

## INDUSTRY OVERVIEW

### 1. OVERVIEW OF PEPTIDE DRUG MARKET

Peptide drugs are composed of a defined sequence of amino acids, typically possessing a molecular weight ranging from 500 to 5,000 Daltons. They function by acting as agonists or antagonists of endogenous peptides or proteins, exerting their therapeutic effects through high-affinity and high-specificity binding to biological targets.

The global peptide drug market has grown from USD61.7 billion in 2019 to USD109.6 billion in 2024 with a CAGR of 12.2%, and is estimated to reach USD233.8 billion by 2030, at a CAGR of 13.5%. Given the advantages of peptide drugs, their clinical applications will further expand to multiple areas such as cardiovascular diseases, tumors, and immune regulation. The peptide drug market in China has experienced an accelerated growth trend due to favorable policies, increasing treatment demand and technological iteration and upgrading. The peptide drug market in China has grown from RMB53.9 billion in 2019 to RMB60.2 billion in 2024, at a CAGR of 2.3%, and is estimated to reach RMB165.2 billion by 2030, at a CAGR of 18.3% during this period.

#### Market Drivers of Peptide Drug Market

***Vast and unmet therapeutic demand created by the pandemic of chronic diseases:*** According to WHO, the global obese population has exceeded one billion and is closely linked to an increased risk of developing numerous conditions, including type 2 diabetes and certain cancers. Peptide drugs, exemplified by GLP-1 agonists, have, for the first time, achieved safe and effective weight loss comparable to bariatric surgery through pharmacological means, addressing this immense market need. Concurrently, the aging of the global population has led to a continuous expansion of the patient base for related chronic conditions such as osteoporosis, providing a stable foundational market for peptide drugs.

***The advent and development of multi-target peptides:*** Compared with single-target peptides, multi-target peptides can simultaneously act upon multiple intrinsically linked targets within a disease, producing synergistic effects that hold promise for enhanced efficacy and safety. For instance, Eli Lilly's dual-target peptide, tirzepatide, has demonstrated significant clinical and commercial value in the fields of glucose control and weight reduction. Compared to single-target drugs, dual- or triple-target GLP-1 agonists demonstrate a 30-50% improvement in weight loss efficacy.

***Innovation in oral formulation development:*** The emergence and commercialization of oral formulations have marked a breakthrough in the field of peptide therapeutics, which significantly enhance patient convenience and treatment compliance. Unlike conventional peptide delivery methods, such as intravenous injection or intramuscular injection, which often require professional medical supervision or frequent clinic visits, oral peptide formulations enable patients to administer medications independently in the comfort of their homes.

### 2. OVERVIEW OF METABOLIC DISEASE DRUG MARKET

Metabolic diseases refer to a series of diseases caused by disorders of substance metabolism in the body (such as carbohydrates, lipids, proteins, purines, etc.). Disorders of substance metabolism in the body can damage organs such as the kidneys; if this condition persists for a long time, it may lead to organ failure, which in turn can induce or exacerbate diseases like chronic kidney disease. Common metabolic diseases include chronic kidney disease, obesity and being overweight, metabolic dysfunction-associated steatohepatitis, and other conditions.

Metabolic diseases represent one of the most significant global healthcare challenges. Approximately 1.2 million people worldwide die directly from CKD each year, with mortality rates among elderly patients ( $\geq 65$  years) being 3 to 5 times higher than in the general population. Obesity and being overweight, a major risk factor for both diabetes and cardiovascular diseases, affected 2.6 billion people globally in 2020, and contributed an estimated US\$1.96 trillion to the global economy in healthcare costs. As the prevalence of these diseases continues to rise, the global burden grows, imposing increasing strain on healthcare systems and economies worldwide.

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Driven by the rising health awareness and expenditure, aging population and growing clinical demand, as well as advancements in disease diagnosis, both global and China metabolic disease drug markets are experiencing a growth trend. The metabolic diseases drug market in China has seen a general growth trend, increasing from US\$13.3 billion in 2019 to US\$16.4 billion in 2024 at a CAGR of 4.3%, and is projected to reach US\$29.3 billion by 2030 at a CAGR of 10.2% from 2024 to 2030, and US\$41.3 billion by 2035 at a CAGR of 7.1% from 2030 to 2035 presenting a higher growth rate than the global metabolic diseases drug market. The global metabolic disease drug market grows from US\$106.3 billion in 2019 to US\$145.4 billion in 2024 at a CAGR of 6.5%, and is projected to reach US\$209.6 billion by 2030 at a CAGR of 6.3% from 2024 to 2030, and US\$232.8 billion by 2035 at a CAGR of 2.1% from 2030 to 2035.

### Overview of Chronic Kidney Disease (CKD) Market

#### *Introduction of CKD*

Chronic kidney disease (CKD) is a group of chronic diseases centered on abnormalities in renal structure or function. Its diagnostic criteria are renal damage or a decrease in glomerular filtration rate (GFR) lasting for 3 months or longer. The core feature of CKD is a progressive decline in renal function, which prevents the kidneys from normally performing key tasks such as excretion of metabolic waste products, regulation of water and electrolyte balance, and endocrine functions. Common etiologies include diabetic nephropathy, hypertensive nephropathy, primary glomerulonephritis, and polycystic kidney disease, among which diabetes and hypertension are the primary driving factors for the global incidence of CKD. Clinically, CKD is classified into stages 1 to 5 based on GFR levels. In stage 1, renal function is basically normal; stage 5 is end-stage renal disease, where patients need to rely on dialysis or renal transplantation to sustain life. CKD not only affects the kidneys themselves but also causes systemic multisystem complications, such as renal anemia, secondary hyperparathyroidism (SHPT), and cardiovascular diseases (e.g., heart failure, arteriosclerosis). Among these, SHPT is particularly common in patients with CKD in middle and advanced stages, seriously endangering patients' quality of life and lifespan.

The global prevalence of chronic kidney disease grew from 905.2 million in 2019 to 1,065.5 million in 2024 at a CAGR of 3.3%, and is projected to reach 1,289.7 million by 2030 and 1,505.1 million by 2035. In China, the prevalence of chronic kidney disease grew from 149.2 million in 2019 to 161.5 million in 2024 at a CAGR of 1.6%, and is projected to reach 175.0 million by 2030 and 185.8 million by 2035.

#### *Market drivers of CKD drugs market*

Market drivers of CKD drug market include the following:

- *Synergistic Effects of Increasing Prevalence and Population Aging.* The prevalence of chronic kidney disease (CKD) is continuously rising, attributable to the high incidence of metabolic disorders such as diabetes mellitus and hypertension, as well as the impacts of unhealthy lifestyles. Coupled with the occult nature of early-stage CKD symptoms, this has escalated the actual burden of diagnosis and treatment. The acceleration of population aging has led to an increase in the proportion of the elderly population with age-related natural decline in renal function, and elderly patients are more prone to comorbid chronic diseases. The superposition of these two factors has rendered the elderly a high-risk group for CKD, and the complexity of their conditions has also elevated the difficulty of diagnosis and treatment as well as the consumption of medical resources.
- *Innovations and Breakthroughs in Diagnostic and Monitoring Technologies.* Innovations in diagnostic and monitoring technologies have optimized the diagnostic and therapeutic workflow of CKD. Artificial intelligence algorithms can accurately identify early signs of renal injury, enhancing diagnostic precision; portable testing devices have facilitated the screening of renal function; the integration of smart wearable devices with telemedicine has enabled real-time monitoring of renal function parameters, furnishing data support for early screening and personalized diagnosis and treatment.

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- *Transformation of Chronic Disease Management Models.* The management model of CKD has shifted from end-stage treatment to full-cycle comprehensive management. The hierarchical diagnosis and treatment system has optimized the allocation of medical resources, digital tools have improved patients' treatment adherence, and the multidisciplinary collaboration model has provided integrated diagnostic and therapeutic services for patients, effectively decelerating the progression of CKD.

### *Entry barriers of CKD drug market*

Entry barriers of CKD drug market include the following:

- *Technical Barriers.* CKD features a complex pathogenesis, and drug research and development requires target design for multiple pathological processes such as renal fibrosis and metabolic disorders, imposing extremely high demands on pharmaceutical enterprises' basic research capabilities and target development technologies. Clinical trials need to enroll large samples of patients across different disease stages, with long follow-up periods and great difficulty in controlling confounding factors. In addition, enterprises producing mainstream existing drugs have established a full-chain patent system covering compounds, processes and indications, forming a technical monopoly, and new entrants are prone to intellectual property disputes.
- *Policy Barriers.* Drug regulatory authorities worldwide implement high standards for the approval of CKD drugs, requiring the provision of clear clinical benefits and comprehensive safety data. The approval process for innovative drugs takes 3-5 years or even longer, and the technical difficulty of consistency evaluation for generic drugs is high. Meanwhile, medical insurance access requires passing strict economic evaluations; drugs not included in the medical insurance catalog have extremely low market accessibility due to high out-of-pocket expenses for patients. Hospital procurement tends to favor mature brands, and new drugs face long cycles of academic promotion and access, further raising the policy threshold.
- *Financial Barriers.* CKD drug research and development is characterized by long cycles and high failure rates, with huge financial investment required only in the clinical trial phase. The production end needs to construct GMP-compliant production lines, entailing high upfront fixed costs. Meanwhile, after the launch of new drugs, continuous capital investment is necessary for market promotion through academic conferences, real-world studies and other means. Enterprises lacking sufficient financial strength are unable to break through this barrier.

### **Overview of Chronic Kidney Disease-Mineral and Bone Disorder (CKD-MBD) Market**

#### *Introduction of CKD-MBD*

Chronic kidney disease-mineral and bone disorder (CKD-MBD) is a common complication in CKD patients, characterized by mineral metabolism disorders, bone metabolism and structural abnormalities, as well as vascular and other soft tissue calcifications. It represents a systemic manifestation of multisystem involvement during CKD progression. Patients with CKD-MBD may experience bone pain, deformities, and increased fracture risk in the skeletal system, while children may also exhibit growth retardation. The cardiovascular system experiences accelerated atherosclerosis and elevated blood pressure due to vascular calcification, triggering coronary heart disease, heart failure, and even sudden death — a major contributor to elevated cardiovascular mortality risk. Additionally, soft tissue calcification causes localized pain, while hyperparathyroidism exacerbates metabolic imbalance, creating a vicious cycle that significantly increases disability rates and mortality while severely compromising quality of life and survival prognosis. The NHANES study found that CKD-MBD patients with serum phosphorus  $\geq 4.5$  mg/dL had a 28% increase in all-cause mortality and a 57% increase in cardiovascular mortality. The CORES study showed that CKD patients with serum calcium  $< 9.5$  mg/dL or  $> 10.5$  mg/dL both experienced elevated all-cause mortality.

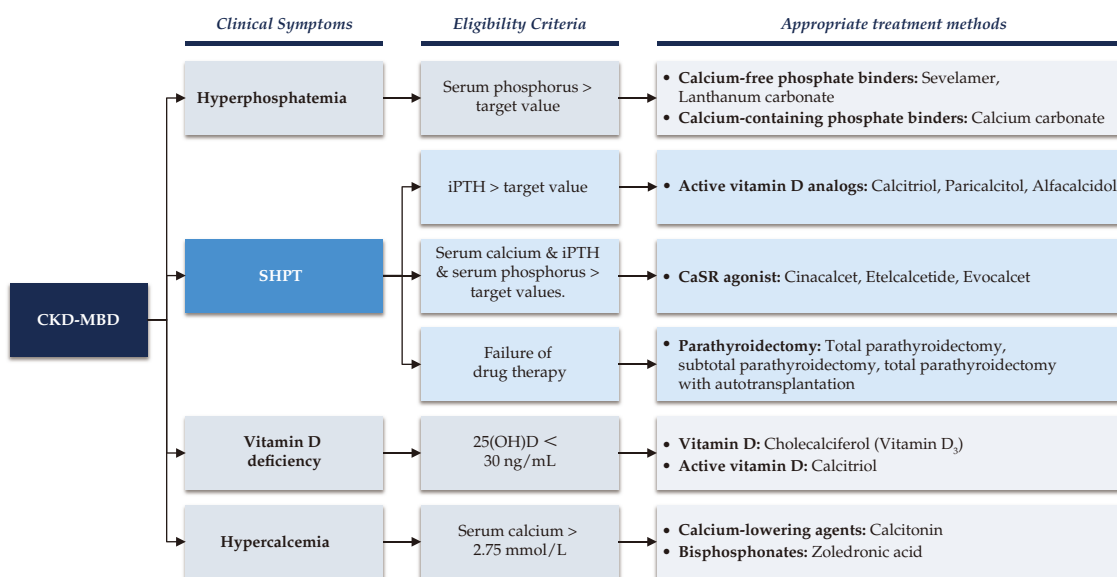
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The global prevalence of CKD-MBD grew from 282.9 million in 2019 to 333.0 million in 2024, and is projected to reach 403.0 million by 2030 and 470.3 million by 2035. The prevalence of CKD-MBD in China grew from 46.1 million in 2019 to 49.9 million in 2024, and is projected to reach 54.1 million by 2030 and 57.4 million by 2035.

### *Main treatment of CKD-MBD*

The treatment of CKD-MBD is a comprehensive regimen centered on correcting calcium-phosphorus metabolism imbalance and inhibiting hyperparathyroidism, mainly consisting of basic nutritional and lifestyle interventions, pharmacotherapy, and surgical treatment. Basic nutritional intervention serves as the foundation for treatment across all stages of CKD-MBD. Dietary adjustments such as phosphorus control and rational calcium supplementation can slow the progression of metabolic disorders, with high safety profile, yet excessive intervention may lead to malnutrition or hypercalcemia. Pharmacotherapy is the core therapeutic approach. Among phosphate binders, calcium-containing preparations rapidly lower serum phosphorus but are prone to inducing hypercalcemia and vascular calcification, while non-calcium-containing preparations are the clinical first choice with low calcium load, though associated with risks of gastrointestinal discomfort or mild metal accumulation. Vitamin D analogs can inhibit PTH secretion, with selective analogs exerting less impact on calcium-phosphorus metabolism. The CaSR agonist is indicated for patients with moderate to severe SHPT, but it tends to cause hypocalcemia and gastrointestinal symptoms. Surgical treatment is targeted at patients with severe SHPT refractory to medical therapy, which can rapidly reduce iPTH levels and alleviate symptoms of renal osteodystrophy, however, it carries perioperative risks such as bleeding and nerve injury, and hypocalcemia is common postoperatively. The following is the CKD-MBD treatment paradigm:

### Treatment Paradigm of CKD-MBD



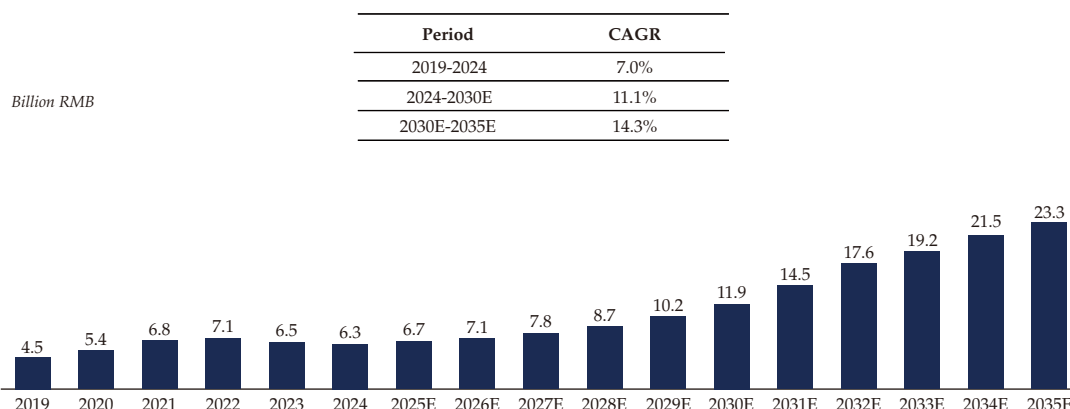
*Source: Chinese guidelines for the diagnosis and treatment of mineral and bone disorders in chronic kidney disease, Frost & Sullivan Report*

### *Market size of CKD-MBD drugs*

In 2024, the market size of CKD-MBD drugs in China reached RMB6.3 billion. It is estimated that the market size will reach RMB11.9 billion by 2030 and RMB23.3 billion by 2035, with the CAGR of 11.1% and 14.3%, respectively, during the period.

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### CKD-MBD drug market in China, 2019-2035



*Source: Frost & Sullivan analysis*

In 2024, the global number for SHPT patients and CKD-MBD patients reached 157 million and 333 million respectively. By 2030, those figures are forecasted to increase to 190 million and 403 million respectively. Given the limited existing treatment options, those patient groups are facing significant unmet clinical needs. With the advancement in drug research and development, the new generation of therapies not only effectively control iPTH and improve overall compliance rates but also significantly reduce the incidence of hypocalcemia, offering superior safety profiles. For instance, our MT1013, as a novel therapeutic agent, demonstrates excellent overall compliance rates for iPTH, serum calcium, and serum phosphorus levels. It exhibits superior control of iPTH compared to existing CaSR agonist on the market. The global SHPT treatment and CKD-MBD treatment markets are poised to yield blockbuster drugs with annual sales reaching billions of US dollars in the coming years. Those segments are forecasted to grow at a CAGR of over 15% and 10% from 2024 to 2030 respectively.

#### ***Main treatment of Secondary Hyperparathyroidism (SHPT)***

In the early stages, SHPT can be effectively managed with medical therapy. For example, phosphorus binding agents, vitamin D and its analogs, and calcium-sensitive receptor agonists can control the patient’s parathyroid hormone levels to some extent in the early stages of the disease.

Phosphorus binding agents inhibit parathyroid cell proliferation by rapidly lowering blood phosphorus levels, which in turn reduces parathyroid hormone levels. Vitamin D and its analogs regulate calcium and phosphorus metabolism and inhibit parathyroid hormone production by inhibiting osteoclasts, promoting osteoblasts, and intestinal calcium absorption. CaSR agonists inhibit parathyroid hormone production by increasing the sensitivity of calcium-sensitive receptors to extracellular calcium and binding to receptor variants.

The potential for severe gastrointestinal reactions, drug-drug interactions, and side effects such as hypercalcemia and hyperphosphatemia greatly reduce patient compliance, while increased drug resistance further reduces efficacy as the patient’s disease progresses. Surgical intervention is still needed for patients who fail drug therapy or have advanced SHPT, with parathyroidectomy being the main surgical procedure.

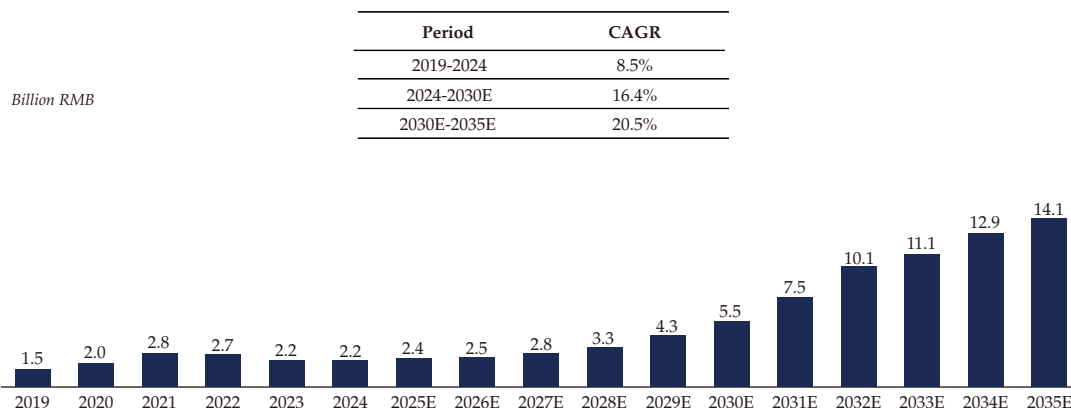
#### ***Market size of SHPT drugs***

From 2019 to 2021, the market size of SHPT drugs in China grew from RMB1.5 billion to RMB2.8 billion, showing rapid growth. However, with the successive launch of generic versions of SHPT treatment drugs and the implementation of the National Centralized Drug Procurement, the market size of China’s SHPT drugs dropped to RMB2.2 billion by 2024.

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Along with the successive approval of peptide-based CaSR agonists — characterized by better adherence, higher safety, and suitability for a wider range of patients — and their inclusion in the NRDL, the penetration rate of CaSR agonist drugs will further increase, driving the rapid growth of China's SHPT drug market. It is estimated that the market size will reach RMB5.5 billion by 2030 and RMB14.1 billion by 2035, with the CAGR of 16.4% and 20.5%, respectively, during the period.

### SHPT drug market in China, 2019-2035



Source: Frost & Sullivan Report

### Competitive landscape of CaSR agonist

As of the latest practicable date, there are two CaSR agonist drugs approved by FDA.

#### Global competitive landscape of CaSR agonist

Target	Drug Name	Brand Name	Company	Indication	Dosage Form	Approval Date
CASR	Etelcalcetide	Parsabiv	Amgen	SHPT	Injection	2017-02-07
CASR	Cinacalcet	Sensipar	Amgen	SHPT, Hypercalcemia	Oral	2004-03-08

Source: FDA, Frost & Sullivan Analysis

As of the latest practicable date, there are three CaSR agonist drugs approved by NMPA.

#### Competitive landscape of CaSR agonist in China

Target	Drug Name	Brand Name	Company	Indication	Dosage Form	Annual Treatment Cost (thousand RMB)	NRDL Status	Market share in 2024 (by revenue)	Approval Date
CASR	Evocalcet	Orkedia	Kyowa Kirin	SHPT	Oral	24.1	Not Included	0.0%	2024-07-30
CASR	Etelcalcetide	Parsabiv	Amgen	SHPT	Injection	43.7	Not Included	0.4%	2023-05-06
CASR	Cinacalcet	Sensipar	Amgen	SHPT, Hypercalcemia	Oral	5.9	List B	99.6%	2014-08-21

Source: FDA, NMPA, Frost & Sullivan Analysis

As of the latest practicable date, there are five CaSR agonist drug candidates for SHPT in the clinical stage globally.

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### Global competitive landscape of CaSR agonist pipelines

Target	Drug Code	Company	Dosage Form	Regulatory Authorities	Clinical Stage	Latest Update Date
CASR	Upacicalcet	Pathalys Pharma	Oral	FDA	Phase III	2025-09-09
CASR	Evocalcet	Kyowa Kirin	Oral	FDA	Phase III	2022-04-25
CASR, OGP	MT1013	Shaanxi Micot Pharmaceutical Technology	Injection	NMPA	Phase III	2025-10-09
				FDA	Phase I	2022-07-29
CASR	SHR-6508	Hengrui Pharmaceutical	Injection	NMPA	Phase III	2025-12-27
CASR	ASP7991	Astellas Pharma	Oral	FDA	Phase II	2024-11-06

*Source: ClinicalTrials.gov, CDE, Frost & Sullivan Analysis*

## Overview of Overweight and Obesity Market

### Introduction of Overweight and Obesity

Overweight and obesity are chronic diseases characterized by excessive fat accumulation that poses risks to health. These conditions are the major contributors to various other health issues, such as diabetes and cardiovascular diseases. The commonly used measure for assessing overweight and obesity is the Body Mass Index (BMI), calculated as weight (kg) divided by height squared (m<sup>2</sup>). According to international standards set by the World Health Organization and the National Institutes of Health, a BMI of 25 kg/m<sup>2</sup> or higher is considered overweight, while a BMI of 30 kg/m<sup>2</sup> or higher defines obesity. In China, the official guidelines suggest that a BMI between 24 kg/m<sup>2</sup> and 28 kg/m<sup>2</sup> indicates overweight, while a BMI of 28 kg/m<sup>2</sup> or higher indicates obesity.

The global prevalence of overweight and obesity patients grew from 2,197.7 million in 2019 to 2,612.5 million in 2024 at a CAGR of 3.5%, and is projected to reach 3,070.6 million by 2030 and 3,477.2 million by 2035. In China, the prevalence of overweight and obesity increased from 548.0 million in 2019 to 640.5 million in 2024 at a CAGR of 3.2%, and is projected to reach 756.5 million by 2030 and 860.5 million by 2035.

### Main treatment of Overweight and Obesity

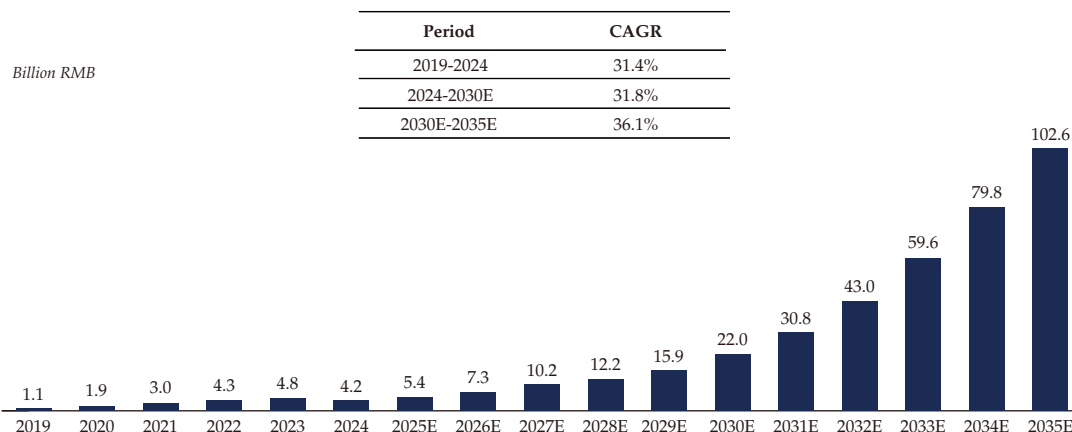
Currently, the treatment for overweight and obesity focuses on reducing and maintaining body weight, as well as managing any associated diseases and complications. A differentiated approach is typically used, depending on the degree of obesity. For patients who are overweight but do not have obesity-related conditions, weight control is primarily achieved through lifestyle interventions such as diet and exercise. For patients whose health condition process from overweight to obese, medication may be added alongside with lifestyle interventions to support weight loss. Surgery is considered a last resort, which is used for patients who are extremely obese and have no effective responses to other treatments. The current standard of care includes orlistat and GLP-1-based therapies (e.g., liraglutide, semaglutide, and tirzepatide). GLP-1 RAs are established as first-line treatments for obesity or overweight management due to their dual efficacy in glycemic control and weight reduction.

Currently, the primary GLP-1 drugs worldwide are semaglutide (a GLP-1 single-target agonist) and tirzepatide (a GIP/GLP-1 dual-target agonist). Although both drugs demonstrate significant weight-loss effects, they still face numerous limitations in clinical application. Semaglutide is associated with gastrointestinal side effects, and weight loss is accompanied by some muscle loss. Long-term medication is required for maintenance, and weight rebound occurs after discontinuation. Tirzepatide demonstrates superior weight loss efficacy compared to semaglutide, but it also exhibits a higher incidence of gastrointestinal side effects, greater muscle loss, and faster weight rebound after discontinuation than semaglutide.

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In 2024, the overweight and obesity drug market in China reached RMB4.2 billion. It is estimated that the overweight and obesity drug market in China will grow to RMB22.0 billion in 2030 and RMB102.6 billion in 2035, with a CAGR of 31.8% from 2024 to 2030 and 36.1% from 2030 to 2035 respectively.

### Overweight and obesity drugs market in China, 2019-2035



*Source: Frost & Sullivan Report*

### Market drivers and future trends of GLP1R polypeptide drugs market

Market drivers and future trends of GLP1R polypeptide drugs market include the following:

- **Large unmet clinical needs.** The prevalence of obesity and overweight has been rising rapidly among both children/adolescents and senior adults across China and globally, due to modern lifestyle factors such as excessive calorie intake and insufficient physical activity. Currently, a number of GLP-1R drugs have been approved; however, there are still many unmet clinical needs, including muscle loss after weight loss, severe rebound and deterioration of body composition profile after discontinuation of treatment, as well as the failure to fully address various comorbidities commonly associated with clinically obese patients.
- **Rising awareness for obesity and overweight management.** The rising public awareness regarding the health risks associated with obesity and overweight has led to a surge in demand for effective obesity and overweight management solutions. In particular, the younger generations, who are increasingly impacted by obesity and overweight, are showing a greater willingness to engage in weight management treatments.
- **Multi-targeted GLP-1 peptide drugs become mainstream.** Multi-targeted drugs have become the core track of competition among global pharmaceutical companies by activating multiple metabolism-related receptors (e.g., GLP-1R, GIPR, GCGR) at the same time to achieve synergistic efficacy and optimization of side effects. The multi-target GLP1-related peptide drugs of many companies have proved to be more effective than single-target drugs, and multi-target GLP1-related peptide drugs are expected to occupy a dominant position in the market.
- **Indications for expansion.** The earliest GLP-1 drugs were only indicated for hypoglycemic therapy in diabetic patients. With clinical exploration and the unmet needs of the large number of obese patients, the indications of GLP-1 peptide drugs have gradually expanded to include metabolic diseases such as obesity, CKD with albuminuria and MASH. According to *Prevalence of Chronic Kidney Disease in China*, more than 80% of CKD patients present with albuminuria. According to Guideline for Primary Care Diagnosis, Treatment and

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Management of Metabolic Associated Fatty Liver Disease (MAFLD) (2025), China has over 40 million MASH patients, yet current medications only provide symptomatic relief with limited efficacy. GLP-1 peptides possess the potential to address these unmet clinical needs and have emerged as one of the most significant therapeutic approaches in the field of metabolic diseases.

### Overview of MASH

Metabolic Associated Steatohepatitis (MASH), a severe subtype of metabolic associated fatty liver disease (MASLD), featured by hepatic fat accumulation, inflammation and fibrosis, is closely linked to obesity and type 2 diabetes. It may progress to cirrhosis and hepatocellular carcinoma and elevate cardiovascular risk, imposing heavy health and social burdens. In China, MASH patients increased from 37.1 million in 2019 to 44.0 million in 2024, and are projected to reach 53.7 million by 2030 and 63.1 million by 2035. Current treatments comprise lifestyle intervention as first-line therapy, targeted pharmacotherapies and liver transplantation for end-stage patients. However, existing regimens are constrained by poor patient compliance, limited drug coverage and lack of approved therapies for advanced cirrhosis, while unclear pathogenesis and non-standard liver biopsy evaluation also restrict drug development and precise care.

### Competitive landscape of GLP1R polypeptide drugs

As of the latest practicable date, there are 13 triple-target GLP1R peptide drug candidates for overweight and obesity in the clinical stage globally. Among these, 11 drug candidates target GLP-1R, GCGR, and GIPR, while one drug targets GLP-1R, GCGR, and FGF21. XTL6001, our GLP1R drug candidate, is the only triple-target GLP-1R peptide drug candidate targeting GLP-1R, GCGR, and MASR. Agonizing MasR can increase protein synthesis and preserve muscle mass. XTL6001 holds the potential to eliminate the side effect of muscle loss associated with GLP-1R agonists during weight loss.

### Global competitive landscape of triple-target GLP1R peptide drugs pipelines

Target	Drug Code	Company	Indication	Regulatory Authorities	Clinical Stage	Latest Update Date
GLP1R, GCGR, MASR	XTL6001	Shaanxi Micot Pharmaceutical Technology	Overweight & Obesity, CKD with proteinuria	NMPA	Phase I	2025-07-03
			Overweight & Obesity	FDA	IND	2024-12-20
GLP1R, GCGR, GIPR	Retatrutide	Eli Lilly	Overweight & Obesity, Diabetes Type 2, Chronic Low Back Pain, ASCVD, CKD, Obstructive Sleep Apnea, Osteoarthritis	FDA	Phase III	2026-03-06
			MASLD	NMPA	Phase III	2025-12-18
	LY4086940	Eli Lilly	Overweight & Obesity, Diabetes Type 2	FDA	Phase I	2025-08-27
			Overweight & Obesity	NMPA	Phase I	2024-07-08
	Efocipegtrutide	Hanmi Pharmaceutical	Overweight & Obesity, NAFLD	FDA	Phase I	2025-03-25
	HM15275		Overweight & Obesity	FDA	Phase I	2025-05-22
	UBT251	Federal Biotechnology	Overweight & Obesity, Type 2 diabetes, MASH, CKD with proteinuria	NMPA	Phase II	2025-11-19
		Novo Nordisk	Overweight & Obesity	FDA	Phase II	2026-02-17
	ZX2021	Jiangsu Kanion Pharmaceutical	Overweight & Obesity	NMPA	Phase II	2025-06-18
	MWN101	Lepu Medical Technology	Type 2 diabetes, Overweight & Obesity	NMPA	Phase II	2025-01-23
	MWN109		Overweight & Obesity	NMPA	Phase II	2026-03-09
			Overweight & Obesity	FDA	Phase I	2025-11-20
	SAR441255	Sanofi	Type 2 diabetes, Overweight & Obesity	NMPA	Phase I	2026-02-08
Overweight			FDA	Phase I	2022-04-25	
HEC-007	HEC Pharmaceutical	Type 2 diabetes, Overweight & Obesity	NMPA	Phase I	2025-08-04	
HRS-4729	Hengrui Pharma	Overweight & Obesity	NMPA	Phase I	2025-01-24	
GLP1R, GCGR, FGF21	MWN105	Lepu Medical Technology	Overweight & Obesity	NMPA	Phase II	2025-09-05
			Type 2 diabetes, Overweight & Obesity	NMPA	Phase I	2024-12-27

Source: [clinicaltrials.gov](https://clinicaltrials.gov), CDE, Frost & Sullivan analysis

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### 3. OVERVIEW OF THE ANTITHROMBOTIC DRUG MARKET

#### Antithrombotic therapy for pan-vascular diseases

Pan-vascular diseases are a group of systemic vascular disorders characterized by shared pathological features of vascular abnormalities, with atherosclerosis accounting for 95% of cases. These diseases primarily affect critical organs such as the heart, brain, kidneys, limbs, and major arteries. Based on the affected vascular, pan-vascular diseases may manifest as: coronary artery diseases (CAD), cerebrovascular disease, peripheral artery disease (PAD), combinations involving two or more vascular territories (multi-vascular disease). Antithrombotic therapy is a cornerstone of management for pan-vascular diseases, primarily consisting of antiplatelet therapy and anticoagulant therapy.

#### *Overview of acute coronary syndrome (ACS) and percutaneous coronary intervention (PCI)*

Acute coronary syndrome (ACS), a type of coronary heart disease (CHD), refers to a group of conditions that include ST-elevation myocardial infarction (STEMI), non-ST elevation myocardial infarction (NSTEMI), and unstable angina. ACS is related to sudden reduced blood flow to the heart.

Percutaneous coronary intervention (PCI) is a non-surgical, invasive procedure with a goal to relieve the narrowing or occlusion of the coronary artery and improve blood supply to the ischemic tissue. This is usually achieved by different methods, the most common being ballooning the narrow segment or deploying a stent to keep the artery open.

From 2019 to 2024, the incidence of ACS worldwide increased from 23.3 million to 26.1 million, representing a compound annual growth rate of 2.3%. It is estimated that by 2030 and 2035, the incidence of ACS worldwide will reach 29.1 million and 31.4 million, respectively. From 2019 to 2024, the incidence of ACS in China increased from 4.5 million to 5.1 million, representing a compound annual growth rate of 2.6%. It is estimated that by 2030 and 2035, the incidence of ACS in China will reach 5.8 million and 6.3 million, respectively.

From 2019 to 2024, the volume of PCI procedures worldwide increased from 6.7 million to 9.9 million, representing a compound annual growth rate of 8.1%. It is estimated that by 2030 and 2035, the volume of PCI procedures worldwide will reach 15.6 million and 21.7 million, respectively. From 2019 to 2024, the volume of PCI procedures in China increased from 1.0 million to 1.9 million, representing a compound annual growth rate of 13.7%. It is estimated that by 2030 and 2035, the volume of PCI procedures in China will reach 4.0 million and 6.0 million, respectively.

#### *Main perioperative treatment of PCI in ACS*

Although PCI has become increasingly technically mature, throughout the entire procedure related medical devices may cause damage to both the access vessel and the coronary artery, potentially leading to severe complications that threaten patient life. To prevent in-stent thrombosis, patients are required to undergo antithrombotic therapy, which includes dual antiplatelet therapy (DAPT) before and after PCI, intraoperative heparin-based anticoagulation, and the use of **glycoprotein IIb/IIIa inhibitors (GPIs)** when necessary. Long-term clinical observations and numerous existing clinical studies have confirmed that one of the most important causes of in-stent thrombosis following PCI is inadequate antiplatelet therapy or premature discontinuation of dual antiplatelet therapy.

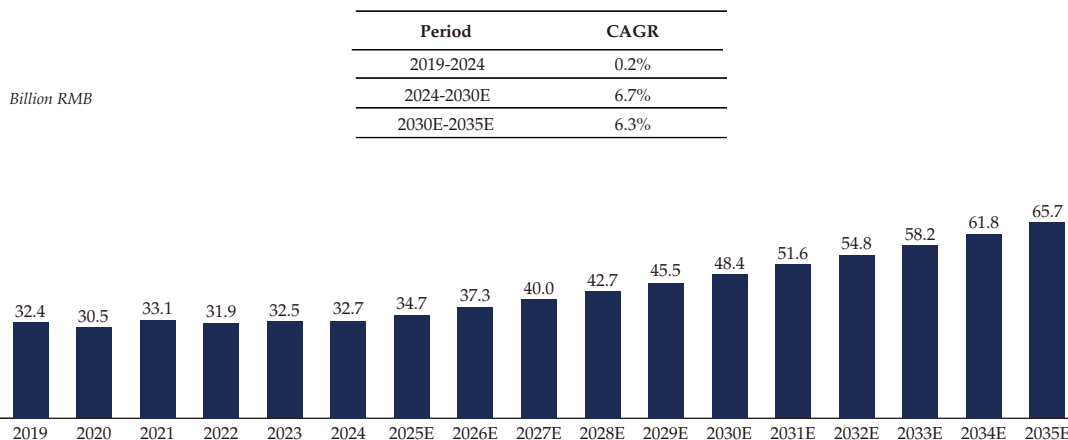
#### *Market size of antithrombotic drugs in China*

Antithrombotic drugs are pharmacological agents used for the prevention and treatment of thromboembolic diseases. They function to reduce the formation of blood clots in arteries and veins or to promote the dissolution of already-formed thrombi. Antithrombotic agents primarily include anticoagulant drugs, antiplatelet drugs, and thrombolytic drugs.

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In 2024, the antithrombotic drugs market in China reached RMB32.7 billion. It is estimated that the antithrombotic drugs market in China will grow to RMB48.4 billion in 2030 and RMB65.7 billion in 2035, with a CAGR of 6.7% from 2024 to 2030 and 6.3% from 2030 to 2035, respectively.

### Market Size and Forecast of Antithrombotic Drugs in China, 2019-2030E



*Source: Expert Interview; Frost & Sullivan Report*

### Market drivers and future trends of antithrombotic drugs market

Market drivers and future trends of antithrombotic drugs market include the following:

- **High Incidence of Cardiovascular Diseases.** Cardiovascular diseases (CVDs) are among the leading causes of mortality worldwide, encompassing conditions such as coronary artery disease (CAD), myocardial infarction (MI), and stroke. The pathogenesis of these diseases is closely associated with thrombosis, where vascular occlusion by blood clots leads to ischemia and hypoxia in myocardial or cerebral tissues, resulting in severe clinical outcomes. With the accelerating progression of global population aging, the incidence and prevalence of CVDs continue to rise steadily, according to the *Report on Cardiovascular Health and Diseases in China 2024*, the incidence of CVDs and cerebrovascular diseases among Chinese residents reached 8.7 million in 2023, and the projected incidence and mortality rates of CVDs in China are expected to rise continuously over the period from 2020 to 2030, driving an increasing demand for antithrombotic therapies. Globally, CAD stands as one of the principal contributors to mortality, necessitating long-term antithrombotic medication for numerous patients to prevent disease progression and recurrence.
- **Advancements in Interventional Therapies.** The continuous development and widespread adoption of cardiovascular interventional procedures such as PCI and heart valve replacement surgeries — have significantly improved the treatment outcomes for patients with cardiovascular diseases. Nevertheless, these interventions are associated with a heightened risk of thrombosis during and after the procedures, necessitating the use of antithrombotic agents for both prophylaxis and therapeutic management. This has driven the expanded application of antithrombotic therapies in the field of interventional cardiology and contributed to the growth of their market demand.

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- Optimization of Combination Therapy Strategies.** In recent years, pharmaceutical companies have intensively invested in R&D to develop novel antithrombotic agents with enhanced efficacy and reduced adverse effects. Researchers have been actively exploring optimized combination regimens of different antithrombotic drugs to improve therapeutic outcomes while minimizing side reactions. Rational drug combinations, innovative single-target therapies, and multi-target combination approaches can simultaneously intervene in multiple pathophysiological pathways of thrombosis formation. These advancements not only provide more effective treatment options for patients but also drive the diversified development of the antithrombotic drug market.
- Innovative Drug Targets and Mechanisms.** Thrombosis involves complex interactions among the coagulation system including thrombin, platelet activation including GPIIb/IIIa receptor and P2Y<sub>12</sub> receptor, and the fibrinolytic system. Given that single-target agents struggle to comprehensively address all pathological procedures, dual-target and multi-mechanism drugs have emerged as hotspots in drug development. For instance, bifunctional antagonists simultaneously target both coagulation and platelet function such as dual-target agents against factor II and GPIIb/IIIa, along with innovative therapeutics combining anticoagulant and anti-inflammatory effects, represent key future directions in antithrombotic drug innovation.

### Competitive landscape of PCI drugs

PCI drugs are primarily used in patients with ACS who are scheduled to undergo PCI. As of the latest practicable date, there were three drugs with an indication for PCI approved by NMPA and three drugs with an indication for PCI approved by FDA.

#### Global competitive landscape of PCI drugs

Target	Drug Name	Brand Name	Company	Indication	Regulatory Authorities	Approval date
GPIIb/IIIa	Bevifibatide	Betagrin	Bio-Thera	• Perioperative antithrombotic therapy for PCI	NMPA	2024-06-25
P2RY12	Cangrelor	Kengreal	CHIESI	• Adjunct to PCI	FDA	2015-06-22
GPIIb/IIIa	Eptifibatide*	NA	Hansoh Pharmaceutical etc.	• ACS patients who are scheduled to undergo PCI	NMPA	2012-10-30
Thrombin	Argatroban	Argatroban	Plano Pharmaceuticals	• HIT; Adult patients with or at risk for HIT undergoing PCI	FDA	2011-05-09
Thrombin	Bivalirudin*	NA	Salubris Pharmaceuticals etc.	• Patients undergoing PTCA or PCI	NMPA	2011-01-01
		Angiomax	Sandoz	• Patients undergoing PCI	FDA	2000-12-15

\*Abbreviations: HIT = heparin-induced thrombocytopenia; PTCA = Percutaneous Transluminal Coronary Angioplast

\*Note: The original drug of Eptifibatide (Integrilin) discontinued manufacturing based on a supply issue with eptifibatide, the active pharmaceutical ingredient in Integrilin. In China, eptifibatide is only approved as a generic drug, with approved manufacturers including Hybio Pharmaceutical Co., Ltd., Beijing SL Pharmaceutical Co., Ltd., Shenyang Shuangding Pharmaceutical Co., Ltd., among others. Bivalirudin is only approved in China as a generic drug, with approved manufacturers including Shenzhen Salubris Pharmaceuticals Co.,Ltd., Yangzijiang Pharmaceutical Group Co., Ltd., among others.

Source: NMPA, FDA, Frost & Sullivan Analysis

## INDUSTRY OVERVIEW

As of the latest practicable date, there were ten PCI drug candidates for in the clinical stage globally.

### Global Competitive Landscape of PCI Drugs Pipeline

Target	Drug Code	Company	Indication	Regulatory Authorities	Clinical Stage	Latest Update Date
GPIIb/IIIa	MT1002	Shaanxi Micot Pharmaceutical Technology	<ul style="list-style-type: none"> <li>Anticoagulation therapy and antithrombotic therapy for ACS patients undergoing PCI;</li> <li>ACS patients undergoing PCI with HIT or HITT</li> </ul>	NMPA	Phase II	2024-05-11
			<ul style="list-style-type: none"> <li>ACS patients undergoing PCI</li> </ul>	FDA	Phase I	2019-08-08
P2RY12	Vicagrel	Jiangsu vcare pharmaceutical	<ul style="list-style-type: none"> <li>Patients with ACS undergoing PCI</li> </ul>	FDA	Phase III	2024-10-01
	DT678	Beijing SL Pharmaceutical	<ul style="list-style-type: none"> <li>Antiplatelet therapy in patients following PCI</li> </ul>	NMPA	Phase II	2026-01-04
	PRT060128	Portola Pharmaceuticals	<ul style="list-style-type: none"> <li>Non-urgent PCI</li> </ul>	FDA	Phase II	2023-08-08
	HY-022619	Hefei medical and Pharmaceutical	<ul style="list-style-type: none"> <li>Antiplatelet therapy in the perioperative treatment of PCI in patients with ACS</li> </ul>	NMPA	Phase I	2026-01-28
	CG-0255	Shanghai CureGene Pharmaceutical	<ul style="list-style-type: none"> <li>Antiplatelet therapy in the perioperative treatment of PCI in patients with ACS</li> </ul>	NMPA	Phase I	2026-03-04
	Cangrelor	Jiangsu Aosaikang Pharmaceutical	<ul style="list-style-type: none"> <li>Antithrombotic therapy in the perioperative treatment of PCI in patients with ACS</li> </ul>	NMPA	Phase I	2019-07-30
LIAS, LIPT1, SLC5A6	CMX-2043	Ischemix, LLC	<ul style="list-style-type: none"> <li>Patients undergoing PCI and Perioperative reperfusion treatment</li> </ul>	FDA	Phase II	2011-06-20
CDH5	FX06	Biopure Corporation	<ul style="list-style-type: none"> <li>Ischemia reperfusion injury in patients undergoing PCI</li> </ul>	FDA	Phase II	2007-12-04
/	SBK009	Chengdu Shibeikang Biopharmaceutical	<ul style="list-style-type: none"> <li>Antiplatelet therapy in the perioperative treatment of PCI in patients with ACS</li> </ul>	NMPA	Phase I	2025-12-23

\*Abbreviations: HIT = heparin-induced thrombocytopenia; HITT=heparin-induced thrombocytopenia with thrombosis

Source: *ClinicalTrials.gov, CDE, Frost & Sullivan Analysis*

#### 4. OVERVIEW OF NEUROLOGICAL DISEASES DRUG MARKET

##### Overview of Ischemic Stroke Market

Ischemic stroke is the most common type of stroke, accounting for about 70%-80% of strokes. It is caused by the sudden reduction or interruption of blood supply to the brain, resulting in ischemia and hypoxia, necrosis and softening of brain tissues, and triggering neurological dysfunction. Ischemic stroke is mainly caused by atherosclerosis, cardiogenic embolism, small blood vessel occlusion, etc., which manifests as weakness of one side of the limb, speech disorder, crooked mouth and other symptoms.

Acute ischemic stroke should be treated promptly within the time window, intravenous thrombolysis can be performed within 4.5 hours, and endovascular thrombolysis can be performed within 6 hours in case of large-vessel occlusion, and antiplatelet, plaque stabilization, etc. are required at the same time. The use of neuroprotective agents can reduce ischemia-induced nerve cell damage and protect brain tissue function. Long-term control of hypertension, diabetes and other risk factors is needed to prevent recurrence.

The global prevalence of ischemic stroke grew from 62.2 million in 2019 to 81.3 million in 2024 at a CAGR of 5.5%, and is projected to reach 105.8 million by 2030 and 127.4 million by 2035. In China, the prevalence of ischemic stroke grew from 17.6 million in 2019 to 22.6 million in 2024 at a CAGR of 5.1%, and is projected to reach 28.9 million by 2030 and 35.1 million by 2035.

## INDUSTRY OVERVIEW

### *Main treatment of Ischemic Stroke*

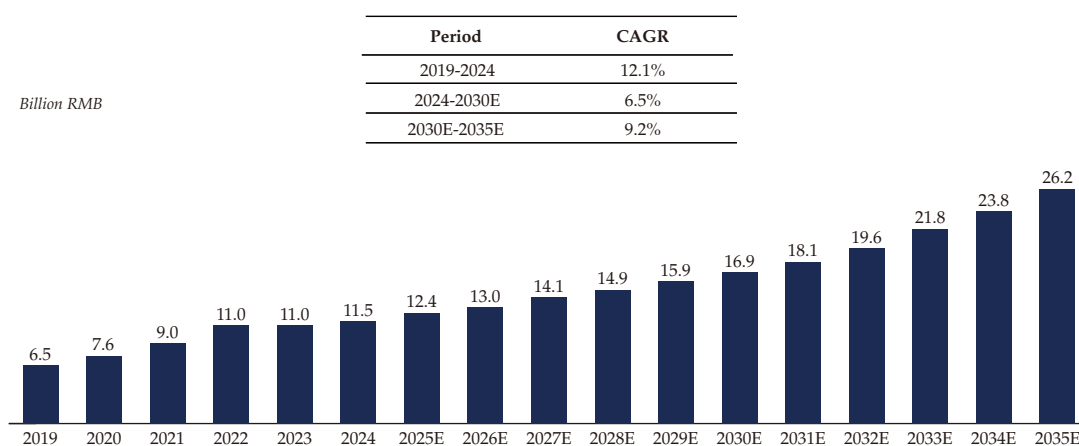
The treatment of ischemic stroke is centered on restoring blood flow and preventing recurrence, and mainly includes surgery and medication. In terms of surgery, endovascular intervention can quickly open up occluded blood vessels, and carotid endarterectomy is suitable for patients with severe carotid stenosis; in medication, thrombolytic drugs are the key to restoring blood flow in the acute stage, antiplatelet and anticoagulant drugs can prevent the enlargement or formation of blood clots, and statins, and drugs for controlling blood pressure, glucose, and lipids are used for long-term prevention and treatment.

However, brain cell damage brought about during cerebral ischemia and the fact that reperfusion can make neutrophils more likely to recruit toward the ischemic area, triggering more severe immune inflammation, can have a significant negative impact on stroke prognosis. Neuroprotective drugs reduce necrosis and apoptosis of neuronal cells caused by ischemia by inhibiting oxidative stress, reducing intracellular calcium overload, and improving mitochondrial function, thereby protecting brain tissue function and effectively improving the prognosis of patients with ischemic stroke.

### *Market size of neuroprotective drugs*

In 2024, the neuroprotective drugs market in China reached RMB11.5 billion. With the successive launch of new neuroprotective drugs with novel mechanisms of action in the future and the popularization of combination therapies, the future of China's neuroprotective drug market will continue to grow, and the market growth rate is expected to accelerate further after a short-term slowdown. It is estimated that the neuroprotective drugs market in China will grow to RMB16.9 billion in 2030 and RMB26.2 billion in 2035, with a CAGR of 6.5% from 2024 to 2030 and 9.2% from 2030 to 2035 respectively.

**Neuroprotective drugs market in China, 2019-2035**



*Source: Frost & Sullivan Report*

### *Market drivers and future trends of neuroprotective drugs market*

Market drivers and future trends of neuroprotective agents market include the following:

- Unmet clinical needs.** Influenced by the aging population and changes in lifestyle, the incidence of neurological diseases represented by stroke has increased significantly, and Alzheimer's disease and Parkinson's disease have also shown a high prevalence. According to *the Panorama of the Burden of Neurological Diseases in China: A National and Provincial-Level Disease Burden Study (1990-2021)*, 16 types of neurological diseases affect 468 million people in China. The neurological deficits and long-term care needs resulting from such diseases have directly given rise to an urgent clinical need for neuroprotective agents.

## INDUSTRY OVERVIEW

- **R&D Innovation.** Neuroprotective drug R&D has shifted from broad-spectrum antioxidant to targeted modulation; new target drugs such as TrKB receptor agonists have demonstrated the potential to promote neuronal repair; and multi-target synergistic drugs and newer formulations such as sublingual tablets and enteric-coated capsules have enhanced efficacy and convenience, driving the trend of neuroprotective agent drugs from symptomatic relief to treatments targeting the mechanism of action.
- **Clinical application scenarios continue to expand.** The clinical application scenarios of neuroprotective drugs continue to broaden, extending from traditional indications to multiple fields. In the field of acute cerebrovascular disease, new dosage forms have broken through the drug delivery limitations, and the application scenarios have been expanded from the acute stage to pre-hospital emergency and recovery management, thus improving accessibility. In the field of neurodegenerative diseases, relevant drugs are included in medical insurance as adjuvant therapy, improving patients' symptoms by promoting nerve regeneration and repair. Meanwhile, its application in the field of rare diseases has made breakthroughs, and gene-targeted neuroprotection cases have emerged.
- **Accelerated development of drugs with new mechanisms.** The mechanism of action of neuroprotective drugs has evolved from single target to multi-pathway synergy, and TrKB receptor agonists have shown potential in improving cognitive function and reducing pathological protein production. In addition, NAD<sup>+</sup> metabolic regulation, oxidative stress and inflammation dual regulation and other innovative mechanisms are advancing simultaneously, and some of them have entered into clinical trials or preclinical stage, which are expected to make breakthroughs in therapeutic mechanisms.

### *Competitive landscape of neuroprotective drugs*

As of the latest practicable date, there are three neuroprotective drugs approved by NMPA.

#### **Competitive landscape of neuroprotective drugs approved by NMPA, China**

Target	Drug Name	Brand Name	Company	Indication	NMPA Approval Date
/	Edaravone and Dexborneol	先必新	Sincere Pharmaceutical	Neuroprotection in acute ischemic stroke	2020-7-29
Bradykinin B2 receptor	Urinary Kallidinogenase	凯力康	Tianpu Biochemical Pharmaceutical	Mild and moderate acute ischemic stroke	2005-6-28
/	Butylphthalide	Enbipu	CSPC	Neuroprotection in acute ischemic stroke	2002-9-30

*Note:* Excludes drugs included in the National Key Monitoring List for Rational Drug Use.

As of the latest practicable date, there are 12 neuroprotective drug candidates for neuroprotection in acute ischemic stroke in the clinical stage in China.

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### Competitive landscape of neuroprotective drug pipelines in China

Target	Drug Code	Company	Clinical Stage	Latest update date
NRF2, mTOR, AMPK	Nitrone Triazine injection	Guangzhou magpie Pharmaceuticals	Phase III	2023-12-18
PDE3	Y-6 sublingual tablet	Neurodawn Pharmaceutical	Phase III	2025-06-03
Thromboxane A2 synthase	piragrel sodium	Hefei Institute of Pharmaceutical Industry	Phase III	2023-08-31
GRIN	Salfaprodil	Zhejiang Apelo Medical	Phase III	2022-01-01
TrkB	MT200605	Shaanxi Micot Pharmaceutical Technology	Phase II	2025-10-21
GRIN	Androtriol	Guangzhou Saipute Medicine	Phase II	2025-06-18
FXII, KLK	ZKLJ02	Zhongke Longjin Biotechnology	Phase I	2025-12-08
/	hNPC-01	Hopstem Biotechnology	Phase I	2024-01-08
/	HY0721	Suzhou Pharmavan Natural & Health	Phase I	2021-12-11
/	GD-11	Jiangsu Vanguard Pharmaceutical	Phase I	2025-09-02
Thromboxane A2 synthase	XY0507	Nanjing Xiangyuan Biomedical Technology	Phase I	2025-05-21

*Source: NMPA, CDE, Frost & Sullivan analysis*