

INDUSTRY OVERVIEW

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OVERVIEW OF THE INFLAMMATORY IMMUNE DISEASES FIELD

Inflammatory immune diseases are a category of disorders triggered by abnormal immune system function. These diseases not only severely impact patients’ quality of life, but also can be life-threatening in certain severe cases, rendering them a key area of focus in the global pharmaceutical industry. Inflammatory immune diseases can be categorized into autoimmune diseases and allergic diseases based on the nature of the immune abnormality and the tissues affected. Autoimmune diseases are characterized by the immune system mistakenly attacking the body’s own tissues, which can affect multiple organ systems including joints, kidneys, skin and the cardiovascular system.

Driven by factors, such as the increasing prevalence of various autoimmune diseases, significant unmet clinical needs and advancements in research and development, the market of autoimmune disease drugs in China has witnessed a rapid growth in recent years. From 2019 to 2025, the market size of autoimmune disease drugs in China grew from RMB16.2 billion to RMB38.1 billion, representing a CAGR of 15.3%. It is expected that the market size will reach RMB228.6 billion by 2033.

Allergic diseases are characterized by an excessive reaction of the immune system to harmless exogenous substances (known as allergens), with affected tissues mostly concentrated in mucosal tissues in contact with the external environment and superficial tissues, such as the respiratory tract, skin and digestive tract. Advancements in precision medicine and emergence of new drugs are fueling the rapid expansion of China’s allergic disease market. The market size of allergic disease drugs in China grew from RMB30.5 billion in 2019 to RMB66.1 billion in 2025, representing a CAGR of 13.7%. It is expected that such market size will reach RMB306.0 billion by 2033.

Market Drivers and Development Trends of Inflammatory Immune Disease Drugs Market

- ***Rising Prevalence Driven by Various Factors:*** In recent years, the global cases of autoimmune diseases have surged, affecting 380 million people, while nearly 30% of the world’s population now live with allergic disease. This rapid growth is fueled by a synergy of accelerated urbanization, increased allergen exposure, lifestyle shifts, and impaired immune tolerance.
- ***Advancements in Medical Standards and Increase in Patients’ Willingness to Seek Medical Treatment.*** In recent years, due to greater public health awareness, faster dissemination of medical knowledge, and the improvement of diagnostic and treatment methods, an increasing number of patients are receiving early diagnosis and actively seeking proper treatment. In recent years, clinical guidelines in therapeutic areas such as atopic dermatitis have explicitly

INDUSTRY OVERVIEW

stipulated elevated medical standards, driving growing demand for innovative therapies. This not only drives the stable demand for existing drugs, but also lay a solid foundation for the market penetration of innovative therapies, thereby further supporting the sustained development of the sector.

- ***Diversification of Therapeutic Targets and Acceleration of Drug Development.*** In addition to traditional therapeutic targets like TNF- α , emerging targets such as JAK, BTK, IL-17 and IL-4R are also achieving breakthroughs, with related pipelines rapidly advancing into clinical trials and commercialization. The diversification of therapeutic targets not only expands treatment options to meet the diverse needs from different patient groups, but also encourages pharmaceutical companies to invest in innovative drug development, thereby injecting sustained momentum for innovation and growth potential into the market.

Entry Barriers for the Inflammatory Immune Diseases Drug Market

- ***Technological Barriers:*** The inflammatory immune disease drug market is characterized by significant technological barriers, particularly arising from the highly complex R&D processes. The successful drug development requires collective understanding of disease mechanisms to enable precise modulation of the immune system, which imposes high technological thresholds.
- ***Capital Barriers:*** Development of inflammatory immune disease drugs typically entails lengthy timeline and requires continuous and substantial capital investment across all stages. In addition, drug developers must establish advanced production facilities that comply with GMP and other applicable standards. Cumulative costs from these critical stages calls for substantial capital investment, posing challenges for new entrants with limited capital strength.
- ***Long-Term Development Cycle Barriers:*** The full R&D cycle for inflammatory immune disease drugs may last for a decade or even longer, with continuous capital investment required at each stage. Meanwhile, given the rapid pace of technological advancement coupled with the uncertainty on R&D outcome, growing R&D investment is imperative to address the complex disease mechanisms, and maintain market competitiveness.

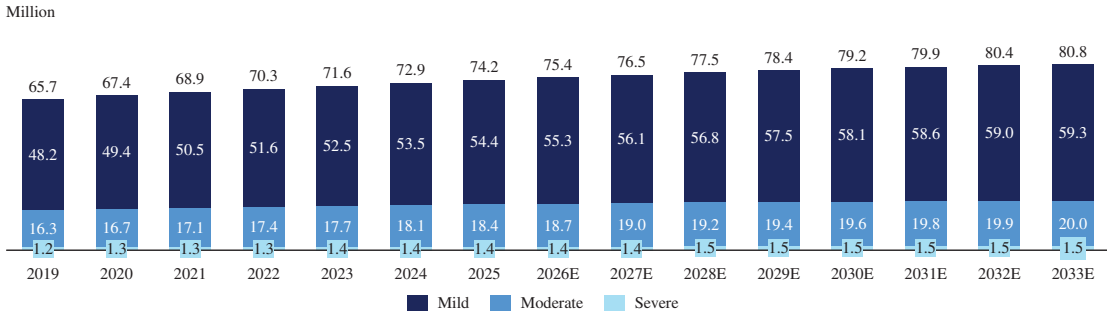
OVERVIEW OF ATOPIC DERMATITIS DRUG MARKET

Atopic dermatitis (“AD”) is a chronic and relapsing inflammatory skin disease characterized by the symptoms of pruritus and skin lesions, often coupled with exudative tendencies. According to the Scoring Atopic Dermatitis severity classification, AD can be categorized into mild, moderate, and severe categories. Among all AD patients, more than 70% have mild disease, over 20% have moderate disease, and only approximately 2% have severe disease.

The number of AD patients in China increased from 65.7 million to 74.2 million in 2025, with a CAGR of 2.0% from 2019 to 2025. By 2033, the number of AD patients in China is expected to reach 80.8 million. In 2025, there were approximately 6.1 million children with AD, approximately 2.0 million adolescents with AD, and approximately 63.7 million adults with AD. In 2025, there were approximately 72.8 million mild to moderate AD patients.

INDUSTRY OVERVIEW

Number of Atopic Dermatitis Patients in China, 2019-2033E

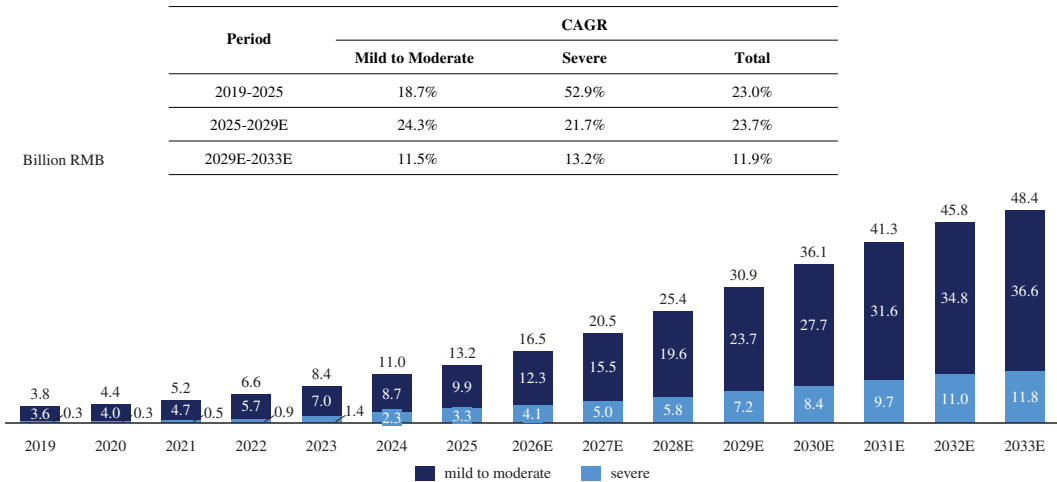


Source: Literature reviews, Frost & Sullivan Analysis

China’s atopic dermatitis drugs market is poised for rapid expansion. While the continuous approval of innovative targeted therapies is addressing critical unmet needs in moderate-to-severe cases, the paradigm for mild-to-moderate AD is also shifting. Specifically, topical targeted agents in late-stage clinical development are expected to replace traditional corticosteroids, offering a safer alternative. The increasing diagnosis rate and rising penetration of innovative drugs are expected to propel the development of China’s atopic dermatitis drugs market. In 2025, the market size for AD drugs in China was approximately RMB13.2 billion. By 2033, the market size is expected to reach RMB48.4 billion. In 2025, the market size for mild to moderate AD drugs in China was approximately RMB9.9 billion. By 2033, the market size is expected to reach RMB36.6 billion.

The faster CAGR from 2025 to 2029 is primarily driven by the continued expansion of China’s AD treatment market from a relatively early stage, together with the increasing adoption of innovative therapies, particularly JAK inhibitors and biologics. In particular, both oral and topical JAK inhibitors are expected to support market growth by broadening treatment options across different disease severities and treatment settings. Growth during this period is also supported by the development of retail pharmacy, online prescription and internet-hospital channels, which are facilitating chronic disease management in dermatology. In addition, as disease severity progresses, clinical management may involve the combined use of multiple therapies, including systemic and topical treatments, which may further support market value growth. The moderation in CAGR from 2029 to 2033 mainly reflects the market approaching maturity and intensifying competition as more products, including JAK inhibitors and other targeted therapies, enter the market.

Historical and Forecasted of China’s Atopic Dermatitis Drug Market Size, 2019-2033E



Source: Frost & Sullivan Analysis

INDUSTRY OVERVIEW

Main Treatment Pathway of Mild to Moderate Atopic Dermatitis

For patients with mild to moderate AD, long-term adequate emollient therapy and moisturizing, coupled with avoidance of allergens and triggering irritants, constitute the foundational treatment. Clinically, topical corticosteroids (“TCS”) are prioritized as first-line therapy for rapid inflammation control; non-steroidal topical anti-inflammatory agents, including topical calcineurin inhibitors (“TCI”) and topical PDE4 inhibitors, may also be prescribed based on lesion location, patient age and tolerability.

Comparison of Main Drugs for Treating Mild to Moderate AD

Generic Name	Original Company ¹	Drug Class	Dosing Frequency	Drug Status	Approval Date	Annual Treatment Cost ²	NRDL Status
Mometasone furoate	MSD	Topical Corticosteroids (TCS)	QD	Approved by NMPA	1998/1/1	18.3 RMB	List B
Pimecrolimus	Novartis	Topical Calcineurin Inhibitors (TCI)	BID	Approved by NMPA	2005/9/29	600.0 RMB	List B
Crisaborole	Anacor Pharmaceuticals	Topical PDE-4 Inhibitors	BID	Approved by NMPA	2020/7/29	635.2 RMB	List B
Ruxolitinib	Novartis	Topical JAK Inhibitors (Off-label Use)	BID	Approved by NMPA	2026/1/27	N/A	N/A
Benvitimod	Thederma	Aryl Hydrocarbon Receptor (AhR) Modulators	BID	Approved by NMPA	2024/11/22	2,189 RMB	List B

Note: 1. Several generic versions of mometasone furoate, pimecrolimus and crisaborole are already available on the market.
2. According to the package insert, the annual treatment duration for mometasone furoate is calculated based on a two-week regimen per year, while the annual treatment duration for pimecrolimus, crisaborole, ruxolitinib and benvitimod is calculated based on a two-month regimen per year.

Abbreviation: QD = Once Daily, BID = Twice Daily

Source: NMPA, Frost & Sullivan analysis

Traditional treatment options based on TCS and TCI offer advantages in cost and accessibility, however, long-term use carries safety concerns (e.g., skin atrophy) and poor tolerability in sensitive areas. These therapies struggle to simultaneously achieve the comprehensive treatment goals of “rapid itch relief, sustained anti-inflammatory action and long-term maintenance”, which constrains effective long-term and standardized disease management.

Market drivers of the mild-to-moderate AD drug market

- The large patient population with mild-to-moderate AD in China provides a solid foundation for market growth:** AD is one of the most common chronic inflammatory skin diseases in China. According to the *Chinese Guidelines for the Diagnosis and Treatment of AD* and multiple epidemiological studies, more than 95% of patients have mild-to-moderate disease. In 2025, the number of patients with mild-to-moderate AD in China reached approximately 72.8 million. The large patient population and the need for long-term disease management continue to support demand for topical therapies.
- The continuous update of clinical guidelines and expert consensus promotes standardized treatment of mild-to-moderate AD:** The *Chinese Guidelines for the Diagnosis and Treatment of AD* and the *Expert Consensus on the Management of Therapeutic Agents for AD (2024 Edition)* recommend severity-based treatment, with emollients combined with topical anti-inflammatory therapies as the cornerstone of treatment for patients with mild-to-moderate AD, followed by proactive maintenance therapy to reduce relapse. The guidelines also standardize the clinical use of topical corticosteroids (TCS), topical calcineurin inhibitors (TCIs) and novel topical therapies such as topical Janus kinase (JAK) inhibitors. As standardized treatment continues to improve, the adoption of topical therapies is expected to increase, supporting the growth of the mild-to-moderate AD treatment market in China.

INDUSTRY OVERVIEW

- **Continuous innovation in topical therapies expands treatment options for mild-to-moderate AD:** While TCS and TCIs remain the cornerstone of treatment, novel topical therapies, including phosphodiesterase-4 (PDE-4) inhibitors, JAK inhibitors and aryl hydrocarbon receptor (AhR) modulators, have expanded treatment options for patients with mild-to-moderate AD. These therapies offer improved efficacy, safety and convenience, supporting broader adoption of topical therapies and continued market growth.

Overview of JAK Inhibitors Market

JAK inhibitors act as a key “hub” to modulate inflammatory and immune responses. By binding to JAK family enzymes (JAK1/2/3), these agents block the JAK/STAT signaling pathway, suppressing pro-inflammatory cytokines. Beyond reducing inflammation, they promote skin barrier repair by upregulating proteins like filaggrin and interrupt the “itch-scratch” cycle by blocking IL-31 signaling.

Compared to the slower response of traditional topical corticosteroids or calcineurin inhibitors, JAK inhibitors can rapidly alleviate symptoms such as rash, erythema, exudation and intense pruritus within a short timeframe, thereby improving patients’ quality of life. JAK inhibitors can effectively reduce the need for steroid use, for steroid-dependent patients, they can decrease the dosage of topical or systemic steroids, or even gradually replace steroids, thereby avoiding adverse reactions such as skin atrophy, telangiectasia and hepatorenal impairment induced by long-term steroid therapy.

The JAK inhibitor market in China experienced remarkable expansion, growing from RMB0.4 billion in 2019 to RMB6.1 billion in 2025, corresponding to a CAGR of 57.5%. This strong growth trajectory is projected to continue, with the market expected to reach RMB39.5 billion by 2033.

Competitive Landscape of AD

As of the LPD, a total of 11 drugs have been approved by the NMPA for the treatment of mild to moderate AD, including 8 TCS (fluocinolone acetonide, cortisone, mometasone, halometasone, clobetasone, halcinonide, betamethasone dipropionate + betamethasone, flumetasone), 1 TCI (pimecrolimus), 1 PDE4 inhibitor (crisaborole) and 1 aryl hydrocarbon receptor modulator (benvitimod).

As of the LPD, a total of 5 drugs for the treatment of mild-to-moderate AD have filed NDA applications with the NMPA, and another 4 drugs indicated for mild-to-moderate AD are in Phase III or Phase II/III clinical trials. All 9 agents are either JAK inhibitors or PDE4 inhibitors. The Group’s pumecitinib gel completed its NDA submission on February 11, 2026.

Drug pipelines for mild to moderate AD Treatment in China

Target	Drug Name/Code	Company	Dosage Form	Clinical Stage	Latest Updated Date
JAK	Pumecitinib	PrimeGenX Therapeutics	Gel	NDA	2026/2/11
JAK	Tofacitinib etocomil	Minghui Pharmaceutical	Ointment	NDA	2026/4/3
PDE4	Difamilast	Otsuka Pharmaceutical	Cream	NDA	2025/9/26
PDE4	Roflumilast cream-ARQ-151	Arcutis Biotherapeutics	Cream	NDA	2025/10/31
JAK	Ruxolitinib Cream	Incyte	Cream	NDA	2026/2/24
JAK	VC005	Jiangsu Vcare Pharmatech	Gel	Phase III	2026/5/28
JAK	QLM3003	Qilu Pharmaceutical	Ointment	Phase III	2026/4/2
PDE4	HY-072808	Hefei medical and Pharmaceutical	Cream	Phase III	2024/6/15
JAK	Ivarmacitinib	Hengrui Pharma	Ointment	Phase II/III	2024/10/12

Note: Following discussions with the CDE, Hengrui Pharma voluntarily withdrew its NDA for Ivarmacitinib because further refinement of the application materials was required.

Source: CDE, Frost & Sullivan Analysis

INDUSTRY OVERVIEW

Compared with other topical agents indicated for mild to moderate AD, PG-011 delivers prominent efficacy with a markedly superior safety profile. It exerts both anti-inflammatory and antipruritic effects, and its gel formulation provides a better application experience than conventional topical cream formulations. The following table illustrates the comparison between PG-011 and other topical agents for mild to moderate AD:

Comparison of topical agents for mild to moderate AD

Dimension	PG-011 (Topical JAK Inhibitor)	Topical Corticosteroids (TCS)	Topical Calcineurin Inhibitors (TCI)	Topical PDE4 Inhibitors
Clinical Advantages	Its efficacy is comparable to TCS and potent TCI, and superior to PDE4 inhibitors; its safety profile is better than TCS and TCI.	It is a first-line classic therapy with definitive efficacy, and its efficacy is superior to PDE4 inhibitors.	Its efficacy is generally comparable to TCS and JAK inhibitors, and superior to PDE4 inhibitors, with no hormonal side effects.	It is a non-hormonal agent with favorable safety profile, and inhibits inflammation in a targeted and precise manner.
Safety and Tolerability	The incidence of adverse events is comparable to that of the drug-free gel placebo group, with extremely low systemic side effects.	Long-term use is associated with severe local side effects; long-term application over large areas may also induce systemic side effects.	Application site irritation is common; it previously carried a black box warning for potential risks of skin cancer and lymphoma.	Application site irritation is common, predominantly presenting as mild-to-moderate burning, stinging or pruritus at the application site.
Medication Convenience	Administered twice daily; evaluations show that the gel formulation achieves higher user satisfaction than cream formulations.	Administered once daily; the dosage is gradually tapered according to disease condition in the later stage of treatment.	Administered twice daily; exposure to sunlight and ultraviolet light should be avoided or minimized during medication.	Administered twice daily; local irritation in some patients may affect long-term treatment adherence.
Annual Treatment Cost	RMB2,400~4,000	<RMB100	~RMB600	~RMB600

Note: The annual treatment cost for PG-011 is calculated based on the estimated price range after inclusion in the NRDL.

Source: Frost & Sullivan Analysis

The following table illustrates the Phase III clinical efficacy indicators of Pumecitinib gel compared to similar topical JAK inhibitors:

Comparison of Topical JAK Inhibitors

Administration and Dosage Form	Pumecitinib Gel		Ivamacitinib Ointment			Ruxolitinib Cream					
	PG-011-AD-301 (BID, 8 Weeks)		(BID, 8 Weeks)			TRuE-AD1 (BID, 8 Weeks)			TRuE-AD2 (BID, 8 Weeks)		
	3% gel	Placebo	1% Ointment	0.5% Ointment	Placebo	1.5% cream	0.75% cream	Placebo	1.5% cream	0.75% cream	Placebo
Percentage Change in EASI	-70.2%	-32.5%	-62.8%	-61.9%	-43.2%	-77.2%	-72.2%	-40.5%	-74.7%	-74.8%	-28.9%
Percentage of Participants Achieving EASI75 . . .	53.8%	10.9%	45.1%	42.6%	17.9%	62.1%	56.0%	24.6%	61.8%	51.5%	14.4%
Percentage of Participants Achieving IGA Success	33.2%	3.4%	26.2%	21.3%	10.6%	53.8%	50.0%	15.1%	51.3%	39.0%	7.6%

Notes:

- (1) Percentage Change in EASI (Eczema Area and Severity Index from baseline): the proportion/degree of improvement in the Eczema Area and Severity Index. Larger absolute value means better drug efficacy.
- (2) Percentage of Participants Achieving EASI 75: the proportion of subjects with an improvement of 75% in EASI score from baseline.
- (3) IGA: Investigator's Global Assessment, with a score range of 0-4 points, where zero indicates no skin lesions, and higher score means more severe symptoms.
- (4) Percentage of Participants Achieving IGA Success: the proportion of participants whose IGA score is zero or one point after medication and has improved by at least two points from baseline, where higher value means better drug efficacy.

Source: Desk Research, Frost & Sullivan analysis

INDUSTRY OVERVIEW

OVERVIEW OF ALLERGIC RHINITIS DRUGS MARKET

Allergic Rhinitis (AR) is a chronic inflammatory driven by IgE-mediated type 2 responses to inhaled allergens. Based on disease course and allergen exposure patterns, allergic rhinitis is typically categorized into seasonal allergic rhinitis and perennial allergic rhinitis. Seasonal AR is triggered by seasonal allergens like pollen (trees, grasses, weeds). Symptoms fluctuate with pollen counts and often include sneezing, rhinorrhea, and ocular irritation. Perennial AR is caused by year-round indoor allergens (dust mites, dander, mold, cockroaches), leading to persistent or recurrent symptoms throughout the year.

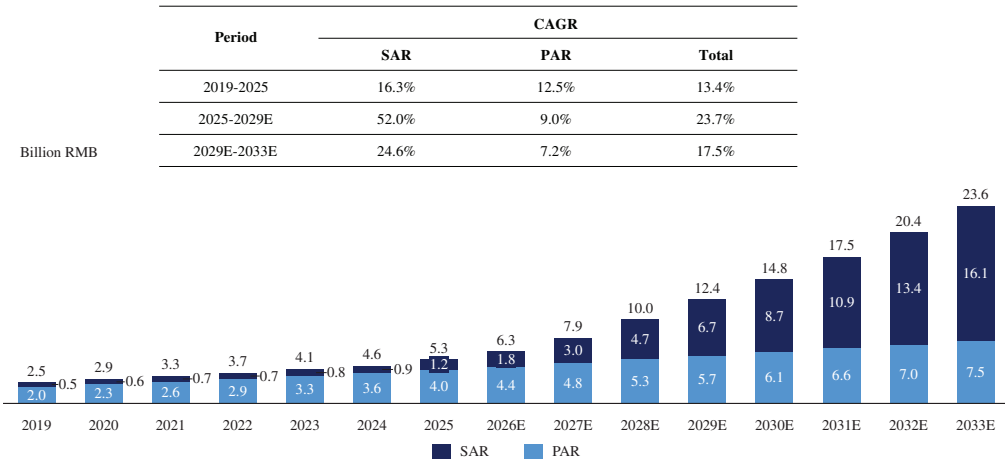
China’s allergic rhinitis patient base is poised for sustained growth, driven by escalating exposure to seasonal and environmental allergens and a rising urban population, where prevalence is historically higher. The number of AR patients in China increased from 232.7 million in 2019 to 247.9 million in 2025. By 2033, the number of AR patients in China is expected to reach 269.6 million. In 2025, there were approximately 184.4 million SAR patients in China, and approximately 63.5 million PAR patients.

Traditional treatment modalities of AR patients, primarily antihistamines and corticosteroids, are increasingly limited by their side-effect profiles and suboptimal long-term adherence. The emergence of innovative targeted therapies, fast-tracked by recent policy reforms, has redefined the standard of care. These next-generation options offer superior safety profiles and sustained symptom control, greatly enhancing patient adherence. The convergence of an expanding patient base, accelerated regulatory approvals, and increasing penetration of innovative drugs is positioning China’s AR market for a rapid growth. Market size for AR drugs in China increased from RMB2.5 billion in 2019 to RMB5.3 billion in 2025, with a CAGR of 13.4% from 2019 to 2025. By 2033, the market size for AR drugs in China is expected to reach RMB23.6 billion. Market size for SAR drugs in China increased from RMB0.5 billion in 2019 to RMB1.2 billion in 2025, with a CAGR of 16.3% from 2019 to 2025. By 2033, the market size for SAR drugs in China is expected to reach RMB16.1 billion.

The faster CAGR of China’s SAR drug market from 2025 to 2029 is primarily driven by the continued expansion of the market from a relatively early stage, together with the increasing adoption of innovative therapies, particularly targeted therapeutic agents. Specifically, targeted agents with distinct mechanisms of action, including anti-IL-4R α monoclonal antibodies, anti-IgE monoclonal antibodies and JAK inhibitors, are expected to be approved and launched successively during this period. By covering patients with moderate-to-severe refractory disease and broadening treatment options across different disease severities and treatment settings, they will serve as the core driver of market growth. Growth during this period is also supported by the development of retail pharmacy, online prescription and internet hospital channels, which improve medication accessibility for chronic allergic diseases and optimize long-term disease management models. In addition, as clinical standards for disease control are upgraded, the growing application of combination regimens comprising targeted therapies and conventional medications such as intranasal corticosteroids and oral antihistamines will further boost market value growth. The moderation in CAGR from 2029 to 2033 mainly reflects the gradual maturation of the market. Meanwhile, as more targeted therapeutic agents and other innovative therapies enter the market and intensify industry competition, the overall growth rate will decelerate accordingly.

INDUSTRY OVERVIEW

Market Size and Forecast of Allergic Rhinitis Drugs in China, 2019-2033E



Source: Frost & Sullivan Analysis

Main Treatment Pathway of Allergic Rhinitis

The management of allergic rhinitis follows an integrated framework that synergizes prevention with pharmacological intervention. This holistic approach, combining avoiding exposure to allergens, patient education, and standardized treatment, aims to achieve both rapid symptom relief and sustained disease control. The standard treatment strategies for SAR and PAR are highly consistent. Intranasal (local) therapy remains the cornerstone of treatment for most mild-to-moderate and certain moderate-to-severe cases. For patients with severe symptoms, poor response to topicals, or systemic comorbidities, systemic therapy is indicated. Furthermore, immunotherapy serves as a disease-modifying (etiological) strategy, inducing immune tolerance through the gradual administration of sublingual or subcutaneous allergens. In addition, targeted biologics have already been approved for the treatment of SAR, whereas no targeted biologics have yet been approved for PAR. Compared to SAR patients, PAR patients are often better suited for surgical intervention.

Comparison of Main Drugs for Treating AR

Generic Name	Original Company ¹	Drug Class	Dosing Frequency	Drug Status	Approval Date	SAR Annual Treatment Costs ²	PAR Annual Treatment Costs ³	NRDL Status
Loratadine	Bayer	Second-generation Oral Antihistamines	QD	Approved by NMPA	1993/1/3	12.0 RMB	36.0 RMB	List A
Azelastine	Viartis	Intranasal Antihistamines	BID	Approved by NMPA	2001/2/5	54.4 RMB	122.4 RMB	List B
Fluticasone furoate	GSK	Intranasal Corticosteroids	QD	Approved by NMPA	2012/6/1	218.2 RMB	654.6 RMB	List B
Budesonide	J&J		BID	Approved by NMPA	1997/1/1	79.8 RMB	239.4 RMB	List B
Montelukast	MSD	Leukotriene Receptor Antagonists (LTRA)	QD	Approved by NMPA	1999/1/1	82.6 RMB	247.9 RMB	List B
Omalizumab	Novartis	Biologics (Off-label Use)	Based on baseline IgE (IU/mL) and body weight (kg)	Approved by NMPA	2017/8/24	/	/	List B
Stapokibart	Keymed Bioscience	Biologics	Q3W	Approved by NMPA	2024/9/10	14,546 RMB	/	List B

Note: 1. Several generic versions of mometasone loratadine, budesonide, and montelukast are already available on the market. 2. According to the package insert, the SAR annual treatment duration for loratadine, azelastine, fluticasone furoate, budesonide and montelukast is calculated based on a two-month regimen per year, and stapokibart on a five-month regimen per year. 3. According to the package insert, the PAR annual treatment duration for loratadine, azelastine and montelukast is calculated based on a six-month regimen per year, while fluticasone furoate and budesonide are calculated based on a 27-week regimen per year.

Abbreviation: QD = Once Daily, BID = Twice Daily, Q2W = Every Two Weeks, Q3W = Every Three Weeks;

Source: NMPA, Frost & Sullivan analysis

INDUSTRY OVERVIEW

While intranasal corticosteroids, antihistamines, and leukotriene receptor antagonists are the main therapies of AR treatment in China, they primarily offer temporary symptom relief. Despite their affordability and rapid onset, these traditional therapies do not alter the disease course, leading to a 60% relapse rate. As patient expectations for quality of life rise, there is a clear shift toward more targeted, user-friendly treatments with superior long-term safety.

Market drivers of the AR drug market

- **The large patient population with AR in China provides a solid foundation for market growth:** AR is one of the most common chronic allergic diseases in China. In 2025, the number of patients with AR in China reached approximately 247.9 million. The large patient population and the need for long-term disease management continue to support demand for AR therapies.
- **The continuous update of clinical guidelines promotes standardized pharmacological treatment for AR:** The *Guidelines for the Diagnosis and Treatment of AR (2022 Revision)* recommend severity-based treatment, with second-generation antihistamines, intranasal corticosteroids and leukotriene receptor antagonists as the main pharmacological treatment options. The guidelines also emphasize regular follow-up and long-term disease management to improve disease control. As standardized treatment continues to improve, the adoption of pharmacological therapies is expected to increase, supporting the growth of the AR treatment market in China.
- **Continuous innovation in AR therapies expands treatment options:** While antihistamines and intranasal corticosteroids remain the mainstay of treatment, novel therapies, including topical JAK inhibitors and biologics targeting type 2 inflammatory cytokines, are expanding treatment options for AR. These innovative therapies are expected to address unmet clinical needs and support continued market growth.

Analysis of Mechanism and Advantages of JAK Inhibitors

JAK inhibitors offer a multi-dimensional advantage in AR treatment through unique mechanism and delivery potential. By simultaneously blocking multiple Th2 pathways, they eliminate the residual inflammation often left by single-target therapies. When delivered via nasal spray, they provide targeted efficacy while mitigating the systemic risks (e.g., hematological or infectious) associated with oral formulations. This makes them a compelling new option for patients who are refractory to or intolerant of conventional medications.

Competitive Landscape of Allergic Rhinitis Treatment

As of the LPD, a total of 60 drugs have been approved by the NMPA for the treatment of AR. These comprise 4 intranasal corticosteroids, 17 second-generation oral antihistamines, 4 first-generation oral antihistamines, 2 intranasal antihistamines, 4 leukotriene modifiers, 4 mast cell stabilizers, 13 compound preparations, 1 biologic agent and 11 other drugs. Among these products, only fexofenadine, stapokibart and Artemisia pollen allergen sublingual drops are indicated exclusively for SAR; all other drugs are approved for both SAR and PAR.

As of the LPD, a total of 2 drugs for the treatment of AR have filed NDA applications with the NMPA, and another 7 drugs indicated for AR are in Phase III clinical trials. Of these 9 agents, 2 are indicated for AR, 6 for SAR, and 1 for PAR. The Group's pumecitinib nasal spray is in Phase III clinical stage.

INDUSTRY OVERVIEW

Drug pipelines for AR Treatment in China

Target	Drug Name/Code	Company	Drug type	Dosage Form	Indication	Clinical Stage	Latest Updated Date
IL-4Rα	Comekibart	Mabgeek Biotech	Biologic	Subcutaneous injection	SAR	NDA	2026/4/23
IL-4Rα	Telikibart	Chongqing GenrixBio Biopharmaceutical	Biologic	Subcutaneous injection	SAR	NDA	2026/2/26
JAK	Pumecitinib	PrimeGenX Therapeutics	Chemical drug	Nasal Spray	SAR	Phase III	2025/12/27
IL-4Rα	SHR-1819	Hengrui Pharmaceutical	Biologic	Subcutaneous injection	SAR	Phase III	2026/7/6
HRH1, PTAFR	rupatifen	Fujian Mindong Lijiexun Pharmaceutical	Chemical drug	Oral	SAR	Phase III	2026/7/2
–	Acarizax	ALK-Abelló	Biologic	Oral	AR	Phase III	2026/5/18
–	MM09	Inmunotek/Hebo Pharmaceutical	Biologic	Oral	AR	Phase III	2026/4/15
IgE	LP-003	LongBio	Biologic	Subcutaneous injection	SAR	Phase III	2026/6/18
IL13	Lebrikizumab	Eli Lilly	Biologic	Subcutaneous injection	PAR	Phase III	2025/6/9

Source: CDE, Frost & Sullivan Analysis

Compared with other nasal spray agents indicated for AR, PG-011 delivers remarkable efficacy and an outstanding safety profile, with dosing convenience on par with that of other intranasal agents. PG-011 provides a novel therapeutic option for patients with moderate-to-severe AR who are unwilling to use intranasal corticosteroids or have corticosteroid intolerance, and is expected to become a new first-line treatment option for this patient population. The following table illustrates the comparison between PG-011 and other nasal spray agents for AR:

Comparison of nasal spray agents for AR

Dimension	PG-011 Nasal Spray	Intranasal corticosteroids	Intranasal second-generation antihistamines	Intranasal mast cell membrane stabilizers
Clinical Advantages	Improvements in nasal and ocular symptoms are superior or comparable to intranasal corticosteroids.	As a first-line classic therapy, it outperforms second-generation antihistamines in controlling nasal symptoms, while no significant difference is observed between the two in relieving ocular symptoms.	It effectively improves both nasal and ocular symptoms, with efficacy superior to intranasal mast cell stabilizers, and has a faster onset of action than corticosteroids and mast cell membrane stabilizers.	It has a relatively slow onset of action but favorable safety, and is suitable for long-term use or prophylaxis before the allergy season.
Safety and Tolerability	The incidence of adverse events is comparable to that of the drug-free nasal spray placebo group, with good tolerability.	Local adverse reactions involving the respiratory, thoracic and mediastinal systems are common but mild, with high systemic safety.	Favorable safety profile. Bitter taste is the main adverse reaction, and nasal irritation is rare.	Adverse reactions are rare and mild, with generally good tolerability.
Medication Convenience	Twice daily	Once to twice daily	Once to twice daily	3 to 4 times daily, with relatively poor convenience
Annual Treatment Cost	RMB400~600	RMB150~300	~RMB100	~RMB100

Note: The annual treatment cost for PG-011 is calculated based on the estimated price range after inclusion in the NRDL.

Source: Frost & Sullivan Analysis

INDUSTRY OVERVIEW

The following table illustrates the clinical data of Pumecitinib nasal spray compared to other nasal spray therapy for AR:

Comparison of Nasal Spray Therapy for AR

	Pumecitinib Nasal Spray (IIa)				Pumecitinib Nasal Spray (IIb)				Olopatadine Hydrochloride and Mometasone Furoate Monohydrate Nasal Spray (GSP301) ⁽¹⁾			
	1.0%, BID	0.6%, BID	0.1%, BID	Placebo	0.6%, BID	0.6%, QD	0.3%, BD	Placebo	GSP301 (665µg/25µg, BID)	Olopatadine hydrochloride (665µg, BID)	Mometasone furoate (25µg, BID)	Placebo
Average baseline rTNSS	9.4	9.8	9.5	8.9	10.1	10.1	9.8	9.8	10.1	10.2	10.2	10.3
Change from baseline (LS mean)	-3.497	-3.479	-3.057	-2.295	-4.187	-3.008	-3.177	-1.983	-3.5	-3.1	-3.1	-2.4
	-1.202	-1.184	-0.762		-2.204	-1.026	-1.195					
LS mean difference (95% CI)	(-2.193, -0.2119) ⁽²⁾	(-2.188, 0.180) ⁽²⁾	(-1.765, 0.240) ⁽²⁾	n/a	(-2.985, -1.423) ⁽²⁾	(-1.793, -0.258) ⁽²⁾	(-1.962, -0.427) ⁽²⁾	n/a	n/a	-0.4 (-0.8, -0.1) ⁽³⁾	-0.5 (-0.9, -0.1) ⁽³⁾	-1.1 (-1.5, -0.7) ⁽³⁾

Notes:

- (1) Data extracted from the FDA-approved label for GSP301.
- (2) Represents the LS mean difference in rTNSS between the relevant treatment group and the placebo group.
- (3) Represents the LS mean difference in rTNSS between the relevant treatment/placebo group and the GSP301 treatment group.

Source: Desk Research, Frost & Sullivan analysis

OVERVIEW OF THE PRURITUS DRUG MARKET

Pruritus (itch) is one of the most common and life-quality-impairing symptoms across a wide range of dermatological and systemic diseases. It is observed in various dermatological diseases such as neurodermatitis and Olmsted syndrome. The total number of chronic pruritus patients in China increased from 255.7 million in 2019 to 263.1 million in 2025. By 2033, the number of chronic pruritus patients in China is projected to reach 272.7 million.

In particular, neurodermatitis is a common chronic inflammatory dermatological disease classified as a disorder of skin neurological function. Olmsted syndrome is a rare congenital dermatological disease with approximately 100 reported cases worldwide and has no targeted specific therapy available.

Main Treatment Pathway of Pruritus

Pruritus management follows disease-specific guidelines through a tiered, multi-modal approach. Using neurodermatitis as a model, the paradigm integrates anti-inflammation, barrier repair, and behavioral intervention. While topical corticosteroids remain the first-line therapy for mild-to-moderate cases, systemic therapy, combining second-generation antihistamines and sedatives, is reserved for refractory pruritus or comorbidities to modulate neuroimmune responses. Current pruritus therapies often provide symptomatic relief at the cost of long-term metabolic or infectious risks. Furthermore, the varied drug responses across neuropathic and inflammatory subtypes underscore the need for precision molecular subtyping. Consequently, China’s R&D landscape is shifting toward biologics and small-molecule targeted drugs, which are poised to displace traditional antihistamines and broad-spectrum immunosuppressants through personalized, high-efficacy interventions.

INDUSTRY OVERVIEW

Analysis of Mechanism and Advantages of TRPV3 Inhibitor

The core mechanism of action for TRPV3 inhibitor is to block the pathological cascade reaction mediated by abnormally activated TRPV3 channels. Compared to traditional modalities, it offers four distinct advantages: (1) Precision Targeting: It selectively targets localized cutaneous TRPV3, eliminating risks of central sedation or systemic immunosuppression. (2) Restorative Efficacy: Beyond symptomatic relief, it actively repairs the skin barrier by modulating keratinocyte function, addressing a critical gap left by neural-only inhibitors. (3) Broad Applicability: Its efficacy extends to both histamine-mediated and non-histamine-mediated pathways, making it effective for a wider range of acute and chronic pruritus. (4) Superior Safety Profile: As a topical agent, it maintains high local concentrations while minimizing systemic exposure.

Competitive Landscape of Pruritus Treatment

As of the Latest Practicable Date, the drugs approved in China for the treatment of pruritus mainly included second-generation antihistamines, most of which have been included in the centralized procurement. As of the Latest Practicable Date, there were 18 drug candidates for the treatment of pruritus in China. Among these, PG-033 developed by PrimeGenX Therapeutics is the only TRPV3 inhibitor, which is currently in Phase I clinical stage. The following is a list of the drug pipelines for the pruritus in China:

Drug pipelines for the Pruritus in China

Target	Drug Name/Code	Company	Indication	Drug Type	Clinical Stage	Latest Update Date
KOR	Anrikefon	Haisco	Uremic pruritus, pruritus, chronic pain	Chemical Drug	Phase III	2024-08-21
	Nalfurafine hydrochloride	3SBio	Hepatic pruritus	Chemical Drug	Phase III	2026-02-02
	STC007	Sun-Novoo Pharma	Uremic pruritus	Chemical Drug	Phase II	2025-09-01
	Difelikefalin	CSL	Uremic pruritus	Chemical Drug	Phase II	2025-08-26
	KL280006	Kelun	Uremic pruritus	Chemical Drug	Phase II	2023-04-28
	RFUS-144	Humanwell	Pruritus, chronic pain, acute pain	Chemical Drug	Phase I	2024-07-12
	SHR 0410	Hengrui	Uremic pruritus	Chemical Drug	Phase I	2021-03-14
ASBT	Linerixibat	GSK	Cholestatic pruritus	Chemical Drug	Phase III	2025-01-13
	Volixibat	Cambrex / Mirum	Cholestatic pruritus, primary biliary cholangitis	Chemical Drug	Phase II	2024-12-27
HRH1	Olopatadine	Sihuan Kebao	Erythema multiforme, eczema, pruritus, dermatitis, urticaria, allergic rhinitis, plaque psoriasis	Chemical Drug	Phase I	2026-01-05
IL-4Ra	Dupilumab	Sanofi	Pruritus	Biological products	Phase III	2022-09-14
TRPV3	PG-033	PrimeGenX Therapeutics	Pruritus	Chemical Drug	Phase I	2026-06-15
GR	PA9060	Plato	Eczema, pruritus, neurodermatitis	Chemical Drug	Phase I	2025-12-28
OPR	RFUS-250	Humanwell	Pruritus, chronic pain, acute pain	Chemical Drug	Phase I	2025-04-03
MRGPRX4	HEP-50768	Haipai Tech	Cholestatic Pruritus and CKD Pruritus	Chemical Drug	Phase I	2026-04-20
IL-31	ATTO-1310	Attovia Therapeutics	Cholestatic Pruritus	Chemical Drug	Phase I	2026-06-11
-	SK-07	Consun	Uremic pruritus	Chemical Drug	Phase I	2024-11-11
-	WS012	Sino-US Huashitong	Primary sclerosing cholangitis	Chemical Drug	Phase I	2024-10-29

* As of July 15, 2026

Source: CDE, Frost & Sullivan Analysis

OVERVIEW OF THE MEMBRANOUS NEPHROPATHY DRUG MARKET

Membranous nephropathy (MN) is an immune-mediated glomerular disease characterized pathologically by diffuse thickening of the glomerular basement membrane. The total number of MN patients in China increased from 2.3 million in 2019 to 2.5 million in 2025. By 2033, the number of MN patients in China is projected to reach 2.8 million.

INDUSTRY OVERVIEW

Main Treatment Pathway of Membranous Nephropathy

The treatment of membranous nephropathy is a comprehensive process with the core objectives to reduce proteinuria, control blood pressure, protect renal function and prevent complications. It follows a stepwise process comprising induction of remission, maintenance therapy and complication management, with treatment regimens dynamically adjusted based on patient risk stratification. As no drugs have been approved by the NMPA for the treatment of membranous nephropathy, clinical treatment for membranous nephropathy is currently often administered off-label.

Currently no specific drugs have been approved for the indication of membranous nephropathy globally, and clinical treatment pathways mainly rely on off-label drug use. Current regimens mostly adopt non-specific supportive treatment with drugs such as angiotensin-converting enzyme inhibitors (ACEI) or angiotensin receptor blockers (ARB), which aim to alleviate clinical manifestations including proteinuria, hypertension and edema. These regimens fail to implement precision intervention targeting the core pathological mechanisms specific to membranous nephropathy, such as immune complex deposition and podocyte injury, and thus cannot fundamentally block disease progression.

Generic Name	Brand Name	Drug Class	Dosing Frequency	Drug Status	NMPA Approval Date	Price	NRDL Status
Rituximab	MabThera	Anti-CD20 Monoclonal Antibody (First-generation)	Q2W (2-dose regimen)/ QW (4-dose regimen)	Approved by NMPA	2002/12/23	RMB744.4 (10 ml: 100 mg)	List B
Obinutuzumab	Gazyva	Anti-CD20 Monoclonal Antibody (Next-generation)	Q2W	Approved by NMPA	2021/6/1	RMB9,369 (40 ml: 1 g)	List B
Cyclophosphamide	Endoxan	Alkylating Agents	QD	Approved by NMPA	2001/3/14	RMB74.1 (14 tablets)	List B
Cyclosporine	Sandimmun	Calcineurin Inhibitors (CNI)	BID	Approved by NMPA	1994/5/27	RMB567.5 (50 ml: 5 g)	List B
Daratumumab	DARZALEX	Anti-CD38 Monoclonal Antibody (Plasma Cell-targeting)	Weeks 1-8: QW; Weeks 9-24: Q2W; From Week 25: QM until disease progression or treatment discontinuation	Approved by NMPA	2019/7/4	RMB1,279.61 (5 ml: 100 mg)	List B
Iptacopan	FABHALTA	Complement Inhibitor	BID	Approved by NMPA	2024/4/24	RMB15,400 (56 tablets)	List B
Belimumab	BENLYSTA	Anti-BLyS/BAFF Monoclonal Antibody	First 3 doses: Q2W; From the 4th dose: QM	Approved by NMPA	2019/7/12	RMB755.0 (120 mg)	List B

Abbreviation: QD = Once Daily, BID = Twice Daily, QW = Once Weekly, Q2W = Every Two Weeks, QM = Once Monthly;

Source: NMPA, Frost & Sullivan analysis

Immunosuppressive regimens used for moderate-to-high-risk patients (e.g., glucocorticoids combined with alkylating agents or calcineurin inhibitors) generally suffer from a narrow therapeutic window. Long-term or cumulative dosage often leads to systemic adverse reactions including myelosuppression, hepatorenal function impairment, severe secondary infections and glucose-lipid metabolism disorders. Clinics face a dilemma between pursuing disease remission and controlling drug toxicity, and the tolerance and compliance of patients with long-term medication have become a bottleneck in treatment.

INDUSTRY OVERVIEW

Analysis of Mechanism and Advantages of JAK/ROCK Dual-Target Inhibitors

JAK/ROCK dual-target inhibitors exert therapeutic effects by intervening in the core pathological processes of membranous nephropathy through multiple dimensions. The core advantage of this dual-target strategy lies in synergistic efficacy enhancement, which not only inhibits immune-inflammatory responses at the source but also directly protects intrinsic glomerular cells and exerts anti-fibrotic effects.

Competitive Landscape of Membranous Nephropathy Treatment

Currently, no drugs have been approved by the NMPA for the treatment of membranous nephropathy in China. As of the Latest Practicable Date, there were 25 drug candidates for the treatment of membranous nephropathy in China, among which PG-018 developed by the Company is the only JAK/ROCK inhibitor and is currently in Phase I clinical trial.

The following is a list of the drug pipelines for the treatment of membranous nephropathy in China.

Drug Pipelines for the Membranous Nephropathy in China

Target	Drug Name/Code	Company	Drug Type	Clinical Stage	Latest Update Date
CD38	Felzartamab	I-Mab	Biological products	Phase III	2026-01-23
CD20	Obinutuzumab	Roche	Biological products	Phase III	2025-02-15
	zuberitamab	BioRay	Biological products	Phase II	2026-02-28
	B007	SPH Crosslink	Biological products	Phase II/III	2024-08-06
	MIL62	Tiangshi	Biological products	Phase III	2024-01-07
BTK	Zanubrutinib	BeiGene	Chemical Drug	Phase II/III	2026-01-21
	Edralbrutinib	Rheos Bio	Chemical Drug	Phase II	2023-08-26
	Civorebrutinib	Everest	Chemical Drug	Phase I	2024-01-08
APRIL / BAFF	Povetacicept	Zai Lab	Biological products	Phase II/III	2025-12-04
	SSS68	3SBio	Biological products	Phase I	2026-06-02
IFNAR1 / APRIL / BAFF	SHR-2173	Hengrui	Biological products	Phase II	2026-01-28
CD20 / CD47	JMT601	Genevant	Biological products	Phase II	2025-09-11
Sialoglycan	Efgitiasialase alfa	Henlius	Biological products	Phase II	2025-07-23
CFH	ALXN1920	AstraZeneca	Biological products	Phase II	2026-02-10
CD19	Budoprutug	Climb Bio	Biological products	Phase II	2026-05-25
TRPC6	Apocotrep	Almac Group / BI	Chemical Drug	Phase II	2026-05-22
CD20 / CD3	MSC303	Tiangshi	Biological products	Phase I / II	2025-06-12
CD19 / BCMA	FKC289	Fosun Kairos	Biological products	Phase I / II	2026-05-21
CD19 / CD3	YK012	Exscientia	Biological products	Phase I	2025-06-10
JAK / ROCK	PG-018	PrimeGenX Therapeutics	Chemical Drug	Phase I	2024-11-01
MC2R	KKD001	Concord	Biological products	Phase I	2025-11-07
CFB	HSK39297	Haisco	Chemical Drug	Phase I	2025-01-11
	HRS-5965	Shengdi	Chemical Drug	Phase I	2024-11-10
C3	QLS7305	Qilu Pharma	Chemical Drug	Phase I	2026-07-06
-	HS-10398	Hansoh	Chemical Drug	Phase I	2024-04-23

* As of July 15, 2026

Source: CDE, Frost & Sullivan Analysis

OVERVIEW OF THE GLAUCOMA DRUG MARKET

Glaucoma is a group of degenerative eye diseases characterized primarily by pathological elevation of intraocular pressure (IOP) and progressive damage to the optic nerve. The total number of glaucoma patients in China increased from 20.5 million in 2019 to 23.8 million in 2025. By 2033, the total number of glaucoma patients in China is expected to reach 28.8 million.

INDUSTRY OVERVIEW

Main Treatment Pathway of Glaucoma

The treatment for glaucoma aims to maintain and preserve patients’ visual function in the long run. Focused on intraocular pressure (IOP) control, the treatment takes a tiered strategy, and delivers individualized interventions through a combination of topical medications, laser therapy and surgical treatment. However, the current pharmacological, laser, and surgical therapies primarily target IOP reduction and cannot reverse optic nerve damage. Some patients are intolerant to or show insufficient response to existing drugs, creating an urgent need for novel neuroprotective or targeted mechanism-based therapies.

As of the Latest Practicable Date, six drugs had been approved by the NMPA in China for the treatment of glaucoma. Concurrently, there are six drug candidates for glaucoma in clinical stages, with two in Phase III clinical stages, three in Phase II clinical stages, and one in Phase I clinical stages.

Source of Industry Information

In connection with this [REDACTED], we have engaged Frost & Sullivan to conduct a detailed analysis of our market and prepare an industry report. Frost & Sullivan, founded in 1961 and based in the United States, is an independent global market research and consulting firm. The company provides services including market assessment, competitive landscape analysis, and strategic and market planning for multiple industries. We have included excerpts from the Frost & Sullivan Report in this Document as we believe such information will assist potential [REDACTED] in understanding our market environment.

The Frost & Sullivan Report was prepared by Frost & Sullivan based on its internal databases, independent third party reports, and publicly available information from authoritative industry organizations. Frost & Sullivan believes that the fundamental assumptions (including those used for future forecasts) adopted in preparing the Frost & Sullivan Report are factual, accurate, and not misleading. We have agreed to pay Frost & Sullivan a fee of RMB580,000 for preparing the Frost & Sullivan Report. This payment is not conditional upon the success of our [REDACTED] or the contents of the Frost & Sullivan Report.

Other than the Frost & Sullivan Report, we have not commissioned any other industry report in connection with this [REDACTED]. Our Directors confirm that, upon reasonable and prudent care, there have been no material adverse changes in the overall market information since the date of the Frost & Sullivan Report that would materially qualify, contradict or affect such information.