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ANALYSIS OF ANTIBODY DRUG MARKET

Overview of Antibody

Antibody, also called immunoglobulin ("**Ig**"), is a large protective protein produced by the immune system in response to the presence of pathogens such as pathogenic bacteria and viruses, which are antigens. Antibodies recognize and latch onto such antigens in order to neutralize and remove them from the body.

Antibodies are currently utilized as medicines for various conditions, including cancer, inflammatory disease, organ transplantation, cardiovascular diseases, respiratory diseases, and ophthalmologic disease. This list is continuously expanding.

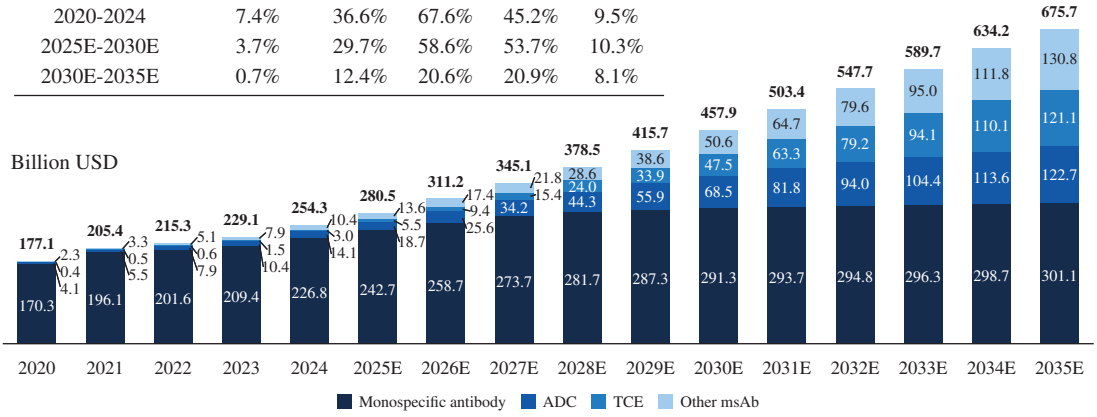
Bispecific antibody ("**bsAb**") is an artificial protein that can simultaneously bind to two different epitopes. TCEs is a type of cell-bridging bsAbs. They are engineered molecules that link a tumor antigen with the CD3 receptor on T cells, thereby forming an immune synapse that triggers cytotoxic killing of tumor cells. TCEs offer the advantage of strong, major histocompatibility complex ("**MHC**")-independent tumor killing and have been clinically validated in therapies such as blinatumomab. However, the application of TCEs faces certain challenges, including the risk of cytokine release syndrome ("**CRS**"), short half-lives, and limited targeting to tumors that express accessible antigens.

Market Size of Therapeutic Antibody

In 2024, global therapeutic antibody market grew to US$254.3 billion, with a CAGR of 9.5% from 2020 to 2024. Monospecific antibody is the largest category in the global therapeutic antibody market by revenue, accounting for about 90% of the market. Though multispecific antibody ("**msAb**") and antibody-drug conjugates ("**ADC**") are still in an early stage of market development, their corresponding markets are expected to grow fast in the upcoming years with technological breakthroughs and advancement of clinical studies.

Historical and Forecasted Global Therapeutic Antibody Market Size, 2020-2035E

CAGR	Monospecific Antibody	ADC	TCE	Other msAb	Total
2020-2024	7.4%	36.6%	67.6%	45.2%	9.5%
2025E-2030E	3.7%	29.7%	58.6%	53.7%	10.3%
2030E-2035E	0.7%	12.4%	20.6%	20.9%	8.1%



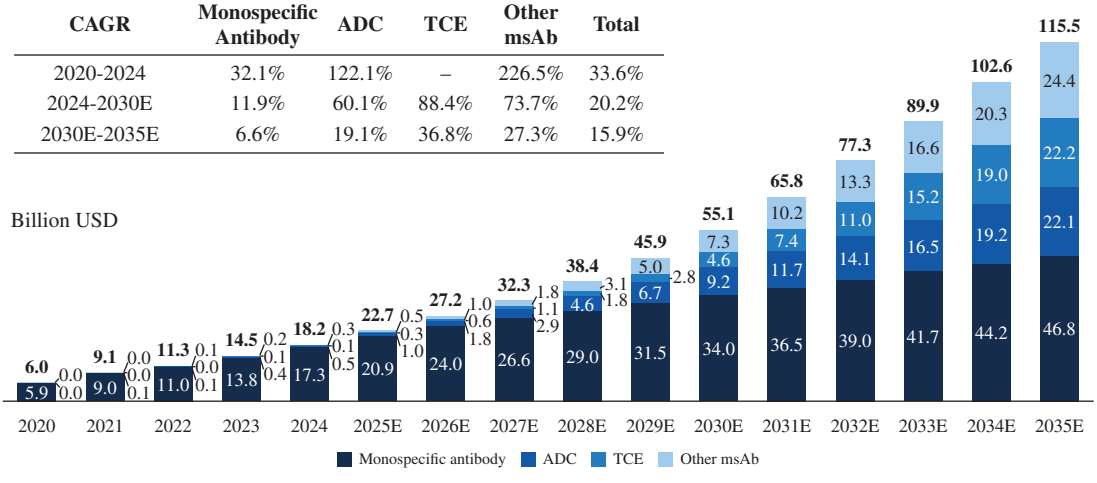
Note: Multispecific antibodies include bispecific, trispecific, and tetraspecific formats.

Source: Literature review, Annual report, Expert interview, Frost & Sullivan analysis

In China, the therapeutic antibody market reached US$18.2 billion in 2024, with a CAGR of 32.1% from 2020 to 2024. Monospecific antibody is the largest category in China's therapeutic antibody market. For msAb and ADC, there are multiple clinical-stage pipelines under development. It is anticipated that the market of msAb and ADC will grow fast in the upcoming years with technological breakthroughs and advancement of clinical studies. China's therapeutic antibody market is expected to witness more diversified reimbursement systems, increased availability of biosimilars and launching of innovative antibody drugs in the next 10 years.

Historical and Forecasted Market Size of Therapeutic Antibody Market in China, 2020-2035E

CAGR	Monospecific Antibody	ADC	TCE	Other msAb	Total
2020-2024	32.1%	122.1%	–	226.5%	33.6%
2024-2030E	11.9%	60.1%	88.4%	73.7%	20.2%
2030E-2035E	6.6%	19.1%	36.8%	27.3%	15.9%



Note: Multispecific antibodies include bispecific, trispecific, and tetraspecific formats.

Source: Literature review, Annual report, Expert interview, Frost & Sullivan analysis

The number of approved antibody drugs and their indications have been continuously increasing globally and in China, with treatment penetration of antibody therapies steadily rising in areas such as oncology, autoimmune diseases, and metabolic disorders. This is particularly notable in oncology, where incidence is increasing year by year: the global incidence grew from 19.29 million in 2020 to 21.91 million in 2025, and is projected to reach 27.02 million by 2035; in China, incidence increased from 4.62 million in 2020 to 5.13 million in 2025, and is expected to reach 6.29 million by 2035. The pipeline for ADCs and monospecific antibodies continues to expand: as of now, there are 1,096 monospecific antibodies candidates, 420 ADC candidates, and 523 msAb candidates under active development globally; in China, there are 469 monospecific antibodies candidates, 264 ADC candidates, and 295 msAb candidates in development. Over the next 5-10 years, multiple ADC and msAb products targeting HER2, TROP2, EGFR, BCMA, and CD20 are expected to gain regulatory approval. In addition, technological advancements in linkers, payloads, and bispecific platforms are continuously improving, which is expected to further enhance efficacy and safety profiles and expand clinical applications.

In China, the NMPA has established accelerated registration pathways, including Breakthrough Therapy designation, Conditional Approval, Priority Review and Special Review, which significantly shorten the time-to-approval for innovative antibody drugs, particularly in oncology and rare diseases. In addition, the publication of biosimilar R&D and evaluation guidelines reduces regulatory uncertainty and facilitates faster market entry of antibody biosimilars. On the reimbursement side, the NRDL negotiation process and the "dual-channel" access policy can improve affordability and availability of high-cost antibody drugs, while centralized procurement mechanisms increasingly support broader uptake, especially for biosimilars. As a result, a growing number of innovative antibody drugs are anticipated to be included in the NRDL, improving patient accessibility and treatment rates. Meanwhile, the increasing penetration of biosimilars is expected to reduce treatment costs and expand patient coverage.

Globally, sustained R&D investment, licensing, and strategic collaborations by pharmaceutical and biotech companies are also key drivers supporting market growth in the antibody therapeutics sector.

ANALYSIS OF THE TCE MARKET

The development of TCEs traces back to its conceptual origin in the 1980s through multiple stages of innovation. After the approval of the first TCE drug catumaxomab in 2009 and the approval blinatumomab as a breakthrough therapy in 2014, the field TCE research entered a rapid phase of development. In 2021, tarlatamab became the first classic first-generation TCE approved for solid tumors, further driving research in advanced designs. Looking ahead, AI in TCE design marks the beginning of a new development phase, offering a transformative potential to optimize molecular engineering and accelerate therapeutic advancement. At present, AI applications are primarily focused on rare diseases. In the future, they are expected to expand toward broader therapeutic indications.

Overview of TCE

Under normal circumstances, T cells have the ability to eliminate abnormal cells. However, tumors are often able to hide from T cells or suppress the signals needed for their activation. TCEs solve this problem by binding both to TAAs on cancer cells and to receptors on the surface of T cells such as CD3. The engagement of such proteins would send an intracellular activation signal that initiates the T cell's immune responses. As a result, the TAAs provide specificity (identifying the cancer cell) while engagement of T-cell receptors such as CD3 provides activation. By physically linking the T cells to the tumor and triggering the activation of the T cells, TCEs activate the immune system to recognize and eliminate cancer cells directly and selectively. This makes TCEs a powerful way to break through tumor defenses and restore the immune system's natural ability to eliminate cancer.

TCEs can be designed in as either bispecific or multispecific format. For bispecific TCEs, they are designed to bind to only two targets: one on T cells (typically CD3) and one to TAAs on cancer cells. Multispecific TCEs, a type of advanced TCE, are designed to bind to multiple functional targets and/or TAAs, with immune cell receptors.

The addition of protease-activatable masking peptides to the TCE's target-binding site may keep the TCE inactive in normal tissues and peripheral circulation. When the TCE enters in the TME, tumor-specific proteases such as urokinase-type plasminogen activator ("**uPA**") and matrix metalloproteinases ("**MMPs**") may cleave the masking peptide, restoring the TCE's target-binding activity and anti-tumor function. As such, masked TCEs are specifically activated only in the TME, while remaining inactive in normal tissue and blood. This may reduce the side effects of traditional TCE drugs and significantly improve the specific tumor targeting, safety and therapeutic index of TCE drugs. Among the proteases, uPA possesses the best tumor-specificity. Thus, the uPA-mediated masked TCEs can minimize the on-target off-tumor toxicity.

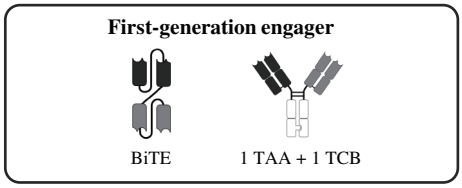
uPA is a protease that plays a key role in tumor invasion and metastasis. It is broadly over-expressed in many cancers. This indicates that uPA is a very important common feature of these malignant tumors. For instance, an immunohistochemical analysis revealed uPA overexpression in approximately 93% of pancreatic tumor samples, often with uniform staining of tumor cells. In contrast, uPA has a low expression level in normal tissues and benign tumors. Other enzymes, such as MMPs and matriptase, are also highly expressed in malignant tumors, but with a lower level of tumor specificity. Some subtypes of MMP, such as MMP-9, showed only focal staining in about 37% of pancreatic tumors, underscoring its more heterogeneous and limited expression pattern. Moreover, there is considerable diversity in matriptase protein expression among breast cancers, with a substantial proportion of human breast tumors and established breast cancer cell lines not expressing detectable amounts of matriptase at all.

TCEs have evolved from early 1+1 bispecific designs to masking, multifunctional, costimulatory formats, while steadily expanding indications from hematologic malignancies to solid tumors, autoimmune and infectious diseases. The development of TCEs is expected to enter an innovation stage driven by AI-assisted design in the future. The following illustrates the evolution of TCE formats.

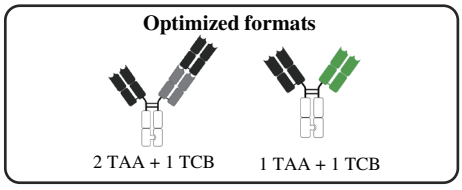
The Evolution of T cell Engager Formats

TCEs have rapidly evolved from early-generation bispecific antibodies to complex constructs.

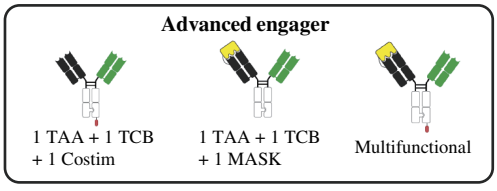
- **1+1 format: foundation of bispecific design**

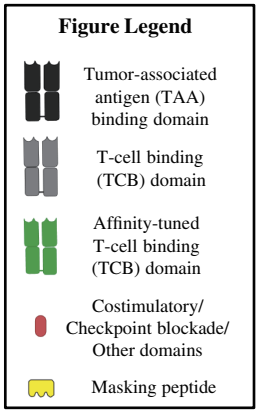


- **2+1 format: harnessing avidity for selectivity**
- **1+1+1 trispecific format: addressing complexity and resistance**



- **Advanced therapies: engage masking multifunctional costimulatory moiety**





Source: Literature review, Frost & Sullivan analysis

Technological Evolution of TCEs

The technological evolution of TCEs represents a shift from basic molecular design to highly intelligent and selective therapeutics. Through advances in data-driven design, structural optimization, tumor-selective activation, and multifunctional logic gating, TCEs are evolving toward safer, more precise, and durable cancer immunotherapies.

Data-driven discovery. The foundation of TCE development lies in the establishment of comprehensive biological and clinical databases, integrating multi-omics, immune profiling, and real-world datasets. Data mining and AI-assisted target screening enable the identification of optimal tumor-immune synapse targets, improving specificity and therapeutic potential.

Structural optimization of TCEs. Structural optimization serves to improve the pharmacokinetics, tumor penetration and safety of TCEs. Technological advances in structural optimization are mainly directed to linker flexibility, antibody valency, and binding kinetics to balance potency and CRS risk. Current designs for structural optimization also incorporate Fc silencing, half-life extension, and manufacturability improvements, forming a bridge between molecular design and large-scale production.

Advanced masked TCEs. The mainstream of TCE innovation lies in development of masking peptides. To overcome the key limitation of on-target off-tumor toxicity, advanced masked TCEs incorporate conditional activation mechanisms, which make TCEs remain inactive in normal tissues but are selectively activated in the TME. The design of masking peptide often uses protease-cleavable linkers or pH-dependent conformational changes to enable spatial control of T-cell activation (pH-dependent activation is not strictly tumor-specific, as acidic conditions can also be present in inflamed or hypoxic normal tissues). The approach enhances the therapeutic window and expands applicability of TCEs toward solid tumors — an area historically limited by safety constraints.

Advanced multifunctional/logic-gated TCEs. The frontier of TCE innovation lies in multifunctional and logic-gated constructs that integrate multiple immune pathways for precise control. These molecules combine tumor antigen recognition with checkpoint or co-stimulatory modulation, enabling "AND/OR/NOT" logic gating to fine-tune T-cell responses and overcome immune resistance. This evolution marks a transition from single-target cytotoxicity to programmable immune modulation, representing the future of solid tumor immunotherapy.

Advantages of TCEs Over Other Modalities

Below is a comparison of the key characteristics of TCE and other treatment modalities.

Characteristic	Small Molecules	Monospecific Antibodies	TCE	CAR-T Cell Therapy
Molecular Type	Small organic compounds, typically <500 Da, chemically synthesized.	Large proteins (~150 kDa), IgG-like structure, produced in mammalian cell lines.	Antibody-based bispecific constructs (various formats: BiTE ~50-60 kDa or IgG-like ~150-200 kDa).	Engineered autologous T cells expressing a chimeric antigen receptor.
Target	Intracellular or extracellular proteins, enzymes, receptors.	Extracellular surface antigens only.	Surface antigens on tumor cells (e.g., CD19, BCMA) and CD3 on T cells.	Surface antigens on tumor cells (e.g., CD19, BCMA).
Administration . .	Usually oral; convenient and patient-friendly.	Intravenous or subcutaneous infusion.	Intravenous infusion or subcutaneous; short-half-life formats often require continuous or frequent dosing.	Single intravenous infusion of autologous cells.
Half-life	Short (hours to days).	Long (weeks).	Variable: short (hours) for BiTE formats; longer (days to weeks) for IgG-like formats.	Long-term persistence (months to years).
Availability	Off-the-shelf; immediate use.	Off-the-shelf; immediate use.	Off-the-shelf; immediate use.	Patient-specific; 3–6 weeks manufacturing time.

Characteristic	Small Molecules	Monospecific Antibodies	TCE	CAR-T Cell Therapy
Safety Profile	Off-target toxicity, drug-drug interactions, acquired resistance.	Infusion-related reactions, immunosuppression, infections.	Cytokine release syndrome (CRS), neurotoxicity; generally manageable with step-up dosing and supportive care.	Severe CRS, immune effector cell-associated neurotoxicity syndrome (ICANS); requires specialized management.
Efficacy Context	Broad applicability including solid tumors; resistance common.	Highly effective in hematological and select solid tumors; penetration limits in dense solid tumors.	Strong, durable responses in hematological malignancies; emerging data in solid tumors.	Deep, durable remissions in certain hematological malignancies; limited success in solid tumors to date.

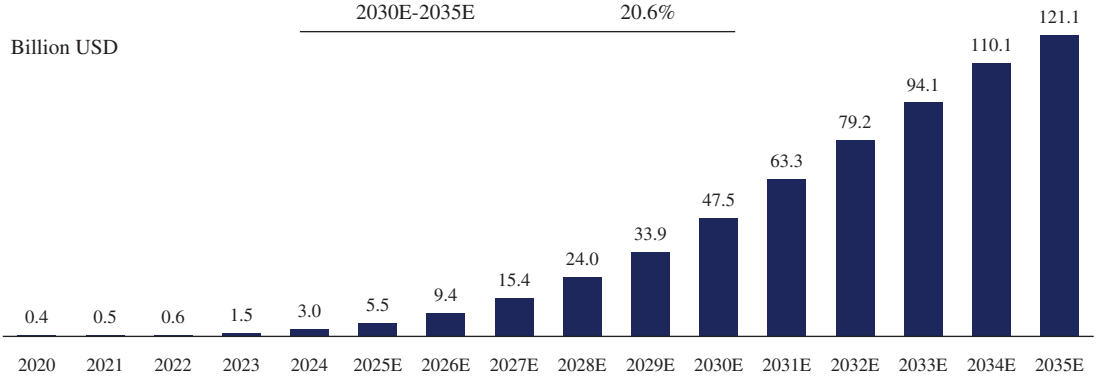
Source: Literature Review, Frost & Sullivan Analysis

The Market for TCE Drugs

The size of the global TCE drugs market reached US$0.4 billion in 2020 and US$3.0 billion in 2024, representing a CAGR of 67.6% from 2020 to 2024.

Global TCE Drugs Market Size and Forecast, 2020-2035E

Period	CAGR
2020-2024	67.6%
2025E-2030E	53.7%
2030E-2035E	20.6%

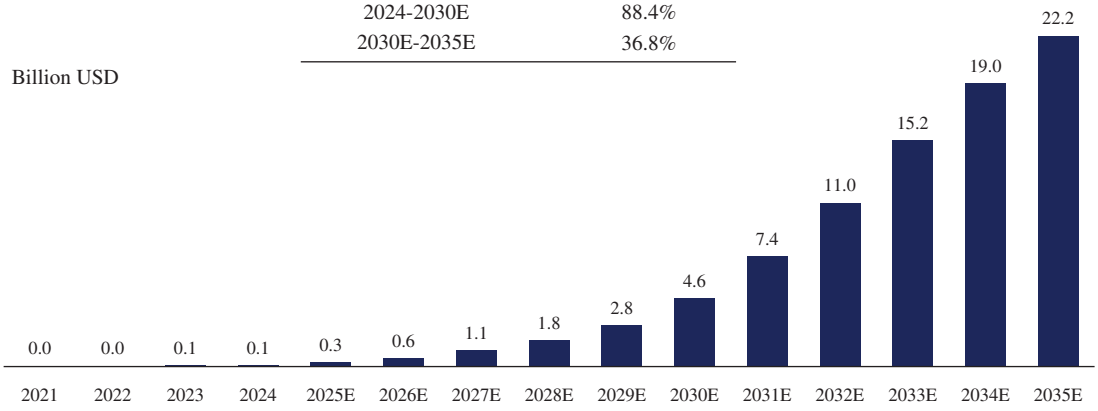


Source: Literature review, Annual report, Expert interview, Frost & Sullivan analysis

The TCE drugs market in China reached US$0.1 billion in 2024, with a CAGR of 104.0% from 2021 to 2024.

China TCE Drugs Market Size and Forecast, 2021-2035E

Period	CAGR
2021-2024	104.0%
2024-2030E	88.4%
2030E-2035E	36.8%



Source: Literature review, Annual report, Expert interview, Frost & Sullivan analysis

The TCE pipelines globally and in China have been rapidly expanding. As of now, there are 183 TCE candidates under development globally and 99 in China. Products targeting BCMA, CD20, DLL3, and other antigens have continued to receive clinical validation and are gradually progressing toward commercialization. TCE therapies have demonstrated high response rates in relapsed/refractory hematologic malignancies and are increasingly being explored in solid tumors. Over the next 5-10 years, more TCE products are expected to gain regulatory approval, thereby increasing market penetration and physician adoption. Meanwhile, a significant unmet clinical need remains in patients with relapsed/refractory tumors. In China, pharmaceutical and biotechnology companies have continued to actively pursue TCE-related business development activities, with 39 transactions recorded between 2020 and 2025. Chinese regulatory authorities are also supporting the development of innovative oncology drugs through policies such as priority review. As more domestically developed TCE products are commercialized and gradually incorporated into the national reimbursement system, patient accessibility and treatment rates are expected to improve further, driving corresponding market growth.

Currently, there are no approved EGFR-targeting TCE products in the global market. Based on the current development progress of global EGFR-targeting TCE pipelines and indication coverage, it is estimated that the first EGFR-targeting TCE product may be launched globally in 2030. Thereafter, with additional products gradually entering commercialization and the clinical value of EGFR-targeting TCE therapies in solid tumors being further validated, market penetration and treatment acceptance are expected to continue increasing. Considering the above factors, the global and China EGFR-targeting TCE market is preliminarily projected to reach US$3.2 billion and US$1.5 billion by 2035, respectively.

Growth Driver in the TCE Drugs Market

Large-capacity antibody libraries. Large-capacity antibody libraries remain a key growth driver for the TCE market. Such libraries enable quick screening and identification of TCEs directed to multiple TAAs, immune checkpoints, and disease-specific epitopes, establishing a solid foundation for antibody discovery.

Integration of multifunctional modules. The integration of multifunctional modules such as masking peptides and checkpoint blocking domains, is accelerating the evolution of TCEs. These modules enhance precision immune activation at the tumor site, reduce systemic toxicity, and enable synergistic anti-tumor effects. Incorporating these advanced functionalities positions TCEs to become more effective and versatile immunotherapies.

AI-driven discovery and optimization. AI is becoming increasingly central to TCE discovery and optimization. Machine learning models help identify optimal epitope combinations, predict off-target interactions, and simulate immune synapse formation, accelerating preclinical candidate screening. AI integration reduces early-stage development risks, improves design precision, and enhances the probability of TCE success, making it a critical future growth driver.

Clinical protocol innovation. Optimized preconditioning regimens and strategies, adaptive dosing, and combination therapies maximize therapeutic potential while managing adverse effects such as CRS. Biomarker-guided and adaptive trial designs accelerate development timelines, improve patient stratification, and expand the clinical applicability of TCEs.

ANALYSIS OF ANTIBODY TARGETS AND RELATED THERAPEUTIC INDICATIONS

LAG-3-Targeting Antibody Drugs

Overview of LAG-3

Lymphocyte Activation Gene 3 ("**LAG-3**") functions as an inhibitory immune checkpoint that regulates T cell activity. LAG-3 may be the drug target for the treatment of a wide spectrum of therapeutic indications, ranging from various solid tumors such as melanoma, lung cancer, and colorectal cancer, to hematological malignancies including leukemias and lymphomas, as well as autoimmune disorders. The involvement of LAG-3 in such diverse disease areas suggests its potential as not only a complementary or synergistic immune checkpoint in cancer immunotherapy, but also a critical modulator in the management of immune-related diseases.

Commercialized LAG-3-Targeting Antibody Drug

As of the Latest Practicable Date, there was one approved LAG-3-targeting antibody combination therapy (Opdualag®). It is mainly used for first-line treatment of unresectable or metastatic melanoma. However, in the adjuvant setting, achieving effective responses has been more challenging due to limited T-cell infiltration in the TME, highlighting the importance of additional immune mechanisms.

Commercialized Antibody Drug Targeting LAG-3

Drug Name	Company	Target	Indication	Region	Approved Date
Opdualag (nivolumab and relatlimab)	BMS	PD-1, LAG-3	Unresectable or metastatic melanoma with tumor cell PD-L1 expression < 1%	US, EU	2022-03 (FDA) 2022-09 (EMA)

Note: As of the Latest Practicable Date.

Source: Clinicaltrials.gov, CDE, NMPA, NCCN, Cutaneous melanoma: ESMO Clinical Practice Guideline for Diagnosis, treatment and follow-up, Frost & Sullivan Analysis

According to both the National Comprehensive Cancer Network ("**NCCN**") Guidelines (v2.2025) and the 2025 European Society for Medical Oncology ("**ESMO**") Clinical Practice Guidelines, relatlimab (a LAG-3 monospecific antibody) is used in combination with nivolumab (a PD-1 inhibitor) as a fixed-dose regimen for the treatment of advanced melanoma. This combination therapy is marketed as Opdualag®. The retail price for the 20 mL vial Opdualag® in the U.S. is approximately US$15,000. Its retail price in certain European regions (e.g., Nordic countries) is approximately US$10,000 per 20 mL vial.

Global Competitive Landscape of LAG-3-Targeting Antibody Drugs

As illustrated in the below table, globally ten antibody drug candidates targeting LAG-3 are under Phase II clinical stage and above.

Pipeline of Antibody Drugs Targeting LAG-3: Phase II and above

Category	Drug Name	Company	Target	Indication	Region	Stage	First Posted Date
Monospecific antibody	Fianlimab	Regeneron Pharmaceuticals	LAG-3	Untreated unresectable advanced/metastatic melanoma	US, EU, other regions	Phase III	2022-03
	Relatlimab/ Nivolumab	BMS	LAG-3	Melanoma	CN	Phase III	2022-04
	DNV3	**The Company**	**LAG-3**	**Locally advanced unresectable/metastatic melanoma**	**CN**	**Phase II**	**2024-10**
	Ieramilimab	Immutep, Novartis	LAG-3	Advanced solid and hematologic malignancies	US	Phase II	2017-12
	Miptenalimab	Boehringer Ingelheim	LAG-3	Advanced or metastatic solid tumors	US, EU, other regions	Phase II	2018-09
	Tuparstobart	Agenus	LAG-3	Merkel cell carcinoma, HNSCC, endometrial cancer	CN, US, EU, other regions	Phase II	2020-07
	LBL-007	Leads Biolabs	LAG-3	NSCLC, esophageal squamous cell carcinoma	CN, US, EU, other regions	Phase II	2022-10
	HLX26	Fosun	LAG-3	Previously untreated advanced NSCLC	CN	Phase II	2023-03
	IBI110	Innovent	LAG-3	Alveolar soft part sarcoma	CN	Phase II	2025-02
Bispecific antibody	IBI323	Innovent	LAG-3, PD-1	NSCLC	CN	Phase II	2022-03
Combined mono antibody	MK-4280A	MSD	LAG-3, PD-1	Previously treated metastatic PD-L1 positive CRC	CN, US, EU, JP, other regions	Phase III	2021-07

Notes:

1. As of 2026.5.11;
2. NSCLC: Non-small-cell Lung Cancer, HNSCC: Head and Neck Squamous Cell Carcinoma; CRC: Colorectal Cancer

Source: Clinicaltrials.gov, CDE, NMPA, Frost & Sullivan Analysis

The world's first LAG-3 antibody began generating sales in 2023, and the global LAG-3-targeting antibody drug market reached US$0.6 billion in 2023. The global market grew to US$0.9 billion in 2024 and is expected to reach US$5.7 billion in 2030 with a CAGR of 35.4% from 2024 to 2030. By 2035, the global market is expected to reach US$11.5 billion with a CAGR of 15.0% from 2030 to 2035. While no LAG-3 antibodies are currently approved in China, the market in China is forecasted to reach RMB0.8 billion in 2027 and RMB3.1 billion in 2030 with a CAGR of 59.0% from 2024 to 2030. By 2035, the market in China is expected to reach RMB6.9 billion with a CAGR of 17.4% from 2030 to 2035.

The LAG-3 pathway, an important immune checkpoint mechanism following PD-1/PD-L1, has been gradually validated in clinical settings. With the commercialization of related products, physician awareness and clinical acceptance are expected to continue increasing, while the incidence of melanoma, the main indication, is also rising steadily. In addition, there are currently 31 LAG-3-targeting antibody product candidates under development globally and 22 in China. In the future, more combination therapies targeting melanoma and other solid tumors are expected to receive regulatory approval. Meanwhile, demand for next-generation immunotherapies among patients with PD-1 resistance or suboptimal response continues to grow. Chinese regulatory authorities continue to support the development and commercialization of innovative oncology drugs. It is expected that, with the increasing use of combination regimens and the expansion of reimbursement coverage, the treatment rate and market penetration of LAG-3 targeting therapies will further increase, thereby driving market growth.

As of the Latest Practicable Date, in terms of the highest clinical stage of pipelines, one monospecific antibody drug candidate targeting LAG-3 for melanoma was in Phase III, two (including DNV3) were in Phase II, and other candidates were in Phase I and/or II stages.

Commercialized Antibody Drug Targeting LAG-3 for Melanoma

Drug Name	Company	Target	Indication	Region	Approved Date
Opdualag (nivolumab and relatlimab)	BMS	PD-1, LAG-3	Unresectable or metastatic melanoma with tumor cell PD-L1 expression < 1%	US, EU	2022-03 (FDA) 2022-09 (EMA)

Pipeline of Antibody Drugs Targeting LAG-3 for Melanoma

Drug Name	Company	Target	Indication	Region	Stage	First Posted Date
Fianlimab	Regeneron Pharmaceuticals	LAG-3	Untreated unresectable advanced/metastatic melanoma	US, EU, other regions	Phase III	2022-03
Relatlimab/ Nivolumab	BMS	LAG-3	Melanoma	CN	Phase III	2022-04
DNV3	**The Company**	**LAG-3**	**Locally advanced unresectable/metastatic melanoma**	**CN**	**Phase II**	**2024-10**
Ieramilimab	Immutep, Novartis	LAG-3	Unresectable or metastatic melanoma	US, EU, other regions	Phase II	2018-04
Tuparstobart	Agenus	LAG-3	Unresectable/metastatic melanoma	US, Australia	Phase I/II	2020-05
LBL-007	Leads Biolabs	LAG-3	Melanoma	CN	Phase I/II	2022-08
GLS -012	Yuheng Biotechnology	LAG-3	Advanced melanoma	CN	Phase I/II	2022-08
MK-4280A	MSD	LAG-3, PD-1	Advanced melanoma	US, EU, JP, other regions	Phase I/II	2020-01
Encelimab	AnaptysBio	LAG-3	Advanced melanoma	US, EU, other regions	Phase I	2016-06
INCA32459	Merus, Incyte Corporation	LAG-3, PD -1	Unresectable or metastatic melanoma	US, EU	Phase I	2022-10
AN8025	Adlai Nortye	LAG-3, PD -L1, CD86	Unresectable or metastatic melanoma	CN, Australia	Phase I	2025-11

Note:

1. As of 2026.5.11

Source: Clinicaltrials.gov, CDE, NMPA, Frost & Sullivan Analysis

Potential Indications of LAG-3-Targeting Antibody Drugs

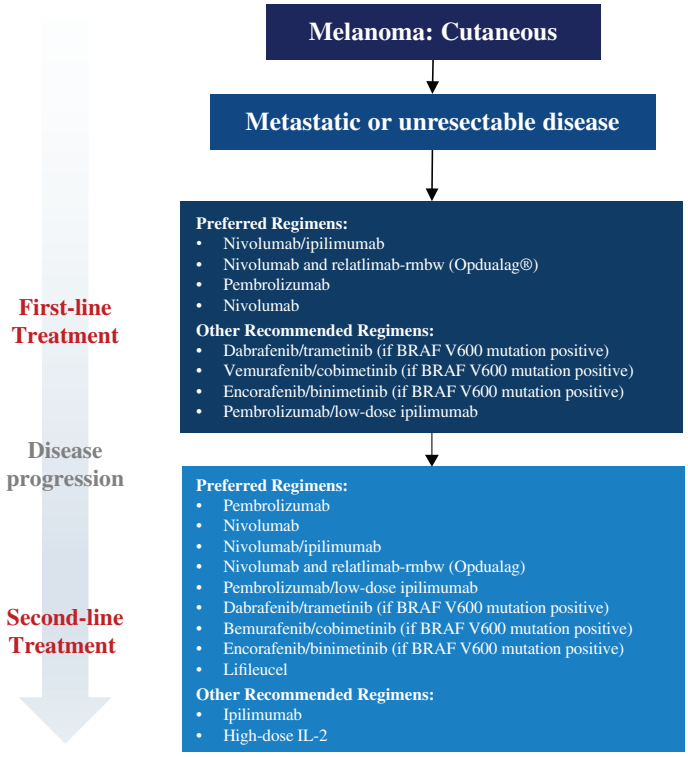
Melanoma

Overview of Melanoma

Melanoma is a type of skin cancer that develops from the melanin-producing cells known as melanocytes. It can be classified into different subtypes based on the tissue of origin. The main subtypes include: cutaneous melanoma, arising from nonhair-bearing skin; acral melanoma, a distinct form originating in the palms, soles, or nail beds; mucosal melanoma, arising from melanocytes in mucosal tissues; and uveal melanoma, originating from melanocytes in the eye's uveal tract. Globally, over 90% of melanomas are cutaneous, while acral and mucosal types are extremely rare. In China, acral melanoma accounts for nearly 50%, mucosal melanoma for approximately 20–30%, and cutaneous and other types for about 20–30%, showing a distribution pattern markedly different from that in Western countries. The pathogenesis of melanoma involves complex interactions between environmental and genetic factors. Ultraviolet radiation is one major environmental trigger of melanoma. Genetics also plays a role in the occurrence of melanoma. Generally, individuals with dysplastic nevus syndrome, also known as familial atypical multiple mole melanoma, are at an increased risk for the development of melanoma.

Treatment strategies for melanoma are guided by the stage and extent of the disease. For localized and locally advanced melanoma, surgery is the cornerstone of curative treatment, including wide excision of the primary tumor and appropriate management of regional lymph nodes. Radiotherapy is reserved for selected highrisk or non-resectable situations and may also be used for

palliative management of metastatic lesions. Regional therapies can be considered for limb-confined disease. Treatment decisions are stage-driven, multidisciplinary, and individualized, with genetic counseling and surveillance recommended for patients at high hereditary risk. For metastatic or unresectable melanoma, the treatment strategies are illustrated below.



Source: NCCN 2025 v2, Frost & Sullivan analysis

Incidence of Melanoma in China and Globally

Globally, the incidence of melanoma was 360.7 thousand in 2020, rising to 387.9 thousand in 2024, with a CAGR of 1.9%. The number is projected to increase to 420.8 thousand in 2030 and 441.6 thousand in 2035. In 2020, the incidence of melanoma in China was 23.9 thousand, rising to 27.3 thousand by 2024 with a CAGR of 3.4% the number is projected to increase to 32.6 thousand in 2030 and 37.0 thousand in 2035. Public health campaigns, wide adoption of sun protection measures, and monitoring of high-risk populations contribute to the slowering growth of melanoma incidence. Major developed markets such as Europe and the U.S. have already established relatively mature screening systems and diagnostic capabilities for melanoma, and the growth rate of newly diagnosed cases is expected to gradually decelerate. The rapid increase in diagnostic penetration driven by improved disease awareness and expanded screening in previous years is also expected to stabilize. As such, the growth of melanoma incidence due to improved diagnostic measures will not occur. In addition, slowing population growth in certain high-incidence regions is likely to limit the increase in new patients. Moreover, rising public awareness of sun protection and strengthened measures to reduce ultraviolet exposure are expected to partially mitigate future incidence growth. Furthermore, the incidence of melanoma in China remains relatively low compared with Western countries, and long-term patient growth is expected to remain relatively moderate.

In China, the number of metastatic or unresectable melanoma patients reached 4.7 thousand patients in 2020, and it increased to 5.2 thousand in 2024, representing 21.8% of all incidence of melanoma in China.

Global and China Melanoma Drug Market

The global melanoma drug market increased from US$14.1 billion in 2020 to US$18.5 billion in 2024, with a CAGR of 7.0%. The global melanoma drug market is projected to reach US$24.0 billion in 2030 and US$26.7 billion in 2035. The melanoma drug market in China increased from US$1.4 billion in 2020 to US$2.0 billion in 2024, with a CAGR of 9.3%. The melanoma drug market in China is projected to increase to US$3.1 billion in 2030 and US$3.6 billion in 2035.

Clinical Needs of Malignant Melanoma Treatment

Treatment resistance and limited progression-free survival. Many patients eventually develop resistance to ICIs or BRAF/MEK inhibitors, leading to disease progression and limited survival benefits. The underlying mechanisms of resistance remain incompletely understood, and effective strategies to overcome resistance are urgently needed.

Limited efficacy of later-line therapeutic options especially with liver metastatis. For melanoma patients with liver metastasis, there is currently no effective treatment option. Also, for patients who fail initial immunotherapy or targeted therapy, subsequent treatment options remain scarce and generally provide modest clinical benefits. Thus, advanced melanoma faces a scarcity of subsequent-line options, which are characterized by low objective response rates and limited survival benefits.

Severe immunotherapy toxicity. Despite significantly improving survival, ICIs still pose a significant clinical challenge due to their toxicity. For example, severe immune-related adverse events ("**irAEs**") occur in more than half of patients receiving ipilimumab plus nivolumab. And severe toxicity occurs (although at lower rates) with relatlimab plus nivolumab and single-agent anti-PD-1 therapy as well. Although the patient response to treatment was better for combination regimens, irAEs were also worse compared to monotherapy regimens.

Lack of biomarkers for guiding individualized treatment. In the decision-making for melanoma treatment, there is still a lack of prospectively validated biomarkers to guide individualized therapy. Existing markers — such as tumor mutational burden ("**TMB**"), lactate dehydrogenase ("**LDH**"), and the S100B protein — either have limited predictive value or have not gained regulatory approval. Consequently, the clinical choice between immunotherapy and targeted therapy primarily relies on physician experience and patient baseline characteristics, falling far short of the goal of precision medicine.

Nasopharyngeal Cancer ("NPC")

Overview of NPC

NPC is a type of head and neck cancer mostly common in epithelia cells lining the inner surface of the nasopharynx.

Incidence of NPC in China and Globally

Globally, the incidence of NPC was 115.9 thousand in 2020 and 125.3 thousand in 2024, with a CAGR of 2.0% from 2020 to 2024. The number is projected to increase to 140.1 thousand in 2030 and 151.9 thousand in 2035. In China, the incidence was 49.7 thousand in 2020 and 52.2 thousand in 2024, with a CAGR of 1.3% from 2020 to 2024. The number is projected to increase to 55.7 thousand in 2030 and 58.6 thousand in 2035.

Global and China NPC Drug Market

The global NPC drug market increased from US$0.3 billion in 2020 to US$0.5 billion in 2024, with a CAGR of 10.1% from 2020 to 2024, and the market is projected to increase to US$1.0 billion in 2030 and US$1.5 billion in 2035. The NPC drug market in China reached US$0.1 billion in 2020 and US$0.1 billion in 2024, with a CAGR of 12.6% from 2020 to 2024, and the market is projected to increase to US$0.3 billion in 2030 and US$0.5 billion in 2035.

Clinical Needs of NPC Treatment

Limited treatment options for advanced NPC. Despite recent advancements, treatment options for advanced NPC remain limited. A primary challenge is the lack of clearly defined driver mutations that can be targeted with precision medicine. NPC exhibits a complicated and heterogeneous genomic profile, complicating the identification of universal therapeutic targets. Additionally, the relatively low incidence of NPC in Western countries has resulted in fewer clinical trials and limited investment in the NPC area.

Low rate of early diagnosis. The early symptoms of NPC may be nonspecific to the disease, such as nasal congestion, a sore throat, or earache. These symptoms can be attributed to various common illnesses, making it challenging to attribute them to NPC without further investigation. Also, NPC is relatively rare compared to other tumors in head and neck regions. This rarity can contribute to a lack of awareness among healthcare professionals, further leading to delayed consideration of NPC in diagnosis and treatment.

Unmet supportive care needs in long-term survivors. The survivors of NPC face numerous life challenges resulting from treatments, including cognitive changes, fatigue, and emotional distress. Although targeted research is lacking, it is likely that NPC survivors will suffer from challenges similar to the general head and neck cancer population, including workplace rehabilitation, sexual dysfunction and fear of cancer recurrence.

EGFR×CD3-Targeting BsAb Drugs

Overview of EGFR×CD3-Targeting BsAbs

Epidermal growth factor receptor ("**EGFR**") is a receptor tyrosine kinase involved in regulating cell proliferation, differentiation, survival, and migration. Excessive upregulation of EGFR activates downstream pro-oncogenic signaling pathways and promotes cancer cell proliferation. EGFR is commonly upregulated in cancers such as in NSCLC, metastatic colorectal cancer, glioblastoma, head and neck cancer, pancreatic cancer, and breast cancer. CD3, expressed by T cells, is tightly connected to the T cell receptor ("**TCR**") to form the TCR-CD3 complex, which is involved in antigen recognition by T cells and T cell signaling.

EGFR×CD3 BsAb is a type of TCE. By simultaneously binding to EGFR on tumor cells and CD3 on T cells, EGFR×CD3 BsAb may bring T cells into close proximity with tumor cells and effectively recruit cytotoxic T cells to tumor sites, thereby enabling MHC-independent precise killing of tumor cells.

As of the Latest Practicable Date, 1 EGFR-targeting bispecific TCE was in the Phase II stage, 3 were in the Phase I/II stage and 2 were in the Phase I stage globally.

Pipeline of TCE Bispecific Antibody Drugs Targeting EGFR

Drug Name	Company	Target	Masking Technology	Indication	Region	Stage	First Posted Date
SMET12	**The Company**	**EGFR, CD3**	**/**	**EGFR-positive advanced/metastatic solid tumors**	**CN**	**Phase II**	**2025-09**
CMDE005	**The Company**	**EGFR, CD3**	**Yes**	**EGFR-positive advanced/metastatic solid tumors**	**CN**	**Phase I/II**	**2024-10**
VIB305	Vibrant Therapeutics	EGFR, CD3	Yes	EGFR-positive advanced solid tumors	CN, Australia	Phase I/II	2025-10
JY016	Dongfang Baitai Biotechnology	EGFR, CD3	/	EGFR-positive advanced solid tumors	CN	Phase I/II	2026-02
BC3448	BioCity Biopharma	EGFR, CD3	/	Locally advanced/metastatic malignant solid tumors	CN	Phase I	2021-12
SAR446368	Sanofi, Amunix Pharmaceuticals, VIR Biotech	EGFR, CD3	Yes	Locally advanced or metastatic solid tumors	US, Australia	Phase I	2025-05

Notes:

1. As of 2026.5.11;

2. Public information indicates that CMDE005, VIB305, and SAR446368 all utilize masking technology; however, only CMDE005 and SAR446368 have been publicly disclosed as using masking peptide technology. VIB305 is described as a logic-gated, masked TCE prodrug.

Source: Clinicaltrials.gov, CDE, NMPA, Frost & Sullivan Analysis

Potential Indications of EGFR×CD3-Targeting Antibodies

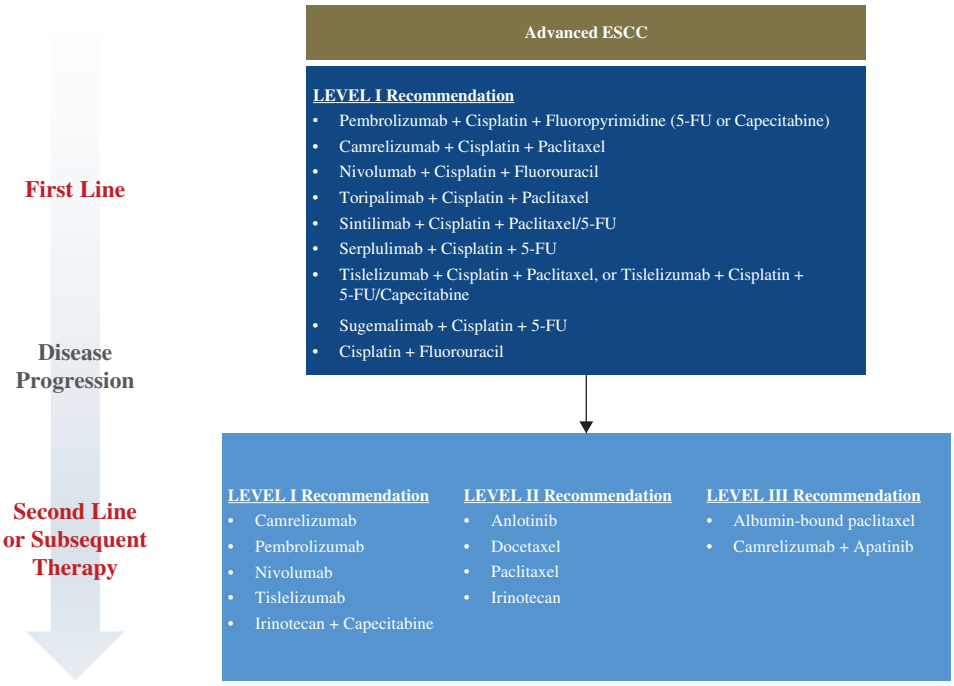
Esophagus Cancer

Overview of Esophagus Cancer

Esophagus cancer, which arises from the lining cells of esophagus, is one of the most common cancers around the world. Based on the tumor cell origin, esophagus cancer can be divided into two types, including esophageal squamous-cell carcinoma ("**ESCC**") that is more common in the developing world, and esophageal adenocarcinoma ("**EAC**") that is more common in developed countries. The most common symptom of esophagus cancer is the difficulty in swallowing. Other typical symptoms include chest pain, hoarseness, weight loss, chronic cough and vomiting. The major risk factor for esophageal cancer is the use of tobacco products. Other risk factors include age, gender and diet — men are generally more likely than women to get esophageal cancer, and frequent drinking of hot beverage may increase the risk of ESCC.

The treatment paradigms of advanced ESCC are illustrated below.

Treatment Paradigm of Advanced ESCC in China



Source: CSCO 2024, Frost & Sullivan Analysis

The potential role of EGFR in cancer therapeutics for ESCC stems from its overexpression in ESCC cancer cells. EGFR is frequently overexpressed in ESCC, with reported rates of overexpression ranging broadly (~30–90% depending on assay thresholds and cohorts).

Incidence of ESCC in China and Globally

Globally, the incidence of ESCC rose from 435.0 thousand in 2020 to 484.0 thousand in 2024. In China, the incidence of ESCC was 189.6 thousand in 2020, which rose to 211.9 thousand by 2024 with a CAGR of 2.9% from 2020 to 2024. The number is projected to increase to 234.5 thousand in 2030 and 253.6 thousand in 2035.

Global and China ESCC Drug Market

The global ESCC drug market increased from US$1.3 billion in 2020 to US$2.3 billion in 2024, with a CAGR of 16.4% and the market is projected to increase to US$7.0 billion in 2030 and US$13.7 billion in 2035. The China ESCC drug market increased from US$0.5 billion in 2020 to US$0.8 billion in 2024, with a CAGR of 14.4%, and the market is projected to increase to US$3.0 billion in 2030 and US$5.6 billion in 2035.

Competitive Landscape of EGFR Targeting Drugs

As of the Latest Practicable Date, there was no EGFR targeting drug approved for the treatment of ESCC, and there were 16 EGFR targeting drug candidates under clinical development of Phase I/II or beyond for the treatment of ESCC.

Pipeline of EGFR Targeting Drug Candidates for ESCC: Phase I/II and above

Drug Name	Company	Target	Type	Indication	Region	Stage	First Posted Date
Izalontamab brenitecan	Biokin Pharma, BMS, etc.	EGFR, HER3	Bispecific ADC	Recurrent or metastatic ESCC, failed prior therapy with PD-1/PD-L1 mAb and chemo	CN	NDA	2026-01
Nimotuzumab	Biotech Pharma	EGFR	Monospecific antibody	ESCC	CN	Phase III	2015-03
Larotinib	HEC Pharma	EGFR, HER2	Chemical	Unresectable locally advanced or metastatic ESCC	CN	Phase III	2020-05
CPO301	CSPC Pharma	EGFR	ADC	Locally advanced or metastatic/recurrent ESCC	CN	Phase III	2026-02
SMET12	**The Company**	**EGFR, CD3**	**Bispecific TCE**	**EGFR-positive advanced/metastatic solid tumors incl. ESCC**	**CN**	**Phase II**	**2025-09**
Cetuximab	BMS, Eli Lilly, etc.	EGFR	Monospecific antibody	ESCC	Israel	Phase II	2020-01
Izalontamab	Biokin Pharma	EGFR, HER3	Bispecific antibody	Recurrent metastatic ESCC	CN	Phase II	2021-08
Pimurutamab	Fosun	EGFR	Monospecific antibody	Advanced ESCC	CN	Phase II	2022-02
Necitumumab	BMS, Eli Lilly, etc.	EGFR	Monospecific antibody	Metastatic solid tumors incl. ESCC	Japan	Phase II	2022-10
JS212	Anwita, Junshi	EGFR, HER3	Bispecific ADC	Advanced ESCC	CN	Phase II	2026-03
SKB571	Kelun-Biotech, MSD	EGFR, c-Met	Bispecific ADC	ESCC	CN	Phase II	2026-04
CMDE005	**The Company**	**EGFR, CD3**	**Bispecific TCE**	**EGFR-positive advanced/metastatic solid tumors incl. ESCC**	**CN**	**Phase I/II**	**2024-10**
MCLA-129	Merus, Betta	EGFR, c-Met	Bispecific antibody	Advanced solid tumors incl. ESCC	US, EU, Korea, Singapore	Phase I/II	2021-05
ABL104	ABLBio, Yuhan Corporation	EGFR, 4-1BB	Bispecific antibody	Locally advanced or metastatic EGFR overexpressing solid tumors incl. ESCC	Korea	Phase I/II	2025-05
HMPL-A580	Hutchmed	EGFR, PI3K, PIKK	ADC	Advanced or metastic solid tumors incl. ESCC	CN, US	Phase I/II	2026-02
JY016	Dongfang Baitai Biotechnology	EGFR, CD3	Bispecific TCE	EGFR-positive advanced solid tumors incl. ESCC	CN	Phase I/II	2026-02

Note:

1. As of 2026.5.11

Source: Clinicaltrials.gov, CDE, NMPA, Frost & Sullivan Analysis

Clinical Needs of ESCC Treatment

Limited response and resistance to immunotherapy. The issue of resistance to immunotherapy is becoming increasingly prominent, and reliable predictive biomarkers for such resistance are lacking. Additionally, not all patients exhibit a favorable response to immune checkpoint blockade, highlighting the urgent need for reliable pre-treatment biomarkers that can predict a patient's response to treatment.

Limited efficacy of systemic therapies. The treatment of advanced ESCC presents numerous challenges. The substantial heterogeneity of the disease poses challenges in achieving comprehensive therapeutic coverage through a single treatment approach, because molecular subtyping of the disease remains insufficiently defined. Consequently, the response rate to targeted therapies is limited, the prognosis remains poor, and the overall five-year survival rate is low (about only 10% for advanced ESCC patients).

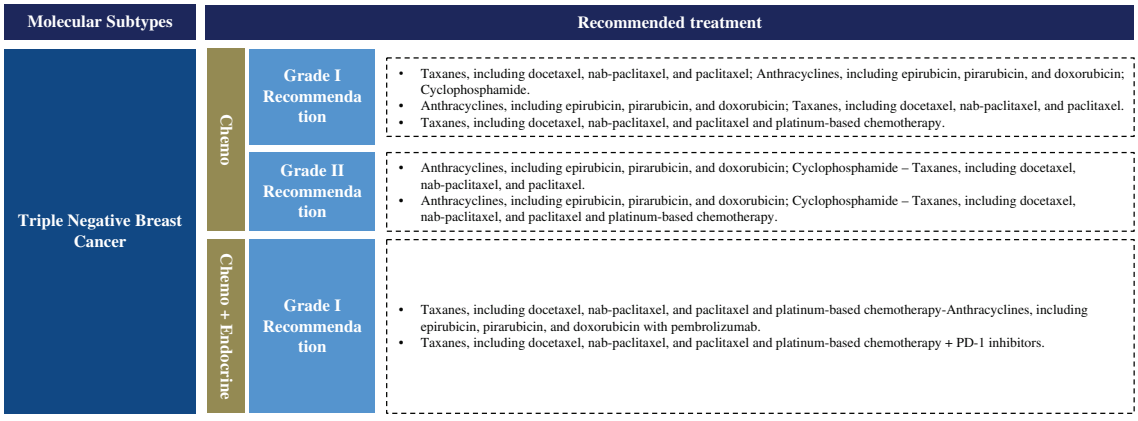
Triple-negative Breast Cancer ("TNBC")

Overview of TNBC

TNBC is a type of breast cancer defined by immunohistochemistry ("**IHC**") as being negative for estrogen receptor ("**ER**"), progesterone receptor ("**PR**"), and human epidermal growth factor receptor 2 ("**HER2**"). It accounts for approximately 15% of all breast cancer cases globally. TNBC is typically diagnosed more frequently in younger and premenopausal women.

The treatment paradigms of TNBC are illustrated below.

Treatment Paradigm of TNBC in China



Note: The treatments listed are arranged according to their level of evidence, with treatments supported by more rigorous and reliable research listed first.

Source: CSCO 2024, Frost & Sullivan Analysis

EGFR overexpression in breast cancer is associated with large tumor size, poor differentiation, and poor clinical outcomes. EGFR is more frequently overexpressed in TNBC compared to other breast cancer subtypes, with reported rates of overexpression ranging from ~70% to ~78% in basal-like tumors, and up to ~89% in all TNBC subtypes. Currently, there is no EGFR targeting agent approved for the treatment of ESCC.

Incidence of TNBC in China and Globally

Globally, the incidence of TNBC was 339.2 thousand in 2020 and 364.9 thousand in 2024, with a CAGR of 1.8% from 2020 to 2024. The number is projected to increase to 394.3 thousand in 2030 and 422.8 thousand in 2035. In China, the incidence was 50.9 thousand in 2020 and 55.9 thousand in 2024, with a CAGR of 2.4% from 2020 to 2024. The number is projected to increase to 59.6 thousand in 2030 and 61.2 thousand in 2035.

China TNBC Drug Market

The TNBC drug market in China reached RMB3.5 billion in 2020 and RMB3.8 billion in 2024, with a CAGR of 1.9% from 2020 to 2024, and the market is projected to increase to RMB5.0 billion in 2030 and RMB5.9 billion in 2035.

Competitive Landscape of EGFR Targeting Drugs

As of the Latest Practicable Date, there was no EGFR targeting drug approved for the treatment of TNBC, and there were 5 EGFR targeting drug candidates under clinical development of Phase II or beyond for the treatment of TNBC.

Pipeline of EGFR Targeting Drug Candidates for TNBC: Phase II and above

Drug Name	Company	Target	Type	Indication	Region	Stage	First Posted Date
Izalontamab brenitecan	Biokin Pharma, BMS, etc.	EGFR, HER3	Bispecific ADC	Unresectable locally advanced or metastatic TNBC	CN	Phase III	2024-04
CPO301	CSPC Pharma	EGFR	ADC	EGFR-Positive recurrent or metastatic breast cancer incl. TNBC	CN	Phase III	2026-02
SMET12	**The Company**	**EGFR, CD3**	**Bispecific TCE**	**EGFR-positive advanced/metastatic solid tumors incl. TNBC**	**CN**	**Phase II**	**2025-09**
Pyrotinib	Hengrui	EGFR, HER2, HER4	Chemical	Metastatic TNBC	CN	Phase II	2020-05
Neratinib	Pfizer, etc.	EGFR, HER2, HER4	Chemical	TNBC	US	Phase II	2019-01

Note:

1. As of 2026.5.11

Source: Clinicaltrials.gov, CDE, NMPA, Frost & Sullivan Analysis

Clinical Needs of TNBC Treatment

Lack of durable immunotherapeutic strategies. Although ICIs have demonstrated clinical benefits in some TNBC patients, most responses are short-lived and fail to achieve durable disease control. There remains a lack of immunotherapeutic strategies capable of extending treatment benefit, such as rational combination regimens or novel immune-modulating approaches, highlighting the need for deeper mechanistic understanding and innovation in this area.

High heterogeneity and variable treatment responses. TNBC exhibits profound molecular and immunological heterogeneity, with subtypes such as basal-like, mesenchymal, and immunomodulatory showing varying drug responses, prognoses, and immune microenvironments. Reliable biomarkers to guide personalized therapy are still lacking, hindering progress in precision oncology.

Lack of effective targeted therapies. TNBC lacks the expression of ER, PR, and HER2, rendering endocrine and HER2-targeted therapies ineffective. Chemotherapy remains the mainstay of treatment, but responses are often limited and resistance frequently develops. There is an urgent need for effective targeted agents tailored to the molecular features of TNBC.

Non-small-cell Lung Cancer ("NSCLC")

Overview of NSCLC

NSCLC refers to any type of epithelial lung cancer other than SCLC. NSCLC accounts for about 85% of lung cancer cases. Factors that contribute to NSCLC including tobacco smoking, exposure to radon/asbestos, arsenic in drinking water and air pollution. Genetic factor may also be relevant under certain circumstances.

Incidence of NSCLC in China and Globally

Globally, the number of NSCLC cases rose from 1,991.7 thousand in 2020 to 2,216.9 thousand in 2024 with a CAGR of 2.7% from 2020 to 2024. The number is projected to increase to 2,569.3 thousand in 2030 and 2,890.4 thousand in 2035. In China, the incidence of NSCLC was 852.8 thousand in 2020, which rose to 946.7 thousand by 2024 with a CAGR of 2.7% from 2020 to 2024. The number is projected to increase to 1,059.4 thousand in 2030 and 1,161.0 thousand in 2035.

Global and China NSCLC Drug Market

The global NSCLC drug market increased from US$52.8 billion in 2020 to US$91.2 billion in 2024, with a CAGR of 12.7%. The global NSCLC drug market is projected to reach US$182.2 billion in 2030 and US$269.6 billion in 2035. The China NSCLC drug market increased from US$6.5 billion in 2020 to US$10.5 billion in 2024. The NSCLC drug market in China is projected to reach US$24.8 billion in 2030 and US$39.5 billion in 2035.

Clinical Needs of NSCLC Treatment

Limited response and resistance to treatment. ICIs have revolutionized NSCLC treatment, but a substantial proportion of patients either do not respond to the treatment or develop acquired resistance. Mechanisms such as tumor immune evasion, T-cell exhaustion, and intratumoral heterogeneity contribute to suboptimal outcomes. Additionally, resistance to third-generation EGFR-TKIs (e.g., osimertinib) remains a critical challenge, highlighting the need for predictive biomarkers, novel combination strategies, and advanced therapeutic modalities.

High recurrence and challenges in long-term disease control. Even after surgery or definitive chemoradiotherapy, recurrence rates in NSCLC patients remain substantial, particularly in Stage II-III. There is a lack of effective adjuvant or maintenance therapies that consistently improve long-term survival.

Insufficient management of brain metastases. A significant need in NSCLC is the lack of clear guidelines for optimally managing brain metastases in patients without targetable genetic alterations. While local therapies like stereotactic radiosurgery or whole-brain radiotherapy remain the standard upfront approach, they carry risks of neurocognitive decline and radiation necrosis. ICIs have shown promise in controlling brain metastases, but its role as a primary treatment remains uncertain due to variable intracranial response rates and a lack of prospective trials comparing it directly to local therapies.

Renal Cell Carcinoma ("RCC")

Overview of RCC

Kidney cancer occurs when healthy cells in one or both kidneys grow out of control and form a lump (which is tumor). General symptoms of kidney cancer involve shortened breath, excessive fatigue, persistent back pain, blood found in the urine, abdominal swelling and recurring fevers. Usually, kidney cancer does not exhibit any symptoms in its early stages, but will as the cancer progresses. RCC is the most common type of kidney cancer, accounting for almost 90% of adult cases. RCC can histologically be further categorized into two subtypes, including clear-cell renal carcinoma ("**ccRCC**") and non-clear-cell renal carcinoma ("**nccRCC**"). Compared to nccRCC, ccRCC has a worse prognosis and is more likely to be symptomatic, present at an advanced stage, and show a greater propensity to metastasize. The occurrence of nccRCC is relatively rare but similarly fatal compared to ccRCC an advanced or metastatic stage. Overall, the 5-year survival rate of kidney cancer patients is 74.7% in the U.S. and 69.8% in China. Survival rates often depend on the stage of the cancer when it is first diagnosed.

Incidence of RCC in China and Globally

Globally, the number of RCC cases rose from 388.2 thousand in 2020 to 417.2 thousand in 2024 with a CAGR of 1.8%. The global incidence is projected to increase to 450.0 thousand in 2030 and 487.7 thousand in 2035. In China, the incidence of RCC in China was 63.9 thousand in 2020, which rose to 68.7 thousand by 2024 with a CAGR of 1.8%. The incidence in China is projected to increase to 75.6 thousand in 2030 and 81.6 thousand in 2035.

China Kidney Cancer Drug Market Size

From 2020 to 2024, the kidney cancer drug market in China increased from RMB2.7 billion to RMB5.2 billion, representing a CAGR of 17.6%, and the market is projected to increase to RMB31.1 billion in 2035.

Clinical Needs of RCC Treatment

Challenges in achieving durable responses. Early-stage RCC is insidious at onset. Its main treatment is surgery, which carries a certain risk of recurrence. For advanced-stage RCC, its main treatments include targeted therapy and immunotherapy. However, advanced-stage RCC has a high mortality rate and poor prognosis. Even when patients initially respond to systemic therapies, sustaining long-term disease control remains a major challenge in RCC. Many patients experience disease progression within months, and existing therapies often provide only transient benefits.

Adverse reactions and toxicity of systemic therapy. Systemic therapies, which are standard therapies for RCC treatment, including immunotherapy alone or in combination, can cause a wide range of adverse effects, some of which may be severe and require prompt intervention. Optimizing safety management remains a critical need.

Limited novel biomarkers and therapeutic targets. RCC is often diagnosed at advanced stages due to its asymptomatic early course, limiting survival and prognosis. Current therapies include surgical resection, targeted therapies (e.g., TKIs, HIF inhibitors, mTOR inhibitors, anti-angiogenic agents), and immunotherapy (primarily ICIs targeting PD-1/PD-L1 or CTLA-4). For advanced or drug-resistant RCC, effective treatment options remain scarce, and novel biomarkers and targets are urgently needed to improve disease management.

Urothelial Carcinoma ("UC")

Overview of UC

Bladder cancer refers to any of several types of cancer arising from the tissues of the urinary bladder, in which cells grow abnormally and may spread to other parts of the body. UC is the most common type of bladder cancer, accounting for about 90% of bladder cancer cases. It starts in the urothelial cells that line the inside of the bladder. Various factors may contribute to the development of bladder cancer, including smoking, age, gender, race, exposure to chemicals, previous cancer treatment, chronic bladder conditions and family history. Despite progress in diagnostic and therapeutic approaches, 10-15% of UC patients have metastasis at initial diagnosis, and the recurrence rate is high. The five-year survival rate for patients with distant metastases is only 4.6%. To date, first-line systemic therapies for UC have limited efficacy. The second-line therapies lack standard regimens and have demonstrated poor efficacy.

Incidence of UC in China and Globally

Globally, the number of UC cases rose from 516.0 thousand in 2020 to 572.9 thousand in 2024 with a CAGR of 2.7% from 2020 to 2024. The global incidence of UC cases is projected to increase to 667.3 thousand in 2030 and 752.2 thousand in 2035. In China, the incidence of UC was 78.5 thousand in 2020, which rose to 89.0 thousand by 2024 with a CAGR of 3.2% from 2020 to 2024. The incidence of UC cases in China is projected to increase to 103.7 thousand in 2030 and 115.9 thousand in 2035.

China UC Drug Market

The size of China's UC drug market was RMB1.3 billion in 2020 and reached RMB2.9 billion in 2024, with a CAGR of 21.8% from 2020 to 2024. The size of UC drug market in China is projected to reach RMB9.0 billion in 2030 and RMB18.6 billion in 2035.

Clinical Needs of UC Treatment

BCG immunotherapy resistance and treatment failure. Bacillus Calmette-Guerin ("**BCG**") remains an important therapy for NMIBC, but its application is challenged by both limited efficacy — due to primary resistance in 20-40% of patients and acquired resistance leading to recurrence — and global shortages of the BCG immunotherapy that restrict accessibility. Also, the treatment options following BCG failure are scarce, highlighting a significant unmet clinical need.

Frequent tumor recurrence following NMIBC therapy. Non-muscle-invasive bladder cancer ("**NMIBC**") has exhibited a high recurrence rate (50-70% within 5 years) across all treatment modalities, including transurethral resection, intravesical BCG, and chemotherapy. Despite adjuvant therapies, frequent cystoscopic surveillance (typically every 3-6 months) is required for monitoring potential recurrence, imposing substantial economic burdens and patient discomfort. The invasive nature of repeated cystoscopies, combined with associated anxiety and procedural risks, underscores the urgent need for less invasive, cost-effective monitoring strategies and more durable treatment options to improve long-term outcomes.

Treatment-limiting toxicities inherent to systemic chemotherapy administration. Cisplatin-based systemic chemotherapy remains an important treatment for advanced bladder cancer. However, its clinical utility is significantly limited by dose-limiting toxicities, particularly nephrotoxicity and myelosuppression, which preclude its use in patients with renal impairment. Alternative non-cisplatin regimens have demonstrated substantially inferior efficacy, creating a critical therapeutic gap.

Colorectal Cancer ("CRC")

Overview of CRC

CRC is the development of cancer from the colon or rectum. It is the consequence of uncontrolled growth of colon cells that can invade/spread to other parts of the body. Signs and symptoms may include blood in the stool, a change in bowel movements, weight loss, abdominal pain and fatigue.

Incidence of CRC in China and Globally

Globally, the number of cases rose from 1,880.7 thousand in 2020 to 2,048.8 thousand in 2024 with a CAGR of 2.2% from 2020 to 2024. The global incidence of CRC is projected to increase to 2,310.6 thousand in 2030 and 2,581.9 thousand in 2035. In China, the incidence of CRC in 2020 was 489.8 thousand, rising to 542.4 thousand by 2024 with a CAGR of 2.6% from 2020 to 2024. The incidence of CRC in China is projected to reach 608.4 thousand in 2030 and 664.6 thousand in 2035.

China CRC Drug Market

In China, the size of CRC drug market is estimated to increase from RMB15.2 billion in 2020 to RMB24.2 billion in 2024 with a CAGR of 12.3% from 2020 to 2024. The CRC drug market in China is projected to reach RMB55.5 billion in 2030 and RMB83.4 billion in 2035.

Clinical Needs of CRC Treatment

TME-driven resistance and variable treatment response. TME contributes significantly to therapeutic resistance, particularly in certain tumor subtypes with poor immune infiltration. Immunosuppressive cells and stromal interactions reduce the efficacy of immuno- and targeted therapies. Heterogeneity in the TME composition further drives variable responses, highlighting the need for strategies that modulate or overcome the TME-mediated resistance.

Challenges in long-term control of recurrent or refractory disease. Recurrent or refractory metastatic CRC poses a major clinical challenge due to rapid resistance development and limited durability of existing therapies. While rechallenge and combination strategies are under exploration, sustained responses are rare. In advanced stages, treatment remains mainly palliative, underscoring the need for approaches that prevent relapse and improve long-term outcomes.

Limited systemic management for advanced metastatic disease. Systemic options for chemorefractory metastatic CRC remain largely palliative. Existing treatments such as regorafenib offer only modest survival benefits with considerable toxicity, restricting the patient's quality of life. Effective targeted therapies are confined to small genomic subgroups, leaving most patients without meaningful alternatives. Novel agents capable of extending survival with acceptable tolerability are urgently needed.

GPC3×CD3-Targeting BsAb Drugs

Overview of GPC3×CD3 BsAbs

GPC3×CD3 BsAbs are engineered molecules designed with two distinct antigen-binding arms that simultaneously recognize glypican-3 ("**GPC3**") on tumor cells and CD3 on T cells. By bridging these two targets, GPC3×CD3 BsAbs recruit and activate T cells in close proximity to GPC3-expressing cancer cells, thereby triggering targeted cytotoxicity and tumor cell destruction through immune-mediated mechanisms. GPC3 is crucial for embryonic development but is minimally expressed in most adult tissues. GPC3 is highly upregulated in various tumors, where it promotes tumor growth and survival, with high expression in approximately 70-80% of hepatocellular carcinomas ("**HCC**") and also in ovarian cancer. CD3 is expressed on T cells and mediates signal transduction for T cell activation.

Currently, no GPC3×CD3 BsAbs has received marketing approval. GPC3×CD3 BsAbs in clinical development, such as ERY974, are primarily intended for the treatment of GPC3-positive solid tumors, with a major focus on hepatocellular carcinoma and ovarian cancer. Some studies have also explored their potential use in lung, gastric and pancreatic cancers.

Global Competitive Landscape of GPC3-targeting TCE Drugs

As of the Latest Practicable Date, three GPC3-targeting TCEs were in Phase I/II stage and three were in Phase I stage globally.

Pipeline of TCEs Targeting GPC3

Drug Name	Company	Target	Indication	Region	Stage	First Posted Date
CMD011	**The Company**	**GPC3, CD3**	**Advanced HCC**	**CN**	**Phase I/II**	**2023-12**
CM350	Kang Nuoya	GPC3, CD3	Advanced solid tumors	CN	Phase I/II	2022-02
AZD9793	Astra Zeneca	GPC3, TCR, CD8	Advanced/metastatic solid tumors	CN, US, JP, other regions	Phase I/II	2025-01
ERY 974	Perseus Proteomics	GPC3, CD3	Advanced solid tumors, HCC	US, EU, JP, Taiwan	Phase I	2016-04
QLS31903	Qilu	GPC3, CD3	Advanced solid tumors	CN	Phase I	2022-12
MTS105	Metis TechBio	GPC3, CD3	Advanced HCC	CN	Phase I	2024-11

Notes:

1. As of 2026.5.11;
2. HCC: Hepatocellular Carcinoma

Source: Clinicaltrials.gov, CDE, NMPA, Frost & Sullivan Analysis

Global GPC3-targeting antibody drug market is expected to reach US$0.6 billion in 2030 and US$4.6 billion in 2035. The GPC3-targeting antibody drug market in China is expected to reach RMB1.4 billion in 2030 and RMB6.1 billion in 2035.

Potential Indications of GPC3-Targeting Antibodies

HCC

Overview of HCC

Liver cancer is the fourth most frequent cancer and the second leading cause of death from cancer in China in 2022. HCC is the most common subtype of liver cancer. HCC occurs in the setting of chronic liver inflammation, and most HCC patients also have an ongoing or chronic liver disease, such as cirrhosis. HCC is most closely linked to chronic viral hepatitis infection (hepatitis B or C) or exposure to toxins such as alcohol or aflatoxin. The major risk factors contributing to HCC include chronic infection with hepatitis B, C, or D viruses, liver cirrhosis, excessive alcohol consumption, exposure to aflatoxins, and tobacco use.

Incidence of HCC in China and Globally

Globally, the number of HCC cases rose from 739.5 thousand in 2020 to 818.1 thousand in 2024 with a CAGR of 2.6% from 2020 to 2024. The global incidence of HCC is projected to increase to 948.3 thousand in 2030 and 1,067.7 thousand in 2030. In China, the incidence of HCC in China was 316.1 thousand in 2020 and rose to 344.5 thousand by 2024 with a CAGR of 2.2% from 2020 to 2024. The incidence of HCC in China is projected to increase 380.7 thousand in 2030 and 412.2 thousand in 2035.

Global and China HCC Drug Market

The global HCC drug market increased from US$2.3 billion in 2020 to US$4.5 billion in 2024, with a CAGR of 17.9%. The global HCC drug market is projected to reach US$11.5 billion in 2030 and US$18.3 billion in 2035. The China HCC drug market increased from US$1.0 billion in 2020 to US$2.1 billion in 2024, with a CAGR of 18.7%. The HCC drug market in China is projected to increase to US$4.2 billion in 2030 and US$6.1 billion in 2035.

Clinical Needs of HCC Treatment

High recurrence rate and limited adjuvant/maintenance options. Even after receiving potentially curative interventions (*e.g.*, resection or local ablation), the likelihood of HCC recurrence remains high, with a recurrence rate of approximately 70% within 5 years among HCC patients. Current options for adjuvant or maintenance therapy are limited, leaving a major gap in long-term disease control and recurrence prevention.

Limited efficacy of systemic therapies. Although main therapies for advanced HCC, including tyrosine kinase inhibitor ("**TKI**"), chemotherapy, and immunotherapy combinations, have improved treatment outcomes, many patients still do not achieve durable responses or experience disease progression. Compared to other cancers, HCC has the lowest five-year survival rate (about 10%), far lower than the average five-year survival rate of around 30% for all tumor patients. The objective response rate achieved by targeted therapies such as sorafenib is only 2%-3%.

Lack of personalized treatment strategies. HCC is a highly heterogeneous disease, both genetically and clinically. However, most treatments are applied broadly without precise patient stratification. This lack of personalized therapeutic approaches limits efficacy and can expose patients to unnecessary toxicity, underscoring the need for biomarkers and strategies that guide tailored treatment.

PD-L1×CD3×X-Targeting Trispecific Antibody Drugs

Overview of PD-L1×CD3×X Trispecific TCE

PD-L1×CD3×X trispecific TCE is designed to simultaneously bind to three different targets: PD-L1, CD3, and "X" which refers to a TAA. The trispecific antibody aims for a synergistic and more potent anti-cancer effect. PD-L1 is primarily expressed on the tumor cell surface, where it acts as a ligand for the inhibitory immune-checkpoint receptor PD-1 on the surface of T cells and inhibits T cell activity. Blocking the PD-1/PD-L1 interaction can promote T cell activation, reinvigorate exhausted T cells, and enhance T cell-mediated antitumor responses. CD3 is expressed on the surface of T cells and forms non-covalent complexes with TCR to form TCR/CD3 receptor complexes. Upon antigen recognition by TCR, CD3 transduces activation signals to trigger T cell activation and the release of cytotoxic molecules such as granzymes and perforins, thereby effectively facilitate killing of tumor cells.

Potential Advantage of Trispecific TCE

The PD-L1×CD3×X trispecific TCE may bring various advantages. The PD-L1×CD3×FOLR1 trispecific antibody is able to target the multifactorial nature of cancer by simultaneously blocking the immune checkpoint, stimulating T cell and inhibiting tumor growth. Similarly, the PD-L1×CD3×PSMA trispecific antibody can engage T cells while targeting PSMA-expressing tumor cells, offering a potential strategy for enhanced efficacy in prostate cancer.

Competitive Landscape of PD-L1×CD3×X-Targeting Antibody Drugs

As of the Latest Practicable Date, no PD-L1×CD3×X trispecific antibody drug candidate was approved and, specifically, no PD-L1×CD3×PSMA or PD-L1×CD3×FOLR1 TCE candidate was in the clinical stage.

REPORT COMMISSIONED BY FROST AND SULLIVAN

In connection with the [**REDACTED**], we have engaged Frost & Sullivan to conduct a detailed analysis and to prepare an industry report on the major markets for which our drug candidates are positioned. Frost & Sullivan is an independent global market research and consulting company founded in 1961 and is based in the United States. We have agreed to pay Frost & Sullivan a total fee of approximately RMB680,000 for the preparation of the Frost & Sullivan Report, and we believe that such fee is consistent with the market rate. The payment of such amount was not contingent upon our successful [**REDACTED**] or on the content of the Frost & Sullivan Report. Except for the Frost & Sullivan Report, we did not commission any other industry report in connection with the [**REDACTED**].

The market projections in the Frost & Sullivan Report were based on the following key 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. The reliability of the Frost & Sullivan Report may be affected by the accuracy of the foregoing key assumptions, including those used to make future projections, are factual, correct and not misleading.