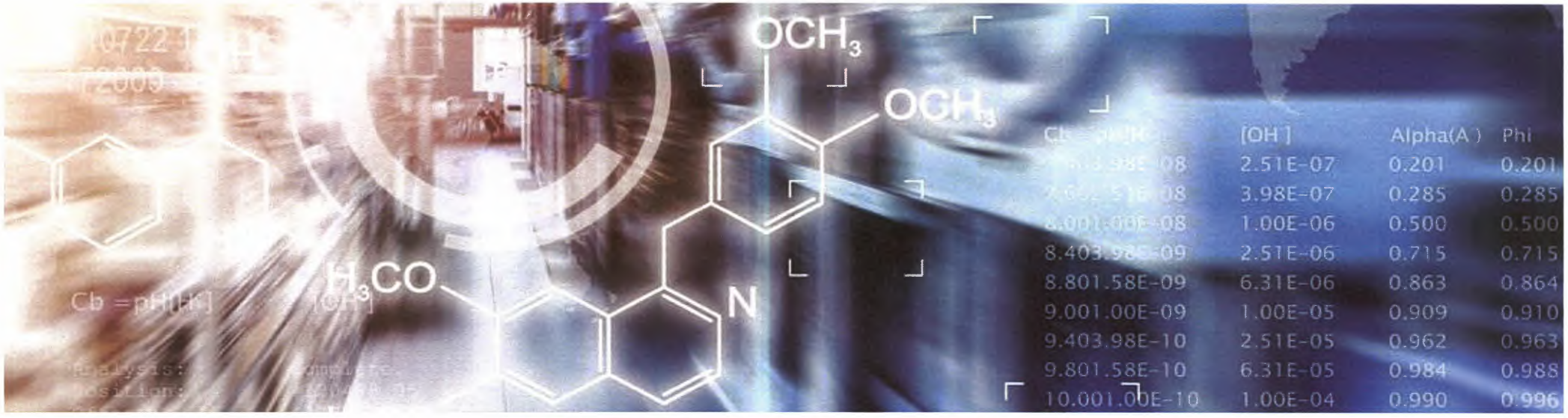

Industry report on Global and China's cancer drug market

China Insights Consultancy

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November 7, 2025

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Title: Founding Partner 创始合伙人

Terms and abbreviations (1/7)

Terms and abbreviations

Abb	Terms	Abb	Terms
ADC	antibody-drug conjugate	BCMA	B-cell maturation antigen
ADCA	Adenocarcinoma	BL	Burkitt Lymphoma
AE	Adverse Event	BPDCN	Blastic plasmacytoid dendritic cell neoplasm
AGA	actionable oncogenic alterations	BRAF	B-Raf Proto-Oncogene
AI	Aromatase inhibitors	BsAb	Bispecific Antibody
AITL	Angioimmunoblastic T-Cell Lymphom	BsADC	Bispecific antibody-drug conjugate
ALK	Anaplastic Lymphoma Kinase	BTKI	Bruton's Tyrosine Kinase Inhibitor
ALL	Acute Lymphoblastic Leukemia	B7H3	B7 homolog 3 protein
AML	Acute Myeloid Leukemia	B7H4	B7 homolog 4 protein
ANDA	Abbreviated New Drug Application	CAF	Cancer-associated fibroblast
APC	Antigen-Presenting Cell	CC	Cervical Cancer
API	Active Pharmaceutical Ingredient	CDE	Center for Drug Evaluation
AR	Androgen Receptor	CDH6	cadherin 6
ARG	Andarginase	CDK	Cyclin-Dependent Kinases
BC	Breast Cancer	CE	European Community

Terms and abbreviations (2/7)

Terms and abbreviations

Abb	Terms	Abb	Terms
CEL	Chronic Eosinophilic Leukemia	CRC	Colorectal Cancer
CGT	Cell and Gene Therapies	CRPC	castration-resistant prostate cancer
cGMP	Current Good Manufacturing Practice	CSCO	Chinese Society Of Clinical Oncology
CHMP	Committee for Medicinal Products for Human Use	CTA	Clinical Trial Application
CHOL	Cholangiocarcinoma	CTLA-4	Cytotoxic T-lymphocyte associated protein 4
CLDN18.2	Claudin-18.2	DAR	Drug-to-Antibody Ratio
CLL	Chronic Lymphocytic Leukemia	DC	Dendritic cell
CMC	Chemistry, Manufacturing and Control	DCR	Disease Control Rate
CML	Chronic Myeloid Leukemia	DLBCL	diffuse large b-cell lymphoma
CMML	Chronic Myelomonocytic Leukemia	DOR	Disease Duration of Response
CMS	Concerned Member State	EC	Esophageal Cancer
CNL	Chronic Neutrophilic Leukemia	ECM	Extracellular matrix
COLO	Colon Cancer	EGFR	Epidermal Growth Factor Receptor
COPD	Chronic Obstructive Pulmonary Disease	EMA	European Medicines Agency
CRBN	Cereblon	ET	Essential Thrombocythemia

Terms and abbreviations (3/7)

Terms and abbreviations

Abb	Terms	Abb	Terms
FDA	Food and Drug Administration	HCC	Hepatocellular Carcinoma
FGF	Fibroblast growth factor	HCL	Hairy Cell Leukemia
FISH	fluorescence in situ hybridization	HER2	Human Epidermal Growth Factor Receptor 2
FL	Follicular Lymphoma	HER3	Human Epidermal Growth Factor Receptor 3
FLT3	fms-like tyrosine kinase 3	HL	Hodgkin Lymphoma
FRα	Folate receptor α	HNC	Head and Neck Cancer
GBC	Gallbladder Cancer	HNSCC	Head and Neck Squamous Cell Carcinoma
GC	Gastric Cancer	HPV	Human Papillomavirus
GCP	Good Clinical Practice	ICI	Immune Checkpoint Inhibitor
GLP	Good Laboratory Practice	IC50	Half Maximal Inhibitory Concentration
GM-CSF	Granulocyte/monocyte colony-stimulating factor	IFN-γ	Interferon γ
GOJ	gastro oesophageal junction	IHC	Immunohistochemistry
GPRC5D	G protein-coupled receptor class C group 5 member D	IL	Interleukin
Gp100	Glycoprotein 100	IND	Investigational New Drug
GVHD	Graft-Versus-Host Disease	ISH	In Situ Hybridization

Terms and abbreviations (4/7)

Terms and abbreviations

Abb	Terms	Abb	Terms
ITD	Internal Tandem Duplication	MMP-2	Matrix Metalloproteinase 2
KRAS	Kristen Rat Sarcoma Viral Oncogene Homolog	MN	Myeloid Neoplasm
LAG-3	Lymphocyte-activation Gene 3	MPN	Myeloproliferative Neoplasms
LBL	Lymphoblastic Lymphoma	MsAb	Multispecific Antibody
LN	Lymphoid Neoplasm	MSI	Tumor Mutational Burden
LPL	Lymphoplasmacytic Lymphoma	MSLN	Mesothelin
mAb	Monoclonal Antibody	MZL	Marginal Zone Lymphoma
MCL	Mantle Cell Lymphoma	NCCN	National Comprehensive Cancer Network
MDS	Myelodysplastic Syndromes	NDA	New Drug Application
MDSC	Myeloid-derived Suppressor Cell	NDRC	National Development and Reform Commission
MET	Mesenchymal-epithelial Transition Factor	NECC	Neuroendocrine Carcinoma of Cervix
MGUS	Monoclonal Gammopathy of Undetermined Significance	Nectin-4	Nectin Cell Adhesion Molecule 4
MIIT	Ministry of Industry And Information Technology	NHL	Non-Hodgkin Lymphoma
MM	Multiple Myeloma	NK cell	Natural Killer Cell
MMA	Marketing Authorization Application	NLPHL	Nodular Lymphocyte-predominant Hodgkin Lymphoma

Terms and abbreviations (5/7)

Terms and abbreviations

Abb	Terms	Abb	Terms
NMPA	National Medical Products Administration	PD-L1	Programmed Death-ligand 1
NPC	Nasopharyngeal Carcinoma	PD-1	Programmed Cell Death Protein 1
NPC	National People's Congress	PFS	Progression-free Survival
NRDL	National Reimbursement Drug List	PGE2	Prostaglandin E2
NSCLC	Non-Small Cell Lung Cancer	PK	Pharmacokinetic
NTRK	Neurotrophic Tyrosine Receptor Kinase	PMDA	Pharmaceuticals and Medical Devices Agency
ORR	Objective Response Rate	PMF	Primary Myelofibrosis
OS	Overall Survival	PN	Parenteral Nutrition
PAAD	Pancreatic Adenocarcinoma	PSMA	Prostate-specific Membrane Antigen
PARP	Poly Adp-ribose Polymerase	PTK7	Protein Tyrosine Kinase 7
PCALCL	Primary Cutaneous Anaplastic Large Cell Lymphoma	PV	Polycythemia Vera
PCI	Prophylactic Cranial Irradiation	RAS	Rat Sarcoma
PCN	Plasma Cell Neoplasms	RCC	Renal Cell Carcinoma
PCNSL	Primary Central Nervous System Lymphoma	RDC	Radionuclide-drug Conjugate
PD	Pharmacodynamic	RET	Rearranged during Transfection

Terms and abbreviations (6/7)

Terms and abbreviations

Abb	Terms	Abb	Terms
RMS	Reference Member State	TCM	Traditional Chinese Medicine
ROS1	ROS proto-oncogene 1	T-DMI	Trastuzumab emtansine
RT	Radiation Therapy	T-Dxd	Trastuzumab deruxtecan
R/R	Relapsed/Refractory	TGF-β	Transforming growth factor-β
SABR	Stereotactic ablative radiotherapy	Th1	T helper type 1 cell
SAE	Serious Adverse Event	TIL	Tumor-infiltrating Lymphocyte
SALCL	Systemic Anaplastic Large Cell Lymphoma	TIME	Tumor immune microenvironment
SCC	Squamous Cell Carcinoma	TKI	Tyrosine Kinase Inhibitor
SCLC	Small Cell Lung Cancer	TLR	Toll-like receptor
SLL	Small Lymphocytic Lymphoma	TMB	Tumor Mutational Burden
SPC	Summary of Product Characteristics	TME	Tumor microenvironment
TAA	Tumor-associated Antigen	TNBC	triple-negative breast cancer
TACE	Transarterial Chemoembolization	TNF-α	Tumor Necrosis Factor-α
TAM	Tamoxifen	TRAE	Treatment-Related Adverse Events
TAM	Tumor-associated M2 macrophages	Treg	Regulatory T cell

Terms and abbreviations (7/7)

Terms and abbreviations

Abb	Terms	Abb	Terms
TROP2	Trophoblast cell surface antigen 2		
UC	Uterine Cancer		
VBP	Volume-Based Procurement		
VEGF	Vascular Endothelial Growth Factor		
VEGFR2	Vascular Endothelial Growth Factor Receptor 2		
WM	Waldenstrom's macroglobulinemia		
wt	Wild Type		

Source: China Insights Consultancy

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China continues to deepen reforms in pharmaceutical review and approval, gradually transitioning the drug market towards a landscape led by innovative drugs (1/2)

Overview of China's policy encouraging innovation in innovative drugs

Department	Policy Name	Key Contents	Issuance Time
National Health Commission	《深化医药卫生体制改革2023年下半年重点工作任务》	Promoting medical and pharmaceutical reform and innovation. Supporting drug R&D innovation, standardizing centralized procurement to ensure quality and availability of medications	2023-07
CDE	《药审中心加快创新药上市许可申请审评工作规范(试行)》	This accelerated review and approval process targets three categories of innovative drugs: breakthrough therapy drugs, innovative drugs for children, and innovative drugs for rare diseases, expediting their market entry to meet the medication needs of relevant patients	2023-04
The State Council	《"十四五"市场监管现代化规划》	Steadily enhance the safety, efficacy, and accessibility of drugs. Optimize management methods to accelerate the market entry of new and high-quality drugs. Improve rapid review and approval mechanisms for innovative drugs and vaccines, speeding up access to urgently needed drugs for clinical use and rare disease treatments. Strengthen guidance for the development of major innovative drugs. Encourage simultaneous domestic and international research and application for new drugs	2023-04
The State Council	《"十四五"国民健康规划》	Deepen the reform of the drug and medical device review and approval system. Accelerate the review and approval of qualifying innovative drugs, urgently needed drugs in short supply, medical devices, and treatments for rare diseases	2022-05
NMPA	《中华人民共和国药品管理法实施条例(修订草案征求意见稿)》	In the event of a patent dispute during a drug registration application, the parties may file a lawsuit in the people's court or apply for an administrative ruling from the State Council's patent administration department. During this period, the technical review of the drug will not be suspended	2022-05
CDE	《单臂临床试验用于支持抗肿瘤药上市申请的适用性技术指导原则》	The development strategy of single-arm clinical trials has significantly shortened the time to market for new drugs. In recent years, many new drugs have demonstrated highly promising efficacy data in the early stages of clinical research. As a result, an increasing number of development companies are opting to use single-arm clinical trials to support the marketing applications for anti-tumor drugs	2022-03
CDE	《药审中心加快创新药上市申请审评工作程序(试行)(征求意见稿)》	The main focus is to encourage the research and development of new drugs to meet clinical needs, promptly summarize and apply experiences from emergency reviews during the pandemic, and accelerate the review process for innovative drugs	2022-02

Source: CDE; NMPA; China Insights Consultancy

China continues to deepen reforms in pharmaceutical review and approval, gradually transitioning the drug market towards a landscape led by innovative drugs (2/2)

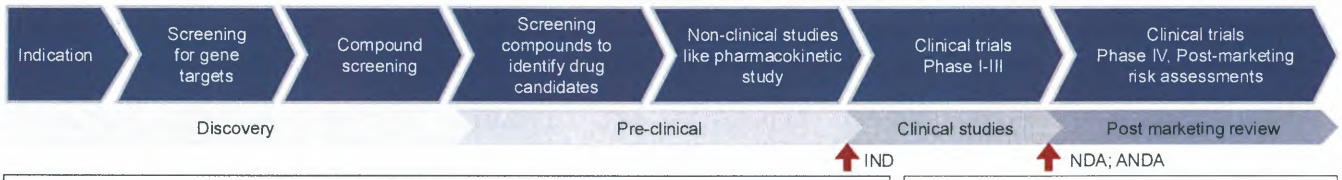
Overview of China's policy encouraging innovation in innovative drugs

Department	Policy Name	Key Contents	Issuance Time
MIIT and others	《"十四五"医药工业发展规划》	Promoting the industrialization and application of innovative drugs and high-end medical devices, and improving the support system for pharmaceutical innovation	2022-01
The State Council	《"十四五"市场监管现代化规划》	Improving the rapid review and approval mechanisms for innovative drugs, vaccines, and medical devices to accelerate the review and approval process for urgently needed drugs for clinical use, treatments for rare diseases, and medical devices	2022-01
NDRC	《"十四五"生物经济发展规划》	Developing synthetic biology technologies and promoting innovation in synthetic biology. Systematically advancing applications in areas such as new drug development, disease treatment, agricultural production material synthesis, environmental protection, energy supply, and new material development	2021-12
NMPA	《"十四五"国家药品安全及促进高质量发展规划》	The regulatory environment supporting high-quality industrial development is further optimized. The reform of the review and approval system continues to deepen, approving a batch of urgently needed innovative drugs for clinical use, accelerating the market entry of innovative drugs with clinical value to promote public health. The evaluation capability of innovative products has significantly improved, enabling globally innovative drugs and medical devices applied for in China to be quickly launched in the domestic market	2021-12
The State Council	《"十四五"全民医疗保障规划》	Improving the evaluation mechanism for drugs covered by medical insurance, strengthening the monitoring of the implementation of the medical insurance drug list and the evaluation of innovative drugs, supporting pharmaceutical innovation, and enhancing the accessibility of negotiated drugs	2021-09
NPC	《中华人民共和国国民经济和社会发展第十四个五年规划和2035年远景目标纲要》	Improving the rapid review and approval mechanisms for innovative drugs, vaccines, and medical devices, accelerating the review and approval of urgently needed drugs and medical devices for clinical use and rare disease treatments, and facilitating the prompt domestic launch of urgently needed new drugs and medical devices already approved abroad	2021-03
NDRC and others	《关于扩大战略性新兴产业投资培育壮大新增长点增长极的指导意见》	Implement a biotechnology benefit project to create a market for domestically innovated drugs and other products	2020-09
NMPA	《突破性治疗药物申评工作程序(试行)》	During clinical trials, applicants can apply for the breakthrough therapy designation for innovative or improved new drugs that treat life-threatening diseases or significantly improve quality of life, typically no later than the start of phase I trials	2020-07

Source: CDE; NMPA; China Insights Consultancy

The CDE of NMPA is responsible for evaluating drug clinical trial applications, drug marketing authorizations, supplementary applications, registration renewal applications of drugs manufactured overseas

Overview of NMPA and CDE new drug application process



Non-clinical research refers to various toxicity tests conducted in laboratory conditions using experimental systems to evaluate drug safety, including single-dose toxicity tests, repeated-dose toxicity tests, reproductive toxicity tests, mutagenicity tests, carcinogenicity tests, various irritancy tests, dependence tests and other toxicity tests related to drug safety evaluation.

Animal experiments are widely used in medical, biomedical and veterinary research, and are essential means of drug development and preclinical testing, including toxicology and safety studies. They help us advance our scientific understanding, serve as models to study disease, help us develop and test potential new medicines and therapies. Animal experiments eliminate some potential drugs as either ineffective or too dangerous to use on human beings.

Good clinical practice (GCP) is an international ethical and scientific quality standard for designing, recording and reporting trials that involve the participation of human subjects. The GCP guidelines detail the requirements for trial documentation, protocol amendments, requirements such as indemnity, reporting lines for adverse events and provision of medical care for trial participants. Compliance with this standard provides public assurance that the rights, safety and wellbeing of trial subjects are protected and that clinical-trial data are reliable.

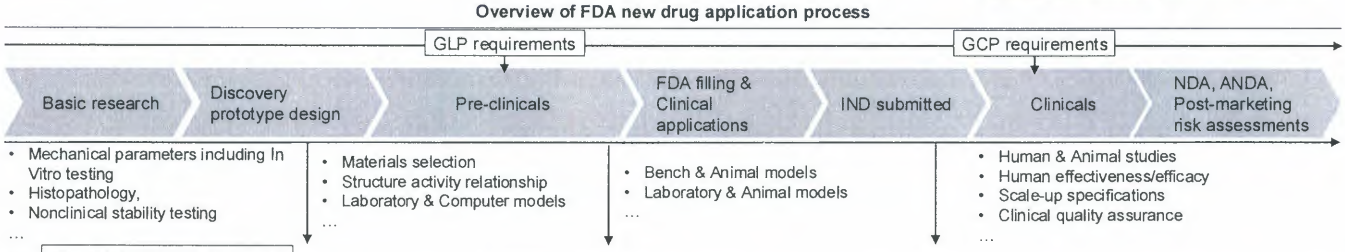
Clinical trials of biomedical interventions typically proceed through four phases:

- Phase I evaluates the tolerability and pharmacokinetics of a drug in human body.
- Phase II conducts a preliminary assessment of the efficacy and safety of a drug in a specific population with defined indication.
- Phase III evaluates overall efficacy and safety profile with an adequate sample size and robust control measures, to provide confirmatory evidence.
- Phase IV is the post-marketing research conducted after the approval, to investigate the efficacy and AEs under widespread use conditions.

Source: NMPA; China Insights Consultancy

The FDA new drug application process is a formal submission wherein drug sponsors propose that the FDA grants approval for a new pharmaceutical to be sold and marketed in the United States

Overview of FDA new drug application process



The FDA approval process

- The FDA's Center for Drug Evaluation and Research (CDER) in charge of overseeing the drug approval process before a drug is marketed. CDER review each drug closely using an independent team of clinicians and scientists who evaluate safety, efficacy and labeling of the drug product. After approval, FDA follow-up continues to make sure new drugs continue to be safe and effective.
- Generally, there are four phases of a drug approval process: 1.Pre-clinical, IND; 2.Clinical; 3.NDA Review; 4.Post-marketing risk assessments. The full research, development and approval process can last from 12 to 15 years. However, In order to incentivize the development of therapies to fill unmet needs for serious conditions, the FDA has developed various programs to expedite drug development and review. These four programs are: **fast track**, breakthrough therapy, accelerated approval, and priority review.
- In addition, supporting the development and evaluation of new treatments for rare diseases is also a key priority for the FDA The FDA has authority to grant **orphan drug designation** to a drug or biological product to prevent, diagnose or treat a rare disease or condition.

The FDA's Fast Track program is designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose is to get important new drugs to the patient earlier. The Fast Track program is intended to help patients with serious conditions receive new drugs more quickly.

The Orphan Drug Act (ODA) was passed in 1983 to encourage the development of drugs for rare diseases. The FDA's Orphan Drug Designation program provides orphan status to drugs and biologics that are intended for the safe and effective treatment, diagnosis or prevention of rare diseases or disorders that affect fewer than 200,000 people in the US. The program provides incentives for sponsors to develop products for rare diseases.

Source: FDA; China Insights Consultancy

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Updated 2024 base year

Top 10 cancer types globally, in China, and in the United States in 2024

Global and China oncology drug | Top 10 cancer

Top 10 cancer types globally, in China, and in the United States in 2024

1,000 cases

Ranking	1	2	3	4	5	6	7	8	9	10
Global	Lung 2,598	Breast 2,397	Colorectcal 2,013	Prostate 1,530	Thyroid 1,181	Gastric 864	Liver 827	Cervical 690	Bladder 640	NHL 588
China	Lung 1,145	Throid 571	Colorectal 556	Breast 375	Liver 361	Gastric/stomach 348	Esophageal 216	Cervical 162	Prostate 159	Pancreas 125
US	Breast 289	Prostate 245	Lung 242	Colorectal 170	Melanoma 108	Bladder 87	NHL 83	Kidney 76	Uterine 70	Leukemia 67

Source: GLOBOCAN; NCC; IARC; China Insights Consultancy

Updated 2024 base year

Epidemiology of the cancers

Cancer > Epidemiology

Epidemiology of the cancers

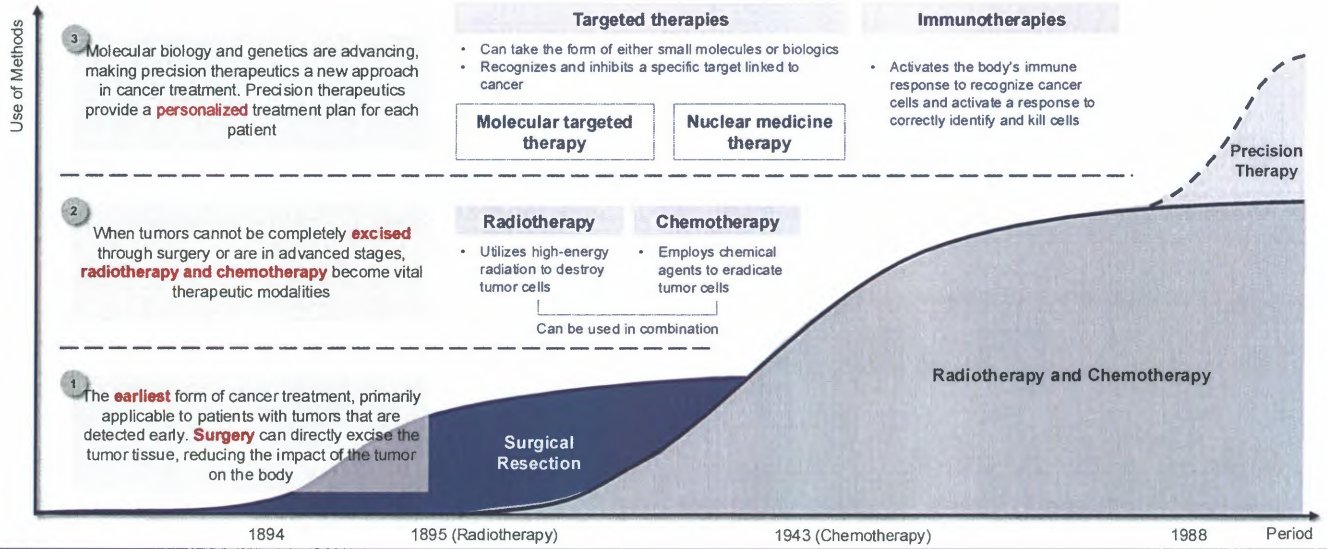
Cancer type	Global			The U.S.			China		
	2024	2028E	2033E	2024	2028E	2033E	2024	2028E	2033E
Solid tumor	Incidence (thousand people)								
CRC	2,056	2,224	2,511	166	175	190	556	631	716
Prostate Cancer	1,529	1,713	1,941	240	256	270	159	212	282
GC	864	1,040	1,291	27	29	31	348	330	313
HNSCC	976	1,073	1,065	53	56	59	136	146	156
Liver Cancer	827	953	1127	45	48	51	361	351	341
CC	690	742	804	14	15	15	162	183	208
Urothelial Carcinoma	512	571	653	68	75	84	82	87	93
Esophageal Cancer	435	534	675	20	21	23	220	203	190
Endometrial Cancer	382	412	448	68	71	75	79	85	91
RCC	393	427	465	63	67	71	62	61	60
OC	339	365	398	22	23	25	62	65	67
SCLC	320	352	399	36	39	42	172	196	223
BTC	253	286	333	14	15	16	98	89	82
NPC	120	135	146	2	2	2	51	50	50
Blood cancer	Prevalence (thousand people)								
NHL	3,065	3,297	3,536	460	473	486	676	827	962
ALL	380	368	361	22	19	17	187	184	180
AML	207	213	219	27	28	29	25	26	26

Source: GLOBOCAN; NCC; IARC; GHDx; China Insights Consultancy

Cancer treatment has evolved from surgical treatment, radiation therapy, and chemotherapy to precision targeted therapy, including immunotherapy and radiopharmaceuticals

Global oncology drug market > Introduction

The Development of Cancer Treatment

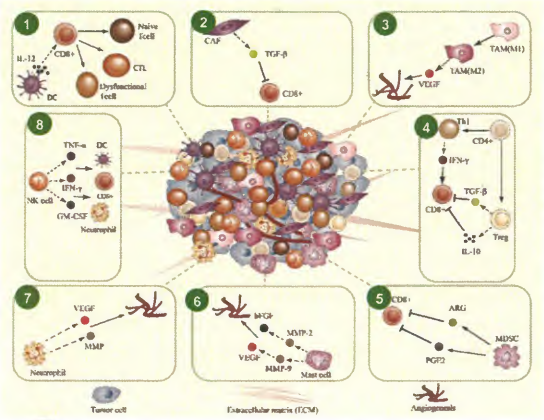


Source: CA-A CANCER JOURNAL FOR CLINICIANS; Nature Reviews Disease Primers; Cancer Discovery; CIC

Tumor microenvironment (TME) is composed of a heterogeneous milieu of tumor and immune cells, where malignant and non-transformed cells interact

Introduction of tumor microenvironment (TME)

- **The tumor microenvironment (TME)** is not simply a group of cancer cells, but rather a dynamic structure that is highly interactive with cancer cells and is shaped to a heterogeneous collection of infiltrating and resident host cells. TME comprises different cell types, including immune cells, cancer-associated fibroblasts, as well as extracellular matrix (ECM). **Tumor-associated M2 macrophages (TAM)** promote growth and induce immunosuppression. High infiltration of TAM within TME has been shown to be associated with poor prognosis in many tumor types
- The interactions among cellular and structural elements within the TME enables cancer cells to **acquire invasive traits** and disseminate from the primary site to distant locations, progressing through a intricate and multistep metastatic process



8 Natural killer (NK) cell can induce innate and adaptive immune responses through the secretion of pro-inflammatory cytokines, including IFN-γ, tumor necrosis factor-alpha (TNF-α), and granulocyte/monocyte colony-stimulating factor (GM-CSF)

1 T cell effector function and differentiation signals can be supported by the dendritic cell (DC) through the interleukin-12 (IL-12) secretion.

2 Cancer-associated fibroblast (CAF) plays an immunosuppressive function by inhibiting CD8+ T cell infiltration and function via secreting transforming growth factor-beta (TGF-β)

3 TAM contributes to angiogenesis through the secretion of vascular endothelial growth factor (VEGF)

4 CD4 + T cell can play immunoactivative or immunosuppressive roles through the differentiation into T helper type 1 cell (Th1) and regulatory T cell (Treg)

5 Myeloid-derived suppressor cell (MDSC) causes suppression of tumor-specific CD8 + T cell response by increasing the levels of prostaglandin E2 (PGE2) andarginase (ARG)

6 Mast cell can promote tumor progression through angiogenesis development by secreting certain proteases, such as matrix metalloproteinase 2 (MMP-2) and MMP-9, and also by releasing VEGF and fibroblast growth factor (bFGF) from the ECM

7 Similar to the mast cell, neutrophil is also capable of developing angiogenesis via secreting VEGF and MMPs

Source: Medical Research Review; China Insights Consultancy

Understanding of tumor immune microenvironment (TIME) is necessary for developing cancer immunotherapies

Impact of TIME in cancer therapy

- **Tumor immune microenvironment (TIME)** include tumor cells, immune cells, cytokines, etc., has been found its impact on immunotherapies, which has achieved good therapeutic effects in various cancers. The interactions between these components, which are divided into anti-tumor and pro-tumor, determine the trend of anti-tumor immunity Drugs targeting immune checkpoints, or their associated ligands have emerged as one of the most successful cancer immunotherapies approaches, especially the clinical impact of **PD-1/PD-L1** blockade and **anti-CTLA-4** monoclonal antibodies in cancer has been extensively studied over the past few decades
- The following table summarizes the key functions of some major immunotherapy targets in the TIME, with an emphasis on how therapeutically enabling the TIME to generate an anti-tumor immune response:

Target	Treatment effects on TIME
PD-1/PD-L1	Promote the expansion and migration of CD8+ T cells and inhibit their apoptosis; amplification of CD4 and T cell subsets; proliferation, survival and activation of macrophages; activation of NK cell response
CTLA-4	Promote the reduction of Treg cells, enhance the activity of effector T cells
LAG-3	Increase populations of APC, NK, and CD8 + T cells

Barriers and opportunity towards effective cancer therapy

➢ However, while current immunotherapies blocking PD-1 or CTLA-4 can activate anti-tumor T cells in many patients across multiple cancer types, **treatments frequently fail**, and some tumors become resistant after initial response. Only **10% to 30%** of all solid tumors are responsive to anti-PD-1/PD-L1 therapies

Barrier

- T cell in filtration blocking
- PD-L1 over-expression
- Recruitment of Tregs
- Hypoxia niche
- Acidic niche
- Inflammation
- Neovascularization
- Innervation
- ECM remodeling

Opportunity

- Drugs targeting hypoxia
- Anti-cancer drugs functional in acidic niche
- ECM targeted therapies
- Targeting innervation
- Targeting VEGF/VEGFR2 against neovascularization
- Enhancing T cells infiltration
- T cell activation- checkpoint inhibitors

Source: : The Lancet, 2020, 9(21): 419-430; Theranostics, 2021, 11(11); J Biomed Sci 29, 83 (2022)5368-5385; China China Insights Consultancy

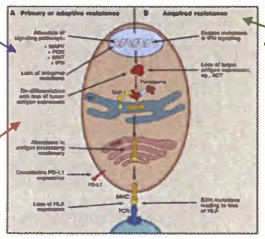
Limitations and unmet needs of immunotherapy and targeted therapy (1/3)

Drug resistance to immunotherapy and targeted therapy

- According to the American Cancer Society, **more than 90%** of cancer patients die from varying degrees of drug resistance. **Resistance to immunotherapy**, particularly in cancer treatment, is a complex challenge that researchers are actively investigating. At present, PD-1/PD-L1 combination therapy is the main medical direction to solve drug resistance and realize patient individualized treatment
- Despite high initial efficacy, **targeted therapies eventually fail in advanced cancers**, as tumors develop resistance and relapse. At present, EGFR-TKI has developed to the third generation, but the drug resistance is still inevitable

Introduction of different resistance mechanisms to immunotherapy

- **Primary resistance:** A cancer does not respond to an immunotherapy strategy. The mechanistic basis of lack of response to immunotherapy may include adaptive immune resistance
- **Adaptive immune resistance:** A mechanism of resistance where a cancer is recognized by the immune system but it protects itself by adapting to the immune attack



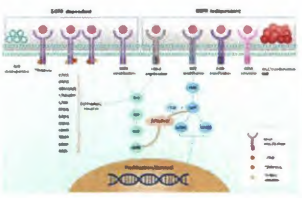
- **Acquired resistance:** A cancer initially responded to immunotherapy but after a period of time it relapsed and progressed

Drug resistance in PD-1/PD-L1[1]

- Based on the data collected by FDA, among the eight clinical trials, a total of 2624 patients with melanoma received anti-PD-1 antibody treatment, of which **1361 (52%)** patients had primary or secondary resistance with progressive disease

Introduction of drug resistance to EGFR TKIs targeted therapy

- Resistance can be acquired during targeted therapies via alterations of drug targets due to the **mutation** of the target proteins or alterations in expression levels due to epigenetic changes.
- Third generation EGFR TKIs drug resistance[2] can be classified to:
  - **EGFR-dependent (~40%)**
    - EGFR pathway related drug resistance mutations, including T790M, C797S, Ex20ins mutations, etc.
  - **EGFR-independent (~60%)**
    - Bypass signal activation: HER2 amplification, BRAF mutation, MET amplification/overexpression
    - Histological transformation: SCLC, SCC transformation



Note: [1]The Lancet. Oncology. 2018 Feb;19(2):229-239. DOI: 10.1016/s1470-2045(17)30846-x.
[2]Sec. Thoracic OncologyVolume 10 - 2020 | https://doi.org/10.3389/fonc.2020.602762

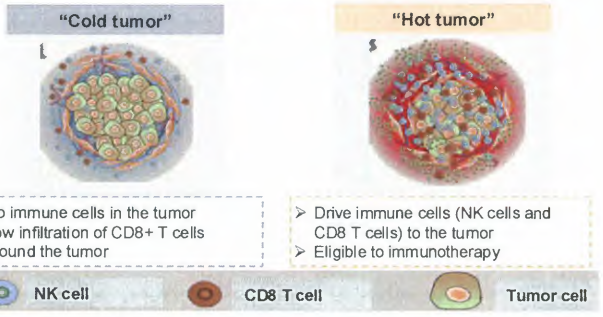
Source: Cell Press ; China Insights Consultancy

Limitations and unmet needs of immunotherapy and targeted therapy (2/3)

Low response rate of immunotherapy

- Despite several spectacular and successful immunotherapy trials of recent years, many cancer patients do not respond to immunotherapy, or their response remains short-lived, and the recurrence of the disease seems to be inevitable mainly due to the rapidly evolving resistance. The study shows that only **20-40%** of patients respond to immunotherapy
- The use of PD-1/PD-L1 monoclonal antibodies significantly enhance the anti-tumor effect of cells and promotes the infiltration of cytotoxic T lymphocytes into tumor tissues. However, immunotherapy targeting the PD-1/PD-L1 only effective in some patients, and most of the patients do not benefit, and some patients had to stop treatment because of immune-related adverse events (irAEs). The emergence of this phenomenon may be closely related to the tumor microenvironment (TME), such as "**cold tumors**" with low expression of PD-1/PD-L1 and severe immune suppression

Difference of "cold" and "hot" tumors



"Cold tumor"
- No immune cells in the tumor
- Low infiltration of CD8+ T cells around the tumor

"Hot tumor"
- Drive immune cells (NK cells and CD8 T cells) to the tumor
- Eligible to immunotherapy

Responsive efficacy of PD-1/PD-L1 in clinical trials

- According to a systematic review[1], with 16,400 patients from 91 clinical trials were included. PD-1/PD-L1 monotherapies has **much lower** ORR compared to combination of PD-1/PD-L1 monotherapy + chemotherapy. However, the DOR of PD-1/PD-L1 inhibitors is longer than the group of PD-1/PD-L1 inhibitors + chemotherapy
- On the other hand, combing PD-1/PD-L1 inhibitors with chemotherapy or targeted therapy will add complexity to treatment and may **increase the risk of toxicity**

Number of studies	Intervention	ORR	DOR (months)
93	Anti-PD-1/PD-L1 mono	17.75%	12.39
7	PD-L1/PD-1 inhibitors + chemo	46.81%	8.09 m
8	PD-L1/PD-1 inhibitors + Immunotherapies	12.25%	N/A

Note: [1] Front Oncol. 2021;11:562315. Published 2021 Apr 16. doi:10.3389/fonc.2021.562315

Source: MedComm (2020); China Insights Consultancy

Limitations and unmet needs of immunotherapy and targeted therapy (3/3)

Global and China oncology drug | Challenge

Tumor heterogeneity poses a barrier in drug development

Definition

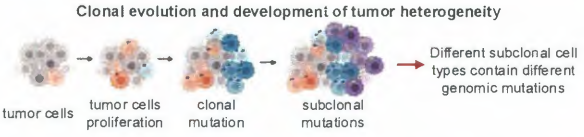
- Tumor heterogeneity refers to the presence of **diverse cell populations** within a tumor, which can vary in terms of their genetic makeup, gene expression profiles, morphology, and behavior. It is well established that tumor heterogeneity is largely driven by **aberrant changes in the TME**, such as high mutational burden, hypoxic conditions and abnormal vasculature, which can lead to **difference in drug sensitivity and prognosis**, a major challenge in drug development and clinical diagnosis
- Tumor heterogeneity is prevalent in most cancer patients and is the major driver **of acquired resistance to all forms of cancer therapy**. Tumor heterogeneity can be classified to intra-tumor and inter-tumor heterogeneity

Intra-tumor heterogeneity

◆ Intra-tumor heterogeneity refers to the presence of more than one clone of cancer cells **within a given tumor mass**

◆ Intra-tumor heterogeneity can be further divided into **spatial** heterogeneity (differences between cells in different regions of the same tumor) and **temporal** heterogeneity (changes in tumor cells over time)

Clonal evolution and development of tumor heterogeneity



➢ Studies[1] have shown that the inconsistent rate of PD-L1 expression between lung cancer primary and metastatic sites is reaches **38%**, and the heterogeneity of EGFR mutations between primary and metastatic sites in NSCLC patients is as high as **28.6%**

Inter-tumor heterogeneity

◆ Inter-tumor heterogeneity is the presence of different genetic alterations in **different metastatic tumors** from a single patient, have been identified in several tumor types

Tumor heterogeneity between individuals

- There is existence of heterogeneity in genetic background among individuals with malignant tumors, which is manifested by **regional and ethnic differences** in genetic predisposition of different tumors
- Due to the innate physiological differences among different ethnic groups, along with the differences in living environment and dietary habits, there may be **differences in the pathogenesis** and development of cancer, which may cause additional clinical risks

Tumor heterogeneity within an individual

- Inter-tumor heterogeneity in the same individual is mainly manifested by the genetic and phenotypic differences between the same tumor cells (different lesions, such as primary tumors and metastases) in different organs
- The study[2] shows that **glioblastoma** exhibits **extensive inter-tumor heterogeneity** in sensitivity to anti-cancer drugs

Note: [1]J Exp Clin Cancer Res. 2019;38(1):193. Published 2019 May 14. doi:10.1186/s13046-019-1192-1. [2]BMC Cancer 19, 628 (2019). https://doi.org/10.1186/s12885-019-5861-4

Source: Cancers 2021; BMC Cancer; China Insights Consultancy

Updated 2024 base year

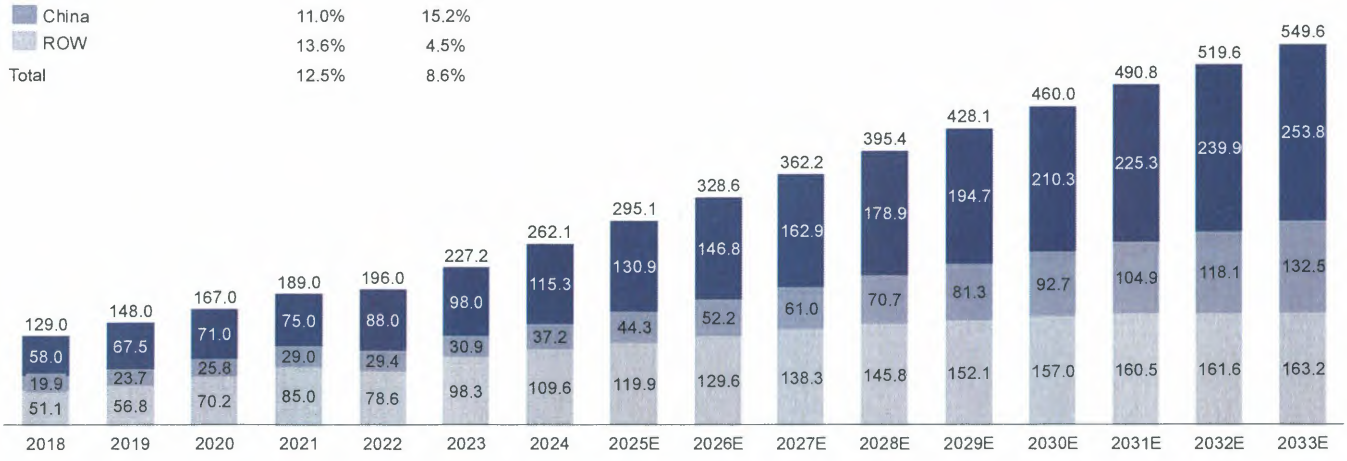
Global oncology drug market size, 2024

Global and China oncology drug | Market size

Global oncology drug market size, 2024

CAGR	2018-2024	2024-2033E
US	12.1%	9.2%
China	11.0%	15.2%
ROW	13.6%	4.5%
Total	12.5%	8.6%

billion USD



source: International Agency for Research on Cancer(IARC); NCCR; Chinese of Society of Clinical Oncology(CSCO);CIC

Updated 2024 base year

Overview of global top-10 selling oncology drugs in 2024

Global and China oncology drug > Top 10 selling drugs

Global top-10 selling oncology drugs, 2024

Brand name	Target	Modality	Generic name	Company	Indications	First FDA approval date	Global sale revenue in 2024 (million USD)
Keytruda	PD-1	mAb	pembrolizumab	Merk	NSCLC, TNBC, CRC, GC etc	2014/09/04	29,480
Darzalex	CD38	mAb	daratumumab	J&J	MM, Amyloidosis	2015/11/16	11,670
Opdivo	PD-1	mAb	nivolumab	BMS	NSCLC, RCC, etc.	2014/12/22	10,920
Tagrisso	EGFR	Small molecule	osimertinib	AstraZeneca	NSCLC	2015/11/13	6,540
Imbruvica	BTKi	Small molecule	ibrutinib	Abbvie, J&J	WM、CLL/SLL、MCL、GVHD	2013/11/13	6,385
Revlimid	CRBN	Small molecule	lenalidomide	BMS	MM、MDS、MCL、FL	2005/12/27	5,980
Xtandi	AR	Small molecule	enzalutamide	Astellas	Prostate cancer	2012/08/31	5,210
Ibrance	CDK 4/6	Small molecule	palbociclib	Pfizer	HR+/HER2- breast cancer	2015/02/03	4,890
Imfinzi	PD-L1	mAb	durvalumab	AstraZeneca	Urothelial carcinoma、NSCLC、SCLC	2017/05/01	4,560
Perjeta	HER2	mAb	pertuzumab	Roche	HER2+ breast cancer	2012/06/08	4,320

Source: China Insights Consultancy

Future trends of oncology drugs development (1/3)

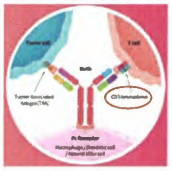
Global and China oncology drug > Future trends

Emerging new drug modalities

- The biopharmaceutical industry is undergoing revolution on oncology and other complex diseases with the innovation and new drug modalities. New modalities has have been emerged in the past 20 years, including gene and cell therapies, RNA drugs, and complex biologics, such as tumor-infiltrating lymphocyte (TIL) therapy, bispecific antibody-drug conjugates (BsADCs), multispecific antibodies, and etc.

Multispecific antibody

- Multispecific antibodies recognize **two or more** epitopes located on the same or distinct targets. This can add capacity through protein design, allowing the molecules to further address unmet medical needs
- There are **over 140** multispecific antibody molecules currently in clinical testing. Many have shown promising results in early-phase clinical trials, indicating potential improvements in patient outcomes



➢ Binding of T-cell-engaging BsAbs to CD3 has been shown to be a promising cancer therapy due to its ability to activate T cells without the restriction of the major histocompatibility complex and directly induce TAA and immune cells to form immune synapses

BsADCs

- BsADCs are an emerging and promising therapeutic modality in oncology, combining the specificity of bispecific antibodies with the cytotoxic potential of traditional ADCs
- Several bsADC candidates are showing promising results in preclinical studies. For instance, a novel T cell-redirecting bsADCs targeting GPRC5D and CD3 demonstrated potent antitumor activity in multiple myeloma models
- As of 2024/01, there are **10** bsADCs in clinical trials

Advantages of BsADCs

➢ Designed to simultaneously target multiple tumor-driven proteins, potentially **overcoming drug resistance**

➢ Recognition of cells co-expressing both targets to **increase tumor specificity** and reduce off-target toxicity

Radiopharmaceuticals

- Radiopharmaceuticals are experiencing significant growth and innovation, driven by their dual roles in diagnostics and therapy, particularly in oncology

Key trends:

➢ **Targeted radiopharmaceuticals:** Radiopharmaceuticals are increasingly designed to target specific cancer cells. Active targeting strategies involve linking radioactive molecules to ligands that bind to cancer-specific receptors

➢ **Supply chain and manufacturing:** The production and distribution of radiopharmaceuticals face challenges due to their short half-lives and the need for just-in-time manufacturing

➢ **New radioisotopes:** Research is exploring alternative radioisotopes like Ac-225 and Pb-212 for both imaging and therapy

Note: TAA=tumor-associated antigens

Source: Biotron; Medpace Corporate; China Insights Consultancy

Future trends of oncology drugs development (2/3)

New targets and biomarkers in precision oncology

- Precision oncology advances with drugs using new mechanisms, enabling broader therapeutic targets. This progress treats larger, biomarker-selected patient groups, enhancing the efficacy and personalization of cancer therapies

Trends	
Advanced in mutation targeting	• Kinase remain at the forefront of precision oncology armamentariums each passing year introduces **new kinase inhibitors** boasting enhanced potency, heightened selectivity against particular kinase isoforms, or refined mutant targeting • In addition to selectivity for individual mutations, inhibitors designed to selectively target single and compound acquired resistance mutations arising from treatment with **earlier-generation ALK/ROS** continue to be developed and approved • Besides the development of newer kinase inhibitors, the indications for which meaningful clinical benefit has been observed for established kinase inhibitors have also continued to expand
Immunomodulatory therapy advances	• Composite biomarkers like tumor mutational burden (TMB) and microsatellite instability (MSI) status persist in customizing immunotherapeutic strategies for specific cancers, contributing to additional drug endorsements • The checkpoint inhibitor dostarlimab received regulatory approval **in combination with chemotherapy** for patients with MSI-high advanced or recurrent endometrial cancers • BDC-1001 is an example of an ISAC consisting of **a mAb conjugated to a Toll-like receptor TLR7/8 agonist**. By binding to a cell-surface protein such as HER2, ISACs are designed to elicit a phagocytic response and T cell–mediated antitumor immunity
Companion diagnostic tests	• It is common practice in the industry to **use companion diagnostic tests** to detect a predictive biomarker, such as PD-L1, EGFR and HER2, in patients to evaluate their likely response to certain treatment

➢ Examples of new inhibitors approved by FDA in 2023:

Name	Target	Indication
quizartinib	FLT3 and FLT3-ITD	AML
RLY-4008	FGFR2	cholangiocarcinoma
repotrectinib	ROS1 and TRK	ROS1 fusion-positive NSCLCs

➢ Examples of inhibitors with expanded indications in NCCN guidelines:

Name	Target	Indication
alectinib	ALK	ALK-positive inflammatory myofibroblastic tumors

Note: ISAC= immune-stimulating antibody conjugates

Source: Cancer Discovery; China Insights Consultancy

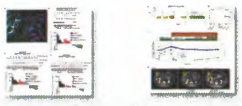
Future trends of oncology drugs development (3/3)

Increase clinical benefits in oncology treatment

Trends	
Trial design revolution	• Clinical trials are pivotal in oncology drug discovery and development, ensuring that safe and effective medications reach patients promptly. The focus of these trials has shifted from traditional studies of cytotoxic chemotherapy in broad histology-based populations to **adaptive, biomarker-driven evaluations** of molecularly targeted agents and immunotherapies in specific patient subsets • In the era of precision oncology, numerous molecularly targeted therapies now achieve inhibition of their targets at doses lower than the maximum tolerated dose. The FDA announced the launch of Project Optimus to facilitate **improved dose-optimization strategies** through multiple mechanisms, including by randomization of patients to different dose levels • The FDA has permitted early introduction of combination therapy involving established precision oncology drugs and novel treatments. This is typically preceded by a lead-in period for the new therapy, allowing for thorough evaluation of toxicity, safety, pharmacodynamics, and pharmacokinetics
Maximization of patient benefits	• As lung cancer and breast cancer transition into the **era of chronic disease management**, the patient-centered treatment model has led to the emergence of subcutaneous preparations as a new trend in the development of cancer drugs in China • **Comprehensive diagnosis and treatment**: comprehensive diagnostics, including genetic testing and biomarker analysis, enable personalized treatment plans tailored to the specific characteristics of the cancer. Comprehensive treatment involves a **multidisciplinary** team of specialists, including oncologists, radiologists, surgeons, pathologists, and other healthcare professionals, which can improve patient outcomes and lead to a higher quality life • **Transition from traditional intravenous injection to subcutaneous injection**: Most of the traditional antibody oncology drugs are administered intravenously, but long-term intravenous therapy will bring challenges to cancer patients and their families, such as loss of social labor, risk of complications and potential cost increase. Subcutaneous injection infusion time is short, saving patients' visit and stay in hospital, eliminating the cost of maintaining venous access every week.

➢ **PF-07284892 (ARRY-558)** is an allosteric SHP2 inhibitor designed to overcome bypass-signaling-mediated resistance when combined with inhibitors of various oncogenic drivers

➢ Preclinical data demonstrated that certain tumors, which had progressed on FDA-approved targeted oncogene inhibitors, could be **resensitized** by adding PF-07284892



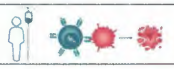
Source: Cancer Discovery; China Insights Consultancy

Table of contents

Analysis of different modalities of oncology biological drugs

Drug modality | Introduction

Analysis of different modalities of oncology biological drugs

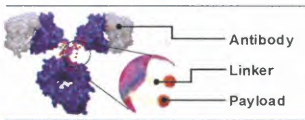
Drug Modalities	Monoclonal Antibody (mAb)	Fusion Protein	Antibody–drug conjugate (ADC)	Bispecific Antibody (BsAb)	Multispecific Antibody (MsAb)	Cell and Gene Therapies (CGT)
Description	Laboratory-produced molecules engineered to target specific antigens	Genetically engineered molecules combining multiple functional domains or proteins into one entity	ADC combines cytotoxic drugs with monoclonal antibodies for targeted tumor destruction	Recombinant molecules designed to target two antigens or epitopes	Recombinant molecules designed to target multiple antigens or epitopes	Genetically modifying cultivated cells to address specific genetic conditions and directly modifying a patient's DNA at the cellular level
Schematic structure						
Pros	• High specificity • Low toxicity	• Enhancing the stability of functional proteins • Extending metabolic half-life	• High specificity • High selectivity • Low systemic toxicity	• Enhanced tumor specificity • Reducing off-target toxicity • Enhancing activation of immune cells • Potential for synergistic therapeutic effects		• Potential for long-term therapeutic effects • Personalized treatment approach
Cons	• Targeting only one antigen • Limited efficacy in some cancers	• Low expression levels • Poor stability compared to mAb	• Challenges in payload stability and conjugation • Safety concerns	• Higher risk of immunogenicity • Cytokine storm • Limited clinical experience		• Safety concerns, including risk of insertional mutagenesis • Limited accessibility
Challenge of Development and Production	• Low yield • High time and monetary costs • Challenges in process scaling	• Screening for the appropriate linker length • Difficulty in protein characterization analysis	• Site-specific quantitative conjugation of antibodies, payload, and linkers • Downstream production purification	• Low druggability • Targets selecting • Constructing expression vectors • Achieving production purification		• Suboptimal therapeutic efficacy • Severe adverse events • High development costs and reimbursement uncertainties • Overcoming immunogenicity and host immune responses
Representative Drugs	• Keytruda® 	• Eylea® 	• Enhertu® 	• Blincyto® 	• GNC-038 (CD19×PD-L1×4-1BB×CD3)	• Kymriah® 

Source: NCI, China Insights Consultancy

Introduction to ADC and its development history

Drug modality > ADC introduction

Introduction to ADC Drug



- **ADC (Antibody-Drug Conjugate)** is a revolutionary cancer treatment method that combines **antibodies, cytotoxic drug(payload), and linker**
- The working principle of ADC involves antibodies specifically binding to antigens on the surface of tumor cells, internalizing into the cell, and releasing payload to kill tumor cells, thus inhibiting tumor growth and spread
- The previous treatment types such as chemotherapy often can only achieve either potent cancer-killing properties or specificity, but not both. By bringing together specificity and potent cancer-killing properties, ADCs have shown to be able to provide patients with the ability to select a drug that is simultaneously more effective and safer than chemotherapies and the previous generation of precision oncology

The evolution of the ADC drug development

Role and effect		First-generation ADC	Second-generation ADC	Third-generation ADC
Antibodies	Determine the specificity and effectiveness of the ADC. Target selection involves identifying antigens overexpressed on cancer cells to enhance ADC efficacy while sparing healthy tissues	Mouse-original or chimeric humanized antibodies	Humanized antibodies	Fully humanized antibodies or Fabs
Linkers	Connect antibody and payload. Determine the stability in the circulation, and the specific release of payload in target tissue	Unstable	Improved stability: cleavable and non-cleavable linkers	Stable in circulation; precise control drugs release into tumor sites
Payloads	Payloads are cytotoxic agents that are released upon internalization. Selecting right payload is essential for inducing targeted cell death while minimizing toxicity to normal cells.	Low potency, including calicheamicin, duocarmycin and doxorubicin	Potency, such as auristatins and mytansinoids	High potency, such as DXd, PBDs, and tubulysin, and novel payloads like immunomodulators
Conjugation methods	Allow precise control over DAR, improving ADC homogeneity, stability, and therapeutic index. Optimizing DAR and conjugation strategies is crucial for enhancing ADC effectiveness in targeted cancer therapy	Random lysines	Random lysines and reduced interchain cysteines	Site-specific conjugation
DAR	Determines the number of drug molecules attached to each antibody, impacting drug loading and efficacy	Uncontrollable (2–8)	4-8	2-8
Advantages	/	• Specific targeting • Increase therapeutic window to some extent	• Improved targeting ability • More potent payloads • Lower immunogenicity	• Higher efficacy though in cancer cells with low antigen • Improved DAR and stability and PK/PD • More potent payloads and less off-target toxicity
Disadvantages	/	• Heterogeneity • Lack of efficacy and narrow TI • Off-target toxicity as premature drug loss • High immunogenicity	• Heterogeneity • Fast clearance for high DARs • Off-target toxicity as premature drug loss • Drug resistance	• Possible toxicity due to highly potent payloads • Catabolism may be different across species • Drug resistance • The linker demonstrates a degree of instability
Representative Drugs	/	**Mylotarg®, Besponsa®**	**Adcetris®, Kadcyla®**	**Polivy®, Enhertu®**

Source: STTT; China Insights Consultancy

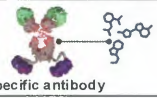
From ADC to XDC

Drug modality > From ADC to XDC

Evolution from ADCs to XDCs


"XDC" drug

- The future trend of conjugated drugs will focus on **new target antigens, effective payloads with novel mechanisms of action, new antibody and carrier forms**, and so on. The selection of target indications and optimal structural combinations is currently a key focus of research and development
- ADC drug technology has expanded from original drug designs to **XDC conjugation**. Currently, there is significant attention on **peptide-drug conjugates** and **radionuclide-drug**, with various other novel conjugated drugs undergoing rapid development

	Alternative formats for the antibody component of ADCs	Alternative formats for the payload component of ADCs	
Conventional formats	• Monoclonal Antibody 	• Chemical drugs 	
Alternative formats	• Bispecific antibody • scFV/Fab • Fusion protein • Peptide • Synthetic polymers • …	• Radionuclide • Steroid • PROTAC • Biotin • Polyethylene glycol (PEG)	• Enzyme • TLR • Peptide • Microprotein • Nucleotide • …
Representative Drugs	• Bispecific ADC • **BL-B01D1**  Bispecific antibody	• **RDC (Radionuclide-drug conjugate)** • **Pluvicto®**  Radionuclide	

Source: China Insights Consultancy

Barriers to ADC drug development

Drug modality | ADC barriers

Barriers to ADC drug development

Targeting appropriate high-expression antigens:

- Heterogeneity in drug binding sites
- Selecting an antigen target for ADCs is challenging due to the necessity of predominant expression on tumor cells, minimal expression in normal cells, extracellular localization for recognition by free ADCs, and non-secretory nature to prevent off-target binding and ensure safety

The antibody affinity needs to be moderate neither too strong nor too weak:

- The antibody should possess high specificity, low immunogenicity, promote effective internalization, and have a long halflife
- Due to the presence of the "binding site barrier (BSB)" in solid tumors, it is necessary to balance the affinity ofantibody

Instability of linker:

- ADC development is more complex than other targeted therapies due to the need for precise antibody-drug linkage
- The linker, acting as a bridge between the antibody and the drug, plays a crucial role in ADC safety by enabling precise control of drug release within cancer cells through accurate cleavage
- Decreased efficacy and increased toxicity can result from altered ADC and free payload blood concentrations

Limited variations of payload:

- Typically, only 2% of the drug reaches the tumor site after intravenous administration. Therefore, the effective payload should have high anti-tumor activity, with a single drug IC50 of 0.01-0.1nM
- While possessing high toxicity, it is essential to maintain high stability

Site-specific conjugation as the mainstream conjugation technique:

- The conjugation technique determines the DAR and homogeneity of ADCs, which can be categorized into random conjugation and site-specific conjugation, with the latter being the mainstream approach
- High uniformity, preservation of the antibody's spatial structure, precise reaction control, and high conjugation efficiency are essential characteristics of the conjugation technique

Source: China Insights Consultancy

Summary of global ADC drug transactions

Drug modality | ADC transactions

Top 10 ADC drug collaboration transactions by global pharmaceutical companies (Sorted by Single Asset Transaction Amount, USD)

- The total consideration is the largest ever for a single-asset collaboration transaction in the ADC space as of the Latest Practicable Date, according to CIC
- Under our license and collaboration agreement with BMS, we and BMS plan to initiate multiple late-stage clinical trials of BL-B01D1 globally, as a front or late line of treatment, in mono or combo settings, for various solid tumors including lung cancer and BC in the next few years

Rank	Date	Transferor	Transferee	Transaction Details	Target	Initial upfront payment, Mn USD	Transaction Amount, Mn USD
1	2023/12/12	Biokin/SystImmune	BMS	BL-B01D1	EGFR/HER3	800	8,400
2	2023/10/19	Daiichi Sankyo	Merck	DS-7300a	B7H3	1,500*	7,500
3	2023/10/19	Daiichi Sankyo	Merck	U3-1402	HER3	750*	7,500
4	2023/10/19	Daiichi Sankyo	Merck	DS-6000	CDH6	750*	7,000
5	2019/03/28	Daiichi Sankyo	AstraZeneca	DS-8201	HER2	1,350	6,900
6	2020/07/27	Daiichi Sankyo	AstraZeneca	DS-1062a	TROP2	1,000	6,000
7	2020/09/14	Seagen	Merck	SGN-LIV1A	LIV-1	600	3,200
8	2021/06/17	Eisai**	BMS	MORAb-202	FRα	650	3,100
9	2021/08/09	Remegen	Seagen	RC48	HER2	200	2,600
10	2017/02/10	Immunomedics	Seagen	IMMU-132	TROP2	250	2,000

*Note: *From the Daiichi Sankyo official website, not including payments due 12/24 months after contract execution. **BMS has returned the rights to the FRα ADC introduced from Eisai.*

Source: China Insights Consultancy

Updated 2024 base year

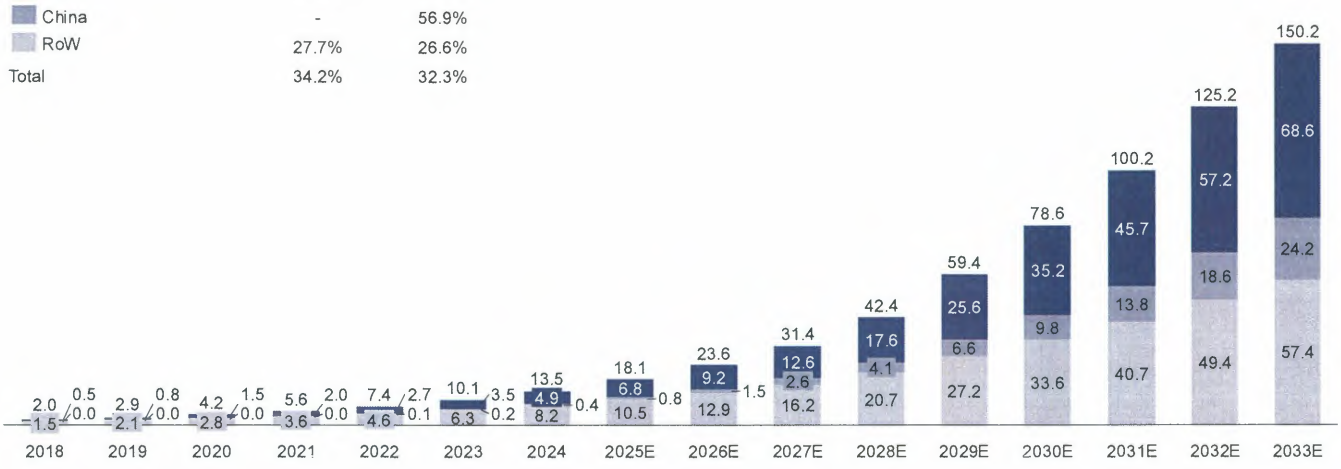
Global ADC market size

Drug modality | ADC market size

Global ADC market size

CAGR	2018-2024	2024-2033E
US	45.7%	34.2%
China	-	56.9%
RoW	27.7%	26.6%
Total	34.2%	32.3%

Billion USD



Source: China Insights Consultancy

Growth drivers and future trends in ADC development

- Expand targets and indications, payloads with fewer side effects, and apply novel site-specific conjugation technology

Drug modality | ADC drivers and trends

Drivers and trends in ADC development

- Our conjugation technology supports both traditional non-specific and precise site specific approaches, providing enhanced flexibility in ADC development. Our proprietary site-specific conjugation yields ADCs with superior tumor-killing efficacy, minimal aggregation, high conjugation efficiency, and enhanced molecular and plasma stability, maintaining their binding affinity post-conjugation

Growth drivers & Future trends	
Further expansion of targets and indications	• From an indications perspective, approved ADC drugs currently cover hematologic malignancies and solid tumors, with solid tumors mainly including breast cancer, gastric cancer, and urothelial carcinoma. ADCs in Phase III clinical trials are expected to expand to **new hematologic and solid tumor indications.** • From a target perspective, approved ADC drugs primarily focus on established targets like HER2, CD22, and Trop2. While global and Chinese ADC pipelines still concentrate on these established targets, **emerging targets** such as EGFRxHER3, MSLN and B7-H3are gradually appearing. • From an antigen selection perspective, there is a shift from tumor cell surface antigens to tumor stroma antigens, tumor vasculature antigens, and driver oncogene proteins.
Payloads with higher potency and lower side effects	• Among the toxins currently in clinical use or already approved, **microtubule inhibitors** (exemplified by MMAE) are the most established. Representative drugs include Adcetris, Polivy, Padcev, Blenrep, Avidity, Tivdak, and Kadcyla. **DNA topoisomerase I inhibitors** (exemplified by Dxd) represent the next generation of toxins with the most promising applications, as seen in drugs like Enhertu and Trodelvy. • The toxicity and physicochemical properties of toxins directly impact the ADC's ability to kill target cells, thereby affecting efficacy. However, the cytotoxic payloads can harm normal cells, leading to side effects such as myelosuppression, liver toxicity, and peripheral neuropathy, which necessitates careful antigen selection, optimized linker chemistry, and precise dosing strategies. New toxins need to have **high cytotoxicity, low immunogenicity, high stability, small molecular weight, and functional groups for modification** to achieve better therapeutic outcomes.
Site-specific conjugation enhances drug stability	• Conjugation methods are divided into random conjugation and site-specific conjugation. Random conjugation, typically used in marketed ADC products, often yields heterogeneous products due to its poor selectivity in DAR distribution. • **Site-specific conjugation**, a current research focus, offers potential for uniform DAR distribution, **enhancing drug homogeneity and safety, thus widening the therapeutic window.**
Cleavable linkers offer significant advantages	• **Cleavable linkers**, essential for bystander killing effects, are the mainstream in ADC linker development, enabling targeting of low antigen expression cells in heterogeneous tumors. • Future linker designs aim to **enhance hydrophilicity** for reduced clearance rates and **increase payload capacity** for improved potency • Further, cleavable linkers may enhance the bystander effect due to their ability to release the cytotoxic drug into the surrounding environment

Source: China Insights Consultancy

Introduction to Bispecific/Multispecific antibody

Drug modality | BsAb/MsAb introduction

Introduction to Bispecific/Multispecific antibody (BsAb/MsAb)

Bispecific antibody

- **Bispecific antibodies and multi-specific antibodies** are novel types of antibodies that possess two or more specific antigen-binding sites
- Compared to monoclonal antibodies, BsAb/MsAb add additional antigen-binding sites, thereby **increasing specificity, improving tumor cell targeting accuracy, and reducing off-target toxicity**
- The general structure of a bi/multi-specific drug involves carefully engineered components to ensure proper target recognition and engagement. This structure often includes linkers or spacers to connect different binding domains while maintaining their functional integrity

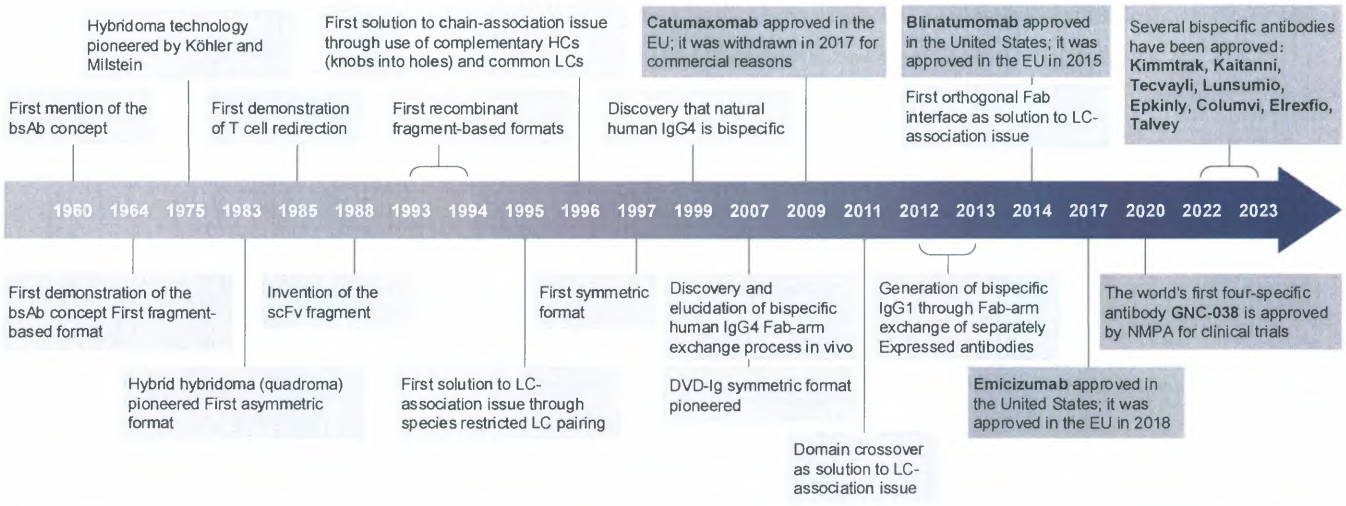
Classification	Bispecific antibody drug (BsAb)		Multispecific antibody drug (MsAb)
	IgG-like with an Fc region	Non-IgG-like without an Fc region	
Representative platform	KiH; CrossMAb; Orthogonal Fab IgG; SEBA	BiTE; Nanobody; DART	GNC; Contorsbody; ProTECT; CODV-Ig
Advantages	CMC: • Good solubility • High stability Efficacy: • Longer half-life • Greater therapeutic potential through Fc-mediated ADCC, CDC, and ADCP effects	CMC: • Lower cost • Higher yield Efficacy: • Lack of Fc fragment, therapeutic effect solely through antigen binding, lower immunogenicity • High penetration, great potential for solid tumor treatment	• Synergistic effect of targeted immunotherapy and escape inhibition • Simultaneous blockade/activation of two distinct immune signaling pathways downstream, enhances cell-killing toxicity • Reducing off-target toxicity
Disadvantages	• Poor permeability • Complex production • Higher immunogenicity	• Short half-life • Frequent dosing requirement • Poor patient compliance	• Complex production • Higher cost • Lower yield
Representative Drugs	Catumaxomab®	Blincyto®	No approved drugs currently

Source: Signal Transduction And Targeted Therapy; China Insights Consultancy

Development of BsAb/MsAb

Drug modality | BsAb/MsAb development

Development of BsAb/MsAb



Note: DVD=dual variable domain; EU=European Union; Fab=antigen-binding fragment; HC=heavy chain;Ig=immunoglobulin; LC=light chain; scFv=single-chain variable fragment

Source: Nature Reviews; China Insights Consultancy

Updated 2024 base year

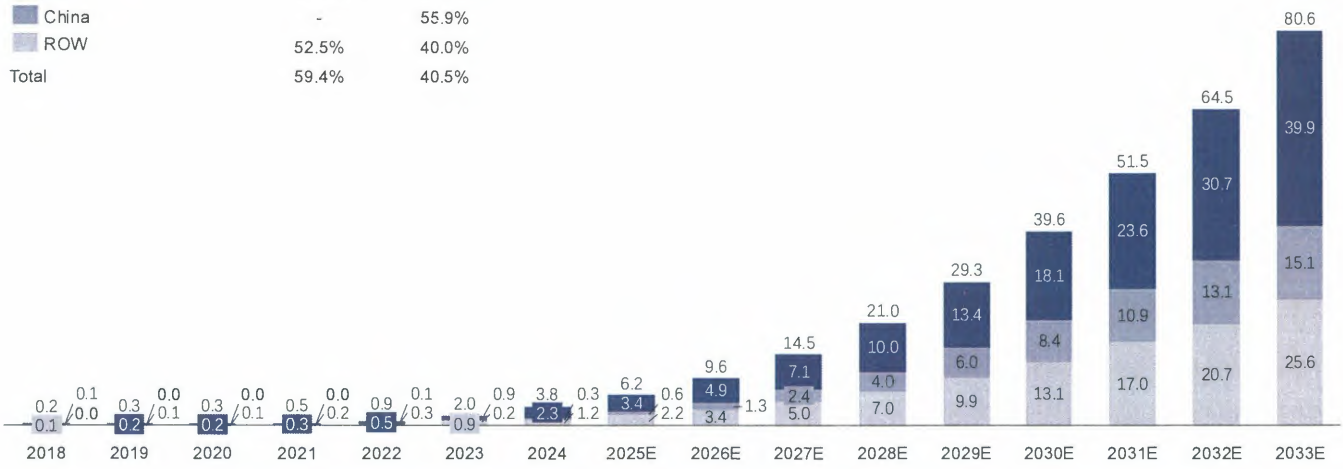
Global BsAb/MsAb oncology drug market size

BsAb/MsAb | Market size

Global BsAb/MsAb oncology drugs market size

CAGR	2018-2024	2024-2033E
US	60.6%	37.6%
China	-	55.9%
ROW	52.5%	40.0%
Total	59.4%	40.5%

Billion USD



Source: China Insights Consultancy

Growth drivers and trends in BsAb/MsAb drugs development

- Rising prevalence of chronic diseases, ongoing advancements in antibody engineering&technology, and growing investments

Drug modality | BsAb/MsAb drivers and trends

Drivers and trends in BsAb/MsAb drugs development

Growth drivers & Future trends	
Rising prevalence of chronic diseases	• The rising prevalence of chronic diseases, is fueling the demand for innovative treatment options like Bispecific/Multispecific antibodies. IARC's 2023 report shows 20 million new cancer cases and 9.7 million deaths globally, with lung and breast cancer being most common. Lung cancer and female breast cancer are the most commonly occurring cancers worldwide, accounting respectively for 12.4% and 11.6% of total new cases in 2023. • Cancer and autoimmune diseases pose significant challenges to patients and healthcare systems worldwide, underscoring the urgency for effective treatments. BsAb/MsAb offer a promising approach by **simultaneously targeting two different antigens**, thereby augmenting therapeutic efficacy. The expanding applications of BsAb/MsAb across different therapeutic areas contribute to the market's growth.
Ongoing advancements in antibody engineering&technology	• Ongoing advancements in antibody engineering and technology have enabled the design and production of bispecific antibodies with improved efficacy and safety profiles. Novel technologies such as **Fc engineering and antibody-drug conjugates** are enhancing the therapeutic potential of BsAb/MsAb. • Recent years have witnessed remarkable progress in developing novel antibody formats and engineering techniques, revolutionizing the generation of BsAb/MsAb. These advancements leverage recombinant **DNA technology and protein engineering** to construct bispecific antibodies with superior pharmacokinetics, reduced immunogenicity, and enhanced tumor penetration.
Growing investments in research and development activities	• Growing investments in research and development activities by pharmaceutical and biotechnology companies are driving the development of BsAb/MsAb. These investments aim to **explore new therapeutic targets and enhance the efficacy of existing treatments.** • Collaborations and partnerships between pharmaceutical companies, biotechnology firms, and academic institutions are driving the development and commercialization of bispecific antibodies. These collaborations leverage complementary expertise and resources to accelerate drug discovery and development processes.
Growing popularity of combination therapies	• The growing popularity of combination therapies, wherein BsAb/MsAb are used alongside other **immunotherapies** or **conventional treatments**, presents synergistic opportunities to enhance treatment efficacy. By leveraging the complementary mechanisms of action of different therapeutic modalities, combination therapies have the potential to improve patient responses and outcomes. • As the understanding of immune system function and dysregulation continues to evolve, BsAb/MsAb stand at the forefront of therapeutic innovation, offering novel strategies for addressing unmet medical needs and improving patient care globally.

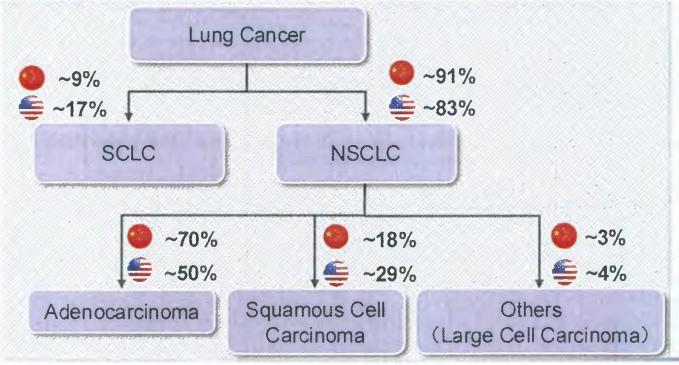
Source: IARC; China Insights Consultancy

Table of contents

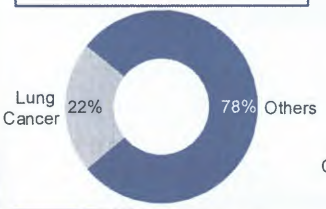
Epidemiology of lung cancer

- **Lung cancer occurs when there is genetic damage to the DNA of cells in the airways**
- **Primary Bronchogenic Carcinoma:** Commonly known as lung cancer, is a malignant tumor originating from the bronchial mucosa or glands. It is one of the most prevalent and deadly malignancies in China and worldwide
- **Ranking:** In 2022, lung cancer ranked first among all newly diagnosed cases of malignancy in China, accounting for 22% of cases

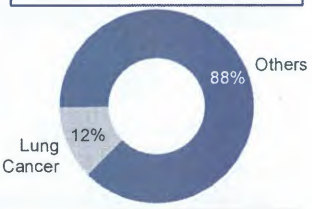
Classification of Lung Cancer Pathology, 2020*



Lung Cancer Proportion in Total Cancer Incidence in China



Lung Cancer Proportion in Global Total Cancer Incidence



Etiological Factor

- **Smoking:** >80% of lung cancer cases in the Western world attributable to cigarette smoking
- **Age:** Incidence and death rates rise significantly after 45; ~53% of cases occur in 55–74 years old in the US
- **Occupational Exposure:** Accounts for 5–10% of global lung cancer cases, such as asbestos, arsenic, and chromium
- **Air Pollution:** The combustion of fossil fuels, and particular matter suspended in the air
- **Chronic Obstructive Pulmonary Disease (COPD):** Primarily occurs due to smoking

Notes: *: Global variations in lung cancer incidence by histological subtype in 2020: a population-based study

Source: The Lancet Oncology, National Cancer Center, IARC, GLOBOCAN, Prospectus, CIC

Updated 2024 base year

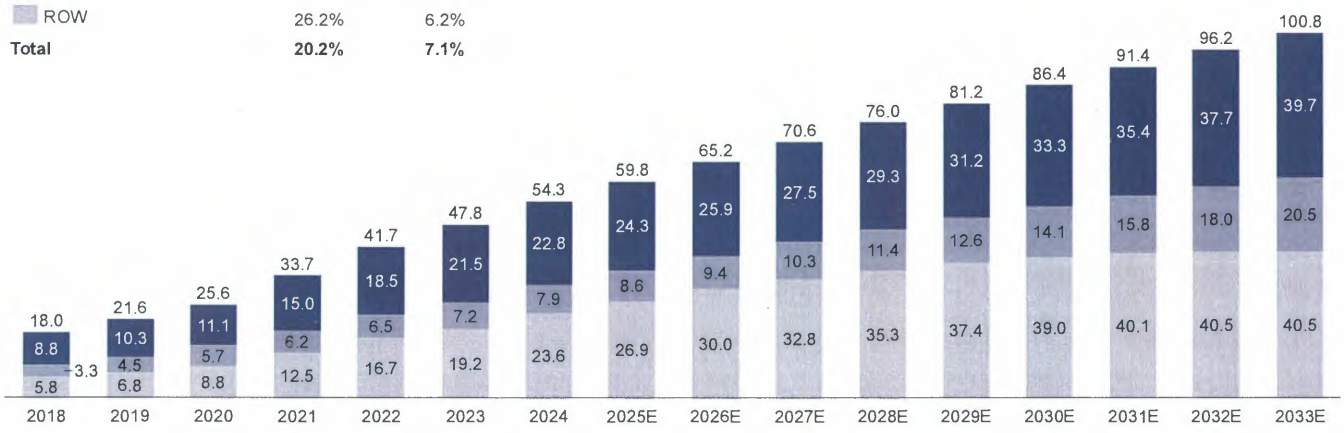
Global Market size of lung cancer drugs, 2018-2033E

Lung cancer | Market size

Global lung cancer drugs market size, 2018-2033E

CAGR	2018-2024	2024-2033E
US	17.2%	6.3%
China	15.5%	11.2%
ROW	26.2%	6.2%
Total	**20.2%**	**7.1%**

billion USD



Source: China Insights Consultancy

Updated 2024 base year

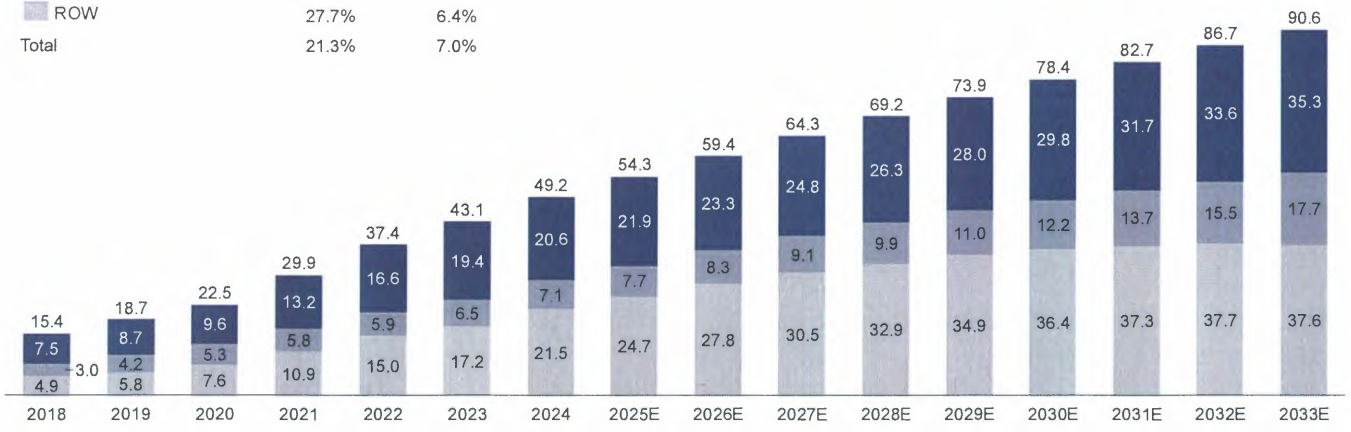
Global Market size of non-small-cell lung cancer drugs, 2018-2033E

Lung cancer | Market size

Global non-small-cell lung cancer drugs market size, 2018-2033E

CAGR	2018-2024	2024-2033E
US	18.4%	6.2%
China	15.3%	10.7%
ROW	27.7%	6.4%
Total	21.3%	7.0%

billion USD



Source: China Insights Consultancy

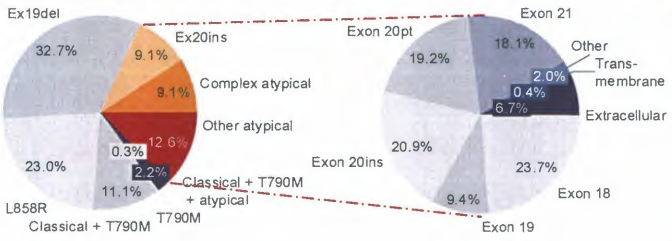
EGFR mutations in NSCLC

NSCLC | EGFRmut

EGFR mutations typically occur in exons 18–21 in NSCLC

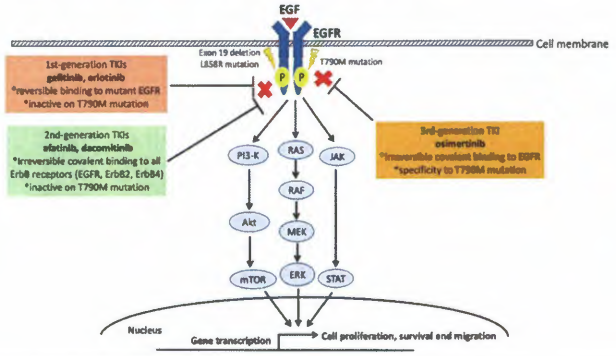
- Epidermal growth factor receptor (EGFR) pathway is a well-studied oncogenic pathway in human NSCLC
- **~67% had classical EGFR mutations (L858R and/or Ex19del ± T790M)**
- ~31% had atypical EGFR mutations, including Ex20ins (~9%), atypical mutations (~13%), or a complex mutation including an atypical mutation (~9%)
  - Atypical EGFR mutations occurred primarily in exons 18 (~24%) and 20 (~21% insertions and ~19% point mutations)
- ~2% had a classical mutation with T790M and an atypical mutation

Percentage of NSCLC Containing Classical and Atypical EGFR Mutations



Limited Targeted Therapy

- Treatment approaches vary based on different subtypes of EGFR mutations
- **For classical (L858R or Ex19del) mutations:** mainly targeted therapies
  - 1st-, 2nd- or 3rd-Tyrosine kinase inhibitors (TKIs) show marked improvements in clinical outcomes
- **For atypical mutations:** No targeted therapies approved by FDA except "S768I, L861Q and G719X" and "Ex20ins" mutations



Source: Int. J. Mol. Sci., Nature Portfolio, CIC

CSCO 2024: Limited efficacy of chemotherapy and immunotherapy for driver gene-negative cases

NSCLC | CSCO treatment pathway

Stage I~III NSCLC

- Operable: Surgical resection + Mediastinal lymph node dissection
- Inoperable: Radiotherapy ± Chemotherapy

Stage IV NSCLC

GENE	FIRST-LINE THERAPY (GRADE I)		SUBSEQUENT THERAPY (GRADE I)	
Gene-Negative Squamous NSCLC	• **PS=0~1:** Platinum-based chemotherapy ± Beva/PD-(L)1 monotherapy/Combination chemotherapy • **PS=2:** Single-agent chemotherapy		• **PS=0~2:**Nivolumab/Tislelizumab/Pemetrexed (only for Non-squamous NSCLC)/Docetaxel • **PS=3~4:** Best supportive care	• Pembrolizumab/Atezolizumab (GRADE II) • **Only for Squamous:** Gemcitabine, Afatinib
Gene-negative Non-squamous NSCLC				
EGFR ("classical")	• Osimertinib, Almonertinib, Furmonertinib, Afatinib, Dacomitinib, Erlotinib, Gefitinib, Befotertinib		• **Initial TKI + local therapy (Oligoprogress/CNS metastasis)** • TKI if T790M positive/Platinum-based chemotherapy ± **Beva (Extensive stage)**	
EGFR ("ex20ins")	• Gene-negative first-line therapy (GRADE I,II)		• **Sunvozertinib**	• Gene-negative ≥2L therapy (GRADE II)
ALK	• **Alectinib, Brigatinib, Lorlatinib, Ensartinib, Ceritinib, Crizotinib, Iruplinalib**		• **Initial TKI (or others) ± local therapy (Oligoprogress/CNS metastasis)** • **TKI if effective (only for ALK)/** Platinum-based chemotherapy ± **Beva (Extensive stage)**	
ROS1	• Entrectinib, Crizotinib			
BRAF V600E	• Dabrafenib + Trametinib	• Gene-negative first-line therapy (GRADE II)	• Gene-positive ≥2L therapy (1L targeted therapy) • Targeted therapy/Gene-negative ≥2L therapy (1L non-targeted therapy)	
NTRK	• Larotrectinib, Entrectinib			
METex14	• Glumetinib, Vebreltinib, Tepotinib		• Savolitinib, Glumetinib, Vebreltinib, Tepotinib	• Gene-negative/positive ≥ 2L therapy (GRADE II)
RET	• Selpercatinib, Pralsetinib	• Gene-negative first-line therapy (GRADE II, III)	• Selpercatinib; Pralsetinib	
KRAS G12C	• Gene-negative first-line therapy (GRADE I, II, III)		• Gene-negative 2L therapy	• Sotorasib; Adagrasib (GRADE II)
HER-2				• Trastuzumab Deruxtecan • Pyrotinib

Source: CSCO 2024; CIC

NCCN version 5.2024

Stage IA~IIIA NSCLC	• Operable: Surgical exploration & resection + mediastinal lymph node dissection or systematic lymph node sampling • Inoperable: Definitive RT, preferably stereotactic ablative radiotherapy			
Stage IIIB~IIIC NSCLC	• Definitive concurrent chemoradiation		• Durvalumab	
Stage IIIA NSCLC	• Stereotactic radiosurgery (SRS) alone or surgical resection		• Systemic Therapy	
Stage IVB NSCLC	**GENE**	**FIRST-LINE THERAPY**	**SUBSEQUENT THERAPY**	
	PD-L1 ≥1%	• PS 0-2: Biomarker-directed therapy • PS 3-4: Supportive care	• Continuation maintenance	**Systemic Therapy (Subsequent)**
	PD-L1 <1%	**Systemic Therapy** • PS 3-4: Supportive care	• Maintenance therapy	
	EGFR ("classical")	• Osimertinib; Osimertinib + pemetrexed (nonsquamous) • Erlotinib, Afatinib, Gefitinib, Dacomitinib	• **Continue Osimertinib; Local therapy for limited lesions** • **Amivantamab-vmjw + carboplatin + pemetrexed (nonsquamous)**	
	EGFR ("atypical")	• **S768I, L861Q, and/or G719X:** Osimertinib, Afatinib; Erlotinib, Gefitinib, Dacomitinib • **Exon 20ins:** Amivantamab-vmjw + carboplatin/pemetrexed	**Systemic Therapy (Subsequent)**	
	KRAS G12C	**Systemic Therapy**	• Sotorasib; Adagrasib	
	ALK	• **Alectinib, Brigatinib, Lorlatinib** • Ceritinib; Crizotinib	• Continue alectinib or brigatinib or ceritinib or lorlatinib • Local therapy for limited lesions	
	ROS1	• Entrectinib, Crizotinib, Repotrectinib • Ceritinib	• Local therapy for limited lesions • Continue entrectinib, crizotinib, repotrectinib, or ceritinib; lorlatinib	
	ERBB2(HER2)	**Systemic Therapy**	• Fam-trastuzumab, deruxtecan-nxki; Ado-trastuzumab emtansine	
	BRAF V600E	• Dabrafenib + Trametinib; Encorafenib + Binimetinib • Vemurafenib or Dabrafenib	**Systemic Therapy (Subsequent/Progression)**	
	NTRK1/2/3	• Larotrectinib or Entrectinib		
	METex14	• Capmatinib or Tepotinib; Crizotinib		
	RET	• Selpercatinib or Pralsetinib; Cabozantinib		

Source: NCCN 2024; CIC

NCCN version 5.2024

SYSTEMIC THERAPY FOR ADVANCED OR METASTATIC DISEASE

ADENOCARCINOMA (PS 0–1)

Preferred
- Pembrolizumab/carboplatin/pemetrexed
- Pembrolizumab/cisplatin/pemetrexed
- Cemiplimab-rwlc/pemetrexed/(carboplatin or cisplatin)

Other Recommended
- Atezolizumab/carboplatin/paclitaxel/bevacizumabe
- Atezolizumab/carboplatin/albumin-bound paclitaxel
- Nivolumab/ipilimumab
- Nivolumab/ipilimumab/pemetrexed/(carboplatin or cisplatin)
- Cemiplimab-rwlc/paclitaxel/(carboplatin or cisplatin)
- Tremelimumab-actl/durvalumab/carboplatin/albumin-bound paclitaxel
- Tremelimumab-actl/durvalumab/(carboplatin or cisplatin)/pemetrexed

ADENOCARCINOMA (PS 2)

Preferred
- Carboplatin/pemetrexed

Other Recommended
- Carboplatin/albumin-bound paclitaxel; Carboplatin/docetaxel; Carboplatin/etoposide; Carboplatin/gemcitabine; Carboplatin/paclitaxel

ADENOCARCINOMA (PS 3-4)

SQUAMOUS CELL CARCINOMA (PS 0–1)

Preferred
- Pembrolizumab/carboplatin/paclitaxel
- Pembrolizumab/carboplatin/albumin-bound paclitaxel
- Cemiplimab-rwlc/paclitaxel/(carboplatin or cisplatin)

Other Recommended
- Nivolumab/ipilimumab
- Nivolumab/ipilimumab/paclitaxel/carboplatin
- Tremelimumab-actl/durvalumab/carboplatin/albumin-bound paclitaxel
- Tremelimumab-actl/durvalumab/(carboplatin or cisplatin)/gemcitabine

SQUAMOUS CELL CARCINOMA (PS 2)

Preferred
- Carboplatin/albumin-bound paclitaxel
- Carboplatin/gemcitabine
- Carboplatin/paclitaxel

Other Recommended
- Carboplatin/docetaxel
- Carboplatin/etoposide

SQUAMOUS CELL CARCINOMA (PS 3-4)

Best supportive care

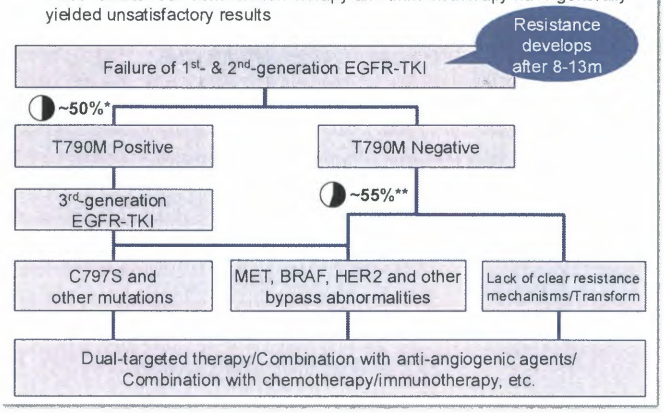
Source: NCCN 2024; CIC

Unmet clinical needs in advanced NSCLC: limited efficacy and resistance to first-Line TKI therapy

NSCLC → Unmet needs

1 Inevitability of Resistance in EGFR-TKIs

- **EGFR Mutation:** Common in East Asian Non-Squamous NSCLC (~48%)
- **First-line:** EGFR-TKI Treatment for sensitive mutations is standard, but resistance is inevitable
- **Post-resistance:** Combination therapy and immunotherapy have generally yielded unsatisfactory results



2 Targeted Drugs for Gene Abnormalities Need to Improve in Variety and Efficacy

- **EGFR Mutations & ALK Rearrangement:** 3rd TKIs have shown superior efficacy in NSCLC patients with specific driver genes
- **ROS1 Rearrangement:** Highly homologous with ALK kinase domain; ALK-positive drugs also effective
- **METex14 Skipping、RET Rearrangement、BRAF V600E Mutation:** Only 1-2 drugs approved domestically, still room for improvement in ORR
- **KRAS mutation:** No drugs available domestically, market remains empty
- **Lack of Driver Gene Mutations:** first-line treatments mainly consist of PD-1/PD-L1 inhibitors, combination chemotherapy, etc

Genotype	Drug	Trial Name	Line	ORR	mPFS
EGFR (19DEl, L858R)	Osimertinib	FLAURA	≥2L	71%	10.1m
ALK	Alectinib	ALEX		51%	10.9m
ROS1	Lorlatinib	NCT01970865		35%	8.5m
METex14	Savolitinib	NCT02897479		48%	6.8m
RET	Pralsetinib	ARROW		61%	17.1m
BRAF V600E	Dabrafenib + Trametinib	BRF113928		69%	10.2m

Notes: *: represents the proportion of patients developing the T790M mutation after acquiring resistance to TKIs; **: represents the proportion of patients who are T790M-negative after developing resistance to TKIs but exhibit bypass abnormalities.

Source: Advances in Clinical Medicine; YXJ; European Journal of Medicinal Chemistry; ClinicalTrials; CIC

NSCLC - ADC pipelines evaluated in both China and the U.S., with the most advanced stage in Phase III

Pipelines of stage III ADCs for NSCLC

Target	Candidates	Company	Highest stage[1]	Trial number[2]	Indication[2]	First posted date[2]	Location[2]
HER3×EGFR	iza-bren	Biokin	III	NCT06382129	EGFRwt NSCLC	2024-04-24	China
				NCT06382116	EGFRmut a/m nsqNSCLC	2024-04-24	China
				NCT06838273	EGFRmut a/m NSCLC	2025-02-20	China
				NCT07100080	EGFRmut a/m nsqNSCLC	2025-08-03	Global
HER3	SHR-A2009	HengRui	III	NCT06671379	EGFRmut a/m nsqNSCLC	2024-11-04	China
				NCT07183189	EGFRmut a/m/rNSCLC	2025-09-19	
EGFR	CPO301	CSPC	III	NCT06927986	EGFRmut a/mNSCLC	2025-04-15	China
TROP2	Dato-DXd*	Daiichi Sankyo/AstraZeneca	III	NCT05215340	a/m nsqNSCLC	2022-01-31	Global
	Trodelvy*	Merck/Gilead	III	NCT05089734	a/mNSCLC	2021-10-22	Global
				NCT05609968	mNSCLC	2022-11-08	Global
	SKB264*	Merck/Kelun	III	NCT06170788	mNSCLC	2023-12-14	Global
HER2	Enhertu*	Daiichi Sankyo/AstraZeneca	III	NCT05048797	HER2mut a/m nsqNSCLC	2021-09-17	Global
				NCT06899126	HER2-OE a/m nsqNSCLC	2025-03-27	Global
	SHR-A1811*	HengRui	III	NCT06430437	HER2mut a/mNSCLC	2024-05-28	China
	BL-M07D1	Biokin	III	NCT07178795	HER2mut a/m nsqNSCLC	2025-09-17	China
ITGB6	SGN-B6A	Seagen	III	NCT06012435	a/m nsqNSCLC	2023-08-25	Global
				NCT06758401	a/m NSCLC	2025-01-03	Global
PD-L1	PF-08046054	Pfizer	III	NCT07144280	a/m NSCLC	2025-08-27	Global

a/m/r NSCLC: advanced/metastatic/recurrent non-small cell lung cancer; nsqNSCLC: non-squamous non-small cell lung cancer
* Represent marketed drugs which are being explored for indication expansion
Note: 1 The highest stage refers to the highest clinical stage of candidates in China and the United States; 2 Represent the trial numbers, indications, first posted dates and locations of the Phase III clinical trials evaluating corresponding drug. 3 Represent the corresponding indication of the trial numbers. 3 Abbvie has withdrawn this phase III trial of ABBV-399 to treat c-met overexpressing NSCLC as of October 2024.

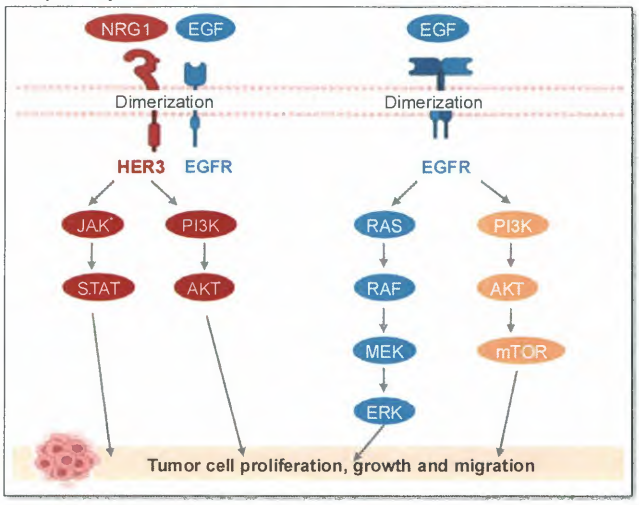
Source: Clinical trials.gov; CDE; China Insights Consultancy

Introduction to EGFR and HER3 pathway

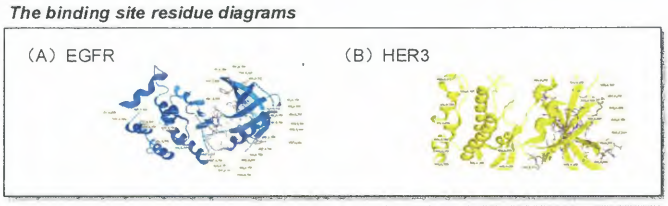
BL-B01D1 | Introduction

Introduction of EGFR and HER3 pathway

The pathway of EGFR and HER3



The binding site residue diagrams



- The **epidermal growth factor receptor (EGFR)** signaling pathway and the receptor **tyrosine-protein kinase erbB-3 (HER3)** are both the most important pathways that regulate growth, survival, proliferation, and differentiation in mammalian cells
- Two primary downstream signaling pathways of EGFR are the PI3K/Akt/PTEN/mTOR and the RAS/RAF/MEK/ERK pathways. **HER3 has been selected as a target protein along with EGFR for treating cancers** because of it lacks intrinsic tyrosine kinase activity and frequently co-expresses and forms heterodimers with other receptor tyrosine kinases (RTKs) to activate oncogenic signaling in cancer cells, and it has ability to activate PI3/AKT pathway responsible for therapy failure. **Studies have shown that EGFR-specific therapy in combination with HER3 therapy can enhance anti-tumor effects and overcome treatment resistance**

Source: Nature; China Insights Consultancy

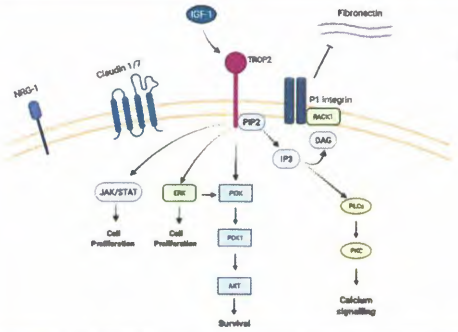
Trop-2 is a member of GA733 protein family playing a role in activating the MAPK/PI3K/AKT pathways which lead to growth, proliferation and metastasis in epithelial cancers

BL-M02D1 | Introduction

The introduction to Trop-2

- The transmembrane glycoprotein Trophoblast Cell Surface Antigen-2 (Trop-2), which is a member of a GA733 protein family that includes Trop-2 and EpCAM (epithelial cell adhesion molecule), exhibits widespread expression in **numerous epithelial cancers**, as well as in certain normal tissues.

Signalling Pathways and biological functions of Trop-2



- Trop-2 has been documented to engage in interactions with multiple proteins, including **insulin-like growth factor-1 (IGF-1), claudin-1 and 7, cyclin D1, and PKC**. Moreover, Trop-2's involvement in calcium signaling also suggests a potential mechanism for activating **the MAPK pathway.**

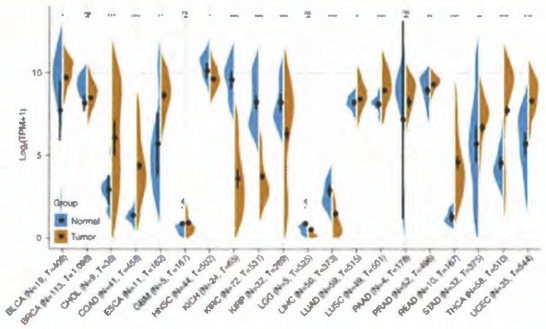
- **Trop-2's works as a regulator of stem cell growth**, potentially involving in the regeneration of diverse tissues and perhaps contributing to physiological events such as hyperplasia.

- **On the other hand, overexpression of Trop-2 has been linked to increased tumor growth, proliferation, and metastasis in numerous epithelial cancers**, including those affecting the head and neck, thyroid, lung, gastrointestinal tract, breast, renal, gynecological regions, and glioma.

Source: China Insights Consultancy

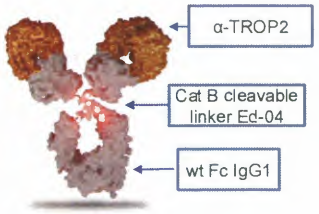
Patients diagnosed with BLCA exhibited the highest expression level of the TROP2 gene; BL-M02D1 attains a high DAR and has launched clinical trails on NSCLC, TNBC and digestive tract tumors

The expression levels of TROP2 in cancers



- The absolute expression levels of TROP2 and overexpression levels of TROP2 compared to normal tissues are high in Bladder Urothelial Carcinoma (BLCA), Cholangiocarcinoma (CHOL), Esophageal carcinoma (ESCA), Uterine Corpus Endometrial Carcinoma (UCEC), and Thyroid carcinoma (THCA).

Molecular Structure of BL-M02D1



- ✓ The new compound **Ed-04**, derived from the alkaloid camptothecin, **induces cell cycle arrest at the S phase, leading to subsequent apoptosis**.
- ✓ BL-M02D1 attains a **high drug-to-antibody ratio (DAR=8)** utilizing a remarkably stable linker.

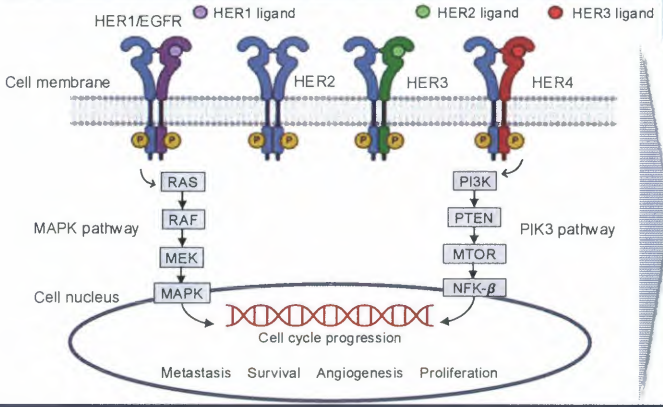
Clinical pipelines of BL-M02D1 in China

Types of locally advanced or metastatic tumors	Clinical stage, launch date			
	Phase I	*Phase I/II*	*Phase II*	*Phase III*
NSCLC		Ib/II, 07/10/23		
COLO, GC, HCC, CHOL, GBC, PAAD		I, 05/19/22		
TNBC			I, 04/26/22	

Introduction and mechanism of HER2

Introduction of HER2

- **Human epidermal growth factor receptor 2 (HER2)** is a member of the human epidermal growth factor receptor family. HER2 is a transmembrane receptor tyrosine kinase and a member of the ErbB family, which also includes HER1 (EGFR), HER3, and HER4. Unlike the other three members, HER2 does not bind to EGF-like ligands but relies on forming heterodimers with other members to activate signaling pathways that regulate cell proliferation and survival. HER2 is overexpressed in various cancers such as BC, GC, lung cancer, ovarian cancer (OC), among others
- In recent years the HER2 has become an important biomarker and anti-HER2 treatments are expected to be standard therapy for those cancers with HER2 over-expression



Mechanism of action of HER2 signal pathway

- HER stands for Human Epidermal Growth Factor Receptor, also known as ERBB. The HER family comprises four members: EGFR (HER1 or ERBB1), HER2 (ERBB2), HER3 (ERBB3), and HER4 (ERBB4).
- Human Epidermal Growth Factor Receptor 2 (HER2) is a tyrosine kinase on chromosome 17 (17q21). It contains three recognizable functional domains: an extracellular domain that binds to members of the HER2 family, a hydrophobic transmembrane domain, and an intracellular domain with tyrosine kinase activity.
- Upon activation, HER2 triggers **the phosphorylation of intracellular tyrosine substrates, initiating signaling pathways that have oncogenic implications**. HER2 does not rely on extracellular ligands for activation and can form heterodimers with any of the other three receptors (HER1, HER3, HER4), making it an ideal dimer partner. After activation, HER2 triggers the **phosphorylation of intracellular tyrosine substrates,** initiating subsequent signaling pathways. **Activating PI3K/AKT/mTOR/NFK-β and the RAS/RAF/MEK/MAPK signaling pathway** promotes cell proliferation, metastasis, angiogenesis, and survival while inhibiting cell apoptosis.

Source: Biomed Pharmacother; China Insights Consultancy

Unmet needs of approved HER2 ADC products

Unmet needs of approved HER2 ADC products

Unmet needs of approved products

- Most of the currently approved HER2 ADC drugs are targeted at patients with HER2 positive or high expression, and there **are limited treatment options for patients with HER2 negative or low expression**. The biggest demand in the breast cancer market does not come from HER2-positive patients, but from the patient group with low HER2 expression.
- The indications of currently marketed products in China mainly focus on breast cancer, gastric cancer and urothelial cancer, and gastric cancer and urothelial cancer are both targeted at patients with HER2-positive or high expression. However, solid tumors have a wide range of indications. For example, cancer types with many patients, such as lung cancer, liver cancer, and biliary tract cancer, have not yet been approved. Therefore, **the coverage of indications for marketed products is relatively limited**, the market need is expected to be filled.
- The increasing number of cancer incidence is positively correlated with aging population in China. **The number of cancer patients is projected to increase with the aging population continuously growing.** At the same time, solid tumor patients account for major proportion of all cancers. There are lots of patients who cannot get properly diagnosed or have targeted treatment.
- Surgery is the first choice to get cured for solid tumors. But for advanced, metastatic and refractory solid tumors, which are most of the cases, there still **lack efficacious therapies for 3rd and beyond line patients**. Besides, current therapies for solid tumors can cause various side effects, such as diarrhea, constipation, weight loss, etc., being less-tolerated for late-line patients.

Source: CDE; China Insights Consultancy

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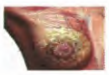
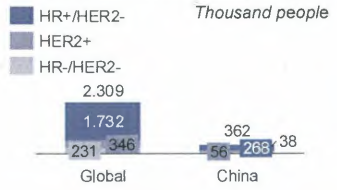
Overview of breast cancer

Introduction to breast cancer

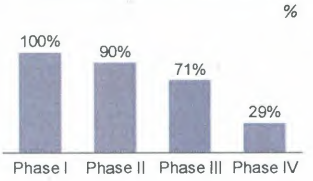


- **Breast cancer (BC)** is a disease that abnormal breast cells grow out of control and form tumors, which the most-commonly diagnosed malignant tumor in women in the world, as well as the first cause of death from malignant tumors.
- In 2022, breast cancer caused 670 000 deaths globally. BC is the second most common type of cancer globally and the most prevalent cancer in the U.S.
- Like many other cancers, causes of breast cancer can vary, but genetic predisposition (BRCA1 or BRCA2 mutations), estrogen and progesterone exposure and lifestyle factors and a few factors that have attributed to the heightened risk of breast cancer.

The incidence of BC, 2022



Five-year survival rate of BC, 2022



Symptoms

Early stage →	Advanced stage
• No apparent symptoms at early stage	• A breast lump or thickening, often without pain • Change in size, shape or appearance of the breast • Dimpling, redness, pitting or other changes in the skin

Stage of BC

Stage	Phase 0	Phase I	Phase II	Phase III	Phase IV
	←	65%	→	27%	6% →
Feature	• CIS	• Early invasive cancer • Tumor size< 2cm	• Tumor size is 2cm-5cm	• Tumor size >5cm	• Tumor in any size

Classification of BC*

HR+/HER2-	HER2+	TNBC
• Tumor have ER or PR, which can promote the growth of HR+ tumors, but without HER2	• Tumor have HER2, which has been shown to be associated with aggressive BC	• Tumor tested negative for ER, PR and HER2
• Low grade, slow growing, best prognosis, higher survival rate	• More aggressive and fast-growing than HR+/HER2 type	• Aggressiveness, early relapse, present in advanced stages

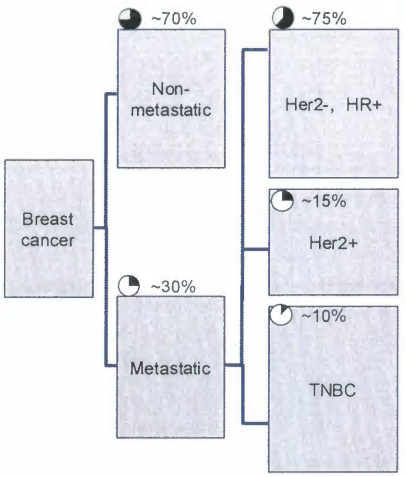
- Treatments for breast cancer, therefore, will depend on immunohistochemistry and will include surgery if at **an early stage and chemotherapy, hormonal therapy and immunotherapies based on various factors.**

Note: *ER: estrogen receptor; PR: progesterone receptor; HER2: human epidermal growth factor receptor 2

Source: China Insights Consultancy

Treatment path for breast cancer

Treatment path for breast cancer (CSCO)



	First-line	Second-line and beyond	
Her2-, HR+	• Without endocrinotherapy/TAM treatment failure (Grade I): AI + CDK4/6 i (Piperoxili; Abemaciclib)	• Nonsteroidal AI/Steroidal AI treatment failure (Grade I): Fluvestrant + CDK4/6 i (Piperoxili; Abemaciclib; Dalpiciclib)	• CDK4/6 i treatment failure (Grade II): Other CDK4/6 i + endocrine therapy; Other targeted drug + endocrine therapy; Rigorously designed clinical trials
Her2+	Trastuzumab sensitive (Grade I): • Taxane + Anti-HER2 McAb + Pertuzumab • Taxane + Anti-HER2 McAb + Pyrotinib	Trastuzumab failure (Grade I): • Pyrotinib + Capecitabine • T-DMI	TKI failure (Grade II): • T-Dxd/T-DMI • Anti-HER2 McAb+Pertuzumab • Rigorously designed clinical trials
TNBC	Taxanes sensitive (Grade I): • Taxanes monotherapy: Paclitaxel; Albumin-bound paclitaxel; Docetaxel • Combined therapy: Taxanes + Capecitabine/Gemcitabine; Taxanes + Platinum	Taxanes failure (Grade I): • Monotherapy: Eribulin; Vinorelbine; Gemcitabine; Capecitabine • Combined therapy: Vinorelbine + Platinum; Gemcitabine + Platinum; Utidelone + Capecitabine; Vinorelbine + Capecitabine	

- First-line treatment for HR+/HER2- BC includes hormone therapies, such as aromatase inhibitors (AIs), and targeted therapies, such as CDK4/6 inhibitors. In second-line settings, primary treatment options include fulvestrant coupled with CDK4/6 inhibitors

Note: TAM: Tamoxifen; AI: Aromatase inhibitors; CDK4/6 i: CDK4/6 inhibitor; McAb: Monoclonal antibody; T-DMI: Trastuzumab emtansine; T-Dxd: Trastuzumab deruxtecan

Source: CSCO; China Insights Consultancy

Treatment path for breast cancer

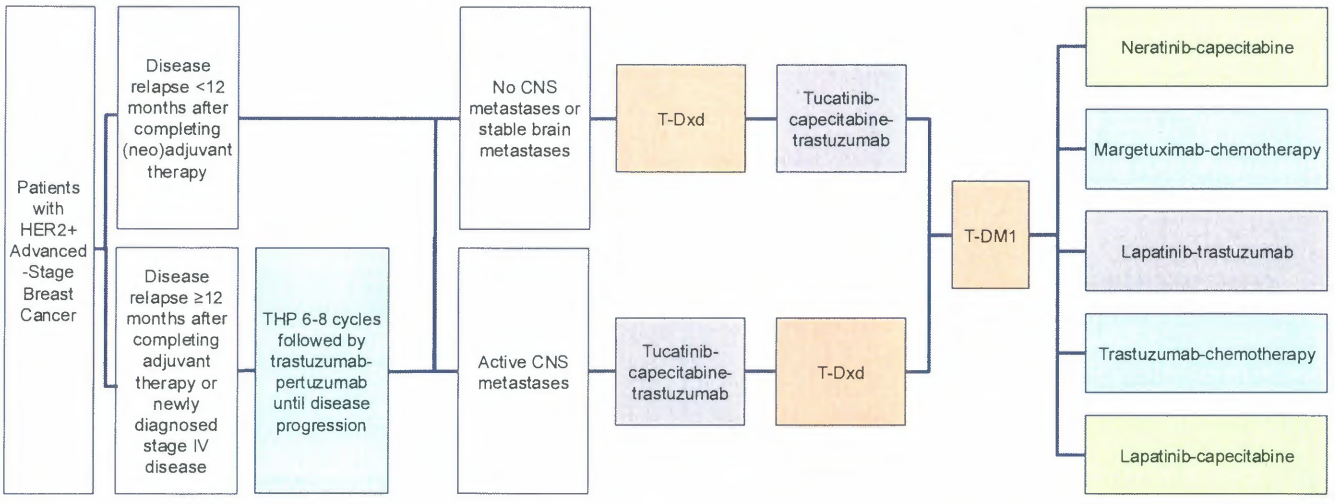
Treatment path for breast cancer (NCCN)

			First-line	Second-line	Third-line and beyond
Breast cancer	Non-metastatic	HER2-, ER+	• No germline BRCA1/2 mutation: Systemic chemotherapy • Germline BRCA1/2 mutation: PARPi (Olaparib, Talazoparib)	• HER2 IHC 1+ or 2+/ISH negative: Fam-trastuzumab deruxtecan-nxki • Not a candidate for Fam-trastuzumab deruxtecan-nxki: Sacituzumab govitecan; Systemic chemotherapy	• Systemic chemotherapy • Biomarker positive (ie, MSI-H, NTRK, RET, TMB-H): Targeted agents
		HER2+	• Pertuzumab + Trastuzumab + Docetaxel • Pertuzumab + Trastuzumab + Paclitaxel	• Fam-trastuzumab deruxtecan-nxki	• Tucatinib + Trastuzumab + Capecitabine • Ado-trastuzumab emtansine (T-DM1)
	Metastatic	TNBC	• PD-L1 CPS≥10 regardless of germline BRCA mutation status: Pembrolizumab + chemotherapy • PD-L1 CPS＜10 and no germline BRCA mutation: Systemic chemotherapy • PD-L1 CPS＜10 and germline BRCA mutation: PARPi/Platinum	• Germline BRCA1/2 mutation: PARPi • Sacituzumab govitecan; Systemic chemotherapy • No germline BRCA1/2 mutation HER2 IHC 1+ or 2+/ISH negative: Fam-trastuzumab deruxtecan-nxki	• Biomarker positive (MSI-H, NTRK, RET, TMB-H) • Systemic chemotherapy

Source: NCCN; China Insights Consultancy

Treatment algorithm for HER2+ breast cancer

Treatment Algorithm for Patients with Advanced-Stage HER2+ Breast Cancer



Source: Nature Reviews Clinical Oncology; China Insights Consultancy

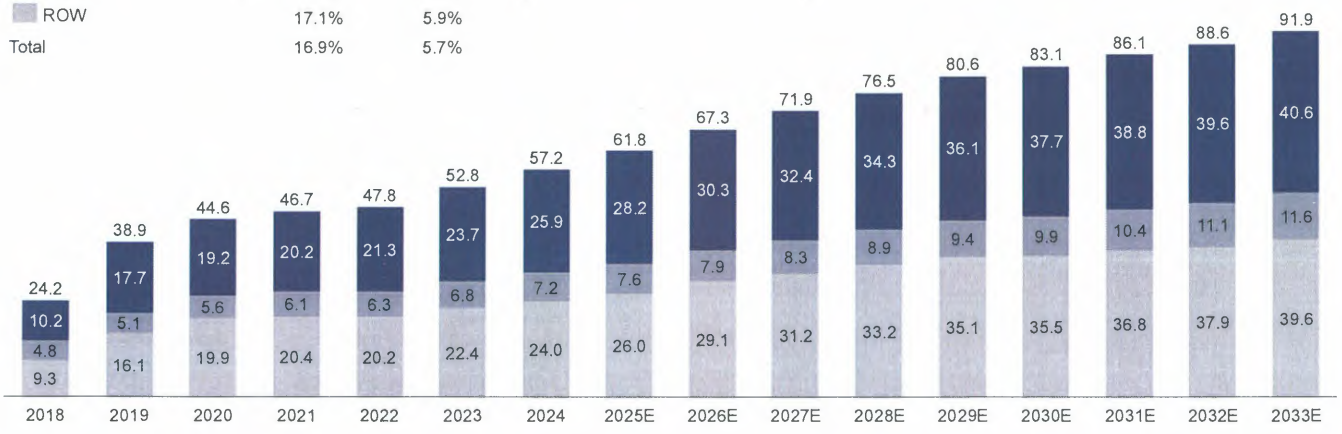
Updated 2024 base year

Global Market size of breast cancer drugs, 2018-2033E

Breast cancer | Market size

Global breast cancer drugs market size, 2018-2033E

CAGR	2018-2024	2024-2033E
US	16.9%	5.1%
China	7.1%	5.5%
ROW	17.1%	5.9%
Total	16.9%	5.7%



Source: China Insights Consultancy

Market opportunity in Breast Cancer

Market opportunity in Breast Cancer

There remain significant unmet clinical needs of breast cancer treatment:

Recurrence/metastatic diseases for HR+/HER2− patients

- For HR+/HER2− patients, recurrence and metastasis pose major challenges despite initial treatment efficacy. Existing therapies have limited effectiveness in managing these recurrent or metastatic cases, necessitating innovative treatments to delay disease progression and improve survival rates

Limited treatment options in the late-stage setting

- Late-stage breast cancer patients face a scarcity of treatment options, particularly after standard therapies fail. The development of new therapies has not kept pace with the demand, highlighting the urgent need for effective treatments that can extend the lives of late-stage patients and enhance their quality of life

Addressing drug resistance in breast cancer therapy

- Drug resistance is a significant hurdle in breast cancer treatment, as patients often develop resistance to therapies over time, reducing or negating their efficacy. Overcoming and managing this resistance is a crucial area of research, requiring the development of drugs that can bypass resistance mechanisms or re-sensitize tumors to existing treatments

Limited treatment options for TNBC patients

- TNBC lacks hormone receptors and HER2 expression, making conventional hormone therapy and HER2-targeted treatments ineffective. Patients with TNBC often rely on chemotherapy, which has limited efficacy and poor prognosis. There is an urgent need for effective treatment options specifically for TNBC to improve survival rates and quality of life for this patient group

Source: China Insights Consultancy

Breast cancer - ADC pipelines evaluated in both China and the U.S., with the most advanced stage in Phase III

Pipelines of stage III ADCs for breast cancer

Target	Candidates	Company	Highest stage[1]	Trial number[2]	Indication[2]	First posted date[2]	Location[2]
HER3×EGFR	iza-bren	Biokin	III	• NCT06382142 • NCT06343948 • NCT06926868	• a/mTNBC • HER2-/HR+ a/m/rBC • a/m/rTNBC	• 2024-04-24 • 2024-04-03 • 2025-04-15	• China • China • Global
HER3	HER3-DXd	Daiichi Sankyo/Merck	III	• NCT07060807	• HER2-/HR+ a/mBC	• 2025-07-11	• Global
TROP2	FDA018	Shanghai Fudan-Zhangjiang Bio-Pharmaceutical	III	• NCT06519370	• a/m/rTNBC	• 2024-07-25	• China
	ESG401	Shanghai Escugen Biotechnology	III	• NCT06383767 • NCT06732323	• HER2-/HR+ a/m/rBC • m/rTNBC	• 2024-04-25 • 2024-12-13	• China • China
	SKB264*	Merck Sharp & Dohme/ Klus Pharma	III	• NCT06081959 • NCT06393374	• HER2-/HR+ a/m/rBC • earlyTNBC	• 2023-10-13 • 2024-05-01	• China • Global
	Trodelvy*	Gilead Sciences	III	• NCT04595565 • NCT05382299	• earlyTNBC • a/mTNBC	• 2020-10-20 • 2022-05-19	• Global • Global
	Dato-DXd*	AstraZeneca	III	• NCT05374512 • NCT05629585	• r/mTNBC • earlyTNBC	• 2022-05-16 • 2022-11-29	• Global • Global
HER2	Enhertu*	AstraZeneca/ Daiichi Sankyo	III	• NCT04784715 • NCT05113251 • NCT05950945	• HER2+ mBC • HER2+ earlyBC • mTNBC	• 2021-03-05 • 2021-11-09 • 2023-07-18	• Global • Global • Global
	A166	Klus Pharma	III	• NCT06968585	• HER2+ a/mBC	• 2023-06-15	• China
	DB-1303	DualityBio	III	• NCT06265428 • NCT06018337	• HER2+ mBC • HR+/HER2- a/mBC	• 2024-02-20 • 2023-08-30	• China • Global
	SHR-A1811*	HengRui	III	• NCT05424835 • NCT05814354 • NCT07111832	• HER2+ BC • HER2-low m/rBC • m/rTNBC	• 2022-06-21 • 2023-04-14 • 2025-08-08	• China • China • China
	TQB2102	Chia Tai Tianqing	III	• NCT06561607 • NCT07008976 • NCT07043725	• HER2-low m/rBC • HER2+ aBC • early HER2+ BC	• 2024-08-20 • 2025-06-06 • 2025-06-29	• China • China • China
	DP303c	CSPC ZhongQi	III	• NCT06313086	• HER2+ aBC	• 2024-03-15	• China
	BL-M07D1	Biokin	III	• NCT06316531 • NCT06830889 • NCT06957886	• HER2+ a/mBC • early HER2+ BC • HER2-low m/rBC	• 2024-03-18 • 2025-02-17 • 2025-05-06	• China • China • China
	FS-1502	Shanghai Fosun	III	• NCT05755048	• HER2+ a/mBC	• 2023-03-06	• China
	JSKN003	Jiangsu Alphamab	III	• NCT06079983 • NCT06846437	• HER2-low m/rBC • HER2+ a/mBC	• 2023-10-12 • 2025-02-26	• China • China
	MRG002	Shanghai Miracogen	III	• NCT04924699	• HER2+ a/mBC	• 2021-06-14	• China
	RC48	RemeGen	III	• NCT04400695	• HER2-low a/rBC	• 2020-05-22	• China

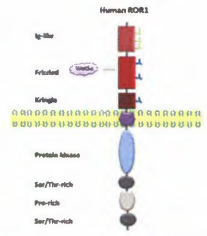
a/m/r BC: advanced/metastatic/recurrent breast cancer
* are the marketed drugs to extend indications

Note: 1 The highest stage refers to the highest clinical stage of candidates in China and the United States; 2 Represent the trial numbers, indications, initiation dates and locations of the Phase III clinical trials evaluating corresponding drugs. 3 Represent the corresponding indication of the trial numbers

Source: Clinical trials.gov; CDE; China Insights Consultancy

ROR1 is a receptor of Wnt5a which can trigger AKT phosphorylation and CREB activation and lead to tumor-cell proliferation for breast, ovarian and lung cancer and mantle cell lymphoma

The introduction to ROR1



- The receptor tyrosine kinase ROR1 functions **as a receptor for Wnt5a and is broadly expressed during embryonic development and across various human cancers.**
- Three splice variants of Ror1 have been characterized, and variant 1 encodes a transmembrane protein comprising 934 amino acids (aa) expressed on the cell surface.

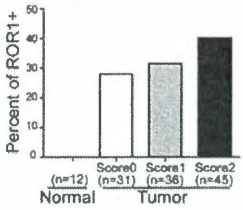
Signalling Pathways and biological functions of ROR1

- ROR1 has the capability to engage with casein kinase 1 epsilon (CK1s), thereby triggering phosphoinositide 3-kinase-mediated AKT phosphorylation and cAMP-response-element-binding protein (CREB) activation, **leading to augmented tumor-cell proliferation.**
- Additionally, **Wnt5a, acting as a ligand for ROR1, can induce ROR1-dependent signaling pathways, further promoting cell growth.**

The expression levels of ROR1 in cancers

- **ROR1 is expressed in both solid and blood tumors.** RNA analysis has revealed the expression of ROR1 in various human solid tumors, such as **breast, ovarian, and lung cancer**.
- Several studies have demonstrated the protein and cell-surface presence of ROR1 in **B-cell chronic lymphocytic leukemia (B-CLL), mantle cell lymphoma (MCL), and a subset of B-cell acute lymphoblastic leukemia (B-cell ALL)** using flow cytometry.

Percentage of ROR1+ in normal tissues and breast tumor tissues



- Study has shown that the presence of ROR1 in human breast cancers carries biological and clinical implications, **suggesting its potential as a therapeutic target for breast cancer treatment.**
- Breast tumor tissues are categorized based on the portion of tumor cells binding with anti-ROR1 mAb. A score of 2 indicates moderate-level of ROR1 mAb staining on more than 50% of tumor cells

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Overview of esophageal cancer

Introduction of esophageal cancer

- The EAC occurs through progressive accumulation of multiple genetic changes leading to malignant proliferation of esophageal cells and the overexpression or abnormal expression of proteins

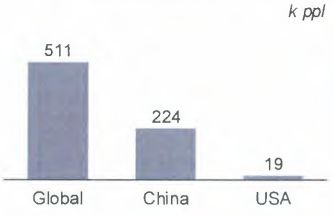
Esophageal cancer (EAC)

- **Squamous cell carcinoma (SCC)**
- **Adenocarcinoma (ADCA)**

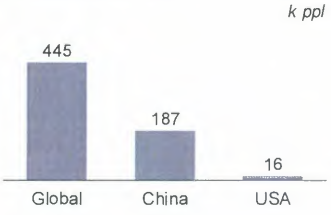
% in different countries: EAC has special clinical features in China

China	**90%**	10%
North America and most European countries	30%	70%

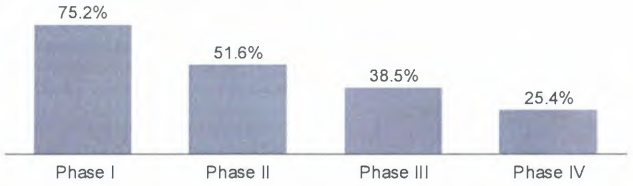
The incidence of EAC, 2022



The mortality of EAC, 2022



5-year Survival Rate in China, 2000-2018



Symptoms

- **Early stage**
  - Dysphagia
  - Loss of weight
  - Burning pain
- **Advanced stage**
  - Nausea, food reflux
  - Superior vena cava syndrome
  - Cough and fever
  - Jaundice

Risk Factors

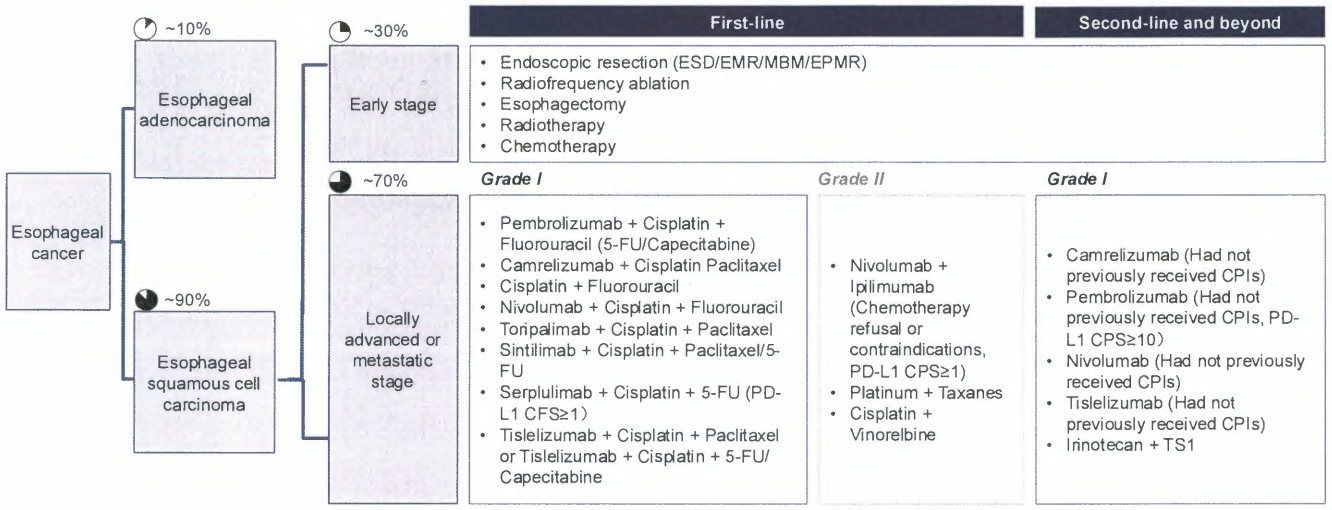
- Dietary factors
  - ➢ foods containing N-nitroso compounds
  - ➢ areca nuts chewing
- Smoking and alcohol
- underlying gastrointestinal diseases and upper gastrointestinal cancer
- HPV
- Genetic factors

Note: *The information sources in the table include the Enterprises' annual report, expert interviews, company sales team recruitment information, etc.

Source: China Insights Consultancy

Treatment path for esophageal cancer

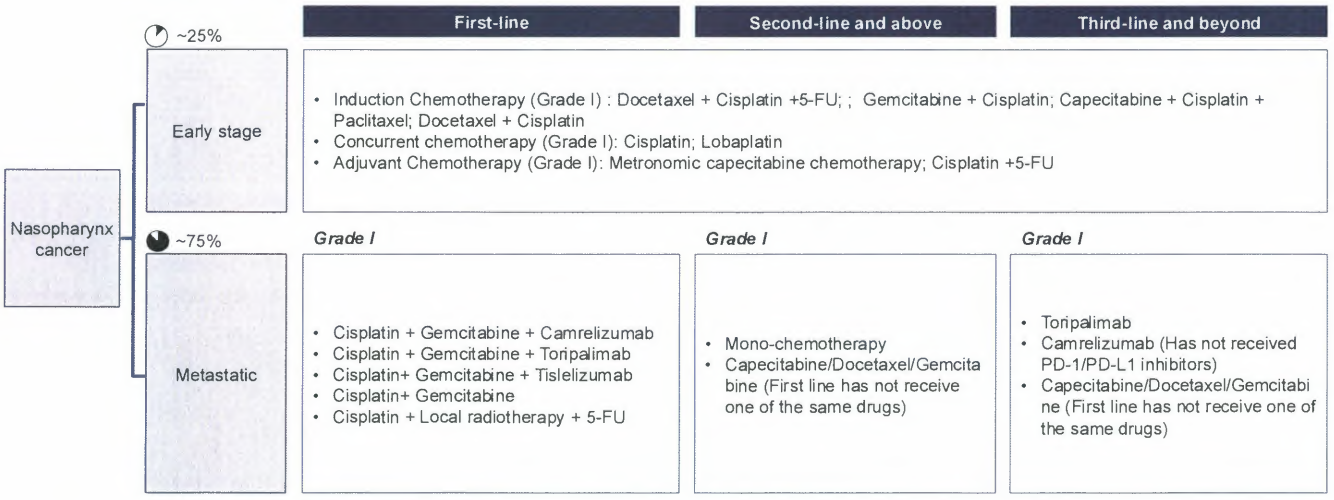
Treatment path for esophageal cancer (CSCO)



Source: CSCO; China Insights Consultancy

Treatment path for esophageal cancer

Treatment path for esophageal cancer (CSCO)



Source: CSCO; China Insights Consultancy

Clinical Trials for advanced-stage ESCC: low response rates, short median PFS, and challenges of drug resistance

Pivotal Phase III Clinical Trials in Advanced-Stage ESCC

First Line of Treatment			Second Line and Beyond	
Pembrolizumab + Chemo vs Chemo (KEYNOTE-590) mPFS: 6.3m vs 5.8m mOS: 12.6m vs 9.8m	Camrelizumab + Chemo vs Chemo (ESCORT-1st) ORR: 72.1% vs 62.1% mPFS: 6.9m vs 5.6m mOS: 15.3m vs 12.0m	Sintilimab + Chemo vs Chemo (ORIENT-15) ORR: 66.1% vs 45.5% mPFS: 7.2m vs 5.7m mOS: 16.7m vs 12.5m	Pembrolizumab vs Chemo (KEYNOTE-181) ORR: 16.7% vs 7.4% mOS: 8.2m vs 7.1m	Camrelizumab vs Chemo (ESCORT) ORR: 20.2% vs 6.4% mOS: 8.3m vs 6.2m
Nivolumab + Chemo/Ipilimumab vs Chemo (CheckMate 648) ORR: 47% vs 28% vs 27% mOS: 13.2m vs 12.8m vs 10.7m	Toripalimab + TP vs TP (JUPITER-06) ORR: 69.3% vs 52.1% mPFS: 5.7m vs 5.5m mOS: 17.0m vs 11.0m	Tislelizumab + Chemo vs Chemo (RATIONALE-306) ORR: 63.5% vs 42.4% mPFS: 7.3m vs 5.6m mOS: 17.3m vs 10.6m	Tislelizumab vs Chemo (RATIONALE-302) ORR: 20.3% vs 9.8% mOS: 8.6m vs 6.3m	Nivolumab vs Chemo (ATTRACTION-3) ORR: 19% vs 22% mOS: 10.9m vs 8.4m

Source: FDA, CDE, ASCO 2024, China Insights Consultancy

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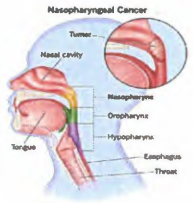
Nasopharyngeal carcinoma is typically classified as a type of epithelial tumor; the incidence of nasopharyngeal carcinoma is significantly higher in China than in other regions of the world

Introduction of Nasopharyngeal Carcinoma (NPC)



- Nasopharyngeal carcinoma (NPC) is a cancer located in the **nasopharynx or upper throat**, typically originating from nasopharyngeal epithelial cells and classified as a type of epithelial tumor. Major risks for NPC include genetic factors, EB virus infection, dietary habits (like consuming preserved foods and betel nut) and environmental factors including occupational exposures
- Specific early diagnosis of NPC is weak and early screening is not widely implemented, leading to **less than 20%** of cases being diagnosed early, **with the majority detected at mid to late stages**
- Radiotherapy-based combination therapy has resulted in a 5-year overall survival rate of **more than 80%** and a localized regional control rate of **more than 90%** for nasopharyngeal cancer. However, local and/or regional recurrence still occurs in **10-15%** of patients

The crude incidence rate of NPC in China is more than six times the U.S. level

Number of new cases in thousand (Crude incidence rate per thousand population), 2022	China	America	Global
Overall Head and Neck Tumors	145.6(0.1031)	58.346(0.1751)	892.128(0.1115)
Nasopharynx	**51.01(0.0361)**	2.008(0.006)	120.434(0.0151)

Main takeaways

- **Incidence rates are particularly high in Asia compared to that of Europe and America.** China is a high-incidence area for NPC, with nearly half of new cases emerging particularly from the southern regions. **The crude incidence rate of NPC is 1.51 per 100,000 person-years globally in 2022, but exceeds 3.6 in China**, where the rate in the southern inland regions of China is about **30 times** higher than in the north.

Source: China Insights Consultancy

The overall 5-year-surivial ratio of patients with recurrent NPC is still low and the number of marketed targeted drugs remains limited, leaving ample room for future drug exploration

Treatment methods

- **Due to its radiation sensitivity and unique location, nasopharyngeal carcinoma is primarily treated with radiotherapy**. NPC's hidden position and complex surrounding anatomy make surgery challenging, while radiotherapy precisely targets the affected area with minimal impact on healthy tissue.

- **For locally advanced NPC, induction chemotherapy combined with concurrent chemoradiotherapy is the main treatment approach**. According to the 2023 CSCO NPC treatment guidelines, this method significantly **enhances five-year overall survival (OS) and progression-free survival (PFS) rates** compared to radiotherapy alone.

- **Targeted and immune therapies are increasingly showing advantages during treatment**. Epidermal growth factor (EGFR) is commonly expressed in advanced nasopharyngeal carcinoma tissues and EGFR targeted antibody drugs exhibit promising treatment effects in combination with chemotherapy drugs. Besides, recent studies also show promising anti-tumor efficacy and safety of PD-1 inhibitors alone or in combination with chemoradiotherapy when treating recurrent/metastatic NPC patients.

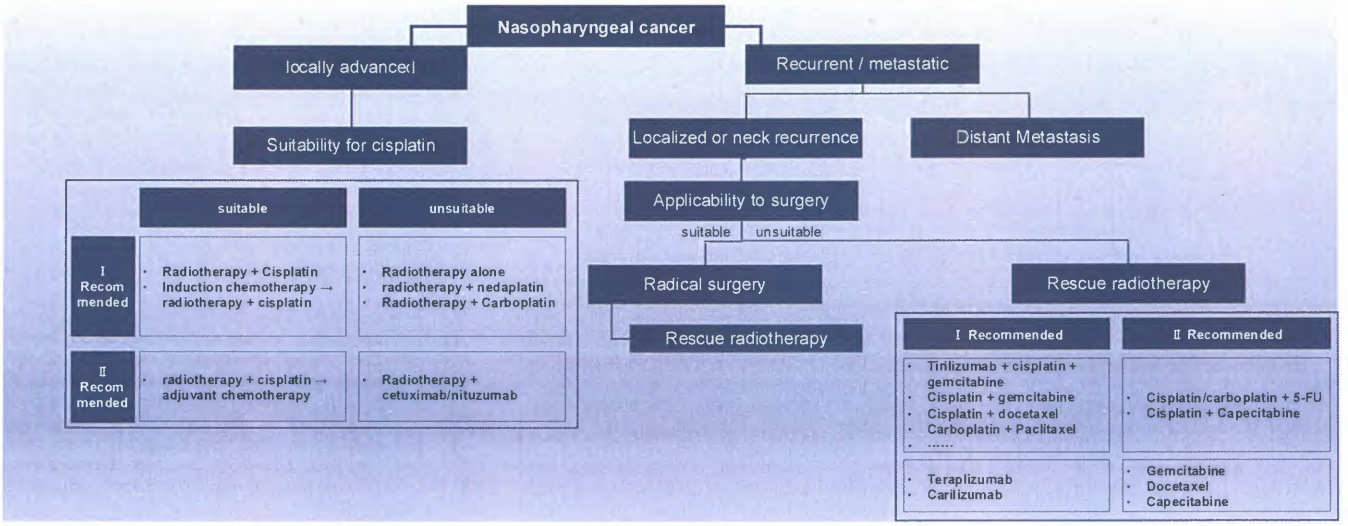
Unmet Clinical Needs:

- **The existing treatments for recurrence and metastasis of NPC are limited and the therapeutic effects and adverse events are still unsatisfying.**
  - ✓ **~10%-15%** of NPC patients experience local and/or regional recurrence. Most recurrences are diagnosed at an advanced stage, making radiotherapy almost the only curative treatment available.
  - ✓ The **overall 5-year-surivial ratio** of patients with recurrent NPC undergoing retreatment is **only ~30%.** The long-term adverse effects associated with radiotherapy are significant, with **severe adverse events** occurring in **48.1%-73.7%** of cases, and deaths due to late complications ranging from **34.7%-69.2%.**
- **The number of marketed targeted drugs and ongoing clinical trials for NPC remains relatively limited, leaving ample room for future drug exploration.**
  - ✓ Currently, the main targeted drugs are monoclonal antibodies targeting EGFR (such as cetuximab and nimotuzumab). While cetuximab in combination with chemotherapy has shown good efficacy, it is associated with certain skin toxicity.

Source: Research progress in the treatment of nasopharyngeal carcinoma; NMPA; China Insights Consultancy

Overview of treatment path of recurrent or metastatic nasopharyngeal cancer

Overview of treatment path of recurrent or metastatic nasopharyngeal cancer by CSCO



Source: CSCO, China Insights Consultancy

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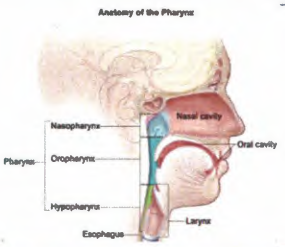
In China, head and neck squamous cell carcinoma accounts for 90% of all head and neck malignancies, including cancers of the lips, oral cavity and larynx

Introduction of Head and Neck Squamous Cell Carcinoma (HNSCC)



- **Head and neck cancer (HNC) is one of the most common cancers worldwide, and head and neck squamous cell carcinoma (HNSCC) is the main type of head and neck cancers.** Head and neck squamous cancers include oral, pharyngeal, oropharyngeal, hypopharyngeal, laryngeal, nasal and nasopharyngeal squamous cell carcinoma. In 2022, there were nearly **900 thousand new cases** of HNC in the world, accounting for 4.47% of all cancers. In that same year, nearly **460 thousand deaths** from HNC occurred globally, accounting for 4.71% of all cancers.
- **HNSCC constitutes ~90% of HNC**, and the remaining 10% of HNC originates from lymphocytes, connective tissue cells (muscles, blood vessels), and salivary gland cells.Risk factors for HNSCC include exposure to tobacco carcinogens, excessive alcohol consumption, and HPV infection, with over 70% of oropharyngeal cancers linked to HPV. Men are 2 to 4 times more likely to develop HNSCC than women

Number of new cases in thousand (Crude incidence rate per thousand population), 2022	China	America	Global
Overall Non-nasopharyngeal Head and Neck Tumors	94.6(0.067)	56.338(0.169)	771.694(0.0964)
Larynx	29.5(0.0209)	12.172(0.0365)	189.191(0.0236)
Lips, Oral Cavity, and Pharynx	65.1(0.0461)	44.166(0.1325)	582.503(0.0728)
Proportion of Head and Neck Squamous Cell Carcinoma		~90%	
Head and Neck Squamous Cell Carcinoma	~85.14	~50.7042	~694.5246

Source: NCCN, Drugs Des Devel Ther. China Insights Consultancy

The treatment pathway for non-nasopharyngeal HNSCC has developed towards targeted therapy and immunotherapy

Main Categories of non-nasopharyngeal HNSCC	Tumor Category Analysis
Oral Cancer	• Non-healing ulcers on the lips or in the mouth, white or red patches inside the mouth, loose teeth, lumps in the mouth, and oral pain. • Usually diagnosed in the early stages
Oropharyngeal and Hypopharyngeal Tumors P16+	• Symptoms include difficulty swallowing, pain during swallowing, or ear pain. • Symptoms often appear in the late stages of the tumor
Oropharyngeal and Hypopharyngeal Tumors P16-	• Presence of neck lumps and asymptomatic primary tumors. • HPV virus-related cancers, which generally have a relatively high survival rate
Laryngeal Tumors	• Laryngeal tumors present with voice changes or severe hoarseness, eventually leading to airway obstruction. • Vocal cord tumors are usually diagnosed early; however, supraglottic laryngeal cancer (above the vocal cords) and subglottic laryngeal cancer (below the vocal cords) often have no symptoms until respiratory obstruction occurs, with the tumors only being discovered when they are large and advanced

Unmet Clinical Needs

- **The current treatment efficacy is unsatisfactory for late-stage HNSCC patients**
  - ✓ In all head and neck squamous cell carcinomas, **over 60%** of patients are diagnosed at an advanced local stage (III-IV, excluding M1). After comprehensive treatment, **40% to 60%** of patients still experience local recurrence or distant metastasis, with a **5-year survival rate under 50%.**
- **Targeted therapy drugs are gradually becoming more diverse, and combination therapy is currently under exploration.**
  - ✓ **Cetuximab**, the EGFR-targeting drug, showed initial effectiveness in treating HNSCC. **Panitumumab, afatinib**, and other drugs at the stage of conducting clinical trials potentially are expected to become new options.
  - ✓ PD-1/PD-L1 inhibitors have shown promising efficacy. Ongoing clinical trials are exploring combining targeted/immunological therapy with radiotherapy and chemotherapy.

Source: China Insights Consultancy

Overview of treatment path of non-nasopharyngeal HNSCC by CSCO

Overview of treatment path of non-nasopharyngeal HNSCC by CSCO

HNSCC Staging	Treatment Plan		
Types of HNSCC	Patient Stratification	First-line Treatment	Second-line and back-line treatment
Early Stage Local HNSCC	Patients Suitable for Surgery	• Surgical resection; radiotherapy is also an option for oropharyngeal, laryngeal, and hypopharyngeal cancers	• /
Early Stage Local HNSCC	Patients Unsuitable for Surgery	• Radiotherapy; for nasopharyngeal cancer suitable for cisplatin use, combine radiotherapy with cisplatin	• /
Recurrent/Metastatic HNSCC	Metastatic NPC	• Cisplatin and gemcitabine • Cisplatin and docetaxel • Carboplatin and PTX	• Gemcitabine/docetaxel/capecitabine • Pembrolizumab/nivolumab/crizotinib/tripalimumab (ICIs) • PD-1
Recurrent/Metastatic HNSCC	Non-NPC Metastatic HNSCC	• Cetuximab (an EGFR inhibitor) + cisplatin/carboplatin + 5-FU [EXTREME regimen] (also recommended with docetaxel and PTX). • Pembrolizumab + cisplatin/carboplatin + 5-FU or pembrolizumab alone. • KEYNOTE-048 showed that pembrolizumab is superior to the EXTREME regimen, establishing it as a first-line treatment option	• Nivolumab • Pembrolizumab, MTX, docetaxel, PTX, and cetuximab • Afatinib
Recurrent/Metastatic HNSCC	Recurrent NPC	• Recurrence: surgery combined with radiotherapy, or consider treatment methods for metastatic NPC	• /

Source: CSCO, China Insights Consultancy

Overview of treatment path of non-nasopharyngeal HNSCC by CSCO

HNSCC | Treatment pathway

Overview of treatment path of non-nasopharyngeal HNSCC by CSCO

HNSCC Staging	Treatment Plan		
Types of HNSCC	Patient Stratification	First-line Treatment	Second-line and back-line treatment
Recurrent/Metastatic HNSCC	Non-NPC Recurrent HNSCC	• Surgery + radiotherapy; if surgery is unsuitable, then radiotherapy alone, or consider treatment methods for metastatic tumors	• /
Late Stage Local HNSCC	Patients Suitable for Surgery	• Oral cancer/T4 laryngeal cancer: Surgery combined with radiotherapy or chemoradiotherapy. • Oropharyngeal cancer/T1-3 laryngeal cancer/hypopharyngeal cancer: If suitable for cisplatin, prioritize surgery supported by radiotherapy or chemoradiotherapy, followed by radiotherapy with cisplatin, and then induction chemotherapy followed by radiotherapy alone; if cisplatin is unsuitable, then surgery.	• Suitable for cisplatin: Radiotherapy combined with cetuximab; for T1-3 laryngeal/hypopharyngeal cancer, induction chemotherapy followed by radiotherapy with cetuximab. • Unsuitable for cisplatin: Radiotherapy combined with cetuximab or radiotherapy alone.
Late Stage Local HNSCC	Patients Unsuitable for Surgery	• Suitable for cisplatin: Prioritize radiotherapy with cisplatin; for oropharyngeal/laryngeal cancer, consider induction chemotherapy followed by standalone chemotherapy; for nasopharyngeal cancer, consider induction chemotherapy followed by radiotherapy with cisplatin. • Unsuitable for cisplatin: Prioritize radiotherapy; for oropharyngeal/laryngeal cancer, consider radiotherapy with cetuximab; for nasopharyngeal cancer, consider radiotherapy with nedaplatin or carboplatin.	• Suitable for cisplatin: For oral cancer, induction chemotherapy followed by radiotherapy; for T1-3 laryngeal cancer, radiotherapy with cetuximab; for nasopharyngeal cancer, second-line treatment with radiotherapy plus cisplatin followed by adjuvant chemotherapy, and third-line treatment with radiotherapy plus cisplatin and nivolumab. • Unsuitable for cisplatin: For nasopharyngeal cancer, second-line treatment with radiotherapy combined with cetuximab or nivolumab

Source: CSCO, China Insights Consultancy

Overview of treatment path of HNSCC by CSCO

HNSCC | Treatment pathway

Overview of treatment path of HNSCC by CSCO

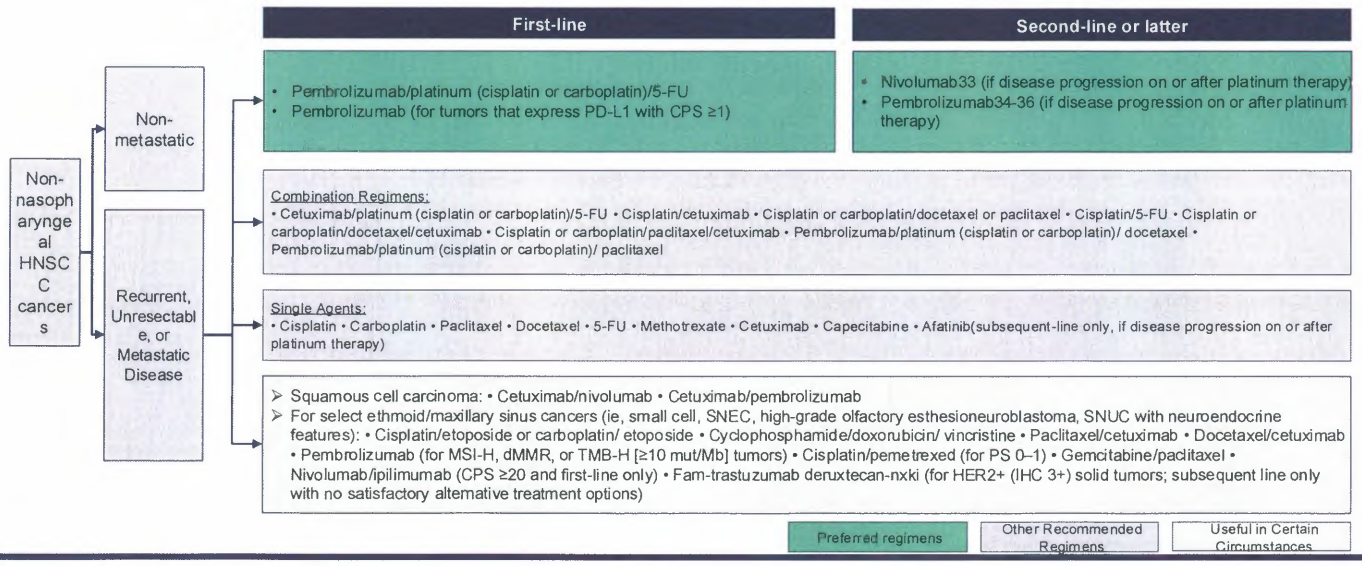
HNSCC Staging	Treatment Plan		
Types of HNSCC	Patient Stratification	First-line Treatment	Second-line and back-line treatment
Recurrent/Metastatic HNSCC	Non-NPC Recurrent HNSCC	• Surgery + radiotherapy; if surgery is unsuitable, then radiotherapy alone, or consider treatment methods for metastatic tumors	• /
Late Stage Local HNSCC	Patients Suitable for Surgery	• Oral cancer/T4 laryngeal cancer: Surgery combined with radiotherapy or chemoradiotherapy. • Oropharyngeal cancer/T1-3 laryngeal cancer/hypopharyngeal cancer: If suitable for cisplatin, prioritize surgery supported by radiotherapy or chemoradiotherapy, followed by radiotherapy with cisplatin, and then induction chemotherapy followed by radiotherapy alone; if cisplatin is unsuitable, then surgery.	• Suitable for cisplatin: Radiotherapy combined with cetuximab; for T1-3 laryngeal/hypopharyngeal cancer, induction chemotherapy followed by radiotherapy with cetuximab. • Unsuitable for cisplatin: Radiotherapy combined with cetuximab or radiotherapy alone.
Late Stage Local HNSCC	Patients Unsuitable for Surgery	• Suitable for cisplatin: Prioritize radiotherapy with cisplatin; for oropharyngeal/laryngeal cancer, consider induction chemotherapy followed by standalone chemotherapy; for nasopharyngeal cancer, consider induction chemotherapy followed by radiotherapy with cisplatin. • Unsuitable for cisplatin: Prioritize radiotherapy; for oropharyngeal/laryngeal cancer, consider radiotherapy with cetuximab; for nasopharyngeal cancer, consider radiotherapy with nedaplatin or carboplatin.	• Suitable for cisplatin: For oral cancer, induction chemotherapy followed by radiotherapy; for T1-3 laryngeal cancer, radiotherapy with cetuximab; for nasopharyngeal cancer, second-line treatment with radiotherapy plus cisplatin followed by adjuvant chemotherapy, and third-line treatment with radiotherapy plus cisplatin and nivolumab. • Unsuitable for cisplatin: For nasopharyngeal cancer, second-line treatment with radiotherapy combined with cetuximab or nivolumab

Source: CSCO, China Insights Consultancy

Overview of treatment path of non-nasopharyngeal HNSCC by NCCN

HNSCC | Treatment pathway

Overview of treatment path of non-nasopharyngeal HNSCC by NCCN



Source: China Insights Consultancy

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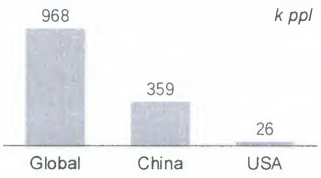
Overview of gastric cancer

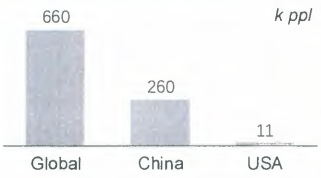
Introduction of gastric cancer

- Gastric cancer (GC) begins in the mucus-producing cells in the innermost lining of the stomach. Nearly all GC are adenocarcinomas, which are mainly caused by gastric mucosa barrier damage
- GC is the 5th most common cancer worldwide which is more common in countries in East Asia than in the US and other Western countries

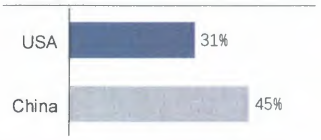
The incidence of GC, 2022



The mortality of GC, 2022



5-year survival rate of GC, 2016



Percent of Distant Stage (IV), 2018

Classification of GC by CSCO in 2022

Classification	HER2-positive	HER2-negative	dMMR/MSI*
Percentage	10%-20%	>80%	15%-20%

Symptoms

Early stage	• Heartburn • Epigastric pain • Nausea, anorexia
Advanced stage	• Loss of weight • Yellowing of the skin and eye • Dysphagia • Hematochezia

Risk factors

- Pathogenic infections includes but not limited to Helicobacter pylori (H. pylori) or Epstein Barr virus (EBV)
  - ➢ Helicobacter Pylori: 90% of cases of the non-cardia subtype are associated with the bacterium
  - ➢ Epstein Barr Virus: EBV has also been shown to influence gastric cancer progression in a subset of cases (10%)
  - ➢ Non-Pathogenic Influences: familial (~10%) or hereditary changes and environmental exposures

Note: * HER2: human epidermal growth factor receptor 2; dMMR/MSI: Defective mismatch repair/microsatellite instability population (whether HER2 positive or negative)

Source: Prz Gastroenterol., Globocan, China Insights Consultancy

Treatment path for gastric cancer

Treatment path for gastric cancer (CSCO)

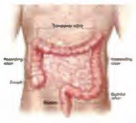
			First-line	Second-line		Third-line
Gastric cancer	Non-metastatic	~15% HER2 positive (IHC 3+/2+ and FISH+)	***Grade I*** • Trastuzumab + Oxaliplatin/ Cisplatin + 5-FU/ Capecitabine	***Grade I*** Has used trastuzumab: • Mono-chemotherapy • Paclitaxel + Remoxiumab	***Grade II*** Has not used trastuzumab: • Trastuzumab + Paclitaxel	***Grade I*** • Disitamab Vedotin • Apatinib • Nivolumab
		~85% HER2 negative	***Grade I*** • PD-L1 CPS≥5: FOLFOX/XELOX + Nivolumab/Sintilimab • PD-L1 TAP≥5: FOLFOX/XELOX + Tislelizumab • Oxaliplatin/Cisplatin + Fluorouracil • Paclitaxel/Docetaxel + Fluorouracil	***Grade I*** • Paclitaxel + Remoxiumab • Mono-chemotherapy		***Grade I*** • Apatinib • Nivolumab
	Advanced metastatic	15%-20% dMMR/MSI (HER2+ or HER2-)	***Grade II*** • Pembrolizumab	***Grade I*** • Envafolimab • Tislelizumab		

Source: CSCO; China Insights Consultancy

Overview of colorectal cancer

Overview of colorectal cancer

Introduction of ovarian cancer



- As the third most common malignancy and the second most deadly cancer, colorectal cancer (CRC) induces estimated 1.9 million incidence cases and 0.9 million deaths worldwide in 2020. The global number of new CRC cases is predicted to reach 3.2 million in 2040, based on the projection of aging, population growth, and human development. In 2020, CRC accounts for 10% of global cancer incidence and 9.4% of cancer deaths, just lower than lung cancer that comprises 18% of deaths

Symptoms:

- ☐ A change in bowel habits
- ☐ Blood in or on your stool (bowel movement)
- ☐ Diarrhea, constipation, or feeling that the bowel does not empty all the way
- ☐ Abdominal pain, aches, or cramps that don't go away
- ☐ Weight loss and you don't know why

Risk factors:

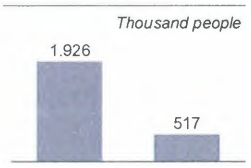
- ☐ Getting older
- ☐ Inflammatory bowel disease such as Crohn's disease or ulcerative colitis
- ☐ A personal or family history of colorectal cancer or colorectal polyps
- ☐ A genetic syndrome such as familial adenomatous polyposis (FAP) or hereditary non-polyposis colorectal cancer (Lynch syndrome)

Lifestyle factors that may contribute to an increased risk of colorectal cancer:

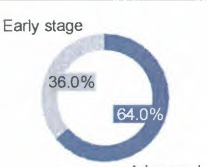
- ☐ Lack of regular physical activity
- ☐ A diet low in fruit and vegetables
- ☐ A low-fiber and high-fat diet, or a diet high in processed meats
- ☐ Overweight and obesity
- ☐ Alcohol consumption
- ☐ Tobacco use

Epidemiology

The incidence of CRC, 2022



Stage of CRC diagnosed

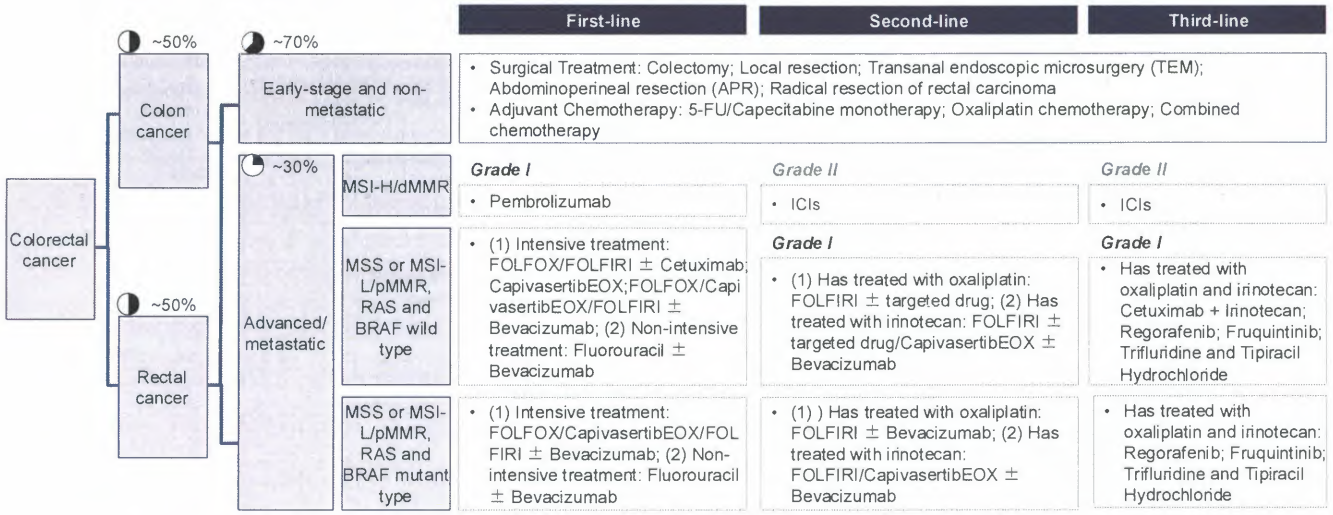


- In China, **CRC patients will usually observe cancer in the advanced stage**. Since the early symptoms of colorectal cancer are not significant, more obvious symptoms such as blood in the stool, abdominal mass, and persistent pain in the pelvis or lower abdomen will appear as the cancer gradually progresses to the advanced stage

Source: NCCN, Transl Oncol., China Insights Consultancy

Treatment path for colorectal cancer

Treatment path for colorectal cancer (CSCO)



Note: * ICIs: Immune checkpoint inhibitors

Source: CSCO; China Insights Consultancy

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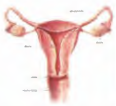
Overview of cervical cancer

Introduction of cervical cancer



➢ **Definition**: Cervical cancer, also known as uterine cervix cancer, is the most common gynecological malignancy that originates in the cervical region of the uterus. Early symptoms are not obvious, and symptoms such as vaginal bleeding appear in the late stage. It can be prevented by regular screening and vaccination. The incidence and mortality rates of cervical cancer rank first among malignant tumors of the female reproductive system in China, and it has shown a trend of rejuvenation in recent years.

Classification

- Squamous-cell carcinoma
  - Human papilloma virus-associated
  - Human papilloma virus-disassociated
- Adenocarcinoma and precancerous lesions
  - HIPV-associated adenocarcinoma and carcinoma in situ
- Other rare types
  - HIPV non-associated adenocarcinoma and carcinoma in situ

Causes, symptoms and risk factors

Causes	• Persistent high-risk HPV infection • Exogenous behavioral risk factors
Symptom	• Vaginal bleeding, • Abnormal leukorrhea • Corresponding symptoms due to tumor invasion of other organs
Risk factors	• Carcinogenicity grade of the human papillomavirus type • Immune status • Presence of other sexually transmitted infections • Number of births • Age at first pregnancy • Use of hormonal contraceptives • Smoking

Epidemiology

- The number of new cases of cervical cancer in the **US** in 2022 reach **66,000**.
- The number of new cases of cervical cancer around the **world** in 2022 reach **662,000**.

Source: GLOBOCAN; Chin J Oncol; IARC; China Insights Consultancy

Overview of treatment path of recurrent or metastatic cervical cancer

Overview of treatment path of recurrent or metastatic cervical cancer by CSCO

	Level I	Lever II	Level III
First-line Therapy	• Cisplatin + Paclitaxel+ Bevacizumab or • Carboplatin + Paclitaxel + Bevacizumab or • Cisplatin + Paclitaxel or • Carboplatin + paclitaxel (previously used cisplatin)	• Pembrolizumab combined with chemotherapy + cisplatin + paclitaxel ± bevacizumab (applicable to PD-L1 positive tumors) • Pembrolizumab combined with chemotherapy + carboplatin + paclitaxel ± bevacizumab (applicable to PD-L1 positive tumors) • Topotecan + paclitaxel + bevacizumab • Topotecan + paclitaxel • Cisplatin + topotecan	• Cisplatin • carboplatin • Paclitaxel
Second-line Therapy		• Albumin-bound paclitaxel • Docetaxel • Gemcitabine • Pemetrexed • Topotecan • Cadonilimab (recurrent or metastatic cervical cancer that has failed with platinum-based chemotherapy) • Serplulimab (adults with MSI-H or dMMR solid tumors) • Envafolimab (MSI-H or dMMR solid tumors) • Participate in clinical studies	• Ifosfamide • Mitomycin • Fluorouracil • Vinorelbine • Irinotecan • Zimberelimab • Pembrolizumab (for tumors that are PD-L1 positive or MSI-H or dMMR) • Nivolumab (for PD-L1-positive tumors)
Others			• Pembrolizumab (for TMB-H tumors) • Larotrectinib or Entrectinib (for tumors with *NTRK* gene fusion)

Source: CSCO; China Insights Consultancy

Overview of treatment path of recurrent or metastatic cervical cancer

Overview of treatment path of recurrent or metastatic cervical cancer by NCCN

Recurrent or metastatic cervical cancer

Squamous Cell Carcinoma, Adenocarcinoma, or Adenosquamous Carcinoma

First-line Therapy

Preferred Regimens

- **PD-L1–positive tumors**
  - Pembrolizumab + cisplatin/paclitaxel ± bevacizumab
  - Pembrolizumab + carboplatin/paclitaxel ± bevacizumab
- **Cisplatin/paclitaxel/bevacizumab**
- **Carboplatin/paclitaxel/bevacizumab**

Other Recommended Regimens

- **Cisplatin/paclitaxel**
- **Carboplatin/paclitaxel** (for patients who have received prior cisplatin therapy)
- **Topotecan/paclitaxel/bevacizumab**
- **Topotecan/paclitaxel**
- **Cisplatin/topotecan**
- **Cisplatin**
- **Carboplatin**

Second-line or Subsequent Therapy

Preferred Regimens

- **Pembrolizumab** for TMB-H tumors or PD-L1–positive or MSI-H/dMMR tumors
- **Tisotumab vedotin-tftv**
- **Cemiplimab**

Other Recommended Regimens

- **Bevacizumab**
- **Paclitaxel**
- **Albumin-bound paclitaxel**
- **Docetaxel**
- **Fluorouracil**
- **Gemcitabine**
- **Pemetrexed**
- **Topotecan**
- **Vinorelbine**
- **Irinotecan**

Useful in Certain Circumstances

- **PD-L1–positive tumors**
  - Nivolumab
- **HER2-positive tumors (IHC 3+ or 2+)**
  - Fam-trastuzumab deruxtecan-nxki
- **RET gene fusion-positive tumors**
  - Selpercatinib
- ***NTRK* gene fusion-positive tumors**
  - Larotrectinib
  - Entrectinib

Small Cell NECC

First-line Therapy

- **Preferred Regimens**
  - Cisplatin/etoposide
  - Carboplatin/etoposide
- **Other Recommended Regimens**
  - Cisplatin/etoposide + atezolizumab (or durvalumab)
  - Carboplatin/etoposide + atezolizumab (or durvalumab)
  - Topotecan/paclitaxel/bevacizumab
  - Cisplatin/paclitaxel
  - Carboplatin/paclitaxel (for patients who have received prior cisplatin therapy)

Second-line or Subsequent Therapy

- **Other Recommended Regimens**
  - Bevacizumab
  - Albumin-bound paclitaxel
  - Docetaxel
  - Topotecan
  - Topotecan/paclitaxel
  - Cisplatin/topotecan
  - Cisplatin
  - Carboplatin
  - Paclitaxel
  - Irinotecan

Source: NCCN; China Insights Consultancy

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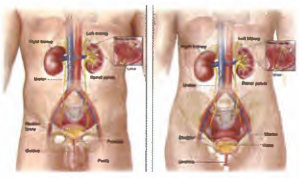
Overview of of urothelial carcinoma

Introduction of of urothelial carcinoma



- Bladder cancer occurs when cells in the bladder start to grow without control. The bladder is a hollow, balloon-shaped organ in the lower part of the abdomen that stores urine. The bladder has a muscular wall that allows it to get larger to store urine made by the kidneys and to shrink to squeeze urine out of the body. Bladder cancer most often begins in the cells (urothelial cells) that line the inside of your bladder. Urothelial cells are also found in your kidneys and the tubes (ureters) that connect the kidneys to the bladder. Almost all bladder cancers are urothelial carcinomas
- UC can be divided into upper urothelial cancer (renal pelvis, ureter) and lower urothelial cancer (bladder, urethra). Bladder cancer is divided into non-muscle-invasive bladder cancer (NMIBC) and muscle-invasive bladder cancer (MIBC).

Symptoms and Causes

- Low-grade fever
- A lump or mass in kidney
- Painful urination (dysuria)
- Tiredness
- Persistent back pain
- Weight loss

- Cigarette smoke: Smoking cigarettes increases your risk of developing urinary system cancers linked to urothelial carcinoma.
- Exposure to certain chemicals: People who work with certain chemicals used in dyes, rubber, leather, paint, some textiles and hairdressing.

Epidemiology

UC affects a large and underserved patient population worldwide

- Bladder urothelial carcinoma accounts for more than 90% of bladder cancers.
- The number of new cases of bladder cancer around the **world** will reach **614,000** in 2022, making it the ninth most common cancer around the world.
- The number of new cases of bladder cancer in the **US** will reach **80,000** in 2022.

In 2022, the number of new cases of bladder cancer is 92,900, with an **incidence rate of 3.48/10w**

In 2022, the number of **deaths** from bladder cancer reached **41,400**, with a **mortality rate of 1.33/10w**

Source: GLOBOCAN; Chin J Oncol; IARC; China Insights Consultancy

Overview of treatment path of locally advanced or metastatic urothelial carcinoma

Overview of treatment path of locally advanced or metastatic urothelial carcinoma by CSCO

Locally advanced or metastatic urothelial carcinoma

		Level I	Level II	Level III
First-line Therapy	Cisplatin eligible	• Gemcitabine + Cisplatin • dd-MVAC (with G-CSF support)	• Gemcitabine + Paclitaxel + Cisplatin	• Disitamab Vedotin + Toripalimab
	Cisplatin ineligible	• Gemcitabine + Carboplatin	• Gemcitabine + Paclitaxel • Gemcitabine • Pembrolizumab	• Disitamab Vedotin + Toripalimab • Atezolizumab
Second-line Therapy	Previous chemotherapy failure	• Clinical study	• Toripalimab • Tislelizumab • Pembrolizumab • Vedolizumab	• Nivolumab • Erdafitinib • Disitamab Vedotin + Toripalimab • Enfortumab Vedotin
	Previous immunotherapy failure	• Clinical study	• Gemcitabine + Cisplatin • Gemcitabine + Carboplatin • Enfortumab Vedotin	• Vinflunine • Pemetrexed • Taxane chemotherapy drugs • Erdafitinib
Third-line Therapy	After failure of chemotherapy and immunotherapy	• Clinical study	• Disitamab Vedotin Enfortumab Vedotin • Sacituzumab govitecan-hziy	• Erdafitinib

Disease stabilization or objective response after 4-6 cycles of first-line chemotherapy

Level I: Clinical study
Level II: Avelumab
Level III: Pembrolizumab

Source: CSCO; China Insights Consultancy

Overview of treatment path of locally advanced or metastatic urothelial carcinoma

Overview of treatment path of locally advanced or metastatic urothelial carcinoma by NCCN

Locally Advanced or Metastatic Disease (Stage IV)

First-Line

	Cisplatin eligible	Cisplatin ineligible
Preferred	• Pembrolizumab and enfortumab vedotin-ejfv	
Recommended	• Gemcitabine and cisplatin + avelumab maintenance therapy • Nivolumab, gemcitabine, and cisplatin + nivolumab maintenance therapy	• Gemcitabine and carboplatin + avelumab maintenance therapy
Useful under certain circumstances	• DDMVAC with growth factor support + avelumab maintenance therapy	• Gemcitabine • Gemcitabine and paclitaxel • Ifosfamide, doxorubicin, and gemcitabine • Pembrolizumab • Atezolizumab

Second-Line

	Post-platinum or other chemotherapy	Post-checkpoint inhibitor	
Preferred	• Pembrolizumab	Preferred regimens for chemotherapy naïve	Cisplatin ineligible: • Enfortumab vedotin-ejfv29 • Gemcitabine and carboplatin • Erdafitinib Cisplatin eligible: • Gemcitabine and cisplatin • DDMVAC with growth factor support • Erdafitinib
Alternative preferred	• Immune checkpoint inhibitor: Nivolumab or Avelumab • Erdafitinibd • Enfortumab vedotin-ejfv		
Other recommended	• Paclitaxel or docetaxel • Gemcitabine • Pembrolizumab and enfortumab vedotin-ejfv	Other recommended	• Paclitaxel or docetaxel • Gemcitabine
Useful under certain circumstance based on prior medical therapy	• Ifosfamide, doxorubicin, and gemcitabine • Gemcitabine and paclitaxel • Gemcitabine and cisplatin • DDMVAC with growth factor support	Useful under certain circumstances based on prior medical therapy	• Ifosfamide, doxorubicin, and gemcitabine • Gemcitabine and paclitaxel

Subsequent-Line

Preferred regimens
- Enfortumab vedotin-ejfv
- Erdafitinib

Other recommended regimens
- Sacituzumab govitecan-hziy
- Gemcitabine
- Paclitaxel or docetaxel
- Ifosfamide, doxorubicin, and gemcitabine
- Gemcitabine and paclitaxel
- Gemcitabine and cisplatin
- DDMVAC with growth factor support

Source: NCCN; China Insights Consultancy

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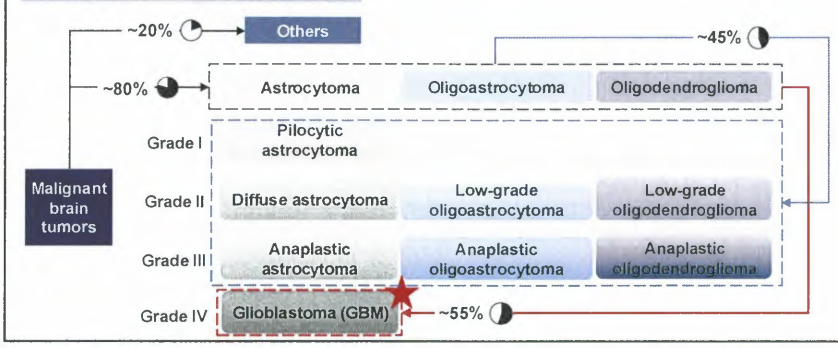
Glioma is the most common primary craniocerebral tumor, the 5-year survival rate largely depends on the classified grade, and glioblastoma usually only accounts for around 7.5% of 5-year survival rate

Overview of glioma

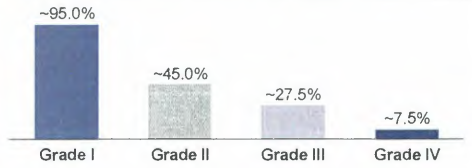
Definition

- **Brain glioma** is a tumor originating from brain glial cells, which is the most common primary tumor caused by brain and spinal cord glial canceration. The risk factors include congenital genetic risk factors and environmental carcinogenic factors
- Gliomas can vary in severity from low-grade (less aggressive) to high-grade (more aggressive) tumors, and can be classified based on the type of glial cell they rise from

Histological classification of gliomas



Five-Year survival rate for glioma



- Glioblastoma (GBM) is the most common and most lethal malignant glioma, accounting for **about 55%** of gliomas.
- 5-year survival rate for glioma varies widely depending on the grade and other factors, but ranges from **5% to 95%**

Source: Brain Tumor Research; China Insights Consultancy

Treatment path for Glioma

Treatment path for Glioma (CSCO)

		Grade I	Grade II	Grade III	Grade IV	Supportive Therapy
First-line	Surgical	Treatment Method: Maximum safe resection of the tumor Follow-up Treatment: Depending on the molecular characteristics of the tumor, the extent of resection, and the patient's condition, radiotherapy or chemotherapy may be required				
First-line	Radiotherapy	(not completely resected or age ≥ 40 years)		(post-surgery)		
First-line	Radiotherapy	Early radiotherapy may be conducted based on risk assessment		Post-surgical radiotherapy, for GBM a total dose of 54-60 Gy is recommended		
First-line	Pharmacological Treatment	(with high-risk factors)		(post-surgery)		Including symptom control, rehabilitation therapy, psychosocial support, etc.
First-line	Pharmacological Treatment	PCV regimen or TMZ		TMZ (Stupp protocol for GBM)		
Second-line and beyond	Re-treatment of Recurrent Glioma					
Second-line and beyond	Immunotherapy			Includes tumor vaccines, oncolytic viruses, immune checkpoint inhibitors, and CAR-T cell therapy, among others		
Second-line and beyond	TTFields Therapy				Utilizing a portable device to generate a medium-frequency, low-intensity electric field for tumor treatment	

Source: CSCO; China Insights Consultancy

Unmet needs of Glioma

Unmet needs of Glioma

High recurrence rate and short survival period

- The average survival time for glioblastoma multiforme (GBM) is only 12-15 months, and the recurrence rate is extremely high. Existing treatment methods are difficult to completely cure or control the disease for a long period.
- The infiltrative growth characteristics of gliomas make it difficult to distinguish the tumor from the surrounding normal tissue, making it hard to completely remove during surgery, thereby increasing the risk of recurrence.

Blood-brain barrier limitations and systemic side effects

- The physiological protective function of the BBB prevents the brain delivery of most drugs, and although the blood-tumor barrier (BTB) forms in certain circumstances and allows drugs to pass through, its permeability is heterogeneous, making strategies relying on BTB to achieve effective drug concentrations difficult to succeed.
- Due to the restrictions of the BBB, many anticancer drugs need to be used at higher doses to ensure that sufficient drug concentrations reach the tumor site. This can lead to an increase in systemic toxicity, such as nausea, vomiting, bone marrow suppression, etc.

Uncertainty of therapeutic effects

- Gliomas are a group of heterogeneous diseases, and even gliomas of the same pathological type and grade can have significant differences in therapeutic effects.
- Factors such as age, tumor location, pathological grading, extent of surgery, tumor size, and other individual patient characteristics can affect therapeutic outcomes and prognosis.

Source: Medical Research Review; China Insights Consultancy

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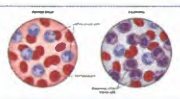
Hematologic malignancy

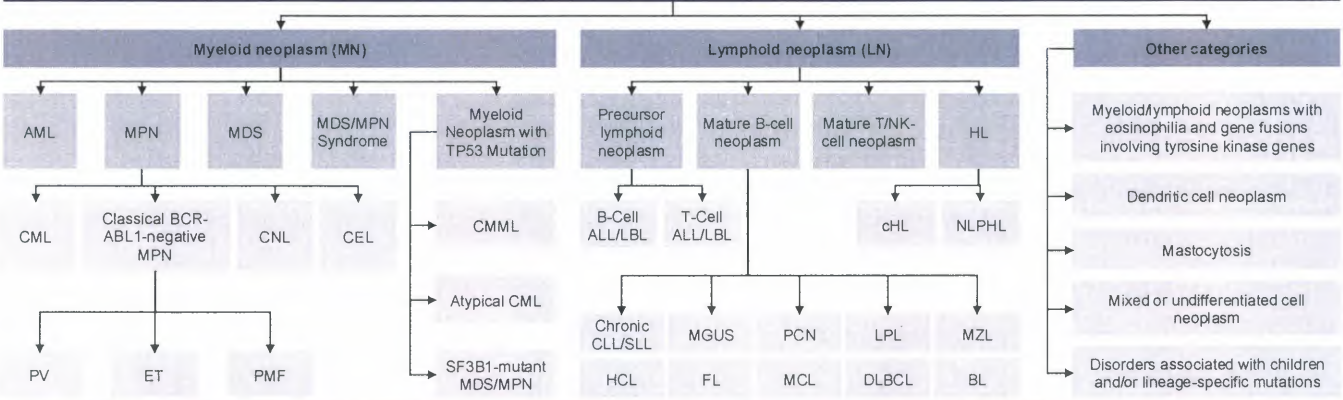
- Hematologic malignancies begin in the cells of the immune system or in blood-forming tissue, such as the bone marrow

Introduction to hematologic malignancy



- **Hematologic malignancies** begin in the cells of the immune system or in blood-forming tissue, such as the bone marrow
- Common types of hematologic cancer are **lymphoma, myeloma, and leukemia**

The main classifications of hematologic cancer



Source: China Insights Consultancy

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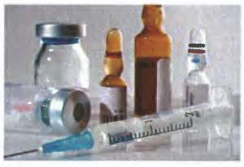
Overview of anesthetic drugs

Anesthetic drug | Overview

Overview of anesthetic drugs



Introduction

- Anesthesia drugs are essential in medical practice to induce a temporary loss of sensation or awareness, facilitating the performance of surgical procedures and other interventions that would otherwise cause significant pain or distress to patients. These drugs can be administered through various modalities, including inhalation, intravenous injection, and regional nerve block techniques
- The administration and choice of anesthesia depend on factors such as the type of surgery, patient health status, and expected duration of the procedure. Advances in anesthesia drugs and techniques continue to improve patient safety, recovery times, and overall outcomes in surgical care

Classification of anesthetic drugs

	Anesthetic drugs	
	General anesthetics	Local anesthetics
Definition	• Anesthetics that can induce a reversible state of unconsciousness	• Anesthetics that cause localized numbness
Mechanism	• Acts on the synapses between nerve cells in different ways, inhibits the brain or nerve centers by changing the release of neurotransmitters in the synapses, making them unable to perceive pain, thereby achieving the purpose of clinical analgesia.	• By blocking the occurrence and conduction of local sensory nerve impulses in the human body, the pain signal cannot be transmitted to the cerebral cortex, reversibly causing the disappearance of pain in local tissues
Representative drugs	• Inhaled anesthetics: ether, halothane, etc. • Intravenous anesthetics: sodium thiopental, ketamine, etc.	• Lidocaine, bupivacaine, ropivacaine, tetracaine, etc.

Source: China Insights Consultancy

Overview of anesthetic drug market in China

Updated 2024 base year

Anesthetic drug | Market size

Market size of anesthetic drug in China, 2018-2033E

	2018-2024	2024-2033E
Anesthetic Drug Market in China	5.3%	5.5%

Billion RMB

Source: Menet; China Insights Consultancy

Overview of anesthetic drug market in China

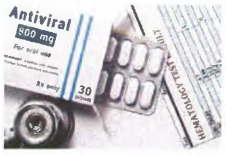
Entry barriers	
Stringent regulatory requirements barrier	• The anesthesia drugs market is highly regulated, with complex frameworks imposed by health authorities. Complying with these stringent regulations can significantly increase development costs and timelines, posing a major barrier to entry.
High research and development costs barrier	• Developing new anesthesia drugs requires extensive research and clinical trials to ensure safety and efficacy. The high costs associated with R&D act as a deterrent for new entrants, as they need to invest substantial resources before generating any revenue.
Established brands and customer loyalty barrier	• Major pharmaceutical companies have well-established brands and loyal customer bases in the anesthesia drugs market. Breaking into this market and gaining market share can be challenging for new players, as healthcare providers often prefer familiar and trusted brands.

Market drivers	
Increasing prevalence of chronic diseases	• The growing incidence of chronic conditions such as cancer, cardiovascular diseases, and osteoarthritis is a major driver for the anesthetic drugs market. These diseases often require surgical interventions, which in turn increases the demand for general anesthesia drugs.
Advancements in R&D and funding	• Increasing funding from private and government organizations for the development of pharmaceutical manufacturing, as well as advancements in R&D activities for the formulation of new anesthetic drugs, are propelling the growth of the market.
Emphasis on patient safety and regional anesthesia	• Developments in anesthetic drugs and techniques that minimize side effects and improve recovery times, as well as the growing interest in regional anesthesia, are contributing to the market's expansion.

Source: China Insights Consultancy

Overview of antiviral drugs

Overview of antiviral drugs



Introduction

- Antiviral drugs play a critical role in combating infections caused by bacteria, viruses, fungi, and parasites, thus safeguarding public health. They are indispensable in preventing and treating infectious diseases, which, if left unchecked, can lead to significant morbidity and mortality
- Antiviral drugs encompass a wide range of categories, including antibiotics, antivirals, antifungals, and antiparasitics. These medications work through various mechanisms, such as inhibiting the growth of pathogens, disrupting their cellular structures, or interfering with their metabolic pathways. The global demand for antiviral drugs is driven by factors such as the prevalence of infectious diseases, the emergence of drug-resistant strains, and the continuous need for new and more effective treatments

Classification of antiviral drugs

	Antiviral drugs			
	Antibiotics	**Antivirals**	**Antifungals**	**Antiparasitics**
Mechanism	• Inhibition of Cell Wall Synthesis • Inhibition of Protein Synthesis • Alteration of Cell Membranes • Inhibition of Nucleic Acid Synthesis • …	• Increase the cell's resistance to a virus, suppress the virus adsorption or its diffusion into the cell and its deproteinization process in the cell • …	• Alteration in drug target • Alteration in sterol biosynthesis • Reduction in the intercellular concentration of target enzyme • …	• Disrupt critical cellular functions, such as DNA replication or protein synthesis, causing metabolic dysfunction and parasite death • …
Representative drugs	• Gentamicin, Cephalexin, Ertapenem, etc.	• Indinavir, Nevirapine, etc.	• Terbinafine, Flucytosine, etc.	• Amodiaquine, Clindamycin-quinine, etc.

Source: China Insights Consultancy

Updated 2024 base year

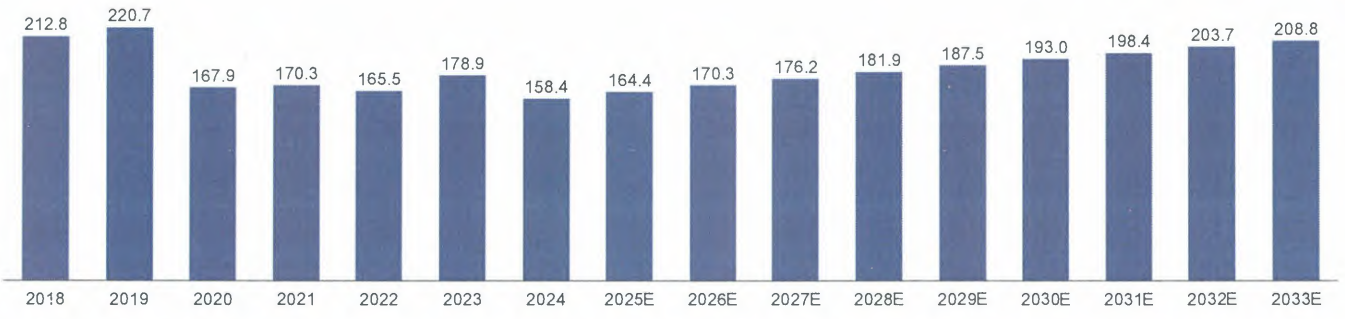
Overview of anti-infective drug market in China

Anti-infective Drug | Market size

Market size of anti-infective drug in China, 2018-2033E

	2018-2024	2024-2033E
Anti-infective Drug Market in China	-3.4%	3.2%

Billion RMB



- The market experienced a contraction from 2020 to 2022 due to the combined impact of VBP policies, which resulting in a reduction in drug prices, and the COVID-19 pandemic, which disrupted supply chains and reduced healthcare facility access

Source: China Insights Consultancy

Overview of antiviral drug market in China

Antiviral Drug | Barriers & drivers

Entry barriers

Technical barrier	• The research and development of antiviral drugs requires a high degree of technical strength and expertise. Newly entered companies need to invest a lot of money and time to establish R&D teams, accumulate technical experience, and conduct clinical trials.
Market entry barrier	• The antiviral drug market has formed a relatively stable competitive landscape. Newly entered companies need to invest a lot of money to establish their brand image, develop sales channels, and deal with fierce competition from competitors.
Regulations and policy barrier	• The antiviral drug industry is subject to strict regulations and policies, including drug registration, approval, production, sales and other aspects. Newly entered companies need to understand and comply with these regulations and policy requirements, otherwise they will face serious legal risks and business risks.

Market drivers

Demand for prevention and treatment of infectious diseases	• With the continuous outbreak and epidemic of infectious diseases around the world, such as influenza, AIDS, and new coronavirus, the demand for antiviral drugs continues to increase. Therefore antiviral drugs play a vital role in the prevention and treatment of infectious diseases.
Technological innovation	• In the process of antiviral drug R&D, technological innovation is an important driving force. With the continuous advancement of key technologies such as molecular biology, genetic engineering, and immunology, the R&D of antiviral drugs has become more efficient and precise.
Policy support	• Governments have continued to increase their support for the antiviral drug industry and promote the development of the industry through policy guidance, capital investment, etc. Especially, the Chinese government think highly of the prevention and control of infectious diseases.

Source: China Insights Consultancy

Overview of Traditional Chinese Medicine (TCM)

Overview of Traditional Chinese Medicine (TCM)

Introduction

- Traditional Chinese Medicine (TCM) is a complete medical system that has been used to diagnose, treat, and prevent illnesses for more than 2,000 years. Chinese herbology is the theory of traditional Chinese herbal therapy, which accounts for the majority of treatments in TCM. Other practices include acupuncture, diet and massage, etc. Herbal medicine is the use of plants to treat disease and enhance general health and wellbeing, Chinese herbal mixtures have been used to treat irritable bowel syndrome, Tourette syndrome, and many other disorders. For example, some evidence suggests that the herb Huangqi (黄芪) and Chaihuang (柴黄) may improve quality of life for patients. The rising global acceptance of traditional Chinese medicine has bolstered the market potential for both Huangqi and Chaihuang, positioning them as valuable assets in preventive and therapeutic healthcare, supported by modern pharmacological studies and a long history of safe usage

Introduction of representative TCM

Representative TCM	Description
Huangqi (黄芪), also known as Astragalus	• Huangqi is renowned for its immunomodulatory and anti-inflammatory properties, traditionally used to enhance immune function. It is prescribed for chronic fatigue, respiratory infections, and as an adjunct therapy in cancer treatment. The growing interest in natural and holistic health solutions has increased the demand for Huangqi-based products
Chaihuang (柴黄), a formulation combining Bupleurum (Chaihu) and Huangqin	• Chaihuang is valued for its heat-clearing and detoxifying properties, effective in treating fever, inflammation, and liver disorders. It is commonly used for upper respiratory tract infections, hepatitis, and digestive issues, working by modulating the immune response and exerting anti-inflammatory effects

Source: China Insights Consultancy

Key policies of the PRC government in promoting traditional Chinese medicine (2024-2025)

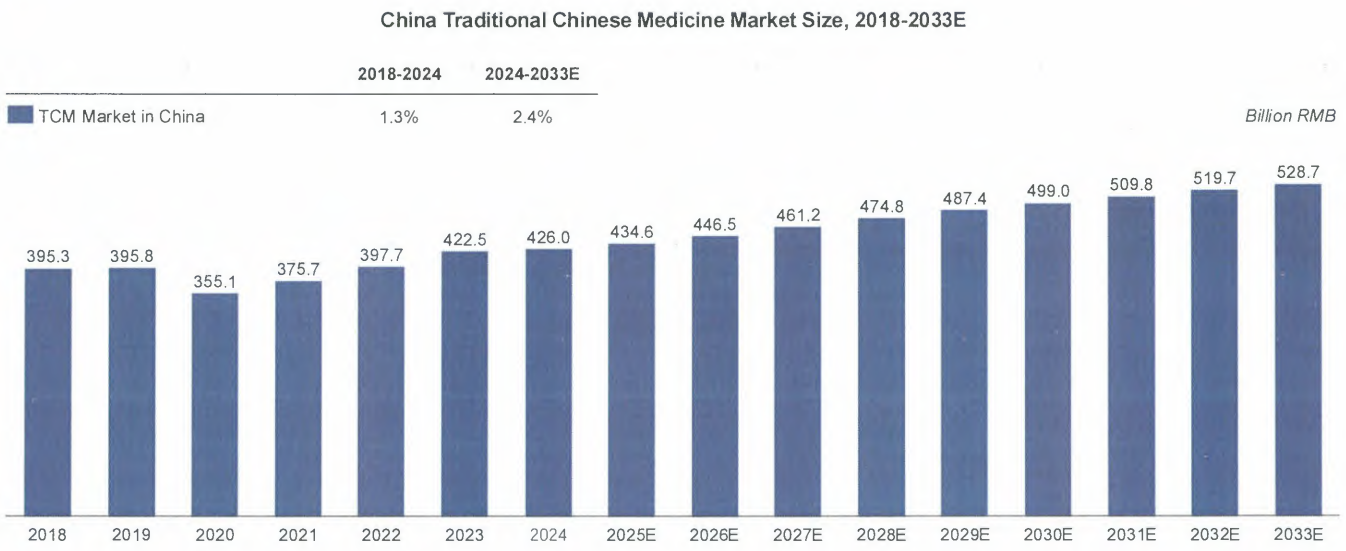
20250925 Updated

Date	Policy	Main Content
Mar 2025	State Council General Office Notice on Improving the Quality of TCM and Promoting High-Quality Development of the TCM Industry (国务院办公厅关于提升中药质量促进中医药产业高质量发展的意见)	Optimizes procurement and tendering policies for TCM products, implements full-process traceability and monitoring for Chinese patent medicines, encourages brand building, clinical value evaluation, technology-driven innovation, and supports high-quality industrial development across the TCM sector.
Jul 2024	Special Provisions on the Management of TCM Standards (《中药标准管理专门规定》)	Strengthens standardization management across the entire TCM production chain, including raw herbs, decoction pieces, and processing methods; promotes production upgrades, quality enhancement, scientific research on TCM standards, and international standard alignment.
Jul 2024	Action Plan for Standardization of Traditional Chinese Medicine (2024-2026) (《中医药标准化行动计划（2024-2026年）》)	Establishes a comprehensive TCM standards system covering national, industry, regional, and group levels; encourages development of regional and local TCM standards, integration with local medicinal resources, and alignment with technological innovation to improve product quality and clinical consistency.

Source: China Insights Consultancy

Updated 2024 base year

China Traditional Chinese Medicine Market Size, 2018-2033E



Source: China Insights Consultancy

Overview of processed TCM market in China

Processed TCM | Barriers & drivers

Entry barriers

Raw material sourcing barrier	• Securing a reliable and high-quality supply of raw medicinal herbs and materials is crucial for Processed TCM manufacturers. New entrants may face challenges in establishing trusted relationships with suppliers, ensuring traceability, and maintaining consistent quality standards for their raw materials.
Brand recognition and market access barrier	• The Processed TCM market in China is dominated by well-established brands with strong brand recognition and loyal customer bases. New entrants may struggle to differentiate their products, build brand awareness, and gain access to distribution channels controlled by established players.
Distribution channel barrier	• Establishing a robust distribution network and gaining access to traditional medicine practitioners, hospitals, and retail channels can be a significant hurdle for new entrants. Existing players often have well-established relationships and distribution agreements that create barriers for newcomers.

Market drivers

Cultural and historical significance	• As an integral part of Chinese heritage, TCM is trusted and utilized by many for its traditional approach to healthcare. The Chinese government promotes TCM as a national treasure and includes it in national health policies, which reinforces its importance and drives market demand.
Integration with modern medicine	• The integration of TCM with modern medical practices is creating a dual approach to healthcare, increasing the demand for processed TCM products.
Health and wellness trends	• With a growing focus on holistic health and wellness, consumers are seeking natural and integrative medicine options. Processed TCM products, which often emphasize herbal remedies and natural components, are benefiting from this trend.

Source: China Insights Consultancy

Overview of parenteral nutrition

Overview of parenteral nutrition

Introduction

- Parenteral nutrition (PN) is a life-sustaining therapy that provides nutritional support to patients who are unable to meet their nutritional needs through oral or enteral routes. Medium and long chain fat emulsion injections are a critical component of parenteral nutrition, supplying essential fatty acids and calories that help maintain energy balance, support cellular functions, and modulate immune responses. These emulsions are composed of triglycerides derived from medium-chain fatty acids (MCFAs) and long-chain fatty acids (LCFAs), offering a balanced and efficient energy source. The integration of both MCFAs and LCFAs enhances the metabolic profile and tolerance of the fat emulsion, making it suitable for a wide range of patients, including those with impaired fat metabolism

Examples of clinical conditions requiring PN

Condition	Mechanism/Indication for PN	Example
Short bowel Intestinal fistula Extensive intestinal mucosal disease	Reduction of absorption capacity Loss of nutrients	Short bowel syndrome, ischemic bowel, complications of colorectal or bariatric surgery, high-output stoma, high-output intestinal fistula Radiation or chemotherapy-related enteritis, mucositis, autoimmune enteropathy, gut graft-versus-host disease
Mechanical bowel obstruction	Blockage of intestinal lumen Recurrent vomiting	Malignant bowel obstruction, intestinal adhesions, stenosis or strictures, inflammatory disease, peritoneal carcinomatosis
Motility disorders	Failure to tolerate adequate oral or enteral intake Recurrent vomiting	Functional gastrointestinal disorders, ileus, scleroderma, acute pancreatitis, post-operatively, gastrointestinal failure associated with critical illness, pseudo-obstruction, adhesive disease
Bowel rest needed	Need to restrict oral or enteral intake	Ischemic bowel, perioperative status, acute pancreatitis, chylous fistula
Other	Failure of oral or enteral nutrition	Unable to achieve or maintain secure oral or enteral access

Source: Nutrients, China Insights Consultancy

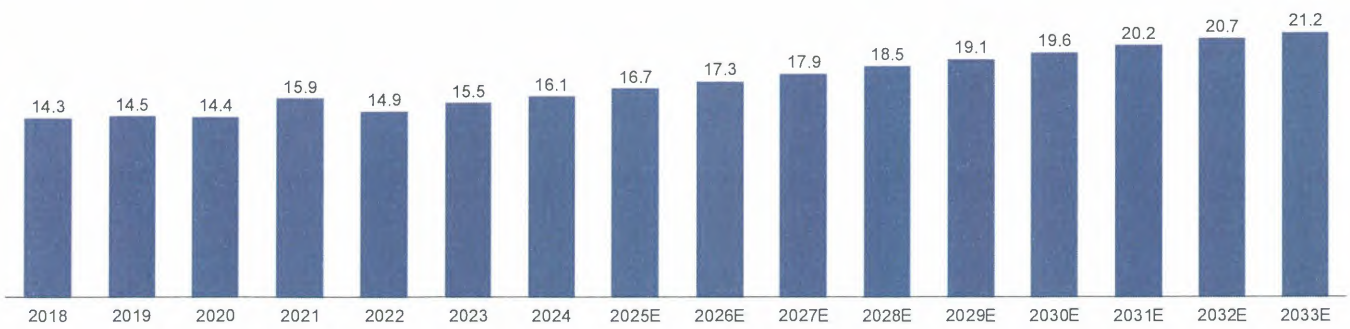
Updated 2024 base year

Overview of parenteral nutrition drug market in China

Overview of parenteral nutrition drug market in China

	2018-2024	2024-2033E
parenteral nutrition drug market	2.0%	3.1%

Billion RMB



Source: China Insights Consultancy

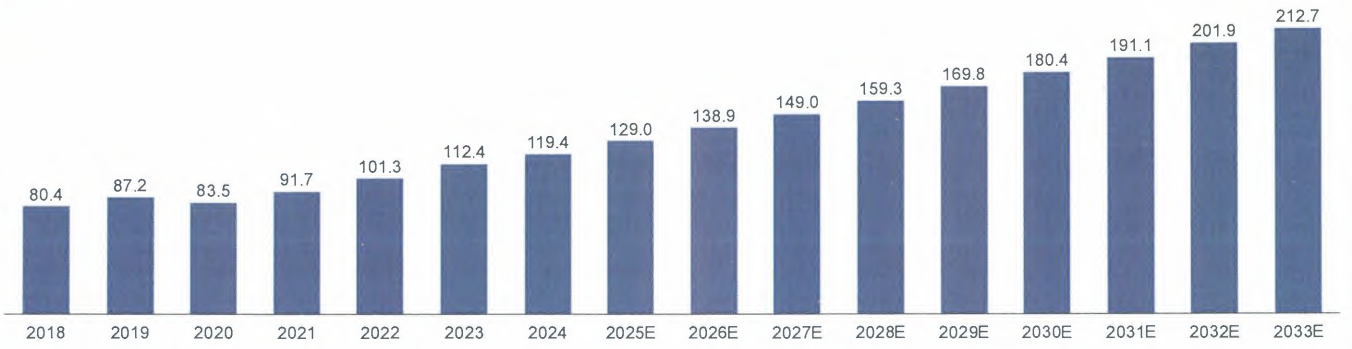
Updated 2024 base year

Overview of pediatric drugs market in China

Market size of pediatric drug in China, 2018-2033E

	2018-2024	2024-2033E
Pediatric drug market	6.8%	6.6%

Billion RMB



Source: China Insights Consultancy

Updated 2024 base year

Competitive landscape of propofol emulsion injection in China, top 5 players, 2024

Competitive landscape of propofol emulsion injection in China, top 5 players, in terms of revenue, 2024

Drug Name	Specification	Company	First approval year	National VBP inclusion	Market share in 2024
Propofol Injectable Emulsion	20ml:0.2g 50ml:0.5g 50ml:1.0g	ASPEN PHARMA	2017	-	42.4%
Propofol Injectable Emulsion	20ml:0.2g 50ml:0.5g 50ml:1.0g	Fresenius Kabi Austria GmbH	2017	-	21.3%
Propofol Injectable Emulsion	10ml:0.1g 10ml:0.2g 20ml:0.2g 50ml:0.5g 50ml:1.0g	西安力邦制药 Xi'an Libang Pharmaceutical	1999	2023.11 (20ml:0.2g)	14.7%
Propofol Injectable Emulsion	10ml:0.1g 20ml:0.2g 50ml:0.5g	四川国瑞药业 Sichuan Guorui Pharmaceutical	2003	2023.11 (50ml:0.5g)	13.3%
Propofol Injectable Emulsion	10ml:0.2g 20ml:0.2g 20ml:0.4g 50ml:0.5g 50ml:1.0g	广东嘉博制药 Jiabo Pharmaceutical	2005	2023.11 (20ml:0.2g)	3.7%

Note: Propofol Injectable Emulsion was enrolled in the 9th round of VBP program
Sichuan Guorui is a subsidiary of Biokin Pharmaceutical.

Source: NMPA; China Insights Consultancy

Updated 2024 base year

Competitive landscape of propofol medium and long chain fat emulsion injection in China, top 5 players, 2024

Competitive landscape of propofol medium and long chain fat emulsion injection in China , top 5 players, in terms of revenue, 2024

Drug Name	Specification	Company	First approval year	National VBP inclusion	Market share in 2024
Propofol Medium and Long Chain Fat Emulsion Injection	10ml:0.1g 20ml:0.2g 50ml:0.5g 50ml:1.0g 100ml:1.0g	Fresenius Kabi Austria GmbH	2015	2021.01 (20ml:0.2g)	36.2%
Propofol Medium and Long Chain Fat Emulsion Injection	10ml:0.1g 20ml:0.1g 20ml:0.2g 50ml:0.5g 100ml:1.0g	四川国瑞药业 Sichuan Guorui Pharmaceutical	2014	-	21.8%
Propofol Medium and Long Chain Fat Emulsion Injection	10ml:0.1g 20ml:0.2g 50ml:0.5g 50ml:1.0g 100ml:1.0g	广东嘉博制药 Jiabo Pharmaceutical	2013	-	13.7%
Propofol Medium and Long Chain Fat Emulsion Injection	20ml:0.2g	江苏盈科生物制药 Jiangsu Yingke Biopharmaceutical	2020	2021.01 (20ml:0.2g)	10.9%
Propofol Medium and Long Chain Fat Emulsion Injection	20ml:0.2g 50ml:0.5g 50ml:1.0g	扬子江药业集团 Yangtze River Pharmaceutical	2021	2021.01 (20ml:0.2g)	8.4%

Note: Propofol Medium and Long Chain Fat Emulsion Injection was enrolled in the 4th round of VBP program;
Sichuan Guorui is a subsidiary of Biokin Pharmaceutical.

Source: NMPA; China Insights Consultancy

Updated 2024 base year

Competitive landscape of dexmedetomidine hydrochloride injection in China, top 10 players, 2024

Competitive landscape of dexmedetomidine hydrochloride Injection in China, top 10 players, in terms of revenue, 2024

Drug Name	Specification	Company	First approval year	National VBP inclusion	Market share in 2024
Dexmedetomidine Hydrochloride Injection	1ml:0.1mg 2ml:0.2mg 50ml:0.2mg	扬子江药业 Yangtze River Pharmaceutical	2018	2018.12 (2ml:0.2mg)	66.6%
Dexmedetomidine Hydrochloride Injection	1ml:0.1mg 2ml:0.2mg 50ml:0.2mg	江苏恒瑞医药 Jiangsu Hengrui Pharmaceutical	2009	-	12.1%
Dexmedetomidine Hydrochloride Injection	2ml:0.2mg	正大天晴药业 Chia-Tai Tianqing Pharmaceutical	2021	-	4.1%
Dexmedetomidine Hydrochloride Injection	1ml:0.1mg 2ml:0.2mg	辰欣药业 Cisen Pharmaceutical	2013	-	3.8%
Dexmedetomidine Hydrochloride Injection	2ml:0.2mg	江苏恩华药业 Jiangsu Nhwa Pharmaceutical	2011	-	3.0%
Dexmedetomidine Hydrochloride Injection	1ml:0.1mg 2ml:0.2mg 4ml:0.4mg 10ml:1.0mg 20ml:0.08mg 50ml:0.2mg 100ml:0.4mg	四川国瑞药业 Sichuan Guorui Pharmaceutical	2011	-	2.2%
Dexmedetomidine Hydrochloride Injection	2ml:0.2mg	四川美大康华康 Sichuan Meidakang Huakang Pharmaceutical	2021	-	1.9%
Dexmedetomidine Hydrochloride Injection	2ml:0.2mg	国药集团工业 China National Pharmaceutical Industry	2020	-	1.9%
Dexmedetomidine Hydrochloride Injection	1ml:0.1mg 2ml:0.2mg	石家庄四药 Shijiazhuang No.4 Pharmaceutical	2021	-	1.2%
Dexmedetomidine Hydrochloride Injection	1ml:0.1mg 2ml:0.2mg	湖南科伦制药 Hunan Kelun Pharmaceutical	2018	-	0.6%

Note: Dexmedetomidine Hydrochloride Injection was enrolled in the "7+4"(pilot round) scheme of VBP program;
Sichuan Guorui is a subsidiary of Biokin Pharmaceutical.

Source: NMPA; China Insights Consultancy

Updated 2024 base year

Competitive landscape of Sevoflurane for inhalation, in terms of revenue, 2024

Competitive landscape of Sevoflurane for inhalation, in terms of revenue, as of LPD

Drug Name	Specification	Company	First approval year	National VBP inclusion	Market share in 2024
Sevoflurane for inhalation	120ml;250ml	恒瑞医药 Hengrui	2009	-	60.7%
Sevoflurane for inhalation	250ml	九石制药 Maruishi Pharmaceutical	2019	-	19.0%
Sevoflurane for inhalation	50ml;100ml;250ml	鲁南贝特制药 Lunan better pharmaceutical	2008	-	10.3%
Sevoflurane for inhalation	250ml	百特制药 Baxter International	2011	-	5.2%
Sevoflurane for inhalation	250ml	河北一品制药 Hebei Yipin Pharmaceutical	2017	-	4.1%
Sevoflurane for inhalation	120ml;250ml	四川百利药业 Sichuan Baili Pharmaceutical	2023	-	0.6%
Sevoflurane for inhalation	250ml	河北山姆士药业 Hebei Samshi Pharmaceutical	2021	-	0.1%
Sevoflurane for inhalation	120ml;250ml	福建海西联合药业 Fujian Highsea United Pharmaceutical	2023	-	<0.1%

Note: Sevoflurane for inhalation not been enrolled into national VBP program yet;
Sichuan Baili is a subsidiary of Biokin Pharmaceutical.

Source: NMPA; China Insights Consultancy

Updated 2024 base year

Competitive landscape of medium and long-chain fat emulsion injection in China, top 5 players, 2024

Competitive landscape of medium and long chain fat emulsion injection in China, top 5 players, in terms of revenue, 2024

Drug Name	Specification	Company	First approval year	National VBP inclusion	Market share in 2024
Medium and Long-chain Fat Emulsion Injection	100ml 250ml	B. Braun	2014	2021.06 (250ml)	33.8%
Medium and Long-chain Fat Emulsion Injection	100ml 250ml	四川科伦药业 Sichuan Kelun Pharmaceutical	2017	2021.06 (250ml)	21.1%
Medium and Long-chain Fat Emulsion Injection	250ml	广东嘉博制药 Jiabo Pharmaceutical	2021	2021.06 (250ml)	15.6%
Medium and Long-chain Fat Emulsion Injection	100ml 250ml 500ml	Baxter	2001	-	9.7%
Medium and Long-chain Fat Emulsion Injection	100ml 250ml 500ml	四川国瑞药业 Sichuan Guorui Pharmaceutical	2012	-	6.0%

Note: Medium and Long-chain Fat Emulsion Injection was enrolled in the 5th round of VBP program;
Sichuan Guorui is a subsidiary of Biokin Pharmaceutical.

Source: NMPA; China Insights Consultancy

Updated 2024 base year

Competitive landscape of ribavirin in China, top 10 players, in terms of revenue, 2024

Competitive landscape of ribavirin in China, top 10 players, in terms of revenue, 2024

Drug Name	Specification	Company	First approval year	VBP inclusion	Market share in 2024
Ribavirin/Ribavirin Spray	0.02g; 0.05g; 0.1g(oral) 0.075g(spray)	上海信谊药厂 Shanghai Sine Pharmaceutical	1995	N/A	11.3%
Ribavirin Injection	1ml:0.1g; 5ml:0.5g; 10ml:1.0g	中嘉生物科技（湖北） Zhongjia Biopaharm(Hubei)	1999	N/A	5.9%
Ribavirin Injection	1ml:0.1g; 2ml:0.25g	陕西顿斯制药 Shaanxi Dunsi Pharmaceutical	1999	N/A	5.2%
Ribavirin Injection	1ml:0.05g; 1ml:0.1g	重庆迪康长江制药 Chongqing Dikang Changjiang Pharmaceutical	2002	N/A	4.6%
Ribavirin	0.05g; 0.1g	广东华南药业集团 Guangdong Huanan Pharmaceutical	1995	N/A	4.6%
Ribavirin Injection	1ml:0.1g	青岛金峰制药 Qingdao Jinfeng Pharmaceutical	1999	N/A	4.0%
Ribavirin Granules/Ribavirin Effervescent Granules	0.05g; 0.1g; 0.15g(granules) 0.15g(effervescent granules)	四川百利药业 Sichuan Baili Pharmaceuticals	2010	N/A	3.7%
Ribavirin Injection	1ml:0.1g	西南药业 Southwest Pharmaceutical Co. Ltd	2002	N/A	3.1%
Ribavirin Injection/Ribavirin Capsules	5ml:0.5g (Injection) 0.15g (Capsules)	浙江诚意药业	2003	N/A	3.1%
Ribavirin Injection	1ml:0.1g; 2ml:0.1g	山东益健药业 Shandong Yijian Pharmaceutical	1999	N/A	3.0%

Note: Ribavirin has not been enrolled into VBP program yet;
Sichuan Baili is a subsidiary of Biokin Pharmaceutical.

Source: NMPA; China Insights Consultancy

Updated 2024 base year

Competitive landscape of ornidazole in China, top 10 players, in terms of revenue, 2024

Competitive landscape of ornidazole in China, top 10 players, in terms of revenue, 2024

Drug Name	Specification	Company	First approval year	National VBP inclusion	Market share in 2024
Ornidazole Tablet/Ornidazole Injection/Ornidazole and Sodium Chloride Injection	3ml:0.5g; etc.(injection) 100ml:0.25g; etc. (ornidazole and sodium chloride injection)	四川科伦制药 Sichuan Kelun Pharmaceutical	2005	2023.03 (3ml:0.5g, injection) 2022.07(0.25g, tablet)	23.2%
Ornidazole Injection/Ornidazole Vaginal Effervescent Tablets/Omidazole Capsules	3ml:0.5g; etc.(injection) 0.5g (vaginal effervescent tablets) 0.25g (capsules)	西安万隆制药 Xi'an Wanlong Pharmaceutical	2003	2023.03 (3ml:0.5g, injection)	15.8%
Ornidazole Capsules	0.25g	扬子江南京海陵药业 Yangtze River Nanjing Hailing Pharmaceutical	2003	-	13.4%
Ornidazole Tablets/Ornidazole Vaginal Suppositories	0.25g; 0.5g (tablets) 0.5g (vaginal suppositories)	华东医药（西安）博华制药 Huadong Medicine (Xi'an) Bodyguard Pharmaceutical	2001	2022.07 (0.5g, tablet)	7.9%
Ornidazole and Sodium Chloride Injection	100ml:0.25g 100ml:0.5g	陕西金裕制药 Shaanxi Jinyu Pharmaceutical	2004	-	5.0%
Ornidazole Dispersible Tablets	0.25g	天方药业 Topfond Pharmaceutical		-	4.0%
Ornidazole Injection	3ml:0.5g 6ml:1.0g	北京双鹭药业 Beijing Shuanglu Pharmaceutical	2018	2023.03 (3ml:0.5g, injection)	2.2%
Ornidazole Tablets/Ornidazole Dispersible Tablets	0.25g; 0.5g (tablets) 0.25g (dispersible tablets)	湖南九典制药* Hunan Jiudian Pharmaceuticals	2004	2022.07(0.25g, tablet) 2022.07(0.5g, tablet)	2.1%
Ornidazole Injection	0.25g	湖北长联杜勒制药 Hubei Changlian Dulle Pharmaceutical	2003	-	2.0%
Ornidazole Injection/Ornidazole Tablets/Omidazole Vaginal Effervescent Tablets	3ml:0.5g; etc.(injection) 0.5g (tablets) 0.5g (vaginal effervescent tablets)	南京圣和药业 Nanjing Sanhome Pharmaceutical	2002	-	1.4%

Note: Jiudian Pharmaceutical is the contract manufacturer of national VBP included ornidazole tablet products of Taiyangsheng (Bozhou) (太阳升(亳州)生物) and Hangzhou Muyuan (杭州沐源)Omidazole Injection was enrolled in the 8th round of VBP program

Source: NMPA; China Insights Consultancy

Updated 2024 base year

Competitive landscape of Racecadotril, top 5 players, in terms of revenue, 2024

Competitive landscape of Racecadotril, top 5 players, in terms of revenue, as of LPD

Drug Name	Specification	Company	First approval year	National VBP inclusion	Market share in 2024
Racecadotril granules	10mg	四川百利药业 Sichuan Baili Pharmaceutical	2005	-	66.4%
Racecadotril granules/ capsules	10mg;30mg;0.1g	江苏正大丰海制药 Jiangsu CTFH Pharmaceutical	2005	-	33.4%
Racecadotril powder/ capsules	30mg; 0.1g	Bioprojet Pharma	2013	-	0.2%
Racecadotril orally disintegrating tablets	6mg	亚宝药业四川制药 Yabao Pharmaceutical	2005	-	<0.1%
Racecadotril tablets	30mg	扬子江北京海燕药业 Beijing Haiyan Pharmaceutical	2005	-	-

Note: Racecadotril has not been enrolled into VBP program yet;
Sichuan Baili is a subsidiary of Biokin Pharmaceutical.

Source: NMPA; China Insights Consultancy

Updated 2024 base year

Competitive landscape of Glucose Electrolyte, in terms of revenue, 2024

Competitive landscape of Glucose Electrolyte, in terms of revenue, as of LPD

Drug Name	Specification	Company	First approval year	VBP inclusion	Market share in 2024
Glucose electrolyte effervescent tablets	0.138g sodium 0.098g potassium 0.16g chloride 1.62g anhydrous glucose 0.384g anhydrous citric acid	四川百利药业 Sichuan Baili Pharmaceutical	2013	-	100.0%

Note: Glucose Electrolytehas not been enrolled into VBP program yet;
Sichuan Baili is a subsidiary of Biokin Pharmaceutical.

Source: NMPA; China Insights Consultancy

20250925
Updated

Competitive landscape of astragalus market, top5 in terms of revenue, 2024

Competitive landscape of astragalus market, top5 in terms of revenue, as of LPD

Drug Name	Specification	Company	First approval year	National VBP inclusion	Market share in 2024
Astragalus granules	4g;15g	四川百利药业 Sichuan Baili Pharmaceutical	1999	-	46.3%
Astragalus slices	0.55g	四川国康药业 Sichuan Guokang Pharmaceutical	2009	-	14.0%
Astragalus slices	0.41g	四川奇力制药 Sichuan Qili Pharmaceutical	2009	-	13.0%
Astragalus granules	4g;15g	南京同仁堂药业 Nanjing Tongrentang Pharmaceutical	1999	-	12.4%
Astragalus granules	4g;15g	贵州汉方药业 Guizhou Hanfang Pharmaceutical	1999	-	6.3%

Note: Sichuan Baili is a subsidiary of Biokin Pharmaceutical.

Source: NMPA; China Insights Consultancy

20250925
Updated

Competitive landscape of Chaihuang market, top5 in terms of revenue, 2024

Competitive landscape of Chaihuang market, top5 in terms of revenue, as of LPD

Drug Name	Specification	Company	First approval year	National VBP inclusion	Market share in 2024
Chaihuang granules/ Chaihuang slices	3g;4g;5g/0.55g(2g)	四川百利药业 Sichuan Baili Pharmaceutical	1999	-	78.1%
Chaihuang oral solution	10ml	山东福牌制药 Shandong FuPai Pharmaceutical	1995	-	8.1%
Chaihuang granules/ Chaihuang slices	4g/0.5g	江西京通美联药业 Jiangxi JTML Pharmaceutical	2000	-	5.4%
Chaihuang slices	0.55g(2g)	陕西盘龙药业 Shaanxi Panlong Pharmaceutical	2005	-	4.4%
Chaihuang granules	4g	河南灵佑药业 Henan Livu Pharmaceutical	2000	-	1.9%

Note: Sichuan Baili is a subsidiary of Biokin Pharmaceutical.

Source: NMPA; China Insights Consultancy

Other supplements

Other supplements

Types of products	Content	Detail
Anesthesia	Market threats/challenges	• **Price may face VBP pressure**: As of LPD, some anesthetic drugs have already been covered in past several rounds of VBP schemes. As VBP schemes roll-out and cover more drugs, it is likely that a wider range of anesthetic drugs would be covered in VBP to improve drug accessibility and reduce medical expenses, which would introduce volatility in market growth.
Parenteral nutrition	Entry barriers	• **Technical barrier**: Parenteral nutrition solutions involve delicate API supply chain, complex formula design, sophisticated production processes and strict quality control. The R&D cycle of parenteral nutrition solutions is extensive, with intensive investment and high capital requirement to fund research activities from basic research to clinical trials, and finally to marketing approval.
Parenteral nutrition	Market opportunities	• **Continuous improvement in the formula of parenteral nutrition**: The formula of parenteral nutrition is becoming more personalized. Companies are optimizing the composition ratio of amino acids and other ingredients to better cater to different patient groups. • **Diversification of specifications**: Traditional single-chamber parenteral nutrition bags require a complex mixing process before use, which increases the risk of contamination and the possibility of operational errors. Multi-chamber bags store different ingredients separately and allow them to be mixed more easily before use without manual errors, which would drive market growth.

Source: Menet; China Insights Consultancy

Other supplements

Other supplements

Types of products	Content	Detail
Parenteral nutrition	Market threats/challenges	• **Price may face VBP pressure**: As of LPD, some parenteral nutrition products have already been covered in the VBP schemes, with a price cut of nearly 70%.
Anti-infective	Market threats/challenges	• **Inclusion into VBP list may lead to reduction in price:** As the development of VBP scheme, more drugs are now included in the list. While acquiring steady sales, the inclusion into VBP list may lead to the reduction in price, causing market volatility. • **Rigid supervision may restrain the growth of anti-infective drugs** With the abuse of anti-infective drugs, the anti-infective drug use in hospitals are under rigid supervision, which may be a challenge to the market growth.
Pediatric drugs	Entry barriers	• **Difficulties in R&D**: Due to the unique target patient groups of pediatric drugs, the development of such drugs encounters R&D barriers. Substantial variation exists between children and adults in the metabolism, renal clearance and other drug disposition mechanisms. Strong differences also exists among children of different ages in the ability to metabolize, absorb, excrete, and transform medications. These differences poses higher requirements in development of pediatric drugs.

Source: Menet; China Insights Consultancy

Other supplements

Other supplements

Types of products	Content	Detail
Pediatric drugs	Market opportunities	• **Supportive polices encourage the development of pediatric drug market:** China government has supported R&D of pediatric drugs by releasing multiple policies encouraging the development of pediatric drugs, such as the 4th batch of encouraged pediatric drugs list released in August 2023 by NHC. The introduction of supportive policies is a major driver for pediatric market growth.
Pediatric drugs	Market threats/challenges	• **High requirement in drug specifications:** Due to the comparably lower patient compliance of children, pediatric drugs must be designed with selected specifications, such as appealing flavors and dosage forms, to cater to certain preferences of children, which requires extra R&D efforts and commitment of capital and talent.
TCM	Market threats/challenges	• **Difficulties in quality control and standardization:** Since most TCMs are made of traditional herbs which are not standardized products, the regulatory and policy framework on TCM is still evolving to establish oversight on TCM quality control and standardization. • **Shortage in valid clinical evidence:** Some TCMs are not equipped with strong enough clinical evidences reported in well-designed clinical trials. Clinical trial design of TCMs often require significant capital and talent dedication, which might exert influence in market growth.

Source: Menet; China Insights Consultancy

VBP statements

- The market size of Dexmedetomidine in China during 2018-2023 was declining due to the fact that Dexmedetomidine was included in the first round of national centralized drug procurement since 2019.
- The market size of Propofol Medium and Long Chain Fat Emulsion in China during 2018-2023 was declining due to the fact that Propofol Medium and Long Chain Fat Emulsion was included in the fourth batch of national centralized procurement since 2021.
- The market size of Medium and Long Chain Fat Emulsion (C8-24) in China during 2018-2023 was declining due to the fact that Medium and Long Chain Fat Emulsion (C8-24) was included in the fifth batch of national centralized procurement since 2021.
- The market size of Omidazole in China during 2018-2023 was declining due to the fact that Ornidazole was included in in the eighth batch of national centralized procurement since 2023.

Source: China Insights Consultancy

OSS verification

- According to CIC, Leweijing was ranked fourth in China's propofol emulsion injection market, with a market size of approximately 12.1% in 2023
- According to CIC, Leweitai was ranked third in China's propofol medium and long chain fat emulsion injection market, with a market share of approximately 20.1% in 2023
- According to CIC, Youmeining was ranked eighth in dexmedetomidine hydrochloride injection market, with a market share of approximately 1.2% in 2023
- According to CIC, Tianze ranked the sixth in China's medium and long chain fat emulsion injection market, with a market size of approximately 5.1% in 2023
- According to CIC, Xinbolin was ranked as the sixth most popular ribavirin product in China, with a market share of approximately 3.4% in 2023
- According to CIC, Aobolin was ranked 17th in China's ornidazole market, with a market share of approximately 0.5% in 2023
- According to CIC, Dulabao was the best-selling racecadotril products in China, with a market share of approximately 66.6% in 2023
- According to CIC, our glucose electrolyte effervescent tablet is the only glucose electrolyte product in China
- Astragalus granule was sold in 30 provinces across China, and was ranked second in China's astragalus market with a market share of approximately 30.0% in 2022, according to CIC
- Chaihuang granule was sold in 25 provinces across China, and was the best-selling Chaihuang granule product in China with a market share of approximately 92.4% in 2022, according to CIC

Source: China Insights Consultancy

OSS verification

- Anesthesia, is the most major branches among nervous system drugs in terms of sales revenue of pharmaceuticals in 2023. Nervous system drugs is the 6th largest therapeutic area in China and anesthesia accounted for 19.0% of it i n the same year. In terms of sales revenue, the anesthesia pharmaceutical market grew at a CAGR of 6.5% from RMB14.9 billion in 2018 to RMB20.4 billion in 2023, according to CIC.
- The significant unmet clinical demands, increase in patients' affordability and willingness to pay for treatment, and favorable government policies will continue to drive the rapid growth of the anesthesia pharmaceutical market in China, according to the same source.
- According to CIC, the market for propofol medium/long chain fat emulsion injection in China was estimated to stabilize at approximately RMB0.7 billion by 2033. Our propofol medium/long chain fat emulsion injection ranked as the 3rd most popular propofol product in China, with a market share of approximately 20.1% in 2023, according to CIC.
- According to CIC, the market for dexmedetomidine hydrochloride injection in China was estimated to stabilize at approximately RMB1.6 billion by 2033 . Our dexmedetomidine hydrochloride injection ranked as the 8th most popular propofol product in China, with a market share of approximately 1.2% in 2023, according to CIC.
- Parenteral nutrition was the • largest therapeutic area in China in terms of sales revenue of pharmaceuticals in •, accounting for •% of the overall pharmaceutical market in the same year. In terms of sales revenue, the parenteral nutrition pharmaceutical market grew at a CAGR of •% from RMB• billion in • to RMB• billion in •, according to CIC. The rising prevalence of chronic diseases, increased awareness of clinical nutrition, advancements in healthcare infrastructure, and favorable government policies will continue to drive the rapid growth of the parenteral nutrition pharmaceutical market in China, according to the same source.
- According to CIC, the market for medium/long chain fat emulsion injection in China was RMB0.7 billion in 2023 and was estimated to stabilize at approximately RMB0.7 billion by 2033. Tianzhe ranked as the 6th most popular nutrition product in China, with a market share of approximately 5.1% in 2023, according to CIC.
- Anti-infectives was the 3rd largest therapeutic area in China in terms of sales revenue of pharmaceuticals in 2023, accounting for 14.0% of the overall chemical pharmaceutical market in the same year. In terms of sales revenue, the anti-infectives pharmaceutical market grew at a CAGR of 5.4% from RMB178.9 billion in 2023 to RMB294.2 billion in 2033, according to CIC.

Source: China Insights Consultancy

OSS verification

- According to CIC, the market for ribavirin granule in China was estimated to be approximately RMB0.9 billion in 2032, and grew at a CAGR of 3.2% from 2023 to 2033. Xinbolin ranked as the 6th most popular anti-infectives product in China, with a market share of approximately 3.4% in 2023, according to CIC.
- Pediatric drugs, including racecadotril and glucose electrolyte solutions, play a vital role in managing common childhood conditions such as acute diarrhea and dehydration. Racecadotril, an enkephalinase inhibitor, effectively reduces fluid secretion in the intestines without altering gut motility, making it ideal for pediatric patients by minimizing adverse effects like constipation. Its use improves clinical outcomes and reduces hospitalization duration, thereby enhancing recovery times. Similarly, glucose electrolyte solutions are fundamental in treating dehydration caused by diarrhea or vomiting. These solutions replenish essential fluids and electrolytes, ensuring proper hydration and electrolyte balance, and are a cornerstone of oral rehydration therapy recommended globally. The inclusion of glucose in these solutions facilitates the efficient absorption of sodium and water in the intestine, boosting rehydration effectiveness. As pediatric dehydration and diarrhea remain prevalent issues worldwide, the demand for these drugs is expected to grow, driven by their proven safety, efficacy, and ease of use, particularly in both developed and emerging markets. Pediatric drugs market, in terms of sales revenue, grew at a CAGR of 9.3% from RMB125.4 billion in 2023 to RMB305.1 billion in 2033, according to CIC.
- According to CIC, the market for racecadotril granule in China was RMB28.5 million in 2023 and was estimated to stabilize at approximately RMB30.0 million by 2033. Dulabao ranked as the 1st most popular pediatric drugs product in China, with a market share of approximately 66.6% in 2023, according to CIC.
- According to CIC, the market size for glucose electrolyte effervescent tablet in China rose from RMB8.1 million in 2018 to RMB18.5 million in 2023 at a CAGR of 18.0%, and is projected to reach RMB47.1 million in 2033 at a CAGR of 8.5% from 2023. Leyeping ranked as the 1st most popular pediatric drugs product in China, with a market share of approximately 100% in 2023, according to CIC.
- Traditional Chinese medicine market, in terms of sales revenue, grew at a CAGR of 1.3% from RMB 395.3 billion in 2018 to RMB 422.5 billion in 2023, according to CIC.
- our astragalus granules achieved a market share exceeding 90% in sample hospitals, according to CIC.
- During the Track Record Period, our Chaihuang granule achieved a market share exceeding 90% in sample hospitals.
- Our chaihuang granule ranked as the most popular Chaihuang granule products in China, with a market share of approximately 92.4% in 2022, according to CIC.
- According to CIC, the market for ornidazole capsule in China was estimated to stabilize at approximately RMB 1.2 billion by 2033.

Source: China Insights Consultancy