The information and statistics set out in this section and other sections of this document were extracted from different official government publications, available sources from public market research and other sources from independent suppliers, and from the independent industry report prepared by Frost & Sullivan in connection with the **[REDACTED]** *(the "**F&S Report**"). The information from official government sources has not been independently verified by us, the Joint Sponsors,* **[REDACTED]***, any of the* **[REDACTED]***, any of their respective directors and advisers, or any other persons or parties involved in the* **[REDACTED]***, and no representation is given as to its accuracy.*

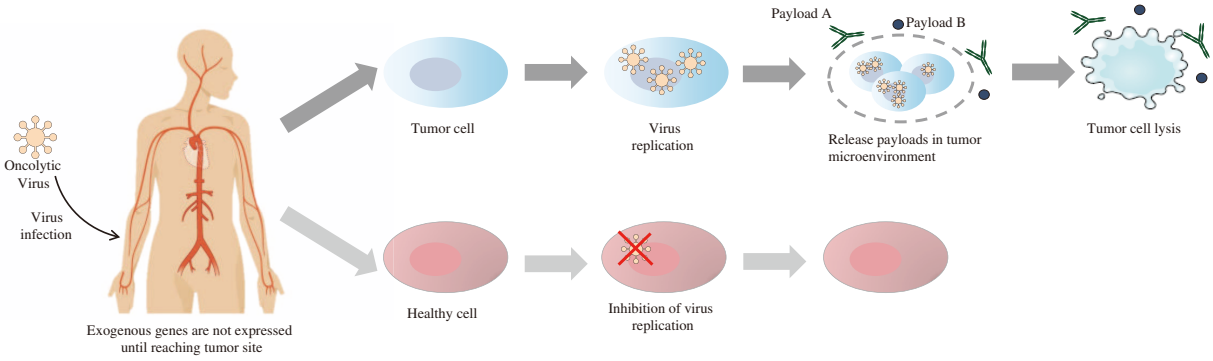
OVERVIEW OF ONCOLYTIC IMMUNOTHERAPY

Introduction to Oncolytic Immunotherapy

Oncolytic immunotherapy, or oncolytic virus therapy, is a cancer treatment that utilizes oncolytic virus, which selectively replicate within tumor cells without harming normal tissues. By exploiting inherent or modified viral tumor selectivity, oncolytic immunotherapy effectively destroys tumors through direct oncolysis, causing extensive tumor cell lysis.

Beyond direct oncolysis, oncolytic immunotherapy exerts profound immunomodulatory effects within the tumor microenvironment. The selective replication of oncolytic virus within tumor cells leads to immunogenic cell death, resulting in the release of both tumor-associated antigens ("**TAAs**") and pro-inflammatory cytokines. These cytokines promote local inflammation and immune cell recruitment, thereby enhancing immune surveillance and converting immunologically "cold" tumors, which are characterized by poor responses to standard immunotherapy, into "hot" tumors by promoting immune cell infiltration and enhancing antigen presentation. This process can sensitize tumors to immune checkpoint inhibitors and other immunotherapies that otherwise show limited efficacy in non-inflamed tumor contexts.

At the same time, TAAs released during oncolysis are captured and presented by antigen-presenting cells, such as dendritic cells, which subsequently activate tumor-specific cytotoxic T cells. Among these, CD8+ T cells directly kill tumor cells, while CD4+ T cells enhance the immune response by supporting the activation and maintenance of CD8+ T cells and other immune cells, resulting in a more robust and sustained anti-tumor effect. Consequently, this systemic immune priming can generate durable anti-tumor responses beyond the initial site of viral infection, a phenomenon often described as the "vaccine-like" effect of oncolytic immunotherapy. The following diagram illustrates the mechanism of action of oncolytic immunotherapy.



Source: Literature Review, Frost & Sullivan Report

Evolution of Oncolytic Immunotherapy

With accumulated research on oncolytic viruses dating back to the mid-19th century, Amgen's T-VEC has became the first FDA-approved oncolytic immunotherapy since 2015. The approval of HSV-1 based T-VEC marked a key milestone in the oncolytic immunotherapy field, to which our Company's founder made significant contributions during its early development. Today, oncolytic immunotherapy has emerged as a highly promising immuno-oncology approach, demonstrating significant potential to transform cancer treatment by harnessing both direct tumor destruction and systemic immune activation. To build on these therapeutic advantages, recent development trends have increasingly focused on evolving viral backbones and optimizing payloads to further enhance efficacy and safety of oncolytic immunotherapy.

Various viral vectors have been extensively explored for use as vector in oncolytic immunotherapy, including DNA viruses such as herpes simplex virus ("**HSV**"), vaccinia virus and adenovirus, as well as RNA viruses such as reovirus and measles virus. Among these, HSV-1 has emerged as the most favored vector for oncolytic immunotherapy development due to its large genome capacity, high modifiability, and promising safety profile, being the backbone of the only FDA-approved oncolytic immunotherapy product as of the Latest Practicable Date. As humans are the natural host for HSV-1, its intrinsic biological compatibility confers a high safety profile and significantly reduces the risk of systemic toxicity. In addition, HSV-1 offers key advantages such as a large genome capacity with engineering potential, compared to RNA viruses and other DNA viruses such as adenovirus. The large genome size allows for the insertion of multiple exogenous immune-enhancing genes and supports diverse therapeutic designs that confer oncolytic immunotherapy with substantial potential and flexibility. For example, in HSV-1 vector, the deletion of virulence genes such as ICP34.5 helps minimize toxicity to normal tissues, thereby enhancing the safety profile of the therapy. In contrast, vectors like Ad5 present a higher risk of hepatotoxicity, restricting their utility in therapeutic applications.

The genome capacity, genetic modifiability and safety profile of viral backbones allow oncolytic immunotherapies to be tailored to diverse clinical needs and tumor types, thereby supporting multiple routes of administration. As a key determinant of therapeutic efficacy and safety, the administration routes are of great importance in the development of oncolytic immunotherapy. Currently, three main administration routes are employed for approved products and clinical candidates:

- ***Intratumoral administration.*** To date, intratumoral administration remains the most common method, involving direct injection of the virus into accessible tumors. It enables high local viral concentration while minimizing systemic exposure but is limited to superficial or image-guided injectable lesions.

- ***Intravenous administration.*** Intravenous injection is considered a breakthrough direction for systemic delivery, aiming to target metastatic and deep-seated tumors. Despite its potential, this route faces significant hurdles, including dose dilution in circulation, rapid immune clearance, immunogenic toxicity such as cytokine release syndrome (CRS), and off-target effects. Particularly, it is a route of administration with the highest drug exposure, the broadest systemic injection, and the highest risk for dosing patients.

- ***Intracavitary administration.*** Intracavitary administration encompasses intravesical, intraperitoneal, and intrapleural delivery routes, enabling localized treatment within the thoracic cavity, abdominal cavity, and bladder, respectively. This administration allows high local drug concentration and reduced systemic toxicity. However, its use is generally confined to cancers located within specific anatomical spaces and may require repeated catheterization.

Beyond viral backbone selection and modification, the engineering of transgene payloads also plays a key role in advancing oncolytic immunotherapy. Payloads are designed to potentiate anti-tumor immunity by expressing immune-modulating agents within the tumor microenvironment, thereby enhancing both local and systemic responses. Before the exploration into modernized promising payloads, GM-CSF remained one of the most widely adopted options. This shift marked the beginning of a transition toward more refined immunotherapeutic payloads, including anti-PD-(L)1 antibodies, which locally inhibit immune checkpoint signaling to reverse T cell exhaustion while minimizing systemic toxicity typically associated with checkpoint inhibitors. Another widely studied payload is IL-12, a pro-inflammatory cytokine that promotes Th1 immune polarization, enhances cytotoxic lymphocyte activity, and facilitates dendritic cell maturation. When delivered via an oncolytic immunotherapy drug, IL-12 can elicit robust anti-tumor effects while avoiding the systemic toxicity observed in recombinant IL-12 therapies. These payloads,

individually or in combination, allow for the rational design of armed oncolytic immunotherapy with enhanced therapeutic breadth, precision and safety, which position oncolytic immunotherapy as a customizable and synergistic platform within the broader immune-oncology landscape.

In addition, oncolytic immunotherapy also offers versatile applications, with demonstrated therapeutic potential both as a monotherapy and in combination with other treatment modalities. As monotherapy, oncolytic immunotherapy can boost the immune response by producing tumor-specific antigens or immune-stimulating molecules like cytokines or checkpoint inhibitors. In combination settings, oncolytic immunotherapy can make tumors more responsive to immune checkpoint inhibitors, support other immunotherapies by promoting antigen release, improve chemotherapy by breaking down tumor barriers, and help reduce recurrence when used around surgery. Due to its flexibility as both monotherapy and combination therapy, along with strong anti-tumor activity, oncolytic immunotherapy holds a significant promise for treating tumors. In 2024, the global cancer incidence reached 21.3 million cases, including 2.0 million in the U.S. and 5.0 million in China. This rising incidence highlights the clinical need for new and effective treatment options, making oncolytic immunotherapy a compelling next-generation approach in the treatment of tumors.

Leveraging optimized backbones, immunostimulatory payloads, and versatile administration routes, oncolytic immunotherapy also act as powerful *in situ* cancer vaccines. By lysing tumor cells within the tumor microenvironment, they trigger the release of tumor-associated antigens alongside viral danger signals, promoting antigen presentation and systemic immune priming. This vaccine-like effect not only enhances local tumor clearance but also facilitates immune surveillance against distant or residual disease, supporting durable and broad anti-tumor responses.

Oncolytic Immunotherapy Drug Market

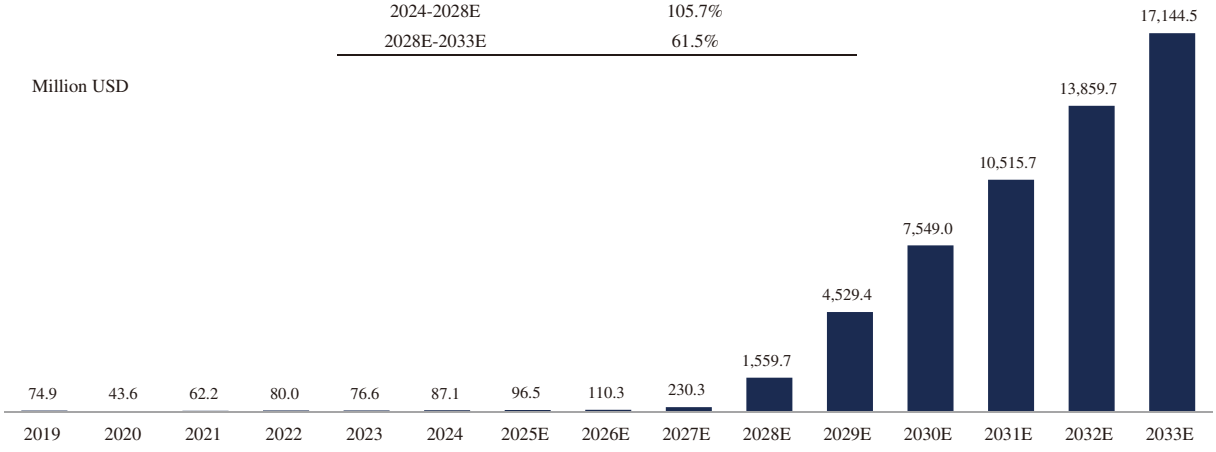
The global oncolytic immunotherapy drug market is currently in its nascent stage, characterized by a limited number of commercialized products and limited clinical adoption. As a result, prescribing practices among physicians are not yet well established, which, with the COVID-19-related disruption, led to the fluctuations of the oncolytic immunotherapy market size between 2019 and 2024. Although T-VEC was approved in 2015, its market penetration during 2019 to 2024 remained modest, in part due to its limited efficacy as a monotherapy in late-stage melanoma.

Recent years have witnessed oncolytic immunotherapy achieving promising readouts and a growing pipeline of drug candidates approaching regulatory milestones. In addition, the scope of targeted indications expanded beyond melanoma to major solid tumors, including bladder cancer, head and neck cancer and others, underscoring the broader therapeutic potential of this modality. For example, the total global incidence of bladder cancer, head and neck squamous cell carcinoma

(HNSCC) and gliomaindications where oncolytic immunotherapy demonstrates significant therapeutic potentialamounted to approximately 2.06 million cases in 2024, and is projected to increase to approximately 2.49 million cases by 2033. As of the Latest Practicable Date, four oncolytic immunotherapy drugs had been approved globally, and six oncolytic immunotherapy candidates were in pivotal Phase II/III or later stage worldwide, with more than 20 additional candidates in Phase I/II. According to Frost & Sullivan, at least 10 new oncolytic immunotherapies are expected to receive global approval between 2026 and 2033. Moreover, oncolytic immunotherapies are increasingly being developed in combination therapies (e.g., with checkpoint inhibitors) and for earlier lines of therapy. Considering the foregoing, the oncolytic immunotherapy market is expected to undergo a rapid expansion in the coming years. The global oncolytic immunotherapy drug market is projected to reach US$1,559.7 million by 2028 from US$87.1 million in 2024, reflecting a CAGR of 105.7% from 2024 to 2028, and further expand to US$17,144.5 million by 2033, representing a CAGR of 61.5% from 2028 to 2033. Meanwhile, the U.S. oncolytic immunotherapy drug market is expected to grow to US$975.2 million by 2028 from US$58.2 million in 2024, representing a CAGR of 102.3% from 2024 to 2028, and further expanded to US$9,640.0 million by 2033, representing a CAGR of 58.1% from 2028 to 2033. The charts below set forth the historical and projected market sizes of oncolytic immunotherapy drug markets globally and in the U.S. for the periods indicated, respectively.

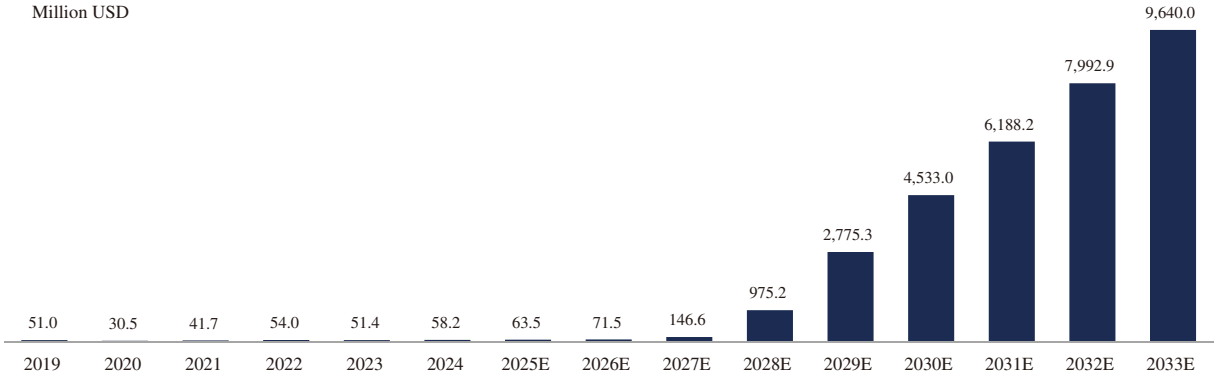
Global Oncolytic Immunotherapy Drug Market, 2019-2033E

Period	CAGR
2019-2024	3.0%
2024-2028E	105.7%
2028E-2033E	61.5%



U.S. Oncolytic Immunotherapy Drug Market, 2019-2033E

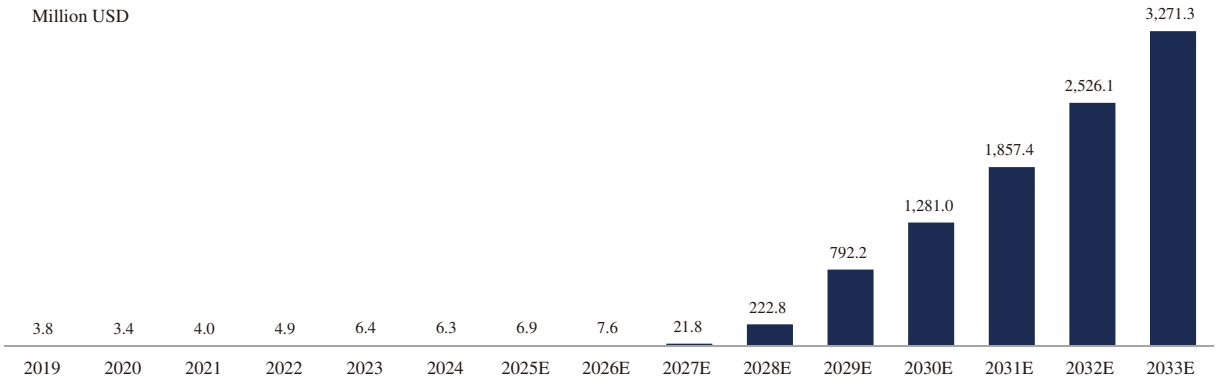
Period	CAGR
2019 -2024	2.7%
2024 -2028E	102.3%
2028E -2033E	58.1%



China also demonstrates notable momentum in the field of oncolytic immunotherapy. As of the Latest Practicable Date, H101 remained the only Ad5-based oncolytic immunotherapy product approved in China, and seven oncolytic immunotherapy candidates in China were in Phase II or more advanced stages. According to Frost & Sullivan, at least six new oncolytic immunotherapies are expected to be approved in China between 2025 and 2033, with their indicated scopes similarly broadening to encompass a wider range of solid tumor types. These developments collectively point to significant anticipated growth in the oncolytic virus drug market in China, which is expected to grow to US$222.8 million by 2028 from US$6.3 million in 2024 and further expand to US$3,271.3 million by 2033, representing a CAGR of 143.9% from 2024 to 2028 and 71.1% from 2028 to 2033. The chart below sets forth the historical and projected market size of oncolytic immunotherapy drug markets in China for the periods indicated.

China's Oncolytic Immunotherapy Drug Market, 2019-2033E

Period	CAGR
2019 -2024	10.5%
2024 -2028E	143.9%
2028E -2033E	71.1%



Source: Annual Report, International Agency for Research on Cancer (IARC), ClinicalTrials.gov, CDE, Frost & Sullivan Report

Competitive Landscape of Oncolytic Immunotherapy

As of the Latest Practicable Date, four oncolytic immunotherapy drugs had been approved globally, including only one Ad5-based oncolytic immunotherapy product (H101) approved in China. The table below sets forth a summary of oncolytic immunotherapy drugs approved as of the Latest Practicable Date.

Drug Name	Company	Vector	Indications	Drug Delivery Method	Approved region	Approved Date	Latest Price	Reimbursement
Rigvir	Latima	ECHO-7	Melanoma	Intramuscular	Armenia, Georgia, Latvia, Uzbekistan	2004-04	$400/2mL	Fully reimbursed in Latvia
H101, 安柯瑞	Shanghai Pharma	Ad5	Nasopharyngeal carcinoma	Intratumoral	China	2005-11	~$360/0.5mL	Not in NRDL
T-VEC, Imlygic	Amgen	HSV-1	Melanoma	Intralesional	US, Europe	2015-10	~$2,130/mL	Depends on insurance plan/Amgen SupportPlus
Delytact / G47Δ	Daiichi Sankyo	HSV-1	Malignant Glioma	Intratumoral	Japan	2021-06	~$9,500/mL	NHI listed

Sources: FDA, CDE, NMPA, Frost & Sullivan Report

Currently, there are one oncolytic immunotherapy candidate under the NDA stage, four in Phase III, one in Phase II/III, 12 in Phase II, 17 in Phase I/II and 35 in Phase I trials globally. The major viral vectors under development include HSV-1 and adenoviral vectors such as Ad5 and AdV. The primary indications being investigated are solid tumors, including melanoma, liver cancer, colorectal cancer, bladder cancer, and head and neck squamous cell carcinoma (HNSCC).

Among these candidates, 58, 14 and 19 are administered via intratumoral, intracavitary (including intravesical), and intravenous routes, respectively. The table below sets forth the current global competitive landscape of oncolytic immunotherapy in Phase II trials and beyond.

Global Competitive Landscape of Oncolytic Immunotherapy (Phase II or Above)

Drug Name	Company	Vector	Indications	Drug Delivery Method	Region	Stage	First Posted Date
RP-1	Replimune	HSV-1	Melanoma	Intratumoral	US	BLA	2025-10
Olvi-Vec	Genelux Corporation	Poxviridae	Epithelial ovarian cancer	Intracavitary, Intravenous	US	Phase III	2022-03
CG0070	CG Oncology	Ad5	NMIBC	Intracavitary	US, Japan, Canada, Australia, Korea, Taiwan	Phase III	2020-06
CAN-2409	Candel Therapeutics	AdV	Prostate cancer	Intratumoral, Intracavitary	US	Phase III	2011-09
BS001	Binhui Biotechnology	HSV-2	Melanoma	Intratumoral	China	Phase III	2023-01
RP-2	Replimune	HSV-1	Metastatic uveal melanoma	Intratumoral	US	Phase II/III	2024-09
MVR-T3011	**ImmVira**	**HSV-1**	**NMIBC, HNSCC**	**Intratumoral, Intracavitary, Intravenous**	**US, China**	**Phase II**	**2025-05**
VCN-01	VCN Biosciences, Theriva Biologics	AdV	Pancreatic cancer	Intratumoral	US, EU	Phase II	2022-06
VG161	CNBG-Virogin Biotech	HSV-1	Intrahepatic cholangiocarcinoma, Bone and soft tissue sarcoma, HCC	Intratumoral	US, China	Phase II	2021-12
AdAPT-001	EpicentRx	Ad5	Sarcoma and refractory solid tumors	Intratumoral	US	Phase II	2020-12
Lerapolturev	Istari Oncology	PV	Glioma, Glioblastoma, Melanoma	Intratumoral	US	Phase II	2016-12
Tasadenoturev	DNAtrix, Alcyone Therapeutics	Ad5	Glioblastoma/Gliosarcoma tumor	Intratumoral	US, Canada	Phase II	2016-06
Gebasaxturev	ViroTarg	CVA21	Melanoma	Intratumoral, Intravenous	US	Phase II	2010-10
Pelareorep	Oncolytics Biotech	Reovirus	Pancreatic cancer, Breast cancer	Intravenous	US	Phase II	2009-10
CVD-1301.V01	Kangwanda Pharmaceutical	Poxviridae	Cervical cancer, Sarcoma, Pancreatic cancer	Intratumoral	China	Phase II	2024-11
YH01	Infinory Pharmaceuticals	AdV	NMIBC	Intratumoral, Intracavitary	China	Phase II	2024-10
OrienX-10	OrienGene Biotechnology, Seven and Eight BioPharma	HSV-1	Unresectable malignant melanoma	Intratumoral	China	Phase II	2017-12
Telomelysin	Oncolys BioPharma	Ad5	Esophageal cancer	Intratumoral	Japan	Phase II	2020-01

Sources: Clinicaltrials.gov, CDE, NMPA, Frost & Sullivan Report

In China, there was only one oncolytic immunotherapy candidate in a Phase III trial, and six in Phase II trials as of the Latest Practicable Date. The tables below sets forth the current China's competitive landscape of oncolytic immunotherapy in Phase II trials and beyond.

China's Competitive Landscape of Oncolytic Immunotherapy (Phase II or Above)

Drug Name	Company	Vector	Indications	Drug Delivery Method	Stage	First Posted Date
BS001	Binhui Biotechnology	HSV-2	Melanoma	Intratumoral	Phase III	2023-01
MVR-T3011	**ImmVira**	**HSV-1**	**NMIBC**	**Intratumoral, Intracavitary, Intravenous**	**Phase II**	**2025-05**
CG0070	CG Oncology	Ad5	NMIBC	Intracavitary	Phase II	2025-12
CVD-1301.V01	Hangzhou Converd	Poxviridae	Cervical cancer, Sarcoma, Pancreatic cancer	Intratumoral	Phase II	2024-11
YH01	Infinory Pharmaceuticals	AdV	NMIBC	Intratumoral, Intracavitary	Phase II	2024-10
VG161	CNBG-Virogin Biotech	HSV-1	Intrahepatic cholangiocarcinoma, Bone and soft tissue sarcoma	Intratumoral	Phase II	2021-12
OrienX-10	OrienGene Biotechnology, Seven and Eight BioPharma	HSV-1	Unresectable malignant melanoma	Intratumoral	Phase II	2017-12

Sources: CDE, NMPA, Frost & Sullivan Analysis

Key Drivers and Development Trend of Oncolytic Immunotherapy

There remain significant unmet medical needs that oncolytic immunotherapy is uniquely positioned to address. Specifically:

- ***Technological differentiation and immune activation.*** Replication-competent oncolytic viruses confer distinct advantages over non-replicating gene therapies, most notably their ability to selectively amplify within the tumor and elicit robust systemic immune responses. Advances in viral engineering, such as the incorporation of immune-modulatory payloads, further potentiate both innate and adaptive immunity, supporting more durable tumor control and improved response rates across clinically heterogeneous patient populations. Moreover, administration methods such as intravesical delivery align well with routine clinical workflows, facilitating practical adoption and reducing operational barriers in real-world settings.

- ***Overcoming resistance to conventional immunotherapies.*** Oncolytic immunotherapy offers a differentiated mechanism for addressing the limitations of existing immunotherapies, particularly in tumors that are immunologically "cold" and poorly responsive to immune checkpoint inhibition. Through selective replication within tumor tissue, oncolytic viruses induce immunogenic cell death, release neoantigens, and enhance antigen presentation by dendritic cells. These effects promote robust infiltration of cytotoxic T cells and convert a previously immunosuppressed tumor environment into one that is more inflamed and immune-reactive. This remodeling of the tumor microenvironment helps counteract primary or acquired resistance to PD-1/PD-L1 or

CTLA-4 blockade and effectively broadens the patient population that may derive benefit from immunotherapy. For patients who have failed or are ineligible for conventional immunotherapies, oncolytic immunotherapy provides a mechanistically distinct approach capable of producing durable tumor control and addressing an important clinical gap.

- ***Advancements in delivery methods.*** Oncolytic immunotherapy is inherently versatile and can be delivered through multiple routes depending on tumor type and anatomical accessibility. Novel administration approaches are expanding the indications and clinical utility of oncolytic immunotherapy, particularly for deep-seated or metastatic tumors. For example, intravesical infusion is particularly well-suited for non-muscle invasive bladder cancer (NMIBC). In contrast, intratumoral administration is more appropriate for tumors such as head and neck squamous cell carcinoma (HNSCC), which are often easily accessible by imaging or direct visualization. This flexibility in administration broadens the clinical utility and applicability of oncolytic immunotherapy across diverse solid tumors.

- ***Expanding therapeutic indications.*** Beyond the currently approved indication for melanoma, nasopharyngeal carcinoma and malignant glioma, oncolytic immunotherapy is being actively investigated across a wider range of solid tumors, such as bladder cancer, pancreatic cancer, NSCLC, HNSCC, and even select hematological malignancies, underscoring their versatility and potential as a platform therapy to address cancers with highly unmet clinical needs. This expansion is supported by increasing regulatory recognition of oncolytic immunotherapy as a viable alternative in settings where conventional therapies, such as BCG for NMIBC, are inadequate or inaccessible. Together with scalable manufacturing and growing clinical experience, these trends position oncolytic immunotherapy as a strategically important modality with long-term potential to reshape treatment paradigms across diverse tumor types.

- ***Enabling synergistic combination strategies***. By remodeling the tumor microenvironment and boosting immune activation, oncolytic immunotherapy enhances the efficacy of conventional immunotherapies, CAR-T therapies, and chemotherapies. This synergistic effect makes oncolytic agents particularly well-suited for multi-modal treatment regimens designed to overcome tumour heterogeneity, resistance mechanisms, and the limited efficacy often observed with monotherapy approaches. Moreover, their strong combinability with existing standards of care offers meaningful strategic flexibility in clinical trial design, regulatory positioning, and potential commercial partnerships. •

- ***Strengthening market access through pricing and reimbursement.*** Establishing sustainable pricing and favorable reimbursement frameworks has been a critical factor in supporting the clinical adoption and commercial growth of oncolytic immunotherapies. Given their innovative mechanisms and often niche indications, oncolytic immunotherapy products are typically positioned at premium price points, reflecting their therapeutic value and manufacturing complexity. Importantly, reimbursement support plays a decisive role in translating this value into real-world utilization, as demonstrated by products such as Delytact® (G47Δ), which is fully covered under Japan's national health insurance system, and Rigvir, which benefits from full reimbursement in Latvia. Even in markets where reimbursement is not yet universal, such as China for H101, established pricing benchmarks and growing clinical use indicate increasing acceptance and provide a foundation for future reimbursement inclusion. For details of the pricing and reimbursement policy for currently approved oncolytic immunotherapy products, see "— Overview of Oncolytic Immunotherapy — Competitive Landscape of Oncolytic Immunotherapy."

- ***Treatment compliance and repeat utilization support market demand.*** Available clinical and real-world data suggest that a meaningful proportion of patients receiving oncolytic immunotherapies are able to undergo repeat or sustained treatment, supporting continued utilization despite the aggressive nature of target indications. Published literature indicates that approximately 20% of patients in clinical trials continued T-VEC treatment through completion of the planned course, while real-world experience with H101 shows that around 40% of patients received more than one treatment course.

Building on these emerging benefits, the development of oncolytic immunotherapy must address several key challenges, which are actively being tackled through ongoing technological and process innovations. Specifically:

- ***Enhancing effectiveness of oncolytic immunotherapy.*** Enhancing the efficacy of oncolytic immunotherapy and overcoming the resistance of conventional immunotherapies have long been central focuses in the development of this area. One of the most promising strategies involves engineering of oncolytic immunotherapies to improve their therapeutic performance. This includes modifying viral genomes to enable more efficient and selective replication within cancer cells, thereby increasing tumor-specific cytotoxicity.

- ***Converting antiviral immunity into anticancer immunity.*** Upon administration, oncolytic immunotherapy may elicit an immune response that leads to the production of neutralizing antibodies, thereby limiting their oncolytic efficacy, especially when administered intravenously. Mitigating this immune clearance is critical. Current

strategies to address this include modifying the viral backbone to preserve its natural ability to evade antibody neutralization, and engineering cytokine-expressing vector cells to enhance anti-tumor immunity and sustain viral activity.

- ***Expanding clinical applications***. Oncolytic immunotherapy is effective against small lesions but typically have limited efficacy against larger lesions or uninjectable metastases due to the restriction of viral spread, physicians' operation skills and intratumoral administration. Enhancing viral vector replication ability, systemic delivery, improving tumor targeting, and boosting immune responses are key areas of ongoing research to fulfill unmet clinical needs.

- ***Improving oncolytic immunotherapy production technologies.*** The manufacturing of oncolytic immunotherapy products encompasses multiple complex steps, including cell culture, viral infection and amplification, harvesting, purification, formulation and quality control. Each step presents distinct technical hurdles. Technologies such as serum-free suspension culture, microcarrier bioreactors and fixed bed bioreactors are being adopted to improve efficiency, though cost-performance balance remains a challenge.

Major Indications for Oncolytic Immunotherapy

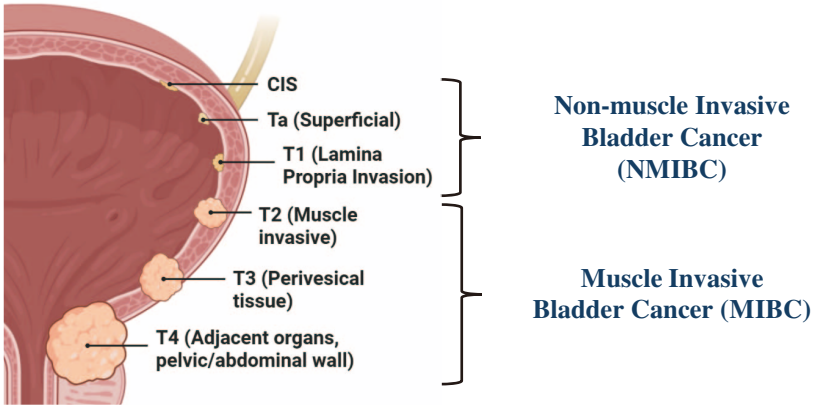
Bladder Cancer

Bladder cancer encompasses a heterogeneous group of malignancies arising from the bladder's various tissues, characterized by abnormal cell growth with the capacity to invade local structures and metastasize. It arises from combined environmental and genetic factors, with cigarette smoking being the predominant cause due to urinary excretion of carcinogenic compounds. Additional major contributors include occupational exposure to aromatic amines, chronic inflammation from infections or irritants (including schistosomiasis in endemic regions), prior pelvic radiotherapy or chemotherapy, and other carcinogenic exposures. Approximately 95% of bladder cancers are urothelial carcinomas, which originate in the inner lining of the bladder and can exhibit diverse patterns of growth and invasion.

Bladder cancer primarily affects older adults — typically individuals aged 65–75 — and is significantly more common in men, reflecting historical patterns of smoking and industrial exposure. While incidence is higher in men, women tend to present with more advanced disease, and geographical variation is notable, with urothelial carcinoma prevalent in developed regions and squamous cell carcinoma more common in schistosomiasis-endemic areas. The incidence of bladder cancer has shown an upward trend in recent years in the U.S., China, and globally, and this trend is expected to continue in the near future. The incidences of bladder cancer reached

637.4 thousand, 83.2 thousand, and 98.8 thousand globally, in the U.S., and China in 2024, respectively, which are expected to increase to 797.7 thousand, 102.8 thousand, and 123.4 thousand in 2033, respectively.

Bladder cancer is broadly classified into two main types based on the depth of tumor invasion: non-muscle invasive bladder cancer (NMIBC) and muscle-invasive bladder cancer (MIBC), representing for approximately 75% and 25% of all newly diagnosed bladder cancer cases, respectively. The below picture depicts the pathologic anatomy of NMIBC and MIBC.



Source: Literature Review, Frost & Sullivan Report

NMIBC

NMIBC refers to malignant urothelial tumors that are confined to the bladder mucosa (stages CIS and Ta) or have invaded only the lamina propria (stage T1) without reaching the muscle layer. NMIBC accounts for approximately 75% of all newly diagnosed bladder cancer cases and typically associated with a lower risk of progression compared to MIBC. The incidences of NMIBC reached 446.2 thousand, 58.0 thousand, and 68.2 thousand globally, in the U.S., and China in 2024, respectively, which are expected to increase to 558.4 thousand, 71.7 thousand, and 85.1 thousand in 2033, respectively.

Based on tumor growth pattern and histological features, NMIBC is classified based into two main subtypes: papillary and carcinoma *in situ* (CIS).

- Papillary NMIBC typically includes stage Ta and T1 tumors, representing for approximately 90% of NMIBC cases. Ta tumors typically involves superficial lesions confined to the mucosal layer, accounting for around 70% of NMIBC cases. T1 tumors

invade the lamina propria, a layer rich in blood and lymphatic vessels, and account for approximately 20% of NMIBC. Due to their access to vascular and lymphatic channels, T1 tumors carry a higher risk of progression compared to Ta lesions.

- CIS NMIBC accounts for the remaining approximately 10% of NMIBC cases and is characterized by flat, high-grade lesions confined to the mucosa (stage CIS). CIS is often more aggressive and has a higher potential for progression despite its non-invasive appearance.

MIBC

MIBC refers to bladder cancer that has invaded the muscularis propria (stages T2 to T4). Approximately 25% of newly diagnosed bladder cancer patients are diagnosed with MIBC, and among them, around 5% present with metastatic disease. Once the tumor breaches the muscle layer, it gains the potential to spread rapidly to surrounding tissues and distant organs, making early-stage intervention critical.

Same as NMIBC, a growing trend has been observed and is expected to persist in MIBC. The incidences of MIBC reached 148.7 thousand, 19.2 thousand, and 22.7 thousand globally, in the U.S., and China, in 2024, which are expected to increase to 186.1 thousand, 23.8 thousand, and 28.4 thousand in 2033, respectively.

Treatment Paradigm for Bladder Cancer

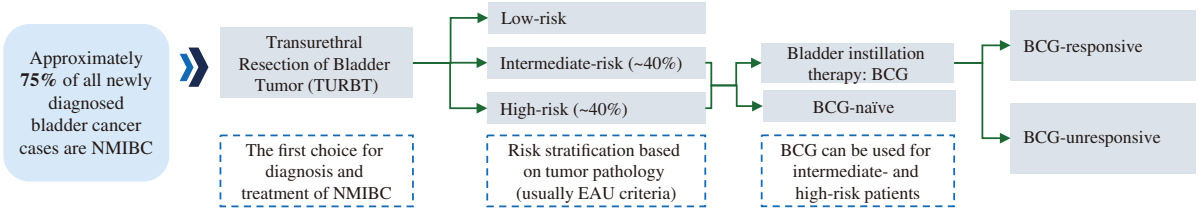
Treatment Paradigm for NMIBC

Transurethral resection of bladder tumor (TURBT) is the standard initial treatment for NMIBC. This endoscopic procedure removes visible tumor lesions from the bladder, providing both diagnostic tissue for pathological evaluation and therapeutic tumor debulking. Following TURBT, intravesical instillation therapy is commonly administered as an adjuvant treatment to reduce the risk of recurrence and progression. This involves direct instillation of therapeutic agents, such as chemotherapeutic drugs or immunotherapy agents, into the bladder. Unlike TURBT, which physically removes macroscopic tumor masses, intravesical instillation therapy targets residual microscopic disease within the bladder mucosa and can also stimulate local immune responses.

There are different adjuvant intravesical instillation strategies based on risk stratification. Patients treated with TURBT are stratified into low-risk, intermediate-risk, and high-risk groups based on tumor pathology Low-risk patients, who represent a small proportion of the NMIBC population, may receive a single immediate postoperative dose of intravesical chemotherapy.

Intermediate-risk patients, accounting for approximately 40% of NMIBC cases, are generally recommended to receive either one year of full-dose Bacillus Calmette-Guérin (BCG) therapy or intravesical chemotherapy. High-risk patients, also comprising around 40% of the population, are advised to undergo a three-year course of full-dose BCG instillation high-risk diseases followed by maintenance therapy to optimize long-term outcomes. Although BCG remains the standard of care for high-risk NMIBC, its use is significantly limited by global supply shortages. In the U.S., BCG supply meets less than 30% of the total demand. In China, there were a total of 61.3 thousand patients with BCG-naïve NMIBC in 2024.

Based on prior exposure to BCG therapy, patients are further categorized into three types: BCG-naïve (no prior BCG treatment), BCG-exposed (previous BCG but not meeting criteria for BCG-unresponsive) and BCG-unresponsive (failure after adequate BCG therapy). Approximately 60% of patients eventually become unresponsive to BCG, facing increased risks of tumor recurrence and progression. The number of patients with BCG-unresponsive NMIBC and BCG-naïve NMIBC amounted to 3.1 thousand and 61.3 thousand in 2024, respectively. Patients with high-risk NMIBC usually face a significantly elevated risk of disease progression, which can lead to poorer prognosis and limited treatment options. The below chart illustrates the primary treatment paradigm of NMIBC. For these high-risk, BCG-unresponsive NMIBC patients, the primary treatment options are radical cystectomy, or, for patients ineligible for or declining surgery, systemic therapy with pembrolizumab.



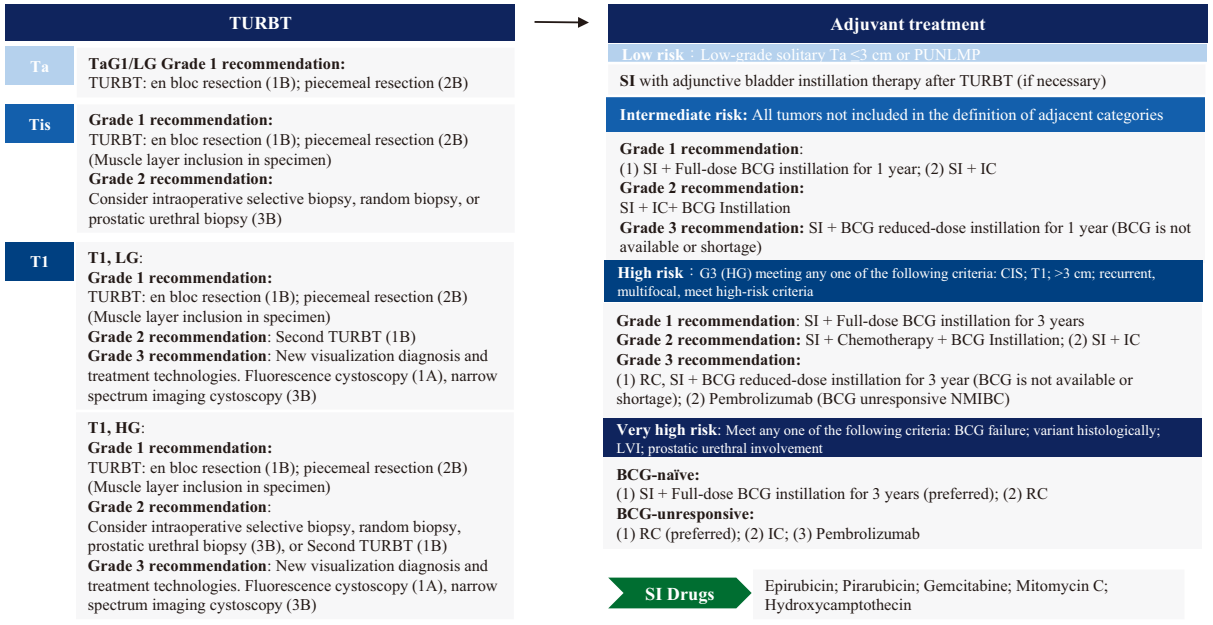
Source: Literature Review, Frost & Sullivan Report

High-risk NMIBC represents roughly 40% of all NMIBC cases. Of these high-risk NMIBC patients, about 40% are BCG-naïve who have never received BCG treatment, while approximately 60% of those who do receive BCG therapy ultimately become BCG-unresponsive.

For BCG-naïve patients, the current preferred approach is TURBT followed by single instillation (SI) of chemotherapy and full-dose intravesical BCG therapy for up to three years, including induction and maintenance phases. Radical cystectomy (RC) may also be considered in high-risk cases. For BCG-unresponsive patients (failure after adequate BCG therapy), the standard of care is RC, which offers the best chance for long-term disease control. For patients who are

ineligible or unwilling to undergo surgery, alternative options include intravesical chemotherapy (IC) or systemic immunotherapy with pembrolizumab, which is FDA-approved for high-risk BCG-unresponsive NMIBC with CIS.

The chart below sets forth the treatment paradigm for NMIBC.



Notes: TUBRT refers to transurethral resection of bladder tumor; TUR refers to transurethral resection; SI refers to single immediate instillation; PUNLMP refers to papillary urothelial neoplasm of low malignant potential; LVI refers to lymphovascular invasion; RC refers to radical cystectomy; IC refers to intravesical chemotherapy.

Source: CSCO 2024, Literature Review, Frost & Sullivan Report

Despite the absence of currently approved oncolytic immunotherapy in the bladder cancer treatment, oncolytic immunotherapy represents an innovative treatment modality with significant practice changing and paradigm shifting potential in NMIBC. In particular, oncolytic immunotherapy offers a promising alternative to address the clinical challenges posed by BCG-unresponsive patients and the global shortage of BCG, thereby fulfilling important unmet medical needs in bladder cancer management. Our Company's Core Product, MVR-T3011, is poised for the second-line treatment of high-risk NMIBC and high-risk BCG-naïve NMIBC, addressing recognized unmet medical need.

Treatment Paradigm for MIBC

For non-metastatic MIBC, treatment usually aims to cure the disease. Thus, treatment decisions primarily depend on the patient's tolerance for radical cystectomy. The standard approach is radical cystectomy to remove the bladder and any regional disease, often combined with neoadjuvant chemotherapy (e,g, dose-dense methotrexate, vinblastine, doxorubicin, and cisplatin or gemcitabine + cisplatin) to kill any tiny cancer cells that might have spread. For patients who are unfit for surgery or prefer bladder preservation, a bladder-sparing strategy offers an alternative curative option — removing as much of the tumor as possible through TURBT, followed by combined chemotherapy and radiation. Depending on the post-operative pathology stage and surgical margins, adjuvant treatment after surgery may involve chemotherapy, radiotherapy, or immune checkpoint inhibitors such as Nivolumab.

For metastatic MIBC, where the cancer has spread beyond the bladder to distant sites, treatment shifts to systemic therapy aimed at prolonging survival and improving quality of life. Cisplatin-based chemotherapy remains the first-line treatment for eligible patients, while immune checkpoint inhibitors as monotherapy and combination therapy with other anti-tumor agents are increasingly used for those who are cisplatin-ineligible or who progress after chemotherapy. Additionally, targeted therapies and clinical trial options are being explored to further improve outcomes.

Similarly, although as of the Latest Practicable Date, oncolytic immunotherapy has not yet been included in the established treatment paradigms for MIBC, it has the potential to be incorporated into future MIBC treatment strategies, particularly as an adjunct to existing therapies, given its differentiated mechanism of action, emerging efficacy signals, and manageable safety profile.

The chart below sets forth the treatment paradigm for MIBC.

Treatment for MIBC	
Treatment for MIBC	
T2-T4a, N0-Nx, M0	**RC tolerable**: **Grade 1 recommendation**: Neoadjuvant chemotherapy (ddMVAC or gemcitabine + cisplatin) + RC (1A) **Grade 2 recommendation**: (1) Neoadjuvant chemotherapy + partial cystectomy (2A) (2) Trimodal therapy + maximal TURBT + immunotherapy (2A) **Grade 3 recommendation:** Simple cystectomy
	RC intolerable: **Grade 1 recommendation**: (1) Maximal TURBT + concurrent chemoradiotherapy (1A); (2) Systematic drug therapy (1A) **Grade 2 recommendation**: (1) Partial cystectomy (2A) (2) If chemotherapy ineligible, use radiotherapy alone (2A) **Grade 3 recommendation:** TURBT (3)
T4b, N0-Nx, M0-M1	**Grade 2 recommendation**: (1) Concurrent chemoradiotherapy (1A) (2) Systematic drug therapy (1A) **Grade 3 recommendation:** (1) Palliative cystectomy + urinary diversion (3); (2) Palliative radiotherapy
Adjuvant Treatment after Surgery for MIBC	
T1, G3 N0-Nx, M0 (after TURBT)	**Grade 3 recommendation**: Adjuvant chemoradiotherapy (3)
T2-4a N0-Nx, M0 (after TURBT)	**Grade 1 recommendation**: Adjuvant chemoradiotherapy (1A)
T2-4a/N+, M0 (after RC)	**Grade 2 recommendation**: Adjuvant chemotherapy (2A); Nivolumab (1A)
ypT2-4a/ypN+, M0 (after RC and NAT)	**Grade 2 recommendation**: Nivolumab (1A)
T4b N0-Nx, M0 (after RC)	**Grade 2 recommendation**: Adjuvant chemotherapy (2A); **Grade 3 recommendation:** Adjuvant radiotherapy (2B)
Tx N0-Nx, M0, R1/R2 (after RC)	**Grade 3 recommendation:** Adjuvant radiotherapy (2B)

Notes: TUBRT refers to transurethral resection of bladder tumor; TUR refers to transurethral resection; RC refers to radical cystectomy; ddMVAC refers to dose-dense methotrexate, vinblastine, doxorubicin, and cisplatin.

Source: *CSCO 2024, Literature Review, Frost & Sullivan Report*

Competitive Landscape of Oncolytic Immunotherapy for Bladder Cancer

In 2024, biologic drugs (including BCG) represented the largest and fastest-growing segment of the global bladder cancer drug market, accounting for approximately 58.1%, while chemical drugs accounted for the remaining 41.9%. As of the Latest Practicable Date, there were 28 approved drugs and 112 drug candidates in Phase II or above clinical stages for the treatment of bladder cancer globally. Currently approved drug modalities are limited to BCG, chemical agents, antibodies, and other biologics. The table below provides a summary of the competitive landscape of innovative new drugs for bladder cancer therapies as of the Latest Practicable Date.

Category	Number of Approved Drugs	Line of Approved Treatment	Approved Monotherapy/ Combination Use	Number of Drugs in Clinical Phase II and Above	Advantage	Limitation
BCG	3	First	Mono	0	• BCG is standard for high-risk NMIBC • The only immunotherapy that reduces the risk of progression from high risk NMIBC to MIBC	• Long -term use may cause adverse events • Global BCG shortage limits clinical accessibility
Chemicals	11	First (for chemotherapy)	Mono/Combo, depends on treatment options	46	• Widely available with low cost • Standard treatment for postoperative instillation in low/intermediate-risk NMIBC	• Limited efficacy with high recurrence rate in high-risk NMIBC
Antibodies	10	First, Second or later, Neoadjuvant	Mono/Combo	56	• Systemic therapy after local treatment failure	• Relatively high cost
Oncolytic Virus	0	/	/	3	• Provides dual anti-tumor mechanisms:direct lysis and immune activation • High local dose via intravesical administration, low systemic toxicity • Can work with ICI, chemo, or radiotherapy	• Currently largely limited to second-line and later, as well as neoadjuvant settings • Currently no approved drugs, relatively limited data to substantiate OVs' efficacy
Other Biologics	4	Second or later	Mono	7	Gene therapy: • Provides BCG-unresponsive patients more clinical options • Offers bladder-sparing option Interleukin/Porphyrin: • Combine immune system activation with porphyrin -based photodynamic tumor cell killing	Gene therapy: • Novel therapy with limited clinical data Interleukin/Porphyrin: • Needs light, and not for deep tumors, limiting efficacy, not commonly used
Total	**28**			**112**		

Source: FDA, CDE, NMPA, Frost & Sullivan Analysis

Looking ahead, biologic therapies are expected to be the primary drivers of market growth, supported by the increasing adoption of immune checkpoint inhibitors, antibody-based therapies, and oncolytic immunotherapy. According to Frost & Sullivan, as oncolytic immunotherapy products receive regulatory approvals and are progressively commercialized for bladder cancer, this modality is expected to account for approximately 10% of the global bladder cancer drug market by 2033. Among these bladder cancer therapies, intravesical BCG has long been the standard of care for high-risk NMIBC; however, it is associated with limitations that affect both clinical outcomes and patient access. A substantial proportion of patients experience recurrence or non-response, and real-world adherence can be inconsistent due to treatment complexity and tolerability. Additionally, recurrent global BCG shortages have further constrained consistent treatment delivery, resulting in variability in outcomes. The table below sets forth a summary of current major marketed bladder cancer therapies as of the Latest Practicable Date.

Major Marketed Drugs for NMIBC

Category	Drug Name	Company	Year of Approval[1]	Indications	Line of Treatment	Therapy	Annual Cost	2024 Annual Sales[2]
Chemical	Epirubicin, gemcitabine, pirarubicin, hydroxycamptothecin, mitomycin C, etc.			Single immediate instillation/ intravesical chemotherapy	First	/	/	/
Chemical	TAR-200	J&J	2025, US	BCG-unresponsive NMIBC with CIS with or without papillary tumors	Second or later	Mono	~$670,000	/
Biologics	Anktiva	ImmunityBio	2024, US	BCG-unresponsive NMIBC with CIS	Second or later	Combo, with BCG	/	/
Biologics	Adstiladrin	Ferring	2022, US	BCG-unresponsive NMIBC with CIS	Second or later	Mono	~$240,000	$76 million
Biologics	Keytruda	Merck	2020, US	BCG-unresponsive NMIBC with CIS	First/Second	Mono	~$180,000	$29,482 million
Biologics	BCG Tice	MSD	1989, US	Treatment and prophylaxis of CIS of urinary bladder; Prophylaxis of primary or recurrent Ta/T1 papillary tumors	First	Mono	~$3,000	/

Major Marketed Drugs for MIBC

Category	Drug Name	Company	Year of Approval[1]	Indications	Line of Treatment	Therapy	Annual Cost	2024 Annual Sales[2]
Chemical	Cisplatin + gemcitabine/ddMAVC, etc.			Chemotherapy	First	/	/	/
Biologics	Imfinzi	AstraZeneca	2025, US	adjuvant treatment following radical cystectomy, for adults with MIBC	Second	Mono	~$120,000	$4,717 million
Biologics	Opdivo	BMS	2017, US	Patients with locally advanced or metastatic urothelial carcinoma	First/Second/ Newadjuvant	Mono	~$185,000	$9,304 million
Biologics	Keydruda	Merck	2025, US	Combination as neoadjuvant treatment followed by adjuvant treatment after cystectomy for adults with MIBC who are ineligible for cisplatin	Adjuvant/ New adjuvant	Combo, with Padcev	~$585,000	$29,482 million
Biologics	Padcev	Pfizer	2025, US			Combo, with Keytruda		$1,588 million

Notes:

1. Refers to the earliest approval date and region for the listed indication.

2. Refers to the total revenue generated by the drug in 2024.

Source: FDA, CDE, NMPA, Frost & Sullivan Analysis

The recent approval of Adstiladrin® (nadofaragene firadenovec) illustrates growing regulatory and clinical acceptance of novel intravesical biologic therapies. Nonetheless, as a non-replicating adenoviral vector, its clinical efficacy relies on transient transgene expression, which may limit the durability of immune activation and long-term disease control. These factors collectively underscore ongoing unmet medical needs and highlight opportunities for alternative bladder-sparing therapies that provide more reliable and sustained clinical benefit.

Against this backdrop, oncolytic immunotherapy has emerged as the novel promising treatment for bladder cancer considering its technological differentiation, immune-activating properties, and potential to overcome resistance to conventional therapies. For details, see "— Overview of Oncolytic Immunotherapy — Key Drivers and Development Trend of Oncolytic Immunotherapy." In addition, as a bladder-preserving approach, oncolytic immunotherapy aligns with the increasing clinical preference for organ-sparing therapies, further underscoring its potential to address unmet medical needs and capture broader clinical adoption. As of the Latest Practicable Date, no oncolytic immunotherapy had been approved for the treatment of bladder cancer. Globally, one oncolytic immunotherapy candidate targeting bladder cancer was in a Phase I/II trial, and four in Phase I trials. The table below sets forth the global competitive landscape of oncolytic immunotherapy for bladder cancer in Phase II trials and beyond as of the Latest Practicable Date.

Drug Name	Company	Vector	Indication	Drug Delivery Method	Regulatory Authority	Stage	First Posted Date
CG0070	CG Oncology	Ad5	NMIBC	Intracavitary	FDA (MRCT)	Phase III	2020-06
MVR-T3011	**ImmVira**	**HSV-1**	**NMIBC**	**Intracavitary**	**FDA (MRCT)**	**Phase II**	**2025-05**
YH01	Yinghui Pharma	AdV	NMIBC	Intracavitary	NMPA	Phase II	2024-10

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

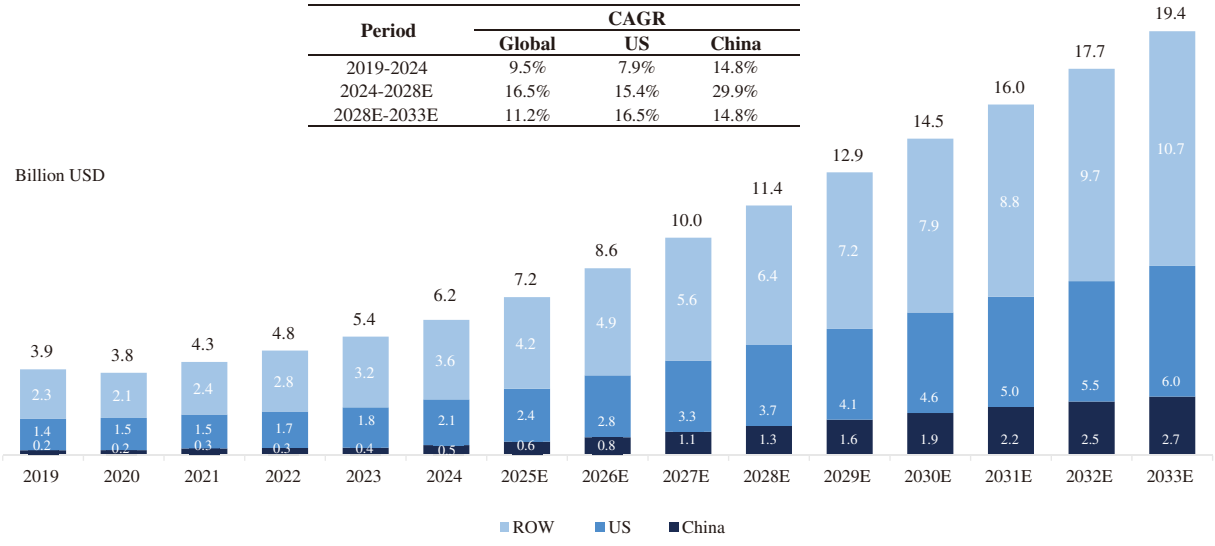
Our Core Product, MVR-T3011, features a differentiated profile designed to drive both local tumor lysis and systemic antitumor immune activation. Its intravesical delivery format is compatible with existing urological workflows, offering a practical balance of efficacy, safety, and accessibility. By combining mechanistic innovation with a clinically practical delivery approach, MVR-T3011 is well positioned to address this unmet need.

Bladder Cancer Drug Market

The global bladder drug market increased from US$3.9 billion in 2019 to US$6.2 billion in 2024, representing a CAGR of 9.5%, which is projected to reach US$19.4 billion in 2033, representing a CAGR of 13.5% from 2024 to 2033. Meanwhile, the U.S. bladder drug market increased from US$1.4 billion in 2019 to US$2.1 billion in 2024, representing a CAGR of 7.9%, which is projected to reach US$3.7 billion by 2028 and US$6.0 billion by 2033, representing a CAGR of 15.4% from 2024 to 2028 and 16.5% from 2028 to 2033. China's bladder drug market increased from US$0.2 billion in 2019 to US$0.5 billion in 2024, representing a CAGR of 14.8%, which is projected to reach US$1.3 billion by 2028 and US$2.7 billion by 2033, representing a CAGR of 29.9% from 2024 to 2028 and 14.8% from 2028 to 2033. The chart below sets forth the historical and projected market sizes of the bladder cancer drug markets for the periods indicated.

Bladder Cancer Drug Market, 2019-2033E

Period	CAGR		
	Global	US	China
2019-2024	9.5%	7.9%	14.8%
2024-2028E	16.5%	15.4%	29.9%
2028E-2033E	11.2%	16.5%	14.8%



Source: Annual Report, IARC, ClinicalTrials.gov, CDE, Frost & Sullivan Report

Head and Neck Squamous Cell Carcinoma

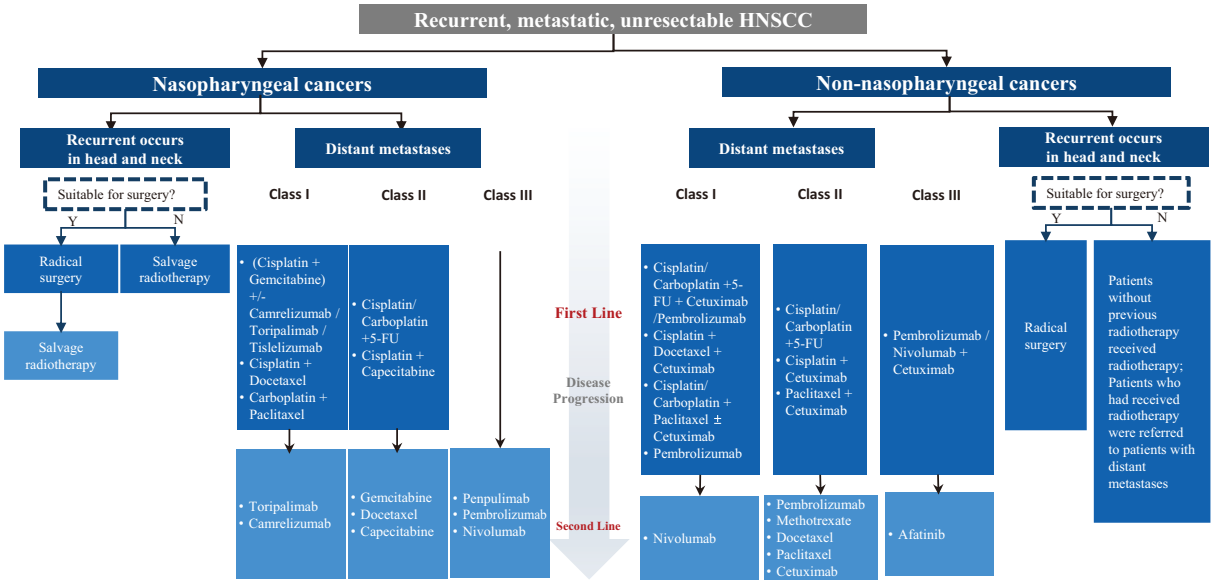
Head and neck squamous cell carcinoma (HNSCC) is a malignant tumor that arises from the squamous epithelium of the oral cavity, pharynx, and larynx, and ranks as the sixth most common cancer globally with a steadily increasing incidence. HNSCC is often diagnosed at an advanced stage due to the lack of early specific symptoms. In 2024, the number of HNSCC cases reached approximately 892.0 thousand globally, 64.0 thousand in the U.S., and 136.0 thousand in China. These figures are projected to rise significantly by 2033 to 1,063.0 thousand worldwide, 72.1 thousand in the U.S., and 152.7 thousand in China, underscoring the urgent need for improved diagnostics and more effective treatment strategies.

Treatment Paradigm for HNSCC

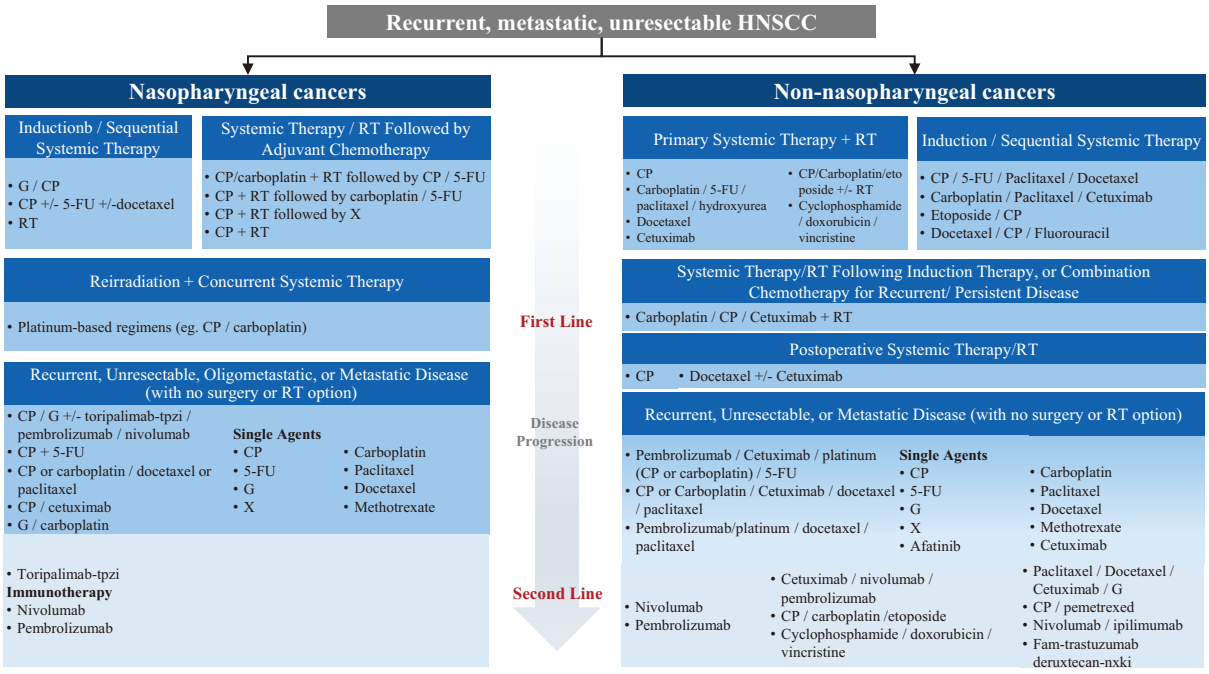
As the most common type of head and neck cancer, HNSCC is typically treated based on the site and stage of disease. Treatment strategies differ depending on whether the tumor is nasopharyngeal in origin. For patients with recurrent, non-metastatic HNSCC involving either the primary lesion or cervical lymph nodes, radical surgery is often the preferred option. If surgery is not feasible, salvage radiotherapy or other local treatments are going to be considered. In metastatic cases, palliative chemotherapy remains the mainstay.

The charts below set forth the treatment paradigm for recurrent, metastatic and unresectable HNSCC in China and the U.S., respectively.

Treatment Paradigm for HNSCC in China



Treatment Paradigm for HNSCC in the U.S.



Notes: Unsuitable for surgery refers to cases where the patient's physical condition precludes operative intervention, surgery is contraindicated under CSCO guidelines, or the tumor is too large to be resected.

Source: *CSCO 2023, Literature Review, Frost & Sullivan Report*

Oncolytic immunotherapy exhibits significant potential to offer an innovative treatment therapy for HNSCC, particularly in light of its differentiated mechanism of action, encouraging efficacy observed in early clinical settings, and the need for additional therapies to address treatment resistance and recurrence under current standards of care. Our Company's Core Product, MVR-T3011, is poised for the third-line treatment of HNSCC for patients after failure of platinum-based chemotherapy and at least one prior anti-PD-(L)1 therapy.

Competitive Landscape of Oncolytic Immunotherapy for HNSCC

As of the Latest Practicable Date, there were seven approved drugs for the treatment of HNSCC globally, including two chemicals and five antibodies. All of these approved therapies are indicated for use as first- or second-line treatments and may be administered either as monotherapy or in combination. As of the same date, there were 137 drug candidates in Phase II or later clinical stages. The table below provides a summary of the competitive landscape for HNSCC.

Category	Number of Approved Drugs	Line of Approved Treatment	Approved Monotherapy/ Combination Use	Number of Drugs in Clinical Phase II and Above	Advantage	Limitation
Chemicals	2	First, Second	Mono/Combo, depends on treatment options	43	• Standard treatment • Synergistic with other treatments • Low cost	• Significant toxicity • Risk of drug resistance • Limited efficacy in some subtypes
Antibodies	5	First, Second	Mono/Combo	83	• Highly targeted, relatively low side effects • Some can be combined with chemo/radiotherapy • Long-term benefit in some advanced/recurrent cases	• Variable efficacy between patients • Comparably high cost • Risk of immune-related adverse events
Oncolytic Virus	0	/	/	2	• Oncolysis and immune stimulation • Tumor-selective replication with low toxicity • May combine well with immune checkpoint inhibitors to boost response rates	• Current approved Ovs always use local delivery (intratumoral) limits systemic efficacy • Currently no approved drugs, limited advanced pipelines and data to substantiate their efficacy
Other Biologics	0	/	/	9	Cell therapy, ASO, gene therapy, peptides, microbiome, etc.: • Potentially target common mutations or viral antigens of HNSCC, e.g., CAR-T, ASO • May modulate tumor microenvironment to improve immunotherapy response • Long-term immune memory to prevent recurrence	• No marketed products, limited clinical data, uncertain long-term efficacy • High heterogeneity may limit consistent efficacy • Potential toxicity or severe inflammation may exist
Total	**7**			**137**		

Source: FDA, CDE, NMPA, Frost & Sullivan Analysis

The table below sets forth a summary of marketed drugs for HNSCC.

Category	Drug Name[1]	Company	Year of Approval[2]	Indications	Line of Treatment	Therapy	Annual Cost	2024 Annual Sales[3]
Biologics	Finotonlimab	Sinocelltech Group	2025, China	Recurrent and/or metastatic HNSCC in combination with platinum-containing chemotherapy	Second	Combo, with platinum-based therapy	~$21,562	/
Biologics	Pembrolizumab	Merck	2016, US	Metastatic or with unresectable, recurrent HNSCC	First/Second	Mono/Combo, with platinum and FU	~$180,000	$29,482 million
Biologics	Nivolumab	BMS	2016, US	Adult patients with recurrent or metastatic HNSCC or after platinum-based therapy.	Second	Mono	~$185,000	$9,304 million
Biologics	Nimotuzumab	CIMYM, InnoKeys, etc.	2024, China	Locally advanced HNSCC	First	Combo, with concurrent chemoradiotherapy	~$5,564	/
Biologics	Cetuximab	Eli Lilly, etc.	2006, US	Recurrent or metastatic HNSCC or locally advanced HNSCC	First/Second	Mono/Combo, with platinum-based therapy and fluorouracil	~$200,000	$627.4 million
Chemical	Temoporfin	Biolitec Pharma	2001, Europe	Advanced HNSCC	Second or later	Mono	/	/
Chemical	Docetaxel	Sanofi, etc.	1995, Europe	Locally advanced HNSCC	First/Second	Combo, with cisplatin and FU	/	/
Chemicals	Cisplatin , carboplatin, gemcitabine, capecitabine, paclitaxel, etc.			Chemotherapy	First	/	/	/

Notes:

1. As of July 31, 2025.
2. Refers to the earliest approval date and region for the listed indication.
3. Refers to the total revenue generated by the drug in 2024.

Source: FDA, CDE, NMPA, Frost & Sullivan Report

As of the Latest Practicable Date, no oncolytic immunotherapy drug has been approved for the treatment of HNSCC. Globally, two oncolytic immunotherapy candidates targeting HNSCC were in a Phase II clinical trial, and eight in Phase I. The table below sets forth the current global competitive landscape of oncolytic immunotherapy drug candidates for HNSCC in Phase II trials and beyond.

Pipeline of OVs for HNSCC (Phase II and above)

Drug Name[1]	Company	Vector	Indication	Drug Delivery Method	Regulatory Authority	Stage	First Posted Date
MVR-T3011	ImmVira	HSV-1	Advanced or metastatic solid tumors, incl. advanced HNSCC	Intratumoral	FDA	Phase IIa[2]	2020-05
AdAPT-001	EpicentRx	Ad5	Sarcoma and refractory solid tumors incl. HNSCC	Intratumoral	FDA	Phase II	2020-12

Note:

1. As of November 24, 2025.

2. The Phase I/II trial of MVR-T3011 began in 2020. After completing the Phase I study, the Phase IIa trial in HNSCC commenced in September 2022.

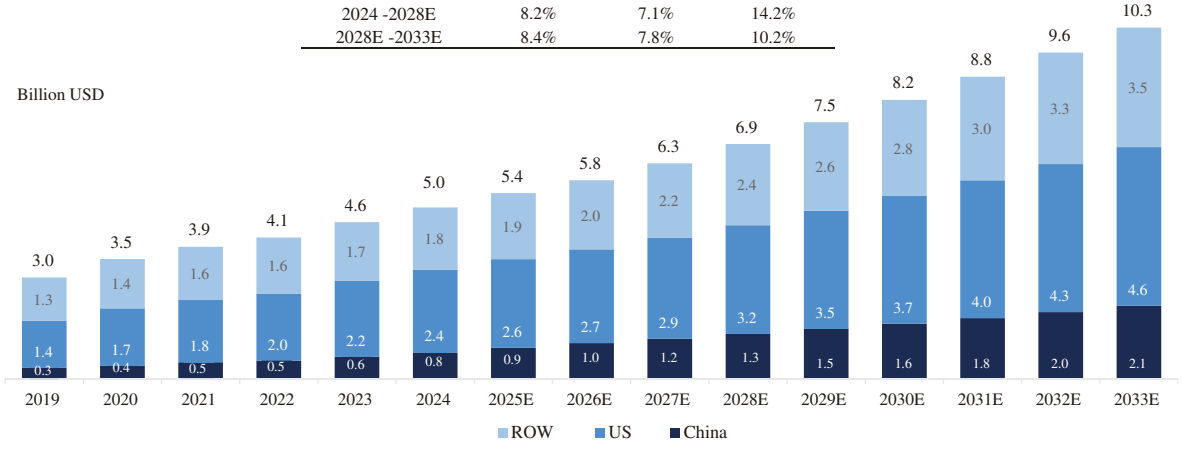
Source: Clinicaltrials.gov, CDE, NMPA, Frost & Sullivan Report

HNSCC Drug Market

The global HNSCC drug market increased from US$3.0 billion in 2019 to US$5.0 billion in 2024, representing a CAGR of 11.1%, which is projected to reach US$6.9 billion by 2028 and US$10.3 billion by 2033, representing a CAGR of 8.2% from 2024 to 2028 and 8.4% from 2028 to 2033. Meanwhile, the U.S. HNSCC drug market increased from US$1.4 billion in 2019 to US$2.4 billion in 2024, representing a CAGR of 11.9%, which is projected to reach US$3.2 billion by 2028 and US$4.6 billion by 2033, representing a CAGR of 7.1% from 2024 to 2028 and 7.8% from 2028 to 2033. The chart below sets forth the historical and projected market sizes of HNSCC globally, in the U.S. and China for the periods indicated.

HNSCC Drug Market, 2019-2033E

Period	CAGR		
	Global	US	China
2019 -2024	11.1%	11.9%	18.9%
2024 -2028E	8.2%	7.1%	14.2%
2028E -2033E	8.4%	7.8%	10.2%



Source: Annual Report, IARC, ClinicalTrials.gov, CDE, Frost & Sullivan Analysis

Glioma

Gliomas are a diverse group of primary tumors that arise from glial cells, which are the supportive cells of the central nervous system (CNS). Glioma encompasses a spectrum of subtypes, including astrocytomas, oligodendrogliomas, and glioblastomas, each differing in aggressiveness

and prognosis. Due to their location in the CNS and infiltrative nature, gliomas often present significant therapeutic challenges and are associated with high morbidity and mortality, underscoring the urgent need for more effective and targeted treatment strategies.

Glioma represents approximately 40% to 60% of all primary brain tumors, with glioblastoma being the most aggressive and common malignant variant. The incidence of glioma has shown a steady growth in recent years globally, in the U.S., and China, and this trend is expected to continue in the near future. The incidences of glioma reached 531.5 thousand, 23.9 thousand, and 75.1 thousand globally, in the U.S., and China in 2024, which are expected to increase to 632.5 thousand, 27.6 thousand, and 91.4 thousand in 2033, respectively.

Treatment Paradigm for Glioma

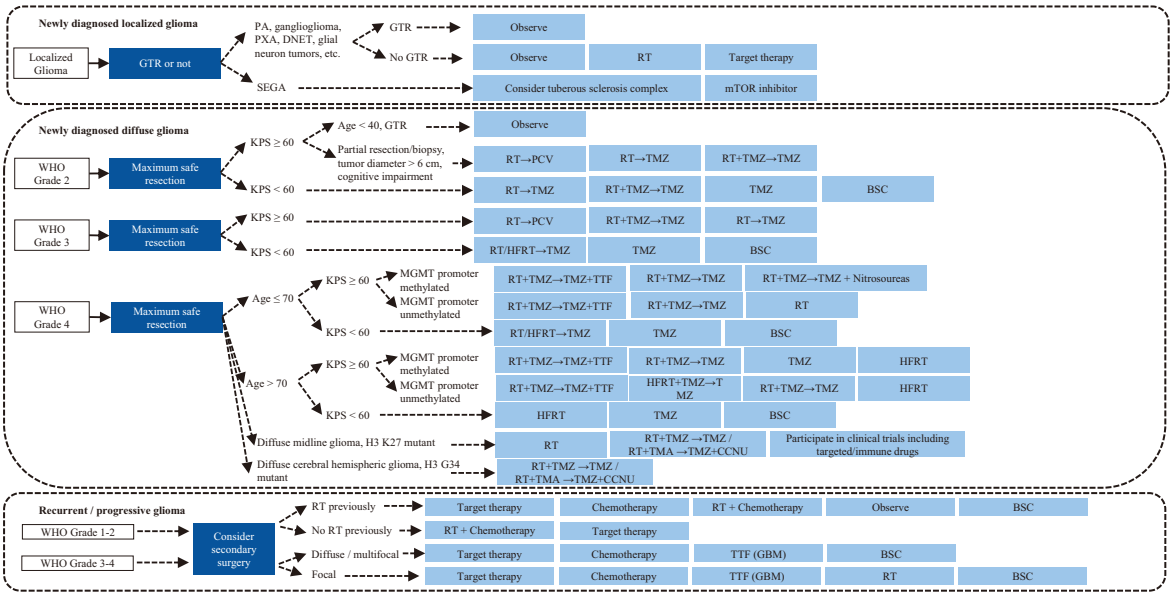
Treatment approaches for glioma are guided by tumor grade, molecular characteristics and location, although availability of therapies and clinical trial access may differ. However, globally, there remains a lack of truly effective treatments for glioma, especially for high-grade and recurrent cases.

In the U.S., the treatment of glioma — depending on its classification as localized, diffuse, recurrent, or aggressive (such as glioblastoma) — typically involves a multidisciplinary approach. For localized low-grade gliomas, maximal safe surgical resection is often followed by active surveillance or adjuvant radiotherapy and chemotherapy, especially for high-risk patients. Diffuse or high-grade gliomas are generally treated with surgical resection, followed by concurrent chemoradiotherapy using temozolomide and maintenance chemotherapy. For recurrent or aggressive gliomas, especially glioblastoma, treatment options include reoperation, re-irradiation, or second-line therapies such as bevacizumab, tumor-treating fields (TTF), clinical trials, or immunotherapy approaches, although prognosis remains poor.

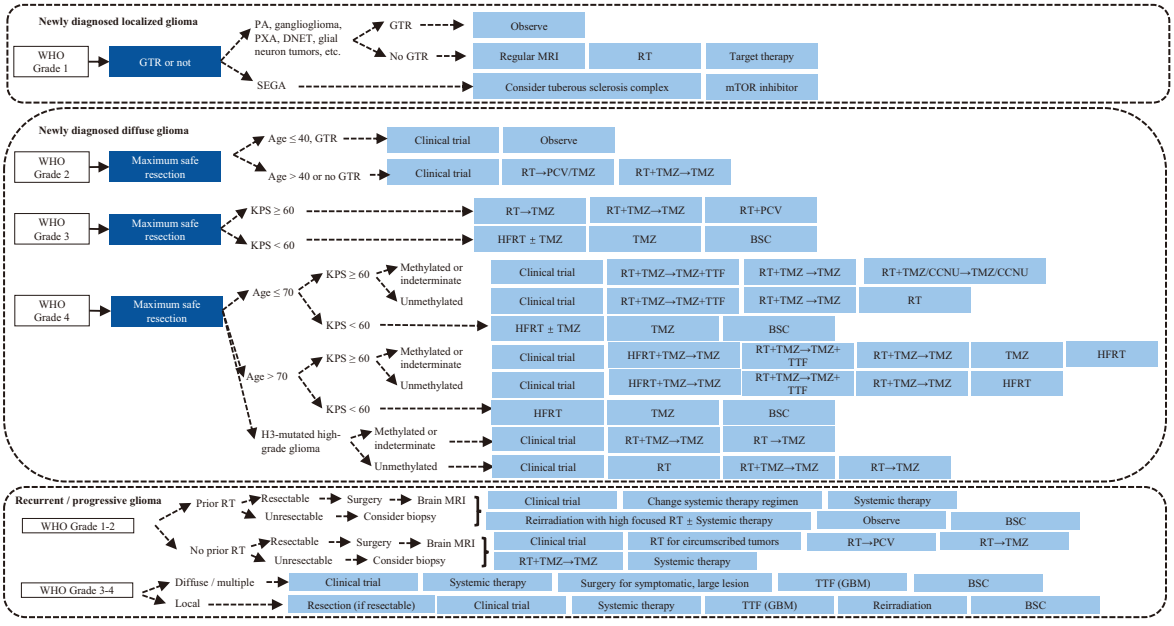
In China, for localized or low-grade gliomas, surgery is the mainstay, with increasing adoption of advanced imaging to improved outcomes. For high-grade or diffuse gliomas, radiotherapy and temozolomide are commonly used. In recurrent cases, reoperation and chemotherapy remain standard of care, while access to newer treatments like TTF or immunotherapy is still limited.

The charts below set forth the treatment paradigm for glioma in China and the U.S., respectively.

Treatment Paradigm for Glioma in China



Treatment Paradigm for Glioma in the U.S.



Notes: GTR refers to gross total resection; RT refers to radiotherapy; PCV refers to procarbazine, lomustine, and vincristine regimen; TMZ refers to temozolomide; BSC refers to best supportive care; HFRT refers to hypofractionated radiotherapy; KPS refers to Karnofsky performance status; TTF refers to tumor-treating fields; PA refers to pilocytic astrocytoma; PXA refers to pleomorphic xanthoastrocytoma; DNET refers to dysembryoplastic neuroepithelial tumor; SEGA refers to subependymal giant cell astrocytoma; CCNU refers to lomustine.

Source: *NCCN 2023, NCCN 2024, CACA 2024, Frost & Sullivan Report*

Leveraging the potent anti-tumor effects and enhanced safety profile, our Company's oncolytic immunotherapy candidate, MVR-C5252 is poised for second- or third-line therapy treatment of glioma.

Competitive Landscape of Oncolytic Immunotherapy for Glioma

As of the Latest Practicable Date, there were 12 approved drugs and 120 drug candidates in Phase II or later clinical stages for the treatment of glioma globally. Among the approved drugs, ten chemical agents have been approved for use across various lines of therapy, either as monotherapy or in combination. Additionally, one antibody drug has been approved specifically as a second-line monotherapy for glioma. The table below provides a summary of the competitive landscape for glioma as of the Latest Practicable Date.

Category	Number of Approved Drugs	Line of Approved Treatment	Approved Monotherapy/ Combination Use	Number of Drugs in Clinical Phase II and Above	Advantage	Limitation
Chemicals	10 (6 small molecule target drugs, 4 chemotherapy drugs)	First, Second, Second or later, Third or later, Adjuvant	Mono/Combo, depends on treatment options	89	**Chemotherapy:** • Standard first -line therapy • Broad -spectrum anticancer activity across stages **Small molecule target drugs:** • Target specific mutations, improving selectivity • Some are oral drugs, improving compliance	**Chemotherapy:** • Common toxicities like myelosuppression • Limited efficacy in certain subtypes **Small molecule target drugs:** • Indication restricted to specific mutation carriers • Resistance can develop, limiting duration of efficacy • High annual cost in some drugs (Vorasidenib, Tovorafeniband the combo of Trametinib & Dabrafenib)
Antibodies	1	Second	Mono	20	• Inhibits angiogenesis • Alleviates symptoms such as cerebral oedema	• Mainly used in recurrence, no significant OS benefit
Oncolytic Virus	1	Second or later	Mono	3	• Targets tumor cells with minimal harm to normal tissue • Induces immune responses against tumor	• Requires intracranial administration, involving high procedural complexity • Currently few approved drugs, limited advanced pipelines and data to substantiate their efficacy
Other Biologics	0	/	/	8	Cell therapy, ASO, gene therapy, peptides, enzyme, etc.: • Novel mechanisms may overcome chemo/radio resistance	• Limited data, uncertain long-term efficacy • Potential severe immune or off-target effects (e.g., cytokine release syndrome from CAR-T/TCR-T, ASO/gene therapy could bring off -target toxicity) • BBB may limit effective drug delivery
Total	**12**			**120**		

Source: FDA, CDE, NMPA, Frost & Sullivan Analysis

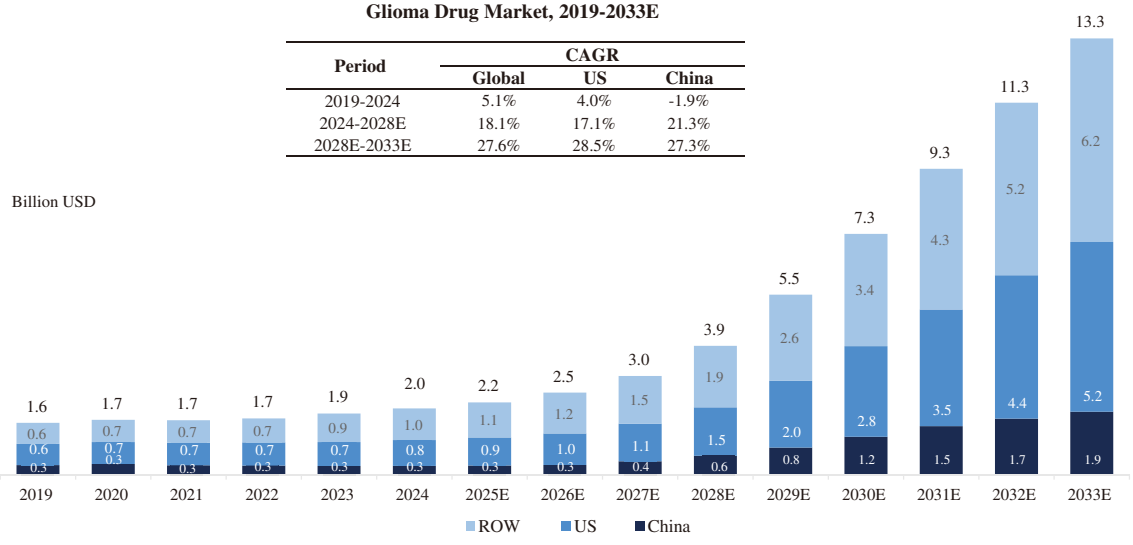
As of November 24, 2025, there was only one oncolytic immunotherapy drug, Teserpaturev/G47Δ, conditionally approved for the treatment of malignant glioma in Japan. Globally, eight oncolytic immunotherapy candidates were in Phase I/II and above development stages (including MVR-C5252) and two in Phase I clinical trials.

Glioma Drug Market

The global glioma drug market increased from US$1.6 billion in 2019 to US$2.0 billion in 2024, representing a CAGR of 5.1%, which is projected to reach US$3.9 billion by 2028 and US$13.3 billion by 2033, representing a CAGR of 18.1% from 2024 to 2028 and 27.6% from 2028 to 2033. The U.S. glioma drug market also showed an upward trend in recent years, growing from US$0.6 billion in 2019 to US$0.8 billion in 2024, with a CAGR of 4.0%. Such increasing trend is expected to persist in the near further, with the U.S. glioma drug market expected to grow to US$1.5 billion by 2028 and US$5.2 billion by 2033, representing a CAGR of 17.1% from 2024 to 2028 and 28.5% from 2028 to 2033. The increasing trend is also projected to present in China's glioma drug market, which is expected to reach US$0.6 billion by 2028 from US$0.3 billion in 2024 with a CAGR of 21.3% from 2024 to 2028, and further expand to US$1.9 billion by 2033 with a CAGR of 27.3% from 2028 to 2033. The chart below sets forth the historical and projected market sizes of the glioma drug markets for the periods indicated globally, in the U.S. and China.

Glioma Drug Market, 2019-2033E

Period	CAGR		
	Global	US	China
2019-2024	5.1%	4.0%	-1.9%
2024-2028E	18.1%	17.1%	21.3%
2028E-2033E	27.6%	28.5%	27.3%



Source: Annual Report, IARC, ClinicalTrials.gov, CDE, Frost & Sullivan Report

OVERVIEW OF ENGINEERED EXOSOMES

Introduction to Engineered Exosomes

Exosomes are small extracellular vesicles that are secreted by nearly all cell types, which can be broadly categorized into natural and engineered types. There are natural exosomes derived directly from cells, such as stem cells, immune cells, or tumor cells, and their molecular cargo often reflects the characteristics of their source.

Engineered exosomes are developed through advanced bioengineering techniques at the cellular level to enhance their efficacy, stability, or targeting ability. Unlike natural exosomes, which inherit a range of unclear or undefined functions from their parent cells, engineered exosomes are specifically designed for targeted indications. They are equipped to deliver precise functional proteins or nucleic acids, enabling more controlled and effective therapeutic outcomes. This precision targeting represents a significant advancement in improving drug delivery efficiency while minimizing off-target effects.

Among cell sources of engineered exosomes, human embryonic kidney 293 (HEK293) cells have emerged as one of the most promising platforms due to their high yield, ease of genetic manipulation, and compatibility with large-scale GMP-compliant production and purification. Exosomes derived from HEK293 cells exhibit low immunogenicity, robust stability, and efficient drug-loading capabilities, making them ideal vehicles for targeted drug delivery. The engineered exosome assets of our Company are all sourced from HEK293 cells. Mesenchymal stem cell (MSC)-derived exosomes, another cell source of engineered exosomes, are well-regarded for their regenerative and immunomodulatory properties, while plant-derived exosomes offer advantages in scalability. The table below illustrates a comparison of exosome sources.

Source	Easy Genetic Engineering	GMP Compliant Production	Standardized Purification Technology	Low Immuno genicity	High Yield	High Stability	Tissue Regeneration Ability
HEK293 Cell	✓	✓	✓	✓	✓	✓	✗
MSC	✗	✗	✗	✓	✗	✗	✓
Plant Cell	✗	✗	✗	✓	✓	✓	✗

Source: Annual Report, IARC, Frost & Sullivan Report

Advantages of Exosomes as a Superior Delivery Platform

Exosome, as a payload delivery system, offers several advantages over lipid nanoparticles (LNPs) and other synthetic carriers. Because exosomes derive from natural cells, they exhibit high biocompatibility and minimal immunogenicity, allowing them to circulate longer in the bloodstream without provoking adverse immune reactions. Their native lipid bilayer and membrane proteins enable efficient penetration of biological barriers such as the blood brain barrier and cell membranes without the need for additional targeting modifications. In contrast, LNPs generally

require peptides or coatings to enter cells. Exosomes also maintain superior stability under physiological conditions, protecting therapeutic cargo from enzymatic degradation and ensuring sustained delivery to target sites.

Beyond these intrinsic properties, engineered exosomes can be tailored to enhance delivery precision and therapeutic versatility. Surface conjugation of disease specific ligands or antibodies directs exosomes toward particular cell types, boosting receptor mediated uptake and minimizing off-target distribution. Their high cargo loading capacity allows simultaneous transport of small molecules, nucleic acids, proteins or gene editing tools within a single vesicle, supporting complex multi-modal treatment strategies. Unlike synthetic nanoparticles with inherent toxicity and modification limitation, exosome platforms combine safety, targeting accuracy and manufacturing scalability, making them a next generation vehicle for precise and effective therapeutic intervention. The table below illustrates a comparison of exosomes with other delivery systems.

Feature	Exosomes	LNPs	Synthetic Nanoparticles
Sources	Natural	Synthetic	Synthetic
Membrane Penetration	Naturally crosses blood-brain barrier/cell membranes	Requires cell-penetrating peptide modification	Depends on size/surface charge
Stability	High	Moderate	Depends on coating
Immunogenicity	Low	Moderate	Moderate
Biocompatibility	High	Moderate	Variable
Targeting Ability	Natural homing/ Targeting modification	Requires ligand conjugation	Passive or active targeting
Drug Loading Efficiency	High	Moderate	Material-dependent

Source: Literature Review, Frost & Sullivan Report

Application of Exosomes

Leveraging the biocompatibility and low immunogenicity, exosomes are widely applied in aesthetic field, as well as in areas such as regenerative medicine, drug delivery, and diagnostics. As versatile biological carriers, exosomes can be integrated into different delivery systems depending on the intended applications, resulting in various forms such as topical skincare serums, injectable fillers, microneedle-assisted delivery systems, and oral dietary supplements.

Exosome-based products are applied across a wide range of aesthetic areas such as skincare, hair care, fat reduction, and other performance-enhancing functional applications. Rather than drugs or medical devices, exosome-based products are commonly categorized as "functional cosmetics" in international markets. Consequently, most products in this space are not subject to rising approvals by authorities like the FDA or EMA. Instead, many enter the market through

alternative registration pathways, such as registration under the International Nomenclature Cosmetic Ingredient (INCI) system. INCI is a globally recognized naming system used for labeling cosmetic ingredients, and registration under this system is often a prerequisite for product commercialization in major markets such as the United States, the European Union, and parts of Asia. Once an ingredient is assigned an INCI name and included in the relevant national or regional cosmetic databases, manufacturers are legally permitted to incorporate the ingredient into topical formulations for skincare and other functional aesthetic purposes, without the need for separate drug or device approvals. This pathway provides a more efficient and commercially viable route for launching exosome-based products, particularly in the beauty and wellness industries where time-to-market and consumer accessibility are the key considerations.

Beyond aesthetic fields, exosomes also exhibit vast potential in clinical applications, from pulmonary fibrosis and dermatitis to the restoration of cardiac, renal, hepatic, and neural function. Their multi-target effects make them a promising tool in regenerative medicine and for addressing complex diseases.

Although the underlying science is still evolving, the unique properties of exosomes, including their natural origin, high biocompatibility, and ability to carry biologically active molecules, continue to attract significant attention worldwide. As regulatory frameworks evolve, these applications may pave the way for broader acceptance and eventual integration into mainstream consumer wellness and medicine.

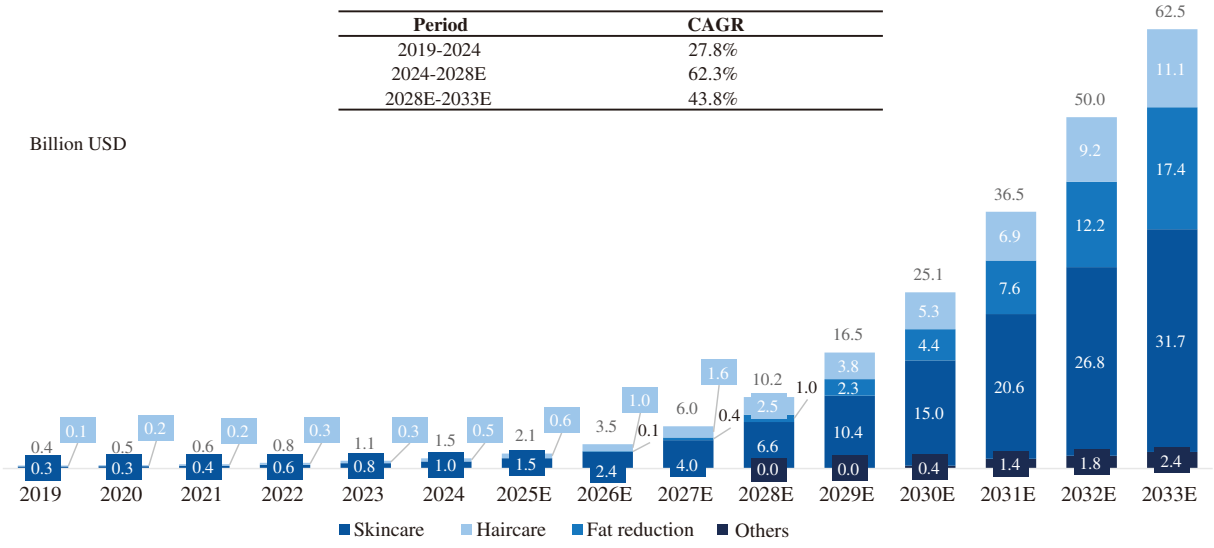
Exosome Treatment Market

As an emerging advanced therapy, exosome-based treatments currently occupy a relatively small market. However, the unique advantages of exosomes, such as strong biocompatibility, low immunogenicity, and the ability to target various tissues, are driving growing interest. With expanding research and broader application in both aesthetics and therapeutical fields, along with supportive registration pathways, the exosome treatment market is expected to grow rapidly in the coming years. The global exosome treatment market grew from US$0.4 billion in 2019 to US$1.5 billion in 2024 at a CAGR of 27.8%, which is projected to reach US$10.2 billion by 2028 and US$62.5 billion by 2033 at a CAGR of 62.3% from 2024 to 2028 and 43.8% from 2028 to 2033, respectively.

Exosomes hold significant potential across a broad spectrum of indications, including aesthetic uses like skincare, haircare, localized fat reduction and others. The chart below sets forth the historical and projected market sizes of the global exosome treatment market, segmented by key functional aesthetic and clinical applications over the indicated periods.

Global Exosomes Treatment Market, 2019-2033E

Period	CAGR
2019-2024	27.8%
2024-2028E	62.3%
2028E-2033E	43.8%



Source: Annual Report, Interview with experts, Frost & Sullivan Report

Engineered exosomes, with their controllable composition and programmable functionality, offer clear differentiation from natural exosomes, which are constrained by heterogeneous cargo, biological variability and limited process consistency. Owing to their superior functional specificity, regulatory compatibility and scalable production, which enable precise cargo loading, targeted surface modification and predictable biological effects, engineered exosome therapies are expected to grow significantly faster than natural exosome therapies and progressively become the primary modality for exosome-based applications. In particular, engineered exosomes have demonstrated significant potential in consumer-oriented applications, including localized fat reduction, hair care and anti-hair loss, and skin care. Such applications are not intended for disease treatment and are not directed at specific pathological conditions. As a result, there is no clearly defined patient population, and the relevant users consist of broad segments of the general public with personal care and health management needs, rather than specific targeted patients. Together with advancements in targeted drug delivery, regenerative medicine, immuno-oncology and high-end consumer health applications such as premium skincare and hair regeneration, the engineered segment is projected to reach US$3.4 billion by 2028 and US$33.0 billion by 2033, representing a CAGR of 57.1% from 2028 to 2033, significantly outpacing the growth of natural exosomes. Consequently, the share of engineered exosomes in the exosome treatment market is projected to grow from 33.9% in 2028 to 52.8% by 2033.

Current Challenges of Engineered Exosomes Production

Engineered exosome production typically involves several complex and highly regulated steps, including cell culture, harvest, purification and concentration, and storage. Due to the technical demands at each stage, the overall production process is costly and faces several key challenges. Specifically:

- Exosomes generally require ultra-low temperatures (around -80°C) to maintain their structural integrity and bioactivity. This poses significant logistical challenges for transportation and long-term preservation, driving up both cost and operational complexity.

- The high cost of raw materials, such as culture media, carrier agents, and purification resins, further contributes to the overall production expense. Maintaining consistent cell quality during large-scale expansion is difficult, and batch-to-batch variability remains a persistent issue, hindering industrial stability.

- High-purity exosome products often require multistep downstream processes including filtration, ultrafiltration, and chromatography, which are labor-intensive and prone to product loss. The lack of globally accepted quality standards or regulatory guidelines further limits the clinical translation and commercialization of exosome-based products.

As such, companies capable of achieving cost control while addressing storage, scalable production, and process reproducibility will hold a distinct competitive advantage in the exosome field.

Major Indications for Engineered Exosome Products

Skin-Related Conditions

Skin-related conditions encompass a broad spectrum, spanning from chronic wounds and acute injuries to surgical complications and intrinsic skin aging. These conditions vary widely in their causes, progression, and treatment needs, but many share a common link to the skin's ability to regenerate and maintain its structural integrity. As the regenerative capacity, repair mechanisms, and overall dermal health of skin naturally decline with age, individuals over 35 have become a core demographic for skin-related treatments and products. The global population aged over 35 is remarkably large, amounting to 3.7 billion in 2024, which is projected to reach 3.9 billion by 2028 and 4.2 billion by 2033.

Exosome Application in Skin-Related Conditions

Exosomes have emerged as a promising, cell-free regenerative strategy for skin-related conditions. Exosomes exert therapeutic effects by delivering functional cargo, such as microRNAs, proteins, and lipids, collectively promoting key regenerative processes. These include the proliferation and migration of keratinocytes and fibroblasts, angiogenesis, immune modulation, extracellular matrix remodeling, and re-epithelialization. Moreover, exosomes can inhibit excessive fibrosis and reduce scar formation. Owing to their low immunogenicity, high biocompatibility, and intrinsic ability to transfer bioactive molecules across cellular membranes, exosomes are increasingly regarded as a next-generation therapeutic modality for chronic wound healing, superficial skin depressions repair, stretch marks, and broader dermatological applications.

Competitive Landscape of Skin-Related Conditions

Skin-related issues require tailored treatment approaches depending on their specific nature. Post-surgical and traumatic wounds typically follow a more structured healing process, emphasizing aseptic technique, timely closure, and ongoing monitoring, though complications like dehiscence and scarring remain common. In contrast, chronic wounds often demand long-term, multidisciplinary care focused on infection control, pressure relief, and optimization of the wound environment, yet they are frequently complicated by poor circulation and comorbidities such as diabetes.

In addition, skin aging and anti-aging issues are primarily addressed through preventive and skin management, including topical agents, aesthetic treatment, and lifestyle modifications. These efforts are challenged by continuous environmental exposure and the irreversible biological processes associated with intrinsic aging.

Functional Skincare Products Market

Functional skincare products serve as a core component in the field of skin aging and anti-aging, while acting as a supportive adjunct in the management of post-surgical, traumatic, and chronic wounds. The global functional skincare products market is fueled by active ingredients designed to address a broad spectrum of skin concerns, including anti-aging, hydration and repair, brightening, oil control and acne treatment, barrier enhancement, and anti-inflammatory soothing. Commonly used ingredients include well-established categories such as vitamins, peptides, acids, collagen, moisturizing agents like hyaluronic acid and ceramides, and antioxidants. In recent years, exosomes, as emerging bioactive substances, have gained extensive attention for their advanced regenerative and signaling properties, further expanding the scope and innovation within the market.

Driven by the growing aging population and increasing awareness of skin health and preventive care across all age groups, the functional skincare products market has experienced rapid growth and is expected to maintain strong momentum in the coming years. The exosome-based functional skincare product market reached US$1.0 billion in 2024, and is projected to increase to US$6.6 billion by 2028 and US$31.7 billion by 2033, with CAGRs of 60.3% from 2024 to 2028 and 36.9% from 2028 to 2033.

Alopecia

Alopecia is one of the main types of hair-related disease, which is broadly categorized into congenital and acquired types. Congenital alopecia, which is relatively rare, is typically caused by genetic mutations or hormonal imbalances that disrupt hair follicle development. In contrast, acquired alopecia is far more prevalent and can result from a wide range of factors including nutritional deficiencies, infections, autoimmune conditions, hormonal disturbances, and neurological disorders. Acquired alopecia is further divided into cicatricial (scarring) and non-cicatricial (non-scarring) types. Cicatricial alopecia leads to permanent hair loss through the destruction of hair follicles and their replacement by scar tissue, often caused by rare inflammatory or infectious conditions. Non-cicatricial alopecia, the more common subtype, includes androgenetic alopecia driven by the miniaturizing effects of dihydrotestosterone on hair follicles.

The global burden of alopecia is substantial and continues to grow. The number of alopecia cases worldwide has reached 1,604.3 million in 2024, which is expected to increase to 1,698.5 million by 2028 and reach 1,816.9 million by 2033.

Exosome Application in Alopecia Treatment

Exosomes have emerged as a promising therapeutic tool in regenerative medicine and the treatment of alopecia, thanks to their ability to deliver a range of bioactive molecules with regenerative and anti-inflammatory effects.

In hair restoration, exosomes can promote the proliferation and differentiation of hair follicle stem cells through carrying growth factors such as VEGF and IGF-1, as well as microRNAs that modulate gene expression and the hair follicle cycle. These bioactive cargos activate intracellular signaling pathways that stimulate follicular regeneration and prolong the growth phase of the hair cycle. In addition to stimulating follicular activity, exosomes play a key role in modulating the scalp's immune and vascular environment. They can deliver anti-inflammatory molecules such as IL-10, IL-6, and TNF-α to regulate immune responses and reduce chronic inflammation that contributes to follicular damage. Specific miRNAs like miR-146a help maintain immune homeostasis, further protecting hair follicles. Simultaneously, exosomes promote angiogenesis by

delivering angiogenic factors that enhance microcirculation, improve oxygen and nutrient supply, and support hair follicle repair. Their ability to transport extracellular matrix proteins and other nutritional components further reinforces follicle health.

Compared with traditional therapies, exosome-based treatments are minimally invasive, show high biocompatibility, and offer multi-targeted mechanisms, making them especially appealing in aesthetic medicine. Their regenerative capabilities and ease of administration contribute to higher patient compliance and satisfaction.

Competitive Landscape of Alopecia Treatment

Alopecia treatment follows the principles of early, comprehensive, long-term, and personalized care. Treatment typically begins with general products such as shampoos and serums containing ingredients like caffeine, biotin, or keratin. These products are easy to access and help maintain scalp health, though their effects are usually mild and preventive in nature. Due to the regenerative properties and ability to mediate intercellular communication, exosomes have demonstrated strong potential to be incorporated as a bioactive component in such formulations of general products. Studies suggest that exosomes can effectively enhance follicle regeneration by increasing the number and length of hair follicles and promoting the transition from the telogen (resting) phase to the anagen (growth) phase.

In addition to general products, many patients turn to home-use devices like scalp massagers for more targeted results. These tools aim to stimulate local blood circulation and follicle activity through physical or light-based mechanisms. While convenient and non-invasive, their clinical efficacy remains limited and often requires long-term, consistent use.

For patients with more pronounced hair loss, approved drug therapies form the cornerstone of medical treatment, including minoxidil, finasteride, and dutasteride. These medications work by improving follicle blood supply or regulating hormonal pathways, and have demonstrated efficacy in many cases, though they may cause side effects and require ongoing use. In more advanced or treatment-resistant cases, surgical and clinical interventions such as microneedle hair transplantation, platelet-rich plasma (PRP), low-level laser therapy (LLLT), and mesotherapy offer more visible and often longer-lasting results. Among these, microneedle hair transplantation is particularly valued for its precision and effectiveness.

Alopecia Treatment Market

The alopecia treatment market has already demonstrated significant potential and is expected to continue exhibiting strong and accelerating growth. The global market size of alopecia treatment increased from US$15.4 billion in 2019 to US$22.1 billion in 2024, representing a CAGR of 7.6%, which is projected to reach US$40.0 billion in 2028, representing a CAGR of 12.5% from 2024 to 2028, and further increase to US$89.9 billion in 2033, representing a CAGR of 17.6% from 2028

to 2033. Within the alopecia treatment market, the exosome-based products accounted for approxiamtely 2.0% in 2024, which is expected to grow significantly to 6.3% and 12.3% by 2028 and 2033, respectively.

Localized Fat Accumulation

Overweight and obesity are defined as abnormal or excessive fat accumulation that may impair health. According to the classification standards of the World Health Organization and the U.S. National Institutes of Health, a body mass index (BMI) of 25 kg/m^2 or higher is considered overweight, while a BMI of 30 kg/m^2 or higher is classified as obesity.

Recent years have witnessed an increasing trend of population with obesity and overweight globally, due to the factors such as changes in dietary structure and lifestyle. The population with obesity globally has increased from 753.3 million in 2019 to 988.1 million in 2024, which is expected to reach 1,178.6 million in 2028 and 1,448.5 million in 2033. The population with overweight globally has increased from 1,444.4 million in 2019 to 1,624.7 million in 2024, which is expected to reach 1,702.8 million in 2028 and 1,762.1 million in 2033.

Given the steady and substantial rise of obesity and overweight populations, together with increasing societal emphasis on body wellness and aesthetic preferences for physical appearance, the fat accumulation treatment market is poised for significant expansion. Driven by the growing demand for personalized and targeted solutions that address specific problem areas, localized fat accumulation treatments, such as non-invasive body contouring and targeted lipolysis, are gaining momentum.

Exosome Application in Localized Fat Accumulation Treatment

The application of exosomes for the treatment of localized fat accumulation has become a major focus in current research and the development of functional aesthetic products. By regulating adipocyte differentiation, lipid synthesis and breakdown, and promoting the browning of white fat, exosomes demonstrate significant potential for body fat regulation, metabolic enhancement, and body contouring.

Exosomes targeting fat metabolism are entering the commercial market in forms such as topical slimming serums, functional supplements, and aesthetic treatments. These products aim to promote fat breakdown, reduce inflammation, support healthy lipid metabolism, and enhance local body contouring effects.

Competitive Landscape of Localized Fat Accumulation Treatment

Diverse procedures have been developed to address localized fat deposits, which typically fall broadly into surgical and non-surgical approaches, with several having received regulatory approval for specific body areas.

Among surgical options, traditional liposuction remains the most established and widely practiced method. It involves the physical removal of fat through suction-assisted techniques and is approved globally for use on various body areas such as the abdomen, thighs, and arms. Although it delivers immediate and lasting results, liposuction is invasive, requires downtime, and carries procedural risks.

Non-surgical treatments have gained popularity due to their lower risk and minimal recovery time. Among them, injectable deoxycholic acid is FDA-approved for reducing submental fat under the chin. It works by destroying fat cells through a few sessions of injection, offering a targeted solution for small areas. Additionally, GLP-1 receptor agonists, originally developed for diabetes, are now widely used for fat reduction by curbing appetite. In comparison, cryolipolysis uses controlled cooling to induce fat cell death and is FDA-cleared for multiple areas including the abdomen, flanks, and chin. Results typically appear within two to three months after one or two sessions.

Similarly, laser-based treatments apply heat to eliminate fat cells while protecting the skin surface, which are painless, require no downtime, and usually show results in six to twelve weeks. Ultrasound-based technologies, on the other hand, use focused sound waves to disrupt fat cells. They are also FDA-cleared for areas like the abdomen and flanks, with gradual improvements seen over several weeks. In addition, red light therapy stimulates fat cells to release their contents, which is FDA-cleared for the abdomen, hips, and thighs, and can produce visible effects within hours. However, maintaining results often requires ongoing lifestyle adjustments.

Localized Fat Accumulation Treatment Market

Driven by rising demand and expanding treatment innovations, the localized fat accumulation treatment market is showing strong and accelerating growth potential. The global market size of localized adipose reduction treatment increased from US$9.0 billion in 2019 to US$23.6 billion in 2024, representing a CAGR of 21.3%, which is projected to reach US$70.4 billion in 2028, representing a CAGR of 31.4% from 2024 to 2028, and further increase to US$191.5 billion in 2033, representing a CAGR of 22.2% from 2028 to 2033. As of the Latest Practicable Date, there were no commercially available exosome-based products for localized fat accumulation treatment.

With the first exosome-based product for localized fat accumulation treatment is expected to commercialize in 2026, the exosome-based products are expected to capture 1.5% and 9.1% of the localized fat accumulation treatment market by 2028 and 2033, respectively.

Pulmonary Fibrosis

Pulmonary fibrosis (PF) is a progressive and irreversible lung disease characterized by chronic injury and scarring of lung tissue, gradually impairing the lungs' ability to function. PF encompasses over 200 types of interstitial lung diseases, with idiopathic pulmonary fibrosis (IPF) being the most prevalent and severe subtype. The global incidence of IPF increased from 554.4 thousand in 2019 to 652.2 thousand in 2024, which is expected to reach 821.7 thousand in 2028 and 1,090.7 thousand in 2033. Current treatments only slow disease progression, highlighting the urgent need for more effective therapeutic strategies.

Exosome Application in Pulmonary Fibrosis Treatment

The ability to penetrate biological barriers, and inherent cell-targeting properties of exosomes allow exosomes as promising candidates for the treatment of PF. Studies have demonstrated that nebulized milk-derived exosomes loaded with siTGF-β1 can alleviate PF in mouse models by inhibiting epithelial-mesenchymal transition (EMT) and enhancing collagen degradation. In silica-induced PF models, human umbilical cord MSC-derived exosomes (HucMSC-EVs) were shown to transfer miR-223-3p, thereby suppressing fibrosis through inhibition of the circPWWP2A/miR-223-3p/NLRP3 axis. Additionally, MSC-derived exosomes promote an immunosuppressive microenvironment in fibrotic lungs by inducing T regulatory cell expansion and polarization of macrophages toward an alternatively activated (M2) phenotype, further contributing to anti-fibrotic effects.

Competitive Landscape of Exosome Drugs for Pulmonary Fibrosis

As of the Latest Practicable Date, no exosome-based drugs for pulmonary fibrosis have been approved or are in clinical stage in China or globally.

Pulmonary Fibrosis Drugs Market

The global pulmonary fibrosis drug market increased from US$3.6 billion in 2019 to US$6.4 billion in 2024, representing a CAGR of 12.0%, which is projected to reach US$9.1 billion in 2028 and US$13.8 billion in 2033, representing a CAGR of 9.3% from 2024 to 2028 and 8.6% from 2028 to 2033.

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 US$117.2 thousand for the preparation and update of the Frost & Sullivan Report, which is not contingent on the **[REDACTED]** proceeding.