
INDUSTRY OVERVIEW

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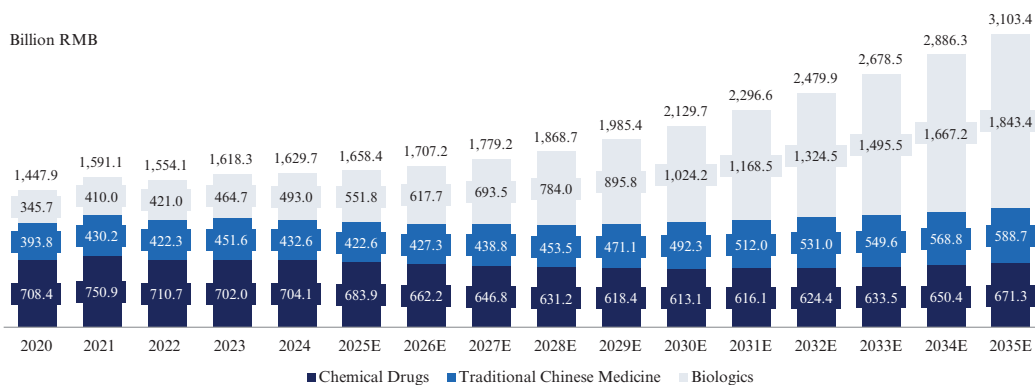
THE PHARMACEUTICAL MARKET IN CHINA

Driven by deepening healthcare system reforms, escalating demand for chronic disease management and the aging population, China’s pharmaceutical market size reached RMB1,629.7 billion in 2024, growing from RMB1,447.9 billion in 2020 at a compound annual growth rate (“CAGR”) of 3.0%, and is expected to reach RMB3,103.4 billion by 2035 at a CAGR of 6.0% from 2024 to 2035. China’s pharmaceutical market can be divided into three core sectors: chemical drugs, traditional Chinese medicine (“TCM”), and biologics. Among these three sectors, biologics have emerged as the most dynamic growth driver, growing from RMB345.7 billion in 2020 to RMB493.0 billion in 2024 at a CAGR of 9.3% and is expected to reach RMB1,843.4 billion in 2035 at a CAGR of 12.7% from 2024 to 2035. This growth trajectory aligns with the increasingly pivotal role of biologics in addressing unmet medical needs, supported by technological breakthroughs in areas such as monoclonal antibodies (“mAbs”), cell and gene therapy, and policy incentives for innovative drug development.

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China Pharmaceutical Market, 2020–2035E

Period	CAGR			
	Chemical Drugs	TCM	Biologics	Total
2020–2024	-0.2%	2.4%	9.3%	3.0%
2024–2035E	-0.4%	2.8%	12.7%	6.0%



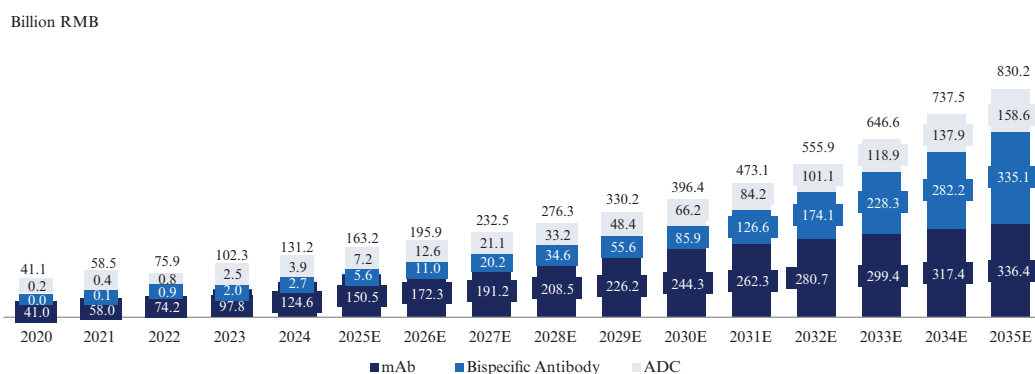
Source: Frost & Sullivan analysis

As a core part of biologics, antibody drugs have emerged as a key driver underpinning innovation and scale expansion of China’s biopharmaceutical industry, due to their unique advantages such as high target specificity and remarkable therapeutic effects. China’s antibody drug market has sustained strong growth, supported by favorable industry fundamentals. The market size of China’s antibody drugs has increased from RMB41.1 billion in 2020 to RMB131.2 billion in 2024 at a CAGR 33.6%. Benefiting from continuous breakthroughs in innovative R&D in the biopharmaceutical field, China’s antibody drug market size is projected to reach RMB830.2 billion by 2035, with a CAGR of 18.3% from 2024 to 2035.

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China Antibody Drug Market, 2020–2035E

Period	CAGR			Total
	mAb	Bispecific Antibody	ADC	
2020–2024	32.1%	254.5%	122.1%	33.6%
2024–2035E	9.5%	55.2%	40.0%	18.3%



Source: Frost & Sullivan analysis

The antibody drug market can be divided into three core sectors: mAb, bispecific antibody, and antibody-drug conjugate (“ADC”). Among these sectors, mAbs mimic the body’s natural antibodies. They specifically target disease-associated antigens, which minimizes off-target effects and enhances treatment effectiveness. Additionally, mAbs often have longer half-lives compared to traditional small-molecule drugs, allowing for less frequent dosing. This can improve patient adherence to therapy. Furthermore, many mAbs can modulate the immune system, offering new mechanisms for the treatment of diseases such as cancer and autoimmune disorders. Bispecific antibodies represent an important advancement in antibody engineering, capable of simultaneously engaging two distinct targets to enhance therapeutic precision and efficacy, such as redirecting immune cells to tumor sites or blocking multiple disease pathways concurrently. ADCs combine the targeting specificity of mAbs with the potent cell-killing ability of cytotoxic payloads, enabling precise delivery of therapeutic agents directly to diseased cells and indirectly to surrounding cells while minimizing systemic toxicity.

OVERVIEW OF AUTOIMMUNE DISEASE DRUG MARKET IN CHINA

Overview

Autoimmune diseases are characterized by aberrant immune system function, wherein the body’s immune response erroneously targets endogenous tissues and organs. This pathological immune dysregulation manifests as either hyperactive immune responses or, in certain cases, immunodeficiencies. Autoimmune disease landscape encompasses over 100 clinically distinct conditions with the potential to affect a wide range of organ systems. Autoimmune diseases can be classified into organ-specific and systemic autoimmune diseases according to the self-antigens targeted by immune cells. Although the exact underlying pathophysiology of these diseases remains unclear, their core pathogenesis is closely associated with a break in immune self-tolerance and is driven by multiple factors:

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genetic and environmental factors together lead to the abrogation of immune self-tolerance mechanisms, triggering the unregulated activation of auto-reactive T and B cells. Meanwhile, other immune components such as antigen-presenting cells and complement are also involved in various stages from the initiation of autoimmune responses to tissue destruction. Given the core pathological characteristics of autoimmune diseases, such as broken immune tolerance and activated abnormal immune pathways, targeted biologics enable etiological treatment by precisely modulating key disease-driving targets.

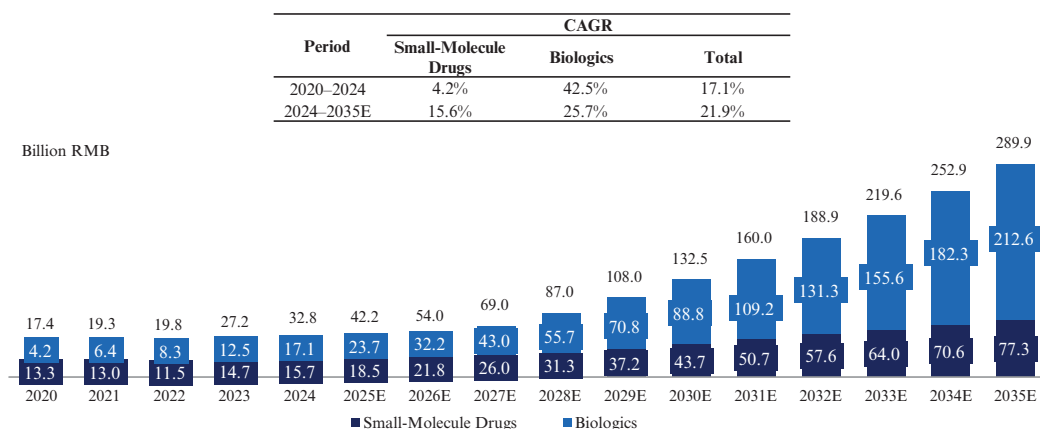
The traditional treatments including salicylates, non-steroidal anti-inflammatory drugs (“NSAIDs”), glucocorticoids, and conventional DMARDs are generally effective to alleviate pain, fever, and inflammatory responses, but these treatments relate to the symptoms of the disease, instead of the root causes of diseases. In comparison, the targeted biologics improve physical functioning and prevent irreversible damage, making disease remission possible. Currently, targeted biologics represent the advanced therapeutic direction, with IL-17A/F inhibitors demonstrating significant technological breakthroughs and application progress, leading the upgrading of treatment strategies.

Market Size

China’s autoimmune disease drug market has maintained a rapid growth momentum. Its market size increased from RMB17.4 billion in 2020 to RMB32.8 billion in 2024, representing a CAGR of 17.1%. The market size is projected to reach RMB289.9 billion in 2035, with a CAGR of 21.9% from 2024 to 2035. Generally, there are two different types of autoimmune disease drugs, namely small-molecule drugs and biologics. Among these two types, the biologics segment has outpaced small-molecule therapeutics due to its superior target specificity, enhanced efficacy profiles in refractory disease states, and favorable safety characteristics, which have driven both physician adoption and patient preference toward biologic therapies as first-line and escalation treatment options. The biologics for autoimmune disease market has increased from RMB4.2 billion in 2020 to RMB17.1 billion in 2024 at a CAGR of 42.5% and is expected to reach RMB212.6 billion in 2035 at a CAGR of 25.7% from 2024 to 2035.

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China Autoimmune Disease Drug Market, 2020–2035E



Source: Frost & Sullivan analysis

Market Drivers and Future Trends

We believe the growth of China’s autoimmune disease drug market will be driven by the following factors and trends.

- Rising Prevalence and Expanding Patient Pool.** China has one of the largest autoimmune disease patient populations globally. Demographic aging is accelerating, driving up the incidence of age-related autoimmune conditions such as rheumatoid arthritis, ankylosing spondylitis (“AS”), and psoriasis, thus expanding the potential patient base and laying a solid demand foundation.
- Increasing Awareness of Autoimmune Diseases and Willingness for Treatment.** Heightened awareness of autoimmune diseases represents a significant market driver, as historically underrecognized conditions have been better identified from expanded public education initiatives, resulting in improved patient understanding of disease pathophysiology, greater acceptance of diagnosis, and enhanced adherence to evidence-based treatment protocols. This growing awareness, coupled with rising disposable incomes and improved access to advanced biologics, has translated into greater patient willingness to pursue proactive treatment and accept long-term therapeutic regimens.
- Advancing and Increasing Accessibility of Biologics.** Biologic therapies have demonstrated clinical superiority over traditional small-molecule drugs in controlling inflammation, delaying disease progression, and improving long-term prognostic outcomes, establishing their position as preferred therapeutic agents. Concurrently, the inclusion of innovative biologics in medical insurance reimbursement negotiations, coupled with the accelerated commercialization of biosimilar alternatives, has improved patient accessibility and unlocked substantial market potential. The limitations of traditional therapies, combined with the superior efficacy and safety profiles of biologics,

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growing clinical demand for personalized treatment approaches, and anticipated launches of novel biologic agents are expected to drive significant market expansion.

- **Bridging the Gaps in Diagnosis and Treatment Between China and International Standards.** The future of China’s autoimmune disease market will focus on establishing a closed-loop diagnosis-to-treatment pathway and upgrading therapeutic strategies. Supportive policies, enhanced diagnostic technologies, and expanded insurance coverage will improve diagnostic standardization and disease awareness in primary healthcare, bringing diagnosis rates closer to those in developed countries. Additionally, increased access to biologics and targeted therapies, coupled with declining treatment costs, will lead to a significant rise in treatment rates. Clinical practice is expected to shift from traditional hormone and immunosuppressive therapies to more efficient and safer targeted treatments.
- **Enhancing Capabilities for Personalized Treatment.** Autoimmune diseases exhibit high variability in symptoms and treatment responses. For years, many patients have experienced drug-related toxicity and a lack of personalized treatment options tailored to their unique conditions. Advances in genetics and medicine are now enabling a deeper understanding of individual disease profiles, resulting in rising availability of and demand for personalized treatments that enhance efficacy and minimize adverse effects. The development of personalized treatment is fueled by the need to meet each patient’s specific requirements, utilizing advancements in diagnostics and therapeutic technologies. This trend is expected to persist as more targeted therapies become available, bolstered by increased research investment and regulatory support for personalized treatment plans.

OVERVIEW OF ONCOLOGY DRUG MARKET IN CHINA

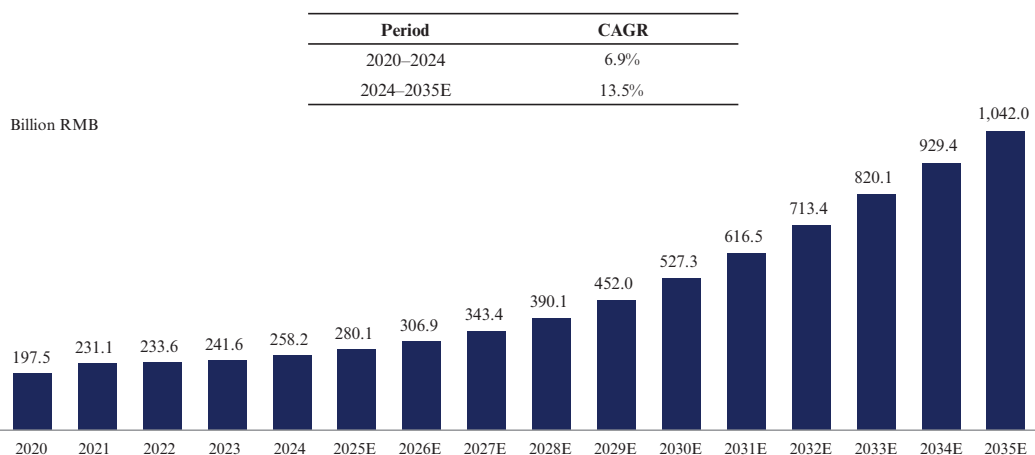
Cancer is a major threat to global human health. Tumors are broadly categorized into benign and malignant types, where malignant tumors, or cancers, are characterized by rapid proliferation, strong invasiveness, and distant metastasis, inflicting severe harm to the human body. The cancer treatment paradigm has evolved progressively, advancing from traditional approaches such as surgery, radiotherapy, and chemotherapy to a new era dominated by targeted therapy, immunotherapy, and cell & gene therapy. Notably, China’s cancer burden exhibits a persistent upward trajectory, with new case incidence increasing from 4.6 million in 2020 to 5.0 million in 2024, and projected to reach 5.9 million by 2035.

Market Size

Driven by rising cancer incidence, increasing life expectancy, and the introduction of innovative therapies, China’s oncology drug market expanded from RMB197.5 billion in 2020 to RMB258.2 billion in 2024 at a CAGR of 6.9%, and is projected to reach RMB1,042.0 billion by 2035, representing a CAGR of 13.5% from 2024 to 2035.

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China Oncology Drug Market, 2020–2035E



Source: Frost & Sullivan analysis

Market Drivers and Future Trends

We believe the growth of China’s oncology drug market will be driven by the following factors and trends.

- Increasing Patient Number and Longer Survival Time.** China’s oncology drug market is experiencing rapid expansion driven by three converging forces: demographic aging that pushes more people into high-cancer-risk age brackets, environmental impact from decades of industrialization contributing to carcinogen exposure, and certain lifestyles characterized by sedentary behavior, processed diets, and tobacco use. The market is increasingly shifting toward late-stage therapeutics as many patients are diagnosed at advanced stages due to limited early screening penetration, creating substantial demand for second-line and third-line treatments that can overcome drug resistance. These demographic, environmental, and technological trends are transforming China into one of the world’s most dynamic and strategically important oncology drug markets, with late-stage precision therapies positioned at the epicenter of growth. In addition, the five-year survival rate for cancer patients in China has increased from 33.3% in 2015 to 43.7% in 2023, with longer patient survival contributing to sustained demand for ongoing therapeutic interventions and market growth.
- Rise of Novel Therapies and Combination Therapies.** China’s oncology market is experiencing robust growth driven by escalating demand for novel cancer therapeutics and treatments for rare oncological conditions, reflecting critical unmet medical needs of patients with advanced, metastatic or drug-resistant cancers where conventional treatment options have proven inadequate. In addition, oncology treatment landscape has undergone a fundamental transformation as combination therapy regimens have increasingly become the standard of care across multiple cancer indications, reflecting accumulating

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clinical evidence demonstrating that multi-modal treatment approaches targeting complementary mechanisms of action deliver superior efficacy compared to monotherapy interventions.

- **Transition Toward Biologics and Precision Medicine.** Novel targeted biologics are progressively replacing conventional chemotherapy as first-line options. Tumor heterogeneity is driving the development of precision medicine, with biomarker-guided therapies demonstrating broad efficacy across cancer subtypes. Advances in treatment are also enabling chronic disease management of cancer, increasing demand for therapies that balance long-term safety with efficacy while overcoming resistance.

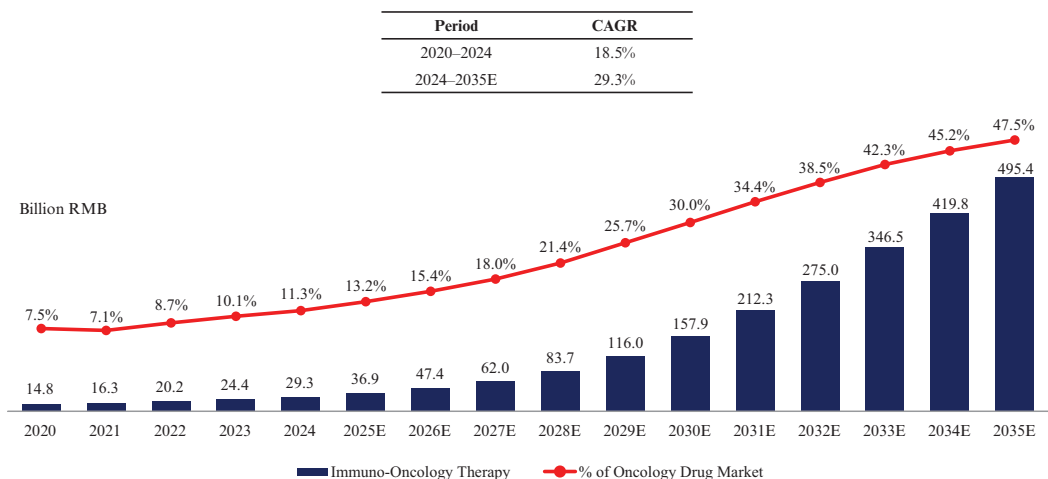
Overview of Immuno-Oncology Drug Market

Oncology therapeutics are generally categorized into three major classes: immuno-oncology therapies, chemotherapy, and targeted therapies. Immunotherapy represents a critical frontier of innovation in oncology treatment. Immuno-oncology therapies encompass a broad range of approaches, including cellular immunotherapies, cytokines, therapeutic cancer vaccines, and antibody-based therapies. Among these modalities, antibody-based therapies have demonstrated particularly significant clinical advantages by enhancing immune-mediated tumor cell killing, notably through the inhibition of immune checkpoints that cancer cells exploit to evade immune surveillance. The success of immune check-point inhibitors not only validated this immunological approach of tackling tumor, but also profoundly changed the oncology treatment landscape, hence, has brought benefits to cancer patients worldwide. In recent years, emerging therapeutic modalities — including next-generation antibody-based treatments such as immuno-oncology agents and ADCs — are expected to play an increasingly pivotal role in cancer treatment.

In China, immuno-oncology drugs accounted for 11.3% of the total oncology drug market in 2024 and are expected to reach 47.5% by 2035. Driven by the approval of immune-oncology drugs and expanding clinical indications, China’s immuno-oncology drug market expanded from RMB14.8 billion in 2020 to RMB29.3 billion in 2024, representing a CAGR of 18.5%, and is projected to reach RMB495.4 billion in 2035, reflecting a CAGR of 29.3% from 2024 to 2035.

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China Immuno-Oncology Drug Market, 2020–2035E



Source: Frost & Sullivan Analysis

Overview of Hematology Malignancy Drug Market

Hematologic malignancies are cancers that arise from immune system cells, or blood-forming tissues, resulting from abnormal differentiation of hematopoietic stem cells, which are responsible for producing all blood cell types via myeloid and lymphoid lineages. It represents the most immunotherapy-responsive segments in oncology.

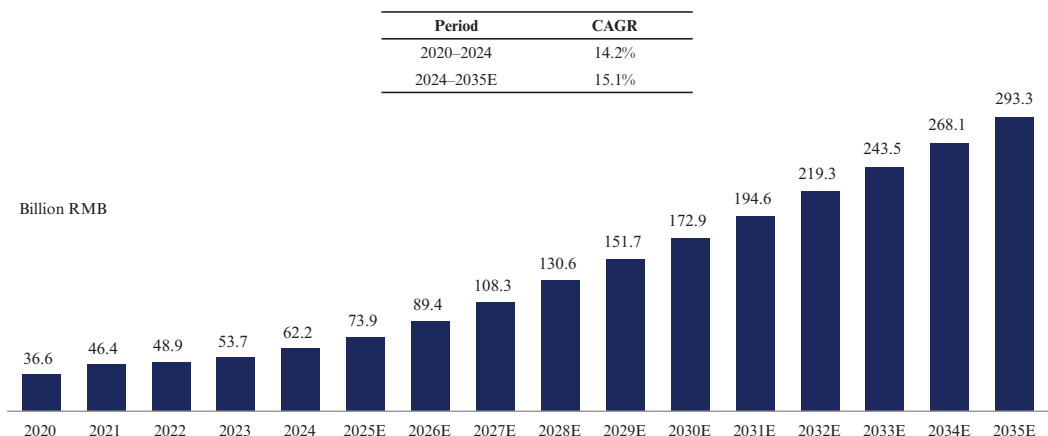
The treatment of hematology malignancy has undergone a revolutionary transformation over the past decades, shifting from general chemotherapy to precise immunology-based therapeutics that target cancer cells specifically. Advances in tumor immunology and molecular biology have enabled the development of therapies that selectively recognize and eliminate malignant cells while sparing normal tissues, leading to improved efficacy and more favorable safety profiles.

Monoclonal antibodies were among the earliest breakthroughs in this paradigm shift. For example, the introduction of rituximab, a CD20-targeting antibody, significantly transformed the treatment paradigm of B-cell non-Hodgkin lymphomas, establishing immunotherapy as a cornerstone of hematologic malignancy care and becoming one of the first blockbuster biologics in oncology. Despite significant advances, hematologic malignancies remain highly heterogeneous, complicating optimal treatment across disease subtypes. High relapse rates, therapy resistance, and poor outcomes in aggressive forms reflect persistent unmet clinical needs, while the high cost of novel therapies continues to limit broad access and long-term adoption in standard care.

In China, driven by the approval of innovative therapies targeting hematologic malignancy and the improved survival rate, China’s hematologic malignancy drug market has experienced rapid growth, increasing from RMB36.6 billion in 2020 to RMB62.2 billion in 2024 at a CAGR of 14.2%, and is expected to reach RMB293.3 billion in 2035, representing a CAGR of 15.1% from 2024 to 2035.

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China Hematologic Malignancy Drug Market, 2020–2035E



Source: Frost & Sullivan Analysis

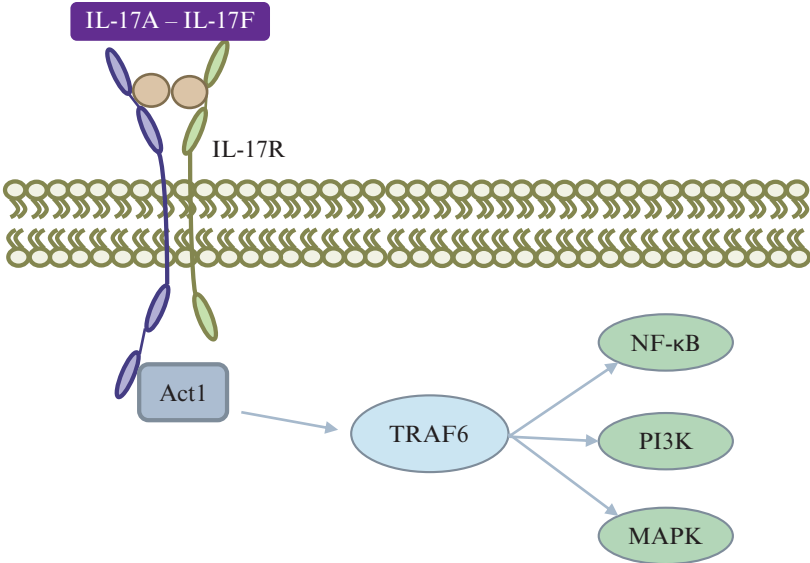
OVERVIEW OF THE IL-17-TARGETED ANTIBODY DRUG MARKET IN CHINA

Overview

IL-17 is a key cytokine implicated in the pathological processes of various autoimmune diseases, including psoriasis and arthritis. The IL-17 family comprises six subtypes, designated IL-17A through IL-17F, with IL-17A and IL-17F attracting most research interest due to their potent biological activity and strong correlation with disease progression.

IL-17 binds to its receptor IL-17R on target cells, inducing receptor heterodimerization and recruiting the ACT1 adapter protein, which subsequently activates downstream signaling molecules such as TRAF6. This cascade triggers key inflammatory pathways, including NF- κ B, PI3K, and MAPK, prompting cells in affected tissues such as the synovium, skin, and intestines to secrete pro-inflammatory factors including IL-6, tumor necrosis factor alpha (“TNF- α ”), and IL-23. These signals recruit inflammatory cells such as neutrophils, ultimately causing tissue damage and disease progression. IL-17-targeted antibody therapies are designed to interrupt this inflammatory cascade at its source by blocking IL-17 signaling, thereby effectively inhibiting disease advancement. The following image illustrates the mechanism of action of IL-17.

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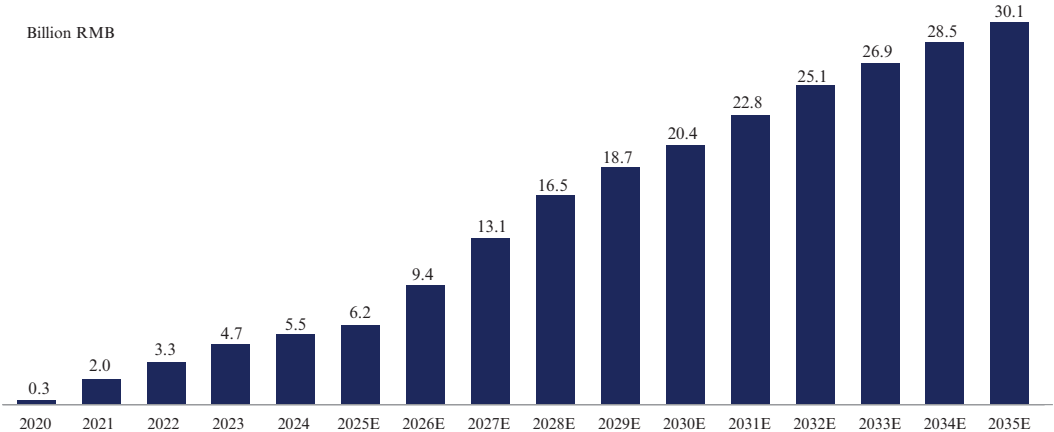


Source: Literature Review, Frost & Sullivan analysis

In terms of market size, the IL-17-targeted antibody drug market in China reached RMB5.5 billion in 2024, reflecting a CAGR of 40.1% from RMB2.0 billion in 2021. Driven by the growing number of approved IL-17 targeted antibodies, this market is projected to expand to RMB30.1 billion in 2035, representing a CAGR of 16.8% from 2024 to 2035.

China IL-17 Targeted Antibody Drug Market, 2020–2035E

Period	CAGR
2021–2024	40.1%
2024–2035E	16.8%



Source: Frost & Sullivan analysis

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Indications and Market Opportunities

Psoriasis

Overview

Psoriasis is an immune-mediated chronic, recurrent autoimmune disease triggered by the interaction of genetic and environmental factors. Environmental exposures serve as important triggering factors that can induce a chronic inflammatory state, with typical pathological manifestations including excessive blood vessel growth in the skin and accelerated replication of skin cells. Clinically, the condition is characterized by well-demarcated, raised erythematous plaques with silvery scales and is non-contagious. Psoriasis can occur at any stage of life, with two onset peaks between 30–39 and 50–69 years of age. Based on the characteristics of clinical manifestations, psoriasis can be classified into four categories: psoriasis vulgaris, pustular psoriasis, erythrodermic psoriasis, and psoriatic arthritis.

- Psoriasis vulgaris is the most common form, comprising two major subtypes. Plaque psoriasis accounts for 80%-90% of all cases, presenting as symmetrical lesions typically distributed on the scalp, knees, elbows, and gluteal cleft. Guttate psoriasis is more common in individuals under 30 years old, characterized by small, drop-like red lesions on the trunk and proximal extremities.
- Pustular psoriasis is characterized by sterile pustules and includes two subtypes. palmoplantar pustular psoriasis is a rare, severe form limited to the palms and soles. Generalized pustular psoriasis can be life-threatening, presenting as widespread inflamed skin with pustules, often accompanied by systemic symptoms including fever and fatigue.
- Erythrodermic psoriasis manifests as generalized erythema covering 90% or more of the body surface area, carrying risks of sepsis and fluid loss due to impaired skin barrier function.
- Psoriatic arthritis affects some psoriasis patients, causing joint swelling, stiffness, and pain. It is a progressive condition that may lead to joint deformity in severe cases.

Prevalence

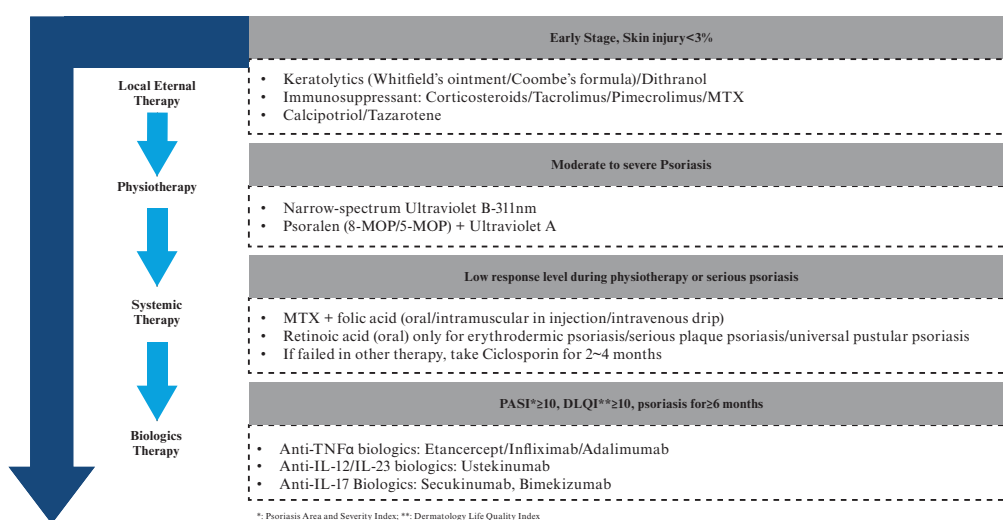
Psoriasis represents a significant health burden in China, with the patient population reaching 7.0 million in 2024, up from 6.9 million in 2020. Its patient population is projected to grow steadily to 7.2 million by 2035.

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Treatment Paradigm

Currently, psoriasis cannot be cured. The core therapeutic goal is to control and stabilize the condition, slow disease progression, and alleviate symptoms such as skin lesions (including erythema, scaling, and plaque thickening) and itching. PASI 75, PASI 90, and PASI 100 — corresponding to 75%, 90%, and 100% reductions in disease severity from baseline — are the established efficacy benchmarks in psoriasis treatment, with PASI 100 (complete skin clearance) increasingly recognized as the ultimate treatment goal.

Psoriasis treatment follows a stepwise, severity-based approach that balances efficacy against potential side effects. For early-stage disease with limited skin involvement (< 3% body surface area), topical therapies serve as the first-line treatment. As disease progresses to moderate to severe psoriasis, physiotherapy and subsequently systemic therapies (including conventional immunosuppressants such as methotrexate and cyclosporine) are introduced. For patients with refractory or severe disease — defined by PASI ≥10, DLQI > 10, and disease duration of six months or longer — biologic therapies represent the most advanced treatment option. Among biologics, IL-17 inhibitors represented by bimekizumab have emerged as a preferred therapeutic class, offering superior efficacy with high PASI 75/90/100 response rates, rapid onset of action, and favorable long-term safety profiles, making them one of the major therapeutics for moderate to severe psoriasis.



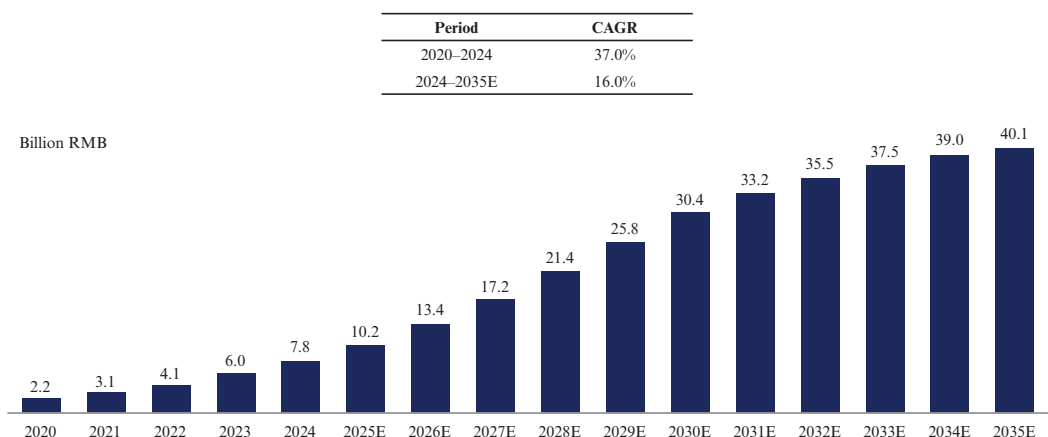
Source: Literature Review, Frost & Sullivan analysis

Market Size

The market size of China's moderate to severe psoriasis drug market grew from RMB2.2 billion in 2020 to RMB7.8 billion in 2024, representing a CAGR of 37.0% during this period. The market is projected to expand to RMB40.1 billion by 2035, reflecting a CAGR of 16.0% from 2024 to 2035. This sustained growth trajectory reflects continued growth in domestic demand for psoriasis treatments and favorable development prospects within the psoriasis therapeutics market.

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China Moderate to Severe Psoriasis Drug Market, 2020–2035E



Source: Frost & Sullivan analysis

Competitive Landscape

As of the Latest Practicable Date, five innovative IL-17-targeted drugs for psoriasis were approved and marketed in China, and there were five innovative IL-17 targeted drugs for psoriasis under biologics license application (“BLA”) stage in the same region.

Marketed Innovative IL-17-Targeted Drugs for Psoriasis in China

Brand Name	Generic Name	Company	Approved Indication	NMPA First Approval Date	Medical Insurance	Specification	Unit Price (RMB)
Cosentyx®	Secukinumab	Novartis	Plaque Psoriasis	2019-03-28	B	1mL: 150mg	778.65
TALTZ®	Ixekizumab	Eli Lilly	Plaque Psoriasis	2019-08-29	B	80mg/ml	1,218.00
LUMICEF®	Brodalumab	Kyowa Kirin	Plaque Psoriasis	2020-06-17	—	1.5mL: 210mg	NA
安达静®	Vunakizumab	Hengrui	Plaque Psoriasis	2024-08-20	—	1mL: 120mg	980.00
金立希®	Xeligezimab	GenrixBio	Plaque Psoriasis	2024-08-20	—	1mL: 100mg	798.00

BLA Stage Innovative IL-17-Targeted Drugs for Psoriasis in China

Drug Code	Company	Target	NMPA First Posted Date
SSGJ-608	3s Guojian Pharmaceutical	IL-17A	2024-11-19
Gumokimab	Akeso Pharmaceuticals	IL-17A	2025-01-27
Bimekizumab	UCB Pharma Our Company	IL-17A, IL-17F	2025-05-27
Roconkibart	Junshi Biosciences	IL-17A	2025-12-06
LZM012/XKH004	Livzon Mabpharm	IL-17A, IL-17F	2025-12-24

Source: NMPA, CDE, Frost & Sullivan analysis

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Bimekizumab, the first approved IL-17A/IL-17F dual-target biological agent globally, can simultaneously block two pro-inflammatory cytokines, thereby inhibiting pro-inflammatory signals more effectively than IL-17 single-target drugs. Head-to-head comparisons have confirmed its superior efficacy compared to certain other approved biologics for psoriasis with comparable safety, positioning it as the best-in-class treatment option.

Head-to-Head Clinical Trial Data of Bimekizumab and Other Drugs for the Treatment of Psoriasis

Clinical Endpoint	Clinical Outcomes of Bimekizumab Compared to Other Drugs		
	Bimekizumab vs Adalimumab	Bimekizumab vs Ustekinumab	Bimekizumab vs Secukinumab
PASI75 4 weeks	76.5% vs 31.4%	77% vs 15%	71.0% vs 47.3%
PASI90 16 weeks	86.2% vs 47.2%	85% vs 50%	85.5% vs 74.3%
PASII00 16 weeks	60.8% vs 23.9%	59% vs 21%	61.7% vs 48.9%
PASII00 24 weeks	66.8% vs 29.6%	/	/
PASII00 48 weeks	/	65% vs 38%	67% vs 46.2%
Safety	<ul style="list-style-type: none"> ● Elevated liver enzymes: 0.7%-1.3% vs 4% ● Severe infection: 0.7%-1.3% vs 2.7% 	similar	similar

Source: Clinical Trials, Literature Review, Frost & Sullivan analysis

Ankylosing Spondylitis

Overview

AS is a chronic inflammatory type of arthritis primarily affecting the spine. Inflammatory responses in the joints and tissues of the spine can cause progressive stiffness, potentially leading to a rigid spine with limited mobility. While the exact cause of AS remains unclear, it is believed to be influenced by a combination of genetic and environmental factors, with over 90% of patients carrying the human leukocyte antigen HLA-B27, which may create conditions that favor IL-17-driven inflammation.

AS exhibits significant multisystem involvement. Clinically, it is characterized by inflammatory low back pain, typically presenting as gradual-onset pain and stiffness in the lower back or sacroiliac region that improves with activity. As the disease advances, ankylosis and reduced spinal mobility may occur, with some patients also experiencing peripheral joint swelling and pain. Extra-articular manifestations commonly include acute anterior uveitis, presenting with sudden eye pain, photophobia, blurred vision, and conjunctival congestion, which can lead to visual impairment if not promptly addressed. Additionally, AS may affect the cardiovascular system (aortitis, aortic valve disease, cardiac conduction abnormalities), gastrointestinal system (gastric ulcers, diarrhea, inflammatory bowel disease), and skeletal system (osteoporosis, heterotopic ossification), with systemic symptoms including fatigue, postural deformities, and diminished lung function.

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Prevalence

The number of AS patients in China reached 3.97 million in 2024, up from 3.89 million in 2020. The patient population is projected to reach 4.20 million by 2035.

Treatment Paradigm

The treatment regimens for AS follow a hierarchical approach based on disease activity and treatment response. First-line therapy involves NSAIDs, which serve as the primary treatment option for patients with active AS, particularly those presenting with inflammatory low back pain and joint swelling or pain. NSAIDs can rapidly alleviate symptoms and reduce inflammation; however, prolonged use may lead to adverse effects including gastrointestinal complications, allergic reactions, and hypertension.

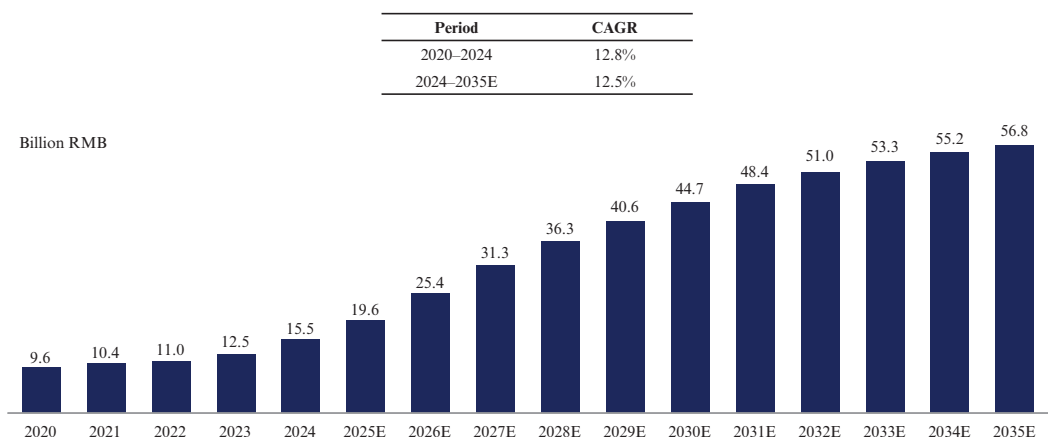
For patients with inadequate response to or intolerance of NSAIDs, biological agents represent second-line therapy. TNF- α inhibitors, such as adalimumab, etanercept, and infliximab, are indicated for active AS patients who fail first-line treatment, as they can rapidly reduce disease activity, significantly improve joint function, and offer durable long-term benefits. IL-17-targeted drugs, such as secukinumab and bimekizumab, are recommended for patients who do not respond adequately to either NSAIDs or TNF- α inhibitors, effectively controlling inflammation and enhancing joint function. IL-17-targeted therapies have demonstrated comparable or superior efficacy to TNF- α inhibitors in clinical trials, providing an important alternative for patients with refractory disease or those who experience diminished response to TNF- α inhibition over time.

Market Size

In terms of market size, China’s AS drug market grew from RMB9.6 billion in 2020 to RMB15.5 billion in 2024, representing a CAGR of 12.8% during this period. The market is projected to expand to RMB56.8 billion by 2035, corresponding to a CAGR of 12.5% from 2024 to 2035, as illustrated in the chart below.

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China Ankylosing Spondylitis Drug Market, 2020–2035E



Source: Frost & Sullivan analysis

Competitive Landscape

As of the Latest Practicable Date, nine innovative biologics for AS had been approved and marketed in China, five of which were IL-17-targeted biologics, as illustrated in the chart below.

Marketed Targeted Innovative Biologics for AS in China

Brand Name	INN	Company	Target	Modality	NMPA First Approval Date	2024 Medical Insurance	Specification	Unit Price (RMB)
Remicade®	Infliximab	Janssen Biotech	TNF- α	mAb	2006/5/3	B	100mg	2,006.80
HUMIRA®	Adalimumab	Abbvie	TNF- α	mAb	2013/3/29	B	0.4ml: 40mg	1,290.00
Enbrel®	Etanercept	Pfizer	TNF- α	Antibody Fusion Protein	2010/2/26	B	0.47ml: 25mg	181.45
Simponi®	Golimumab	Janssen Biotech	TNF- α	mAb	2017/12/28	B	0.5ml: 50mg	4,900.00
Cosentyx®	Secukinumab	Novartis	IL-17A	mAb	2020/4/26	B	1ml: 150mg	778.65
Taltz®	Ixekizumab	Eli Lilly	IL-17A	mAb	2022/7/26	B	80mg/ml	1,218.00
BIMZELX® (倍捷乐®)	Bimekizumab	UCB Pharma Our Company	IL-17A, IL-17F	mAb	2024/7/16	—	1.0ml: 160mg	2,500.00
安达静®	Vunakizumab	Hengrui	IL-17A	mAb	2024/8/20	—	1.0ml: 120mg	980.00
金立希®	xeligekimab	GenrixBio	IL-17A	mAb	2024/8/20	—	1.0ml: 100mg	798.00

Source: NMPA, Frost & Sullivan analysis

Non-Radiographic Axial Spondyloarthritis

Axial spondyloarthritis can be classified into radiographic axial spondyloarthritis (also known as AS) and non-radiographic axial spondyloarthritis (“nr-axSpA”). nr-axSpA represents an early stage of axial spondyloarthritis that has not yet manifested radiographic signs of structural bone changes. Unlike AS, patients with nr-axSpA do not exhibit characteristic changes on X-ray despite having significant inflammation. Diagnosis relies on

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magnetic resonance imaging (“MRI”) to confirm active inflammation of the sacroiliac joints, or comprehensive assessment combining clinical symptoms, laboratory tests, and other imaging results.

The symptoms of nr-axSpA primarily arise from axial inflammation. Chronic low back pain is typically more intense at night or in the morning and is often relieved by activity, with patients also experiencing morning stiffness and limited mobility in the back and neck after periods of rest. Sacral pain manifests as dull pain or tenderness in the sacroiliac joints, worsening with pressure or movement and potentially affecting activities such as bending or lifting the legs. Peripheral symptoms may include joint swelling and pain, enthesitis (such as pain in the heel or sole), and occasional systemic symptoms including mild fever, fatigue, or slight weight loss, with a minority of patients also presenting with ocular or intestinal inflammation. Although most cases of nr-axSpA do not progress, a subset of patients may slowly advance to AS. The estimated probabilities of progression for newly diagnosed nr-axSpA patients are 6.4% at 5 years, 17.3% at 10 years, and 26.4% at 15 years.

Prevalence

The number of nr-axSpA patients in China reached 2.97 million in 2024, up from 2.92 million in 2020. The patient population is projected to expand to 3.15 million by 2035. This steady growth pattern underscores enhanced early diagnosis rates and stable expansion of the patient population.

Treatment Paradigm

The management of nr-axSpA in adults follows a stratified treatment approach combining both non-surgical and surgical methods, aiming to control inflammation, enhance function, and correct deformities. Non-surgical treatment serves as the first line of intervention, including non-pharmacological measures such as functional exercise and physiotherapy, alongside NSAIDs. For patients with active nr-axSpA who exhibit persistent symptoms after four weeks of NSAID therapy, Tumor Necrosis Factor inhibitors (“TNFi”) are recommended. Second-line therapy involves transitioning to other biologic disease-modifying antirheumatic drugs (“DMARDs”), with IL-17 inhibitors emerging as a key therapeutic option for patients who do not respond adequately to NSAIDs or TNFi. IL-17 plays a central role in the pathogenesis of axSpA by driving inflammation and structural damage, making IL-17-targeted therapies highly effective in controlling disease activity and improving patient outcomes. Additional therapies may include DMARDs for those with concurrent peripheral arthritis, local corticosteroid injections for ongoing active sacroiliitis (while avoiding long-term high-dose systemic corticosteroids), and other analgesics or antibiotics as necessary. Surgical treatment is considered only when non-surgical options fail to alleviate symptoms or control disease progression, resulting in significant functional impairment or when deformities severely impact quality of life.

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Treatment Diagram for nr-axSpA in Adults

Treatment Diagram for nr-axSpA in Adults			
Non-Surgical Treatment	First-line Treatment	Non-Pharmacological Therapy	Functional exercise, physiotherapy, etc.
		Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)	<ul style="list-style-type: none"> NSAIDs are preferred for adult active nr-axSpA; start with the lowest effective dose and assess regularly. If ineffective after 2 weeks at the maximum tolerated dose with one NSAID, switch to another. For patients with contraindications or intolerance to NSAIDs, other analgesics may be considered.
		Tumor Necrosis Factor Inhibitors (TNFi, conditionally recommended)	<ul style="list-style-type: none"> For active nr-axSpA with ongoing activity after 4 weeks of NSAID therapy, TNFi are strongly recommended, provided the patient has at least one of the following: elevated CRP, MRI inflammation, or radiographic sacroiliitis. For adult nr-axSpA patients in stable phase, TNFi can be used as monotherapy for maintenance; treatment should not be stopped or reduced, and effective originator TNFi should be continued without switching to a biosimilar.
	Second-line Treatment	Biologics: TNFi or IL-17 Inhibitors	For patients with an inadequate response to NSAIDs and TNFi, other biologic DMARDs, particularly IL-17 inhibitors such as bimekizumab and secukinumab, may be used. The efficacy criteria and considerations for use are consistent with those for TNFi.
Surgical Treatment	Adjunctive Therapy for Specific Circumstances	DMARDs, corticosteroids, other analgesics, antibiotics, etc.	<ul style="list-style-type: none"> DMARDs are recommended for ax-SpA patients with concomitant peripheral arthritis. Long-term, high-dose systemic corticosteroids are not recommended for ax-SpA. Local corticosteroid injections are conditionally recommended for persistent active sacroiliitis despite NSAID therapy.
		Cervicothoracic osteotomy	Surgical intervention should only be considered when patient function is impaired or deformity significantly affects quality of life, and adequate non-surgical treatment fails to provide relief or control progression.
		thoracolumbar osteotomy	
		joint replacement	The goals of surgery are to alleviate pain and improve deformity and ankylosis in the spine (cervical, thoracic, lumbar) and large peripheral joints. Surgery is not curative for ax-SpA, and patients must continue comprehensive non-surgical management postoperatively.

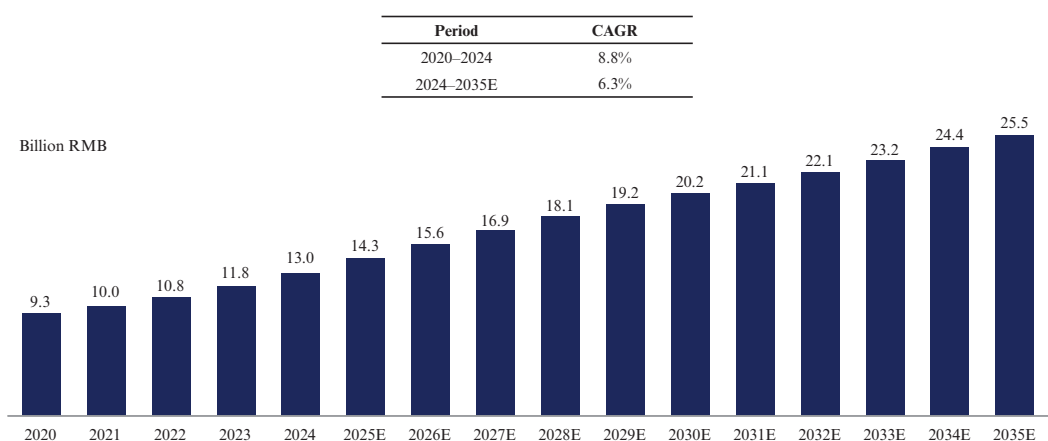
Source: Chinese Expert Consensus on the Diagnosis and Treatment of Axial Spondyloarthritis (2023 Edition), Frost & Sullivan analysis

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Market Size

The market for nr-axSpA drugs in China grew from RMB9.3 billion in 2020 to RMB13.0 billion in 2024, representing a CAGR of 8.8% during this period. The market is projected to further grow to RMB25.5 billion by 2035, corresponding to a CAGR of 6.3 from 2024 to 2035, as illustrated in the chart below.

China nr-axSpA Drug Market, 2020–2035E



Note: China’s nr-axSpA drug market primarily includes biologics, NSAIDs, DMARDs and analgesics.

Source: Frost & Sullivan analysis

Competitive Landscape

As of the Latest Practicable Date, there were only two approved drugs for nr-axSpA in China, namely bimekizumab and upadacitinib, which are illustrated in the table below.

Marketed Drugs for nr-axSpA in China

Brand Name	INN	Company	Target	Drug Type	Mode of Administration	Modality	NMPA Approval Date	2024 Medical Insurance	Specification	Unit Price (RMB)
RINVOQ®	Upadacitinib	AbbVie	JAK1	Innovative Chemical Drug	Tablet	Chemical Drug	2022/02/18	B	30mg	111.32
BIMZELX® (倍捷乐®)	Bimekizumab	UCB Pharma Our Company	IL-17A, IL-17F	Innovative Biologic	Injection	mAb	2024/09/14	—	1.0ml: 160mg	2,500.00

Source: NMPA, Frost & Sullivan analysis

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As of the Latest Practicable Date, secukinumab was also under a phase 3 clinical trial in China for the treatment of nr-axSpA. Bimekizumab has demonstrated a favorable clinical profile compared to secukinumab based on reported clinical trials in non-head-to-head settings, as illustrated in the table below.

Clinical Trial Data of Bimekizumab and Secukinumab for the Treatment of nr-axSpA

Indicator	Bimekizumab vs Placebo	Secukinumab vs Placebo
Efficacy		
ASAS40 16 weeks	47.7% vs 21.4%	40.0% vs 28.0%
ASAS40 (Group of patients who have not received TNFi therapy) 16 weeks	46.6% vs 22.9%	41.5% vs 29.2%
ASAS20 16 weeks	68.8% vs 38.1%	56.8% vs 45.7%
BASDAI 16 weeks	-3.07 vs -1.55	-2.35 vs -1.46
BASFI 16 weeks	-2.39 vs -0.91	-1.75 vs -1.01
ASQoL16 weeks	-4.94 vs -2.30	-3.45 vs -1.84
Safety		
Treatment-Emergent Adverse Events (“TEAEs”)	62.5% vs 56.3%	64.3% vs 54.3%
Serious Adverse Events (“SAEs”)	0% vs 0.8%	1.1% vs 1.6%

Source: Clinical Trials, Literature Search, Frost & Sullivan analysis

Hidradenitis Suppurativa (“HS”)

HS, also known as acne inversa, is a chronic, recurrent inflammatory skin condition caused by follicular obstruction affecting the pilosebaceous unit. It commonly occurs in areas where apocrine sweat glands are distributed, such as the armpits, groin, perineum, and perianal region. The disease typically manifests during adolescence, with primary symptoms including painful, deep inflammatory nodules, followed by the formation of abscesses, sinus tracts, and scarring. HS significantly impacts patients’ quality of life due to persistent pain, malodorous discharge, and the psychological burden associated with visible lesions and scarring. The chronic and progressive nature of the disease often leads to considerable physical discomfort and emotional distress, highlighting the need for effective therapeutic interventions. In 2024, the prevalence of HS in China was 481.1 thousand, increasing from 472.9 thousand in 2020, and is expected to reach 500.2 thousand in 2035.

The management of HS follows a stratified treatment approach based on disease severity using the Hurley staging system, encompassing initial treatment, acute attack management, and adjuvant therapy. For initial treatment, first-line options vary by severity: Hurley I (mild) patients receive topical medications and/or oral tetracycline antibiotics; Hurley II (moderate) patients are treated with oral tetracycline antibiotics; and Hurley III (severe) patients require combination therapy with oral metronidazole, moxifloxacin, and rifampin. For patients who are unresponsive to first-line therapy, second-line treatment options include clindamycin combined with rifampin, oral retinoids,

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sulfonamides, zinc supplements, colchicine, or thalidomide for Hurley I patients, while Hurley II and III patients may transition to biological agents, with IL-17 inhibitors emerging as a promising therapeutic option due to their ability to target key inflammatory pathways implicated in HS pathogenesis. Acute attack management involves intralesional injection of corticosteroids for mild to moderate cases, and short-term oral corticosteroids or corticosteroid injections into skin lesions for severe cases. Adjuvant therapy includes surgical interventions such as incision and drainage, decortication, decubitus ulcer debridement, scalp reduction surgery, and localized enlarged excision of skin lesions, alongside physical therapy, with treatment intensity escalating according to Hurley stage severity.

Secukinumab, an IL-17A antibody, was the only approved and marketed drug for HS in China as of the Latest Practicable Date. There are also five pipeline biologics under clinical trial or at the NDA stage for the treatment of HS in China, including bimekizumab, for which an NDA has been submitted.

Marketed Drugs for HS in China

Brand Name	INN	Company	Target	Drug Type	Mode of Administration	Modality	NMPA First Approval Date	2024 Medical Insurance	Specification	Unit Price (RMB)
Cosentyx®	Secukinumab	Novartis	IL-17A	Innovative Biologic	Injection	mAb	2019/03/28 (HS indication: 2025/03/11)	B	1ml: 150mg	778.65

Pipeline Biologics for Treating HS in China

Drug Code/INN	Company	Target	Modality	Highest Phase	First Posted Date
Bimekizumab	UCB Pharma Our Company	IL-17A, IL-17F	mAb	NDA	2025-05-28
Vilobelimab	Beijing Defengrui Biological Technology/Staidson(Beijing) Biopharmaceuticals	C5a	mAb	Phase 2	2021-03-22
Tulisokibart	Merck Sharp & Dohme	TL1A	mAb	Phase 2	2025-07-02
Brivekimig	Sanofi	OX40L, TNF- α	Bispecific Nanobody	Phase 2	2025-12-18
NBL-012	Shanghai Xinshi Biopharmaceutical	IL23p19	mAb	Phase 1	2021-06-03
HB0043 (HB1734)	Huaota/Huabo Biopharm	IL-17A, IL36R	Bispecific Antibody	Phase 1	2025-12-01

Source: NMPA, CDE, Frost & Sullivan analysis

OVERVIEW OF THE CD20-TARGETED MONOCLONAL ANTIBODY MARKET

Overview

mAbs that target the CD20 antigen on B cells have been successfully employed in clinical settings for B cell depletion, primarily to treat various forms of cancer and autoimmune diseases, such as diffuse large B-cell lymphoma (“DLBCL”) and primary membranous nephropathy (“PMN”). The first CD20-targeted mAb, rituximab, was approved by the FDA in 1997 and has since become a cornerstone in the treatment of lymphoma, as well as in the management of rheumatoid arthritis.

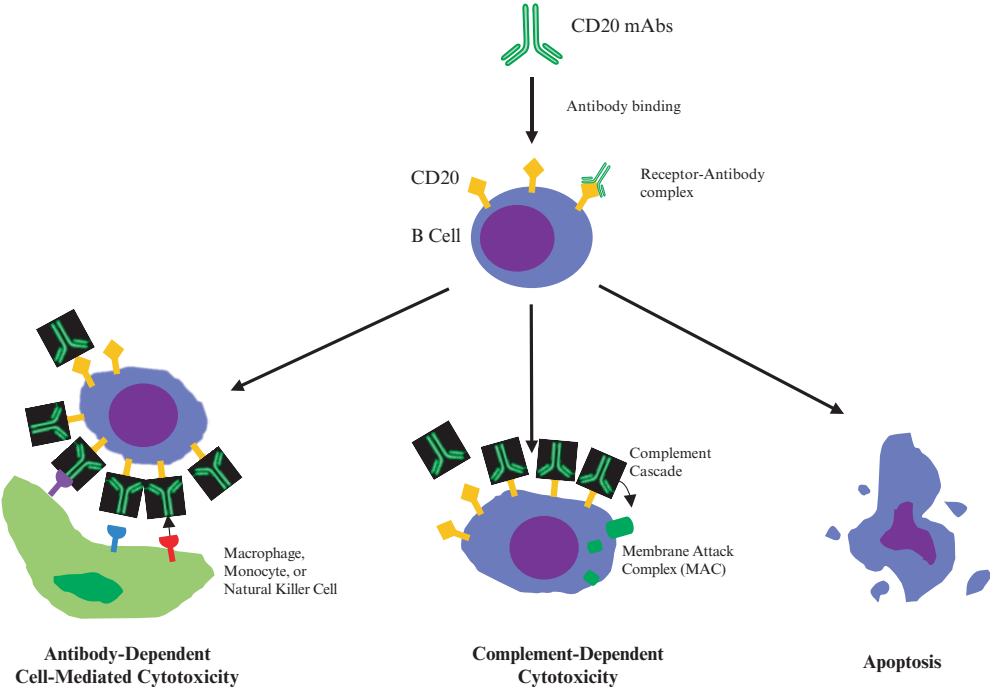
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CD20-targeted mAbs achieve tumor killing through three core pathways that act synergistically to enhance antitumor efficacy:

- **Direct Induction of Non-Classical Apoptosis.** After specific binding of CD20-targeted mAbs to the CD20 antigen on the surface of tumor B cells, cross-linking and aggregation of multiple CD20 molecules are triggered, which further activates the non-classical apoptotic signaling pathway and induces tumor cell death. Unlike classical apoptosis, this pathway is independent of typical apoptosis initiators but mediates programmed cell death through Src kinase-related signaling pathways.
- **Complement-Dependent Cytotoxicity (“CDC”).** The binding of CD20-targeted mAbs to the CD20 antigen activates the body’s complement system, initiating the complement cascade reaction and ultimately forming the membrane attack complex (“MAC”). This complex inserts into the tumor cell membrane, leading to membrane perforation and leakage of intracellular substances, thereby directly lysing tumor cells. CDC represents one of the important pathways for CD20-targeted mAbs to rapidly kill tumor cells.
- **Complement-Enhanced Antibody-Dependent Cellular Cytotoxicity (Complement-Enhanced “ADCC”).** After CD20-targeted mAbs initiate complement activation, complement cleavage fragments are generated and subsequently recognized by complement receptors (“CRs”) on the surface of immune cells such as natural killer cells and macrophages. Simultaneously, immune cells bind to the Fc segment of CD20-targeted mAbs through Fc receptors, forming a synergistic effect of CR-Fc receptor interaction, which significantly enhances the recognition and killing efficiency of tumor cells and further amplifies the antitumor effect of the ADCC pathway.

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The following image illustrates the mechanism of action of CD-20 targeted mAbs.



Source: Literature Review, Frost & Sullivan analysis

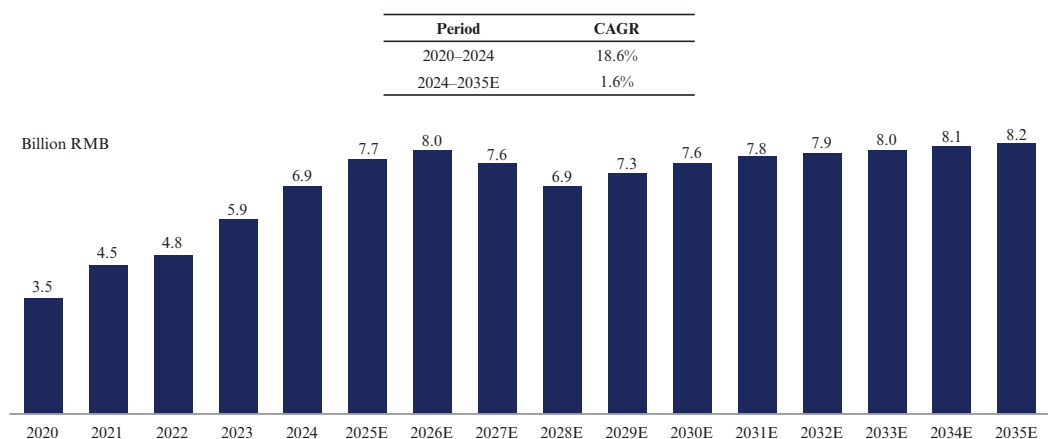
Market Size

The market size of CD20 mAb drugs in China grew from RMB3.5 billion in 2020 to RMB6.9 billion in 2024, representing a CAGR of 18.6% during this period. The anticipated decrease in market size in 2026 and 2027 reflects the potential downward price pressure on rituximab and its biosimilars brought about by potential centralized drug procurement. This shift in industry dynamics has created a favorable growth opportunity for innovative

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alternatives, especially Category 1 innovative drugs. Looking ahead, the market size of CD20 mAb drugs in China is projected to reach RMB8.2 billion in 2035, as illustrated in the chart below.

China CD20 mAb Drug Market, 2020–2035E



Source: Frost & Sullivan analysis

Indications and Market Opportunities

Diffuse Large B-cell Lymphoma (“DLBCL”)

Overview

DLBCL is the most common type of non-Hodgkin lymphoma (“NHL”), representing a fast-growing, aggressive cancer that originates from B cells, a type of white blood cell responsible for producing antibodies. DLBCL typically presents with rapidly growing tumors in the lymph nodes and may also affect the spleen, liver, bone marrow, or other tissues and organs. Based on gene expression profiling and biological characteristics, DLBCL is primarily divided into three molecular subtypes: germinal center B-cell-like (“GCB”) DLBCL, activated B-cell-like (“ABC”) DLBCL. While DLBCL is often treated with a combination of chemotherapy, immunotherapy, and other targeted therapies, not all cases respond effectively, with ABC DLBCL generally associated with poorer prognosis compared to the GCB subtype. This heterogeneity in treatment response necessitates ongoing research into alternative treatments for resistant or recurring forms of the disease.

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Incidence

The number of new DLBCL cases in China increased from 31.8 thousand in 2020 to 34.5 thousand in 2024. The incidence is expected to continue rising, reaching 42.3 thousand by 2035. This sustained growth trend reflects the expanding clinical treatment needs for DLBCL in China. Combined with significant unmet medical needs, particularly in addressing drug resistance and disease recurrence, this epidemiological trajectory underscores the market value and clinical significance of innovative targeted therapeutic drugs, such as zuberitamab.

Treatment Paradigm

The treatment of DLBCL follows a structured approach encompassing first-line and second-line therapies, with CD20-targeted mAbs playing a central role across treatment regimens. Standard first-line treatment combines CD20-targeted mAbs with multi-agent chemotherapy, with R-CHOP (rituximab plus cyclophosphamide, doxorubicin, vincristine, and prednisone) serving as the established standard of care for over two decades. Upon disease progression or relapse, second-line treatment is stratified based on patient eligibility for autologous stem cell transplantation (“ASCT”), with transplant-eligible patients receiving salvage immunochemotherapy followed by high-dose therapy and ASCT, while transplant-ineligible patients are treated with alternative regimens or novel targeted therapies.

CD20-targeted mAbs serve a pivotal role in DLBCL treatment strategies across all treatment lines. As a validated therapeutic target highly expressed on B-cell lymphomas, CD20-targeted mAbs effectively induce tumor cell death through multiple mechanisms, including ADCC, CDC, and direct apoptosis. The addition of CD20-targeted therapy to standard chemotherapy has significantly improved overall survival and progression-free survival rates compared to chemotherapy alone. Moreover, CD20-targeted agents enable dose-modified treatment regimens for elderly or frail patients who cannot tolerate full-intensity chemotherapy, thereby expanding treatment access while maintaining clinical benefit, underscoring the clinical significance of next-generation CD20-targeted agents with enhanced efficacy and safety profiles.

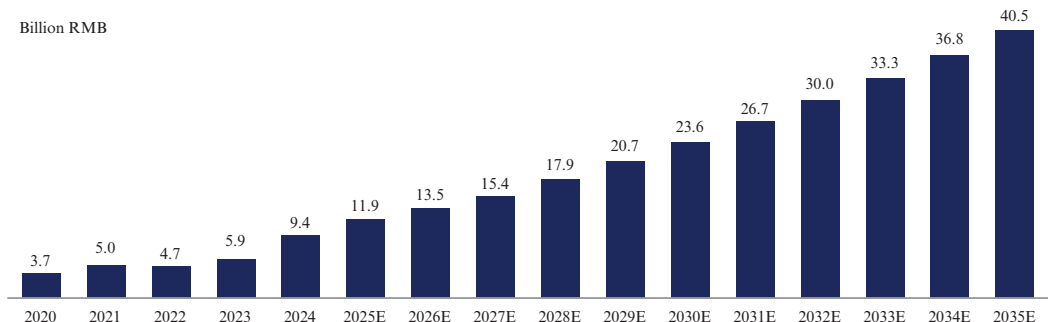
Market Size

The market for DLBCL drugs in China grew from RMB3.7 billion in 2020 to RMB9.4 billion in 2024, representing a CAGR of 26.4% during this period. Looking ahead, the market is projected to reach RMB40.5 billion by 2035, with a CAGR of 14.2% from 2024 to 2035. This robust growth trajectory reflects the rising demand for effective treatment options and the continued advancement of innovative therapies in the DLBCL treatment landscape.

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China DLBCL Drug Market, 2020–2035E

Period	CAGR
2020–2024	26.4%
2024–2035E	14.2%



Source: Frost & Sullivan analysis

Competitive Landscape

As of the Latest Practicable Date, there were eight CD20-targeted mAb drug for DLBCL approved and marketed in China, all of which had been included in the China’s National Reimbursement Drug List (“NRDL”). Among these products, most products are biosimilars of rituximab, and zuberitamab is the only NMPA-approved Category 1 innovative biologic. The chart below shows the marketed CD20-targeted mAbs for DLBCL in China.

Marketed CD20-targeted mAbs for DLBCL in China

Brand Name	INN	Classification	Company	NMPA First Approval Date	Medical Insurance	Specification	Unit Price (RMB)
Mabthera®	Rituximab	Approved Biologics in Foreign Jurisdictions (Category 3.1)	Roche	2000-03-15	B	50ml: 500mg 10ml: 100mg	7,866.16 2,294.44
汉利康®	Rituximab	Biosimilars	Shanghai Henlius	2019-02-22	B	50ml: 500mg	4,683.82
达伯华®	Rituximab	Biosimilars	Innovent	2020-09-30	B	10ml: 100mg	1,030.00
安平希®	Ripertamab	Modified New Biologics (Category 2)	SinoCelltech	2022-08-23	B	50ml: 500mg	4,621.42
安瑞昔®	Zuberitamab	Innovative Biologics (Category 1)	Our Company	2023-05-12	B	10ml: 100mg	1,408.98
得利妥®	Rituximab	Biosimilars	ChiaTai Tianqing	2023-05-26	B	10ml: 100mg	1,028.00
生利健®	Rituximab	Biosimilars	Shanghai Institute of Biological Products	2024-03-19	B	10ml: 100mg	1,026.00
益立达®	Rituximab	Biosimilars	Shandong New Time Pharmaceutical	2025-06-17	B	10ml: 100mg	1,025.00

Source: NMPA, Frost & Sullivan analysis

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Notably, zuberitamab has demonstrated a favorable efficacy and safety profile in combination therapies with the CHOP regimen. In a head-to-head comparison, the overall response rate (“**ORR**”) of patients treated with the zuberitamab combination regimen was higher than that of the rituximab combination regimen, indicating that more DLBCL patients achieved effective disease control or remission with this treatment. Furthermore, the proportion of patients remaining progression-free at 1, 2, and 3 years was slightly higher in the zuberitamab group compared to the rituximab group, suggesting that patients treated with zuberitamab maintained disease stability for a longer duration and exhibited a lower risk of disease progression.

Head-to-Head Clinical Trial Data of Zuberitamab and Rituximab for the Treatment of DLBCL

<u>Indicator</u>	<u>Zuberitamab in combination with CHOP regimen</u>	<u>Rituximab in combination with CHOP regimen</u>
Efficacy		
ORR (FAS)	83.5%	81.4%
ORR (PPS)	95.3%	93.7%
1-year PFS	88.1%	80.9%
2-year PFS	82.5%	73.5%
3-year PFS	78.0%	70.9%
1-year OS	96.3%	94.2%
2-year OS	92.2%	85.4%
3-year OS	87.7%	83.1%
Safety		
TEAEs	99.7%	100.0%
SAEs	44.3%	50.0%
Grade ≥ 3 TEAEs	92.0%	92.3%

Source: Frost & Sullivan analysis

In addition, patients with the germinal center B-cell-like (“**GCB**”) subtype, accounts for approximately 56% of DLBCL patients. In treating GCB subtype DLBCL, combination therapy using zuberitamab and the CHOP regimen has demonstrated superior outcomes compared to combination therapy using rituximab and the CHOP regimen, showing improved efficacy in maintaining disease remission, prolonging progression-free survival and event-free survival, and extending overall survival.

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Head-to-Head Clinical Trial Data of Zuberitamab and Rituximab in Treating GCB Subtype of DLBCL

GCB Subtype Data	
Indicator	Zuberitamab + CHOP regimen vs Rituximab + CHOP regimen
PFS	HR = 0.41
EFS	HR = 0.51
OS	HR = 0.25
DOR	HR = 0.47

Source: Frost & Sullivan analysis

Primary Membranous Nephropathy (“PMN”)

Overview

Membranous nephropathy (“MN”) is a common pathological subtype of nephrotic syndrome in adults, with a high and increasing incidence in developing countries such as China. Based on etiology, MN can be classified into PMN, also referred to as idiopathic MN and accounting for 70%-80% of cases, and secondary MN.

PMN is characterized by autoantibodies against podocyte antigens, particularly phospholipase A2 receptor (“PLA2R”), leading to subepithelial immune complex deposition, complement activation, and glomerular basement membrane (“GBM”) thickening. Diagnostic methods for PMN include light microscopy, which shows diffuse GBM thickening, and electron microscopy, which reveals subepithelial electron-dense deposits. Clinically, patients typically present with nephrotic syndrome characterized by significant proteinuria and edema. PMN is also associated with co-morbidities such as malignancies and autoimmune diseases, with biomarkers like anti-PLA2R antibodies playing a significant role in diagnosis and disease monitoring. The identification of PLA2R as a major target antigen has advanced the understanding of PMN pathogenesis and facilitated the development of targeted therapeutic approaches, including B cell-depleting therapies such as CD20-targeted mAbs.

Prevalence

The number of patients with PMN in China increased from 3.73 million in 2020 to 3.92 million in 2024. Looking ahead, the patient population is expected to continue rising, reaching 4.44 million by 2035.

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Treatment Paradigm

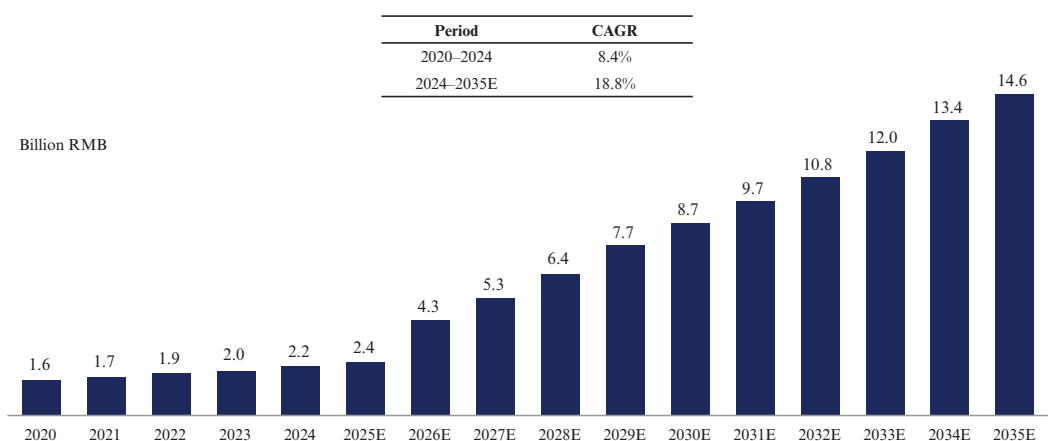
The management of PMN follows a risk-stratified treatment approach based on disease severity assessment. According to the Kidney Disease: Improving Global Outcomes (“KDIGO”) guidelines, patients are categorized into low, intermediate, high, or very high risk groups, which guides treatment decisions. For low-risk patients, watchful waiting is recommended. Intermediate-risk patients may be managed with watchful waiting or treated with CD20-targeted mAbs or calcineurin inhibitors with or without corticosteroids. For high-risk patients, treatment options include CD20-targeted mAbs, cyclophosphamide plus corticosteroids, or calcineurin inhibitors plus rituximab. Very high-risk patients are typically treated with cyclophosphamide plus corticosteroids.

By precisely targeting the CD20 antigen on the surface of B cells, a key molecule in B-cell development, CD20-targeted mAbs enable the specific clearance of pathogenic B cells responsible for autoantibody production. The use of these CD20-targeted mAbs in conjunction with other immunosuppressive therapies has demonstrated optimized outcomes, particularly in high-risk patients, highlighting the clinical significance of CD20-targeted therapies such as zuberitamab in addressing the unmet needs in PMN treatment.

Market Size

The market size of PMN drugs in China increased from RMB1.6 billion in 2020 to RMB2.2 billion in 2024, representing a CAGR of 8.4% during this period. Looking ahead, the market is projected to grow rapidly, reaching RMB14.6 billion by 2035, with a CAGR of 18.8% from 2024 to 2035.

China PMN Drug Market, 2020–2035E



Source: Frost & Sullivan analysis

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Despite this robust market growth, PMN treatment in China faces significant unmet needs. First, the economic burden associated with current therapies remains substantial. Traditional small-molecule immunosuppressants, such as cyclophosphamide and tacrolimus, are associated with high relapse rates and significant long-term toxicity, including bone marrow suppression and infection risks. Despite guidelines recommending CD20-targeted mAbs for medium to high-risk MN, these agents remain unapproved for this indication in China. Consequently, patients must pay out-of-pocket, leading to limited utilization of CD20-targeted mAbs and highlighting a significant gap between clinical recommendations and real-world accessibility. Second, insufficient treatment responses present a considerable challenge, as clinical studies indicate that 20–40% of refractory PMN patients do not adequately respond to existing therapies. This underscores the need for innovative biologic treatments, such as CD20-targeted mAbs, that could offer more effective solutions and better outcomes for patients experiencing relapses. As one of the effective therapeutic methods for PMN, CD20-targeted mAb drugs are well-positioned to benefit from this market growth, with their market penetration rate and commercial value expected to be further enhanced.

Competitive Landscape

As of the Latest Practicable Date, no CD20-targeted mAb drug had been approved for PMN in China. As of the same date, there were four CD20-targeted mAb drugs in phase 2 or above clinical trials for PMN patients, as summarized below.

CD20-targeted mAbs for PMN in China (Phase 2 and above)

Drug Code	Company	Highest Phase	First Posted Date
MIL62	Beijing Mabworks Biotech	BLA	2025-05-27
Obinutuzumab	Roche	Phase 3	2021-05-13
B007	Shanghai Shangyao Cross linked Pharmaceutical	Phase 2/3	2024-06-05
Zuberitamab	Our Company	Phase 2	2024-10-14

Source: Frost & Sullivan analysis

OVERVIEW OF GOUT DRUG MARKET

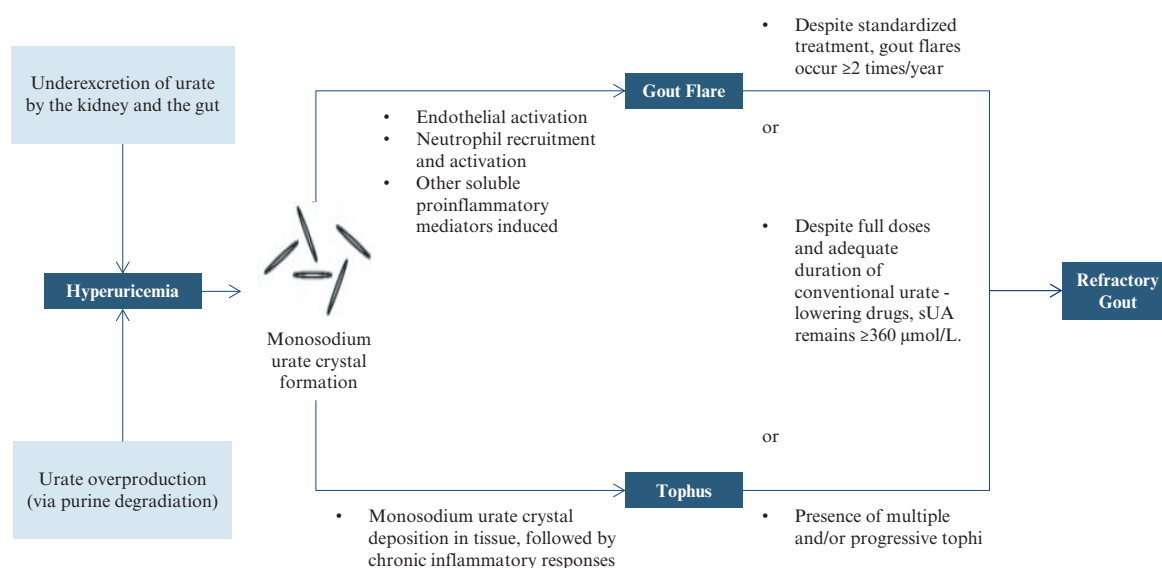
Overview

Gout is the most common form of inflammatory arthritis, characterized by the formation and deposition of monosodium urate crystals in joints and other tissues due to chronic hyperuricemia. It is also an independent risk factor for chronic kidney disease (“CKD”), hypertension, cardiovascular disease, and diabetes.

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Gout manifests as recurrent acute attacks of severe joint pain and swelling, known as gout flares, which significantly impair patients’ quality of life. Hyperuricemia, defined as serum uric acid (“sUA”) levels exceeding 7 mg/dL (420 μmol/L), represents the fundamental metabolic abnormality underlying gout. This condition arises predominantly from impaired renal excretion of uric acid (accounting for approximately 90% of cases) or, less commonly, from overproduction of uric acid. Tophi are formed from monosodium urate crystal deposition in tissues due to chronic hyperuricemia and frequent gout flares, which can persist despite comprehensive treatment. Refractory gout, a more severe and challenging form of the disease, is defined by two key characteristics: persistent clinical symptoms and the inability to lower sUA levels below the therapeutic target of 6 mg/dL (360 μmol/L), despite the use of urate-lowering therapies (“ULTs”). Additionally, refractory gout is characterized by frequent flare-ups, occurring more than twice a year, as well as the presence of tophi or progressive tophaceous gout. The relationship among hyperuricemia, gout flare, tophi and refractory gout can be shown in the below figure.

Pathological Mechanism of Gout



Source: Literature Review, Frost & Sullivan analysis

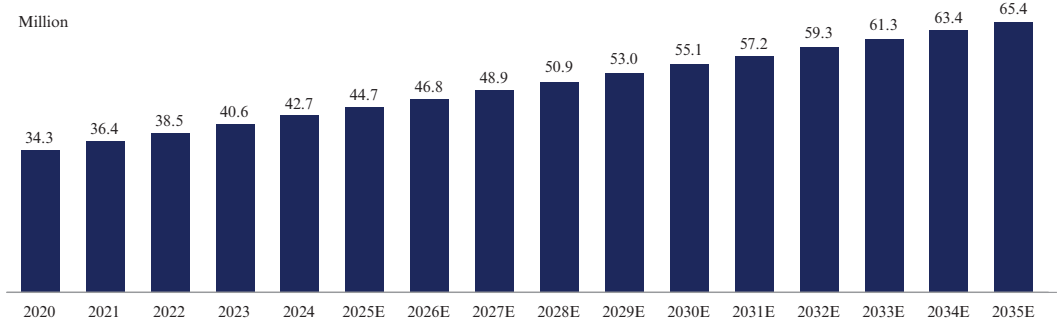
Prevalence

In China, gout patient population expanded from 34.3 million in 2020 to 42.7 million in 2024, at a CAGR of 5.6%. By 2035, the number is expected to rise to 65.4 million, representing a CAGR of 4.0% from 2024 to 2035.

INDUSTRY OVERVIEW

China Prevalence of Gout, 2020–2035E

Period	CAGR
2020–2024	5.6%
2024–2035E	4.0%



Source: Literature Review, Frost & Sullivan analysis

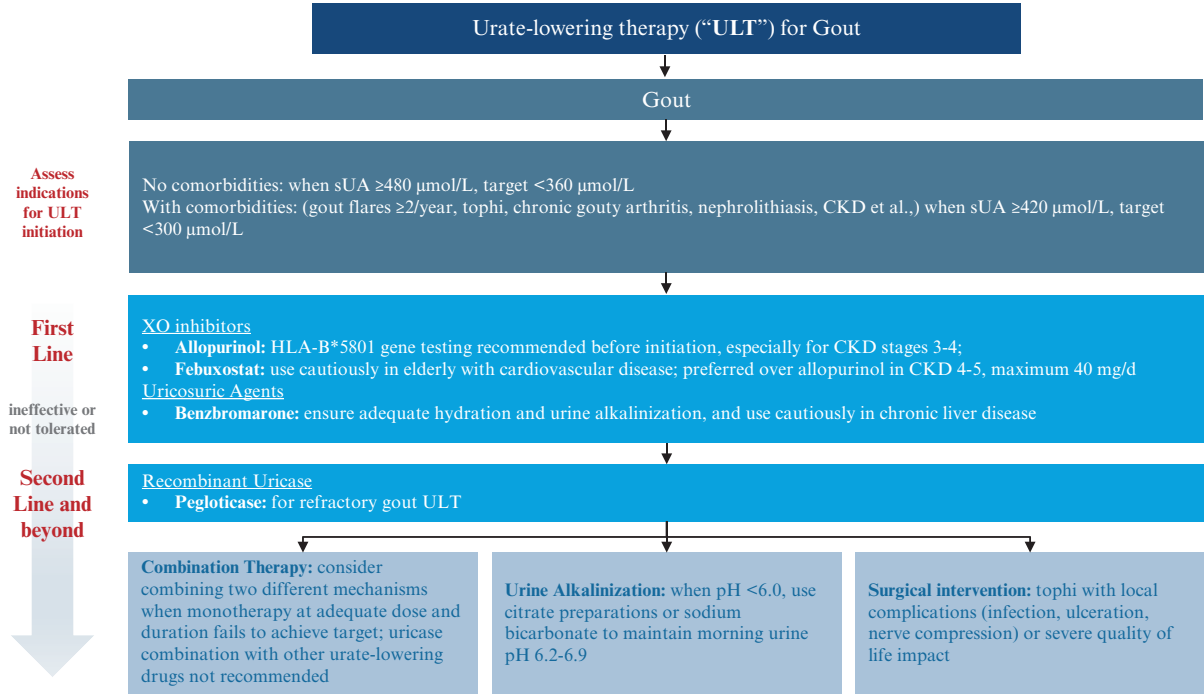
Treatment Paradigm

The treatment of gout in China follows guideline-recommended ULTs tailored to patients’ sUA levels and comorbidities. The sUA target is <360 umol/L without comorbidities and <300 umol/L for patients with frequent flares, tophi, or CKD. First-line therapies include xanthine oxidase inhibitors (“**XO inhibitors**”) such as allopurinol, with HLA-B*5801 gene testing (an allele test associated with the risk of severe adverse skin reactions induced by allopurinol and genetic susceptibility to gout) recommended, and febuxostat, preferred in advanced CKD. Uricosuric agents like benzbromarone are used cautiously, while recombinant uricase (e.g., pegloticase) is reserved for refractory gout. Combination therapy is advised when monotherapy fails, alongside urine alkalinization and surgical intervention for tophi-related complications. This structured approach ensures effective and individualized care.

Despite the availability of XO inhibitors and traditional uricosuric agents, approximately 40% of patients fail to achieve or maintain sUA levels below 6mg/dL — due to insufficient efficacy at tolerable doses, poor treatment adherence, safety concerns such as hepatic and renal impairment, and contraindications related to cardiovascular, hepatic, or renal comorbidities. This unmet need is particularly aggravated in patients with refractory and tophaceous gout, who often present with long-standing severe hyperuricemia, extensive urate deposits causing progressive joint damage and disability, and severely limited therapeutic options. The following chart sets forth the treatment paradigm of gout in China.

INDUSTRY OVERVIEW

Treatment Paradigm of Gout in China



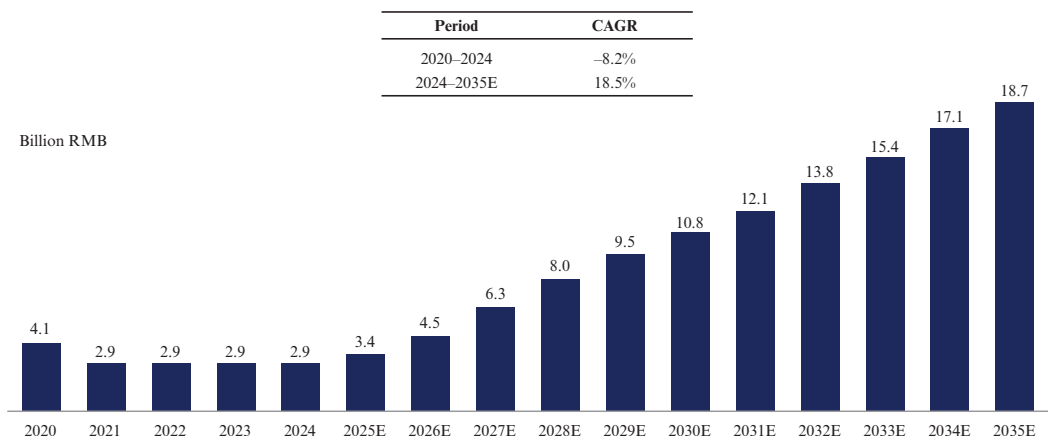
Source: Chinese Guidelines for the Diagnosis and Treatment of Hyperuricemia and Gout (2024 Edition), Frost & Sullivan analysis

Market Size

The gout drug market in China also experienced a slight decline from RMB4.1 billion in 2020 to RMB2.9 billion in 2024, primarily due to insufficient efficacy of existing therapies and the impact of centralized drug procurement policies which reduced drug prices. Driven by increasing disease prevalence and the development and approval of new innovative drugs with differentiated mechanisms and improved efficacy, China’s gout drug market is expected to expand from RMB2.9 billion in 2024 to RMB18.7 billion in 2035 at a CAGR of 18.5% from 2024 to 2035.

INDUSTRY OVERVIEW

China Gout Drug Market Size, 2020–2035E



Source: Frost & Sullivan analysis

Competitive Landscape

As of the Latest Practicable Date, there were over 20 innovative small-molecule drugs approved for gout in China, and the mainstream therapies were shown in the table below.

Major Marketed Small-molecule Drugs for Gout in China

Drug Type (Targets)	INN	Originator Brand Name	Modality	Company	NMPA Year of Approval	2024 Medical Insurance	Specification	Unit Price (RMB)
XO inhibitor	Allopurinol	Zyloprim [*]	Small molecule	GSK	1995	A	0.1g	1.33
	Febuxostat	Uloric [*]	Small molecule	Takeda	2018	B	40mg	2.05
URAT1 inhibitor	Benzbromarone	Narcaricin [*]	Small molecule	Sanofi	2004	B	50mg	1.97
	Probenecid	Benemid [*]	Small molecule	Merck	2006	B	0.25g	0.44
	Dotinurad	Urece [*]	Small molecule	Fuji Yakuhin /Eisai	2024	/	2mg	19.96

Source: NMPA, Frost & Sullivan analysis

As of the Latest Practicable Date, there were 15 URAT1-targeting candidates under clinical development for the treatment of gout, among which two were in phase 3 trials or above. As of the same date, there were seven candidates with mechanisms of actions other than URAT1 inhibition in China, including BR2251. Among these, only one had advanced to phase 3 trial or later stage of development.

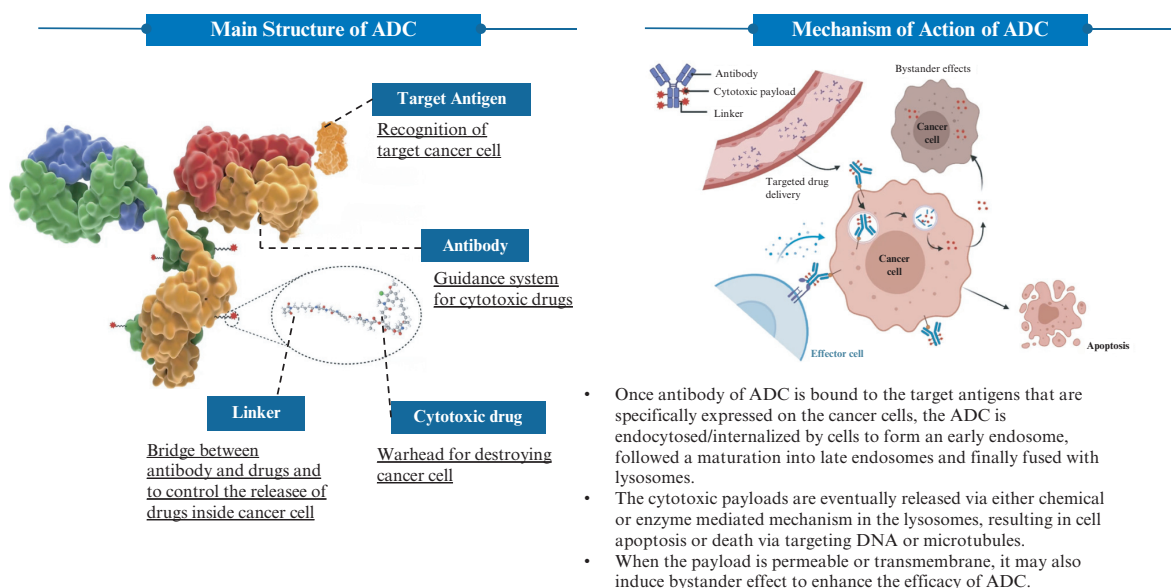
INDUSTRY OVERVIEW

OVERVIEW OF ANTIBODY-DRUG CONJUGATE (“ADC”) MARKET

Overview of ADCs

ADCs are one of the fastest-growing treatment modalities for cancers. An ADC comprises three core components: a tumor-targeting antibody that confers selectivity, a highly cytotoxic payload that kills cancer cells, and a linker that controls payload release.

The following diagrams illustrate an ADC’s structure and its mechanism of action:



Source: Literature Review, Frost & Sullivan analysis

INDUSTRY OVERVIEW

Traditional chemotherapy and radiotherapy, though effective, lacks selectivity and often causes severe systemic toxicity due to its inability to distinguish between rapidly dividing cancer cells and normal cells. ADCs are designed to overcome this limitation through a targeted approach: they use mAbs to selectively deliver highly potent cytotoxic drugs directly to tumor cells. Upon binding to tumor-specific antigens, the ADC is internalized by the cancer cell, where the cytotoxic payload is released to induce cell death. This mechanism enables the use of exceptionally potent cytotoxins — often too toxic for conventional systemic administration — while confining their effects primarily to malignant cells, thereby widening the therapeutic window and improving both efficacy and tolerability.

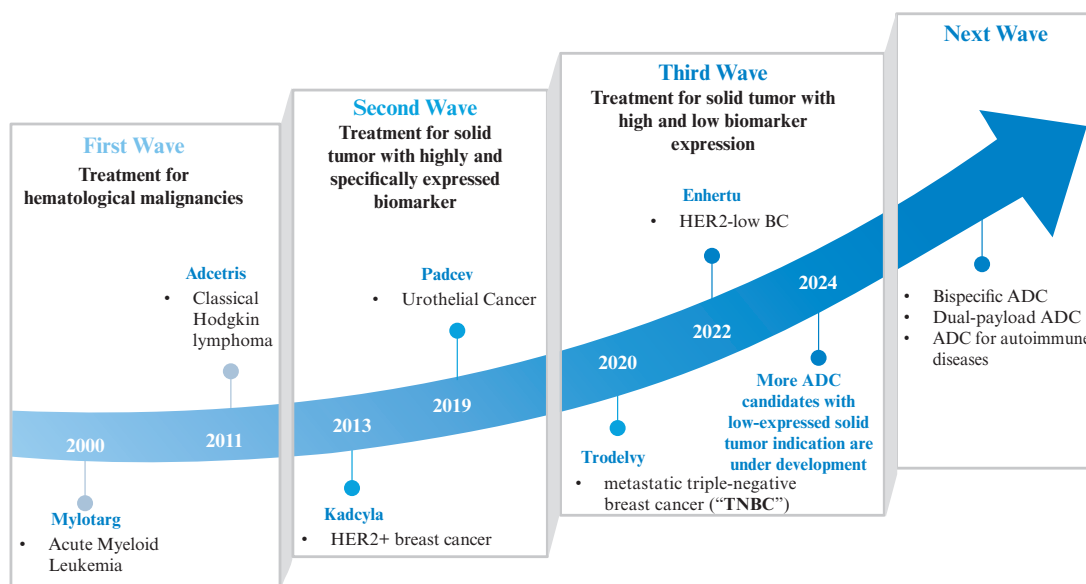
Evolution of ADCs

Despite their vast therapeutic potential, early generations of ADCs faced various challenges, including intolerable toxicity and suboptimal efficacy that stymied numerous ADC development programs from the 1980s to the 2000s. The first ADC, Mylotarg[®], was approved by the FDA in 2000 for the treatment of acute myeloid leukemia. Since then, ADC technology has undergone continuous innovation, bringing substantial improvements in stability, tolerability and efficacy. Examples include the introduction of bystander killing effects through new payloads with better cross-cell permeability, the evolution from chimeric antibodies to humanized antibodies, cleavable linkers for payload release in the tumor microenvironment, and advancements in site-specific conjugation techniques to improve therapeutic window. These technological breakthroughs have expanded the application of ADCs from blood cancers only to a growing number of solid tumors. Significant efforts are being made to investigate new and emerging targets with no approved drugs, such as receptor tyrosine kinase-like orphan receptor 1 (“**ROR1**”) and LIV-1. There are also continuous efforts to optimize each of the three ADC components for difficult-to-treat tumors with low or ultralow protein expression, such as HER2-low breast cancer.

The next wave ADCs are expected to leverage novel linkers and payloads, moving beyond traditional cytotoxic agents to employ innovative molecules such as immunomodulatory payloads. Other innovation fronts in ADC development include the exploration of novel bispecific and multi-specific formats, and potential combination therapies with other treatment modalities to create synergistic effects. All these advancements will pave the way for ADCs to expand towards earlier lines of treatment and therapeutic areas beyond oncology.

INDUSTRY OVERVIEW

The table below sets forth the details of the evolution of ADCs and representative products and their treatment potential.



Source: FDA, NMPA, Frost & Sullivan analysis

Major Considerations and Challenges in ADC Design and Development

ADCs require holistic and intricate design based on features of each component and characteristics of the target disease. Modifications to each component can have a substantial influence on the pharmacological properties and clinical profiles of the ADC.

- **Antibody selection** requires careful consideration of the target antigen’s expression profile, internalization rate, and potential for off-target toxicity, where the chosen antibody possesses the desired specificity and affinity to ensure efficient and targeted delivery of the payload to the tumor cells. However, challenges remain in identifying suitable antigens with limited expression in healthy tissues, developing antibodies with optimal pharmacokinetic and pharmacodynamic properties, and mitigating potential immunogenicity of the antibody. In addition, new targeting backbones, such as bispecific antibodies, are being developed to achieve synergistic anti-tumor effects and increase tumor specificity. The complexity of combining targets with different targeting moieties introduces new challenges and opportunities in antibody selection and engineering.

INDUSTRY OVERVIEW

- **Payload design** is a crucial factor to the success of an ADC drug, and involves selecting a cytotoxic agent with the optimal potency and a mechanism of action suitable for the target tumor type. A well-designed payload typically possesses a small molecular weight for good tissue penetration, coupled with appropriate pharmacokinetic properties to minimize systemic exposure while maintaining sufficient tumor concentration. The ADC field has benefited from a diverse arsenal of validated payloads, including microtubule inhibitors such as monomethyl auristatin E (“MMAE”) and DM1, DNA-damaging agents, and topoisomerase inhibitors like deruxtecan, each offering distinct advantages for different therapeutic contexts. Novel payload classes beyond traditional cytotoxic agents are explored, including immunomodulatory payloads designed to reprogram the tumor microenvironment and amplify anti-tumor immune responses. In addition, an emerging innovation in payload design is the dual-payload approach, which combines two distinct therapeutic agents within a single ADC construct. These agents may include two cytotoxic drugs with complementary mechanisms, or a cytotoxic payload paired with an immunomodulatory agent such as a STING agonist to simultaneously kill tumor cells and activate anti-tumor immune responses. This strategy can potentially enhance anti-tumor activity through synergistic mechanisms, reduce the likelihood of resistance development, and expand the therapeutic window by optimizing the balance between efficacy and tolerability.
- **Linker design** focuses on selecting a linker that is stable in circulation to minimize premature payload release and systemic toxicity, while also enabling efficient release of the active drug within the target cells and tissues. Linkers can be broadly categorized into cleavable and non-cleavable linkers, chosen based on payload properties and the desired release mechanism. For example, cleavable linkers can achieve more targeted and precise delivery through their controlled release mechanism, whereas non-cleavable linkers are typically more stable in circulation. Other linker design considerations include ensuring consistent drug-to-antibody ratio (“DAR”) through site-specific conjugation, and minimizing the impact of the linker on the ADC’s pharmacokinetics and immunogenicity.

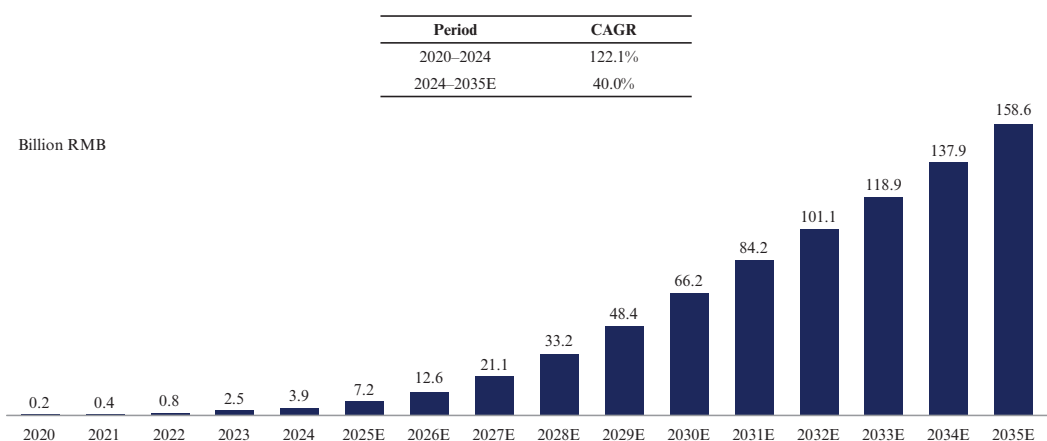
INDUSTRY OVERVIEW

ADC Market Size

The global ADC market grew rapidly from US\$4.1 billion in 2020 to US\$14.1 billion in 2024 at a CAGR of 36.6% and is projected to continue its robust growth at a CAGR of 21.7% from 2024 to 2035, and reach US\$122.7 billion in 2035.

The ADC market in China has experienced rapid growth in recent years, following the approval of the first ADC, Roche’s Kadcyla[®], in 2020. China’s ADC market grew from RMB0.2 billion in 2020 to RMB3.9 billion in 2024 at a CAGR of 122.1%, and is expected to reach RMB158.6 billion in 2035 at a CAGR of 40.0% from 2024 to 2035.

China ADC Drug Market, 2020–2035E



Source: Frost & Sullivan analysis

ROR1 ADC DRUG MARKET

Overview

Receptor tyrosine kinase-like orphan receptor 1 (“**ROR1**”) is a transmembrane protein that is predominantly expressed during embryonic development and shows minimal to no expression in most normal adult tissues. In contrast, ROR1 is aberrantly expressed across a range of malignancies, including hematologic cancers such as B-cell lymphomas and chronic lymphocytic leukemia, as well as solid tumors such as NSCLC. ROR1 expression has been associated with tumor cell survival, invasiveness and unfavorable clinical outcomes. Its limited expression in normal tissues, together with high expression in certain malignancies (e.g., reported ROR1 expression rates of up to approximately 83% in DLBCL), suggests a potentially favorable therapeutic window for selective targeting.

INDUSTRY OVERVIEW

For patients with relapsed or refractory hematologic malignancies, particularly B-cell lymphomas and chronic lymphocytic leukemia, treatment has evolved toward targeted agents, including Bruton’s tyrosine kinase (“**BTK**”) inhibitors, BCL-2 inhibitors and anti-CD20 mAbs, often in combination with chemotherapy. Despite these advances, many patients ultimately progress on or become intolerant to available therapies, and options in later lines of treatment remain limited. In advanced solid tumors such as NSCLC and TNBC, first-line treatment typically consists of platinum-based chemotherapy in combination with immune checkpoint inhibitors or other targeted agents where biomarker-appropriate. Nevertheless, responses are frequently not durable, and therapeutic choices for patients with relapsed or refractory disease are constrained, with modest efficacy and cumulative toxicity concerns.

In this context, ROR1-targeted ADCs offer a differentiated approach by combining the specificity of targeted therapy with the cytotoxic potency of chemotherapy. By delivering payloads directly to ROR1-expressing tumor cells rather than exposing normal tissues to high systemic chemotherapy doses, ROR1 ADCs have the potential to improve anti-tumor activity, help address resistance mechanisms that are independent of BTK, BCL-2 or immune checkpoint pathways, and provide a more favorable benefit-risk profile relative to standard cytotoxic regimens in heavily pretreated populations.

Globally, ROR1 ADCs remain at an exploratory stage of development, with multiple product candidates in clinical evaluation across hematologic malignancies and solid tumors but no product yet approved, and ongoing studies focused on optimizing tumor selection, treatment combinations and ADC design. Biparatopic ROR1 ADCs, which simultaneously bind two distinct epitopes on ROR1, may offer additional advantages in target engagement and payload delivery and have the potential to better address intratumoral heterogeneity in ROR1 expression and support more durable anti-tumor responses.

INDUSTRY OVERVIEW

Competitive Landscape of ROR1 ADC Drugs

The global pipeline for ROR1 ADCs is rapidly expanding, with multiple candidates currently in clinical development across both hematological malignancies and solid tumors. As of the Latest Practicable Date, there were seven ROR1 ADC candidates under clinical development worldwide, among which, our Company’s BR111 was the first and only biparatopic ADC targeting ROR1 that has entered the clinical stage globally.

ROR1 ADC Drug Candidates under Clinical Development Globally

Drug Code	Company	Indications	Co-Therapy	Highest Phase	First Posted Date
Zilovertamab Vedotin (MK2140, VLS101)	Merck Sharp & Dohme	DLBCL B-cell tumors, mantle cell lymphoma Reiter’s syndrome Follicular lymphoma Chronic lymphocytic leukemia/small lymphocytic lymphoma B-cell acute lymphoblastic leukemia, Burkitt lymphoma, neuroblastoma, Ewing sarcoma	R-CHP, R-CHOP Monotherapy, nemtabrutinib (MK1026) Monotherapy	Phase 2/3 Phase 2 Phase 1/2	2021–12–01 2022–07–14 2024–05–01
HDM2005	Hangzhou Zhongmei Huadong Pharmaceutical	DLBCL	R-GemOx, R-CHP	Phase 1/2	2025–07–30
CS5001 (ABL202, LCB71)	CStone Pharmaceuticals	Solid tumors Pancreatic cancer, triple-negative breast cancer, B-cell NHL Mantle cell lymphoma DLBCL Follicular lymphoma, Hodgkin lymphoma	DA-EPOCH-R	Phase 1	2022–03–15
IM-1021 (ZPC-21)	Immunome	Solid tumors Pleural mesothelioma, liposarcoma, non-squamous non-small cell lung cancer, pancreatic cancer, follicular lymphoma DLBCL Mantle cell lymphoma, chronic lymphocytic leukemia/small lymphocytic lymphoma, triple-negative breast cancer, ovarian epithelial carcinoma	Monotherapy	Phase 1	2025–02–12
BR111 (ROR1/ROR1)	Our Company	Solid tumors, B-cell NHL	Monotherapy	Phase 1	2025–04–14
TQB2101	ChiaTai Tianqing	Solid tumor	Monotherapy	Phase 1	2025–04–24
SYS6005	CSPC PHARMACEUTICAL GROUP	Tumor, B-cell tumor	Monotherapy	Phase 1	2025–05–06

Source: CDE, Clinical Trials, Frost & Sullivan analysis

INDUSTRY OVERVIEW

LIV-1 ADC DRUG MARKET

Overview

LIV-1, also known as SLC39A6, is a transmembrane zinc transporter that plays a role in zinc homeostasis and has been implicated in epithelial-to-mesenchymal transition, cell migration and invasion. LIV-1 expression is relatively restricted in most normal adult tissues but is frequently upregulated in a range of solid tumors, particularly in breast cancer, including hormone receptor-positive/HER2-negative (“HR + /HER2-”) breast cancer and TNBC subtypes, and in other epithelial malignancies such as prostate and gynecologic cancers. LIV-1 expression rate in breast cancer, prostate cancer, ovarian cancer and uterine cancer is 93%, 72%, 48% and 30%, respectively. LIV-1 expression has been associated with more aggressive tumor behavior, increased metastatic potential and unfavorable prognosis. Its cell surface localization, together with differential expression between tumor and normal tissues, provides a biological rationale for LIV-1 as a therapeutic target for ADCs.

LIV-1 ADCs leverage a similar mechanistic principle to other ADCs, using an anti-LIV-1 antibody to selectively deliver cytotoxic payloads to LIV-1-expressing tumor cells with the objective of enhancing tumor-specific cell killing while limiting systemic exposure. Globally, LIV-1 ADCs remain at a very early, exploratory stage of development, with only a small number of product candidates currently in clinical or preclinical evaluation and no approved products to date. However, the high prevalence and intensity of LIV-1 expression observed in certain advanced solid tumors, together with the limited treatment options available for patients with relapsed or refractory disease, suggest a meaningful potential opportunity for LIV-1 ADCs to address significant unmet medical needs in selected tumor types and patient populations.

Competitive Landscape of LIV-1 ADC Drugs

As of the Latest Practicable Date, no LIV-1-targeted ADCs were approved globally, and there were two LIV-1-targeted ADC candidates under clinical development around the globe. Our Company’s BRY812 was China’s first and only LIV-1-targeted ADC candidate to enter clinical development.

IL-4R ADC Drug Market

Overview

IL-4R ADCs represent an emerging class of precision therapies that combine IL-4 receptor (“IL-4R”)-directed mAbs with potent intracellular payloads. IL-4R, also known as IL-4R α , is a central component of type I and type II IL-4/IL-13 receptor complexes and plays a pivotal role in type 2 inflammatory pathways. It is highly expressed on pathogenic Th2 cells, type 2 innate lymphoid cells and alternatively activated macrophages, and plays an important role in Th2-biased immune responses, alternative macrophage activation and allergic inflammation. By binding to IL-4R and delivering an intracellular payload into IL-4R-expressing cells, IL-4R-targeted ADCs are designed to selectively modulate or deplete disease-driving immune cell populations while sparing IL-4R-negative cells.

INDUSTRY OVERVIEW

IL-4R ADCs are being explored for type 2 inflammatory disorders, including atopic dermatitis and asthma, in which a substantial proportion of patients remain inadequately controlled despite guideline-directed use of available therapies. The current treatment paradigm for moderate to severe atopic dermatitis and asthma is built on a backbone of inhaled or topical corticosteroids, often in combination with additional controller therapies, with systemic corticosteroids reserved for acute exacerbations or refractory disease due to their well-recognized long-term safety concerns. In recent years, this paradigm has increasingly incorporated targeted biologics, including IL-4R-targeted antibodies such as dupilumab, IL-5/IL-5R antibodies and anti-IgE therapies, which have become key components of the standard of care for eligible patients with type 2 inflammation disorders. These biologics have meaningfully improved clinical outcomes by blocking key cytokine pathways and reducing corticosteroid exposure; however, published data suggest that a sizeable proportion of patients have suboptimal or incomplete responses, and many patients require long-term or even lifelong treatment to maintain disease control. As a result, there remains a significant unmet need for therapies that can provide deeper and more durable responses, further reduce systemic corticosteroid dependence and improve overall safety and tolerability.

Against this backdrop, IL-4R ADCs offer a differentiated mechanistic approach compared with pathway-blocking antibodies and systemic corticosteroids. By coupling IL-4R pathway engagement with targeted intracellular delivery of cytotoxic or immunomodulatory payloads, this modality is intended to concentrate pharmacologic activity within IL-4R-expressing inflammatory cells while limiting systemic exposure. Such a design has the potential to achieve robust anti-inflammatory effects with a reduced overall steroid burden, lower systemic toxicity and more durable disease control in patients who are insufficiently managed on current standard of care, representing a promising new direction for the treatment of atopic dermatitis, asthma and other type 2 inflammatory conditions.

Competitive Landscape of IL-4R ADC Drugs

As of the Latest Practicable Date, no IL-4R ADCs had been approved for treating type 2 inflammatory disorders globally, and there was only one IL-4R ADC candidate around the globe under clinical development for the treatment of asthma. We submitted an IND application to the NMPA for our Company’s IL-4R ADC candidate, BR2060, in December 2025, and plan to initiate a phase 1/2a clinical trial in atopic dermatitis in the first half of 2026.

TROP2 ADC Drug Market

Overview

Trophoblast cell surface antigen 2 (“**TROP2**”) is a transmembrane protein that has essential functions in embryonic and organ development with low expression in normal tissues. TROP2 is a clinically valuable ADC target as it is overexpressed in a wide range of highly prevalent or hard-to-treat cancers, including advanced tumors with limited actionable targets. For example, TROP2 shows high expression rates in cervical cancer (89%), thyroid cancer (83%), TNBC (78%), squamous cell carcinoma (75%) and prostate cancer (71%), respectively.

INDUSTRY OVERVIEW

By binding to TROP2 on tumor cells and delivering a cytotoxic payload intracellularly, TROP2-targeted ADCs are designed to achieve potent, targeted cell killing while limiting off-tumor toxicity, thereby expanding the therapeutic window beyond that of conventional chemotherapy.

The current treatment paradigm for advanced solid tumors varies by cancer type but generally begins with platinum-based chemotherapy in NSCLC and gastric cancer, hormone therapy or chemotherapy in breast cancer, and fluoropyrimidine-based chemotherapy in colorectal cancer, often in combination with targeted agents or immune checkpoint inhibitors where biomarker-indicated. Despite advances in first-line therapy, a substantial proportion of patients experience disease progression, and treatment options in the second-line and beyond become increasingly limited. TROP2 ADCs have emerged as an important therapeutic option primarily in the relapsed or refractory setting, where they have demonstrated clinically meaningful improvements in objective response rates, progression-free survival and, in some settings, overall survival compared with standard chemotherapy in heavily pretreated populations. Several TROP2-targeted ADCs have received regulatory approvals in major markets for indications such as metastatic TNBC, HR+/HER2- breast cancer and metastatic NSCLC, validating TROP2 as a therapeutic target and establishing this modality as a key component of late-line treatment strategies.

In China, the TROP2 ADC market remains at an early stage of development despite a large and growing patient population with TROP2-expressing solid tumors. Ongoing clinical development is exploring the use of TROP2 ADCs in earlier lines of therapy, in combination with immune checkpoint inhibitors and other targeted agents, and across a broader range of tumor types. As clinical data mature and testing practices become more standardized, TROP2 ADCs — including such next-generation modalities — are expected to play an increasingly important role in the treatment paradigm for advanced solid tumors in China and to support sustained growth of this market segment.

Competitive Landscape of TROP2 ADC Drugs

As of the Latest Practicable Date, there were three TROP2 ADCs approved in China, i.e., Trodelvy[®], which was indicated for metastatic TNBC and metastatic HR+/HER2- breast cancer in the U.S. and in China, 佳泰莱[®] indicated for metastatic TNBC and metastatic EGFR-mutated non-squamous NSCLC in China, and Datroway[®] for metastatic HR+/HER2- breast cancer and EGFR-mutated NSCLC in the U.S. and metastatic HR+/HER2- breast cancer in China.

As of the same date, there were over 20 TROP2 ADC candidates under clinical development globally, among which there was only one dual-payload TROP2 ADC candidate. Our Company’s BR113 represents a novel TROP2 ADC candidate designed to integrate a cytotoxic payload (exatecan) and an immunostimulatory payload (STING agonist) within a single ADC molecule. We submitted an IND application to the NMPA for BR113 in December 2025 and plan to initiate a phase 1 clinical trial in solid tumors in the first half of 2026.

INDUSTRY OVERVIEW

OTHER TARGETED THERAPY MARKETS

TNF- α -targeted Monoclonal Antibody Market

Overview

Tumor necrosis factor alpha (“TNF- α ”)-targeted mAbs are biologic therapeutics designed to specifically neutralize TNF- α , a pro-inflammatory cytokine that functions as a central regulator of innate immunity and the Type 1 T helper cell-mediated immune response. Under physiological conditions, TNF- α contributes to host defense against intracellular pathogens and certain viral infections. However, its dysregulated overexpression triggers a cascade of pathogenic inflammatory signaling. This aberrant activity drives the onset and progression of multiple immune-mediated inflammatory diseases (“IMIDs”), including rheumatoid arthritis, Crohn’s disease, psoriatic arthritis, AS, ulcerative colitis, and severe chronic plaque psoriasis. By binding to both soluble and transmembrane TNF- α and preventing receptor activation, mAbs against TNF- α effectively suppress excessive inflammation and modulate immune responses in these conditions.

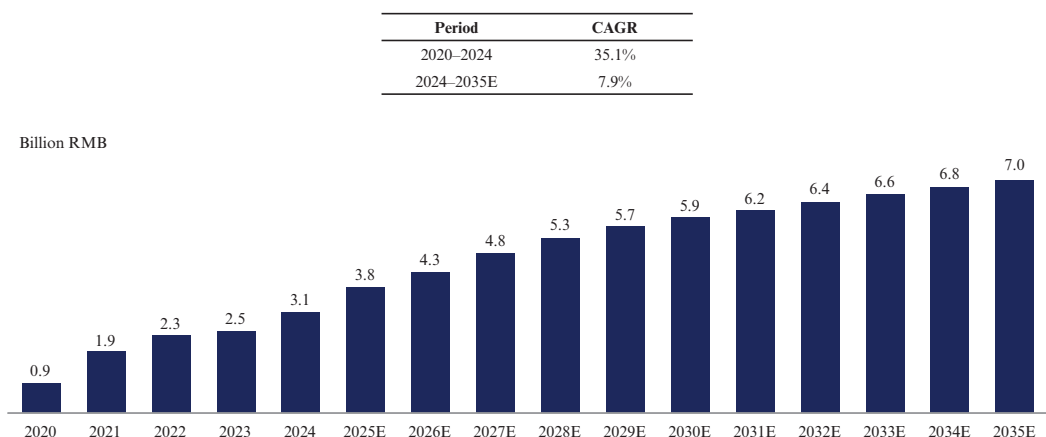
Across these IMIDs, TNF- α inhibition has become an established standard of care. The typical treatment paradigm begins with conventional DMARDs or other immunosuppressants, with biologic intervention reserved for patients with inadequate response or loss of response. Approved TNF- α inhibitors, including infliximab, adalimumab, etanercept, golimumab, and certolizumab pegol, have demonstrated strong efficacy in lowering disease activity, improving quality of life, and preventing long-term structural damage. These agents are commonly used as monotherapy or in combination regimens, with treatment strategies tailored to disease stage, severity, and patient response to optimize outcomes in chronic autoimmune conditions.

TNF- α -targeted mAbs demonstrate favorable clinical advantages over conventional immunosuppressive therapies through their targeted mechanism, rapid onset of action, and durable disease control. By intercepting a master cytokine at the apex of the inflammatory cascade, TNF- α blockade provides more robust and sustained suppression of inflammation with improved functional recovery and lower relapse rates. Moreover, next-generation antibodies are being engineered with enhanced pharmacokinetic stability, reduced immunogenicity, and more convenient dosing profiles, further optimizing long-term treatment adherence and outcomes. Collectively, TNF- α -targeted biologics remain the therapeutic backbone for IMIDs and continue to set the benchmark for efficacy and clinical reliability in inflammatory disease management.

As a major type of TNF- α -targeted biologic, China’s adalimumab market has experienced rapid growth, increasing from RMB0.9 billion in 2020 to RMB3.1 billion in 2024 at a CAGR of 35.1%. The market is expected to continue to grow to RMB7.0 billion in 2035 at a CAGR of 7.9% from 2024 to 2035. In China’s adalimumab market, the Company ranked first in terms of revenue with a market share of 31.9% in 2024.

INDUSTRY OVERVIEW

China Adalimumab Drug Market, 2020–2035E



Source: Frost & Sullivan analysis

Competitive Landscape

As of the Latest Practicable Date, 12 biosimilar TNF- α mAbs had been approved in China, among which eight were adalimumab biosimilars and four were infliximab biosimilars.

Marketed TNF- α mAb in China — Biosimilar

Brand Name	INN	Company	Approved Indications	NMPA First Approval Date	Medical Insurance	Specification	Unit Price (RMB)
格乐立®	Adalimumab	Bio-Thera Solutions	AS, rheumatoid arthritis, psoriasis, Crohn's disease, plaque psoriasis, polyarticular juvenile idiopathic arthritis	2019-11-04	B	0.4ml: 20mg	635.29
安健宁®	Adalimumab	Our Company	AS, rheumatoid arthritis, plaque psoriasis, noninfectious uveitis, juvenile idiopathic arthritis	2019-12-06	B	0.8ml: 40mg	1,090.00
苏立信®	Adalimumab	Innovent	AS, rheumatoid arthritis, psoriasis, juvenile idiopathic arthritis, noninfectious uveitis, Crohn's disease, plaque psoriasis	2020-09-02	B	0.8ml: 40mg	1,088.00
汉达远®	Adalimumab	Fosun Pharmaceutical	Rheumatoid arthritis, plaque psoriasis, AS, psoriasis, noninfectious uveitis, Crohn's disease, polyarticular juvenile idiopathic arthritis	2020-12-02	B	40mg (0.8ml)/bottle	899.00
泰博维®	Adalimumab	SINO BIOPHARMACEUTICAL	Rheumatoid arthritis, AS psoriasis	2022-01-18	B	40mg (0.8ml)/bottle	799.00
君迈康®	Adalimumab	Junshi Biosciences	Rheumatoid arthritis, AS, psoriasis, plaque psoriasis, Crohn's disease, uveitis, polyarticular juvenile idiopathic arthritis	2022-03-01	B	40mg (0.8ml)/vial	998.00
安佳润®	Adalimumab	Sinocelltech	Plaque psoriasis, rheumatoid arthritis, AS, psoriasis, Crohn's disease, uveitis, polyarticular juvenile idiopathic arthritis	2023-06-07	B	40mg (0.8ml)/bottle	1,060.00

INDUSTRY OVERVIEW

Brand Name	INN	Company	Approved Indications	NMPA First Approval Date	Medical Insurance	Specification	Unit Price (RMB)
生安宁®	Adalimumab	China Pharmaceutical Group	Rheumatoid arthritis, AS, plaque psoriasis, Crohn’s disease, uveitis, psoriasis, polyarticular juvenile idiopathic arthritis	2025-08-05	B	40mg/0.8mL/ bottle	798.00
类停®	Infliximab	Mabpharm	Rheumatoid arthritis, Crohn’s disease, ulcerative colitis, ankylosing spondylitis, psoriasis, fistulizing Crohn’s disease	2021-07-12	B	100mg	1,268.00
安佰特®	Infliximab	Our Company	Crohn’s disease, ulcerative colitis, rheumatoid arthritis, AS, psoriasis, fistulizing Crohn’s disease	2021-09-24	B	100mg	1,268.00
佳佰健®	Infliximab	EddingGenor	Rheumatoid arthritis, Crohn’s disease, ulcerative colitis, AS, psoriasis, fistulizing Crohn’s disease	2022-02-23	B	100mg	1,268.00
赛昔®	Infliximab	Celltrion	Rheumatoid Arthritis	2023-06-30	B	100mg/bottle	NA

Source: NMPA, Frost & Sullivan analysis

IL-6 Targeted Monoclonal Antibody Market

Overview

Since approximately 50% of patients treated with TNF- α inhibitors develop TNF- α refractory symptoms, other drugs with different mechanisms of action have been developed. Among these, interleukin-6 (IL-6)-targeted therapies have emerged as an important alternative approach. IL-6 is a multifunctional proinflammatory cytokine produced by various cell types, including T cells and B cells, lymphocytes, monocytes, and fibroblasts. IL-6 plays a key role in activating the inflammatory pathways that lead to the signs and symptoms of rheumatoid arthritis and other inflammatory autoimmune diseases. IL-6 can induce various inflammatory responses due to its wide presence in diverse organ cells such as livers, bones, osteoblasts and inflamed joints while increasing B-cell and T-cell activities. Therefore, blocking IL-6R could effectively prevent the cascading inflammatory responses, hence avoiding the occurrence of diverse undesirable diseases such as autoimmune diseases and pain in organs.

The China IL-6 targeted mAb drug market has experienced rapid growth, increasing from RMB0.1 billion in 2020 to RMB0.5 billion in 2024, representing a CAGR of 39.8% during this period. Looking ahead, the market is projected to continue its strong expansion, reaching RMB2.8 billion by 2035, with CAGR of 16.0% from 2024 to 2035.

INDUSTRY OVERVIEW

Competitive Landscape

As of the Latest Practicable Date, there were four IL-6R biosimilars approved in China. All of these drugs were included in the NRDL.

Marketed IL-6R mAbs in China — Biosimilar

Brand Name	INN	Company	Approved Indications	NMPA First Approval Date	Medical Insurance	Specification	Unit Price (RMB)
施瑞立®	Tocilizumab	Bio-Thera Solutions	Rheumatoid Arthritis, systemic juvenile idiopathic arthritis, cytokine release syndrome	2023-01-16	B	4ml: 80mg	746.96
安维泰®	Tocilizumab	LIVZON MABPHARM	Rheumatoid Arthritis, systemic juvenile idiopathic arthritis, cytokine release syndrome	2023-01-18	B	4ml: 80mg	746.96
安佰欣®	Tocilizumab	Our Company	Rheumatoid Arthritis, systemic juvenile idiopathic arthritis, cytokine release syndrome	2024-06-25	B	4ml: 80mg	745.00
考普瑞宁®	Tocilizumab	Mabtech	Rheumatoid Arthritis	2024-10-16	B	4ml: 80mg	742.00

Source: NMPA, Frost & Sullivan analysis

HER2-Targeted mAb Market

Overview

Human epidermal growth factor receptor 2 (“**HER2**”) is a ligand-orphan receptor that cannot be directly activated by any ligands of the epidermal growth factor family. However, when ligands bind to other ErbB receptors, HER2 can form heterodimers with other members of the ErbB family, triggering downstream signaling pathways. HER2 is expressed in many human tumors, with HER2 mutation considered a potential driver of tumorigenesis. Studies have shown that abnormal expression of the HER2 gene exists in a variety of cancers, including breast cancer, ovarian cancer, gastric cancer, uterine cancer, cervical cancer, and biliary tract cancer. The HER2 positivity rate varies across cancer types: breast cancer at 25.4%, urothelial cancer at 36.0%, gastric cancer at 23.7%, and non-small cell lung cancer at 60.0%. Notably, the degree of cancer progression is closely related to HER2 gene overexpression, with HER2-high tumors demonstrating reduced sensitivity to chemotherapy and higher propensity for recurrence.

Trastuzumab, a humanized HER2-targeted mAb, has demonstrated anti-tumor activity against human cancer cells overexpressing HER2 and is widely used in the treatment of breast cancer and gastric cancer patients with HER2 overexpression. Trastuzumab binds to subdomain IV (D4) of the HER2 extracellular domain to interfere with HER2 phosphorylation, thereby inhibiting the activation of downstream signaling pathways and reducing homodimer formation. Pertuzumab, another HER2-targeted mAb, acts on the dimerization domain of HER2 (subdomain II, D2) by blocking the heterodimerization of HER2 with other HER family members, including EGFR, HER3, and HER4. This mechanism inhibits two major intracellular signaling pathways — the

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MAP kinase pathway and the PI3K pathway — leading to cancer cell growth arrest and apoptosis. The complementary mechanisms of trastuzumab and pertuzumab provide a strong rationale for their combined use in HER2-positive malignancies.

HER2-targeted therapies represent a substantial market opportunity in the treatment of breast cancers. The molecular classification of breast cancer into HER2-positive, HR +/HER2-negative, and triple negative subtypes has enabled increasingly precise and effective treatment strategies. From 2020 to 2024, the HER2+ breast cancer drug market in China increased from RMB10.5 billion to RMB14.7 billion, representing a CAGR of 8.9%. China’s HER2+ breast cancer drug market will continue to grow in the future and is forecasted to reach RMB36.4 billion by 2035, which represents a CAGR of 8.6% from 2024 to 2035.

Competitive Landscape

As of the Latest Practicable Date, seven biosimilars had been approved by NMPA. All of the biosimilars were included in the NRDL.

Marketed HER2 mAb in China — Biosimilar

Brand Name	INN	Company	Approved Indications	NMPA First Approval Date	Medical Insurance	Specification	Unit Price (RMB)
汉曲优®	Trastuzumab	Fosun Pharmaceutical	HER2-positive breast cancer, gastric cancer	2020-08-12	B	150mg	1,688.00
安瑞泽®	Trastuzumab	Our Company	HER2-positive breast cancer, gastric cancer	2023-02-28	B	150mg	1,585.00
赛妥®	Trastuzumab	SINO BIOPHARMACEUTICAL	HER2-positive breast cancer, gastric cancer	2023-07-25	B	150mg	1,587.00
安赛汀®	Trastuzumab	Anhui Anke Biotechnology	HER2-positive breast cancer, gastric cancer	2023-10-27	B	150mg	1,575.00
安曲妥®	Trastuzumab	Qilu Pharmaceuticals	HER2-positive breast cancer, gastric cancer	2024-06-28	B	150mg	1,407.00
安赛珠®	Pertuzumab	Qilu Pharmaceuticals	HER2-positive breast cancer	2024-12-17	B	150mg	3,961.00
帕乐坦®	Pertuzumab	SINO BIOPHARMACEUTICAL	HER2-positive breast cancer	2024-12-17	B	150mg	3,961.00

Source: NMPA, Frost & Sullivan analysis

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REPORT COMMISSIONED BY FROST AND SULLIVAN

In connection with the [REDACTED], we have engaged Frost & Sullivan to conduct a detailed analysis and prepare an industry report on the major markets for which our drug candidates are positioned. Frost & Sullivan is an independent global market research and consulting company which was founded in 1961 and is based in the United States. We have agreed to pay Frost & Sullivan a total fee of approximately RMB800 thousand for the preparation of the Frost & Sullivan 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 Frost & Sullivan Report. Except for the Frost & Sullivan Report, we did not commission any other industry report in connection with the [REDACTED].

The market projections in the Frost & Sullivan Report were based on the following key assumptions: (i) the overall social, economic and political environment globally is expected to remain stable during the forecast period; (ii) the economic and industrial development globally 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 Frost & Sullivan Report may be affected by the accuracy of the foregoing key assumptions.