Antibodies to watch in 2025

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Agenda

- Objectives, definitions
- Trends and success rates of therapeutic antibody formats
  - Trends in approvals
  - Success rates
  - Trends in FIH
- First approvals of antibody therapeutics granted in 2024, in 2025, and those in review
- “Antibodies to Watch” for possible transition to regulatory review by the end of 2025
- Outlook for the future, 2010-25

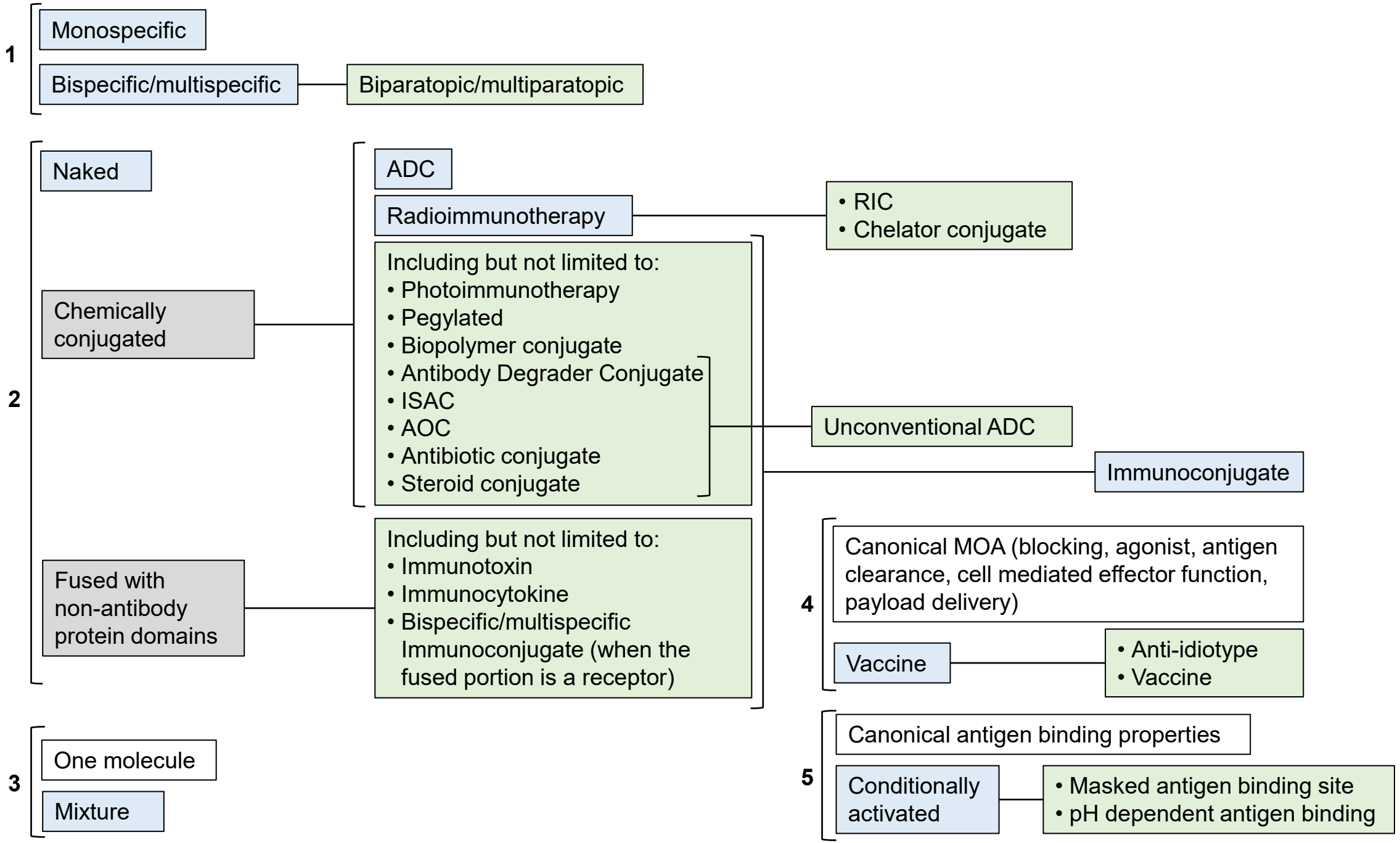
Objectives

- To determine trends in antibody therapeutic development over time
  - Overall, as well as focus on particular therapeutic areas, formats, or targets
- To determine clinical success rates for antibody therapeutics development, as conducted by the biopharmaceutical industry
  - Clinical phase transition rates
  - Overall marketing approval rates
- To assess innovation in the biopharmaceutical industry

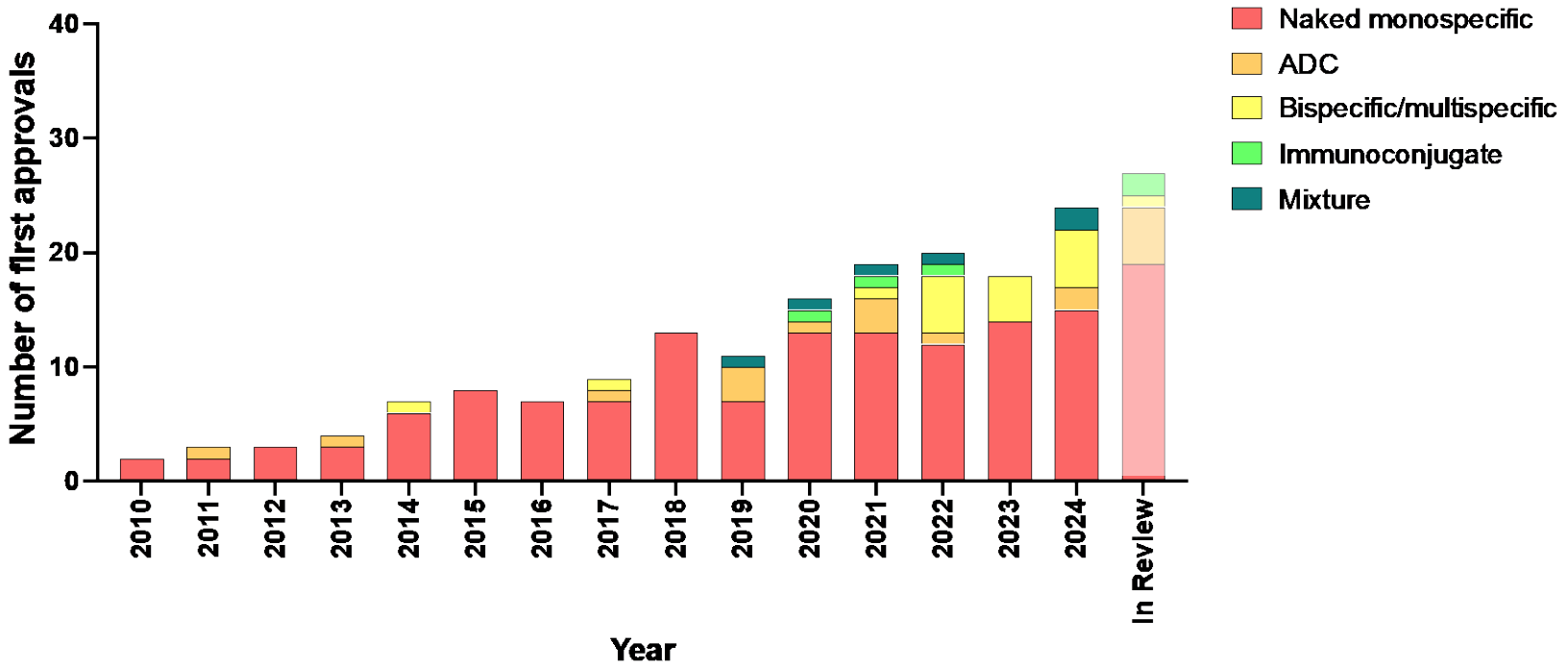
Definitions, inclusion/exclusion criteria

- **Antibody therapeutic**: Recombinant protein-based molecule with at least one antigen binding site derived from an antibody-gene that is evaluated as a therapeutic; excludes polyclonal antibodies from a natural source, antibody-encoding DNA, Fc only / Fc fusion proteins, and diagnostics
- **Commercial sponsor**: Public or private for-profit entity; excludes non-profit and government entities
- **Innovative**: Unique in composition of matter; excludes biosimilars
- **Clinical status**: Most advanced clinical study; excludes early-stage studies for molecules in Phase 2/3 or 3 studies or in reg.review, approved
- **First**: First instance of an event; excludes second, third, etc.

Therapeutic antibody formats: Trends and success rates


1
Monospecific
Bispecific/multispecific
Biparatopic/multiparatopic
2
Naked
Chemically conjugated
ADC
Radioimmunotherapy
• RIC
• Chelator conjugate
Including but not limited to:
• Photoimmunotherapy
• Pegylated
• Biopolymer conjugate
• Antibody Degrader Conjugate
• ISAC
• AOC
• Antibiotic conjugate
• Steroid conjugate
Unconventional ADC
Immunoconjugate
Fused with non-antibody protein domains
Including but not limited to:
• Immunotoxin
• Immunocytokine
• Bispecific/multispecific Immunoconjugate (when the fused portion is a receptor)
3
One molecule
Mixture
4
Canonical MOA (blocking, agonist, antigen clearance, cell mediated effector function, payload delivery)
Vaccine
• Anti-idiotype
• Vaccine
5
Canonical antigen binding properties
Conditionally activated
• Masked antigen binding site
• pH dependent antigen binding

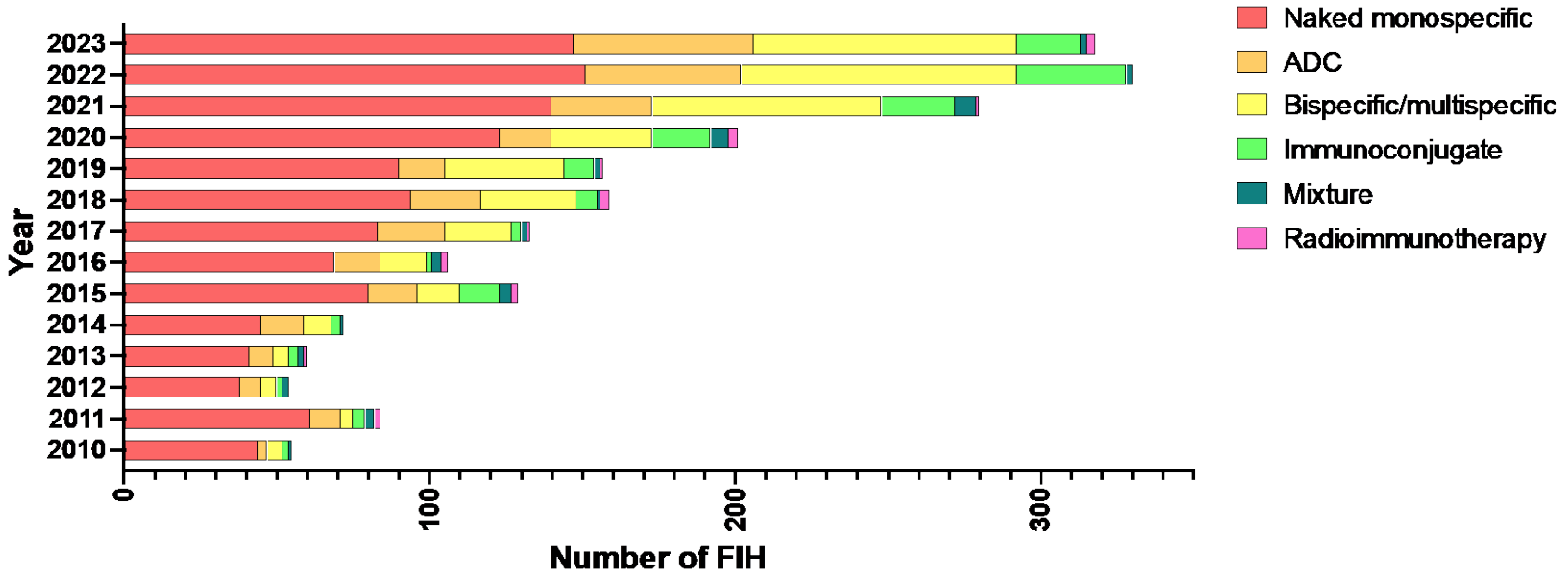
Annual first approvals for antibody therapeutics during 2010–2024, and antibodies in review



Molecules are counted only once and categorised as: Naked monospecific (canonical format), antibody–drug conjugate (ADC) (when conjugated to a cytotoxic drug, including bispecific ADC), Bispecific/multispecific (naked), Immunoconjugates (antibodies conjugated to molecules (excluding cytotoxic drugs, radioisotopes and chelators), or fused to non-immunoglobulin derived protein domains, including immunoconjugate mixtures), Mixture, Radioimmunotherapy (including radioimmunoconjugates (RIC) and antibody chelator conjugates).

Data as of December 31, 2024.

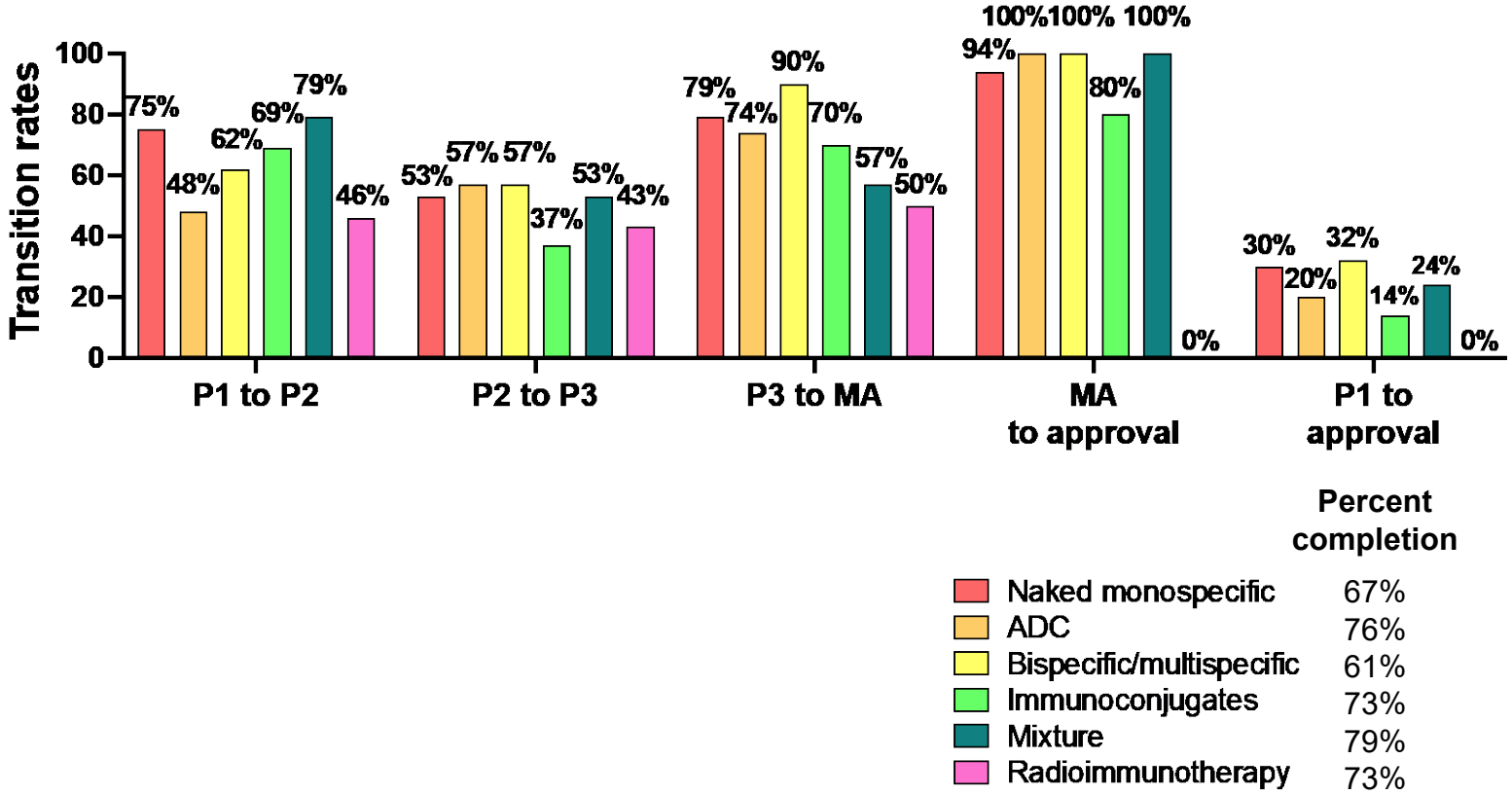
Annual number of antibody therapeutics entering clinical study, 2010–2023



Molecules are counted only once and categorised as: Naked monospecific (canonical format), antibody–drug conjugate (ADC) (when conjugated to a cytotoxic drug, including bispecific ADC), Bispecific/multispecific (naked), Immunoconjugates (antibodies conjugated to molecules (excluding cytotoxic drugs, radioisotopes and chelators), or fused to non-immunoglobulin derived protein domains, including immunoconjugate mixtures), Mixture, Radioimmunotherapy (including radioimmunoconjugates (RIC) and antibody chelator conjugates).

Data as of December 7, 2024.

Phase transition and approval success rates



Clinical phase transition and global approval success rates for antibody therapeutics that entered clinical study during 2000-2019, stratified by molecular category. Red bars, naked monospecific. Orange bars, ADC. Yellow bars, bispecific/multispecific. Light green bars, Immunoconjugate. Dark green bars, antibody mixture. Pink bars, antibody for radioimmunotherapy (including RIC and antibody chelator conjugates).
Cohorts included only novel antibody therapeutics in clinical studies sponsored by commercial firms; biosimilars were excluded.

Data as of December 7, 2024.

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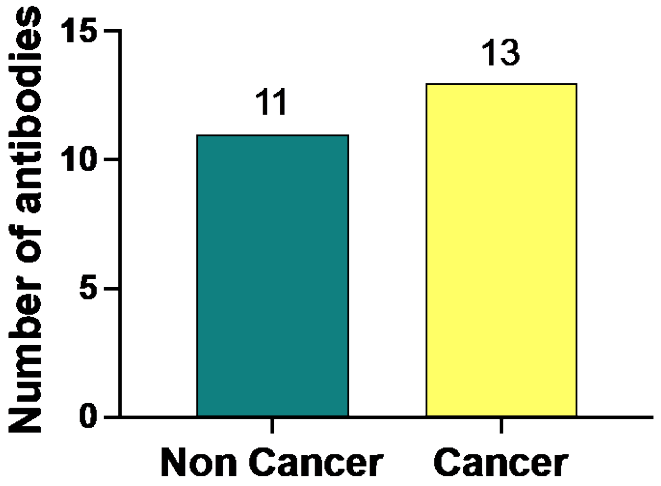
First approvals in 2024



First approvals in US or EU (and RoW)

Non-cancer indication:

INN (Brand name)	Target(s); Format	Indication first approved	Country/region of approval in 2024
Donanemab (Kisunla)	Amyloid β (N3pG); Humanized IgG1κ	Early Alzheimer's disease	US, Japan, UK
Axatilimab (Niktimvo)	CSF-1R; Humanized IgG4κ	Graft vs. host disease	US
Marstacimab (HYMPAVZI)	TF pathway inhibitor; Human IgG1λ	Hemophilia	US, EU
Crovalimab (派圣凯®, PiaSky)	Complement C5; Humanized IgG1κ	Paroxysmal nocturnal hemoglobinuria	US, EU, Japan, China

First approvals in RoW only

Non-cancer indication:

INN (Brand name)	Target(s); Format	Indication first approved	Country/region of approval in 2024
Mazorelvimab, Zamerovimab (克瑞毕®)	Rabies virus glycoprotein; Humanized IgG1κ, mixture of 2 mAb	Rabies, post-exposure prophylaxis	China
Vunakizumab (安达静®)	IL-17A; Humanized IgG1κ	Psoriasis	China
Xeligekimab (金立希®)	IL-17A; Human IgG4κ	Psoriasis	China
Stapokibart (Kangyueda, 康悦达®)	IL-4R alpha; Humanized IgG4κ	Atopic dermatitis	China
Ebronucimab (伊喜宁)	PCSK9; Human IgG1λ	Primary hypercholesterolemia and mixed hyperlipidemia, heterozygous familial hypercholesterolemia	China
Ongericimab (君适达®)	PCSK9; Humanized IgG4κ	Hypercholesterolemia	China
Seniprutug (Tribuvia)	TCR Vbeta9; Humanized IgG1κ	Axial spondyloarthritis	Russia

First approvals in US or EU (and RoW)

Cancer indication:

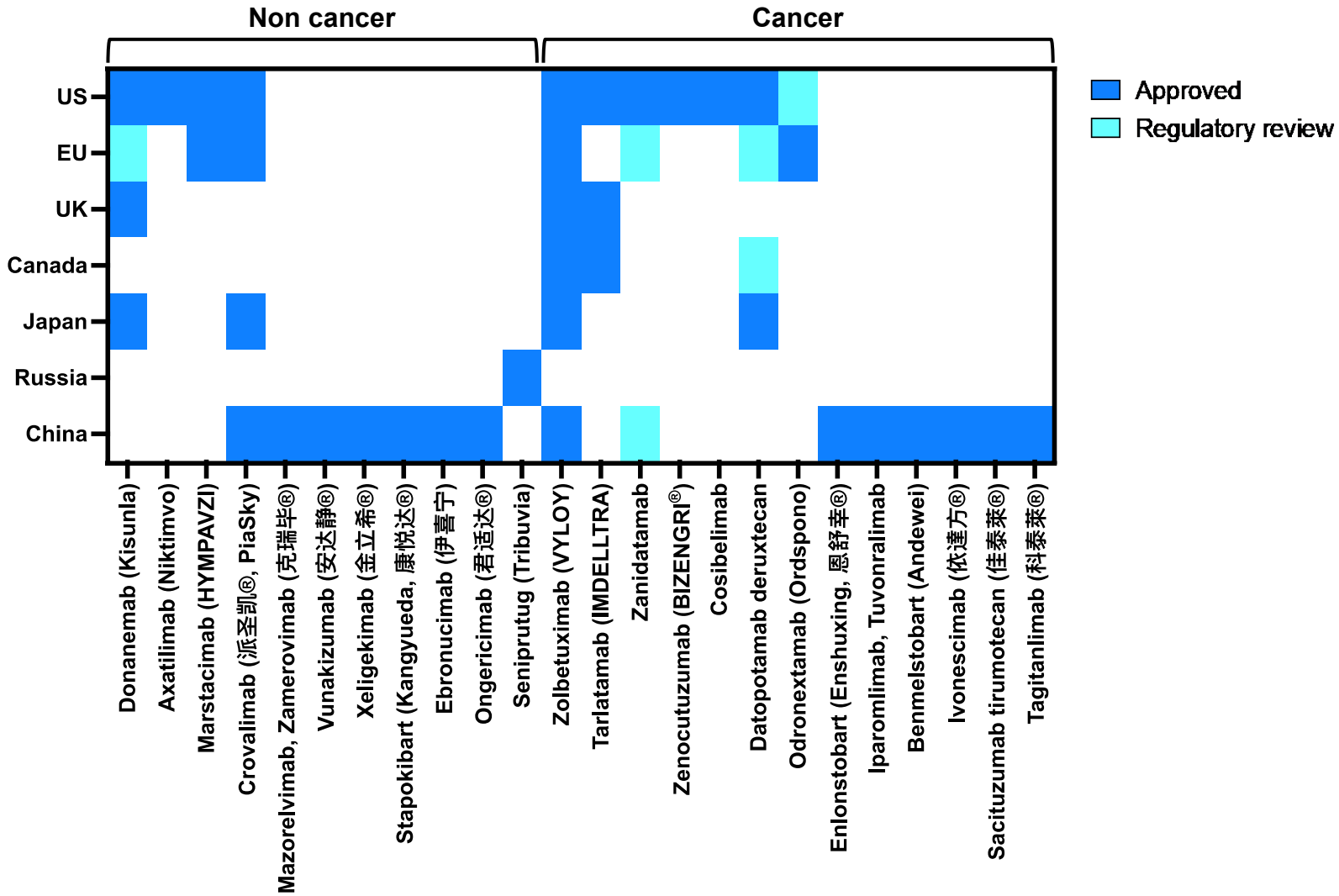
INN (brand name)	Target; format	Indication first approved	Country/region of approval in 2024
Zolbetuximab (VYLOY)	Claudin 18.2; Chimeric IgG1κ	HER2-neg. gastric or GEJ adenocarcinoma	US, EU, Japan, UK
Tarlatamab (IMDELLTRA)	DLL3, CD3; scFv-scFv-scFc bispecific	Small cell lung cancer	US
Zanidatamab (Ziihera®)	HER2; Humanized biparatopic bispecific frag.	HER2+ biliary tract cancer	US
Zenocutuzumab (BIZENGRI®)	HER2, HER3; Humanized IgG1κ; Bispecific	NRG1+ pancreatic ductal adenocarcinoma or NSCLC	US
Odronextamab (Ordspono)	CD20, CD3; Human IgG4κ bispecific	Diffuse large B-cell lymphoma	EU
Cosibelimab	PD-L1; Human IgG1λ	Cutaneous squamous cell carcinoma	US
Datopotamab deruxtecan	TROP-2; Humanized IgG1; ADC	HR+ HER2-neg breast cancer	US, Japan

First approvals in RoW only

Cancer indication:

INN (brand name)	Target; format	Indication first approved	Country/region of approval in 2024
Enlonstobart (Enshuxing, 恩舒幸®)	PD-1; Human IgG4κ	Cervical cancer	China
Iparomlimab, Tuvonralimab (齐倍安®)	PD-1, CTLA-4; mixture 2 monospecific antibodies	Cervical cancer	China
Benmelstobart (Andewei)	PD-L1; Humanized IgG1κ	Small cell lung cancer	China
Ivonescimab (依達方®)	PD-1, VEGF-A; IgG1κ-[scFv]2 bispecific	Lung cancer	China
Sacituzumab tirumotecan (佳泰莱®)	TROP-2; Humanized IgG1κ ADC	Triple-neg BC, NSCLC	China
Tagitanlimab (科泰莱®)	PD-L1; Humanized IgG1κ	Nasopharyngeal cancer, solid tumor indications	China

Antibodies approved in 2024



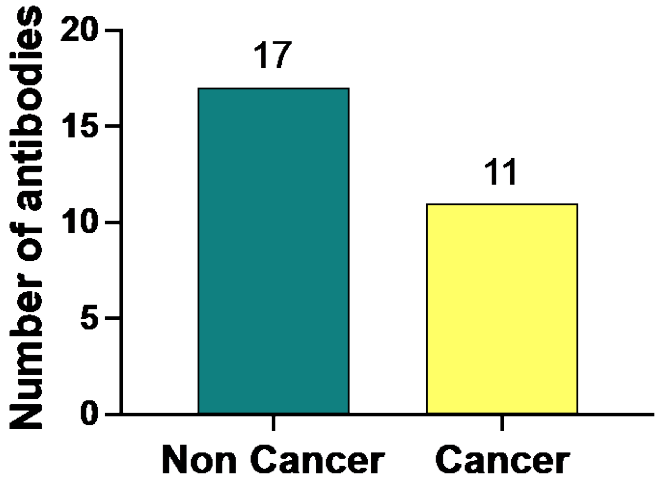
Data as of January 30, 2025.

First approvals in 2025

INN (Brand name)	Target(s); Format	Indication first approved	Country/region of approval in 2024*
Vilobelimab	Complement C5a; Chimeric IgG4κ	SARS-CoV-2-induced acute respiratory distress syndrome	EU
Garadacimab	Factor XIIa; Human IgG4λ	Hereditary angioedema	Australia [EU(+) review, US, Japan, Switzerland, Canada, UK]

*Approval updates: https://www.antibodysociety.org/antibody-therapeutics-product-data/

Antibodies in regulatory review*
(excludes all approved products)



*Updates: https://www.antibodysociety.org/antibody-therapeutics-product-data/

Data as of January 30, 2025.

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Regulatory review in US or EU (and RoW)

Non-cancer indication:

INN or drug code	Target; format	Indication under review	Country/region of review
Bentracimab	Ticagrelor; Human IgG1λ Fab	Reversal of the antiplatelet effects of ticagrelor	US
Nipocalimab	FcRn; Human IgG1λ	Generalized myasthenia gravis	EU, US
Sipavibart	SARS-CoV-2; Human IgG1λ	Prophylaxis of COVID-19	EU (+), Japan
Narsoplimab	MASP-2; Human IgG4λ	Hematopoietic stem cell transplant-associated thrombotic microangiopathy	US (2nd cycle)
Clesrovimab	RSV (F glycoprotein); Human IgG1κ	Prevention of RSV infection	EU, US
Depemokimab	IL-5; Humanized IgG1κ	Asthma with type 2 inflammation; chronic rhinosinusitis with nasal polyps (CRSwNP)	EU, Japan, China
Apitegromab	Myostatin; Human IgG4κ	Spinal muscular atrophy	US

Regulatory review in US or EU (and RoW)

Cancer indication:

INN or drug code	Target; format	Indication under review	Country/region of review
Telisotuzumab vedotin	cMET, Humanized IgG1κ, ADC	NSCLC	US
Patritumab deruxtecan	HER3; Human IgG1κ, ADC	NSCLC	US (2nd cycle)
Linvoseltamab	BCMA, CD3; Human IgG4κ, Bispecific	Multiple myeloma	EU, US (2nd cycle)
Bifikafusp alfa, Onfekafusp alfa	Fibronectin EDB; Human immunoconjugate, immunocytokine mixture (scFv-IL2, scFv-TNF)	Melanoma	EU

Regulatory review in RoW only

Non-cancer indication:

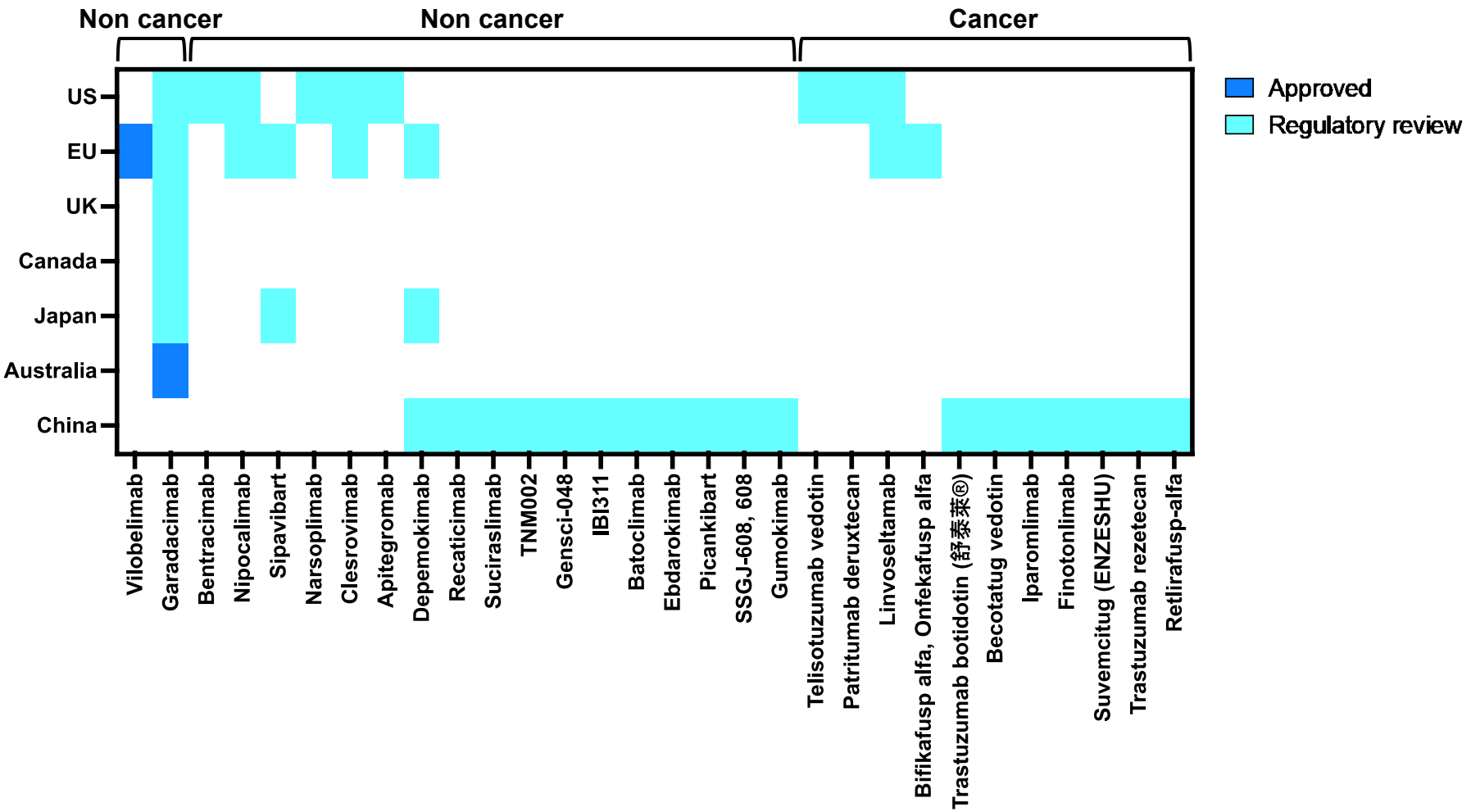
INN or drug code	Target; format	Indication under review	Country/region of review
Recaticimab	PCSK9; Humanized IgG1κ	Hypercholesterolemia	China
Suciraslimab	CD22; Chimeric IgG1κ	Rheumatoid arthritis	China
TNM002	Tetanus toxin; Human	Prophylaxis of *C. tetani* infection	China
Gensci-048	IL-1 beta	Acute gouty arthritis	China
IBI311	IGF-1R	Thyroid eye disease	China
Batoclimab	FcRn; Human IgG1λ	Generalized myasthenia gravis	China (resubmission)
Ebdarokimab	IL-12/23p40; Humanized IgG1κ	Psoriasis	China
Picankibart	IL-23p19; Human IgG1κ	Psoriasis	China
SSGJ-608	IL-17A	Psoriasis	China
Gumokimab	IL-17A; Chimeric/ humanized IgG1κ	Psoriasis	China

Regulatory review in the RoW only

Cancer indication:

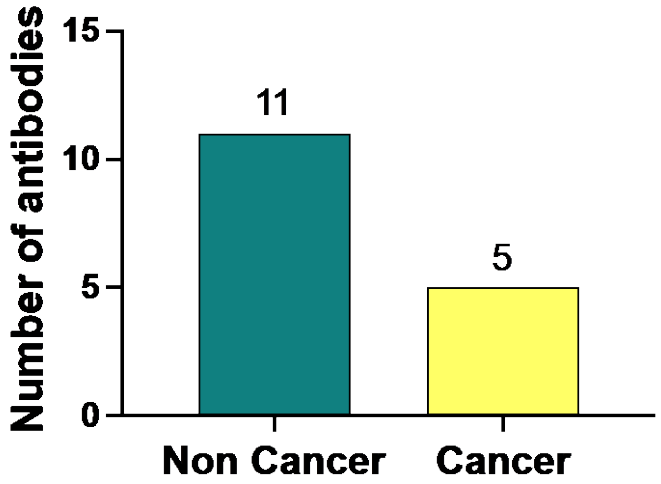
INN or drug code	Target; format	Indication under review	Country/ region of review
Trastuzumab botidotin (舒泰莱®)	HER2; Humanized IgG1κ ADC	HER2+ breast cancer (BC)	China
Becotatug vedotin	EGFR; Humanized IgG1k ADC	Nasopharyngeal cancer	China
Iparomlimab	PD-1; Humanized/chimeric IgG4κ	Cancer	China
Finotonlimab	PD-1; Humanized IgG4κ	Head and neck squamous cell , hepatocellular carcinoma	China
Suvemcitug (ENZESHU)	VEGF-A; Humanized IgG1κ	Epithelial ovarian, fallopian tube, primary peritoneal cancer.	China
Trastuzumab rezetecan	HER2; Humanized IgG1κ ADC	NSCLC	China
Retlirafusp alfa	PD-L1, TGF beta; Humanized IgG4κ Bispecific, Immunoconjugate	Metastatic gastric and gastroesophageal junction adenocarcinoma	China

Antibodies approved in 2025 and currently in regulatory review



Data as of January 30, 2025.

“Antibodies to Watch” for possible transition to regulatory review by the end of 2025



Data as of January 24, 2025.

Non-cancer indication:

INN or drug code	Target(s); Format	Indication of relevant* late-stage study	Est. submission year, country#	Most advanced clinical phase
ANX005	Complement C1q; Humanized IgG4κ	Guillain-Barré syndrome	2025H1, US	Phase 3
Sibeprenlimab	APRIL; Humanized IgG2κ	Immunoglobulin A nephropathy	2025H1	Phase 3

*Indication for which a regulatory submission is anticipated. #First marketing application submission dates and country are estimates based on company announcements and pivotal trial completion dates.

Data as of January 24, 2025.

Non-cancer indication:

INN or drug code	Target(s); Format	Indication of relevant* late-stage study	Est. submission year, country#)	Most advanced clinical phase
Denecimig	Factor IXa, Factor X; Human IgG4; Bispecific	Hemophilia	2025	Phase 3
Astegolimab	IL-33R; Human IgG2κ	COPD	2025	Phase 3
Cendakimab	IL-13; Humanized IgG1κ	Eosinophilic esophagitis	2025	Phase 3
SSGJ-613	IL-1 beta; Humanized	Psoriasis	2025, China	Phase 3
Itepekimab	IL-33; Human IgG4κ	COPD	2025H2, EU, US	Phase 3
Veligrotug	IGF-1R; Humanized IgG1κ	Thyroid eye disease	2025H2	Phase 3
Anselamimab	Amyloid; Chimeric IgG1κ	Amyloid light chain amyloidosis	~2025	Phase 3
Sonelokimab	IL-17A, IL17F, albumin; Humanized VHH-VHH'-VHH; Trispecific	Hidradenitis suppurativa	~2025H2	Phase 3
Ersodetug	Insulin receptor; Human IgG2κ	Congenital hyperinsulinism	~2025H2	Phase 3

*Indication for which a regulatory submission is anticipated. #First marketing application submission dates and country are estimates based on company announcements and pivotal trial completion dates. Data as of November 21, 2024.

Cancer indication:

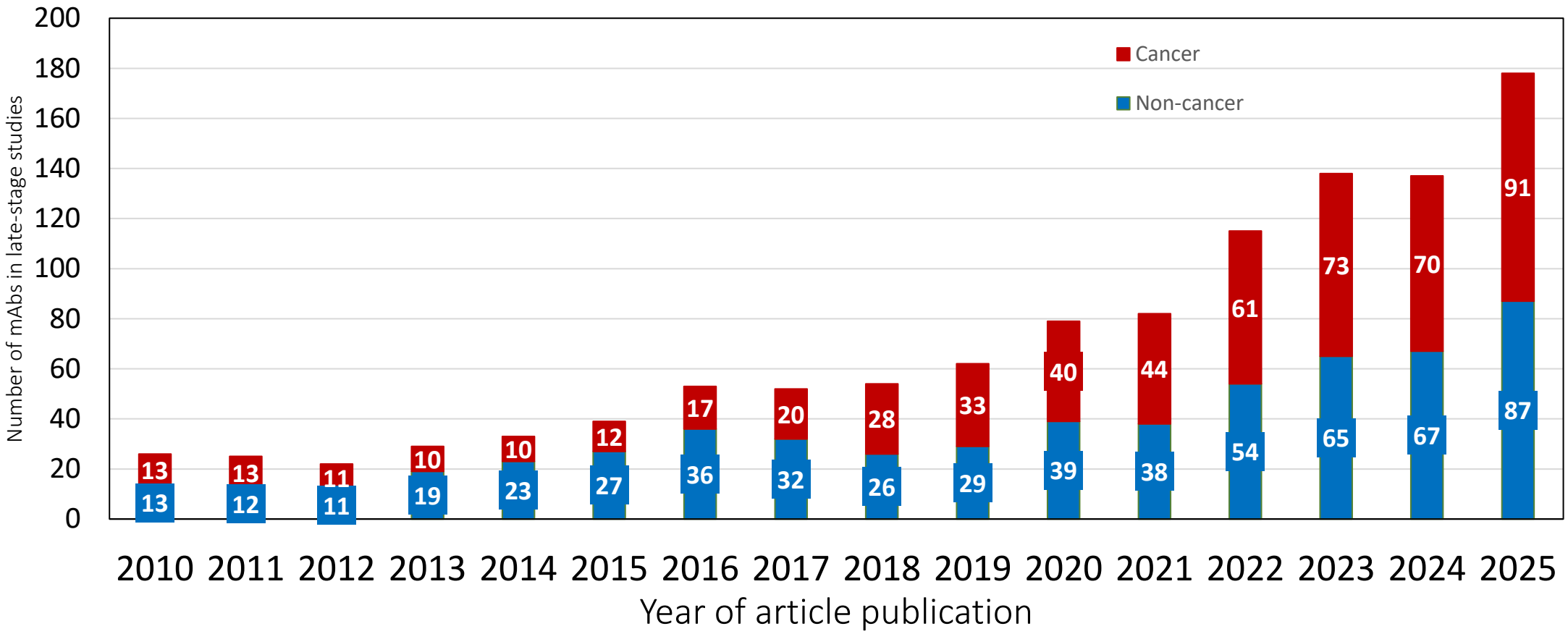
INN or drug code	Target(s); Format	Indication of relevant* late-stage study	Est. submission year, country#	Most advanced clinical phase
Erfonrilimab	PD-L1, CTLA-4; Humanized/chimeric IgG1, Bispecific	NSCLC	2024, China	Phase 3
Anbenitamab	HER2; Humanized IgG1k; biparatopic bispecific	NSCLC	2025, China	Phase 3
Nofazinlimab	PD-1; Humanized; IgG4k	Hepatocellular carcinoma	2025, China	Phase 3
Cobolimab	TIM3; Humanized IgG4k	NSCLC	2025H1, US, EU	Phase 3
Tiragolumab	TIGIT; Human IgG1k	NSCLC	2025	Phase 3

*Indication for which a regulatory submission is anticipated. #First marketing application submission dates and country are estimates based on company announcements and pivotal trial completion dates.

Data as of December 31, 2024.

Outlook for the future, 2010-25

Antibodies in late-stage studies over time



Data incl. late-stage studies listed as not yet recruiting on clinicaltrials.gov, excludes antibodies for COVID. Data from 'Antibodies to watch' articles published in *mAbs*. Table of antibodies in late-stage studies available at https://www.antibodysociety.org/antibodies-in-late-stage-clinical-studies.

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Key messages

- Antibody therapeutics with unconventional format (i.e., ADCs, bispecific/multispecifics, immunoconjugates) are entering clinical studies and being granted marketing approvals world-wide in increasing numbers recently.
- Success rates vary according to the format of therapeutic antibodies.
- 24 antibody therapeutics were granted a first approval in 2024, 2 so far in 2025, and 28 are currently in regulatory review in at least one country or region.
- Nearly half of the antibodies in regulatory review for first approval in US are in second cycle of review.
- Based on recent company disclosures, 16 investigational antibody therapeutics are forecast to enter regulatory review by the end of 2025.

Acknowledgements

- Antibodies to Watch
  - Dr. Silvia Crescioli (Business Intelligence Creator, The Antibody Society, Inc.)
  - Dr. Hélène Kaplon (Translational Medicine Department, Institut de Recherches Internationales Servier, France)
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  - Dr. Vaishali Kapoor (Washington University in St. Louis School of Medicine, US)
- Financial support and encouragement
  - The Antibody Society, and their members and corporate sponsors

Join The Antibody Society to keep up to date!

- The Antibody Society is a non-profit trade association
- Business intelligence focused on the commercial antibody therapeutic sector
  - Antibody News distributed via LinkedIn and email to members
    - Business deals, acquisitions, financing news
    - Regulatory agency designations, e.g., orphan drug, FT, PRIME
    - Antibodies entering first-in-human or more advanced clinical studies
    - Marketing application submissions and approvals in the US, EU and ROW
    - Withdrawals and terminations
  - Annual Antibodies to Watch article published in *mAbs*
  - Up-to-date data on late-stage pipeline, antibodies in regulatory review and approved can be downloaded from antibodysociety.org
  - Complete clinical pipeline data provided to corporate sponsors

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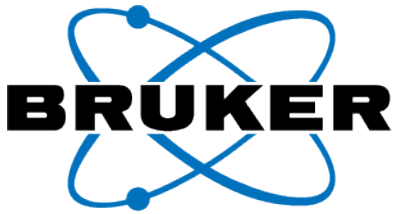
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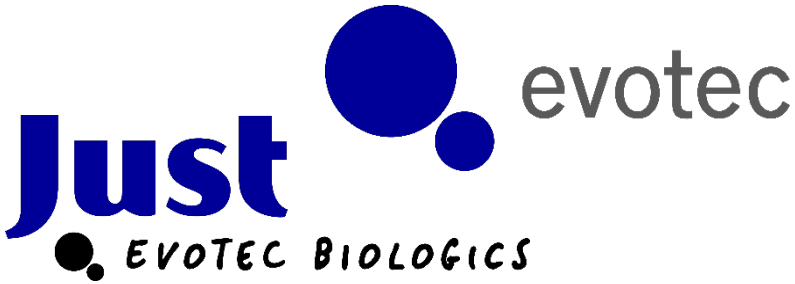
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