INDUSTRY OVERVIEW

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THE PHARMACEUTICAL MARKET IN CHINA

China's pharmaceutical market is projected to witness continuous growth, from RMB1,629.7 billion in 2024 to RMB3,103.4 billion in 2035 at a CAGR of 6.0%. Amid the rapid growth of biologics and other modalities, chemical drugs remain the cornerstone of China's pharmaceutical market, accounting for approximately 43.2% of domestic drug sales in 2024 and maintaining their position as the largest therapeutic category by volume and accessibility. Chemical drugs continue to dominate essential therapeutic areas in China, such as cardiovascular and metabolic diseases, inflammatory disorders, and other chronic conditions.

Within China's pharmaceutical market, innovative drugs have experienced, and are expected to continue experiencing, faster growth than generic drugs. This trend is attributable to the significant industry-wide investments devoted to the research and development of innovative drugs, implementation of favorable government policies and expedited pathways promoting drug innovation, in addition to the competitive advantages arising from the innovative drugs' superior efficacy and safety compared to existing treatments. China's innovative drug market reached RMB814.4 billion in 2024, and is projected to reach RMB2,172.1 billion in 2035 at a CAGR of 9.3% from 2024.

DRUG MARKET FOR IMMUNOLOGY AND INFLAMMATION IN CHINA

Immunology and inflammation are fundamental to the pathophysiology of a wide spectrum of respiratory and critical care diseases. While the immune system serves as the body's primary defense mechanism, immune dysregulation — characterized by excessive, prolonged, or aberrant inflammatory responses — can precipitate into severe tissue damage, fibrosis, and organ dysfunction. This underlying pathology drives conditions ranging from acute, life-threatening hyper-inflammatory states, such as acute lung injury ("**ALI**")/acute respiratory distress syndrome ("**ARDS**"), sepsis and severe pneumonia, to chronic, progressive fibrotic or inflammatory disorders, including inflammatory bowel disease ("**IBD**"), bronchiectasis, and chronic rhinosinusitis. Effective therapeutic intervention in these pathways is critical to modulating the immune response, preventing structural lung damage, and improving patient survival.

Acute Lung Injury and Acute Respiratory Distress Syndrome

Overview

ALI represents a spectrum of critical respiratory conditions characterized by rapid onset respiratory failure and refractory hypoxemia. ARDS is the most severe subset of ALI, distinguished by specific severity criteria and potential progression to multiple organ dysfunction. ARDS involves acute inflammatory injury to the alveolar-capillary membrane, resulting in increased vascular permeability, pulmonary edema, and severe impairment of gas exchange as part of a systemic inflammatory response.

ALI/ARDS constitute a major clinical challenge in intensive care medicine, with substantial morbidity and mortality burden. In China, among critically ill patients hospitalized for over 24 hours, ALI/ARDS incidence is estimated at 27.1%, with mortality rates escalating by disease severity: 18.8%, 32.2% and 60% for mild, moderate and severe ARDS cases, respectively. The aggregate ICU mortality for ARDS patients is approximately 34%. These findings underscore the critical need for effective therapeutic interventions, particularly drugs targeting the underlying inflammatory pathophysiology of ALI/ARDS.

Market Opportunities

The incidence of ALI/ARDS in China was 614.1 thousand cases in 2024 and is estimated to reach 683.8 thousand in 2035. The treatment of ALI/ARDS typically involves a multifaceted approach that combines advanced ventilation strategies with drug therapies. While respiratory support through high-flow nasal oxygen, noninvasive ventilation, and lung-protective mechanical ventilation remains fundamental, drug therapies play an increasingly important role in addressing the underlying inflammatory processes that drive these conditions.

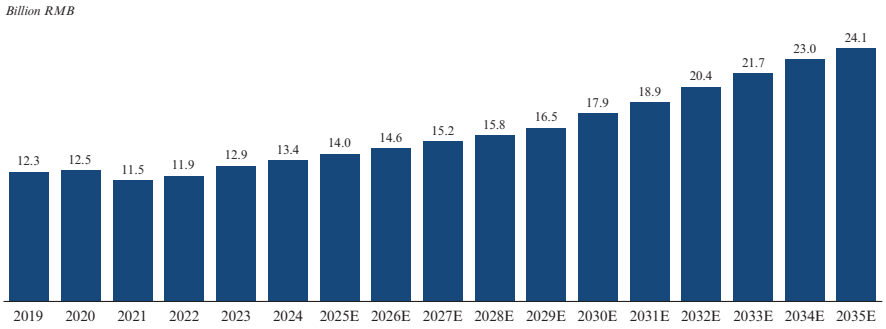
The table below sets out an overview of the drug therapies for ALI/ARDS patients:

Drug Therapy	Mechanism of Action	Clinical Benefits	Limitations
Sivelestat Sodium	Blocks a specific enzyme (neutrophil elastase) released by white blood cells that normally breaks down lung tissue proteins, preventing further damage to the lung during inflammation	Improved pulmonary function, significantly reduced duration of mechanical ventilation, and lower mortality rates in ALI/ARDS patients	Only one drug has been approved in China; clinical experience and market recognition gradually developing
Neuromuscular Blockade (NMB)	Temporarily paralyzes breathing muscles by blocking nerve signals, preventing patients from "fighting" the ventilator, reducing harmful pressure and stretching forces on damaged lungs during mechanical ventilation	Reduces ventilator-associated lung injury; improves 28-day survival in moderate-severe cases	Requires deep sedation; risk of ICU-acquired weakness with prolonged use; not specifically indicated for ALI/ARDS
Corticosteroids	Anti-inflammatory drugs that suppress the body's immune response by reducing inflammatory chemical messengers (like IL-6, TNF-α)	Alleviates lung inflammation	Suppresses natural immune defenses; increased risk of high blood sugar and secondary infections; variable efficacy; high doses may increase mortality rates; not specifically indicated for ALI/ARDS
Targeted Immunotherapy .	Precision drugs that specifically block overactive immune pathways (like JAK enzymes or IL-6 receptors)	More precise than general steroids; JAK inhibitors (baricitinib, tofacitinib) shown to improve outcomes in viral ARDS	Effectiveness mainly proven in viral ARDS; high medication costs and limited access; not specifically indicated for ALI/ARDS

The ALI/ARDS drug market is expected to increase from RMB13.4 billion in 2024 to RMB24.1 billion in 2035 at a CAGR of 5.5%. This market is primarily driven by an increasing patient population and China's policy initiatives to enhance critical care medical infrastructure. The chart below sets forth the market size of ALI/ARDS drugs in China during the relevant periods.

Market Size of ALI/ARDS Drugs in China, 2019–2035E(1)

Period	CAGR
2019-2024	1.8%
2024-2035E	5.5%



Source: Frost & Sullivan

Note:

(1) The COVID-19 pandemic caused sharp increases in critical care visits during 2019–2020. Since ALI/ARDS is a common form of severe respiratory failure in critical care settings, the pandemic caused an increase in demand for ALI/ARDS drugs during this period.

Among the pharmacological approaches, sivelestat sodium has demonstrated strong potential in mitigating lung inflammation. Sivelestat sodium distinguishes itself through its selective neutrophil elastase inhibition mechanism, which directly interrupts the inflammatory cascade to reduce lung injury. Clinically, this translates to meaningful patient benefits including improved pulmonary function, significantly reduced duration of mechanical ventilation, and lower mortality rates in ARDS patients. By effectively modulating neutrophil-mediated inflammation, sivelestat sodium not only mitigates lung injury but also shows potential for protecting other organs from inflammation-induced damage, expanding its therapeutic relevance in critical care. The "Expert Consensus on the Clinical Application of Sivelestat Sodium" (《西維來司他鈉臨床應用專家共識》) recommends its early integration into standard treatment protocols for severe pneumonia with systemic inflammatory response syndrome ("**SIRS**"), sepsis, and patients undergoing extracorporeal circulation surgery.

Compared to intravenous injection, nebulized sivelestat sodium potentially achieves superior drug concentration in the respiratory tract, while reducing systemic side effects (such as neutrophil-mediated organ damage, gastrointestinal reactions and central nervous system ("**CNS**") toxicity). This targeted approach represents a notable therapeutic advancement, potentially expanding treatment options for respiratory conditions where systemic administration has proven inadequate or poorly tolerated.

Competitive Landscape

As of the Latest Practicable Date, sivelestat sodium was the only drug approved for SIRS-associated ALI/ARDS globally, with Xiweina being the first and only domestically developed sivelestat sodium approved in China. As of the same date, H057, an inhalable sivelestat sodium developed by our Company, was the only sivelestat sodium candidate under clinical development in China, indicated for acute exacerbation of bronchiectasis and community-acquired pneumonia ("**CAP**").

Chronic Rhinosinusitis

Overview

Chronic rhinosinusitis ("**CRS**") is a persistent sinus inflammation lasting over 12 weeks, causing nasal congestion, thick nasal fluids, facial pressure, and often reduced sense of smell. This condition stems from various factors including nasal abnormalities, infections, immune issues, and environmental triggers. The prevalence of CRS has shown an upward trend in recent years. In China, CRS is estimated to affect over 100 million people or about 8% of the population. While severely diminishing patients' quality of life, CRS also consumes substantial medical resources, creating a heavy socioeconomic burden for countries worldwide.

CRS is classified into two types: CRS without nasal polyps ("**CRSsNP**") and CRS with nasal polyps ("**CRSwNP**"), with the former occurring four times more frequently than the latter. Based on immunological characteristics, CRS can be divided into type 2 inflammation (eosinophil-mediated, more common in Western populations) and non-type 2 inflammation (type 1 or 3, predominantly neutrophil-driven and more prevalent in Asian populations). These classifications exhibit racial and regional differences that directly impact treatment efficacy. Research shows that CRSsNP patients in China predominantly exhibit neutrophil infiltration, underscoring the important need for developing targeted therapeutic approaches specifically addressing neutrophilic inflammation pathways in this population.

Market Opportunities

The prevalence of CRSsNP in China was 106.8 million cases in 2024 and is estimated to reach 128.9 million in 2035, accounting for 75%~90% of the total CRS cases. The CRSsNP drug market in China was estimated at approximately RMB3.2 billion in 2024 and is expected to reach RMB15.0 billion in 2035 at a CAGR of 15.2% from 2024 to 2035.

Clinical management of CRSsNP primarily relies on conventional therapies such as glucocorticoids, macrolide antibiotics, antimicrobials, antihistamines, antileukotrienes, decongestants, nasal irrigation, and surgical interventions, with no targeted therapies currently approved in China. Patients with CRSsNP often experience persistent or recurrent symptoms despite prolonged medication and surgical treatments. Acute exacerbations can lead to temporary worsening of symptoms, and traditional pharmacological and surgical approaches often fail to provide satisfactory outcomes. Targeted therapies approved outside China for CRS primarily focus on type 2 inflammation and are indicated only for CRSwNP, leaving a global gap in treatments specifically targeting CRSsNP or non-type 2 (neutrophil-dominated) CRS.

DPP1 is a promising target for treating neutrophil-driven conditions because it activates neutrophil serine proteases that, while essential for normal immune function, cause tissue damage when dysregulated. Unlike conventional treatments, DPP1 inhibitors can potentially deliver superior safety due to reduced systemic immunosuppression risks, while maintaining advantages of high target specificity, minimal side effects, and sustained long-term efficacy. Based on the preclinical and clinical trial evidence available to date, DPP1 inhibitors represent a promising therapeutic approach for neutrophil-dominated inflammatory diseases, including CRS, bronchiectasis, COPD, and asthma.

Competitive Landscape

As of the Latest Practicable Date, no innovative DPP1 inhibitors had been approved in China and our YD0293 was the only DPP1 inhibitor candidate specifically targeting CRSsNP globally and in China.

Community-Acquired Pneumonia

Overview

CAP is a respiratory infection that develops outside healthcare settings, distinguishing it from hospital-acquired pneumonia. As the most common pneumonia type, CAP stems from various pathogens — including bacteria, viruses, fungi, and parasites — that trigger fluid accumulation in alveoli (oxygen-absorbing air sacs in lungs), impairing air exchange. CAP's universal susceptibility across age groups underscores its significant public health burden worldwide.

CAP manifests clinically through dyspnea (shortness of breath), fever and coughing, and pleuritic chest pain. Severe CAP is a critical form of CAP marked by respiratory failure, sepsis, or multiorgan dysfunction. Despite existing treatments — primarily antibiotics — this life-threatening condition results in a high hospitalization rate at 10–20%, with mortality reaching 5–10% among severe cases and vulnerable patients, particularly elderly patients and those with comorbidities or immunocompromised status, highlighting the critical need for improved therapeutic interventions.

Market Opportunities

The incidence of CAP in China was 11.8 million cases in 2024 and is estimated to reach 14.4 million in 2035. The CAP drug market in China was estimated at approximately RMB14.9 billion in 2024 and is expected to reach RMB28.7 billion in 2035 at a CAGR of 6.2%.

Therapeutic management for CAP primarily involves antibiotics (targeting bacterial causes), antipyretics (fever reducers), and antitussives (cough suppressants). Hospitalized CAP patients typically receive one of three antibiotic approaches: beta-lactam antibiotics (like penicillins) used alone, beta-lactam antibiotics combined with other antibiotics for wider bacterial coverage, or respiratory fluoroquinolones as single-drug therapy. Current CAP treatments face significant limitations, including frequent empirical antibiotic use due to often unidentified pathogens and bacterial resistance. Among the novel therapeutic options under clinical development, sivelestat sodium presents significant opportunities as an anti-inflammatory therapy for CAP patients by inhibiting neutrophil elastase activity to suppress inflammation and protect lung function.

Competitive Landscape

As of the Latest Practicable Date, all approved CAP drugs in China were antibiotics. As of the same date, our H057 was one of the only two small-molecule inhibitors — and the only inhalant — under clinical development in China for the treatment of CAP.

The following tables illustrate the competitive landscape of clinical-stage small-molecule inhibitors for CAP in China.

Small-molecule Inhibitor Candidates for CAP Under Clinical Development in China

Drug Name	Target	Dosage Form	Indications	Phase of Trial	Company	First Post Date
SR1375	PLA2G7	Capsule	CAP	Phase II	Simr Biotech	2024–08
H057	Neutrophil Elastase	Inhalant	CAP	Phase I	Our Group	2025–03

Note: The table above only shows clinical-stage Category I and Category II drugs registered on the CDE website.
Source: CDE, Frost & Sullivan

Bronchiectasis

Overview

Bronchiectasis is a chronic structural airway disease characterized by irreversible bronchial dilatation and distortion, accompanied by mucus retention, persistent airway inflammation, and recurrent infections. It is primarily driven by neutrophil-predominant inflammation, where impaired mucus clearance and bacterial infections activate neutrophils to release neutrophil elastase. This enzyme creates a destructive cycle by promoting inflammation, damaging airway cilia, and breaking down structural proteins like elastin, leading to progressive airway destruction. Clinically, it manifests as chronic cough, sputum production, recurrent hemoptysis, and repeated pulmonary infections. Bronchiectasis commonly coexists with chronic obstructive pulmonary disease ("**COPD**"), asthma, and other respiratory disorders, forming so-called "overlap syndromes."

Bronchiectasis represents a significant health concern in China due to its high prevalence, chronic respiratory symptoms, frequent exacerbations requiring hospitalization, and progressive lung function decline that impacts patients' quality of life and healthcare resources.

Market Opportunities

The prevalence of bronchiectasis in China was 26.8 million cases in 2024 and is estimated to reach 35.0 million in 2035. The bronchiectasis drug market in China was estimated at approximately RMB14.2 billion in 2024 and is expected to reach RMB36.4 billion in 2035 at a CAGR of 8.9% from 2024 to 2035.

Effective bronchiectasis management requires close attention to both stable-phase care and acute exacerbations. The management of bronchiectasis during stable periods employs a comprehensive strategy to interrupt the cycle of infection and inflammation. Airway clearance therapy, including chest physiotherapy and structured breathing techniques, facilitates mucus expectoration and improves respiratory function. Pharmacological interventions such as hypertonic saline and mucolytic agents enhance mucus clearance, while long-term antibiotic therapy has demonstrated efficacy in reducing exacerbation frequency in selected patient populations.

During acute exacerbations, treatment focuses on: (i) symptom improvement, (ii) returning to baseline stability, and (iii) reducing symptom duration. After discharge, the key goals are preventing future inflammation and prolonging time between exacerbations. Antibiotic therapy represents the primary therapeutic intervention for acute exacerbations of bronchiectasis, though current treatment approaches face substantial clinical limitations. Empirical antibiotic selection must proceed without microbiological confirmation, frequently resulting in suboptimal pathogen coverage and contributing to antimicrobial resistance development. Furthermore, antibiotic penetration into infected bronchiectatic airways may be compromised by ineffective drug delivery mechanisms and bacterial biofilm formation.

In response to these unmet needs, novel therapeutic approaches, such as neutrophil elastase inhibitors, are emerging to address the underlying inflammatory pathophysiology. Inhalable sivelestat sodium, a selective neutrophil elastase inhibitor, can potentially achieve direct delivery to affected airways while targeting the root cause of bronchiectasis exacerbations — the destructive cycle of neutrophil-mediated inflammation and progressive airway damage.

Competitive Landscape

As of the Latest Practicable Date, there was no targeted treatment for bronchiectasis approved in China. As of the same date, there were seven targeted therapies under clinical development in China for the treatment of bronchiectasis.

Inflammatory Bowel Disease

IBD is a chronic, relapsing, immune mediated disorder of the gastrointestinal tract, primarily comprising ulcerative colitis and Crohn's disease. It is generally believed to arise from a complex interaction among genetic susceptibility, environmental exposures, gut microbiota disruption and dysregulated immune responses. Common symptoms of IBD include diarrhea, abdominal pain, rectal bleeding, weight loss, fatigue and fever, which may substantially impair patients' quality of life and daily functioning. The prevalence of IBD in China was estimated at 0.8 million in 2024 and is expected to reach 1.3 million in 2032. Ulcerative colitis is the most prevalent form of IBD, accounting for approximately 75% of IBD cases. Clinically, ulcerative colitis is characterized by mucosal inflammation that typically begins in the rectum and extends proximally in a continuous pattern, whereas Crohn's disease may affect any part of the gastrointestinal tract and often involves discontinuous, transmural inflammation.

Current clinical management of IBD in China generally follows a step-up treatment paradigm, under which aminosalicylates, glucocorticoids, immunomodulators, biologics and surgery are introduced progressively based on disease severity and patient response. Despite the availability of these treatment options, remission rates remain below 50%, indicating a persistent therapeutic ceiling. In addition, existing therapies continue to face significant limitations, including primary non-response or secondary loss of response, infection risks associated with certain immunosuppressive or biologic agents, and limited treatment options for special patient populations, such as those with refractory perianal fistulizing disease, ulcerative proctitis or serious comorbidities. As a result, IBD remains a persistent chronic disease with significant unmet clinical needs, and there continues to be strong demand for more effective, safer and more targeted therapies. The IBD drug market in China was estimated at RMB10.9 billion in 2024 and is expected to increase to RMB36.9 billion in 2032.

As of the Latest Practicable Date, approved targeted therapies for IBD in China were predominantly monoclonal antibodies, with no PDE4B inhibitor approved. As of the same date, no PDE4B inhibitor targeting IBD in China had entered Phase II clinical development or beyond.

Sepsis

Sepsis is a life-threatening systemic condition triggered by the body's dysregulated response to infection, leading to widespread tissue damage and organ dysfunction. Characteristic symptoms of sepsis include fever, tachycardia, tachypnea, and altered mental status, often originating from infections in the lungs, urinary tract, abdomen, or skin. In its most severe form, sepsis progresses to septic shock, defined by persistent hypotension and multi-organ failure due to circulatory collapse. The resulting hypoperfusion critically damages the lungs, kidneys, liver, and other organs, carrying a high mortality risk. Globally, sepsis affects over 100 million people annually, claiming over 20 million lives — accounting for a substantial proportion of critical care fatalities. The incidence of sepsis in China was 9.1 million cases in 2024 and is estimated to reach 12.8 million in 2035.

Furthermore, sepsis survivors typically suffer from persistent cognitive impairment, creating substantial long-term healthcare burdens. Despite this significant disease burden, the field has historically lacked targeted pharmacological interventions, with conventional approaches yielding suboptimal outcomes. Sepsis management in China primarily relies on early broad-spectrum

antibiotics (e.g., carbapenems, β-lactams), fluid resuscitation, vasopressors (e.g., norepinephrine), and organ support (e.g., mechanical ventilation). However, existing treatments face significant limitations, including (i) rising antimicrobial resistance, reducing antibiotic efficacy; (ii) high mortality rates (~30–50%) due to uncontrolled inflammation and organ failure; and (iii) limited targeted therapies for immune dysregulation, with most regimens focusing on infection control rather than modulating the host response. The sepsis drug market in China was estimated at approximately RMB25.2 billion in 2024 and is expected to reach RMB58.2 billion in 2035 at a CAGR of 7.9% from 2024 to 2035.

These gaps underscore the urgent need for novel therapies, particularly immunomodulatory agents, to improve treatment benefits. As of the Latest Practicable Date, there were seven Category I innovative drugs under clinical development in China for the treatment of sepsis, with our YD0743 being one of the immunomodulatory agents.

DRUG MARKET FOR PAIN MANAGEMENT IN CHINA

Pain management remains a critical challenge in global healthcare, with significant gaps in safe and effective treatment options. While analgesics play a vital role in alleviating pain, current therapies often fall short in balancing efficacy with safety, particularly for chronic pain conditions. For example, opioids, though potent, carry substantial risks of addiction, respiratory depression, and misuse, fueling public health concerns worldwide.

There is a pressing need for innovative non-opioid analgesics that provide robust pain relief without these systemic risks. This demand is particularly acute in China, which is poised to become the world's largest and fastest-growing pain management market, driven by an aging population and increasing chronic disease burden.

Nav1.8 Inhibitors: Emerging Non-Opioid Analgesics

Overview

Nav1.8 inhibitors represent a promising class of non-opioid analgesics that specifically target voltage-gated sodium channels primarily expressed in peripheral nerves. By selectively inhibiting Nav1.8 — a crucial component in pain signal transmission — these inhibitors offer a distinctive therapeutic advantage: potent pain relief without the CNS effects that lead to addiction, respiratory depression, and other severe side effects associated with traditional opioids.

Market Opportunities

As a novel class of non-opioid analgesic, Nav1.8 inhibitors have potential applications across multiple pain indications, including postoperative acute pain, diabetic peripheral neuropathic pain ("**DPNP**"), and osteoarthritis pain. These markets are experiencing robust growth driven by aging demographics, increasing disease prevalence, and expanding healthcare access, while current treatment options remain limited by inadequate efficacy, addiction risks, or safety concerns.

Postoperative Acute Pain

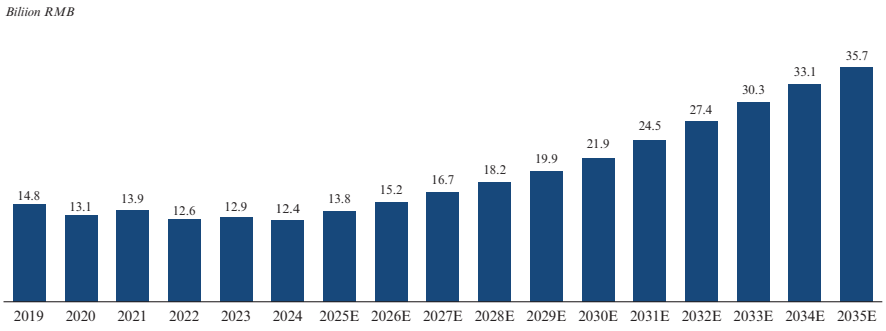
Postoperative acute pain, defined as pain immediately following surgical procedures, encompasses both somatic and visceral components and generally persists for three to seven days, though it may last several weeks after major surgeries such as thoracic operations or joint replacements requiring extensive rehabilitation. Inadequate pain control can result in significant short-term complications affecting cardiovascular, respiratory, gastrointestinal, and urinary systems, while long-term consequences include sleep disturbances, chronic pain syndromes,

psychological disorders, and drug dependence. The incidence of postoperative acute pain in China increased from 71.3 million cases in 2019 to 123.7 million in 2024 at a CAGR of 11.7%, and is projected to reach 273.1 million cases in 2035 at a CAGR of 7.5% from 2024 to 2035. Current treatment approaches utilize multimodal analgesia combining nonsteroidal anti-inflammatory drugs ("**NSAIDs**"), acetaminophen, local anesthetics, and opioids; however, the substantial addiction risks associated with opioid use have driven increasing demand for potent, non-addictive analgesic alternatives.

The postoperative analgesia drug market in China exhibited volatility with an overall declining trend from RMB14.8 billion in 2019 to RMB12.4 billion in 2024, primarily due to price reductions under the national VBP schemes, tightened regulatory controls on opioid prescribing and utilization, and temporary reduction in elective surgical activities during the COVID-19 pandemic. However, the market is projected to enter a robust recovery and expansion phase from 2024 onwards, reaching RMB35.7 billion in 2035 at a CAGR of 10.1% from 2024 to 2035. This anticipated growth is driven by several key factors, including (i) sustained growth in surgical volumes particularly in aging-related procedures, and (ii) evolution of pain management practices from single-agent opioid-based approaches to multimodal and non-opioid analgesia. The chart below sets forth the market size of postoperative analgesia drugs in China during the relevant periods.

Market Size of Postoperative Analgesia Drugs in China, 2019-2035E

Period	CAGR
2019-2024	-3.5%
2024-2035E	10.1%



Source: Frost & Sullivan

DPNP

Peripheral neuropathic pain arises from damage to or dysfunction of peripheral nerves, resulting in chronic pain that significantly impairs patients' quality of life. In China, DPNP represents substantial disease burdens within this therapeutic area.

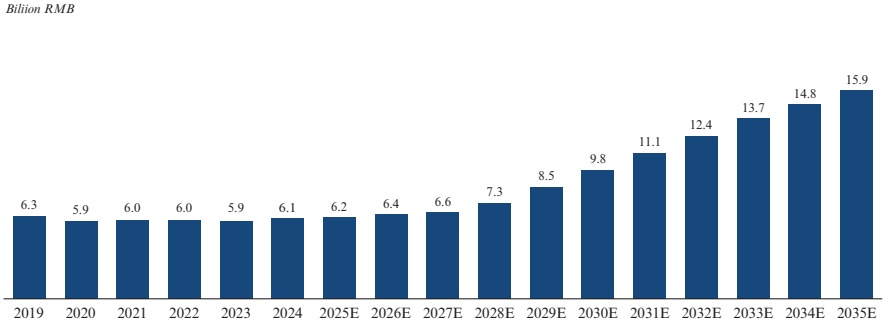
DPNP occurs in diabetic patients due to peripheral nerve damage caused by prolonged hyperglycemia. It is characterized primarily by bilateral limb pain, typically beginning in the feet and progressing upwards to the legs and hands, and is associated with significant functional impairment. The prevalence of DPNP in China rose from 30.0 million cases in 2019 to 34.2 million in 2024 at a CAGR of 2.7%, and is expected to reach 40.2 million by 2035 at a CAGR of 1.5% from 2024 to 2035.

Current pharmaceutical treatment options for DPNP primarily include calcium channel modulators, serotonin-norepinephrine reuptake inhibitors ("**SNRIs**"), antidepressants, topical agents, opioids and cannabinoids. However, many patients achieve inadequate pain relief or discontinue therapy due to tolerability issues, including dizziness, somnolence, weight gain, and peripheral edema. These limitations underscore a significant unmet medical need for novel therapies with improved efficacy and tolerability in the treatment of DPNP.

The DPNP drug market in China remained relatively stable at around RMB6.0 billion from 2019 to 2024. Driven by several key factors, including (i) sustained growth in the prevalence of diabetes, (ii) heightened awareness of diabetic complications, and (iii) innovations in analgesic mechanisms as well as the development of multimodal pain management approaches, such as Nav1.8 inhibitors, the DPNP drug market is expected to reach RMB15.9 billion in 2035 at a CAGR of 9.2% from 2024 to 2035. The chart below sets forth the market size of DPNP drugs in China during the relevant periods.

Market Size of DPNP Drugs in China, 2019-2035E

Period	CAGR
2019-2024	-0.7%
2024-2035E	9.2%



Source: Frost & Sullivan

Osteoarthritis Pain

Osteoarthritis pain is the predominant clinical symptom of osteoarthritis, a chronic and heterogeneous joint disease. The severity of pain often correlates with the degree of structural joint damage and may fluctuate over time, manifesting as either constant or intermittent pain patterns. Mechanistically, osteoarthritis pain represents a mixed pain phenotype that encompasses both inflammatory and mechanical injury-induced pain, as well as neuropathic pain resulting from neural sensitization. This complexity renders osteoarthritis pain a primary driver of functional limitation and diminished quality of life, leading to impaired mobility, difficulty with daily activities, and significant impacts on mood and sleep. In China, the prevalence of osteoarthritis pain rose from 85.7 million cases in 2019 to 89.5 million in 2024 at a CAGR of 0.9%, and is expected to reach 104.7 million by 2035 at a CAGR of 1.4% from 2024 to 2035.

Current pharmaceutical management for osteoarthritis pain primarily comprises topical agents (such as NSAID patches), oral medications (including acetaminophen, NSAIDs, and opioids), and intra-articular injections (such as corticosteroids). However, these treatments face distinct limitations: topical therapies often lack sufficient potency, while oral and injectable options are constrained by significant safety risks, including hepatic, renal, and cardiovascular impairment, addiction potential, or short duration of action. Accordingly, a critical gap remains for long-acting

treatments that can deliver effective pain relief without compromising patient safety. The osteoarthritis pain drug market in China presents a substantial opportunity, with the market size reaching RMB26.7 billion in 2024. It is expected to increase to RMB52.0 billion in 2035 at a CAGR of 6.2% from 2024 to 2035.

While traditional non-opioid analgesics serve as first-line treatment for mild to moderate and neuropathic pain, severe pain management often necessitates opioid therapy. Nav1.8 inhibitors represent a novel therapeutic approach that bridges this gap — their peripheral selectivity and robust analgesic properties offer opioid-comparable pain relief without CNS complications, while addressing pain types unresponsive to traditional non-opioid analgesics.

The table below sets forth the key differentiating features of Nav1.8 inhibitors against traditional non-opioid analgesics, including NSAIDs, SNRIs and calcium channel blockers.

Drug Type	Nav1.8 Inhibitors	Other Non-Opioid Analgesics		
		NSAIDs	**SNRIs**	**Calcium channel blockers**
Mechanism of Action	Block Nav1.8 sodium channels in peripheral nerves, reducing the transmission of pain signals from the periphery to the CNS	Inhibit cyclooxygenase enzymes (COX-1, COX-2), reducing prostaglandin synthesis and inflammatory mediators	Strengthen the CNS's descending inhibitory pain pathways through inhibition of serotonin and norepinephrine reuptake	Bind to voltage-gated calcium channels ($\alpha 2\delta$ subunits) in the CNS, reducing neurotransmitter release (e.g., glutamate) involved in pain signaling
CNS effects	Minimal CNS effects	Limited CNS effects	CNS effects of varying severity, typically manifesting as changes in mental status, dizziness, and other neurological symptoms	
Patient population	Patients with moderate-to-severe acute pain, addressing a critical therapeutic gap between the limited efficacy of NSAIDs and the significant safety concerns associated with opioid therapy and other non-opioid analgesics	First-line therapy for chronic pain conditions, particularly neuropathic pain, given their established efficacy in managing nerve-related pain, with topical lidocaine and capsaicin available as supplementary options		
Representative drugs	Suzetrigine (VX-548)	Ibuprofen	Duloxetine	Pregabalin, gabapentin

Source: Literature Review, Frost & Sullivan

The first generation of Nav1.8 inhibitors exhibited significant limitations during clinical development, including poor bioavailability that necessitated daily doses of one to two grams for patients. Next-generation Nav1.8 inhibitors such as VX-548 deploy an optimized chemical structure that demonstrates superior pharmacological properties, serving as a safer, targeted alternative for pain management, particularly for conditions requiring long-term treatment where opioid risks are a significant concern.

Competitive Landscape

As of the Latest Practicable Date, no Nav1.8 inhibitor had been approved in China, and suzetrigine (VX-548) was the only Nav1.8 inhibitor approved globally for the treatment of moderate-to-severe acute pain.

The following table illustrates the competitive landscape of clinical-stage Nav1.8 inhibitor candidates in China.

Nav1.8 Inhibitor Candidates Under Clinical Development in China

Drug Name	Indications	Phase of Trial	Company	First Post Date
HBW-004285	Postoperative abdominal surgery pain	Phase IIb/III	Chengdu Haibowei Pharmaceutical	2025–12
	Postoperative analgesia for correcting hallux valgus	Phase II		2025–07
	Postoperative orthopedic surgery analgesia	Phase II		2025–08
HRS-2129	Postoperative abdominal surgery pain	Phase II/III	Hengrui Pharmaceutical	2025–09
	Postoperative orthopedic surgery pain	Phase Ib/II		2025–02
	Knee Osteoarthritis	Phase Ib		2026–01
	Diabetic peripheral neuropathic pain	Phase Ib		2026–01
HL-1186	DPNP	Phase II	Our Group	2025–03
	Postoperative acute pain	Phase IIa		2025–03
	Osteoarthritis pain	Phase I		2025–03
JMKX000623	DPNP	Phase II	Shanghai Jiyu Pharmaceutical	2024–07
	Pain	Phase I		2022–03
JKN2306	Postoperative laparoscopic surgery pain	Phase I/II	Guangzhou Fermion Technology/Joincare Haibin Pharmaceutical	2025–01
KHN702	Postoperative acute pain	Phase Ib	Kanghong Pharmaceutical	2025–11
TRD208	Postoperative acute pain	Phase I	Beijing Tide Pharmaceutical	2025–10

Note: The table above only shows clinical-stage Category I innovative drugs registered on the CDE website.
Source: CDE; Frost & Sullivan

THE ONCOLOGY DRUG MARKET IN CHINA

Cancers remain one of the leading causes of death worldwide, posing severe threats to human health and creating significant socioeconomic burdens. In China, cancers have become the primary mortality cause, with over 5.0 million new cancer cases reported in 2024 — accounting for 23.6% of global incidence. Notably, China recorded 2.6 million cancer deaths in 2022, comprising over a quarter of global cancer mortality in the same year. Lung cancer and colorectal cancer were the most common cancer types in China by incidence in 2024, affecting 1,113.8 thousand and 542.4 thousand patients, respectively. The high incidence and mortality rates, coupled with the urgent need to improve patients' quality of life, underscore both substantial unmet clinical needs and market opportunities in oncology therapeutics.

In line with the continuous growth of cancer incidence, China's oncology drug market has expanded rapidly in recent years, growing from RMB182.7 billion in 2019 to RMB258.2 billion in 2024 at a CAGR of 7.2%, and is expected to reach RMB1,042.0 billion in 2035 at a CAGR of 13.5% from 2024 to 2035.

Levofolinic Acid: Key Roles in Cancer Therapy

Overview

Levofolinic acid (levoleucovorin) is the biologically active L-isomer of folinic acid and an essential reduced form of folate. It plays critical roles in DNA synthesis and repair through its involvement in purine and pyrimidine nucleotide production as well as amino acid metabolism. These functions make it an important agent in oncology care, where it both enhances chemotherapy effectiveness and helps protect healthy cells.

Levofolinic acid has been developed in two main salt forms. The original calcium salt suffers from poor solubility, which can cause crystal precipitation and complications such as vascular blockage when high doses are required. In contrast, the sodium salt is far more soluble and avoids the risks associated with excess calcium, offering a safer and more reliable option for clinical use.

Market Opportunities

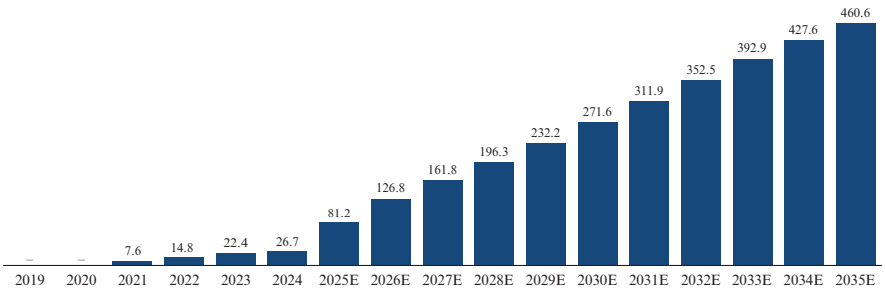
Levofolinic acid is clinically essential in two key therapeutic areas: (i) as a required component drug of 5-FU-based chemotherapy regimens (e.g., FOLFOX/FOLFIRI) for colorectal cancer, where it enhances antitumor efficacy, and (ii) as the standard rescue therapy for high-dose methotrexate (HDMTX) treatment, rapidly reversing drug-induced cytotoxicity.

Colorectal cancer is the second most common cancer and a leading cause of cancer mortality in China. The incidence of colorectal cancer in China was 542.4 thousand in 2024 and is estimated to reach 664.6 thousand in 2035. Currently, the FOLFOX regimen — comprising 5-fluorouracil (5-FU), folinic acid analogues, and platinum-based agents — represents the standard first-line chemotherapy for colorectal cancer and other gastrointestinal tumors. The concomitant administration of 5-FU with levofolinic acid in sodium salt formula has been shown to extend progression-free survival in patients with metastatic CRC ("**mCRC**"), while reducing the risk of death by approximately 40%.

The sodium levofolinate market in China, estimated at RMB26.7 million in 2024, is projected to grow at a CAGR of 29.6% and reach RMB460.6 million in 2035, driven by rising cancer incidence and the shift toward optimized chemotherapy regimens. The chart below sets forth the market size of sodium levofolinate in China during the relevant periods.

Market Size of Sodium Levofolinate in China, 2019–2035E

Period	CAGR
2021-2024	52.1%
2024-2035E	29.6%



Source: Frost & Sullivan

Competitive Landscape

As of the Latest Practicable Date, Zuoyu was one of the only two sodium levofolinate products approved in China. The following tables illustrate the competitive landscape of marketed sodium levofolinate in China.

Marketed Sodium Levofolinate in China

Drug name	Indications	Company	NMPA First Approval	NDRL Inclusion	Sales in 2024	Market Share in 2024
Zuoyu 佐愈®	• Administration with 5-FU for the treatment of mCRC • Rescue after high-dose methotrexate administration • Reduction of toxicity caused by excessive use of folate antagonists or impaired elimination of methotrexate	Our Group	2021–06	N/A	RMB25.9 million	>90%
Haifuxin 海复欣®	• Rescue after high-dose methotrexate administration • Reduction of toxicity caused by excessive use of folate antagonists or impaired elimination of methotrexate • Administration with 5-FU for the treatment of mCRC	Healthnice Pharmaceutical	2022–09	N/A	Undisclosed	<10%

Source: Frost & Sullivan

DRUG MARKET FOR OTHER CHRONIC DISORDERS IN CHINA

Benign Prostatic Hyperplasia

Benign prostatic hyperplasia ("**BPH**") is a common chronic condition in middle-aged and elderly men primarily characterized by urinary obstruction, and the most common benign condition contributing to lower urinary tract symptoms ("**LUTS**") in aging males. It is histologically characterized by hyperplasia of both stromal and epithelial components of the prostate, anatomically manifested as prostate enlargement, and clinically by LUTS primarily resulting from bladder outlet obstruction as confirmed by urodynamic studies.

The prevalence of BPH in China was 21.0 million cases in 2024 and is estimated to reach 23.5 million in 2035. The histopathological incidence of BPH increases with age, affecting over 50% of men by age 60 and up to 83% by age 80. Epidemiological studies suggest that men in Asian populations may have a higher susceptibility to moderate-to-severe BPH-related symptoms compared to those in Western populations. As disease symptoms worsen, pharmacological treatment becomes the primary intervention to alleviate symptoms and delay disease progression.

Silodosin is the first-line therapy for BPH recommended in both Chinese and international treatment guidelines. Silodosin, as the most selective α1A receptor antagonist currently available, demonstrates 162-fold greater binding affinity for α1A versus α1B receptor subtypes — a significant improvement over tamsulosin's 9.55-fold selectivity. This enhanced receptor specificity translates to superior clinical outcomes in managing LUTS and BPH, while minimizing cardiovascular and other systemic adverse effects. The market size of BPH drugs in China was estimated at approximately RMB3.4 billion in 2024 and is expected to reach RMB7.2 billion in 2035 at a CAGR of 6.9% from 2024 to 2035.

As of the Latest Practicable Date, silodosin therapy in China was only available in twice-daily capsule, and our H077 was the first and only silodosin candidate in sustained-release formulation under clinical development. Compared to conventional silodosin capsules, sustained-release formulations of silodosin offer multiple clinical advantages, including: (i) enhanced patient compliance through simplified dosing schedules; (ii) stabilized plasma drug concentrations that minimize peak-trough fluctuations compared to immediate-release formulations, reducing concentration-dependent adverse effects; and (iii) potentially improved tolerability of silodosin-specific side effects through gradual drug release that avoids sudden concentration spikes.

Resistant Hypertension

Resistant hypertension is a clinically significant subtype of hypertension, defined as persistently elevated blood pressure above 130/80 mmHg despite the use of three or more antihypertensive drugs from different classes, or controlled blood pressure requiring four or more medications. This condition is marked by poor responsiveness to intensive medical therapy, placing patients at higher risk of cardiovascular events and highlighting a critical unmet need for new treatment strategies. According to WHO Guidelines for the pharmacological treatment of hypertension in adults, a large multicenter study across high-, middle-, and low-income countries found that only 40.6% of hypertension patients received treatment, with only 13.2% achieving blood pressure control, showing that blood pressure remains uncontrolled in the majority of hypertension patients.

The prevalence of hypertension in China was 353.6 million cases in 2024 and is estimated to reach 423.9 million in 2035. Resistant hypertension affects an estimated 15% of all hypertension patients and represents a major challenge in cardiovascular care. Multi-target drugs represent a next-generation approach to hypertension, acting on several biological pathways simultaneously. By addressing the multifactorial nature of the disease, they provide more effective blood pressure

control, stronger cardiovascular and renal protection, and simplified treatment through single-formulation design. This not only improves adherence but also reduces the risk of side effects and drug interactions, making them particularly valuable for patients with resistant or complex hypertension.

Sacubitril valsartan sodium/amlodipine compounds exemplify this multi-target innovation. By modulating the renin-angiotensin system, enhancing protective peptides, and regulating calcium channels, they achieve superior blood pressure reduction while offering additional organ protection. This integrated, multi-pathway mechanism directly targets the complex pathophysiology of hypertension, offering new treatment options for patients who do not respond adequately to conventional therapies.

As of the Latest Practicable Date, there were no sacubitril valsartan sodium/amlodipine compound approved in China, and our H062 was one of the only two sacubitril valsartan sodium/amlodipine compound preparations under clinical development in China.

REPORT COMMISSIONED BY FROST AND SULLIVAN

In connection with the [REDACTED], we have engaged Frost & Sullivan to conduct a detailed analysis and prepare an industry report in relation to our key marketed products and drug candidates. Frost & Sullivan, founded in 1961, is an independent global market research and consulting company based in the United States. We have agreed to pay Frost & Sullivan a total fee of RMB0.66 million for the preparation of the Frost & Sullivan Report, which we believe to be consistent with the market rate. The payment of such amount is not contingent upon our successful [REDACTED] or on the findings contained in the Frost & Sullivan Report. Except for the Frost & Sullivan Report, we did not commission any other industry report in connection with the [REDACTED].

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