***The information and statistics set out in this section and other sections of this document were extracted from the CIC Report prepared by CIC, which was commissioned by us, and from various official government publications and other publicly available publications. We engaged CIC to prepare the CIC Report, an independent industry report, in connection with the* [REDACTED]. *The information from official government sources has not been independently verified by us, the Sole Sponsor,* [REDACTED]*, any of their respective directors, employees, agents or advisers, or any other person or party involved in the* [REDACTED].**

GLOBAL AND CHINA HEMATOLOGIC MALIGNANCY MARKET

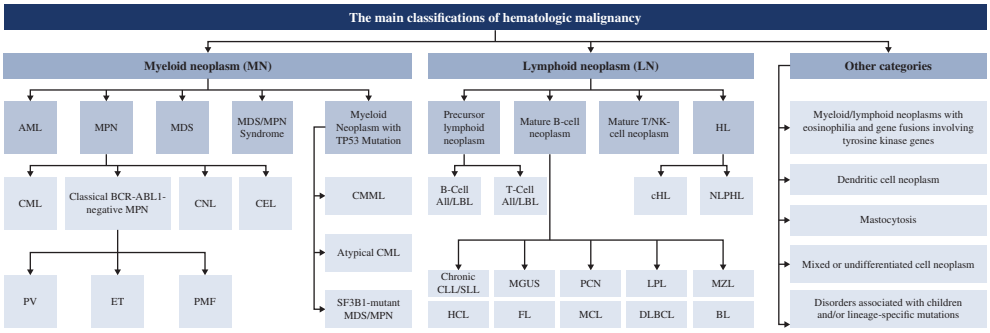
Overview of the Hematologic Malignancy

Hematologic malignancies (HMs) are cancers that arise from blood-forming tissues such as the bone marrow or from immune system cells, resulting from abnormal differentiation of hematopoietic stem cells (HSCs), which are responsible for producing all blood cell types via myeloid and lymphoid lineages.

The hematologic cancer landscape comprises three types with distinct therapeutic needs and growth trajectories: (i) lymphomas are cancers of the lymphatic system, with Hodgkin's lymphoma characterized by the presence of rare Hodgkin and Reed-Sternberg (HRS) cells derived from Epstein — Barr virus-positive B cells featuring mutated immunoglobulin genes; (ii) multiple myeloma is a B-cell cancer marked by the uncontrolled growth of mutated plasma cells, driven by genetic alterations such as mutations in KRAS, NRAS, BRAF, and FAM46C, which lead to abnormal proliferation and bone marrow damage; and (iii) leukemias are blood cancers characterized by the rapid production of immature blood cells in acute forms, while chronic leukemias progress more slowly, with chronic myeloid leukemia (CML) affecting stem cells differentiating into myeloid cells, and chronic lymphocytic leukemia (CLL) targeting B or T lymphocytes.

Epidemiology of HM

HM collectively represent a substantial and growing global health burden. In 2025, the global prevalence of HM amounted to 5.7 million, which is expected to grow to 6.7 million in 2035 at a CAGRs of 1.8% from 2026 to 2030 and 1.5% from 2031 to 2035. In China, in 2025, the prevalence of HM amounted to 1.0 million, which is expected to steadily grow to 1.2 million in 2035. In U.S., in 2025, the prevalence of HM amounted to 1.0 million, which is expected to steadily grow to 1.1 million in 2035. Hematologic malignancies are a diverse and complex group of neoplasms that originate from hematopoietic or lymphoid tissues, primarily affecting the blood, bone marrow, and lymph nodes. These malignancies are broadly characterized by the uncontrolled proliferation of abnormal blood cells, which interferes with the production and function of healthy blood cells.



Source: Globocan, CIC

Non-Hodgkin lymphoma (NHL) is a major group of blood cancers arising from lymphocytes, key white blood cells in the immune system. It includes numerous B-cell and T-cell subtypes that can occur in lymph nodes or extranodal sites such as the gastrointestinal tract, bone marrow, liver, and central nervous system. In 2025, the global prevalence of non-hodgkin lymphoma cases amounted to 2.7 million, increasing from 2.5 million in 2021, and is expected to reach 3.0 million in 2035. In China, the prevalence of non-hodgkin lymphoma cases amounted to 0.5 million in 2025, increasing from 0.4 million in 2021 and is expected to reach 0.6 million in 2035. In U.S., the prevalence of NHL amounted to 0.4 million in 2025, increasing from 0.3 million in 2021 and is expected to reach 0.5 million in 2035.

Market Size of HM Drugs

Benefiting from the transformation of the treatment paradigm for HM, the global HM drug market has shown sustained growth, rising from US$33.4 billion in 2021 to US$60.7 billion in 2025, at a CAGR of 12.6%. The market is projected to maintain its growth with CAGRs of 9.9% from 2026 to 2030 and 7.7% from 2031 to 2035, with the market size expected to reach US$143.8 billion by 2035. In China, driven the approval of novel therapeutics targeting HM and the improved survival rate the hematologic malignancy drug market in China has experienced rapid expansion, doubling from RMB22.3 billion in 2021 to RMB45.0 billion in 2025 at a CAGR of 15.8%. This strong growth trend is expected to continue with CAGRs of 13.6% from 2026 to 2030 and 11.2% from 2031 to 2035, reaching RMB148.4 billion in 2035.

Market Drivers and Future Trends of HM Drugs

Next-generation targeted therapy advancements. Ongoing research into novel molecular targets and therapeutic platforms, including the continuous iteration of small-molecule drug design aimed at improving safety and efficacy profiles, continues to yield clinical breakthroughs. Emerging modalities demonstrate promising efficacy in refractory settings, driving market growth through expanded treatment options with improved therapeutic indices.

Combination therapy as a market growth catalyst. Rational drug combinations leveraging synergistic mechanisms, particularly BTK inhibitors with Bcl-2 inhibitors or immunotherapies, have demonstrated enhanced clinical responses, broader indication coverage, and delayed resistance development. These optimized regimens are establishing new standards of care while creating substantial market opportunities through increased treatment duration and expanded patient eligibility.

Increasing treatment demand and a chronic disease management paradigm shift. The growing incidence of hematologic malignancies, driven by population aging and environmental factors, has created substantial medical needs. A notable share of patients also develop refractory or relapsed disease. The advent of breakthrough targeted therapies has significantly improved clinical outcomes, transforming many hematologic cancers into chronic conditions. This therapeutic evolution has generated sustained demand for effective targeted agents among long-term survivors seeking both survival benefits and quality-of-life improvements.

Policy support for drug development and commercialization. Regulatory advancements have accelerated the development and commercialization of novel hematologic oncology drugs. For example, the Notice on Strengthening Medical Care and Guarantee for Children with Hematological Malignancies, jointly issued by five ministries, requires the establishment of a national network for the diagnosis and treatment of pediatric hematological malignancies, promotes unified clinical standards, and improves referral and multidisciplinary management mechanisms. The policy also strengthens drug-supply guarantee for key oncology medicines and directs regulatory authorities to prioritize review and approval for urgently needed pediatric drugs, thereby improving treatment accessibility and standardization for hematological malignancies. The Healthy China 2030 blueprint sets national strategic goals to elevate the overall quality, safety, and accessibility of medicines and medical devices.

GLOBAL AND CHINA BTK INHIBITOR MARKET

Introduction to BTK Inhibitor

Bruton's tyrosine kinase (BTK), a cytoplasmic member of the Tec family of non-receptor tyrosine kinases, is expressed in B cells and cells of myeloid lineage but absent in T cells, plasma cells, and natural killer cells. It plays a central role in three independent pathways: B cell activation through BCR signaling, immune complex-mediated monocyte and macrophage activation via Fc-γ receptor signaling (driving cytokine production such as IL-1β, IL-6, and TNF-α), and osteogenesis through osteoclast expansion. Mechanistically, BTK activation upon antigen recognition initiates PLC-γ signaling, leading to NFκB and MAPK pathway activation, transcriptional reprogramming, and subsequent B cell proliferation and differentiation. Inhibition of BTK therefore impairs B cell growth, suppresses inflammatory cytokine release, and interferes with IL-21-mediated B cell maturation. These key functions have made BTK inhibition a cornerstone in treating hematologic malignancies and inflammatory diseases.

Advantages of BTK Inhibitors

The treatment landscape of B-cell malignancies has evolved to include multiple therapeutic modalities, including BTKi, CAR-T, ADCs, bsAbs and other emerging targeted approaches, as reflected in clinical studies and treatment guidelines. Among these, BTKi represent a well-established class of therapy and are widely used across multiple treatment settings in certain indications, supported by their oral administration, relatively manageable safety profiles and established clinical experience in long-term use. In contrast, CAR-T and bsAbs have demonstrated high response rates in R/R patients in clinical trials, but are generally associated with more complex safety management, including risks such as cytokine release syndrome, as well as higher treatment costs and more limited accessibility. ADCs deliver cytotoxic agents through targeted mechanisms and have shown clinical activity in later-line settings, although their use may be associated with treatment-related toxicities and may depend on antigen expression. Emerging modalities such as molecular glue degraders and HDAC inhibitors are currently under clinical investigation and may provide additional options for patients with limited treatment alternatives. Overall, while different therapeutic approaches exhibit differentiated clinical profiles and are used in distinct treatment settings, BTKi are expected to remain an important and widely used component of treatment paradigms in certain disease settings.

Development of BTK Inhibitors

BTK inhibitors are classified by binding mechanism: covalent (irreversible) or non-covalent (reversible). Non-covalent inhibitors reversibly bind the ATP pocket independently of C481, using multiple contacts for potency against wild-type and mutant BTK. This offers improved selectivity (reducing off-target toxicity), retained activity against the key resistance mutation, and dosing flexibility. Their development addresses unmet needs in covalent-failure patients, enhances tolerability, and supports earlier-line use, expanding opportunities in this key therapeutic area. The BTK inhibitor class has evolved through four distinct generations, each addressing limitations of prior agents while expanding therapeutic potential and market opportunities. The following table sets forth the main characteristics of four generations of BTK inhibitors.

BTK inhibitor generations comparison

Parameter	1st Generation	2nd Generation	3rd Generation	4th Generation
Representative Drug	**Ibrutinib**	**Acalabrutinib, Zanubrutinjb Orelabrutinib**	**Pirtobrutinib**	**Rocbrutinib (LP-168)**
Binding Mode	covalent	covalent	non-covalent	Covalent & non-covalent
Oral Bioavailability	Low	Moderate	High	High
Half-Life	4-6h	1-4h	~19h	~17h
Target Selectivity	Poor	Moderate	Moderate	Excellent
Toxicity (TRAE Discontinuation Rate)	Very High (12%-32%)	Moderate (10%-23%)	Moderate (6%)	Low (0.7%)
Majormechanism of resistance	C481x, L528W	C481x, L528W	T474I, L528W, etc.	Not reported
Status	Approved	Approved	Approved	NDA filed
List price (per 100mg)	~RMB120	~RMB95-200	~RMB215	-

Sources: CSCO, RESONATE(2) trial, ASCEND trial, BRUIN trial, CIC

First-generation BTK inhibitors established clinical efficacy but suffered from off-target toxicity, while second- and third-generation agents improved selectivity and overcame resistance, enhancing safety, efficacy, and treatment options for a broader patient population. The next generation of BTK inhibitors, exemplified by LP-168, represents a novel engineering approach that combines both covalent & non-covalent binding mechanisms within a single molecule, potentially offering the sustained target occupancy of irreversible inhibitors while maintaining activity against C481S mutations through reversible binding interactions. Unlike earlier BTK inhibitors, LP-168 engages BTK at distinct binding sites, enabling dual-site modulation that may further enhance inhibitory potency and resistance coverage. This dual-mechanism design aims to overcome the binary limitations of previous generations by providing multiple modes of BTK engagement, thereby potentially preventing or delaying resistance development while maintaining selectivity. However, the potential clinical advantages of LP-168 remain to be definitively demonstrated and validated through the results of our ongoing and future clinical trials. Furthermore, even if regulatory approval is obtained, the ultimate commercial success of LP-168 will depend heavily on successful pricing negotiations and the effective execution of our marketing and commercialization efforts.

Resistance to BTK Inhibitors

The emergence of resistance to BTKi therapy varies by disease type based on published clinical studies of currently approved BTK inhibitors, including ibrutinib, acalabrutinib and other agents in the class. In R/R MCL, clinical studies of BTKi have reported overall response rates of approximately 60%-80%, suggesting that approximately 20%-40% of patients may exhibit primary resistance. Among responders, median duration of response of approximately 20-26 months and 24-month response rates of around 50% indicate that approximately half of the patients may develop acquired resistance within two years of treatment. In treatment-naïve CLL/SLL, BTKi have demonstrated high overall response rates of above 95%, suggesting a low level of primary resistance of generally less than 5%. Long-term follow-up data show sustained responses, with approximately 90%-95% of patients remaining progression-free at four years, indicating a low rate of acquired resistance over time[1]. In R/R CLL/SLL, BTKi have demonstrated overall response rates of approximately 90%, suggesting that approximately 10% of patients may exhibit primary resistance. Median progression-free survival of approximately 40-50 months indicates that acquired resistance develops gradually over time, with approximately 40-60% of patients experiencing disease progression over 3 years. The mDoR for BTK inhibitors is often not reached in CLL/SLL clinical studies, reflecting the durable responses observed in a large proportion of patients.

In R/R MZL, clinical studies of BTKi have reported overall response rates of approximately 45%-60%, suggesting that approximately 40%-55% of patients may exhibit primary resistance and among responders, mDoR of around 30 months indicates that disease progression occurs gradually over time, with approximately one third of patients developed resistance within one to two years of treatment. In R/R DLBCL, BTK inhibitors demonstrate relatively modest activity with overall response rates of approximately 40% in non-GCB subtype, suggesting that approximately 60% of patients may exhibit primary resistance. Among responders, responses are typically short-lived, and Kaplan-Meier curves show that progression-free survival declines rapidly over time, with only a small proportion of patients, generally less than 20%, remaining progression-free beyond 6 months, suggesting that the majority of patients experience disease progression within this period[2]. This limited durability largely reflects the limited dependence of many tumors on B-cell receptor signalling, rather than a clearly attributable BTKi-specific resistance mechanism.

Indications and Treatment Pathways for BTK Inhibitors

BTK plays an important role in B cell regulation, making it a strong candidate for targeted inhibition of B cells in a number of inflammatory diseases, including rheumatoid arthritis. In oncology, BTK inhibitors have received regulatory approvals across multiple B-cell malignancies, including MCL, CLL/SLL, DLBCL and MZL, among others.

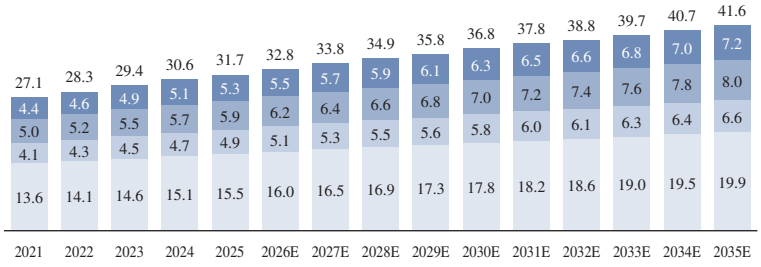
MCL

Mantle Cell Lymphoma (MCL) is a type of aggressive B-cell lymphoma that requires tailored treatment based on patient fitness and disease stage. The disease's dependence on BCR-mediated survival signals makes it exceptionally responsive to BTK inhibition. The prevalence of MCL in China increased from 27.1 thousand people in 2021 to 31.7 thousand in 2025, representing a CAGR of 4.0%, and is expected to reach 41.6 thousand by 2035, corresponding to CAGRs of 2.9% from 2026 to 2030 and 2.4% from 2031 to 2035. The prevalence of MCL in US increased from 16.6 thousand people in 2021 to 19.8 thousand in 2025, representing a CAGR of 4.5%, and is expected to reach 26.0 thousand by 2035, corresponding to a CAGR of 3.2% from 2026 to 2030 and 2.2% from 2031 to 2035. In MCL, the five-year survival rate is generally reported at approximately 30%, and treated patients may achieve a median overall survival of approximately 6 years. This represents a stable and durable addressable patient population for BTK inhibitors, driven by the need for long-term treatment management. At diagnosis, approximately 75-85% of patients present with advanced-stage disease (Stage III-IV). In real-world practice, nearly 70% of patients are younger than 65 years and may be considered eligible for autologous stem cell transplantation ("**ASCT**"); however, fewer than 25% of these patients ultimately undergo ASCT due to fitness, comorbidities, or treatment-related considerations.

China prevalence of MCL, 2021-2035E

CAGR	2021-2025	2026E-2030E	2031E-2035E
1L	4.6%	3.3%	2.6%
2L	4.6%	3.3%	2.6%
3L	4.5%	3.2%	2.5%
others	3.4%	2.6%	2.2%
Total	**4.0%**	**2.9%**	**2.4%**

k ppl



Source: CSCO, NCCN, CIC

Treatment Pathway for MCL

Front-line Treatment

For newly diagnosed MCL, treatment selection is driven by transplant eligibility. Younger, fit patients typically receive intensive chemoimmunotherapy regimens (e.g., alternating R-CHOP/R-DHAP), followed by ASCT. Older or transplant-ineligible patients are generally treated with bendamustine-rituximab (BR) or modified R-CHOP regimens. Among transplant-eligible patients, induction therapy is typically administered using intensive chemo-immunotherapy regimens. Apart from the patients who are indolent while diagnosed, the rest 80% of patients, who are aggressive/classic MCL patients will receive induction therapy. Within this transplant-eligible patients receiving induction therapy, approximately 50% of patients receive rituximab-based combination regimens, with the remaining patients treated with other intensive induction approaches. The integration of BTK inhibitors into frontline therapy represents a paradigm shift. BTKi-containing regimens have demonstrated better results over standard chemoimmunotherapy in select populations, leading to guideline recommendations — such as zanubrutinib plus rituximab — as preferred frontline options for elderly or unfit patients. In front-line settings, BTK inhibitors are predominantly used in combination with immunochemotherapy and/or other targeted agents rather than as routine monotherapy.

*Maintenance and Relapsed/Refractory ("**R/R**") Setting*

Following frontline therapy, patients with clinical response often enter maintenance with rituximab ± covalent BTKi until progression or toxicity; yet ~45% relapse within five years, and up to 70% progress over time.

In R/R settings, BTK inhibitors are cornerstone therapy per NCCN/CSCO guidelines, preferred as second-line standard, with ~80% of R/R patients receiving BTKi regimens. BTKi-naïve cases typically start covalent BTKi (ibrutinib, acalabrutinib, zanubrutinib) as monotherapy or with rituximab/venetoclax. Covalent BTKis dominate (~95% usage), mainly as monotherapy or with rituximab/venetoclax; ncBTKi uptake remains low due to access/cost barriers. In third-line and later settings, particularly following progression on prior covalent BTKi therapy, treatment options may include ncBTKi (e.g., pirtobrutinib), CAR-T, venetoclax-based regimens, lenalidomide-rituximab, or allogeneic transplant for eligible patients.

Treatment Sequencing

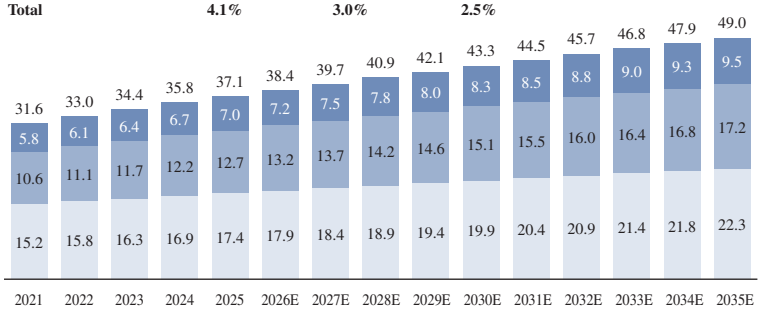
No fixed sequencing exists between BTK inhibitors and BCL-2 therapies; selection is individualized by prior therapy, disease features, resistance, and tolerance. Covalent BTKi resistance (often C481S mutations or pathway shifts) underscores needs for novel agents and optimized strategies. Frontline use favors BTKi/BCL-2 combinations; R/R settings apply BCL-2 ± BTKi based on prior exposure. Switching within BTKis occurs due to intolerance, toxicity, resistance, or relapse. Post-covalent BTKi patients may receive ncBTKi monotherapy like pirtobrutinib (access-dependent). LP-168, a next-gen dual covalent/ncBTKi, targets post-BTKi use, showing objective responses and manageable safety in covalent-pretreated R/R B-cell malignancies, plus activity post-ncBTKi. BTKis form MCL's therapeutic backbone across lines, per NCCN/CSCO as second-line preferred (~80% R/R adoption). BTKi-naïve R/R starts covalent BTKi ± rituximab/venetoclax; post-covalent progression options include ncBTKi (e.g., pirtobrutinib), CAR-T, lenalidomide-rituximab, venetoclax combos, or allogeneic transplant for cure in eligible cases.

CLL/SLL

CLL/SLL represents one of the most prevalent adult leukemia and the cornerstone indication for BTK inhibitors, with the disease's pathogenesis driven by aberrant B-cell receptor signaling that promotes malignant B-cell survival and proliferation in lymphoid tissues. The prevalence of CLL/SLL in China rose from 31.6 thousand in 2021 to 37.1 thousand in 2025, with a CAGR of 4.1%, and is projected to reach 49.0 thousand by 2035, representing CAGRs of 3.0% from 2026 to 2030 and 2.5% from 2031 to 2035. The prevalence of CLL/SLL in U.S. increased from 195.9 thousand people in 2021 to 229.5 thousand in 2025, representing a CAGR of 4.0%, and is expected to reach 296.2 thousand by 2035, corresponding to CAGRs of 2.9% from 2026 to 2030 and 2.1% from 2031 to 2035. In CLL/SLL, the five-year survival rate is reported at approximately 88%. Treated patients may achieve a median overall survival of up to 10 years. In certain patient populations, BTK inhibitor based therapy may further extend survival outcomes. This represents a stable and durable addressable patient population for BTK inhibitors, driven by the need for long-term treatment management.

China prevalence of CLL/SLL, 2021-2035E

CAGR	2021-2025	2026E-2030E	2031E-2035E
1L	4.7%	3.4%	2.7%
2L r/r	4.7%	3.3%	2.6%
others	3.4%	2.6%	2.3%
Total	**4.1%**	**3.0%**	**2.5%**



Source: CSCO, NCCN, CIC

Treatment Pathway for CLL/SLL

The treatment landscape for CLL/SLL has undergone a fundamental transformation with BTK inhibitors establishing dominance across all lines of therapy, effectively replacing chemoimmunotherapy as the standard of care. In the frontline setting, BTK based regimens and BCL-2 inhibitor-based fixed duration regimens are preferred options, while traditional chemoimmunotherapy is reserved for selected patients with favorable disease biology or those unable to receive targeted therapy. Within targeted therapy, such as BTKi and BCL-2 inhibitor based regimens are used across multiple lines of therapy without a guideline mandated fixed sequence. Either class may be selected in the frontline setting, and sequential use is common in relapsed or refractory disease based on prior exposure. The choice between BTKi and BCL-2 inhibition is driven by disease biology, comorbidities, prior exposure and treatment objectives, rather than a predetermined order. After resistance or intolerance to BTKi, ncBTKi such as pirtobrutinib may be considered, while a failure of both BTKi and venetoclax will typically shift the treatment to alternative therapies with other mechanisms of action. BTKi based regimens, administered as monotherapy or in combination, represent a core first line treatment approach and are used in over 60% of cases and approximately 5% of patients relapse based on current BTKi based regimen with 1 year.

Around 30% of CLL/SLL patients relapse post-frontline therapy, with ~60% and 70% progressing within 5 and 10 years, respectively. In R/R settings, treatment hinges on prior exposure and resistance: BTKi-naïve patients favor BTK inhibitors (~25% second-line use), while prior-BTKi cases shift to alternatives like BCL-2 regimens. Post-cBTKi, switching to another cBTKi or ncBTKi (e.g., pirtobrutinib, if accessible) may apply; C481S-mutated resistance suits ncBTKi, whereas BTKi-independent cases turn to venetoclax or PI3K inhibitors.

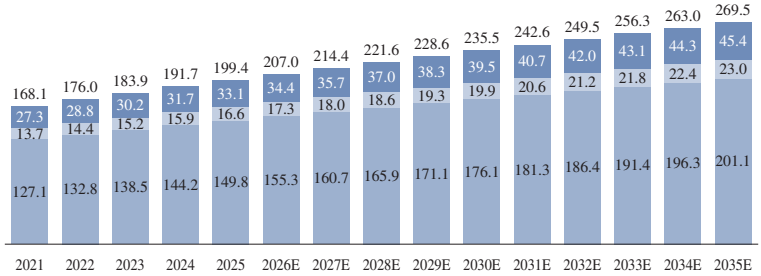
DLBCL

Diffuse large B-cell lymphoma (DLBCL), the most common aggressive non-Hodgkin lymphoma accounting for 40-50% of NHL, represents an evolving frontier for BTK inhibitors, particularly in the non-germinal center B-cell (non-GCB) subtype, where chronic BCR signaling drives lymphomagenesis, with BTK inhibitors demonstrating promising activity in relapsed/refractory settings. The prevalence of DLBCL in China increased from 168.1 thousand people in 2021 to 199.4 thousand in 2025, corresponding to a CAGR of 4.4%, and is anticipated to reach 269.5 thousand by 2035, representing a CAGR of 3.3% from 2026 to 2030 and 2.7% from 2031 to 2035. The prevalence of DLBCL in U.S. increased from 98.0 thousand people in 2021 to 113.4 thousand in 2025, corresponding to a CAGR of 3.7%, and is anticipated to reach 140.6 thousand by 2035, representing a CAGR of 2.5% from 2026 to 2030 and 1.7% from 2031 to 2035. Non-GCB DLBCL accounts for approximately 68% of the overall DLBCL population in China. Its prevalence increased from 114.3 thousand people in 2021 to 135.6 thousand in 2025, corresponding to a CAGR of 4.4%, and is expected to reach 183.2 thousand by 2035, representing a CAGR of 3.3% from 2026 to 2030 and 2.7% from 2031 to 2035. Non-GCB DLBCL accounts for approximately 40% of the overall DLBCL population in US. The prevalence of non-GCB DLBCL in U.S. increased from 39.2 thousand people in 2021 to 45.3 thousand in 2025, corresponding to a CAGR of 3.7%, and is anticipated to reach 56.2 thousand by 2035, representing a CAGR of 2.5% from 2026 to 2030 and 1.7% from 2031 to 2035.

China prevalence of DLBCL, 2021-2035E

CAGR	2021-2025	2026E-2030E	2031E-2035E
1L	4.9%	3.5%	2.8%
3L	5.0%	3.6%	2.8%
others	4.2%	3.2%	2.6%
Total	**4.4%**	**3.3%**	**2.7%**

k ppl



Source: CSCO, NCCN, CIC

In DLBCL, the five-year survival rate is commonly reported at approximately 65%. Treated patients frequently achieve a median overall survival of up to 8 years. Subtype specific median overall survival data are not consistently reported. Clinical experience and expert opinions indicate a higher relapse risk relative to other subtypes. This represents a stable and durable addressable patient population for BTK inhibitors, driven by the need for long-term treatment management.

Treatment Pathway for DLBCL

In DLBCL, immunochemotherapy remains the established frontline standard of care. Targeted agents are incorporated in specific clinical contexts rather than used routinely prior to chemotherapy. In the relapsed or refractory setting, treatment selection is stratified by transplant eligibility and patient fitness. Immunochemotherapy based regimens continue to play an important role, while targeted and immunotherapy based options are added selectively based on disease characteristics, prior therapy and access considerations. Within targeted therapy, DLBCL does not follow a defined sequencing paradigm between BTK and BCL-2 inhibition. BTK is selective and biology-driven, primarily considered in biomarker-defined populations such as non-GCB disease, most often in the relapsed or refractory setting and typically in combination regimens, rather than as a universal targeted backbone.

To date, no BTK inhibitor has been approved for the treatment of DLBCL. According to guidelines, BTK inhibitors are positioned in clinical practice mainly for non-GCB disease and mainly in the relapsed or refractory setting (accounting for over 30% DLBCL patients), which represents a major potential indication for BTKi. According to NCCN guidelines, ibrutinib is specifically listed as a treatment option for relapsed/refractory non-GCB DLBCL, either as monotherapy or in combination with lenalidomide and rituximab, acknowledging the role of chronic BCR signaling in this molecular subtype. For patients who are not candidates for CAR-T cell therapy or have failed prior treatments, BTK inhibitor-based regimens offer an oral, generally well-tolerated option as monotherapy and higher rates in combination approaches. While salvage chemotherapy followed by autologous stem cell transplant and CAR-T cell therapy remain preferred options for eligible patients, BTK inhibitors are establishing their niche in the growing population of elderly or frail patients who cannot tolerate intensive therapies.

Non-GCB DLBCL

According to the CSCO and NCCN guidelines for DLBCL, BTK inhibitors are positioned as a therapeutic option for selected patients with non-GCB DLBCL, notwithstanding that no BTK inhibitor has been formally approved for the treatment of DLBCL. In China, the CSCO 2025 lymphoma guidelines note that ibrutinib in combination with immunochemotherapy has shown improved outcomes in younger patients, with ages generally less than 60 years old, with non-GCB DLBCL, and therefore include ibrutinib-containing immunochemotherapy regimens as a consideration in selected frontline settings. In contrast, the NCCN guidelines primarily position BTK inhibitors in the relapsed or refractory setting, where ibrutinib-based regimens are included among salvage treatment options for non-GCB DLBCL. The addressable market for non-GCB DLBCL is referenced by its share within the overall DLBCL patient population, with non-GCB cases representing approximately 50-60% of diagnosed DLBCL.

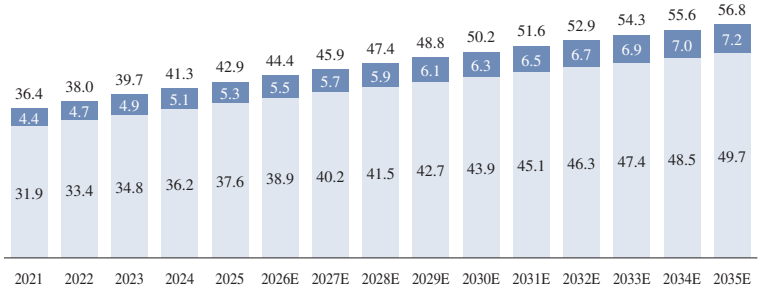
MZL

MZL has emerged as an important BTK inhibitor-responsive indication with ibrutinib, zanubrutinib, and pirtobrutinib FDA-approved for relapsed/refractory disease based on impressive overall response rates of 50-80% and median progression-free survival exceeding 2 years, establishing BTK inhibitors as preferred oral therapeutic options that spare patients from chemotherapy while offering durable disease control in this typically indolent but incurable B-cell malignancy where BCR signaling plays a central pathogenic role. The prevalence of MZL in China rose from 36.4 thousand in 2021 to 42.9 thousand in 2025, with a CAGR of 4.2%, and is expected to reach 56.8 thousand by 2035, corresponding to a CAGR of 3.1% from 2026 to 2030 and 2.5%

from 2031 to 2035. The prevalence of MZL in U.S. rose from 23.4 thousand in 2021 to 28.3 thousand in 2025, with a CAGR of 4.9%, and is expected to reach 37.8 thousand by 2035, corresponding to a CAGR of 3.4% from 2026 to 2030 and 2.3% from 2031 to 2035. In MZL, the five-year survival rate is reported at approximately 90%. Treated patients may attain a median overall survival of over 5 years. Certain patient subsets, including those ineligible for surgical intervention, may experience materially shorter survival. Some reports indicate overall survival of approximately 3 to 4 years in these populations. Approximately 30% of MZL patients are R/R MZL patients within 5 years. MZL typically follows an indolent course with prolonged survival and repeated relapses, and while a small subset of patients with localized stage I disease may be curable, most advanced-stage patients are expected to relapse over long-term follow-up.

China prevalence of MZL, 2021-2035E

CAGR	2021-2025	2026E-2030E	2031E-2035E
1L	4.7%	3.3%	2.6%
others	4.2%	3.0%	2.4%
Total	**4.2%**	**3.1%**	**2.5%**



Source: CSCO, NCCN, CIC

Treatment Pathway for MZL

In MZL, treatment selection is determined by disease subtype, stage, tumor burden and treatment objectives. For stage I-II disease, management is primarily localized, with radiotherapy or anti-CD20 antibody therapy such as rituximab as main options of treatment. For stage III-IV disease, frontline treatment is predominantly immunochemotherapy-based, while targeted therapies are introduced in later lines in the relapsed or refractory setting, with covalent BTK commonly used as monotherapy from second line onwards and non-covalent BTK such as pirtobrutinib reserved as monotherapy in subsequent lines following prior BTK exposure.

Within targeted therapy, BTKi are the preferred and most commonly used option in R/R MZL, supported by clinical evidence and guidelines. There is no established paradigm of interchangeability or routine combination use between BTK and BCL-2 inhibition in this disease. BTK inhibitors are generally not used in first-line treatment for MZL and are more commonly introduced from second line onwards. Upon relapse or progression, BTK become an important R/R oral systemic treatment option recommended by guidelines, with BTK utilization rate commonly at approximately 50% to 60% in the relapsed or refractory setting.

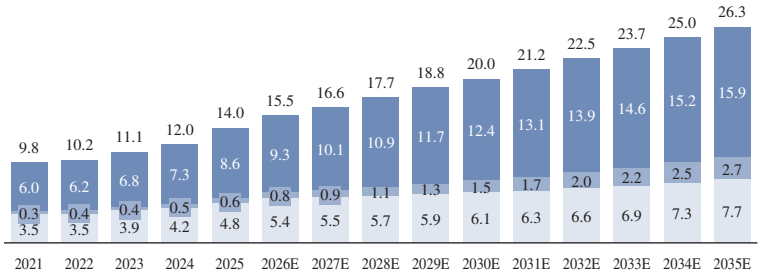
Market Size of BTK Inhibitors Drugs

Driven by the increasing inclusion of BTK inhibitors in treatment guidelines globally, with NCCN and CSCO recommendations now positioning agents like zanubrutinib, acalabrutinib, and pirtobrutinib across multiple lines of therapy, the global BTK inhibitor drugs market shows steady growth momentum. From 2021 to 2025, the market exhibits a CAGR of 9.3%, growing from US$9.8 billion to US$14.0 billion. The market is expected to reach US$20.0 billion in 2030 and US$26.3 billion in 2035, representing CAGRs of 6.6% from 2026 to 2030 and 5.6% from 2031 to 2035. The following chart sets forth the growth of the BTK inhibitors drug market in globally.

Market size of BTK inhibitor, global, 2021-2035E

CAGR	2021-2025	2026E-2030E	2031E-2035E
US	9.2%	7.3%	4.8%
China	18.4%	18.0%	11.9%
RoW	8.3%	3.3%	5.1%
Total	**9.3%**	**6.6%**	**5.6%**

billion USD



Source: NCCR, CSCO, NMPA, NRDL, Annual reports, CIC

Growth of the global BTKi market:

Historical growth drivers:

Product evolution and adoption of targeted therapies: The treatment paradigm has transitioned from chemotherapy-based approaches toward targeted therapies, with second-generation covalent BTKi supporting increased utilization and broader clinical adoption. Their uptake has been supported by clinical data demonstrating improved tolerability and efficacy profiles relative to earlier treatment options. Sustained treatment demand and utilization profile: For many B-cell malignancies, BTKi are administered on a continuous basis over extended durations, resulting in a recurring utilization profile. A sizeable prevalent patient population, ongoing incidence and prolonged treatment duration have supported stable demand and contributed to historical market growth.

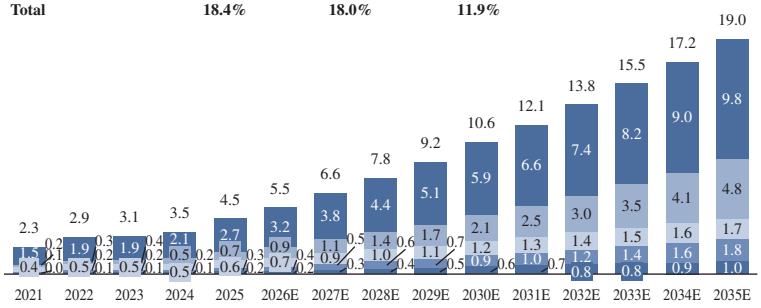
Projected growth assumptions:

Advances in next-generation technologies and product innovation: Continued innovation in BTK-targeting modalities is expected to expand the treatable patient population and extend therapy sequencing options, particularly in the relapsed or refractory setting. Next-generation approaches, including agents designed to address resistance and improve selectivity, are expected to support further penetration of BTKi and continued market expansion. Advances in next-generation technologies and product innovation: Innovation in BTK-targeting modalities is expected to further expand the treatable patient population and extend therapy sequencing options, particularly in the R/R setting. Next-generation approaches, including agents designed to overcome resistance and improve selectivity, are expected to deepen BTKi penetration and support continued market expansion.

The BTK inhibitor market in China demonstrates significant growth potential. From 2021 to 2025, the market shows a robust CAGR of 18.4%, growing from RMB2.3 billion to RMB4.5 billion. Looking forward, the market is expected to continue to expand substantially, projected to reach RMB19.6 billion in 2035 at CAGRs of 18.0% from 2026 to 2030 and 11.9% from 2031 to 2035. The following chart sets forth the growth of the BTK inhibitors drug market in China.

Market size of BTK inhibitor in China, 2021-2035E

CAGR	2021-2025	2026E-2030E	2031E-2035E
CLL/SLL	14.8%	16.4%	10.3%
DLBCL	40.1%	23.6%	17.2%
MCL	11.7%	12.3%	6.5%
MZL	29.7%	21.5%	15.2%
Others	37.3%	26.1%	9.2%
Total	**18.4%**	**18.0%**	**11.9%**



Sources: NCCR, CSCO, NMPA, NRDL, Annual reports, CIC

In the China BTK inhibitor market, CLL/SLL, DLBCL, MCL and MZL accounted for 59.2%, 15.7%, 14.3% and 7.2%, respectively, in 2025. By 2035, CLL/SLL, DLBCL, MCL and MZL are expected to account for approximately 51.6%, 25.0%, 8.7% and 9.7%, respectively, corresponding to market sizes of approximately RMB9.8 billion, RMB4.7 billion, RMB1.7 billion and RMB1.8 billion, respectively. From 2026 to 2030, the BTK inhibitor market size for CLL/SLL, DLBCL, MCL and MZL is expected to grow at a CAGR of approximately 16.4%, 23.6%, 12.3%, 21.5%, respectively, and from 2031 to 2035, the corresponding markets are expected to grow at CAGRs of approximately 10.3%, 17.2%, 6.5% and 15.2%, respectively.

To further illustrate the treatment-line distribution within major BTK inhibitor-addressed indications, in 2025, 2L R/R CLL/SLL accounted for approximately RMB1.2 billion, representing 27.0% of the China BTK inhibitor market. For 3L DLBCL, BTK inhibitor usage amounted to approximately RMB0.6 billion in 2025, representing 13.0% of the China BTK inhibitor market. For MCL, 2L R/R MCL and 3L R/R MCL contributed approximately RMB0.4 billion and RMB0.2 billion, respectively, representing 8.5% and 5.0% of the China BTK inhibitor market.

In general, disease prevalence is largely epidemiology-driven and therefore grows at a relatively stable and moderate pace, with limited short-term catalysts. By contrast, the market size of drugs is primarily driven by increasing treatment penetration, supported by multiple commercial and clinical factors, including earlier-line adoption, expanded treatment eligibility, longer duration of therapy, and the introduction of next-generation therapies, which may evolve more dynamically over time.

Specifically for BTK inhibitors, the apparent mismatch between market growth and the relatively moderate CAGR of disease prevalence is primarily driven by: (i) product innovation and upgrades, as next-generation BTK inhibitors with improved efficacy and safety profiles enable broader use across treatment settings and support higher value per patient; (ii) increasing treatment penetration, as BTK inhibitors are adopted across broader patient populations and earlier lines of therapy, contributing to market growth beyond patient population expansion; and (iii) longer treatment duration, as improved clinical outcomes and tolerability extend the duration of therapy over time, increasing per-patient drug utilization and supporting overall market CAGR.

Growth of the China BTKi market:

Historical growth drivers:

Reimbursement access and improved affordability: Broader NRDL inclusion of major BTKi has reduced patient out-of-pocket costs and improved affordability, supporting increased utilization across regions and healthcare settings. Rise of domestic innovators and market expansion: China-originated BTKi have achieved rapid commercialization, supported by clinical development progress and pricing accessibility, contributing to increased market penetration and overall market expansion. Improved diagnostics and standardization of clinical practice: Enhanced diagnostic capabilities and wider adoption of clinical guidelines have supported earlier diagnosis and increased use of targeted therapies, including BTKi.

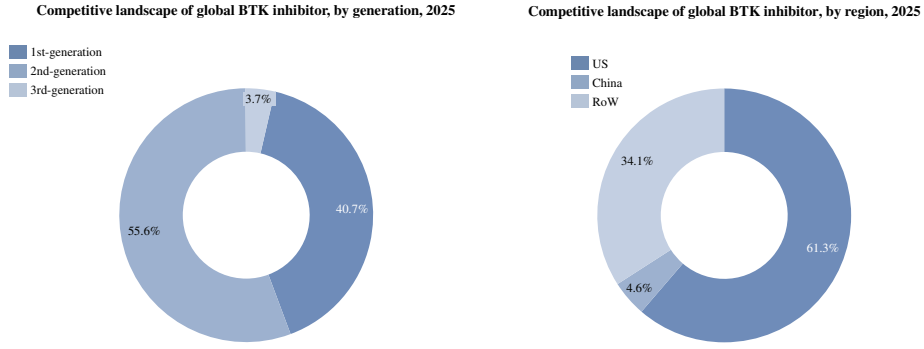
Projected growth assumptions:

Continued treatment paradigm transition and demand for subsequent therapies: The shift from chemotherapy-based regimens toward targeted therapies is expected to continue in both frontline and relapsed settings. Increased use of BTKi in earlier lines may lead to a growing number of patients requiring subsequent therapies, including next-generation BTKi and other novel mechanisms such as BTK degraders, which is expected to support continued market growth.

Competitive Landscape

In 2025, the global BTKi market totaled US$14.0 billion, with U.S. accounting for US$8.6 billion, China for US$0.64 billion, and the rest of the world for US$4.80 billion. In the same year, the 1st-generation BTKi products contributed US$5.7 billion (40.7%), 2nd-generation BTKi products contributed US$7.8 billion (55.6%), and 3rd-generation BTKi products accounted for the remaining US$0.5 billion (3.7%). The following charts set for the competitive landscape of BTKi market by region and generation.

Competitive landscape of global BTK inhibitor, 2025



Sources: Annual reports, Expert interviews, CIC

As of the Latest Practicable Date, there were five approved BTK inhibitor drugs globally and in China. The average unit price of BTK inhibitors currently marketed in China is approximately RMB160 per 100 mg.

FDA and/or NMPA approved oncology BTK inhibitors, as of LPD

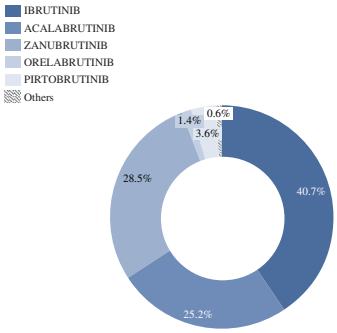
Brand name	INN	Binding mode	Company	First approval date/region	Indications	Route of administration	List price	NRDL*
IMBRUVICA® 億珂®	Ibrutinib	Covalent	Janssen	2013/11 FDA 2018/01 NMPA	2L+ MCL, 2L+ CLL/SLL, 2L+ MZL, WM, cGVHD	Oral	¥15,000 (140mg*90)	Category B
CALQUENCE® 康可期®	Acalabrutinib	Covalent	AstraZeneca	2017/10 FDA 2023/03 NMPA	2L+ MCL, 2L+ CLL/SLL	Oral	¥10,000 (100mg*56)	Category B
BRUKINSA® 百悅澤®	Zanubrutinib	Covalent	BeiGene	2019/11 FDA 2020/06 NMPA	2L+ MCL, 2L+ CLL/SLL, 2L+ MZL, WM, FL	Oral	¥5,000 (80mg*64)	Category B
宜諾凱®	Orelabrutinib	Covalent	InnoCare	2020/12 NMPA	2L+ MCL, 2L+ CLL/SLL, 2L+ MZL	Oral	¥3,000 (50mg*30)	Category B
JAYPIRCA® 捷帕力®	Pirtobrutinib	Non-covalent	Eli Lilly	2023/01 FDA 2024/10 NMPA	3L+ MCL, 3L+ CLL/SLL	Oral	¥3,000 (50mg*28)	Category B

Sources: FDA, NMPA, CIC

* Under the NRDL framework in China, Category B medicines refer to clinically effective drugs that are subject to partial reimbursement. Patients are required to bear a portion of the treatment cost, and the reimbursement level is determined by local medical insurance policies and may vary across regions. As a result, while NRDL inclusion generally improves patient affordability and access, patients remain responsible for a certain level of out-of-pocket expenses, and the realized pricing may differ depending on regional reimbursement practices.

The following charts summarizes the global market share of approved BTK inhibitors in 2025 in terms of revenue.

Competitive landscape of global BTK inhibitor, 2025



Ranking	Drug	Market share
1	Ibrutinib	40.7%
2	Zanubrutinib	28.5%
3	Acalabrutinib	25.2%
4	Pirtobrutinib	3.6%
5	Orelabrutinib	1.4%
others		**0.6%**
Total		**100%**

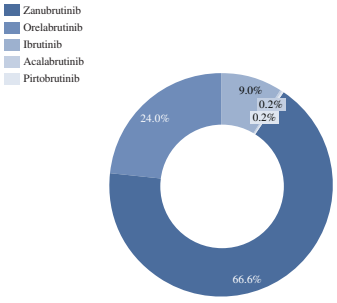
Source: Annual reports, Expert interviews, CIC

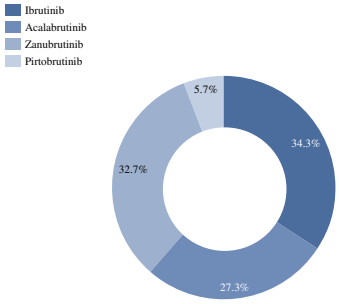
Competitive landscape of BTK inhibitor in China and US, 2025

Competitive landscape of BTK inhibitor in China, 2025

Competitive landscape of BTK inhibitor in the US, 2025

The following charts summarizes the market share of approved BTK inhibitors in 2025 in China and the United States in terms of revenue.





Source: Annual reports, Expert interviews, CIC

As of the Latest Practicable Date, there were six BTK inhibitors under Phase III or above stage globally for oncology indications. Among these product candidates, only LP-168 has entered NDA review stage in China. In addition, there were seven BTK candidates in Phase II, two BTK candidates in Phase I/II, and 14 BTK candidates in Phase I stages. BTK PROTAC degraders are considered a relevant emerging modality within the broader BTK-targeted treatment landscape and have been included in the aforementioned number of BTK candidates. However, specific candidates such as NX-2127 are currently at an early clinical stage and therefore not included in the table below.

Global BTK-targeted oncology therapy pipeline in Phase III or above

Development code	INN	Binding mode/ Mechanism	Company	Stage	Highest stage Indication	Trial location
LP-168	Rocbrutinib	Covalent + Non-covalent	Lupeng	NDA*	MCL, CLL/SLL	/
MK-1026	Nemtabrutinib	Non-covalent	Merck	Phase III	CLL/SLL	China, US, others
BGB-16673	Catadegbrutinib	Degrader	Beigene	Phase III	CLL/SLL	China, US, others
HMPL-760	–	Non-covalent	Hutchmed	Phase III	DLBCL	China
HBW-3220	–	Non-covalent	Hyperway	Phase III	CLL/SLL	China

Source: CDE, ClinicalTrials.gov, CIC

* LP-168's current NDA application under review is for its use as a monotherapy for the treatment of adult patients with relapsed or refractory MCL who have previously received at least two prior lines of systemic therapy, including a BTK inhibitor, thereby positioning it as a potential third-line treatment option for MCL. Such NDA application is supported by a Phase II Registrational Clinical Trial in R/R MCL Patients in China (NCT05716087). For details, please see "Business — Our Drug Portfolio — Core Product LP-168 — "Covalent & Non-covalent" Dual-mechanism BTK Inhibitor under NDA stage — Summary of Clinical Development."

The following table summarizes the number of BTKis for each indication by development stage.

# of BTKis	MCL	CLL/SLL	DLBCL	MZL
IND	/	/	/	/
Phase I	14	16	15	14
Phase I/II	6	4	6	4
Phase II	2	1	3	4
Phase II/III	/	/	/	/
Phase III	/	5	5	/
NDA	1	/	/	/

The following tables summarizes non-BTK inhibitor pipeline drugs in phase III and above stages for MCL, CLL/SLL, DLBCL and MZL.

Global Non-BTKi Pipeline for MCL in Phase III and Above

INN	Company	Target	Modality	Stage	Indication	Trial location
Glofitamab	Roche	CD20, CD3	bsAb	Phase III	3L+ MCL	Global incl. China

Source: CDE, ClinicalTrials.gov, CIC

Global Non-BTKi Pipeline for CLL/SLL in Phase III and Above

Development code	Company	Target	Modality	Stage	Indication	Trial location
DZD8586	Dizal	LYN, BTK	Dual inhibitor	Phase III	2L+ CLL/SLL	China
TQB3909	Chia Tai-Tianqing	BCL-2	mAb	Phase III	2L+ CLL/SLL	China

Source: CDE, ClinicalTrials.gov, CIC

Global Non-BTKi Pipeline for DLBCL in Phase III and Above

Development code/INN	Company	Target	Modality	Stage	Indication	Trial location
Polmacabtagene autoleucel	Imunopharm	CD19	CAR-T	NDA	2L+ DLBCL	/
Golcadomide	Bristol-Myers Squibb	CRBN, IKZF1, IKZF3	Molecular Glues Degrader	Phase III	1L DLBCL	Global excl. China
Zilovertamab Vedotin	Merck Sharp & Dohme	ROR1	ADC	Phase III	1L DLBCL	Global excl. China
SHR-A1912	Hengrui	CD79B	ADC	Phase III	2L DLBCL	China
Purinostat Mesylate	Zenitar	HDAC	Small molecule inhibitor	Phase III	2L DLBCL	China
rondecabtagene autoleucel	Lyell	CD19, CD20	CAR-T	Phase III	2L DLBCL	US
Surovatamig	AstraZeneca	CD19, CD3	bsAb	Phase III	1L LBCL	Global incl. China
SCTB35	SinoCellTech	CD20, CD3	bsAb	Phase III	2L+ DLBCL	China

Source: CDE, ClinicalTrials.gov, CIC

Global Non-BTKi Pipeline for MZL in Phase III and Above

INN	Company	Target	Modality	Stage	Indication	Trial location
Odronextamab	Regeneron	CD20, CD3	bsAb	Phase III	2L MZL	Global excl. China

Source: CDE, ClinicalTrials.gov, CIC

Growth Drivers

The following summarizes the major growth drivers for global and China's BTK inhibitor market.

Global BTK Inhibitor Market

- **Product evolution**: The treatment paradigm has transitioned materially from chemotherapy-based approaches toward targeted agents, with second-generation covalent BTK inhibitors driving higher utilization and broader adoption. Third-generation and emerging fourth-generation covalent BTK inhibitors are increasingly addressing a key unmet need, namely the effective management of patients who relapse on or are intolerant to first-generation therapy, including those with resistance mutations. Their accelerating uptake has been supported by clinical data demonstrating improved tolerability and activity against resistance-associated mutations observed after first-generation BTK inhibitors exposure.

- **Advances in next-generation technologies**: Innovation in BTK-targeting modalities continues to expand the treatable patient population and extend therapy sequencing options, particularly in the R/R setting. Next-generation approaches, including agents designed to overcome on-target resistance and improve selectivity, are reinforcing the role of BTK pathway targeting beyond earlier lines of therapy. This innovation cycle, supported by ongoing clinical readouts and guideline updates, is expected to further deepen its penetration and sustain market momentum.

- **Sustained treatment demand and underlying patient base**: For many B-cell malignancies, BTK inhibitors are administered on a continuous basis over extended durations, resulting in a recurring utilization profile. The combination of a sizeable prevalent patient population, ongoing incidence and long treatment duration supports structurally stable demand. The need for chronic disease control and prolonged therapy courses underpins sustained market utilization and contributes to continued market expansion.

China's BTK inhibitor market

- **Reimbursement access and improved affordability**: Broader NRDL inclusion of major BTK inhibitors has materially reduced patient out-of-pocket costs and lowered financial barriers that previously constrained uptake. Improved affordability has expanded access across regions and hospital tiers.

- **Rise of domestic innovators and an evolving market structure**: China-originated BTK inhibitors have achieved rapid commercialization, supported by competitive clinical profiles, cost advantages and scaled national commercialization capabilities. Their increasing market share reflects a shift from an import-led market toward a more diversified and competitive landscape. In parallel, global clinical participation and partnering activity involving selected domestic products further underscore the strengthening innovation capacity of China-based companies.

- **Improved diagnostics and standardization of clinical practice**: Enhanced diagnostic capabilities, including in lower-tier healthcare settings, are facilitating earlier identification and classification of hematologic malignancies. At the same time, broader dissemination of standardized clinical guidelines is supporting more consistent adoption of targeted therapies, such as BTK inhibitors. Together, these factors expand the number of patients receiving timely and guideline-concordant treatment.

- **Treatment paradigm transition and demand for subsequent therapies**: Clinical practice in China continues to shift from chemotherapy-based regimens toward targeted therapies in both frontline and relapsed settings. As BTK inhibitors are increasingly used earlier in the treatment course, resistance and intolerance are expected to drive demand for subsequent therapies. This dynamic supports the development and adoption of next-generation options, including next-generation BTK inhibitors, which are intended to address emerging resistance mechanisms and extend durable disease control.

Key Assumptions for the Project Growth of BTK Inhibitors Market

The market projections for BTK-targeting therapies adopt key assumptions, such as (i) global macroeconomic environment and healthcare expenditure are expected to maintain a broadly steady growth trend over the next decade; (ii) underlying demand drivers, including population aging, improving diagnostic coverage, rising treatment awareness and greater affordability supported by reimbursement expansion, are expected to continue increasing the treated patient base; (iii) BTK inhibitor penetration is assumed to rise gradually across approved hematologic indications in line with guideline adoption, broader hospital formulary coverage and increasing physician familiarity, while treatment duration remains broadly consistent with current clinical practice; (iv) pricing is assumed to follow a stable and rational trajectory, reflecting NRDL dynamics, tendering and competitive intensity, with incremental price adjustments partially offset by volume growth; and (v) there will be no extreme force major events or abrupt regulatory or reimbursement changes that would fundamentally disrupt patient access, clinical utilization or the competitive landscape.

GLOBAL AND CHINA Bcl-2 INHIBITOR MARKET

Overview

Apoptosis is a regulated process essential for tissue homeostasis by eliminating abnormal cells; its impairment drives tumorigenesis and drug resistance. It proceeds via extrinsic (death receptor) or intrinsic (mitochondrial) pathways, with the latter controlled by the Bcl-2 family: anti-apoptotic proteins (Bcl-2, Bcl-XL, MCL-1) promote survival, while pro-apoptotic effectors (BAX, BAK) and BH3-only sensors promote death. Bcl-2, a key anti-apoptotic member, resides on the mitochondrial outer membrane and sequesters pro-apoptotic proteins via its BH3-binding groove, preventing BAX/BAK oligomerization, mitochondrial permeabilization, and release of cytochrome c/SMAC that trigger caspases. Cancer cells often overexpress Bcl-2 to evade apoptosis; under stress, BH3-only proteins bind Bcl-2, displacing effectors to restore the balance. Cancer cells often overexpress Bcl-2 to tip the pro- and anti-apoptotic balance and evade apoptosis. Under stress, BH3-only proteins bind Bcl-2's hydrophobic groove, displacing sequestered effectors to neutralize its function; this frees BAX/BAK to oligomerize, permeabilize mitochondria, and release cytochrome c/SMAC, triggering caspases. Small-molecule Bcl-2 inhibitors mimic BH3-only proteins, binding the groove with high affinity to restore apoptosis. This approach excels in Bcl-2-dependent cancers, where venetoclax surpasses the apoptotic threshold for rapid tumor death, affirming Bcl-2 inhibition as a precision strategy.

Indications for Bcl-2 Inhibitor Drugs

Bcl-2 inhibitors have transformed hematologic oncology as targeted therapies, with venetoclax proving efficacy in Bcl-2-dependent blood cancers. CLL/SLL remains the primary indication, delivering deep, durable responses that reshape paradigms and sustain market demand. Expansion targets R/R MDS (especially BTKi-naïve patients), MF (addressing apoptotic defects in this underserved neoplasm), and combinations in R/R AML/MDS to counter resistance and enhance outcomes.

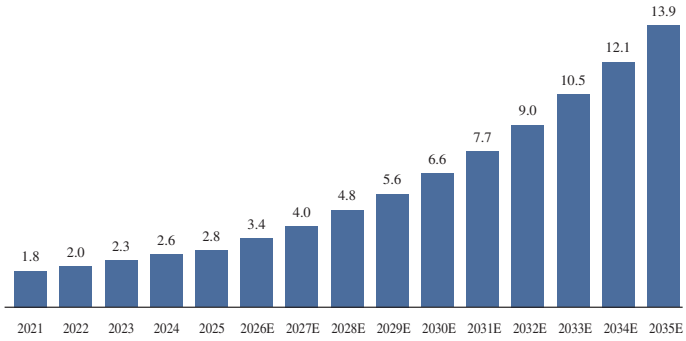
Market Size

The global Bcl-2 inhibitors market has shown sustained growth, rising from US$1.8 billion in 2021 to US$2.8 billion in 2025 at a strong CAGR of 11.4%, and is projected to reach US$13.9 billion in 2035, representing CAGRs of 23.9% from 2026 to 2030 and 15.8% from 2031 to 2035. The following chart sets forth the growth of the Bcl-2 inhibitor drug market globally.

Market size of BCL-2 inhibitor, global, 2021-2035E

CAGR	2021-2025	2026E-2030E	2031E-2035E
BCL-2 inhibitor, Global	11.4%	23.9%	15.8%

billion USD



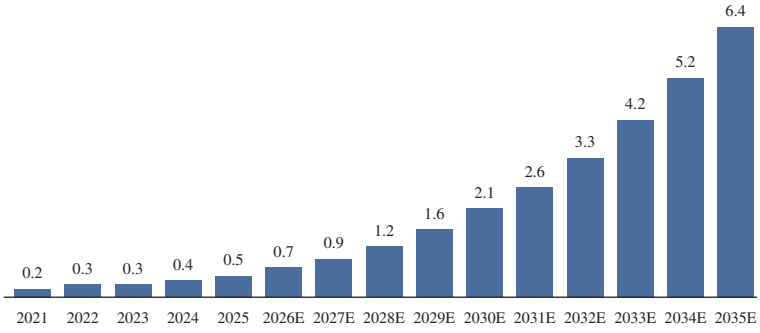
Sources: Globocan, NCCN, Annual reports, CIC

China's Bcl-2 inhibitor market demonstrates robust growth momentum, expanding from RMB0.2 billion in 2021 to RMB0.5 billion in 2025. Looking forward, the market is projected to reach RMB6.4 billion in 2035, with CAGRs of 40.2% from 2026 to 2030 and 24.8% from 2031 to 2035. The following chart sets forth the growth of the Bcl-2 inhibitor drug market in China.

Market size of BCL-2 inhibitor, China, 2021-2035E

CAGR	2021-2025	2026E-2030E	2031E-2035E
BCL-2 inhibitor, China	35.5%	40.2%	24.8%

billion RMB



Sources: NCCR, CSCO, NMPA, NRDL, Annual reports, CIC

Competitive Landscape

As of the Latest Practicable Date, there are three approved Bcl-2 inhibitor drugs globally. Venetoclax, developed by AbbVie, was the only Bcl-2 inhibitor approved by the FDA. The following table sets forth the approved Bcl-2 inhibitor drugs globally.

Globally approved Bcl-2 inhibitors

Brand name	INN	Company	First approval date/region	Indication	Route of administration	NRDL
VENCLEXTA® 唯可來®	Venetoclax	AbbVie	2016/04 FDA 2020/12 NMPA	CLL/SLL, newly diagnosed AML	Oral	Category B
利生妥®	Lisaftoclax	Ascentage	2025-07 NMPA	CLL/SLL (post-BTKi)	Oral	Not included
百悦達®	Sonrotoclax	BeiGene	2025-12 NMPA	CLL/SLL (post-BTKi), MCL (post-BTKi)	Oral	Not included

Sources: FDA, NMPA, CIC

As of the Latest Practicable Date, there are six Bcl-2 inhibitor drugs under CDE-registered clinical trials in China, including our LP-108, which is under a Phase II clinical trial in China.

Global and China Bcl-2/Bcl-xL Inhibitor Drug Market

Overview

Among Bcl-2 family, Bcl-xL is one of the critical anti apoptotic proteins that is localized in the mitochondria and promotes cell survival by preventing mitochondrial outer membrane permeabilization and subsequent caspase activation.

Dual Bcl-2/Bcl-xl inhibitors exert their therapeutic effects through simultaneous inhibition of both Bcl-2 and Bcl-xL, offering distinct advantages over single-target inhibitors: overcoming resistance in cancer therapy, broadened therapeutic.They work by targeting critical anti-apoptotic proteins that cancer cells rely on for survival. Bcl-2 family proteins, particularly Bcl-2 and Bcl-xL, are located at the mitochondria and function to prevent cell death by blocking the release of pro-apoptotic factors. These inhibitors act as BH3 mimetics, binding to the BH3-binding groove of Bcl-2/Bcl-xL proteins and disrupting their ability to sequester pro-apoptotic proteins like BAX and BAK. This disruption releases the pro-apoptotic proteins, allowing them to oligomerize at the mitochondrial membrane and form pores that release cytochrome c and other factors, ultimately triggering the caspase cascade and programmed cell death.

Indications for Bcl-2/Bcl-xL Inhibitor Drugs

Bcl-2/Bcl-xL inhibitor drugs are designed to target both the Bcl-2 and Bcl-xL proteins, broadening their therapeutic scope compared to agents that exclusively inhibit Bcl-2. While Bcl-2-selective inhibitors are primarily approved for B-cell malignancies such as chronic lymphocytic leukemia and certain non-Hodgkin lymphomas, dual Bcl-2/Bcl-xL inhibitors extend indications to include tumors where Bcl-xL drives survival or resistance, for example, select solid tumors, myeloma, and acute leukemias with high Bcl-xL expression. By simultaneously blocking two key anti-apoptotic safeguards, these dual inhibitors can overcome compensatory survival pathways that limit the efficacy of Bcl-2-only drugs, offering a more potent induction of apoptosis in cancers reliant on both proteins.

Competitive Landscape for Bcl-2/Bcl-xL Inhibitor Drugs

As of the Latest Practicable Date, there are three Bcl-2/Bcl-xL dual inhibitor drug candidates under clinical trial globally, including our LP-118. Among these drug candidates, LP-118 is the only oral dual inhibitor targeting both Bcl-2 and Bcl-xL, designed using the BeyondX Oral MedChem Platform. It strikes a careful balance between strong anti-tumor effects and reduced platelet toxicity, addressing the narrow therapeutic window challenge typical of Bcl-xL inhibition. This makes LP-118 a potential candidate for treating cancers resistant to current Bcl-2 inhibitors while minimizing side effects.

The following table sets forth the competitive landscape of Bcl-2/Bcl-xL dual inhibitor drug candidates under clinical trials globally.

Global oncology Bcl-2/Bcl-xL inhibitor pipeline

Development code	INN	Company	Stage	Indications	Route of administration	First Posted date	Trial location
LP-118	–	Lupeng	Phase I	Advanced solid tumor, R/R NHL	Oral	2021-07	China, US
ABT-263	Navitoclax	AbbVie	Phase III	MF+, solid tumor, lymphoma, leukemia	Oral	2020-07	US, Others
APG-1252	Pelcitoclax	Ascentage	Phase I/II	RR NHL+, NSCLC	Intravenous	2022-01	China

Sources: ClinicalTrials.gov, CDE, CIC

SCLC DRUG MARKETS

Overview

Small-cell lung cancer (SCLC) is an aggressive neuroendocrine carcinoma primarily affecting current or former smokers, characterized by rapid growth and early metastasis. This aggressive malignancy is strongly associated with tobacco exposure, with nearly 98% of cases occurring in current or former smokers.

Incidence of SCLC

The increasing prevalence of SCLC globally and in China is largely attributed to factors such as unhealthy lifestyle, increased consumption of tobacco and exposure to air pollution and radon. The global incidence of SCLC grew from 291.3 thousand in 2021 to 332.1 thousand in 2025 at a CAGR of 3.3%, and are expected to reach 443.2 thousand in 2035 at CAGRs of 2.7% from 2026 to 2030 and 3.0% from 2031 to 2035. In China, the incidence of SCLC grew from 152.7 thousand in 2021 to 177.9 thousand in 2025 at a CAGR of 3.9% in China, and are expected to reach 240.6 thousand in 2035 at CAGRs of 3.0% from 2026 to 2030 and 2.9% from 2031 to 2035. In U.S., the incidence of SCLC increased from 39.2 thousand in 2021 to 41.2 thousand in 2025, at a CAGR of 1.3%, and are expected to increase to 49.3 thousand in 2035, with CAGRs of 2.0% from 2026 to 2030 and 1.7% from 2031 to 2035.

Treatment Pathway of SCLC

SCLC treatment varies by stage and symptoms. Limited-stage uses systemic therapy (cisplatin/etoposide or carboplatin/etoposide) plus mediastinal radiation. Extensive-stage without local symptoms/brain metastases employs combination regimens (carboplatin + etoposide ± atezolizumab/durvalumab, or ± irinotecan; cisplatin + irinotecan) with supportive care. Localized symptoms receive initial steroids, then systemic therapy and radiation; brain metastases get systemic therapy plus radiation. Second-line+ options (stratified by CTFI ≥6 months) include lurbinectedin, topotecan, platinum doublets, nivolumab/pembrolizumab, paclitaxel, temozolomide, CAV, docetaxel, gemcitabine, or oral etoposide, with palliative care as needed.

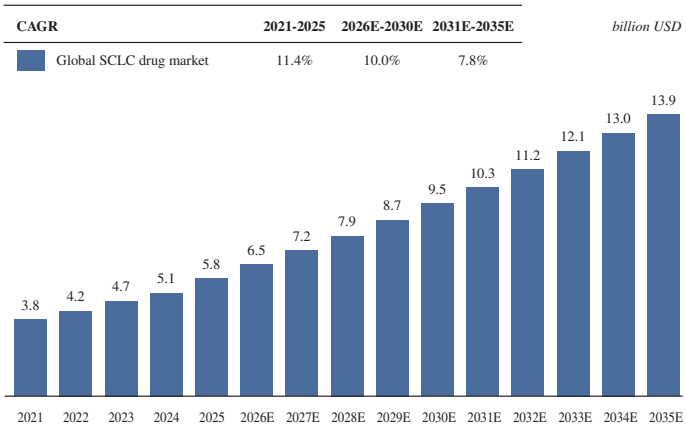
Mechanism of Bcl-2 and Bcl-xL in SCLC Treatment

Bcl-2 and Bcl-xL are anti-apoptotic proteins that play significant roles in the survival and progression of SCLC. By inhibiting programmed cell death, these proteins enable cancer cells to evade apoptosis, contributing to tumor growth and resistance to conventional therapies. Overexpression of Bcl-2 and Bcl-xL is commonly observed in SCLC, correlating with poor prognosis and treatment resistance. Targeting these proteins with specific inhibitors restores apoptotic signaling, leading to enhanced cancer cell death. This therapeutic approach holds promise for overcoming drug resistance and improving clinical outcomes in SCLC patients. Emerging dual inhibitors and degrader technologies that simultaneously target both Bcl-2 and Bcl-xL demonstrate potent anti-tumor efficacy, supporting further development as innovative treatments for this aggressive malignancy.

Market Size

The global SCLC drug size has increased from US$3.8 billion in 2021 to US$5.8 billion in 2025, at a CAGR of 11.4%, primarily driven by the increasing number of approved SCLC drugs. Going forward, the market size is expected to continue to grow to US$13.9 billion in 2035 with CAGRs of 10.0% from 2026 to 2030 and 7.8% from 2031 to 2035.

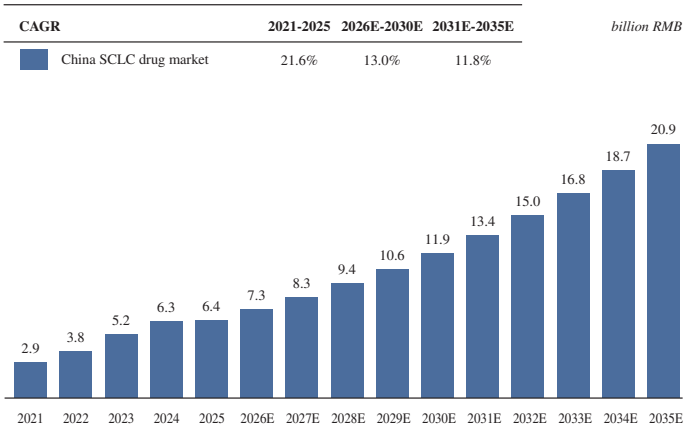
Market size of SCLC drug globally, 2021-2035E



Sources: Globocan, NCCN, Annual reports, CIC

China's SCLC drug market increased from RMB2.9 billion in 2021 to RMB6.4 billion in 2025 with a CAGR of 21.6%, and is expected to increase to RMB20.9 billion in 2035 at CAGRs of 13.0% from 2026 to 2030 and 11.8% from 2031 to 2035. The following chart sets forth the growth of the China SCLC drug markets.

Market size of SCLC drug in China, 2021-2035E



Sources: NCCR, CSCO, NMPA, NRDL, Annual reports, CIC

GLOBAL AND CHINA AUTOIMMUNE DISEASE MARKET

Overview and Prevalence of Autoimmune Diseases

Autoimmune diseases are disorders in which the immune system mistakenly attacks the body's own healthy tissues and organs. They include a wide range of disorders affecting various systems, such as multiple sclerosis (MS), chronic spontaneous urticaria, immune thrombocytopenia (ITP), polymyositis (PM), among others. These diseases can vary widely in symptoms and severity, with some affecting specific organs and others impacting multiple body systems. The followings are the main classifications for autoimmune disease:

- MS is a chronic autoimmune disease that damages nerves in the brain and spinal cord, leading to symptoms ranging from mild impairment to severe disability. The prevalence of MS in China increased from 33.1 thousand in 2021 to 34.1 thousand in 2025 and is expected to reach 35.5 thousand in 2035, with CAGRs of 0.4% from 2026 to 2030 and 0.3% from 2031 to 2035. The prevalence of MS in U.S. increased from 419.4 thousand in 2021 to 440.7 thousand in 2025 and is expected to reach 493.3 thousand in 2035, with 1.2% from 2026E to 2030E and 1.1% from 2031E to 2035E. According to the guidelines for the diagnosis and treatment of MS, management consists of acute-phase interventions and long-term disease modifying treatment. Acute relapses are treated with high-dose corticosteroids, plasma exchange, or IVIG to alleviate symptoms. Long-term care relies on disease-modifying therapies (DMTs) to reduce relapse frequency and slow disability progression, supplemented by symptomatic management, rehabilitation, and lifestyle interventions.

- CSU is the most common type of chronic urticaria, causing recurrent hives and sometimes angioedema for over six weeks, with a substantial impact on quality of life. The prevalence of CSU in China increased from 9.6 million in 2021 to 10.8 million in 2025, representing a CAGR of 3.0%. Due to factors like rapid urbanization, environmental pollution, lifestyle changes, and increased awareness and diagnosis, the prevalence of CSU in China are expected to increase to 13.8 million in 2035 at CAGRs of 2.5% from 2026 to 2030 and 2.3% from 2031 to 2035. The prevalence of CSU in U.S. increased from 1.3 million in 2021 to 1.4 million in 2025, representing a CAGR of 2.5%, and is expected to reach 1.7 million in 2035, with CAGRs of 2.2% from 2026 to 2030 and 1.9% from 2031 to 2035. According to the Chinese Guidelines for the Diagnosis and Treatment of Urticaria, CSU is managed using a stepwise approach beginning with second-generation antihistamines at standard or increased doses, followed by biologics such as the anti-IgE antibody omalizumab. For patients who do not respond, alternative therapies such as cyclosporine or dupilumab may be considered. Emerging BTK inhibitors, supported by accumulating clinical evidence and expert consensus in refractory CSU, may offer an additional therapeutic option for patients who are ineligible for or unresponsive to omalizumab.

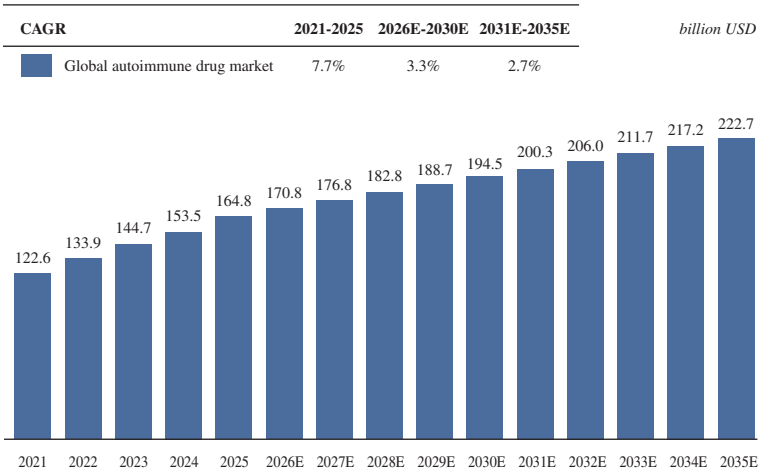
- ITP is an autoimmune disorder marked by low platelet counts, leading to bleeding symptoms that can range from skin bruises to life-threatening hemorrhage. The prevalence of ITP in China increased from 89.7 thousand in 2021 to 99.6 thousand in 2025, with a CAGR of 2.6%. The prevalence of ITP in China is expected to reach 120.8 thousand in 2035 at CAGRs of 2.2% from 2026 to 2030 and 1.7% from 2031 to 2035. The prevalence of ITP in U.S. increased from 783.5 thousand in 2021 to 912.5 thousand in 2025, with a CAGR of 3.9%. The prevalence of ITP in U.S. is expected to reach 1,167.5 thousand in 2035 at CAGRs of 2.8% from 2026 to 2030 and 2.0% from 2031 to 2035. According to the Chinese adult ITP guideline, therapy is stratified by disease severity and line of treatment. Emergency management for life-threatening bleeding or urgent surgical needs includes IVIg, high-dose intravenous methylprednisolone and/or rhTPO, with platelet transfusion when necessary. First-line therapy consists of corticosteroids or IVIg. Second-line options include TPO receptor agonists, rituximab, or combination therapy. Third-line treatment involves immunomodulators and cytotoxic agents such as decitabine.

- PMN is an autoimmune kidney disease and the leading cause of nephrotic syndrome in adults, often associated with anti-PLA2R antibodies and proteinuria. The prevalence of PMN in China increased from 2.1 million in 2021 to 2.3 million in 2025, with a CAGR of 2.8%. The prevalence of PMN in China is expected to increase to 3.0 million in 2035, at CAGRs of 2.5% from 2026 to 2030 and 2.6% from 2031 to 2035. The prevalence of PMN in U.S. increased from 79.2 thousand in 2021 to 86.6 thousand in 2025, with a CAGR of 2.2%. The prevalence of PMN in US is expected to reach 98.3 thousand in 2035, at CAGRs of 1.4% from 2026 to 2030 and 1.0% from 2031 to 2035. Management of PMN in China follows the Chinese Guidelines for the Diagnosis and Treatment of Membranous Nephropathy, which adopt a risk-stratified approach. Low-risk patients receive conservative management including blood-pressure control, RAAS inhibitors, and regular monitoring. Moderate-risk patients may require immunosuppressive therapy, commonly involving rituximab. High-risk patients are treated with corticosteroids in combination with traditional immunosuppressants, with rituximab increasingly incorporated to improve efficacy and tolerability.

Market Size

Due to the complexity of treatment for autoimmune diseases it is anticipated that there will be significant growth potential for autoimmune disease drugs, particularly for novel autoimmune therapies. The global autoimmune drug market size increased from US$122.6 billion in 2021 to US$164.8 billion in 2025 at a CAGR of 7.7% and is projected to reach US$222.7 billion in 2035 at CAGRs of 3.3% from 2026 to 2030 and 2.7% from 2031 to 2035. In 2025, the global autoimmune drug market reached US$164.8 billion, of which targeted therapies generated US$116.8 billion, accounting for 70.9% of total sales. The following chart sets forth the growth of the global autoimmune drug market.

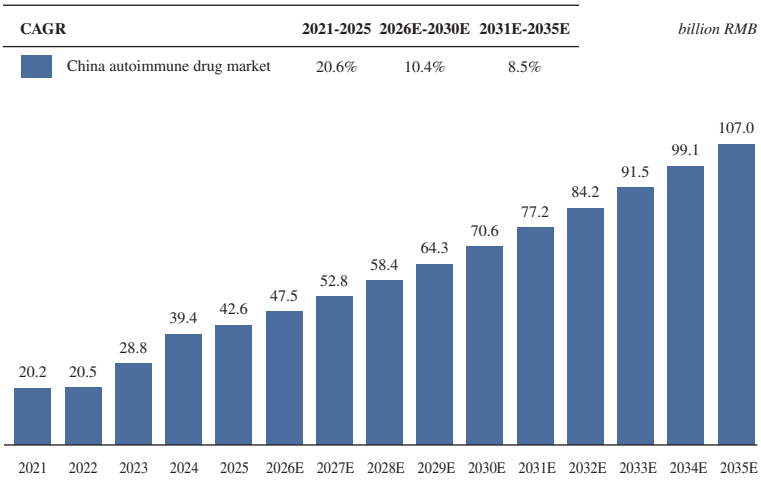
Market size of global autoimmune drug, 2021-2035E



Sources: Chin J Dermatol., Chin J Tuberc Respir Dis., NMPA, NRDL, CIC

The autoimmune disease drug market increased from RMB20.2 billion in 2021 to RMB42.6 billion in 2025 at a CAGR of 20.6%, and is projected to reach RMB107.0 billion in 2035 at CAGRs of 10.4% from 2026 to 2030 and 8.5% from 2031 to 2035. In China, the autoimmune drug market reached RMB42.6 billion in 2025, with targeted therapies generating RMB15.4 billion, accounting for 36.3% of sales. The following chart sets forth the growth of the China autoimmune drug market.

Market size of autoimmune drug in China, 2021-2035E



Source: Chin J Dermatol., Chin J Tuberc Respir Dis., NMPA, NRDL, CIC

Competitive Landscape of BTK Inhibitors in Autoimmune Diseases

The following table summarizes the approved BTK inhibitors for autoimmune diseases as of the Latest Practicable Date.

Globally approved autoimmune BTK inhibitors

Brand name	INN	Binding mode	Company	First approval date/region	Indications	Route of administration	NRDL
WAYRILZ™	Rilzabrutinib	Covalent	Sanofi	2025/08 FDA	ITP	Oral	N/A
RHAPSIDO® **瑞普多®**	Remibrutinib	Covalent	Novartis	2025/09 FDA 2025/11 NMPA	CSU	Oral	Not included

Source: NMPA, FDA, CIC

As of the Latest Practicable Date, two BTK inhibitors for autoimmune diseases, Wayrilz (Rilzabrutinib) and Rhapsido (Remibrutinib) has been approved globally. As of the same date, there are 13 autoimmune BTK inhibitor drug candidates undergoing clinical development. The following table sets forth the competitive landscape of autoimmune BTK inhibitor drug candidates as of the Latest Practicable Date.

Global BTK inhibitors pipeline for autoimmune diseases

Development code	INN	Binding mode/ Mechanism	Company	Stage	Indications	Trial location
LP-168[1]	Rocbrutinib	Covalent + Non-covalent	Lupeng/Hansoh	Phase IIa	RMS*, CSU, ITP, PMN	China
SAR442168	Tolebrutinib	Covalent	Sanofi	Phase III	MS	China, US, others
–	Fenebrutinib	Non-covalent	Roche	Phase III	MS	China, US, others
ICP-022	Orelabrutinib	Covalent	InnoCare	Phase III	ITP*, MS*, SLE*, NMOSD	China
BGB-3111	Zanubrutinib	Covalent	Beigene	Phase II/III	PMN*, LN, ITP, AIHA, CAD	China, US, others
HWH486	–	Covalent	Humanwell	Phase IIa	CSU	China
TQB3702	–	Covalent	Chia Tai-tianqing	Phase II	SLE	China
TM471-1	–	Covalent	Emicro	Phase II	CSU, RMS	China
HZ-A-018	–	Covalent	Healzen	Phase II	ITP, CSU	China
LOXO-305	Pirtobrutinib	Non-covalent	Eli Lilly	Phase I/II	ITP	China, US, others
–	Edralbrutinib	Covalent	Reistone	Phase I	AID	China
BGB-16673	Catadegbrutinib	Degrader	Beigene	Phase I	CSU	China
BIIB145	–	Degrader	Biogen	Phase I	MS	China

Notes: Stage, the first post date, trial status shown represent the most advanced indication only, marked with (*). For multiple indications simultaneously at the highest stage, the earliest date applies.

1. LP-168 non-oncology indications are developed, registered, manufactured, and commercialized by Hansoh Pharma in China.

Sources: ClinicalTrials.gov, CDE, CIC

OVERVIEW OF MODERN DRUG DISCOVERY OR BIOAVAILABLE SMALL MOLECULE MEDICINE

Lipinski's Rule of Five is a widely applied empirical guideline in the development of oral small-molecule drugs. Indeed, with rational design, certain compounds that exceed the Rule of Five's limits can still be developed into effective oral drugs. Therefore, expanding the explored chemical space and formulating entirely new, disruptive principles for oral drug design are crucial to innovative drug discovery. Compared to traditional small-molecule drugs that strictly follow the Rule of Five, bRo5 oral drugs often employ novel biological mechanisms of action or can hit targets that were previously considered "undruggable" by conventional small molecules. Despite the high therapeutic potential of bRo5 molecules, their development is hindered by a significant global industry bottleneck. The physicochemical characteristics typical of this class — including high molecular weight, complex structures, and low water solubility — create substantial challenges in achieving oral absorption. As a result, while the industry aspires to harness bRo5 molecules, the ability to engineer these complex compounds into viable, orally bioavailable medicines remains a formidable technical hurdle. Because "bRo5" small molecules typically have larger molecular weights and more complex structures. As a result, the CMC of bRo5 small molecules has become a challenge for the industry. To overcome these challenges, CMC R&D teams need deep expertise across multiple areas. For example, key areas of expertise include: (1) designing complex synthetic routes; (2) optimizing manufacturing processes; (3) maintaining rigorous quality control; (4) screening and selecting formulations; and (5) utilizing advanced solubilization technique. This broad foundation allows them to develop effective CMC strategies for bRo5 compounds. Some well-established techniques for improving solubility — such as Hot Melt Extrusion (HME) and Spray Drying — play an indispensable role in developing oral formulations for bRo5 small molecules.

REPORT COMMISSIONED BY CHINA INSIGHTS CONSULTANCY

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 which was founded in 2013 and is based in Shanghai. We have agreed to pay CIC a total fee of approximately RMB680,000 for the preparation of the CIC Report, and we believe that such fees are consistent with the market rate. The payment of such amount is 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 were based on the following key assumptions: (i) the overall social, economic and political environment globally and in China is expected to remain stable during the forecast period; (ii) the economic and industrial development globally and in China 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.