



Global Antibody Drug Industry Development Blue Book

2026

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■ Abstract

Antibody therapeutics, with their high specificity and clear targeting mechanisms, play a central role in treating cancer, autoimmune diseases, and other major conditions. The global development of antibody drugs has evolved from basic scientific discovery to clinical breakthroughs, with continuous iteration of key technologies and the emergence of landmark products, driving the industry from a single-mAb era toward diversified, engineered, and complex modalities. Fueled by growing demand, technological innovation, and structural upgrades, the global antibody market continues to expand steadily, with emerging categories such as ADCs and bispecific antibodies rising rapidly. Meanwhile, China's antibody industry, supported by favorable policies, mature technological systems, international expansion, and enhanced end-to-end capabilities, is increasingly shaping the global biopharmaceutical landscape.

Frost & Sullivan hereby releases the "Global Antibody Therapeutics Industry Bluebook" (hereinafter, the "Bluebook"), providing a systematic review of the global and Chinese antibody sectors, including market scale and structure, technology evolution, industry chain coordination, and emerging field strategies, aimed at offering industry, investment, and research stakeholders with structured insights and trend guidance.

■ Global Antibody Industry Continues Expansion with Accelerated Structural Upgrades

Driven by growing clinical demand, expanding indications, and technological innovation, the global antibody market continues to grow, with steady increases in sales across key segments. Monoclonal antibodies (mAbs) remain the market backbone, while emerging modalities such as bispecific antibodies and ADCs are rapidly rising due to higher therapeutic potential and broader indication coverage, accelerating overall market structural upgrades.

■ Parallel Development of Multiple Antibody Modalities, R&D Focus Shifting to Frontier Areas

mAbs continue to be optimized and maintain their foundational role, while bispecifics and ADCs expand rapidly as core innovation directions with widening indications. New formats, including multispecific antibodies, nanobodies, and fusion proteins, are increasingly entering R&D pipelines. Coupled with AI-assisted design and synthetic biology applications, antibody therapeutics are evolving toward more complex structures and multi-mechanism synergistic functions.

■ Enhanced Industry Chain Coordination, Localization, and Scale-Up

The antibody industry chain spans raw materials, process development, and clinical translation. Upstream raw materials and discovery platforms are increasingly integrated, and critical equipment is partially domestically sourced. Local CDMOs are gaining global market share, establishing end-to-end capabilities from process development to commercial supply.

■ China Market Enters High-Growth Phase, Internationalization Strengthens

Supported by policy, mature technology systems, and capital, the Chinese antibody market is accelerating, with innovation capacity and portfolio-based strategies gradually forming. Global transactions are active, and Chinese companies are expanding abroad through license-out agreements. Their service systems and quality standards are increasingly aligned with FDA and EMA requirements, enabling multi-region clinical trials, overseas registration, and global commercialization, with competition progressively extending toward globalization.

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Chapter 1

Overview



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1.1 Definition and Classification of Antibody Therapeutics

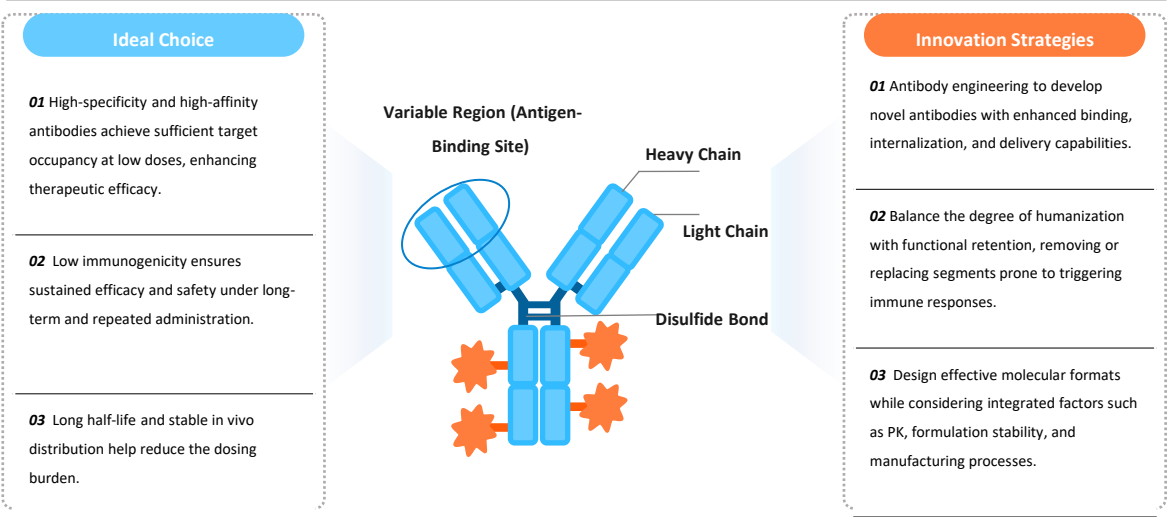
Antibody therapeutics occupy a central role in biomedicine due to their high specificity and targeted mechanisms.

1.1.1 Overview of Antibody Therapeutics

Antibody therapeutics are a class of biologics derived from antibody molecular structures. They function by utilizing exogenous antibodies to target disease-associated proteins. Through specific binding to surface domains of the target protein, these drugs modulate the biological functions of both the target proteins and relevant cell populations to exert therapeutic efficacy.

These drugs are characterized by high specificity, allowing precise targeting through recognition of defined epitopes; high affinity, ensuring stable and strong binding to enhance efficacy; low immunogenicity, with humanized designs minimizing host immune responses; and long half-life, maintained through FcRn-mediated recycling to provide stable blood concentrations, improving safety and patient compliance.

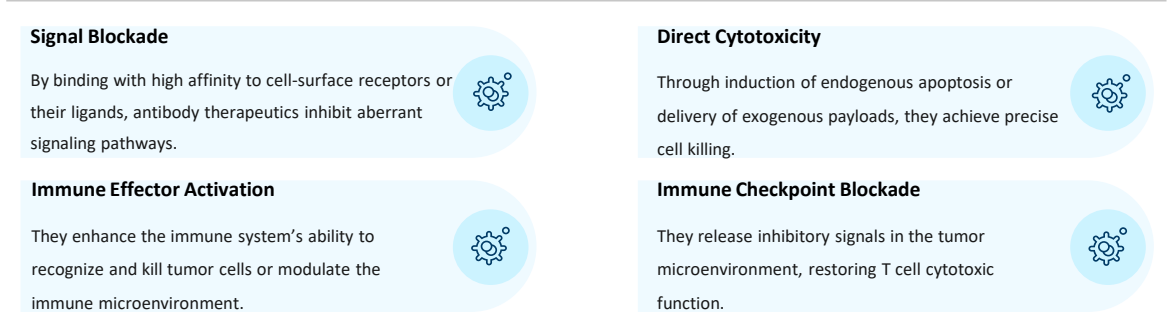
Figure: Antibody Structure Diagram



1.1.2 Mechanisms of Action of Antibody Therapeutics

Antibody therapeutics achieve multidimensional, synergistic treatment in oncology and autoimmune diseases through core mechanisms such as precise signal blockade, targeted cell killing, immune microenvironment activation, and immune checkpoint modulation, driving modern medicine toward precision therapy.

Figure: Key Mechanistic Principles for Exam Questions



Source: literature search, Frost & Sullivan Analysis

1.1 Definition and Classification of Antibody Therapeutics

Antibody drug structures are becoming increasingly complex, with more diverse mechanisms of action.

1.1.3 Antibody Therapeutics Categories

The evolution of antibody therapeutics is highly dependent on molecular structural engineering, as structural differences directly determine antibodies' behavior in target recognition, tissue penetration, immune activation, and ultimately their therapeutic potential. Classification based on structure reflects the diversity of functional mechanisms while highlighting differences in manufacturing complexity, clinical indications, and development pathways.

Engineered antibodies have become the main innovation frontier, with the industry focus shifting from “whether an antibody exists” to “how to design better antibodies.” Antibody structures have iterated along precise engineering pathways: from traditional IgG monoclonal antibodies with simple structures and standardized functions, to bispecific and multispecific antibodies combining multiple functional domains, to small functional fragments with unique tissue-penetrating capabilities, and further to antibody-drug conjugates (ADCs), which couple antibodies to cytotoxic payloads, continuously expanding design possibilities.

Monoclonal antibodies remain the market cornerstone

Represented by full-length IgG constructs, naked antibodies dominate oncology and autoimmune disease treatment due to their natural high specificity and long half-life. While competition in this segment is intense, centered on target innovation and biosimilar cost and market penetration, mature manufacturing processes and extensive clinical data ensure that mAbs will remain a key revenue driver in the near future.

Functional engineering enables high-value niche markets

Fc modifications, for instance, can precisely tune effector functions such as ADCC and CDC, optimizing the therapeutic window and enhancing product differentiation. Despite high specificity, single-target antibodies may face limitations against tumor heterogeneity and immune escape. Bispecific and multispecific antibodies overcome this by rational design, enabling a single molecule to engage multiple antigens, performing complex functions beyond the reach of natural IgGs, such as enforced immune synapse formation or synergistic signal blockade. Globally and in China, several companies have established bispecific/multispecific platforms supporting candidate discovery, structural screening, and manufacturability optimization, e.g., Roche's CrossMab, Regeneron's VelociMab, and Oncocan's FIT-Ig.

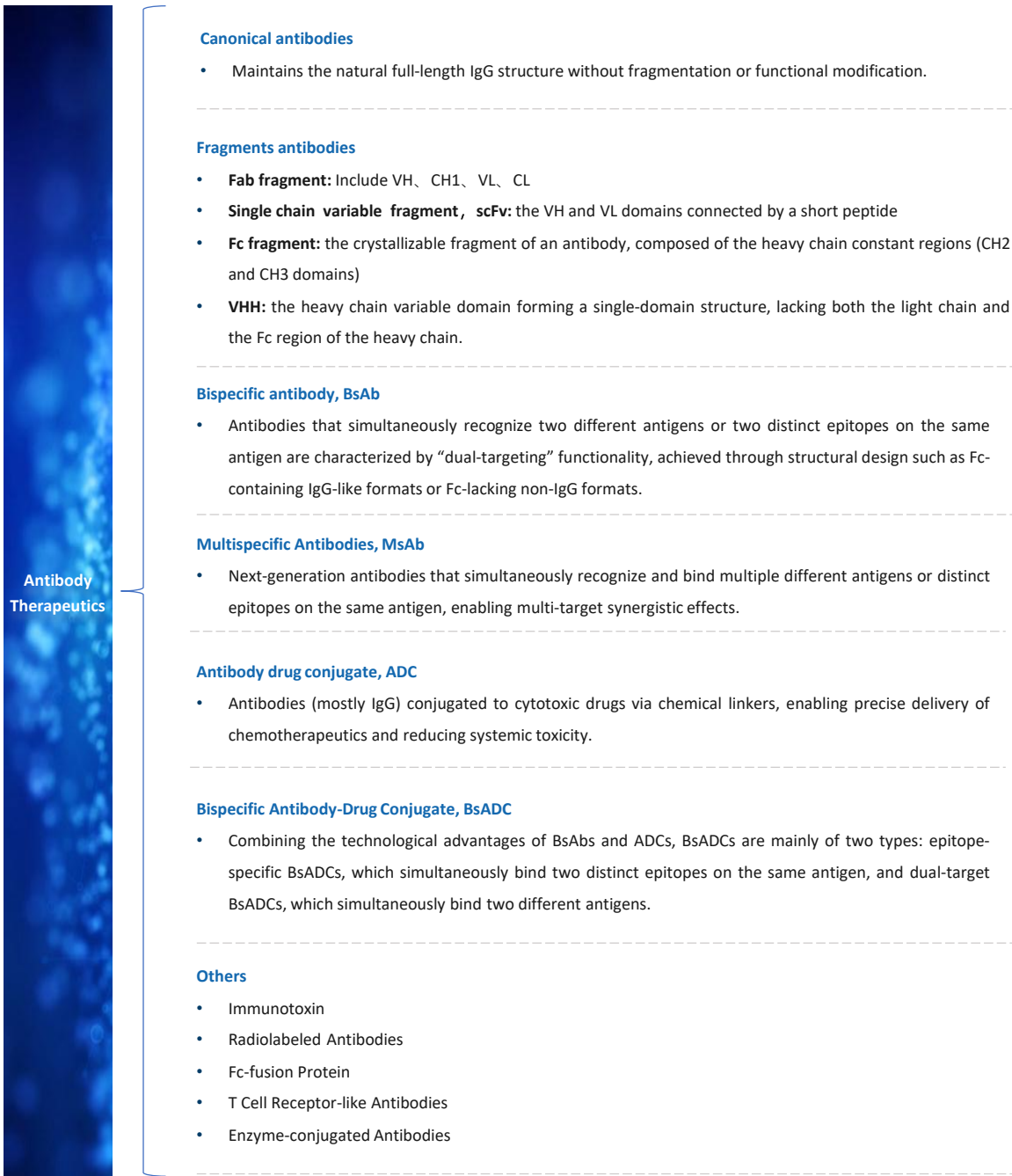
ADC technology addresses a clear clinical need: safely delivering potent cytotoxins to tumors while minimizing damage to normal tissues. Conventional chemotherapy lacks specificity and has a narrow therapeutic window, whereas antibodies alone offer targeting but limited cytotoxicity. ADCs combine these advantages, using antibodies as “guidance systems” to precisely deliver cytotoxic payloads. Advances in platform technology are now enabling more complex formats, such as bispecific ADCs (BsADCs), combining dual-targeting with potent cytotoxic effects.

Fragmentation and miniaturization open new applications

To overcome the limitations of full-length antibodies, smaller fragments such as Fab, scFv, and nanobodies have been developed. Their unique pharmacokinetics enable applications in radiological imaging, CNS diseases requiring blood-brain barrier penetration, and as building blocks for more complex synthetic biology constructs. In particular, nanobodies, with stable structures and ease of prokaryotic production, improve dosing convenience and expand therapeutic versatility.

1.1 Definition and Classification of Antibody Therapeutics

Figure: Structural Classification of Antibody Therapeutics



Source: literature search, Frost & Sullivan Analysis

1.2 Global and Chinese Antibody Industry Development History

The global antibody therapeutics industry has evolved from basic scientific discoveries to clinical breakthroughs, with key technologies and landmark products continuously driving the sector toward a new stage of diversification, engineering, and intelligent innovation.

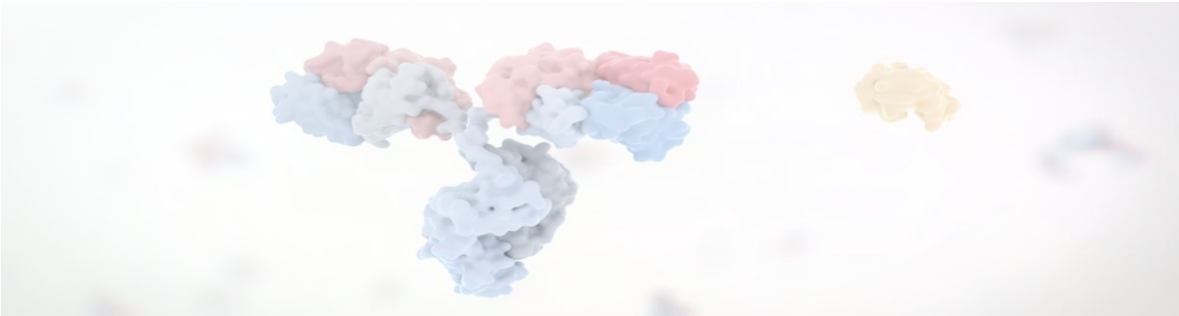
1.2.1 Evolution of the Global Antibody Therapeutics Industry

The global antibody therapeutics industry has evolved through a long trajectory from scientific exploration to commercialization and continuous innovation. In the 1970s, César Milstein and Georges Köhler invented hybridoma technology, enabling the first production of monoclonal antibodies from a single B cell. This breakthrough provided a robust foundation for large-scale in vitro production of highly specific, structurally uniform, and stable antibodies, laying the scientific groundwork for modern antibody therapeutics. In 1986, the first monoclonal antibody drug, OKT3, was approved, greatly stimulating antibody research and marking the beginning of industrialized antibody therapeutics. During the 1990s, chimeric and humanized antibody technologies matured, using recombinant DNA to reduce immunogenicity and significantly improve safety and efficacy. In 1997, the first humanized antibodies were approved by the FDA, representing the industrialization of humanized engineering approaches. The chimeric antibody rituximab, launched in 1997, became the first blockbuster antibody drug, driving widespread application in oncology and immune diseases.

Following rituximab, antibody development entered an accelerated phase. In 1998, trastuzumab was approved, demonstrating the clinical and commercial value of humanized antibodies in precise tumor targeting. In 2002, adalimumab was approved and became one of the first commercially successful fully human therapeutic antibodies, propelling rapid growth in the autoimmune field. It showed outstanding efficacy in rheumatoid arthritis and became the first antibody therapeutic with global sales exceeding \$10 billion. Fully human antibodies gradually became a mainstream research trend. Between 2018 and 2024, the FDA approved 65 innovative antibodies, of which 22 were fully human (33.8% of total approvals). During the same period, the NMPA approved 84 innovative antibodies, including 34 fully human antibodies (40.5% of approvals).

In the 21st century, phage display technology and Fc engineering further expanded antibody screening and effector functions, driving diversification. Early ADCs, exemplified by gemtuzumab ozogamicin (2000), underwent iterative optimization of linkers, payloads, and conjugation methods, reaching rapid development in the 2010s. During the same decade, bispecific antibodies and nanobodies were commercialized: catumaxomab (2009, EU) validated early bispecific antibody commercialization, blinatumomab (2014) enabled broader clinical use of T cell–redirecting bispecifics, and caplacizumab (2018, EU) marked the first approved nanobody with advantages in small size, tissue penetration, and distribution.

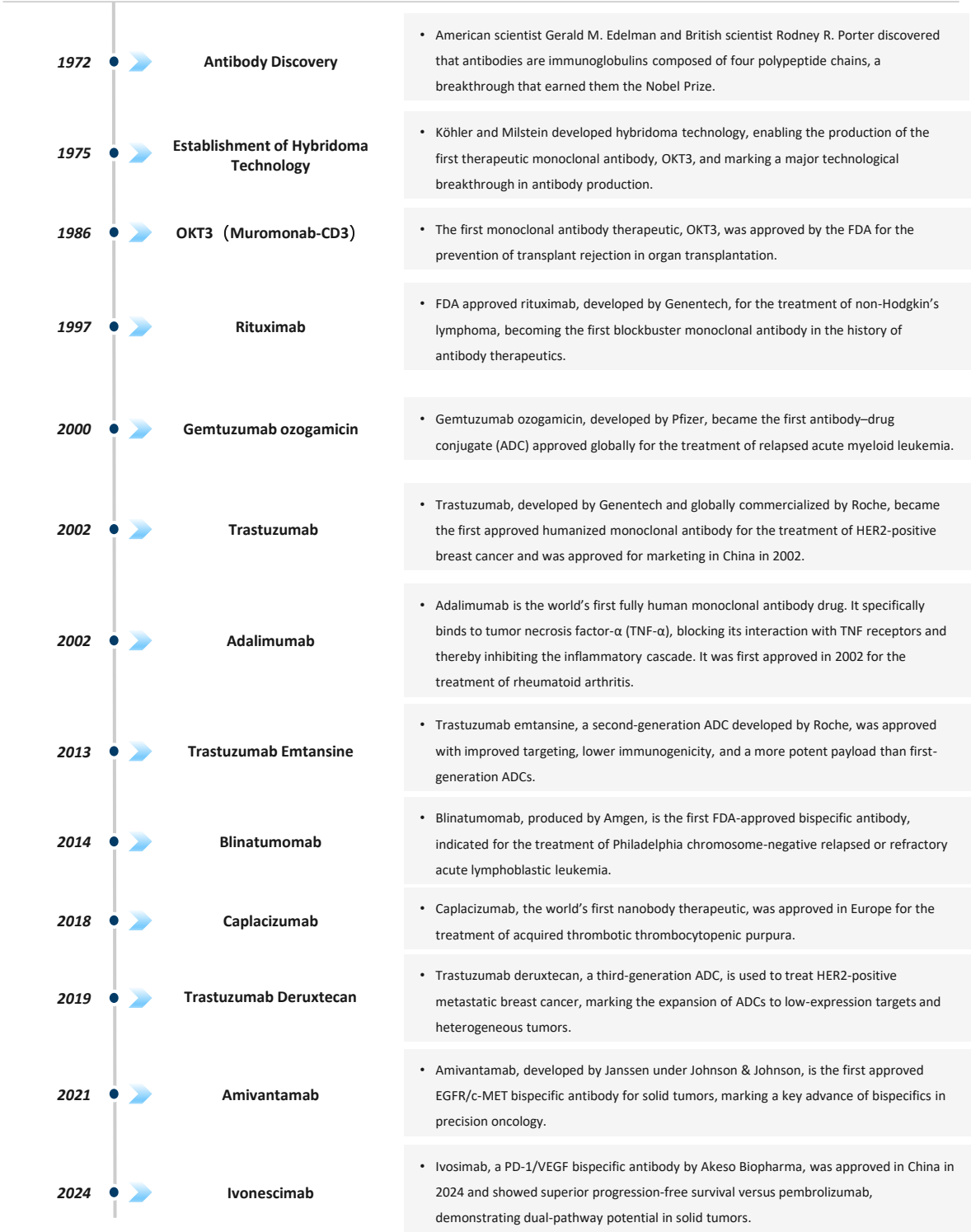
Recently, artificial intelligence, deep learning, and synthetic biology have been integrated into antibody R&D, enhancing structural prediction, affinity optimization, and discovery efficiency, while enabling innovative modalities such as multi-target and conditionally activated antibodies. Overall, each key breakthrough has not only introduced new antibody formats but also expanded applications and market potential. With the growth of biosimilars and mature platform manufacturing, industry competition is increasingly stratified, balancing innovation with cost efficiency.



Source: literature search, public information, Frost & Sullivan Analysis

1.2 Global and Chinese Antibody Industry Development History

Figure: Key Milestones in Global Antibody Therapeutics Development



Source: public information, Frost & Sullivan Analysis

1.2 Global and Chinese Antibody Industry Development History

China's antibody industry has evolved from imitation to independent innovation, emerging as a significant new force in the global biologics landscape.

1.2.2 Development Stages of China's Antibody Industry

Overall, China's antibody industry has progressed from early-stage technology accumulation toward international expansion. Driven by supportive policies, local advantages in cost and production efficiency, and continuous advancement in original technologies, the industry's competitiveness is steadily strengthening. Past gaps are gradually being addressed, providing a solid foundation for Chinese companies to compete globally and expand overseas.

1.0 Technology Introduction and Industrialization Exploration (2000-2014)

The early development of China's antibody industry was marked by technology introduction and domestic industrialization from scratch. Based on China–Germany biopharma collaboration, Betta Pharmaceuticals explored humanized antibody technologies for commercialization. In 2008, Nimotuzumab (Thixin®) was approved in China and is widely recognized as the country's first domestically produced humanized monoclonal antibody. Reports indicate that it generated around RMB 60 million in sales within the first reporting year, demonstrating initial commercial viability. During this period, China's antibody industrialization system was still nascent. Key manufacturing processes and supporting capabilities were relatively weak, some equipment and consumables relied on external supply, and regulatory review and industrialization efficiency required improvement, highlighting the need for systematic development in cost control and supply chain management.



2.0 Policy-Driven Growth and Rise of Biosimilars (2015-2019)

In December 2017, China issued the "Opinions on Encouraging Drug Innovation through Priority Review", defining 18 scenarios—including urgently needed oncology and rare disease drugs—as eligible for accelerated review. This spurred the approval of clinically valuable antibodies for difficult-to-treat malignancies. Annual antibody approvals jumped from 10 in 2007–2016 to an average of ~20 per year from 2017–2024, driving domestic process upgrades, though imports remained dominant. Since 2015, the CFDA's "Technical Guidelines for Biosimilar R&D (Trial)" guided local biosimilar development. In 2019, Fosun Pharma's Hanlikang, a rituximab biosimilar, became the first locally developed antibody biosimilar approved, reducing treatment costs and improving accessibility through market competition.



3.0 Innovation Breakthroughs and International Expansion (2020-2026)

Chinese antibody drugs have entered a new phase of original innovation and global expansion. By 2021, domestic products accounted for nearly 40% of NMPA-approved antibodies, with multiple milestones: conditional approval of Vedicitumab (domestic ADC) in June; Envrolimab (subcutaneous PD-L1 antibody) in November; and emergency approval of Ambavimab/Romiscivimab combination therapy in December. In October 2023, the domestic PD-1 antibody Toripalimab-tpzi gained FDA approval for nasopharyngeal carcinoma, demonstrating the ability of Chinese antibodies to achieve registration and commercialization under overseas regulatory frameworks. The industry is rapidly internationalizing and gaining global recognition. International collaboration has surged: outbound licensing deals grew from 17 deals worth \$2.2 B (2020) to 71 deals totaling \$68.9 B (2025), reflecting enhanced innovation and competitiveness, with overseas partnerships increasingly driving long-term market growth. In terms of accessibility, dynamic insurance listing and negotiation mechanisms expanded antibody coverage: from 2017–2024, 66 innovative biologics (110 products) were added to the insurance catalog, with average price reductions of ~57.6%. For example, Sintilimab saw a 63.7% price cut in 2020, broadening patient access and supporting "volume-for-price" strategies. The national biologics centralized procurement system is also advancing: in January 2025, Anhui proposed leading a nationwide alliance, and by August 2025, data collection for selected monoclonal antibodies began, marking key preparatory steps for alliance procurement.

Source: public information, Frost & Sullivan Analysis

1.3 Antibody Industry Value Chain Analysis

The antibody therapeutics value chain spans from raw material preparation and process development to clinical translation, with standardization and scalability becoming key drivers of cost efficiency and innovation.

1.3.1 Antibody Therapeutics Value Chain

The antibody therapeutics industry spans a structured value chain from R&D to commercialization. Upstream provides key materials and technology platforms such as antigen preparation, antibody screening tools, cell culture media, and vectors. Midstream focuses on candidate optimization, engineering, preclinical research, process development, and GMP manufacturing, enabling clinical entry and scalable production. Downstream covers hospital use, market access, and commercialization, determining real-world adoption and market growth. With continued policy support, the industry is increasingly moving toward higher value-added segments.

Upstream

Raw Material Supply and Technology Service Platforms: The Foundation and Source of Industry Innovation

The upstream segment of the antibody therapeutics value chain provides standardized raw materials, equipment, and consumables, together with technology platforms such as animal models, gene editing, and antibody discovery. These capabilities improve supply stability, cost control, and early-stage R&D efficiency, supporting continuous pipeline development and industrialization. As antibody structures become more complex, higher requirements are placed on cell line stability, expression systems, process scale-up, and analytical capabilities. At the same time, the upstream market has long been dominated by a few global leaders, and supply chain fluctuations have highlighted reliance on imported media, reagents, bioreactors, and model systems, driving increased focus on localized supply and technology platform development.

Upstream companies can generally be grouped into three categories: (1) raw material and reagent suppliers that influence cell culture performance and experimental reproducibility; (2) equipment and consumables providers, such as single-use bioreactors, supporting process development, scale-up, and production; and (3) technology platform and model providers, including animal models, gene editing, and antibody discovery platforms, which support target validation, pharmacology studies, and candidate screening in early-stage research. Some platform companies further extend into third-party R&D outsourcing services, covering stages from target discovery to preclinical research.

Figure: Types of Enterprises in the Upstream Antibody Therapeutics Value Chain

Enterprise Type	Examples	Introduction
Raw Material Supplier Providing culture media, tool enzymes, antigens, etc.	Thermo Fisher Scientific 	Its Gibco and HyClone brands provide culture media for cell lines such as CHO and HEK293
	Merck 	Sigma-Aldrich supplies chemically defined media and serum-free media
	NEB 	provides restriction enzymes, including recombinant forms, covering most commonly used cleavage sites
Equipment/Consumables Bioreactors, purification systems, etc.	Cytiva 	Xcellerex XDR single-use bioreactors, Allegro STR single-use bioreactors
	Sartorius 	BIOSTAT STR single-use bioreactors, Ambr 250 high-throughput miniature bioreactors
	Tofflon 	Cover benchtop, stainless-steel, and single-use systems
	Duoning 	single-use bioreactor platforms such as the DuoBioX Pro series and DuoWave wave systems
Tech Platforms & Models	Cyagen 	own proprietary fully human antibody mouse models, offering large-scale, standardized gene-edited animal model libraries and services
R&D Outsourcing	Cyagen 	Offer integrated CRO services covering antibody discovery, pharmacology evaluation, and preclinical research
	Viva 	Services include target antigen preparation, functional antibody screening, cell line development, and antibody expression

Source: public information, Frost & Sullivan Analysis

1.3 Antibody Industry Value Chain Analysis

Midstream

Developers and Manufacturers: Translating Innovations into Clinical Products

Midstream R&D companies are primarily responsible for developing antibody molecules with therapeutic value or novel mechanisms, tackling traditionally “undruggable” targets and designing new functional approaches such as protein degradation, endocytosis promotion, or signal complex remodeling, while focusing on key cell populations and pathways in complex diseases like tumors, neuroinflammation, and fibrosis. Discovery of these molecules relies on advanced platforms, including single-cell sequencing to isolate high-affinity, naturally paired antibodies from immunized animals or convalescent donors, and large-capacity synthetic libraries using phage or yeast display for directed screening. As antibodies progress toward commercialization, midstream roles extend to CMC process development, GMP production, and quality control, ensuring candidate molecules can be efficiently, stably, and compliantly manufactured. Monoclonal antibodies emphasize process optimization and cost-effective scale-up, bispecific antibodies face challenges in structural stability, chain mispairing, and scale-up consistency, and ADCs require precise conjugation, in vivo stability, and uniform drug-to-antibody ratios, demanding integrated biochemical and bioprocess capabilities.

To meet these challenges, companies are establishing standardized, modular processes from cell line development to purification and scale-up, while partnering with CDMOs to enhance R&D-manufacturing integration, shorten development timelines, and control costs without compromising safety or product consistency.

Figure: Representative Enterprises in the Midstream of the Antibody Drug Industry Chain

Enterprise Field	Examples	Representative Products or Services
mAb R&D and Manufacturing Enterprises	BeiGene  百济神州	Sintilimab (TEVIMBRA®): As of H1 2025, it has been approved in over 65 markets, including the US, Europe, and Japan, making it one of the PD-1 inhibitors with the most approved indications.
	Innovent Biologics  信达生物制药	Sintilimab (Tyvyt®): It is one of the earliest PD-1 inhibitors in China to achieve rapid market uptake through national reimbursement negotiations.
	Affinity Biopharmaceutical  AFT 复星医药	IMD-303: Engineered antibodies featuring tumour microenvironment activation/conditioned activation design for solid tumour therapy
bsAb R&D and Manufacturing Enterprises	EpimAb Biotherapeutics 	Currently there is no EGFR/cMET bispecific antibody approved for colorectal cancer worldwide. EMB-01 is the first such antibody globally to enter Phase II clinical trials in this field.
	Akeso 	Cadonilimab (开坦尼®): The world's first approved PD-1/CTLA-4 bispecific antibody, offering a new treatment option for patients with advanced cervical cancer.
ADC R&D Enterprises	Kelun-Biotech  凯伦生物	Sacituzumab Tirumotecan (佳泰莱®): The first domestically developed TROP2 ADC in China to receive full regulatory approval, with its lung cancer indication filling the gap for post-line treatment of EGFR-mutant lung cancer in the country.
	RemeGen  荣昌生物	Disitamab Vedotin (爱地希®): The first ADC approved in China, demonstrating its unique value in gastric cancer, urothelial carcinoma, and liver-metastatic breast cancer.
Nanobody Drug R&D Enterprises	Alphamab Oncology  康宁杰瑞	Envafolimab (恩维达®) is the world's first subcutaneously administered PD-L1 inhibitor. Leveraging the small molecular weight and high stability of its nanobody, it can be formulated at high concentrations, enhancing dosing convenience.
CDMO	WuXi Biologics 	The expanded services cover drug discovery, clinical development, and commercial manufacturing, supporting modalities including monoclonal antibodies, bispecific antibodies, and ADCs.

Downstream

Clinical Application and Commercialization

As antibody drug indications expand and patient populations grow, downstream development is increasingly focused on building a closed-loop ecosystem spanning clinical research, regulatory access, commercialization, and patient education to fully realize industrial value.

Meanwhile, the domestic innovation environment is improving. Future reimbursement reforms—such as clearer innovation drug classification, optimized renewal rules, and dedicated pricing pathways for commercial insurance—may provide more rational pricing mechanisms and more stable market expectations for truly innovative antibody therapeutics.

Source: public information, Frost & Sullivan Analysis

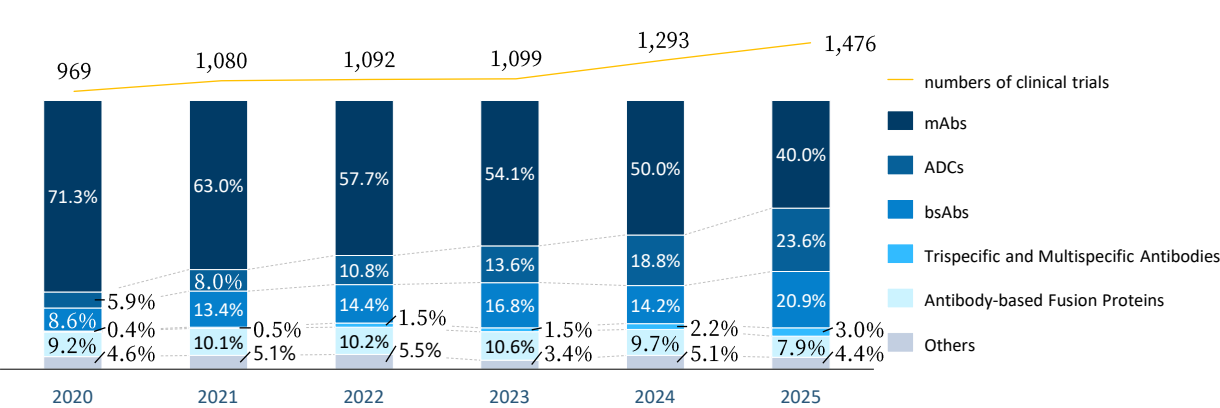
1.4 Global and China Antibody Therapeutics R&D Landscape

The number of antibody therapeutics entering clinical trials globally and in China has steadily increased, with monoclonal antibodies remaining the dominant modality, while recent R&D has increasingly focused on bispecific antibodies and ADCs.

1.4.1 Global Distribution of Antibody Therapeutics by Modality in Clinical Trials

The number of antibody therapeutics entering clinical trials globally has increased year by year. While the number of traditional monoclonal antibody trials has gradually declined, they still account for the largest share overall. In contrast, ADCs and bispecific antibodies have shown strong and sustained growth: from 2020 to 2025, the share of ADC trials rose rapidly from 5.9% to 23.6%, making it the fastest-growing category, while the share of bispecific antibody trials increased steadily from 8.6% to 20.9%.

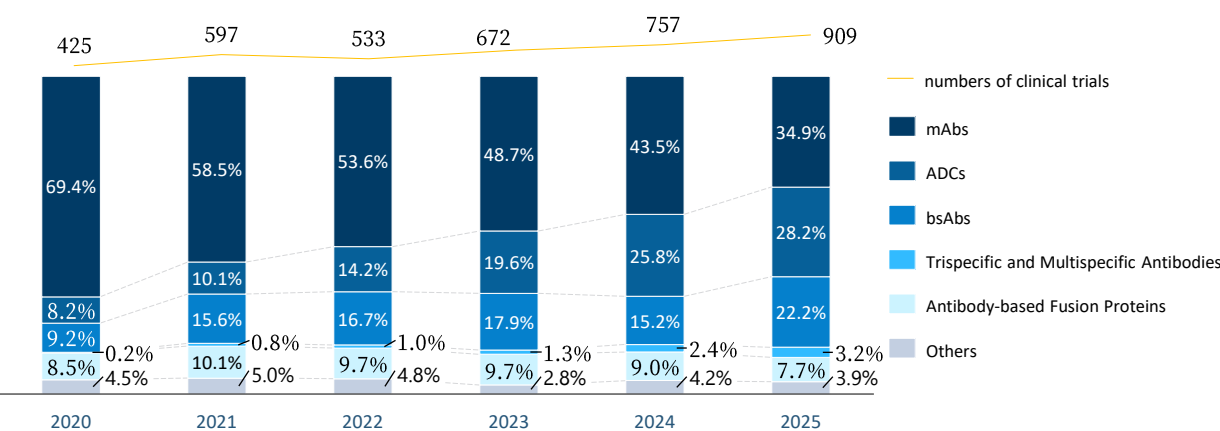
Figure: Global Number of Antibody Therapeutics Entering Clinical Trials and Distribution by Modality, 2020-2025



1.4.2 Distribution of Antibody Therapeutics by Modality in Clinical Trials in China

China’s antibody drug R&D trends align with global patterns, with the development focus shifting from monoclonal antibodies to higher-potential platforms such as ADCs and bispecific antibodies. The overall number of antibody therapeutics entering clinical trials in China has steadily increased, with traditional monoclonal antibodies remaining the dominant category. Meanwhile, ADCs and bispecific antibodies have shown strong growth: ADC trials surged from 35 in 2020 to 256 in 2025, while bispecific antibody trials increased from 39 to 202. Additionally, clinical trials for trispecific/multispecific antibodies and antibody-based fusion proteins have also steadily risen.

Figure: Number of Antibody Therapeutics Entering Clinical Trials in China and Distribution by Modality, 2020-2025



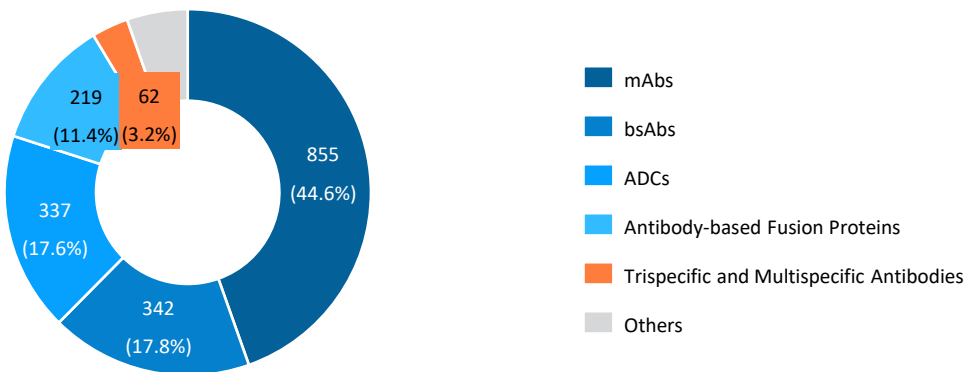
Source: CDE, ClinicalTrials.gov, Frost & Sullivan Analysis

1.4 Global and China Antibody Therapeutics R&D Landscape

1.4.3 Global Distribution of Antibody Therapeutics in Clinical Development by Modality

From 2020 to 2025, monoclonal antibodies dominated the global clinical pipeline with 855 ongoing trials, holding an absolute leading position. Bispecific antibodies and ADCs followed with 342 and 337 trials, respectively, forming the core of current next-generation antibody R&D. In addition, antibody-based fusion proteins (219 trials) have maintained significant R&D activity. Although trispecific and multispecific antibodies (62 trials) currently represent a smaller share, they point to important directions for future innovation.

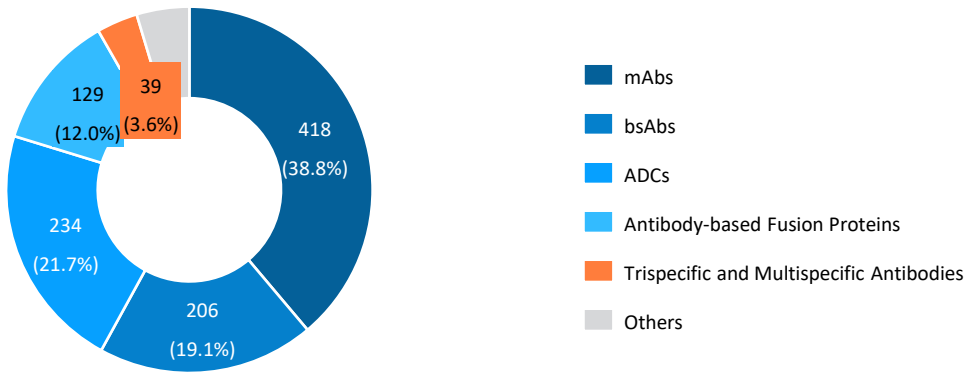
Figure: Global Number of Antibody Therapeutics in Clinical Development and Distribution by Modality, 2020-2025



1.4.4 China Distribution of Antibody Therapeutics in Clinical Development by Modality

From an overall perspective, monoclonal antibodies hold an absolute lead with 418 ongoing trials, forming the backbone of China’s antibody drug development pipeline. Meanwhile, bispecific antibodies (206 trials) and ADCs (234 trials) have emerged as the two core innovative directions, with trial numbers significantly ahead of other emerging categories. Antibody-based fusion proteins (129 trials) also maintain strong R&D activity. Although trispecific and multispecific antibodies (39 trials) currently represent a smaller share, they indicate active exploration in frontier technologies. Overall, China’s antibody R&D landscape mirrors global trends: while monoclonal antibodies remain dominant, resources are increasingly focused on advancing the two most promising areas—bispecific antibodies and ADCs.

Figure: China Number of Antibody Therapeutics in Clinical Development and Distribution by Modality, 2020-2025



Source: CDE, ClinicalTrials.gov, Frost & Sullivan Analysis

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Chapter 2

Analysis of the Current Status and Future Trends of the Global Antibody Industry



02

2.1 Global Antibody Therapeutics Market Size and Growth Trends

The global antibody therapeutics market continues to grow steadily, with ADCs and bispecific antibodies driving expansion into higher-value products and broader indications.

2.1.1 Global Market Size and Market Structure Analysis

In the global antibody therapeutics field, molecular formats continue to evolve, including multispecific and cell-engaging constructs, while clinical applications expand from hematologic malignancies to solid tumors and from later-line to earlier-line treatment. The global antibody therapeutics market grew from US\$177.1 billion in 2020 to US\$254.3 billion in 2024, and is projected to reach US\$457.9 billion by 2030 and US\$675.7 billion by 2035.

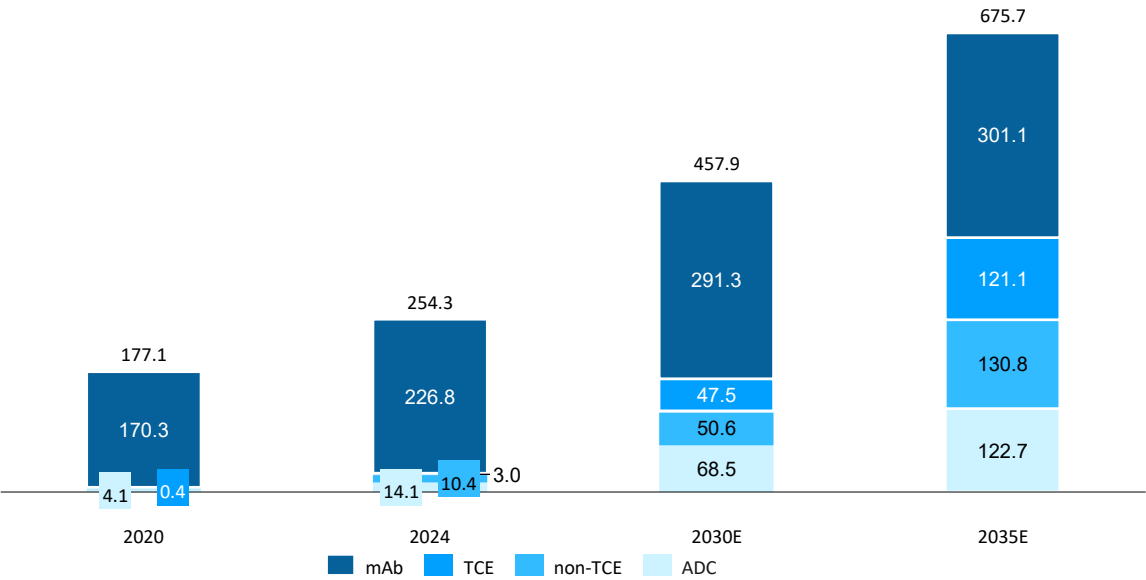
Market growth increasingly reflects platform evolution rather than reliance on traditional monoclonal antibodies alone. While monoclonal antibodies grow steadily, TCEs, non-TCE multispecific antibodies, and ADCs are expected to deliver faster growth. By 2035, ADCs are projected to expand from US\$14.1 billion (5.6%) in 2024 to US\$122.7 billion (18.2%), non-TCE multispecific antibodies from US\$10.4 billion (4.1%) to US\$130.8 billion (19.4%), and TCEs from US\$3.0 billion (1.2%) to US\$121.1 billion (17.9%).

Although monoclonal antibodies remain the largest segment, their share is expected to decline from 96.2% in 2020 to 44.6% by 2035, as the market shifts toward TCEs, multispecific antibodies, and ADCs. Regulatory progress is also accelerating this trend—for example, tarlatamab (DLL3×CD3) received FDA accelerated approval in May 2024 for small cell lung cancer.

Figure: Global Antibody Therapeutics Market Size (2020-2035E)

Unit: US\$ Billion

CAGR	mAb	TCE	Non-TCE	ADC	total
2020-2024	7.4%	67.6%	45.2%	36.6%	9.5%
2024-2030E	4.3%	58.6%	30.2%	30.1%	10.3%
2030E-2035E	0.7%	20.6%	20.9%	12.4%	8.1%



Source: public information, Frost & Sullivan Analysis

2.1 Global Antibody Therapeutics Market Size and Growth Trends

2.1.2 Analysis of Drivers and Constraints in the Global Antibody Industry

The global antibody therapeutics industry is entering a new cycle characterized by intensive innovation and increasing global integration. Continuous clinical value realization and technological breakthroughs are creating new market opportunities, while challenges such as growing competition, product homogeneity, and cost pressures are accelerating industry evolution. In this globalized landscape, antibody developers need to build integrated capabilities in clinical value creation, manufacturing efficiency, and market adaptability to secure a competitive position in the industry’s future transformation.

Figure: Drivers and Constraints in the Global Antibody Industry

Drivers	Constraints
Unmet Medical Needs Driving Market Expansion Antibody drugs have demonstrated superior efficacy in high-burden therapeutic areas, particularly in oncology and autoimmune diseases where traditional therapies are limited. There is a robust patient demand for precise, safe, and long-term therapeutic solutions.	High Costs Hindering Global Accessibility Antibody development is capital-intensive across R&D, manufacturing, quality control, and cold-chain logistics. Exorbitant annual treatment costs remain a significant barrier to adoption, particularly in low- and middle-income countries.
Structural Innovation Powering Product Upgrades Global innovators are moving beyond traditional IgG structures to advance novel formats like BsAbs, ADCs, nanobodies, and Fc-engineered proteins. These innovations address complex biological mechanisms, enhancing efficacy and safety while building strong patent barriers and premium pricing potential.	Target Overcrowding and Homogenized Competition The global market faces intense "involution" around popular targets, leading to a surplus of "me-too" and "me-better" products. This results in overlapping positioning and escalating price wars. In mature markets (US, EU, Japan), newcomers face high barriers without clear differentiation or robust clinical data.
AI and Bioengineering Accelerating R&D Efficiency The integration of antibody engineering with AI, high-throughput screening, and AlphaFold structure prediction is significantly shortening cycles from target discovery to candidate optimization. This paradigm shift reduces both technical thresholds and financial barriers for enterprises.	Cost-Containment Pressures Impacting Biologics Global healthcare systems are tightening access and pricing negotiations for biologics. Trends such as biosimilar substitution in the West, budget caps in Japan, and Volume-Based Procurement (VBP) in China are forcing developers to refine their pricing, market access, and indication strategies.
New Paradigms Mitigating Capital Cycle Volatility The maturity of global CRO/CDMO sectors has integrated the value chain from cell line development to GMP manufacturing. By transforming antibody drug development from "capital-intensive" to "platform-enabled" via modular processes, R&D firms can better navigate capital cycle fluctuations and achieve sustainable innovation.	Rising Supply Chain Security and Geopolitical Risks The antibody industry relies on highly globalized collaboration for cell banks, raw materials, and clinical trials. Recent geopolitical shifts, export restrictions, and technical barriers have made supply chain stability a critical and mandatory variable for global pharmaceutical companies.

Source: public information, Frost & Sullivan Analysis

2.2 China Antibody Therapeutics Market Overview and Growth

Potential

China’s antibody therapeutics market is entering a high-growth phase, driven by policy support, technological advancement, and capital investment, demonstrating strong innovation potential and global competitiveness.

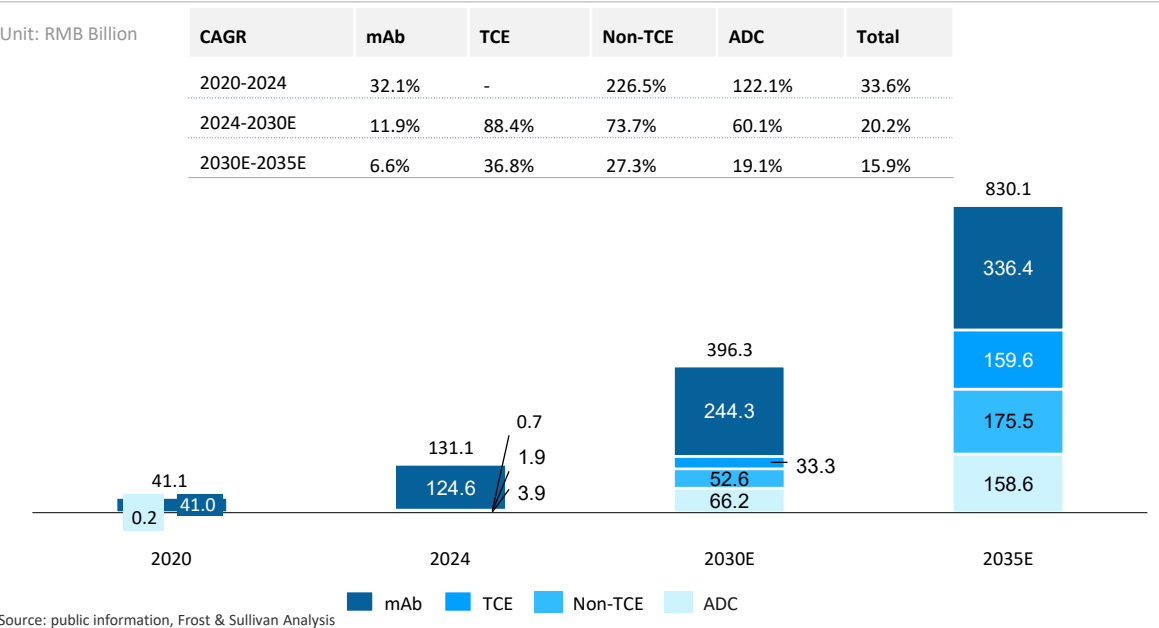
2.2.1 China Market Size and Market Structure Analysis

China’s antibody therapeutics market is entering a new phase of rapid growth. In 2024, the market size reached RMB 131.2 billion, and is projected to expand to RMB 396.4 billion by 2030 and further to RMB 830.1 billion by 2035. The market is expected to grow at a CAGR of 20.2% from 2024 to 2030, followed by 15.9% from 2030 to 2035. This growth is not driven solely by the expansion of existing indications, but also by continuous innovation in antibody therapeutics that is reshaping treatment paradigms and increasing the value per product.

On one hand, monoclonal antibodies have already established mature clinical applications in major indications such as oncology and autoimmune diseases. With broader reimbursement coverage and improved accessibility, their growth is mainly driven by increasing penetration and expansion of the treated patient population. The monoclonal antibody market is projected to grow from RMB 124.6 billion in 2024 to RMB 244.3 billion by 2030, nearly doubling, and further to RMB 336.4 billion by 2035, reflecting continued adoption under expanding reimbursement coverage.

On the other hand, high-technology modalities such as bispecific antibodies and ADCs are scaling rapidly, indicating a structural shift in market growth. Even with relatively stable patient populations, clearer patient stratification, improved clinical benefits, and higher technological and manufacturing barriers are raising the treatment value per patient and accelerating commercialization. The bispecific antibody market is projected to increase from RMB 2.6 billion in 2024 to RMB 85.9 billion by 2030, reaching RMB 335.1 billion by 2035. Among these, TCE bispecific antibodies are expected to grow from RMB 0.75 billion in 2024 to RMB 33.3 billion by 2030 and RMB 159.6 billion by 2035, with a CAGR of 88.4%, highlighting strong potential in cancer immunotherapy. Non-TCE bispecific antibodies are also projected to expand from RMB 1.9 billion in 2024 to RMB 52.6 billion by 2030 (CAGR 73.7% during 2024–2030) and RMB 175.5 billion by 2035. Meanwhile, the ADC market is expected to grow from RMB 3.9 billion in 2024 to RMB 66.2 billion by 2030 and RMB 158.6 billion by 2035, with a CAGR of 60.1% from 2024 to 2030.

Figure: China Antibody Therapeutics Market Size (2020-2035E)



2.2 China Antibody Therapeutics Market Overview and Growth

Potential

China’s antibody therapeutics market is rapidly evolving toward a new landscape centered on combinational innovation and global competition, driven by policy support, maturing technology platforms, international expansion, and strengthened full-industry-chain capabilities.

2.2.2 Analysis of Key Drivers of China’s Antibody Industry

2.2.2.1 Policy Support and Institutional Incentives: Laying the Foundation for Development

 **Top-Level Strategy and Macro Planning: Establishing the strategic importance of biopharmaceuticals and promoting innovation-driven development**

Policy	Date	Authority	Core Meaning
"Healthy China 2030" Planning Outline	2016.10.25	CPC Central Committee; State Council	Centered on the theme of "Joint Contribution, Shared Benefits, and Health for All," it aims to improve the collaborative innovation system among government, industry, academia, research, and clinical sectors. It prioritizes the development of biologics, strengthening R&D for new drugs, and sets the goal of aligning drug quality standards with international levels by 2030 to enter the ranks of global pharmaceutical powerhouses.
14th Five-Year Plan for Bioeconomy Development	2022.5.10	NDRC	Aimed at building national strategic sci-tech strength in biotechnology by reinforcing key technology breakthroughs and optimizing market access and medical insurance policies. It provides essential support for industrial growth through increased fiscal, tax, and financial incentives, as well as the cultivation of a professional talent pipeline.
14th Five-Year Plan for Pharmaceutical Industry Development	2021.12.22	Nine departments including the NMPA	Focuses on high-quality development driven by innovation to safeguard public health. Key tasks include advancing the R&D of innovative drugs like antibodies and ADCs, achieving breakthroughs in industrialization technologies, optimizing industrial layouts to create high-level clusters, and deepening international collaboration to facilitate high-quality "bringing in" and "going out."
Opinions on Deepening Regulatory Reform of Drugs and Medical Devices to Promote High-Quality Industry Development	2025.1.3	State Council	Intends to deepen regulatory reforms by optimizing review and approval mechanisms and accelerating the market entry of clinically urgently needed products. It seeks to establish a modernized supervision and standard system, promote the application of innovative products through medical insurance payment integration, and ultimately drive the high-quality development of China's pharmaceutical industry.

 **Regulatory and Legal Framework: Strengthening the legal and regulatory safeguards for pharmaceutical oversight**

Policy	Date	Authority	Core Meaning
"14th Five-Year" Plan for National Drug Safety and Promotion of High-Quality Development	2021.12.30	NMPA and 7 other departments	Aims to elevate drug regulatory capacity to international advanced levels. It focuses on deepening the reform of the review and approval system to accelerate the launch of innovative and clinically urgently needed drugs. On the premise of "ensuring safety," it clarifies "development promotion" measures to optimize the industrial regulatory environment.
Announcement on Optimizing Matters Concerning Drug Registration, Review, and Approval	2018.5.28	NMPA; NHC	Implements Priority Review and Approval (PR) for drugs treating major and rare diseases. It allows eligible overseas-marketed drugs to apply for domestic listing directly based on overseas clinical trial data, significantly reducing the time-to-market for imported innovative drugs.
Pilot Work Plan for Segmented Production of Biological Products	2024.10.21	NMPA	Adopts a "one product, one policy" approach for innovative biologics, allowing separate DS and DP production by different enterprises to optimize resource allocation and industrial specialization.

Source: public information, Frost & Sullivan Analysis

2.2 China Antibody Therapeutics Market Overview and Growth Potential

CDE Technical Principles: Guiding the Path for Innovative Drug R&D

Policy	Date	Authority	Core Meaning
Technical Guiding Principles for Clinical Pharmacology Research of Antibody-Drug Conjugates (ADCs)	2025.9.16	CDE, NMPA	Identifies toxicity as the primary dose-limiting factor. Requires comprehensive PK/PD and immunogenicity studies of components. Emphasizes early assessment of intrinsic/extrinsic factors to support precision dosing and risk-benefit evaluation.
Technical Guiding Principles for Clinical R&D of Bispecific Antibody Antitumor Drugs	2022.11.23	CDE, NMPA	Prioritizes clinical value and structural mechanisms in R&D. Focuses on First-in-Human (FIH) risks and optimal dosing strategies. Sets specific requirements for multi-domain immunogenicity testing and biomarker development.

Policy Empowerment: Multi-pronged Industrial Support to Enhance Efficiency and Reduce Costs

Policy	Date	Authority	Core Meaning
Implementation Plan for the Pilot Comprehensive Reform of Pudong New Area (2023-2027)	2024.1.22	General Offices of the CPC Central Committee and State Council	Establishes biopharma collaborative innovation mechanisms. Supports international-benchmarked pricing for new products and the construction of a Yangtze River Delta medical tissue bank aligned with international standards.
Measures for Full-Chain Support of Pharmaceutical and Medical Device Development in Shenzhen	2025.4.2	Shenzhen NDRC, NHC, Market Supervision, and Medical Insurance Bureau	Utilizes "Open Competition" (Jiebang Guashuai) to tackle ADCs and cell therapies. Offers rewards up to RMB 60M for marketed Class 1 innovative drugs. Promotes specialized "AI + Pharma" and Synthetic Biology parks.

2.2.2.2 Evolution of Technology Platforms: Building the Core of Differentiated Competitiveness

Antibody drug R&D is increasingly characterized by combinational and platform-based innovation, requiring companies to develop systematic capabilities in modular technology integration, rapid target switching, and parallel pipeline development. Some Chinese pharmaceutical companies have begun establishing modular R&D platforms, laying the foundation for the continuous innovation and rapid iteration of multiple antibody modalities.

Figure: Introduction to Selected Chinese Antibody Development Platforms

 **EpimAb: FIT-Ig Bispecific Platform**

- FIT-Ig integrates two mAb sequences into a single bispecific antibody without amino acid mutations or linkers. This unique approach enhances both druggability and manufacturing efficiency.

 **Kelun-Biotech: OptiDC™ ADC & Novel Conjugates Platform**

- OptiDC™ utilizes a comprehensive component library to develop customized ADCs and novel conjugates. It supports systematic R&D across diverse targets and indications, expanding into non-oncology therapeutic areas.

 **Akeso: Tetrabody Tetraivalent Bispecific Technology**

- Tetrabody is a proprietary platform that overcomes critical CMC challenges associated with large-molecule bispecifics, such as low expression levels, structural heterogeneity, and instability.

 **DualityBio: DITAC ADC Platform**

- DITAC is a topoisomerase inhibitor-based ADC platform featuring proprietary payloads (P1003& P1021). It enhances systemic stability, ensures tumor-specific release, and accelerates toxin clearance *in vivo*.

Source: public information, literature search, Frost & Sullivan Analysis

2.2 China Antibody Therapeutics Market Overview and Growth Potential

Figure: Introduction to Selected Chinese Antibody Development Platforms

 **Affinity Biopharma: TMEA Conjugate R&D Platform**

- Affinity’s proprietary TMEA (Tumor Microenvironment Specific Activation) technology offers broad applicability. It effectively reduces systemic toxicity and expands the therapeutic window, providing a significant competitive advantage for developing First-in-Class anti-tumor drugs.

 **Alphamab Oncology: KN026 Bispecific Antibody Platform**

- KN026 is a HER2 bispecific antibody developed using the proprietary CRIB (Fc heterodimer) platform. It utilizes conventional manufacturing processes and simultaneously binds to two non-overlapping epitopes of HER2. This ensures potent signaling blockade while maintaining a molecular structure identical to native IgG.

2.2.2.3 Global Expansion and Internationalization: Opening Pathways for Global Value Realization

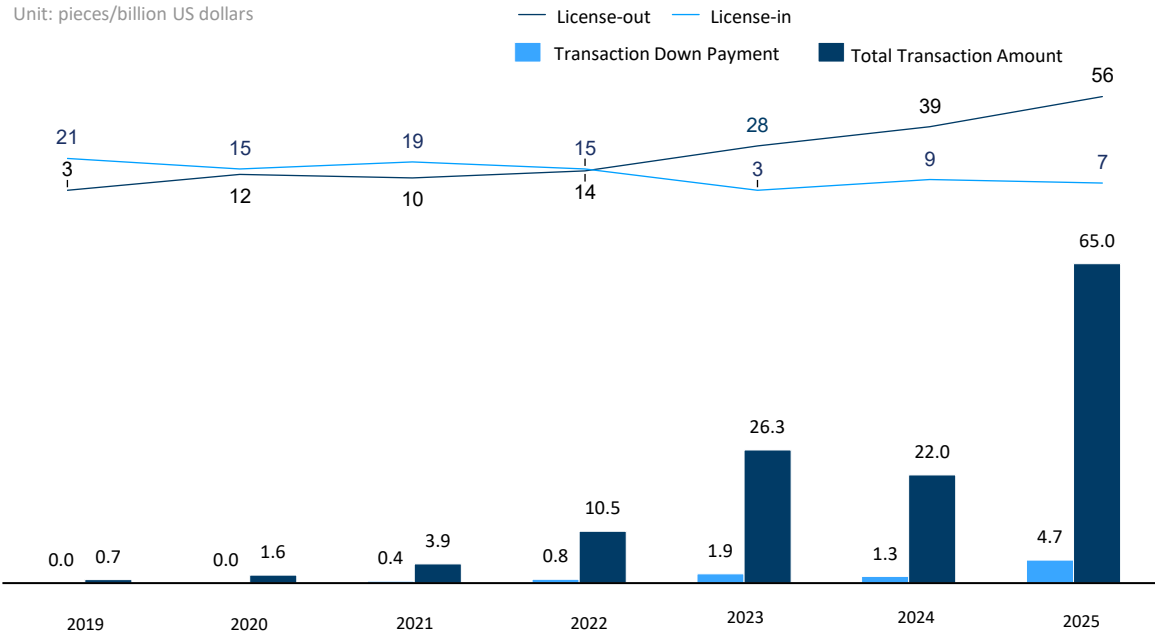
License-out Deals of Chinese Antibody Therapeutics

In recent years, both the frequency and value of license-out deals for Chinese antibody therapeutics have increased significantly. From 2019 to 2025, license-out transactions grew steadily, with a sharp surge in 2023 and 2025. The number of deals rose from 3 in 2019 to 56 in 2025, representing more than a tenfold increase. Over the same period, the total transaction value expanded from US\$0.1 billion to US\$65.0 billion, highlighting the rapid growth of outbound licensing.

Meanwhile, license-in transactions have declined since 2021, falling to single digits between 2023 and 2025, indicating that Chinese companies are gradually shifting their strategic focus from technology import to global licensing and commercialization.

Figure: 2019-2025 Antibody Drug License-out Transactions in China

Unit: pieces/billion US dollars



Note: The number and value of transaction events are based on incomplete statistics. Transaction values are calculated based on publicly disclosed information and include only biopharmaceutical companies whose **highest-level headquarters of the out-licensing party are located in China.

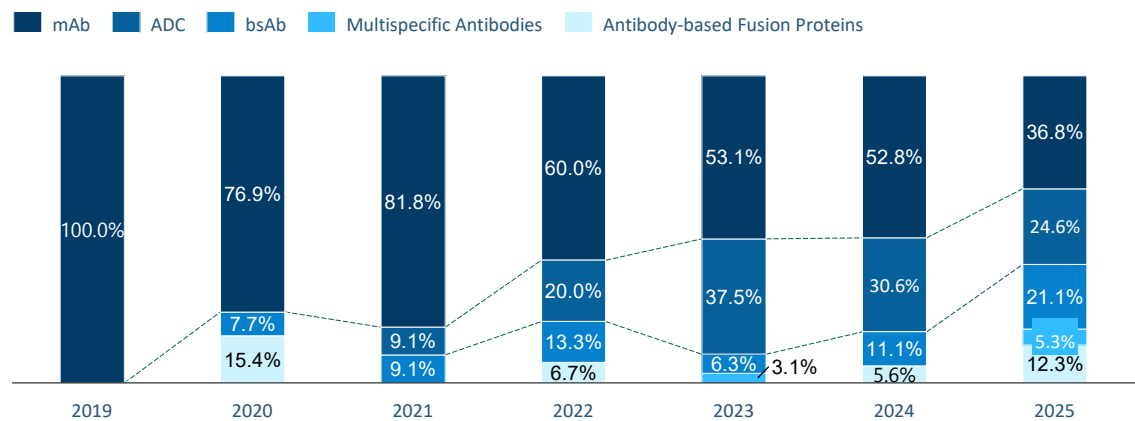
Source: Insight, Frost & Sullivan Analysis

2.2 China Antibody Therapeutics Market Overview and Growth Potential

License-out Deals of Chinese Antibody Therapeutics by Modality

In 2019, all license-out deals involving Chinese antibody therapeutics were monoclonal antibodies, accounting for 100% of cases. In the following years, this share gradually declined to 52.8% by 2024. Bispecific antibodies first appeared in license-out transactions in 2020, when Shanghai Henlius Biotech licensed the overseas rights of its EGFR×4-1BB bispecific antibody HLX35 to Binacea Pharma for US\$770 million. Since then, the share of bispecific antibodies in license-out deals has risen rapidly, reaching 21.1% by 2025, reflecting increasing international recognition of their technological value. ADCs first appeared in license-out transactions in 2021, marking the beginning of global expansion for China-developed ADCs. By 2023, ADCs accounted for over one-third of license-out cases. In May 2023, WuXi Biologics signed a licensing agreement with GlaxoSmithKline for several innovative T-cell engager bispecific/multispecific antibodies, marking the first time such modalities entered similar transactions. In September 2024, EpimAb Biotherapeutics licensed the global rights of its BCMA-targeting TCE EMB-06 to Vignette Bio, including US\$60 million upfront and up to US\$575 million in milestone payments.

Figure: 2019-2025 License-out Deals of Chinese Antibody Therapeutics by Modality

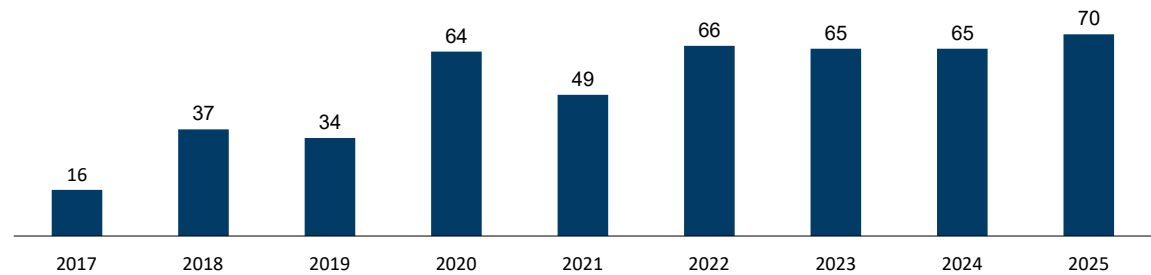


2.2.2.4 Overseas Clinical Trials of Chinese Antibody Therapeutics

Annual Trends in Overseas Clinical Trials

Between 2017 and 2025, Chinese biopharmaceutical companies initiated a total of 432 overseas clinical trials for antibody therapeutics. Since the emergence of PD-1/PD-L1 immune checkpoint inhibitors, companies such as Junshi Biosciences and BeiGene have actively launched clinical programs abroad, entering the global market. Subsequently, in innovative antibody modalities such as ADCs and multispecific antibodies, China has become a major source of global innovation. Notably, in the ADC field, many clinical-stage drugs worldwide originate from Chinese companies.

Figure: Number of Antibody Therapeutics Clinical Trials Initiated Overseas by Chinese Companies, 2017–2025



Source: CDE, ClinicalTrials.gov, Frost & Sullivan Analysis

Note: Clinical trials that have been suspended or terminated are not included in the statistics.

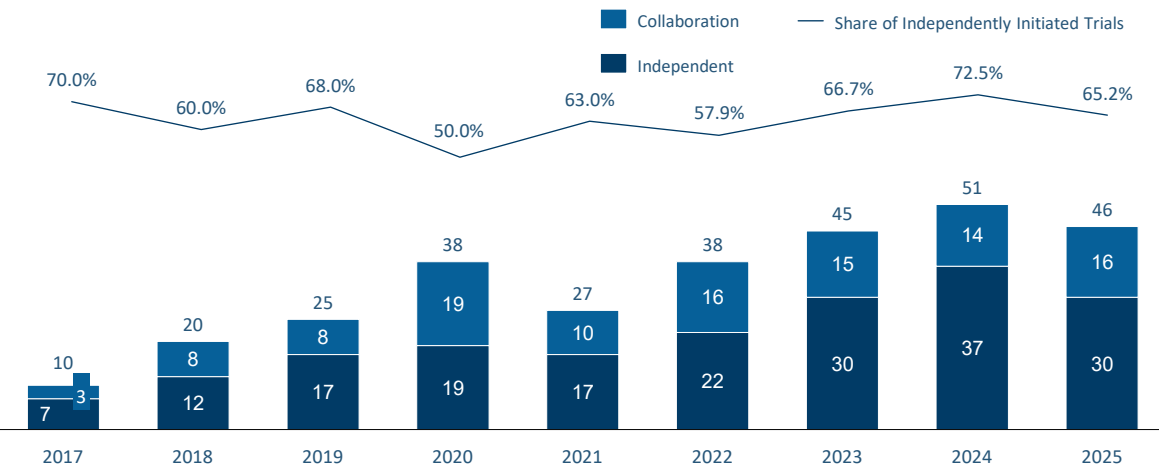
2.2 China Antibody Therapeutics Market Overview and Growth Potential

Overseas Multicenter Clinical Trials of Chinese Antibody Therapeutics

From the perspective of trial types, overseas clinical studies conducted by Chinese companies include both multicenter trials in collaboration with multinational pharmaceutical companies and independently initiated studies by domestic firms. In 2017, independently initiated trials accounted for 70.0% of the total. This share later declined to around 50%, but rebounded to 72.5% in 2024 and slightly decreased to 65.2% in 2025, remaining generally within the 50%–70% range in recent years.

With the accumulation of R&D capabilities and international regulatory experience, Chinese companies have significantly strengthened their ability to conduct independent global clinical trials, gradually reducing their reliance on external partnerships.

Figure: International Multicenter Antibody Therapeutics Clinical Trials Initiated Globally by Chinese Companies, 2017-2025



Note: Suspended and terminated clinical trials are not included in the statistics. “Overseas” refers to all countries and regions outside Mainland China, Hong Kong, Macao, and Taiwan. “Collaboration” refers to clinical trials jointly initiated by Chinese biopharmaceutical companies and overseas partners, while “Independent” refers to trials initiated solely by Chinese biopharmaceutical companies.

2.2.2.5 Strengthening Full Value Chain Capabilities: Building Scalable and Integrated Support

The antibody therapeutics industry chain consists of three interconnected segments—upstream manufacturing, midstream innovation and R&D, and downstream commercialization. The upstream focuses on process development, quality control, and CDMO capabilities to support efficient production. The midstream drives innovation through antibody discovery, engineering, and advanced modalities such as bispecific antibodies and ADCs, supported by modular platforms and rapid validation systems. The downstream covers clinical development, regulatory approval, market access, and global commercialization, determining the ultimate market value and penetration of products. Efficient development relies on close coordination across these segments: mature upstream manufacturing enables rapid midstream innovation, midstream breakthroughs are realized through downstream commercialization, and market feedback further guides R&D and production strategies.

Within this framework, Cyagen Biosciences represents a leading force in upstream R&D tools and model platforms. Through its proprietary HUGO-ab® series of fully humanised antibody mouse models and its one-stop CRO services covering everything from antibody discovery and pharmacology/pharmacodynamics evaluation to preclinical research, the company provides critical support for the early-stage development and mechanism validation of antibody therapeutics, helping the industry reduce R&D uncertainty and enhance experimental efficiency. EpimAb Biotherapeutics focuses on the midstream innovation segment, advancing multiple clinical pipelines based on its proprietary FIT-Ig bispecific antibody platform while gradually expanding international collaborations. Together, such companies illustrate how different segments of the industry chain reinforce one another with upstream capabilities enabling efficient innovation and midstream breakthroughs driving downstream commercialization and global expansion, supporting a more sustainable growth model for the antibody therapeutics industry.

Source: public information, literature search, Frost & Sullivan Analysis

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Chapter 3

Monoclonal Antibody



03

3.1 Overview of Monoclonal Antibody

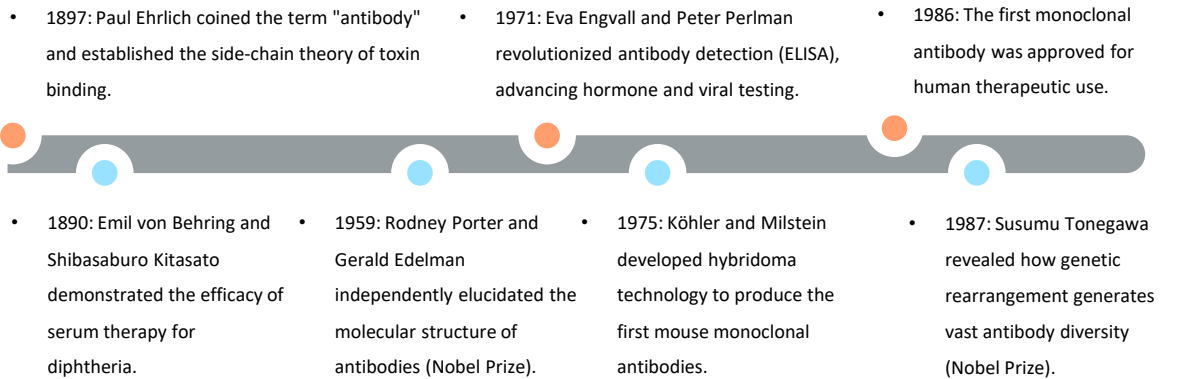
Monoclonal antibodies exhibit high target specificity, and technological evolution from murine to fully human antibodies has significantly reduced immunogenicity. They now show broad therapeutic potential in major diseases such as cancer and autoimmune disorders.

3.1.1 Definition and Development of Monospecific Antibodies

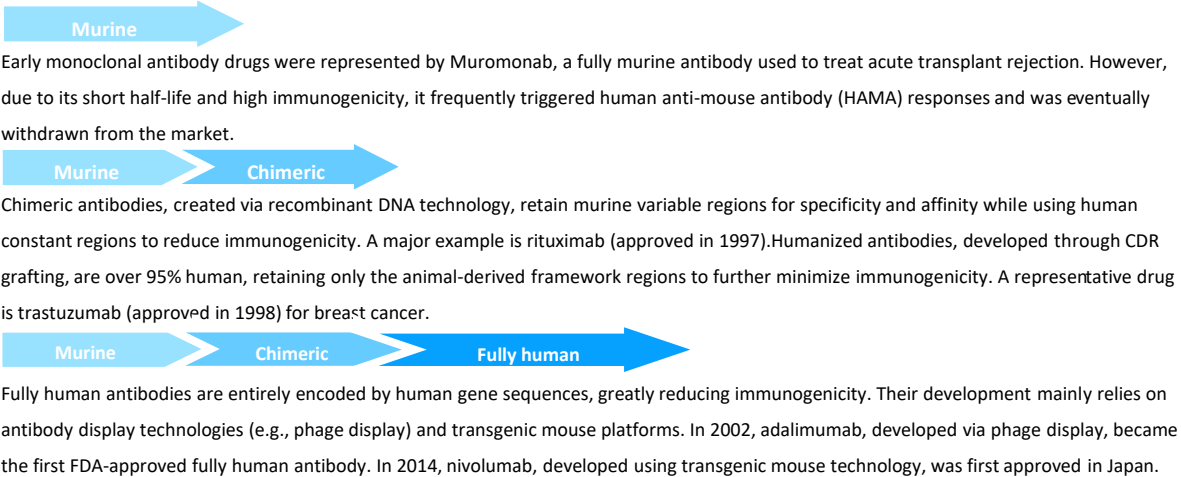
Monoclonal antibodies are highly homogeneous antibodies produced by a single B-cell clone and directed against a specific antigen epitope. Although manufactured at large scale in laboratories, they retain structures and functions similar to natural antibodies while often exhibiting greater target specificity.

In 1975, Georges J. F. Köhler and César Milstein developed the hybridoma technology, enabling the production of murine monoclonal antibodies and laying the foundation for large-scale antibody manufacturing. Subsequent advances in recombinant DNA and antibody engineering technologies made it possible to convert murine antibodies into humanized and fully human antibodies, significantly reducing immunogenicity and improving therapeutic safety and efficacy. Today, monoclonal antibodies are not only essential tools in molecular immunology research, but also widely used as targeted therapies for diseases including cancer, transplant rejection, autoimmune disorders, and infectious diseases, with emerging potential in certain neurodegenerative conditions.

Figure: the Early Development of Monoclonal Antibody Therapeutics



3.1.2 Monoclonal Antibody Technological Evolution: Clear development pathway with engineering advances continuously enhancing target specificity and therapeutic potential



Source: public information, literature search, Frost & Sullivan Analysis

3.2 Analysis of Monoclonal Antibody Market Landscape and Commercialization

Global and Chinese markets are driven by mature core products and high-growth emerging drugs, though some face patent expirations. R&D remains focused on high-incidence cancers.

3.2.1 Global and Chinese Monoclonal Antibody Market: Commercial Performance, Leading Products, and Therapeutic Area Trends

Monoclonal antibodies maintain strong commercialization, supported by both mature products and emerging drugs, though some face patent expirations. Globally, they account for about one-third of top-selling drugs over \$5 billion annually, with 30 antibodies generating \$179 billion among the 100 best-sellers.

By therapeutic area, oncology leads with Keytruda at \$29.48 billion. Immunology and inflammation products, including Dupixent (\$14.09 B), Darzalex (\$11.67 B), Skyrizi, Stelara, Humira, and Cosentyx, continue to show double-digit growth, representing roughly half of the top ten antibody products.

Figure: Top 10 Global Monoclonal Antibody Sales in 2024 (Unit: USD Billion)

Note: Compiled based on published financial reports, with exchange rates calculated using the average rate for the year 2024.

Product	Generic Name	Company	Target	Main Indications	2024 Sales	YoY
Keytruda	Pembrolizumab	MSD	PD-1	Melanoma, NSCLC, HNSCC, cHL	294.8	17.9%
Dupixent	Dupilumab	Sanofi	IL4R	AD, Asthma, CRSwNP, PN, EoE	140.9	21.6%
Skyrizi	Risankizumab	AbbVie	IL23A	PsO, PsA, CD, UC	117.2	51.0%
Darzalex	Daratumumab	J&J	CD38	MM, AL	116.7	19.8%
Stelara	Ustekinumab	J&J	IL12	PsO, PsA, CD, UC	103.6	-4.6%
Opdivo	Nivolumab	BMS/Ono	PD-1	RCC, NSCLC, Melanoma	101.4	1.1%
Humira	Adalimumab	AbbVie	TNF-α	RA, AS, PsO, CD	89.9	-37.6%
Ocrevus	Ocrelizumab	Roche	CD20	MS	76.4	7.4%
Prolia/Xgeva	Denosumab	Amgen	RANKL	OP, SBM	66.0	7.1%
Cosentyx	Secukinumab	Novartis	IL17A	PsO, PsA, AS	61.4	23.3%

Source: public information, literature search, Frost & Sullivan Analysis

3.2 Analysis of Monoclonal Antibody Market Landscape and Commercialization

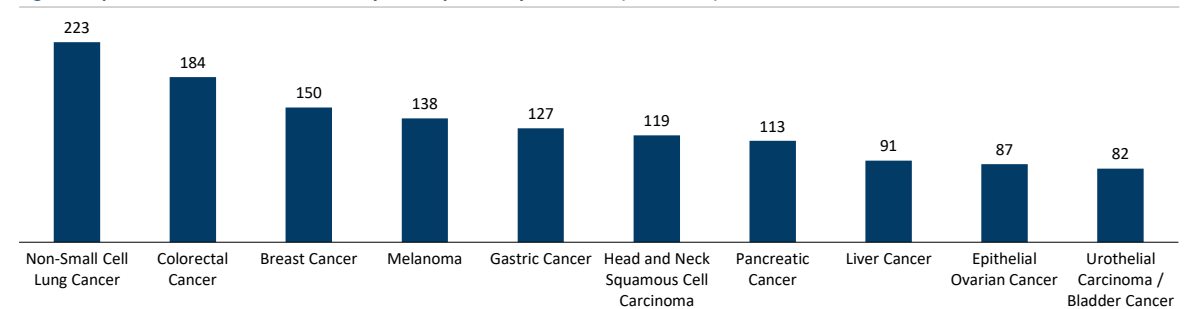
Skyrizi (Risankizumab) has seen rapid growth in recent years. This IL-23 (p19) inhibitor is commercialized for psoriasis, psoriatic arthritis, and inflammatory bowel disease. According to AbbVie, global net sales rose from \$0.36 B in 2019 to \$11.72 B in 2024, a 51% year-on-year increase, reflecting strong momentum. With commercialization established in major markets (US, EU, Japan), AbbVie continues Phase III and follow-up studies to expand indications, patient populations, and dosing regimens, supporting future growth.

In contrast, Humira (adalimumab), the early anti-TNF- α fully human antibody approved by the FDA in 2002, generated significant revenue during its patent exclusivity. After losing exclusivity and facing biosimilar competition, sales declined sharply from \$21.24 B in 2022 to \$8.99 B in 2024, a 37.6% drop, illustrating the impact of market competition on mature blockbusters.

3.2.2 Monoclonal Antibody R&D Pipeline Remains Strong, Focused on Key Cancer Indications

Globally, non-small cell lung cancer (NSCLC) and colorectal cancer lead in pipeline numbers, establishing a core position in antibody R&D. Other high-incidence cancers, including breast cancer and melanoma, also attract attention. This reflects that pharmaceutical companies prioritize mainstream diseases with large market potential, directing the bulk of innovation resources to these indications.

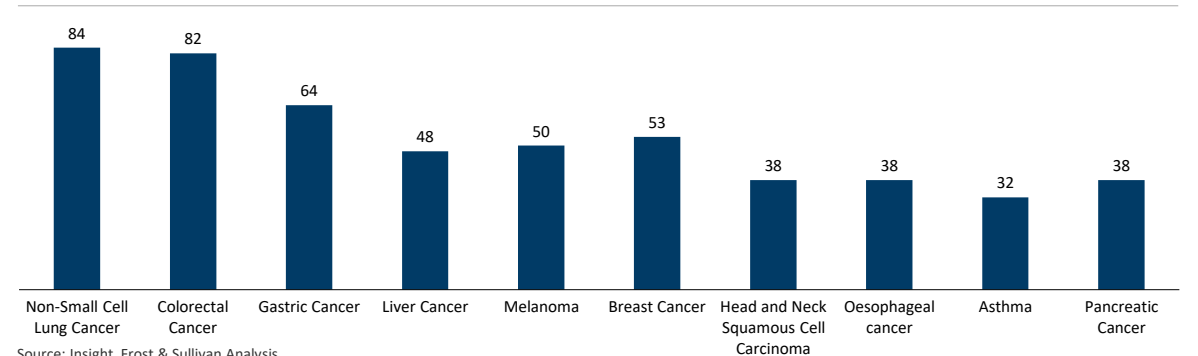
Figure: Top 10 Global Monoclonal Antibody R&D Pipelines by Indication (2021-2025)



In oncology, NSCLC and colorectal cancer lead in pipeline numbers, reflecting a focus on indications with large patient populations, concentrated clinical need, and established development pathways.

At the same time, pipelines targeting “China-specific” cancers remain prominent: gastric cancer (64 projects) and liver cancer (48 projects) rank high, while esophageal cancer (38 projects) also enters the top ten. This shows a strategic shift toward cancers highly relevant to the Chinese population with significant unmet needs, creating a differentiated, locally focused portfolio. Among the top ten indications, asthma is the only non-oncology disease, indicating efforts to expand into non-cancer areas.

Figure: Top 10 China Monoclonal Antibody R&D Pipelines by Indication (2021-2025)



Source: Insight, Frost & Sullivan Analysis

3.3 Development and Prospects of Monoclonal Antibodies

Monoclonal antibodies can continuously achieve cost reduction and efficiency gains through manufacturing process optimization, supply chain and raw material management, and strategic cost control, thereby enhancing market accessibility and overall competitiveness while ensuring quality and stable supply.

3.3.1 Ongoing Cost Optimization and Differentiated Competition Strategies

As monoclonal antibodies mature clinically and supply becomes abundant, market competition is shifting from simply achieving launch and volume to ensuring stable supply at controlled cost while maintaining sustainable differentiation. Cost efficiency is driven globally by reimbursement pressures and competitive dynamics: in Europe, payers like NHS/NICE use budget impact thresholds to trigger pricing negotiations; in the US, Medicare price negotiations, strengthened by the Inflation Reduction Act (IRA), limit price growth and enhance cost control; in Japan, reimbursement mechanisms manage both new and existing products, with increased adjustment frequency. In China, national negotiations and tenders have included roughly 150 drugs annually, with new biologics seeing an average price reduction of 57.6% between 2017 and 2024.

At the same time, the rise of biosimilars and same-target competitors intensifies pricing and market access pressure. According to FDA references citing AAM data, biosimilars’ average sales price (ASP) is typically less than half of the reference product at launch, and policies in Japan and China aim to expand biosimilar penetration (e.g., Japan targeting ~60% by 2029; China progressively moving centralized procurement from insulin to monoclonal antibodies). Meanwhile, the patent cliff and price pressure transmission prompt original manufacturers and generics alike to further explore efficient cost control and market response strategies. In this context, biopharmaceutical companies pursue manufacturing optimization, supply chain and raw material management, and strategic cost control, supporting market expansion, price stability, and differentiated competitiveness.

 Manufacturing Process Optimization	 Supply Chain and Raw Material Management	 Strategic Cost Control
- Improve antibody expression and stability via cell line engineering and media/process optimization, ensuring consistent quality attributes like glycosylation. - Use automated, continuous production and intensification techniques (e.g., perfusion culture) to boost productivity and reduce facility investment. - Apply real-time monitoring and predictive modeling to optimize processes, lower batch failure risk, and ensure reproducibility during scale-up.	- Centralize procurement of key raw materials such as cell culture media, enzymes, and chemicals to enhance bargaining power and secure better prices. Gradually increase the use of domestically sourced materials to reduce reliance on single import channels while ensuring quality and compliance. - Establish long-term strategic partnerships with core suppliers to lock in stable pricing and enable early-stage collaboration on optimized, cost-effective materials. - Optimize inventory and turnover through demand forecasting and batch shelf-life management to minimize waste and expiration costs.	- After patent expiry and biosimilar entry, originators can use unbranded or licensed versions and pricing strategies to retain market share. - Multi-product companies leverage platform-based processes to cut development costs and gain scale efficiencies. - Smaller firms can use CDMO platforms to reduce capital spending and boost cost flexibility and commercialization speed.

Source: public information, literature search, Frost & Sullivan Analysis

3.3 Development and Prospects of Monoclonal Antibodies

Monoclonal antibodies are moving from IV and SC injections to oral and inhaled forms to improve compliance and reduce treatment burden.

3.3.2 Formulation and Administration Optimization

Optimization of monoclonal antibody formulations and administration routes aims to improve patient compliance, reduce discomfort, and maintain efficacy while overcoming physiological barriers (e.g., crossing the blood–brain barrier via nasal or assistive techniques). Common routes include intravenous (IV) and subcutaneous (SC) injection, with emerging approaches under development such as oral, inhalation, intranasal, intravitreal, transdermal/microneedle delivery, and targeted delivery systems.



Intravenous (IV) Injection

The classic monoclonal antibody route, IV injection delivers the drug directly into the bloodstream, suitable for antibodies with short half-lives or requiring rapid onset. Drawbacks include the need for clinical administration and potential patient discomfort. Example: Pembrolizumab.

Subcutaneous (SC) Injection

SC injection is widely used, offering convenience with high-concentration or co-formulated solutions. Although absorption is slower than IV, therapeutic effects remain strong. High-concentration formulations reduce dose volume and injection frequency. Example: Adalimumab.

Oral Administration

Oral delivery offers convenience but is challenging due to poor intestinal absorption of large antibody molecules. Advances include structural modification, permeation enhancers, and nanocarriers. Example: Omadacyclumab is under oral delivery development.

Inhalation Delivery

Monoclonal antibodies can be delivered directly to the respiratory tract and lungs via nebulized solutions or dry powder formulations, achieving high local concentration, low systemic exposure, and reduced systemic side effects. Nhalon Biopharma’s ARIs platform, protected by three US and EU patents, enables inhaled antibodies to trap viruses and pathogens in airway mucus, prevent pulmonary spread, and clear pathogens rapidly through natural mucus.

Intranasal Delivery

Absorption through the nasal mucosa can provide systemic exposure and, crucially, bypass the blood-brain barrier (BBB) to deliver drugs directly to the central nervous system (CNS). While established for small molecules and peptides, monoclonal antibodies are still in early-stage research, facing challenges in transport and stability. Potential applications include neurological diseases (e.g., Alzheimer’s, multiple sclerosis) and local treatments (e.g., allergic rhinitis).

Intravitreal Injection, IVT

For ocular diseases like wet age-related macular degeneration, IVT remains the most mature delivery route. Example: Ranibizumab. Future developments aim at long-acting formulations or ocular implants to reduce injection frequency and minimize pain and infection risk.

Transdermal/Microneedle Delivery

Traditional transdermal delivery cannot penetrate the stratum corneum, limiting use for large antibodies. Microneedles create temporary microchannels into the epidermis or dermis, enabling painless or minimally painful delivery. Example: PD-1 inhibitor microneedle patches.

Targeted Delivery Systems

Antibodies can be combined with carriers like liposomes or nanoparticles, or designed as bispecifics, to concentrate at disease sites such as tumors or inflamed tissue. Example: NIH’s AAV8 vector delivers an anti-HV antibody gene (VRCo7) to human cells for sustained in vivo antibody production, currently in Phase II trials.

Source: public information, literature search, Frost & Sullivan Analysis

3.3 Development and Prospects of Monoclonal Antibodies

Combination therapies are emerging as a key developmental pathway for monoclonal antibodies to enhance their upper efficacy limits, delay the onset of resistance, and broaden their range of indications.

3.3.3 Combination Therapy to Overcome Single-Target Limitations

The development and progression of many diseases involve multiple pathways, making single-target interventions sometimes insufficient to fully control key pathogenic mechanisms or sustain long-term effects. In clinical practice, combination therapies are increasingly favored, particularly in oncology and certain immune-inflammatory diseases, to achieve deeper responses, longer progression-free survival, or more durable disease control, as single-agent treatments can plateau or encounter resistance.

From a R&D perspective, many projects incorporate combination potential from early stages. Common strategies include combining immunotherapy with chemotherapy or radiotherapy, dual immune-pathway (“dual-immuno”) approaches, anti-angiogenesis combinations, or pairing antibodies with small molecules or ADCs. The goal is to enhance efficacy, deepen and prolong patient response, and mitigate resistance.

However, combination regimens bring greater complexity in safety management, clinical trial design, patient selection, dosing sequences, and biomarker strategies, as well as increased treatment costs and reimbursement considerations. Their widespread adoption depends on balancing improved efficacy with manageable risks and economic viability, gradually establishing replicable clinical pathways and payment support frameworks.

Figure: Selected Combination Therapy Types and Clinical Examples

Combination Type	Regimen	Clinical Case
Intra-Checkpoint Combinations	PD-1 + LAG-3	Nivolumab + Relatlimab : A Phase II neoadjuvant study in resectable NSCLC showed feasible safety and pathological response signals. In melanoma (Opdualag), the RELATIVITY-047 trial demonstrated significant PFS gains and positive OS trends, validating dual-checkpoint blockade.
IO + Targeted Therapy	Anti-EGFR+Anti-VEGF	Cetuximab + Bevacizumab + Erlotinib : A Phase I dose-escalation study in mCRC (n=41) showed favorable tolerability, with 25% of patients achieving SD ≥ 6 months or PR.
Targeting Tumor Microenvironment (TME)	ICIs + IDO1 Inhibitor	Pembrolizumab + Epacadostat : ECHO-202/KEYNOTE-037 (Phase I/II) study in advanced solid tumors (n=62) demonstrated manageable safety and disease control signals, supporting TME modulation via immunosuppressive pathway inhibition.
Immune Agonist Combinations	ICIs + 4-1BB Inhibitor	LVGN6051 (exlinkibart) +Pembrolizumab : Currently in Phase I escalation/expansion for refractory NSCLC, melanoma, and GI cancers. The strategy combines checkpoint blockade with co-stimulation to enhance response depth and durability.

Source: public information, literature search, Frost & Sullivan Analysis

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Chapter 4

Bispecific Antibody



04

4.1 Overview of Bispecific Antibody

Bispecific antibodies are engineered antibodies that simultaneously bind to two or more antigens, exerting their biological functions through three core mechanisms: cell bridging, receptor bridging, and factor bridging.

4.1.1 Definition and Development of Bispecific Antibody

Bispecific antibodies (BsAbs) are engineered antibodies created via cell fusion or recombinant DNA techniques, capable of simultaneously binding two different antigens or two distinct epitopes on the same antigen. Their key advantage is “one molecule, two targets”: they can recruit effector cells such as T cells to tumor sites to enhance immune synapse formation and cytotoxicity, and/or simultaneously block two pathogenic pathways or induce receptor clustering to improve efficacy and potentially delay resistance.

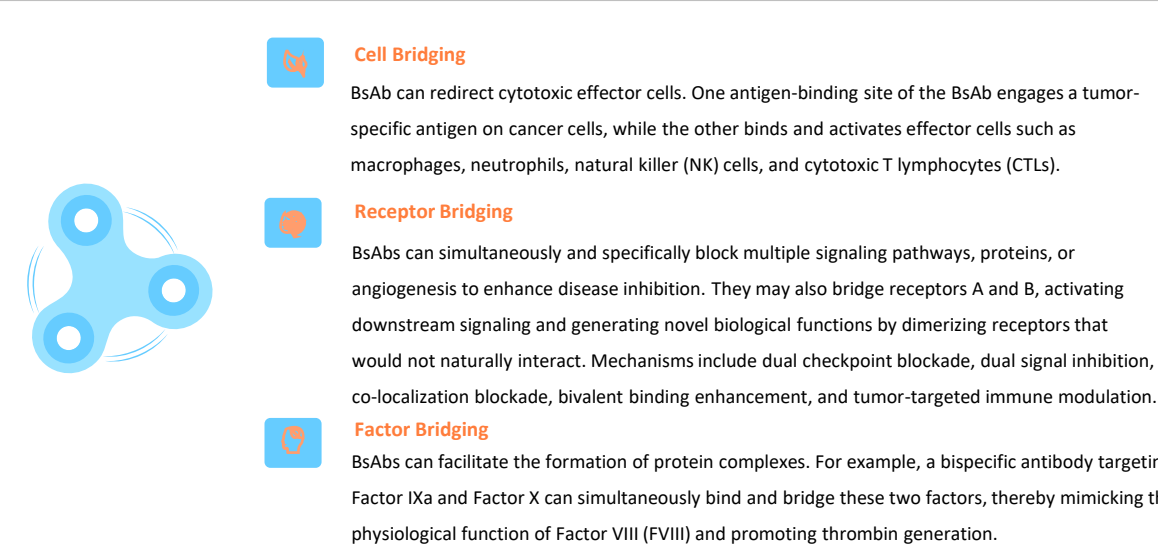
In 1960, Nisonoff and colleagues at the Roswell Park Memorial Institute in New York pioneered the original concept of bispecific antibodies. Subsequently, in 1983, Milstein and Cuello successfully generated bispecific molecules using hybrid-hybridoma technology, marking the beginning of early bioengineering exploration in this field. In 1997, Coloma and colleagues at Morrison’s lab engineered single-chain variable fragments (scFv) with IgG heavy chains, enabling recombinant IgG-like bispecific antibodies and laying the foundation for platforms such as ScFv-IgG and BiTE.

Early research focused on bispecific fragments (e.g., Fab) assembled via chemical conjugation, but low efficiency, structural heterogeneity, and scaling challenges limited practical application. With advances in recombinant protein engineering, antibody engineering, and industrial processes, BsAbs have entered rapid development: modern techniques allow systematic control over size, valency, half-life, and in vivo distribution, improving stability and developability while expanding structural diversity. Today, bispecific antibodies show clinical potential across oncology, autoimmune diseases, and infectious diseases, representing a key evolution from single-target to multi-mechanism therapeutic strategies.

4.1.2 Mechanism of Bispecific Antibody

According to the Technical Guidelines for Clinical Development of Bispecific Antibody Antitumor Drugs issued by China’s National Medical Products Administration, the core mechanisms of bispecific antibodies can be classified into three categories: “cell bridging,” “receptor bridging,” and “factor bridging.”

Figure: Classification of Bispecific Antibodies by Core Mechanism of Action



Source: public information, literature search, Frost & Sullivan Analysis

4.2 Clinical Value Analysis of Bispecific Antibodies

Bispecific antibodies leverage their core ability to simultaneously bind two distinct antigens or epitopes, giving rise to diverse mechanisms of action, including T-cell redirection.

4.2.1 Bispecific Antibodies Demonstrate Clear Clinical Advantages

Bispecific antibodies (BsAbs) can simultaneously target two antigens or epitopes within a single molecule, enabling biological effects that are difficult for conventional monoclonal antibodies to achieve and generating corresponding clinical value. Typical mechanisms include: (1) T-cell redirecting BsAbs, such as TAA×CD3, which bridge tumor cells and T cells to enhance immune synapse formation, improving effector cell recruitment and cytotoxicity; (2) dual-pathway regulatory BsAbs, including dual checkpoint blockade, EGFR×c-MET or HER3×EGFR dual inhibition, and PD-L1×4-1BB co-stimulatory regulation, which concurrently target two key pathways or enhance immune activation in specific microenvironments; (3) tumor microenvironment–related co-localization or neutralization strategies, such as PD-L1×TGF-β, to overcome immunosuppressive conditions.

Additional designs include dual-epitope targeting on the same antigen to enhance binding stability and blockade, as well as tumor-targeted immune modulation and precision delivery. Overall, these diverse mechanisms expand therapeutic potential, support resistance management, and facilitate future indication expansion.

Figure: Mechanisms of Action of Bispecific Antibodies

Sub-mechanism	Mechanism Introduction	Product Case	Category
T-cell Redirection	TAA×CD3 bridges T-cells to tumor cells, triggering targeted cytotoxicity.	- M701 (EPCAM×CD3) - A-319 (CD19×CD3) - EMB-06 (BCMA×CD3)	Cell Bridging
Dual Checkpoint Blockade	Simultaneously inhibits two checkpoint pathways to enhance immune disinhibition.	- AK104 (PD-1×CTLA-4) - IBI318 (PD-1×PD-L1)	Receptor Bridging
Dual Signaling Inhibition	Blocks two tumor receptors/pathways to increase coverage and reduce bypass escape.	- EMB-01 (EGFR×c-MET) - SI-B001 (HER3×EGFR)	Receptor Bridging
Co-localization Blockade	Combines checkpoint and immunosuppressive factor pathways for synergistic local disinhibition.	SHR-1701 (PD-L1×TGF-β)	Factor Bridging
Biparatopic/Biepitopic	Binds two epitopes on the same target to enhance blockade, stability, or receptor modulation.	- KN026 (HER2×HER2) - MBS301 (HER2×HER2)	Receptor Bridging
Tumor-Targeted Immunomodulator	One end targets TAA, the other regulates checkpoints for localized immunomodulation.	- IBI315 (HER2×PD-1) - IMM0306 (CD20×CD47)	Cell/Receptor Bridging
Receptor Co-stimulation/Downregulation	Promotes disinhibition and activates co-stimulatory signals via spatial clustering.	ES101 (PD-L1×CD137)	Receptor Bridging
Precision Targeted Delivery	One end targets the tumor, while the other promotes internalization/transcytosis to enhance delivery.	CD63/aHER2-ADC	Receptor Bridging

Source: public information, literature search, Frost & Sullivan Analysis

4.2 Clinical Value Analysis of Bispecific Antibodies

Achieving functional upgrades beyond monoclonal antibodies to overcome the limitations of single-target therapies, thereby providing more comprehensive and precise treatment strategies for complex diseases.

4.2.2 Iterative Value of Bispecific Antibodies in the Antibody Therapy System

4.2.2.1 Functional Iteration: From Blocking and Labeling to Bridging and Remodeling

Conventional mAbs typically target a single antigen via pathway blockade or Fc-mediated effector functions. Beyond dual-target binding, bsAb development now focuses on structural engineering to optimize PK, stability, and safety. Industry innovation centers on Fc modulation, functional modules, and novel architectures to refine in vivo performance and potency.

Fc Region Modulation: Retaining/removing Fc region to regulate half-life, stability and immune response intensity.

By retaining, removing or engineering the Fc region, developers can balance half-life, stability, and Fc-mediated effector functions. For example, the BiTE blinatumomab lacks an Fc region and, without FcRn recycling, has a short half-life of ~2 hours, requiring continuous IV infusion. In contrast, many IgG-like bispecifics retain the Fc but may employ “Fc silencing” to reduce unwanted effector activity while maintaining stable in vivo exposure. Acasunlimab (PD-L1×4-1BB) is described as an Fc-silenced IgG1, with 4-1BB agonism dependent on PD-L1 binding. Similarly, the ophthalmic bispecific faricimab (VEGF-A×Ang-2) has an Fc engineered to avoid FcRn and Fcγ receptor binding, reducing systemic exposure and minimizing Fc-mediated risks, as confirmed in FDA review documents.

Fused functional components: Integrating functional units such as co-stimulation and immunomodulation to enhance mechanisms of action and broaden the therapeutic indication spectrum.

A common strategy is to integrate targeting and immune-modulatory functions within the same molecule, allowing the antibody to localize to target tissues while simultaneously delivering additional immune activity. A representative example is bintrafusp alfa (M7824), which fuses an anti-PD-L1 antibody with the extracellular domain of TGF-β receptor II (a TGF-β trap) to simultaneously block PD-L1 and neutralize TGF-β, thereby alleviating immunosuppression in the tumor microenvironment. Another approach combines tumor targeting with co-stimulatory activation. For instance, PRS-343 (HER2×4-1BB) genetically fuses a 4-1BB-specific Anticalin with a trastuzumab variant, enabling HER2-dependent 4-1BB clustering and activation, concentrating co-stimulatory signaling within the tumor site.

Novel design architecture: The iteration of dual-antagonists also encompasses configuration and valence state design, alongside the evolution of manufacturability platforms.

In T-cell engagers, glofitamab (CD20×CD3) adopts a defined 2:1 format—two CD20-binding sites and one CD3-binding site. Roche reports that this configuration enhances binding to B-cell targets while enabling effective T-cell redirection, illustrating how valency and structural design can modulate functional activity. From a manufacturing perspective, the industry has developed mature approaches to address issues such as chain mispairing in IgG-like bispecific antibodies. One example is controlled Fab-arm exchange (cFAE), described in Nature Protocols, which enables efficient generation of bispecific antibodies with a native IgG architecture and is scalable from laboratory to large-scale production.

In addition, some bispecific antibodies adopt engineering strategies such as heavy-chain heterodimerization or common light chain designs to ensure correct pairing and improve manufacturability. For example, Cyagen's HUGO-Light™ fully human common light chain antibody mouse introduces a pre-rearranged human light chain sequence into the mouse Igκ/Igλ loci while knocking out other light chain genes, ensuring all antibodies carry the same light chain. When generating bispecific antibodies, two different heavy chains pair with this shared light chain, eliminating heavy–light chain mispairing and increasing correct assembly from ~25% to over 95%. This approach simplifies bispecific antibody recombination, shortens development timelines from 12–18 months to 6–8 months, and has been applied in developing targets such as PD-1/CTLA-4

4.2 Clinical Value Analysis of Bispecific Antibodies

Through the establishment of systematic technology platforms, bispecific antibody development is becoming more standardized and efficient, enabling key challenges in the R&D process to be effectively addressed.

4.2.2.2 Platform Evolution: Systematic Platform Development

Another key development trend for bispecific antibodies is the maturation of platform-based technologies. From an R&D and manufacturing perspective, major challenges have long included: ensuring correct heavy- and light-chain pairing and assembly; achieving the desired structure and pharmacological function while maintaining manufacturability; and meeting diverse requirements for molecular size, valency, PK/PD, and effector functions across different therapeutic scenarios. To address these challenges, the industry has gradually established multiple reusable bispecific antibody platforms. Some platforms focus on antibody frameworks and pairing optimization, solving heterodimerization and chain mispairing issues—such as Knobs-in-Holes (KIH), CrossMab, and Xencor’s XmAb—which enable IgG-like bispecifics to follow development and scale-up processes similar to conventional antibodies. Others emphasize immune cell engagement or redirection, including platforms like BiTE, DART, and Triomab, designed to efficiently connect effector cells with target cells. Additional platforms aim at functional enhancement or multi-functional fusion, such as ART-Ig and DVD-Ig, enabling dual-epitope or dual-target activity within a single molecule. Emerging proprietary platforms, including FIT-Ig, further support pipeline development through specific bispecific architectures.

Overall, platform evolution improves molecular assembly, manufacturability, and quality consistency, while enabling modular combinations across targets and therapeutic settings. This shift is helping bispecific development move from highly customized, project-by-project design toward more standardized and efficient platform-driven innovation.

Figure: Introduction to Selected Dual-Antibody Technology Platforms

Platform Type	Platform	Technical Features	Examples	Company
IgG-like BsAb assembly	Knobs-in-Holes (KIH)	Fc CH3 modification for heterodimerization; asymmetric IgG-like structure	Emicizumab IX factor × X Factor	
	KIH + CrossMab	Prevents LC/HC mismatching; enables production of various BsAbs and Fab-derivatives; asymmetric IgG-like structure	RG7221 VEGF × ANG2	
	X-Mab (Fab-scFv)	Charge-based Fc CH3 heterodimerization; Fab-scFv format prevents LC/HC mismatching; asymmetric IgG-like structure	XmAb14045 CD123 × CD3	
	FIT-Ig	No amino acid mutations, linker peptides, or non-antibody sequences required	EMB-06 BCMA × CD3	
	CRIB	Full-framework charge network optimization to enhance heterodimerization and reduce homodimerization	KN026 HER2 × HER2	

Source: Frost & Sullivan analysis, literature search

4.2 Clinical Value Analysis of Bispecific Antibodies

Platform Type	Platform	Technical Features	Examples	Company
Common Light Chain	ART-Ig	Enhances efficacy via dual-antigen binding or provides novel pharmacology by bridging two antigens	Hemlibra Factor VIII × Factor VIIIa	
	DVD-Ig	Tandemly connects VL/VH of a second antigen to IgG chains; symmetric IgG-like structure	ABT122 TNF × IL-17	
	HUGO-Light™	Uses a common light chain to eliminate LC mismatching and simplify downstream purification	\	
Cell engager formats	BITE	Tandemly connects VLA-VHB and VLB-VHA domains via short peptide linkers	Blinatumomab CD19 × CD3	
	DART	Connects two chains (VLA-VHB + VLB-VHA) via covalent linkages	Flotetuzumab CD123 × CD3	
	TandAb	Recruits CD16A and utilizes Fv domains to target Hodgkin lymphoma cells	AFM13 CD30 x CD16a	
Trifunctional antibody	Trionmab	Binds tumor antigen and CD3; Fc-FcγR interaction recruits innate immune cells for trifunctional bridging	Catumaxomab EpCAM × CD3	
Conditional activation	DPL	Generate antibodies with dynamic binding sites; Generate shielded antibodies engineered for selective activation within the tumour microenvironment; Generate bispecific antibodies via T-cell capture agents	ADG138 HER2 × CD3	

Source: Frost & Sullivan analysis, literature search

4.2 Clinical Value Analysis of Bispecific Antibodies

Bispecific antibodies have progressively expanded the depth and breadth of treatment through iterative development, from monotherapy and combination therapy to functional integration.

4.2.2.3 Evolution of Therapeutic Strategies: From Monotherapy to Combination and Multifunctional Integration

To overcome the limitations of monotherapy in efficacy ceilings and drug resistance, combination therapy has long been used in clinical practice, where drugs with different mechanisms of action are administered together to improve overall therapeutic benefit. However, traditional combinations are largely additive in nature, requiring separate administration, more complex dosing schedules, and more complicated safety management due to overlapping toxicities. They also tend to increase treatment costs and management burden.

Against this backdrop, bispecific antibodies can be viewed as an evolution of combination strategies. By integrating two binding specificities and mechanisms within a single molecule, BsAbs enable both actions to occur under the same drug exposure, potentially simplifying dosing regimens and providing a more consistent molecular basis for synergistic effects. Conceptually, bispecific antibodies share similarities with dual-antibody combinations, but differences in molecular design and in vivo behavior may lead to distinct efficacy, safety profiles, and clinical positioning.

PD-1 x CTLA-4

The combination of PD-1 and CTLA-4 inhibition is one of the more established strategies to enhance immunotherapy efficacy. For example, the combination of ipilimumab (anti-CTLA-4) and nivolumab (anti-PD-1) has demonstrated clinical benefit across multiple tumor types, but also carries a higher burden of high-grade toxicity. A meta-analysis of immune checkpoint inhibitor adverse events reported that the incidence of grade 3–5 immune-related adverse events (irAEs) associated with CTLA-4 inhibition is approximately 27.2%, compared to 17.3% for PD-1/PD-L1 inhibitors. In combination regimens, the rate of severe treatment-related adverse events is also notable; for instance, the CheckMate 9LA trial reported a ≥3–4 grade treatment-related adverse event rate of 47%.

Against this backdrop, cadonilimab (AK104), a PD-1/CTLA-4 bispecific antibody, integrates the “dual-drug combination” logic into a single molecule. Publicly available studies and reviews describe it as a tetravalent, Fc-null design aimed at reducing Fc-mediated effector function risks and improving safety. In the first-in-human phase I study (NCT03261011), the incidence of ≥grade 3 immune-related adverse events was 6.7%. In a pivotal phase II study in patients with recurrent/metastatic cervical cancer after platinum-based chemotherapy failure (NCT03852251, COMPASSION-03), the cervical cancer cohort achieved an objective response rate (ORR) of approximately 32.3%.

HER2 x HER2

In HER2-positive breast and gastric cancers, the combination of trastuzumab and pertuzumab has become a standard of care. Trastuzumab targets HER2, while pertuzumab binds a distinct HER2 epitope and blocks HER2/HER3 dimerization, thereby enhancing the therapeutic effect against HER2-dependent tumors.

Correspondingly, a HER2×HER2 bispecific antibody can be seen as integrating the “dual-epitope, same-target” strategy into a single molecule. For example, KN026 (HER2×HER2) has shown antitumor activity in previously treated patients with HER2-high gastric or gastroesophageal junction cancers, with an ORR of approximately 56% in the high-expression cohort. Additionally, in a combined analysis of phase Ib/II studies where KN026 was administered with another immuno-bispecific antibody (KN046, PD-L1×CTLA-4), the overall ORR was reported as 55.6%, while the first-line HER2-positive gastric cancer subgroup achieved an ORR of 78.9% (30 responses among 38 patients).

4.3 Development Directions of Bispecific Antibodies

Bispecific antibodies are expanding from hematologic cancers to solid tumors and non-oncology diseases, with an increasing diversity of targeted antigens.

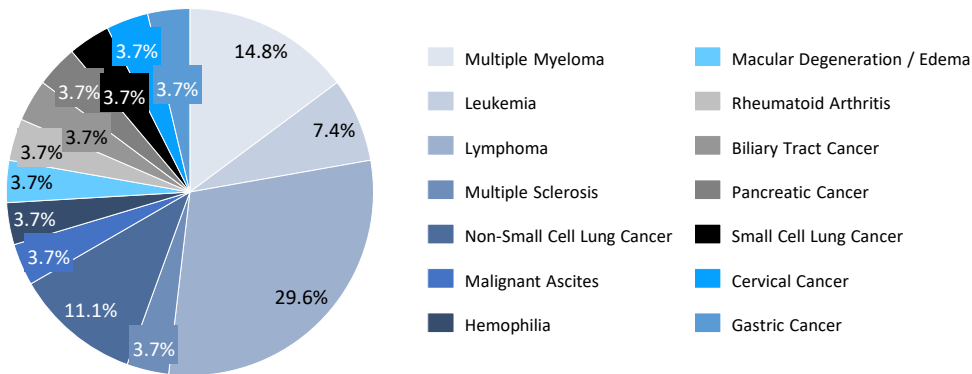
4.3.1 Indication Expansion and Deepening: From Hematologic to Solid Tumors, and Beyond Oncology

4.3.1.1 Global Indication Distribution of Approved Bispecific Antibodies

Approved bispecific antibodies are currently concentrated in malignant hematologic diseases, with the largest number targeting lymphoma (29.6%) and multiple myeloma (14.8%). In solid tumors, non-small cell lung cancer also shows notable drug coverage. Other indications—including multiple sclerosis, malignant ascites, hemophilia, macular degeneration/edema, rheumatoid arthritis, cholangiocarcinoma, gastric cancer, pancreatic cancer, and cervical cancer—are each addressed by a single approved drug.

The exploration of bispecific antibody indications is clearly expanding and deepening. Applications are extending from hematologic malignancies to more challenging solid tumors, and from oncology to autoimmune diseases, ophthalmic disorders, neurological conditions, infectious diseases, and rare diseases. For example, Roche’s VABYSMO is used for wet age-related macular degeneration and diabetic macular edema, while HEMLIBRA treats hemophilia A. These developments highlight the potential of bispecific antibodies to address numerous unmet clinical needs.

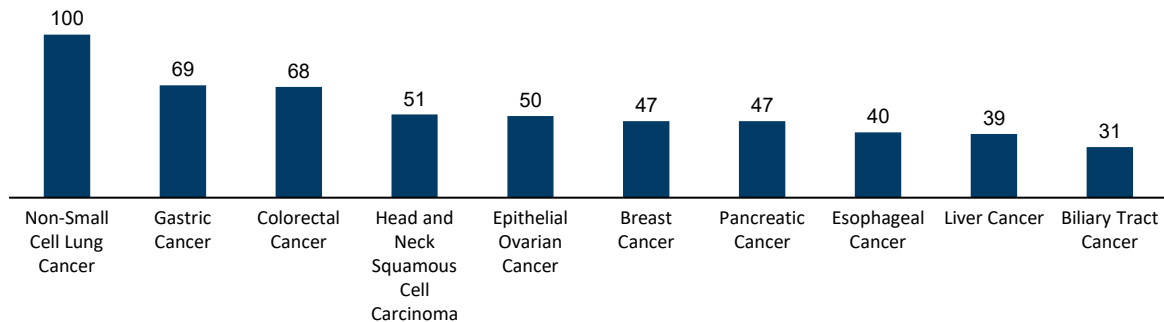
Figure: Global Distribution of Approved Bispecific Antibody Drugs by Indication (as of December 31, 2025)



4.3.1.2 Global Distribution of Bispecific Antibody Pipeline by Indication

The top ten indications for bispecific antibodies (BsAbs) in development worldwide are all tumor-related. Non-small cell lung cancer leads with 100 BsAbs in development, followed by gastric cancer with 69 BsAbs, and colorectal cancer with 68 BsAbs. Other common cancers, such as breast and pancreatic cancer, also have several dozen BsAbs in development.

Figure: Global Bispecific Antibody Pipeline by Indication (as of December 31, 2025)



Source: ClinicalTrials.gov, Frost & Sullivan analysis

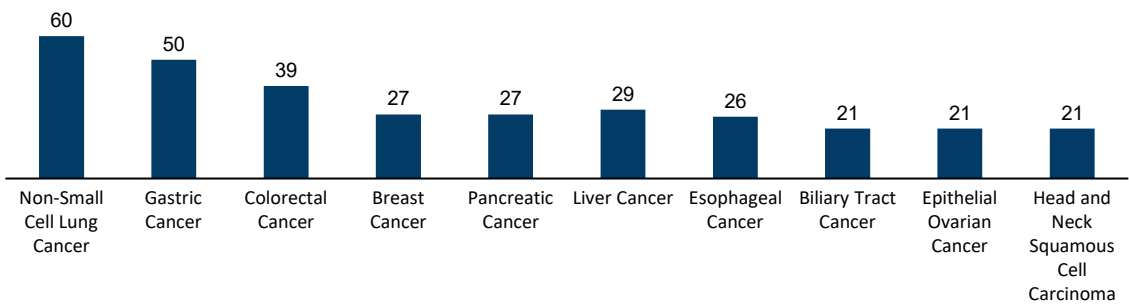
4.3 Development Directions of Bispecific Antibodies

4.3.1.3 Distribution of Investigational Bispecific Antibody Pipeline in China

The distribution of investigational bispecific antibodies in China largely aligns with global trends, with the top five indications concentrated in major disease areas such as non-small cell lung cancer, gastric cancer, colorectal cancer, breast cancer, and pancreatic cancer. At the same time, the Chinese market shows certain structural differences: hepatocellular carcinoma, esophageal cancer, and biliary tract cancer have relatively higher coverage in China’s bispecific antibody pipeline.

This difference is partly related to China’s disease spectrum and clinical needs. Cancers such as liver and esophageal cancer have higher incidence and disease burden in China, with significant unmet medical needs. This drives companies to allocate more resources to target selection and combination strategy development in these areas, resulting in a higher proportion of these indications in the domestic pipeline compared with the global average.

Figure: Investigational Bispecific Antibody Pipeline in China, by Indication (as of December 31, 2025)



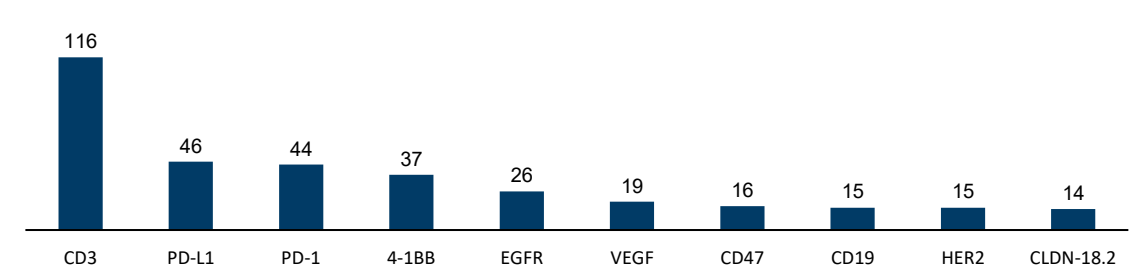
4.3.2 Target Distribution: Immune-Dominated, Advances in Solid Tumors, and Continuous Deepening of Established Targets

4.3.2.1 Global Investigational Bispecific Antibody Pipeline by Target

Globally, the most studied BsAb targets are CD3, PD-1/PD-L1, 4-1BB, and EGFR. CD3-based BsAbs (116 candidates) dominate, with focus shifting from whether to use CD3 to which targets to combine it with. PD-L1 (46) and PD-1 (44) remain key immunotherapy targets, with active development for differentiated BsAbs, new combinations, and expanded indications—largely in China.

4-1BB (37) enhances T-cell activation and anti-tumor immunity, while EGFR (26) addresses resistance in solid tumors. Hot targets will face intense clinical and commercial competition, with differentiation relying on affinity optimization and conditional activation. Emerging targets such as B7-H3, TIGIT, LAG-3, MET, and FR α are also under active development.

Figure: Global Investigational Bispecific Antibody Pipeline, by Target (as of December 31, 2025)



Source: ClinicalTrials.gov, Frost & Sullivan analysis

4.3 Development Directions of Bispecific Antibodies

4.3.2.2 Target Distribution of Approved Bispecific Antibodies in China

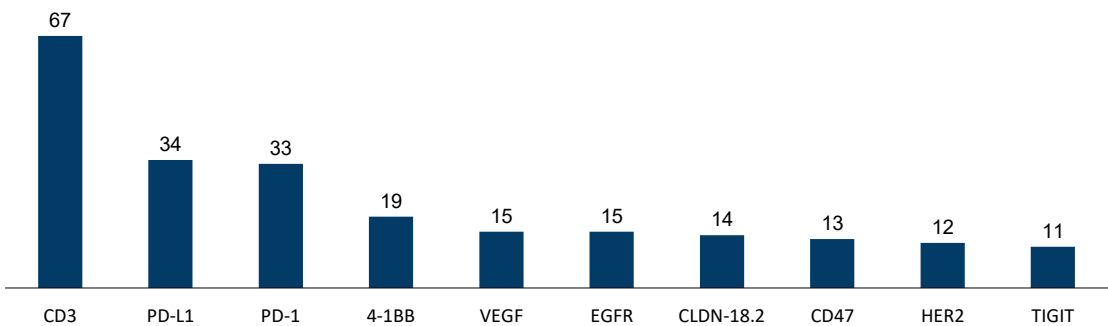
Overall, the target landscape of BsAb development in China broadly aligns with global trends. Immune-related targets dominate the top ten, occupying the first four positions (CD3, PD-L1, PD-1, and 4-1BB). Among them, CD3 (67) ranks first, reflecting that T-cell redirection—represented by T-cell engagers (TCEs)—remains one of the most established technical approaches. These molecules typically adopt a “tumor-associated antigen (TAA) × CD3” structure to recruit and activate effector T cells, forming a key foundation for BsAb development in hematologic malignancies and certain solid tumors.

PD-L1 (34) and PD-1 (33) rank second and third, indicating that “immune checkpoint blockade plus” remains a mainstream BsAb design strategy in China. A common approach is integrating additional inhibitory pathways or co-stimulatory signals into a single molecule to enhance response depth and broaden the benefiting population. Meanwhile, the relatively high presence of 4-1BB (19) reflects ongoing efforts to enhance co-stimulation within the tumor microenvironment. Given the systemic toxicity seen with early single-target 4-1BB agonists, recent designs often aim to restrict 4-1BB activation to the tumor site through conditional activation strategies.

The inclusion of TIGIT (11) among the top ten also reflects interest in next-generation immunotherapy combinations, although several phase III studies—such as Roche’s tiragolumab SKYSCRAPER program—have faced setbacks, indicating that this strategy remains under clinical validation.

Beyond immune targets, several solid tumor–related targets are also actively pursued, including VEGF (15), EGFR (15), CLDN18.2 (14), CD47 (13), and HER2 (12). This pattern reflects parallel development strategies in China: leveraging validated targets such as EGFR, HER2, and VEGF through dual-pathway or immune-combination designs, while also exploring emerging targets like CD47 to address tumor-specific biology and immunosuppressive mechanisms.

Figure: China Investigational Bispecific Antibody Pipeline, by Target (as of December 31, 2025)



Source: ClinicalTrials.gov, Frost & Sullivan analysis

4.4 Commercialization Potential of Bispecific Antibodies

Breakthrough efficacy demonstrated by bispecific antibodies in pivotal clinical trials has established their market value and strong pricing power, reinforcing their existing commercial advantages while continuing to unlock greater commercial potential.

4.4.1 Bispecific Antibodies Exhibit Blockbuster Characteristics with Strong Commercial Value

Currently, 19 bispecific antibody products have been approved globally. In 2024, the top-selling product was Roche’s Emicizumab, generating USD 5.36 billion in annual sales. Emicizumab is used to treat hemophilia A, a condition caused by deficiency or dysfunction of coagulation factor VIII (FVIII), leading to recurrent bleeding episodes, particularly in joints and muscles. The drug simultaneously targets coagulation factors IXa and X, bridging FIXa and FX to mimic the function of FVIII in the coagulation cascade. With subcutaneous administration and infrequent dosing, it has become a new standard therapy for hemophilia A. Since receiving FDA approval in 2017, the drug has been approved in multiple countries and regions, with its eligible patient population expanding to include children, neonates, and patients receiving prophylactic treatment from birth.

Another Roche bispecific antibody, Faricimab (Vabysmo), generated USD 620 million in sales in its first year and reached USD 4.41 billion in 2024, making it the second highest-selling bispecific antibody globally. In the first half of 2025, sales reached USD 2.6 billion, with full-year revenue expected to exceed USD 5 billion. Faricimab is the first approved VEGF×Ang-2 bispecific antibody for neovascular age-related macular degeneration (nAMD), diabetic macular edema (DME), and retinal vein occlusion (RVO). By simultaneously inhibiting Ang-2 and VEGF-A, it targets two key disease pathways. Long-term studies have shown durable efficacy and favorable safety in nAMD patients over follow-up periods of up to four years. The drug received FDA approval in early 2022 for wet AMD and DME, with the RVO indication added in October 2023.

The third highest-selling bispecific antibody is Amgen’s BLINCYTO, whose sales have steadily increased since launch—from USD 115 million in 2016 to USD 472 million in 2021, reaching USD 1.22 billion in 2024. Several recently launched products also achieved notable sales in 2024, including Genmab’s Epcoritamab (USD 281 million), Johnson & Johnson’s Teclistamab (USD 549 million), and Amgen’s Tarlatamab-dlle (USD 115 million).

Figure: Globally marketed bispecific antibody drugs (1/2)

Prodct Name	Drug Name	Company	Target	Indication	Approval Date
LYNOZYFIC	Linvoseltamab	Regeneron	BCMA/CD3	MM	04/2025 (EMA)
BLINCYTO	Blinatumomab	Amgen	CD3/CD19	B-ALL; R/R Leukemia	12/2014 (FDA)
					11/2015 (EMA)
					05/2025 (NMPA)
ORDSPONO	Odronextamab	Regeneron	CD20/CD3	FL; DLBCL	08/2024 (EMA)
EPKINLY	Epcoritamab	Genmab	CD20/CD3	R/R DLBCL	05/2023 (FDA)
LUNSUMIO	Mosunetuzumab	Roche	CD20/CD3	FL	07/2022 (FDA)
					06/2022 (EMA)
					12/2024 (NMPA)
TECVAYLI	Teclistamab	Johnson & Johnson	BCMA/CD3	HM	08/2022 (EMA)
					01/2023 (FDA)
					06/2024 (NMPA)

Source: Frost & Sullivan analysis, literature search, public information

4.4 Commercialization Potential of Bispecific Antibodies

Figure: Globally marketed bispecific antibody drugs (2/2)

Product Name	Drug Name	Company	Target	Indication	Approval Date
TALVEY	Talquetamab-tgvs	Johnson & Johnson	CD3/GPRC5D	MM	08/2023(FDA) 02/2025(NMPA)
ELREXFIO	Elranatamab	Pfizer	BCMA/CD3	MM	08/2023(FDA) 03/2025(NMPA)
COLUMVI	Glofitamab	Roche	CD20/CD3	DLBCL	06/2023(FDA)
IMDELLTRA	Tarlatamab-dlle	Amgen	DLL3/CD3	NSCLC	05/2024(FDA)
KORJUNY	Catumaxomab	Lindis Biotech	CD3/EpCAM	MA	02/2025(EMA)
RYBREVANT	Amivantamab	Jassen	EGFR/c-Met	NSCLC	05/2021(FDA) 12/2021(EMA) 02/2025(NMPA)
HEMLIBRA	Emicizumab	Fixa/FX	Roche	Hemophilia A	11/2017 (FDA) 02/2012 (EMA) 11/2018 (NMPA)
VABYSMO	Faricimab	Ang-2/VEGF	Roche	Wamd; DME	01/2022(FDA) 09/2022(EMA) 12/2023(NMPA)
NANOZORA	Ozoralizumab	TNF- α /TNF- α	Sanofi/Ablynx	RA	09/2022(Japan)
ZIIHERA	Zanidatamab	HER2/HER2	Jazz Pharms	BTC	11/2024(FDA) 07/2025(EMA) 05/2025(NMPA)
BIZENGRI	Zenocutuzumab	HER2/HER3	Merus N.V.	PC; NSCLC	12/2024(FDA)
依达方	Ivonescimab	PD-1/VEGF	Akeso	NSCLC	05/2024(NMPA)
开坦尼	Cadonilimab	PD-1/CTLA	Akeso	CC; GC	06/2022(NMPA)

Source: Frost & Sullivan analysis, literature search, public information

4.4 Commercialization Potential of Bispecific Antibodies

Breakthrough efficacy demonstrated by bispecific antibodies in pivotal clinical trials has established their market value and strong pricing power, reinforcing their existing commercial advantages while continuing to unlock greater commercial potential.

4.4.2 High Clinical Value Supports Premium Pricing

Breakthrough efficacy demonstrated by bispecific antibodies in pivotal clinical trials forms the basis for their relatively high pricing and rapid market adoption. For example, the DLL3-targeting bispecific antibody tarlatamab (IMDELLTRA) showed strong clinical efficacy in extensive-stage small cell lung cancer (ES-SCLC), leading to FDA accelerated approval in 2024, later converted to full approval. The product was also included in TIME's Best Inventions of 2024, highlighting its clinical innovation and industry impact. Another representative product, blinatumomab (BLINCYTO) targeting CD19×CD3, has achieved high remission rates in B-cell acute lymphoblastic leukemia (B-ALL) and continues to expand into earlier treatment lines and broader patient populations. Its commercial performance reflects the pathway from clinical value to payer recognition and market uptake, with global sales reaching approximately USD 1.2 billion in 2024.

As an advanced therapeutic modality, the pricing of bispecific antibodies reflects not only the complexity of R&D and manufacturing but also their clinical benefits and treatment efficiency. Public data indicate that IMDELLTRA has a U.S. WAC price of about USD 31,500 for the initial treatment cycle, with subsequent dosing costing around USD 30,000. HTA and pharmacoeconomic data show similarly high costs for BLINCYTO: UK NICE documents report an average cost of about £56,476 per cycle, while Canada's CADTH estimates drug costs of CAD 47,652 for the first 28-day cycle and CAD 55,594 for subsequent cycles, supporting the relatively high treatment value of BsAbs in mature markets.

Additional HTA data further illustrate this trend. CADTH reports that epcoritamab (CD20×CD3) costs about CAD 14,000–26,000 per 28-day cycle during the initiation phase; teclistamab (BCMA×CD3) costs around CAD 30,000 for the first cycle and CAD 27,000 thereafter; and talquetamab (GPC5D×CD3) ranges from CAD 29,000–37,000 per cycle under recommended dosing. In the UK, SMC analyses based on BNF list prices estimate that mosunetuzumab (CD20×CD3) costs about £66,660 for the first eight cycles. Although these figures are largely list prices and actual net prices may vary due to reimbursement negotiations or discounts, they nonetheless indicate that bispecific antibodies generally command premium pricing and high per-treatment value in mature healthcare markets.

4.4.3 From a Single Product to a Platform-Based Valuation Model

In bispecific antibody (BsAb) R&D, market valuation increasingly emphasizes a company's ability to continuously generate multiple candidates, extending value from a single product to a sustainable platform.

Mature platform engineering—heavy/light chain pairing, heterodimer formation, structural control, manufacturability, and quality consistency—can be reused across targets, improving design efficiency, screening, and iteration, enabling multi-project pipelines.

Platform value is also validated through partnerships and licensing. For example, Genmab's DuoBody collaborations with AbbVie cover multiple BsAb projects, including upfront payments, milestone payments, and tiered royalties, while Xencor's XmAb platform deals with Novartis and Amgen illustrate multi-target, multi-program value capture.

Thus, BsAb company valuation depends not only on a single product's revenue potential but also on a platform's ability to optimize structures, output new candidates, and generate recurring collaboration cash flow, forming a more sustainable commercial value base.

4.4 Commercialization Potential of Bispecific Antibodies

The combined effects of “substitution” and “creation” will continue to unlock broader commercial potential for bispecific antibodies.

4.4.4 Substitution Effect

One of the core strategies for bispecific antibodies is to enter and replace parts of the large existing markets dominated by current standard-of-care (SOC) therapies. In clinical trials—particularly in head-to-head comparisons with SOC—bispecific antibodies have demonstrated superior efficacy across multiple hematologic and solid tumors. As a result, BsAb therapies can address gaps left by existing treatments or provide more convenient options, supporting strong market demand and commercialization potential.

Figure: Marketed Bispecific Antibodies Benchmarking Existing Standard-of-Care (SoC) Therapies

Disease Type	SOC	SOC Efficacy	BsAb	BsAb Efficacy
MM	Daratumumab + Lenalidomide + Dexamethasone (DRd)	First Relapse Rate: 49% First Releapse ORR:92% PFS: 27.0 months OS:<47.0 months	Teclistamab	ORR: 63.0% in patients with ≥3 prior lines of therapy; 39.4% achieved CR or better
B-ALL	Intensive multi-drug chemotherapy followed by high-dose chemotherapy consolidation	Median OS of 24 weeks in relapsed ALL patients receiving chemotherapy	Blinatumomab	Study I: mOS: 9.8 months (14.1 months in responders) Study II: mOS: 7.7 months (vs. 4.0 months for SOC); CR rate: 34% (vs. 16% for SOC)
R/R LBCL	Salvage chemotherapy + ASCT consolidation	ORR: 26% mOS: 6.3 months Cure Rate: 10%	Epcoritamab	ORR: 63.1%; Median DOR: 20.8 months; CR: 40.1%; Median DOCR: 20.3 months; mPFS: 4.4 months; OS: 18.5 months
FL	Copanlisib therapy	CR Rate: 14%	Mosunetuzumab	CR Rate: 60.0%
Malignant ascites (MA)	Prior to catumaxomab, no specialized drugs existed	OS: about 1-6 months	Catumaxomab	Compared to paracentesis alone, catumaxomab combined with paracentesis achieved 6-month and 12-month survival rates of 27.5% vs. 6.7% and 11.4% vs. 3.4%, respectively
SCLC	First-line treatment includes platinum-based chemotherapy. Radiotherapy is required for LS-SCLC, while PD-L1 inhibitors are added for ES-SCLC	5-year OS: about 5-10%	Tarlatamab-dlle	DeLLphi-301 Trial: ORR: 40%; mDOR: 9.7 months; mOS: 14.3 months

Source: Frost & Sullivan analysis, literature search, public information

4.4 Commercialization Potential of Bispecific Antibodies

4.4.5 Creation Effect

The incremental potential of bispecific platforms also lies in their ability to open new therapeutic scenarios. In hematologic malignancies and certain solid tumors, BsAbs can provide new treatment options for patients with limited benefit from existing therapies or those who have developed resistance, through mechanisms such as cell redirection, dual-pathway blockade, and localized immune modulation.

As clinical evidence accumulates and treatment experience grows, products with favorable risk–benefit profiles are expected to move from later lines to earlier treatment settings and expand into broader patient populations and combination regimens. This shift is likely to increase the eligible patient base and overall treatment scale, further expanding the market potential of bispecific antibodies.

Intractable diseases	Malignant ascites (MA) results from tumor cell dissemination in the peritoneal cavity, increased peritoneal permeability, and impaired lymphatic drainage, leading to abnormal fluid accumulation. It is commonly seen in advanced ovarian and gastrointestinal cancers and can cause abdominal distension, pain, dyspnea, nausea, and malnutrition. Before the approval of catumaxomab, treatment was mainly symptomatic, including repeated paracentesis, peritoneovenous shunting, and diuretics. Catumaxomab (Removab) was approved in the EU on April 20, 2009, for intraperitoneal treatment of EpCAM-positive malignant ascites, becoming the first drug specifically indicated for this condition. Its authorization was withdrawn in 2017 for commercial reasons and later reapproved under the name Korjuny. Clinical studies show that catumaxomab can prolong puncture-free survival and improve symptom control compared with repeated paracentesis alone.
Earlier-Line Treatment Expansion	Relapsed/refractory Diffuse Large B-Cell Lymphoma (DLBCL) is an aggressive form of Non-Hodgkin Lymphoma (NHL). First-line therapy typically uses the R-CHOP regimen, with reviews reporting cure rates of over 60%. However, about 10–15% of patients are primarily refractory or relapse early, and another 20–25% relapse after initial remission. Prognosis for relapsed/refractory patients remains poor, with median overall survival often around 10 months. Standard second-line treatment has traditionally included high-dose chemotherapy followed by Autologous Stem Cell Transplantation, though many patients—particularly older or comorbid populations—are not eligible. Evidence from the STARGLO Trial shows that Glofitamab (CD20×CD3) combined with GemOx significantly improves outcomes compared with R-GemOx, with median PFS of 12.1 months vs 3.3 months at the primary analysis. According to the CSCO Lymphoma Guidelines 2025, this regimen has been recommended for transplant-ineligible patients.

Source: Frost & Sullivan analysis, literature search, public information

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Chapter 5

ADC



05

5.1 Overview of ADCs

ADCs link antibodies to cytotoxic payloads through chemical linkers, enabling targeted delivery of the drug to tumor cells and thereby enhancing efficacy while reducing systemic toxicity.

5.1.1 Introduction to ADC Drugs

ADC (Antibody-Drug Conjugate, ADC) consist of an antibody targeting a specific antigen linked to a cytotoxic payload (e.g., small-molecule drugs) via a chemical linker. This design combines precise targeting with potent cytotoxicity, improving drug stability and tumor selectivity while reducing systemic toxicity and enhancing therapeutic efficacy. Clinically, ADCs are mainly used for targeted treatment in oncology and other diseases.

The antibody component directs the payload to tumor cells for targeted killing. Some ADCs also exert a bystander effect, eliminating neighboring tumor cells. In addition, certain ADCs may trigger immune-mediated mechanisms such as antibody-dependent cellular cytotoxicity (ADCC), complement-dependent cytotoxicity (CDC), or antibody-dependent cellular phagocytosis (ADCP). Effective ADC design requires careful optimization and integration of all components to achieve optimal therapeutic performance.

Figure: Schematic Structure of ADC

Antibody

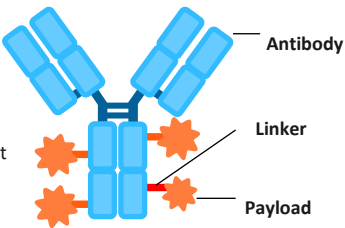
Responsible for identifying and binding to specific antigens on the surface of tumour cells (such as HER2, CD19, TROP2, etc.), ensuring the precise delivery of the drug.

Linker

To link antibodies with cytotoxic drugs, the complex must remain stable in the bloodstream but be capable of being cleaved by enzymes or chemically broken down within tumour cells to release the payload.

Payload

These are typically highly effective chemotherapeutic agents whose toxicity far exceeds that of conventional chemotherapeutic agents; however, thanks to targeted delivery, they can reduce systemic side effects.



5.1.2 Principle of ADC Design

The design principles for ADC drugs include ensuring high affinity between the antibody and the target, as well as low immunogenicity; guaranteeing the stability and safety of the drug; and optimising drug loading and linker design to enhance therapeutic efficacy and minimise damage to healthy cells. Furthermore, by optimising the drug-conjugate engineering and enhancing biological advantages, the targeting and efficacy of ADC drugs are improved, thereby ensuring their therapeutic advantages.

Figure: Principle of ADC Design

Ideal Choice		Innovative Strategies	
	Superior PK Profile Low immunogenicity and cross-reactivity, high target affinity, and optimal plasma half-life.		Antibody Engineering Optimizes binding, internalization, and delivery via novel formats (e.g., BsAbs, Nanobodies, and Probodyes).
	Stability & Safety Ensures stability to prevent premature cleavage and off-target toxicity; maintains proper hydrophilicity.		Payload Compatibility Tailors design based on payload potency, solubility, metabolism, and mechanism of action (MoA).
	Functional Characteristics High anti-tumor activity and adequate hydrophilicity with functional groups for linker conjugation.		Biology-First Principle Prioritizes target/tumor biology and antibody traits over simply increasing toxicity.

Source: Frost & Sullivan analysis, literature search

5.2 Analysis of Marketed ADCs

Accelerated ADC innovation is driving a surge in blockbuster approvals. Featuring diverse configurations of targets, antibodies, payloads, and linkers, marketed ADCs deliver superior clinical efficacy in oncology.

5.2.1 Landscape of Approved ADCs

As of 2025, 20 ADCs have been approved globally, including 15 in China, covering indications such as lymphoma, leukemia, multiple myeloma, breast cancer, head and neck cancer, and urothelial carcinoma. As solid tumors account for approximately 85% of all cancers, and remain more complex and difficult to treat, ADC development is increasingly expanding from hematologic malignancies to solid tumors.

Approved ADCs also show significant diversity in target selection, antibody formats, payloads, and linker designs. Different targets and antibodies enable selective recognition of tumor cells, improving therapeutic specificity and efficacy. The payload determines cytotoxic potency, while the linker's stability and cleavability influence effective payload release within tumor cells.



- Target Analysis:**
- The 19 globally marketed ADCs cover 13 targets, including c-Met, FR α , FIIII, HER2, CD19, EGFR, BCMA, TROP2, Nectin-4, CD79b, CD22, CD30, and CD33. HER2 remains the most prevalent target among approved products.



- Antibody Analysis:**
- As the "guidance system" of ADCs, antibodies have evolved from murine to chimeric and humanized formats. IgG1 is the dominant isotype due to its optimal molecular weight, high serum concentration, long half-life, and potent ADCC/CDC effector functions. IgG4 is utilized in specific cases where antibody-mediated immune activation is not required.



- Linker Analysis:**
- Linkers must balance systemic stability with precise target release. While a few products use non-cleavable linkers to minimize off-target toxicity, the majority employ cleavable linkers to leverage the bystander effect for enhanced efficacy.



- Payload Analysis:**
- Considered the "magic bullets," microtubule inhibitors are the most common (50% of marketed ADCs), followed by DNA-damaging agents. Notably, Topoisomerase (TOP) I inhibitors have emerged as a highly promising next-generation payload class due to their moderate toxicity and favorable clinical profile.



- Conjugation Analysis:**
- ADC conjugation is shifting from random to site-specific technologies. Compared to stochastic methods, site-specific conjugation offers superior preclinical activity, a wider therapeutic index (TI), and significantly improved safety and efficacy.

Source: FDA, PDMA, NMPA, CDE, literature search, Frost & Sullivan analysis

5.2 Analysis of Marketed ADCs

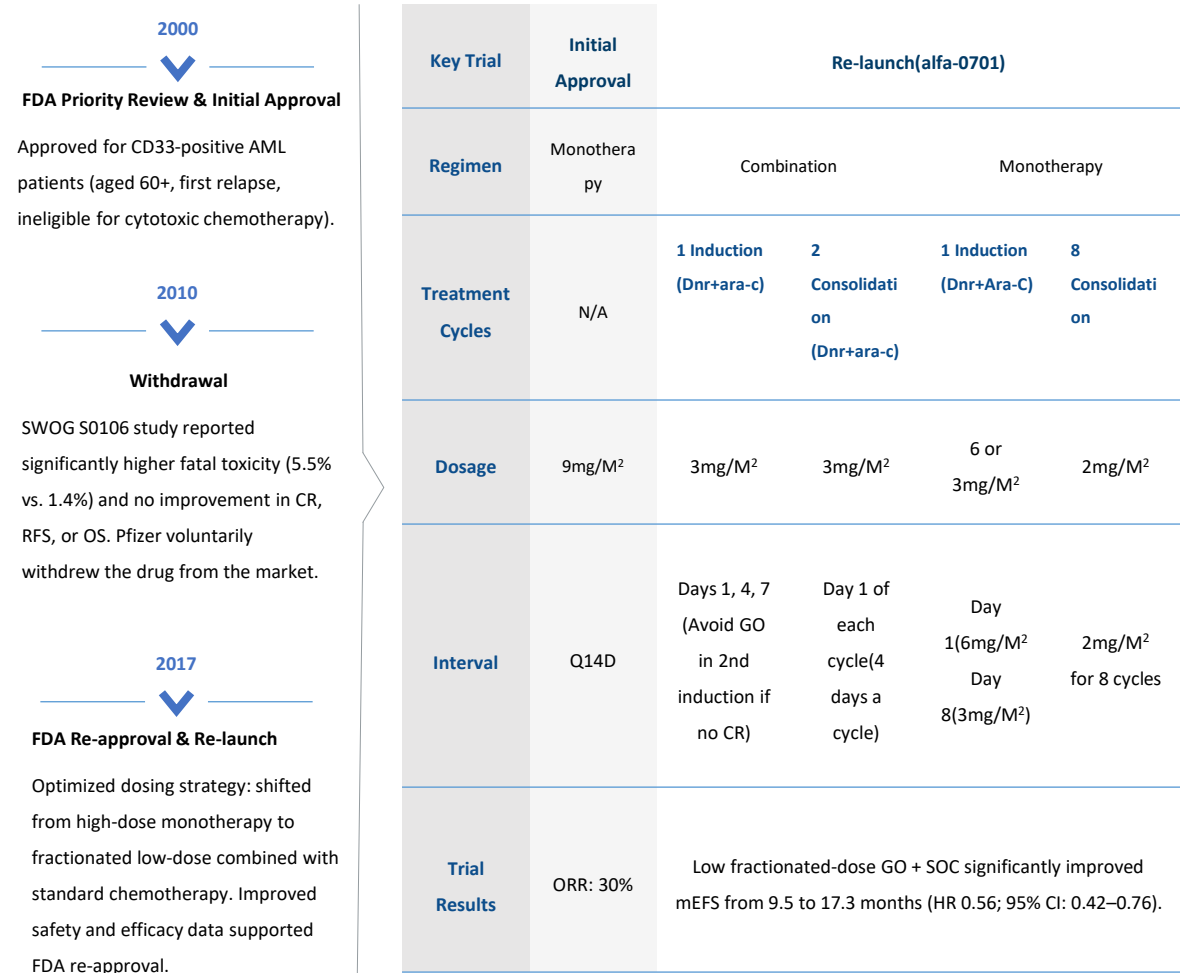
Mylotarg™ was the first ADC approved globally, marking a pioneering milestone. After being withdrawn due to safety concerns and later reintroduced following optimized clinical strategies, it provided valuable lessons for subsequent ADC development.

5.2.2 Analysis of Marketed ADC—— Mylotarg™

Mylotarg™ (Gemtuzumab Ozogamicin) received accelerated approval from the U.S. FDA, becoming the world’s first marketed ADC for the treatment of acute myeloid leukemia (AML). Mylotarg™ was originally developed by Wyeth and was later acquired by Pfizer through its \$68 billion acquisition of Wyeth in 2009. Following the SWOG S0106 study, which failed to confirm continued clinical benefit and raised safety concerns, Pfizer voluntarily withdrew the drug from the market in June 2010 and initiated further studies.

Through dose adjustments and modified dosing schedules, clinical trials including ALFA-0701, AML-19, and MyloFrance-1 were conducted. In September 2017, the FDA reapproved Mylotarg™ for the treatment of newly diagnosed CD33-positive AML in adults, as well as relapsed or refractory CD33-positive AML in adults and pediatric patients aged 2 years and older.

Figure: Clinical Development and Approval History of Mylotarg™



Source: FDA, company website, literature search, Frost & Sullivan Analysis

5.2 Analysis of Marketed ADCs

Kadcyla® is the world’s first ADC to be approved for the treatment of solid tumours, consolidating Roche’s leading position in the field of breast cancer treatment and making it the first pharmaceutical company to achieve commercial success in the ADC sector.

5.2.3 Analysis of Marketed ADC—Kadcyla®

Kadcyla® (ado-Trastuzumab Emtansine, T-DM1) was the first ADC approved for the treatment of solid tumors and the first ADC approved in China. As a representative second-generation ADC, it links the HER2-targeting humanized IgG1 antibody trastuzumab with the microtubule inhibitor DM1 via a non-cleavable thioether linker, using ImmunoGen’s tumor-activated prodrug (TAP) technology.

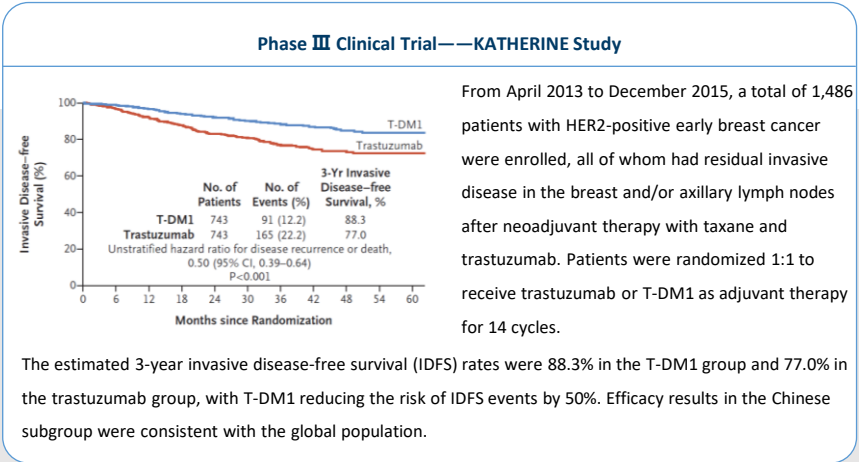
Kadcyla® received FDA approval in 2013 for HER2-positive metastatic breast cancer previously treated with trastuzumab and a taxane. In 2020, it was approved in China through CDE priority review, marking the beginning of the ADC therapeutic era in China. Since its launch, Kadcyla® has achieved strong commercial success, with cumulative revenue exceeding USD 10 billion.

Figure: Analysis of Key Clinical Data of Kadcyla®

Early-stage Breast Cancer



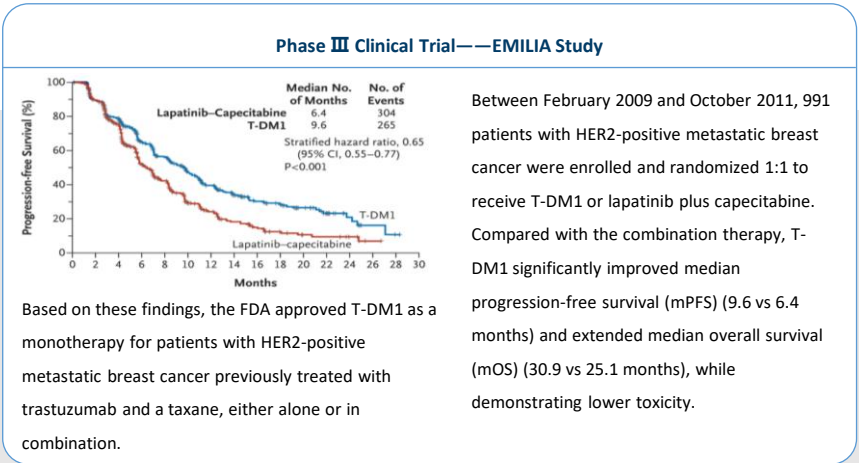
HER2+ breast cancer is highly aggressive. Despite neoadjuvant therapy, 30%-60% of patients still exhibit residual invasive disease (non-pCR), necessitating a switch to more effective adjuvant treatments to improve cure rates.



Advanced Breast Cancer



The trastuzumab–pertuzumab dual-target regimen developed by Roche is the standard first-line therapy for HER2-positive metastatic breast cancer. However, as patient survival improves, drug resistance becomes increasingly common, and second-line treatment options remain limited in efficacy.



Source: FDA, NMPA, CDE, company website, literature search, Frost & Sullivan Analysis

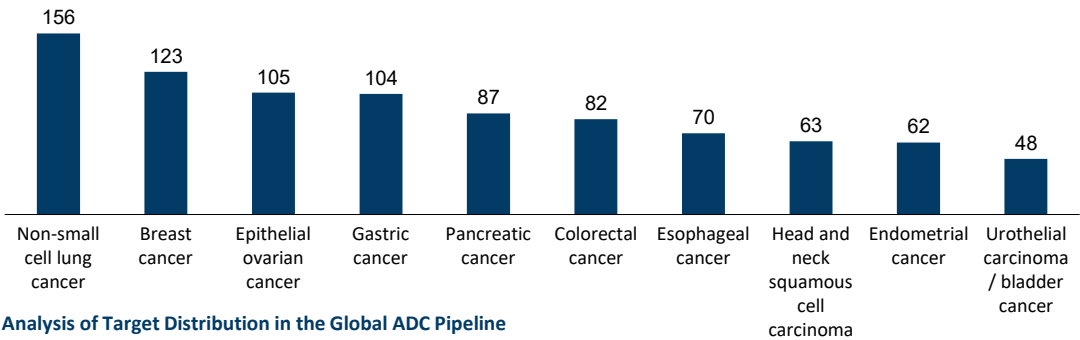
5.3 Analysis of ADC Pipeline in Development

In recent years, innovation in the field of ADC research and development has accelerated both globally and in China

5.3.1 Analysis of Indication Distribution in the Global ADC Pipeline

As of 2025, there are over 1,200 registered ADC clinical trials globally, predominantly in oncology. Among solid tumors, development is most concentrated in non-small cell lung cancer, breast cancer, and epithelial ovarian cancer, while approximately one-fifth of the pipeline targets hematologic malignancies. This broad and diversified clinical landscape reflects both research focus and investor confidence, and signals the potential for a new wave of ADC approvals reshaping the market.

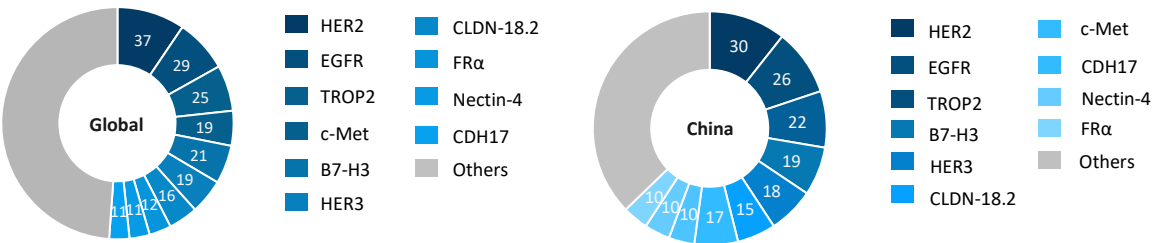
Figure: Top 10 ADC Pipeline Candidates by Indication (Global & China, as of December 31, 2025)



5.3.2 Analysis of Target Distribution in the Global ADC Pipeline

Target selection remains a key innovation area in ADC development. Globally, ADC targets in clinical development are highly diverse, whereas in China they are more concentrated. Leading targets include HER2, TROP2, EGFR, HER3, and CLDN18.2, with HER2 continuing to dominate as a primary focus.

Figure: Top 10 ADC Pipeline Candidates by Indication (Global & China, as of December 31, 2025)



5.3.3 ADC Candidates in the Global Marketing Authorization Stage

The ADC field has seen rapid growth in recent years, with two ADCs currently in the global filing stage. Pivekimab sunirine, developed by AbbVie, is an IL3RA-targeting ADC and has submitted a Biologics License Application (BLA) to the U.S. FDA for the treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN). BL-B01D1 (Lunkang Yilongtumab), a EGFR×HER3 bispecific ADC developed by China's Boli Tianheng, has completed multiple Phase III trials in China with promising results and filed for approval in China in November 2025.

Source: ClinicalTrials.gov, Frost & Sullivan Analysis

5.4 Analysis of Development Trends in the ADC Industry

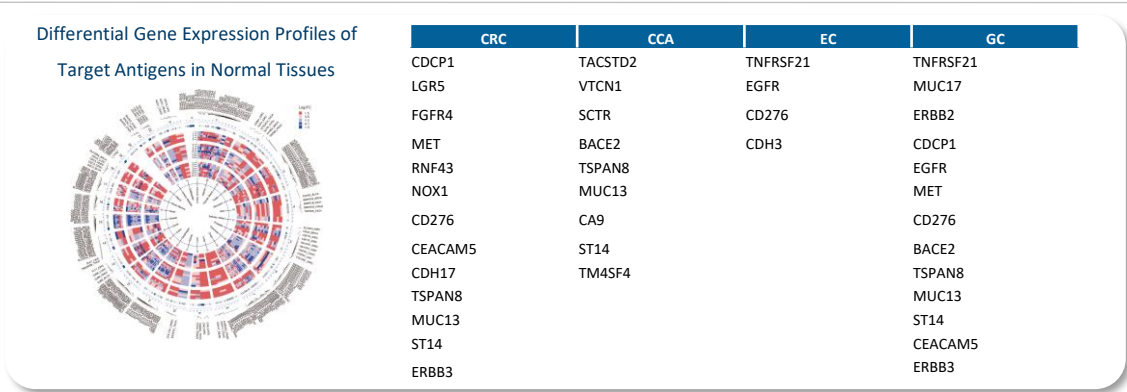
Ongoing research in ADC technology and cancer biology is expected to drive the discovery of new targets and payloads, improve linker design and conjugation methods, and enable next-generation ADCs with enhanced efficacy and reduced adverse effects.

5.4.1 Development of Novel Targets and Payloads

1 Next-Generation Target Selection

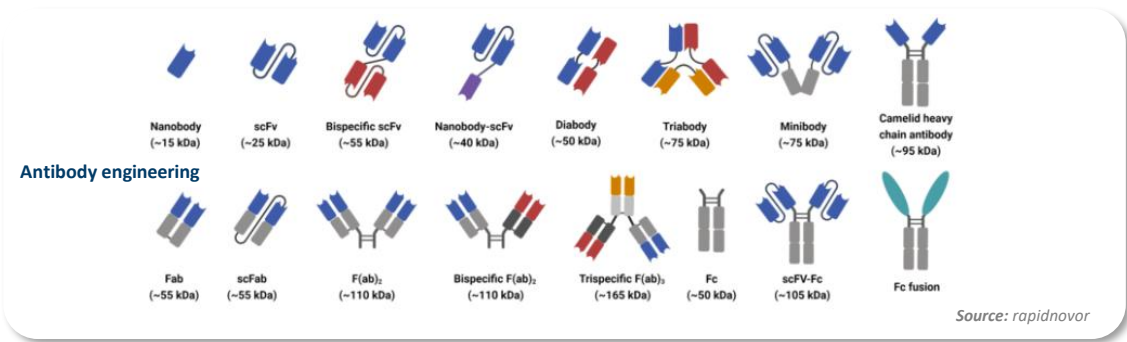
In December 2023, Jiacheng Fang et al. published "The target atlas for antibody-drug conjugates across solid cancers" in Cancer Gene Therapy. By integrating multi-omics databases (transcriptomics, proteomics, and genomics), the study identified potential surface antigens for precision ADC targeting. The research yielded 165 target-indication combinations and 75 cell surface protein candidates, 35 of which are novel and exhibit ideal characteristics for ADC development, opening new frontiers for therapeutic targeting.

Figure: Potential Therapeutic Surface Proteins and Target-Indication Combinations



2 Next-Generation Antibody Design

- Smaller Antibodies:** Traditional IgG antibodies (~150 kDa) are relatively large, limiting their ability to penetrate tumor vasculature and stroma. Tumor exposure is a key factor for anti-tumor activity. To improve ADC efficacy in solid tumors, smaller antibody formats are being developed, such as single-chain antibodies (scFv), antibody fragments (Fab), diabodies, and nanobodies.
- Probody:** Inspired by prodrugs, Probodyes are masked antibodies—via peptides covering the variable region or pH-dependent designs—that remain inactive until reaching the tumor site, reducing toxicity and improving bioavailability.
- Bispecific Antibodies:** These can bind two different antigens, or two epitopes of the same antigen, either simultaneously or sequentially. This can enhance selectivity, increase internalization, overcome resistance, and broaden ADC applicability.



Source: literature search, Frost & Sullivan Analysis

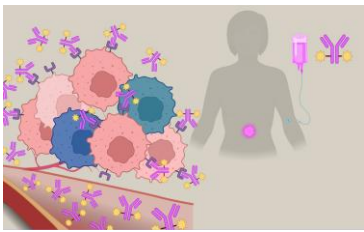
5.4 Analysis of Development Trends in the ADC Industry

3 Next-Generation Antibody Design

Novel Chemical Triggers: New triggers—such as cyclobutane-1,1-dicarboxamide (cBu) triggers, silicon ether-based triggers and 1,2,4-trioxolane (TRX) scaffolds—can enhance tumor-selective delivery. In addition, novel photo-cleavable and bioorthogonal cleavable triggers overcome the limitations of conventional intracellular ADC drug release, enabling the use of non-internalizing antibodies.

Tagworks is a startup developing next-generation ADCs using click-to-release technology, which enables selective in vivo payload release. This approach allows targeted activation of ADCs, masked immunomodulators, other prodrugs, and off-target deactivation in radioimmunotherapy. Their lead candidate, TGW101, targets TAG72—a clinically validated, non-internalizing antigen widely expressed in solid tumors. Preclinical studies show that TGW101-ADC activation in tumors maintains high auristatin levels in the tumor microenvironment, producing strong therapeutic effects.

Figure: ADC injection and targeted tumor therapy



Source: Tagworks

4 Next-Generation Conjugation

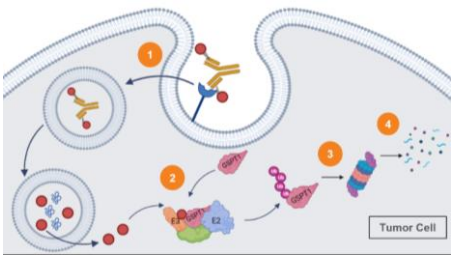
Site-Specific Conjugation: Beyond traditional methods like reactive cysteine engineering, disulfide re-bridging, non-natural amino acid incorporation, and enzymatic modification, techniques such as glyco-conjugation and pClick are rapidly advancing. Site-specific conjugation produces ADCs with uniform DAR, reduces heterogeneity, and improves pharmacokinetics, further driving ADC development.

5 Next-Generation Payloads

Protein Degraders: Targeted protein degradation technologies, including PROTACs and molecular glues, can address “undruggable” targets. Coupling degraders with antibodies to form Degradant-Antibody Conjugates (DACs) combines their advantages, offering differentiation in the competitive ADC field. Two DACs are currently in clinical development: ORM-5029 (Orum Therapeutics) and BMS-986497 (Bristol Myers Squibb).

Dual-Payload ADCs: To overcome resistance, antibodies can be conjugated with two or more different payloads, expanding future ADC design options.

TPD²™ Technical Diagram



Source: Orum Therapeutics

- **Orum Therapeutics** has developed TPD²™ (Dual Precision Targeted Protein Degradation) technology, which uses antibodies to deliver small-molecule protein degraders to cancer cells and other targets. This platform has produced two clinical candidates, ORM-5029 and ORM-6151 (acquired by Bristol Myers Squibb in Nov 2023 for \$180M as BMS-986497).
- **TPD²™ Technology:** ① Antibody targets tumor antigens to deliver molecular glues into cells. ② Molecular glue binds the target protein and E3 ligase. ③ Proteasome degrades the ubiquitinated target. ④ Continuous protein degradation induces cancer cell death.

5.4 Analysis of Development Trends in the ADC Industry

The use of ADC drugs in combination with other treatments enhances therapeutic efficacy whilst also extending the product lifecycle

5.4.2 Combination Therapy to Enhance Efficacy

Combining ADCs with other treatments can overcome the limitations of monotherapy while leveraging ADC strengths. The most promising combinations are those that act additively or synergistically on tumor cells or the tumor microenvironment without overlapping unacceptable toxicities. Preclinical and clinical studies are actively exploring ADCs combined with chemotherapy, targeted therapy, immunotherapy, or even dual-ADC strategies.

01

ADC combined with targeted therapy

Combining ADCs with targeted agents can overcome resistance and clonal heterogeneity, enhance inhibition of oncogenic signaling pathways, increase surface antigen availability, sensitize low-antigen tumors, and modulate the tumor microenvironment—ultimately improving tumor killing.

HER2CLIMB-02

Purpose

To evaluate the efficacy and safety of tucatinib (TUC) in combination with T-DM1 in patients with unresectable locally advanced or metastatic HER2-positive breast cancer

Result

Patients treated with tucatinib + T-DM1 showed significantly improved PFS compared with placebo + T-DM1 (9.5 vs 7.4 months; HR=0.76, 95% CI: 0.61–0.95).

➤ Among patients with baseline brain metastases, the PFS benefit was more pronounced with tucatinib + T-DM1 versus placebo + T-DM1 (7.8 vs 5.7 months; HR=0.64, 95% CI: 0.46–0.89).

02

ADC combined with immunotherapy

In April 2023, the FDA granted accelerated approval to Padcev® (enfortumab vedotin, Astellas) plus pembrolizumab (Merck) as first-line treatment for urothelial carcinoma, marking the first approved PD-1 + ADC regimen. Pembrolizumab contributed 45.9% of Merck’s revenue in 2024, and with its U.S. patent expiring in 2028, combination strategies may help extend its lifecycle and maintain market advantage.

NCT03288545

Purpose

To evaluate the efficacy of enfortumab vedotin in combination with pembrolizumab and/or chemotherapy in patients with locally advanced or metastatic urothelial carcinoma (first- or second-line), as well as in muscle-invasive bladder cancer (MIBC).

Result

➤ Among patients receiving the combination regimen (n=121), the confirmed ORR was 68% (95% CI: 58.7–76.0) per blinded independent central review (RECIST v1.1), including a 12% CR rate. The median DOR was 22.1 months in the dose-escalation/Cohort A, while it was not reached in Cohort K.

03

Dual-ADC combination

Sacituzumab govitecan (SG) and enfortumab vedotin (EV) are both standard monotherapies for metastatic urothelial carcinoma (mUC) with distinct targets and payloads, offering complementarity. Preclinical studies show that SG combined with microtubule inhibitors significantly enhances antitumor activity. Moreover, SG and EV have largely non-overlapping toxicity profiles, supporting good tolerability. Dual-ADC strategies provide new options for frontline therapy design.

NCT04724018

Purpose

To evaluate the safety and the maximum tolerated doses (MTDs) of sacituzumab govitecan (SG) and enfortumab vedotin (EV) in heavily pretreated patients with metastatic urothelial carcinoma (mUC).

Result

➤ The incidence of grade ≥3 adverse events was 78% (18/23), including one grade 5 AE (pneumonitis possibly related to EV). The recommended phase II dose is SG 8 mg/kg plus EV 1.25 mg/kg with prophylactic G-CSF support, while the maximum tolerated dose is SG 10 mg/kg plus EV 1.25 mg/kg. ADC combination regimens demonstrate favorable safety and tolerability in cancer treatment.

Source: literature search, Frost & Sullivan Analysis

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Chapter 6

Other Antibodies



06

6.1 Other Antibodies — Multispecific Antibodies

Multispecific antibodies can simultaneously target three or more distinct targets or antigens, offering excellent clinical potential in terms of functional complexity and heterogeneity; however, their structural complexity also presents additional technical challenges.

6.1.1 Definition and Mechanisms of Action

Multispecific antibodies (MsAbs)—here mainly referring to trispecific and higher-order formats—are engineered antibodies capable of binding ≥ 3 distinct targets/epitopes simultaneously. Common designs include dual tumor antigen recognition combined with an effector-binding domain (e.g., CD3), or integrating targeting, immune modulation, and barrier penetration within a single molecule. Compared with bispecifics, trispecifics offer greater functional complexity and potential to address tumor heterogeneity and resistance, but with increased design challenges and safety risks.

Multivalent T-cell engagers (TCEs): Trispecifics can bind two tumor-associated antigens (reducing antigen escape) while recruiting CD3⁺ T cells for cytotoxicity (e.g., TAA1 $\times$ TAA2 $\times$ CD3), improving coverage and killing efficiency in heterogeneous tumors.

Dual blockade & immune modulation: Simultaneous inhibition of immunosuppressive pathways (e.g., PD-L1) with co-stimulatory or regulatory functions, or parallel blockade of multiple disease pathways to delay resistance.

Enhanced specificity: Requiring co-expression of two tumor antigens increases tumor selectivity and reduces off-target toxicity in normal tissues.

6.1.2 Theoretical Advantages and Technical Challenges

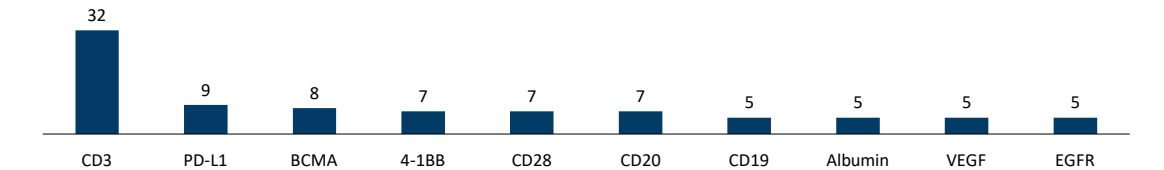
Theoretical Advantages	- Overcome heterogeneity: Targeting multiple antigens reduces antigen-escape-related failure. - Boost cytotoxicity: Dual binding enhances effector cell-mediated tumor killing. - Multifunctional integration: Combines targeting, immune activation, and microenvironment modulation in one molecule, lowering PK/PD mismatch and toxicity.
Technical Challenges	- Molecular engineering & structural complexity: Multiple binding domains increase risks of misfolding, instability, aggregation, and inter-domain interference. - Production & pairing: Multi-chain/multi-domain designs raise mispairing, low expression, and purification challenges, requiring specialized platforms. - Pharmacokinetics & dosing: Structural variations affect half-life, tissue distribution, and Fc function, demanding a balance between efficacy and safety.

6.1.3 Global Multispecific Antibody Development Pipelines

Target Profiles of Global Multispecific Antibody Development Pipelines

CD3 is the most central target in multi-specific antibody development, with a far greater number of candidates than any other target. PD-L1 and 4-1BB are common synergistic targets. BCMA is also attracting significant attention as a tumour target. In addition, traditional tumour targets such as EGFR (5) and VEGF (5) are also utilised in the construction of multispecific antibodies; albumin (5) is more commonly used to prolong in vivo exposure time and improve pharmacokinetic performance. Overall, the top 10 hotspots are predominantly molecules related to immune activation or immune guidance, reflecting that multispecific antibody R&D primarily focuses on enhancing the immune system’s ability to recognise and eliminate tumours.

Figure: Top 10 Hot Targets in Global Multispecific Antibody R&D Pipeline (as of December 31, 2025)



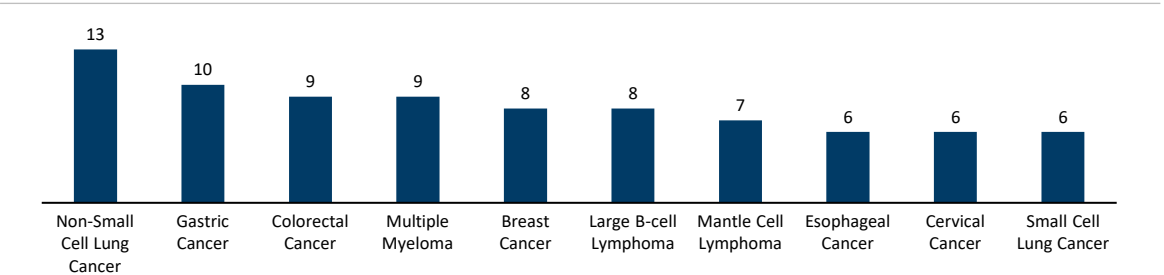
Source: literature search, Frost & Sullivan Analysis

6.1 Other Antibodies — Multispecific Antibodies

Global Multispecific Pipeline by Indication

NSCLC leads as the top R&D focus by project count. Gastric, colorectal, and multiple myeloma follow, constituting the Tier-1 R&D hotspots. Breast cancer and lymphoma gain significant traction, while esophageal, cervical, and SCLC remain key areas of interest. Although oncology (especially solid tumors) remains the central pillar of multispecific development, the therapeutic map is showing a clear trend toward diversification.

Figure: Top 10 Hot Indications in Global Multispecific Antibody R&D Pipeline (As of Dec 31, 2025)



Currently, approximately 300 multispecific antibody pipelines are under development globally, with over two-thirds still in preclinical stages. A prevalent design strategy for clinical-stage trispecifics involves integrating dual Tumor-Associated Antigens (TAAs) and an immune effector arm into a single molecule to enhance tumor recognition and cytotoxicity. For instance, five clinical trispecific T-cell engagers targeting BCMA×CD3×GPC5D, such as J&J’s JNJ-79635322 (ramantamig), highlight the intense R&D focus on relapsed/refractory multiple myeloma (R/R MM).

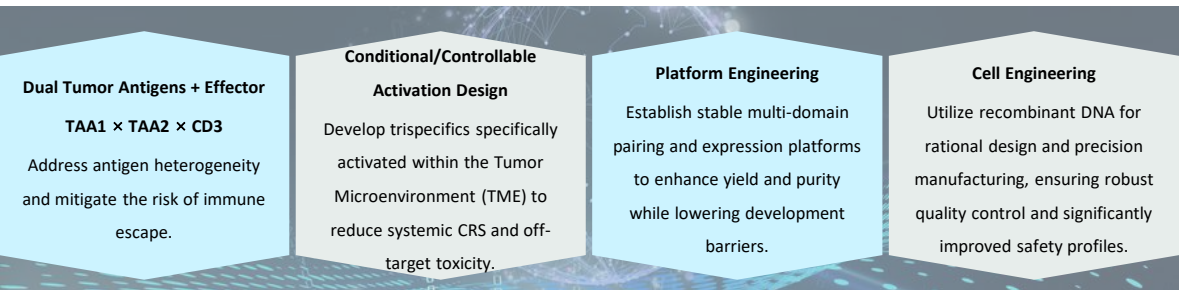
Trispecifics are also advancing beyond hematology into solid tumor immunotherapy. CStone’s CS2009 (PD-1/VEGF/CTLA-4) has entered global early-stage clinical trials, differentiating itself by integrating checkpoint modulation and anti-angiogenesis. Simultaneously, effector engagement is diversifying beyond T-cells; NK engagers (e.g., TriKE) recruit NK cells via CD16 and provide activation via IL-15. Other designs combine TAAs with CD3 and co-stimulatory signals (e.g., CD28) to simultaneously achieve tumor recognition, T-cell activation, and functional enhancement.

Overall, trispecific antibodies are evolving toward systemic clinical and platform-based development, with indications expanding from hematology to solid tumors. The strategic prioritization of these assets by Big Pharma is evidenced by dedicated platforms like Merus’s Triclonics and partnerships such as the Gilead-Merus collaboration. Meanwhile, the Chinese multispecific sector is surging in sync with global trends, with at least 10 cross-border deals to date reflecting a highly active clinical and industrial landscape.

6.1.4 Development Direction

Following the early 2000s approvals of Anti-Human T Lymphocyte Immunoglobulin and Anti-Digoxin Polyclonal Antibodies, the multispecific drug sector experienced a nearly 20-year hiatus until a new wave of breakthroughs emerged around 2017. Currently, multispecific antibodies are evolving along several key strategic pathways:

Figure: Strategic Directions for Multispecific Antibody Development



Source: literature search, Frost & Sullivan Analysis

6.1 Other Antibodies — Nanobodies

Nanobodies, with their small size, high stability, solubility, strong affinity, and excellent tissue penetration, have emerged as an important class of antibody therapeutics, gaining attention for their compact and simple structure.

6.2.1 Definition and Mechanism

Antibody engineering has shifted toward smaller, simpler formats that retain key binding functions while improving performance, and these structures are increasingly used as modular platforms for drug development.

Nanobodies (NANOBODY®) exemplify this trend. Derived from naturally occurring heavy-chain-only antibodies (HCAbs) in camelids or sharks, they lack light chains and reduce the antigen-binding region of conventional IgG to a single variable domain. These single-domain antibodies (sdAbs), also known as VHH or VNAR, have advanced steadily in therapeutic and diagnostic applications since their discovery in the 1990s, driven by progress in display technologies, structural biology, and protein engineering.

6.2.2 Structural Principles and Key Advantages

Compared with conventional antibodies, nanobodies offer advantages in structure and functionality, including smaller size, higher stability, and greater engineering flexibility. Comprising a single antigen-binding domain (~15 kDa), they are much smaller than IgG, enabling better tissue diffusion and penetration—particularly in dense environments such as solid tumors—and facilitating delivery to complex sites like the brain and lungs, thereby expanding applications in oncology, CNS, and respiratory diseases. In terms of physicochemical properties, nanobodies exhibit high stability and solubility, maintaining activity across a wide range of pH and temperatures. This makes them well-suited for inhalation, local delivery, and formulation-sensitive applications. Their relatively low immunogenicity also supports repeated or long-term dosing. From a molecular recognition and engineering perspective, nanobodies show high specificity and can access cryptic or conformational epitopes that are often inaccessible to conventional antibodies. Their simple, modular structure enables the design of multivalent, multispecific, or multifunctional constructs, and facilitates conjugation with drugs, toxins, or nanocarriers to enhance targeted delivery—potentially improving efficacy while reducing systemic toxicity.

6.2.3 Potential Applications

Nanobodies can be viewed as a modular platform technology. As compact and easily engineered building blocks, they can be integrated into diverse drug formats, enabling innovation in antibody design and delivery strategies.

In bispecific and multispecific formats, nanobodies are used to construct T-cell engagers by targeting tumor antigens and T-cell markers, with tunable affinity, valency, and geometry to enhance selectivity while reducing immune-related toxicity (e.g., CRS). Their modularity also supports multivalent and multi-target designs, allowing functional integration and half-life extension.

In ADCs, nanobodies offer smaller size, better tissue access, and high stability, enabling site-specific conjugation, improved consistency, and greater flexibility in payload and linker design.

In cell therapy, nanobodies can replace scFv as CAR binding domains, avoiding VH–VL pairing issues, reducing aggregation and T-cell exhaustion, and enabling access to challenging epitopes.

For delivery, nanobodies are well-suited for inhalation, intranasal, local, gastrointestinal, and brain-targeted applications, improving local exposure and reducing systemic toxicity. They can also serve as targeting ligands for nanoparticles, liposomes, exosomes, mRNA-LNPs, and viral vectors to enhance tissue-specific delivery.

6.1 Other Antibodies — Nanobodies

As applications expand, the advancement of nanobodies increasingly depends on the maturity of discovery and engineering platforms. Despite their intrinsic advantages in size, stability, and tissue penetration, successful drug development requires robust discovery systems, including engineered animal models, immunization and screening platforms, and downstream affinity optimization and molecular engineering. As these technologies mature, discovery efficiency and developability have improved, driving the field toward platform-based R&D.

Genetically engineered animal models are becoming key tools for nanobody discovery. Some humanized nanobody mouse models can generate heavy-chain-only antibodies without light chains, preserving structural advantages while reducing immunogenicity in clinical translation. For example, HUGO-Nano™, a fully human nanobody mouse platform developed by Cyagen, enables efficient generation of translatable nanobody candidates and accelerates the development of innovative therapies.

6.2.4 Approved Nanobody-Based Products and Derivatives (Global)

As of 2025, four nanobody-related products have been approved globally, including both nanobody drugs and VHH-based derivatives. Key examples include:

Caplacizumab (Cablivi®): Approved in the EU in September 2018 for acquired thrombotic thrombocytopenic purpura (aTTP). A bivalent single-domain antibody targeting the vWF A1 domain, it inhibits vWF–GPIb interaction and microthrombus formation. In the Phase III HERCULES trial, it improved platelet recovery and reduced recurrence (12% vs 38%). Developed by Ablynx (acquired by Sanofi); ~€250M revenue in 2024.

Envafohimab (Enweida®): A subcutaneous PD-L1 nanobody-Fc fusion approved by China NMPA in November 2021 for MSI-H/dMMR unresectable or metastatic solid tumors. It is among the first subcutaneous PD-(L)1 therapies and the first pan-tumor immunotherapy approved in China, with cumulative sales exceeding RMB 1.7B over three years.

Ozoralizumab (Nanozora®): A trivalent anti-TNF-α nanobody composed of two anti-TNF VHHs and one anti-HSA VHH for half-life extension. Approved in Japan in September 2022 for rheumatoid arthritis with inadequate prior response. Ciltacabtagene autoleucl (CARVYKTI®): A VHH-based CAR-T therapy targeting BCMA, using dual VHH domains instead of scFv to enhance binding stability and recognition. Reported global net sales reached ~\$960M in 2024, demonstrating clinical and commercial validation of VHH in cell therapy.

Figure: Approved Nanobody-Based Products and Derivative Therapies Worldwide

Type	Drug	Target	Company	Approved Agency	Approved Date	Indication
NANOBODY®/VHH	Ozoralizumab	TNF-α	Taisho	PMDA	2022.09	RA
	Envafohimab	PD-L1	3D Med / Simcere / Alphamab	ISAF	2024.01	Adv. Solid Tumors
				NMPA	2021.11	Adv. Solid Tumors
				NMPA	2025.11	
	Caplacizumab	VWF	Sanofi	PMDA	2022.09	aTTP
				FDA	2019.02	
				EMA	2018.08	
				NMPA	2024.08	
VHH based CAR-T	Ciltacabtagene autoleucl	BCMA	Legend / Janssen	PMDA	2022.09	R/R MM
				EMA	2022.05	
				FDA	2022.02	

Source: literature search, public information, Frost & Sullivan Analysis

6.1 Other Antibodies — Antibody Fusion Proteins

Antibody fusion proteins, created by linking functional proteins to antibody Fc domains, offer extended half-life and high affinity. Ongoing research focuses on overcoming challenges such as stability and immunogenicity to further expand their applications.

6.3.1 Definition and Mechanism

Antibody fusion proteins are recombinant proteins formed by genetically fusing an immunoglobulin Fc region (typically human IgG1 Fc) with a functional protein, such as a receptor domain, ligand-binding domain, cytokine, single-domain antibody, or other protein fragments. Common formats include receptor–Fc, ligand–Fc, and antibody fragment–Fc. This design combines the Fc’s extended half-life and effector functions (which can be silenced) with the specific binding activity of the fused domain.

Receptor “Trap”	Fuses the ligand-binding domain of a soluble receptor to an Fc region, enabling it to bind and neutralize natural ligands with high affinity. This blocks ligand signaling through cell-surface receptors (e.g., Aflibercept traps VEGF family molecules).
Signal Antagonism / Occupancy	The fusion protein occupies the ligand or ligand-binding site, preventing downstream pro-inflammatory or growth-promoting signals (e.g., Etanercept uses a soluble TNF receptor domain to bind and neutralize TNF-α/β).
Half-Life Extension & Effector Modulation	The Fc region binds to the neonatal Fc receptor (FcRn) to reduce lysosomal degradation and extend circulation time; the Fc region can also mediate ADCC/CDC (which can be engineered for enhancement or attenuation) to provide additional immune effector functions.

6.3.2 Technical Advantages and Challenges

 High Affinity and Broad-Spectrum Binding The receptor domain naturally recognizes multiple ligands or possesses natural binding sites; fusion enables broad-spectrum neutralization.	 Extended Half-Life FcRn-mediated recycling extends circulation time and sustains tissue action, significantly reducing dosing frequency.	 Modulable Fc Functions Fc immune effector functions (e.g., ADCC/CDC) can be engineered to be retained, enhanced, or silenced as needed.	 Simplified Dosing Regimen A single multi-functional entity avoids the PK/PD mismatches and drug interactions common in combination therapies.	 Clear Production Pathway Structurally simpler than complex mAbs, these recombinant proteins can be easily produced using mature mAb manufacturing platforms.
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6.3.3 Representative Drug Examples

Drug	Name	Target / Mechanism	Indication
Aflibercept	Eylea,	VEGF “Trap”: Fuses VEGFR1 & 2 extracellular domains with IgG1 Fc.	Eylea: wAMD, DME, etc.
	Zaltrap	Neutralizes VEGF-A/B and PlGF to inhibit angiogenesis.	Zaltrap: mCRC.
Etanercept	Enbrel	TNF-α Decoy Receptor: Fuses TNFR2 extracellular domain with IgG1 Fc. Binds and neutralizes TNF-α to inhibit inflammation.	RA, AS, Psoriasis, etc.

Source: literature search, public information, Frost & Sullivan Analysis

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Chapter 7

Global and Chinese Antibody Industry Development Trends



07

7.1 Global Development and Collaboration Trends in the Antibody Industry

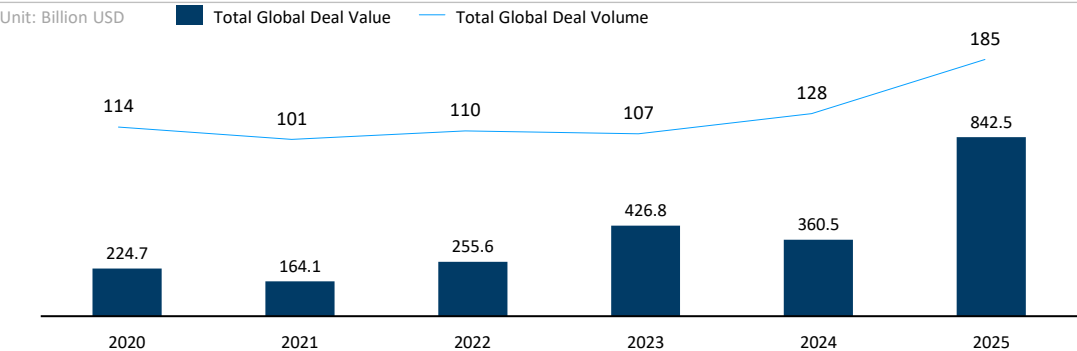
The global antibody market is highly active with growing deal sizes and volumes. Chinese pharma companies are successfully expanding globally via active "license-out" agreements, shifting their focus from mature mAbs to innovative modalities like bsAbs and ADCs.

7.1.1 Rising Momentum in Cross-Border Licensing and Collaboration for Innovative Antibodies

Globally, the number of antibody licensing deals grew steadily by over 50%, increasing from 114 in 2020 to 185 in 2025.

Global deal values also trended upward, rising from \$22.47 billion in 2020 to \$42.68 billion in 2023. Despite a slight dip in 2024, the total value surged to \$84.25 billion in 2025.

Figure: Global Cross-Border Antibody Licensing Deals: Volume and Total Value (2020.1.1 - 2025.12.31)



7.1.2 Merger and Acquisition Focus on Novel Antibody Technologies to Drive Global Integration

In recent years, major overseas pharma companies have increasingly used M&A to access high-quality pipelines and R&D capabilities, maintaining innovation amid patent cliffs and rising development costs. They focus on acquiring assets in hot areas like bispecific antibodies and ADCs. Concurrently, innovative Chinese biotech firms are entering the global M&A pool, valued not just for individual products but for differentiated antibody design and engineering platforms. These assets provide overseas buyers with new technologies and a foothold in China. For example, BioNTech initially acquired rights to Pumice Biotech’s Phase III bispecific antibody PM8002 outside Greater China for up to \$1B in 2023, then fully acquired the company in 2024, illustrating a trend of M&A as a path to integrated antibody technology and development capabilities.

In July 2021, Amgen acquired biotech company Teneobio for \$900M upfront plus \$1.6B in milestone payments, aiming to access Teneobio’s proprietary heavy-chain antibody platform and bispecific antibody technology. The acquisition strengthened Amgen’s R&D in bispecifics and provided diverse molecular building blocks to accelerate next-generation therapies in key indications.



In 2023, Pfizer completed its \$43B acquisition of biotech company Seagen, one of the largest pharma deals in recent years. The deal secured Seagen’s leading ADC technology platform and four approved oncology drugs. By combining Seagen’s proprietary ADC expertise with its own production and commercialization capabilities, Pfizer aims to strengthen its oncology portfolio and position cancer treatments as a key growth driver, reflecting a trend of big pharma using strategic acquisitions to lead in next-generation cancer therapies.

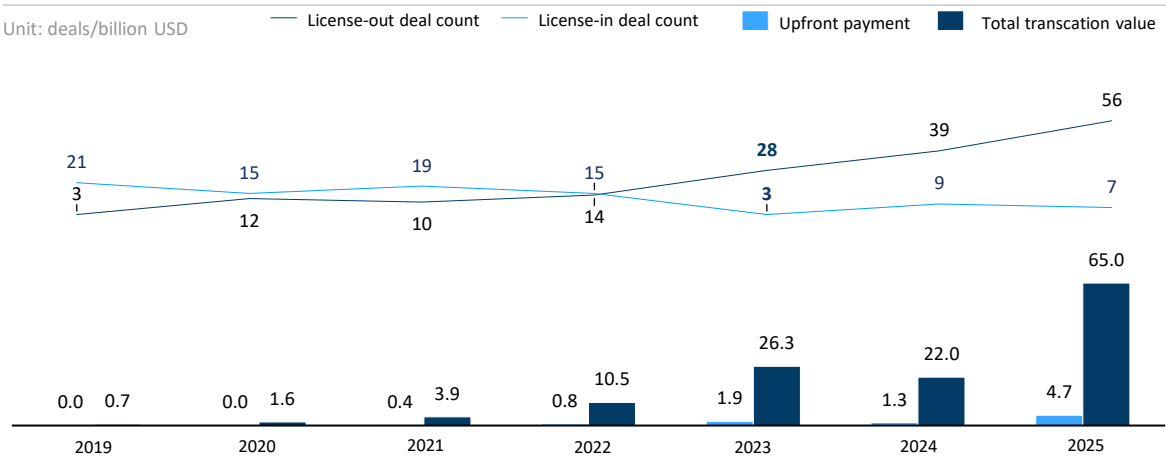


7.1 Global Development and Collaboration Trends in the Antibody Industry

7.1.3 Current Status of Chinese Antibody Drugs Going Global

China’s antibody industry is increasingly international, driven by advances in antibody screening, affinity maturation, and molecular optimization. PD-1/PD-L1 monoclonal antibodies are now in global multi-center trials and have achieved overseas approvals or commercial partnerships. Improved ADC and bispecific antibody technologies create differentiated competitive advantages, supported by strong domestic engineering platforms and CMC capabilities. License-out has become a key path for globalization: from 2019 to 2025, Chinese antibody license-out deals grew from 3 to 56, with total deal value rising from \$700M to \$65B, reflecting a rapid expansion of overseas collaborations.

Figure: 2019-2025 Chinese antibody Drug License-Out deal Activity



7.1.4 Summary of Major Deals

With advances in antibody and ADC technologies, cross-border licensing has become a key way for pharma companies to expand pipelines. From 2019 to 2025, multiple high-value license-out deals emerged globally, mainly in ADCs and bispecific antibodies, with the top five deals exceeding \$6B each.

Figure: Top 5 License-Out Deals by Total Value (2019–2025)

Rank	Licensor	Licensee	Deal Highlights	Date
1	Qilu Bio	AIMEDBIO/ Biohaven	Licensing deal exceeding \$13B, covering its first-in-class ADC GQ1011 and core bispecific platform technology	2025.01.24
2	Xinda Bio	Takeda	Strategic collaboration up to \$11.4B, including global co-development and commercialization of IBI363 and overseas rights for IBI343 & IBI3001	2025.10.22
3	Betta Tianheng	BMS	Licensing agreement up to \$8.4B, granting global rights outside Greater China for first-in-class bispecific ADC BL-B01D1	2023.12.12
4	Roivant Sciences	Roche	Roche acquired rights to Telavant for ~\$7.25B, gaining development, manufacturing, and commercialization of anti-TL1A antibody RVT-3101 in US & Japan	2023.07.14
5	3SBio	Pfizer	3SBio granted Horizon rights to PD-1/VEGF bispecific SSGJ-707 outside Greater China, total deal up to \$6.05B	2025.07.25

Source: public information, Frost & Sullivan Analysis

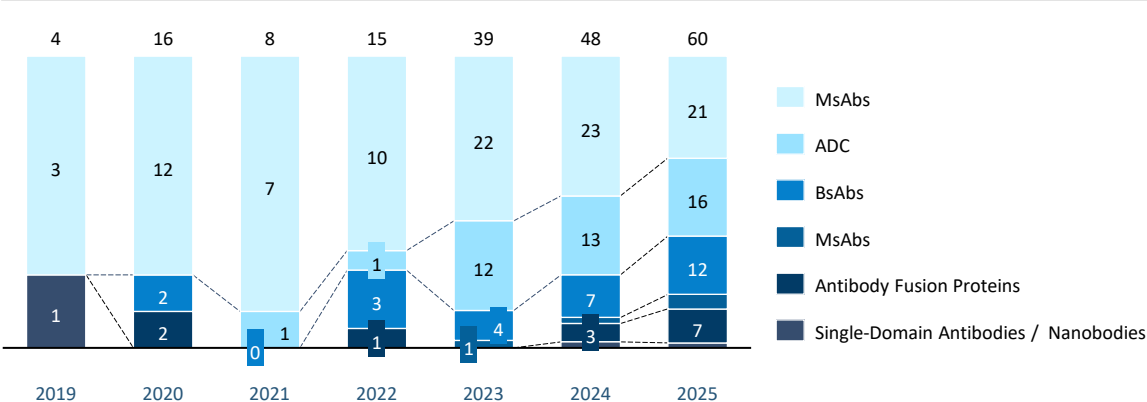
7.1 Global Development and Collaboration Trends in the Antibody Industry

7.1.5 The Portfolio of Outbound Antibody Deals is Becoming Increasingly Diversified

The number of outbound transactions involving antibody drugs has grown steadily, rising from 4 deals in 2019 to 60 in 2025. Meanwhile, modalities have expanded from monoclonal antibodies and single-domain/nanobodies in 2019 to a broad mix including monoclonal antibodies, ADCs, bispecific and multispecific antibodies, antibody fusion proteins, and nanobodies. Among these, ADCs and bispecific antibodies are showing particularly strong momentum.

In November 2020, Henlius licensed ex-China rights of its EGFR/4-1BB bispecific antibody HLX35 to Binacea Pharma for USD 770 million. In 2021, ADCs made their first appearance in outbound deals, marking the beginning of China’s ADC globalization. By 2023, ADCs accounted for nearly one-third of license-out transactions. Within the license-out model, monoclonal antibodies remain the most active category due to their technological maturity, while next-generation formats such as bispecifics and ADCs are increasingly driving differentiated competition, with some products gaining early traction in global markets.

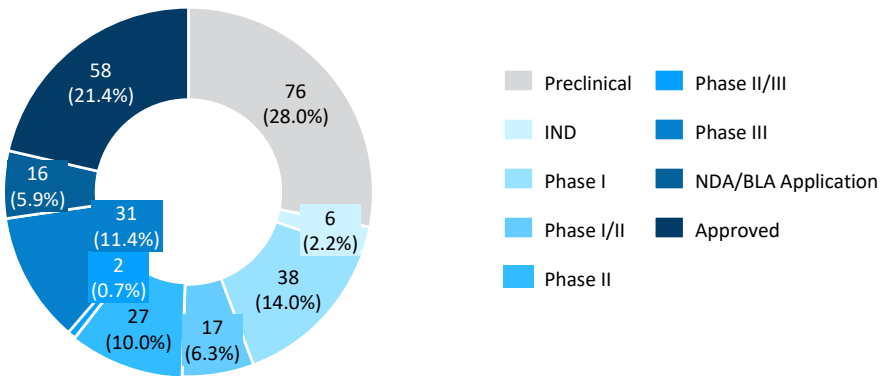
Figure: 2019-2025 Licence-out Transactions for Antibody Drugs in China, Broken Down by Ingredient Category



7.1.6 Clinical Stage Distribution of Global Cross-Border Antibody Deals

Driven by growing global oncology demands, favorable overseas pricing/reimbursement, and regulatory convergence (e.g., China joining ICH), early-stage projects increasingly pursue simultaneous global development. Notably, in the past five years, 28.0% of globally licensed antibodies were in the Preclinical stage, and 14.0% were in Phase I.

Figure: 2020-2025 Clinical Distribution of Global Cross-Border Transactions for Antibody Drug Licensing, Licensing-in and Collaborations, 2020–2025



Source: Insights, Frost & Sullivan Analysis

7.2 Opportunities Driven by Emerging Technologies

AI technologies are significantly improving the efficiency and success rates of antibody drug development through assisted design and generative discovery, and are becoming a key source of competitive advantage.

7.2.1 AI-driven Drug Design is Shortening and Streamlining the Antibody R&D Process from Discovery through Engineering to Optimization

AI-driven technologies are significantly improving efficiency across the "discovery—engineering—optimization" pipeline in antibody R&D. By leveraging algorithms like generative models and protein structure prediction, AI accelerates candidate screening, sequence analysis, and the evaluation of multi-dimensional properties (e.g., developability, immunogenicity, stability), thus optimizing experimental resource allocation. Currently, platform development follows two main paths: companies building internal proprietary data-driven platforms, and AI biotechs offering external de novo generative design capabilities.

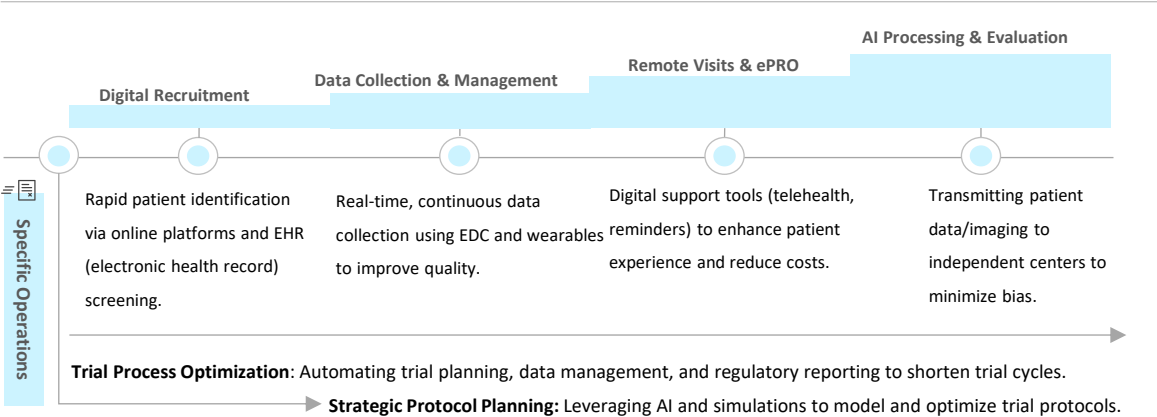
In practice, various platform cases have emerged. For example, Cyagen's AbSeek® intelligent antibody computational platform focuses on antibody discovery and antibody engineering, covering the entire process from screening to optimization. It provides tools such as antibody sequence analysis, structure and function prediction, lead antibody optimization, and antibody molecule generation, and is equipped with computational and visualization modules to support the simplification and automation of the antibody design process. Additionally, platforms like BigHat Biosciences' Milliner™ integrate machine learning with high-throughput experiments to create a rapid "design—build—test—learn" closed loop. Overall, AI tools are evolving into integrated systems, driving continuous industry investment.

7.2.2 Digital Clinical Trials and AI-Assisted Clinical Design Improve Antibody Clinical R&D Efficiency and Reduce Costs

Digital tools (e.g., digital recruitment, ePRO) and AI models for dose selection and biomarker screening are increasingly utilized in antibody clinical trials to enhance enrollment, minimize data lag, and improve endpoint analysis. For drugs with "bell-shaped" dose-responses, such as immune agonists or bispecific antibodies, AI integrates single-cell multi-omics data to quantitatively characterize immune networks. This directly guides biological dose selection, patient stratification, and combination therapy strategies.

In industry practice, GSK partnered with Tempus, utilizing AI and de-identified patient data to optimize trial design and accelerate Phase II site selection and enrollment. Meanwhile, Roche integrated third-party AI algorithms into its digital pathology workflow to quantify biomarkers like PD-L1 and screen for MSI, supporting robust patient stratification. Additionally, AstraZeneca collaborated with Immunai to apply single-cell multi-omics AI models for key decisions in oncology trials, such as dose and biomarker analysis. These cases demonstrate AI's powerful expansion from early discovery into core clinical development stages.

Figure: Digital Clinical Trial Process



Source: Frost & Sullivan Analysis

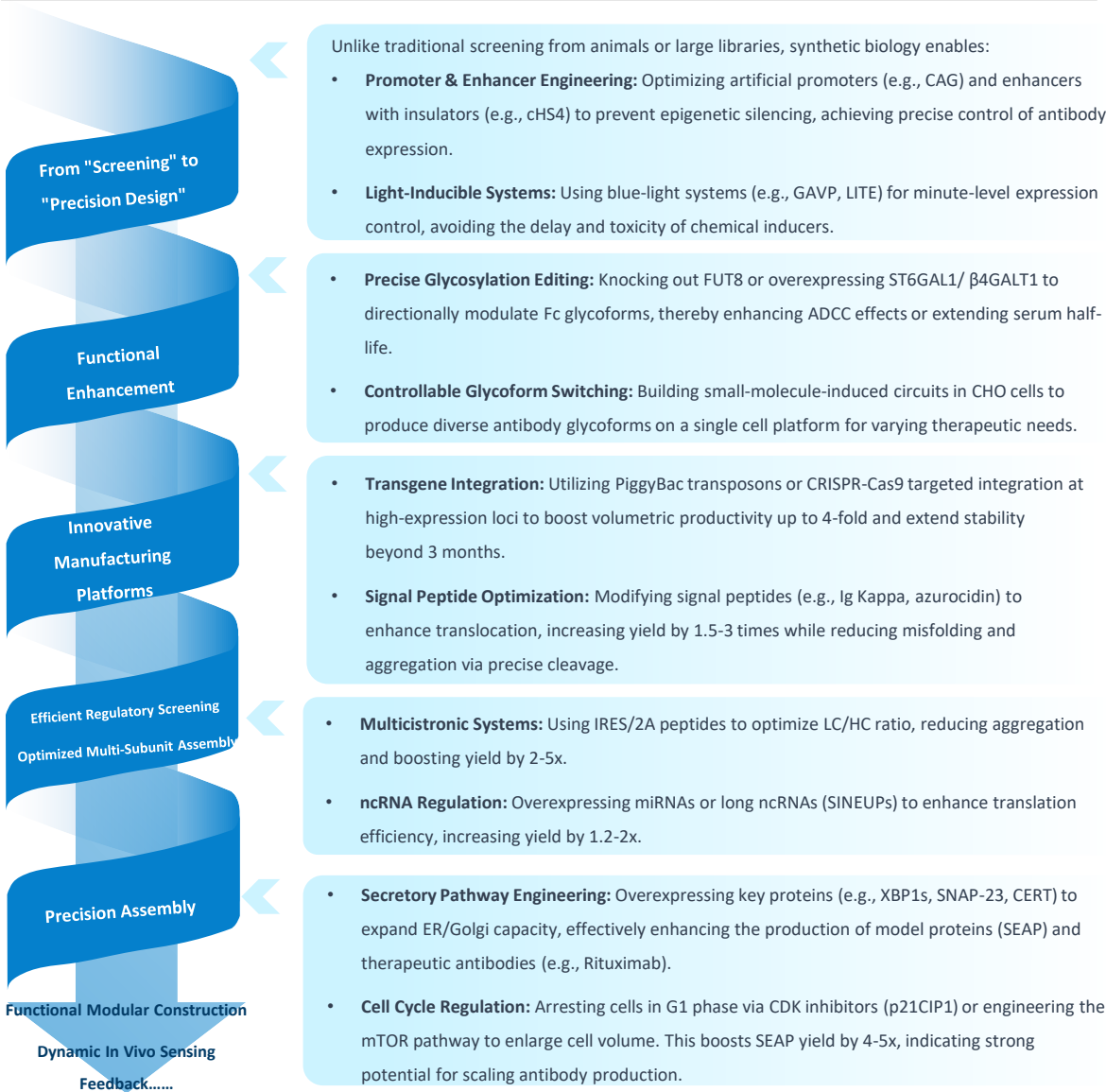
7.2 Opportunities Driven by Emerging Technologies

Synthetic biology is reshaping the design, production and development of antibodies through multi-dimensional engineering

7.2.3 Synthetic Biology is Revolutionising Antibody Development

Synthetic biology is revolutionising antibody development across multiple dimensions. Its focus has shifted from traditional expression optimisation to the systematic programming of systems such as expression regulation, cellular factories, product quality and complex assembly. By targeting core challenges such as antibody expression efficiency, structural complexity and functional customisation, it is systematically advancing the development of antibody therapeutics.

Figure: Synthetic biology processes driving the development of antibody therapeutics



Source: literature search, public information, Frost & Sullivan Analysis

7.2 Opportunities Driven by Emerging Technologies

Next-generation antibodies are rapidly evolving along three paths—structural innovation, functional enhancement, and conditional regulation—shaping a new ecosystem for complex antibody drug development.

7.2.4 Emergence of Novel Antibody Formats

Emerging antibody formats—including nanobodies/single-domain antibodies, multivalent antibodies, and conditionally activated antibodies—are rapidly advancing along three paths: structural innovation, functional enhancement, and conditional control. The goal is to optimize molecular structure, enhance efficacy, and achieve more precise targeting.

Nanobodies and single-domain antibodies offer small size, strong tissue penetration, and high engineering flexibility, showing promise in oncology, autoimmune, and CNS diseases. Bispecific/multispecific antibodies and ADCs enable dual-targeting for synergistic or bridging effects, expanding beyond the scope of traditional monoclonal antibodies. Meanwhile, conditionally activated antibodies aim to improve safety by activating selectively within specific microenvironments.

These approaches differ in design: smaller, optimized structures improve tissue penetration; multi-target designs enhance pathway modulation or cell engagement; and condition-triggered mechanisms (e.g., pH, enzymes, hypoxia, antigen density) enable more precise activity with reduced off-target effects.

Figure: Design Dimensions, Implementation & Cases of Emerging Antibodies

Design Dimension	Implementation & Advantages	Representative Forms & Applications
Size & Penetration	• Smaller size: Penetrates BBB & solid tumor cores • High tissue penetration	Nanobodies / VHs: • CNS diseases, solid tumors, radioconjugates
Valency & Synergy	• Multivalent design: Enhances avidity, overcomes low Ag expression • Multi-target synergy: Blocks multiple pathways simultaneously	Multispecific Antibodies: • Targeting complex proteins (e.g., multimers), preventing tumor escape
Logic & Safety	• Conditional activation: Triggered only when target (A) & microenvironment (B) coexist, reducing off-target toxicity • "AND" logic gate design	Conditionally Active Antibodies: • Activated specifically in TME, widening therapeutic window



7.3 Localization of the Industrial Chain

Upstream raw materials—such as culture media, reagents, cell lines and chromatography resins—are deeply integrated with the antibody discovery platform, creating a seamless workflow

7.3.1 Synergy between Raw Materials and Technology Platforms: from Substituting Consumables to Achieving Self-sufficiency at the Source

A. Media & Reagents: Outperformance and Supply Chain Security

Domestic media have moved from “usable” to “high-performing.” Leading players, through high-throughput screening and formulation optimization, are benchmarking against global leaders such as Thermo Fisher Scientific / Gibco and Merck / Sigma-Aldrich.

Quality: For example, OPM Biosciences achieves VCD $>90 \times 10^6$ cells/mL and titers up to 8.4 g/L in CHO-K1 fed-batch culture— $\sim 1.74 \times$ higher than a leading imported benchmark.

Cost: Imported media (e.g., Gibco, Cytiva) typically price at RMB 400–800/L, versus RMB 200–400/L for leading domestic suppliers. Local production avoids cold-chain shipping, logistics, and tariffs (~ 15 – 20% of cost), enabling price advantages.

Lead time: During 2020–2022 supply disruptions, imported media often required 12–16 weeks due to cross-border cold chain and customs processes. Domestic suppliers reduced this to 2–4 weeks, significantly lowering preclinical development delays.

B. Cell Lines: Breaking the Licensing Monopoly

Commercial cell lines were historically dominated by imported platforms such as Lonza’s CHO-GS system, which involve high upfront fees plus downstream royalties. Domestic players are shifting to “one-time buyout” or “media-bundled” models, eliminating ongoing payments. For example, OPM Biosciences’s SureCHO-K1+ cell line, combined with its proprietary media, can achieve 6–10 g/L expression, with clear IP ownership and no milestone or royalty obligations—often bundled with media purchase or offered at low licensing cost. CDMOs such as JOINN Biologics have also developed proprietary cell lines, shifting from reliance on external platforms to fully in-house systems. Regulatory compliance: Leading domestic suppliers (e.g., OPM Biosciences, Duoning Biotechnology, BioEngine) have filed DMFs with the U.S. Food and Drug Administration, indicating growing regulatory recognition of domestic cell line platforms.

C. Chromatography Resins: From Single Breakthroughs to Broad Expansion

NanoMicro Technology pioneered monodisperse microsphere technology, addressing key bottlenecks and paving the way for the broader rise of domestic resin suppliers. Bestchrom has established strong adoption in ion exchange and hydrophobic resins, while Sunresin and other players continue to improve Protein A resins in alkali resistance and lifespan—at roughly half the price of imported products such as MabSelect. Protein A affinity resins are the most critical and widely used materials in antibody purification and account for the majority of the resin market due to their high unit cost. Their localization is therefore key to significantly reducing antibody production costs at large-scale commercialization.

D. Antibody Discovery Platforms: Deep Integration with Upstream Inputs for Seamless Workflows

Historically, this space was dominated by overseas platforms such as HuMab-Mouse, KM Mouse (UltiMAB), XenoMouse, and VelocImmune. China has now developed proprietary alternatives, led by players like Cyagen Biosciences and Biocytogen.

Cyagen Biosciences emphasizes flexibility, service depth, and AI enablement. Its HUGO-Ab[®] platform offers a cost-effective, IP-clear alternative to traditional high-cost licensing models by providing “in vivo-ready” antibody discovery inputs. Its key advantage lies in a closed-loop “model + AI + validation” system: leveraging large-scale gene-editing data, AI-driven antigen design (especially for challenging targets like Claudin 18.2, CD3, STEAP1, KLK2), HUGO mouse immunization, and high-throughput single B-cell sequencing for rapid screening. This approach is particularly effective for emerging formats such as nanobodies and multispecific antibodies, significantly shortening the timeline from target to preclinical candidate. Meanwhile, Biocytogen’s RenMice[®] platform not only provides fully humanized mouse models but also enables large-scale screening to directly output antibody candidates.

Source: literature search, public information, Frost & Sullivan Analysis

7.3 Localization of the Industrial Chain

Key equipment such as bioreactors and purification systems has been partially replaced by domestic alternatives, thereby improving supply efficiency and cost control

7.3.2 Equipment Localization: Advancing Upstream and Downstream Capabilities

In China’s antibody industry, equipment localization has become a key driver of resilience and competitiveness. Core systems such as bioreactors and downstream purification equipment have achieved partial domestic substitution, significantly shortening lead times, reducing procurement and maintenance costs, and enhancing manufacturing scalability and process flexibility. By building a more self-sufficient equipment ecosystem, the industry is reducing reliance on imported systems and consumables, laying a more efficient and robust foundation for large-scale commercial production.

■ Upstream Bioreactor Production

Bioreactors are critical equipment for cell culture in biopharmaceutical manufacturing, with high technical barriers. The market was initially dominated by international players such as Sartorius, Cytiva, and Siemens, while domestic substitution offers significant potential. Local manufacturers are gaining ground through advantages in cost, supply chain responsiveness, and customization, alongside ongoing technological catch-up.

Based on materials in contact with cells and media, bioreactors are categorized into stainless steel and single-use systems. Stainless steel bioreactors offer strong scalability and eliminate recurring consumable costs, making them suitable for large-scale commercial production. In contrast, single-use bioreactors require lower upfront investment and avoid cleaning validation, providing clear advantages in R&D and early-stage commercialization.

 Stainless Steel Bioreactor Systems	 Single-Use Bioreactor Systems
Domestic companies have progressively overcome key technical challenges in large-scale stainless steel bioreactors, including fluid dynamics design, gas–liquid mass transfer, scale-up of mixing, and high-precision welding. Represented by Toftlon, local platforms now support scale-up to 10,000 L and above, accelerating domestic substitution in large-scale commercial manufacturing.	The key barrier for single-use bioreactor bags lies in membrane materials. Several domestic companies have achieved in-house development and mass production, breaking the import monopoly on high-quality films. For example, LePure Biotech has developed its proprietary LeKrius® film, validated through biocompatibility and physicochemical testing, with E&L support.

■ Downstream Purification System

Purification systems require high separation purity and strict data integrity. Downstream processes are typically controlled by distributed control systems (DCS) or single-use automation platforms, which integrate sensor data and execute predefined workflows to ensure batch consistency and GMP compliance.

- ◆ **DCS** is suited for large-scale, continuous antibody manufacturing (typically ≥10,000 L stainless steel lines), linking previously isolated units into a centrally monitored and coordinated system. Domestic vendors such as SUPCON and Hollysys have achieved performance comparable to Emerson, with tailored modules for precise control of gradient elution and pH.
- ◆ **Single-use automation systems** are designed for disposable processes, requiring strong plug-and-play compatibility and algorithmic compensation for sensor drift. For example, Hanbang Technology offers industrial chromatography systems (Bio-SC series) with control software compliant with FDA 21 CFR Part 11, enabling auto-recognition and calibration of single-use sensors and ensuring tamper-proof audit trails.

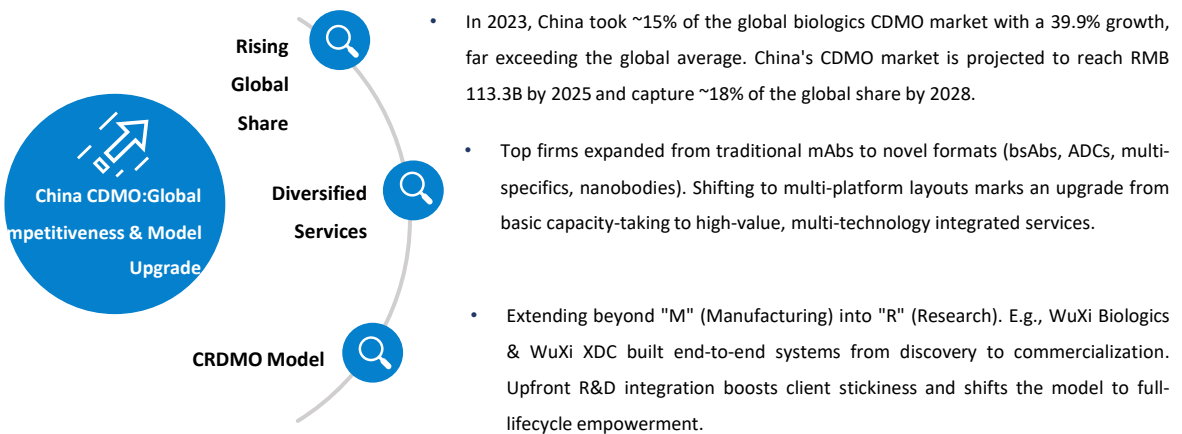
7.3 Localization of the Industrial Chain

Local CDMOs are steadily increasing their global market share and possess end-to-end capabilities spanning from process development to commercial-scale supply, thereby supporting the accelerated translation of antibody research and development.

7.3.3 CDMO Capabilities — End-to-End Support Accelerating Antibody Development

The CDMO model originated in Europe and the U.S. to meet pharma outsourcing needs from R&D to manufacturing. In recent years, China has become a key destination for global CDMO capacity transfer, driven by cost, technology, and integrated supply chain advantages. The industry has moved beyond simple capacity expansion, mastering advanced CMC capabilities—such as bispecific mismatch control and ultra-high-density perfusion—and is emerging as a global hub for complex biologics manufacturing.

Figure: the Global Competitiveness and Model Upgrades of China’s CDMO Sector



Biologics CDMO services span an integrated chain from early process dev and analytical research to GMP manufacturing, regulatory filing, and commercial supply. Future trends highlight: more comprehensive, long-term partnerships; deepened technical capabilities for complex product scale-up; scalable yet flexible capacity supporting multi-product, continuous, and high-density manufacturing; enhanced supply chain and cost management for competitive delivery; and globalized service systems to effectively meet worldwide demands.

Figure: Innovative Case Studies of Biopharmaceutical CDMOs in China

TCR Constant Domain Replacement	WuXi Biologics’s WuXiBody™ is a proprietary bispecific antibody platform that replaces the CH1/CL domains of one parental antibody with TCR constant domains, inherently resolving heavy/light chain mispairing without complex protein engineering. The platform enables expression levels above 2.5 g/L, with peaks up to 16 g/L, shortens development timelines by 6–18 months, and reduces production costs by up to 90%. It is compatible with both fed-batch and concentrated fed-batch processes, significantly lowering bispecific manufacturing costs to near monoclonal antibody levels and advancing the transition from “can be made” to “can be made affordably and efficiently.”
Continuous Perfusion Process	Traditional processes rely on batch culture, while the latest trend is perfusion, enabling continuous protein harvest at very high cell densities. WuXi Biologics’s WuXiUP continuous platform delivers output equivalent to 10,000–20,000 L stainless steel capacity using 1,000–2,000 L single-use bioreactors, with 140+ applications. Its WuXiUI platform integrates intensified fed-batch and perfusion, boosting productivity by 3–6× and achieving 2,000 L GMP scale—allowing a 2,000 L single-use system to match the output of a traditional 20,000 L facility, significantly reducing capex and footprint.

Source: Company Websites, Frost & Sullivan Analysis

7.3 Localization of the Industrial Chain

China's antibody industry has progressively aligned with international standards, establishing quality systems compliant with FDA/EMA inspections and building reliable global supply capabilities.

7.3.4 Quality System Globalization — Aligning with International Standards and Connecting to Global Markets

Overall, China's antibody industry is steadily aligning its quality management and regulatory framework with international standards such as ICH, and is increasingly capable of delivering products and services to regulated global markets. On the regulatory side, since joining ICH in 2017, China has continuously promoted the implementation of ICH guidelines, advancing convergence with global practices in drug registration and quality management. The 2025 edition of the Chinese Pharmacopoeia, for example, further strengthens risk management principles and incorporates elements of ICH Q9, driving a shift toward risk-based, lifecycle quality management.

On the industry side, a growing number of leading antibody and CDMO companies have passed inspections or pre-approval inspections by U.S. and European regulators with favorable outcomes (e.g., no critical findings or data integrity issues), providing strong validation for participation in global supply and regulatory filings.

At the same time, globalization raises the bar for auditable CMC and process quality systems. Entry into regulated markets depends not only on product innovation, but on establishing internationally accepted, lifecycle quality management capabilities. Alignment with global standards enables consistent process control, validated analytical methods, traceable supply chains, and auditable data integrity—supporting overseas filings, inspections, and sustained commercial supply. Accordingly, internationalization typically evolves from early-stage clinical and regulatory expansion to commercial supply, and further toward technology and product out-licensing.

Within this framework, license-out represents a market-based validation of global capabilities. When evaluating assets, multinational pharma companies look beyond clinical and mechanistic value to the completeness of CMC packages, scalability and tech transfer feasibility, and the auditability of quality systems. The more robust these capabilities, the lower the execution risk and the greater the potential for high-quality global partnerships and market integration.



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Chapter 8

Introduction to Selected Companies in the Antibody Sector



08

8.1 Cyagen Biosciences

■ Company Overview

Cyagen, established in 2006, is a national-level "Little Giant" and High-tech Enterprise. As an innovative CRO, the company leverages proprietary gene-editing technology to provide end-to-end preclinical services—from model construction to efficacy evaluation—focusing on oncology, neuroscience, immunology, metabolism, and ophthalmology. Its signature HUGO-Ab® fully human antibody mouse platform enables high-efficiency discovery of mAbs, common light chain antibodies, and nanobodies, significantly accelerating clinical translation. Supported by over 1,000 employees and a 40,000 facility, Cyagen adopts a "Data + Model" dual-driven strategy to empower global pharmaceutical innovation.

■ Cyagen Antibody Drug Discovery Platform: Synergistic Technologies Empowering End-to-End Development

Amid growing technological innovation among domestic companies, Cyagen Biosciences stands out with a "full-scenario coverage" platform strategy. Its HUGO-Ab® fully human antibody mouse platform is not a single product but a differentiated suite comprising HUGO-Mab® fully human antibody mice, HUGO-Light™ fully human common light chain mice, and HUGO-Nano™ fully human nanobody mice. Specifically, these two resolve mispairing and poor penetration to form an end-to-end R&D matrix from mAbs to bi/multispecific antibodies.



HUGO-Mab® : Strengthening mAb Development by Resolving Druggability Issues



HUGO-Mab® mice address core limitations of early fully human platforms: restricted diversity, low affinity, and poor clinical druggability. Utilizing Cyagen's proprietary TurboKnockout® in-situ replacement and chromosomal translocation technologies, mouse variable region genes are completely replaced with human ones.

- **Versatile Strains:** Off-the-shelf HUGO-Mab® mice available in BALB/c, C57BL/6, and SJL backgrounds.
- **Full Germline Preservation:** Humanized heavy, κ light, and λ light chains fully retain the human antibody germline.
- **Broad Antigen Compatibility:** Strong immune responses against proteins, peptides, mRNA-LNP, and overexpressing cells.
- **Superior Affinity:** With titers comparable to wild-type, the platform simulates natural affinity maturation to yield antibodies with 10^{-9} M. It has already driven multiple candidates into preclinical development.

HUGO-Light™ : Overcoming Mispairing Bottlenecks to Build a "LEGO-style" Multi-specific Factory



Core Advantages: Exponential Screening Efficiency & "Plug-and-Play" Candidates

HUGO-Light™ mice redefine complex antibody development. By in-situ inserting a pre-rearranged human light chain variable sequence (e.g., Vk1-39/Jk5) into mouse Ig κ /Ig λ loci and knocking out endogenous light chains, the immune system exclusively secretes antibodies with a single common light chain (CLC) for any target.

- **Streamlined Screening, Multiplied Efficiency:** Eliminating stochastic pairing allows researchers to focus solely on high-affinity heavy chain (VH) selection. This boosts correct assembly rates from ~25% to over 95%, slashing R&D cycles from 12-18 months to just 6-8 months.
- **Simplified Structure, Full Potency:** Despite structural simplification, immune performance is uncompromising. The platform has yielded high-functioning candidates for difficult targets like CD3, TCR, KLK2, and STEAP1, with CD3 leads showing clear human/cyno cross-reactivity.
- **Modular "LEGO-style" Assembly:** High-quality VH binders act as standardized "bricks" that combine seamlessly with the fixed CLC for "plug-and-play" construction of complex modalities:
 - **BsAbs/MsAbs:** Rapid assembly of combos like PD-1 $\times$ VEGF or EGFR $\times$ HER3.
 - **T-cell Engagers (TCE):** Efficient CD3 $\times$ TAA bispecifics for T-cell activation.
 - **Brain Shuttle:** Targeted CNS delivery via TFR1 or CD98HC.
- **One-time Purchase, Permanent License:** Mice and CLC patents are bundled for sale. Buy out all rights with no milestone payments to accelerate your drug development timeline.
- HUGO-Light™ not only lowers the entry barrier for complex antibody R&D but serves as the preferred engine for biopharmas to master next-generation multifunctional therapeutics.

8.1 Cyagen Biosciences

HUGO-Nano™ : Overcoming “Weak IgG Penetration” to Reshape Specialized Therapeutics



Core Advantages: Fully Human Small Molecules + Ultra-high Activity; Unlocking “Undruggable” Targets

HUGO-Nano™ was engineered to overcome traditional IgG limitations, such as large size (~150 kDa) and poor penetration. It efficiently generates 15 kDa fully human nanobodies—just 1/10 the size of conventional antibodies—offering disruptive solutions through four core advantages:

- **Fully Human Sequences, Zero Immunogenicity Risk:** Unlike camelid-derived nanobodies, HUGO-Nano™ directly outputs fully human sequences. This eliminates complex humanization and bypasses immune rejection risks, significantly slashing development time and costs.
- **Superior Stability:** DSF Tm values exceed 60°C. Accelerated stability tests (40°C, 14 days) show <10% main peak variation across SEC, icIEF, and CE-SDS analysis.
- **Flexible Single Domains, Infinite Combinations:** As natural single-domain antibodies, these “molecular parts” can be rapidly linked via genetic engineering to build bispecifics, multispecifics, or novel conjugates for synergistic multi-targeting.
- **Deep Penetration, Precision Targeting:** The ultra-small size allows access to hidden clefts or pockets unreachable by traditional antibodies. It effectively crosses the blood-brain barrier (BBB) and penetrates deep into solid tumors, enhancing specificity and efficacy.

From BBB crossing to deep tumor targeting and gene therapy vector construction, HUGO-Nano™ leverages its “Small Size + Fully Human + High Activity” to shatter traditional antibody limits and accelerate the clinical translation of innovative therapies.

■ AbSeek® Intelligent Antibody Computational Platform——Engineering the Future, Empowering Innovation

AbSeek® is engineered to accelerate antibody drug development. Leveraging Cyagen’s 20-year expertise, it integrates AI and bioinformatics into a one-stop intelligent solution covering the entire discovery, optimization, and validation workflow.

Centered on AI, AbSeek® integrates 30+ proprietary and open-source tools for sequence analysis, structure prediction, affinity optimization, and immunogenicity assessment. It streamlines phylogenetic analysis and structural modeling for the heavy-chain-only sequences from HUGO-Light™ and HUGO-Nano™, simplifying complex data into actionable insights.

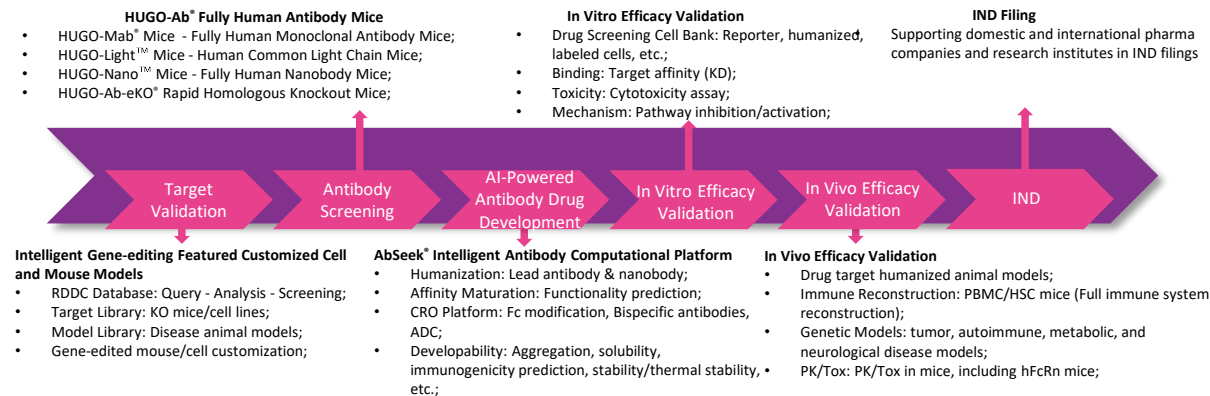
The AbMart module (Global Hot Antibody Target Database) serves as an efficient tool for project initiation. By aggregating global pipeline data, it visualizes competitive landscapes to help researchers assess market potential and risks. From target selection and molecular design to screening, functional validation, and druggability optimization, AbSeek® addresses core R&D pain points to double development efficiency.

■ Cyagen AI-Driven Fully Human Antibody Solutions: Synergistic Tech Empowering R&D

Integrating the HUGO-Ab® mouse and AbSeek® computational platforms, Cyagen has established a full-process technical closed loop: “**Target Immunization → Sequence Acquisition → AI Analysis → In Vivo/In Vitro Efficacy Validation.**”

By focusing on “Sub-scenario Adaptation + Efficiency Optimization,” this architecture slashes discovery cycles by over 50% compared to traditional methods. It comprehensively supports diverse R&D needs—from basic mAbs to complex bispecifics, and from systemic administration to localized targeting—becoming a global leader in functional breadth, adaptability, and technical integration among fully human antibody mouse platforms.

Figure: Cyagen One-Stop Process Flowchart





8.2 Epimab Biotherapeutics

■ Company Overview

Epimab Biotherapeutics is a clinical-stage biopharmaceutical company specializing in the development of multispecific antibodies. Leveraging its extensive in-house research expertise and proprietary technological capabilities—including the internally developed bispecific antibody platforms FIT-Ig (Fabs-In-Tandem Immunoglobulin) and MAT-Fab (Monovalent Asymmetric Tandem Fab) — Epimab is advancing and globally deploying a portfolio of differentiated pipeline programs. These include innovative preclinical and clinical-stage assets aimed at delivering transformative therapies for patients with cancer.

Innovation at the Source through Independent R&D



- Core products target global unmet clinical needs
- A sustainable pipeline of first-in-class (FIC) and best-in-class (BIC) assets
- As of December 2025, three drug candidates have entered global clinical development

Innovative, Patent-Protected Bispecific Antibody Technology Platforms



- Secured patent protection across multiple global jurisdictions for its leading bispecific antibody platforms
- Multiple programs have demonstrated that the FIT-Ig platform enables efficient bispecific development with monoclonal antibody-level quality and speed

World-Class Management Team Comprising Accomplished, Multidisciplinary Experts



- Dr. Chenbing Wu is a globally recognized expert in bispecific antibodies, with numerous distinguished achievements in the field
- The management team brings extensive industry experience spanning early discovery, clinical development, CMC, and BD

■ Business Model

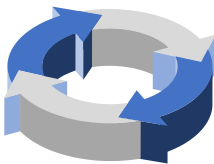
Epimab Biotherapeutics centers its operations on proprietary bispecific antibody technology platforms. Leveraging nearly a decade of industry experience, the company engages in the discovery, development, and commercialization of bispecific antibodies and T-cell engagers (TCEs). By capitalizing on its R&D capabilities, modular antibody engineering platforms, and strategies spanning preclinical to clinical development, Epimab has built a diversified product pipeline. Strategic collaborations—including licensing and co-development with global partners—further strengthen its business footprint and capture market opportunities.

Core Business Model

Leveraging proprietary technology platforms, the company develops bispecific antibodies and TCEs. Through internal development, external licensing and strategic co-development partnerships, it builds a diversified pipeline to capture emerging market opportunities.

Technology Toolbox

Equipped with core patented platforms such as FIT-Ig and MAT-Fab, along with a proprietary CD3 antibody library, the company supports the rapid, modular construction of bispecific antibodies and enables flexible optimization of TCE formats and affinity.

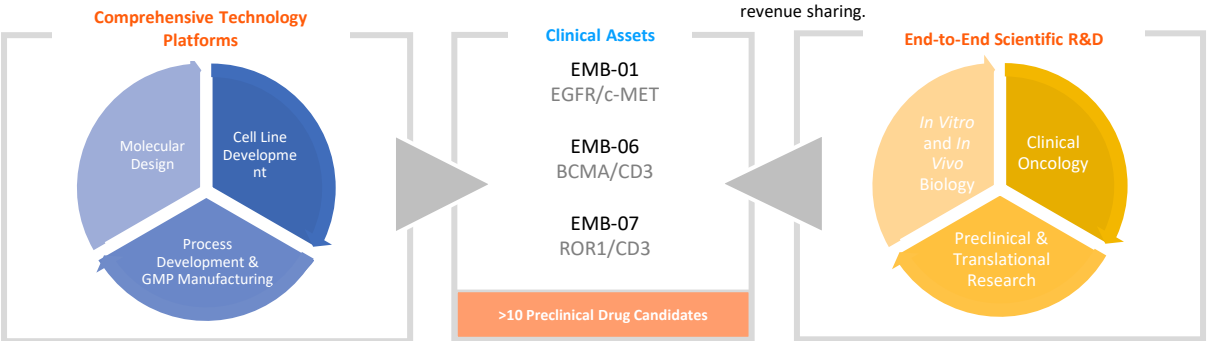


Pipeline Development Strategy

Adopts a customized asset development strategy, flexibly selecting independent advancement, out-licensing, or co-development based on therapeutic area, development stage, and market potential to maximize value while managing risk.

Strategic Collaboration Achievements

Established high-value global licensing partnerships with Candid (formerly Vignette Bio) and Juri, accelerating pipeline development, validating the technology platforms, and securing non-dilutive funding with potential future revenue sharing.



Sources: Company Prospectus, Company Website, Public information, Frost & Sullivan analysis



8.2 Epimab Biotherapeutics

■ Antibody Technology Platforms

Epimab Biotherapeutics has established a multispecific antibody technology platform ecosystem. Its core platforms include proprietary bispecific antibody platforms such as FIT-Ig (Fabs-In-Tandem Immunoglobulin) and MAT-Fab (Monovalent Asymmetric Tandem Fab) as well as the T-FIT (TCR-Fab in Tandem) platform designed to generate TCR-guided T-cell engagers (TCR-TCEs).

Representative Bispecific Antibody Platforms	
Platform	Core Features
FIT-Ig	Integrates two distinct Fab domains into a single IgG-based molecule without artificial linkers or mutations, retaining natural antibody structure for dual-target binding. The platform enables a “plug-and-play” approach, efficiently generating FIT-Ig bispecifics from any two parental Fab sequences with minimal engineering. Its modular design targets multiple disease pathways—including oncology, autoimmune, and infectious diseases—offering potential advantages in stability, specificity, safety, and manufacturability.
MAT-Fab	Utilizes tandem Fab units fused to the Fc region via a cross-over design to achieve monovalent binding to two distinct epitopes or antigens within a single asymmetric structure. Structural constraints enforce correct heavy-light chain pairing, reducing light chain mispairing. This platform is particularly suited for T-cell redirecting applications, enabling simultaneous binding to tumor-associated antigens and effector cell markers while modulating Fc-mediated effector functions.
T-FIT	The T-FIT platform uses a modular bispecific design that preserves TCR specificity while adding a CD3-engaging arm to redirect T cells toward tumors. This enables “off-the-shelf” immunotherapies with minimized off-target effects, expanded antigen coverage beyond conventional antibodies, and reduced production complexity compatible with standard antibody manufacturing. By simultaneously engaging peptide–HLA on tumor cells and CD3 on T cells, it triggers potent cytotoxicity, demonstrated in preclinical models.

■ Clinical-Stage Drug Candidates

Epimab Biotherapeutics currently has three global clinical-stage assets: EMB-01, EMB-06, and EMB-07. Its flagship product, EMB-01, is among the first EGFR/c-MET bispecific antibodies worldwide to enter Phase II trials in colorectal cancer (CRC). EMB-01 binds both EGFR and c-MET with high-affinity tetraivalent binding, rapidly inducing co-degradation of the two receptors. Clinical data have shown encouraging efficacy signals in patients with later-line metastatic colorectal cancer (mCRC).

Global Clinical-Stage Drug Candidates										
Project	Target	Indications	LoT	Monotherapy/ Combination	IND	I	II	III	Regulatory Agencies	Rights
EMB-01	EGFR& cMET	Advanced/Metastatic GI Cancers(CRC,HCC, GC,BTC)	≥3L	Monotherapy					FDA, NMPA	Global
		mCRC	≥3L	Monotherapy					NMPA	Global
		mCRC	2L, 3L	+ Chemotherapy					NMPA	Global
EMB-06	BCMA& CD3	SLE、gMG	R/R	Monotherapy					NMPA	China
		TED	-	Monotherapy					NMPA	China
EMB-07	ROR1& CD3	Hematological Malignancies / Solid Tumors	≥3L/ ≥2L	Monotherapy					NMPA	Global
		DLBCL	1L, 2L	Combination					NMPA	Global

Sources: Company Prospectus, Company Website, Public information, Frost & Sullivan analysis

Note: Pipeline statistics are current as of October 2025



8.3 Affinity (Shanghai) Biopharmaceutical Co., Ltd.

■ Company Overview

Affinity Biopharmaceutical is a clinical-stage biopharma founded in 2011, with headquarters in the Shanghai FTZ. Led by TME-activation expert Dr. Chen Liu, the company utilizes its proprietary, first-in-class TMEA (Tumor Microenvironment Activation) platform to develop next-gen cancer therapies. These highly selective, low-toxicity drugs address the critical limitations of traditional chemo and targeted treatments, effectively reshaping the oncology treatment paradigm. Focusing on its TMEA-XDC and TMEA-IO platforms, Affinity Biopharmaceutical will showcase its latest research findings at AACR and ESMO 2025.

Core Tech Platforms

- A globally pioneering tumor microenvironment-activated multispecific intelligent conjugate platform, including TMEA-XDC and TMEA-IO.
- The company has developed 30+ innovative oncology pipeline assets, with 5 candidates currently in clinical trials.

Strategic Collaboration & Licensing

- The company has out-licensed the domestic rights to two drug candidates, with ongoing collaborative trials on multiple pipelines with leading domestic and global pharma partners.
- It aims to develop first-in-class and best-in-class therapies to improve oncology outcomes.

Independent R&D Excellence

- Legubicin, an in-house-developed tumor microenvironment-activated albumin-conjugated therapy for soft tissue sarcoma, demonstrated a superior therapeutic window, reduced cardiotoxicity, and significantly improved progression-free survival, with a favorable overall survival trend in a first-line, double-blind, head-to-head clinical trial.

■ Business Model and Strategic Planning

The company leverages its tumor microenvironment-activated (TMEA) platform to build an R&D system encompassing multiple technology modules, including TMEA-ALDC, TMEA-SMDC, TMEAbody, and TMEAkine, enabling precise drug delivery. It focuses on advancing oncology innovation through strategic collaborations to accelerate drug development.

R&D Structure and Pipeline

The company has built a diversified portfolio across tumor microenvironment-activated multispecific conjugates (TMEA-XDC), including ALDC, SMDC, and ADC, as well as immunotherapies (TMEA-IO) such as antibodies, TCEs, and cytokines.

Its platform enables enhancement and de-risking of small molecules and biologics, generating novel proprietary molecules with global IP. The pipeline spans both small and large molecules assets, including first-in-class assets with global rights and significant commercial potential.

Current Representative Clinical Research Findings

TMEA-XDC: Legubicin (ALDC) is in clinical studies for soft tissue sarcoma, lung, ovarian, and choriocarcinoma, demonstrating superior efficacy and safety versus standard therapy in completed Phase II/III sarcoma trials. The small molecule conjugate Legusacitaxel has completed Phase I and will advance into multiple tumor indications, including bladder and ovarian cancers.

TMEA-IO: IMD101 (IL-2 TMEAkine) remains inactive in circulation but is fully activated in the tumor microenvironment, showing favorable safety and efficacy, with planned clinical development in melanoma and solid tumors.

Looking forward, the company will focus on tumor microenvironment-activated chemotherapy, immunotherapies, and ADCs, leveraging low toxicity to enable combination regimens.

Sources: Company Website, Public information, Frost & Sullivan analysis



8.3 Affinity (Shanghai) Biopharmaceutical Co., Ltd.

■ TMEA Platform

The company’s broad-spectrum TMEA platform supports conjugation of cytotoxics, immunostimulants, kinase inhibitors, and novel biologics including cytokines, antibodies, or T-cell engagers.

TMEA (Tumor Microenvironment Activated) drugs sense the tumor microenvironment to enable targeted delivery and release, reducing on-target toxicity and enhancing efficacy. By using environment-activated chemical groups, the platform transforms traditional drugs into tumor-targeted, activatable therapies, minimizing systemic and organ-specific toxicity, expanding the therapeutic window, and prolonging drug half-life.

Upon tumor-specific cleavage, drugs are fully reactivated with high efficiency, avoiding premature loss. Pan-cancer protease targets extend indication coverage beyond single-molecule dependence. Proprietary conjugation chemistry further optimizes molecular stability and developability while reducing immunogenicity.

■ Company Pipeline

Clinical-Stage Drug Candidates									
Program	Modality	Target / Payload	Indication	Rights	Pre-clinical	IND	Phase I	Phase II	Phase III
TMEA-XDC									
QHL-108 Legubicin	TMEA-ALDC	Doxorubicin Topo II	STS	Global					
			NSCLC	Global					
			OC	Global					
QHL-236 Legutaxel	TMEA-SMDC	Paclitaxel	BC	Global					
			OC	Global					
QHL-1618	TMEA-ALDC	DXd	Solid Tumor	Outside Greater China					
QHL-1231	TMEA-ALDC	AXL / VEGF / CMET	Solid Tumor	Global					
QHL-1031	TMEA-ALDC	TLR7/8	Solid Tumor	Global					
IMD-1828	TMEA-ADC	CLDN6-DXd	Solid Tumor	Global					
IMD-2113		EGFR-TROP2-DXd-ISAC	Solid Tumor	Global					
IMD-2358		ROR1-DXd-ISAC	Solid Tumor	Global					
TMEA-IO									
IMD-101	TMEAkine	IL-2	Melanoma	Global					
IMD-2032		PD1-IL2	Solid Tumor	Global					
IMD-2035		PD1-VEGF-IL2	Solid Tumor	Global					
IMD-303	TMEAbody	CTLA-4	Solid Tumor	Global					
IMD-1005		CD47	Solid Tumor	Global					
IMD-1743	TMEA-TCE	CLDN6-CD3	Solid Tumor	Global					
IMD-2816		CDH17-CD3	Solid Tumor	Global					

Sources: Company Website, Public information, Frost & Sullivan analysis

Note: Pipeline statistics are current as of February 2026



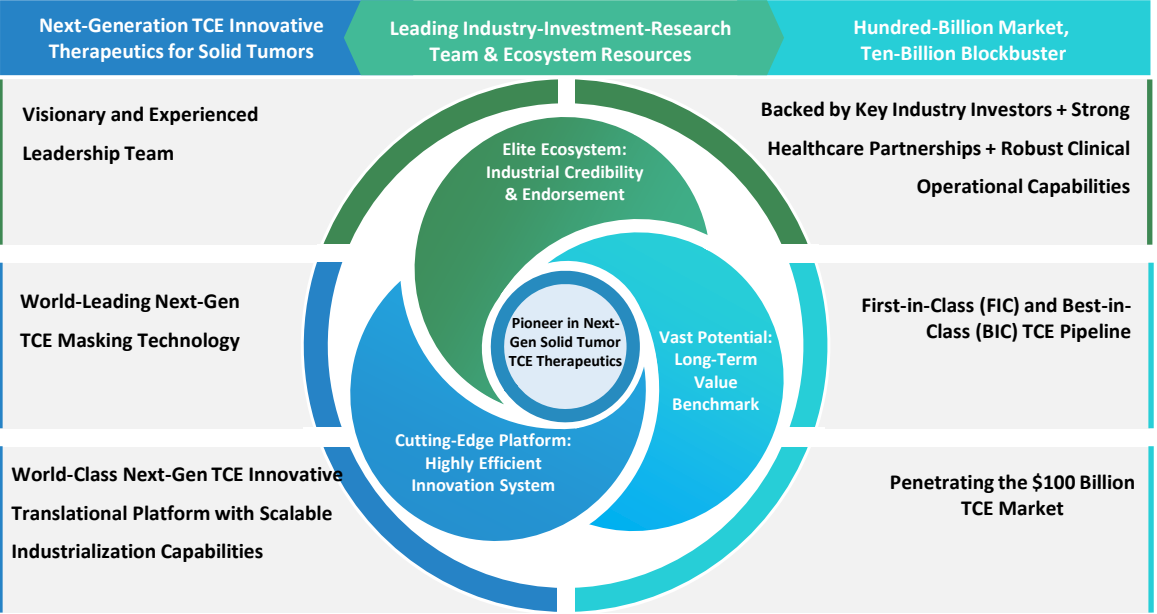
8.4 CentryMed

Company Overview

CentryMed is a clinical-stage biotechnology company founded in 2017, focused on developing novel T cell engager (TCE) therapies. The company has four clinical-stage candidates, including two core products: DNV3 for advanced/metastatic solid tumors and lymphomas, and SMET12 for EGFR-positive advanced solid tumors. Each candidate is developed using proprietary platforms, including a multi-channel antibody discovery platform, H-shaped bispecific TCE platform (H-BiTE), protease-activated bispecific TCE platform (Pro-BiTE), and multifunctional/logic-gated TCE platform.

CentryMed’s multi-tiered R&D structure spans the full innovation pathway from drug discovery to clinical translation, with coordinated oversight by drug discovery scientists and clinical experts. In addition, the company operates dual R&D centers in the United States and China, using a cross-time-zone model to enable continuous research cycles and efficient platform integration.

Key Advantages



Core Pipeline

Focusing on solid tumors, CentryMed drives original innovation across six TCM/TCE pipelines. With DNV3, SMET12, CMD011, and CMDE005 leading global clinical progress—with CMDE005 designed as a protease-activated masked TCE to enable conditional activation—and CMDE101/102 as First-in-Class (FIC) candidates, CentryMed demonstrates systematic R&D and strategic foresight in next-gen TCE technology.

Figure: Overview of core pipelines

Note: Pipeline statistics are current as of March 2026

Platform	Pipeline	Target	Indication	Pre-clinical	Phase I	Phase II	Phase III	Clinical Progress	Commercial Rights
TCM	DNV3	LAG-3	Malignant Melanoma					Global Top 2 (Malignant Melanoma)	Global
	SMET12	EGFR×CD3	Solid Tumor (ESCC/TNBC)					Global Top 1	Global
	CMD011	GPC3×CD3	HCC					Global Top 2	Global
TCE	CMDE005	EGFR×CD3	Solid Tumor					Global Top 2	Global
	CMDE101	FOLR1×PD-L1×CD3	Solid Tumor					FIC	Global
	CMDE102	PSMA×PD-L1×CD3	Solid Tumor					FIC	Global

Sources: Company Website, Public information, Frost & Sullivan analysis



8.5 Mabgeek Biotechnology

■ Company Overview

Mabgeek is a clinical-stage biopharma focused on long-acting antibodies for allergic, autoimmune, and other immune-related diseases. Since its founding in 2016, the company has built an end-to-end R&D system around its proprietary TEADA platform, covering discovery, engineering optimization, preclinical studies, and global clinical development. The pipeline includes seven innovative candidates, with the lead MG-K10—the only clinically validated long-acting anti-IL-4Rα antibody—offering potential for improved efficacy, extended dosing intervals, lower treatment costs, and better patient adherence. Mabgeek leverages platform-based innovation and strategic collaborations to advance long-acting antibody development from discovery to global commercialization.

■ Antibody Technology Platform

Mabgeek has built a systematic technology platform for long-acting antibodies and highly developable molecules, covering candidate screening, developability assessment, half-life extension, and high-concentration formulation. This end-to-end platform supports continuous pipeline innovation and differentiation.

Platform	Core Characteristics
TEADA HTS Platform	Rapid screening based on high throughput, affinity, and bioactivity. Early-stage identification of stable, high-expression molecules to boost R&D success.
Druggability Assessment Platform	Predicts human stability, non-specific binding, and immunogenicity via in vivo/vitro models to lower late-stage risks and enhance translation.
Long-acting Engineering Platform	Optimizes FcRn binding via Fc engineering to extend half-life for Q4W/Q8W dosing, improving patient compliance and long-term feasibility.
High-Concentration Formulation Platform	Enables >100 mg/mL subcutaneous (SC) and inhaled powder development to enhance drug bioavailability and commercial edge.

■ Clinical-Stage Pipeline

Mabgeek anchors its I&I portfolio on IL-4Rα, diversifying into differentiated targets like TSLP, MASP-2, and IL-11RA. Leveraging a global R&D system for blockbuster indications, the pipeline is structured for tiered advancement and multi-indication expansion.

Drug	Target	Indication	Pre-clinical	IND	Phase I	Phase II	Phase III	BLA	Commercial rights	
MG-K10	IL-4Rα	Mod-to-sev Adult AD								Global *With the exception of joint development initiatives for certain indications in some regions
			SGP							
		Adolescent AD								
		Pediatric AD								
		Adult & Adolescent AD	USA							
		Mod-to-sev Adult & Adolescent Asthma								
		Seasonal Allergic Rhinitis								
		Adult Prurigo Nodularis								
		COPD								
		CSU								
	CRSwNP									
	EoE									
MG-014	TSLP	Asthma								Global
		COPD								
MG-013	MASP-2	IgAN								Global
		aHUS								
MG-015	IL-11RA	Fibrosis-related Diseases								Global
MG-018	\ (mAb)	Dermatology								Global
MG-208	\ (bsAb)	Dermatology								Global
MG-242	\ (bsAb)	Derm / Respiratory								Global

Sources: Company Website, Public information, Frost & Sullivan analysis

Note: Pipeline statistics are current as of February 2026

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Contact Us

Fred Mao

**Frost & Sullivan Greater China Life Sciences Business Senior
Partner and Managing Director**



Email:

fred.mao@frostchina.com

Knowledge Center

Frost & Sullivan Greater China Life Sciences Knowledge Center



Email:

hcknowledgecenter@frostchina.com

