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OVERVIEW OF ONCOLOGY DRUG MARKET AND IMMUNE CELL THERAPY MARKET

Overview

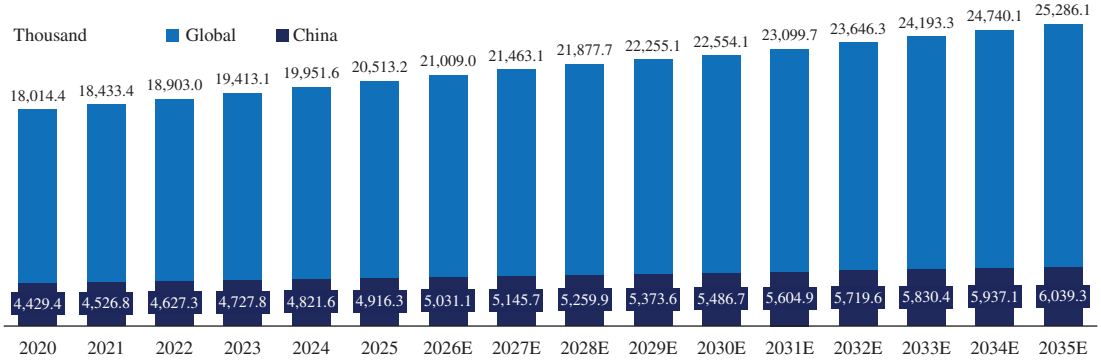
Cancer is a broad group of diseases that involve uncontrolled growth and development of cells in the body, and is one of the foremost reasons of deaths throughout the world. Over the past century, cancer treatments have experienced significant evolution from surgery, radiotherapy, chemotherapy, targeted therapies to immuno-oncology therapies.

Market Size of Oncology Drugs

In China, the incidence of solid tumors remains significant and continues to increase. Solid tumor incidence reached at 4.9 million cases in 2025, and is expected to rise to 5.5 million cases by 2030, representing a CAGR of 2.2% during the period. By 2035, incidence in China is projected to reach 6.0 million cases, corresponding to a CAGR of 1.9% between 2030 and 2035. The expanding patient base in China supports increasing demand for innovative oncology drugs and treatment options.

Global and China Incidence of Solid Tumor, 2020-2035E

Period	CAGR	
	China	Global
2020-2025	2.1%	2.6%
2025-2030E	2.2%	1.9%
2030E-2035E	1.9%	2.3%

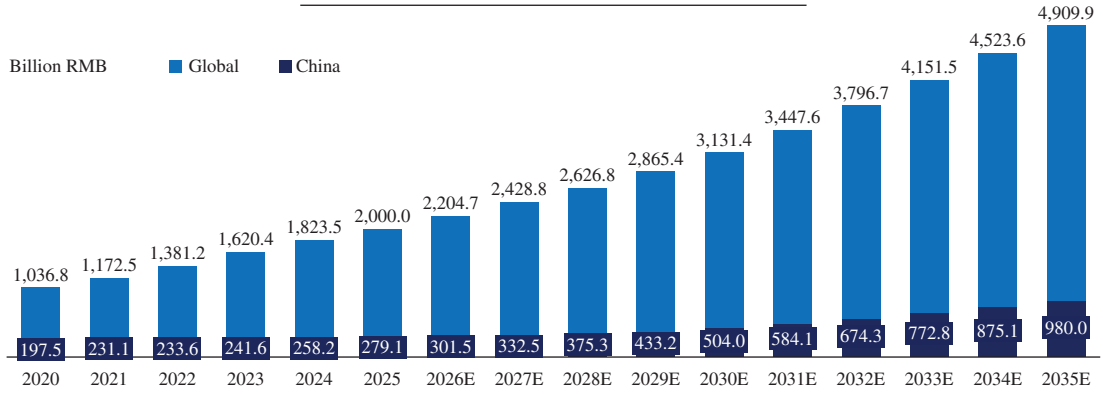


Source: Frost & Sullivan Analysis

In China, the oncology drug market reached RMB279.1 billion in 2025, reflecting a CAGR of 7.2% from 2020 to 2025. The market is expected to accelerate in the coming years, increasing to RMB504.0 billion by 2030, with a CAGR of 12.5% from 2025 to 2030, and further expanding to RMB980.0 billion by 2035, representing a CAGR of 14.2% between 2030 and 2035.

Global and China Oncology Drug Market, 2020-2035E

Period	CAGR	
	China	Global
2020-2025	7.2%	14.0%
2025-2030E	12.5%	9.4%
2030E-2035E	14.2%	9.4%

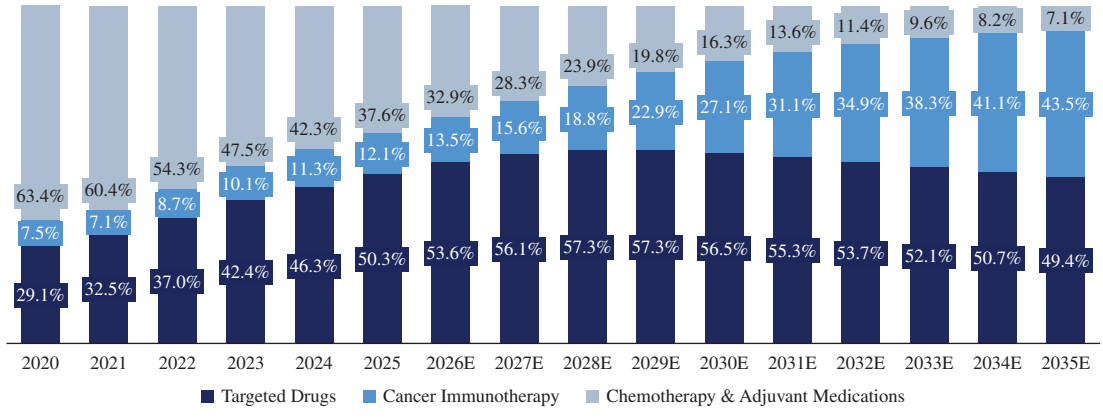


Source: Frost & Sullivan Analysis

Oncology therapeutics are generally classified into three major categories: targeted therapies, cancer immunotherapies, and chemotherapy and adjuvant treatments. Among these, the immuno-oncology segment has been expanding particularly rapidly, representing 12.1% of the global oncology drug market in 2025. This segment is expected to continue its strong growth trajectory, reaching 43.5% by 2035.

The table below sets out the breakdown of the China oncology drug market by treatment modality from 2020 to 2035.

Proportion of Current Treatment Modalities in China Oncology Drug Market



Source: Frost & Sullivan Analysis

Major Cancer Treatments

Cancer treatment has undergone significant evolution as scientific understanding of tumors has advanced — from observations of tumor tissues to insights at the cellular and genetic levels. Historically, treatment relied primarily on surgery, radiotherapy, and chemotherapy. With continued progress in molecular biology and oncology, targeted therapies and, more recently, immunotherapies have emerged, offering more precise and effective options for patients.

As a result, modern cancer care now comprises a broad spectrum of treatment approaches, each designed to address tumors through different mechanisms and with increasingly personalized strategies. The table below provides an overview of the key treatment principles and mechanisms associated with the major cancer treatment modalities.

Introduction and Analysis of Major Cancer Treatments

Cancer Treatments	Treatment Principles and Mechanisms
Surgery	Involves removing the tumor and surrounding tissue during the procedure. It is most effective for early-stage tumors confined to a specific area but has limited effectiveness for metastatic tumors.
Chemotherapy	Uses one or more cytotoxic drugs to inhibit or slow tumor cell growth. It affects all rapidly dividing cells, leading to side effects such as fatigue, hair loss, bruising, bleeding, and infections. It is often used together with other treatments.
Radiotherapy	Uses high-dose radiation to kill tumor cells and shrink the tumor, but it can also affect surrounding healthy cells, leading to side effects like fatigue, nausea, and skin reactions. It is often combined with other treatments.
Targeted Therapy	Acts on specific molecular targets associated with tumors, causing less harm to normal cells than traditional therapies. This category includes small-molecule drugs and large-molecule drugs.
Immunotherapy	Activates the patient's immune system to fight cancer. Major approaches include cytokines, monoclonal antibodies, immune checkpoint inhibitors, cell-based immunotherapies, and cancer vaccines.

Source: Frost & Sullivan Analysis

Overview of Immuno-oncology Therapies

Immuno-oncology therapies broadly fall into three principal categories: immune checkpoint inhibitor (ICI) therapies, cancer vaccines, and adoptive cell immunotherapies (T-cell based therapies).

T-cell-based therapies are a type of immuno-oncology treatment that use a patient's own immune cells to fight cancer. The three main approaches are TIL therapy, TCR-T therapy and CAR-T therapy, which differ mainly in where the cells come from and how they are prepared. In TIL therapy, immune cells are taken directly from a patient's tumor, expanded and activated in the laboratory, and then infused back into the patient to help the body better recognize and attack cancer cells. In TCR-T therapy, T cells are collected from the patient's blood and genetically modified to express optimized natural T cell receptor, which can better recognize specific cancer markers, allowing them to target tumor cells. In CAR-T therapy, T cells are also collected from blood but are engineered with synthetic receptors that enable them to directly recognize and bind to cancer cells, helping them attack tumors more effectively.

The following summarizes the analysis of major adoptive T-cell therapies:

Analysis of Major Adoptive T-cell Therapies

	TIL	CAR-T	TCR-T
Cell Source	Tumor Tissue	Peripheral Blood	Peripheral Blood
Culture Cycle	16~22 days	21~28 days	No standard culture cycle
Gene Engineering	Generally not needed	Required	Required
Target Ability	Multiple heterogeneous targets	Membrane antigens	Few identified tumor antigens with HLA pairing
Safety	High*	Low	Low
Tumor Microenvironment Entry Ability	Strong	Weak	Moderate
Clinical Efficacy for Solid Tumors	Various types of solid tumors	Poor efficacy in solid tumors	Effective in a few types of solid tumors
Advantages	• Strong tumor specificity • Minimal off-target toxicity • Capable of eliminating solid tumors	• Strong membrane antigen recognition • Excellent efficacy in hematologic tumors • Long survival time in the body	• Simple structure, easy to enter tumor microenvironment • Naturally expressed in humans with weak immune rejection • Long survival time in the body
Disadvantages	• Tumor microenvironment suppression • Complex manufacturing process • Generally requires high-dose IL-2 infusion	• Poor efficacy in solid tumors • Potential off-target toxicity	• Easily evaded by tumor cells • Recognition mechanism requires HLA matching

Source: Government Website, Frost & Sullivan Analysis

Note: TIL therapy itself has a high safety profile, and adverse events mainly stem from the use of high-dose IL-2 and high-intensity lymphodepletion chemotherapy.

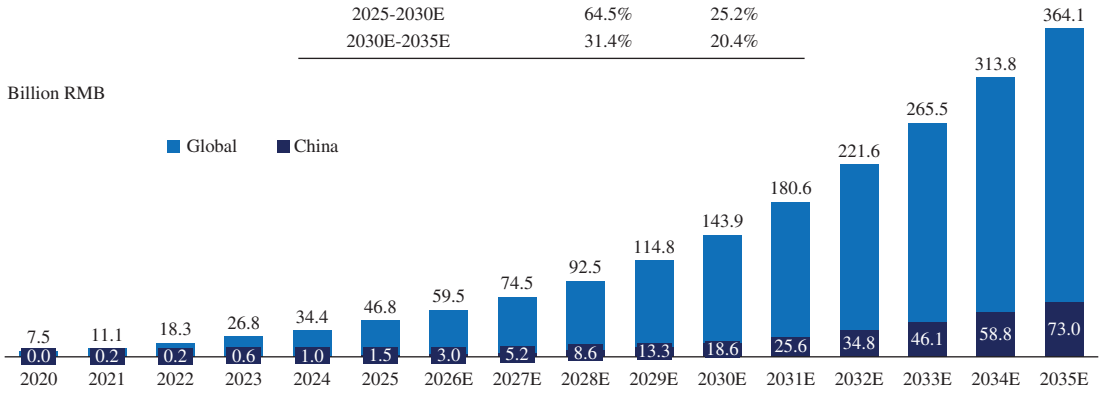
Market Size of Immune Cell Therapy

Global immune cell therapy market size reached RMB46.8 billion in 2025, with a CAGR of 44.4% from 2020 to 2025. The market size is expected to reach RMB143.9 billion in 2030, with a CAGR of 25.2% from 2025 to 2030. The market will further grow to RMB364.1 billion in 2035, with a CAGR of 20.4% from 2030 to 2035.

China immune cell therapy market size reached RMB1.5 billion in 2025. The market size is expected to reach RMB18.6 billion in 2030, with a CAGR of 64.5% from 2025 to 2030. The market will further grow to RMB73.0 billion in 2035, with a CAGR of 31.4% from 2030 to 2035.

Global and China Immune Cell Therapy Market, 2020-2035E

Period	CAGR	
	China	Global
2020-2025	–	44.4%
2025-2030E	64.5%	25.2%
2030E-2035E	31.4%	20.4%



Source: Frost & Sullivan Analysis

OVERVIEW OF TIL THERAPY MARKET

Development of TIL Therapy

Over the past 40 years, TIL therapy has transitioned through several technical stages involving advancements in clinical science, manufacturing, and therapeutic design. Early-stage research utilized autologous tumor-resident lymphocytes, though these initial iterations were characterized by prolonged manufacturing lead times and inconsistent cultivation success rates. Subsequent improvements in cell culture techniques enabled the development of GMP-grade, non-genetically modified TIL therapies, leading to the first regulatory approval of a commercial TIL product for solid tumors in 2024. More recently, the field has incorporated genetic engineering to enhance anti-tumor activity and address the immunosuppressive tumor microenvironment. These developments demonstrate a maturation of TIL technology and its expanding application in clinical oncology.

Advantages of TIL Therapy in the Treatment of Solid Tumors

Pan-tumor applicability

TIL therapy has shown therapeutic potential across multiple solid tumor types, including melanoma, cervical cancer, and head and neck cancers. Unlike conventional therapies that typically target a single antigen, TIL therapy involves isolating and expanding a heterogeneous population of tumor-infiltrating lymphocytes capable of recognizing a wide range of tumor antigens. This multi-antigen targeting enables broader antitumor activity and offers a potential treatment option for refractory solid tumors with limited existing therapies, thereby extending its clinical application prospects.

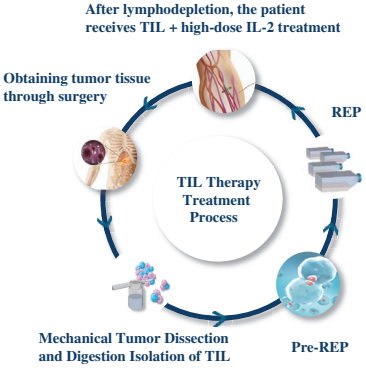
Strong potential for combination use

Another advantage of TIL therapy is its compatibility with combination treatment strategies. In clinical research, TIL therapy is commonly administered alongside lymphodepleting chemotherapy and IL-2. Lymphodepleting chemotherapy is used prior to TIL infusion to reduce the patient's existing lymphocytes and create a more favorable environment for TIL engraftment and expansion. Subsequent combination with immune checkpoint inhibitors, such as PD-1 blockers, helps mitigate immunosuppressive signaling within the tumor microenvironment, supporting the function and persistence of infused TILs. Through these complementary mechanisms, combination regimens aim to enhance antitumor activity and address resistance observed with monotherapies.

Standard TIL Therapy Treatment Process

TIL therapy is an individualized treatment approach that uses a patient's own immune cells to target cancer. It involves collecting tumor tissue from the patient and isolating the immune cells present within the tumor. These cells are then expanded and activated outside the body under controlled laboratory conditions to increase their number and activity. Once prepared, the cells are infused back into the patient to enhance the body's immune response against the tumor. Prior to infusion, patients typically undergo a preparatory treatment to reduce existing immune cells, which may help improve the effectiveness of the infused cells. The diagram below outlines the key stages of the TIL therapy process.

Standard TIL Therapy Treatment Process



Step 1. Tumor Tissue Procurement
Tumor tissue is obtained through surgery.

Step 2. Isolation of TILs
Tumor tissue is fragmented into small pieces using mechanical methods and/or biochemical methods (such as enzymes) to facilitate TIL isolation.

Step 3. Pre-REP
TILs are rejuvenated with high-concentration of IL-2.

Step 4. Rapid Expansion Protocol (REP)
High-concentration IL-2, anti-CD3 antibody, and irradiated allogeneic peripheral blood mononuclear cells (feeder cells) are used to promote rapid T-cell proliferation and achieve a highly activated state.

Step 5. TIL Infusion
After lymphodepletion, TILs are infused into the patient, followed by high-dose IL-2 treatment.

Source: Literature Research, Frost & Sullivan Analysis

Global Competitive Landscape of TIL Therapy

Lifileucel (AMTAGVI) is the world's first approved TIL therapy. It received approval from the U.S. FDA on February 16, 2024.

Multiple players are developing TIL therapies targeting solid tumors. GC101 has entered a registrational Phase II clinical trial in China. GC101 has also obtained the first manufacturing certificate for TIL therapies in China. The table below sets forth details of the global pipeline of TIL therapies:

Company	Candidates	Indication	Phase	First post date	Location
Iovance	Lifileucel	Unresectable or metastatic melanoma previously treated with a PD-1 blocking antibody, and if BRAF V600 mutation positive, a BRAF inhibitor with or without a MEK inhibitor	Approved	2024/2	US, Canada, Australia
	Lifileucel	Melanoma (Combo with Pembrolizumab)	Phase III	2023/2	Global
	Lifileucel	Endometrial cancer	Phase II	2024/7	US
	Lifileucel	NSCLC	Phase II	2020/11	US
	IOV-4001	Melanoma, NSCLC	Phase I/II	2022/5	US
Juncell	GC101	Melanoma	Registrational Phase II	2024/12	China
	GC101	NSCLC	Phase I	2024/9	China
	GC203	Advanced malignant solid tumor	Phase I	2024/5	China
Grit	GT 101	Cervical cancer	Phase II	2024/3	China
	GT 201	Advanced solid tumor	Phase I	2023/10	China, US
Obsidian	OBX-115	Solid Tumors	Phase I/II	2023/9	US
KSQ	KSQ-001EX	Solid Tumors	Phase I/II	2024/2	US
	KSQ-004EX	Solid Tumors	Phase I/II	2024/9	US
Intima	CISH Inactivated TIL	NSCLC	Phase I/II	2022/10	US
	CISH Inactivated neoantigen-specific TIL	Gastrointestinal Cancer	Phase I/II	2020/6	US
AgonOx	AGX148	Solid Tumors	Phase I	2023/6	US
TCRcure/Hervor	HV-101	Advanced solid tumor	Phase I	2023/7	China
NeogenTC	NEOG-100	Solid Tumors	Phase I	2023/10	N/A(2)
Lanma Bio	LM103	Advanced solid tumor	Phase I	2023/12	China
Aeonvital	ReT01 ACT	Advanced solid tumor	Phase I	2024/1	China
Biosyngen	BST02	Liver cancer	Phase I	2024/4	China
Sino-Cell Biomedicine	HS-IT101	Melanoma, NSCLC	Phase I	2025/4	China
CuraCell	CC-38	Colorectal Cancer, Prostate Cancer	Phase I/II	2025/7	Germany

Note:

(1) Ongoing Clinical trials with first posted date up to 2025/12/05, registered trial sponsors are included.

(2) Location data is not available on ClinicalTrials.gov.

Source: Clinicaltrials, Frost & Sullivan Analysis

As of December 5, 2025, Lifileucel is the only TIL therapy that has been approved for marketing globally. It is a single-dose treatment for advanced melanoma and is priced at US$515,000. Lifileucel is covered by US Medicare and Medicaid, as well as several commercial insurance policies. Lifileucel has been approved for marketing in the United States, Canada, and Australia, but has not yet received marketing approval in Europe (the European Union). Lifileucel is not currently available in Chinese mainland.

Current Technical Challenges of TIL Therapy

Although TIL therapy has shown promising potential in the treatment of solid tumors, its development and broader clinical adoption are currently limited by several technical and operational challenges. These limitations span patient eligibility, manufacturing complexity, process standardization, and treatment timelines. The key challenges are summarized below.

- ***Tumor tissue sourcing limitations:*** TIL therapy faces a fundamental limitation in its reliance on surgically accessible tumor tissue. This initial requirement for invasive tissue harvesting not only imposes a physical burden on patients but also excludes a significant number of those with unresectable, deep-seated, or high-risk anatomical lesions from treatment eligibility.

- ***Challenges in TIL enrichment and functional restoration:*** The *ex vivo* expansion of TILs is technically complex and carries a risk of unsuccessful cell growth.

- ***Difficulties in developing standardized processes across solid tumors:*** Substantial heterogeneity among solid tumors makes it challenging to establish a universal TIL manufacturing process. Differences in tumor biology affect the ability to reliably enrich, restore, and expand tumor-specific T cells to the required scale, impacting consistency and standardization.

- ***Dependence on feeder cells in early manufacturing:*** TIL expansion typically requires irradiated feeder cells to provide essential growth signals. This adds to material costs, technical complexity, and production time, while the use of patient-specific biological materials limits scalability and introduces potential risks such as contamination or variability.

- ***Lengthy production timelines:*** TIL manufacturing often requires several weeks from tumor resection to product infusion. This extended timeline can delay treatment initiation and increases the risk of disease progression, particularly for patients with rapidly advancing cancers.

- ***Clinical challenges:*** High-intensity lymphodepleting chemotherapy is a standard component of current TIL therapy, yet its associated side effects — such as cytopenia and increased infection risk — also represent major clinical challenges. In addition, high-dose IL-2 — commonly required to support T-cell survival and activity *in vivo* — can lead to frequent and sometimes severe toxicities, further complicating clinical use.

Cost Analysis of TIL Therapy

The manufacturing of TIL therapy is a complex, resource-intensive process involving multiple stages that contribute to the aggregate production cost. Primary cost drivers include the collection of tumor tissue, specialized core manufacturing processes, the operation of GMP-compliant facilities, rigorous quality control testing, and final product release and logistics. The table below summarizes the principal cost categories, their constituent components, and their respective contributions to the total manufacturing costs.

Cost Analysis of TIL therapy

Cost Category	Specific Cost Components	Description & Impact on Cost	Estimated Proportion	China's average cost of major materials (thousand RMB/ per patient)*
Starting Material Acquisition	• Tumor Resection Surgery • Specialized Logistics	First, the tumor tissue is surgically removed from the patient. It is then immediately shipped to the manufacturing facility using specialized cold-chain logistics, with strict temperature control and tight timing.	~5%	~30-40
Core Manufacturing Process	• Cell Processing & Isolation • Cell Culture Media & Reagents • Feeder Cells • Growth Factors • GMP-Grade Consumables	This is the most expensive part. Immune cells are extracted from the tumor and then grown in large quantities – up to billions – using costly nutrients and growth factors. All materials must meet pharmaceutical-grade quality standards.	~35-45%	~190-400
Facility & Operational Costs	• Cleanroom Suite Operation • Laboratory Equipment • Highly Skilled Personnel	Production must take place in extremely expensive, sterile cleanrooms. The equipment is costly, and highly trained technicians must monitor the cells around the clock for several weeks. Labor costs are significant.	~20-25%	~110-220
Quality Control (QC) & Analytics	• Sterility Testing • Mycoplasma Testing • Endotoxin Testing • Cell Potency & Viability Assays • Identity Testing	Every batch must pass a series of strict tests to ensure there is no contamination, that the cells are active and effective, and that they belong to the correct patient. The instruments and reagents used for these tests are expensive, but this step is critical for patient safety.	~20-25%	~110-220
Final Product & Release	• Cryopreservation • Bagging & Final Packaging • Final Product Shipping	After manufacturing and testing are complete, the living cells are frozen, packaged in special cryogenic containers, and shipped back to the hospital at extremely low temperatures (below -130°C) for infusion into the patient.	~5%	~30-40

Source: Literature Research, Frost & Sullivan Analysis

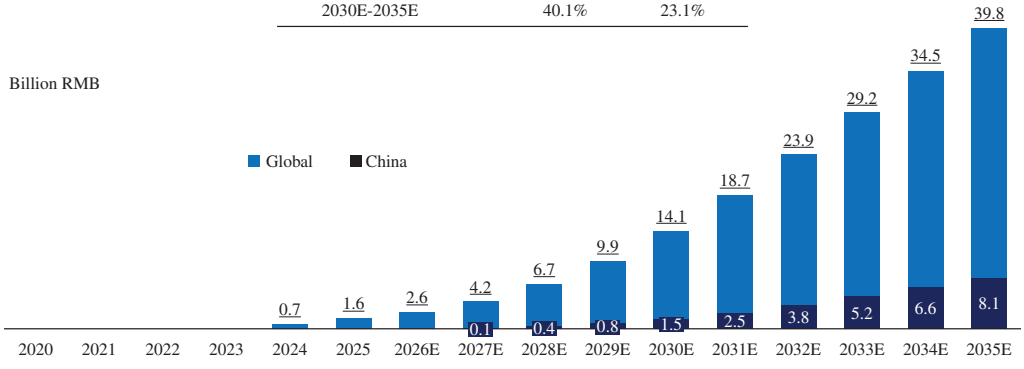
Market Size of TIL Therapy

Global TIL therapy market has reached RMB1.6 billion in 2025. It is projected to grow to RMB14.1 billion and RMB39.8 billion in 2030 and 2035, respectively, with the CAGR of 54.5% during 2025-2030 and 23.1% during 2030-2035.

Currently, the most advanced TIL therapy candidate has entered registrational Phase II clinical trials in China. Taking into account the time requirements of clinical trial design, development timelines, and regulatory approval pathways, the TIL therapy drug is expected to receive marketing approval in China around 2027, with a market size of RMB1.5 billion in 2030. The Chinese TIL therapy market is expected to reach RMB8.1 billion by 2035, with a CAGR of 40.1% from 2030 to 2035, which is higher than the global CAGR.

Global and China TIL Therapy Market, 2020-2035E

Period	CAGR	
	China	Global
2020-2025	N/A	N/A
2025-2030E	N/A	54.5%
2030E-2035E	40.1%	23.1%



Source: Company annual reports, Frost & Sullivan Analysis

Development Trends of Gene-modified TIL Therapy in Addressing Unmet Clinical Needs

Gene-modified TIL therapy represents an emerging direction in the evolution of cell-based immunotherapies for solid tumors. Building on the foundation of conventional TIL therapy, this approach applies genetic engineering technologies to enhance TIL function, improve therapeutic durability, and overcome limitations associated with the tumor microenvironment. Key development trends are outlined below.

- ***Treatment process optimization:*** TIL therapy is progressing toward safer and more convenient treatment protocols that avoid high-intensity lymphodepletion, high-dose IL-2, and feeder cells. Through technological innovation, next-generation TIL products aim to simplify the treatment process, reduce toxicity, and maintain or even improve therapeutic outcomes. These advances may eventually enable TIL administration outside intensive care settings, broadening patient access.

- ***Expanding application scope:*** TIL therapy has already been investigated across a wide range of solid tumors — such as melanoma, non-small cell lung cancer, cervical cancer, and ovarian cancer — and is expected to expand into additional tumor types as clinical research deepens.

- ***Achieving scalability:*** Future commercial success will rely on resolving current manufacturing limitations, including personalization, high costs, and lengthy production timelines. The industry is moving toward standardized and scalable manufacturing platforms that can significantly shorten production cycles and reduce costs.

- ***Combination therapy exploration:*** Combining TIL therapy with immune checkpoint inhibitors, particularly PD-1 antibodies, is a major developmental focus aimed at overcoming tumor microenvironment suppression and enhancing efficacy. Additional combinations — with targeted therapies, oncolytic viruses, and other modalities — are under clinical evaluation and show promising synergistic potential.

Growth Drivers of TIL Therapy Market

The TIL therapy market is expected to expand rapidly in the coming years, supported by a combination of clinical, technological, and regulatory factors. Several macro- and industry-level trends are driving increased adoption and accelerating development of TIL-based treatments. The principal growth drivers are outlined below.

- ***Rising cancer incidence:*** China cancer incidence continues to increase, as illustrated by melanoma, the incidence increased from 23.9 thousand to 28.2 thousand in China between 2020 and 2025, with a CAGR of 3.4%. With many patients diagnosed at advanced stages where existing treatment options provide limited benefit. The case of Chinese melanoma patients is illustrative, the predominant primary sites of these patients are acral and mucosal regions, and their mutational profiles differ significantly from those of Western populations. Consequently, 56% of patients present at an advanced stage (Stage III-IV), and objective response rates to standard therapies (e.g., BRAF inhibitors) and immunotherapies are low. This has created a significant unmet clinical need across multiple solid tumors, including melanoma, non-small cell lung cancer, and ovarian cancer. Clinical studies of TIL therapy have reported encouraging disease control and response rates in several treatment-refractory solid tumors, providing a data foundation supporting future commercialization.

- ***Supportive regulatory environment in China:*** The NMPA has introduced comprehensive policies and guidelines to regulate clinical trials and pharmaceutical studies for cell therapy products, effectively reducing R&D uncertainty and encouraging broader industry participation. This supportive environment for TIL therapy innovation is evidenced by several key initiatives, including the Clinical Application Guidelines for TIL Cell Therapy issued in January 2025 and the July 2025 Guideline on Preparation and

Quality Control of Tumor-Infiltrating Lymphocyte (TIL) Preparations, which established unified standards for patient selection and manufacturing. Furthermore, the Center for Drug Evaluation's (CDE) November 2024 publication of Technical Guidance on Clinical Pharmacology for Cell Therapies further ensures patient safety while supporting robust clinical development. Collectively, these domestic policies form a cohesive framework that standardizes the advancement and commercialization of TIL therapy in China.

- ***Advancements in technology:*** Ongoing technological innovation is strengthening the therapeutic potential of TIL therapy. Approaches such as lowering IL-2 requirements, gene editing to reduce immunosuppressive signals, and combination strategies with oncolytic viruses or immune checkpoint inhibitors may broaden indications and improve outcomes. These developments underscore the potential advantages of TIL therapy in solid tumor treatment and are attracting increasing clinical and market attention. In summary, reducing IL-2 can enhance the safety profile of TIL therapy, improve its sustainability and accessibility and provide more patients with a safe and effective treatment option. Traditional TIL therapy requires high-dose IL-2 administration to patients after cell infusion to support the expansion, survival, and activity of T cells in vivo. However, high-dose IL-2 is the primary cause of severe toxicities associated with TIL therapy, including fever, hypotension, and liver and kidney dysfunction. Patients may require hospitalization in severe cases. Therefore, the strategy of "IL-2 reduction" aims to lower the production, administration, and treatment costs of IL-2, as well as reduce toxicity, while maintaining therapeutic efficacy. Additionally, this approach may broaden the applicable patient population by expanding indications.

OVERVIEW OF MAJOR THERAPEUTIC AREAS IN SOLID TUMOR TREATMENT

Melanoma

Overview

Advanced melanoma is characterized by malignancy that has metastasized to distant organs — such as the lungs, liver, brain, or bones — or to distant lymph nodes. Melanoma is the most aggressive form of skin cancer and can also occur in other parts of the body, including the eyes and mucosal surfaces such as the nasal passages or throat. It originates from melanocytes, the pigment-producing cells responsible for skin, hair, and eye coloration. The patient diagnosis rate for melanoma ranges approximately from 55% to 75%. The prevalence rates of melanoma in 2020, 2025, 2030, and 2035 are 6, 12, 19, and 28 per 100,000 population in China, respectively. Melanoma patients receiving third-line or later therapy take approximately 8% to 10% of all melanoma cases in China.

Typical early signs include new or changing skin lesions or moles that vary in size, shape, or color. Lesions may bleed or appear noticeably different from surrounding moles. Concerning features include skin sores that do not heal and moles that become red, swollen, itchy, tender, bleeding, or painful.

Diagnosis relies on clinical evaluation, physical examination, and biopsy of suspicious lesions. For advanced disease, imaging techniques such as CT, MRI, PET-CT, ultrasound, and bone scans are commonly used to assess potential metastasis and determine disease extent.

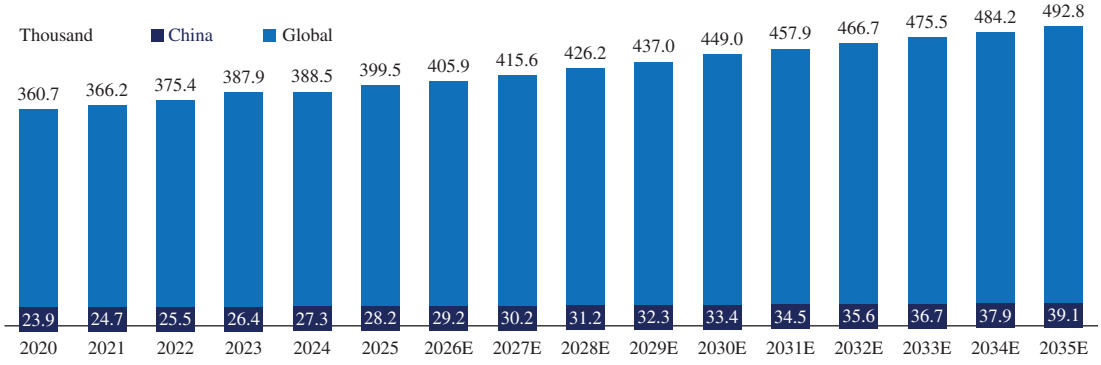
Incidences of Melanoma

From 2020 to 2025, the number of newly diagnosed melanoma cases worldwide increased from 360.7 thousand to 399.5 thousand, representing a CAGR of 2.1%. Global incidence is expected to continue rising, reaching 449.0 thousand cases by 2030 and 492.8 thousand cases by 2035, corresponding to projected CAGRs of 2.4% from 2025 to 2030 and 1.9% from 2030 to 2035.

In China, the melanoma patient population reached 28.2 thousand in 2025 and is expected to grow to 33.4 thousand by 2030, representing a CAGR of 3.4% from 2025 to 2030. By 2035, the number of patients is projected to increase to 39.1 thousand, corresponding to a CAGR of 3.2% between 2030 and 2035.

Global and China Incidence of Melanoma, 2020-2035E

Period	CAGR	
	China	Global
2020-2025	3.4%	2.1%
2025-2030E	3.4%	2.4%
2030E-2035E	3.2%	1.9%



Source: Frost & Sullivan Analysis

Treatment paradigm of Melanoma in China

Systemic therapies play a key role in improving survival outcomes for patients with advanced melanoma. Current treatment approaches typically include targeted therapies, chemotherapy, immunotherapy, standardized response evaluation criteria, and supportive care measures tailored to manage symptoms and maintain quality of life.

Current Treatment options

First-line melanoma treatment varies by stage and subtype. For early-stage resectable disease, surgery offers a potential cure with 90% 5-year survival, though risks include wound infection and lymphedema. For advanced cutaneous or acral melanoma without brain metastases, immunotherapy (PD-1/PD-L1 antibodies) provides an ORR of 11%-16% but may cause rash, diarrhea, or hepatitis. For BRAF-mutated patients, targeted therapy (Dabrafenib+Trametinib; Vemurafenib/Cabozantinib+Atezolizumab) achieves a higher ORR of 86.7% (Dabrafenib+Trametinib), with mild to moderate side effects such as fever and rash. For mucosal melanoma, chemotherapy yields a lower ORR of 20% and carries risks of myelosuppression and bleeding.

Currently, several second-line options are available for patients with metastatic or unresectable melanoma progressing after first-line therapy. Immunotherapy or combination immunotherapy may overcome drug resistance and delay disease progression, but immune-related adverse events require close monitoring. Targeted therapy or combination targeted therapy is indicated for patients with corresponding mutations, though overlapping side effects (fever, rash, diarrhea) may necessitate dose adjustment. Chemotherapy (e.g., dacarbazine, temozolomide, taxanes) offers palliative relief for patients without other options, helping control disease progression, but is associated with myelosuppression, gastrointestinal toxicity, and alopecia. These treatments provide clinical benefits but are limited by various toxicities.

Global Competitive Landscape of TIL Therapy for Melanoma Treatment

A number of companies are actively advancing TIL and gene-modified TIL therapies worldwide, with programs at various stages of clinical development. Among these, Juncell has emerged as one of the leading innovators, progressing its GC101 program into Phase II clinical evaluation. The table below provides an overview of key industry players, their product candidates, development phases, and trial locations.

Company	Candidates	Phase	First post date	Location
Iovance	Lifileucel	Approved	2024/2	US, Canada
	Lifileucel	Phase III (Combo with Pembrolizumab)	2023/2	Global
	IOV-4001	Phase I/II	2022/5	US
Juncell	GC101	Registrational Phase II	2024/12	China
Sino-Cell Biomedicine	HS-IT101	Phase I	2025/4	China
KSQ	KSQ-004EX	Phase I/II	2024/9	US
	KSQ-001EX	Phase I/II	2024/2	US
Lanma Bio	LM103	Phase I	2023/12	China
Obsidian	OBX-115	Phase I/II	2023/9	US
AgonOx	AGX-148	Phase I	2023/6	US
Adaptimmune	ADP-TILIL7	Phase I	2024/1	Denmark

Source: Clinicaltrials, CDE, Frost & Sullivan Analysis

Clinical Data Comparison of TIL Therapy for the Treatment of Melanoma

Company	Mono/ Combo	Product	Type of technology used	Clinical stage	Line of treatment	Administration	Safety	Efficacy
Juncell	Mono	GC101	Autologous TIL from resected tumor	Registrational Phase II	≥3L	Injection	CTR20221207 (n=10)	
							Grade 3-4 TRAEs included leukopenia/ neutropenia/lymphopenia/monocytopenia (20%) and hypertension (10%)	PFS: 5.5m
Lanma Bio	Mono	LM103	Autologous TIL from resected tumor	Phase I	3L	Injection	CTR20233999 (n=12)	
							Grade 3-4 TEAEs included leukopenia (100%), lymphopenia/neutropenia (91.7%), fever (83.3%), thrombocytopenia (66.7%), and anemia (33.3%)	PFS: N/A
Iovance	Mono	Lifileucel	Autologous TIL from resected tumor	marketed	≥3L	Injection	5-yr Analysis of C-144-01 (n=153)	
							Treatment-related mortality (7.5%), ICU stay (23.6%), prolonged cytopenias lasting for 30+ days (45.5%)	PFS: 4.1m
Obsidian	Mono	OBX-115	Autologous TIL from resected tumor modified *ex vivo* with synthetic control	Phase I/II	2L, 3L	Injection	Phase-I Single-center (n=10)	
							No DLTs. Grade 2 CRS (n=2), 5 patients had Grade 3 AEs (pain, ALT/AST increase, hyponatremia, hypokalemia/dehydration)	PFS: N/A

Note: The table above only presents product information for which clinical data have been publicly disclosed.

Source: Clinicaltrials, CDE, Frost & Sullivan Analysis

The key IP rights of Lifileucel expire in December 2042. Amtagvi is the world's only approved TIL therapy, priced at US$515,000 when it was launched in 2024 and increased to US$563,000 in 2025. In the TIL therapy market, Amtagvi holds a near-100% share. It has been covered by Medicare, Medicaid, and major commercial insurers, with approximately 75%+ of Amtagvi patients having commercial insurance coverage (as of 2024.6.28).

Non-small-cell Lung Cancer (NSCLC)

Overview

NSCLC is any type of epithelial lung cancer other than small cell lung cancer (SCLC). The most common types of NSCLC are squamous cell carcinoma, large cell carcinoma, and adenocarcinoma. All types can occur in unusual histologic variants and developed as mixed cell-type combinations. The patient diagnosis rate for NSCLC ranges approximately from 85% to 88%. The prevalence rates of NSCLC in 2020, 2025, 2030, and 2035 are 128, 233, 356, and 495 per 100,000 population in China, respectively. NSCLC patients receiving third-line or later therapy take approximately 12% to 15% of all NSCLC cases.

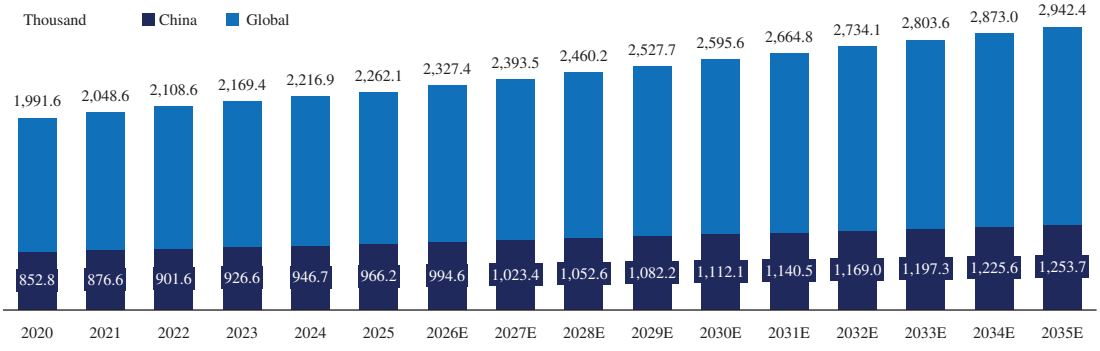
Incidences of NSCLC

From 2020 to 2025, the number of newly diagnosed NSCLC cases worldwide rose from 2.0 million to 2.3 million, reflecting a CAGR of 2.6%. Global incidence is expected to continue increasing, reaching 2.6 million cases by 2030 and 2.9 million cases by 2035, corresponding to projected CAGRs of 2.8% from 2025 to 2030 and 2.5% from 2030 to 2035.

The incidence rate of NSCLC in Chinese mainland in 2020 was 60 per 100,000 population. In China, the patient population for NSCLC reached 1.0 million in 2025 and is forecast to grow to 1.1 million by 2030, representing a CAGR of 2.9% between 2025 and 2030. By 2035, the number of patients is projected to increase to 1.3 million, reflecting a CAGR of 2.4% between 2030 and 2035.

Global and China Incidence of NSCLC, 2020-2035E

Period	CAGR	
	China	Global
2020-2025	2.5%	2.6%
2025-2030E	2.9%	2.8%
2030E-2035E	2.4%	2.5%



Source: Frost & Sullivan Analysis

Treatment paradigm of NSCLC in China

Most patients with NSCLC are diagnosed at an advanced or metastatic stage. For these late-stage cases, the SOC often involves chemotherapy, molecular targeted therapy, and immunotherapy, which can be used either alone or in combination. Monotherapy or combination therapies are utilized across first-line to salvage treatments, tailored based on genetic mutations.

Currently, no TIL-based therapy has been approved for the treatment of NSCLC. Meanwhile, multiple TIL therapy programs for NSCLC treatment are at various stages of clinical development, with the most advanced candidate having entered Phase II clinical trial in China.

Current Treatment options

Currently, multiple treatment options are available for NSCLC. First-line targeted therapy (e.g., EGFR, ALK, ROS1 inhibitors) achieves ORR of approximately 80% and significantly prolongs PFS and OS in patients with corresponding mutations, but may cause rash, diarrhea, or rare interstitial pneumonia. For patients without driver mutations, options include: immunotherapy plus chemotherapy (improves survival, with fatigue and immune-related side effects); immunotherapy alone (for high PD-L1 expression, durable responses with mild side effects); or chemotherapy ± anti-angiogenic drugs (slows progression, with bone marrow suppression and bleeding risks; bevacizumab is contraindicated in squamous cell carcinoma).

In second-line treatment, targeted therapy for patients with acquired resistance mutations (e.g., EGFR T790M, ALK progression), achieves an ORR of 40-70% and overcomes drug resistance, with side effects similar to but slightly milder than first-line. For patients without driver mutations who progressed after first-line chemo/immunotherapy combination, immunotherapy (CheckMate 078: median OS ~12 months, ORR ~17%) may be used; immune-related adverse events are less severe than first-line but require monitoring for late-onset reactions. For NSCLC patients who progress after first-line treatment with no targeted/immunotherapy options, chemotherapy (e.g., ramucirumab + docetaxel) offers modest benefit (REVEL: median OS 10.5m for ramucirumab + docetaxel vs. 9.1m for docetaxel) but causes myelosuppression, GI toxicity, and bleeding risk (contraindicated in squamous cell carcinoma).

Third-line treatment options for NSCLC are limited. Chemotherapy (e.g., docetaxel, pemetrexed) offers palliative relief with lower efficacy but carries cumulative myelosuppression and fatigue. For patients with newly detected driver mutations via re-biopsy, targeted therapy may provide clinically meaningful disease control. For immunotherapy-naive patients, immunotherapy monotherapy may be considered, though efficacy is lower than second-line. When standard options are exhausted, clinical trials (e.g., novel targeted drugs, dual immunotherapy) offer potential but with unknown safety risks requiring close monitoring.

Global Competitive Landscape of TIL Therapy for NSCLC treatment

A number of companies globally are advancing NSCLC programs using TIL or gene-modified TIL therapies, reflecting growing interest in applying cell-based immunotherapy to this high-incidence solid tumor type. These programs vary in development stage, technology approach, and geographic focus. The table below provides an overview of key industry participants, their product candidates, clinical phases, and trial locations.

Company	Candidates	Phase	First post date	Location
Iovance	Lifileucel	Phase II	2020/11	US
	IOV-4001	Phase I/II	2022/5	US
Juncell	GC101	Phase Ib/II	2024/9	China
Sino-Cell Biomedicine	HS-IT101	Phase I	2025/8	China
KSQ	KSQ-004EX	Phase I/II	2024/9	US
	KSQ-001EX	Phase I/II	2024/2	US
Aeonvital	ReT01 ACT	Phase I	2024/1	China
Obsidian	OBX-115	Phase I/II	2023/9	US
Intima	CISH Inactivated TIL	Phase I/II	2022/10	US

Source: Clinicaltrials, CDE, Frost & Sullivan Analysis

Clinical Data Comparison of TIL Therapy for the Treatment of NSCLC

Company	Mono/ Combo	Product	Type of technology used	Clinical stage	Line of treatment	Administration	Safety	Efficacy
Juncell	Mono	GC101	Autologous TIL from resected tumor	Phase Ib/II	≥3L	Injection	TIL-ST-I (n=12)	
							G3+ TRAE included leukopenia (25%), neutropenia (16.7%), lymphopenia/thrombocytopenia (8.3%)	ORR: 41.7% (5)
Iovance	Mono	LN-145	Autologous TIL from resected tumor	Phase II	3L	Injection	IOV-LUN-202 (n=39)	
							Trial was once suspended due to a patient death potentially related to the lymphodepletion in December 2023	ORR: 25.6% (10)

Gynecological Cancer

Overview

Gynecological cancers encompass cervical cancer, ovarian cancer, and uterine cancer, each affecting different parts of the female reproductive system. The patient diagnosis rate for ovarian cancer is estimated approximately at 90%, endometrial cancer is estimated approximately at 80%, and cervical cancer ranges approximately from 70% to 90%. The five-year survival rate for gynecological cancer is 68% and the postoperative recurrence rate is 35%.

Cervical cancer arises from the cervix, the lower part of the uterus, and is primarily caused by persistent infection with high-risk human papillomavirus (HPV), a common sexually transmitted virus. Because of its relatively high incidence, long disease development cycle, well-defined precancerous stages, and significant treatment burden, cervical cancer is one of the few cancers for which routine screening is recommended in average-risk, asymptomatic populations. Early detection is critical, as precancerous lesions — known as cervical intraepithelial neoplasia (CIN) — can progress to invasive cancer over time. Low-grade CIN rarely progresses, whereas high-grade CIN can develop into squamous cell carcinoma or adenocarcinoma over a period of 10 to 15 years

if left untreated. Most cervical cancers (around 90%) are squamous cell carcinomas. Treatment is generally unnecessary for low-grade CIN, while high-grade CIN is typically managed with ablation or excision procedures such as LEEP, which significantly reduce the risk of progression to invasive cancer.

Ovarian cancer develops in the ovaries, the reproductive glands that produce eggs. It occurs when cells in the ovaries begin to grow uncontrollably. Early warning signs include abdominal bloating, indigestion, nausea, changes in appetite, pelvic or lower back pressure, a frequent or urgent need to urinate, constipation, changes in bowel movements, increased abdominal girth, fatigue, and changes in menstruation. In more advanced stages, ovarian cancer can present with ovarian cysts, masses, or tumors.

Endometrial cancer, also known as uterine corpus cancer, is an epithelial malignancy that occurs in the endometrium. It is one of the most common gynecological cancers, primarily affecting perimenopausal and postmenopausal women. Over the past two decades, the incidence of endometrial cancer has increased, with patients becoming younger as life expectancy rises and lifestyle changes occur. In Western countries, endometrial cancer is the leading gynecological malignancy, while in China, it is the second most common, after cervical cancer, accounting for about 20% to 30% of gynecological malignancies.

Incidences of Gynecological Cancer

From 2020 to 2025, global cervical cancer incidence increased from 604.1 thousand to 702.6 thousand cases, reflecting a CAGR of 3.1%. The number of new cases is projected to reach 760.1 thousand by 2030 and 814.5 thousand by 2035, corresponding to CAGRs of 1.6% from 2025 to 2030 and 1.4% from 2030 to 2035.

Global uterine cancer incidence rose from 417.4 thousand in 2020 to 452.9 thousand cases in 2025, representing a CAGR of 1.6%. Incidence is expected to increase to 502.7 thousand by 2030 and 551.4 thousand by 2035, with projected CAGRs of 2.1% from 2025 to 2030 and 1.9% from 2030 to 2035.

Global ovarian cancer incidence grew from 314.0 thousand to 347.0 thousand cases between 2020 and 2025, at a CAGR of 2.0%. The number of new cases is forecast to reach 381.6 thousand by 2030 and 415.6 thousand by 2035, corresponding to CAGRs of 1.9% from 2025 to 2030 and 1.7% from 2030 to 2035.

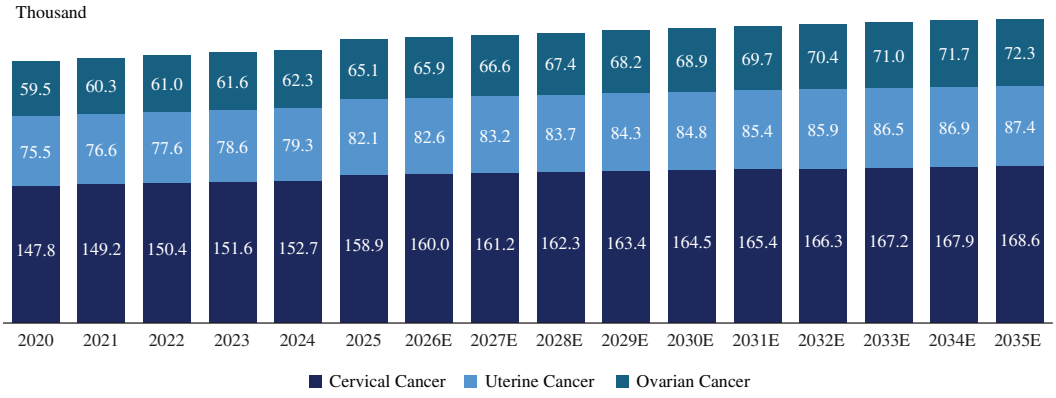
From 2020 to 2025, the number of newly diagnosed cervical cancer cases in China increased from 147.8 thousand to 158.9 thousand, representing a CAGR of 0.8%. Incidence is projected to reach 164.5 thousand by 2030 and 168.6 thousand by 2035, corresponding to CAGRs of 0.7% from 2025 to 2030 and 0.6% from 2030 to 2035.

New uterine cancer cases in China rose from 75.5 thousand in 2020 to 82.1 thousand in 2025, reflecting a CAGR of 1.2%. The number of cases is expected to increase to 84.8 thousand by 2030 and 87.4 thousand by 2035, with projected CAGRs of 0.8% from 2025 to 2030 and 0.7% from 2030 to 2035.

For ovarian cancer, incidence in China increased from 59.5 thousand to 65.1 thousand between 2020 and 2025, representing a CAGR of 1.1%. New cases are forecast to reach 68.9 thousand by 2030 and 72.3 thousand by 2035, corresponding to CAGRs of 0.7% from 2025 to 2030 and 0.6% from 2030 to 2035.

China Incidence of Gynecological Cancer, 2020-2035E

Period	Cervical cancer	Uterine Cancer	Ovarian Cancer
2020-2025	0.8%	1.2%	1.1%
2025-2030E	0.7%	0.8%	0.7%
2030E-2035E	0.6%	0.7%	0.6%



Source: Frost & Sullivan Analysis

Treatment paradigm of Cervical Cancer in China

The treatment of cervical cancer mainly includes surgery and radiotherapy. Chemotherapy is widely used in combination with surgery and radiotherapy and in the treatment of advanced recurrent cervical cancer, using platinum (mainly cisplatin) based monotherapy or combined chemotherapy. The following chart illustrates treatment paradigm of cervical cancer recommended by the CSCO.

For first-line treatment of cervical cancer, multiple regimens are available. Cisplatin or carboplatin plus paclitaxel with or without bevacizumab is a standard option. For PD-L1-positive tumors, pembrolizumab combined with cisplatin or carboplatin plus paclitaxel with or without bevacizumab is recommended. Other alternatives include topotecan plus paclitaxel with or without bevacizumab, cisplatin plus topotecan, or cisplatin/carboplatin/paclitaxel alone.

For second-line treatment after disease progression, several options exist. Tisotumab vedotin-ttfv is approved for this setting. Additionally, multiple agents may be considered, including albumin-bound paclitaxel, docetaxel, gemcitabine, pemetrexed, topotecan, cadonilimab, serplulimab, tislelizumab, envafolimab, fluorouracil, ifosfamide, irinotecan, mitomycin, vinorelbine, zimberelimab, pembrolizumab (Suitable for tumours with PD-L1 positivity or those exhibiting TMB-H and MSI-H/dMMR), and nivolumab.

Treatment paradigm of Ovarian Cancer in China

The treatment paradigm for ovarian cancer contains surgery, postoperative adjuvant chemotherapy (first-line) and second-line therapy: Adjuvant chemotherapy mainly uses paclitaxel, carboplatin, doxorubici, docetaxel, etc. Second-line therapy can be categorized by platinum-based chemotherapy, non-platinum chemotherapy, and other drugs. Chemo drugs includes cisplatin, carboplatin, gemcitabine, doxorubicin, paclitaxel, docetaxel, etc.

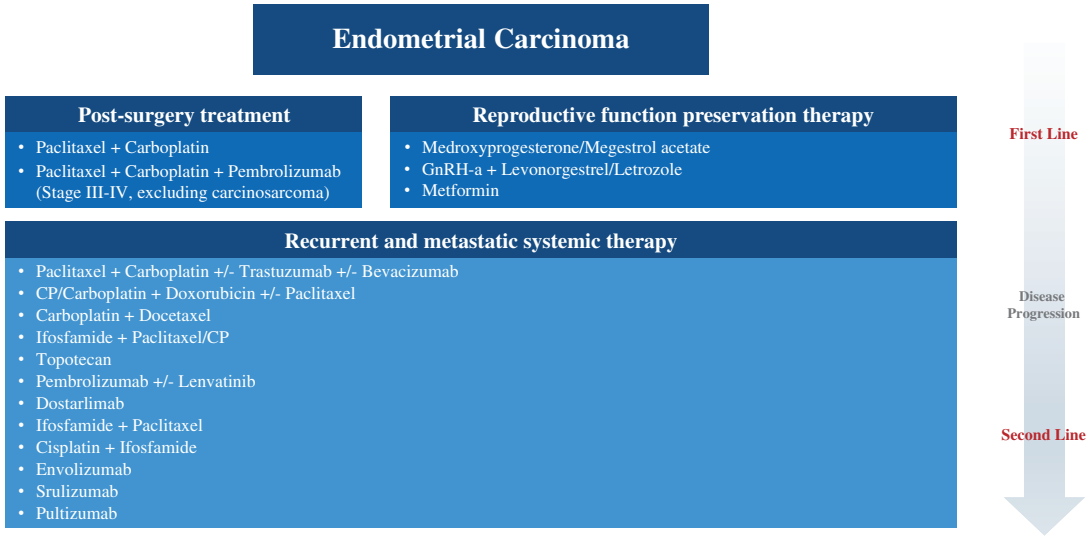
Currently, treatment for ovarian cancer is determined by disease stage and platinum sensitivity. For early-stage disease (Stage I), options include paclitaxel plus carboplatin, carboplatin plus doxorubicin liposomes, or carboplatin plus docetaxel. For advanced-stage disease (Stage II-IV), paclitaxel plus carboplatin with or without bevacizumab, and carboplatin plus docetaxel are the standard first-line regimens. For recurrent disease, treatment is guided by platinum sensitivity.

In platinum-sensitive recurrence, secondary surgical cytoreduction followed by platinum-based combination chemotherapy with or without maintenance therapy, PARP inhibitors for BRCA1/2-mutated tumors, niraparib plus bevacizumab, or hormone therapy is recommended. Non-platinum chemotherapy or immune checkpoint inhibitors may also be considered.

In platinum-resistant recurrence, chemotherapy options include doxorubicin liposome, weekly paclitaxel, topotecan, docetaxel, oral etoposide, or gemcitabine, each with or without bevacizumab. Other options include doxorubicin liposome plus apatinib, sunitinib, or chemotherapy plus suxibatin.

Treatment paradigm of Endometrial Carcinoma in China

Currently, treatment for endometrial carcinoma in China includes post-surgery therapy, fertility-preserving options, and systemic therapy. For post-surgery treatment, paclitaxel plus carboplatin is standard, with pembrolizumab added for Stage III-IV disease (excluding carcinosarcoma). For fertility preservation, therapies such as medroxyprogesterone, megestrol acetate, metformin or GnRH-a with levonorgestrel/letrozole are used. For recurrent or metastatic disease, options include paclitaxel + carboplatin +/- trastuzumab +/- bevacizumab, CP/carboplatin + doxorubicin +/- paclitaxel, carboplatin + docetaxel, ifosfamide + paclitaxel/CP, topotecan, pembrolizumab +/- lenvatinib, dostarlimab, ifosfamide + paclitaxel, cisplatin + ifosfamide, envolizumab, sruilizumab, and pultizumab.



Notes: RT = Radiation therapy; CP = cisplatin; X = capecitabine; 5-FU = 5-Fluorouracil; G = gemcitabine

Source: CSCO 2025, Literature Review, Frost & Sullivan Analysis

Global Competitive Landscape of TIL Therapy for Gynecologic Cancer Treatment

Company	Candidates	Indication	Phase	First post date	Location
Iovance	Lifileucel	Endometrial cancer	Phase II	2024/7	US
Grit	GT101	Cervical cancer	Phase II	2024/3	China
Juncell	GC203	Gynecological cancer	Phase I	2024/5	China
	GC101	Cervical cancer	Phase I	2022/5	China
KSQ	KSQ-004EX	Cervical cancer	Phase I/II	2024/9	US
Lanma Bio	LM103	Cervical cancer	Phase I	2023/12	China
Sino-Cell Biomedicine	HS-IT101	Cervical cancer	Phase I	2023/12	China
AgonOx	AGX-148/RXI-762	Gynecological cancer	Phase I	2023/6	US

Source: Clinicaltrials, CDE, Frost & Sullivan Analysis

SOURCE OF INFORMATION

We engaged Frost & Sullivan, a market research consultant, to prepare the Frost & Sullivan Report for use in this Document. The information from Frost & Sullivan disclosed in this Document is extracted from the Frost & Sullivan Report and is disclosed with the consent of Frost & Sullivan. In preparing the Frost & Sullivan Report, Frost & Sullivan collected and reviewed publicly available data such as government-derived information, annual reports, trade and medical journals, industry reports and other available information gathered by not-for-profit organizations as well as market data collected by conducting interviews with industry key opinion leaders. Frost & Sullivan has exercised due care in collecting and reviewing the information so collected and independently analyzed the information, but the accuracy of the conclusions of its review largely relies on the accuracy of the information collected. We agreed to pay Frost & Sullivan a fee of RMB1.01 million for the preparation and update of the Frost & Sullivan Report, which is not contingent on the [**REDACTED**] proceeding.