subunit of spike of SARS-CoV cross-react with the newly-emerged SARS-CoV-2, bioRxiv.

90. Wrapp D, et al. (2020) Structural Basis for Potent Neutralization of Betacoronaviruses by Single-Domain Camelid Antibodies. Cell 181(5): 1004-15.e15. https://doi.org/10.1016/j.cell.2020.04.031

91. Yuan M, et al. (2020) A highly conserved cryptic epitope in the receptor binding domains of SARS-CoV-2 and SARS-CoV. Science 368(6491): 630-3. https://doi.org/10.1126/science.abb7269

92. Chi X, et al. (2020) Humanized Single Domain Antibodies Neutralize SARS-CoV-2 by Targeting Spike Receptor Binding Domain. bioRxiv: 2020.04.14.042010. https://doi.org/10.110½020.04.14.042010

93. Wu Y, et al. (2020) A noncompeting pair of human neutralizing antibodies block COVID-19 virus binding to its receptor ACE2. Science 368(6496): 1274-8. https://doi.org/10.1126/science.abc2241

94. Ye L, et al. (2020) Human monoclonal antibodies block the binding of SARS-CoV-2 spike protein to angiotensin converting enzyme 2 receptor. medRxiv: 2020.04.06.20055475. https://doi.org/10.110½020.04.06.20055475

95. Rogers TF, et al. (2020) Isolation of potent SARS-CoV-2 neutralizing antibodies and protection from disease in a small animal model. Science. https://doi.org/10.1126/science.abc7520

96. Matho MH, et al. (2018) Structure-function characterization of three human antibodies targeting the vaccinia virus adhesion molecule D8. J Biol Chem 293(1): 390-401. https://doi.org/10.1074/jbc.M117.814541

97. Kaever T, et al. (2014) Potent neutralization of vaccinia virus by divergent murine antibodies targeting a common site of vulnerability in L1 protein. J Virol 88(19): 11339-55. https://doi.org/10.1128/jvi.01491-14

98. Bernet J, et al. (2011) Disabling complement regulatory activities of vaccinia virus complement control protein reduces vaccinia virus pathogenicity. Vaccine 29(43): 7435-43. https://doi.org/10.1016/j.vaccine.2011.07.062

99. Shin YW, et al. (2019) Selection of Vaccinia Virus-Neutralizing Antibody from a Phage-Display Human-Antibody Library. J Microbiol Biotechnol 29(4): 651-7. https://doi.org/10.4014/jmb.1812.12024

100. Gilchuk I, et al. (2016) Cross-Neutralizing and Protective Human Antibody Specificities to Poxvirus Infections. Cell 167(3): 684-94.e9. https://doi.org/10.1016/j.cell.2016.09.049

101. Crickard L, et al. (2012) Protection of rabbits and immunodeficient mice against lethal poxvirus infections by human monoclonal antibodies. PLoS One 7(11): e48706. https://doi.org/10.1371/journal.pone.0048706

102. Tkaczyk C, et al. (2018) Alanine Scanning Mutagenesis of the MEDI4893 (Suvratoxumab) Epitope Reduces Alpha Toxin Lytic Activity In Vitro and Staphylococcus aureus Fitness in Infection Models. Antimicrob Agents Chemother 62(11). https://doi.org/10.1128/aac.01033-18

103. Zhou C, et al. (2016) Pharmacokinetics and pharmacodynamics of DSTA4637A: A novel THIOMAB™ antibody antibiotic conjugate against Staphylococcus aureus in mice. MAbs 8(8): 1612-9. https://doi.org/10.1080/19420862.2016.1229722

104. Nualnoi T, et al. (2018) Immunoglobulin G subclass switching impacts sensitivity of an immunoassay targeting Francisella tularensis lipopolysaccharide. PLoS One 13(4): e0195308. https://doi.org/10.1371/journal.pone.0195308

105. Lu Z, et al. (2014) Functional and structural characterization of Francisella tularensis O-antigen antibodies at the low end of antigen reactivity. Monoclon Antib Immunodiagn Immunother 33(4): 235-45. https://doi.org/10.1089/mab.2014.0022

106. Lu X, et al. (2019) Double Lock of a Human Neutralizing and Protective Monoclonal Antibody Targeting the Yellow Fever Virus Envelope. Cell Rep 26(2): 438-46.e5. https://doi.org/10.1016/j.celrep.2018.12.065

107. Adungo F, et al. (2016) Development and Characterization of Monoclonal Antibodies to Yellow Fever Virus and Application in Antigen Detection and IgM Capture Enzyme-Linked Immunosorbent Assay. Clin Vaccine Immunol 23(8): 689-97. https://doi.org/10.1128/cvi.00209-16

108. Julander JG, et al. (2014) Humanized monoclonal antibody 2C9-cIgG has enhanced efficacy for yellow fever prophylaxis and therapy in an immunocompetent animal model. Antiviral Res 103: 32-8. https://doi.org/10.1016/j.antiviral.2013.12.011

109. Bailey MJ, et al. (2019) Human Monoclonal Antibodies Potently Neutralize Zika Virus and Select for Escape Mutations on the Lateral Ridge of the Envelope Protein. J Virol 93(14). https://doi.org/10.1128/jvi.00405-19

110. Van Rompay KKA, et al. (2020) A combination of two human monoclonal antibodies limits fetal damage by Zika virus in macaques. Proceedings of the National Academy of Sciences 117(14): 7981-9. https://doi.org/10.1073/pnas.2000414117

111. Qu P, et al. (2020) A new class of broadly neutralizing antibodies that target the glycan loop of Zika virus envelope protein. Cell Discov 6: 5. https://doi.org/10.1038/s41421-019-0140-8

112. Wang B, et al. (2019) A Novel DT40 Antibody Library for the Generation of Monoclonal Antibodies. Virologica Sinica 34(6): 641-7. https://doi.org/10.1007/s12250-019-00142-z

113. Wang J, et al. (2017) A Human Bi-specific Antibody against Zika Virus with High Therapeutic Potential. Cell 171(1): 229-41.e15. https://doi.org/10.1016/j.cell.2017.09.002

114. Khandia R, et al. (2018) Modulation of Dengue/Zika Virus Pathogenicity by Antibody-Dependent Enhancement and Strategies to Protect Against Enhancement in Zika Virus Infection. Frontiers in Immunology 9(597). https://doi.org/10.3389/fimmu.2018.00597

115. Wang Q, et al. (2017) Monoclonal Antibodies against Zika Virus: Therapeutics and Their Implications for Vaccine Design. Journal of Virology 91(20): e01049-17. https://doi.org/10.1128/jvi.01049-17

116. Hasan SS, et al. (2017) A human antibody against Zika virus crosslinks the E protein to prevent infection. Nature Communications 8(1): 14722. https://doi.org/10.1038/ncomms14722

117. Li C, et al. (2018) A Single Injection of Human Neutralizing Antibody Protects against Zika Virus Infection and Microcephaly in Developing Mouse Embryos. Cell Rep 23(5): 1424-34. https://doi.org/10.1016/j.celrep.2018.04.005

118. Long F, et al. (2019) Structural basis of a potent human monoclonal antibody against Zika virus targeting a quaternary epitope. Proc Natl Acad Sci U S A 116(5): 1591-6. https://doi.org/10.1073/pnas.1815432116

119. Niu X, et al. (2019) Convalescent patient-derived monoclonal antibodies targeting different epitopes of E protein confer protection against Zika virus in a neonatal mouse model. Emerging Microbes & Infections 8(1): 749-59. https://doi.org/10.1080/22221751.2019.1614885

120. Woehrl B, et al. (2011) Complement component 5 contributes to poor disease outcome in humans and mice with pneumococcal meningitis. The Journal of clinical investigation 121(10): 3943-53. https://doi.org/10.1172/JCI57522

121. Singh SP, et al. (1999) Recognition specificity of monoclonal antibodies which protect mice against Salmonella typhimurium infection. Res Microbiol 150(6): 385-94. https://doi.org/10.1016/s0923-2508(99)80073-4

122. Chin CF, et al. (2017) Delineation of B-cell Epitopes of Salmonella enterica serovar Typhi Hemolysin E: Potential antibody therapeutic target. Sci Rep 7(1): 2176. https://doi.org/10.1038/s41598-017-01987-8

Isolation of monoclonal antibodies

Immortalized cell and *in vitro* transcription/translation technologies

Company	Technology	Notes/References
Vir Bio	Memory B cells are immortalized with high efficiency using Epstein-Barr virus (EBV) in the presence of a Toll-like receptor (TLR) agonist, while plasma cells are maintained in single-cell cultures by using interleukin 6 (IL-6) or stromal cells; functional assays used to identify rare antibodies.	Vir Bio isolated potent and broadly neutralizing antibodies against influenza and four different paramyxoviruses 1
MedImmune	Memory B cells are activated and amplified using Epstein-Barr virus infection, co-cultured with CHO-muCD40L cells, and then assessed by functional screenings. An *in vitro* transcription and translation (IVTT) approach was used to analyze variable (V) genes recovered from each B cell sample and identify the relevant heavy/light chain pair(s).	2
Nagoya University Hideo Nakano	Ecobody technology: rapid and cost-effective monoclonal antibody screening method from single animal B cells using reverse transcription (RT)-PCR and *Escherichia coli* cell-free protein synthesis (CFPS), which allows evaluation of antibodies within two working days.	3

Novel display and bispecific monoclonal antibody technologies

Company	Technology	Notes/References
Abzyme Therapeutics	*In vitro* antibody discovery/optimization triple-mode platform with proprietary self-diversifying libraries (N-terminal and C-terminal camelid VHH libraries), rapid target-directed antibody maturation and FACS-based single cell sorting approach Bispecific AbZ2 single-chain antibodies: fusing a single domain antibody onto the C-terminus of another VHH fragment	Preclinical monospecific and bispecific antibodies for the treatment of human and animal diseases in oncology, ophthalmology, CNS disorders, Lyme disease, virus-induced encephalitis and influenza 4
Light Chain Bioscience *(formely Novimmune)*	Developed methodologies that allow 'in format' phage display selection and screening of bispecific antibodies early in discovery. Novimmune's kappa-lambda (κλ) bispecific antibody platform generates fully human bispecific IgG molecules undistinguishable from a standard human IgG.	5
Xcella Biosciences	Fully human antibody library (xEmplar) precisely designed to replicate the natural immune repertoire with an eye for improved developability. Optimized CDR compositions and framework selection combined with the elimination of amino acid motifs that increase aggregation and off-target reactivity results in a library that yields many diverse and developable hits. The xPloration functional screening platform enables functional screens measuring functional activity of millions of antibody variants within hours using microcapillary arrays.	Seven candidates in the preclinical pipeline for oncology 6

(table continues on next page)

Novel proteomics approach using B-cells

Company	Technology	Notes/References
Digital Proteomics LLC	Immuno-proteogenomics (combining mass spec with next-generation sequencing of antibodies in serum)	*Partners:* Genentech, Merck, Mapp BioPharm; spin-off company from Univ San Diego 7
Cell Signaling technology	Proteomics approach that identifies antigen-specific antibody sequences directly from circulating polyclonal antibodies in the serum of an immunized animal. The approach involves affinity purification of antibodies followed by analysis using liquid chromatography coupled to tandem mass spectrometry. High-confidence peptide spectral matches of antibody variable regions are obtained by searching a reference database created by next-generation DNA sequencing of the B-cell immunoglobulin repertoire of the immunized animal. Finally, heavy and light chain sequences are paired and expressed as recombinant monoclonal antibodies.	Isolated monoclonal antibodies for five antigens from the sera of immunized rabbits and mice that surpass binding by the original affinity-purified polyclonal antibodies 8

Novel high-throughput B-cell technologies

Company	Technology	Notes/References
University of Texas, Austin George Georgiou	Use high-throughput sequencing to discover native, antigen-specific human antibodies. Single B cells (>5 × 104 capacity per experiment) are deposited in a high-density microwell plate (125 pl/well) and lysed *in situ*. mRNA is then captured on magnetic beads, reverse transcribed and amplified by emulsion VH:VL linkage PCR. The linked transcripts are analyzed by Illumina high-throughput sequencing.	9
Abcellera	High-throughput screening assay incorporated into microwells/microfluidic chambers	10
Adimab/ Arsanis	Flow Cytometry – B cell cloning technology that works with yeast-based antibody discovery and optimization platform	Adimab has over 280 antibody discovery programs with 20 in the clinical stages. Adimab licences RSV mbs to Arsanis for clinical development. Adimab has applied this technology to Ebola, RSV, CD3, and Zika as academic and NGO partnerships. 11

Novel microfluidic and multiplexed B-cell technologies

Company	Technology	Notes/References
Sphere Fluidics	Proprietary microfluidic technology that allows the ultra-high throughput analysis of isolated cells in miniaturized (pL to nL) picodroplets – enables faster, less costly and more effective sample screening and discovery of antigen-specific antibody discovery. Cyto-Mine® technology is the first integrated device to be able to automatically perform all of these crucial techniques in a single compact system. ESI-Mine™ platform can be used for high-throughput mass spectrometry (MS) analysis – splits picodroplet for MS and the other part for growth on a chip so that it can be retrieved.	12

(table continues on next page)

Novel microfluidic and multiplexed B-cell technologies (continued)

Company	Technology	Notes/References
HiFiBio	Microfluidic system, DropMap, in which single cells are compartmentalized in tens of thousands of 40-pL droplets and analyzed in two-dimensional droplet arrays using a fluorescence relocation-based immunoassay. System enables immune monitoring and optimization of immunization and vaccination protocols and antibody screening.	Preclinical pipeline with ten candidates for immunology and oncology 13
Trellis Biosciences	Proprietary cell-spot, B-cell multiplexed screening and cloning technology; simultaneous screening on ten different parameters such as specificity, affinity, and cross-reactivity with other antigens	Five preclinical human mAbs therapeutics against AMR bacteria, HCMV, Influenza, RSV, and cancer indications 14, 15

Humanized animal models

Company	Technology	Notes/References
Ligand OmniAb	Ligand's OmniAb® platforms (OmniRat®, OmniMouse® and OmniFlic®) are based on novel, transgenic rodents that produce highly diversified antibody repertoires. This platform offers accelerated discovery of fully human mono- and bispecific antibodies that are naturally optimized *in vivo* for manufacturability, therapeutic efficacy and reduced immunogenicity.	16
Kymab	Knock-in mouse The Kymouse™ strains have more than 5.4 million base-pairs of the human immunoglobulin genes in their genome — more than any other model. In IntelliSelect™, we capture all relevant antibody sequences from single B cells, understand their evolutionary relationships and convert them into expression vectors to generate recombinant antibodies for high-throughput assays.	Atopic dermatitis mAb in phase II, two cancer mAbs in phase I testing. Preclinical pipeline of candidates for graft-vs-host disease, hemophilia, immune and cancer disorders. 17
Regeneron	VelociMouse® enables immediate generation of genetically altered mice directly from modified embryonic stem cells. Shortened the time needed to engineer genetically modified mice, while at the same time reducing costs and improving precision.	18
Merck KGaA	Heavy chain repertoires from immunized transgenic OminRats™ were combined with common light chains from existing therapeutic antibodies in novel yeast surface display Fab libraries, and screened for binders by yeast surface display. Strategy represents a combination of *in vivo* immunization with an *in vitro* selection method, which allows for the integration of existing therapeutic antibodies into a bispecific format.	19,20

References

1. Vir. A world without infectious disease. Accessed 9/9/19 from https://www.vir.bio/

2. Shi X, et al. (2016) A bispecific antibody effectively neutralizes all four serotypes of dengue virus by simultaneous blocking virus attachment and fusion. mAbs 8(3): 574-84. https://doi.org/10.1080/19420862.2016.1148850

3. Ojima-Kato T, et al. (2017) Ecobody technology: rapid monoclonal antibody screening method from single B cells using cell-free protein synthesis for antigen-binding fragment formation. Scientific Reports 7(1): 13979. https://doi.org/10.1038/s41598-017-14277-0

4. Abzyme Therapeutics. Abzyme Therapeutics Small Domian. Big Impact. Accessed 9/9/19 from http://abzymetx.com/

5. Fischer N, et al. (2015) Exploiting light chains for the scalable generation and platform purification of native human bispecific IgG. Nature Communications 6: 6113. https://doi.org/10.1038/ncomms7113, https://www.nature.com/articles/ncomms7113#supplementary-information

6. Chen B, et al. (2015) High-throughput analysis and protein engineering using microcapillary arrays. Nature Chemical Biology 12: 76. https://doi.org/10.1038/nchembio.1978, https://www.nature.com/articles/nchembio.1978#supplementary-information

7. Digital Proteomics LLC. Digital Proteomics is reimagining antibody discovery and sequencing. Accessed 9/9/19 from https://www.digitalproteomics.com

8. Cell Signaling Technology. Cell Signaling Technology. Accessed 9/9/19 from https://www.cellsignal.com

9. Georgiou G, et al. (2014) The promise and challenge of high-throughput sequencing of the antibody repertoire. Nature Biotechnology 32: 158. https://doi.org/10.1038/nbt.2782

10. Abcellera. Abcellera. Accessed 9/9/19 from https://www.abcellera.com/discovery

11. Adimab. Adimab. Accessed 9/9/19 from http://www.adimab.com/discovery

12. Liu X, et al. (2016) High-throughput screening of antibiotic-resistant bacteria in picodroplets. Lab Chip 16(9): 1636-43. https://doi.org/10.1039/c6lc00180g

13. Eyer K, et al. (2017) Single-cell deep phenotyping of IgG-secreting cells for high-resolution immune monitoring. Nat Biotechnol 35(10): 977-82. https://doi.org/10.1038/nbt.3964

14. McCutcheon KM, et al. (2014) Multiplexed screening of natural humoral immunity identifies antibodies at fine specificity for complex and dynamic viral targets. MAbs 6(2): 460-73. https://doi.org/10.4161/mabs.27760

15. 15. Trellis Bioscience. Pipeline. Accessed 9/9/19 from http://www.trellisbio.com/pipeline.html

16. Ligand. OmniAb. Accessed 9/9/19 from https://www.ligand.com/technologies/omniab

17. Kymab. Making the best antibody platform better. Accessed 9/9/19 from https://www.kymab.com/technology/antibody-development

18. Dechiara TM, et al. (2009) VelociMouse: fully ES cell-derived F0-generation mice obtained from the injection of ES cells into eight-cell-stage embryos. Methods Mol Biol 530: 311-24. https://doi.org/10.1007/978-1-59745-471-1_16

19. Rosowski S, et al. (2018) A novel one-step approach for the construction of yeast surface display Fab antibody libraries. Microbial cell factories 17(1): 3-. https://doi.org/10.1186/s12934-017-0853-z

20. Krah S, et al. (2017) Generation of human bispecific common light chain antibodies by combining animal immunization and yeast display. Protein Eng Des Sel 30(4): 291-301. https://doi.org/10.1093/protein/gzw077

Biosimilar guidelines in BRICS-TM

In vivo and *in vitro* requirements

	Brazil ANVISA	**Russian Federation** FSSH	**India** CDSCO	**China** CFDA	**South Africa** SAHPRA	**Turkey** TMMDA	**Mexico** COFEPRIS
In vitro	Not defined	Not defined	Cell-based bioassay	Not defined	Binding and functional assay	Binding and functional assay	Not defined
PK/PD	Mandatory	Not defined	Not defined	Comparative	Not defined	Dose concentration response assessment	Not defined
Toxicity	Repeat-dose	Not defined	Repeat-dose	Single dose and repeat dose	Repeat dose	Repeat dose	Not defined
Immunogenicity	Not defined	Not defined	Comparative Ab response	Not defined	Comparative bioactivity	Non-predictive in human	Not defined
Safety	Not defined	Not defined	Not defined	Comparative safety	Comparative safety	Not defined	Not defined
Local tolerance	Not defined	Not defined	In line with WHO	Not defined	Not defined	For novel excipients	Not defined

Clinical requirements

	Brazil ANVISA	**Russian Federation** FSSH	**India** CDSCO	**China** CFDA	**South Africa** SAHPRA	**Turkey** TMMDA	**Mexico** COFEPRIS
Clinical efficacy	Required but not defined	Not defined	Equivalence non-inferiority or comparability phase III trial	Equivalent efficacy design trial	Clinical comparability trial	Not defined	Not defined
Clinical immunogenicity	Not defined	Not defined	Obtained in PK/PD studies	Required but not defined	Required but not defined	Not defined	Not defined
Comparative safety data	Required but not defined	Not defined	Obtained in PK/PD studies of phase III trial is waived	Adverse effect comparison done with reference drug	In line with EMA	Not defined	Not defined

ANVISA: Agência Nacional de Vigilância Sanitária; FSSH: Federal Service for Surveillance in Healthcare (Roszdravnadzor); CDSCO: Central Drugs Standard Control Organisation; CFDA: China Food and Drug Administration; SAHPRA: South African Health Products Regulatory Authority; TMMDA: Turkish Medicines and Medical Devices Agency; COFEPRIS: Comisión Federal para la Protección contra Riesgos

PK/PD = Pharmacokinetics/Pharmacodynamics

Sources: Chopra R, Lopes G. (2017) Improving Access to Cancer Treatments: The Role of Biosimilars. Journal of Global Oncology 3(5): 596-610. https://doi.org/10.1200/jgo.2016.008607; Rahalkar H, et al. (2018) Quality, Non-clinical and Clinical Considerations for Biosimilar Monoclonal Antibody Development: EU, WHO, USA, Canada, and BRICS-TM Regulatory Guidelines. Frontiers in Pharmacology 9(1079). https://doi.org/10.3389/fphar.2018.01079; Clarivate Analytics. (2019) Cortellis database search. Accessed 1/7/19.