The information and statistics set out in this section and other sections of this document were extracted from official government publications, available sources from public market research and other sources from independent suppliers. In addition, we engaged China Insights Industry Consultancy Limited, or CIC, to prepare an independent industry report, or the CIC Report, for the [**REDACTED**]. *The information from official government sources have not been independently verified by us, the Sole Sponsor, the* [**REDACTED**]*, the* [**REDACTED**]*, the* [**REDACTED**]*,* [**REDACTED**]*,* [**REDACTED**]*, any of the* [**REDACTED**]*, any of their respective directors, officers, employees, advisers and agents or any other persons or parties involved in the* [**REDACTED**]*, except for CIC, and no representation is given as to its accuracy. Accordingly, the information from official and non-official sources contained herein may not be accurate and should not be unduly relied upon.*

GLOBAL AND CHINA PHARMACEUTICAL INDUSTRY

The pharmaceutical industry is a crucial component of the economy. According to CIC, the size of global pharmaceutical market increased from US$1,239.0 billion in 2018 to US$1,569.6 billion in 2023 with a CAGR of 4.8%, and is expected to reach US$2,410.0 billion in 2035, representing a CAGR of 3.6% from 2023 to 2035. The size of pharmaceutical market in China increased from RMB1,551.2 billion in 2018 to RMB1,763.9 billion in 2023 with a CAGR of 2.6%, and is expected to reach RMB3,683.9 billion in 2035, representing a CAGR of 6.3% from 2023 to 2035.

In the pharmaceutical industry, small molecules and biologics represent two distinct categories of drugs, with small molecule drugs playing a significant role in drug development today. The small molecule drugs can target both cell surface and intracellular sites, expanding the range of potential drug targets. Additionally, from a patient convenience perspective, oral small molecules enhance accessibility and improve patient compliance by reducing the need for frequent hospital visits, thereby conserving medical resources and lowering treatment costs.

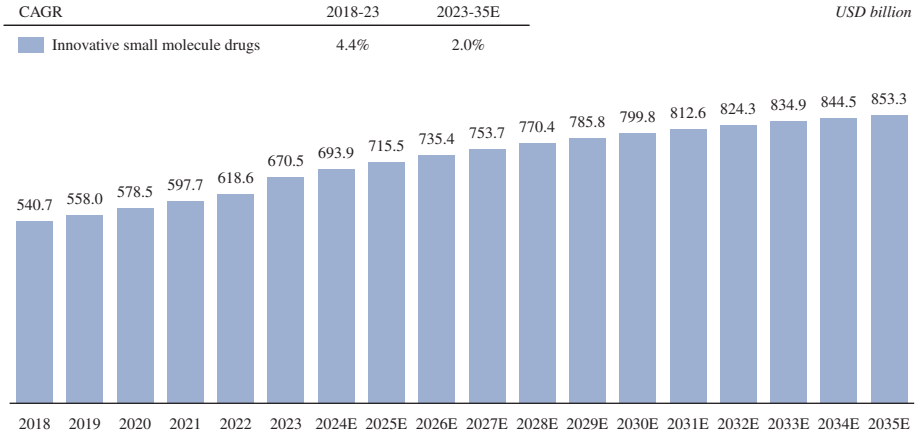
Small molecule drugs can be categorized into brand-name and generic drugs. When a new drug is introduced, it is patented and sold under a brand name. Once the patent expires, other companies may produce and sell generic versions of the drug. Although generics may differ slightly from the brand-name version, they must demonstrate similar efficacy. Both brand-name and generic drugs play crucial roles in public health, with brand-name drugs often representing innovative treatments that address unmet medical needs, while generics offer more affordable alternatives, enhancing accessibility and reducing healthcare costs without compromising effectiveness. Together, they contribute to a well-balanced and accessible healthcare system.

INNOVATIVE SMALL MOLECULE DRUG INDUSTRY

Innovative small molecules are at the forefront of drug development due to their versatility and effectiveness in treating a wide range of conditions, from infectious diseases and cancer to neuropsychiatric and reproductive disorders. They represent the most widely approved drug class, with 30 approved small molecule drugs in the U.S. in 2023, accounting for 55% of all approved drugs, and 48 approved small molecule drugs in China in 2023, accounting for 59% of all approved drugs.

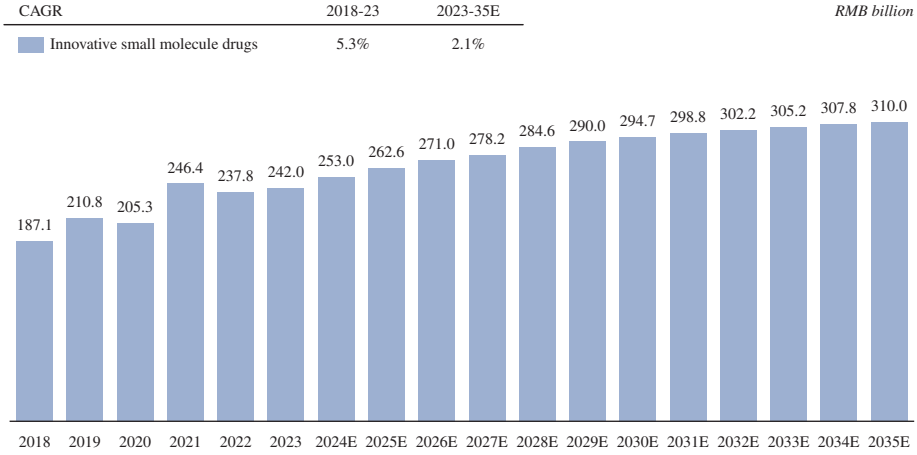
As a result, the global market for innovative small molecule drugs has experienced significant growth, increasing from US$540.7 billion in 2018 to US$670.5 billion in 2023, representing a CAGR of 4.4%. The market is expected to reach US$853.3 billion by 2035, reflecting a CAGR of 2.0% from 2023 to 2035. Similarly, the innovative small molecule drugs market in China has steadily expanded, growing from RMB187.1 billion in 2018 to RMB242.0 billion in 2023, at a CAGR of 5.3%. It is projected to continue growing at a CAGR of 2.1% from 2023 to 2035, reaching RMB310.0 billion by 2035.

Historical and Forecasted Global Market Size of Innovative Small Molecule Drugs, 2018-2035E



Source: WHO, China Insights Consultancy

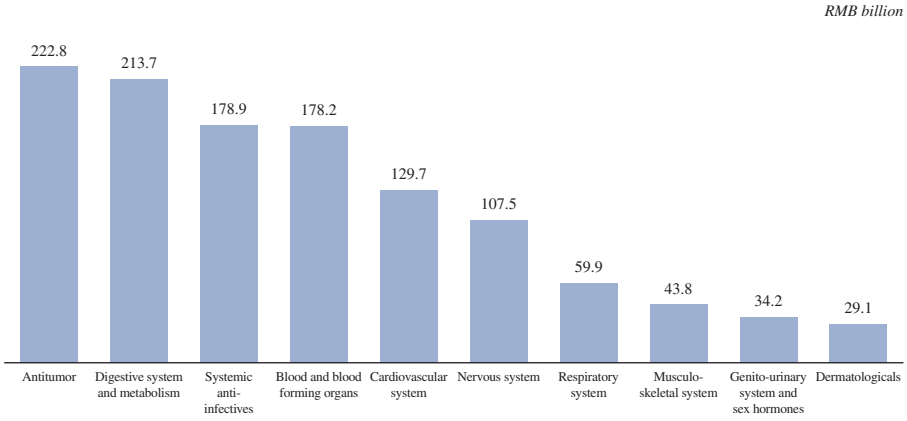
Historical and Forecasted Market Size of Innovative Small Molecule Drugs in China, 2018-2035E



Source: National Bureau of Statistics, NHC, China Insights Consultancy

Antiviral, neuropsychiatric, and reproductive health drugs are important segments of the pharmaceutical industry in China. According to CIC, the systemic anti-infectives market ranked third in terms of sales, with a value of RMB178.9 billion in 2023, highlighting the critical importance of infectious disease prevention and treatment. Antiviral drugs, which target widespread and potentially life-threatening diseases, constitute an important portion of this market. Neuropsychiatric drugs, driven by a large patient population and high treatment demand, ranked sixth in sales, generating RMB107.5 billion in 2023. While the market for reproductive health drugs is comparatively smaller, it holds significant growth potential fueled by increasing public health awareness and improving living standards.

Top Ten Therapeutic Areas in China, 2023



Notes:

1. Systemic anti-infectives include systemic antiviral drugs, systemic antibacterial drugs, immune sera and immunoglobulins, systemic antifungal drugs and vaccines.

2. In this context, "Nervous system" refers to "Neuropsychiatric drugs", while "Genito-urinary system and sex hormones" corresponds to "Reproductive health drugs."

Source: National Bureau of Statistics, NHC, China Insights Consultancy

Growth Drivers and Future Trends

The growth of the innovative small molecule drug market is driven by several key factors. Technological advancements, particularly breakthroughs in biotechnology, genomics, and molecular biology, are enabling the development of more targeted, precise, and personalized therapies. At the same time, increased investments are focused on identifying new therapeutic targets and improving existing treatments, further advancing the development of breakthrough medicines. Collaboration between pharmaceutical companies, academic institutions, and technical organizations is also vital, as the sharing of expertise and resources accelerates the drug discovery and development process. Additionally, the demand for new therapies is being fueled by unmet clinical needs, particularly for diseases with limited treatment options. For example, the emergence of new diseases, such as COVID-19 and antibiotic-resistant infections, as well as the rising prevalence of chronic conditions such as neuropsychiatric disorders, is driving the need for novel treatments.

Entry Barriers

New entrants in the innovative drug development market face several significant barriers. First, technological and expertise gaps can be a major obstacle for startup companies, as advanced knowledge in molecular biology, chemistry, and clinical development is essential, and larger, established players typically have the resources and skilled personnel needed to navigate these complexities. In the realm of antiviral therapies, rapid viral mutations, the emergence of drug resistance, and the need to selectively eliminate viruses without damaging human cells further complicate development efforts. In addition, finding suitable animal models for antiviral drug evaluation is challenging, and the outcomes observed in animal models can often differ significantly from those seen in humans. Also, drug development for neuropsychiatric disorders also faces several challenges. The inherent complexity of the pathogenesis of neuropsychiatric disorders, combined with the challenge of achieving effective drug penetration across the blood-brain barrier, poses significant obstacles to treatment development. Furthermore, different neuropsychiatric disorders present unique therapeutic challenges: antidepressants struggle with slow onset of action and substantial placebo effects; antiepileptic drugs must precisely target abnormal neuronal activity while minimizing severe side effects; and antipsychotic drugs require careful balancing of efficacy with adverse effects, such as metabolic syndrome. Together, these challenges result in difficulties in drug discovery and extended development timelines.

Moreover, the high capital investment required for drug discovery, preclinical testing, clinical trials, and regulatory approval creates a financial challenge, especially for smaller companies. Intellectual property protections, such as patents, data exclusivity, and trade secrets, further hinder new entrants by safeguarding the competitive edge of established players. Finally, the clinical trials process is complex and costly, with difficulties in recruiting patients for large-scale, multi-phase trials, particularly for rare diseases or specific patient populations, which can cause delays in development timelines.

Antiviral Drugs

A virus is a pathogen that relies entirely on living host cells to replicate, as it cannot carry out life processes independently. It invades an organism using an infection mechanism and hijacks the host's cellular machinery to produce new viral particles. Drugs targeting viral infection are critically needed due to the rapid spread of viruses and their high mutation rates, which enable them to evade treatment, disrupt normal life, and cause societal panic. The global antiviral drug market was valued at US$94.2 billion in 2023 and is projected to remain relatively stable, reaching US$97.4 billion by 2035, with a CAGR of 0.3% from 2023 to 2035. In China, the antiviral drug market was valued at RMB24.9 billion in 2023 and is expected to reach RMB44.9 billion by 2035, growing at a CAGR of 5.0% from 2023 to 2035.

Structurally, a virus consists of nucleic acid, either DNA or RNA, encased in a protective protein shell. Viral replication differs depending on the type of nucleic acid. DNA viruses, typically double-stranded, replicate within the cell nucleus, leveraging the host's replication and transcription systems. In contrast, RNA viruses, which are usually single-stranded, replicate predominantly in the cytoplasm. Due to the high error rate during RNA replication, RNA viruses exhibit greater genetic variability compared to DNA viruses, making them more prone to mutations and increasing their potential to cause antiviral drug resistance. Studies indicate that RNA viruses have a higher mutation rate compared to DNA viruses, leading to their rapid evolution and greater adaptability to changing environments. This high variability underscores the need for accelerated drug development to effectively combat RNA virus infections.

RNA viruses rely on RdRp for their replication. RdRp is a viral enzyme that synthesizes RNA from an RNA template, facilitating the replication of viral genomes and transcription of structural proteins necessary for virus proliferation. This enzyme operates without a counterpart in mammalian cells. Furthermore, considering that RdRp is essential for RNA virus replication and is highly conserved, it serves as an excellent therapeutic target for antiviral drug development. By targeting RdRp, the replication of RNA viruses, such as those causing influenza, hepatitis C, and emergent diseases such as MERS and SARS, can be effectively disrupted, reducing their ability to propagate and cause disease.

Among RdRp inhibitors, nucleoside analog inhibitors, including VV116, are particularly effective. These compounds mimic natural nucleosides, allowing their incorporation into the growing RNA strand during replication. Once incorporated, nucleoside analog inhibitors either terminate the viral DNA or RNA extension or induces lethal mutations to viral genome, resulting in robust antiviral effects. Furthermore, nucleoside analog inhibitors exhibit broad-spectrum antiviral activity due to the conserved nature of RdRp across RNA viruses. These properties position nucleoside analog inhibitors as a cornerstone in antiviral drug development, addressing the challenges posed by RNA virus infections.

RSV Drugs

RSV is a non-segmented, negative-sense, single-stranded RNA virus that primarily spreads through hands, fomites, and aerosols. The global prevalence of RSV is expected to increase from 136.2 million in 2023 to 157.0 million in 2035, with a CAGR of 1.2%. In China, the prevalence is forecasted to rise from 25.5 million in 2023 to 26.2 million in 2035, with a CAGR of 0.2%. Infants and young children are the primary victims of RSV infection, with 50-70% being infected in their first year of life and 90% in their second year. In China, infants and young children aged one to 24 months account for approximately 30.6% of the RSV patient population in 2023.

RSV treatment drugs are of major clinical needs. Although RSV vaccines and prophylactic treatments can reduce the incidence of infections, they do not guarantee complete immunity, and reinfections are common throughout life. RSV infections can range from mild to severe, particularly in vulnerable populations such as premature infants, the elderly, and immunocompromised individuals, who may experience severe complications such as bronchiolitis or pneumonia. Studies indicate that the global hospitalization rate for RSV-related diseases in children aged five years and younger is approximately 1.7%, with an in-hospital mortality rate of around 0.5%. Among older adults (≥65 years), the hospitalization rate ranges from 15% to 25%, while the in-hospital mortality rate is estimated at 6% to 8% worldwide.

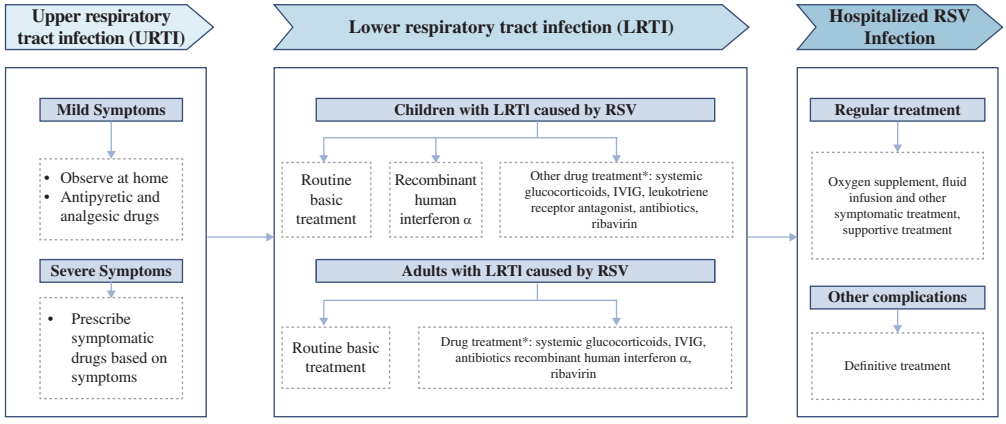
While preventive measures reduce the risk of infection, they cannot eliminate severe cases, and treatment options remain essential to manage complications, reduce hospitalization, and prevent mortality. Additionally, vaccines and monoclonal antibodies have limitations in accessibility, cost, and population coverage, leaving some individuals without preventive therapies. The mutagenicity of RSV also leads to the emergence of new variants, which may evade immunity from previous infections or vaccines, necessitating new treatments. Given that RSV infection cannot be prevented by long-term immunity, repeated treatments are needed for managing recurrent infections throughout life.

For infants and young children who are infected with RSV, capsules and tablets are generally not suitable for direct use. Dosage forms that can be safely swallowed, such as dry suspensions or liquids, are preferred for this age group. A dry suspension offers a practical and patient-friendly solution for these groups. By ensuring accurate dosing and enhancing compliance, dry suspensions provide a more effective method of medication delivery. This approach can potentially improve treatment outcomes and expand access to RSV therapeutics.

Treatment Paradigm

Currently, the standard treatment for RSV is primarily supportive care, including oxygen supplementation, nasal decongestants, hydration, and nutrition, along with the use of bronchodilators, epinephrine, and steroids. For pediatric RSV infections, clinical treatment options include interferon, ribavirin, and bronchodilators, though routine use of ribavirin is not recommended due to significant side effects and insufficient evidence supporting its efficacy in treating RSV. In adults, treatment for RSV infection is largely confined to supportive care, such as bronchodilators, supplemental oxygen, intravenous infusions, and antipyretics.

Treatment Paradigm of RSV in Different Susceptible Population in China



Abbreviations: IVIG = intravenous immunoglobulin.

Note:

* None of the drug treatments are recommended for adults. Additionally, except for recombinant human interferon α, all other drug treatments are not recommended for children.

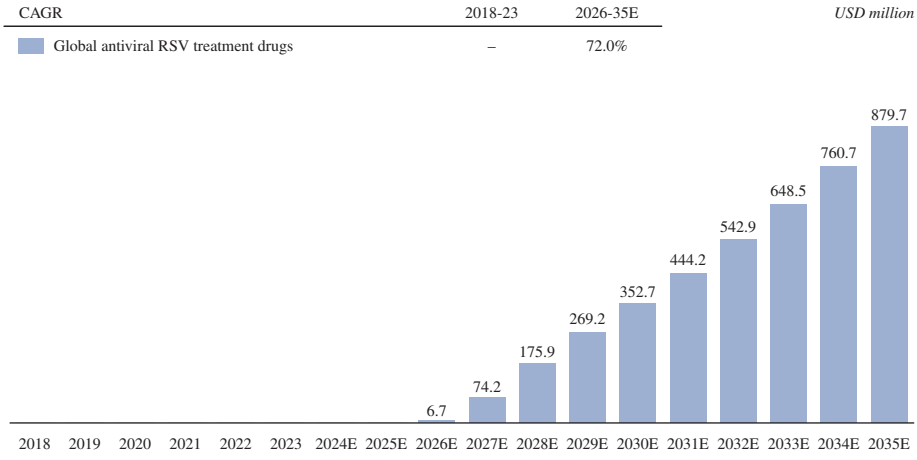
Source: AAP, Expert Consensus on the Diagnosis, Treatment, and Prevention of Respiratory Syncytial Virus Infection in Children (2023 Edition) (《兒童呼吸道合胞病毒感染診斷、治療和預防專家共識(2023版)》) and Guidelines for the Treatment and Prevention of Lower Respiratory Tract Infections Caused by Human Respiratory Syncytial Virus (2024 Edition) (《人呼吸道合胞病毒下呼吸道感染治療及預防指南(2024版)》), China Insights Consultancy

However, according to the latest Guidelines for the Treatment and Prevention of Lower Respiratory Tract Infections Caused by Human Respiratory Syncytial Virus (2024 Edition), the efficacy of antiviral drugs such as ribavirin remains unclear, and their potential side effects make them unsuitable for routine use. Additionally, medications like corticosteroids and bronchodilators have limited effectiveness in treatment and should be used with caution. Therefore, there is an urgent need for innovative therapeutic options to treat RSV infections.

Market Size

The development of small molecule antiviral products for RSV treatment represents a significant unmet medical need on a global scale. However, as of the Latest Practicable Date, no small molecule antiviral products for RSV treatment were available worldwide. With the approval of the first innovative small molecule antiviral therapy anticipated in 2026, the global market is expected to reach US$6.7 million in 2026 and grow substantially to US$879.7 million by 2035 with a CAGR of 72.0% from 2026 to 2035.

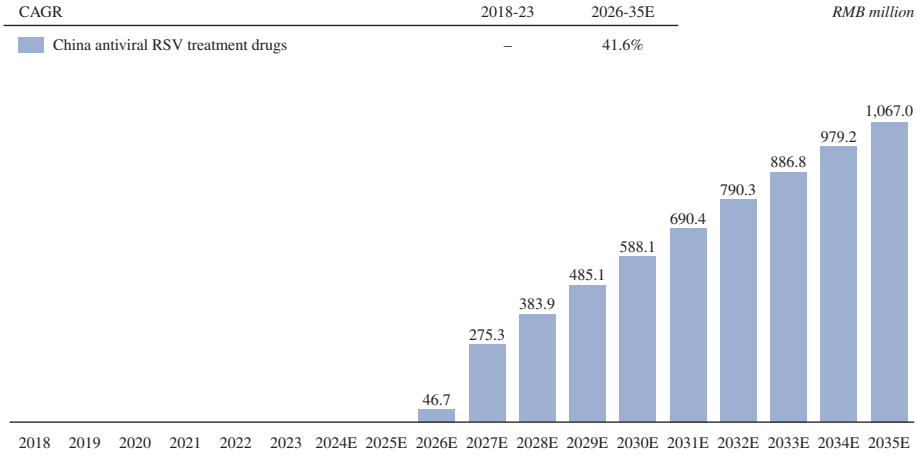
Historical and Forecasted Global Market Size of Antiviral Therapy for RSV Treatment, 2018-2035E



Source: UN, The Lancet, The Journal of Infectious Diseases, China Insights Consultancy

Similarly, in China, there were no small molecule antiviral products approved for RSV treatment as of the Latest Practicable Date. However, with the anticipated approval of the first innovative small molecule antiviral drug in 2026, the market for small molecule antiviral therapy for RSV treatment in China is expected to reach RMB46.7 million in 2026, growing substantially to RMB1,067.0 million by 2035 with a CAGR of 41.6% from 2026 to 2035.

Historical and Forecasted Market Size of Antiviral Therapy for RSV Treatment in China, 2018-2035E



Source: The Journal of Infectious Diseases, Journal of Clinical Pediatrics, China Insights Consultancy

Competitive Landscape

As of the Latest Practicable Date, no innovative small molecule antiviral therapies had been approved on a global scale for the treatment of RSV. Globally, six small molecule antiviral drug candidates were under development for RSV treatment.

In China, two small molecule antiviral drug candidates were in development for RSV treatment. Among these products, VV116 was the only candidate targeting RdRp. VV116 dry suspension also stood out as the only dry suspension formulation designed for convenient administration to infants and young children, which was in a Phase II/III clinical trial as of the Latest Practicable Date.

Global Competitive Landscape of Small Molecule Antiviral Drug for RSV Treatment

Candidate	Formulation	MoA	Company	Clinical phase	Study Location	First posted date	Indication
AK0529	Enteric capsules	F protein	Ark Biopharmaceutical	III	China	2024/03/12	RSV for children
VV116	**Dry Suspension**	**RdRp**	**the Company**	**II/III**	**China**	**2024/01/23**	**RSV for children**
EDP-938	Tablets	N protein	Enanta	IIb	U.S.	2022/10/06	RSV for adults
AK0529	Enteric capsules	F protein	Ark Biopharmaceutical	II	China	2018/12/13	RSV for adults
EDP-938	Tablets	N protein	Enanta	II	U.S.	2021/03/25	RSV for children
EDP-323	Oral administration	RdRp (L protein)	Enanta	IIa	U.S.	2023/12/14	RSV for adults
GS-5245	Oral administration	RdRp	Gilead Sciences	II	U.S.	2024/09/05	RSV for adults
VV116	**Dry Suspension**	**RdRp**	**the Company**	**I**	**China**	**2024/03/22**	**RSV for adults**
S-337395	Injection	RdRp (L protein)	Shionogi/UBE Corporation	I	U.S.	2024/02/21	RSV for adults

Abbreviations: RdRp = RNA-dependent RNA polymerase; IFN = interferon.

Notes: The clinical trial of EDP-938 for the treatment of adult patients with RSV in the U.S. failed to meet the primary endpoint.

Source: ClinicalTrials.gov, CDE, China Insights Consultancy

COVID-19 Drugs

SARS-CoV-2, which caused the COVID-19 pandemic, is a positive-sense, single-stranded RNA virus that primarily affects the respiratory system, causing flu-like symptoms such as cough, fever, muscle pain, and difficulty in breathing. According to the WHO, there were more than 700 million cases of COVID-19 worldwide from its outbreak until 2024. Research indicates that the large-scale emergence of the COVID-19 pandemic has had a profound impact on the global economy and society, particularly in the early stages, when healthcare systems in many countries were overwhelmed by the surge in cases. This led to shortages of medical resources and delays in providing timely treatment to patients.

COVID-19 treatments worldwide fall into two main categories: large molecule neutralizing antibodies targeting the spike protein and small molecule drugs that inhibit viral replication. While neutralizing antibodies are costly, administered via injection, and often ineffective against variants like Omicron, small molecule drugs provide better clinical outcomes, affordability, and ease of administration through oral formulations. These advantages contribute to the broader adoption of small molecules among patients.

Currently, the recommended antiviral treatment of COVID-19 is still small molecule drugs. Antiviral medications, include nirmatrelvir and remdesivir, are administered to inhibit viral replication and reduce viral load. Severe cases may require a combination of antiviral drugs, corticosteroids, and immunomodulators like IL-6 inhibitors or baricitinib to manage inflammation and prevent cytokine storms. These treatments provide a multi-faceted approach to combating the disease. However, current COVID-19 treatments face limitations in efficacy, side effect risks, drug resistance, unequal access, and high costs. Additionally, viral mutations, individual variability, and complex immune responses further complicate effective treatment.

As of the Latest Practicable Date, 10 small molecule antiviral drugs had been fully approved or conditionally approved globally for COVID-19 treatment, and two fully approved for marketing in China. VV116 was the only product that has gained full marketing approval both in China and internationally. In 2023, Veklury (remdesivir) led the global market, while Paxlovid dominated the Chinese market with a 58% share. Together with other top products, the leading players accounted for nearly 100% of the sales in 2023, highlighting the concentrated nature of the competitive landscape.

Severe Fever with Thrombocytopenia Syndrome Virus Drugs

SFTSV is a segmented, negative-strand RNA virus. Its genome encodes RdRp to facilitate viral replication and transcription. The virus primarily targets human lymph nodes, leading to lymphadenopathy and necrotizing lymphadenitis, and rapidly replicates in the lymph nodes and spleen after entering systemic circulation, resulting in viremia. This triggers immune dysfunction, cytokine storms, endothelial damage, and, in severe cases, death due to bleeding or multiple organ failure.

According to The Lancet in 2024, the overall pooled infection rate of SFTSV was 18.94 per ten million people. SFTSV can be life-threatening, with an estimated case fatality rate of approximately 7.8%. Reports indicate that SFTSV is associated with a high mortality rate of up to 44.7% in cases involving organ failure and central nervous system complications, with mortality rates exceeding 20% in Japan and South Korea. Developing a treatment for SFTSV is crucial for society, as it addresses a pressing medical need for a disease currently lacking effective therapeutic options. The spread of SFTSV poses public health risks, often leading to societal and familial anxiety due to its potential to cause outbreaks.

Treatment Paradigm

Currently, general treatment of SFTSV focuses on symptom management, emphasizing lifestyle adjustments, including balanced nutrition, regular exercise, mental health support, and basic health monitoring. Complications treatment addresses specific medical issues arising from the condition, employing targeted therapies and specialized interventions. TCM offers a holistic alternative, utilizing herbal remedies, acupuncture, and balance-focused practices to enhance the body's internal harmony. Nevertheless, as of the Latest Practicable Date, there was no antiviral drug for SFTSV, and existing treatments were mainly symptomatic supportive treatment and treatment for complications. Therefore, there is a significant medical need for developing antiviral drugs for SFTSV treatment.

Treatment Paradigm of SFTSV in China

General treatment	1. **Nutritional support therapy.** Rest in bed, give easily digestible, nutritious semi-liquid or soft food, ensure calorie supply and maintain water, electrolyte and acid-based balance. 2. **Physical cooling** is given to patients with fever, and drugs can be used to reduce fever when the fever is high. 3. **Plasma and platelets** can be transfused for patients with obvious bleeding or significantly reduced platelet count (such as less than 20 x 10^9/L). 4. For severe and critical patients with progressive deterioration of the condition and over-activation of the body's inflammatory response, **glucocorticoids** should be used early and short-term as appropriate. 5. Severe and critical cases should be transferred to the **ICU** for treatment. 6. **Antiviral treatment**: Ribavirin (use with caution). Favipiravir (patients with low viral load), calcium channel blockers (Benidipine Hydrochloride and Nifedipine have a certain inhibitory effect) 7. **Glucocorticoids** are not recommended as a routine treatment for SFTS
Complications treatment	1. **Viral myocarditis**. Rest in bed and strengthen monitoring; control the intake and output, and avoid excessive fluid load; give coenzyme Q10, vitamin C and other nutritional myocardial treatments. 2. **Encephalitis**. Give symptomatic comprehensive treatment such as mannitol to reduce intracranial pressure; pay attention to airway protection and give mechanical ventilation when necessary. 3. **Secondary bacterial and fungal infections**. For those who are considered to have secondary bacterial and fungal infections, antibacterial or fungal drugs can be given empirically, and the treatment plan can be adjusted according to the drug sensitivity results.
Traditional Chinese Medicine treatment	1. **Mild.** Recommended prescription: Yin Qiao San (銀翹散). 2. **Severe.** Recommended Chinese patent medicine: Xue Bi Jing Injection (血必淨注射液). 3. **Recovery period.** Recommended prescription: Zhu Ye Shi Gao Tang (連翹竹葉石膏湯).

Abbreviations: SFTS = severe fever with thrombocytopenia syndrome.

Sources: Diagnosis and Treatment Plan for Fever with Thrombocytopenia Syndrome (2023 Edition) (發熱伴血小板減少綜合徵診療方案(2023版)), Expert Consensus on the Diagnosis and Treatment of Severe Fever with Thrombocytopenia Syndrome (2022) (重症發熱伴血小板減少綜合徵診治專家共識(2022)), China Insights Consultancy

Competitive Landscape

As of the Latest Practicable Date, no drugs have been approved for the treatment of SFTSV in China. VV261 stood out as the first and only small molecule antiviral drug for SFTSV treatment in China, which was in the Phase I clinical stage.

Competitive Landscape of Small Molecule Antiviral Drug for SFTSV Treatment in China

Candidate	MoA	Company	Clinical phase	First posted date	Indication
VV261	RdRp	the Company	I	2024/08/27	SFTSV

Sources: CDE, China Insights Consultancy

Neuropsychiatric Drugs

Neuropsychiatry focuses on psychiatric disorders related to brain dysfunction or the indirect effects of extracranial diseases, addressing affective, cognitive, and behavioral issues. Key conditions within the neuropsychiatric domain include depression, schizophrenia, epilepsy, bipolar disorder, Parkinson's disease, and Alzheimer's disease. These disorders can result from genetic, traumatic, or age-related factors, as well as external stressors such as life events, abuse, and substance use. Treatment typically combines medication with psychotherapy.

With advancements in diagnostic methods and the aging population, neuropsychiatric disorders have emerged as a significant global health challenge. According to WHO, worldwide, the number of individuals affected by these disorders was 3,497.2 million in 2023 and is projected to reach 3,997.0 million by 2035. In China, approximately 239.6 million individuals were affected in 2023, with this number expected to grow to 258.5 million by 2035. The global market for neuropsychiatric drugs was valued at US$198.5 billion in 2023, with an expected growth to US$254.0 billion by 2035. The market for neuropsychiatric drugs in China was valued at RMB 107.5 billion in 2023, and is projected to increase to RMB137.5 billion in 2035.

Current drug treatments for neuropsychiatric disorders face several significant challenges, with medication non-adherence being the most prominent. Issues including missed doses, underdosing, or premature discontinuation, significantly undermines treatment outcomes, prognosis, and functional recovery. This is especially concerning for chronic or lifelong conditions, as poor adherence leads to suboptimal symptom control, and diminished patient confidence in medications. Delayed onset, unreliable effects, and high recurrence rates are often cited as reasons why these treatments fail to meet patients' therapeutic needs. Additionally, the complexity and heterogeneity of neuropsychiatric disorders make it difficult to identify effective therapeutic targets. Moreover, common side effects such as sedation, dizziness, and gastrointestinal issues further complicate treatment, negatively affecting patients' daily lives and work, and further reducing adherence. These challenges highlight the need for safer and more effective therapies.

For medications designed to treat neuropsychiatric disorders, achieving a higher concentration in the brain while limiting distribution to peripheral tissues and organs is a key goal. Ensuring good blood-brain barrier permeability allows for effective treatment at lower doses, which helps reduce side effects and enhances patient adherence.

Anti-depression Drugs

Depressive disorder refers to a group of mental disorders characterized by a dysphoric mood and a loss of interest and pleasure, with or without illusion, delusion, and agitation symptoms. The onset of depressive disorder may drive the patients to commit suicide. According to the clinical features, the disease can be categorized into major depressive disorder, seasonal mood disorder, perinatal depression, persistent depressive disorder, and depression with psychotic symptoms.

Depression is a common and dangerous condition affecting a large population and has become a major health issue. According to GBD2021, worldwide, the number of individuals affected by these disorders was 355.3 million in 2023 and is projected to reach 399.4 million in 2035. In China, approximately 50.4 million individuals were affected in 2023, with this number expected to grow to 53.1 million in 2035.

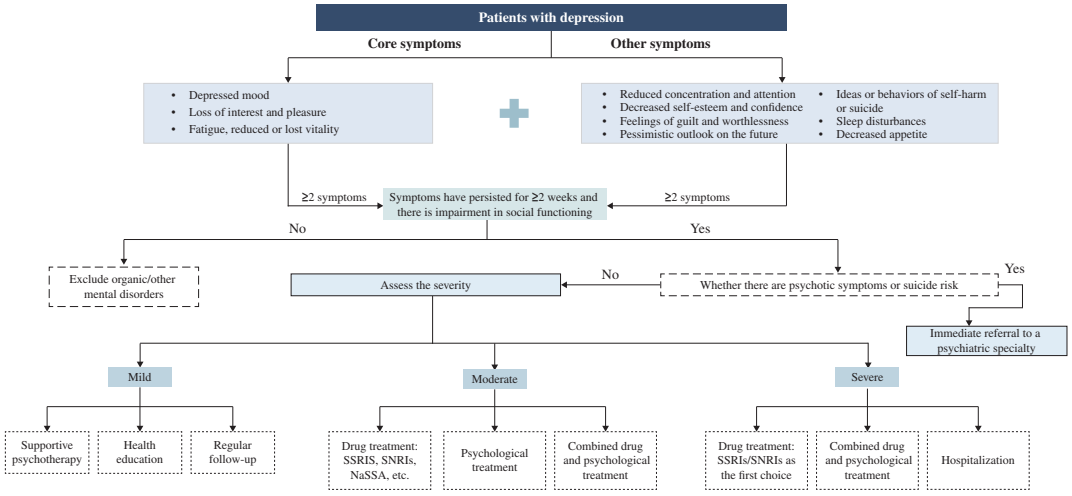
Rapid-onset treatment plays a crucial role in reducing suicide rates among individuals with depression. Traditional approaches often require weeks or months before demonstrating significant effects, leaving patients in a vulnerable state during the interim. Immediate intervention methods, such as fast-acting medications, can quickly address severe symptoms and stabilize at-risk individuals. While antidepressants are effective, one-third to half of individuals with depression do not respond to multiple antidepressants, and an even larger proportion may achieve only a partial response. Therefore, there is a pressing need to develop, evaluate, and better understand the effectiveness of new therapeutic agents or treatment modalities.

Treatment Paradigm

Depressive disorders can be treated based on their severity, categorized as mild, moderate, or severe. Mild cases may benefit from tailored interventions such as supportive psychotherapy, health education, and regular follow-up. Moderate to severe cases typically require pharmacological treatment, including SSRIs, SNRIs, or NaSSAs, with or without psychological therapy. For individuals at risk of suicide, immediate referral to a psychiatric specialist is strongly recommended.

Medication therapy is the primary treatment for depressive disorder, with various drugs approved to target neurotransmitter imbalances. First-line treatments, including escitalopram, are preferred due to their efficacy and safety in modulating 5-HT, norepinephrine, and dopamine levels. However, these drugs have notable limitations, including a delayed onset of action and a poor response in approximately 30-40% of patients undergoing first-line treatment. Second-line options, such as tricyclic antidepressants and tetracyclic antidepressants such as amitriptyline and clomipramine, are less favored due to safety concerns and poor patient compliance. Third-line treatment include monoamine oxidase inhibitors, though restricted by dietary limitations and safety issues, are used for patients who do not respond to first- and second-line treatments. Additionally, traditional Chinese medicines are approved for mild to moderate depression, and esketamine was approved for the treatment of depression in China, yet it can be abused for its hallucinogenic properties.

Treatments of Depressive Disorder in China



Abbreviations: *SSRIs = selective serotonin reuptake inhibitors; SNRIs = serotonin and norepinephrine reuptake inhibitors; NaSSA = noradrenergic and specific serotonergic antidepressants.*

Source: *Guidelines for Primary Care Diagnosis and Treatment of Depression (2021 Edition) (抑鬱症基層診療指南(2021年)), China Insights Consultancy*

There is a significant unmet medical need in the development of antidepressants. Patients with depressive disorder often struggle with poor treatment adherence and high recurrence rates, with up to 40% failing to achieve full recovery, leading to recurring symptoms. Long-term therapy is crucial for a cure, but maintaining patient compliance remains a major challenge, with interruptions often contributing to relapse. Antidepressants are also associated with severe side effects, such as gastrointestinal issues, migraines, hypertension, and sexual dysfunction, with 86% of patients reporting at least one side effect, 55% of which are considered bothersome. These side effects create a psychological burden, further diminishing compliance and hindering overall prognosis. Additionally, while antidepressants typically take several days to show therapeutic effects, side effects emerge much sooner, intensifying patient distress.

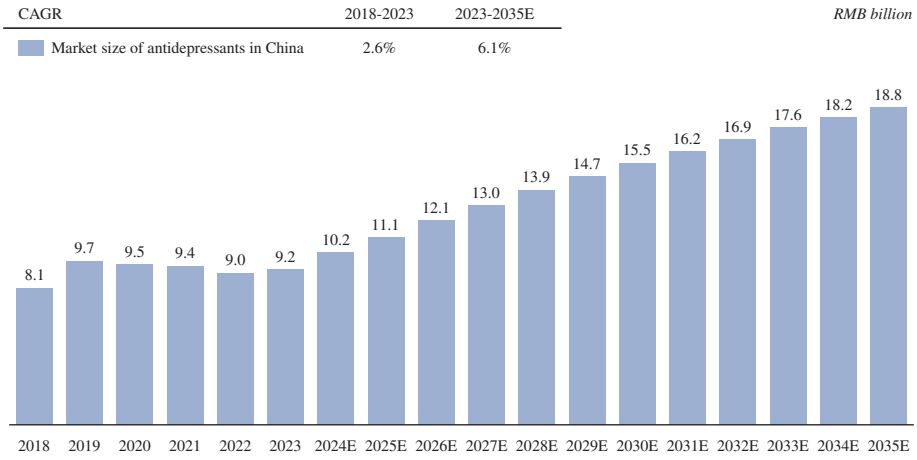
Traditional antidepressants have a slow onset of action due to the low sensitivity of 5-HT receptors. Typically, these medications begin to show effects after about two weeks, and it takes four to six weeks for their full effects to become apparent. This delay can temporarily worsen symptoms and increase both the physical and psychological burden on patients. Reducing the onset time is crucial for improving patient compliance and enhancing the efficacy of antidepressants. By inhibiting 5-HT reuptake and targeting 5-HT receptors, these medications can potentially elevate 5-HT levels in the synaptic cleft, offering faster relief of depression-related symptoms, reducing the incidence and severity of gastrointestinal side effects, thereby increasing patient compliance. Unlike traditional treatments, novel antidepressants aim to more rapidly alter the level of neurotransmitter, enabling quicker therapeutic effects.

While esketamine has the benefit of rapid onset, its association with abuse risk limits its suitability for long-term use. Esketamine is a controlled substance classified as a Schedule III drug under the DEA Controlled Substances Act. Beyond addressing abuse concerns, the safety profile of medications becomes especially critical for patients requiring extended treatment. This underscores the importance of striking a balance between safety and efficacy when selecting drug targets, ultimately fostering better patient adherence.

Market Size

The antidepressant market is projected to experience steady growth in the coming years. In China, the antidepressant market was valued at RMB8.1 billion in 2018, rising to RMB9.2 billion in 2023, reflecting a CAGR of 2.6% over the five-year period. It is anticipated to grow to RMB18.8 billion in 2035, at a CAGR of 6.1% from 2023 to 2035.

Historical and Forecasted Market Size of Drugs for Depressive Disorder in China, 2018-2035E



Note: During 2020-2023, the allocation of medical resources was impacted, particularly for the treatment of non-acute conditions. Additionally, while public awareness of mental health issues increased, market growth was hindered by disruptions in supply chains and challenges in accessing medical services during this period.

Source: Guideline for primary care of major depressive disorder, China Insights Consultancy

Competitive Landscape

As of the Latest Practicable Date, 24 innovative small molecule antidepressants had been approved for marketing in China. Additionally, there were 14 innovative small molecule antidepressants under Phase II or later stage clinical development in China. LV232, an inhibitor of 5-HTT and an antagonist of 5-HT_3 receptor, was the only product exclusively targeting both the 5-HTT and 5-HT_3 receptor, underscoring its unique mechanism of action.

Competitive Landscape of Innovative Small Molecule Antidepressants under Phase II or Later Stage Clinical Development in China

Candidate	Target	Company	Clinical phase	First posted date	Indication
Ammoxetine	NET, 5-HTT	CSPC Pharmaceutical	III	2025/01/14	Depressive disorder
JJH201501	DAT, NET, 5-HTT	Jebel Pharmaceutical	III	2024/04/09	Depressive disorder
Aticaprant	κ opioid receptor	Janssen Research & Development	III	2023/10/12	Depressive disorder
Mitizodone Phosphate	5-HT receptor, 5-HT_{1A} receptor	Sunshine Lake Pharma	II/III	2021/07/12	Depressive disorder
LV232	**5-HTT, 5-HT_3 receptor**	**The Company**	**II**	**2025/01/16**	**Depressive disorder**
ZG-001	BDNF-TrkB	Zhigen Pharmaceutical	II	2025/01/14	Adult depressive disorder with suicidal intention
NH102	5-HT_{2A} receptor, DAT, NET, 5-HTT	Nhwa Pharmaceutical	II	2024/11/01	Depressive disorder
BI1569912	GluN2B, NMDA receptor	Boehringer Ingelheim GmbH	II	2024/07/12	Depressive disorder
MI078	N/A	Minova Pharmaceutical	II	2024/07/01	Perinatal depression
SAL0114	NMDA receptor	Salubris Pharmaceutical	I/II	2024/01/15	Depressive disorder
JS1-1-01	DAT, NET, 5-HTT	Tasly Pharmaceutical	II	2023/12/04	Depressive disorder
HS-10353	GABAA receptor	Hansoh Pharmaceutical	II	2023/07/03	Perinatal depression
			II	2023/07/05	Depressive disorder
Liafensine	DAT, NET, 5-HTT	Denovo Biopharmaceutical	II	2022/07/29	Refractory depressive disorder
GW117	5-HT_{2C} receptor, MT_1/MT_2 receptor	Guangwei Pharmaceutical	II	2022/05/27	Depressive disorder

Source: CDE, China Insights Consultancy

Antiepileptic Drugs

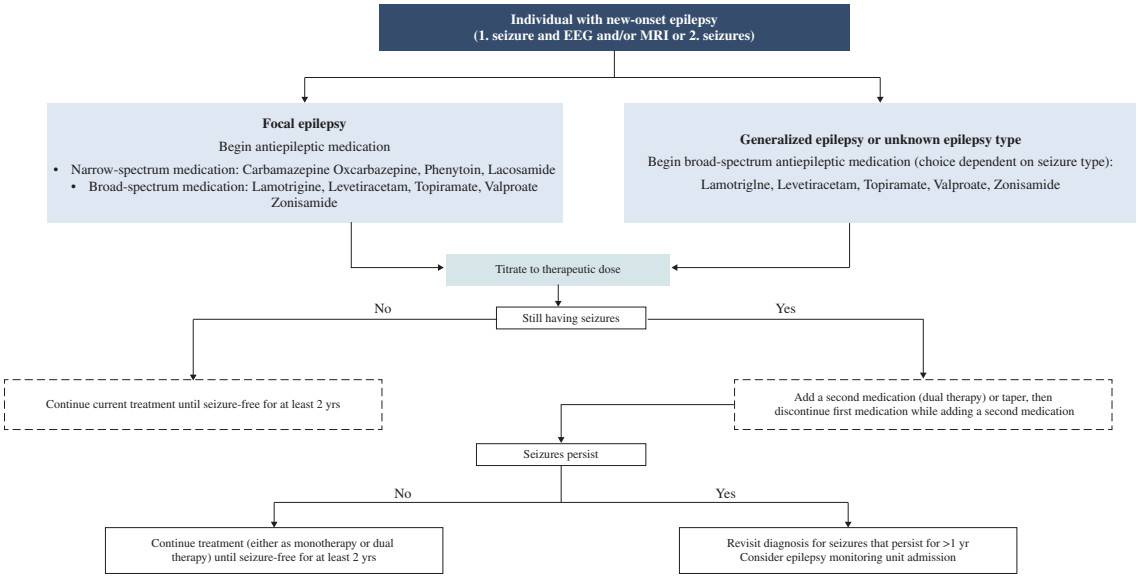
Epilepsy is a chronic neurological disorder characterized by recurrent seizures, affecting millions of people globally. In 2023, approximately 64.4 million people worldwide are living with epilepsy, and this number is expected to rise to 71.7 million by 2035. In China, approximately 10.3 million people are affected by epilepsy in 2023, with projections indicating an increase to 12.6 million in 2035. Epilepsy is often caused by an imbalance between excitatory and inhibitory states in the nervous system. During an epileptic seizure, individuals may experience involuntary convulsions in a specific part of the body or throughout the entire body (focal or generalized seizures), often accompanied by loss of consciousness and urinary or fecal incontinence. Epileptic seizures are transient clinical events caused by abnormal, excessive, and synchronized neuronal discharges in the brain. Epilepsy significantly impacts patients' daily lives, extending beyond the seizures themselves. Many individuals with epilepsy face barriers in education, employment, and social interactions due to their condition. These challenges are often compounded by coexisting mental health disorders such as anxiety and depression, which further complicate treatment and reduce quality of life.

Treatment Paradigm

The treatment pathway for epilepsy begins with the diagnosis of new-onset epilepsy, which is confirmed through seizure history and diagnostic tests. For focal epilepsy, treatment typically starts with narrow-spectrum antiepileptic medication. For generalized epilepsy or cases with an unknown type, broad-spectrum antiepileptic medications are initiated based on the specific seizure type. After a patient receives the treatment, if seizures persist, the next step is to add a second medication (dual therapy) while tapering off the first. If seizures still continue, the diagnosis is revisited, especially if seizures persist for more than a year, and admission to an epilepsy monitoring unit may be considered. If seizures are controlled, treatment is maintained (either monotherapy or dual therapy) until the patient remains seizure-free for at least two years.

The treatment of epilepsy depends on the type of seizure and involves various first-line, add-on, and other reference treatments. Among all epilepsy patients, approximately 40% are non-convulsive (primarily manifesting as absence seizures), while the rest exhibit convulsive symptoms. Of patients with convulsive symptoms, approximately one-third have generalized seizures, and two-thirds have focal seizures. For generalized seizures, first-line treatments include valproate, lamotrigine, carbamazepine, oxcarbazepine, and levetiracetam. For focal seizures, first-line treatments include carbamazepine, lamotrigine, oxcarbazepine, levetiracetam, and valproate.

Medication Treatment Paradigm of Epilepsy in China



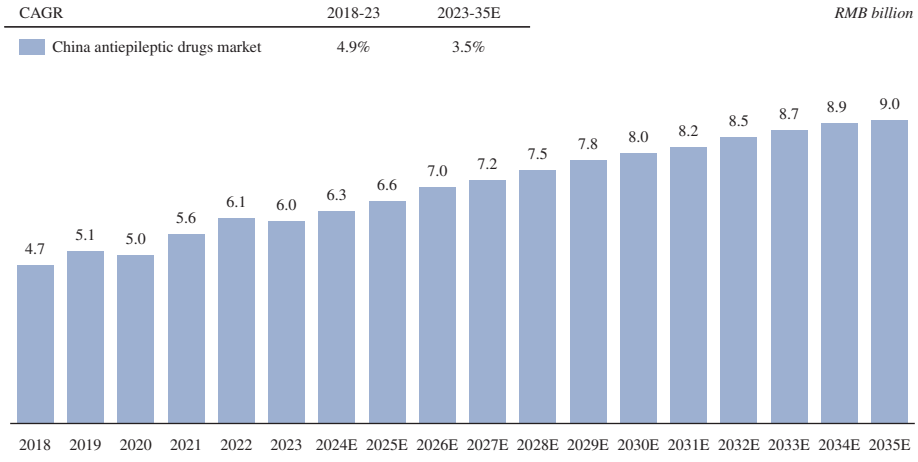
Source: New-Onset Seizure in Adults and Adolescents, Clinical Diagnosis and Treatment Guidelines Epilepsy Subsection (2023 Revised Edition) (臨床診療指南癲癇病分冊(2023修訂版)), China Insights Consultancy

Current epilepsy medications face persistent challenges, including limited efficacy and significant side effects. Antiepileptic drugs, such as phenobarbital, phenytoin, carbamazepine, and clonazepam, are associated with notable side effects such as drowsiness, dizziness, and nausea, and require strict dosage control due to numerous drug interactions. Other antiepileptic drugs, including gabapentin, lamotrigine, levetiracetam, and pregabalin, offer fewer side effects but have not substantially improved the overall efficacy or tolerability of treatment. Additionally, although 70% of epilepsy patients achieve seizure control with antiepileptic drugs, approximately 30% suffer from refractory epilepsy, where seizures remain uncontrolled despite treatment. These challenges highlight a significant unmet clinical need for the development of safer and more effective innovative therapies.

Market Size

The antiepileptic drug market is projected to experience steady growth in the coming years. In China, the market was valued at RMB4.7 billion in 2018, rising to RMB6.0 billion in 2023, reflecting a CAGR of 4.9% over the five-year period. It is anticipated to grow to RMB9.0 billion in 2035, at a CAGR of 3.5% from 2023 to 2035.

Historical and Forecasted Market Size of Antiepileptic Drugs in China, 2018-2035E



Sources: Clinical Diagnosis and Treatment Guidelines for Epilepsy (2023 Revised Edition), China Insights Consultancy

Competitive Landscape

As of the Latest Practicable Date, there were 23 innovative antiepileptic small molecules approved for marketing in China. Additionally, there were six innovative small molecule antiepileptic drugs under development in China.

Competitive Landscape of Innovative Small Molecule Antiepileptic Drugs under Clinical Development in China

Candidate	Company	Clinical phase	First posted date	Indication
TAK-935	Takeda Pharmaceutical	III	2022/05/16	Treatment of seizures associated with Dravet syndrome or Lennox-Gastaut syndrome in patients 2 years of age and older
派恩加演片 (Pynegabine)	Hainan Haiyao	II	2024/04/23	Focal epilepsy in patients who are refractory to or intolerant of other antiepileptic medications
TPN102	**The Company**	**I**	**2020/03/17**	**Epilepsy**
WX0005	Harbin Pharmaceutical Group	I	2020/05/25	Intended for the treatment of epilepsy
Phenzolzine capsule	Jilin Yinglian Shangde	I	2021/04/19	Tonic-clonic seizures, absence seizures, and temporal lobe epilepsy
NS-041	Neushen Therapeutics	I	2024/11/29	Epilepsy

Note: TAK-935 failed to achieve two of the primary endpoints in a Phase III clinical trial.

Sources: CDE, China Insights Consultancy

Antipsychotic Drugs

Schizophrenia is a severe mental disorder characterized by disturbances in perception, emotion, cognition, and behavior, typically emerging in young adulthood and often resulting in lifelong suffering. In 2023, schizophrenia affected 24.6 million people globally, with the number expected to reach 30.3 million in 2035. In China, the condition affected 15.2 million people in 2023, with projections indicating 18.0 million in 2035. The disorder presents with positive symptoms such as hallucinations, delusions, and thought disturbances, as well as negative symptoms including social withdrawal, emotional blunting, and lack of motivation. While the precise causes remain unclear, schizophrenia is believed to arise from a combination of genetic, neurodevelopmental, neurobiochemical, and social psychological factors.

Treatment Paradigm

Antipsychotic drugs are the preferred treatment for schizophrenia. They can be generally divided into conventional and atypical drugs. Conventional antipsychotic drugs primarily target D_2 receptor, while atypical antipsychotic drugs target multiple receptors, including those for dopamine and 5-HT, to offer a broader range of targets and improved efficacy in modulating neurotransmitter balances. Atypical antipsychotic drugs are now considered first-line treatments due to their better efficacy and safety profiles. In addition to medication, electroconvulsive therapy and modified electroconvulsive therapy are also recommended treatments, particularly during the acute phase. Psychological and social interventions are also recommended to help patients reintegrate into society and regain social skills.

Treatment Paradigm of Schizophrenia in China

Medication Therapy	• **Antischizophrenic drugs are the preferred treatment of schizophrenia.** As the course of schizophrenia can be roughly divided into acute phase, stable phase, and recovery phase with different clinical manifestation and treatment target, the medication therapy for schizophrenia should be performed and watched by professional medical expertise in order to reach the best therapeutical effect.
Physiotherapy	• **Electroconvulsive therapy (ECT) and modified electroconvulsive therapy (MECT) have been proved to be effective to schizophrenia patients, especially those who are at an acute phase.** Some clinical evidence also suggested that transcranial magnetic simulation (TMS) and deep brain stimulation (DBS) may be an effective therapeutical method, which requires further clinical trials to validate.
Psychological and Social Intervention	• Though the mental symptoms of schizophrenia may be relieved through medication therapies and physiotherapies, it is also important to reestablish the patients' social abilities. **Psychological and social interventions are considered as an effective way for the patients to return to normal social life.**

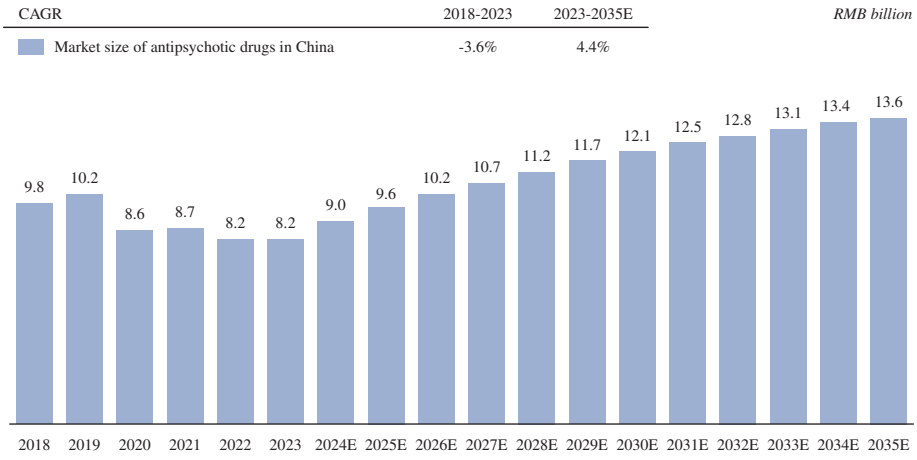
Sources: Psychiatry, China Insights Consultancy

Current treatments for schizophrenia primarily rely on antipsychotic medications, which effectively alleviate positive symptoms such as hallucinations and delusions but have limited impact on negative symptoms, including social withdrawal, emotional blunting, and cognitive impairments. Moreover, long-term use of these medications carries risks of severe side effects, such as metabolic disturbances and movement disorders, resulting in poor patient adherence and an increased risk of relapse. Consequently, there is an urgent need for safer and more effective therapies that comprehensively address multiple dimensions of the disorder.

Market Size

The antipsychotic drug market is projected to experience steady growth in the coming years. In China, the market was valued at RMB8.2 billion in 2023 and is anticipated to grow to RMB13.6 billion in 2035, at a CAGR of 4.4% from 2023 to 2035.

Historical and Forecasted Market Size of Antipsychotic Drugs in China, 2018-2035E



Note: During 2020-2023, the allocation of medical resources was impacted, particularly for the treatment of non-acute conditions. Additionally, while public awareness of mental health issues increased, market growth was hindered by disruptions in supply chains and challenges in accessing medical services during this period.

Sources: Lancet psychiatry, China Insights Consultancy

Competitive Landscape

As of the Latest Practicable Date, 22 innovative antipsychotic small molecules had been approved for marketing in China. Additionally, there were 16 innovative small molecule antipsychotic drugs under clinical development in China.

Competitive Landscape of Innovative Small Molecule Antipsychotic Drugs under Clinical Development in China

Candidate	Target	Company	Clinical phase	First posted date	Indication
BI 425809	GlyT1	Boehringer Ingelheim International	III	2021/04/01	Schizophrenia
KarXT	M_1/M_4 receptor, mACh receptor	Zai Lab/Karuna Therapeutics	III	2023/04/23	Schizophrenia
SIPI6398	5-HT_{1A} receptor, 5-HT_{2A} receptor, D_2 receptor	Zhongze Therapeutics	II	2023/10/27	Schizophrenia
HS-10380	5-HT_{1A} receptor, D_2 receptor, D_3 receptor	Hansoh Pharmaceutical	II Ib/II	2024/04/19 2023/06/19	Schizophrenia at acute phase Schizophrenia
NHL35700	PDE10A	Nhwa Pharmaceutical	II	2024/04/02	Schizophrenia
JX11502MA	5-HT_{1A} receptor, 5-HT_{2A} receptor, D_2 receptor	Jingxin Pharmaceutical	II	2024/05/13	Adult schizophrenia
CY150112	DRD3	Nhwa Pharmaceutical	Ib	2022/01/18	Schizophrenia
Pomaglumetad methionil	mGluR2 and mGluR3	Denovo Biopharma	I	2019/10/18	Schizophrenia
MK-8189	PDE10A	MSD International	I	2021/10/19	Schizophrenia
TPN672	5-HT_{1A} receptor, 5-HT_{2A} receptor, D_2/D_3 receptor	Kanion Pharmaceutical	I	2022/07/11	Schizophrenia
VV119	**D_2 receptor, D_3 receptor, 5-HT_{1A} receptor, 5-HT_{2A} receptor, 5-HTT**	**The Company**	**I**	**2023/10/18**	**Schizophrenia**
NH300231	5-HT_{2A} receptor, DRDs	Nhwa Pharmaceutical	I	2024/01/02	Schizophrenia
HS-10509	N/A	Hansoh Pharmaceutical	I	2024/02/27	Schizophrenia
LPM526000133	N/A	Luye Pharma Group	I	2024/05/06	Schizophrenia with negative symptoms
LPM787000048	5-HT_{2C} receptor and TAAR1	Luye Pharma Group	I	2024/08/13	Schizophrenia
NS-136	M_4 receptor	Neushen Therapeutics	I	2024/11/12	Schizophrenia

Sources: CDE, China Insights Consultancy

Reproductive Health Drugs

Reproductive health conditions affect both male and female reproductive systems, with a wide range of disorders. In women, common conditions include polycystic ovary syndrome, endometriosis, infertility, cervicitis, and sexually transmitted infections. For men, reproductive health issues primarily involve andrology-related disorders such as ED, PE, BPH, oligospermia, and azoospermia. ED, in particular, can lead to psychological distress, diminished self-esteem, and relationship challenges, while also potentially indicating underlying cardiovascular or metabolic issues. PE significantly impacts sexual satisfaction and overall quality of life. Chronic urinary symptoms associated with BPH can disrupt daily activities and sleep, progressively increasing the risk of urinary retention and further reducing quality of life.

The market size of reproductive disease drug global market was US$78.2 billion in 2023 and is projected to remain relatively stable, with a slight increase to US$78.4 billion in 2035. The reproductive drug market in China has shown significant growth, driven by increased awareness of reproductive health, rising drug penetration, and higher household income levels. With economic development and improved patient affordability, more people can access and afford reproductive health medications. As such, in China, the reproductive disease drug market was valued at RMB34.2 billion in 2023, and is projected to reach RMB39.8 billion in 2035.

PDE5 Inhibitors

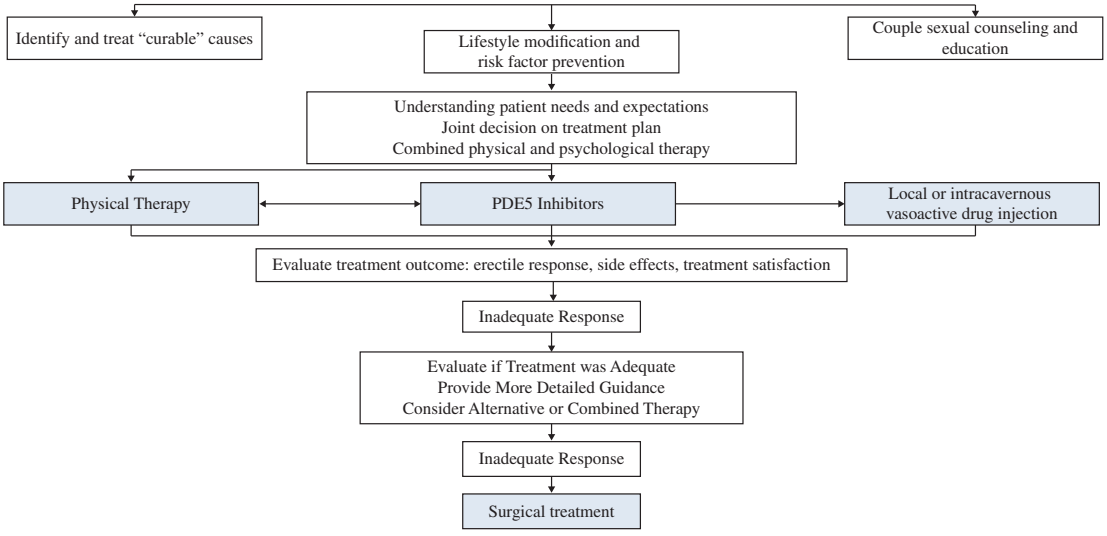
PDE5 inhibitors work by inhibiting phosphodiesterase type 5, increasing cyclic guanosine monophosphate levels in cavernoma smooth muscle, enhancing nitric oxide-mediated vasodilation, thereby improving erectile function. They are the first-line medication for ED treatment with a Grade A recommendation.

The global market size of PDE5 inhibitors was US$10.0 billion in 2023 and is projected to remain relatively stable, with a slight increase to US$10.1 billion in 2035. In China, the PDE5 inhibitor market was valued at RMB9.3 billion in 2023. With the expanded medical insurance coverage, improved healthcare channels, and rising disposable income, the market size of PDE5 inhibitor is projected to reach RMB15.2 billion in 2035.

Treatment Paradigm for ED

The treatment of ED involves a comprehensive approach, starting with identifying and treating any curable underlying causes, such as diabetes or hypertension. Lifestyle modifications, including improved diet, increased physical activity, and reduced alcohol or smoking, are recommended to address risk factors. Couple sexual counseling and education are provided to address emotional and relational aspects, while treatment plans are tailored to the patients' needs, preferences, and expectations through shared decision-making. A combined approach of physical therapies, such as PDE5 inhibitors and vasoactive drug injections, alongside psychological support is often utilized. If treatment response is inadequate, further evaluation is necessary, with consideration for alternative therapies or combined treatments. In some cases, surgical options may be explored.

Treatment Paradigm for ED in China



Sources: The Chinese Society of Andrology's Guidelines for the Diagnosis and Treatment of ED, China Insights Consultancy

PDE5 inhibitors remain to be the first-line treatment of ED and are the most commonly prescribed medication for this condition. However, many of the marketed PDE5 inhibitors, including sildenafil, tadalafil, and vardenafil, exhibit high inhibitory activity on PDE6 and PDE11, leading to significant adverse effects in patients. Recorded side effects include back pain, muscle pain, headache, upper abdominal discomfort, nasal congestion, flushing, vision blurred, dizziness and palpitation. Due to the safety concerns, special considerations are included in the drug specifications to warn their use in patients with renal or hepatic impairment. However, as a lifestyle medication, a compound used to treat ED is expected to meet heightened safety requirements. This highlights a significant opportunity for the development of new PDE5 inhibitors with improved safety profiles to better meet patient needs.

Competitive Landscape for ED Treatment

As of the Latest Practicable Date, the FDA approved four PDE5 inhibitors for the treatment of ED: sildenafil from Pfizer, vardenafil from Bayer, tadalafil from Eli Lilly, and avanafil from Metuchen. In China, the NMPA approved these four PDE5 inhibitors as well as aildenafil from Youcare Pharmaceutical Group for ED treatment. Sildenafil and tadalafil dominate the market, holding the majority of market share both in China and globally in 2023.

As of the Latest Practicable Date, there were seven PDE5 inhibitors under development for ED treatment in China. TPN171 stood out as one of the two product candidates that submitted NDA applications.

Competitive Landscape of PDE5 Inhibitor for ED Treatment under Clinical Development in China

Candidate	MoA	Company	Clinical phase	First posted date	Indication	Single/ Combo
TPN171	**PDE5i**	**the Company**	**NDA**	**2024/03/01**	**ED**	**Single**
Youkenafil Hydrochloride	PDE5i	Yangtze River Pharmaceutical	NDA	2024/01/30	ED	Single
TPN729MA	PDE5i	Topfond Pharmaceutical	III	2022/10/09	ED	Single
Fadanafil	PDE5i	Xuanzhu Bio	II	2021/08/10	ED	Single
DDCI-01	PDE5i	Chongqing Dikangerle Pharmaceutical	II	2023/11/21	LUTS secondary to BPH with ED	Single
cms203	PDE5i	Shandong Lukang Pharmaceutical	II	2023/12/25	ED	Single
Xiongdenafil Citrate	PDE5i	Suzhou Maidixian Pharmaceutical	I	2019/07/30	ED	Single

Sources: CDE, China Insights Consultancy

CHINA GENERIC DRUG INDUSTRY

To enhance competition and increase drug accessibility, generic drugs are introduced to the market. In order to obtain marketing approval, generic drugs must demonstrate they are as safe and effective as the brand-name drug, achieving both pharmaceutical equivalence and clinical equivalence. Pharmaceutical equivalence means that the active ingredients, dosage form, strength, route of administration, and labeling of the generic drug must match those of the brand-name drug. For oral formulations, clinical equivalence is typically demonstrated through bioavailability studies. This requires that the rate and extent of drug absorption in the body (as measured by C_{max} and AUC) for the generic fall strictly within the range of 80% to 125% of the brand-name drug.

The size of the generic drug market in China decreased from RMB703.9 billion in 2018 to RMB654.3 billion in 2023, due to disruptions in supply chains and challenges in accessing medical services. It is expected to grow at a CAGR of 0.9% from 2023 to 2035, reaching RMB724.6 billion by 2035.

Growth Drivers and Future Trends

To foster competition in the pharmaceutical sector, the Chinese government has introduced several policies designed to promote the development of high-quality generic drugs. One such policy grants a market exclusivity period to the first chemical generic drug that successfully challenges a patent and is approved for marketing. During this period, the drug regulatory authority will not approve any other generic versions of the same drug for 12 months, except in cases of joint patent challenges. This exclusivity is limited to the original patent term of the challenged drug. Furthermore, China's centralized volume-based procurement ("**VBP**") initiative aims to reduce drug prices by purchasing drugs that have passed consistency evaluations in bulk, which helps lower patient costs and drive industry development. For companies selected in the VBP process, drug sales volumes are guaranteed by national and provincial governments, enabling cost reductions through economies of scale. This not only minimizes marketing and sales expenses but also allows generic drug manufacturers to manage costs and preserve profit margins.

Dapoxetine Hydrochloride

Dapoxetine hydrochloride is indicated for the treatment of PE symptoms in men aged 18 to 64 years. PE is a common form of male sexual dysfunction, characterized by a short intravaginal ejaculatory latency time, lack of control over ejaculation, sexual satisfaction issues, and relationship difficulties with a partner. In China, the PE market was valued at RMB1,523.6 million in 2023 and is projected to reach RMB3,536.8 million by 2035, growing at a CAGR of 7.3%.

PE treatment typically involves three main approaches: pharmacological therapy, behavioral therapy, and sexological psychological interventions. Given the complex etiology and symptomatology of PE, pharmacological therapy is often combined with psychological and behavioral interventions for more effective management. For patients with PE, addressing other conditions such as ED, sexual dysfunctions, or urogenital infections (e.g., prostatitis) is also recommended. Dapoxetine hydrochloride and local anesthetics are considered first-line treatment options for PE.

Our major competitors include both national and regional manufacturers of dapoxetine hydrochloride, as well as an international pharmaceutical company. The table below provides a description of their business scopes and respective market shares:

Ranking	Company	Headquarter	Market Share	Scope of Business	Product Description
1	Group A	Shandong, China	30.0%	the research and development, production and sales of anti-tumor drugs, cardiovascular and cerebrovascular drugs, diabetes drugs, dermatology drugs, gynecological disease drugs, and biological drugs	Tablet, 30mg
2	Group B	Berlin, Germany	17.0%	the production and sale of high-quality pharmaceutical products, mainly in the fields of gastroenterology, pain management, cardiovascular diseases, biologics and oncology	Tablets, 30mg, brand name drug
3	Group C	Sichuan, China	15.0%	the research and development, production and sales of products, mainly in anesthesia and analgesia, central nervous system, anti-infection, parenteral nutrition and other fields	Tablets, 60mg
4	Group D	Jiangsu, China	14.0%	the production and sale of tablets, hard capsules, granules, suppositories, and APIs, mainly in the fields of urinary system, antihistamines, cardiovascular, steroid hormones and antibiotics	Tablets, 30mg
5	Group E	Henan, China	6.7%	the production, sales and pharmaceutical operation of finished preparations, chemical synthesis APIs and biological fermentation APIs, mainly in antibiotics, cardiovascular and cerebrovascular diseases, diabetes and other fields	Tablets, 30mg
Others			**17.3%**		
Total			**100%**		

Sources: China Insights Consultancy

Rebamipide

Rebamipide is a medication commonly prescribed to treat gastrointestinal disorders such as PUD, gastritis, and Helicobacter pylori infection. It has been shown to increase gastric mucosal prostaglandins, inhibit the production of the superoxide anion radical, scavenge the hydroxyl radical, suppress the production of inflammatory cytokines, and reduce gastric mucosal inflammatory cell infiltration. The market size for rebamipide was valued at RMB901.8 million in 2023, with projections indicating growth to RMB1,505.5 million by 2035, reflecting a CAGR of 4.4%.

PUD is a disease defined by a localized defect in the gastric or duodenal mucosa, typically due to an imbalance between protective factors and aggressive elements such as gastric acid and pepsin, often linked to *Helicobacter pylori* infection or NSAID use. Gastritis, characterized by inflammation of the gastric mucosa, can be acute or chronic, with chronic gastritis most commonly caused by *Helicobacter pylori* infection.

The treatment goals for PUD include eliminating the underlying cause, such as eradicating *Helicobacter pylori* or discontinuing NSAIDs, relieving symptoms, promoting ulcer healing, preventing recurrence, and avoiding complications. For chronic gastritis, the focus is on addressing the root cause, alleviating symptoms, improving the health of the gastric mucosa, enhancing the patient's quality of life, and preventing relapses or complications. The primary treatment for both conditions involves pharmacotherapy, supplemented by dietary and lifestyle modifications.

Our major competitors include both national and regional manufacturers of rebamipide, as well as an international pharmaceutical company. The table below provides a description of their business scopes and respective market shares:

Ranking	Company	Headquarter	Market Share	Scope of Business	Product Description
1	Group F	Zhejiang, China	54.5%	the R&D, production and sale of drugs in digestion field	Tablets, 0.1g
2	Group G	Tokyo, Japan	35.5%	the R&D, production and sale of nutraceuticals (nutrition and pharmaceuticals) and cosmedics (cosmetics and medicine)	Tablets, 0.1g, brand name drug
3	Group H	Chongqing, China	10.0%	the R&D, production and sale of APIs and pharmaceutical preparations, mainly in cardiovascular, nervous system, anti-infection and other categories	Tablets, 0.1g
Others					
Total			**100%**		

Sources: China Insights Consultancy

REPORT COMMISSIONED BY CHINA INSIGHTS CONSULTANCY

In connection with the [**REDACTED**], we have engaged China Insights Consultancy Limited to conduct a detailed analysis and prepare an industry report on the small molecule drug market in China and globally. China Insights Consultancy Limited is an independent global market research and consulting company which was founded in 2014 and is based in Shanghai. Services provided by China Insights Consultancy Limited include market assessments, competitive benchmarking and strategic and market planning for a variety of industries. The contract sum to China Insights Consultancy Limited is RMB500,000 for the preparation of the CIC Report. The payment of such amount was not contingent upon our successful [**REDACTED**] or on the results of the CIC Report. Except for the CIC Report, we did not commission any other industry report in connection with the [**REDACTED**]. We have included certain information from the CIC Report in this document because we believe such information facilitates an understanding of the small molecule drug market for potential [**REDACTED**]. China Insights Consultancy Limited prepared its report based on its in-house database, independent third-party reports and publicly available data from reputable industry organizations. Where necessary, China Insights Consultancy Limited contacts companies operating in the industry to gather and synthesize information in relation to the market, prices and other relevant information. China Insights Consultancy Limited believes that the basic

assumptions used in preparing the CIC Report, including those used to make future projections, are factual, correct and not misleading. China Insights Consultancy Limited has independently analyzed the information, but the accuracy of the conclusions of its review largely relies on the accuracy of the information collected. China Insights Consultancy Limited research may be affected by the accuracy of these assumptions and the choice of these primary and secondary sources.

The market projections in the commissioned report are based on the following key assumptions: (i) the overall social, economic and political environment in the global economy is expected to remain stable during the forecast period; (ii) relevant key drivers are likely to maintain a steady growth trend over the next decade; (iii) increasing number of drug penetration, increasing amount of R&D expenditures, increasing patient affordability, etc.

Our Directors, after taking reasonable care, confirm that to the best of their knowledge, there is no material adverse change in the market information since the date of the relevant data contained in the CIC Report and up to the Latest Practicable Date which may qualify, contradict or have an impact on the information in this section.