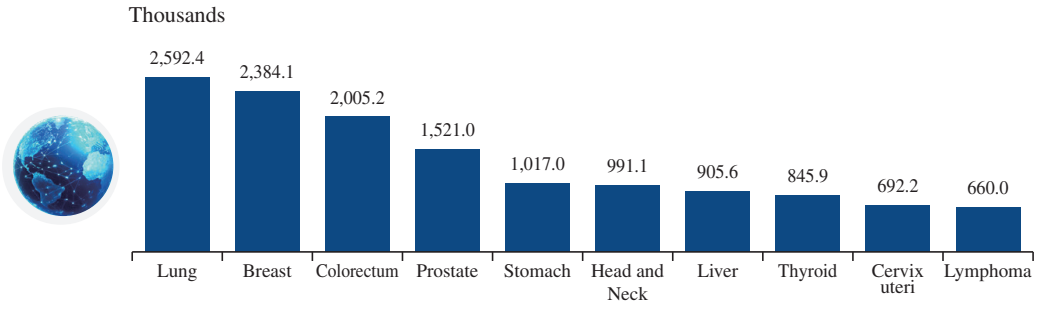
Certain information and statistics set out in this section have been extracted from various official government publications, market data providers and a report commissioned by us and prepared by an independent third party, Frost & Sullivan. The information from official government sources has not been independently verified by us, the [**REDACTED**]*, Joint Sponsors,* [**REDACTED**]*,* [**REDACTED**]*,* [**REDACTED**]*, any of the* [**REDACTED**]*, any of their respective directors and advisers, or any other persons or parties involved in the* [**REDACTED**]*, and no representation is given as to its accuracy.*

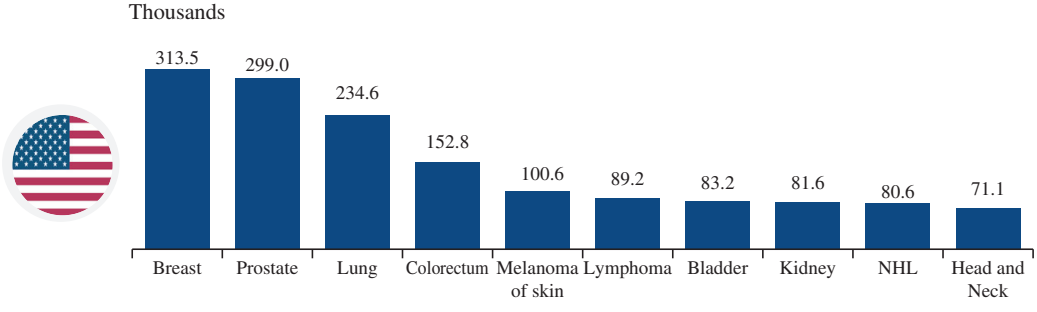
OVERVIEW OF THE ONCOLOGY DRUG MARKET

Cancer is the leading cause of mortality worldwide, resulting in approximately 10 million deaths globally each year. Global cancer incidence reached 21.3 million in 2024 and is expected to reach 26.6 million in 2034. As illustrated in the charts below, lung cancer, BC and colorectal cancer ("**CRC**") were the top three cancers by global incidence in 2024, with 2,592 thousand cases, 2,384 thousand cases and 2,005 thousand cases, respectively.

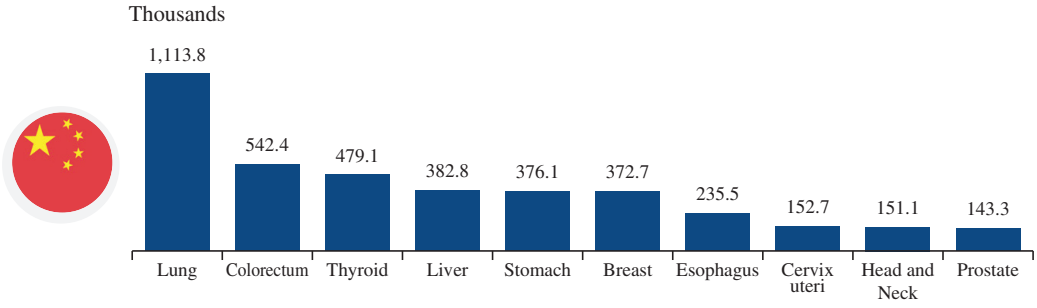
Top 10 Cancers by Incidence Globally, 2024



Top 10 Cancers by Incidence in the United States, 2024



Top 10 Cancers by Incidence in China, 2024



Note: Head and neck cancer, as a collective term for cancers that occur in various parts of the head and neck, is not included in the ranking of single cancer incidence.

Source: Globocan, IARC, NCCR, Frost & Sullivan

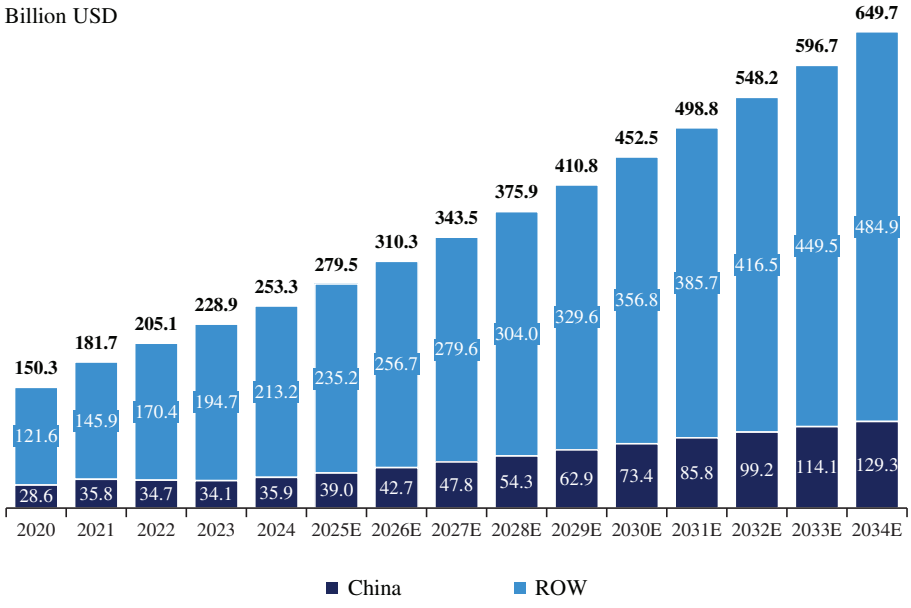
Global Oncology Drug Market Size

Cancer, a broad group of diseases in which abnormal cells grow in an uncontrolled manner, is a leading cause of death globally. New incidences have been on the rise, totaling 5.0 million and 21.3 million in China and globally in 2024 and, together with the growing patient base, breakthroughs in innovative therapies, enhanced payment capabilities, and favorable policies, have collectively driven the rapid, driving the continued growth of the oncology drug market.

The oncology drug market globally and in China has expanded rapidly in recent years. From 2020 to 2024, the global oncology market expanded from US$150.3 billion to US$253.3 billion, representing a CAGR of 13.9% during this period. The global oncology market is expected to reach US$452.5 billion by 2030, representing a CAGR of 10.2% from 2024 to 2030 and estimated to reach US$649.7 billion by 2034, representing a CAGR of 9.5% from 2030 to 2034. The following diagram sets forth the size of the oncology drug market globally and in China for the periods indicated:

Global Oncology Drug Market, 2020-2034E

Period	CAGR		
	China	ROW	Global
2020-2024	5.8%	15.1%	13.9%
2024-2030E	12.6%	9.0%	10.2%
2030E-2034E	15.2%	8.0%	9.5%



Source: Frost & Sullivan

Despite the advancement of various cancer treatment modalities in recent years, there remains an unmet need for novel, differentiated therapies that can enhance the overall survival of cancer patients. These unmet needs have grown even more pressing as the patient population continues to expand.

Overview of Immuno-oncology Drug Market

Overview of Immuno-oncology Drugs

Immuno-oncology therapies represent a transformative pillar in cancer care, leveraging the body's own immune system to mount or enhance antitumor responses. Over recent years, these therapies have redefined cancer treatment paradigms by offering the potential for durable remissions, particularly in advanced malignancies. Immuno-oncology encompasses a broad

range of therapeutic modalities, each targeting distinct components or mechanisms of the immune response. The main classifications include cellular immunotherapy, cytokines, antibody-like drugs, oncolytic viruses, and fusion proteins. Cellular immunotherapies such as CAR-T and TCR-T involve the *ex vivo* manipulation and reinfusion of tumor-specific immune cells, while cytokine therapies utilize key signaling proteins like IL-2 or IFN-α to modulate immune activity. Antibody-like drugs include monoclonal antibodies, bispecific antibodies, and antibody-drug conjugates (ADCs), each designed to recognize and disrupt tumor-associated pathways. Fusion proteins and oncolytic viruses further expand the therapeutic arsenal, either by combining functional protein domains or harnessing viral specificity to target and destroy cancer cells.

The clinical applications of immuno-oncology therapies are diverse and continue to expand as new agents and combinations emerge. PD-1/PD-L1 inhibitors, such as pembrolizumab and nivolumab, have been widely adopted for a range of cancers including melanoma, non-small cell lung cancer, and renal cell carcinoma, by preventing immune evasion and amplifying T cell responses. CAR-T cell therapy has demonstrated significant efficacy in hematological malignancies such as leukemia and lymphoma, as well as in select solid tumors. Combination strategies, integrating immune checkpoint inhibitors with chemotherapy, radiotherapy, or anti-angiogenesis agents, are increasingly prevalent and have been shown to overcome resistance and enhance overall response rates. Additionally, bispecific antibodies and bifunctional fusion proteins are under development to simultaneously target multiple immunosuppressive pathways, offering synergistic effects and reducing clinical complexity. Of particular interest in recent years are bispecific antibodies that target both T cells and tumor-specific antigens, known as T-cell engagers ("**TCEs**"). These molecules have shown early potential by recruiting and activating T cells in close proximity to tumor cells, thereby eliciting an antitumor effect.

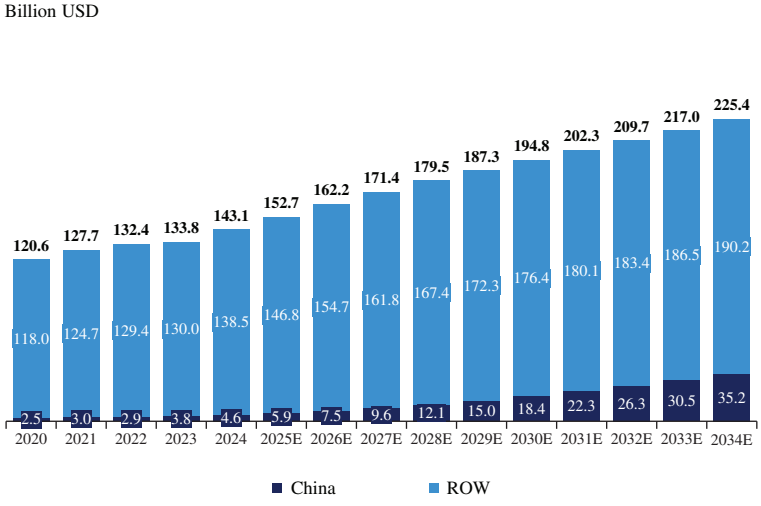
Immuno-oncology products provide a range of benefits that distinguish them from traditional cancer therapies. Cellular immunotherapies, such as CAR-T, have yielded remarkable clinical outcomes, with some patients achieving complete remission. Cytokine therapies, though less specific, can prolong survival and modulate immune responses on a systemic level. Checkpoint inhibitors, by releasing inhibitory brakes on T cells, enable the immune system to recognize and attack tumor cells with greater efficacy. Oncolytic viruses offer the dual advantage of direct tumor lysis and enhanced immune activation, particularly when genetically modified for tumor selectivity. Despite these benefits, challenges remain. Cellular therapies may be associated with cytokine release syndrome and long-term safety concerns, while cytokines can induce autoimmunity and tissue damage due to their broad activity. The efficacy of checkpoint inhibitors is limited in "cold" tumors lacking immune infiltration, and the effectiveness of oncolytic viruses may be reduced by pre-existing immunity.

Market Size of Immuno-oncology Drugs

Globally, immuno-oncology drug market increased from has experienced rapid expansion, fueled by both the rising incidence of cancer and the introduction of next-generation immunotherapies. The market size of immuno-oncology increased from US$120.6 billion in 2020 and reached US$143.1 billion in 2024 at a CAGR of 4.4% and is forecasted to reach US$194.8 billion by 2030 at a CAGR of 5.3% from 2024 to 2030, and further to reach US$225.4 billion by 2034, indicating a CAGR of 3.7% from 2030 to 2034. The immuno-oncology drug market in China also grew at a remarkable CAGR of 15.9%, increasing from US$2.5 billion in 2020 to US$4.6 billion in 2024. This growth trajectory is expected to continue, with projections indicating the market will reach US$18.4 billion by 2030 at a CAGR of 26.2% from 2024 to 2030, and US$35.2 billion by 2034 at a CAGR of 17.5% from 2030 to 2034. The following table describes the immuno-oncology drug market globally and in China from 2020 to 2034:

Historical and Forecasted of Global Autoimmune Disease Drug Market Size, 2020-2034E

CAGR	China	ROW	Total
2020-2024	15.9%	4.1%	4.4%
2024-2030E	26.2%	4.1%	5.3%
2030E-2034E	17.5%	1.9%	3.7%



Source: Frost & Sullivan

Emerging Immuno-oncology Drug Targets

Cluster of differentiation 3 (CD3) is a multi-chain protein complex and a crucial T-cell co-receptor involved in the activation of both cytotoxic T cells (CD8+ naive T cells) and T helper cells (CD4+ naive T cells). Structurally, CD3 is composed of several chains (ϵ, γ, δ, ζ) that associate with the T-cell receptor (TCR), forming the TCR-CD3 complex essential for T-cell activation. The TCR itself has a very short intracellular tail, necessitating the

involvement of CD3 chains for effective signal transduction upon antigen recognition. Upon engagement with antigen-presenting cells, the TCR-CD3 complex transmits activation signals into the T cell, initiating immune responses against tumors or infected cells. This central role in T-cell activation makes CD3 an attractive and emerging target for immuno-oncology therapies, particularly in the development of bispecific antibodies that can redirect T cells to cancer cells irrespective of their original antigen specificity.

Despite their promise, CD3-targeted bispecific antibodies face several significant challenges in clinical development, particularly for solid tumors. While they have shown substantial efficacy in hematologic malignancies, with agents like blinatumomab already approved for some B-cell cancers, their impact in solid tumors is hampered by the immunosuppressive tumor microenvironment, the risk of on-target off-tumor toxicities, and the complex structural nature of the CD3 protein. Research is increasingly focused on overcoming these hurdles through several key strategies, including optimizing CD3 affinity to improve biodistribution and efficacy, developing combination regimens with checkpoint inhibitors to enhance anti-tumor responses, and implementing novel dosing strategies such as step dosing to reduce toxicities like cytokine release syndrome. Furthermore, advances in understanding the mechanisms of resistance and toxicity are likely to inform the next generation of CD3-bispecific antibody ("**BsAb**") therapies. As clinical and preclinical data accumulate, particularly regarding the combination of CD3 BsAbs with other immunotherapies and their application to solid tumors, CD3-targeted strategies are poised to play a central role in the future landscape of immuno-oncology drug development.

OVERVIEW OF BISPECIFIC ANTIBODY DRUG MARKET

Overview of Antibody Drugs

Antibody drugs are highly specific therapeutic agents derived from the immune system's natural ability to recognize and neutralize foreign substances. Antibody drugs are typically monoclonal antibodies (mAbs) that target specific antigens present on the surface of cells, allowing for precise intervention in disease processes. The mechanism of action of antibody drugs involves binding to their target antigens, which can lead to direct inhibition of pathogenic molecules, recruitment of immune effector functions to eliminate target cells, or delivery of cytotoxic agents in the case of antibody-drug conjugates (ADCs). Antibody drugs are classified into several categories, including murine, chimeric, humanized, and fully human antibodies, each representing advancements aimed at reducing immunogenicity and improving safety.

Building on the foundational understanding of antibody drugs, recent years have witnessed significant developmental trends that have shaped the landscape of antibody-based therapeutics. A primary focus has been on enhancing the safety profile of these drugs. This has been achieved through the evolution from murine to chimeric, humanized, and ultimately fully human antibodies, each successive generation exhibiting reduced immunogenicity and a lower incidence of anti-drug antibody (ADA) responses, thereby minimizing adverse effects and improving patient tolerance. In parallel, efficacy has seen remarkable improvement through

advances in antibody engineering, such as modifications to the Fab region to increase binding affinity and Fc glycosylation to optimize immune effector functions. The emergence of innovative modalities, including ADCs that deliver cytotoxic payloads, bispecific antibodies capable of engaging two distinct targets, and single-domain antibodies with enhanced binding characteristics which has further augmented therapeutic effectiveness. Additionally, the therapeutic scope of antibody drugs has expanded considerably due to ongoing discoveries of novel targets and advancements in engineering technologies. While initially confined to applications such as preventing acute organ transplant rejection, antibody drugs are now widely employed in the treatment of cancers, autoimmune disorders, ophthalmologic diseases, and beyond, underscoring their versatility and growing clinical impact.

Market Size of Antibody Drugs

Globally, antibody drug market increased from has experienced rapid expansion, fueled by the rising incidence of cancer and the expanding therapeutic indications that ADC drugs can cover. The market size of antibody drug increased from US$177.1 billion in 2020 and reached US$254.3 billion in 2024 at a CAGR of 9.5% and is forecasted to reach US$474.4 billion by 2030 at a CAGR of 11.0% from 2024 to 2030, and further to reach US$645.5 billion by 2034, indicating a CAGR of 8.0% from 2030 to 2034. The antibody drug market in China also grew at a remarkable CAGR of 32.3%, increasing from US$6.0 billion in 2020 to US$18.2 billion in 2024. This growth trajectory is expected to continue, with projections indicating the market will reach US$53.8 billion by 2030 at a CAGR of 19.8% from 2024 to 2030, and US$102.2 billion by 2034 at a CAGR of 17.4% from 2030 to 2034. The following table describes the antibody drug market globally and in China from 2020 to 2034:

Global and China Antibody Drug Market, 2020-2034E

CAGR	China	Global
2020-2024	32.3%	9.5%
2024-2030E	19.8%	11.0%
2030E-2034E	17.4%	8.0%

Source: Frost & Sullivan

BISPECIFIC ANTIBODY: BRIDGING PRECISION TARGETING AND IMMUNE ACTIVATION IN MODERN THERAPY

Evolution of Disease Treatment Paradigm

The therapeutic landscape for major diseases — including cancer and autoimmune disorders — has undergone a profound transformation. For decades, systemic therapies, such as chemotherapy and radiotherapy, have served as cornerstone treatments, delivering broad-spectrum efficacy across various disease types. However, the nonspecific nature of these interventions often results in unintended cytotoxicity to healthy tissues, leading to significant side effects that compromise patient quality of life. Recognizing these limitations, the biopharmaceutical industry has pioneered a new era of precision medicine and immunotherapy, fundamentally reshaping the disease treatment paradigm. By leveraging targeted approaches that distinguish diseased cells from healthy ones, precision therapies enhance treatment specificity, reducing off-target effects and improving tolerability. Meanwhile, immuno-oncology and immune-modulating strategies harness the body's intrinsic defense mechanisms, offering highly adaptable and durable responses against complex diseases. These advancements mark a paradigm shift, steering therapeutic development toward more effective, personalized, and biologically intelligent solutions, ultimately redefining standards of care across oncology and immune-mediated conditions.

Among these innovations, bispecific antibodies have emerged as a groundbreaking therapeutic approach, uniquely designed to engage multiple biological targets simultaneously. Unlike conventional monoclonal antibodies that bind to a single antigen, bispecific antibodies possess dual specificity — allowing them to both directly target diseased cells and harness the immune system's capabilities. This dual mechanism represents a significant advancement in disease treatment, bridging the gap between precision targeting and immune activation.

In oncology, bispecific antibodies can redirect immune cells — such as T cells — to attack cancer cells, thereby offering a potent immuno-oncology strategy. Meanwhile, in autoimmune diseases, bispecific therapies can modulate immune responses and mitigate excessive inflammation to help normalize immune function. These advancements exemplify the shift toward highly tailored, multifunctional therapies, reshaping the future of disease management beyond traditional treatment modalities.

Introduction to Bispecific Antibody Structure and Mechanism

Bispecific antibodies are a novel class of engineered therapeutic proteins capable of simultaneously binding two distinct antigens or epitopes. The classification of bispecific antibodies can be based on their structural format and molecular composition. One notable distinction lies in the presence or absence of the Fc (fragment crystallizable) region. Bispecific antibodies that retain the Fc region are generally categorized as IgG-like antibodies, while those lacking it are referred to as non-IgG-like or Fc-free formats. Within the IgG-like category, further subclassification is made based on molecular symmetry — either symmetric or asymmetric architectures. These structural differences have profound implications for the antibodies' pharmacokinetics, effector functions, manufacturability, and clinical applications. The following table sets forth the comparison of different structures for bispecific antibodies:

	 Non-IgG	 Symmetric IgG	 Asymmetric IgG
Advantage	• Simple Structure • The clinical dosage is low, less than one-tenth of the original amount of antibodies • Weak immunogenicity • Short half-life (only 2 hours)	• Similar to the structure and stability of natural IgG • Mature technology, high expression	• Solved the technical limits of Knob-into-hole technology in common light chain • Realizes the bivalent binding of tumor antigens, which can reduce the toxicity caused by CD3 antibodies when binding to tumor antigens
Disadvantage	• Unstable structure, low expression and difficult process	• limited spatial bispecific binding effect	• Long technical route, difficult design and process
Marketed Examples	• Blinatumomab (BLINCYTO) applies Tandem scFV and BiTE technology platform. Amgen was marketed in 2014 for treating acute lymphocytic leukemia	• PD-1 and CTLA-4 bispecific antibody Cadonilimab which was listed in 2022	• Emicizumab (HEMLIBRA) applies KIH technology platform, marketed by Roche in 2017, hemophilia A • Catumaxomab (Removab) applies Triomab asyme 1+1 (Rat-mouse hybrid IgG) platform, developed by TRION Pharma GmbH and Neovii Biotech GmbH in 2009 (withdrawn from the market in 2017), malignant pleural effusion

Source: Frontiers in Immunology, 2021: 1555., Analysis and Characterization of Antibody-based Therapeutics. Elsevier, 2020: 167-179., Journal of Immunology Research, 2019, 2019., Antibodies, 2018, 7(3): 28., Journal of hematology & oncology, 2015, 8(1): 1-14., Frost & Sullivan

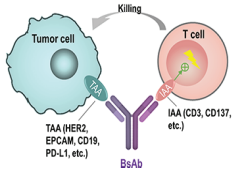
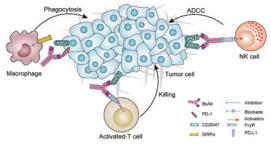
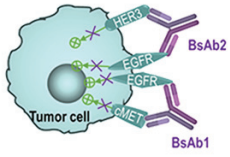
- *Non-IgG-like bispecific antibodies.* Non-IgG-like bispecific antibodies, such as those based on single-chain variable fragments ("scFvs"), are characterized by their simple molecular architecture and small size. These features confer several advantages, including low immunogenicity, efficient tissue and tumor penetration, and cost-effective production in prokaryotic or lower eukaryotic systems. However, the absence of the Fc region results in a short plasma half-life — typically around two hours — due to the lack of neonatal Fc receptor (FcRn)-mediated recycling. Additionally, these formats do not support Fc-mediated effector functions such as antibody-dependent cellular cytotoxicity, antibody-dependent cellular phagocytosis, or complement activation. As a result, they often require extensive optimization to enhance stability and expression, which can increase production costs.

- *IgG-like bispecific antibodies.* In contrast, IgG-like bispecific antibodies retain the Fc region, enabling Fc-mediated effector functions and extended half-life through FcRn recycling.

    - *Symmetric IgG-like bispecific antibodies.* Symmetric IgG-like bispecific antibodies closely resemble natural IgG molecules in structure and stability, benefiting from mature manufacturing technologies and high expression yields. However, their symmetric design can limit the spatial flexibility required for effective bispecific binding.

    - *Asymmetric IgG-like bispecific antibodies.* Asymmetric IgG-like bispecific antibodies address this limitation by enabling bivalent binding to tumor antigens, thereby improving specificity and reducing off-target toxicity. These formats, while offering superior therapeutic potential, involve more complex design and production processes.

This dual-targeting capability of bispecific antibodies enables them to exert unique mechanisms of action that are not achievable with conventional monoclonal antibodies. Fundamentally, bispecific antibodies can either block two biological pathways concurrently or physically bring two different cell types or molecular targets into close proximity, thereby enhancing their interaction and therapeutic efficacy. The following table sets forth the comparison of different mechanisms of bispecific antibodies:

	CD3 T cell engagers	Dual checkpoints blockade	Dual signaling inhibitions
Mechanism	These bsAbs bind to CD3 expressed by the T cell and a specific antigen expressed by the tumor cell, resulting in the formation of an immune synapse. This stimulates the T cell and "re-directs" cytotoxicity against the tumor cell.	These bsAbs can bind to different targets modulating immune responses, thus allowing combined biological effects and synergies.	Tumors and other diseases often involve multiple signaling pathways, and the blocking of a single signaling pathway often fails to completely inhibit the disease process, but also tends to lead to the activation of other compensatory pathways.
Example	• BCMA+CD3 • CD19+CD3	• CD47 + PD-L1 • PD-1 + CTLA-4	• EGFR+cMET
Illustration			

Source: Literature review, Frost & Sullivan

Clinical Advantages of Bispecific Antibody-based Therapies

Bispecific antibodies offer a range of clinical advantages that distinguish them from both monoclonal antibody monotherapies and combination therapies.

- *Compared to monoclonal antibodies, bispecific antibodies demonstrate superior specificity and reduced off-target toxicity and resistance caused by single pathway blockage.* By engaging two different surface antigens, bispecific antibodies enhance binding precision and reduce the likelihood of unintended interactions, which translates into a more favorable safety profile. Furthermore, bispecific antibodies are less prone to inducing drug resistance. Many tumors co-express multiple growth-promoting receptors, and targeting two such receptors could simultaneously disrupt non-overlapping signaling pathways, thereby enhancing antiproliferative effects and mitigating the emergence of resistance mechanisms.

- *When evaluated against combination therapies involving two separate monoclonal antibodies, bispecific antibodies offer compelling advantages in terms of cost and clinical feasibility.* Bispecific antibodies have the potential to achieve therapeutic effects at lower doses due to their enhanced potency. This dose efficiency can help reduce drug manufacturing and treatment costs. Additionally, bispecific antibodies can simplify treatment regimens by requiring only a single injection or infusion per administration, in contrast to the multiple injections or infusions needed if each of the two targets was administered as separate drugs. This simplification can help streamline clinical development, improve patient compliance and facilitate broader clinical adoption.

- *Bispecific antibodies offer a distinct clinical advantage by bringing two different cell types into close proximity, generating a synergistic effect that enhances therapeutic efficacy.* Bispecific antibodies can recruit immune effector cells such as T cells or NK cells to directly engage tumor cells, driving enhanced cytotoxicity beyond what monoclonal antibodies can achieve alone. This mechanism substantially enhances therapeutic efficacy, as seen with TCEs that connect T cells to cancer cells, triggering targeted immune responses that overcome resistance mechanisms seen with traditional therapies.

Global Landscape of Bispecific Antibody Technology Platforms

The following figure provides a comparative overview of the technology characteristics of major bispecific antibody platforms worldwide to date:

Company	Platform	Technology characteristics	Examples
Genentech/Roche . .	Knobs-in-Holes (KIH)	Formation of heterodimer through modified Fc CH3 segment; asymmetric structure of IgG-like antibody	Emicizumab (HEMLIBRA) (IX factor × X Factor)
Genentech/Roche . .	KIH CrossMab	Avoid light and heavy chain mismatches through CrossMab; allow the production of a variety of bispecific antibodies and Fab-based antibody derivatives; IgG-like antibody asymmetric structure	RG7221 (VEGF × ANG2)
Genentech/Roche . .	ART-Ig	Enhances efficacy by simultaneously binding with two types of antigen or provides new pharmacology by bridging two antigens	Hemlibra (Factor VIII × Factor VIIIa)
Xencor	X-Mab (Fab-scFv)	The modified Fc CH3 segment is formed into a heavy chain heterodimer through charge action, and light and heavy chain mismatches are avoided through Fab-scFv; IgG-like antibody asymmetric structure	XmAb14045 (CD123 × CD3)
Abbott	DVD-Ig	On the light and heavy chains of the variable region of an IgG antibody, the light and heavy chain variable regions that target another antigen are respectively connected in tandem; IgG-like symmetric antibody	ABT122 (TNF × IL-17)
EpimAb Biotherapeutics . .	FIT-Ig	Does not require any amino acid mutations or include any linkers or non-antibody sequence to form bispecific antibodies	EMB-01 (EGFR/cMET) EMB-06 (BCMA × CD3)
ITabMed	iTAb	Generate bispecific antibody and poly-specific antibodies via T cell Engager	A-319 (CD19 × CD3)
Alphamab Oncology	CRIB	Adjust the charge network distribution between different Fc chains by complete antibody frame structure, enhance the formation of heterodimer; reduce homodimer formation	KN026 (HER2 × HER2)

Company	Platform	Technology characteristics	Examples
YZY Bio	YBODY	The asymmetric structure, PK/PD and process are similar to those of mab; merged KiH and charge interaction strategy to achieve correct match of heavy chains; the Fc segment was modified by Knob hole and salt	M701 (EpCAM × CD3)
Adagene	DPL	Composed of 3 technologies: NEObody, SAFEbody and POWERbody; Generate antibodies with dynamic binding sites; generate masked antibodies designed to be selectively activated in TME; generate bispecific antibody via T-cell engagers	ADG138 (HER2 × CD3)
AffiMed	TandAb	Using CD16A targeting Fv domains, identifying Hodgkin lymphoma cells	AFM13 (CD30 × CD16a)
Amgen	BiTE	Apply a short peptide chain to connect the four parts of VLA-VHB+VLB-VHA in series	Blinatumomab (BLINCYTO) (CD19 × CD3)
Macrogenics	DART	VLA-VHB+VLB-VHA, connect two chains relying on covalent chain	Flotetuzumab (CD123 × CD3)
Trion Pharma	Triomabs	Binding of tumor cells and T cells through the SCFv functional region, respectively	Catumaxomab (Removab) (EpCAM × CD3)

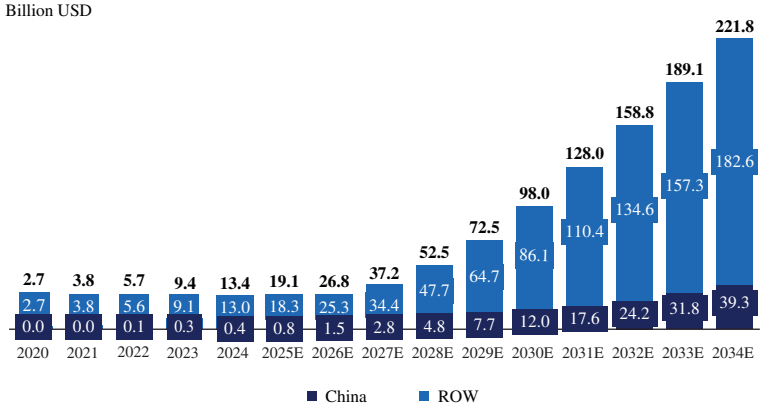
Source: Public information, Frost & Sullivan

Bispecific Antibody Market Size

Bispecific antibody drugs, due to their innovative therapeutic mechanisms, broad clinical application prospects, and continuously expanding R&D pipelines, are anticipated to directly propel the market into a rapid expansion phase. Growth is driven by rising clinical demand, premium pricing and reimbursement, supportive policies, robust late-stage pipelines, and bispecific antibodies' dual targeting that improves efficacy, reduces resistance, broadens indications, enables T-cell redirection, and supports combination and multi-use strategies. Globally, bispecific antibody drug market has experienced rapid expansion from US$2.7 billion in 2020 to US$13.4 billion in 2024 with a CAGR of 49.0% and is forecasted to expand significantly, projected to reach US$98.0 billion by 2030, representing a CAGR of 39.4% and further reach US$221.8 billion by 2034, indicating a CAGR of 22.6% from 2030 to 2034. The following diagram sets forth the bispecific antibody market size globally and in China for the periods indicated:

Global and China's Bispecific Antibodies Market, 2020-2034E

Period	CAGR		
	China	ROW	Global
2020-2024	250.8%	48.0%	49.0%
2024-2030E	78.4%	37.0%	39.4%
2030E-2034E	34.6%	20.7%	22.6%



Source: Frost & Sullivan

Competitive Landscape of Bispecific Antibody Drugs

As of the Latest Practicable Date, there were 19 approved bispecific antibodies globally and 12 approved bispecific antibodies in China. The following table sets forth the marketed bispecific antibody drugs globally and in China as of the Latest Practicable Date:

Marketed products globally

Product	Drug Name	Company	Target	Indications	LOT	Country	Approval Time
LYNOZYFIC	Linvoseltamab	Regeneron	BCMA/CD3	MM	Last line	USA	07/2025
					Last line	EU	04/2025
BLINCYTO	Blinatumomab	Amgen	CD3/CD19	B-ALL	First line	USA	12/2014
					First line	EU	11/2015
					First line	Japan	09/2018
					First line	China	11/2020
HEMLIBRA	Emicizumab	Roche	Fixa/FX	Hemophilia A	First line	USA	11/2017
					First line	EU	02/2018
					First line	Japan	03/2018
					First line	China	11/2018
RYBREVANT	Amivantamab	Janssen	EGFR/c-Met	NSCLC (EGFR ex20ins mutation)	First Line	USA	03/2024
					Second line	USA	05/2021
				NSCLC (sensitive mutation of EGFR)	First Line	USA	08/2024
					Second line	USA	09/2024
				NSCLC (EGFR ex20ins mutation)	First line	EU	06/2024
					Second line	EU	12/2021
				NSCLC (sensitive mutation of EGFR)	First line	EU	12/2024
					Second line	EU	08/2024
				NSCLC (EGFR ex20ins mutation)	First line	Japan	03/2025
					Second line	Japan	05/2025
				NSCLC (sensitive mutation of EGFR)	Second line	Japan	09/2024
				NSCLC (EGFR ex20ins mutation)	First line	China	02/2025
				Non-squamous NSCLC	Second line	China	04/2025
				NSCLC (sensitive mutation of EGFR)	First Line	China	08/2025
VABYSMO	Faricimab	Roche	Ang-2/VEGF	Wet AMD	First line	USA	01/2022
				DME	First line	USA	01/2022
				RVO-ME	First line	USA	10/2023
				Wet AMD	First line	EU	09/2022
				DME	First line	EU	09/2022
				RVO-ME	First line	EU	07/2024
				Wet AMD	First line	China	12/2023
				DME	First line	China	12/2023
				RVO-ME	First line	China	04/2024
				Wet AMD	First line	Japan	03/2022
				DME	First line	Japan	03/2022
				RVO-ME	First line	Japan	03/2024
				Angioid streaks	First line	Japan	05/2025
ORDSPONO	Odronextamab	Regeneron	CD20/CD3	FL	Third line	EU	08/2024
				DLBCL	Third line	EU	08/2024
EPKINLY	Epcoritamab	Genmab	CD20/CD3	FL	Third line	USA	06/2024
					Second line	USA	11/2025
				DLBCL	Third line	USA	05/2023
				FL	Third line	EU	08/2024
				DLBCL	Third line	EU	09/2023
				FL	Third line	Japan	02/2025
				DLBCL	Third line	Japan	09/2023
				PMBCL	Third line	Japan	09/2023
NANOZORA	Ozoralizumab	Sanofi/Ablynx	TNF-α/TNF-α	Rheumatoid arthritis	Second line	Japan	09/2022
LUNSUMIO	Mosunetuzumab	Roche	CD20/CD3	FL	Third line	USA	12/2022
					Third line	EU	06/2022
					Third line	Japan	12/2024
					Third line	China	12/2024
TECVAYLI	Teclistamab	Johnson & Johnson	BCMA/CD3	MM	Last line	USA	10/2022
					Last line	EU	08/2022
					Last line	Japan	12/2024
					Last line	China	06/2024
TALVEY	Talquetamab	Johnson & Johnson	CD3/GPRC5D	MM	Last line	USA	08/2023
					Last line	EU	08/2023
					Last line	Japan	06/2025
					Last line	China	02/2025
ELREXFIO	Elranatamab	Pfizer	BCMA/CD3	MM	Last line	USA	08/2023
					Last line	EU	12/2023
					Last line	Japan	03/2024
					Last line	China	03/2025
COLUMVI	Glofitamab	Roche	CD20/CD3	DLBCL	Third line	USA	06/2023
					Third line	EU	07/2023
					Second line	EU	04/2025
					Third line	China	11/2023
					Second line	China	04/2025
IMDELLTRA	Tarlatamab	Amgen	DLL3/CD3	SCLC	Second line/Third line	USA	05/2024
					Second line/Third line	Japan	12/2024
					Third line	UK	01/2025
					Third line	Korea	06/2025
					Second line/Third line	Brazil, Canada, Israel	02/2025
ZIIHERA	Zanidatamab	Jazz Pharms	HER2/HER2	Biliary tract cancer	Second line	USA	11/2024
					Second line	EU	07/2025
					Second line	China	05/2025
BIZENGRI	Zenocutuzumab	Merus N.V.	HER2/HER3	Pancreatic cancer	Second line/Third line	USA	12/2024
				NSCLC	Second line	USA	12/2024
KORJUNY	Catumaxomab	Lindis Biotech	CD3/EpCAM	Malignant Ascites	Third line and above	EU	02/2025
依达方	Ivonescimab	Akeso	PD-1/VEGF	NSCLC	First line	China	04/2025
				Non-squamous NSCLC	Second line/Third line	China	05/2024
開坦尼	Cadonilimab	Akeso	PD-1/CTLA	Cervical cancer	First line	China	05/2025
					Second line	China	06/2022
				Gastric carcinoma	First line	China	09/2024

Note: MM=Multiple Myeloma; NSCLC=Non-Small Cell Lung Cancer; AMD=Age-related Macular Degeneration; DME=Diabetic Macular Edema; DLBCL=Relapsed or Refractory Diffuse Large B-Cell Lymphoma; FL=Follicular Lymphoma; B-ALL=B-cell Acute Lymphoblastic Leukemia; ROV-ME=Macular Edema Secondary to Retinal Vein Occlusion; PMBL=Primary Mediastinal Large B cell Lymphoma

Source: FDA, EMA, Frost & Sullivan

As of the Latest Practicable Date, amivantamab, developed by Janssen, is the first EGFR/cMET bispecific antibody marketed globally, having received approval for the treatment of NSCLC, and is currently leading in Phase III clinical development for CRC. This milestone not only validates the importance of this dual-target approach in oncology, but also lays a solid foundation for the development of subsequent drugs in this class. EMB-01 is among the earliest EGFR/cMET bispecific antibodies globally to have advanced into Phase II clinical trials for CRC. The following table sets forth the selected information of amivantamab and EMB-01.

	EMB-01	Amivantamab
Company	EpimAb	Janssen
Targets	EGFR/cMET	EGFR/cMET
Indication	mCRC	mCRC
Country	China, US	US, UK, China, etc.
The Highest Clinical Stage	Phase II	Phase III
Line of Treatment	Third line	First line
Monotherapy or combination	Mono	Combo
Mechanism	• EMB-01 is a tetravalent bispecific antibody that structured in a way that simultaneously binds to both EGFR and cMET on the same cell surface. • EMB-01 can efficiently block EGFR and cMET signaling crosstalk while inducing internalization and degradation of both receptor.This mechanism of action not only inhibits tumor growth but also counteracts resistance pathways driven by EGFR or cMET signal transduction.	• Amivantamab is a monovalent antigen – binding, fully human Fc – active immunoglobulin G1 (IgG1) bispecific antibody that targets both the EGFR and the MET receptor. Amivantamab has two arms: one arm binds to the extracellular domain of EGFR to block the binding between the receptor and its ligand EGF, while the other arm prevents the HGF ligand from binding to the MET receptor. • Amivantamab induces the degradation of both receptors in vivo and simultaneously inhibits EGFR as well as one of the more common mechanisms of resistance to EGFR – targeting therapy through the MET pathway.

Source: Literature Review, Frost & Sullivan

The following tables set forth certain pricing information of marketed bispecific antibodies.

Pricing Comparison of Innovative Bispecific Antibodies between China and the United States

Product	Target	China		United States	
		Price	Average annual cost	Price	Average annual cost
Amivantamab (Janssen)	EGFR/c-Met	RMB5,104/bottle (350 mg/7 ml)	Combined with carboplatin and pemetrexed < 80 kg: around RMB490,000 ≥ 80 kg: around RMB592,000	US$1,440/bottle (350 mg/7 ml)	Combined with carboplatin and pemetrexed < 80 kg: around US$131,000 ≥ 80 kg: US$174,000
Elranatamab (Pfizer)	BCMA/CD3	RMB21,059/bottle (44 mg/1.1 mL)	Suppose the patient remains on medication, receiving at least 24 weeks of treatment and achieving sustained remission for at least 2 months: around RMB1.23 million	US$7,556/bottle (44 mg/1.1 mL)	For a full course of treatment, the annual cost is around US$330,000, with an average monthly list price of US$41,500
		RMB32,000/bottle (76 mg/1.9 mL)		US$13,051/bottle (76 mg/1.9 mL)	
Teclistamab (Johnson & Johnson)	BCMA/CD3	RMB9,552/bottle (30 mg/3.0 ml)	Suppose a patient weighs 60 kg and remains on medication, maintaining sustained remission for at least 6 months: around RMB1.22 million	US$1,322/bottle (30 mg/3 mL)	Assuming a weight of 75 kg, the annual cost is around US$353,000, with the monthly cost is US$26,964
		RMB33,246/bottle (153 mg/1.7 ml)		US$6,741/bottle (153 mg/1.7mL)	

Pricing and Reimbursement for Marketed Innovative Bispecific Antibodies in China

Product	Target	Time of marketing	Launch price	Average annual cost	Time of entry into the NRDL	Reimbursement price	Average annual cost
Ivonescimab (Akeso)	PD-1/VEGF	May 2024	RMB2,299/bottle (100 mg)	Suppose a weight of 60 kg: around RMB497,000	December 2024	RMB736/bottle (100 mg)	Suppose a patient weighs 60 kg: around RMB159,000
Cadonilimab (Akeso)	PD-1/CTLA-4	June 2022	RMB13,220/bottle (125 mg)	Suppose a weight of 60 kg: around RMB1.03 million	December 2024	RMB1,860/bottle (125 mg)	Suppose a patient weighs 60 kg: around RMB145,000

Source: Public information, Frost & Sullivan

Note: Not including any complimentary medication services

Differences in drug pricing logic and payment structure between China and the United States

	China	USA
Pricing	China **takes government-led negotiations + centralized procurement** as the core. In the early stage of the market, innovative drugs are mostly priced by enterprises independently, but if they want to enter medical insurance, they must negotiate a significant price reduction (common reduction of 50-80%), and the negotiated price directly determines the payment standard of public medical institutions across the country. Some commonly used drugs are further reduced in price through "volume procurement".	The United States is **market-led + third-party bargaining**. Pharmaceutical companies set their own prices based on R&D investment, clinical value, competitive landscape and expected returns, and the initial price is often very high. The actual price paid is negotiated between pharmaceutical companies and commercial insurance companies and PBMs (drug benefit management companies), and there are rebates, discounts and contractual rebates, and the net price paid by the patient varies greatly depending on the insurance plan.
Payment	The proportion of patient out-of-pocket payments is generally lower than that of the United States, and once drugs enter medical insurance, the price and accessibility have increased significantly. The profit margins of pharmaceutical companies can be driven by sales volume. • Public payment (medical insurance) : basic medical insurance for urban employees and medical insurance for urban and rural residents covers > 95% of the population. Drugs in the medical insurance catalogue shall be reimbursed according to the national/local regulations. Before reimbursement, it is necessary to meet the minimum payment line and the classification restrictions of the medical insurance catalog (Class A is fully reimbursed, Class B needs to be paid out-of-pocket, and Class C is fully paid). • Commercial insurance/Huimin Insurance: the proportion is still small, but the growth rate is fast; Most of them are supplementary to medical insurance, covering imported special drugs or high-value drugs outside the catalog. • Out-of-pocket part: full self-payment for drugs outside medical insurance; The out-of-pocket ratio of drugs in medical insurance, the part below the deductible line, and the part that exceeds the ceiling line are also borne by the patient.	Drug pricing can be much higher than the global level, and there is almost no price control in the early stage of marketing, but the actual payment amount of patients is highly dependent on the type of insurance and the results of negotiations, and high out-of-pocket ratios often lead to accessibility problems. • Public payments: 1) Medicare (seniors, partially disabled) : Medicare pays for some separately payable Medicare Part B-covered drugs and biologics using the average sales price (ASP) methodology at a rate of ASP plus 6%. 2) Medicaid (low-income people): Implemented by state, drug prices are reduced through a statutory rebate mechanism. • Business insurance: purchased by employers or individuals, coverage and patient out-of-pocket ratios vary widely. PBMs control the entry of drugs into the formulary catalog through negotiations and rebate arrangements. • Out-of-pocket portion: copay or coinsurance can be as high as 20-40%, especially for specialty drugs. High deductible insurance plans (HDHPs) require some patients to pay thousands of dollars out of pocket.

Source: Public information, Frost & Sullivan

Entry Barriers

The major entry barriers for new entrants to the bispecific antibody market are set forth as follows:

- *Chain mismatch complexity.* Chain mismatch presents a fundamental technical challenge in bispecific antibody development and is one of the earliest obstacles encountered in the field. The issue stems from antibody architecture: while monoclonal antibodies consist of two identical heavy chains and two identical light chains, yielding a single defined structure upon assembly, bispecific antibodies require the expression of two different heavy chains and two different light chains to enable dual antigen targeting. This results in a combinatorial assembly process where the four chains can form up to 16 possible structural configurations. Even after accounting for mirror-image pairs, only one of the ten remaining configurations represents the intended therapeutic product, posing a significant hurdle in achieving structural fidelity and product consistency.

- *Selection of appropriate bispecific format.* The selection of appropriate bispecific formats can be a complicated decision due to the complexity of target biology, CMC feasibility, valency constraints, Fc region properties, and structural symmetry. Different target combinations require tailored formats to optimize target affinity and selectivity to ensure therapeutic efficacy. From a manufacturing perspective, symmetric designs often offer a more simplified CMC process, whereas asymmetric architectures may require mutations posing CMC challenges. Valency selection can impact binding kinetics, with the choice of monovalent and bivalent binding influencing receptor engagement. Additionally, the presence or absence of Fc domain and/or functions can impact half-life as well as target cell cytotoxicities.

- *Lower success rate in clinical development thus far.* While the development trajectory of monoclonal antibodies has been well established since rituximab's approval in 1997, with an overall Phase I-to-approval success rate stabilizing at approximately 20%, recent data from JAMA Oncology (2024) indicate that bispecific antibodies achieve only an 8% clinical success rate. This discrepancy underscores the complexities inherent in bispecific design, manufacturability, and clinical validation, further constraining new entrants in the field.

Growth Drivers and Future Trends

The growth of the bispecific antibody market is expected to be driven by the following factors and to exhibit the following trends:

- *Enhanced and durable efficacy.* Bispecific antibodies offer a dual-targeting mechanism that simultaneously inhibits two distinct signaling pathways, thereby maximizing synergistic therapeutic effects. This approach not only enhances cytotoxic activity but also significantly reduces the likelihood of treatment resistance by engaging multiple antigen targets. By mitigating tumor cell escape mechanisms and minimizing the off-target effects associated with monoclonal antibodies, bispecific antibodies improve overall therapeutic efficacy. Given the multifactorial nature of cancer and other complex diseases — where multiple signaling pathways contribute to pathogenesis — single-target immunotherapies often prove insufficient for complete tumor eradication. Conversely, bispecific antibodies increase binding specificity by engaging two distinct cell-surface antigens, leading to improved safety and efficacy profiles.

- *Expanded therapeutic versatility.* The dual specificity of bispecific antibodies unlocks diverse clinical applications, including T-cell redirection for tumor cell lysis, simultaneous blockade of multiple disease-driving pathways, targeted delivery of therapeutic payloads, and dual engagement of distinct pathological mediators. This multifaceted functionality positions bispecific antibodies as a transformative therapeutic modality capable of addressing complex and refractory diseases with unmet medical needs. As the field continues to evolve, bispecific platforms are expected to reshape treatment paradigms across oncology, autoimmune disorders, and other high-burden disease areas.

- *Expanding investigations into solid tumor treatment.* Despite their success in hematologic malignancies, bispecific antibodies have demonstrated limited efficacy in treating solid tumors, largely due to challenges such as on-target off-tumor toxicity, inadequate T-cell infiltration, and functional impairment of tumor-infiltrating lymphocytes within an immunosuppressive tumor microenvironment. Continued research and development are expected to yield novel tumor-associated antigens that improve targeting specificity, alongside advances in conditional masking technologies designed to mitigate off-tumor effects. These innovations will be pivotal in expanding the therapeutic reach of bispecific antibodies into solid tumors, potentially overcoming historical limitations in treatment response and safety.

- *Broader therapeutic indications beyond oncology.* While bispecific antibodies are predominantly utilized in oncology, their unique dual-targeting capabilities position them as versatile therapeutic agents across a spectrum of disease areas, including inflammatory disorders, neurodegenerative diseases, and rare conditions requiring highly selective modulation of biological pathways. In particular, bispecific antibodies such as T-cell engagers have demonstrated strong clinical efficacy in multiple autoimmune diseases (e.g., SLE, rheumatoid arthritis) through an underlying cell depletion mechanism, which has unlocked a significant market opportunity. As novel targets continue to be identified, bispecific antibodies are poised to redefine therapeutic approaches and address unmet medical needs across a diverse range of indications, offering substantial benefits to patients worldwide.

TCE: REDEFINING IMMUNE MODULATION FOR PRECISION THERAPY IN CANCER AND AUTOIMMUNE DISEASES

Overview of TCE

Bispecific antibodies have revolutionized the landscape of targeted immunotherapy by enabling dual antigen recognition, thereby enhancing treatment specificity and therapeutic efficacy. The foundation of bispecific antibodies lies in their ability to simultaneously engage two distinct molecular targets, a capability that has been widely exploited to improve immune cell recruitment, modulate signaling pathways, and overcome drug resistance mechanisms. Among the most impactful applications of bispecific antibodies is their role in engineering TCEs, a class of biotherapeutics designed to redirect the immune system toward diseased cells with high precision. Through bispecific formats, TCEs facilitate direct linkage between cytotoxic T cells and target antigens on cells of interest to facilitate cell killing while minimizing unintended toxicity.

TCEs have demonstrated a significant potential to revolutionize modern disease treatment strategies, particularly in immuno-oncology and autoimmune disease modulation. Traditional cancer therapies, such as chemotherapy and radiation, lack specificity, often resulting in systemic toxicity and limited efficacy. In contrast, TCEs leverage immune cell cytotoxicity by binding one arm to a tumor-associated antigen on cells and the other to CD3 on T cells, thereby triggering antigen-specific tumor eradication. This mechanism ensures selective tumor killing while preserving healthy tissues. Beyond oncology, TCEs are emerging as promising therapeutic agents in autoimmune disorders by depleting B cells and plasma cells that secrete autoantibodies, leading to pathological inflammation and tissue damage. By selectively redirecting immune responses, TCEs offer a targeted intervention that could reset the immune system and treat autoimmune diseases — a critical advantage over conventional immunosuppressants.

The evolution of TCEs continues to drive advancements in therapeutic innovation, redefining immune modulation across oncology, autoimmunity, and beyond. As research progresses, optimizing their structural design, enhancing safety profiles, and expanding clinical applications will be critical in shaping the next generation of immunotherapies.

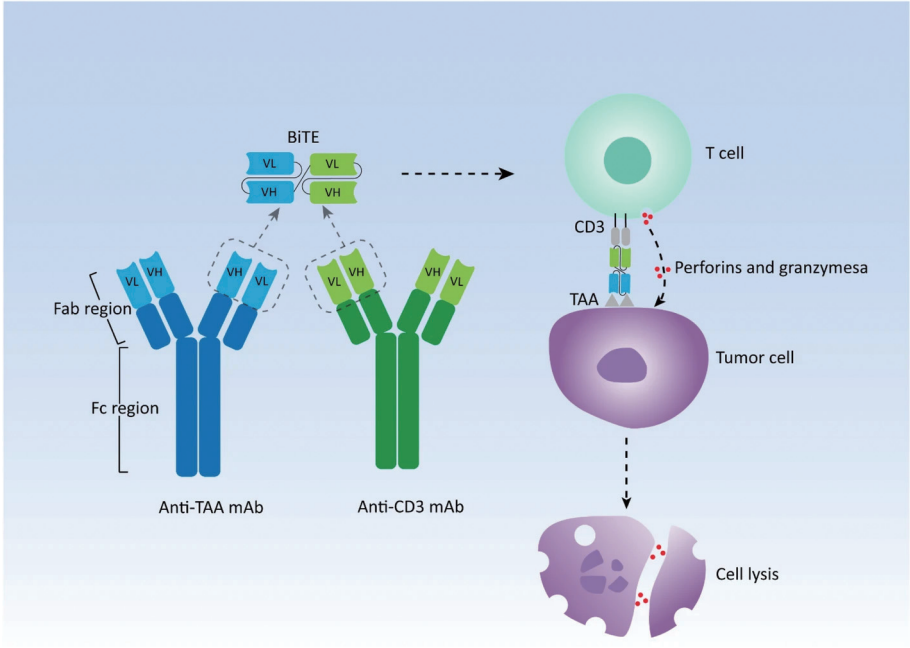
Introduction to TCE Structure and Mechanism

Structurally, a TCE molecule can be constructed in multiple bispecific formats. Additionally, the tumor-associated antigen moiety can also take the form of targeting region on a normal Fab arm, scFv, or nanobodies. The targeting moiety can recognize and bind to the antigen or receptor on disease cells, ensuring specificity, while the other key component is a CD3 binding region that allows for T cell binding and immune activation. This bispecific configuration facilitates T-cell recruitment and engagement, enabling precise immune redirection toward diseased cells. Importantly, TCEs bypass the dependency on major histocompatibility complex presentation, rendering them effective even in tumors with major histocompatibility complex-I deficiency. TCEs can elicit antigen-specific T-cell responses even at low antigen densities — a threshold often below the reach of naked monoclonal antibodies or antibody-drug conjugates. This capability highlights TCE's versatility and therapeutic potential in cancer immunotherapy.

The mechanism of action of TCEs in tumor targeting is fundamentally governed by their molecular architecture, which enables precise immune activation. This mechanism involves simultaneous engagement of a tumor-associated antigen on malignant cells and the CD3 receptor on cytotoxic T cells. This dual-targeting approach facilitates the physical linkage of tumor cells with T cells, promoting the formation of an immunological synapse. Upon engagement, T cells undergo activation and release cytotoxic effectors such as perforin and granzymes, which induce tumor cell membrane disruption and apoptosis, thereby facilitating tumor clearance.

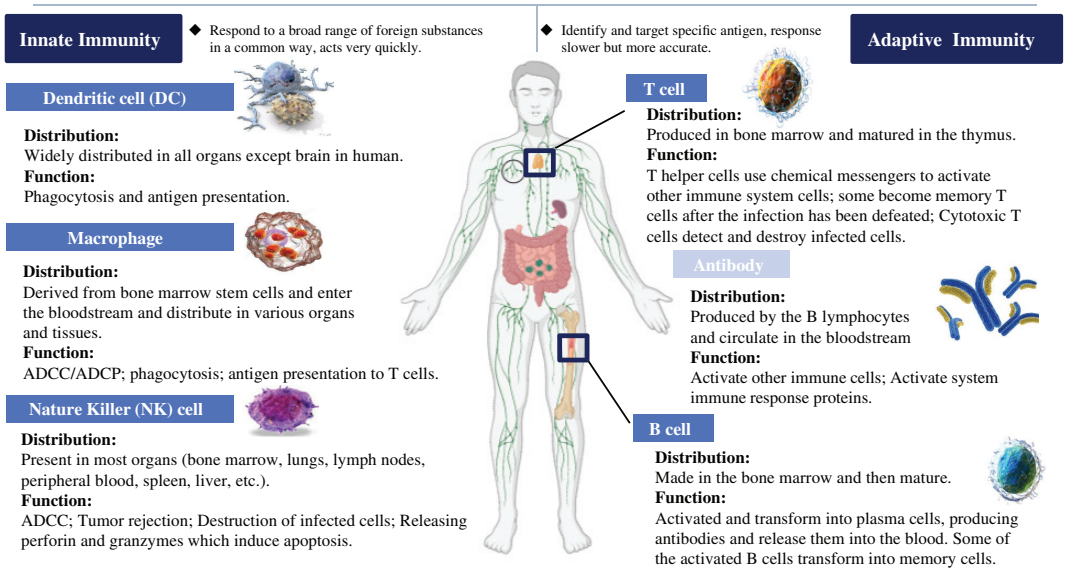
CD3, a multi-chain protein complex and a crucial T-cell co-receptor involved in the activation of both cytotoxic T cells (CD8+ naive T cells) and T helper cells (CD4+ naive T cells). Structurally, CD3 is composed of several chains (ϵ, γ, δ, ζ) that associate with the TCR, forming the TCR-CD3 complex essential for T-cell activation. The TCR itself has a very short intracellular tail, necessitating the involvement of CD3 chains for effective signal transduction upon antigen recognition. Upon engagement with antigen-presenting cells, the TCR-CD3 complex transmits activation signals into the T cell, initiating immune responses against tumors or infected cells. This central role in T-cell activation makes CD3 an attractive and emerging target for immuno-oncology therapies, particularly in the development of bispecific antibodies that can redirect T cells to cancer cells irrespective of their original antigen specificity.

The following diagram illustrates the mechanism of action of TCE in cancer treatment:



Source: Frost & Sullivan, literature review

The functionality of TCEs is deeply embedded within the framework of the immune system, particularly the interplay between innate and adaptive immunity. While innate immunity serves as the first line of defense against pathogens and abnormal cells, adaptive immunity confers long-lasting immune responses tailored to distinct antigens. TCEs operate within this adaptive immune framework, acting as molecular bridges that enhance T-cell recognition and activation against disease-associated targets. By refining the activation thresholds of T cells and ensuring controlled immune engagement, TCEs can harness the cytotoxic potential of the immune system and mitigate excessive inflammatory reactions. The ability to fine-tune adaptive immune responses while leveraging innate immune surveillance positions TCEs as a transformative modality in precision medicine. The following diagram illustrates innate immunity and adaptive immunity, as well as the function of T cells in adaptive immunity:



Note: *Antibody does not belong to adaptive immune cells, but it is an important immune active substance secreted by B cells.

Source: Literature review. Frost & Sullivan

By integrating dual-target specificity with immune activation, TCEs redefine precision oncology, offering a transformative approach to tumor eradication. Their capacity to leverage both direct cytotoxic mechanisms and Fc-mediated immune modulation establishes them as a cornerstone of next-generation cancer therapeutics, with ongoing innovations continuously expanding their clinical utility.

Competitive Landscape of TCEs

The following table sets forth the marketed TCEs globally as of the Latest Practicable Date:

Marketed products globally

Product	Drug Name	Company	Target	Indications	LOT	Country	Approval Time
LYNOZYFIC	Linvoseltamab	Regeneron	BCMA/CD3	MM	Last line	USA	07/2025
					Last line	EU	04/2025
BLINCYTO	Blinatumomab	Amgen	CD3/CD19	B-ALL	First line	USA	12/2014
					First line	EU	11/2015
					First line	Japan	09/2018
					First line	China	11/2020
ORDSPONO	Odronextamab	Regeneron	CD20/CD3	FL	Third line	EU	08/2024
				DLBCL	Third line	EU	08/2024
EPKINLY	Epcoritamab	Genmab	CD20/CD3	FL	Third line	USA	06/2024
					Second line	USA	11/2025
				DLBCL	Third line	USA	05/2023
				FL	Third line	EU	08/2024
				DLBCL	Third line	EU	09/2023
				FL	Third line	Japan	02/2025
				DLBCL	Third line	Japan	09/2023
				PMBCL	Third line	Japan	09/2023
LUNSUMIO	Mosunetuzumab	Roche	CD20/CD3	FL	Third line	USA	12/2022
					Third line	EU	06/2022
					Third line	Japan	12/2024
					Third line	China	12/2024
TECVAYLI	Teclistamab	Johnson & Johnson	BCMA/CD3	MM	Last line	USA	10/2022
					Last line	EU	08/2022
					Last line	Japan	12/2024
					Last line	China	06/2024
TALVEY	Talquetamab	Johnson & Johnson	CD3/GPRC5D	MM	Last line	USA	08/2023
					Last line	EU	08/2023
					Last line	Japan	06/2025
					Last line	China	02/2025
ELREXFIO	Elranatamab	Pfizer	BCMA/CD3	MM	Last line	USA	08/2023
					Last line	EU	12/2023
					Last line	Japan	03/2024
					Last line	China	03/2025
COLUMVI	Glofitamab	Roche	CD20/CD3	DLBCL	Third line	USA	06/2023
					Third line	EU	07/2023
					Second line	EU	04/2025
					Third line	China	11/2023
					Second line	China	04/2025
IMDELLTRA	Tarlatamab	Amgen	DLL3/CD3	NSCLC	Second line/Third line	USA	05/2024
					Second line/Third line	Japan	12/2024
					Third line	UK	01/2025
					Third line	Korea	06/2025
					Second line/Third line	Brazil, Canada, Israel	02/2025
KORJUNY	Catumaxomab	Lindis Biotech	CD3/EpCAM	Malignant Ascites	Third line and above	EU	02/2025

Note: MM=Multiple Myeloma; NSCLC=Non-Small Cell Lung Cancer; AMD=Age-related Macular Degeneration; DME=Diabetic Macular Edema; DLBCL=Relapsed or Refractory Diffuse Large B-Cell Lymphoma; FL=Follicular Lymphoma; B-ALL=B-cell Acute Lymphoblastic Leukemia; ROV-ME=Macular Edema Secondary to Retinal Vein Occlusion; PMBL=Primary Mediastinal Large B cell Lymphoma

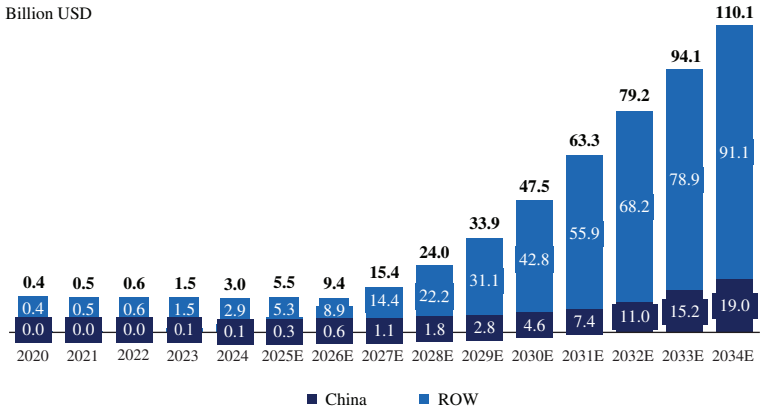
Source: FDA, EMA, NMPA. Frost & Sullivan

TCE Market Size

Globally, the TCE drug market has experienced rapid expansion from US$0.4 billion in 2020 and reached US$3.0 billion in 2024 at a CAGR of 67.6% and is forecasted to expand significantly, projected to reach US$33.9 billion by 2030, representing a CAGR of 58.6% from 2024 to 2030 and further reach US$110.1 billion by 2034, indicating a CAGR of 23.4% from 2030 to 2034. The core driving factors behind the rapid development of the global TCE bispecific antibody market lie in its technological breakthroughs, which has potentials to broaden the boundaries of therapeutic areas, while its clinical potential has also validated the feasibility of its global commercialization, paving the way for its rapid growth in the future. The following diagram sets forth the TCE market size globally and in China for the periods indicated:

Global and China's TCE Bispecific Antibodies Drug Market, 2020-2034E

Period	CAGR		
	China	ROW	Global
2020-2024	–	66.1%	67.6%
2024-2030E	88.4%	56.8%	58.6%
2030E-2034E	42.2%	20.8%	23.4%



Source: Frost & Sullivan

Current Challenges

The major current challenges in the TCE market are set forth as follows:

- *Challenges in addressing limited efficacy, especially in solid tumors.* TCEs have demonstrated substantial potential in hematological malignancies, exemplified by the FDA-approved blinatumomab (CD3/CD19) (BLINCYTO developed by Amgen), which is currently used to treat certain B-cell malignancies. Numerous other TCEs are undergoing preclinical and clinical evaluation for both hematologic and solid tumors. However, while TCEs have shown success in hematologic cancers, their therapeutic efficacy in solid tumors remains limited. This discrepancy is largely

attributable to the unique biological and structural challenges presented by solid tumors. Solid tumors contain multiple inhibitory cell types, including cancer-associated fibroblasts, regulatory T cells, and tumor-associated macrophages, which collectively impair effector T-cell functionality and reduce TCE effectiveness. Additionally, immune checkpoint pathways restrict the cytolytic activity of tumor-infiltrating lymphocytes, and TCEs may induce activation-induced cell death in these lymphocytes, further compromising antitumor responses.

- *Obstacles to overcome on-target, off-tumor toxicities.* In hematological malignancies, transient depletion of B cells or myeloid subsets is generally reversible, provided hematopoietic stem cells remain unaffected, allowing replenishment of cellular populations. However, in solid tumors, tumor-associated antigens are often expressed on normal tissues, which may trigger widespread activation of immune cells and result in massive cytokine release. This increases the risk of immune-mediated toxicity (cytokine release syndrome) and organ dysfunction, which, in severe cases, may result in fatality. A preclinical study utilizing a TCE targeting EGFR illustrated this risk. Consequently, strategies to mitigate cytokine release syndrome while preserving efficacy remain imperative. These strategies include fine-tuning the affinity of the CD3-binding domain to regulate T-cell activation intensity, minimizing uncontrolled cytokine surges. Optimizing synaptic distance between effector and target cells may enhance precision in immune engagement, reducing excessive immune activation.

Entry Barriers

The major entry barriers for new entrants to the TCE market are set forth as follows:

- *Identifying the optimal CD3 binder.* Finding the right CD3 binder requires a delicate balance between affinity and specificity — while high-affinity CD3 binding can enhance T-cell engagement and activation, excessive binding strength could lead to higher rates and severity of cytokine release syndrome.

- *Bispecific antibody engineering expertise.* Different targets could require different structural formats and valency (e.g., 1x1, 1x2, or 2x2) as well as the choice of relative target and CD3 affinities to optimize cell killing. Therefore, the expertise and experience to design and produce different bispecific formats can be an important entry barrier for new market entrants.

- *Optimization of binding site distance.* The spatial configuration between the CD3 and target binding sites is also an important factor. If the distance is too short, excessive immune engagement may occur, increasing the risk of systemic toxicity; conversely, an extended distance may weaken synaptic formation, reducing overall efficacy.

Growth Drivers and Future Trends

The growth of the TCE market is expected to be driven by the following factors and to exhibit the following trends:

- *Combination of TCEs with other therapies for enhanced efficacy*. Preclinical and clinical investigations have demonstrated that treatment with TCEs induces upregulation of PD-L1 on tumor and immune cells, as well as PD-1 on T cells, at least in part due to interferon-gamma (IFN-γ) production. This suggests that combining TCEs with checkpoint blockade may enhance antitumor responses. Indeed, preclinical studies have shown promising synergistic effects, and clinical trials are actively exploring the therapeutic potential of such combinations.

- *Promising potential in autoimmune disease treatment*. TCEs offer a novel approach to restoring immune balance. Traditional biologics often provide broad immunosuppression, leading to unintended systemic effects, whereas TCEs enable precise immune modulation by selectively redirecting T-cell activity to pathogenic cells. Particularly, TCEs induce targeted, T-cell-mediated B-cell depletion, which may contribute to immune reset by eliminating autoreactive B-cell populations and allowing the immune system to recalibrate. Additionally, improved target selection — such as dual-specificity strategies aimed at autoreactive T cells and regulatory pathways — has expanded therapeutic applicability across diseases like rheumatoid arthritis, lupus, and inflammatory bowel disease.

- *Advancement in masking domain technology.* Future advancements in TCE masking domain technology aim to enhance tumor specificity while mitigating on-target off-tumor toxicity, a major challenge in bispecific antibody development. Conditional activation strategies, including protease-dependent masking domains, are being refined to ensure TCEs remain inactive in circulation and selectively activate only within the tumor microenvironment.

- *Advancement of trispecific and multi-specific engagers.* The development of trispecific and multi-specific engagers represents a significant breakthrough in antibody engineering, expanding the therapeutic landscape for oncology and immunology. Trispecific antibodies are designed to simultaneously engage three distinct antigenic epitopes, either on tumor cells or immune effector cells, enhancing both target specificity and immune activation. This multi-targeting capability enables superior tumor cell eradication, mitigates resistance mechanisms, and refines immune modulation strategies beyond traditional monoclonal or bispecific approaches. With more flexible targeting architectures and diversified mechanisms of action, TCE trispecific antibodies are increasingly shaping next-generation therapeutic strategies.

- *Integration of co-stimulatory signals to enhance T-cell activation and broaden efficacy.* TCEs are incorporating co-stimulatory signaling domains to augment immune activation and improve therapeutic outcomes. Within natural immune synapses, T-cell activation requires two distinct signals: The first signal is initiated by the binding of major histocompatibility complex-peptide complexes to the T-cell

receptor, activating the CD3 signaling cascade. The second signal, mediated by co-stimulatory molecules, functions as an amplifier, reinforcing the activation cascade and sustaining full T-cell engagement. By integrating co-stimulatory domains, TCEs enhance the robustness and durability of T-cell responses, expanding their therapeutic reach across immunologically "cold" tumors, which historically exhibit low T-cell infiltration and poor responsiveness to conventional immunotherapies.

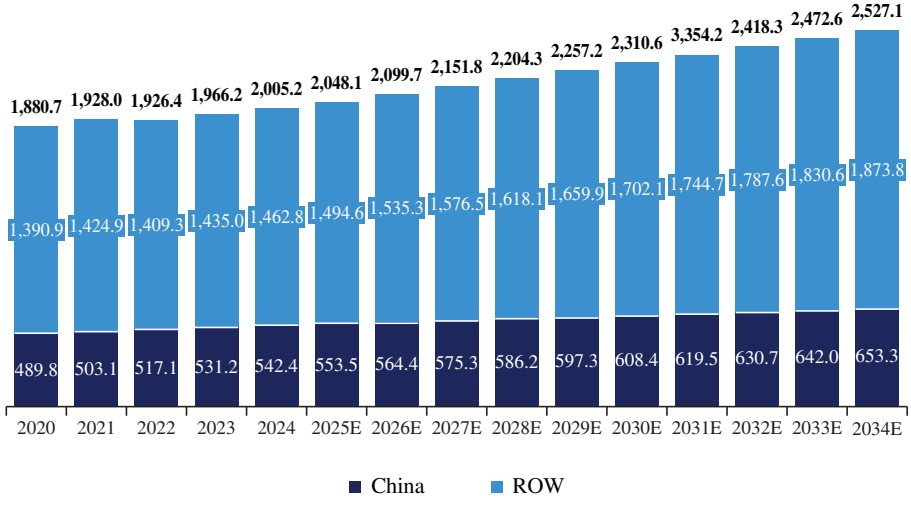
THE CRC DRUG MARKET

CRC Market Size

CRC, also referred to as bowel cancer, colon cancer, or rectal cancer, is defined as any cancer that affects the colon and the rectum, which together form the lower part of the digestive tract. Most CRC cases originate from polyps, abnormal growths in the colon or rectum, that can become malignant if not excised. In China, CRC incidence ranked second and mortality ranked fourth among all malignant tumors in 2024. The number of new CRC cases in China rose from 489.8 thousand in 2020 to 542.4 thousand in 2024, and is projected to reach 653.3 thousand by 2034. Globally, CRC incidence increased from 1.9 million in 2020 to 2.0 million in 2024, and is expected to reach 2.5 million by 2034, reflecting a consistent upward trend. The following diagram sets forth historical and projected incidences of CRC globally and in China for the periods indicated:

Global Incidence of Colorectal Cancer by Region, 2020-2034E

Period	CAGR		
	China	ROW	Global
2020-2024	2.6%	1.3%	1.6%
2024-2030E	1.9%	2.6%	2.4%
2030E-2034E	1.8%	2.4%	2.3%

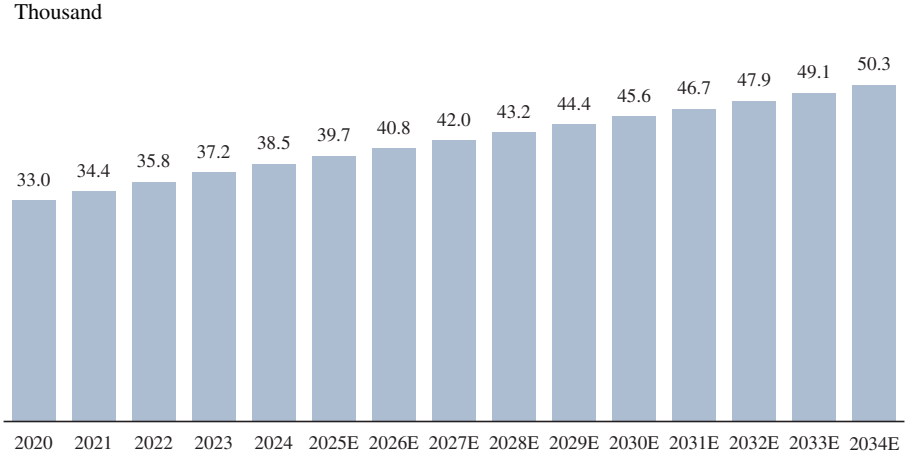


Source: IARC, Frost & Sullivan

In China, the addressable patient population of EMB-01 on mCRC increased from 33.0 thousand in 2020 to 38.5 thousand in 2024 at a CAGR of 3.9, and is expected to reach 45.6 thousand by 2030 with a CAGR of 2.9% and 50.3 thousand by 2034 with a CAGR of 2.5%. As CRC incidence rises and survival improves, the treatable mCRC population grows. Meanwhile, better screening, staging, and molecular diagnostics increase detection and accelerate timely treatment initiation, together driving expansion of the mCRC patient pool, which underpins sustained growth in mCRC drug demand. The following diagram sets forth historical and projected incidences of the addressable patient population of EMB-01 in China for the periods indicated:

Addressable Patient Population of EMB-01 on mCRC in China, 2020-2034E

Period	CAGR
2020-2024	3.9%
2024-2030E	2.9%
2030E-2034E	2.5%

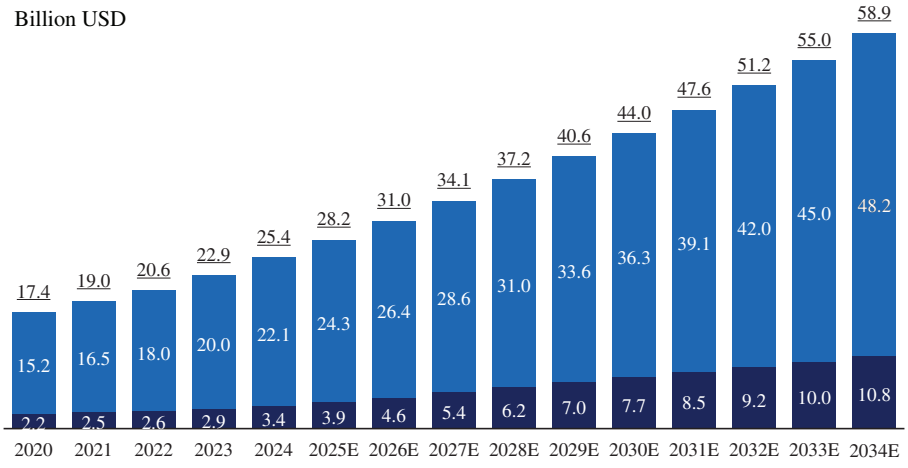


Source: Frost & Sullivan

The CRC drug market in China has experienced notable expansion, growing from US$2.2 billion in 2020 to US$3.4 billion in 2024, indicating a CAGR of 11.1%. The CAGR will increase to 14.9% during 2024 to 2030, and 8.7% from 2030 to 2034, with the market size expected to reach US$7.7 billion by 2030 and USD10.8 billion by 2034. Globally, the CRC drug market reached US$25.4 billion in 2024, up from US$17.4 billion in 2020, with a CAGR of 10.0%. Growth will accelerate to a CAGR of 9.6% between 2024 and 2030, and is expected to maintain a CAGR of 7.6% from 2030 to 2034, with the market size reaching US$44.0 billion by 2030 and US$58.9 billion by 2034. The expansion of the market size for CRC drugs is primarily driven by multiple factors, including the rising incidence of colorectal cancer, the popularization of early screening, breakthroughs in the research and development of new therapies along with their accessibility to the general public, and the growing medical needs in emerging markets. For mCRC drug market, growth is driven by expanding patient pool, improved screening and biomarker testing, precision medicine adoption, evolving multi-line treatment paradigms, increased eligibility for targeted and immunotherapies, longer survival extending therapy duration, and broader access and reimbursement supporting sustained market demand. The following diagram sets forth the CRC drug market size globally and in China for the periods indicated:

Global CRC Drug Market Size by Region, 2020-2034E

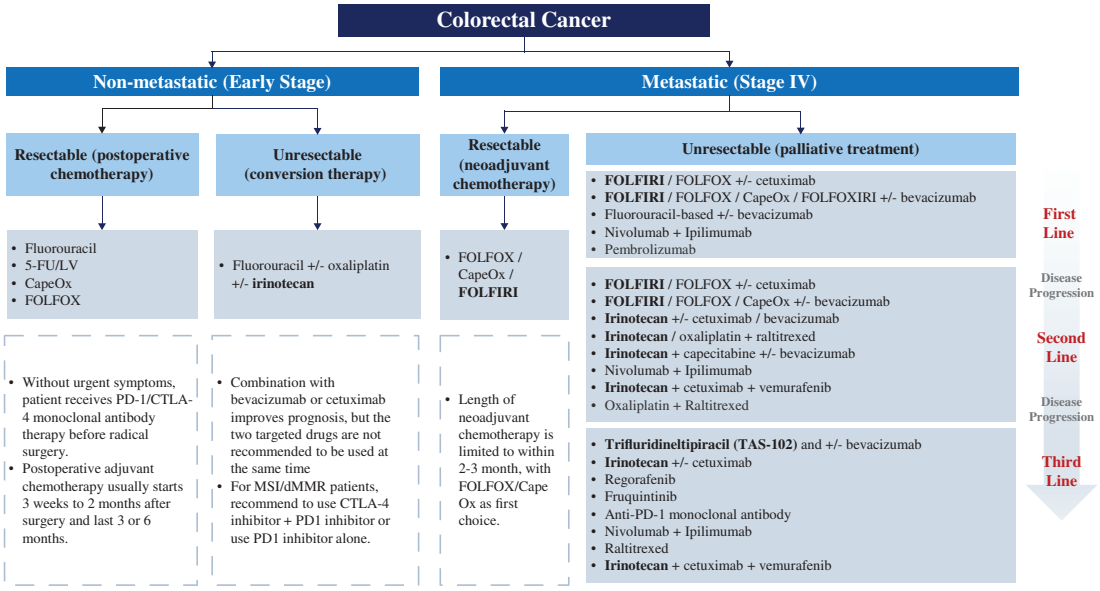
Period	CAGR		
	China	ROW	Global
2020-2024	11.1%	9.8%	10.0%
2024-2030E	14.9%	8.6%	9.6%
2030E-2034E	8.7%	7.3%	7.6%



Source: IARC, Frost & Sullivan

Treatment Paradigm for CRC

Current treatment paradigm for CRC in China follows a stratified approach based on disease stage. Early-stage and resectable cases are managed with surgery followed by adjuvant chemotherapy, which typically uses fluorouracil-based regimens such as FOLFOX or CapeOx. For metastatic or unresectable cases, sequential use of systemic chemotherapies, including FOLFOX, FOLFIRI, and CapeOx in combination with targeted agents like bevacizumab or cetuximab is standard as first-line treatment. Following the progression after first-line treatment, in alignment with evolving national guidance, the Chinese Society of Clinical Oncology (CSCO) Clinical Practice Guidelines for Colorectal Cancer Diagnosis and Treatment (2025) further specify third-line options for metastatic CRC, recommending palliative therapies that include monotherapies such as regorafenib, fruquintinib, trifluridine/tipiracil (TAS-102) and PD-1 inhibitors and combination regimens, including trifluridine/tipiracil (TAS-102) plus bevacizumab, irinotecan plus cetuximab (not officially approved by the FDA or NMPA) and nivolumab plus ipilimumab. The following diagram illustrates the treatment paradigm for CRC in China:



Notes: FOLFOX = oxaliplatin + leucovorin + 5-FU; FOLFIRI = irinotecan + leucovorin + 5-FU; CapeOx = oxaliplatin + capecitabine.

Source: CSCO 2025, Frost & Sullivan

Current SOC options for mCRC achieve only modest survival benefits and remain constrained by eligibility and toxicity limitations. In the first line, pembrolizumab delivers a median PFS of 16.5 months and a 24-month restricted mean survival of 13.7 months with lower Grade ≥3 treatment-related adverse events (22%, n=153), but its efficacy is largely confined to the ~15% of patients with dMMR/MSI-H, limiting applicability; chemotherapy ± bevacizumab/cetuximab provides a median PFS of 8.2 months and a 24-month restricted mean survival of 10.8 months, but with substantial Grade ≥3 toxicity (66%, n=154) and cumulative

chronic toxicities (e.g., oxaliplatin neuropathy, irinotecan diarrhea). In the second line, nivolumab plus ipilimumab achieves a 48-month PFS rate of 54% and OS rate of 71% (n=119), yet this benefit is again largely restricted to MSI-H/dMMR tumors and combination immunotherapy carries higher Grade 3–4 adverse event rates versus monotherapy. In later lines, fruquintinib offers median OS of 9.3 months and PFS of 3.7 months in FRESCO (Grade 3–4 treatment-emergent AEs: 61.2%; serious AEs: 15.5%; n=416) and median OS of 7.6 months with PFS of 3.7 months in FRESCO-2 (Grade ≥3 TEAEs: 60%; n=180); however, durability is limited, resistance emerges, and toxicity remains frequent. Across regimens, the survival gains are modest for the majority with pMMR/MSS disease, options narrow after early lines due to resistance and molecular exclusions, and escalating toxicity further constrains long-term disease control. The following table sets forth the survival rate of standard therapies for the treatment of mCRC as of the Latest Practicable Date and their limitations.

Survival rate for mCRC standard therapy

Line of Therapy	Study	Drugs	Therapeutic Efficacy
First Line	KEYNOTE-177	Chemotherapy ± bevacizumab/ cetuximab	PFS: 8.2 months 24-month Restricted Mean Survival: 10.8 months Grade ≥3 Treatment-Related Adverse Events: 66% (n = 154)
		Pembrolizumab	PFS: 16.5 months 24-month Restricted Mean Survival: 13.7 months Grade ≥3 Treatment-Related Adverse Events: 22% (n = 153)
Second Line	CheckMate - 142	Nivolumab + Ipilimumab	48-month PFS Rate: 54% 48-month OS Rate: 71% (n = 119)
Third Line	FRESCO	Fruquintinib	Median OS: 9.3 months Median PFS: 3.7 months Grade 3-4 Treatment-Emergent Adverse Events: 61.2% Serious Adverse Events: 15.5% (n = 416)
	FRESCO-2		Median OS: 7.6 months Median PFS: 3.7 months Grade ≥3 treatment-emergent adverse events: 60% (n = 180)

Limitations of existing mCRC therapy

01 Low Immunotherapy Response Rates
Immune checkpoint inhibitors demonstrate high efficacy only in mCRC patients with the dMMR/MSI-H molecular subtype, who represent a mere 15% of the total mCRC population.

02 Immune-Related Toxicity
As the mCRC backbone, chemotherapy has a defined toxicity profile. Acute toxicities include myelosuppression, while chronic toxicities feature oxaliplatin-induced peripheral neuropathy and irinotecan's delayed-onset diarrhea.
Immunotherapy poses a distinct challenge with immune-related adverse events (irAEs). In KEYNOTE-177, 22% of pembrolizumab-treated patients had ≥3 Grade irAEs.
Combination therapies, though standard for better efficacy, also increase toxicity risks. The JCOG1018 trial showed adding oxaliplatin to FP/bevacizumab raised ≥Grade 3 toxicity from 52% to 69%. Similarly, CheckMate 142 found nivolumab plus ipilimumab had higher Grade 3-4 adverse events than monotherapy.

03 Resistance Drivenby Tumor Escape Mechanisms
A major challenge in managing mCRC is the eventual development of acquired resistance to targeted therapies. A key limitation of EGFR-targeted therapy, as instance, is that tumor cells evade treatment by activating alternative signaling pathways (e.g., via MET or HER2) or acquiring mutations in the EGFR gene itself, which bypass the therapeutic blockade and sustain tumor proliferation.

Source: Literature Review, Frost & Sullivan

However, there remain unmet needs in current CRC treatment:

- *Limited treatment options in late-stage CRC management.* In China, third-line treatment options for CRC remain limited, with existing therapies offering modest survival benefits and suboptimal disease control for patients with refractory disease. While regorafenib, TAS-102 (± bevacizumab), and fruquintinib provide some therapeutic benefit, their mechanisms — primarily targeting angiogenesis and cytotoxic pathways — fail to address tumor immune evasion and resistance mechanisms, which are critical in late-stage CRC. Emerging bispecific antibody therapies present a transformative opportunity in late-stage CRC treatment by simultaneously engaging multiple tumor-associated pathways. As bispecific antibody platforms continue to evolve, their ability to enhance immune activation,

improve tumor specificity, and mitigate off-target toxicities positions them as a promising next-generation strategy for late-stage CRC management. Integrating bispecific antibodies into the treatment paradigms for the pretreated CRC patients could redefine therapeutic outcomes, offering more durable responses and broader applicability compared to existing options.

- *Poor prognosis.* Effective therapies for mCRC remain limited, contributing to poor patient outcomes. CRC is categorized into four stages, with five-year survival rates declining progressively — from 94% in stage I, to 82% in stage II, 67% in stage III, and only 11% in metastatic (stage IV) disease. As the understanding of CRC molecular mechanisms deepens, the development of novel therapeutics, including bispecific antibodies, along with personalized treatment regimens, is anticipated to address these critical deficiencies.

- *High heterogeneity.* CRC exhibits significant molecular heterogeneity, yet current therapeutic strategies have not fully addressed this complexity. For instance, cMET (MET protein) overexpression is frequently observed in advanced solid tumors, including mCRC. Clinical data support the tolerability and manageability of cMET-directed antibody therapies, demonstrating favorable anti-tumor activity, improved progression-free survival ("**PFS**"), and superior efficacy in patients with high MET expression.

Bispecific antibody therapeutics capable of simultaneously targeting EGFR and cMET represent a promising future direction, addressing key limitations of current treatment paradigms.

- *Overcoming resistance mechanisms.* EGFR-directed monoclonal antibody therapies, such as cetuximab and panitumumab, have demonstrated clinical benefit in a subset of patients; however, resistance often emerges through compensatory upregulation of alternative signaling pathways, particularly cMET. cMET overexpression has been implicated in escape mechanisms that sustain tumor proliferation despite EGFR blockade. Bispecific antibodies engineered to inhibit both pathways simultaneously offer a strategic advantage by disrupting these compensatory signaling networks.

- *Enhanced tumor suppression.* Preclinical studies have shown that bispecific EGFR/cMET antibodies effectively inhibit downstream oncogenic signaling, resulting in superior anti-tumor activity compared to single-target agents. This dual inhibition leads to broader suppression of mitogenic and survival pathways, reducing tumor viability and enhancing apoptosis.

- *Improved therapeutic selectivity and efficacy.* Bispecific constructs allow for greater tumor-specific targeting by leveraging differential receptor expression patterns. The ability to engage two tumor-associated antigens within a single molecule minimizes off-target effects while maximizing therapeutic potency. Patient-derived xenograft models have demonstrated enhanced tumor regression and prolonged PFS with EGFR/cMET bispecific approaches, further validating their clinical potential. EMB-01 is among the earliest EGFR/cMET bispecific antibodies to enter Phase II clinical trials for colorectal cancer on a global basis. By leveraging a dual-targeting mechanism and low-toxicity design to address resistance mechanisms and improve outcomes in this specific patient subset. Notably, in left-sided RAS/RAF wild-type mCRC, EMB-01 has demonstrated a partial response rate of 24.1%, surpassing the current SOC and underscoring its potential clinical value. The expected market penetration of EMB-01 can be further supported by the substantial population of CRC patients who failed first- and second-line treatment. It is estimated that up to 82.3% of mCRC patients experience treatment failure in first-line therapy, with the rate remaining high at 74.3% in second-line treatment. While frontline therapy demonstrates substantial resistance, later-line treatments (third-line and beyond) are addressing critical clinical gaps through precision stratification and innovative therapeutic combinations, highlighting their market potential.

The growth of the mCRC drug market is expected to be driven by improving mCRC drug access with policy support. The 2025 National Reimbursement Drug List (NRDL) & Commercial Health Insurance Innovative Drug Directory Adjustment has preliminarily approved Fruquintinib Capsules for inclusion in both the NRDL and the Commercial Health Insurance Innovative Drug Directory, creating a multi-tiered payment mechanism for high-value innovative drugs in mCRC, where basic medical insurance covers essentials and commercial insurance supplements advanced therapies. The 2024 NRDL newly incorporates Cetuximab Beta Injection, explicitly indicated with FOLFIRI as first-line treatment for RAS/BRAF wild-type mCRC, directly improving access to key targeted therapies and reducing patient financial burdens. The Guidelines on Improving Outpatient Chronic and Critical Disease Insurance extend coverage to outpatient chemotherapy, targeted therapy, and immunotherapy for malignant tumors, reimbursing eligible expenses at inpatient rates with no deductible. This policy greatly enhances the outpatient treatment experience for mCRC, lowering long-term costs and improving adherence and quality of life.

Competitive Landscape of EGFR/cMET Bispecific Antibody Drugs for CRC

As of the Latest Practicable Date, there was no marketed EGFR/cMET bispecific antibody for the treatment of CRC globally. In addition, in China's CRC pipeline, there are 230 innovative biological products under development, including 40 bispecific antibodies (BsAbs), of which 28 target third-line CRC — such as Alphamab's KN026 (HER2 BsAb) in combination with KN046 (PD-L1/CTLA-4 BsAb), which is in Phase II (NCT04521179) for HER2-positive mCRC after at least two prior lines of therapy. While no EGFR/cMET bispecific antibody has been approved, these emerging options illustrate the breadth of approved and investigational treatment regimens beyond standard chemotherapy and targeted combinations. Furthermore, by 2034, the total addressable patient population of CRC patients in 3L or above settings and suitable for EGFR/c-MET bispecific antibody treatment is estimated to be approximately 50.3 thousand, and the number of targeted addressable patients expected on EMB-01 (i.e., patients with mCRC who have failed first- and second-line treatments) is estimated to be approximately 8.7 thousand. The following table sets forth the EGFR/cMET bispecific antibody candidates for the treatment of CRC under development globally and in China as of the Latest Practicable Date:

Global and China Pipelines

Product	Company	Target	Indication	Highest Clinical Phase	Mono/Combo	LOT	First Posted Date	Country
EMB-01	Our Company	EGFR/c-Met	CRC	II	Mono	Third-line	2025/11/05	China
Amivantamab	Janssen	EGFR/c-Met	Solid tumors (including CRC)	III	Combo	First-line	2022/05/11	US, China, etc.
TQB2922	ChiaTai Tianqing	EGFR/c-Met	CRC	I/II	Combo	Third-line/ Last-line	2025/06/17	China
MCLA-129	Betta Pharmaceuticals	EGFR/c-Met	Solid tumors (including CRC)	I/II	Mono/Combo	Second line/ Third-line	2021/05/13	China
HS-20117	Hansoh Biopharmaceutical	EGFR/c-Met	Solid tumors, (including CRC)	I	Combo	Second-line/ Third-line/ Last-line	2025/04/16	China
FPI-2053	Fusion Pharmaceuticals	EGFR/c-Met	Solid tumors, (including CRC)	I	Combo	Second-line	2023/11/27	US, Canada

Source: Clinical Trials, Frost & Sullivan

The following table sets forth the EGFR/cMET bispecific antibody candidates for the treatment of mCRC under development globally and in China as of the Latest Practicable Date:

Global and China Pipelines

Product	Company	Target	Indication	Highest Clinical Phase	Mono/Combo	LOT	First Posted Date	Country
EMB-01	Our Company	EGFR/ cMET	mCRC	II	Mono	Third-line	2022/01/04	China, US
Amivantamab	Janssen	EGFR/ cMET	Solid tumors (including mCRC)	III	Combo	First-line	2024/10/29	US, UK, China, etc.
TQB2922	ChiaTai Tianqing	EGFR/ cMET	mCRC	I/II	Combo	Third-line/ Last-line	2025/6/17	China
MCLA-129	Betta Pharmaceuticals	EGFR/ cMET	Solid tumors (including mCRC)	I/II	Mono/Combo	Second line/ Third-line	2021/05/13	China
FPI-2053	Fusion Pharmaceuticals	EGFR/ cMET	Solid tumors, (including mCRC)	I	Combo	Second-line/ Third-line/ Last-line	2023/11/27	US

Source: Clinical Trials, Frost & Sullivan

The following table summarizes the targeted addressable patients of EMB-01 in China in 2024:

Program	Indication	LOT	New Cases of Targeted Indication in China (thousands)	Number of Targeted Addressable Patients in China (thousands)
EMB-01	mCRC	Third Line	542.2	38.5

Source: Frost & Sullivan

The following table summarizes the addressable patients and market size of major indications of EMB-01 in China for the period indicated:

Program	Indication	Unit		Year of 2024	2030E	2034E	CAGR (2024-2030E)	CAGR (2030E-2034E)
EMB-01	mCRC	Addressable Patients	Thousand cases	38.5	45.6	50.3	2.9%	2.5%
		Market	Billion USD	3.1	4.1	7.4	8.2%	10.6%

Note: The calculation of addressable patient population is based on 100% penetration rate.

Source: Frost & Sullivan

The following table summarizes the addressable mCRC patient population for EMB-01 in 2024 in China:

Indication	Market	New Cases	Late Stage Rate	Early Stage Recurrence Rate	Number of Late Stage CRC Patients	Proportion of CRC Patients that is Stratified Based on Genotypic Profiles	Patients Suitable for EGFR/ c-MET BsAbs	Proportion of Patients Receiving 1st Line Treatment	Patients in 1st Line Treatment	Proportion of Patients Receiving 2nd Line Treatment	Patients in 2nd Line Treatment	Proportion of Patients Receiving 3rd Line Treatment	Patients in 3rd Line Treatment	Addressable Patients in 2024
	Billion USD	Thousand cases	%	%	Thousand cases	%	Thousand cases	%	Thousand cases	%	Thousand cases	%	Thousand cases	Thousand cases
mCRC	3.1	542.4	35.6%	30.0%	297.9	32.1%	95.7	95.5%	91.4	73.2%	66.9	57.6%	38.5	38.5

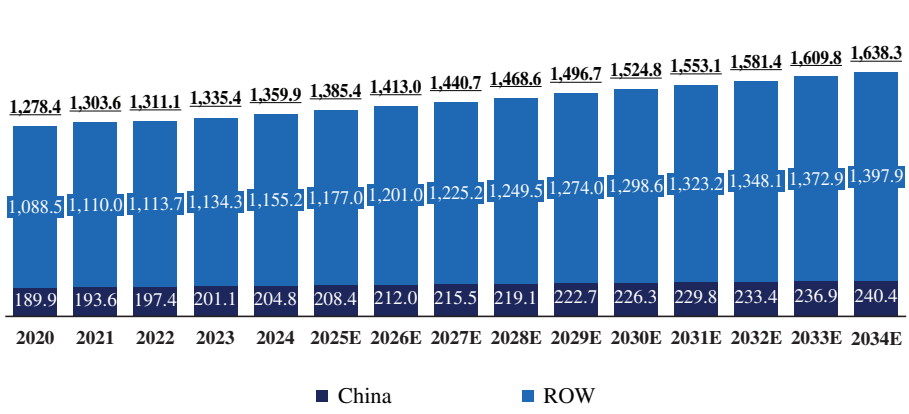
Source: Frost & Sullivan

THE HEMATOLOGIC MALIGNANCIES DRUG MARKET

Hematologic malignancies encompass a range of malignant diseases that originate from myeloid or lymphocytic hematopoietic lineages, with the most prevalent forms including various types of leukemia, lymphoma, and multiple myeloma. The following diagram sets forth historical and projected incidences of hematologic malignancies globally and in China for the periods indicated:

Global Incidence of Hematological Malignancies, 2020-2034E

Period	CAGR		
	China	ROW	Global
2020-2024	1.9%	1.5%	1.6%
2024-2034E	1.8%	2.1%	2.1%



Source: IARC, NCCR, Frost &Sullivan

THE DLBCL DRUG MARKET

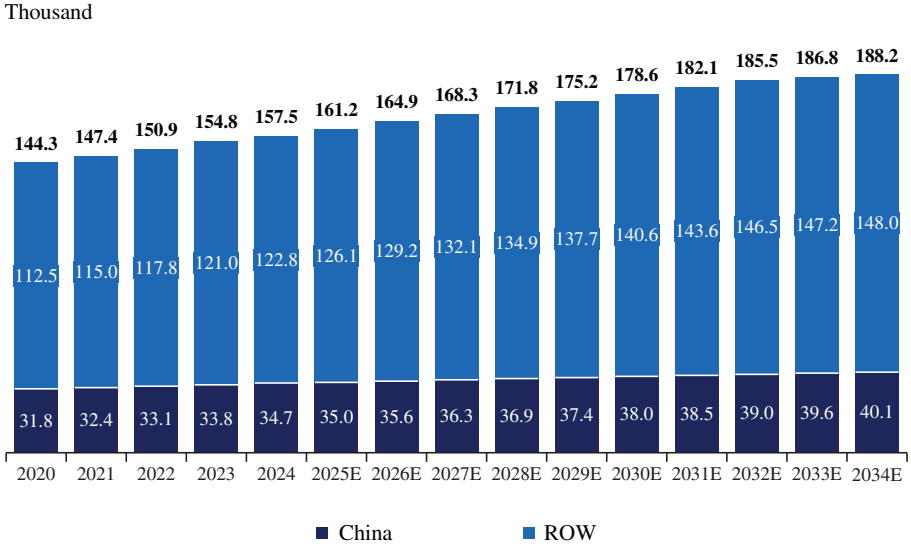
DLBCL Market Size

Lymphoma is a heterogeneous group of hematologic malignancies originating from lymphocytes, a key component of the immune system. Broadly classified into Hodgkin lymphoma and non-Hodgkin lymphoma ("**NHL**"), the latter accounts for approximately 90% of all lymphoma cases worldwide. Diffuse Large B-Cell Lymphoma ("**DLBCL**") is the most prevalent subtype of NHL, accounting for approximately 40% of NHL cases in China. It is an aggressive, fast-growing B-cell malignancy, characterized by significant heterogeneity at the molecular level, leading to varied clinical outcomes.

The number of new DLBCL cases in China rose from 31.8 thousand in 2020 to 34.7 thousand in 2024, and is projected to reach 40.1 thousand by 2034. Globally, DLBCL incidence increased from 144.3 thousand in 2020 to 157.5 thousand in 2024, and is expected to reach 188.2 thousand by 2034, reflecting a consistent upward trend. The following diagram sets forth historical and projected incidences of DLBCL globally and in China for the periods indicated:

Global Incidence of DLBCL, 2020-2034E

Period	CAGR		
	China	ROW	Global
2020-2024	2.2%	2.2%	2.2%
2024-2034E	1.5%	2.1%	2.0%

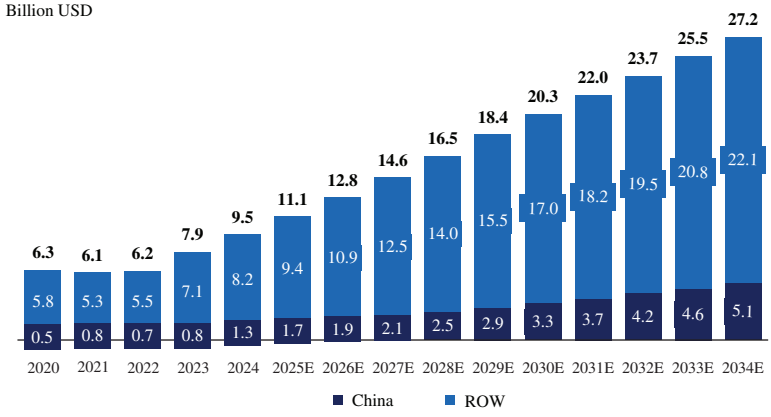


Source: IARC, NCCR, Frost & Sullivan

The DLBCL drug market in China has experienced expansion, growing significantly from US$0.5 billion in 2020 to US$1.3 billion in 2024, at a CAGR of 25.1%. The market is projected to continue expanding at a CAGR of 16.6% from 2024 to 2030, reaching US$3.3 billion in 2030. Between 2030 and 2034, the CAGR is expected to slow to 11.8%, with market size climbing to US$5.1 billion by 2034. Globally, the DLBCL drug market expanded from US$6.3 billion in 2020 to US$9.5 billion in 2024, representing a CAGR of 10.5%, and is expected to further expand to US$20.3 billion by 2030, with a CAGR of 13.5% from 2024 to 2030. The global DLBCL drug market is projected to reach US$27.2 billion by 2034, with a CAGR of 7.7% from 2030 to 2034. Multiple factors are collectively driving the expansion of the DLBCL market, such as the growing patient pool stemming from rising incidence rates and an aging population, R&D breakthroughs and clinical applications of innovative therapies, advancements in diagnostic technologies and optimized treatment strategies. The following diagram sets forth the DLBCL drug market size globally and in China for the periods indicated:

Global DLBCL Drug Market, 2020-2034E

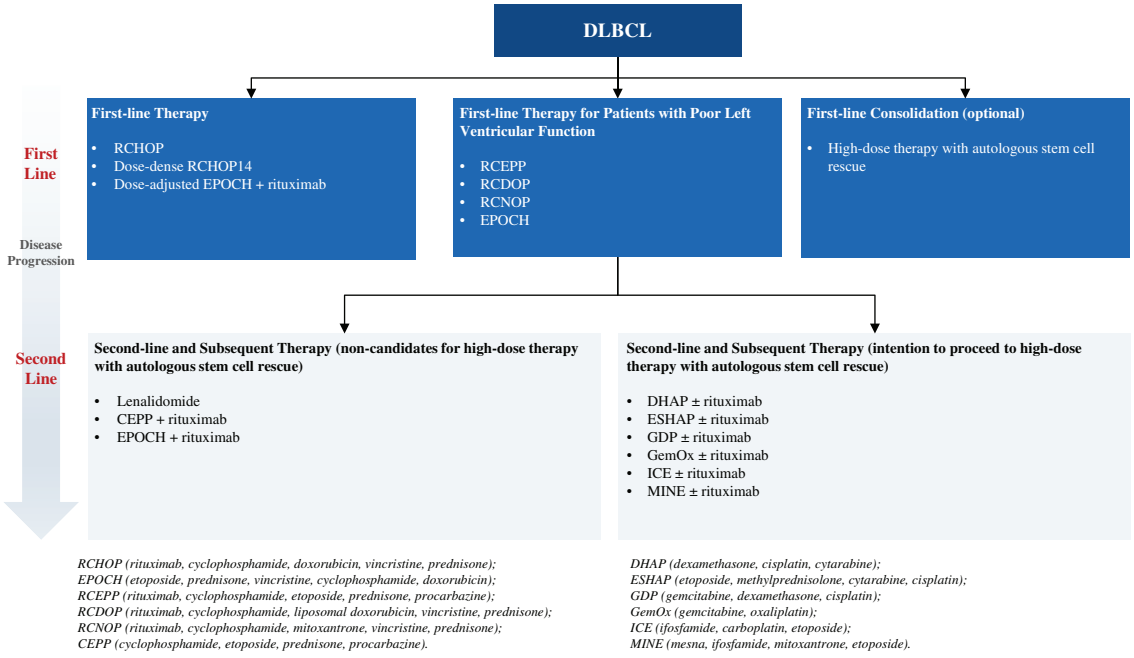
Period	CAGR		
	China	ROW	Global
2020-2024	25.1%	8.9%	10.5%
2024-2030E	16.6%	13.0%	13.5%
2030E-2034E	11.8%	6.8%	7.7%



Source: Frost & Sullivan

Treatment Paradigm for DLBCL

In China, while R-CHOP remains the dominant first-line approach, second-line strategies closely align with global standards, incorporating EPOCH-R, DHAP, GDP, GemOx, and other salvage regimens. The availability of novel immunotherapies, such as CAR-T and bispecific antibodies, continues to expand treatment possibilities for transplant-ineligible and chemo-refractory patients. The following diagram illustrates the treatment paradigm for DLBCL in China:



Source: The Chinese Guidelines for the Diagnosis and Treatment of Diffuse Large B-Cell Lymphoma, Frost & Sullivan

However, there remain unmet needs in current DLBCL treatment:

- *High relapse rate.* DLBCL is the most prevalent form of aggressive lymphoma, characterized by rapid progression and high proliferative potential. While the disease is highly chemosensitive at initial treatment, frontline chemoimmunotherapy using rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone (R-CHOP) achieves curative intent in approximately 60-65% of patients. However, nearly one-third of patients present with primary refractory disease or experience relapse (R/R DLBCL) following an initial response. These individuals typically face a poor prognosis, with limited therapeutic options available upon recurrence, resulting in high treatment failure rates and disease-related mortality. Addressing relapse and refractory mechanisms remains a pivotal challenge in improving survival outcomes.

- *High disease heterogenicity.* DLBCL exhibits considerable molecular and clinical heterogeneity, leading to variable therapeutic responses and treatment resistance. While advancements in genomic profiling and molecular classification have contributed to a refined understanding of disease subtypes, approximately half of patients remain unclassified under current molecular frameworks. The lack of definitive biomarker-driven treatment strategies has limited personalized therapy approaches, necessitating broader precision medicine initiatives to optimize patient-specific interventions.

- *Optimizing combination therapies with novel agents.* Unlike solid tumors, DLBCL lacks a single dominant driver mutation, making monotherapy approaches insufficient for durable remission. While traditional small molecule inhibitors and epigenetic-modifying agents demonstrate potential, their standalone efficacy remains suboptimal in addressing DLBCL's intrinsic complexity. Immunotherapeutic innovations, including CAR-T cell therapy and bispecific antibodies, have emerged as critical additions to the R/R DLBCL treatment landscape, but challenges persist in determining optimal combinatorial regimens to maximize therapeutic synergy while minimizing toxicity. The integration of next-generation immunotherapies, targeted agents, and novel combination strategies remains an evolving field, requiring continued clinical investigation and translational research to establish effective multi-modal treatment paradigms.

The emergence of ROR1/CD3 TCE therapies introduces a novel mechanism to overcome the deficiencies of existing treatment modalities for DLBCL:

- *Targeting ROR1 to address tumor heterogeneity.* Receptor tyrosine kinase-like orphan receptor 1 ("**ROR1**") is an oncofetal protein selectively expressed in certain aggressive DLBCL subtypes, including therapy-resistant cases. The validity of targeting ROR1 is supported by strong translational evidence. Recent studies have suggested that ROR1 is implicated in primary refractory DLBCL, Richter's syndrome as well as transformed follicular lymphoma (to DLBCL). Additionally, ROR1 expression is associated with unfavorable prognosis and promotes tumorigenesis. Unlike CD20-targeting monoclonal antibodies with predominant effects via antibody-dependent cell-mediated cytotoxicity, complement-dependent cytotoxicity, and direct CD20 ligation which may be impacted by resistance of CD20 loss, ROR1-directed approaches enable another layer of robust target engagement in DLBCL cells that exhibit immune evasion mechanisms, providing an alternative pathway for tumor suppression.

- *CD3 engagement for enhanced T-cell cytotoxicity.* By linking CD3-positive T cells to ROR1-expressing malignant B cells, ROR1/CD3 TCE therapy initiates a potent immune-mediated cytotoxic response, effectively bypassing resistance pathways associated with conventional antibody therapies. This dual-target approach enhances tumor clearance and offers superior selectivity for malignant cells. Additionally, ROR1/CD3 may be added to the current combination therapies to further boost overall response and reduce the development of resistance. Furthermore, it provides a valuable and viable component in chemo-free or chemo-light combo settings to DLBCL patients who are not tolerant to strong chemo therapies.

- *Off-the-shelf immunotherapy with broad applicability.* Unlike CAR-T therapies and autologous stem cell transplantation, which require patient-derived modifications of T cells and lymphodepletion, ROR1/CD3 TCEs function as allogeneic, off-the-shelf therapies with immediate availability. This eliminates manufacturing delays and logistical barriers, accelerating treatment initiation for R/R DLBCL patients who require urgent therapeutic intervention. Additionally, the manufacturing cost of bispecific antibodies is substantially lower compared to CAR-T therapies, making ROR1/CD3 TCEs a more financially viable option in broader clinical applications of both front lines and late lines.

  The emergence of ROR1/CD3 TCE, which behaves like a monoclonal biologic, ensures consistent pharmacokinetics, predictable dosing, and streamlined as well as possible subcutaneous administration — similar to conventional antibody therapies. This familiarity in drug behavior allows for greater physician adoption while maintaining robust immune engagement against ROR1-expressing DLBCL cells. As an immediate-use therapy, ROR1/CD3 TCEs bridge the gap between targeted precision immunotherapy and real-world accessibility, offering a scalable, lower-cost solution to meet the unmet needs of DLBCL patients who require effective and rapidly deployable treatment.

The growth of the DLBCL drug market in China is also expected to be driven by the policy support as following:

- *Annual NRDL updates and major/critical disease coverage streamline access.* Rituximab-based R-CHOP remains first-line, while polatuzumab vedotin is already on the NRDL, signaling a pathway for next-generation CD20/CD19 antibodies, ADCs, and bispecifics once clinical and economic value are proven. Inpatient and day-care delivery of immunochemotherapy can be substantially reimbursed when regimens are guideline-endorsed and on hospital formularies, improving affordability and adherence.

- *Supplementary insurance expands early access for innovative therapies.* City-level Huiminbao and the Commercial Health Insurance Innovative Drug List offer interim or parallel reimbursement for cutting-edge DLBCL drugs not yet fully covered by the NRDL, building a multi-tiered payment structure that reduces patient burden, accelerates real-world uptake beyond top tertiary centers, and supports continuity of care across settings.

Competitive Landscape of ROR1/CD3 TCE for DLBCL

As of the Latest Practicable Date, there is no marketed ROR1/CD3 TCE for the treatment of DLBCL globally. EMB-07 remains the only clinical-stage ROR1/CD3 bispecific antibody candidate for the treatment of hematologic malignancies in China as of the Latest Practicable Date. The following chart sets forth the selected information of all ROR1/CD3 bispecific antibody candidates for the treatment of DLBCL globally and in China as of the Latest Practicable Date:

Global and China Pipelines

Product	Company	Target	Drug Type	Indication	Highest Clinical Phase	Mono/Combo	LOT	First Posted Date	Country
EMB-07	Our Company	ROR1/CD3	Bispecific Antibody	DLBCL	I	Mono	Second-line/ Third-line/ Last-line	2022/11/03	China, Australia
NVG-111	NovalGen	ROR1/CD3	Bispecific Antibody	DLBCL	I/II	Mono	Second Line/ Third Line/ Last Line	2020/07/31	UK

Source: Clinical trials, Frost & Sullivan

The following table summarizes the targeted addressable patients of EMB-07 in China in 2024:

Program	Indication	LOT	New Cases of Targeted Indication in China (thousands)	Number of Targeted Addressable Patients in China (thousands)
EMB-07	DLBCL	Second Line and above	34.7	8.7

Source: NMPA, Frost & Sullivan

The following table summarizes the addressable patients and market size of major indications of EMB-07 in China for the period indicated:

Program	Indication	Unit		Year of 2024	2030E	2034E	CAGR (2024-2030E)	CAGR (2030E-2034E)
EMB-07	DLBCL	Addressable Patients	Thousand cases	8.7	9.9	10.5	2.1%	1.5%
		Market	Billion USD	1.3	3.3	5.1	16.6%	11.8%

Note: The calculation of addressable patient population is based on 100% penetration rate.

Source: Clinical trials, Frost & Sullivan

THE MULTIPLE MYELOMA DRUG MARKET

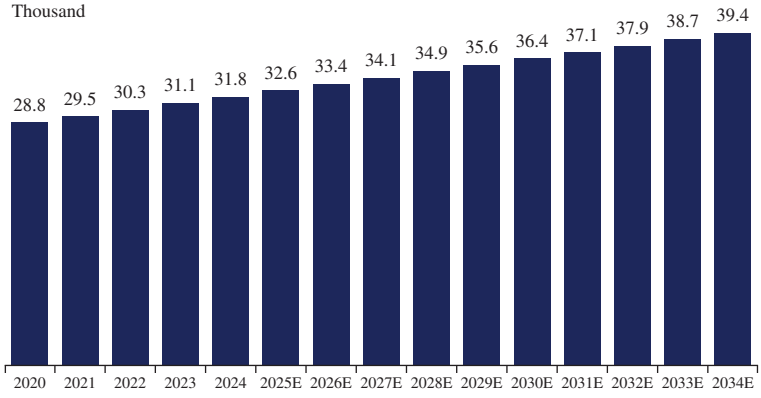
Multiple Myeloma Market Size

Multiple myeloma ("**MM**") is a hematologic malignancy characterized by uncontrolled proliferation of plasma cells in the bone marrow. These malignant plasma cells disrupt normal hematopoiesis, leading to bone destruction, anemia, hypercalcemia, kidney dysfunction, and immune suppression. The disease is clinically heterogeneous, with patients exhibiting variable progression rates and survival outcomes. MM is classified into hyperdiploid MM (h-MM) and non-hyperdiploid MM (nh-MM), with h-MM generally associated with a more favorable prognosis, while nh-MM is aggressive and linked to worse survival rates.

In recent years, advancements in targeted therapies and immunotherapy have significantly transformed MM management. However, high relapse rates, treatment resistance, and the need for personalized regimens continue to pose challenges, driving ongoing innovation in the MM drug market. The MM drug market has experienced rapid expansion, fueled by rising disease incidence, increasing adoption of novel therapies, and advancements in precision medicine. In China, the number of new MM cases reached 31.8 thousand in 2024, growing at a CAGR of 2.6% from 2020 to 2024. From 2024 to 2030, the incidence is projected to rise further to 36.4 thousand, with a CAGR of 2.2%. Between 2030 and 2034, growth is expected to continue at a slower pace, reaching 39.4 thousand by 2034 with a CAGR of 2.0%. The following diagram sets forth historical and projected incidences of MM in China for the periods indicated:

Incidence of Multiple Myeloma in China, 2020-2034E

Period	CAGR
2020-2024	2.6%
2024-2030E	2.2%
2030E-2034E	2.0%

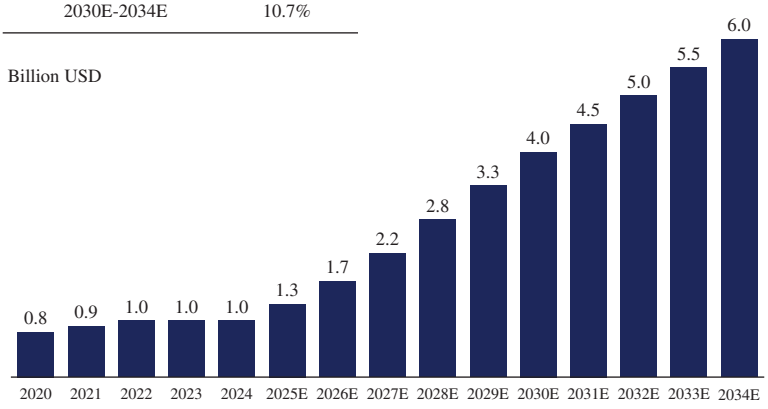


Source: NCCR, Frost & Sullivan

Parallel to the rising patient population, China's MM drug market size increased from US$0.8 billion in 2020 to US$1.0 billion in 2024, with a CAGR of 7.7% from 2020 to 2024. The market is expected to grow rapidly from 2024 to 2030 with a CAGR of 24.9%, reaching US$4.0 billion by 2030. From 2030 to 2034, the market will continue to expand at a CAGR of 10.7%, with the size projected to climb to US$ 6.0 billion by 2034. The accelerated launch of innovative drugs has driven a comprehensive upgrade in the treatment landscape, further meeting the diverse treatment needs of patients. In addition, medical insurance policies have significantly improved patients' payment capacity and greatly enhanced drug accessibility. Under the combined effect of these factors, the scale of China's multiple myeloma drug market continues to expand. The following diagram sets forth the MM drug market size in China for the periods indicated:

Historical and Forecasted of China Multiple Myeloma Drug Market Size, 2020-2034E

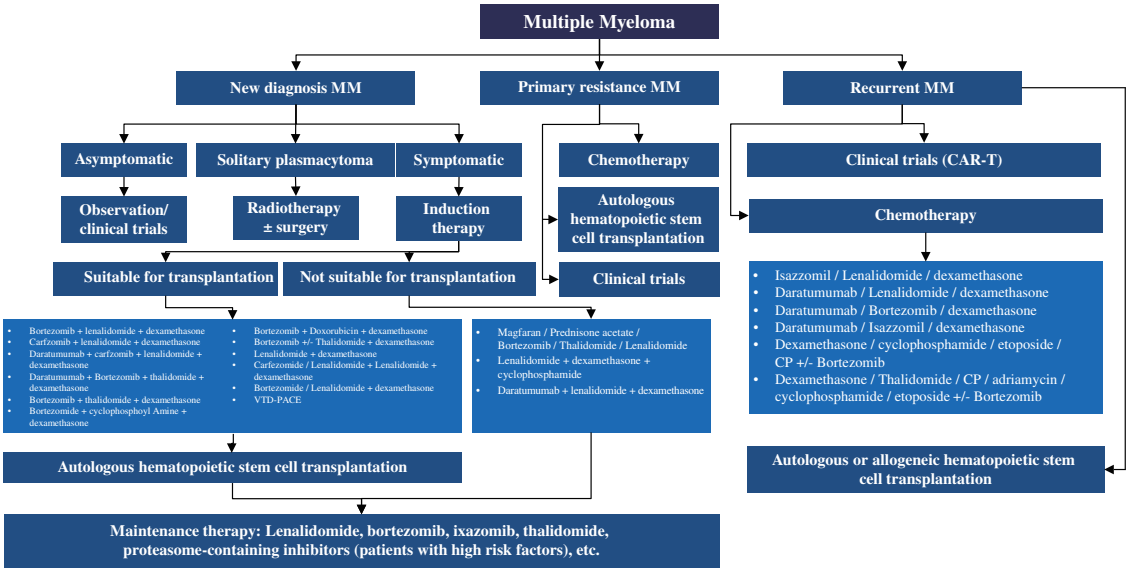
Period	CAGR
2020-2024	7.7%
2024-2030E	24.9%
2030E-2034E	10.7%



Source: Frost & Sullivan

Treatment Paradigm for MM

MM treatment is highly individualized, depending on disease progression, transplant eligibility, and response to prior therapies. The standard therapeutic approach involves a combination of proteasome inhibitors, immunomodulatory drugs, monoclonal antibodies, and corticosteroids. The following diagram illustrates the treatment paradigm for MM in China:



Notes: RT = Radiation therapy; CP = cisplatin; X = capecitabine; 5-FU = 5-Fluorouracil; G = gemcitabine; VTD-PACE = Bortezomib + dexamethasone thalidomide + Cisplatin + Doxorubicin + cyclophosphamide + etopoxib

Source: CSCO2025, literature review, Frost & Sullivan

Competitive Landscape of BCMA/CD3 TCE for MM

The following table sets forth marketed BCMA/CD3 TCEs for the treatment of MM globally as of the Latest Practicable Date:

Global Marketed Products

Product	Company	Target	Drug Type	Indication	Mono/Combo	LOT	First Posted Date	Country
ELREXFIO	Pfizer	BCMA/CD3	Bispecific Antibodies	Multiple Myeloma	Mono	Last line	2023/8/14	USA
						Last line	2023/12/8	EU
						Last line	2024/3/26	Japan
						Last line	2025/3/4	China
TECVAYLI	Johnson & Johnson	BCMA/CD3	Bispecific Antibodies	Multiple Myeloma	Mono	Last line	2022/10/25	USA
						Last line	2022/8/24	EU
						Last line	2024/6/18	China
						Last line	2024/12/27	Japan
LYNOZYFIC	Regeneron	BCMA/CD3	Bispecific Antibodies	Multiple Myeloma	Mono	Last line	2025/7/2	USA
						Last line	2025/4/28	EU

Source: FDA, Frost & Sullivan

The following table summarizes the targeted addressable patients of EMB-06 in the treatment of MM in China in 2024:

Program	Indication	LOT	New Cases of Targeted Indication in China (thousands)	Number of Targeted Addressable Patients in China (thousands)
EMB-06	MM	Third Line and above	31.8	13.0

Source: NMPA, Frost & Sullivan

The following table summarizes the addressable patients and market size of major indications of EMB-06 in China for the period indicated:

Program	Indication	Unit		Year of 2024	2030E	2034E	CAGR (2024-2030E)	CAGR (2030E-2034E)
EMB-06	MM	Addressable Patients	Thousand cases	13.0	15.1	16.4	2.5%	2.0%
		Market	Billion USD	1.0	4.0	6.0	24.9%	10.7%

Note: The calculation of addressable patient population is based on 100% penetration rate.

Source: Clinical trials, Frost & Sullivan

The following table sets forth the BCMA/CD3 TCE candidates for the treatment of MM under development globally and in China as of the Latest Practicable Date:

Global Pipelines

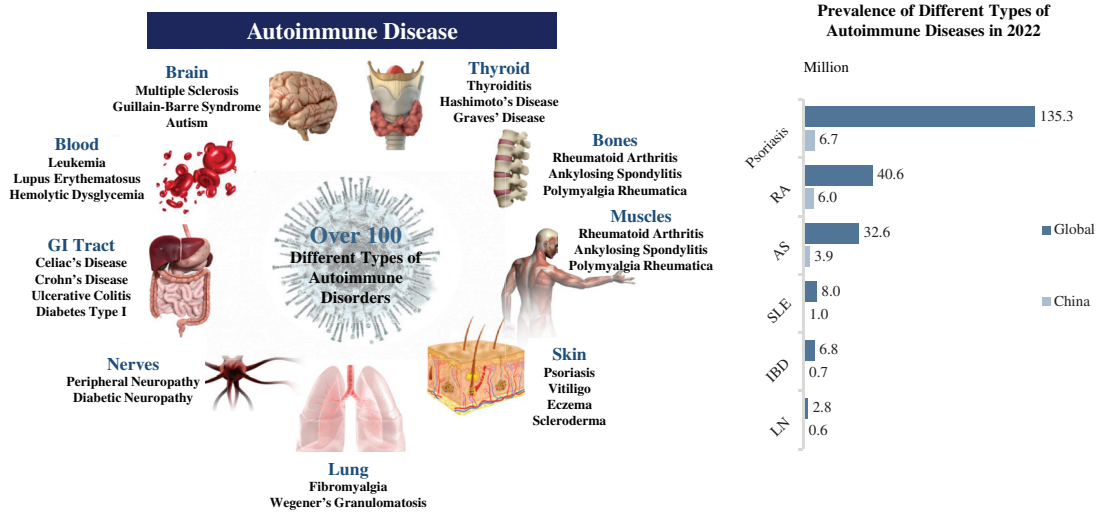
Product	Company	Target	Indication	Highest Clinical Phase	Mono/Combo	LOT	First Posted Date	Country
EMB-06	Our Company	BCMA/CD3	Multiple Myeloma	II	Mono	Third-line/Last-line	2021/02/03	China, Australia
GR1803	Genrixbio Pharmaceutical	BCMA/CD3	Multiple Myeloma	II	Mono	Second-line/ Third-line/ Last-line	2025/03/12	China
F182112	Shandong New Time Pharmaceutical	BCMA/CD3	Multiple Myeloma	II	Combo	Second-line/ Third-line/ Last-line	2025/03/11	China
YKST02	Excyte Biopharma Ltd	BCMA/CD3	Multiple Myeloma	I	Mono	Third-line/Last-line	2024/05/08	China
Etentamig	AbbVie	BCMA/CD3	Multiple Myeloma	III	Mono	Third-line/Last-line	2023/12/06	China, US, etc.
TQB2934	Chiatai Tianqing	BCMA/CD3	Multiple Myeloma	I	Mono	Second-line/ Third-line/ Last-line	2022/12/12	China
BCD-248	Biocad	BCMA/CD3	Multiple Myeloma	II	Mono	Third-line/Last-line	2024/10/30	Russia
CM336	Keymed Biosciences	BCMA/CD3	Multiple Myeloma	III	Mono	Third-line/Last-line	2025/09/18	China
REGN5459	Regeneron Pharmaceuticals	BCMA/CD3	Multiple Myeloma	I/II	Mono	Last Line	2019/09/10	US

Source: NMPA, Clinical Trials, Frost & Sullivan

THE AUTOIMMUNE DRUG MARKET

Overview of Autoimmune Diseases

Autoimmune diseases encompass a broad spectrum of chronic conditions characterized by immune system dysregulation, in which the body mistakenly attacks its own tissues. These disorders affect millions worldwide, with common indications including rheumatoid arthritis, systemic lupus erythematosus, multiple sclerosis, inflammatory bowel disease, and type 1 diabetes. The prevalence of autoimmune diseases has been steadily increasing, attributed to genetic, environmental, and lifestyle factors, underscoring the urgent need for innovative and more effective treatment strategies. The following diagram illustrates the types of autoimmune disease and prevalence of different types of autoimmune diseases:

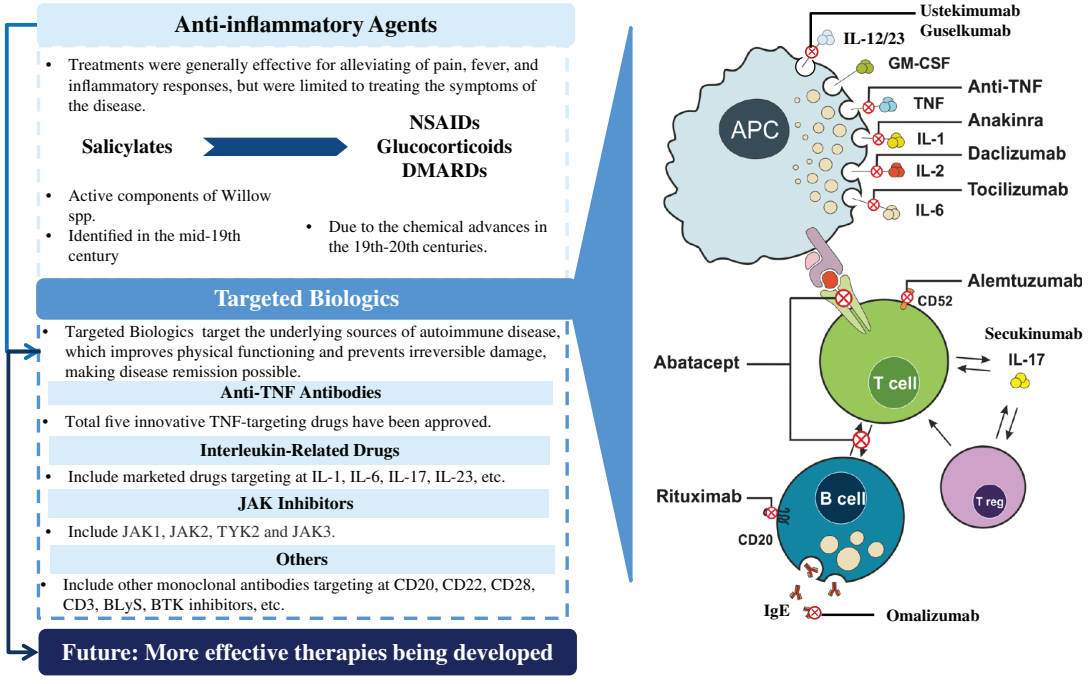


Note: RA: Rheumatoid arthritis; AS: Ankylosingspondylitis; SLE: Systemic lupus erythematosus; IBD: Inflammatory bowel diseases; LN: Lupus nephritis

Source: Literature review, Frost & Sullivan

Treatment Revolution for Autoimmune Disease

Current standard-of-care therapies focus on immune suppression, using corticosteroids, disease-modifying antirheumatic drugs (DMARDs), biologics (e.g., TNF inhibitors), and JAK inhibitors. While these treatments provide symptomatic relief, many patients fail to achieve long-term disease control, leading to high relapse rates, adverse side effects, and drug resistance, necessitating a paradigm shift toward precision-targeted and disease-modifying therapies. The following diagram illustrates the treatment revolution for autoimmune diseases:



Note:
NSAIDs: Non-steroidal anti-inflammatory drugs
DMARDs: Disease-modifying anti-rheumatic drugs
Source: Literature review, Frost & Sullivan

The following table sets forth the comparison of autoimmune disease treatment:

Treatment Category	Common Types	Common Drugs	Mechanism	Advantages
Biologics	Biologics	• Adalimumab • Etanercept • Golimumab • Infliximab • Tocilizumab • Ustekinumab • Rituximab • Abatacept	Control the progression of autoimmune diseases by precisely targeting key molecules (e.g., tumor necrosis factor-alpha (TNF-α), interleukin-6 (IL-6), interleukin-17 (IL-17)) or cells (e.g., B cells, T cells) within the immune system, thereby blocking abnormal immune responses. Their mechanisms include neutralizing pro-inflammatory cytokines, inhibiting specific immune cells, blocking co-stimulatory signals, or modulating lymphocyte trafficking.	Newly emerging effective biologic drugs are available for patients with severe or resistant diseases.
Small Molecule	Nonsteroid anti-inflammatory drugs (NSAIDs)	• Aspirin • Ibuprofen • Naproxen	Block prostaglandins, which can sensitize the nerves and magnify pain feelings during inflammation.	Work quickly and generally have fewer side effects than corticosteroids.
	Conventional DMARDs	• Methotrexate • Leflunomide	Inhibit the enzymes that affect DNA-synthesis for the proliferation of white blood cells, thus causing immunosuppression.	Long-term medication can effectively control symptoms and achieve stable efficacy.
	Corticosteroids	• Methylprednisolone • Dexamethasone • Prednisone	Stop the release of molecules that cause inflammation and also stop the body from having an immune response.	Fast and strong anti-inflammatory effect that can be applied in many situations.
	JAK inhibitors	• Tofacitinib • Baricitinib	Inhibit immune cell function by inhibiting signal transduction of cytokines and growth factors.	Have shown satisfactory efficacy in patients resistant to other medications.
	Other Immuno-suppressants	• Such as mTOR inhibitors (Sirolimus, Everolimus)	Block the mammalian target of rapamycin (mTOR) which regulates cellular metabolism, growth, and proliferation.	Have shown tumor responses in clinical trials against both autoimmune diseases and various tumor types.

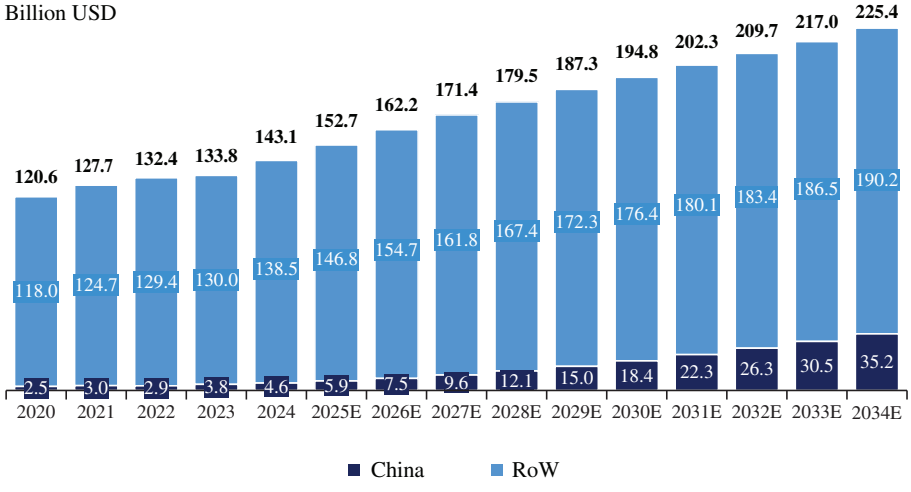
Source: Literature review, Frost & Sullivan

Autoimmune Disease Drug Market Size

The autoimmune disease drug market represents one of the fastest-growing segments in pharmaceutical innovation, driven by increasing disease prevalence, advancements in biologics and cell therapy, and the emergence of novel immunomodulatory agents. In China, the autoimmune disease drug market has witnessed robust growth, increased from US$2.5 billion in 2020 to US$4.6 billion in 2024, with a CAGR of 15.9% from 2020 to 2024. The market size is expected to expand rapidly to US$18.4 billion by 2030, representing a CAGR of 26.2% from 2024 to 2030 and further reach US$35.2 billion by 2034, reflecting a CAGR of 17.5% from 2030 to 2034. The medication regimens for autoimmune diseases have gradually shifted toward the iteration of new-generation targeted drugs and biological drugs. Meanwhile, the market size of autoimmune disease drugs is jointly influenced by multiple factors, such as the rising incidence and prevalence of diseases, the increase in confirmed patients due to advances in diagnostic technologies, the improved accessibility of drugs brought by the optimization of medical insurance policies and payment systems, the enhanced health awareness and treatment compliance of patients, the release of demand in emerging markets, and the upgrading of treatment methods driven by industry innovation and competition. The following diagram sets forth autoimmune diseases drug market size globally and in China for the periods indicated:

Historical and Forecasted of Global Autoimmune Disease Drug Market Size, 2020-2034E

CAGR	China	RoW	Total
2020-2024	15.9%	4.1%	4.4%
2024-2030E	26.2%	4.1%	5.3%
2030E-2034E	17.5%	1.9%	3.7%



Source: Frost & Sullivan

Competitive Landscape of Bispecific Antibody Drugs Treating Autoimmune Diseases

As of the Latest Practicable Date, there are no marketed bispecific antibody drugs for the treatment of autoimmune diseases globally. The following table sets forth the bispecific antibody candidates for the treatment of autoimmune diseases under development globally and in China as of the Latest Practicable Date:

Global Pipelines

Product	Company	Target	Drug Type	Indication	Highest Clinical Phase	Mono/ Combo	First Posted Date	Country
EMB-06	Our Company	BCMA/CD3	Bispecific Antibody	Autoimmune Diseases	I	Mono	2024/04/25	China
REGN5459	Regeneron	BCMA/CD3	Bispecific Antibody	Lupus Nephritis	I	Mono	2025/05/16	France
F182112	Shandong New Time Pharmaceutical	BCMA/CD3	Bispecific Antibody	Systemic Lupus Erythematosus	I	Mono	2025/08/26	China
GR1803	Genrixbio Pharmaceutical	BCMA/CD3	Bispecific Antibody	Systemic Lupus Erythematosus	I/II	Mono	2025/11/14	China
CM336/ OM336	Keymed Biosciences, Ouro Medicines	BCMA/CD3	Bispecific Antibody	Immune Thrombocytopenia	I/II	Mono	2025/9/01	China
				Autoimmune Cytopenias	I	Mono	2025/7/24	Australia
				Active Sjogren's Disease, Idiopathic Inflammatory Myopathy	I	Mono	2025/10/22	Australia, New Zealand

China Pipelines

Product	Company	Target	Drug Type	Indication	Highest Clinical Phase	Mono/ Combo	First Posted Date	Country
EMB-06	Our Company	BCMA/CD3	Bispecific Antibody	Autoimmune Diseases	I	Mono	2025/7/29	China
F182112	Shandong New Time Pharmaceutical	BCMA/CD3	Bispecific Antibody	Systemic Lupus Erythematosus	I	Mono	2025/08/26	China
GR1803	Genrixbio Pharmaceutical	BCMA/CD3	Bispecific Antibody	Systemic Lupus Erythematosus	I/II	Mono	2025/11/14	China
CM336	Keymed Biosciences	BCMA/CD3	Bispecific Antibody	Immune Thrombocytopenia	I/II	Mono	2025/9/18	China

Source: Clinical trials, Frost & Sullivan

The following table summarizes the targeted addressable patients of EMB-06 for the treatment of autoimmune diseases in China in 2024:

Program	Indication	LOT	New Cases of Targeted Indication in China (thousands)	Number of Targeted Addressable Patients in China (thousands)
EMB-06	Autoimmune Diseases	Third Line and above	*39,400	*10,300

Source: NMPA, Frost & Sullivan

Note: Prevalence-based estimates are utilized to represent the existing patient population. The considerable heterogeneity among autoimmune diseases — marked by substantial differences in pathogenesis and clinical manifestations — complicates the use of incidence data. Moreover, the chronic and relapsing nature of most autoimmune diseases often results in patients making multiple healthcare visits. Accurately determining incidence would thus require distinguishing new cases from pre-existing ones, further increasing the complexity of statistical analysis.

Entry Barriers

The new entrants to the market targeting autoimmune diseases may face the following entry barriers:

- *Demonstrating at least comparable efficacy compared to existing treatments.* There are multiple treatments that are approved for autoimmune diseases (e.g., TNF, JAK inhibitors, IL-17, IL-23, or IL-4/13) which have strong clinical efficacy and adoption. New market entrants will need to demonstrate at least comparable efficacy if it has a dosing advantage or targets a novel pathway, but ideally can show superior efficacy compared to the existing standard of care. Beyond efficacy, safety and tolerability are also important consideration. Autoimmune treatments often require chronic administration. In addition, given the availability of multiple approved mechanisms of action, it can be challenging to find new pharmacological treatment pathways.

- *Time-consuming and costly R&D process.* For most autoimmune disease drugs, Phase III trials are typically required for approval and first-in-human studies have to be started in healthy volunteers. This can lengthen regulatory approval timelines for autoimmune disease treatments, demanding substantial capital investment over extended periods and presenting significant financial risks that challenge even well-established pharmaceutical enterprises.

Growth Drivers and Future Trends

The growth of the autoimmune disease market is expected to be driven by the following factors:

- *Development of more treatment modalities.* More effective and diverse therapeutic options for the treatment of autoimmune diseases (e.g., oral IL-23 or BTK) are under development. Advances in biologic therapies, including monoclonal antibodies and targeted immunomodulators, have significantly improved treatment outcomes and expanded the range of available interventions. Additionally, precision medicine and biomarker-driven approaches are enabling more tailored treatments, improving efficacy while minimizing adverse effects.

- *Growing public awareness of autoimmune diseases.* Economic growth and technological advancements in diagnostic testing have significantly enhanced public awareness and early detection of autoimmune diseases in China. As disease education and healthcare accessibility improve, higher diagnosis and treatment rates are observed, particularly for lifelong, chronic autoimmune conditions. The increasing adoption of precision screening tools is driving earlier intervention and optimized disease management, reinforcing the demand for next-generation therapies.

- *Encouraging policies and reimbursement system.* The NMPA has introduced proactive policies to stimulate novel drug research and development, fostering accelerated innovation in the autoimmune disease sector. Simultaneously, national and provincial reimbursement reforms aim to expand patient access to advanced biologics, reducing financial barriers and enhancing affordability for broader populations. These regulatory initiatives are expected to accelerate the uptake of innovative therapeutics and shape a more sustainable market ecosystem.

- *Strengthening autoimmune drug access with policy support.* The annually updated NRDL has increasingly included innovative biologics for autoimmune diseases through national price negotiations, enabling broad coverage and rapid uptake once approved. Provincial outpatient chronic and special disease programs recognize long-term autoimmune care needs, allowing higher reimbursement ratios and lower or no deductibles for repeated biologic injections and infusions in ambulatory settings, which reduces out-of-pocket spending and sustains adherence. Commercial health insurance and city-level "Huiminbao," alongside innovative drug lists, provide supplementary pathways that bridge early access gaps for high-cost therapies prior to or in parallel with NRDL entry, accelerating patient reach and market penetration. Together, these policies establish a multi-layered payment framework in which basic medical insurance covers essential outpatient biologic use while commercial products complement advanced indications, improving affordability, continuity of care, and real-world outcomes for patients with immune-mediated conditions across diverse regions.

The future development of autoimmune disease drugs is likely to witness the following trends:

- *Development of dual-targeting modalities.* Bispecific antibodies represent an emerging therapeutic modality that can simultaneously engage two distinct antigens or receptors, enabling more precise targeting in autoimmune diseases. These dual-targeting biologics significantly enhance therapeutic efficacy by blocking multiple signaling pathways or eliminating various pathogenic cell populations concurrently. By engaging both pathogenic immune cells and regulatory pathways, these engineered constructs provide precise immune recalibration, mitigating excessive inflammation while preserving protective immune surveillance. This approach enhances disease control while reducing systemic toxicity, offering a more refined treatment alternative to broad-spectrum immunosuppressants. The autoimmune disease landscape offers numerous potential targets for bispecific antibody development, including B-cell and T-cell depletion targets, TNFs, interleukins, integrins, and other key immune mediators.

- *Development of treatments with multi-indication applications.* A deeper understanding of immune dysfunction and biologic pathways is driving the development of a single therapeutic agent that can effectively target multiple autoimmune diseases by addressing shared immune dysregulation pathways. For example, unlike traditional biologics, which often require separate drugs for distinct indications, TCEs leverage precise immune modulation to intervene at critical pathogenic junctions applicable across different disorders. TCEs designed to redirect autoreactive T cells or deplete pathogenic B cells can be effective in rheumatoid arthritis, lupus, and multiple sclerosis — conditions that share underlying inflammatory pathways.

- *Expansion of oral treatment options.* Oral drug delivery is emerging as a promising approach in autoimmune disease treatment. Compared to traditional injectable therapies, oral medications offer substantial advantages in enhancing patient compliance and simplifying medication management — particularly beneficial for autoimmune patients requiring long-term therapy. In addition, oral therapies reduce reliance on clinic-based administration and lower the risk of injection-related complications, making treatment more convenient and patient-friendly.

- *Extended half-life optimization.* Emerging biotherapeutic modalities — including bispecific antibodies, engineered nanobodies, and Fc-based constructs — are incorporating advanced half-life extension technologies such as neonatal Fc receptor recycling enhancement, albumin conjugation, and hydrodynamic radius optimization to achieve sustained pharmacokinetic profiles. This evolution in drug design will offer significant therapeutic outcomes through improved patient compliance, reduced healthcare utilization costs, and extended market exclusivity via differentiated product profiles.

SOURCE OF INFORMATION

We commissioned Frost & Sullivan to conduct an analysis of and to prepare a report on the major markets for which our drug candidates are positioned. We agreed to pay Frost & Sullivan a total fee of RMB678,000. Except as otherwise noted, all of the data and forecasts contained in this section are derived from the Frost & Sullivan Report. Frost & Sullivan is an independent global market research and consulting company which was founded in 1961 and is based in the United States. Services provided by Frost & Sullivan include market assessments, competitive benchmarking, and strategic and market planning for a variety of industries.

The Frost & Sullivan Report was compiled based on the following assumptions: (i) the overall social, economic and political environment globally and in China is expected to remain stable during the forecast period; (ii) the economic and industrial development globally and in China is likely to maintain a steady growth trend over the next decade; (iii) related key industry drivers are likely to continue driving the growth of the market during the forecast period; and (iv) there is no extreme force majeure or industry regulation in which the market may be affected dramatically or fundamentally.

In compiling and preparing the Frost & Sullivan Report, Frost & Sullivan used the following key methodologies to collect multiple sources, validate the data and information collected, and cross-check each respondent's information and views against those of others: (i) secondary research, which involved reviewing published sources including national statistics, annual reports of listed companies, industry reports and data based on Frost & Sullivan's own research database; and (ii) primary research, which involved in-depth interviews with the industry participants.

Frost & Sullivan's projections are made based on various market determinants and their coefficients assigned to a market which indicate their relative importance. The market determinants represent both subjective assumptions and objective factors, therefore, the projected data may not be consistent with the real data.

The Directors and Joint Sponsors have exercised reasonable care in selecting and identifying the named information sources, compiling, extracting and reproducing the information, and in ensuring that there is no material omission of the information.