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OVERVIEW OF THE BIOLOGIC DRUG MARKET FOR AUTOIMMUNE AND ALLERGIC DISEASES

Biologic drugs are large-molecule drugs, which include monoclonal antibodies (mAbs), recombinant proteins, vaccines and other emerging categories. China's biologics market expanded from US$32.3 billion in 2017 to US$63.5 billion in 2021, at a CAGR of 18.4% and is estimated to reach US$185.9 billion in 2030, at a CAGR of 12.7% from 2021 to 2030. Biologics accounted for approximately 15.3% and 25.8% of China's overall pharmaceuticals market in 2017 and 2021, respectively, and the market share is estimated to rise further to 43.8% in 2030. The rapid growth in China's biologics market is primarily attributable to better diagnosis with enhanced accuracy, more treatment options and improved drug affordability, which trends are expected to continue and drive further growth in the market.

Autoimmune diseases are associated with disorders that lead to abnormally high activity of the immune system, causing the body to mistakenly attack and damage its own tissues. There are over 100 different types of autoimmune diseases, which can affect almost any part of the body, *e.g.*, the skin, joints, muscles, bones and digestive system. Allergic diseases are conditions caused by hypersensitivity of the immune system due to contact with allergens in the external environment, such as pollen, certain food, medication and insect stings, which can also affect multiple organs. Autoimmune and allergic diseases can trigger serious symptoms such as acute pain, persistent itchiness and disfigurement and, in some cases, may even lead to life-threatening complications and be fatal. In addition, despite their non-contagious nature, the social stigma often associated with these diseases due to the visibility of the lesions and inadequate understanding in the general public may further affect patients' mental well-being and reduce their quality of life, posing a significant socioeconomic burden on both the patients and society. Most autoimmune and allergic diseases are chronic diseases and require long-term care at high costs. It has been challenging to develop effective treatments of these diseases for long-term use because their pathogeneses are yet to be fully understood. In recent years, the emergence of targeted biologic therapies has brought profound changes to the treatment paradigm for these diseases with improved efficacy and safety profiles.

Biologic Drug Market for Autoimmune and Allergic Diseases in China

Although autoimmune and allergic diseases represent the second-largest therapeutic area globally, market development in China has lagged significantly behind. While the total patient population of autoimmune and allergic diseases in China exceeded 420 million as compared to 100 million in the United States in 2020. China's autoimmune and allergic drug market was 7.5% of that of the United States in 2020. The global market size of autoimmune and allergic disease drugs amounted to US$187.5 billion while China's autoimmune and allergic drug market was only US$9.0 billion in 2022. In addition, biologic drugs dominate developed markets, but their penetration in China remains low. In 2020, biologic drugs accounted for more than 60% of the autoimmune and allergic drug market in the United States, but only about 10% of the China market. The China's autoimmune and allergic disease drug market is estimated to grow to US$41.5 billion in 2030, at a CAGR of 21.1% from 2022, and with the proportion of biologic drugs increased to about 60%.

Despite the historical underdevelopment, the China autoimmune and allergic disease drug market has been changing in recent years. A number of blockbuster drugs developed by MNCs were approved in China and admitted to the NRDL. While unit prices dropped, sales soared. As a result, there remains significant market potential for biologic drugs for autoimmune and allergic diseases in China. Recognizing the great market potential, an increasing number of Chinese pharmaceutical companies have begun to conduct R&D on autoimmune and allergic disease drugs and achieved noticeable progress. For example, the number of IND approvals of biologic drugs in China for major inflammatory skin diseases* increased from nil in 2017 to 22 in 2022. The chart below sets forth the details of major domestic biopharmaceutical companies targeting autoimmune and allergic diseases in China, including the number of biologic drugs and candidates which have obtained IND approval as of the Latest Practicable Date, as well as the indication coverage of each company.

* including psoriasis, atopic dermatitis, prurigo nodularis and chronic spontaneous urticaria.

Companies	Number of Biologics	Number of Indications[1]		
Qyuns	7[2]	12[2]	6	6[2]
Bio-Thera	7	14	4	10
Hisun	6	9	1	8
Sunshine Guojian	5	8	2	6
Chia Tai Tianqing	5	8	5	3
Keymed Bio	4	6	4	2
Genrix Bio	3	9	4	5
Suncadia	3	8	1	7
Junshi Pharma	3	8		8
Akeso Bio	3	4	1	3

■ Autoimmune Diseases ■ Allergic Diseases

Source: Frost & Sullivan Report (based on annual reports of relevant companies and information published by the NMPA)

Notes:

(1) Different subtypes or severities of same indication or different product candidates with same indication are only counted once for the purpose of indication coverage.

(2) Include one IND-approved drug candidate that the Company had put on hold.

Market Drivers and Future Trends

The primary drivers and future trends of the biologic drug market for autoimmune and allergic diseases in China include:

- *Vast underserved medical needs.* Although the superior efficacy and safety profile of biologics has resulted in growing acceptance among patients and doctors globally, the penetration rate of biologics in China remains low. There is still great potential for biologic drugs to capture more market share in China in competition with other pharmaceutical products for the same indications.

- *Favorable government policies in China.* China is striving to establish clear regulatory pathways to assure market access for quality biologic drugs. For example, the CDE issued the Guidelines for Biosimilar Similarity Evaluation and Indication Extrapolation Techniques (《生物類似藥相似性評價和適應症外推技術指導原則》) in 2021, which is designed to further regulate and guide the development as well as evaluation of biosimilar drugs and to promote the development of the biomedical industry. Later in 2022, the CDE also issued the Technical Guidelines for Clinical Pharmacological Studies of Biosimilars (《生物類似藥臨床藥理學研究技術指導原則》) and provided technical guidance on the clinical pharmacological research of biosimilars to further promote R&D of biosimilars in China.

- *Expansion of approved biologic drugs and indications*. In the past, the number of approved biologic drugs and indications in China was relatively limited. Until 2022, there had been only 51 approved mAbs cumulatively in China, compared with 126 in the U.S. Particularly, among the approved innovative mAbs in China, only nine were developed by Chinese domestic companies and the rest were developed by MNCs, suggesting room for further participation from Chinese domestic companies in the China biologic drug market. In addition, dupilumab, an anti-IL-4Rα antibody, has been approved by the FDA for five indications since 2017 but only received NMPA approval for one indication since 2020. It is expected that more innovative biologic drugs for a wider spectrum of indications will be available in the China market in light of favorable government policies as well as increasing R&D investment in biologic drugs from Chinese domestic drug developers to seize the market opportunities.

- *Improved affordability*. The high costs associated with current biologic therapies have imposed significant socioeconomic burden on both the patients and society and discouraged wide application of biologic drugs as first-line treatments for autoimmune and allergic diseases. In recent years, the inclusion of innovative biologic drugs in the NRDL has led to significant price cuts. Additionally, advancement in science and improvement of manufacturing technology are expected to further reduce the costs associated with biologic drugs in China, which in turn could improve their affordability and accessibility.

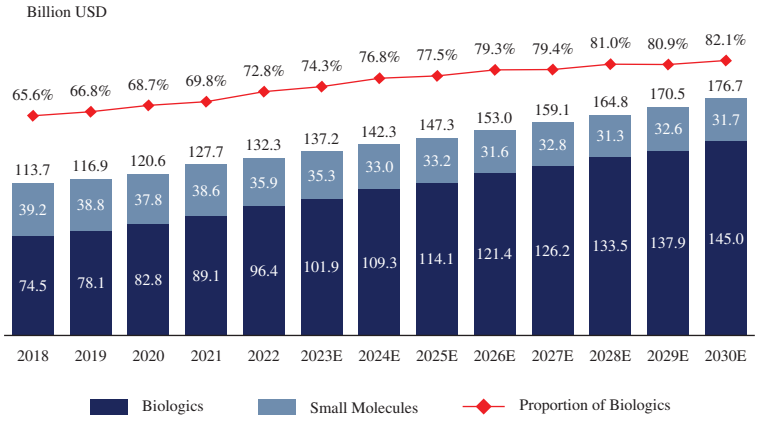
OVERVIEW OF THE AUTOIMMUNE DISEASE DRUG MARKET

The global autoimmune disease drug market increased from US$113.7 billion in 2018 to US$132.3 billion in 2022, at a CAGR of 3.9%, and is estimated to reach US$176.7 billion in 2030, at a CAGR of 3.7% from 2022 to 2030. The biologic drug market for autoimmune diseases amounted to US$96.4 billion in 2022 and is estimated to increase to US$145.0 billion in 2030, accounting for 72.8% and 82.1% of the global market in 2022 and 2030, respectively. The following chart sets forth the historical and estimated global autoimmune disease drug market for the periods indicated.

Global Autoimmune Disease Drug Market, 2018-2030E

CAGR:

Period	Biologics	Small Molecules	Total Market
2018-2022	6.6%	-2.1%	3.9%
2022-2025E	5.8%	-2.6%	3.6%
2025E-2030E	4.9%	-0.9%	3.7%



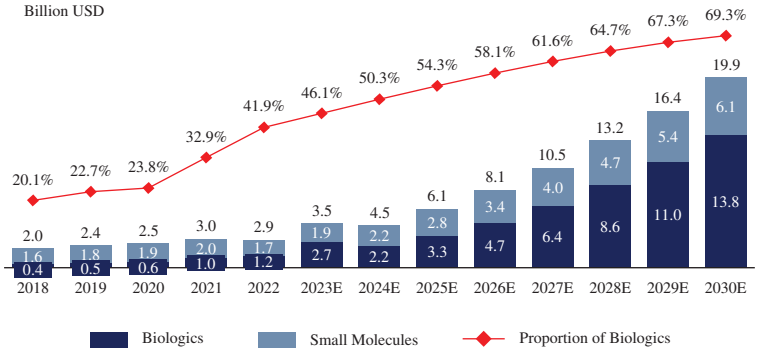
Source: Frost & Sullivan Report (based on annual reports of relevant companies, literature review and expert interviews)

Given the large patient pool in China and the advancement of innovative therapies for autoimmune diseases, China's autoimmune disease drug market is expected to grow rapidly. It increased from US$2.0 billion in 2018 to US$2.9 billion in 2022, at a CAGR of 9.8%, and is estimated to reach US$19.9 billion in 2030, at a CAGR of 27.0% from 2022 to 2030. Biologic drugs' share of China's autoimmune disease drug market is estimated to increase from 41.9% in 2022 to 69.3% in 2030. The following chart sets forth the historical and estimated autoimmune disease drug market in China for the periods indicated.

China Autoimmune Disease Drug Market, 2018-2030E

CAGR:

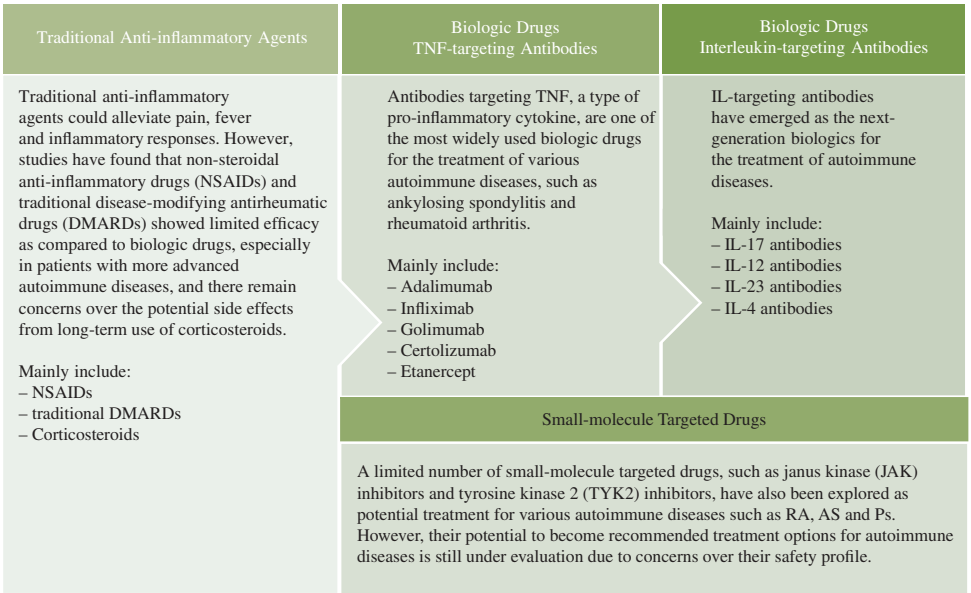
Period	Biologics	Small Molecules	Total Market
2018-2022	31.9%	1.3%	9.8%
2022-2025E	38.9%	17.7%	27.4%
2025E-2030E	33.1%	17.1%	26.7%



Source: Frost & Sullivan Report (based on annual reports of relevant companies, literature review and expert interviews)

Evolution of Autoimmune Disease Treatments

There are several major types of treatments that target autoimmune diseases. The following diagram illustrates the evolution of the autoimmune disease treatments.



Traditional anti-inflammatory agents are commonly used treatment options for patients with autoimmune diseases, particularly during the initial stages of disease. They have shown the potential to rapidly improve symptoms by alleviating pain, reducing fever and mitigating inflammatory responses. However, traditional anti-inflammatory agents are also noted with limited efficacy in patients with more severe symptoms and there remain concerns over the potential side effects from long-term use of some of these agents. For example, NSAID therapy may lead to side effects such as nausea, allergy and high blood pressure in long-term use. Biologic drugs have emerged as effective innovative therapies for many autoimmune diseases over the past decades. Biologic drugs have revolutionized autoimmune disease treatment by targeting specific factors driving disease progression, instead of suppressing the immune system undiscriminatingly, thereby reducing the serious side effects that can result. Antibodies targeting TNF, a type of pro-inflammatory cytokine, are one of the most widely used biologic drugs for the treatment of various autoimmune diseases, such as ankylosing spondylitis (AS) and rheumatoid arthritis (RA). TNF inhibitors have shown potential to control disease activity and provide substantial improvements in patients' daily function, with durable treatment effect. However, there remain substantial limitations associated with TNF inhibitors. Studies have shown that up to 40% of patients become intolerant or fail to achieve adequate disease control with anti-TNF therapies.

In recent years, studies have demonstrated that interleukins, a type of cytokines, play essential roles in modulating the growth, differentiation and activation of various immune cells, including T cells, during inflammatory and immune responses. Therefore, IL inhibitors have emerged as the next-generation biologic drugs for autoimmune diseases. The IL family include a variety of cytokines, among which those related to T helper cells 17 and T helper cells 2 (Th17 and Th2), such as IL-17A and IL-23, are the most studied.

- *IL-17A antibodies*. As of the Latest Practicable Date, there were two anti-IL-17A antibodies approved globally, namely, secukinumab and ixekizumab, both of which were also approved in China. Secukinumab is currently approved in over 90 countries worldwide, including the U.S., the EU, Japan and China. In China, secukinumab is approved for the treatment of AS and moderate-to-severe plaque psoriasis. In 2022, secukinumab recorded sales of US$4.8 billion and US$601.4 million globally and in China, respectively. IL-17A antibodies are expected to experience rapid increase in their market shares, primarily driven by improving drug affordability and fast expansion of approved indications. As of the Latest Practicable Date, there were 14 IL-17A antibodies in clinical development in China.

- *IL-23 antibodies.* As of the Latest Practicable Date, there were four IL-23 antibodies approved globally, namely, ustekinumab, guselkumab, tildrakizumab and risankizumab. Among them, guselkumab had been approved in China. As of the Latest Practicable Date, there were seven antibody candidates targeting IL-23 in the clinical stage in China.

Other promising innovative biologic treatments for autoimmune diseases include interferon (IFN) inhibitors and B cell–related therapies. IFNs are a family of cytokines that help enhance antiviral responses and immune activation, and have been found to play important roles in autoimmune and chronic inflammatory responses. B cell–related therapies aim to inhibit autoreactive B cell activation and autoantibody production. Popular B cell–related targets include, among others, B lymphocyte stimulator (BLyS), also known as B cell activating factor (BAFF), a member of the TNF cytokine family and a key factor in the differentiation and survival of B cells; a proliferation inducing ligand (APRIL); and various membrane protein present on B cells, such as CD20, CD40 and CD80. IFN inhibitors and B cell–related therapies have been approved by the FDA (B cell–related therapies were also approved by the NMPA) as treatment for SLE and are under investigation as potential treatment options for other autoimmune diseases such as RA and lupus nephritis (LN).

However, drug accessibility and treatment compliance for biologic drugs in the treatment of autoimmune diseases have historically been relatively low in China, primarily due to limited number of approved biologic drugs, high treatment cost associated with the MNC-developed blockbuster drugs and lack of awareness and education regarding autoimmune diseases. For example, according to a study conducted from 2010 to 2012, the penetration rate of biologic drugs in RA patients in the U.S. was approximately 50.7%, compared to 8.3% for China in a study conducted several years later, from 2016 to 2017.

In addition, small-molecule targeted therapies, such as janus kinase (JAK) inhibitors, have also been explored as potential treatment for autoimmune diseases such as psoriasis, RA and AS. JAK is a family of signaling molecules involved in the intracellular transduction of immune signaling of various cytokine receptor cells. JAK inhibitors have shown clear clinical benefit in patients with certain autoimmune diseases in terms of symptom relief and reduction of inflammation. However, the FDA and the EMA required warning for several first-generation JAK inhibitors with respect to the increased risks of major cardiovascular events and malignancies in patients and the long-term safety profile of later-generation candidates is still under evaluation. Other small-molecule drugs under investigation for the treatment of autoimmune diseases also include TYK2 inhibitors and PDE-4 inhibitors.

Major Autoimmune Diseases

Ankylosing Spondylitis

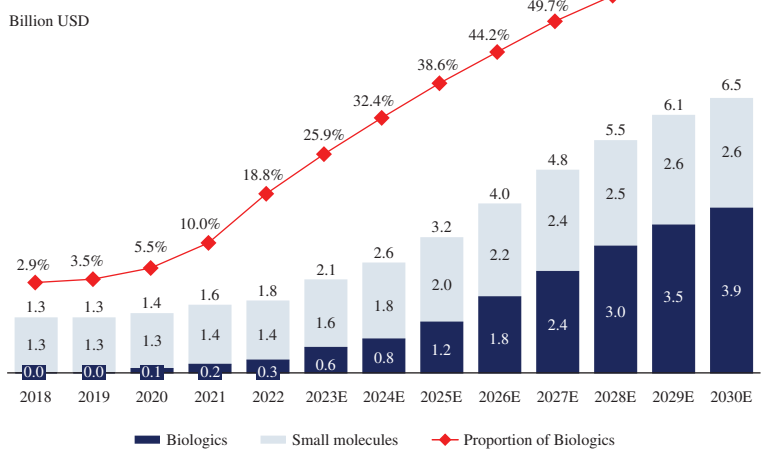
Ankylosing spondylitis (AS) is a chronic progressive inflammatory disease that is primarily characterized by inflammation of the spinal joints, leading to reduced flexibility of the joints and stiffness in the spine over time. The prevalence of AS in China reached 3.9 million in 2022, and is expected to remain relatively stable over the next decade. A considerable proportion of AS patients first develop symptoms in their early adulthood or adolescence, and require long-term treatment to control disease progression.

The AS drug market in China increased from US$1.3 billion in 2018 to US$1.8 billion in 2022, at a CAGR of 7.9%. It is estimated to reach US$6.5 billion in 2030, representing a CAGR of 17.4% from 2022 to 2030. The market for biologic drugs indicated for AS in China is estimated to increase from US$0.3 billion in 2022 to US$3.9 billion in 2030, representing 18.8% and 60.0% of China's AS drug market in 2022 and 2030, respectively. The significant growth of China's AS drug market despite a relatively stable patient population has been, and is expected to continue to be, primarily driven the quickly expanding biologic drug market for AS, benefiting from the improving awareness and acceptance by AS patients for biologic therapies, as well as the reduced treatment costs of such therapies after their admission into the NRDL. The historical and expected growth of China's AS biologic drug market is primarily attributable to the sales of biologics that have been successfully commercialized, such as secukinumab and adalimumab (a TNF inhibitor), and the number of biologic drugs expected to be approved in the near future based on the progress of their clinical trials. The following chart sets forth the historical and estimated AS drug market in China for the periods indicated.

AS Drug Market in China, 2018-2030E

CAGR:

Period	Biologics	Small Molecules	Total Market
2018-2022	72.0%	3.1%	7.9%
2022-2025E	54.9%	11.0%	21.9%
2025E-2030E	25.8%	5.8%	15.2%



Source: Frost & Sullivan Report (based on annual reports of relevant companies, literature review and expert interviews)

Treatment Paradigms for AS in China

There is currently no cure for AS and available treatments aim to control inflammation, prevent joint damage and provide symptom relief. Medications indicated for AS mainly include NSAIDs, traditional DMARDs and corticosteroids. NSAIDs are recommended as the first-line treatment and standard of care for AS in China. NSAID therapies can quickly improve patients' lower back pain and stiffness, as well as reduce joint swelling and pain. However, they are noted with limited efficacy in patients with more severe disease and their effectiveness in suppressing bone erosion and remodeling associated with AS remains unclear. Corticosteroids are often recommended for the treatment of AS in combination with NSAIDs or traditional DMARDs for patients with severe symptoms. However, there are safety risks associated with long-term systemic use of corticosteroids. Maintenance treatment with systemic use of corticosteroids can cause a series of severe adverse effects, such as osteoporosis, adrenal suppression and hyperglycemia (high blood sugar), and dose-dependent growth suppression in children and adolescents. In the past decades, biologic drugs have emerged as effective innovative therapies for AS. The diagram below illustrates the recommended treatment paradigm for AS in China.

Treatment Diagram of AS in China

	NSAIDs Therapy	Traditional DMARDs* Therapy	Corticosteroids Therapy	Biologics Therapy
Drugs	Traditional NSAIDs*	Sulfasalazine	Corticosteroids	TNF inhibitors; IL inhibitors
Pharmaco-logy	Quickly improve patients' lower back pain and stiffness, reduce joint swelling and pain	Relief joint pain, swelling and stiffness; Reduce serum IgA levels; Relief peripheral arthritis symptoms	Anti-inflammatory; Anti-allergic and immunosuppressive; Inhibit inflammatory mediators, like TNF-α	Support the immune system to block TNF and reduce inflammation caused by too much TNF/IL
Dosage	The same NSAIDs should be used for at least 2 weeks; change to another NSAIDs if ineffective after 2-4 weeks	This medicine takes effect slowly; increase 0.25g per week from 2.0g and use for 4-6 weeks, or even 1-3 years	Internal injection in the joint cavity; oral and intravenous application are not recommended; apply less than 2-3 times a year	The TNF-α inhibitor treatment is recommended for 6-12 weeks, or even 2 years. Change to IL inhibitors or another inhibitor if ineffective
Side Effects	Stomach pain; heartburn; nausea; allergy; high blood pressure, etc.	Digestive symptoms; rash; blood Cell reduction; headache; dizziness, etc.	Long-term large-dose use can cause osteoporosis and muscular atrophy, etc.	Nausea; headache; itchiness; dizziness; difficulty breathing; chest pain, etc.

**:* NSAIDs (Nonsteroidal Anti-inflammatory Drugs) include aspirin, acetaminophen, indomethacin, naproxen, etc. Commonly used traditional DMARDs (disease-modifying anti-rheumatic drugs) include methotrexate, leflunomide, sulfasalazine, hydroxychloroquine, azathioprine, cyclophosphamide, etc.

Source: Diagnosis and Treatment of Ankylosing Spondylitis in China (2020) and Frost & Sullivan analysis

There are two classes of approved biologic drugs in China for the treatment of AS, namely, TNF inhibitors and IL-17 inhibitors. TNF, most prominently TNF-α, is a type of pro-inflammatory cytokine produced by certain types of white blood cells during acute inflammation and plays a role in the regulation of the immune system. Dysregulation of TNF may lead to excessive inflammation, which in turn may cause various autoimmune and immune-mediated disorders. TNF inhibitors block the binding of TNF to TNF receptors, thereby suppressing their biological effects. TNF inhibitors are recommended as second-line treatment for AS patients by prevailing clinical guidelines and currently one of the most commonly used biologic drugs for AS in China. However, studies have shown that up to 40% of patients with AS become intolerant or fail to achieve adequate disease control with anti-TNF therapies, indicating significant heterogeneity in treatment response. Thus, there remains an unmet medical need for novel treatments with a different mechanism of action.

With recent scientific advancements demonstrating the role of IL-17A in AS pathogenesis, IL-17A antibodies have emerged as a new class of biologic drugs for AS and have been recommended by prevailing clinical guidelines as second-line standalone treatment (the same designation as TNF inhibitors) for AS patients with high disease activity after receiving first-line traditional treatments. Therefore, either IL-17A inhibitors or TNF inhibitors could be recommended for AS patients failing first-line treatments, while between the two classes of biologics, IL-17A inhibitors have also shown clear clinical benefit in patients who are intolerant to or fail to achieve adequate disease control with TNF inhibitors. In addition, the dosing regimens for certain IL-17A inhibitors are more convenient than those of many TNF inhibitors. For example, secukinumab could be administered once every four weeks, while adalimumab, one of the best-selling TNF inhibitors, requires a dosing regimen of once every two weeks. As a result, there has been an increasing acceptance of IL-17A inhibitors as a new class of biologic therapy for AS by medical practitioners and patients, as evidenced by the quickly increasing sales of secukinumab, which achieved sales of US$601.4 million in China in 2022 (with sales for AS treatment accounting for a significant portion). Consequently, the market share of IL-17A inhibitors in AS biologic drug market in China surpassed that of TNF inhibitors in 2022. We believe that QX002N will primarily compete with anti-IL-17 drugs and other biologic drugs, primarily TNF inhibitors, in China.

In addition to traditional treatments and targeted biologics, tofacitinib by Pfizer, a small molecule Janus kinase (JAK) inhibitor, has been approved for AS treatment by the FDA and the NMPA. However, tofacitinib is recommended by the FDA only for AS patients who are intolerant or non-responsive to one or more TNF inhibitors as there still remain concerns over the safety profile of JAK inhibitors.

As of the Latest Practicable Date, there were 19 biologic drugs approved for AS treatment in China, comprising 17 TNF inhibitors (including Humira (adalimumab) and 7 adalimumab biosimilars) and 2 IL-17A antibody drugs, namely, secukinumab and ixekizumab, both of which had also been approved by the FDA. No biosimilar or generic of secukinumab or ixekizumab had been approved for the treatment of AS in China as of the Latest Practicable Date. As of the same date, in addition to QX002N, there were 21 biologic drug candidates indicated for AS in the clinical stage in China, comprising 12 TNF inhibitors (including 8 proposed adalimumab biosimilars) and 9 IL-17 inhibitors.

The following table sets forth details of QX002N and IL-17 antibody drugs or drug candidates for AS in the clinical stage in China as of the Latest Practicable Date.

Marketed IL-17A Inhibitors for AS in China

Target	Brand Name	INN	Company	NMPA Approval Time	Median Price[1]	NRDL Inclusion	Expected Patent Expiration[2]
IL-17A	Cosentyx	Secukinumab	Novartis	2020	1,188.0	Yes	2025
	Taltz	Ixekizumab	Eli Lilly	2022	1,218.0	Yes	2026

Clinical-Stage IL-17A Inhibitor Candidates for AS in China

Target	Drug Code	Company	Status	First Posted Date
IL-17A	**QX002N**	**the Company**	**Phase III**	**2023-08-31**
	GR1501	GenrixBio	Phase III	2022-04-26
	Netakimab	Biocad	Phase III	2022-09-30
	SHR-1314	Hengrui	Phase II/III	2021-04-08
	AK111	Akeso	Phase II	2021-05-07
	JS005	Junshi	Phase II	2021-09-30
	HB0017	Huabo	Phase II	2023-04-12
	Secukinumab-CMAB015	MabPharm	Phase I	2023-01-18
IL-17A, IL-17F	Bimekizumab	UCB	Phase III	2019-10-25
	LZM012	Livzon	Phase III	2023-07-28

Source: Frost & Sullivan Report (based on annual reports of relevant companies and information published by the NMPA)

Notes:

(1) Reflects the NRDL median price for minimum formulation unit in 2022 in RMB.

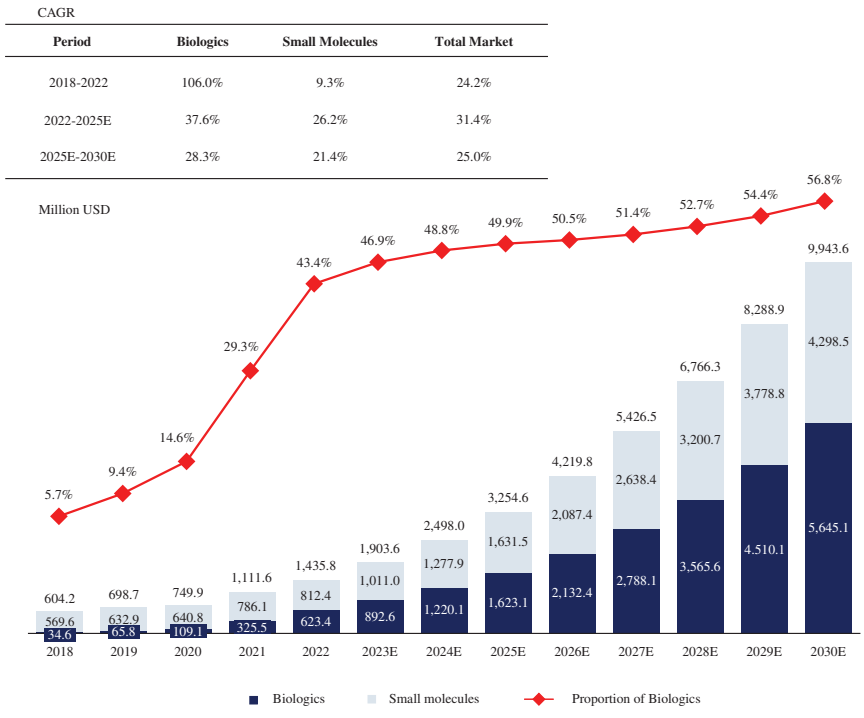
(2) Reflects the present anticipated expiration time of the relevant amino acid sequence patent in the PRC.

Psoriasis

Psoriasis (Ps) is a common chronic skin disease with no cure, with plaque Ps being the most common type. The prevalence of Ps in China has generally remained stable, which increased from 6.5 million in 2017 to 6.7 million in 2022, and is anticipated to reach 6.8 million in 2030. 20% to 30% of the patients have moderate-to-severe Ps.

The Ps drug market in China grew rapidly from US$604.2 million in 2018 to US$1,435.8 million in 2022, at a CAGR of 24.2%, and is estimated to increase to US$9,943.6 million in 2030, at a CAGR of 27.4% from 2022 to 2030. The significant growth of the Ps drug market in China is primarily attributable to (i) a higher penetration rate of biologics in the Ps drug market in China with a rapid growth rate, which is expected to reach 56.8% in 2030, mainly driven by the sales of biologics that have been successfully commercialized (*e.g.*, secukinumab, ustekinumab and ixekizumab) and a higher demand for biologics as Ps patients need treatments with better efficacy and a complete or near-to-complete elimination of symptoms has gradually become the requirement for Ps treatments by prevailing guidelines; (ii) major Ps biologics have been gradually included in the NRDL and experienced a decrease in their prices, which has improved the affordability of these drugs and is expected to further drive the growth of the Ps drug market in China; (iii) the increasing prevalence of Ps in China and the number of Ps patients in China is expected to reach 6.8 million in 2030, which also contributes to the growth of the Ps drug market in China; and (iv) there have been increasing marketing efforts to further expand the coverage of biologics in the Ps drug market in China. Biologic drugs accounted for 43.4% of the market in 2022, which is estimated to increase to 50.3% in 2030. The following table sets forth the size of the Ps drug market in China for the periods indicated.

Psoriasis Drug Market in China, 2018-2030E



Source: Frost & Sullivan Report (based on annual reports of relevant companies, literature review and expert interviews)

Treatment Paradigms for Ps in China

Because Ps is incurable, the goal of treatment is to control disease progression and maintain long-term efficacy. Treatment paradigms are based on the patients' conditions, including the type of Ps, the severity of the conditions and any co-morbidities. Topical drugs are usually used to treat patients with mild Ps but can cause local adverse reactions if used long term. It may be inconvenient for patients with extensive rashes and there is significant variation in patient compliance. Non-steroidal anti-inflammatory drugs (NSAIDs) and disease-modifying anti-rheumatic drugs (DMARDs) are also commonly used to control Ps and alleviate symptoms such as pain, stiffness and swelling. However, studies have found that NSAIDs and conventional DMARDs showed limited efficacy as compared to targeted biologic drugs, which has become a main treatment option for moderate-to-severe plaque Ps in China.

Small-molecule targeted drugs are a relatively new class of medications as a potentially promising treatment option for Ps patients. For example, JAK inhibitors have shown promising clinical results but may lead to more severe side effects and higher toxicity, causing the FDA to advise that they should be used with caution for patients with certain risk factors. PDE-4 inhibitors, another family of small-molecule drugs, have shown good safety profile but with limited efficacy. As a result, their use as a recommended long-term treatment option for a broad section of Ps patients remains under evaluation. Recently, tyrosine kinase 2 (TYK2) inhibitors, a newer family of small-molecule targeted drugs, have demonstrated in clinical studies promising efficacy profiles for treating Ps and improvements on traditional limitations of JAK-related toxicities.

Since the first biologic drug for Ps treatment, namely, an anti-IL-8 humanized mAb, was approved in China in 2003, there have been over ten biologic drugs approved for Ps in China in recent years. They belong to two main types, namely, TNF inhibitors and IL inhibitors, which are considered first-generation and second-generation drugs. TNF, most prominently TNF-α, is a type of pro-inflammatory cytokine produced by certain types of white blood cells during acute inflammation and plays a role in the regulation of the immune system. TNF inhibitors block the binding of TNF to TNF receptors, thereby suppressing their biological effects. Adalimumab, a TNF-α inhibitor and sold under the brand name Humira, was the world's best-selling drug for eight years in the last ten (2013-2022). As TNF inhibitors have significant limitations, including multiple adverse effects and a high rate of non-responsiveness, IL inhibitors present a promising treatment for Ps. Common IL targets under investigation include IL-17A and IL-23. Among IL inhibitors, IL-23 is expected to be one of the mainstream targets for Ps treatment given its key role in alleviation of inflammation and its superior efficacy and safety profile in comparison with IL-17A inhibitors in clinical studies. For example, risankizumab, an IL-23p19 inhibitor, demonstrated superior efficacy and similar safety with less frequent dosing compared with secukinumab, an IL-17 inhibitor, in a Phase III clinical trial in patients with chronic, moderate-to-severe plaque Ps (the IMMerge study), as measured by PASI 90 at week 52. The chart below sets forth the global sales of marketed biologics targeting IL-23 and IL-17A in 2022.

Target	Drug	Global sales 2022 (million USD)	SUM – Global sales 2022 (million USD)
IL-23	Ustekinumab	9,723	17,556
	Guselkumab	2,668	
	Tildrakizumab-asmn	Undisclosed	
	Risankizumab-rzaa	5,165	
IL-17A	Secukinumab	4,788	7,270
	Ixekizumab	2,482	

Source: Frost & Sullivan Report (based on annual reports of relevant companies)

Competitive Landscape of Biologics for Ps Treatment in China

As of the Latest Practicable Date, there were 21 biologic drugs for Ps approved in China, including 13 TNF inhibitors (including Humira (adalimumab) and 6 adalimumab biosimilars) and 8 IL inhibitors, among which ustekinumab was the only approved IL-12/IL-23 inhibitor while guselkumab and tildrakizumab were the only approved IL-23 inhibitors. As of the same date, besides QX001S and QX004N, there were 28 biologic drug candidates for Ps in the clinical stage in China, including 12 IL-17 inhibitors, 8 TNF-α inhibitors (including 7 proposed adalimumab biosimilars), 3 targeting IL-23, 3 targeting IL-12/IL-23 (including 2 proposed ustekinumab biosimilars) and 2 targeting IL-36R. Due to the aforementioned limitations of TNF inhibitors, we believe that QX001S and QX004N will primarily compete with other IL inhibitors. The following table sets forth details of QX001S and QX004N as well as approved biologic drugs and drug candidates in the clinical stage for Ps in China that are IL inhibitors as of the Latest Practicable Date.

Marketed IL Inhibitors for Psoriasis in China

Target	Brand Name	International Nonproprietary Name (INN)	Company	NMPA Approval Time	Branded or Biosimilar	Availability of biosimilar	2022 NRDL covered	NRDL Median price in 2022[1] (RMB)
IL-23	Tremfya	**Guselkumab**	Janssen (J&J)	2019	Branded	—	No	—
	益路取	**Tildrakizumab-asmn**	Sun Pharma; Kangzhe Biotech	2023	Branded	—	No	—
IL-12, IL-23	Stelara	**Ustekinumab**	Janssen (J&J)	2017	Branded	—	Yes	4,318.0
IL-17A	Cosentyx	**Secukinumab**	Novartis	2019	Branded	—	Yes	1,188.0
	TALTZ	**Ixekizumab**	Eli Lilly	2019	Branded	—	Yes	1,218.0
IL-17RA	LUMICEF	**Brodalumab**	Kyowa Kirin	2020	Branded	—	No	—
IL-8	Enboke (恩博克)	—	ASIA SPACE	2003	Branded	—	Yes	270.0
IL-36R	Spevigo	**Spesolimab**	Boehringer Ingelheim	2022	Branded	—	No	—

Clinical-Stage IL Inhibitor Candidates for Psoriasis in China

Target	Drug Code	Company	Status	First Posted Date
IL-23	IBI112	Innovent	Phase III	2022-12-26
	QX004N	**the Company**	**Phase II**	**2023-01-06**
	Risankizumab	Boehringer Ingelheim	Phase I	2019-07-18
	NBL-012	NovaRock (a subsidiary of CSPC)	Phase I	2021-06-03
IL-12, IL-23	**Ustekinumab-QX001S**	**the Company**	**NDA**	**2023-08-12**
	Ustekinumab-BAT2206	Biothera	Phase III	2021-06-25
	AK101	Akeso	Phase III	2021-10-28
	Ustekinumab-SYSA1902	CSPC	Phase III	2023-01-29
IL-17A	GR1501	GenrixBio	NDA	2023-03-25
	SHR-1314	Hengrui	NDA	2023-04-27
	JS005	Junshi	Phase III	2023-07-12
	Secukinumab-BAT2306	Biothera	Phase III	2022-07-25
	SSGJ-608	Sunshine Guojian	Phase III	2022-11-10
	AK111	Akeso	Phase III	2023-02-15
	HB0017	Huaota Biopharm; Huabo Bio	Phase II	2022-08-22
	Netakimab	BIOCAD	Phase I	2022-10-19
	Secukinumab-CMAB015	Mabpharm	Phase I	2023-01-18
	NVS451	National Vaccine & Serum Institute	Phase I	2023-05-08
	FTC001/CNTO6785	Shandong Fontacea	Phase I	2023-06-26
IL-17A, IL-17F	LZM012	LIVZON	Phase III	2023-06-27
IL-36R	HB0034	Huaota Biopharm; Huabo Bio	Phase I	2022-09-05
	Imsidolimab	AnaptysBio	Phase III	2023-03-09

Source: NMPA, CDE, Frost & Sullivan Report

Note:

(1) Reflects the median price for a drug's minimum formulation unit as included in the NRDL.

Systemic Lupus Erythematosus

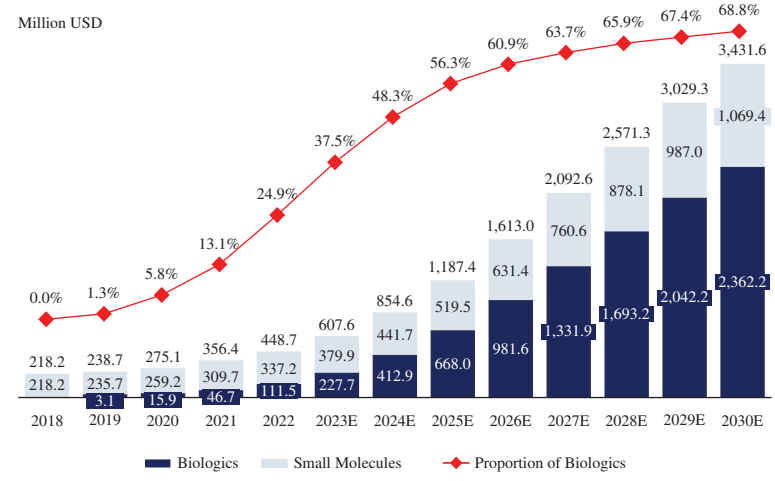
Systemic lupus erythematosus (SLE) is an autoimmune disease associated with substantial morbidity and mortality. It is the most common type of lupus, causing widespread inflammation and tissue damage in the affected organs. The prevalence of SLE in China reached approximately 1 million in 2022 and is expected to remain relatively stable over the next decade.

The SLE drug market in China increased from US$218.2 million in 2018 to US$448.7 million in 2022, at a CAGR of 19.7%. It is estimated to reach US$3.4 billion in 2030, representing a CAGR of 29.0% from 2022 to 2030. The market for biologic drugs indicated for SLE in China is estimated to increase from US$111.5 million in 2022 to US$2.4 billion in 2030, representing 24.9% and 68.8% of China's SLE drug market in 2022 and 2030, respectively. The improving awareness and acceptance by the prevailing treatment guidelines and SLE patients for biologic therapies, as well as the reduced treatment costs of such therapies after their admission into the NRDL have led to a quickly increasing penetration rate of biologic drugs, which has been and is expected to continue to be the primary driver behind the growth of China's SLE drug market despite a relatively stable patient population. The increasing penetration rate of China's SLE biologic drugs is primarily attributable to the sales of biologics that have been successfully commercialized and admitted into the NRDL, *i.e.*, belimumab and telitacicept, and the number of biologic drugs expected to be approved in the future. The following chart sets forth the historical and estimated SLE drug market in China for the periods indicated.

SLE Drug Market in China, 2018-2030E

CAGR:

Period	Biologics	Small Molecules	Total Market
2018-2022	—	11.5%	19.7%
2022-2025E	81.6%	15.5%	38.3%
2025E-2030E	28.7%	15.5%	23.6%



Source: Frost & Sullivan Report (based on annual reports of relevant companies, literature review and expert interviews)

Treatment Paradigms for SLE in China

The types of drugs that have been used to treat SLE mainly include corticosteroids, traditional DMARDs (such as hydroxychloroquine), NSAIDs and biologic drugs. Corticosteroids are recommended as initial treatment for SLE patients. Low-dose corticosteroids, hydroxychloroquine or NSAIDs are recommended for patients with mild symptoms. For SLE patients with more severe conditions, combined therapies of corticosteroids, biologic drugs and traditional DMARDs are recommended. High doses of corticosteroids can be helpful in severe cases of SLE, but the patients face considerable risk of disease progression, relapse over time and serious side effects, including osteoporosis (weak bones), high blood pressure and diabetes. In addition, treatment with traditional DMARDs may result in an increased risk of serious infections and certain types of cancer. Hydroxychloroquine may offer relief for SLE-related symptoms, such as arthritis, fatigue and rashes, but is associated with increased risk of retinopathy. There remain significant unmet needs for new therapeutics for SLE that effectively control disease activity, have a favorable safety profile and improve the patients' quality of life. Over the past decades, there has been growing interest in the development of biologic drugs indicated for SLE, including, most importantly, interferon (IFN) receptor inhibitors and B cell depletion therapies aiming to inhibit autoreactive B cell activation and autoantibody production.

As of the Latest Practicable Date, there were two approved B cell depletion therapies in China indicated for SLE, namely, belimumab and telitacicept. Belimumab is a human monoclonal antibody that inhibits BLyS (or BAFF), a member of the TNF cytokine family produced by myeloid lineage cells, such as dendritic cells and macrophages, and a key factor in the differentiation and survival of B cells. Belimumab was also approved by the FDA in 2011, making it the first new drug approved for SLE treatment globally in more than 50 years. Telitacicept targets two cell-signaling molecules critical for B cell development: BLyS and a proliferation inducing ligand (APRIL). As of the Latest Practicable Date, telitacicept had not been approved outside of China. No biosimilar or generic of belimumab or telitacicept had been approved for the treatment of SLE in China as of the Latest Practicable Date.

As of the Latest Practicable Date, there was only one IFN receptor inhibitor approved by the FDA for SLE treatment, namely, anifrolumab. It was approved by the FDA in 2021, making it the only new SLE treatment in more than 10 years. As of the same date, no drug of the same target was approved for SLE by the NMPA.

As of the same date, in addition to QX006N, there were 12 biologic drug candidates for SLE in the clinical stage in China, two of which were IFNAR1 inhibitors. Other targets under investigation include BAFF and various membrane/transmembrane proteins, such as CD38 and CD22. The following table sets forth details of QX006N and biologic drugs and drug candidates for SLE in the clinical stage in China as of the Latest Practicable Date.

Marketed Targeted Biologics for SLE in China

Target	Brand Name	INN	Company	NMPA Approval Time	Median Price[(1)]	NRDL Inclusion
BAFF	Benlysta	Belimumab	GSK	2019	727.5	Yes
BAFF/APRIL	Tai'ai (泰愛)	Telitacicept	Remegen	2021	818.8	Yes

Clinical-Stage Biologic Drug Candidates for SLE in China

Target	Drug Code	Company	Status	First posted Date
IFNAR1	Anifrolumab	AstraZeneca	Phase III	2021-08-09
	GR1603	Genrix Bio	Phase I/II	2021-12-03
	QX006N	**the Company**	**Phase I**	**2021-11-23**
BAFF	UBP1213sc	Junshi	Phase I	2022-02-18
BAFFR	VAY736	Novartis	Phase III	2023-01-09
CLEC4C	BIIB059	Biogen; Vetter Pharma-Fertigung	Phase III	2022-06-07
CD20	Obinutuzumab	Roche	Phase III	2022-10-27
	MIL62	Mabworks	Phase II/III	2023-02-08
CD40L	Dapirolizumab Pegol	UCB	Phase III	2022-11-07
CD38	CM313	Keymed	Phase I/II	2022-07-08
CD22	SM03	Longrui	Phase I	2015-01-07
CD79B, FCGR2B	PRV-3279	Zhongmei Huadong	Phase II	2023-08-02
Undisclosed	SHR-2001	Hengrui	Phase I	2023-07-10

Source: Frost & Sullivan Report (based on annual reports of relevant companies and information published by the NMPA)

Note:

(1) Reflects the NRDL median price for minimum formulation unit in 2022 in RMB.

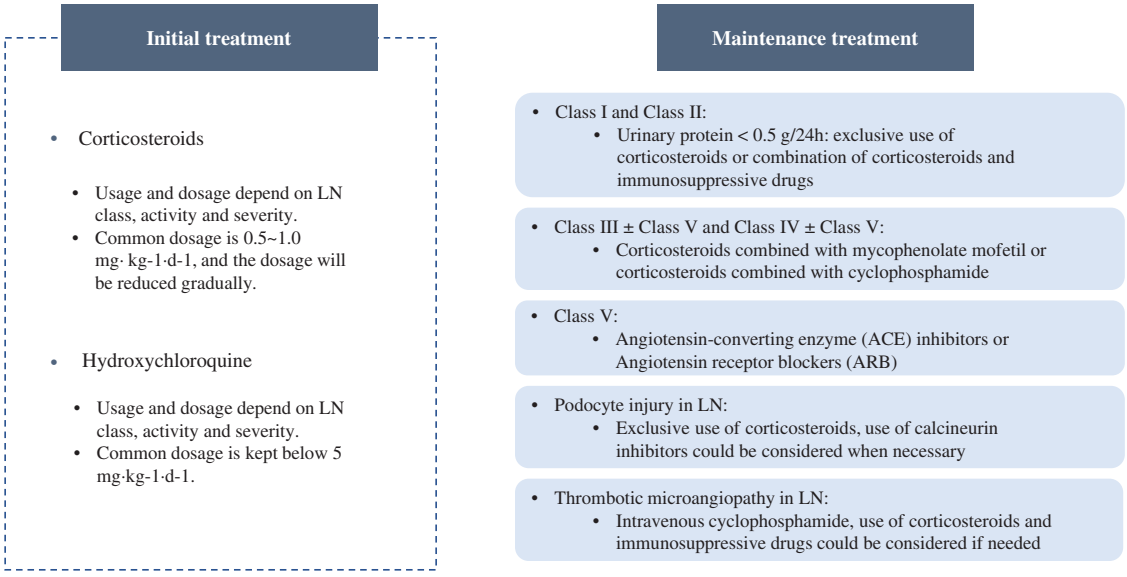
Lupus Nephritis

Lupus Nephritis (LN) is the most common severe complication of SLE, involving inflammation of and possible organ damage to the kidneys. The prevalence of LN in China was approximately 567,700 in 2022, and is expected to remain relatively stable over the next decade.

The LN drug market in China increased from US$104.7 million in 2018 to US$211.4 million in 2022, and is estimated to reach US$1.6 billion in 2030, representing a CAGR of 29.2% from 2022 to 2030. The growth of China's LN drug market is mainly driven by the expected sales growth of recently approved biologic drug and the increase in the number of innovative drugs expected to be approved in the near future based on the progress of their clinical trials, especially biologic drugs that generally have higher prices than traditional treatment options. Additionally, the improving ability and propensity of the patients in China to pay for long-term advanced therapies also contribute to the expected expansion of the LN drug market. The market for biologic drugs indicated for LN in China is estimated to increase to US$1.1 billion in 2030, representing 67.4% of China's LN drug market in 2030.

Similar to treatment options for SLE, the types of drugs that have been used to treat LN mainly include corticosteroids, traditional DMARDs (such as hydroxychloroquine) and biologic drugs, with corticosteroids and hydroxychloroquine recommended as initial treatment options and standard of care. As the investigation of biologic drugs for the treatment of LN is still at an early stage, there is no clear designation of line of treatment for biologic drugs for this indication. Compared to SLE, biologic drugs and drug candidates indicated for LN are even more limited. The diagram below illustrates the recommended treatment paradigm for LN in China.

Treatment Diagram of LN in China



Source: Standards for the Diagnosis and Treatment of Lupus Nephritis (2021) and Frost & Sullivan analysis

As of the Latest Practicable Date, belimumab was the only targeted biologic drug approved by the FDA or NMPA for the treatment of LN. See "—Systemic Lupus Erythematosus—Treatment Paradigms for SLE in China" for more details on belimumab. As of the same date, there were 11 biologic drug candidates for LN in the clinical stage in China, 3 of which were IL-17 inhibitors. Other targets under investigation include B cell membrane proteins, such as CD80/CD86 and CD20.

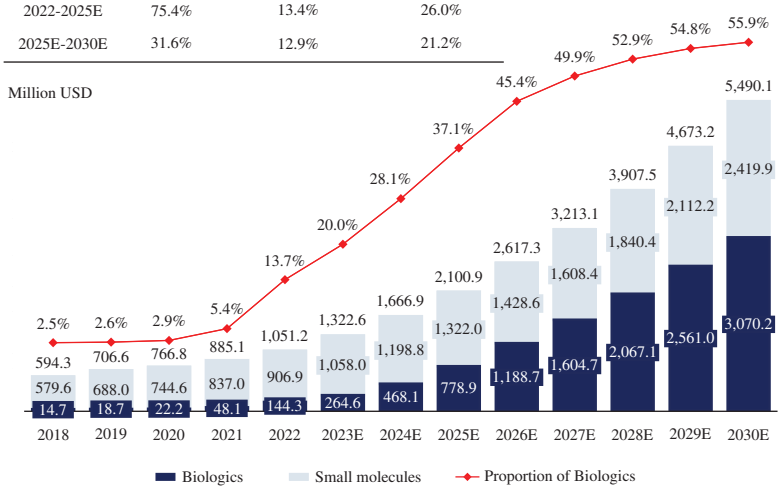
Inflammatory Bowel Disease

Inflammatory bowel disease (IBD) is a broad term that describes conditions characterized by chronic inflammation of the gastrointestinal tract, including ulcerative colitis (UC) and Crohn's disease (CD). The total prevalence of UC and CD in China increased from 490,500 in 2018 to 674,200 in 2022, at a CAGR of 8.3%, and is estimated to reach 1,154,200 in 2030, at a CAGR of 7.0% from 2022 to 2030. The UC/CD drug market in China grew rapidly in recent years, from US$594.3 million in 2018 to US$1,051.2 million in 2022, representing a CAGR of 15.3%, and is estimated to reach US$5,490.1 million in 2030, representing a CAGR of 23.0% from 2022 to 2030. Biologic drugs accounted for 13.7% of the UC/CD drug market in China in 2022, which is estimated to increase to 55.9% in 2030. The following table sets forth the UC/CD drug market in China for the periods indicated.

UC/CD Drug Market in China, 2018-2030E

CAGR:

Period	Biologics	Small Molecules	Total Market
2018-2022	76.9%	11.8%	15.3%
2022-2025E	75.4%	13.4%	26.0%
2025E-2030E	31.6%	12.9%	21.2%



Source: Frost & Sullivan Report (based on annual reports of relevant companies, literature review and expert interviews)

Treatment Paradigms for UC/CD in China

Treatment of UC/CD usually involves either drug therapy or surgery. Several types of medications may be used to treat UC/CD, including anti-inflammatory drugs, glucocorticoids, immunosuppressants and biologic drugs. Anti-inflammatory drugs mainly include aminosalicylic acids (5-ASA), which can reduce inflammation but studies have shown that they are not effective at inducing remission in active CD or preventing relapse in inactive CD. While patients can initially respond to glucocorticoid therapy, a large portion of them develop a dependency on glucocorticoids or have a relapse within one year. In addition, use of glucocorticoids is often limited by a relatively high risk of serious adverse effects including bone loss, metabolic complications, increased intraocular pressure and glaucoma and potentially lethal infections. Immunosuppressants may also trigger profound side effects such as short-term and long-term toxicities due to their non-specific, anti-proliferative or anti-metabolic features. In the past five years, the introduction of biologic drugs has heralded a new era of evolving biologically targeted treatments for UC/CD. However, biologics have not yet been recommended as a main treatment option for UC/CD by prevailing clinical guidelines.

There are three types of approved biologic drugs in China for the treatment of UC/CD, namely, TNF-α inhibitors, integrin α4 (ITGA4)/integrin β7 (ITGB7) inhibitors and IL-12/IL-23 inhibitors. TNF-α inhibitors block the binding of TNF to TNF receptors, thereby suppressing their biological effects. Integrin α4/integrin β7 inhibitors bind to the surface of white blood cells so they cannot pass through tissue layers and exacerbate inflammation. However, use of certain integrin α4/integrin β7 inhibitors carries an increased risk of progressive multifocal leukoencephalopathy, a severe brain condition. In contrast, IL-23 and IL-12 inhibitors, such as ustekinumab, have exhibited strong safety profile while maintaining satisfactory efficacy. However, all such classes of biologics are likely to result in drug resistance, forcing CD patients to switch between such classes of biologics to prolong treatment.

Competitive Landscape of Biologics for UC/CD Treatment in China

As of the Latest Practicable Date, there were 12 biologic drugs for UC/CD approved in China, including ten TNF-α inhibitors (including Remicade (infliximab), Humira (adalimumab), three infliximab biosimilars and five adalimumab biosimilars), one integrin α4/integrin β7 inhibitor, namely, vedolizumab, and one IL-12/IL-23 inhibitor, namely, ustekinumab. No biosimilar or generic of ustekinumab or vedolizumab had been approved for the treatment of UC/CD in China as of the Latest Practicable Date. The TNF-α inhibitors, integrin α4/integrin β7 inhibitors and IL-12/IL-23 inhibitors are expected to continue to be mainstream biologic treatments for UC/CD in the near future. As of the same date, there were 11 biologic drug candidates for UC/CD in clinical stage in China, seven of which were IL-12/IL-23 inhibitors or IL-23 inhibitors. The following tables sets forth details of QX004N as well as approved biologic drugs and biologic drug candidates for UC/CD in the clinical stage in China as of the Latest Practicable Date.

Marketed Targeted Biologics for UC/CD in China

Target	Brand Name	INN	Company	Median Price[1]	Indications	NMPA Approval Time	NRDL Inclusion
IL-12/IL-23	Stelara	Ustekinumab	Janssen (J&J)	4,318	CD	2020	Yes
TNF-α	Remicade	Infliximab	Janssen (J&J)	2,007	CD	2006	Yes
					UC	2018	
	QLETLI (格樂立)	Adalimumab-BAT1406	Bio-Thera	1,080	CD	2019	Yes
	Anjianning (安健寧)	Adalimumab-HS016	Hisun	1,148	CD	2019	Yes
	Humira	Adalimumab	AbbVie	1,290	CD	2020	Yes
	SULINNO (蘇立信)	Adalimumab-IBI303	Innovent	1,088	CD	2020	Yes
	Leiting (類停)	Infliximab-CMAB008	MabPharm	1,268	CD	2021	Yes
					UC	2021	
	Anbaite (安佰特)	Infliximab-HS626	Hisun	1,268	CD	2021	Yes
					UC	2021	
	Jiayoujian (佳佑健)	Infliximab-GB242	Yuxi Genor Biotechnology	1,280	CD	2022	Yes
					UC	2022	
	Junmaikang (君邁康)	Adalimumab-UBP1211	Junshi Pharma	998	CD	2022	Yes
	安佳潤®	Adalimumab-SCT630	SinoCelltech	N/A	CD	2023	No
Integrin α4/ Integrin β7	Entyvio	Vedolizumab	Takeda	4,980	CD	2020	Yes
					UC	2020	

Note:

(1) Reflects the NRDL median price per minimum formulation unit in 2022 in RMB.

Clinical-Stage Biologic Drug Candidates for UC/CD Treatment in China

Target	Drug Code	Company	Indications	Status	First Posted Date
IL-12/IL-23	Ustekinumab-BAT2206	Bio-Thera	CD	Phase I	2020-05-06
			UC	Phase I	2020-05-06
	AK101	Akeso	UC	Phase I	2020-08-13
IL-23	Risankizumab	AbbVie	CD	Phase III	2019-11-13
			UC	Phase III	2020-03-27
	LY3074828	Eli Lilly	CD	Phase III	2020-04-24
			UC	Phase III	2020-01-15
	Guselkumab	Janssen (J&J)	CD	Phase III	2020-06-08
			UC	Phase II/III	2020-06-10
	IBI112	Innovent	UC	Phase II	2022-04-28
	QX004N	**the Company**	**CD**	**Phase I**	**2022-12-28**
TNF-α	Adalimumab-TQZ2301	Chia Tai Tianqing	CD	Phase I	2018-11-13
			UC	Phase I	2018-11-13
TNFSF15	PF-06480605	Pfizer	UC	Phase II	2021-03-11
			CD	Phase I	2021-11-17
IL6ST	Olamkicept	IMAB	UC	Phase II	2018-08-03
Undisclosed	HZBio2	Grand pharma	CD	Phase I	2022-05-16
			UC	Phase I	2022-05-16

Source: Frost & Sullivan Report (based on annual reports of relevant companies and information published by the NMPA)

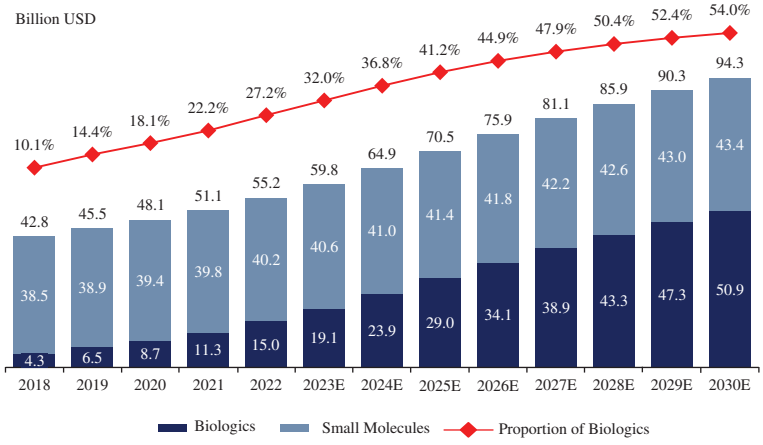
OVERVIEW OF THE ALLERGIC DISEASE DRUG MARKET

The global allergic disease drug market increased from US$42.8 billion in 2018 to US$55.2 billion in 2022, at a CAGR of 6.6%, and is estimated to reach US$94.3 billion in 2030, at a CAGR of 6.9% from 2022 to 2030. Biologic drugs' share of the global market is estimated to increase from 27.2% in 2022 to 54.0% in 2030. The following table sets forth the global allergic disease drug market for the periods indicated.

Global Allergic Disease Drug Market, 2018-2030E

CAGR:

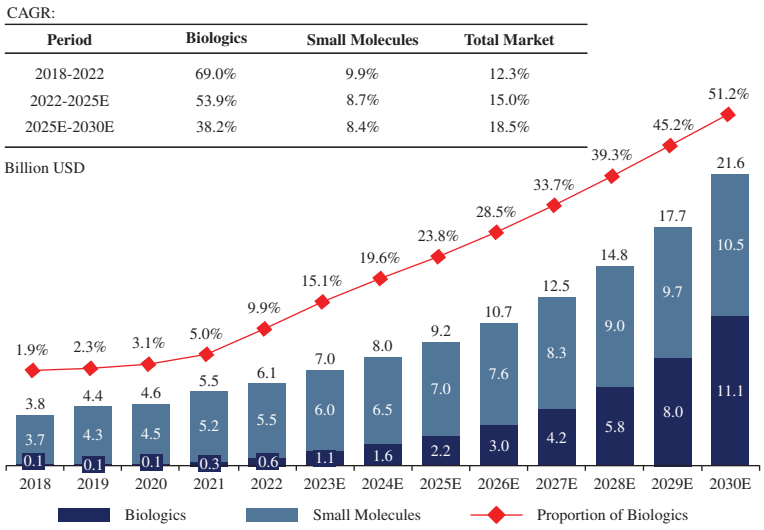
Period	Biologics	Small Molecules	Total Market
2018-2022	36.5%	1.1%	6.6%
2022-2025E	24.6%	1.0%	8.5%
2025E-2030E	11.9%	0.9%	6.0%



Source: Frost & Sullivan Report (based on annual reports of relevant companies, literature review and expert interviews)

The allergic disease drug market is further driven by a huge patient pool and increasing awareness of early diagnosis and treatment in China. The allergic disease drug market in China increased from US$3.8 billion in 2018 to US$6.1 billion in 2022, at a CAGR of 12.3%, and is estimated to reach US$21.6 billion in 2030, at a CAGR of 17.1% from 2022 to 2030. Biologic drugs' share of China's allergic disease drug market is estimated to increase rapidly from 9.9% in 2022 to 51.2% in 2030. The following table sets forth the allergic disease drug market in China for the periods indicated.

China Allergic Disease Drug Market, 2018-2030E



Source: Frost & Sullivan Report (based on annual reports of relevant companies, literature review and expert interviews)

Evolution of Allergic Disease Treatments

Allergy desensitization is a therapy that aims to weaken a patient's allergic reactions by exposing them to gradually increasing doses of allergens. Allergy desensitization is widely used for treatment of allergies of pollen, mites, animal dander and certain medications, but it is barely effective for systemic allergic diseases without a specific allergen, such as AD, PN, CRSwNP, asthma and COPD. Antihistamines and glucocorticoids are then introduced into the treatment of allergic diseases to suppress or alleviate symptoms in various allergic diseases. However, such traditional treatment options are generally limited in efficacy and associated with severe adverse events, especially for long-term treatment.

Since the first biologic drug, an IgE inhibitor, was approved for the treatment of allergic diseases by the FDA in 2003, biologic drugs have been widely used globally for the treatment of allergic diseases. Several cytokines and pathways, such as IL-4, IL-5, IL-13, TSLP and JAK, were found to be involved in the activation of type 2 immune response. Among all type 2 inflammatory cytokines, IL-4 and its receptor are the most studied.

The market for anti-IL-4Rα antibodies emerged when the first anti-IL-4Rα antibody, dupilumab, was approved by the FDA in 2017. In China, dupilumab was approved by the NMPA in 2020 and included in the NRDL in 2021, and remains the only marketed anti-IL-4Rα. Dupilumab is currently approved in U.S., Europe, Japan and other countries around the world for the treatment of moderate-to-severe AD as well as asthma or CRSwNP in different age populations. Dupilumab's global sales increased from US$0.3 billion in 2017 to US$8.7 billion in 2022, at a CAGR of 102.3%. As of the Latest Practicable Date, there were 12 IL-4Rα-targeting biologic drug candidates (excluding dupilumab) in the clinical stage in China, including QX005N.

Due to the relative late start of development, biologic antibodies were first approved for the treatment of allergic diseases in China in 2017. To date, market penetration and treatment compliance with biological therapies for allergic diseases remain relatively low in China as a result of the high costs associated with current biologic therapies. For example, biologic drugs only accounted for 3.5% of the asthma drug market in China in 2022.

Small-molecule targeted therapies, such as JAK inhibitors, can also be used to treat allergic diseases. However, the FDA and the EMA has required warning for several JAK inhibitors with respect to their safety concerns. See "—Overview of the Autoimmune Disease Drug Market—Evolution of Autoimmune Disease Treatments."

Major Allergic Diseases

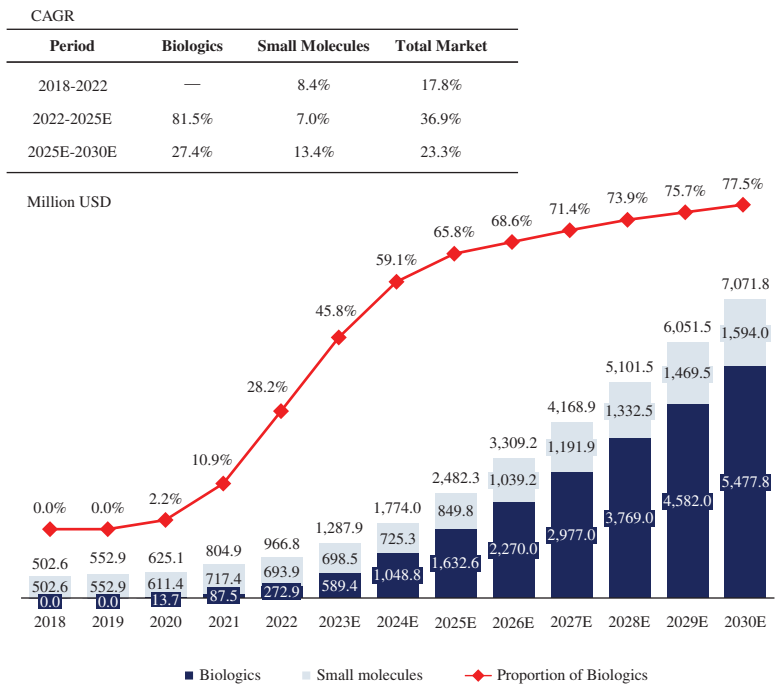
Atopic Dermatitis

Atopic Dermatitis (AD) is one of the most common skin disorders globally and in China. The prevalence of AD in China increased from 64.0 million in 2018 to 70.3 million in 2022, at a CAGR of 2.4%, and is anticipated to reach 78.5 million in 2030, at a CAGR of 1.4% from 2022 to 2030. The number of adult patients with AD in China increased from 31.5 million in 2018 to 35.8 million in 2022 and is anticipated to further increase to 43.4 million in 2030. The number of children/adolescent patients with AD in China increased from 32.5 million in 2018 to 34.5 million in 2022 and is anticipated to further increase to 35.1 million in 2030. In addition, 30% of the patients have moderate-to-severe AD. The number of patients with moderate-to-severe AD increased from 17.7 million in 2018 to 19.5 million in 2022 and is anticipated to reach 21.9 million in 2030. The number of patients with mild AD increased from 46.3 million in 2018 to 50.8 million in 2022 and is anticipated to reach 56.5 million in 2030.

The AD drug market in China increased from US$502.6 million in 2018 to US$966.8 million in 2022, at a CAGR of 17.8% and is estimated to grow rapidly to reach US$7,071.8 million in 2030, at a CAGR of 28.2% from 2022 to 2030. The expected rapid growth from 2022 to 2023 is primarily because (i) the sales of dupilumab (the only biologic drug approved in China for AD and included in the NRDL as of the Latest Practicable Date) in China since its approval for AD in 2020 experienced substantial growth from US$13.7 million in 2020 to US$248.1 million in 2022, at a CAGR of 325.0%, indicating a high demand for AD biologics in China and further growth of the China AD drug market; (ii) there has been increasing R&D of AD biologics by domestic companies and several domestically developed AD biologic drug candidates have entered the clinical trial stage, which, once approved for commercialization, are expected to further drive the growth of the China AD drug market; and (iii) the diagnosis and treatment rates of AD are expected to increase due to improving affordability and health awareness of Chinese AD patients, which is also expected to contribute to the rapid growth of the China AD drug market. In addition, the anticipated significant growth of AD drug market in China from 2021 to 2030 is also attributable to (i) the improved penetration rate of biologics

with a high growth rate in China, which is expected to increase from 28.2% in 2022 to 77.5% in 2030 and mainly driven by the sales of dupilumab in China, and other potential IL-4Rα inhibitors to be approved in China are also taken into consideration; (ii) dupilumab has been included in the NRDL and experienced a decrease in its prices, which is expected to further drive the significant growth of the AD drug market in China; and (iii) the increasing prevalence of moderate-to-severe AD in China and the number of patients with moderate-to-severe AD in China is anticipated to reach 21.9 million in 2030, which also contributes to the growth of the AD drug market in China. Biologic drugs accounted for 28.2% of the AD drug market in China in 2022, which is estimated to increase to 77.5% in 2030. The following table sets forth the size of the AD drug market in China for the periods indicated.

Atopic Dermatitis Drug Market in China, 2018-2030E

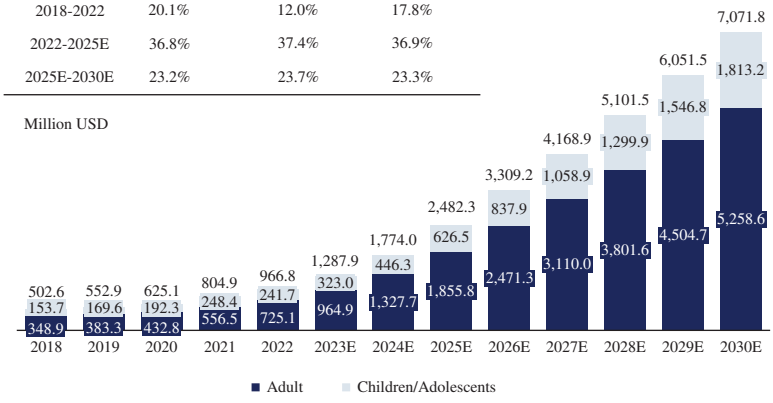


Source: Frost & Sullivan Report (based on annual reports of relevant companies, literature review and expert interviews)

The following table sets forth the breakdown of the AD drug market in China by age for the periods indicated.

Atopic Dermatitis Drugs Market in China Breakdown by Age, 2018-2030E

CAGR	Adult	Children/Adolescents	Total
2018-2022	20.1%	12.0%	17.8%
2022-2025E	36.8%	37.4%	36.9%
2025E-2030E	23.2%	23.7%	23.3%

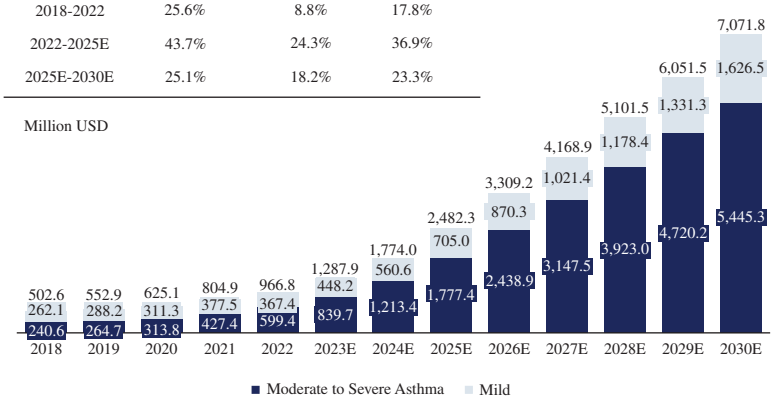


Source: Literature review, Frost & Sullivan Report

The following table sets forth the breakdown of the AD drug market in China by severity for the periods indicated.

Atopic Dermatitis Drugs Market in China Breakdown by Severity, 2018-2030E

CAGR	Moderate to Severe Asthma	Mild Asthma	Total
2018-2022	25.6%	8.8%	17.8%
2022-2025E	43.7%	24.3%	36.9%
2025E-2030E	25.1%	18.2%	23.3%

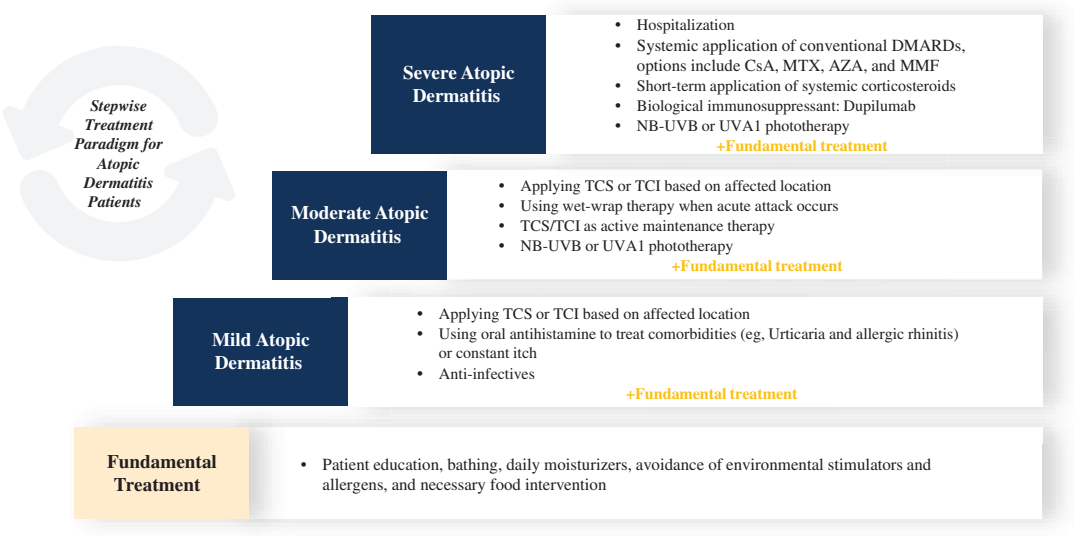


Source: Literature review, Frost & Sullivan Report

Treatment Paradigms for AD in China

Treatment of AD usually involves a step-up approach, *i.e.*, depending on the severity and extent of a patient's symptoms, different medication and treatment options may be recommended. The standard of care for AD in China mainly includes bathing, improvement of the living environment and food intervention. In addition, topical corticosteroids and calcineurin inhibitors are the first line of treatment and important drugs for AD. However, overuse of these drugs may cause side effects, including thinning skin or impaired immune system. In severe cases of AD, phototherapy and conventional DMARDs are recommended by the Guideline for Diagnosis and Treatment of AD in China (2020) (《中國特應性皮炎診療指南(2020版)》). In recent years, biologic drugs with better safety and efficacy profiles have become an emerging treatment for both moderate and severe AD. They could be used as a standalone treatment or in combination with other existing treatments such as phototherapy. Systematic application of biologics may be recommended if a patient has an inadequate response or intolerance to existing topical treatments or phototherapy. For example, dupilumab (an anti-IL-4Rα antibody) is recommended for an initial injection of 600 mg for adults and subsequent injections of 300 mg at a frequency of Q2W, and it can be used for long-term maintenance therapy in combination with topical drugs and moisturizers. Furthermore, dupilumab was studied in over 2,800 patients across 6 pivotal trials that included monotherapy and concomitant TCS, and demonstrated clinically meaningful improvement in concomitant TCS trials (in adults, children and infants to preschoolers with AD) and improvement in monotherapy trials (in adults and adolescents with AD), as measured by improvements in the IGA (IGA 0 or 1) and EASI (EASI-75) scores at week 16. According to the Guideline for Diagnosis and Treatment of AD in China (2020), biologics, as a main treatment option for AD patients, are recommended to be combined with topical drugs and moisturizers for long-term use. In particular, as IL-4, IL-13, IL-5 and IL-10 are important cytokines involved in the pathogenesis of AD, they present potential targets suitable for biologics development. IL-4Rα is the mainstream target under investigation for AD treatment due to its role in controlling the signaling of both IL-4 and IL-13, and research on other targets, such as IL-31, IL-33 and OX40, is also ongoing. However, these targets remain early-stage in their R&D progress and will continue to be subject to scientific uncertainty, while IL-4Rα has already been validated and has also led to successful commercialization of biologics with this target. In addition, small-molecule treatments, including PDE-4 inhibitors and JAK inhibitors, have been explored as potential treatment options for AD patients. In particular, PDE-4 inhibitors have shown a good safety profile but limited efficacy, while JAK inhibitors are approved for patients who have had an inadequate response or intolerance to one or more TNF inhibitors.

The diagram below illustrates the treatment paradigm for AD in China:



*CsA: cyclosporine A; MTX: methotrexate; AZA: azathioprine; MMF: mycophenolate mofetil; TCS: topical corticosteroids; TCI: topical calcineurin inhibitors

Sources: Chinese Society of Dermatology, Frost & Sullivan

Competitive Landscape of Biologics for AD Treatment in China

As of the Latest Practicable Date, dupilumab (an anti-IL-4Rα antibody) was the only biologic drug approved in China for AD, which had also been admitted to the NRDL. Since its launch in 2017, the global sales of dupilumab (under the brand name Dupixent) increased sharply from US$256.5 million in 2017 to US$8,681.2 million in 2022, at a CAGR of 102.3%. Since its approval in China in 2020, the sales of dupilumab in China (as disclosed by Sanofi) also experienced a sharp increase from US$13.7 million in 2020 to US$248.1 million in 2022, at a CAGR of 325.0%. As of the same date, in addition to QX005N, there were 16 biologic drug candidates for AD in the clinical stage in China, among which 9 were IL-4Rα inhibitors and other disclosed targets under investigation included IL-13, TSLP, IL-33, ST2, CD200R, OX40 and IL-2R. As IL-4Rα remains the mainstream target under investigation for AD treatment, we believe QX005N will primarily compete with other IL-4Rα inhibitors. The following table sets forth details of QX005N as well as approved biologic drugs and drug candidates for AD in the clinical stage in China that target IL-4Rα as of the Latest Practicable Date.

Marketed Anti-IL-4Rα Biologics for AD in China

Target	Brand Name	INN	Company	NMPA Approval Time	Branded or Biosimilar	Availability of biosimilar	2022 NRDL covered	NRDL Median price in 2022[1] (RMB)
IL-4Rα	Dupixent	Dupilumab	Sanofi / Regeneron	2020	Branded	—	Yes	3,160.0

Clinical-Stage Anti-IL-4Rα Biologic Drug Candidates for AD in China

Target	Drug Code	Company	Status	First posted Date
IL-4Rα	CM310	Keymed Bioscience	Phase III	2022-02-28
	CBP-201	Connect Biopharmaceuticals	Phase II	2020-11-20
	QX005N	**the Company**	**Phase II**	**2022-07-14**
	MG-K10	Mabgeek	Phase II	2022-07-19
	SSGJ-611	Sunshine Guojian	Phase II	2022-08-24
	SHR-1819	Hengrui	Phase II	2022-09-27
	TQH2722	Chia Tai Tianqing	Phase II	2023-03-27
	GR1802	Genrix Bio	Phase I / II	2021-10-09
	AK120	Akeso	Phase I / II	2021-08-20
	BA2101	Boan Bio	Phase I	2023-01-16

Source: NMPA, CDE, Frost & Sullivan Report

Note:

(1) Reflects the median price for a drug's minimum formulation unit as included in the NRDL.

Prurigo Nodularis

Prurigo Nodularis (PN) is a chronic skin disorder characterized by the presence of hard and extremely itchy bumps known as nodules, which tend to be found in easy-to-scratch areas, such as the arms, legs, the upper back and abdomen. The prevalence of PN in China increased slightly from 1.9 million in 2018 to 2.0 million in 2022, and is anticipated to reach approximately 2.1 million in 2030.

There has been a lack of effective treatments for PN and development of the PN drug market in China is still at an early stage with no biologic drug approved as of the Latest Practicable Date.

Treatment Paradigms for PN in China

The standard of care for PN involves topical creams, such as topical antihistamine, steroids and anesthetics, and systemic drugs, such as antihistamine, steroids and opioid receptor agonists or antagonists. However, some PN treatments such as topical steroids and topical anesthetics are recommended to be used only for a limited duration due to their side effects. Because of the discovery of new therapeutic targets in recent years, there has been increasing research on biologic drugs for treating PN as a potentially promising treatment option. Biologics have become a guideline treatment option but as a relatively new class of drugs, they have not yet been recommended as a main treatment option for PN.

The diagram below illustrates the treatment paradigm for PN in China:

Medical treatment options

Topical treatment	Systemic treatment
• Topical antihistamine: treat local or generalized pruritus.	• Antihistamine: effective control of histamine-based pruritus.
• Topical steroids: critical treatment for inflammatory skin irritations, also used in non-inflammatory and systemic cases.	• Steroids: systemic steroids to rapidly and effectively control inflammatory skin disease condition.
• Topical anaesthetics: used to effectively control local itchiness.	• Opioid receptor agonists or antagonist: effective treatment of pruritus subtypes.
• Topical capsaicin: used externally to control local and limited itchiness.	• Antiepileptic drugs: effectively treat pruritus subtypes.
• Topical calcineurin inhibitors: used to control itchiness caused by inflammatory skin diseases.	• Antidepressant: act on 5-hydroxytryptamine (serotonin) and histamine to control itchiness.
• Others: include mint, zinc oxide, camphor to reduce itchiness.	• Serotonin receptor inhibitor: inhibit serotonin receptor to control itchiness.
	• Thalidomide: commonly used to control prurigo nodularis and persistent pruritus that is not responsive to other treatments.
	• Immunosuppressant: used to control inflammatory skin disease itchiness.
	• Biologic targeted therapy: monoclonal antibody against interleukin-31 receptor that is associated with prurigo nodularis.

Sources: Guidelines for Management of Chronic Pruritus (2018), Mayoclinic, Frost & Sullivan

Competitive Landscape of Biologics for PN Treatment in China

As of the Latest Practicable Date, dupilumab was the only treatment approved for PN by the FDA and by the NMPA in China. As of the same date, there were only two biologic drug candidates for PN in the clinical stage in China, including QX005N, as set out below.

Marketed Targeted Biologics for PN in China

Brand Name	INN	Company	Target	NMPA Approval Time
Dupixent	Dupilumab	Sanofi	IL-4Rα	2023

Clinical-Stage Biologic Drug Candidates for PN in China

Target	Drug Code	Company	Status	First posted Date
IL-4Rα	**QX005N**	**the Company**	**Phase II**	**2022-12-16**
	BA2101	Boan Biotech	Phase I	2023-01-16

Source: NMPA, Frost & Sullivan Report

Chronic Spontaneous Urticaria

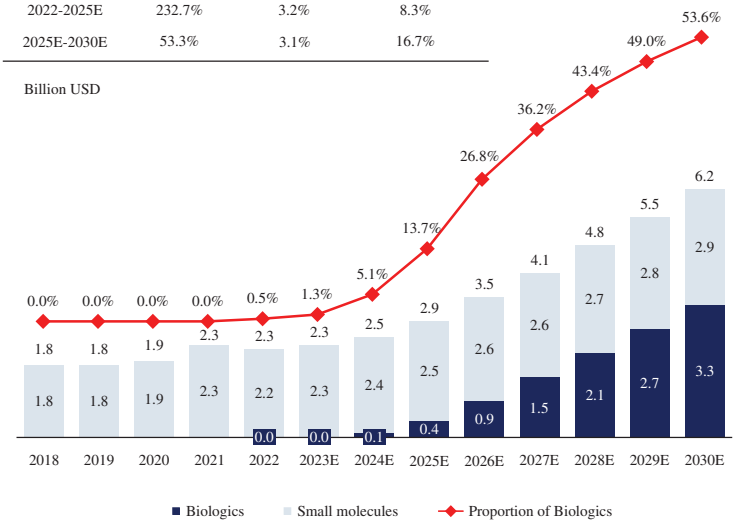
Chronic spontaneous urticaria (CSU) is characterized by the occurrence of urticaria (a common and heterogeneous inflammatory skin disorder characterized by itchy swelling on the skin surface and can be accompanied by angioedema, which is swelling of the subcutaneous tissues under the skin) for six weeks or longer without identifiable specific triggers. The prevalence of CSU in China was approximately 25.0 million in 2022, and is anticipated to reach approximately 29.7 million in 2030.

There has been a lack of effective treatments for CSU and development of the CSU drug market in China is still at an early stage, with omalizumab (an IgE inhibitor and sold under the brand name Xolair) being the only biologic drug approved for CSU in China as of the Latest Practicable Date. The CSU drug market in China increased from approximately US$1.8 billion in 2018 to approximately US$2.3 billion in 2022, at a CAGR of 6.3%, and is estimated to reach approximately US$6.2 billion in 2030, at a CAGR of 13.2% from 2022 to 2030. Omalizumab, the first biologic drug approved in China, was approved in 2022, which accounted for approximately 0.5% of the CSU drug market in China in the same year. Biologic drugs are estimated to account for approximately 53.6% of the CSU drug market in China in 2030. The following table sets forth the size of the CSU drug market in China for the periods indicated.

CSU Drugs Market in China, 2018-2030E

CAGR

Period	Biologics	Chemical	Total Market
2018-2022	—	5.0%	6.3%
2022-2025E	232.7%	3.2%	8.3%
2025E-2030E	53.3%	3.1%	16.7%

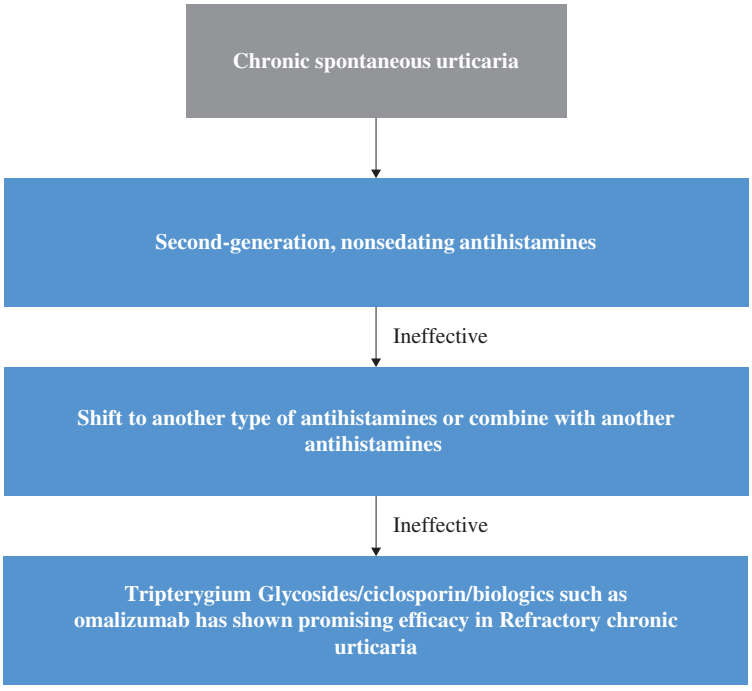


Source: Frost & Sullivan report (based on annual reports of relevant companies, literature review and expert interviews)

Treatment Paradigms for CSU in China

The standard of care for CSU in China includes H_1 antihistamines, the most common first-line treatment of urticaria, which are shifted to tripterygium glycosides, ciclosporin or biologics (such as omalizumab) when antihistamine treatments become ineffective, particularly for patients with refractory chronic urticaria. Because of the discovery of new therapeutic targets in recent years, there has been increasing research on biologic drugs for treating CSU as a potentially promising treatment option, which (including IgE inhibitors) are recommended by prevailing clinical guidelines as third-line treatment for CSU patients.

The diagram below illustrates the treatment paradigm for CSU in China:



Sources: Diagnosis and Treatment of Urticaria in China (2018 ver.), Frost & Sullivan

Competitive Landscape of Biologics for CSU Treatment in China

As of the Latest Practicable Date, omalizumab was the only biologic drug approved for CSU in China. As of the same date, there were five biologic drug candidates for CSU in the clinical stage in China, including two IgE inhibitors and three IL-4Rα inhibitors, as set out below.

Marketed Targeted Biologics for Chronic Spontaneous Urticaria in China

Brand Name	INN	Company	Target	NMPA Approval Time	Branded or Biosimilar	Availability of biosimilar	2022 NRDL covered	NRDL Median price in 2022[2] (RMB)
Xolair	Omalizumab	Novartis/ Genentech[1]	IgE	2022	Branded	–	Yes	1,406.0

Biologic Pipeline for Chronic Spontaneous Urticaria Treatment in China

Target	Drug Code	Company	Status	First posted Date
IgE	Omalizumab-SYN008	CSPS Baike	NDA	2023-06-21
	LP-003	LongBio Pharma	Phase I	2022-06-10
IL-4Rα	Dupilumab	Sanofi	Phase III	2020-04-24
	GR1802	Genrixbio	Phase II	2023-03-03
	BA2101	Boan Biotech	Phase I	2023-01-16

Source: MNPA, Clinical Trials, Frost & Sullivan Report

Notes:

(1) Novartis and Genentech co-develop and co-promote omalizumab. Novartis markets omalizumab outside the United States.

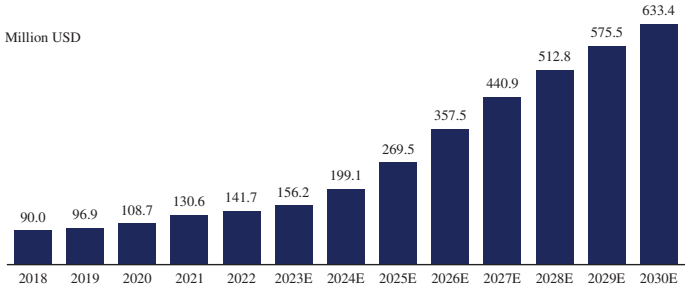
(2) Reflects the median price for a drug's minimum formulation unit as included in the NRDL.

Chronic Rhinosinusitis with Nasal Polyposis

Chronic rhinosinusitis with nasal polyps (CRSwNP) is a subgroup of chronic rhinosinusitis (CRS) characterized by the presence of fleshy swellings (nasal polyps) that develop in the lining of the nose and paranasal sinuses, which is believed to arise due to chronic inflammation. The prevalence of CRSwNP in China increased from 19.1 million in 2018 to 20.4 million in 2022, and is estimated to reach 22.3 million in 2030. The CRSwNP drug market in China increased from US$90.0 million in 2018 to US$141.7 million in 2022, representing a CAGR of 12.0%, and is estimated to reach US$633.4 million in 2030, representing a CAGR of 20.6% from 2022 to 2030. The following table sets forth the CRSwNP drug market in China for the periods indicated.

CRSwNP Drug Market in China, 2018-2030E

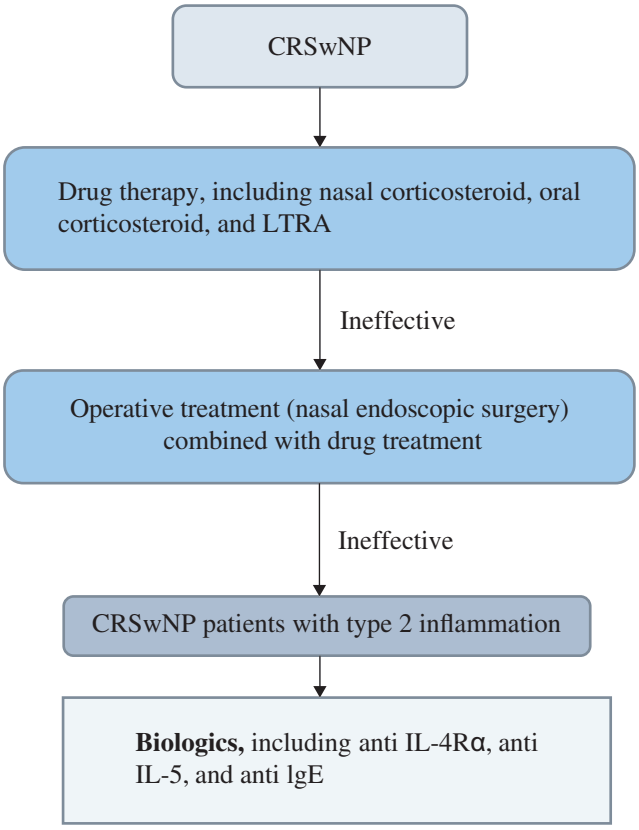
Period	CAGR
2018-2022	12.0%
2022-2025E	23.9%
2025E-2030E	18.6%



Source: Frost & Sullivan Report (based on annual reports of relevant companies, literature review and expert interviews)

Treatment Paradigms for CRSwNP in China

CRSwNP was traditionally treated with nasal saline irrigations and surgery. However, efficacy of nasal saline irrigation is limited, and there is a high nasal polyps recurrence rate of up to 60% post surgery. Corticosteroids, leukotriene receptor antagonist (LTRA), biologics and antibiotics have subsequently emerged as treatment options for CRSwNP patients. Antibiotics therapy after desensitization are primarily used for NSAID-exacerbated respiratory disease, a chronic eosinophilic, inflammatory disorder of the respiratory tract occurring in patients with asthma and/or CRSwNP. Corticosteroids for CRSwNP include intranasal corticosteroids, systemic corticosteroids and corticosteroid-eluting implants, which are primarily used following endoscopic sinus surgery. While intranasal and systemic corticosteroids are effective to some extent in the management of CRSwNP, their long-term benefits are limited. According to the Guidelines for the Diagnosis and Treatment of CRS in China (2018) (中國慢性鼻竇炎診斷和治療指南(2018)), it is difficult to maintain the clinical efficacy of systemic corticosteroids in the treatment of CRSwNP, which may lead to recurrence of nasal polyps. Moreover, systemic corticosteroids can only be administered cautiously given their association with serious systemic side effects. In contrast, biologics are proved to be more effective and safer in the treatment of CRSwNP in both clinical and animal studies. However, as a relatively new class of drugs, they have not yet been recommended as a main treatment option for CRSwNP by prevailing clinical guidelines. Currently, the standard of care for CRSwNP include corticosteroid, LTRA and surgery. The diagram below illustrates the recommended treatment pathway for CRSwNP in China.



Source: *Chinese Guidelines for Diagnosis and Treatment of Chronic Rhinosinusitis (2018), Chinese Expert Consensus on the Use of Biologics in Patients with Chronic Rhinosinusitis (2022), Frost & Sullivan analysis*

Biologic drug candidates for CRSwNP in China primarily include IL-4Rα inhibitors, IL-5 inhibitors and TSLP inhibitors. IL-4Rα is a promising target for CRSwNP as IL-4Rα controls the signaling of both IL-4 and IL-13, the key Th2 cytokines. As IL-5 is a key signaling factor for eosinophil activation by Th2 cells and is highly expressed in eosinophilic diseases, IL-5 inhibitors can be particularly effective for treatment of eosinophilic CRSwNP. However, the efficacy of IL-4Rα inhibitors and IL-5 inhibitors has shown to be correlated to the levels of certain type 2 biomarkers, such as blood eosinophil counts and IgE. In contrast, as TSLP is an upstream regulator of type 2 inflammation, TSLP inhibitors can be a treatment for patients with low-level or no expression of type 2 biomarkers.

Competitive Landscape of Biologics for CRSwNP Treatment in China

As of the Latest Practicable Date, only three biologics had been approved by the FDA for the treatment of CRSwNP, namely, dupilumab targeting IL-4Rα, omalizumab targeting IgE and mepolizumab targeting IL-5, and none had been approved in China. As of the same date, there were 14 biologic drug candidates for CRSwNP in the clinical stage in China, including six IL-4Rα inhibitors, three IL-5 inhibitors, four TSLP inhibitors and one IL-5Rα inhibitor. The following table sets forth details of QX005N as well as the biologic drug candidates for CRSwNP in the clinical stage in China as of the Latest Practicable Date.

Clinical-Stage Biologic Drug Candidates for CRSwNP in China

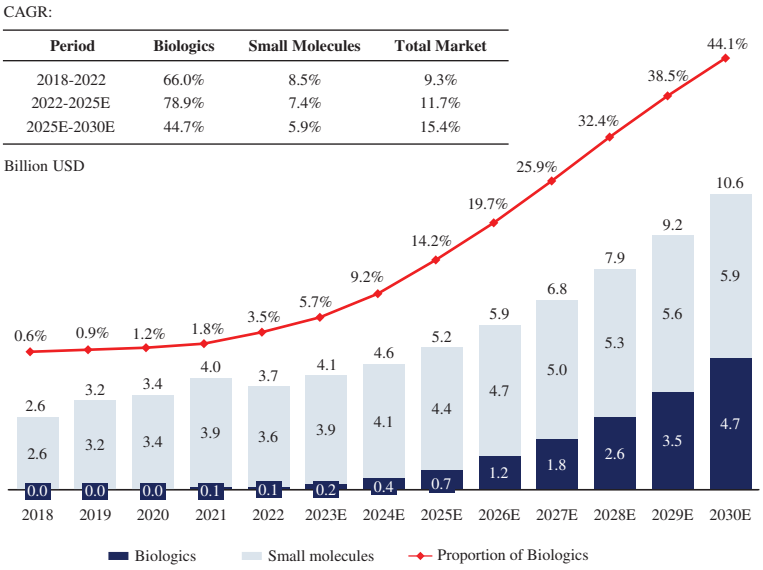
Target	Drug Code	Company	Status	First posted Date
IL-4Rα	CM310	Keymed Bioscience	Phase III	2022-06-20
	GR1802	Genrix Bio	Phase II	2023-01-03
	QX005N	**the Company**	**Phase II**	**2023-01-06**
	Dupilumab	Sanofi	Phase III	2023-03-24
	SSGJ-611	Sunshine Guojian	Phase II	2023-04-27
	CBP-201	Connect Biopharm	Phase I	2023-06-20
IL-5	Mepolizumab	GSK	Phase III	2021-04-12
	Depemokimab	GSK	Phase III	2022-05-20
	Mepolizumab-BAT2606	Biothera	Phase I	2022-07-27
TSLP	Tezepelumab	Amgen/AstraZeneca	Phase III	2021-03-25
	SHR-1905	Hengrui	Phase II	2023-05-29
	TQC2731	Chia Tai Tianqing	Phase II	2023-08-01
	CM326	Keymed Bioscience	Phase I / II	2022-03-14
IL-5Rα	Benralizumab	AstraZeneca	Phase III	2020-06-02

Source: Frost & Sullivan Report (based on annual reports of relevant companies and information published by the NMPA)

Asthma

Asthma, a condition that affects the lungs and respiratory functions, is one of the world's most common diseases. The prevalence of asthma in China increased from 62.5 million in 2018 to 67.3 million in 2022, and is estimated to reach 78.1 million in 2030. The number of patients with moderate-to-severe asthma increased from 21.9 million in 2018 to 23.6 million in 2022 and is anticipated to reach 27.4 million in 2030. The number of patients with mild asthma increased from 40.7 million in 2018 to 43.7 million in 2022 and is anticipated to reach 50.8 million in 2030. The asthma drug market in China grew from US$2.6 billion in 2018 to US$3.7 billion in 2022, representing a CAGR of 9.3%, and is estimated to reach US$10.6 billion in 2030, representing a CAGR of 14.1% from 2022 to 2030. Biologic drugs accounted for 3.5% of the asthma drugs market in China in 2022, which is estimated to increase to 44.1% in 2030. The following table sets forth the asthma drug market in China for the periods indicated.

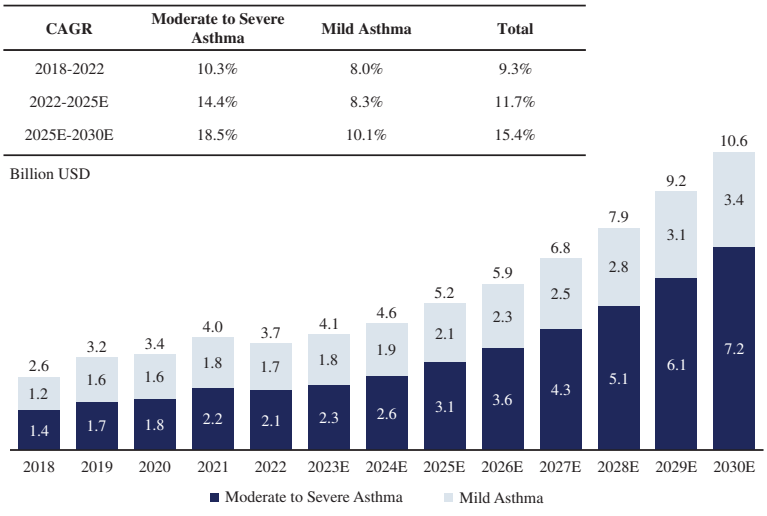
Asthma Drug Market in China, 2018-2030E



Source: Frost & Sullivan Report (based on annual reports of relevant companies, literature review and expert interviews)

The following table sets forth the breakdown of the asthma drug market in China by severity for the periods indicated.

Asthma Drugs Market in China Breakdown by Severity, 2018-2030E



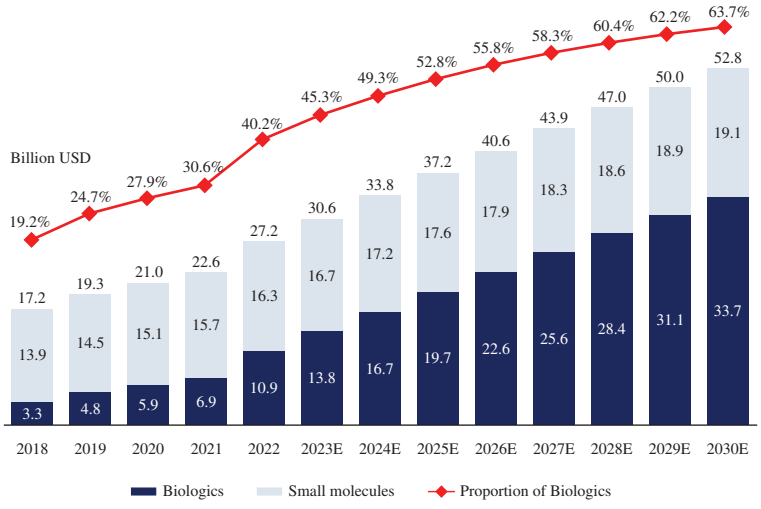
Source: Frost & Sullivan Report (based on literature review and Frost & Sullivan analysis)

The global prevalence of asthma increased from 742.1 million in 2018 to 783.3 million in 2022, and is estimated to reach 860.1 million in 2030. The global asthma drug market grew from US$17.2 billion in 2018 to US$27.2 billion in 2022, representing a CAGR of 12.1%. Driven by the sales of biologic drugs, the market is estimated to reach US$52.8 billion in 2030, representing a CAGR of 8.6% from 2022 to 2030. The following table sets forth the global asthma drug market for the periods indicated.

Global Asthma Drug Market, 2018-2030E

CAGR:

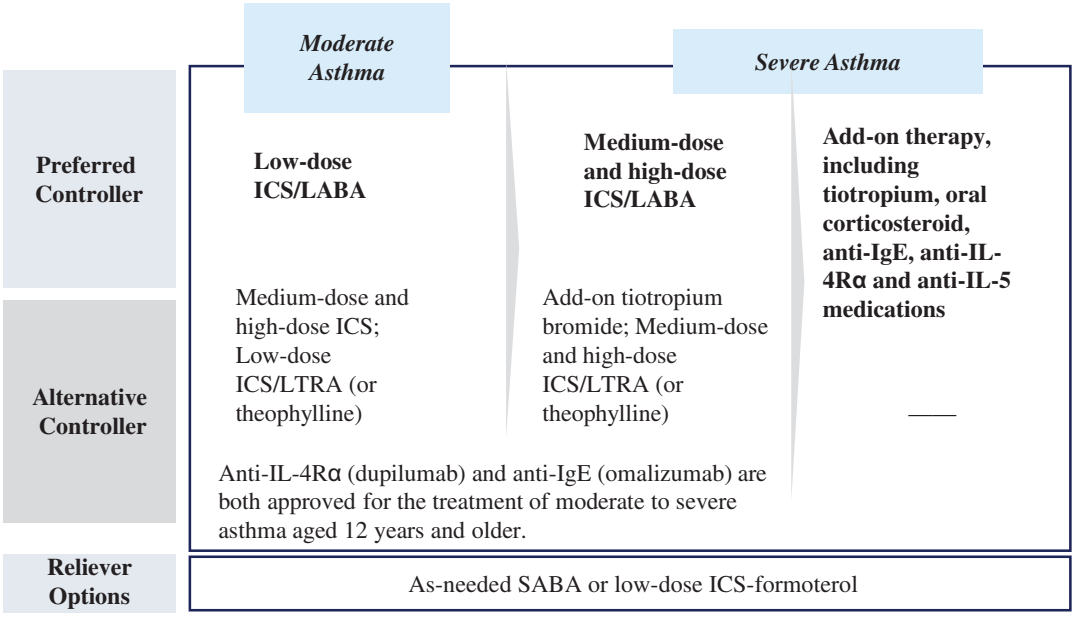
Period	Biologics	Small Molecules	Total Market
2018-2022	34.8%	4.0%	12.1%
2022-2025E	21.6%	2.6%	11.0%
2025E-2030E	11.4%	1.7%	7.2%



Source: Frost & Sullivan Report (based on annual reports of relevant companies, literature review and expert interviews)

Treatment Paradigms for Asthma

The primary treatment for asthma is often long-term medications for the control and management of asthma symptoms because it is considered a chronic disease. Such long-term medications mainly include inhaled corticosteroids (ICSs) and bronchodilators, including long-acting β2-agonist (LABA), long-acting muscarinic antagonist (LAMA), short-acting β2-agonist (SABA), and short-acting muscarinic antagonist (SAMA). Conventional treatment options, such as corticosteroids, lack effectiveness in controlling moderate and severe asthma conditions. Moreover, the maintenance treatment of systemic corticosteroids can cause dose-dependent growth suppression and a series of severe adverse effects in children and adolescents, which leaves them with even more limited treatment options. In recent years, certain biologic drugs were introduced to treat asthma. However, as a relatively new class of drugs, they have not yet been recommended as a main treatment option for asthma by prevailing clinical guidelines. Currently, the standard of care for moderate-to-severe asthma includes ICS and LABA. The diagram below illustrates the recommended treatment pathway for adults and adolescents with moderate-to-severe asthma in China.



Source: Asthma Group of Chinese Thoracic Society, Literature Review, Frost & Sullivan analysis

Note:

(1) The treatment options can be applied to adults, adolescents, and children ≥ 6 years old; theophylline is not recommended for children ≤ 12 years old.

Biologic drugs and candidates for asthma primarily include IgE inhibitors, IL-5 inhibitors, IL-4Rα inhibitors and TSLP inhibitors. Omalizumab, an IgE inhibitor, was the first targeted biologic therapy developed and approved for severe asthma. IgE inhibitors can limit the degree of release of mediators of the allergic response by inhibiting the interaction between IgE and the IgE receptors. As IL-5 is a key signaling factor for eosinophil activation by Th2 cells and is highly expressed in eosinophilic diseases, IL-5 inhibitors have also been developed for treatment of asthma and are the most common type of biologics for treatment of asthma in the United States. An IL-4Rα inhibitor, which blocks both the IL-4 and IL-13 signaling pathways, and an TSLP inhibitor, which can be effective for patients with low-level or no expression of type 2 biomarkers, subsequently obtained FDA approval for treatment of asthma.

Competitive Landscape of Biologics for Asthma Treatment in China

As of the Latest Practicable Date, there was two biologic drugs for asthma approved in China, including omalizumab and omalizumab alfa. As of the Latest Practicable Date, no generic or biosimilar of omalizumab or omalizumab alfa had been approved for the treatment of asthma in China. As of the same date, there were 31 biologic drug candidates for asthma in the clinical stage in China, including nine TSLP inhibitors, seven IL-4Rα inhibitors, four IL-5 inhibitors and four IgE inhibitors (including four omalizumab biosimilars), as well as drugs targeting IL-5Rα, ST2 and IL-25. The following tables sets forth details of QX008N as well as the approved biologic drug and biologic drug candidates for asthma in clinical stage in China as of the Latest Practicable Date.

Marketed Targeted Biologics for Asthma in China

Target	Brand Name	INN	Company	Median Price[1]	NMPA Approval Time	NRDL Inclusion
IgE	Xolair	Omalizumab	Novartis/Genentech[2]	1,406	2017	Yes
	Aomaishu (奥遒舒)	Omalizumab alfa	Mabpharm	N/A	2023	No

Notes:

(1) Reflects the NRDL median price per minimum formulation unit in 2022 in RMB.

(2) Novartis and Genentech co-develop and co-promote omalizumab. Novartis markets omalizumab outside the United States.

Clinical-Stage Biologic Drug Candidates for Asthma in China

Target	Drug Code	Company	Status	First posted Date
TSLP	Tezepelumab	AstraZeneca	Phase III	2019-07-15
	TQC2731	Chia Tai Tianqing	Phase II	2022-06-21
	SHR-1905	Hengrui	Phase II	2022-09-29
	CM326	Keymed Bioscience	Phase II	2023-03-17
	QX008N	**the Company**	**Phase I**	**2022-07-08**
	HBM9378	Harbour Biomed; Kelun-Biotech	Phase I	2022-08-29
	LQ043	Novamab	Phase I	2023-01-13
	GR2002	Genrixbio	Phase I	2023-05-25
	STSA-1201	Staidson Biopharmaceuticals	Phase I	2023-08-01
IL-4Rα	Dupilumab	Sanofi	Phase III	2018-12-13
	CM310	Keymed Bioscience	Phase II/III	2023-03-08
	CBP-201	Connect Biopharmaceuticals	Phase II	2021-08-18
	GR1802	Genrix Bio	Phase II	2022-05-12
	MG-K10	Mabgeek	Phase I / II	2022-04-29
	SHR-1819	Hengrui	Phase I	2021-02-01
	LQ036	Novamab	Phase I	2022-11-17
IL-5	Mepolizumab	GSK	NDA	2018-08-31
	GSK3511294	GSK	Phase III	2021-09-18
	SSGJ-610	Sunshine Guojian	Phase II	2022-08-22
	SHR-1703	Suncadia Bio; Hengrui	Phase II	2022-09-05
IL-4Rα, IL-5	RC1416	Regenecore	Phase I	2023-06-20
IL-5Rα	Benralizumab	AstraZeneca	Phase III	2017-07-26
IgE	Omalizumab-HS632	Hisun	Phase I	2020-04-29
	Omalizumab-SYN008	CSPC Baike	Phase I	2020-11-03
	Omalizumab-SYB507	Yuanda Shuyang	Phase I	2020-11-09
	JYB1904	Jiye Biotechnology	Phase I	2022-04-28
IL-25	XKH001	Kanova biopharma	Phase I	2022-03-07
ST2	9MW1911	Mabwell	Phase I	2021-10-13
	TQC2938	Chia Tai Tianqing	Phase I	2023-03-31
Undisclosed	Recombinant ε and γ Human Immunoglobulin Fc Fusion Protein	Kexin Biotech	Phase I	2018-11-16
	MG-ZG122	Mabgeek	Phase I	2022-12-12

Source: Frost & Sullivan Report (based on annual reports of relevant companies and information published by the NMPA)

Competitive Landscape of Biologics for Asthma Treatment outside China

As of the Latest Practicable Date, there were six biologic drugs for the treatment of asthma approved by FDA, including only one TSLP-targeting biologic (tezepelumab by Amgen/AstraZeneca, approved in December 2021). As of the same date, there were 19 biologic drug candidates for asthma in clinical stage outside China, including only two TSLP inhibitors. The following tables sets forth details of the approved biologic drug and biologic drug candidates for asthma in clinical stage outside China as of the Latest Practicable Date.

FDA Approved Targeted Biologics for Asthma

Target	Brand Name	INN	Company	Median Price[1]	FDA Approval Time	NRDL Inclusion
IgE	Xolair®	Omalizumab	Genentech/Novartis[2]	1,406	2003	Yes
IL-5	Nucala®	Mepolizumab	GSK	N/A	2015	No
	Cinqair®	Reslizumab	Teva Pharmaceutical	N/A	2016	No
	Fasenra®	Benralizumab	AstraZeneca	N/A	2017	No
IL-4Rα	Dupixent®	Dupilumab	Sanofi/Regeneron	3,160	2018	No[3]
TSLP	Tezspire®	Tezepelumab	Amgen/AstraZeneca	N/A	2021	No

Notes:

(1) Reflects the NRDL median price per minimum formulation unit for the drug's included indication in 2022 in RMB.

(2) Genentech and Novartis co-develop and co-promote omalizumab.

(3) This drug has not been included in the NRDL for the treatment of asthma.

Global Clinical-Stage Biologic Drug Candidates in Asthma Treatment

Target	Drug Code	Company	Status	First Posted Date
TSLP	SHR-1905	Atridia	Phase I	2021-03-16
	AZD8630	AstraZeneca	Phase I	2021-11-08
IL-4Rα	CBP-201	Connect Biopharmaceuticals	Phase II	2021-02-26
IL-5	Depemokimab	GSK	Phase III	2021-01-22
IgE	FB825	Oneness Biotech	Phase II	2021-08-17
IL-33	SAR440340	Sanofi/Regeneron	Phase II	2018-01-02
	Tozorakimab	AstraZeneca	Phase II	2020-09-30
IL-17A	CJM112	Novartis	Phase II	2017-10-03
Tryptase	MTPS9579A	Genentech	Phase II	2019-09-17
PSGL-1	SelK2	Tetherex Pharmaceuticals	Phase II	2020-09-07
CD4	Tregalizumab	T-Balance Therapeutics	Phase II	2020-12-17
IL-6	FB704A	Oneness Biotech	Phase II	2021-08-24
LIGHT	AVTX-002	Avalo Therapeutics	Phase II	2022-03-21
OX40L	Amlitelimab	Sanofi	Phase II	2022-06-16
CD6	Itolizumab	Equillium	Phase I	2019-07-05
ST2	melrilimab	GSK	Phase I	2020-04-28
IL-17RB	SM17	SinoMab	Phase I	2022-04-18
IL-13/TSLP	SAR443765	Sanofi	Phase I	2022-05-09
TLSPR	UPB-101	Upstream Bio	Phase I	2022-07-07

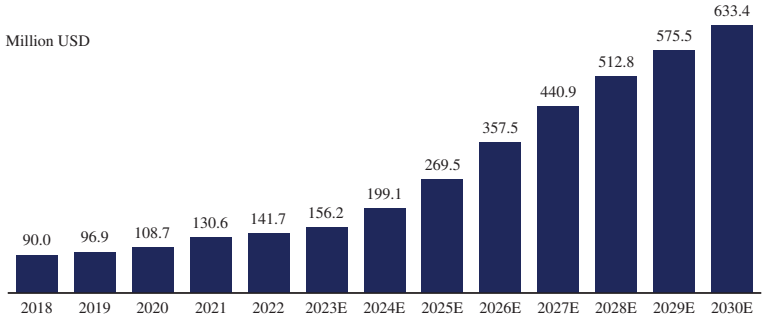
Source: Frost & Sullivan Report (based on annual reports of relevant companies and information published by the FDA)

Chronic Obstructive Pulmonary Disease

Chronic obstructive pulmonary disease (COPD) is a chronic inflammatory lung disease which obstructs air flow from the lungs. The prevalence of COPD in China increased from 103.5 million in 2018 to 106.4 million in 2022, and is estimated to reach 110.7 million in 2030. The COPD drug market in China increased from US$2.3 billion in 2018 to US$3.2 billion in 2022, representing a CAGR of 8.6%, and is estimated to reach US$6.3 billion in 2030, representing a CAGR of 8.8% from 2022 to 2030. The following table sets forth the COPD drug market in China for the periods indicated.

COPD Drug Market in China, 2018-2030E

Period	CAGR
2018-2022	12.0%
2022-2025E	23.9%
2025E-2030E	18.6%



Source: Frost & Sullivan Report (based on annual reports of relevant companies, literature review and expert interviews)

Treatment Paradigms for COPD in China

COPD is mainly treated with drugs to prevent and control chronic inflammation and reduce clinical symptoms. Meanwhile, COPD patients can also be treated by rehabilitation, oxygen therapy and surgery. Control drugs for long-term treatment of COPD primarily include corticosteroids, including inhaled corticosteroids (ICSs) and systemic corticosteroids, long-acting bronchodilators (LABA and LAMA) and anti-inflammatory drugs, such as PDE4 inhibitors. Other drug treatments such as mucolytic, antioxidant drugs and immunomodulators can also be used to control inflammation. In the initial treatment of COPD, patients are recommended to use one type of bronchodilator. For patients with higher moderate exacerbations and more severe dyspnea, combination therapy of LABA and LAMA are recommended. For patients with higher eosinophil count, combined therapy of ICS with LABA and LAMA are recommended to improve lung function and reduce exacerbations. However, approximately 40% of moderate-to-severe COPD patients on the triple therapy of ICS with LABA and LAMA still remain uncontrolled and continue to experience exacerbations. Therefore, there are significant unmet clinical needs from COPD patients.

Biologic drug candidates for COPD in China primarily include IL-4Rα inhibitors, IL-5 inhibitors, ST2 inhibitors and IL-33 inhibitors. As asthma and COPD share common pathophysiological mechanisms, IL-4Rα and IL-5, two of the most commonly developed targets for treatment of asthma, are also being developed as targets for treatment of COPD. Since IL-33 can induce Th2 cytokine production and promote the pathogenesis of COPD, IL-33 and its receptor, ST2, can be promising targets for the treatment of COPD as well. However, as a relatively new class of drugs, biologics have not yet been recommended as a main treatment option for COPD by prevailing clinical guidelines.

Competitive Landscape of Biologics for COPD Treatment in China

As of the Latest Practicable Date, no biologic had been approved for the treatment of COPD. As of the same date, there were six biologic drug candidates for COPD in the clinical stage in China, including one IL-4Rα inhibitor, one IL-5 inhibitor, two IL-33 inhibitors, one IL-5Rα inhibitor and one ST2 inhibitor. The following table sets forth details of the biologic candidates for COPD in the clinical stage in China as of the Latest Practicable Date.

Clinical-Stage Biologic Drug Candidates for COPD in China

Target	Drug Code	Company	Status	First Posted Date
IL-4Rα	Dupilumab	Sanofi	Phase III	2019-10-08
IL-5	Mepolizumab	GSK	Phase III	2021-02-02
IL-33	Itepekimab	Sanofi	Phase III	2021-04-28
	MEDI3506	AstraZeneca	Phase III	2022-06-02
IL-5Rα	Benralizumab	AstraZeneca	Phase III	2021-05-27
ST2	9MW1911	Mabwell Bioscience	Phase I/II	2023-02-14

Source: Frost & Sullivan Report (based on annual reports of relevant companies and information published by the NMPA)

Sanofi announced on March 23, 2023 that dupilumab reached the primary endpoint and all key secondary endpoints and demonstrated significant reduction in exacerbations of moderate-to-severe COPD in its Phase III clinical trial for COPD, demonstrating a potential that an IL-4Rα inhibitor will become the first approved biologic drug for the effective treatment of COPD.

SOURCE OF INFORMATION

In connection with the [**REDACTED**], we have commissioned Frost & Sullivan to conduct an analysis of and prepare an industry report on the global and Chinese drug market for autoimmune and allergic diseases. Frost & Sullivan is an independent global market research and consulting company which was founded in 1961 and is based in the United States. Services provided by Frost & Sullivan include market assessments, competitive benchmarking and strategic and market planning for a variety of industries. The sum of our contract with Frost & Sullivan for preparation of its report and conducting clinical audit is RMB860,000. The payment of such amount was not contingent upon our successful [**REDACTED**] or on the results of the report. Except for the report prepared by Frost & Sullivan, we did not commission any other industry report in connection with the [**REDACTED**]. Frost & Sullivan prepared its report based on its in-house database, independent third-party reports and publicly available data from reputable industry organizations. Where necessary, Frost & Sullivan contacts companies operating in the industry to gather and synthesize information in relation to the market, prices and other relevant information. Frost & Sullivan believes that the basic assumptions used in preparing its report, including those used to make future projections, are factual, correct and not misleading. Frost & Sullivan has independently analyzed the information, but the accuracy of the conclusions of its review largely relies on the accuracy of the information collected. Frost & Sullivan research may be affected by the accuracy of these assumptions and the choice of these primary and secondary sources.