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THE PHARMACEUTICAL MARKET

Overview

The global pharmaceutical industry continues to expand amid demographic aging, rising healthcare expenditure and sustained scientific innovation. The global pharmaceutical market increased from US$1,333.0 billion in 2020 to US$1,795.3 billion in 2025 at a CAGR of 6.1%, and is projected to reach US$2,807.4 billion in 2035, representing a CAGR of 4.6% from 2025 to 2035. As a major engine of global pharmaceutical growth, the pharmaceutical market in China increased from US$202.6 billion in 2020 to US$240.6 billion in 2025 at a CAGR of 3.5%, and is expected to reach US$437.8 billion in 2035, representing a CAGR of 6.2% from 2025 to 2035.

China has evolved from a generics-focused market into an innovation-oriented ecosystem, driven by regulatory reforms such as the Marketing Authorization Holder ("**MAH**") system and NRDL inclusion. By 2025, ten China-originated drugs had received FDA approval, eight of which have been approved since 2023, underscoring a rapid alignment with global regulatory standards. Meanwhile, China's share of global business development transaction value increased significantly from 6% in 2020 to 30%. Leveraging strengths in immunotherapy, antibodies, small molecules, and cell therapy, pharmaceutical companies in China have become key drivers of global innovation and cross-border collaboration.

Key Therapeutic Areas: Oncology and Inflammation & Immunology

Oncology and inflammatory & immunology ("**I&I**") diseases represent the two of the most significant therapeutic areas globally, collectively driving substantial market demand. In 2025, oncology drugs held the leading position in the global pharmaceutical market, with a market share of 16.9%. This dominance was mirrored in China, where oncology ranked first with a market share of 16.3% . In contrast, a structural divergence exists in the I&I segment — while I&I therapies accounted for approximately 12.9% of the global market in 2025, they represented only 5.6% in China. This significant disparity underscores a profound under-penetration of I&I treatments domestically, highlighting a compelling growth opportunity for innovative therapies to bridge this gap and address increasing clinical demand.

Development of Small-molecule Drugs

Within the broader context of precision medicine, despite the emergence of diverse therapeutic modalities, small-molecule drugs continue to maintain a substantial market presence, underpinned by distinct and enduring competitive advantages, including: (i) patient convenience, as oral formulations allow self-administration, reducing reliance on hospital-based infusions typical of biologics; (ii) notable tissue penetration, with small molecules reaching intracellular targets that are largely inaccessible to large-molecule biologics; (iii) cost efficiency, where simplified manufacturing and supply chains lower production costs, enhancing affordability and scalability; (iv) global access, since eliminating cold-chain requirements simplifies logistics, improving market access and payer acceptance worldwide; and (v) combination potential, as oral administration and rapid systemic clearance enable easy integration into combination therapies, balancing efficacy and safety.

Market Drivers and Future Trends

The continued growth of the pharmaceutical market is primarily driven by three key factors: (i) a highly supportive policy environment in China, underscored by a series of recent government initiatives — such as *the Implementation Plan for Supporting the Development of Innovative Drugs Across the Entire Chain* (2024) (《全鏈條支持創新藥發展實施方案》) and *Several Measures to Support the High-quality Development of Innovative Drugs* (2025) (《支持創新藥高質量發展的若干措施》) — designed to accelerate regulatory reviews, encourage differentiated R&D, and optimize pricing and reimbursement mechanisms; (ii) an expanding addressable patient pool, as population aging, lifestyle and environmental factors, and improved disease awareness and diagnostic capabilities continue to increase the diagnosed prevalence and treatment demand across oncology, immunology and inflammation-related diseases; and (iii) the increasing clinical adoption of innovative therapies across these therapeutic areas. In oncology, treatment paradigms are evolving from traditional chemotherapy and broadly applied regimens toward targeted small molecule drugs, immunotherapies and other precision treatment modalities, which are increasingly used across defined patient populations and treatment lines to improve disease control and extend treatment duration. In immunology and inflammation-related diseases, treatment approaches are also shifting from conventional symptomatic control and broad immunosuppression toward targeted and mechanism-based therapies, including small molecule drugs and biologics, which support more tailored disease management, improved treatment convenience and broader long-term use among eligible patients.

Challenges and Risks for Innovative Drugs

The development and commercialization of therapies in the pharmaceutical market, particularly for innovative drugs, face several market risks and challenges, including (i) long development cycles, high R&D costs, and inherent uncertainties in clinical and regulatory outcomes that could lead to delays or failures; (ii) intense competition driven by rapid technological evolution and the emergence of competing therapies from peers; (iii) evolving market access, pricing, and reimbursement policies, such as NRDL inclusion and government cost-containment measures; (iv) unpredictable market acceptance by physicians and patients, which depends on perceived clinical advantages, safety, and affordability; and (v) operational challenges in commercialization and distribution, particularly regarding hospital access, distributor network management, and the retention of qualified sales personnel.

THE ONCOLOGY THERAPEUTICS MARKET

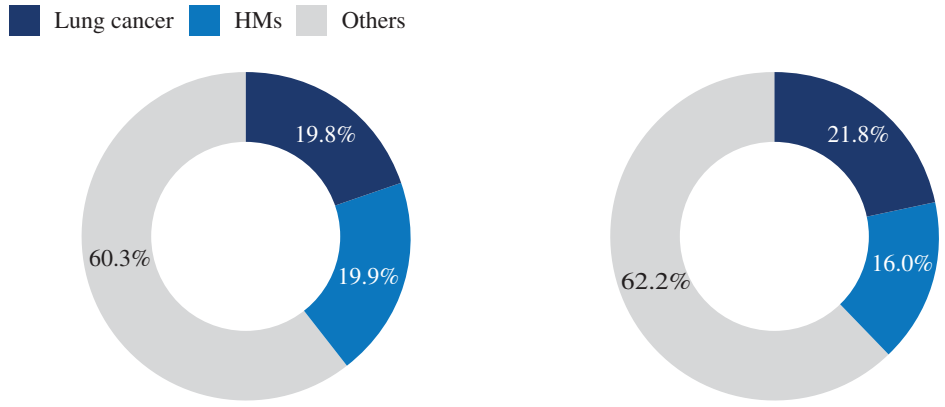
The Oncology Therapeutics Market Size

According to CIC, the global oncology treatment drug market grew from US$167.0 billion in 2020 to US$304.1 billion in 2025 at a CAGR of 12.7%, and is expected to reach US$729.2 billion in 2035, representing a CAGR of 9.1% from 2025 to 2035. In China, the market grew from US$25.8 billion in 2020 to US$39.1 billion in 2025, and is expected to reach US$131.2 billion in 2035, representing a CAGR of 12.9% from 2025 to 2035. The growth of the global oncology treatment market is driven by rising cancer prevalence and expanding access to diagnosis and treatment. It is further accelerated by the adoption of innovative therapies, sustained investment in R&D, favorable reimbursement and policy support, particularly in high-growth markets such as China.

Key Tumor Types: Lung Cancer and Hematologic Malignancies

Within the global oncology therapeutics landscape, lung cancer and hematologic malignancies ("**HMs**") together comprised approximately 40% of the total oncology treatment market in 2025. Lung cancer remains the leading type among solid tumors, with more than 2.5 million new cases worldwide in 2025 — approximately 40% occurring in China, where incidence was approximately two-fold higher than the next most common cancer. Five-year survival rates remain modest, at 28.1% in the U.S. and 28.7% in China. HMs, arising from abnormal differentiation of hematopoietic stem cells, exceeded 5.7 million prevalent cases globally in 2025, with China contributing over 1.0 million cases, or approximately 20% of the global total.

Oncology Market Composition by Key Therapeutic Areas in terms of sales value, 2025



In the global oncology treatment market *In the oncology treatment market in China*

Source: WHO, Annual reports, CIC

Key Challenges in Global Oncology Therapeutics Market

Despite continuous advancements in cancer treatment, the global oncology therapeutics market remains constrained by several critical challenges, including: (i) drug resistance, as both intrinsic and acquired resistance drive relapse and disease progression, posing the greatest challenge to long-term cancer control; (ii) blood–brain barrier ("**BBB**") penetration, as the BBB restricts most anticancer drugs from entering the central nervous system ("**CNS**"), which limits therapeutic concentrations in the brain and worsens the prognosis for CNS metastases, making it technically difficult to design molecules that can cross this barrier safely and potently; (iii) tumor heterogeneity, where diverse subclones and microenvironmental factors lead to variable drug responses and adaptive resistance, reinforcing the need for combination and precision-based strategies; and (iv) safety and toxicity concerns, which remain a major hurdle in oncology drug development, often limiting optimal dosing, patient adherence, and long-term use.

The Non-small Cell Lung Cancer Market

Overview

Lung cancer remains one of the highest-burden cancers globally, with non-small cell lung cancer ("**NSCLC**") accounting for around 85% of all cases and exhibiting increasing incidence across major regions. According to CIC, global NSCLC incidence is projected to increase from approximately 1.9 million cases in 2020 to 2.9 million cases in 2035. China substantially drives this growth, with incidence expected to grow from approximately 0.8 million cases in 2020 to 1.3 million cases in 2035. In addition, 55% NSCLC patients are diagnosed at an advanced stage. Consequently, it remains a leading cause of cancer mortality and represents a substantial and persistent unmet medical need globally and in China.

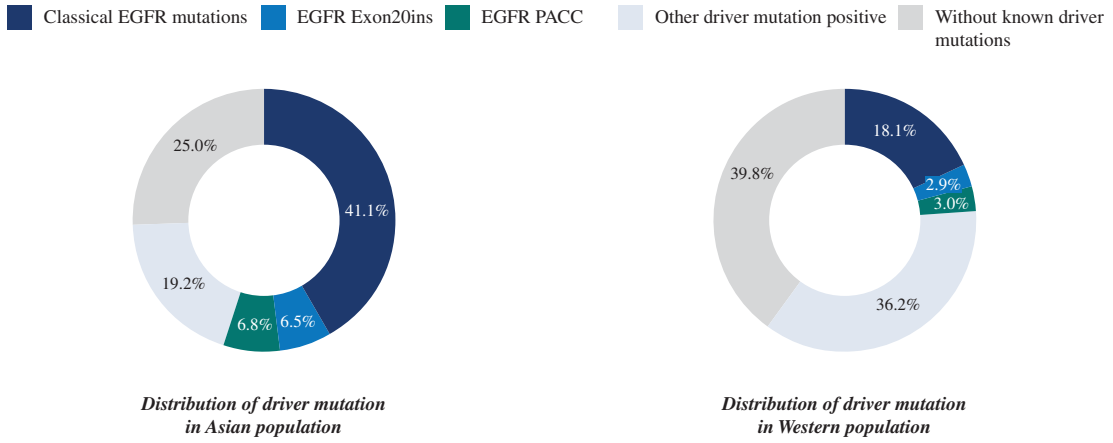
According to CIC, the global NSCLC drug market grew from US$22.5 billion in 2020 to US$54.3 billion in 2025 at a CAGR of 19.2%, and is projected to reach US$115.8 billion in 2035, representing a CAGR of 7.9% from 2025 to 2035. China remains a key growth engine, with its market size increasing from US$5.3 billion in 2020 to US$7.7 billion in 2025 at a CAGR of 7.5% and expected to reach US$23.0 billion in 2035, reflecting a CAGR of 11.6% from 2025 to 2035.

Key molecular subtypes in NSCLC

NSCLC is classified into driver mutation-positive and driver-negative subtypes. Driver mutation-positive cases account for approximately 75% of cases in Asian populations and 58% in Western populations, involving actionable alterations in genes such as EGFR, ALK, and ROS1.

EGFR is the most prevalent molecular subtype, primarily driven by exon 19 deletions and the L858R mutation, while the T790M is a common resistance mutation emerging after early-generation EGFR TKI therapy. Atypical mutations include exon20ins and PACC variants (e.g., G719X, S768I). EGFR mutation prevalence differs markedly by region — over 50% in NSCLC patients in China versus 24% in the U.S. and other Western populations.

Distribution of Driver Mutation in Key Molecular Subtypes of NSCLC



Distribution of driver mutation in Asian population

Distribution of driver mutation in Western population

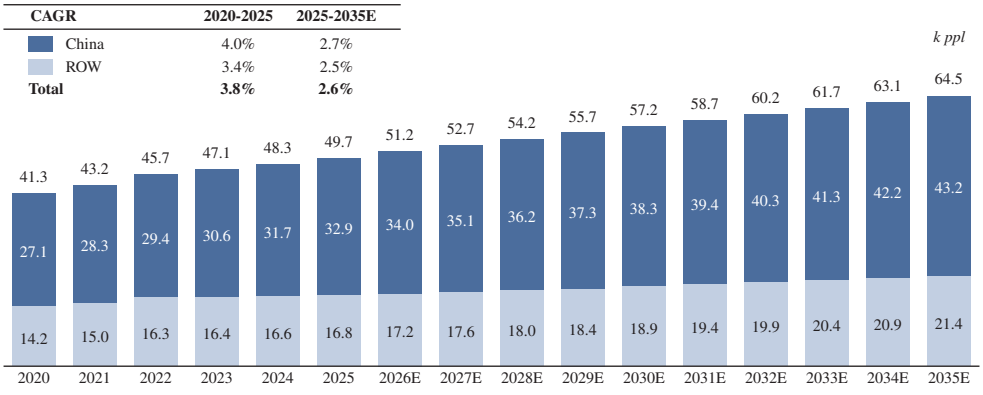
Source: Healthbook TIMES Onco Hema., Int. J. Mol. Sci., Nature Portfolio, Journal of Clinical Medicine, Heliyon, J Clin Oncol., CIC

The EGFR Exon20ins NSCLC Market

Overview of EGFR exon20ins NSCLC

EGFR exon20ins mutations account for approximately 12% to 15% of total EGFR mutant patients. The global incidence of EGFR exon20ins NSCLC increased from 63.7 thousand cases in 2020 to 76.7 thousand cases in 2025 and is expected to reach 99.6 thousand cases in 2035. In China, incidence increased from 41.2 thousand cases in 2020 to 50.1 thousand cases in 2025 and is anticipated to reach 65.7 thousand cases in 2035. The global incidence of 2L/2L+ EGFR exon20ins NSCLC increased from 41.3 thousand cases in 2020 to 49.7 thousand cases in 2025 and is expected to reach 64.5 thousand cases in 2035. In China, incidence increased from 27.1 thousand cases in 2020 to 32.9 thousand cases in 2025 and is anticipated to reach 43.2 thousand cases in 2035.

Global Incidence of 2L/2L+ EGFR Exon20ins NSCLC, 2020-2035E



Source: GLOBOCAN, WHO, CIC

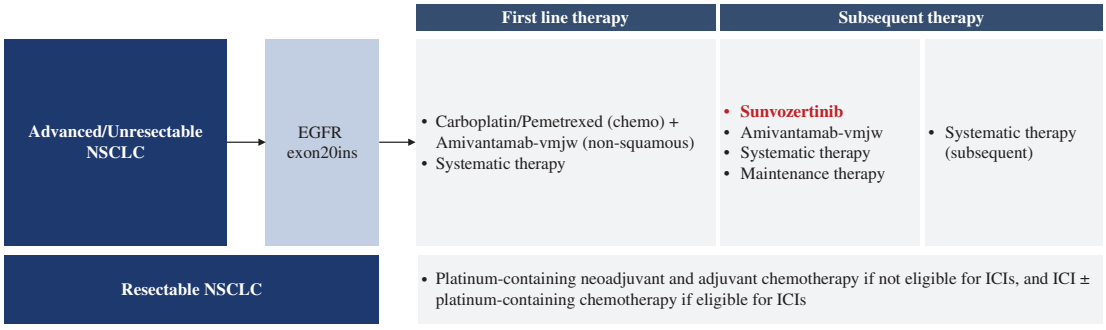
EGFR exon20ins mutations alter the kinase domain, creating steric hindrance that blocks most EGFR TKIs, leading to poor treatment response. Detection rates have historically been low due to a lack of targeted therapies. With new exon20ins-specific drugs now available, more sensitive diagnostics are expected to increase identified cases.

Treatment paradigm and unmet needs for EGFR exon20ins NSCLC

Treatment paradigm for EGFR exon20ins NSCLC

Globally and in China, approximately 75% of incident cases of EGFR exon20ins NSCLC are diagnosed at an advanced stage. Among these patients, approximately 90% receive first-line treatment, representing an estimated 69.0 thousand cases globally and 45.1 thousand cases in China in 2025. Subsequently, roughly 70% of those treated in the first-line setting will progress to require second- and later-line therapies, accounting for 49.7 thousand cases globally and 32.9 thousand in China in 2025. Under the NCCN guidelines, first-line treatment for advanced non-squamous NSCLC with EGFR exon20ins mutations is carboplatin/pemetrexed plus amivantamab. Subsequent options include sunvozertinib, amivantamab, or other systemic therapies.

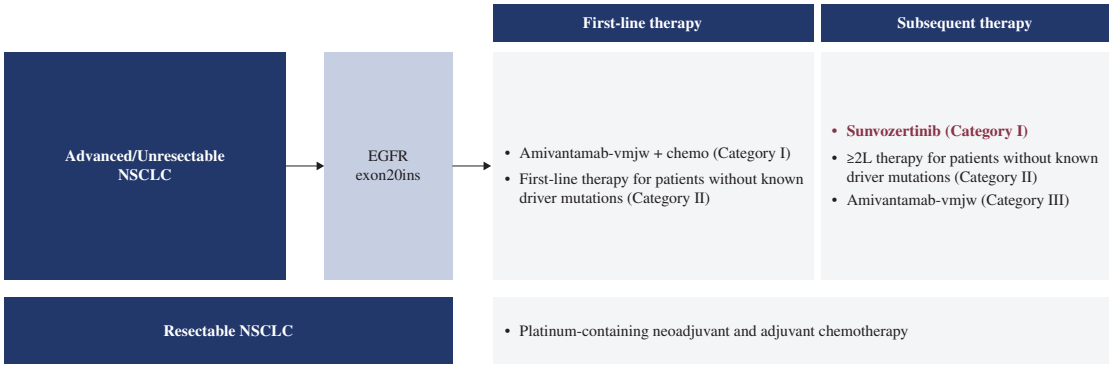
Treatment Paradigm for EGFR Exon20ins NSCLC, NCCN (the U.S.)



Source: NCCN, CIC

Under the CSCO guidelines, first-line treatment for EGFR exon20ins-positive advanced NSCLC prioritizes amivantamab plus chemotherapy (Category I). For subsequent lines, sunvozertinib is recommended as a Category I option, along with chemotherapy regimens for driver-negative patients (Category II) and amivantamab (Category III).

Treatment Paradigm for EGFR Exon20ins NSCLC, CSCO (China)



Source: CSCO, CIC

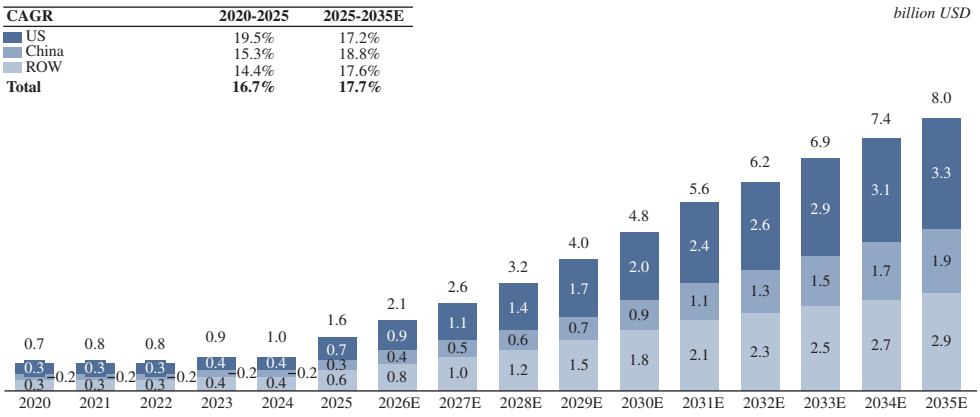
Unmet needs in EGFR exon20ins NSCLC

For second-line advanced EGFR exon20ins NSCLC, before targeted options such as ZEGFROVY® and Rybrevant® became available, chemotherapy provided only modest responses and limited disease control, highlighting a major gap versus classic EGFR mutations. In first-line, no oral therapies have been approved. For resectable disease, no mutation-specific targeted therapy is currently recommended, and platinum-based chemotherapy remains standard in the perioperative setting.

The market size of EGFR exon20ins NSCLC

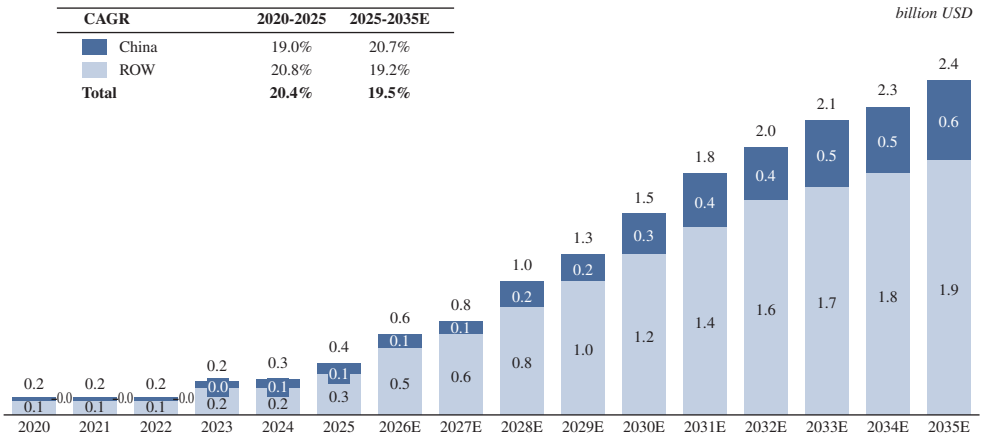
The global EGFR exon20ins NSCLC market grew from US$0.7 billion in 2020 to US$1.6 billion in 2025 at a CAGR of 16.7%, and is expected to increase to US$8.0 billion in 2035, representing a CAGR of 17.7% from 2025 to 2035. The global 2L/2L+ EGFR exon20ins NSCLC market grew from US$0.2 billion in 2020 to US$0.4 billion in 2025, and is expected to increase to US$2.4 billion in 2035, representing a CAGR of 19.5% from 2025 to 2035. The 2L/2L+ EGFR exon20ins NSCLC market in China grew from US$0.04 billion in 2020 to US$0.1 billion in 2025, and is expected to increase to US$0.6 billion in 2035, representing a CAGR of 20.7% from 2025 to 2035.

The EGFR Exon20ins NSCLC Market Size, 2020-2035E



Source: NCCN, CSCO, CIC

The 2L/2L+ EGFR Exon20ins NSCLC Market Size, 2020-2035E



Source: NCCN, CSCO, CIC

Global competitive landscape of EGFR exon20ins NSCLC therapies

As of the Latest Practicable Date, there were four approved drugs for EGFR exon20ins NSCLC globally — ZEGFROVY® (舒沃哲®), Rybrevant® (锐珂®, amivantamab-vmjw, Ivesa® (艾弗沙®) and Ambiray® (安比锐®)). As an oral small-molecule drug, ZEGFROVY® offers significant advantages in convenience and patient compliance over intravenous infusion. In addition, it has been recommended by the NCCN guidelines and approved in both China and the U.S., underscoring its internationally recognized clinical value. Its inclusion in the NRDL further enhances affordability and market competitiveness, providing a clear pricing advantage.

Global Approved Drugs for EGFR Exon20ins NSCLC

INN	Brand name	Company	Target	Modality	Indication	Treatment Line	Mono/Combo	Clinical Stage	Approval Date	NCCN Inclusion	NRDL Inclusion
Sunvozertinib	Zegfrovy® 舒沃哲®	Our Company/ AstraZeneca	EGFR	Small-molecule	Locally advanced/ metastatic NSCLC with EGFR Exon20ins mutation progressing on/after Platinum-containing chemotherapy	2L/2L+	Mono	Approved	NMPA: 2023-08-22 FDA: 2025-07-02	Yes	Yes, 2024
Amivantamab	Rybrevant® 锐珂®	J&J	EGFR/c-MET	Antibody	NSCLC with EGFR Exon20ins mutation	1L	Combo with chemo (Platinum-containing)	Approved	NMPA: 2025-02-11 FDA: 2021-05-24	Yes	No
Firmonertinib	Ivesa® 艾弗沙®	Allist/Arrivent	EGFR	Small-molecule	EGFR Exon20ins NSCLC	2L+	Mono	Approved	NMPA: 2026-02-02	No	No
Andamertinib	Ambiray® 安比锐®	Avistone	EGFR	Small-molecule	Locally advanced/ metastatic NSCLC with EGFR Exon20ins mutation progressing on/after Platinum-containing chemotherapy	2L	Mono	Approved	NMPA: 2026-04-30	No	No

Source: FDA, NMPA, CIC

As of the same date, seven drug candidates had advanced to Phase 2 clinical development or beyond globally, as illustrated below.

Global Drug Candidates Under Clinical Development (Phase 2 or Beyond) for EGFR Exon20ins NSCLC

Drug	Company	Target	Modality	Indication	Treatment Line	Mono/Combo	Clinical Stage	Approval Date/First Posted Date	Location
Zipalertinib (CLN081)	Taiho Oncology/ Zai Lab	EGFR	Small-molecule	EGFR Exon20ins NSCLC	2L+	Mono	NDA	2026-03-10	The U.S.
				EGFR Exon20ins NSCLC	1L	Combo	3	2023-08-03	Global
					Adjuvant	Combo	3	2023-08-17	Global
Sunvozertinib (DZD9008)	Our Company/ AstraZeneca	EGFR	Small-molecule	EGFR Exon20ins NSCLC	1L	Mono	NDA	2022-12-30	Global
				EGFR Exon20ins NSCLC	Adjuvant	Mono	3	2025-08-17	Global
PLB1004	Avistone	EGFR	Small-molecule	EGFR Exon20ins nsq NSCLC	1L	Mono	3	2024-01-09	China
Firmonertinib	Allist/Arrivent	EGFR	Small-molecule	EGFR Exon20ins nsq NSCLC	1L	Mono	3	2023-05-11	Global
YK-029A	Puhe Biopharma	EGFR	Small-molecule	EGFR Exon20ins NSCLC	1L	Mono	3	2023-03-23	China
JMT101	CSPC Pharma/ JMT-Bio	EGFR	Antibody	EGFR Exon20ins NSCLC	1L	Combo	3	2024-04-11	China
					2L+	Combo	2	2021-11-24	China
BEBT-109	BeBetter Med	EGFR	Small-molecule	EGFR Exon20ins NSCLC	2L+	Mono	2	2021-12-31	China
					1L	Combo	2	2024-06-18	China

Source: Clinicaltrials.gov, FDA, NMPA, CDE, CIC

The tables below set forth a comparison of key therapies in the 2L+ and 1L treatment of EGFR Exon20ins NSCLC, respectively.

Comparison of Key Therapies under Development in the 2L+ Treatment of EGFR Exon20ins NSCLC*

Drug name	Sunvozertinib		Amivantamab	PLB-1004	Firmonertinib
Company	Our Company and AstraZeneca		Janssen	Avistone	Allist
Data Source	WU-KONG6 (NCT05712902)	WU-KONG1B (NCT03974022)	CHRYSALIS (NCT02609776)	KANNON (NCT06015503)	FURMO-003 (NCT06015503)
Trial Phase of Reported Data	Phase 2	Phase 2	Phase 1	Phase 2	Phase 2
Administration	PO		IV	PO	PO
Dosage	Mono 300 mg QD	Mono 200 mg QD	Mono 1400 mg ≤80 kg QW for first 4 weeks, Q2W from week 5	Mono 240 mg QD	Mono 240 mg QD
Patient Baseline	2L+, All previously at least chemo treated	2L, All previously at least 1L systemic therapy treated	2L+, All previously chemotherapy treated	2L+, All previously chemo/immunotherapy treated	2L+, All previously chemo treated, 22.5% had CNS metastases
Efficacy **ORR**	60.8%	45.9%	40%	42.7%	44.3%
Efficacy **mPFS**	–	8.4m	8.3m	6.2m	8.3m
Efficacy **mDoR**	8.3m	11.1m	11.1m	8.7m	8.3m
Safety	Drug-related TEAE leading to drug discontinuation 10%	TRAEs leading to drug discontinuation 4.4%	AE leading to discontinuation 10%	TRAE leading to treatment discontinuation 2.2%	TRAE leading to treatment discontinuation 5.6%

Abbreviations: IV= intravenous administration; PO= oral administration.
**Note:* Based on non-head-to-head comparisons.
Source: Clinicaltrials.gov, ASCO, ESMO, CIC

Comparison of Key Therapies under Development in the 1L Treatment of EGFR Exon20ins NSCLC*

Drug name	Sunvozertinib	Amivantamab
Company	Our Company and AstraZeneca	Janssen
Data Source	WU-KONG28	PAPILLON (NCT04538664)
Trial Phase of Reported data	Phase 3	Phase 3
Administration	PO	IV
Treatment Plan	Mono 300 mg QD	Combo with chemo 1400 mg ≤80 kg
Patient Baseline	1L	1L
Efficacy mPFS	10.3m	11.4m
Safety	Treatment-related adverse event leading to drug discontinuation 7.4%	Discontinuation of drug 11%

Abbreviations: IV= intravenous administration; PO= oral administration.
**Note:* Based on non-head-to-head comparisons.
Source: The New England Journal of Medicine

The EGFR PACC NSCLC Market

Overview of EGFR PACC NSCLC

Among EGFR mutations, P-loop and αC-helix compressing ("**PACC**") mutations account for about 12.5% and are widely distributed across exons 18 to 21. The global incidence of EGFR PACC NSCLC increased from 65.4 thousand cases in 2020 to 78.1 thousand cases in 2025 and is expected to reach 101.5 thousand cases in 2035. In China, incidence grew from 42.8 thousand cases in 2020 to 52.0 thousand cases in 2025 and is anticipated to reach 68.2 thousand cases in 2035.

EGFR PACC mutations exhibit high molecular heterogeneity, making them prone to under-detection by conventional PCR assays. Next-generation sequencing ("**NGS**") is therefore recommended for comprehensive identification. These mutations alter the P-loop and αC-helix orientation, changing spatial conformation and reducing the drug-binding pocket size. This structural change impairs stable binding of traditional EGFR TKIs, limiting their therapeutic efficacy.

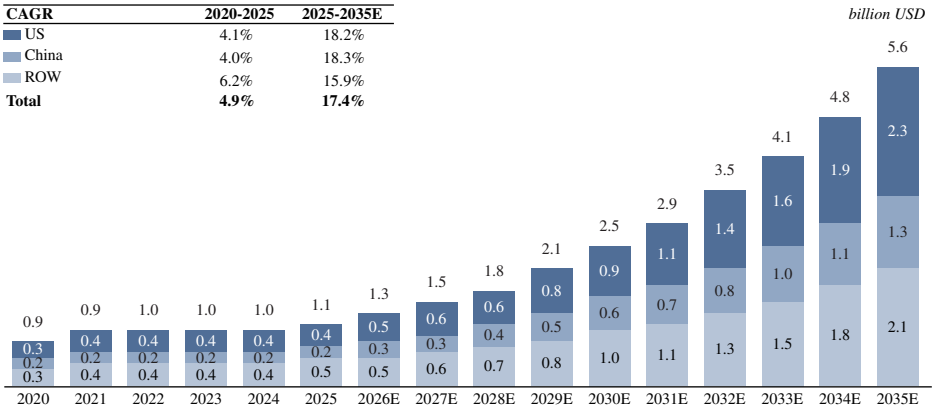
Treatment paradigm and unmet needs for EGFR PACC NSCLC

Approved EGFR kinase inhibitors may have clinical activities to certain types of mutations, but overall, their clinical benefits are rather limited, and chemo doublet are the only option. Multiple studies have shown that patients with these mutations exhibit poorer prognosis than those with classical EGFR common mutations (exon 19 deletions and L858R), underscoring a significant unmet medical need for effective, well-tolerated therapies with broader activity cross the EGFR mutation spectrum.

The market size of EGFR PACC NSCLC

The global EGFR PACC NSCLC market grew from US$0.9 billion in 2020 to US$1.1 billion in 2025 at a CAGR of 4.9%, and is expected to reach US$5.6 billion in 2035, representing a CAGR of 17.4% from 2025 to 2035.

The EGFR PACC NSCLC market size, 2020-2035E



Source: NCCN, CSCO, CIC

Global competitive landscape of EGFR PACC NSCLC therapies

As of the Latest Practicable Date, no drug had been approved for EGFR PACC NSCLC globally. As of the same date, there were eight drug candidates under clinical development globally, as illustrated below.

Global Drug Candidates Under Clinical Development for EGFR PACC NSCLC

Drug	Company	Target	Indication	Treatment Line	Mono/Combo	Clinical Stage	First Posted Date	Location
Sunvozertinib (DZD9008)	Our Company/ AstraZeneca	EGFR	EGFR PACC NSCLC	Adjuvant	Mono/Combo	3	2025-08-12	Global
				1L	Mono	Post-PoC	/	China
Firmonertinib	Allist/ArriVent	EGFR	EGFR PACC NSCLC	Adjuvant	Mono/Combo	3	2025-06-06	China
				1L	Mono	3	2025-05-02	China, the U.S.
PLB1004	Avistone	EGFR	EGFR PACC nsqNSCLC	1L	Mono	2/3	2025-12-09	China
Zipalertinib (CLN081)	Taiho Oncology/ Zai Lab	EGFR	NSCLC with atypical EGFR mutation	1L	Mono	2	2023-08-01	Global
Enozertinib (ORIC-114)	ORIC	EGFR/HER2	NSCLC with atypical EGFR mutation	3L+	Mono	1/2	2022-04-07	Global
BDTX-1535	Black Diamond Therapeutics	EGFR	NSCLC with atypical EGFR mutation	1L	Mono	1/2	2022-02-25	The U.S.
BH-30643	BlossomHill Therapeutics	EGFR	NSCLC with atypical EGFR mutation	2L/2L+	Mono	1/2	2024-11-26	Global
VRN110755	Voronoi	EGFR	EGFR PACC NSCLC	2L/2L+	Mono	1/2	2026-07-13	Global

Source: Clinicaltrials.gov, CDE, CIC

The EGFR-mutant NSCLC Market

Overview of EGFR-mutant NSCLC

Driver EGFR mutations represent a major molecular subset of NSCLC, with an overall prevalence of approximately 30% globally and over 50% in China. These mutations are dominated by the classical exon 19 deletions and exon 21 L858R mutation, which collectively account for around 75% of EGFR-mutant cases. NSCLC harboring these classical EGFR mutations is referred to as EGFR-mutant NSCLC.

The global incidence of EGFR-mutant NSCLC increased from 529.8 thousand cases in 2020 to 632.0 thousand cases in 2025 and is projected to rise to 821.5 thousand cases in 2035. In China, incidence grew from 342.4 thousand cases in 2020 to 415.9 thousand cases in 2025 and is anticipated to reach 545.6 thousand cases in 2035. The global incidence of 2L/2L+ EGFR-mutant NSCLC increased from 128.4 thousand cases in 2020 to 422.2 thousand cases in 2025 and is expected to reach 647.8 thousand cases in 2035. In China, prevalence increased from 89.9 thousand cases in 2020 to 279.9 thousand cases in 2025 and is anticipated to reach 430.6 thousand cases in 2035.

Treatment paradigm and unmet needs for EGFR-mutant NSCLC

Treatment paradigm for EGFR-mutant NSCLC

The following table sets forth the treatment paradigm for EGFR-mutant NSCLC recommended by NCCN and CSCO.

Treatment Paradigm for EGFR-mutant NSCLC, NCCN (the U.S.)

			First-line therapy	Subsequent therapy
Advanced or Metastasis NSCLC	EGFR mutation	EGFR Exon 19 Deletion or L858R Mutation	***Preferred*** • Osimertinib • (Carboplatin or Cisplatin)/Osimertinib/Pemetrexed (non-squamous) • Lazertinib + Amivantamab-vmjw ***Useful in certain circumstances*** • Afatinib or Dacomitinib or Erlotinib or Erlotinib + Bevacizumab or Erlotinib + Ramucirumab or Gefitinib or Lazertinib	• Osimertinib • Carboplatin/Pemetrexed + Amivantamab-vmjw (non-squamous) • Datopotamab deruxtecan-dlnk (non-squamous) • Lazertinib + Amivantamab-vmjw
		EGFR S768I, L861Q, and/or G719X Mutations	***Preferred*** • Afatinib or Osimertinib ***Other recommended*** • Dacomitinib or Gefitinib or Osimertinib	• Osimertinib • Datopotamab deruxtecan-dlnk (non-squamous)

Treatment Paradigm for EGFR-mutant NSCLC, CSCO (China)

		First-line therapy	Subsequent therapy
Advanced IV stage NSCLC	EGFR ("classical")	**Category I Recommendations** • 3rd gen TKIs: Osimertinib, Almonertinib, Firmonertinib, Befotertinib, Rilertinib, Rezivertinib • 2nd gen TKIs: Afatinib, Dacomitinib • 1st gen TKIs: Gefitinib, Erlotinib, Icotinib • Zorifertinib (for patients with CNS metastases) • Combination: Osimertinib + Chemotherapy **Category II Recommendations** • Gefitinib/Erlotinib + Chemotherapy (PS=0–1) • Erlotinib + Bevacizumab • Platinum-doublet Chemotherapy ± Bevacizumab (non-squamous) **Category III Recommendations** • Amivantamab-vmjw + Lazertinib	**Oligoprogression or CNS Progression** **Category I Recommendations** • Continue prior EGFR TKIs + Local Therapy **Category II Recommendations** • Re-biopsy to identify resistance mechanism **Widespread Progression** **Category I Recommendations** • For 1st/2nd gen TKI failure (T790M-positive): Osimertinib, or Almonertinib/ Firmonertinib/Befotertinib…; • For T790M-negative or 3rd gen TKI failure: Platinum-doublet Chemotherapy ± Bevacizumab (non-squamous); • Ivonescimab + Chemotherapy; • Pemetrexed + Cisplatin + Bevacizumab + Sintilimab; **Category II Recommendations** • For re-detected T790M-positive: Platinum-doublet Chemotherapy ± Bevacizumab (non-squamous); Sac-TMT; • Amivantamab-vmjw + Chemotherapy; Re-biopsy to evaluate other resistance mechanisms

Source: NCCN, CSCO, CIC

Unmet needs in EGFR-mutant NSCLC

While the standard of care for EGFR-mutated NSCLC has evolved toward third-generation EGFR TKIs, meaningful clinical limitations persist across durability of response, central nervous system control, safety, and coverage of molecular heterogeneity, leaving substantial unmet medical needs. The key unmet needs in EGFR-mutant NSCLC include: (i) drug resistance, as most patients eventually develop resistance to third-generation EGFR TKIs and face limited post-progression options, with chemotherapy yielding only modest efficacy (ORR 30-40%, mPFS 5.3 months, mOS 9.6 months) and newer bispecific antibodies and ADCs showing suboptimal responses and safety concerns; (ii) limited BBB penetration, since third-generation TKIs have a CSF-to-free plasma ratio of approximately 20%, which restricts CNS efficacy in a population where CNS metastases occur in approximately 30% of patients at diagnosis, rise to 50-60% within three years, and remain a major cause of mortality post-resistance; (iii) cardiac safety concerns, given that osimertinib causes dose-dependent QT prolongation, requiring ECG monitoring and restricting its use in at-risk patients; and (iv) limited efficacy in certain EGFR mutations, where osimertinib is highly effective against classical mutations but shows reduced activity in complex mutations (e.g. G719X, L861Q, S768I).

The market size of EGFR-mutant NSCLC

The global EGFR-mutant NSCLC market grew from US$8.1 billion in 2020 to US$12.1 billion in 2025 at a CAGR of 8.5%. It is projected to further expand to US$25.4 billion in 2035, representing a CAGR of 7.7% from 2025 to 2035. The market size in China increased from US$1.8 billion in 2020 to US$2.8 billion in 2025 at a CAGR of 9.0%, and is expected to reach US$5.9 billion in 2035, reflecting a CAGR of 7.9% from 2025 to 2035. The global 2L/2L+ EGFR-mutant NSCLC drug market grew from US$1.7 billion in 2020 to an estimated US$7.2 billion in 2025 at a CAGR of 32.9%. It is projected to further expand to US$16.5 billion in 2035, representing a CAGR of 8.6% from 2025 to 2035. The market size in China increased from US$0.1 billion in 2020 to US$0.6 billion in 2025 at a CAGR of 32.6%, and is expected to reach US$2.8 billion in 2035, reflecting a CAGR of 17.3% from 2025 to 2035.

Global competitive landscape of EGFR-mutant NSCLC therapies

The following table sets forth the third-generation and beyond EGFR TKIs approved for NSCLC with EGFR Exon19del or Exon21 (L858R) mutation/classical EGFR mutations.

Global Approved Third-generation or beyond EGFR TKIs for EGFR-mutant NSCLC

Product	Company	Target	RoA	Approved indications			First Approval Date	NRDL
				1L EGFR-mutant NSCLC with Exon19del or Exon21 (L858R) mutation	NSCLC progressing on/after EGFR TKI with EGFR T790M mutation	Adjuvant		
Osimertinib	AstraZeneca	EGFR	p.o.	• YES	• YES	• YES	FDA 2015.11 NMPA 2021.04	YES
Almonertinib	Hansoh	EGFR	p.o.	• YES, and maintenance therapy	• YES	• /	NMPA 2020.03	YES
Firmonertinib	Allist	EGFR	p.o.	• YES	• YES	• /	NMPA 2021.03	YES
Befotertinib	Betta Pharmaceuticals	EGFR	p.o.	• YES	• YES	• /	NMPA 2023.05	YES
Rezivertinib	Beta Pharma	EGFR	p.o.	• YES	• YES	• /	NMPA 2024.05	YES
Rilertinib	Sanhome	EGFR	p.o.	• YES	• YES	• /	NMPA 2024.06	YES
Zorifertinib	AstraZeneca/Chintai	EGFR	p.o.	• YES, with CNS metastasis	• /	• /	NMPA 2024.11	YES
Limertinib	Ask Pharma	EGFR	p.o.	• YES	• YES	• /	NMPA 2025.01	YES
Lazertinib	J&J	EGFR	p.o.	• YES, combo with amivantamab	• /	• /	FDA 2024.08 NMPA 2025.07	/
Mefatinib	Huadong Medicine	EGFR/HER2	p.o.	• YES	• /	• /	NMPA 2025.10	/

Source: FDA, NMPA, CIC

As of the Latest Practicable Date, there were over 15 post third-generation EGFR-TKI candidates for EGFR-mutant NSCLC globally, as illustrated below.

Global EGFR-TKI Candidates for Post-3rd-generation EGFR-TKI EGFR-mutant NSCLC

Drug	Company	Treatment Line	Mono/Combo	Clinical Stage	First Posted Date	Location
HS-10504	Hansoh Pharmaceutical	2L/2L+	Mono	3	2026-08-10	China
DZD6008	Our Company	2L/2L+	Combo with chemo	2	2025-07-17	China
		1L/2L+	Mono	1/2	2025-02-06	Global
		1L/2L+	Combo with Sunvozertinib	1/2	2025-07-23	China
WSD0922-FU	Wayshine Biopharm	2L/2L+	Mono	2	2025-03-11	Global
BDTX-1535	Black Diamond Therapeutics	2L/2L+	Mono	1/2	2022-02-25	The U.S.
DAJH-1050766	DIAO Jiuhong Pharmaceutical	2L/2L+	Mono	1/2	2022-05-07	China
JIN-A02	J Ints Bio	2L/2L+	Mono	1/2	2022-05-27	The U.S., South Korea, Thailand
HS-10375	Hansoh Pharmaceutical	2L/2L+	Mono	1/2	2022-06-28	China
BBT-207	Bridge Biotherapeutics	2L/2L+	Mono	1/2	2023-06-27	South Korea
BH-30643	BlossomHill Therapeutics	2L/2L+	Mono	1/2	2024-11-26	Global
H002	RedCloud Bio	2L/2L+	Mono	1/2a	2022-09-23	Global
PH009-1	Puhe Pharmaceutical	2L/2L+	Mono	1/2a	2024-09-19	China
WSD0922-FU	Wayshine Biopharm	2L	Combo with osimertinib	1/2	2025-10-03	China
VRN1107511	Voronoi	2L/2L+	Mono	1/2	2026-07-13	Global
QLH11811	Qilu Pharmaceutical	2L/2L+	Mono	1	2022-09-26	China
AST2303	Allist/Abbisko	2L/2L+	Mono	1	2024-12-23	China
STX-241	Pierre Fabre	2L/2L+	Mono	1	2025-06-13	China

Note: Only active trials are presented (first posted date since January 2022)
Source: Clinicaltrials.gov, CDE,CIC

The NSCLC Without Known Driver Mutations Market

Overview of without known driver mutations NSCLC

Among NSCLC patients, those without identifiable driver mutations (including EGFR, ALK, ROS1 and other actionable mutations) constitute one of the largest subgroups, accounting for approximately 25% in Asian populations and 40% in Western populations. NSCLC without identifiable driver mutations is referred to as without known driver mutations NSCLC. Patients with NSCLC without known driver mutations generally lack effective targeted therapies and therefore rely predominantly on chemotherapy and immunotherapy, which often demonstrate limited durability of benefit.

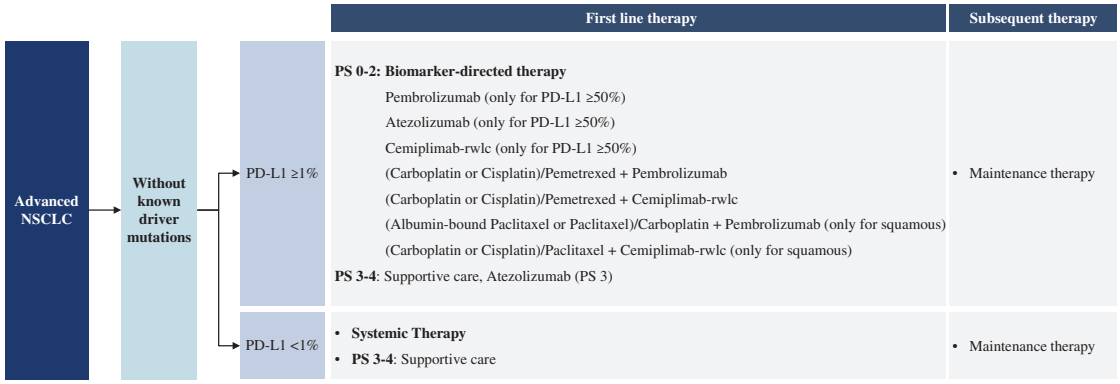
The global incidence of NSCLC without known driver mutations increased from 449.0 thousand cases in 2020 to 527.6 thousand cases in 2025 and is projected to rise to 681.2 thousand cases in 2035. In China, incidence grew from 155.6 thousand cases in 2020 to 189.1 thousand cases in 2025 and is anticipated to reach 248.0 thousand cases in 2035.

Treatment paradigm and unmet needs of NSCLC without known driver mutations

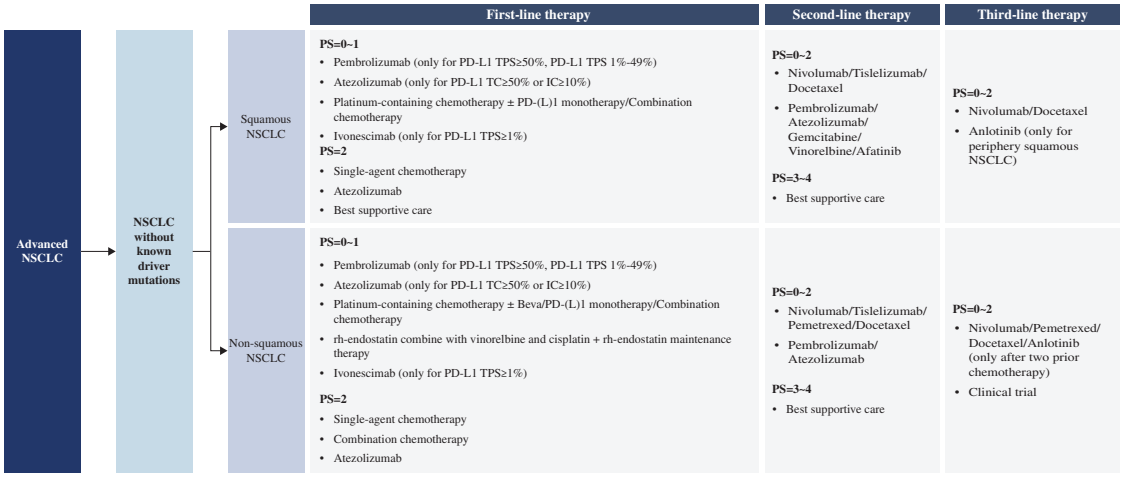
Treatment paradigm for NSCLC without known driver mutations

The following table sets forth the treatment paradigm for NSCLC without known driver mutations according to NCCN and CSCO.

Treatment Paradigm for NSCLC Without Known Driver Mutations, NCCN (the U.S.)



Treatment Paradigm for NSCLC Without Known Driver Mutations, CSCO (China)



Abbreviation: PS = performance status
Source: NCCN, CSCO, CIC

Unmet needs in NSCLC without known driver mutations

The key unmet medical needs in NSCLC without known driver mutations primarily include: (i) limited durability in patients with high PD-L1 expression (TPS ≥50%), where current regimens achieve strong objective response rates but many patients eventually develop resistance, underscoring the need to improve progression-free and overall survival beyond current standards; (ii) suboptimal response rates in the large subgroup with low or intermediate PD-L1 expression (TPS 1-49%), even with chemotherapy combinations, highlighting the need to enhance efficacy and address the "cold" tumor microenvironment; and (iii) safety and tolerability concerns, as immune-related adverse events and cumulative chemo-immunotherapy toxicity increase patient burden, limiting long-term adherence and clinical utility.

The market size of NSCLC without known driver mutations

The global NSCLC without known driver mutations market grew from US$13.3 billion in 2020 to US$23.2 billion in 2025 at a CAGR of 11.8%. It is projected to further expand to US$42.6 billion in 2035, representing a CAGR of 6.3% from 2025 to 2035. The market size in China increased from US$2.4 billion in 2020 to US$3.2 billion in 2025 at a CAGR of 5.9%, and is expected to reach US$6.7 billion in 2035, reflecting a CAGR of 7.9% from 2025 to 2035.

Global competitive landscape of NSCLC without known driver mutations treatment

Janus kinase ("**JAK**") inhibitors offer a differentiated value proposition in NSCLC without known driver mutations by modulating aberrant JAK-STAT-mediated inflammatory and immune-evasive signaling. By suppressing tumor growth and reshaping the tumor microenvironment, this approach potentially enhance sensitivity to immunotherapy in a population with limited targeted options.

As of the Latest Practicable Date, no small-molecule targeted therapy had been approved for NSCLC without known driver mutations globally. As of the same date, golidocitinib was the only JAK-targeted drug candidate under clinical development globally.

The table below sets forth a comparison of key therapies in the treatment of NSCLC without known driver mutations.

Comparison of Key Therapies under Development in the Treatment of NSCLC without known driver mutations*

Drug name		Golidocitinib	Ivonescimab (AK112)	Dato-DXd	sac-TMT (SKB264)
Company		Dizal	Akeso/Summit	Daiichi Sankyo/AstraZeneca	Kelun/MSD
Target		JAK1	PD-1/VEGF	TROP2	TROP2
Data Source		JACKPOT33 (NCT06198907)	HARMONi-2 (NCT05499390)	TROPION-Lung02 (NCT04526691)	OptiTROP-Lung05 (NCT06448312)
Trial Phase of Reported Data		IIT	Phase 3	Phase 1b	Phase 2
Administration		PO	IV	IV	IV
Treatment Plan		golidocitinib 150 mg QD +sintilimab 200 mg Q3W	Mono 20 mg/kg Q3W	Combo with Pembro 4.0/6.0 mg/kg Q3W	Combo with Pembro 4 mg/kg Q2W
Patient Baseline		1L, PD-L1 positive advanced NSCLC without driver mutations	1L, PD-L1 TPS ≥1%	1L	1L, without EGFR or ALK mutations, PD-L1 TPS ≥1%
Efficacy	ORR	TPS ≥50% cohort: 84.2% TPS 1-49% cohort: 50%	TPS 1-49%: 42.6% TPS ≥50%: 60.2%	54.8%	70.2%
	mPFS	NA	TPS 1-49%: 8.0m TPS ≥50%: 11.1m	11.2m	NR
	mDoR	NA	TPS 1-49%: 90.4% (DCR) TPS ≥50%: 89.6% (DCR)	20.1m	NR
Safety		Grade ≥3 TRAE 31.9%	≥Grade 3 TRAEs: 29%	SAEs: 12%	Grade ≥3 TEAEs: 55.3%

Abbreviations: IV= intravenous administration; PO= oral administration.
**Note:* Based on non-head-to-head comparisons.
Source: Clinicaltrials.gov, ASCO, Cancer research on prevention and treatment, CIC

The Non-Hodgkin's Lymphoma Market

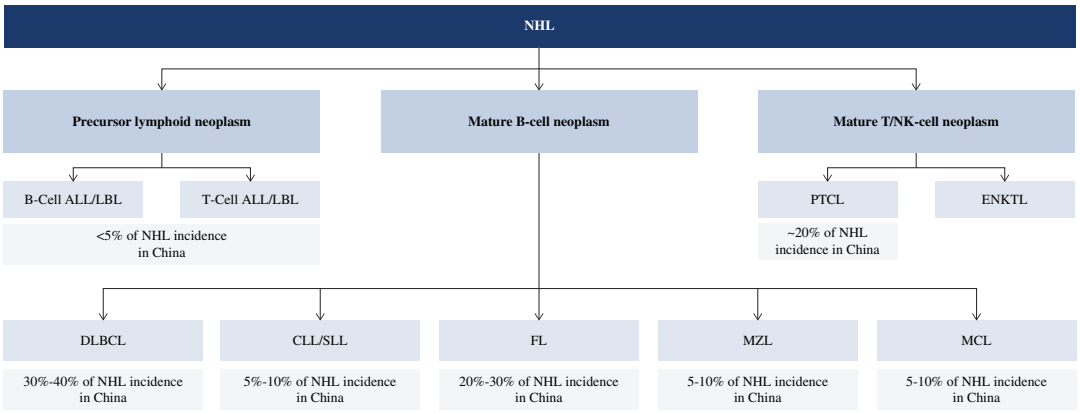
Overview of NHL

Lymphoma is a group of malignant tumors originating from lymphocytes, accounting for around 50% of all hematological malignancies. It is characterized by painless lymph node enlargement, hepatosplenomegaly, and systemic involvement, often accompanied by fever, night sweats, and unexplained weight loss. Lymphomas are classified into non-Hodgkin lymphoma ("**NHL**") and Hodgkin lymphoma ("**HL**"), with NHL accounting for about 80%-90% of cases.

The global prevalence of NHL increased from 2.4 million cases in 2020 to 2.7 million cases in 2025 and is projected to rise to 3.0 million cases in 2035. In China, prevalence increased from 0.4 million cases in 2020 to 0.5 million cases in 2025 and is expected to reach 0.6 million cases in 2035.

Main subtypes and characteristics of NHL

NHL is a heterogeneous group of lymphoid malignancies classified into precursor lymphoid neoplasms, mature B-cell neoplasms, and mature T/NK-cell neoplasms. The following graph illustrates the main subtypes of NHL.



Source: ESMO, NHC, CSCO, CIC

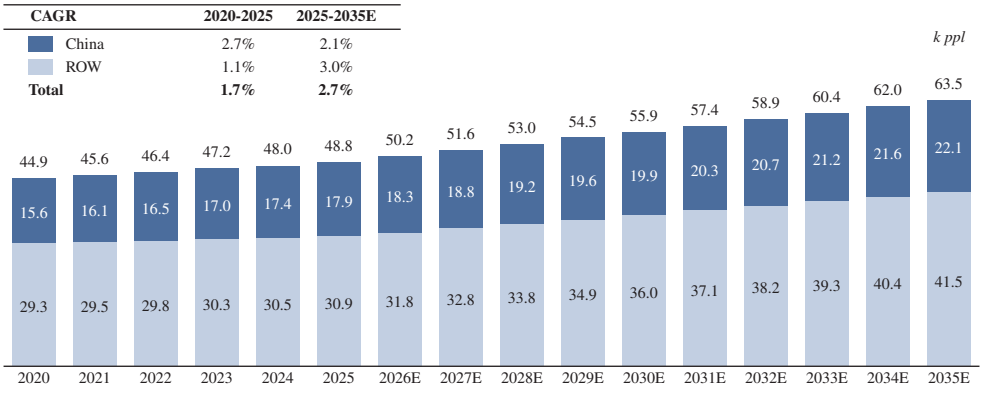
The PTCL Market

Overview of PTCL

PTCL is a highly heterogeneous and aggressive NHL subtype. In China, PTCL accounts for approximately 20% of all NHL cases — significantly higher than in the U.S. (~5%) and globally (~10%). It is characterized by rapid progression, frequent primary refractoriness or early relapse, limited options beyond first-line therapy, and poor long-term outcomes despite intensive chemotherapy. Median OS in r/r PTCL is around 5.8 months, and the 5-year overall survival following first relapse is less than 30%, underscoring the aggressive nature of the disease.

The global incidence of PTCL increased from 68.1 thousand cases in 2020 to 73.9 thousand cases in 2025 and is projected to rise to 96.3 thousand cases in 2035. In China, incidence grew from 23.4 thousand cases in 2020 to 26.8 thousand cases in 2025 and is anticipated to reach 33.2 thousand cases in 2035. The global incidence of r/r PTCL increased from 44.9 thousand cases in 2020 to 48.8 thousand cases in 2025 and is projected to rise to 63.5 thousand cases in 2035. In China, incidence grew from 15.6 thousand cases in 2020 to 17.9 thousand cases in 2025 and is anticipated to reach 22.1 thousand cases in 2035.

Global Incidence of r/r PTCL, 2020-2035E



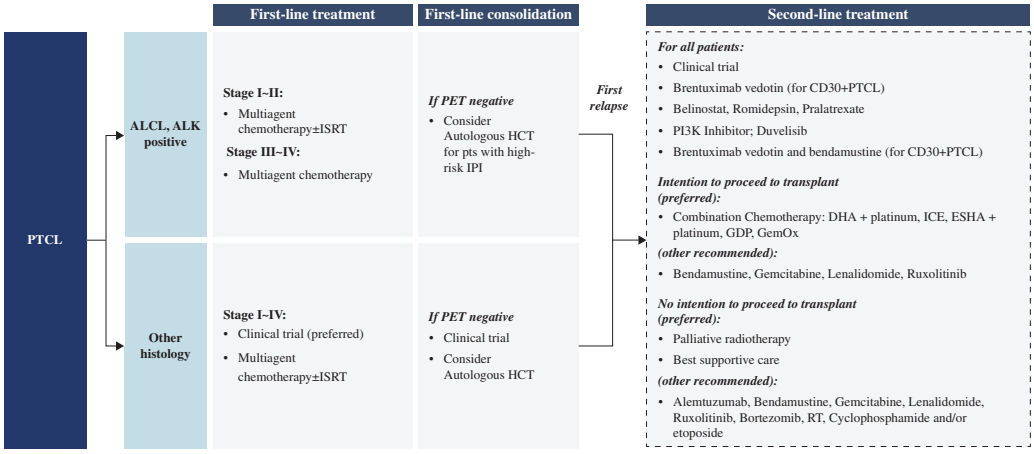
Source: GLOBOCAN, Blood, CIC

Treatment paradigm and unmet needs of PTCL

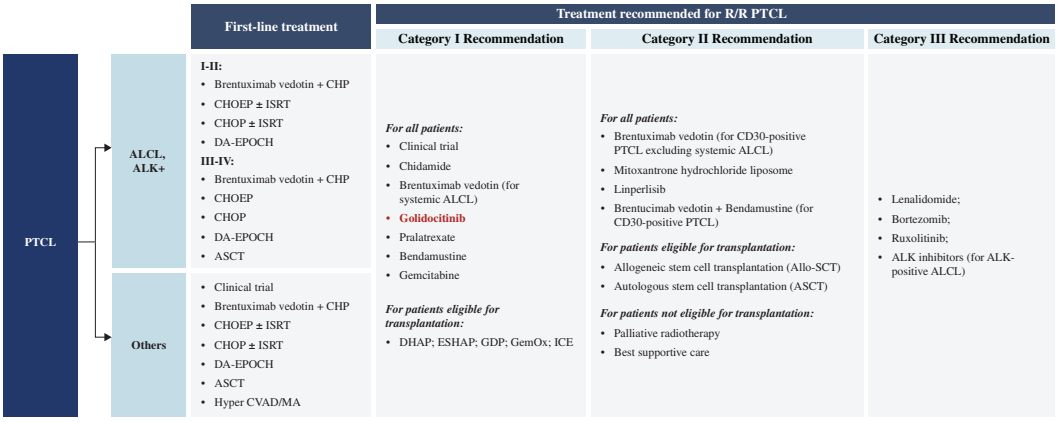
Treatment paradigm for PTCL

Globally and in China, over 95% of newly diagnosed PTCL patients receive first-line treatment, representing 71.7 thousand cases globally and 26.3 thousand cases in China in 2025. Following first-line therapy, approximately 70% of patients who experience disease progression or relapse receive second-line treatment, accounting for 48.8 thousand cases globally and 17.9 thousand cases in China in 2025. The following table sets forth the treatment paradigm for PTCL according to NCCN and CSCO.

Treatment Paradigm for PTCL, NCCN (the U.S.)



Treatment Paradigm for PTCL, CSCO (China)



Source: NCCN, CSCO, CIC

Unmet needs in PTCL

First-line PTCL standard of care remains CHOP -based chemotherapy, though outcomes are poor and most patients relapse. No preferred therapy exists for ALK-negative PTCL due to lack of targeted options. In the r/r setting, treatment is empirical as no standard second-line regimen has been established. Conventional salvage chemotherapy offers limited benefit: an ORR of approximately 20%, a complete response ("**CR**") of approximately 10%, a median PFS of 3.5 months, and an OS of approximately 5.8 months. Prior to 2024, options were largely confined to intravenous single-agent therapies (e.g., HDAC inhibitors, antifolates), with ORRs generally under 30% and no demonstrated survival improvement.

In June 2024, golidocitinib, a highly selective JAK1 inhibitor, was approved in China by the NMPA as the first and only JAK1-selective inhibitor indicated for r/r PTCL, fundamentally changing the treatment paradigm by offering promising efficacy and improved tolerability.

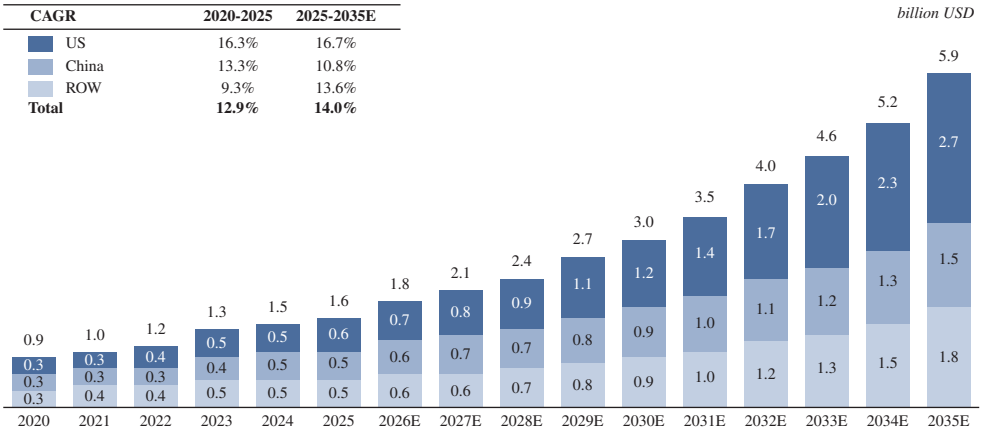
JAK inhibitors for the treatment of PTCL

The JAK family consists of four non-receptor tyrosine kinases (JAK1, JAK2, JAK3, and TYK2) that drive JAK-STAT signaling, playing essential roles in immunity, hematopoiesis, and inflammation. Aberrant JAK-STAT activation is a hallmark of hematological malignancies, particularly in myeloproliferative neoplasms and T-cell lymphomas. Globally, over ten JAK inhibitors have been approved, mostly for I&I indications. In oncology, only golidocitinib have received regulatory approval for the treatment of PTCL.

The market size of PTCL

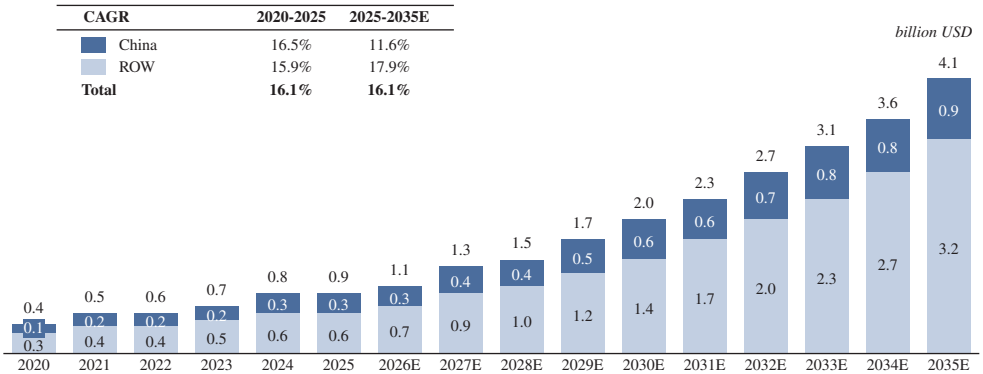
According to CIC, the global PTCL drug market grew from US$0.9 billion in 2020 to US$1.6 billion in 2025 at a CAGR of 12.9%. It is projected to further expand to US$5.9 billion in 2035, representing a CAGR of 14.0% from 2025 to 2035. The market size in China increased from US$0.3 billion in 2020 to US$0.5 billion in 2025 at a CAGR of 13.3%, and is expected to reach US$1.5 billion in 2035, reflecting a CAGR of 10.8% CAGR from 2025 to 2035. The global r/r PTCL market grew from US$0.4 billion in 2020 to US$0.9 billion in 2025, and is expected to increase to US$4.1 billion in 2035, representing a CAGR of 16.1% from 2025 to 2035. The r/r PTCL market in China grew from US$0.1 billion in 2020 to US$0.3 billion in 2025, and is expected to increase to US$0.9 billion in 2035, representing a CAGR of 11.6% from 2025 to 2035.

The PTCL Drugs Market Size, 2020-2035E



Source: NCCN, CSCO, Future Oncology, Drug labels, NHSA, CIC

The r/r PTCL Drugs Market Size, 2020-2035E



Source: NCCN, CSCO, Future Oncology, Drug labels, NHSA, CIC

Global competitive landscape of PTCL treatment

As of the Latest Practicable Date, seven drugs had been approved for PTCL globally, as illustrated below. Golidocitinib is the world's first and only JAK1-selective inhibitor for r/r PTCL, offering a novel therapeutic approach. Clinical data show an ORR of 44% and CRR of 24%, surpassing HDAC inhibitor, folate antagonist and liposomal injection. It achieves a median duration of response of 20.7 months and median OS of 24.3 months, with the lower discontinuation rate of 7.3%, indicating favorable tolerability. Besides, its oral administration enhances patient convenience and compliance.

Global Approved Drugs for PTCL

INN	Brand name	Company	Target	Indication	Combo/Mono	Treatment line	First approval date	NCCN Inclusion	NRDL Inclusion
Pralatrexate	FOLOTYN®	Acrotech Biopharma	DHFR, TS	r/r PTCL	Mono	2L+	FDA: 2009-09-24 NMPA: 2020-08-26	Yes	/
Brentuximab Vedotin	ADCETRIS® 安适利®	Seagen/Takeda	CD30	sALCL or other CD30+ PTCL	Combo Mono	1L 2L+	FDA: 2011-08-19 NMPA: 2020-05-12	Yes	Yes, 2023
Belinostat	BELEODAQ®	Acrotech Biopharma	HDAC	r/r PTCL	Mono	2L+	FDA: 2014-07-03	Yes	/
Chidamide	爱谱沙®	Chipscreen	HDAC	r/r PTCL	Mono	2L+	NMPA: 2014-12-23	/	Yes, 2017
Mitoxantrone Hydrochloride Liposome (Lipo-MIT)	多恩达®	CSPC	TOPOii, DNA/RNA	r/r PTCL	Mono	2L+	NMPA: 2022-01-07	/	Yes, 2023
Golidocitinib	高瑞哲®	Our Company	JAK1	r/r PTCL	Mono	2L+	NMPA: 2024-06-18	/	Yes, 2024
Zeprumetostat	艾瑞璟®	Hengrui	EZH2	r/r PTCL	Mono	2L+	NMPA: 2025-08-26	/	/

Source: FDA, NMPA, CIC

The following table sets forth the comparison of key therapeutic outcomes of major approved therapies for PTCL.

Comparison of Approved Therapies for PTCL

Drug	Golidocitinib	Chidamide	Pralatrexate	Mitoxantrone Hydrochloride
MoA	JAK1 inhibitor	HDAC inhibitor	Folate Antagonist	Liposomal injection
ORR	44%	28%	27%	41%
CRR (Complete Response Rate)	24%	14%	8%	22%
mPFS	5.6 months	2.1 months	3.5 months	7.5 months
mDoR (median Duration of Response)	20.7 months	9.9 months	9.4 months	11 months
mOS	24.3 months	21.4 months	14.5 months	16.3 months
Discontinuation Rate	7.3%	17%	23%	13.7%

Source: Drug labels, The Lancet, Annals of Oncology, J Clin Oncol., ASH, CIC

The CLL/SLL Market

Overview of CLL/SLL

Chronic lymphocytic leukemia ("**CLL**") and small lymphocytic lymphoma ("**SLL**") represent different manifestations of the same mature B-cell clonal malignancy, characterized by morphologically mature but dysfunctional B lymphocytes with identical pathology and immunophenotype. CLL involves peripheral blood and bone marrow, while SLL is primarily nodal with low circulating tumor cells. Despite these differences, they are managed as a single entity (CLL/SLL). CLL/SLL is a major B-cell NHL subtype, accounting for approximately 8% of NHL globally and 15% in the U.S. It is less common in Asia — in China, it represents approximately 5-10% of NHL cases. The global prevalence of CLL/SLL increased from 637.2 thousand cases in 2020 to 734.7 thousand cases in 2025 and is projected to rise to 862.3 thousand cases in 2035. In China, prevalence grew from 30.2 thousand cases in 2020 to 37.1 thousand cases in 2025 and is

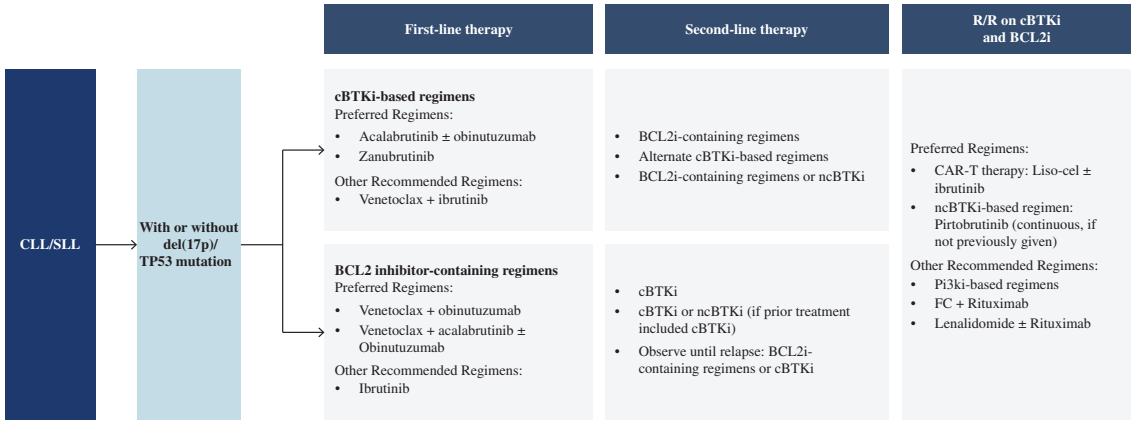
anticipated to reach 49.0 thousand cases in 2035. The global prevalence of r/r CLL/SLL increased from 176.2 thousand cases in 2020 to 203.1 thousand cases in 2025 and is expected to reach 238.4 thousand cases in 2035. In China, prevalence increased from 8.4 thousand cases in 2020 to 10.3 thousand cases in 2025 and is anticipated to reach 13.6 thousand cases in 2035.

Treatment paradigm and unmet needs of CLL/SLL

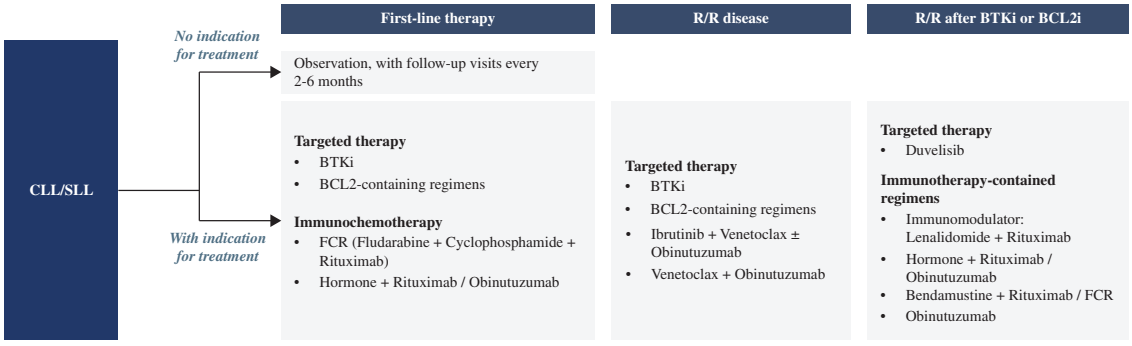
Treatment paradigm for CLL/SLL

The following table sets forth the treatment paradigm for CLL/SLL according to NCCN and CSCO.

Treatment Paradigm for CLL/SLL, NCCN (the U.S.)



Treatment Paradigm for CLL/SLL, CSCO (China)



Abbreviations: cBTKi = Covalent BTK inhibitors; ncBTKi = Non-covalent BTK inhibitors
Source: NCCN, CSCO, CIC

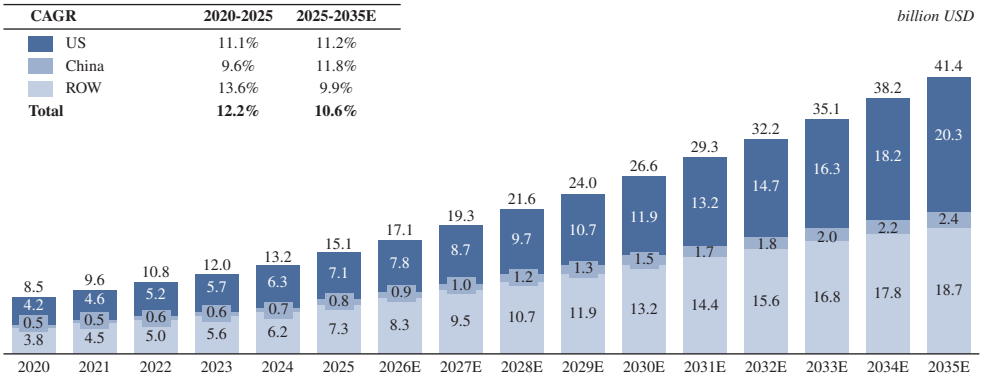
Unmet needs in CLL/SLL

BTK inhibitor-based regimens are foundational in treating CLL/SLL and B-cell NHL by disrupting B-cell receptor ("**BCR**") signaling. However, their durability is often limited by resistance, primarily driven by C481X mutations impairing BTK binding or activation of alternative pathways. Prolonged exposure leads to acquired resistance, highlighting the need for mutation-agnostic frontline strategies. Dual inhibition targeting BTK and upstream kinases like Lyn may offer more comprehensive BCR suppression and address both canonical and compensatory resistance mechanisms.

The market size of CLL/SLL

According to CIC, the global CLL/SLL drug market grew from US$8.5 billion in 2020 to US$15.1 billion in 2025 at a CAGR of 12.2%. It is projected to further expand to US$41.4 billion in 2035, representing a CAGR of 10.6% from 2025 to 2035. China remains a key growth engine, with market size increasing from US$0.5 billion in 2020 to US$0.8 billion in 2025 at a CAGR of 9.6%, and is expected to reach US$2.4 billion in 2035, reflecting a CAGR of 11.8% from 2025 to 2035. The global r/r CLL/SLL drug market grew from US$2.7 billion in 2020 to an estimated US$6.5 billion in 2025 at a CAGR of 19.1%. It is projected to further expand to US$28.8 billion in 2035, representing a CAGR of 16.0% from 2025 to 2035. The market size in China increased from US$0.2 billion in 2020 to US$0.3 billion in 2025 at a CAGR of 16.4%, and is expected to reach US$1.7 billion in 2035, reflecting a CAGR of 17.2% from 2025 to 2035.

The CLL/SLL Drugs Market Size, 2020-2035E



Source: NCCN, CSCO, Drug labels, NHSA, CIC

Global competitive landscape of CLL/SLL treatment

As of the Latest Practicable Date, five BTK inhibitors had been approved for CLL/SLL globally, among which only pirtobrutinib binds to the ATP pocket of BTK in a reversible, non-covalent manner. As of the same date, there were six BTK inhibitors for CLL/SLL had advanced to Phase 2 clinical development or beyond globally, as illustrated below.

Global Approved BTK inhibitors for CLL/SLL

INN	Brand Name	Company	Target	Binding mode	Indication	First Approval Date	NRDL
Ibrutinib	IMBRUVICA® 亿珂®	Janssen	BTK	Covalent	CLL/SLL ± 17p deletion, MCL, WM, cGVHD	2013/11 FDA 2018/01 NMPA	YES
Acalabrutinib	CALQUENCE® 康可期®	AstraZeneca	BTK	Covalent	CLL/SLL, MCL	2017/10 FDA 2023/03 NMPA	YES
Zanubrutinib	BRUKINSA® 百悦泽®	BeiGene	BTK	Covalent	CLL/SLL, MCL, WM, FL, MZL	2019/11 FDA 2020/06 NMPA	YES
Orelabrutinib	Innobruka® 宜诺凯®	InnoCare	BTK	Covalent	CLL/SLL, MCL, MCL	2020/12 NMPA	YES
Pirtobrutinib	JAYPIRCA® 捷帕力®	Eli Lilly	BTK	Non-Covalent	CLL/SLL, MCL	2023/01 FDA 2024/10 NMPA	YES

Source: FDA, NMPA, CIC

Global BTK Inhibitors Under Clinical Development for CLL/SLL (Phase 2 or beyond)

Drug	Company	Target	Drug Type	Indication	Treatment Line	Mono/Combo	Clinical Stage	First Posted Date	Location
MK-1026 Nemtabrutinib	Merck	BTK	ncBTKi	CLL/SLL	1L	Mono	3	2022-11-22	Global
BGB-16673	BeOne	BTK	Degrader	r/r CLL/SLL	2L+	Mono	3	2025-02-26	Global
				CLL/SLL	1L	Combo	2	2026-04-03	The U.S.
Birelentinib (DZD8586)	Our Company	LYN/BTK	Dual inhibitor	r/r CLL/SLL	2L+	Mono	3	2025-08-24	China
				CLL/SLL	1L	Combo	2	2025-09-04	China
HBW-3220	Hyperway	BTK	ncBTKi	r/r CLL/SLL	2L+	Mono	3	2025-12-05	China
LP-168	Lupeng	BTK	cBTKi and ncBTKi	r/r CLL/SLL	2L+	Mono	3	2026-01-15	Global
				r/r CLL/SLL	2L+	Combo	2	2026-05-27	China
NX-5948 Bexobrutideg	Nurix/Roche	BTK	Degrader	r/r CLL/SLL	2L+	Mono	3	2026-04-07	Not publicly available

Abbreviations: cBTKi = Covalent BTK inhibitor; ncBTKi = Non-covalent BTK inhibitor
Source: Clinicaltrials.gov, CDE, CIC

The DLBCL Market

Overview of DLBCL

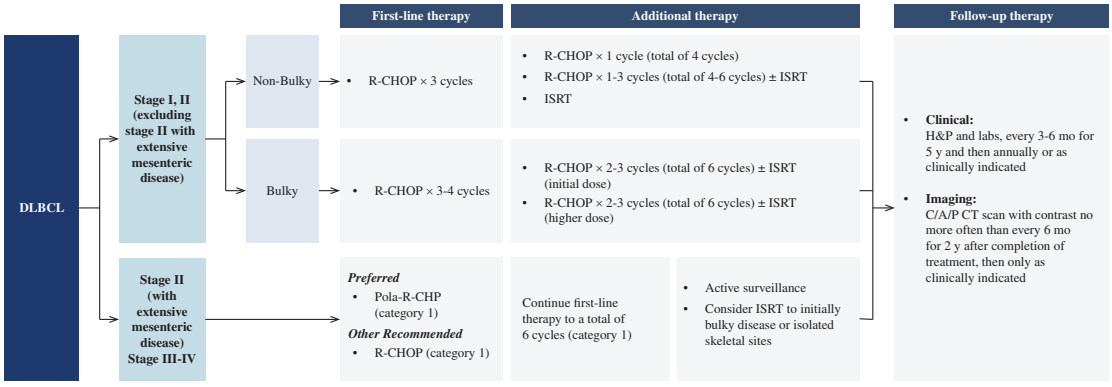
Diffuse large B-cell lymphoma ("**DLBCL**") is an aggressive malignancy arising from mature B cells, characterized by diffuse infiltration of large atypical B cells. It is the most common NHL subtype worldwide. Biologically heterogeneous, it is classified into germinal center B-cell-like ("**GCB**") and non-GCB subtypes based on cell-of-origin. GCB arises from germinal center B cells and is associated with more favorable outcomes. Non-GCB subtype (including activated B-cell-like, or ABC) features chronic B-cell receptor and NF-κB activation, inferior prognosis, and higher relapse rates, accounting for approximately 50-60% of cases. There is a significant unmet need for small-molecule therapies in DLBCL. BTK inhibitors show activity primarily in non-GCB but limited efficacy in GCB. Besides, the 5-year cumulative incidence rate for r/r DLBCL is 20%, with subsequent salvage chemotherapy yielding an ORR of only 30% and a CR rate of just 9%. Median survival is only 5.9 months, with a 2-year OS rate of merely 16%. The global prevalence of DLBCL increased from 809.0 thousand cases in 2020 to 936.8 thousand cases in 2025 and is projected to rise to 1,113.2 thousand cases in 2035. In China, prevalence grew from 160.1 thousand cases in 2020 to 199.4 thousand cases in 2025 and is anticipated to reach 269.5 thousand cases in 2035. The global number of new r/r DLBCL patients increased from 85.3 thousand cases in 2020 to 106.0 thousand cases in 2025 and is expected to reach 167.1 thousand cases in 2035. In China, number of new r/r DLBCL cases increased from 14.6 thousand cases in 2020 to 19.2 thousand cases in 2025 and is anticipated to reach 30.2 thousand cases in 2035.

Treatment paradigm and unmet needs of DLBCL

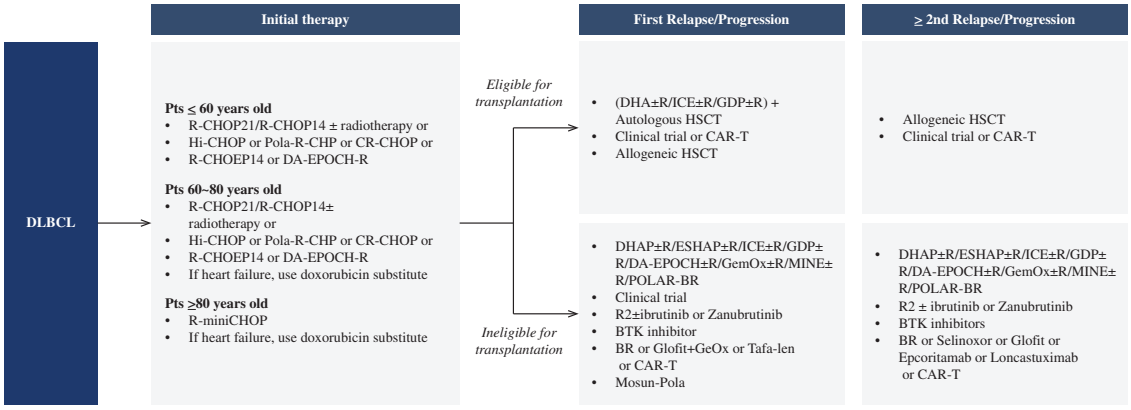
Treatment paradigm for DLBCL

The following table sets forth the treatment paradigm for DLBCL according to NCCN and CSCO.

Treatment Paradigm for DLBCL, NCCN (the U.S.)



Treatment Paradigm for DLBCL, CSCO (China)



Source: NCCN, CSCO, CIC

Unmet needs in DLBCL

R-CHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone) remains the frontline standard of care for newly diagnosed DLBCL, but 30-50% of patients experience refractory disease or relapse — 15%-25% are refractory during treatment, and 20%-30% relapsing after achieving complete response. Second-line regimens followed by ASCT are commonly used, but most patients are ineligible. Those who are second-line refractory or relapse after ASCT have poor outcomes: a median OS of 5-8 months and an ORR of just 26%.

Overall, the market remains heavily reliant on biologics that offer limited efficacy, while cell therapies face accessibility barriers. No small-molecule targeting Lyn/BTK or BCR signaling is approved specifically for DLBCL. While a few BTK inhibitors show efficacy in non-GCB DLBCL, GCB subtypes remains underserved. This leaves significant space for differentiated oral agents capable of delivering broad and durable efficacy across both non-GCB and GCB DLBCL.

The market size of DLBCL

According to CIC, the global DLBCL drug market grew from US$3.3 billion in 2020 to an estimated US$7.2 billion in 2025 at a CAGR of 16.7%. It is projected to further expand to US$24.9 billion in 2035, representing a CAGR of 13.3% from 2025 to 2035. The market size in China increased from US$0.6 billion in 2020 to US$1.4 billion in 2025 at a CAGR of 19.2%, and is expected to reach US$4.3 billion in 2035, reflecting a CAGR of 12.3% from 2025 to 2035. The global r/r DLBCL drug market grew from US$1.4 billion in 2020 to an estimated US$3.3 billion in 2025 at a CAGR of 19.5%. It is projected to further expand to US$11.5 billion in 2035, representing a CAGR of 13.3% from 2025 to 2035. The market size in China increased from US$0.2 billion in 2020 to US$0.6 billion in 2025 at a CAGR of 22.1%, and is expected to reach US$2.0 billion in 2035, reflecting a CAGR of 12.3% from 2025 to 2035.

Global competitive landscape of DLBCL treatment

As of the Latest Practicable Date, no BTK inhibitor had been approved for DLBCL globally. As of the same date, there were six BTK inhibitors under Phase 2 or later stage for DLBCL, as illustrated below.

Global BTK pipelines for DLBCL (phase 2 and beyond)

Drug	Company	Target	Indication	Treatment Line	Mono/Combo	Clinical Stage	First Posted Date	Location
Acalabrutinib	Acerta Pharma	BTK	ND non-GCB DLBCL	1L	Combo with R-CHOP	3	2020-08-28	Global
HMPL-760	Hutchmed	BTK	r/r DLBCL	2L+	Combo with R-GemOx	3	2025-12-05	China
Birelentinib (DZD8586)	Our Company	LYN/BTK	r/r DLBCL	2L+	Mono/Combo	1/2	2024-08-06	China
			DLBCL	1L	Combo with R-CHOP	1b/2	2025-06-05	China
TQB3702	Chia Tai-tianqing	BTK	r/r DLBCL	2L+	Combo	2	2024-08-21	China
LP-168	Lupeng	BTK	r/r non-GCB DLBCL	2L+	Mono	2	2025-09-19	China
			ND non-GCB DLBCL	1L	Combo with R-CHOP	1b	2024-02-09	China
Poseltinib	Hanmi Pharmaceuticals	BTK	r/r DLBCL	2L+	Combo	1/2	2025-12-08	Global excl. the U.S. and China

Source: Clinicaltrials.gov, CDE, CIC

THE INFLAMMATION & IMMUNOLOGY THERAPEUTICS MARKET

Overview

Inflammatory & immunology ("**I&I**") diseases are conditions in which the immune system malfunctions, attacking healthy tissues and causing chronic inflammation and tissue damage, including autoimmune diseases and allergies. These disorders affect an estimated 50-80 million people globally, representing 5%-10% of the world population. Prevalence is higher in developed nations and rising in developing countries.

The Market Size of I&I

According to CIC, the global I&I drug market grew from US$131.3 billion in 2020 to US$232.3 billion in 2025 at a CAGR of 12.1%. It is projected to further expand to US$428.4 billion in 2035, representing a CAGR of 6.3% from 2025 to 2035. The market size in China increased from US$5.1 billion in 2020 to US$13.4 billion in 2025 at a CAGR of 21.1%, and is expected to reach US$42.0 billion in 2035, reflecting a CAGR of 12.1% from 2025 to 2035.

The BTK and JAK Inhibitors Market for the Treatment of I&I Disease

Mechanism and future potential of BTK inhibitors

BTK is a cytoplasmic Tec family kinase expressed in B cells and myeloid lineage cells, but not in T cells, plasma cells, or NK cells. It plays a central role in BCR signaling, Fc-γreceptor mediated immune activation, and osteoclast-driven osteogenesis. BTK inhibition thus suppresses B cell proliferation, inflammatory cytokine release, and B cell maturation-making it a cornerstone in treating hematologic malignancies and inflammatory diseases.

Future potential lies in expanding clinical applications through improved selectivity and safety. Next-generation BTK inhibitors with enhanced kinase selectivity and optimized profiles aim to reduce off-target effects and enable chronic use in non-oncologic settings, as seen with emerging I&I indications like rilzabrutinib in ITP.

Mechanism and future potential of JAK inhibitors

JAK inhibitors are oral small molecules that target JAK1, JAK2, JAK3, and TYK2, blocking JAK-STAT signaling downstream of multiple pro-inflammatory cytokines. This produces broad anti-inflammatory and immunosuppressive effects across diseases such as rheumatoid arthritis, atopic dermatitis ("**AD**"), and inflammatory bowel disease ("**IBD**"). Development has evolved from non-selective to more selective inhibitors to reduce off-target effects like JAK2-associated myelosuppression.

In AD, JAK inhibitors enable oral targeting of type 2 inflammation and itch pathways (e.g., IL-4/IL-13, IL-31). Agents like upadacitinib and abrocitinib provide rapid itch relief and skin clearance, even in patients with inadequate response to topical therapies or biologics. Ongoing efforts focus on selective JAK inhibition and optimized dosing for long-term disease control. In IBD, JAK inhibitors offer oral modulation of multiple cytokine pathways driving chronic intestinal inflammation. Tofacitinib, filgotinib, and upadacitinib have shown efficacy in ulcerative colitis, and upadacitinib in Crohn's disease, addressing unmet needs in biologic-refractory patients. Further refinement of isoform selectivity aims to enhance efficacy and safety in long-term management.

The ITP Market

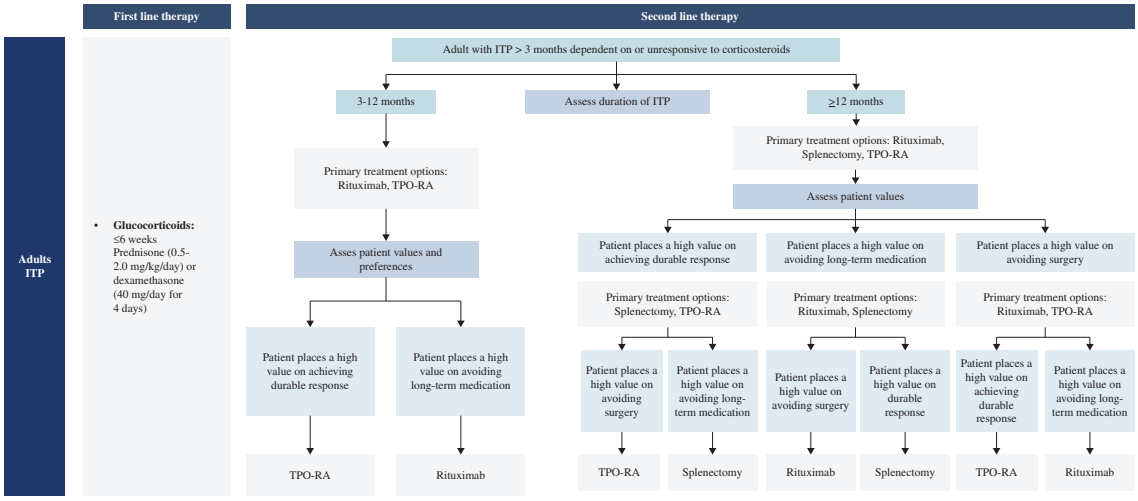
Disease overview of ITP

Primary immune thrombocytopenia ("**ITP**") is an acquired autoimmune bleeding disorder characterized by low platelet counts resulting from immune-mediated platelet destruction and impaired platelet production. It arises from a loss of immune tolerance to platelet autoantigens, driving both humoral and cellular dysregulation. Central to its pathogenesis are pathogenic anti-platelet autoantibodies targeting glycoproteins such as GPIIb/IIIa or GPIb/IX. The global prevalence of ITP increased from 1,283.9 thousand cases in 2020 to 1,487.7 thousand cases in 2025 and is projected to rise to 1,887.2 thousand cases in 2035. In China, prevalence grew from 234.5 thousand cases in 2020 to 294.6 thousand cases in 2025 and is anticipated to reach 449.7 thousand cases in 2035. The global prevalence of 2L/2L+ ITP patients increased from 577.8 thousand cases in 2020 to 669.5 thousand cases in 2025, and is expected to reach 849.2 thousand cases in 2035. In China, the prevalence of 2L/2L+ ITP patients increased from 105.5 thousand cases in 2020 to 132.6 thousand cases in 2025 and is anticipated to reach 202.4 thousand cases in 2035.

Treatment paradigm for ITP

The treatment of ITP follows the principle of individualized therapy, encouraging patient involvement in decision-making.

Treatment Paradigm for ITP



Source: ASH 2019, CIC

Unmet needs in ITP

Durable disease control remains a key challenge in ITP. Current options lack durable responses: rituximab effects are transient, TPO-RAs require continuous use, and splenectomy is invasive. There is a need for non-surgical therapies that provide lasting platelet control without long-term treatment dependence.

The market size of ITP

The global ITP drug market grew from US$2.0 billion in 2020 to US$3.0 billion in 2025 at a CAGR of 7.4%. It is projected to further expand to US$7.2 billion in 2035, representing a CAGR of 9.7% from 2025 to 2035. The market size in China increased from US$0.2 billion in 2020 to US$0.5 billion in 2025 at a CAGR of 15.4%, and is expected to reach US$1.3 billion in 2035, reflecting a 11.3% CAGR from 2025 to 2035. The global 2L/2L+ ITP drug market grew from US$1.9 billion in 2020 to an estimated US$2.9 billion in 2025 at a CAGR of 8.8%. It is projected to further expand to US$7.1 billion in 2035, representing a CAGR of 9.4% from 2025 to 2035. The market size in China increased from US$0.2 billion in 2020 to US$0.4 billion in 2025 at a CAGR of 14.9%, and is expected to reach US$1.3 billion in 2035, reflecting a CAGR of 12.5% from 2025 to 2035.

Global competitive landscape of ITP treatment

As of the Latest Practicable Date, only one BTK inhibitor — Wayrilz® — had been approved for ITP globally. As of the same date, there were six BTK inhibitors under clinical development for ITP globally, as illustrated below.

Global Approved BTK Inhibitors for ITP

Drug	Brand name	Company	Target	Indication	First approval date
Rilzabrutinib	Wayrilz®	Sanofi	BTK	Persistent or chronic ITP who have had an insufficient response to a previous treatment	FDA: 2025-08-29

Global BTK Inhibitors Under Clinical Development for ITP

Drug	Company	Target	Indication	Clinical Stage	First Posted Date	Location
Orelabrutinib	InnoCare	BTK	Chronic ITP	NDA	2026-05-29	China
CX1440	Biosun Pharma	BTK	ITP	3	2023-07-17	China
Rilzabrutinib	Sanofi	BTK	ITP	3	2025-10-24	China
HZ-A-018	Healzentx	BTK	Persistent or chronic ITP	2	2025-08-22	China
Birelentinib (DZD8586)	Our Company	LYN/BTK	ITP	2	2025-12-12	China
Pirtobrutinib	Eli Lilly	BTK	ITP	1/2	2024-12-06	Global

Source: FDA, Clinicaltrials.gov, CDE,CIC

As of the Latest Practicable Date, there were neither JAK inhibitors approved nor any under industry-sponsored clinical development for ITP globally.

REPORT COMMISSIONED BY CIC

In connection with the [**REDACTED**], we have engaged CIC to conduct a detailed analysis and prepare an industry report on the major markets for which our drug candidates are positioned. CIC is an independent global market research and consulting company that provides market research on a variety of industries including biotechnology. We have agreed to pay CIC a total fee of RMB0.6 million for the preparation of the CIC Report, and we believe that such fees are consistent with the market rate. The payment of such amount was not contingent upon our successful [**REDACTED**] or on the results of the CIC Report. Except for the CIC Report, we did not commission any other industry report in connection with the [**REDACTED**].

The market projections in the CIC Report were based on the following key assumptions: (i) the overall social, economic and political environment in China is expected to remain stable during the forecast period; (ii) China's economic and industrial development is likely to maintain a steady growth trend over the next decade; (iii) related key industry drivers are likely to continue driving the growth of the market during the forecast period; and (iv) there is no extreme force majeure or industry regulation in which the market may be affected dramatically or fundamentally. The reliability of the CIC Report may be affected by the accuracy of the foregoing key assumptions.

The Directors and the Joint Sponsors have exercised reasonable care in selecting and identifying the named information sources, compiling, extracting and reproducing the information, confirm that to the best of their knowledge and belief, there are no material omissions of the information. After making reasonable inquiries, our Directors confirm that, to the best of their knowledge, there has been no detrimental change in the market information demonstrated in the CIC Report since the date of the report that may qualify, contradict or have an impact on the information in this Document, including, in particular, the information set out in the Industry Overview section.