

INDUSTRY OVERVIEW

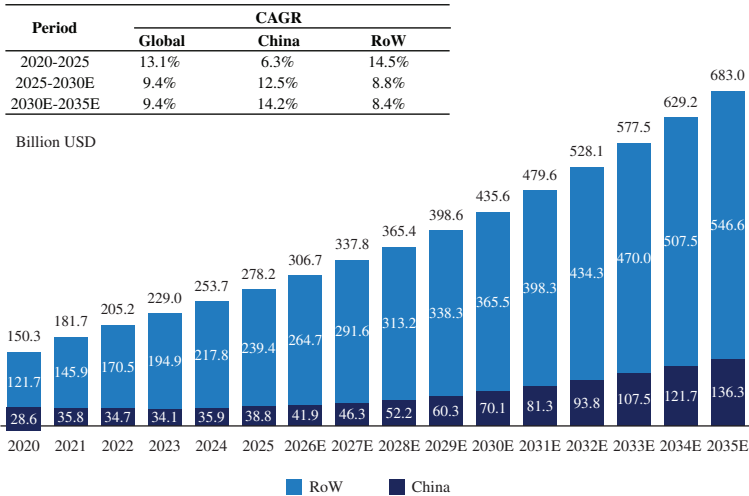
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OVERVIEW OF ONCOLOGY DRUG MARKET

Market Size and Future Trends of Oncology Drug Market

Oncology remains the largest and fastest-growing therapeutic area within the global pharmaceutical market and is widely recognized as a core driver of industry expansion. Supported by demographic shifts, prolonged patient survival, rising prevalence of cancer, and continuous advances in treatment modalities, the oncology drug market is expected to maintain strong growth in the future. The slower CAGRs for the global oncology drug market from 2025 to 2030 and from 2030 to 2035 are mainly driven by a high base effect created by breakthrough therapies in the earlier period, increasing global pricing and reimbursement pressure, a moderation in innovation momentum after the initial wave of immune checkpoint inhibitors and ADCs, and intensified competition including biosimilar entries. Similar to the global market, China’s oncology drug market is large and the sales of oncology products in China has risen steadily in the recent years. The projected CAGRs for China’s oncology drug market from 2025 to 2030 and from 2030 to 2035 are supported by rising cancer incidence and an aging population, the continuous launch and adoption of innovative therapies, expanding reimbursement coverage, and higher treatment penetration particularly in lower-tier cities, which together underpin faster growth relative to the global average. The chart below illustrates the market size and growth rate of the historical and forecasted global and China’s oncology drug market from 2020 to 2035.

Global Oncology Drug Market, 2020-2035E

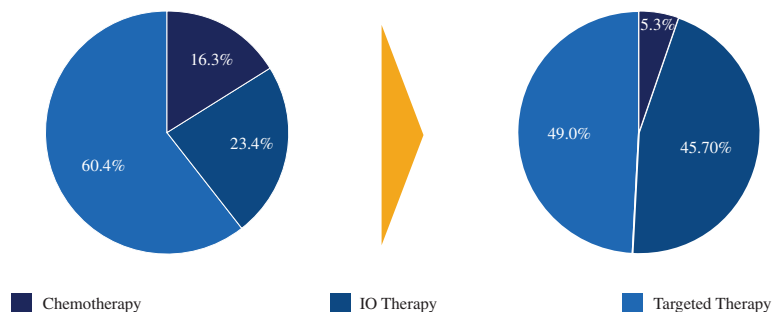


Source: Annual Reports, Expert Interviews, Frost & Sullivan Analysis

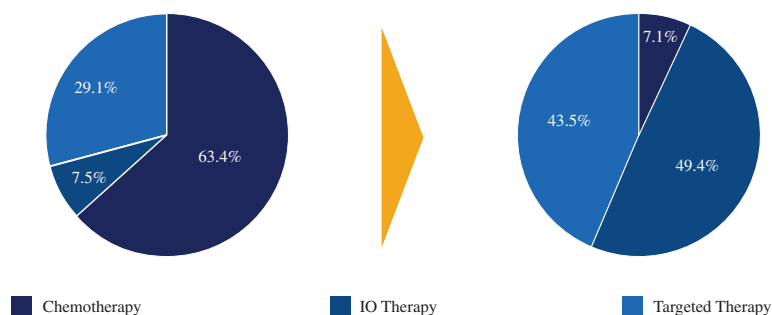
INDUSTRY OVERVIEW

Cancer therapies have gone through a long process of development in history, and they will continue to evolve over time. The chart below illustrates the comparison between the historical and forecasted global and China’s market share of innovative oncology drugs and conventional oncology drugs in 2020 and 2035E, respectively.

Breakdown of the Oncology Market by Therapy in Global, 2020 and 2035E



Breakdown of the Oncology Market by Therapy in China, 2020 and 2035E



Source: Annual Reports, Expert Interviews, Frost & Sullivan Analysis

The most prevalent types of cancer globally included lung, breast and colorectal cancers. In China, lung, colorectal and thyroid cancers were major tumor types. These figures reflect the increasing burden of oncology diseases and the growing demand for effective treatment solutions. The divergence in cancer incidence creates significant opportunities for domestic biopharmaceutical companies to pursue differentiated strategies that are tailored to local epidemiological characteristics and that enhance both clinical relevance and commercial potential.

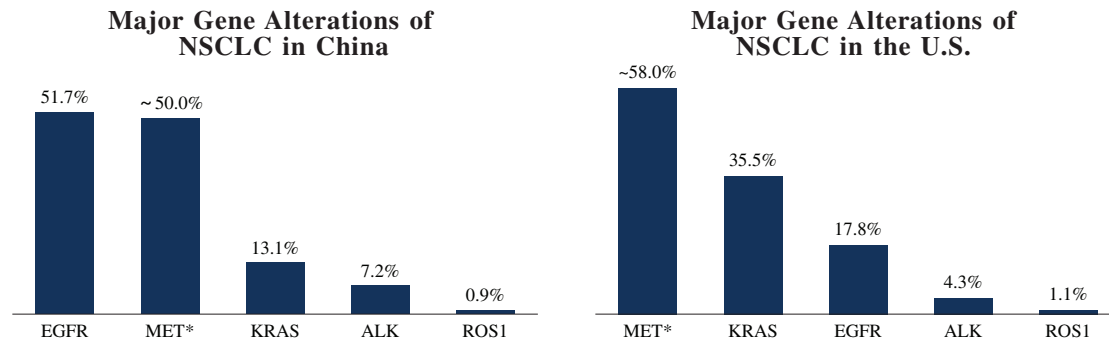
Overview of Lung Cancer Drug Market

Lung cancer is one of the most common and deadly malignancies worldwide. It is broadly divided into two categories: small cell lung cancer (SCLC), which accounts for approximately 15% of cases, and non-small-cell lung cancer (NSCLC), which accounts for the remaining 85%. NSCLC therefore represents the predominant subtype and the primary focus of therapeutic development. As a class, NSCLCs are relatively insensitive to chemotherapy, as compared to SCLC. All types of NSCLC can occur in unusual histologic variants and developed as mixed cell-type combinations.

Lung cancer incidence and mortality have been increasing worldwide and in China. The number of new cases of lung cancer patients worldwide increased from 2.3 million in 2020 to 2.7 million in 2025, and is expected to increase to 3.5 million by 2035. The number of new cases of lung cancer patients in China has increased from 1.0 million in 2020 to 1.1 million in 2025, and is expected to increase to 1.5 million by 2035. The consistently high incidence of lung cancer in China reflects a stable and substantial treatment demand. This long-term disease burden provides a strong market foundation for pharmaceutical companies’ continued investment and strategic focus in the lung cancer therapeutic area.

INDUSTRY OVERVIEW

Epidermal growth factor receptor (EGFR), v-Ki-ras2 Kirsten rat sarcoma viral oncogene (KRAS), mesenchymal-epithelial transition factor (MET) and anaplastic lymphoma kinase (ALK) are the most commonly mutated oncogenes that involve the pathogenesis of NSCLC as “genetic drivers.” These four types of mutations have been widely targeted for therapeutic development. The chart below illustrates the percentage of major genetic alteration of NSCLC in China and the U.S.



Note:

* MET pathway alterations include MET exon 14 skipping, MET gene amplification, and MET protein overexpression

Source: NIH, Frost & Sullivan Analysis

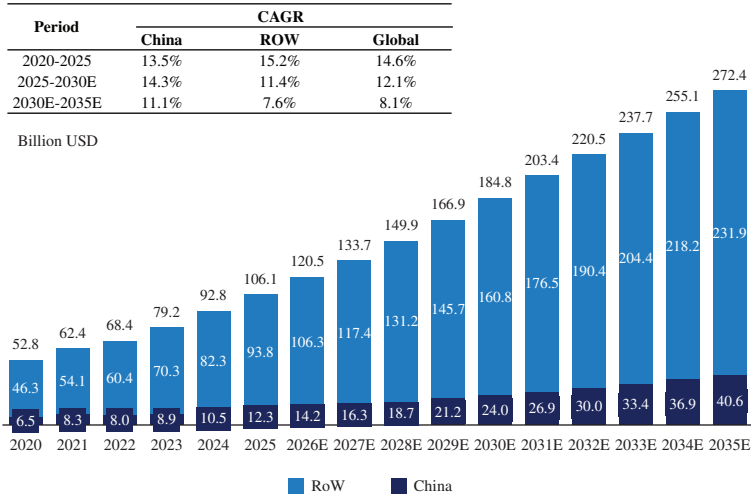
- EGFR.** EGFR has an extracellular ligand-binding domain, a transmembrane anchoring region, and an intracellular C-terminal phosphorylation domain. Mutation and dysregulation of the EGFR family is closely linked to different types of cancer, so EGFR becomes the target of multiple cancer therapies. Blocking EGFR may impede cancer cell growth. The proportion of EGFR mutations in NSCLC patients is significantly higher in China (51.7%) compared with the U.S. (17.8%), reflecting marked differences between Asian and Western populations. The EGFR tyrosine kinase inhibitor (TKI) is a substance that blocks the activity of the EGFR protein. In specific, 47% of NSCLC patients with EGFR mutation will develop T790M mutation after disease progression on a first or second-generation EGFR TKI, and 7% of NSCLC patients with EGFR mutation will develop C797S mutation after disease progression on third-generation EGFR TKI.
- MET.** MET is a receptor tyrosine kinase encoded by the MET proto-oncogene located on chromosome 7q31. Upon activation by its ligand hepatocyte growth factor (HGF), MET initiates multiple downstream signaling cascades, including PI3K/AKT, RAS/MAPK and STAT3, which are critical for regulating cell proliferation, survival, motility and invasion. MET pathway alterations (including MET exon 14 skipping, MET gene amplification, and MET protein overexpression) have been reported in approximately 50% of NSCLC patients in China and approximately 58.0% of NSCLC patients in the U.S.
- ALK.** ALK is a member of the insulin receptor superfamily of receptor tyrosine kinases that are encoded by ALK gene. When activated through phosphorylation, ALK tyrosine kinase will activate multiple downstream signal transduction pathways, which play a pivotal role in cell proliferation and survival. In NSCLC, the EML4-ALK results from an inversion in the short arm of chromosome two, fusing the N-terminal domain of EML4 to the intracellular kinase domain of ALK (3' gene region), resulting in a constitutively active ALK tyrosine kinase. Among patients with NSCLC, 7.2% of patients in China had concomitant ALK mutations.
- KRAS.** The KRAS gene, the predominant subtype of RAS mutations within the RAS/MAPK pathway, shows marked differences in prevalence between populations. In NSCLC, KRAS mutations are observed in 13.1% of Chinese patients compared with 35.5% of patients in the United States.

The global NSCLC drug market is expected to grow at slower CAGRs from 2025 to 2030 and from 2030 to 2035, as the market shifts from a period of breakthrough innovation to structural consolidation. The slowdown is mainly driven by the maturity of first- and second-generation immunotherapies and targeted therapies, pricing and reimbursement pressures across major markets, and increasing competition arising from patent expiries and biosimilar entries. While next-generation modalities such as ADCs, bispecific antibodies and cell and gene therapies are expected to support continued expansion, their incremental contribution and smaller eligible patient

INDUSTRY OVERVIEW

populations limit their overall impact, especially as diagnosis and treatment rates in developed markets have largely stabilized. The chart below illustrates the market size and growth rate of the historical and forecasted global and China’s NSCLC drug market from 2020 to 2035.

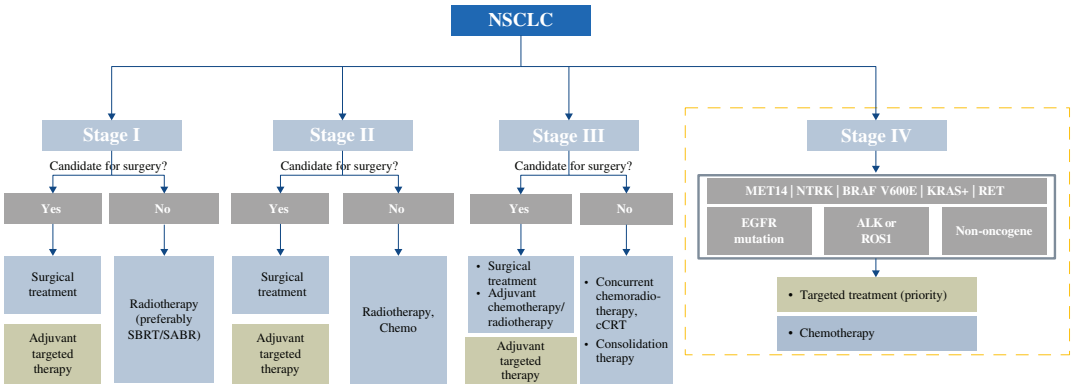
Global NSCLC Drug Market, 2020-2035E



Source: Annual Reports, Expert Interviews, Frost & Sullivan Analysis

Surgical treatment, chemotherapy, radiotherapy, targeted therapies and postoperative adjuvant therapies play different roles in treatment of patients at different stages. The following charts summarized the treatment paradigm of NSCLC and Stage IV NSCLC, and postoperative adjuvant treatment pathways for NSCLC in China.

Treatment Paradigm of NSCLC in China

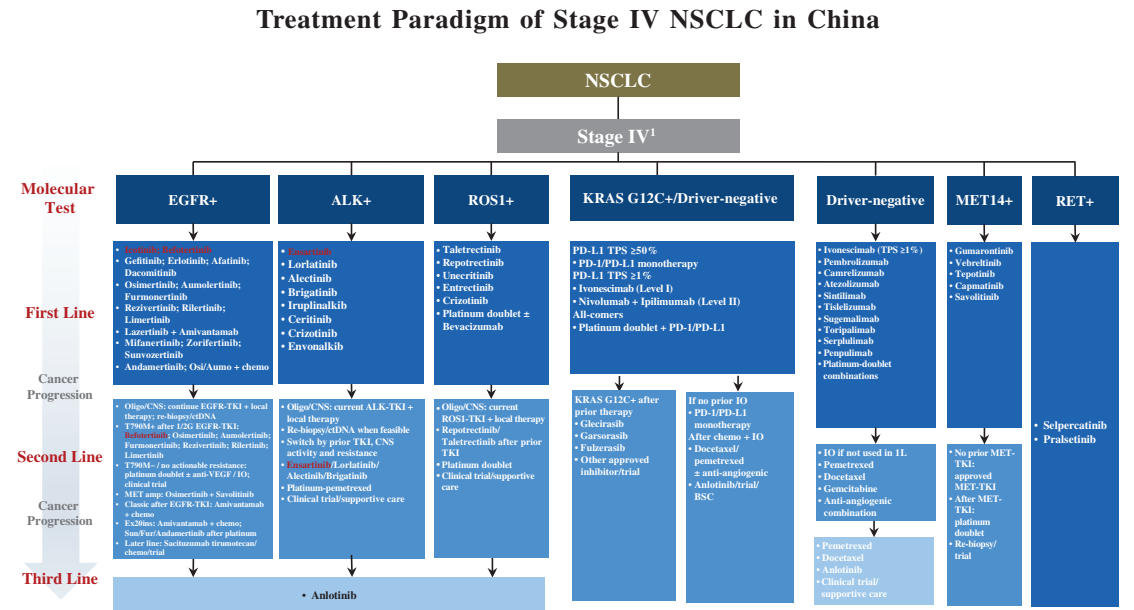


Note:

- (1) The treatment paradigm for patients with BRAF V600E mutation and NTRK rearrangement can refer to the non-oncogene-driven part.

Sources: CSCO Guidelines for the Diagnosis and Treatment of Non-Small Cell Lung Cancer (2026 Edition), Literature Review, Frost & Sullivan Analysis

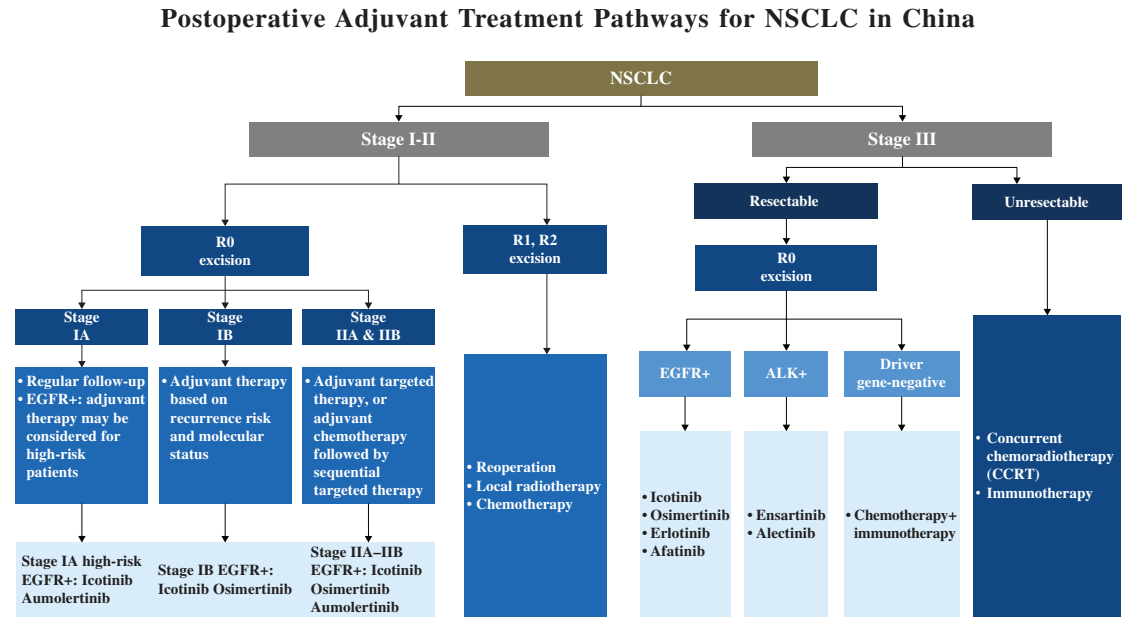
INDUSTRY OVERVIEW



Note:

(1) The treatment paradigm focuses more on the innovative drugs, without the inclusion of conventional chemotherapy.

Sources: CSCO Guidelines for Diagnosis and Treatment of NSCLC (2026 Edition), Frost & Sullivan Analysis



Sources: Guidelines for Perioperative Diagnosis and Treatment of Driver Gene-Positive Non-Small Cell Lung Cancer (2026 Edition), CMA, Frost & Sullivan Analysis

Even after radical resection, a significant proportion of NSCLC patients experience disease recurrence, with relapse rates estimated at 30% to 55%. Though platinum-based adjuvant chemotherapy has long been the standard of care, its benefit remains limited, only improving five-year survival rate by 5.4%. This modest efficacy underscores that conventional chemotherapy alone is insufficient to fully reduce the recurrence risk in high-risk early-stage NSCLC patients. As a result, there remains a substantial unmet clinical need for more effective postoperative therapies capable of reducing recurrence risk and improving long-term survival outcomes.

INDUSTRY OVERVIEW

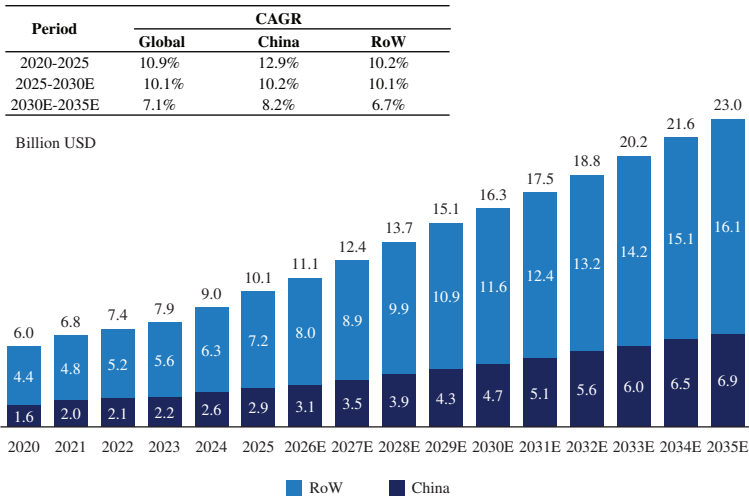
Recent clinical trials have demonstrated the potential of adjuvant targeted therapies to transform the treatment paradigm. The Phase III EVIDENCE trial showed that adjuvant treatment with icotinib extended median disease-free survival (mDFS) to 47.0 months compared with 22.1 months for platinum-based chemotherapy, representing a 64% reduction in recurrence risk (HR = 0.36, $p < 0.0001$). Our Phase III trial of ensartinib in stage IB–IIIB ALK+ NSCLC has reported encouraging interim results in the adjuvant setting, indicating the potential to reshape the current treatment landscape for ALK+ NSCLC patients after curative surgery.

Overview of EGFR TKI Market

EGFR+ lung cancer refers to lung cancers that show evidence of an EGFR mutation. EGFR TKIs are now the main choice for treating NSCLC with EGFR mutations. These medications tend to have fewer side effects than chemotherapy by targeting cancer cells with specific mutation while sparing normal cells.

The global market size of EGFR TKIs is expected to reach US\$23.0 billion by 2035. China’s EGFR TKI drug market demonstrates a more balanced but still steady growth outlook. Market expansion will continue to be supported by broader use of EGFR TKIs in combination and sequential treatment regimens and increasing patient access. However, growth will be partially tempered by price reductions under NRDL negotiations as well as competition from generics and other follow-on products. The following charts show the historical and forecasted market size and growth rate of EGFR TKIs drug in global and China’s market from 2020 to 2035.

Global EGFR TKI Drug Market, 2020-2035E



Source: Annual Reports, Expert Interviews, Frost & Sullivan Analysis

The development of EGFR TKIs has undergone several generations of innovation, reflecting continuous advances in the understanding of resistance mechanisms, mutation coverage and treatment safety. First-generation EGFR TKIs reversibly bind to EGFR and demonstrated clear efficacy in prolonging progression-free survival in patients with EGFR-mutant NSCLC. However, resistance mutations, particularly T790M, limited their long-term effectiveness. Second-generation EGFR TKIs were designed to irreversibly bind EGFR via covalent bonds and to broaden HER family inhibition. While these agents improved potency, they were still unable to fully overcome T790M-driven resistance and were associated with higher toxicity. Third-generation EGFR TKIs target common EGFR-sensitizing mutations in patients with NSCLC and are also specifically active against the T790M resistance mutation. They also demonstrated blood-brain barrier penetration, thereby improving outcomes in patients with brain metastases and offering enhanced safety and efficacy. Currently, fourth-generation EGFR TKIs are under clinical investigation. These agents are designed to overcome emerging resistance mechanisms with the aim of expanding mutation coverage, further improving safety profiles and providing more durable disease control.

INDUSTRY OVERVIEW

In China, the treatment of EGFR+ NSCLC has become increasingly precise and stage-specific. For operable patients, postoperative adjuvant therapy provides the greatest therapeutic benefit, with different options for patients of different stages. In advanced NSCLC, including certain Stage IIIB and Stage IV disease, patients are typically treated with first-generation EGFR TKIs or with second-generation agents. Upon the development of resistance, including resistance associated with the T790M mutation, third-generation EGFR TKIs offer effective subsequent treatment options. This structured treatment pathway reflects the continuous evolution of EGFR-targeted therapies.

We distinguish ourselves in the competitive market of EGFR TKIs with a portfolio covering both first-generation and third-generation EGFR TKIs, namely icotinib and befotertinib. This enables comprehensive patient care from initial treatment to resistance management. Notably, icotinib has outperformed peers to become the best-selling first-generation EGFR TKI in China, further reinforcing our strong market position. The following diagram summarized the competitive landscape of marketed EGFR TKIs in China as of the Latest Practicable Date.

Competitive Landscape of Marketed EGFR-TKIs in China

	Brand Name	Generic Name	Originator	Treatment Line	NMPA Approval	NRDL/NEML
1 st generation	Iressa	Gefitinib	AstraZeneca	1L/2L/3L	Dec 2004	List B/NEML
	Tarceva	Erlotinib	Roche	1L/2L/3L/Adj	Apr 2006	List B
	Conmana®/ 凯美纳®	Icotinib	Betta Pharmaceuticals	1L/2L/Adj	Jun 2011	List B/NEML
2 nd generation	Giotrif	Afatinib	Boehringer Ingelheim	1L/2L	Feb 2017	List B
	Vizimpro	Dacomitinib	Pfizer	1L	May 2019	List B
3 rd generation	Tagrisso	Osimertinib	AstraZeneca	1L/2L/Adj	Mar 2017	List B/NEML
	Ameile	Aumolertinib	Jiangsu Hansoh Pharmaceutical	1L/2L/Adj	Mar 2020	List B
	Aifusha	Furmonertinib	Allist	1L/2L	Mar 2021	List B
	Surmana® 赛美纳®	Befotertinib	Betta Pharmaceuticals	1L/2L	May 2023	List B
	Zegfrovy	Sunvozertinib	Dizal Pharmaceutical Co., Ltd	2L	Aug 2023	List B
	Sanrisso	Rilertinib	Nanjing Shenghe Pharm	1L/2L	Jun 2024	List B
	Ruibida	Rezivertinib	Beta Pharm	1L/2L	May 2024	List B
	Zorifer	Zorifertinib	AstraZeneca/Chentai Pharm	1L	Nov 2024	List B
	Aoyixin	Limertinib	Innovent/ASK Pharm	1L/2L	Jan 2025	List B
	Lazcluze	Lazertinib	Johnson & Johnson	1L	Jul 2025	Not included
	/	Mefatinib	East China Pharmaceutical/Suzhou Maitai Bio-Technology	1L	Oct 2025	Not included
	/	Andamertinib	Beijing avistone	2L	Apr 2026	Not included

Note: NEML: National Essential Medicines List

Sources: Literature Review, Frost & Sullivan Analysis

INDUSTRY OVERVIEW

The following diagram summarized the competitive landscape of EGFR TKIs pipelines at Phase II clinical stage or later in China as of the Latest Practicable Date.

Drug Name/Code	Company	Clinical Phase	Treatment Line	Date ⁽¹⁾
Zipalertinib	Otsuka Pharma	NDA	2L	Nov 2025
Adonertinib	Jiangsu Chia Tai Fenghai/Shanghai Henlius	NDA	1L	Feb 2026
TY-9591	TYK Medicines	NDA	1L	Feb 2026
Gefitinib	AstraZeneca	III	Adj	Jul 2011
Olafertinib	Neu Pharma	III	1L	Oct 2020
Alflutinib	Allist Pharmaceuticals	III	Adj	Mar 2021
Lazertinib	Johnson & Johnson	III	2L/3L	Aug 2021
Rilertinib	Nanjing Shenghe Pharm	III	Adj	Dec 2022
Befotertinib	Betta Pharmaceuticals	III	Adj	Feb 2023
YK-029A	Yuekang BioPharma	III	1L	Mar 2023
Sutetinib	Suzhou Taolve	III	1L	Jul 2025
HS-10504	Hansoh	III	2L/3L	Aug 2026
BEET-109	BeBetter Med	II	2L	Dec 2021
WSD0922	Wayshine Biopharm	II	2L	Mar 2025
AP-L1898	Wigen	II	2L/3L	Apr 2026

Note:

- (1) For drugs in the clinical trial phase, date refers to the date of first public announcement. For drugs in the NDA phase, date refers to the CDE acceptance date.

Sources: CDE, Frost & Sullivan Analysis

The future development trends of EGFR+ NSCLC treatment primarily include the following:

- **Sequential Treatment.** In China, first-generation TKIs maintain substantial cost-effectiveness advantages while continuing to deliver meaningful clinical benefit. Some clinical studies further indicate that sequential treatment strategies, in which patients start with first-generation EGFR TKIs and later transition to third-generation agents once resistance develops, may potentially achieve greater overall survival than single-agent approaches. This makes sequential therapy a compelling option that balances affordability with clinical outcomes.
- **Adoption in the Adjuvant Setting.** The clinical use of EGFR TKIs is extending from advanced NSCLC to earlier disease stages. Given the strong clinical evidence and rapidly growing demand for effective postoperative management, EGFR TKIs are expected to see broad adoption in the adjuvant setting, becoming a key growth driver of the overall market.
- **Accelerated Adoption of Combination Strategies.** Combination regimens involving EGFR TKIs with anti-angiogenic agents, chemotherapy or immunotherapy are advancing rapidly and in some cases are becoming standard practice. Both clinical and real-world data show that such strategies improve PFS and enhance management of resistance. These developments are expected to strengthen the role of EGFR TKIs in multi-line treatment strategies and expand their overall clinical value.

The EGFR+ NSCLC drug market is supported by sustained patient growth driven by high mutation prevalence, wider gene testing and improving treatment accessibility, while clinical practice continues to evolve toward earlier diagnosis and optimized full-cycle management. As the market becomes more mature, pricing pressure from reimbursement negotiations, the entry of generics and increasing competition among similar agents are expected to temper growth. The landscape is also influenced by patent expiries and the emergence of newer modalities that may gradually draw a small portion of later-line demand. Despite these dynamics, the market maintains notable entry barriers, as participants must meet stringent clinical and regulatory requirements, demonstrate clear therapeutic differentiation and build sufficient physician confidence to compete effectively.

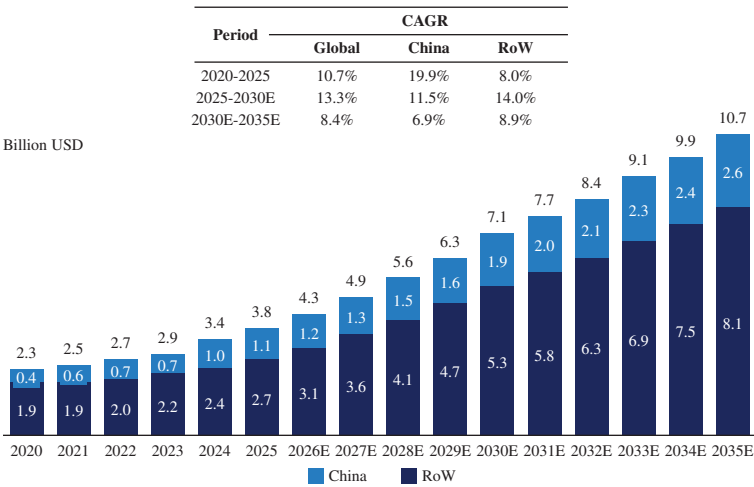
INDUSTRY OVERVIEW

Overview of ALK TKI Market

ALK+ lung cancer refers to lung cancer that shows evidence of an ALK mutation. The treatment period of ALK+ lung cancer patients is almost two times of that for EGFR+ lung cancer patients. For late stage ALK+ NSCLC patients, ALK tyrosine kinase inhibitor (ALK TKI) is typically recommended as the first-line treatment option. If ALK+ tumors keep progressing after initial treatment of chemotherapy, ALK TKI is also recommended as second-line and later-lines treatment option until the patients develop resistance to all suitable targeted therapy options of ALK TKIs and switch to other alternative treatments.

The estimated CAGRs for the global ALK TKI drug market from 2025 to 2030 and from 2030 to 2035 are underpinned by the continued adoption of second- and third-generation ALK TKIs with improved CNS penetration and resistance profiles, as well as broader molecular testing coverage that supports earlier and wider detection of ALK-positive NSCLC. Earlier high growth for the China ALK TKI drug market was driven by the rapid uptake of second- and third-generation ALK TKIs and improvements in molecular testing coverage. Looking ahead, the market is expected to remain supported by wider use of ALK TKIs in first-line and combination settings, as well as the growing evidence supporting their use as adjuvant therapy in patients with early-stage disease, although overall growth will be tempered by NRDL price reductions, the entry of domestic generics and the gradual saturation of later-generation products. The following charts show the historical and forecasted market size and growth rate of ALK TKI drug in the global and China’s market from 2020 to 2035.

Global ALK TKI Drug Market, 2020-2035E



Source: Annual Reports, Expert Interviews, Frost & Sullivan Analysis

INDUSTRY OVERVIEW

Currently, there are six marketed ALK TKIs approved by the FDA, five approved by the EMA and ten approved by the NMPA. Ensartinib stands out as the first and only domestically developed ALK TKI to enter the global market. The following diagram summarized the competitive landscape of marketed ALK TKI in China as of the Latest Practicable Date.

	Brand Name	Generic Name	Originator	Treatment Line	NMPA Approval	NRDL Status
1st generation	Xalkori	Crizotinib	Pfizer	1L/2L	Jan 2013	List B
2nd generation	Zykadia	Ceritinib	Novartis	1L/2L	May 2018	List B
	Alecensa	Alectinib	Roche	1L/2L/Adj	Aug 2018	List B
	Ensacove®/ 贝美纳®	Ensartinib	Betta Pharmaceuticals	1L/2L	Nov 2020	List B
	Alunbrig	Brigatinib	Takeda	1L/2L	Mar 2022	List B
	Qilikin	Iruplinalkib	Qilu Pharmaceutical	1L/2L	Jun 2023	List B
	Anluqing	Envonalkib	Chia Tai Tianqing	1L	Jun 2024	List B
	Xuanfeining	Dirozalkib	Xuanzhu Biotechnology/Simcere Pharmaceutical	1L	Aug 2025	Not Include
	/	Conteltinib	Shouyao Holdings	1L/2L	Jun 2026	Not Include
3rd generation	Lorbrena	Lorlatinib	Pfizer	1L/2L	Apr 2022	List B

Sources: NMPA, Frost & Sullivan Analysis

The following diagram summarized the competitive landscape of marketed ALK TKI in the U.S. as of the Latest Practicable Date.

	Brand Name	Generic Name	Originator	Treatment Line	FDA Approval
1st generation	Xalkori	Crizotinib	Pfizer	1L/2L	Aug 2011
2nd generation	Zykadia	Ceritinib	Novartis	1L/2L	Apr 2014
	Alecensa	Alectinib	Roche	1L/2L/Adj	Dec 2015
	Alunbrig	Brigatinib	Takeda	1L/2L	Apr 2017
	Ensacove®/ 贝美纳®	Ensartinib	Xcovery Holdings/ Betta Pharmaceuticals	1L	Dec 2024
	Lorbrena	Lorlatinib	Pfizer	1L/2L	Nov 2018

Note:

- (1) Alectinib was initially granted accelerated approval in December 2015. Brigatinib was initially granted accelerated approval in April 2017.

Sources: FDA, Frost & Sullivan Analysis

The following diagram summarized the competitive landscape of marketed ALK TKI in the EU as of the Latest Practicable Date.

	Brand Name	Generic Name	Originator	Treatment Line	EMA Approval
1st generation	Xalkori	Crizotinib	Pfizer	1L/2L	Oct 2012
2nd generation	Zykadia	Ceritinib	Novartis	1L/2L	May 2015
	Alecensa	Alectinib	Roche	1L/2L/Adj	Feb 2017
	Alunbrig	Brigatinib	Takeda	1L/2L	Nov 2018
3rd generation	Lorbrena	Lorlatinib	Pfizer	1L/2L	May 2019

Sources: EMA, Frost & Sullivan Analysis

INDUSTRY OVERVIEW

The following diagram summarized the competitive landscape of ALK TKI pipelines in clinical stage in the global market as of the Latest Practicable Date.

Competitive Landscape of ALK-TKI Pipeline for NSCLC in China				
Drug Name/Code	Company	Clinical Stage	Indications	First Posted
Ensartinib	Betta Pharmaceuticals	NDA	Adj	Nov 2025
Deulorlatinib	Shenzhen TargetRx Biopharmaceutical	III	1L/2L	Oct 2023
Ficonalkib	Shouyao Holdings	III	1L	Jan 2024
XZP-3621	Xuanzhu Biopharmaceutical	II	1L/2L	Jul 2022
Iruplinalkib	Qilu Pharmaceutical	II	Adj	Mar 2023
CGT-9475	CGeneTech	I/II	2L	Mar 2025
SY-12321	Shouyao Holdings	I/II	1L/2L/3L	Jul 2026
APG-2449	Ascentage Pharma Group International	I	1L/2L	Apr 2019

Competitive Landscape of ALK-TKI Pipeline for NSCLC in US				
Neladalkib	Nuvalent	NDA	2L/3L	Apr 2026

Competitive Landscape of ALK-TKI Pipeline for NSCLC in EU				
Ensartinib	Xcovery/Betta Pharmaceuticals	NDA	1L	Feb 2025
Neladalkib	Nuvalent	III	1L	Jan 2025

Sources: CDE, Frost & Sullivan Analysis

The future development trends of ALK+ NSCLC treatment primarily include the following:

- **Increasing ALK+ NSCLC Incidence.** The incidence of ALK+ NSCLC grows continually, due to population aging and air pollution. Subject to CSCO guideline of NSCLC, patients with ALK+ NSCLC take the proportion of 7.2% among all NSCLC patients. The amount of ALK+ NSCLC patients will keep increasing, thereby driving the sustainable increase of the ALK TKI market.
- **Demand for Next-Generation ALK TKI.** Drug resistance occurs commonly in most ALK+ NSCLC cases, which leads to inevitable tumor progression accompanied by cerebral metastasis. Sequential treatment is accepted by most HCPs as the preferred follow-up treatment for drug-resistant ALK+. Patient desire innovative ALK TKI to extend their lives.
- **Molecular Testing.** With the development of gene sequencing and biomarkers, the detection of ALK rearrangement is becoming one of routine diagnosis items for NSCLC. Along with the approval of NGS based molecular testing kits covering ALK test, precision diagnosis will be widely applied in diagnosis of ALK+ NSCLC.
- **Combination Immunotherapy.** Immune checkpoint inhibitors have transformed cancer treatment, but immune monotherapy has shown limited efficacy in ALK+ NSCLC. Combining immunotherapy with ALK TKIs offers promising potential, as TKIs can enhance cytotoxic T lymphocyte activity and reduce T-cell apoptosis. Such combinations may help overcome resistance to initial therapy and extend PFS in ALK+ NSCLC patients.
- **Guideline-Endorsed Role of Second-Generation ALK Inhibitors.** Leading oncology guidelines recommend second-generation ALK TKIs as the preferred first-line treatments for advanced ALK+ NSCLC, owing to their superior central nervous system efficacy and overall survival benefits compared with first-generation agents.

INDUSTRY OVERVIEW

The ALK TKI drug market is supported by rising molecular testing coverage and increasing availability of next-generation inhibitors, which continue to drive patient uptake and reinforce their role as guideline-recommended first-line therapies. As diagnosis improves and the ALK+ NSCLC population gradually grows, treatment strategies are shifting toward more structured long-term management, including sequential use of later-generation agents and early exploration of combination approaches for resistant disease. Nevertheless, pricing pressure from NRDL negotiations, the entry of domestic generics and the challenge of resistance are expected to moderate future revenue growth. Emerging oncology modalities may introduce incremental competition, although validated alternatives to ALK-targeted therapies remain limited. High R&D requirements, the clinical complexity of overcoming resistance mutations and strong physician confidence in established products continue to create meaningful barriers to entry.

Overview of Drug Market for Pan-Tumor Indications

The incidence of solid tumors worldwide increased from approximately 18.0 million cases in 2020 to approximately 20.5 million cases in 2025, and is expected to further increase to approximately 25.3 million cases by 2035. The incidence of solid tumors in China increased from approximately 4.4 million cases in 2020 to approximately 4.9 million cases in 2025, and is expected to further increase to approximately 6.0 million cases by 2035.

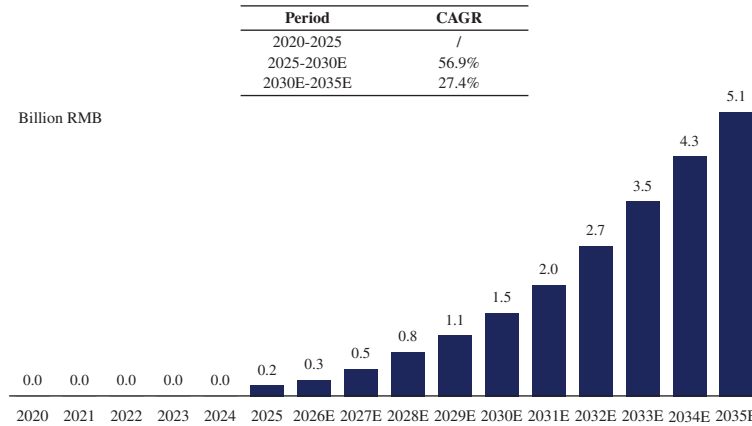
Overview of Market of EGFR/c-MET Bispecific Antibodies

EGFR is a transmembrane receptor tyrosine kinase that plays a crucial role in regulating cell proliferation, survival, and differentiation, and its over-expression or constitutive activation due to mutations can lead to uncontrolled tumor growth and metastasis. Mesenchymal-epithelial transition factor (c-MET) is another receptor tyrosine kinase that, when aberrantly activated, including MET exon14 skipping alteration, MET gene amplification and MET protein over-expression, can promote tumor progression, invasion, and resistance to targeted therapies, making it an attractive therapeutic target in various cancer types.

The synergistic relationship between EGFR and c-MET in cancer pathogenesis is characterized by cross-talk, co-activation, and reciprocal regulation, leading to enhanced tumor growth, survival, and resistance to targeted therapies. In particular, EGFR TKI resistance is closely attributed to c-MET aberrant activation. The collaborative effects of these receptor tyrosine kinases extend beyond the tumor cells themselves, influencing the tumor microenvironment by promoting angiogenesis, epithelial-mesenchymal transition, and immune evasion. Given their synergistic relationship, dual inhibition of EGFR and c-MET has emerged as a promising therapeutic strategy to overcome resistance and improve patient outcomes in various cancers driven by these aberrant signaling pathways.

The following charts show the historical and forecasted market size and growth rate of China’s EGFR/c-MET bispecific antibody drug market from 2020 to 2035.

China EGFR/C-Met Bispecific Antibody Market, 2020-2035E



Source: Expert Interviews, Frost & Sullivan Analysis

INDUSTRY OVERVIEW

As of the Latest Practicable Date, only one EGFR/c-MET bispecific antibody had been approved in China and seven were in clinical development. The following diagram summarized the competitive landscape of approved drugs and pipelines in clinical stage in China’s EGFR/c-MET bispecific antibody drug market as of the Latest Practicable Date.

Drug Name/Code	Company	Clinical Stage ¹	Indications	Date ²
Amivantamab	Johnson & Johnson/Gemab	Approved	NSCLC	Feb 2025
HS-20117	Changzhou Hengbang Pharmaceutical	III	NSCLC	May 2024
MCLA-129	Betta Pharmaceuticals	II	NSCLC	Mar 2025
EMB-01	Epimab Biotherapeutics	I/II	Advanced/Metastatic Solid Tumors	Dec 2018
SHR-9839	Jiangsu Hengrui Pharmaceuticals	I/II	Advanced Solid Tumors	Jun 2024
TQB2922	Chiatai Tianqing Pharmaceutical Group	I/II	Colorectal Cancer	Jun 2025
HS-20117-2	Shanghai Hansoh	I/II	Advanced/Metastatic Solid Tumors	Aug 2025
JH021	Biotech Pharmaceutical	I	NSCLC	May 2026

Notes:

- (1) Clinical stage shown refers to the most advanced indication currently under clinical development.
- (2) Date refers to the date of first public announcement.

Sources: CDE, Frost & Sullivan Analysis

A major trend in EGFR/c-MET bispecific antibody development is the exploration of combination therapies. Bispecific antibodies inherently integrate the mechanisms of two distinct therapeutic targets, creating a natural advantage for combination strategies. Current clinical studies mainly focus on the combined use of EGFR/c-MET bispecific antibodies with EGFR TKIs and other targeted therapies. These approaches aim to overcome acquired resistance, enhance clinical efficacy and extend treatment durability, thereby positioning EGFR/c-MET bispecific antibodies as an important next-generation option in precision oncology.

Overview of Market of RAS-Targeted Drugs

RAS proteins regulate multiple signaling pathways and play a critical role in cellular processes such as proliferation and division. The RAS family consists of three isoforms encoded by distinct genes: KRAS, HRAS, and NRAS. RAS mutations are among the most common oncogenic drivers in human cancers, with approximately 19% of patients harboring a RAS mutation. KRAS is by far the most frequently altered isoform, accounting for about 75% of all RAS mutations. In pancreatic ductal adenocarcinoma (PDAC), the prevalence of KRAS mutations is particularly high, reaching up to 85%.

INDUSTRY OVERVIEW

The evolving landscape of RAS-targeted therapy, two novel strategies are gaining increasing attention:

- *KRAS-directed PROTACs.* By degrading KRAS proteins rather than simply inhibiting them, PROTACs can eliminate multiple mutant variants, including those resistant to conventional inhibitors. Their catalytic clearance mechanism allows for sustained suppression without requiring continuous occupancy of the binding site, offering the potential for more durable therapeutic benefit. The trend is to extend beyond single mutations toward multi-KRAS mutant coverage, broadening applicability across diverse patient subgroups.
- *Pan-RAS inhibitors.* Unlike mutation-specific drugs, pan-RAS inhibitors simultaneously target KRAS, NRAS, and HRAS isoforms, preventing compensatory activation of wild-type RAS proteins. This pan-isoform approach is expected to deliver broader clinical utility and reduce the likelihood of acquired resistance. The trend is toward positioning pan-RAS as a “next frontier,” with preclinical data showing strong activity across tumor types such as pancreatic cancer, NSCLC, and colorectal cancer.

As of the Latest Practicable Date, four small-molecule drugs targeting RAS had been approved in China, and 49 drug candidates were in clinical development.

Overview of Bevacizumab Market

Vascular endothelial growth factor (VEGF) is a signal protein produced by cells that stimulates the formation of blood vessels and other important physiologic process. A potential anticancer therapy can be developed by using anti-VEGF agent with several medicinal effects. Bevacizumab is designed to directly bind to VEGF extracellularly to prevent interaction with VEGF receptors (VEGFRs) on the surface of endothelial cells, and thereby inhibiting VEGF’s angiogenic activity. By suppressing tumor angiogenesis, bevacizumab has established its clinical role in the treatment of multiple solid tumors, including colorectal cancer, NSCLC, renal cell carcinoma and ovarian cancer, and has become one of the representative drugs of anti-angiogenic therapy. There is abundant clinical evidence indicating the superior efficacy of bevacizumab when used in combination with other therapies. By exerting both anti-vascular and anti-angiogenesis effect on vessel surrounding the tumor, bevacizumab can result in both reduction of tumor size and inhibition of tumor growth.

As of the Latest Practicable Date, a total of 13 bevacizumab products have been approved in China. Certain biosimilars have obtained broader approvals covering glioblastoma, cervical cancer and hepatocellular carcinoma. This variation in approved indications has created a differentiated competitive landscape. The following diagram summarized the competitive landscape of marketed drugs in China’s bevacizumab market as of the Latest Practicable Date.

INDUSTRY OVERVIEW

Competitive Landscape of Marketed Bevacizumab in China

Brand Name	Generic Name	Company	Original Drug/ Biosimilar	NMPA Approval	Indications	NRDL/NEML
Avastin	Bevacizumab	Roche	Original Drug	Feb 2010	Glioblastoma Hepatocellular carcinoma Non-squamous NSCLC Colorectal cancer Cervical cancer Epithelial ovarian carcinoma	List B/NEML
Ankeda	Bevacizumab -QL1101	Qilu Pharmaceutical	Biosimilar	Dec 2019	Colorectal cancer Non-squamous NSCLC	List B
Byvasda	Bevacizumab -IBI305	Innovent	Biosimilar	Jun 2020	NSCLC Non-squamous NSCLC Hepatocellular carcinoma Colorectal Cancer Glioblastoma Cervical cancer Epithelial ovarian carcinoma	List B
Boyounuo	Bevacizumab -LY01008	Shandong BoAn Biotechnology	Biosimilar	Apr 2021	Colorectal cancer Non-squamous NSCLC Epithelial ovarian carcinoma	List B
Airuituo	Bevacizumab -BP102	Hengrui Pharma	Biosimilar	Jun 2021	Non-squamous NSCLC Colorectal cancer Glioblastoma	List B
Pobevcy	bevacizumab -tnjn	Bio-Thera Solutions	Biosimilar	Nov 2021	NSCLC Colorectal cancer Glioblastoma Cervical cancer Epithelial ovarian carcinoma	List B
贝安汀®	Bevacizumab-MIL60	Betta Pharmaceuticals	Biosimilar	Nov 2021	Cervical cancer Glioblastoma Ovarian epithelial cancer Colorectal cancer Non-squamous NSCLC	List B
Pusintin	Bevacizumab -TAB008	TOT Biopharm (Suzhou)	Biosimilar	Nov 2021	Non-squamous NSCLC Colorectal cancer Glioblastoma Cervical cancer Hepatocellular carcinoma Epithelial ovarian carcinoma	List B
HLX04	Bevacizumab -HLX04	Shanghai Henlius Biopharmaceutical	Biosimilar	Nov 2021	Colorectal cancer Non-squamous NSCLC Glioblastoma Hepatocellular carcinoma Cervical cancer Epithelial ovarian carcinoma	List B
Anbeisi	Bevacizumab -TQB2302	Nanjing Shunxin Pharmaceutical of Chiatai Tianqing	Biosimilar	Feb 2023	Glioblastoma Colorectal cancer Cervical cancer NSCLC Epithelial ovarian carcinoma Hepatocellular carcinoma	List B
Anbeizhu	Bevacizumab -SCT510	SinoCelltech	Biosimilar	Jun 2023	NSCLC Hepatocellular carcinoma Glioblastoma Colorectal cancer Cervical cancer Epithelial ovarian carcinoma	List B
Anbeiyou	Bevacizumab -WBP264	Hualan Genetic Engineering	Biosimilar	Nov 2024	Non-squamous NSCLC Colorectal cancer Glioblastoma Cervical cancer Hepatocellular carcinoma Epithelial ovarian carcinoma	List B
Shengweining	Bevacizumab -SIBP 04	Shanghai Institute Of Biological Products	Biosimilar	Jan 2025	Non-squamous NSCLC Colorectal cancer Glioblastoma Cervical cancer Hepatocellular carcinoma Epithelial ovarian carcinoma	List B

Sources: NMPA, Frost & Sullivan Analysis

Overview of Breast Cancer Drug Market

Breast Cancer is the most commonly diagnosed malignant tumor in women worldwide and one of the leading causes of death from malignant tumors. Clinically, breast cancer is classified into distinct molecular subtypes based on the expression of hormone receptors (HRs) and human epidermal growth factor receptor 2 (HER2). This molecular stratification provides a clear framework for individualized treatment selection.

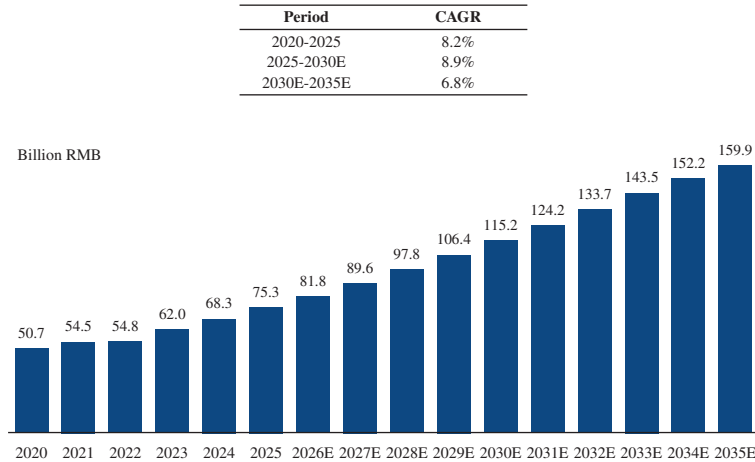
INDUSTRY OVERVIEW

The incidence of breast cancer increases year by year. The number of breast cancer patients in China increased from 339.3 thousand in 2020 to 379.1 thousand in 2025, and is expected to increase to 407.7 thousand by 2035.

According to the 2025 CACA guidelines, early-stage HER2+ breast cancer is mainly treated with surgery, followed by adjuvant therapy, while Stage III patients generally require neoadjuvant therapy before surgery. In Stage IV disease, systemic and targeted therapies are the mainstay. In advanced settings, treatment follows a stepwise approach. First-line therapy is centered on trastuzumab plus pertuzumab combined with chemotherapy, which has become the global and domestic standard of care due to its proven survival benefits. After disease progression, patients may receive T-DXd as the preferred second-line treatment, followed by regimens such as pyrotinib, T-DM1 or other HER2-targeted combinations, providing multiple treatment options across later lines. This pathway demonstrates the pivotal role of trastuzumab and pertuzumab dual blockade in shaping the standard treatment paradigm for HER2+ breast cancer in China.

The total breast cancer drug market of China is forecasted to reach RMB159.9 billion by 2035. The estimated CAGRs from 2025 to 2030 and from 2030 to 2035 are supported by rising disease incidence, increased screening and early detection, and the broader adoption of innovative therapies including CDK4/6 inhibitors, ADCs and bispecific antibodies. Growth is further underpinned by NRDL inclusion and expanding treatment access in lower-tier cities. The following chart shows the historical and forecasted market size and growth rate of breast cancer drug in China’s market from 2020 to 2035.

China Breast Cancer Drug Market, 2020-2035E



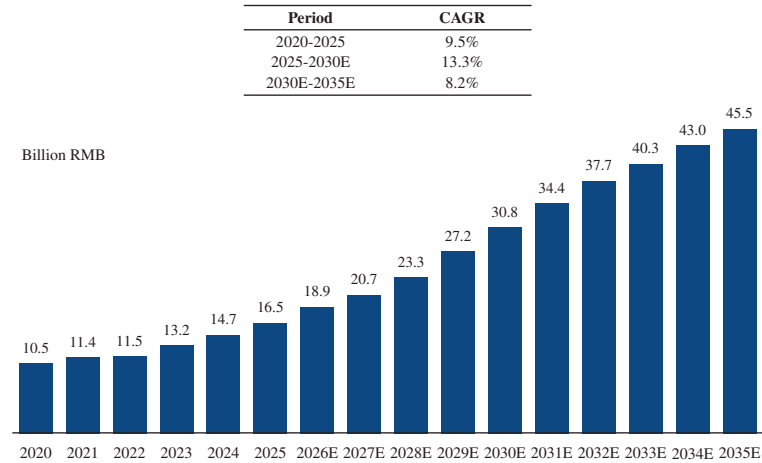
Source: Annual Reports, Expert Interviews, Frost & Sullivan Analysis

Overview of Market of HER2 Monoclonal Antibodies

The total HER2+ breast cancer drug market in China is forecasted to reach RMB45.5 billion by 2035. The projected market growth is supported by the mature use of HER2-targeted therapies such as trastuzumab, pertuzumab and ADCs, as well as the entry of domestic biosimilars that improve accessibility. Growth will remain moderate given the high level of market penetration, though combination regimens and continued ADC innovation are expected to sustain long-term expansion. The following chart shows the historical and forecasted market size and growth rate of HER2+ breast cancer drug in China’s market from 2020 to 2035.

INDUSTRY OVERVIEW

China HER2+ Breast Cancer Drug Market, 2020-2035E



Source: Annual Reports, Expert Interviews, Frost & Sullivan Analysis

As of the Latest Practicable Date, a total of five pertuzumab drugs have been approved for the treatment of HER2+ breast cancer in China. The following diagram summarized the competitive landscape of marketed pertuzumab drugs in China’s market as of the Latest Practicable Date.

Drug Name	Code	Company	Patent Drug/Biosimilar	Phase	Date ⁽¹⁾
Perjeta	Pertuzumab	Roche	Patent Drug	Approved	Dec 2018
帕乐坦®	Pertuzumab-TQB2440	Chia Tai-tianqing Pharmaceutical	Biosimilar	Approved	Dec 2024
安赛珠®	Pertuzumab-QL1209	Qilu Pharmaceuticals	Biosimilar	Approved	Dec 2024
贝泽汀®	Pertuzumab-HS627	BioRay Pharmaceuticals/ Betta Pharmaceuticals	Biosimilar	Approved	Feb 2026
汉倍优®	Pertuzumab-HLX11	Fosun	Biosimilar	Approved	May 2026

Note:

(1) Date refers to the date of first public announcement.

Sources: CDE, Frost & Sullivan Analysis

INDUSTRY OVERVIEW

As of the Latest Practicable Date, a total of six trastuzumab drugs have been approved for the treatment of HER2+ breast cancer in China. The following diagram summarized the competitive landscape of marketed trastuzumab drugs in China’s market as of the Latest Practicable Date.

Drug Name	Code	Company	Patent Drug/Biosimilar	Phase	Date ⁽¹⁾
赫赛汀®	Trastuzumab*	Roche	Patent Drug	Approved	Sep 2002
安曲妥®	Trastuzumab-QL 1701	Alteogen/Qilu Pharmaceuticals	Biosimilar	Approved	Jun 2024
安赛汀®	Trastuzumab (ANKEBIO)	Anhui Anke Biotechnology (Group) Co., Ltd	Biosimilar	Approved	Oct 2023
赛妥®	Trastuzumab-TQB211	Chia Tai-tianqing Pharmaceutical	Biosimilar	Approved	Jul 2023
安瑞泽®	Trastuzumab-HS022	BioRay Pharmaceuticals/ Betta Pharmaceuticals Co. Ltd	Biosimilar	Approved	Feb 2023
汉曲优®	Trastuzumab-HLX02	Shanghai Henlius Biotech, Inc.	Biosimilar	Approved	Aug 2020
/	Trastuzumab-SIBP 01	China National Medicines Corporation Ltd.	Biosimilar	NDA	Nov 2025
/	Trastuzumab-HL02	Hualan Genetic Engineering Co., Ltd	Biosimilar	III	Apr 2019

Note: Trastuzumab* is included in the NEML List.

(1) Date refers to the date of first public announcement.

Sources: CDE, Frost & Sullivan Analysis

The HER2+ breast cancer drug market in China continues to expand, supported by rising breast cancer incidence, higher HER2 testing penetration and broader access to targeted therapies driven by NRDL inclusion. Market growth is further reinforced by the widespread use of trastuzumab and pertuzumab, together with the uptake of biosimilars that improve affordability and regional accessibility, while next-generation therapies such as HER2-targeted ADCs are being gradually introduced into clinical practice. At the same time, increasing biosimilar competition and reimbursement-driven price pressure are expected to weigh on margins, placing greater emphasis on manufacturing quality, clinical comparability and real-world data to support product differentiation. Over the longer term, emerging modalities including ADCs, bispecific antibodies and combination regimens may expand treatment options for advanced or resistant patients and modestly shift market share. Despite these dynamics, high development and manufacturing requirements for biologics, strict clinical comparability standards and strong physician loyalty to established brands continue to create meaningful barriers to entry.

Overview of Market of CDK4/6 Inhibitors

Cyclin-dependent kinases (CDKs) are a family of enzymes that play a crucial role in regulating the cell cycle, the process by which cells divide and replicate. CDKs are activated by binding to regulatory proteins called cyclins, forming cyclin-CDK complexes. Two specific members of the CDK family, CDK4 and CDK6, are essential for the G1 phase of the cell cycle. In this phase, cells prepare for DNA synthesis and eventual division. When binding to cyclin D proteins, these kinases (cyclin D-CDK4/6 complexes) can inactivate tumor suppressor proteins, ultimately promoting cell cycle progression. However, in many cancers, including breast cancer, the CDK4/6 pathway becomes dysregulated, leading to uncontrolled cell proliferation and tumor growth. This has made CDK4 and CDK6 attractive targets for cancer therapies. Targeting this dysregulated pathway, CDK4/6 inhibitors are a class of drugs designed to selectively inhibit the activity of CDK4 and CDK6 enzymes. By blocking these kinases, CDK4/6 inhibitors can induce cell cycle arrest in the G1 phase, preventing cancer cells from dividing and proliferating. This mechanism of action is particularly effective in cancers driven by CDK4/6 pathway dysregulation, such as HR+/HER2- breast cancer.

INDUSTRY OVERVIEW

As of the Latest Practicable Date, a total of seven CDK4/6 inhibitors have been approved and seven were in clinical development for the treatment of HR+/HER2- breast cancer in China. The following diagram summarized the competitive landscape of marketed CDK4/6 inhibitors in China’s market as of the Latest Practicable Date.

Brand Name	Generic Name	Originator	Treatment Line	Approval Time
Ibrance	Palbociclib	Pfizer/Amgen/Seagen	1L	Jul 2018
Verzenio	Abemaciclib	Eli Lilly	1L/2L/Adj	Dec 2020
Airuikang	Dalpiciclib	Jiangsu Hengrui Medicine	1L/2L/Adj	Dec 2021
Kisqali	Ribociclib	Novartis/Otsuka Pharmaceutical	1L/Adj	Jun 2023
Rujianing	Lerociclib	Genor BioPharma	1L/2L	May 2025
Futuoning	Fovinaciclib	Fosun Pharmaceutical	1L/2L	May 2025
康美纳®	Tibremciclib	Betta Pharmaceuticals	2L	Jun 2025

Sources: Literature Review, Frost & Sullivan Analysis

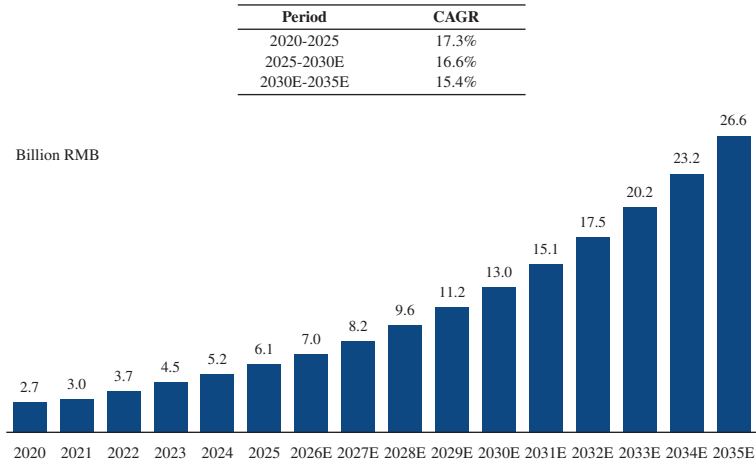
Overview of Kidney Cancer Drug Market

Kidney cancer occurs when healthy cells in one or both kidneys grow out of control and form a tumor. RCC is the most common type of kidney cancer, accounting for approximately 90% of cases. RCC represents the dominant subtype and the principal focus of clinical management and therapeutic development, making it the primary target of innovation in kidney cancer treatment.

The number of kidney cancer patients in China increased from 71.0 thousand in 2020 to 78.0 thousand in 2025, and is expected to increase to 92.7 thousand by 2035. In China, the treatment of RCC is centered on surgery for localized disease and systemic therapy for advanced cases. With the development of innovative therapies, targeted therapy and immunotherapy have become the core treatment strategies, either as monotherapy or in combination, and are now widely adopted in clinical practice.

The growth of the kidney cancer drug market in China is driven by rising renal cell carcinoma incidence, broader adoption of VEGFR TKI and IO TKI combination therapies, and expanding NRDL coverage that improves treatment accessibility. The chart below illustrates the market size and growth rate of the historical and forecasted China’s kidney cancer drug market from 2020 to 2035.

China Kidney Cancer Drug Market, 2020-2035E



Source: Annual Reports, Expert Interviews, Frost & Sullivan Analysis

INDUSTRY OVERVIEW

VEGF signaling pathway is a complex process in which VEGF stimulates the formation of new blood vessels that supply oxygen and nutrients to support tumor growth and metastasis. The pathway is activated through binding of VEGF with VEGFR. VEGFR inhibitors block this pathway by preventing receptor activation, thereby suppressing the formation of tumor-associated vasculature. Through the inhibition of neovascularization, VEGFR inhibitors effectively deprive tumors of their nutrient and oxygen supply, leading to growth arrest and delayed disease progression. Clinically, VEGFR inhibitors have been widely applied in the treatment of multiple solid tumors, including RCC, hepatocellular carcinoma and thyroid cancer. In particular, RCC treatment has long relied on VEGFR-targeted agents as a standard therapeutic backbone, establishing VEGFR inhibition as one of the most validated and widely used anti-angiogenic strategies in oncology.

As of the Latest Practicable Date, a total of seven VEGFR inhibitors have been approved for the treatment of kidney cancer in China. The following diagram summarized the competitive landscape of marketed VEGFR inhibitors in China as of the Latest Practicable Date.

Generic Name	Representative Product			Earliest NMPA Approval Date	NRDL Inclusion
	Brand Name	Manufacturer	Treatment Line		
Fruquintinib	Elunate	Hutchmed	2L	May 2026	Yes
Anlotinib	Fokewei	Chia Tai-tianqing Pharmaceutical	1L	May 2025	Yes
Vorolanib	伏美纳®	Betta Pharmaceuticals	2L	Jun 2023	Yes
Pazopanib	Votrient	Novartis	1L/2L	Feb 2017	Yes
Axitinib	Inlyta	Pfizer	1L/2L	Apr 2015	Yes
Sunitinib	Sutent	Pfizer	1L/2L	Oct 2007	Yes
Sorafenib	Nexavar	Bayer AG/Amgen	2L	Aug 2006	Yes

Sources: CDE, Frost & Sullivan Analysis

The clinical application of VEGFR inhibitors is evolving beyond traditional monotherapy. Increasingly, VEGFR inhibitors are being developed and adopted in combination with immune checkpoint inhibitors, where synergistic effects can enhance anti-tumor efficacy and improve long-term outcomes. At the same time, their use is expanding from later-line therapy toward earlier treatment settings, reflecting both clinical evidence and guideline support.

China’s kidney cancer drug market continues to expand, supported by rising RCC incidence and the broad clinical use of VEGFR inhibitors as the backbone of targeted therapy, with NRDL inclusion and wider adoption in earlier-line and maintenance settings further enhancing patient access. Treatment practice is gradually shifting toward VEGFR inhibitor and PD-1 inhibitor combination regimens, which are increasingly used in advanced disease. At the same time, intensified competition among VEGFR inhibitors, reimbursement-driven price pressure, and ongoing challenges in resistance management and treatment sequencing are expected to moderate revenue growth. Over the longer term, immune checkpoint inhibitors and emerging targeted combinations may divert part of the advanced-line population. Despite these competitive dynamics, the market maintains meaningful entry barriers due to the need for robust long-term survival evidence, complex kinase selectivity optimization, high CMC reproducibility standards and strong physician familiarity with established products.

OVERVIEW OF HYPOALBUMINEMIA DRUG MARKET

Overview of Hypoalbuminemia

Hypoalbuminemia is a clinical condition characterized by plasma albumin levels falling below 30 g/L. As the most abundant plasma protein synthesized by the liver, albumin plays a vital role in maintaining oncotic pressure and transporting a variety of endogenous and exogenous substances.

INDUSTRY OVERVIEW

A decline in albumin concentration often reflects underlying systemic disorders and is commonly associated with conditions such as liver cirrhosis, nephrotic syndrome, severe infections, and cerebral edema. Clinically, human albumin is widely used to restore oncotic pressure and stabilize hemodynamics in a range of critical conditions, including cirrhosis with ascites, severe sepsis or septic shock, malignant ascites, and perioperative or postoperative hypotension.

Limitations of Traditional Human Serum Albumin Therapy

Traditional human serum albumin therapy faces multiple constraints that limit its long-term sustainability and scalability, including supply constraints, production and safety challenges, and technological limitations. In addition to supply constraints, human serum albumin production itself is highly complex, requiring multiple steps of extraction, purification, and viral inactivation. Pathogen risks cannot be fully eliminated, and stringent regulations have further limited expansion of capacity. Technological limitations also persist, as many domestic manufacturers still rely on cold ethanol fractionation with lower yields, longer cycles, and weaker safety profiles compared with chromatography. While chromatography has been widely adopted internationally, only a few Chinese firms employ it, resulting in reduced efficiency and narrower product portfolios.

Innovative Pathway and Technology Advantages of Recombinant Human Albumin Injection (Rice)

Recombinant human albumin injection (rice) is developed using a proprietary plant expression system. The human serum albumin gene is stably introduced into rice endosperm cells, enabling high-level synthesis and accumulation of the target protein in rice grains. The harvested rice undergoes milling, buffer extraction, and a series of purification processes including precipitation, filtration, removal of host proteins, and viral inactivation. This results in recombinant human serum albumin of high purity and quality, demonstrating structural and functional equivalence to plasma-derived human serum albumin while ensuring a controlled and scalable production process.

The rice expression system offers multiple advantages over traditional plasma fractionation. It is highly cost-efficient, with yields equivalent to the albumin content of plasma but at significantly lower production costs. The platform achieves high yield and scalability, producing 20–30 g/kg of brown rice and supporting large-scale, cGMP-compliant manufacturing. As a plant-derived product, recombinant human albumin injection (rice) eliminates risks of bloodborne pathogen transmission, strengthening both safety and regulatory acceptance. Moreover, standardized cultivation and purification enhance batch-to-batch consistency and reduce variability, ensuring a stable supply of recombinant human serum albumin with reliable quality.

Competitive Landscape of Recombinant Human Albumin in China

As of the Latest Practicable Date, only one recombinant human albumin has been approved for the treatment of hypoalbuminemia in China. The following diagram summarizes the competitive landscape of marketed and clinical-stage recombinant human albumin products in China as of the Latest Practicable Date.

Name	Company	Expression System	Indication	Phase	Date ⁽¹⁾
HY1001/ 奥福民®	Wuhan Healthgen Biotechnology Corp/ Betta Pharmaceuticals	Rice	Hypoalbuminemia	Approved	Jul 2025
Recombinant Human Albumin	Shanghai Anruite Biomedical Technology	Yeast	Hypoalbuminemia	NDA	Mar 2026
Recombinant human serum albumin	Beijing Protgen Biotechnology Development	Yeast	Hepatic ascites	NDA	Aug 2026
Recombinant human serum albumin	Shandong Kingtone Biotechnology	Bacterial	Hypoalbuminemia	I	Feb 2024

Note:

(1) Date refers to the date of first public announcement.

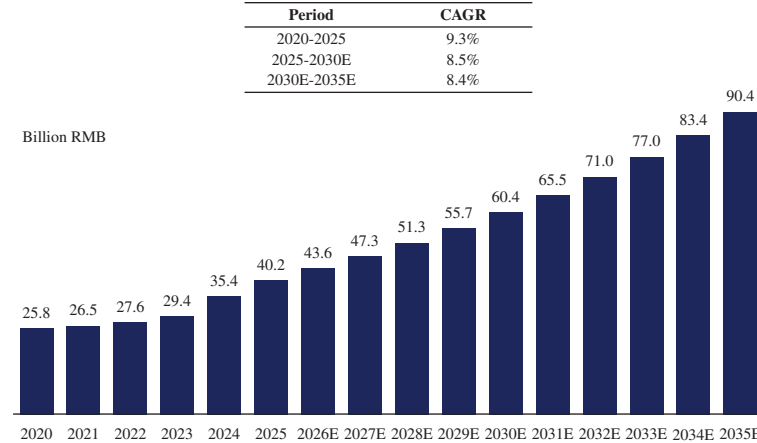
Sources: CDE, Frost & Sullivan Analysis

INDUSTRY OVERVIEW

Market Size of Albumin-Based Therapeutics Drug Market in China

The growth of the total hypoalbuminemia drug market in China reflects steady clinical demand for albumin and increasing contribution from recombinant human serum albumin, particularly rice-derived recombinant human serum albumin, which is gradually supplementing plasma-derived supply under national self-sufficiency initiatives. The chart below illustrates the market size and growth rate of the historical and forecasted China’s albumin-based therapeutics drug market from 2020 to 2035.

China Albumin-Based Therapeutics Drug Market, 2020-2035E



Source: Annual Reports, Expert Interviews, Frost & Sullivan Analysis

China’s albumin-based therapeutics drug market continues to be driven by strong and persistent clinical demand from liver cirrhosis, nephrotic syndrome and critical-care indications amid structurally limited plasma-derived supply and increasing policy support for recombinant alternatives. Adoption is gradually shifting toward recombinant human albumin products, which is expected to first supplement supply shortages and expand as clinical comparability, cost-effectiveness and hospital procurement access strengthen. Nonetheless, large-scale substitution remains at an early stage and is constrained by the need for further clinical validation, hospital acceptance, clear reimbursement pathways and the high cost and complexity of recombinant biologics manufacturing. The market may also be influenced by fluctuations in plasma collection capacity and competition from emerging recombinant platforms. Entry barriers remain substantial due to demanding process-development and GMP requirements, quality-consistency standards and the significant investment and regulatory engagement needed to secure hospital uptake.

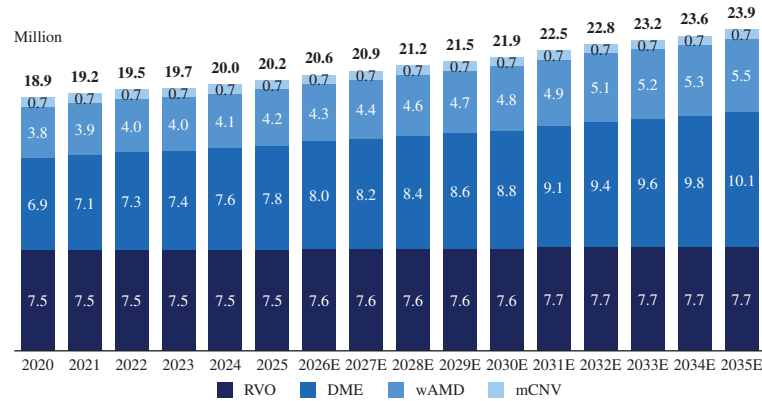
OVERVIEW OF OPHTHALMIC DRUG MARKET

Overview of Retinal Diseases

Retinal diseases are vision-threatening conditions caused by abnormal blood vessel growth, hemorrhage, and exudation in the retina. Major clinical indications include (i) wet age-related macular degeneration (wAMD): the leading cause of irreversible blindness in the elderly, characterized by abnormal choroidal neovascularization and leakage; (ii) Diabetic macular edema (DME): a complication of diabetic retinopathy, which arises from vascular leakage and swelling in the macula; (iii) retinal vein occlusion-associated macular edema (RVO-ME): vision loss caused by obstruction of central or branch retinal veins leading to ischemia and fluid accumulation; and (iv) Pathologic myopic choroidal neovascularization (mCNV): a complication of high myopia driven by structural stress and abnormal neovascularization in the choroid. The chart below shows the epidemiology analysis of major retinal diseases in China from 2020 to 2035.

INDUSTRY OVERVIEW

Epidemiology Analysis of Major Retinal Diseases in China, 2020-2035E



Sources: Literature Review, Frost & Sullivan Analysis

Treatment for wAMD and mCNV

According to current clinical guidelines in China, intravitreal anti-VEGF therapies are the standard first-line treatment for wAMD. Anti-VEGF agents are administered via intravitreal injection, and many patients require frequent injections, particularly in the initial treatment phase, to achieve optimal disease control and maintain vision. Combination regimens are also recommended for certain subtypes.

For mCNV, intravitreal anti-VEGF therapies are also considered the preferred treatment option. Clinical practice guidelines recommend anti-VEGF agents as the mainstay of therapy to effectively inhibit neovascularization, reduce fluid leakage, and preserve visual function.

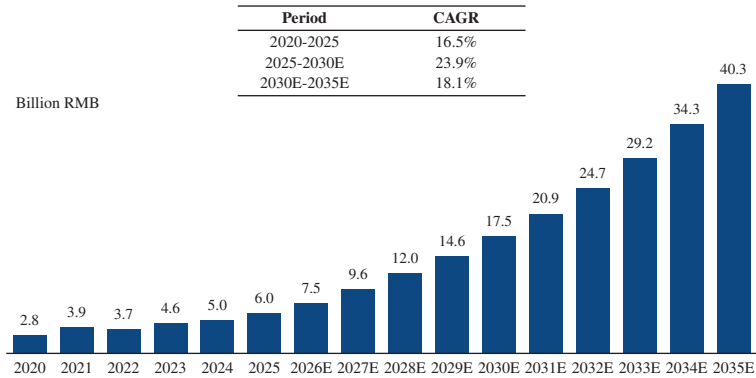
Overview of Anti-VEGF Biologic Market

Pathological retinal vascular diseases are primarily driven by excessive VEGF signaling. Elevated VEGF levels promote abnormal vessel growth beneath the retina and increase vascular permeability, resulting in hemorrhage, fluid accumulation, retinal scarring, and progressive vision loss. Intravitreal injection of anti-VEGF drugs effectively inhibits the formation of new blood vessels, reduces vascular leakage, and restores retinal stability, thereby helping to preserve central vision. The therapeutic effect typically lasts for several months, and anti-VEGF therapy remains the cornerstone of treatment for retinal vascular diseases.

With the launch of biosimilars in the future, the popularization of education on the use of monoclonal antibodies for fundus diseases by doctors, and the improvement of patients' medication compliance, the total market of anti-VEGF antibody drugs for fundus diseases in China is expected to grow. The growth is supported by rising prevalence of wAMD, DME and RVO and broader adoption of anti-VEGF therapies following NRDL inclusion. Growth is further driven by the launch of long-acting and dual-target agents and improved diagnosis and treatment uptake in lower-tier cities. The chart below illustrates the market size and growth rate of the historical and forecasted China's market of anti-VEGF drugs for fundus diseases from 2020 to 2035.

INDUSTRY OVERVIEW

China Anti-VEGF Drug Market for Fundus Diseases, 2020-2035E



Sources: Literature review, Frost & Sullivan analysis

As of the Latest Practicable Date, a total of five anti-VEGF drugs, namely LUCENTIS® (Novartis), EYLEA® (Bayer), Langmu® (Kanghong), VABYSMO® (Roche) and BEOVU® (Novartis), and two biosimilars have been approved for the treatment of fundus diseases in China.

China’s anti-VEGF market for fundus diseases continues to expand, supported by the rising prevalence of wAMD, DME and RVO, population aging and improving diagnostic coverage through OCT and fundus screening, with reimbursement expansion substantially increasing patient access across regions. As treatment practice evolves, the market is moving toward long-acting agents, biosimilars and dual-target therapies that reduce injection burden and improve compliance, alongside growing domestic innovation and broader uptake in lower-tier cities. Nonetheless, frequent intravitreal injections, limited reimbursement scope, hospital capacity constraints and pricing pressure following NRDL inclusion remain key challenges that may temper growth. Over the longer term, emerging modalities such as gene therapy, sustained-release delivery systems and intensified tender competition may influence demand patterns and add competitive pressure. Despite these dynamics, meaningful entry barriers persist due to stringent requirements for aseptic formulation, intraocular safety and long-term vision outcomes, as well as the need for robust hospital-based injection networks, economic evidence and formulary inclusion to support broad commercialization.

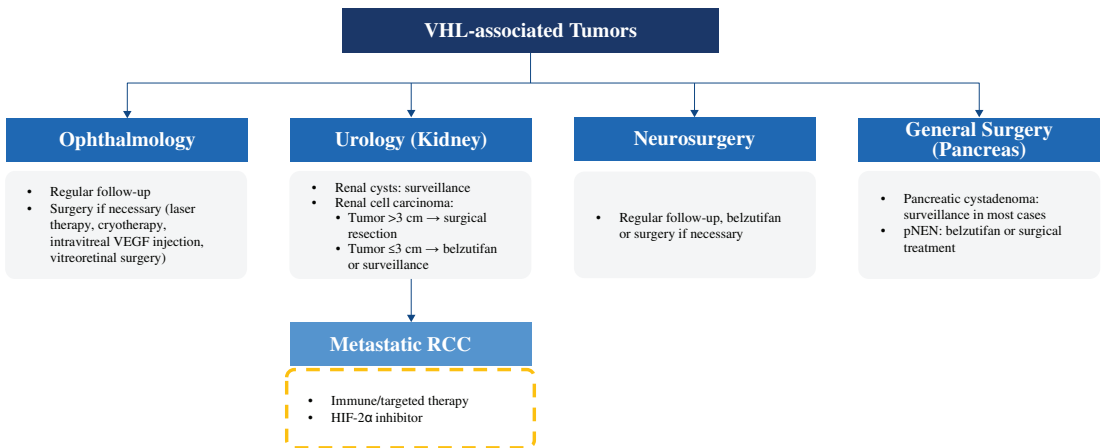
OVERVIEW OF OTHER DRUG MARKET

Overview of VHL Drug Market

Von Hippel-Lindau (VHL) syndrome is an autosomal dominant hereditary disorder caused by mutations in the VHL tumor suppressor gene. The following charts summarized the treatment flow of VHL-related tumors.

INDUSTRY OVERVIEW

Treatment flow of VHL-Associated Tumors



Sources: Chinese Expert Consensus on the Diagnosis and Treatment of von Hippel-Lindau Syndrome (2025 Edition), Frost & Sullivan Analysis

As of the Latest Practicable Date, only one HIF-2 α drug has been approved for the treatment of VHL-associated tumors in China. The following diagram summarizes the competitive landscape of marketed and clinical-stage HIF-2 α pipelines for the treatment of VHL-associated tumors in China as of the Latest Practicable Date.

Code/Drug Name	Company	Indications	Phase	Date ⁽¹⁾
Belzutifan	Merck Sharp & Dohme	VHL-associated Tumors	Approved	Nov 2024
NKT2152	Hansoh Pharmaceutical/ NiKang Therapeutics/ Shanghai Hansoh BioMedical	VHL-associated Tumors	I	Jun 2024
BPI-452080	Betta Pharmaceuticals	VHL-associated Tumors	I	Apr 2023

Note:

(1) Date refers to the date of first public announcement.

Sources: CDE, Frost & Sullivan Analysis

Overview of AML Drug Market

Acute myeloid leukemia (AML) is a cancer of the early blood-forming cells. AML is characterized by a rapid increase in the number of immature blood cells, in which the genetic information of the blood cells is damaged, and cannot shoulder the responsibility of normal blood cells. AML is usually found in the blood and bone marrow, the spongy, red tissue in the inner part of the large bones. It can sometimes spread to other parts of the body. AML usually progresses quickly and aggressively, requires immediate treatment. The incidence of AML in China increased from 27.6 thousand in 2020 to 30.5 thousand in 2025, and is expected to reach 38.1 thousand by 2035.

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 RMB900,000 for the preparation and update of the Frost & Sullivan Report, which is not contingent on the [REDACTED] proceeding.