Independent Market Study of Global Peptide Drug Industry

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For and on behalf of
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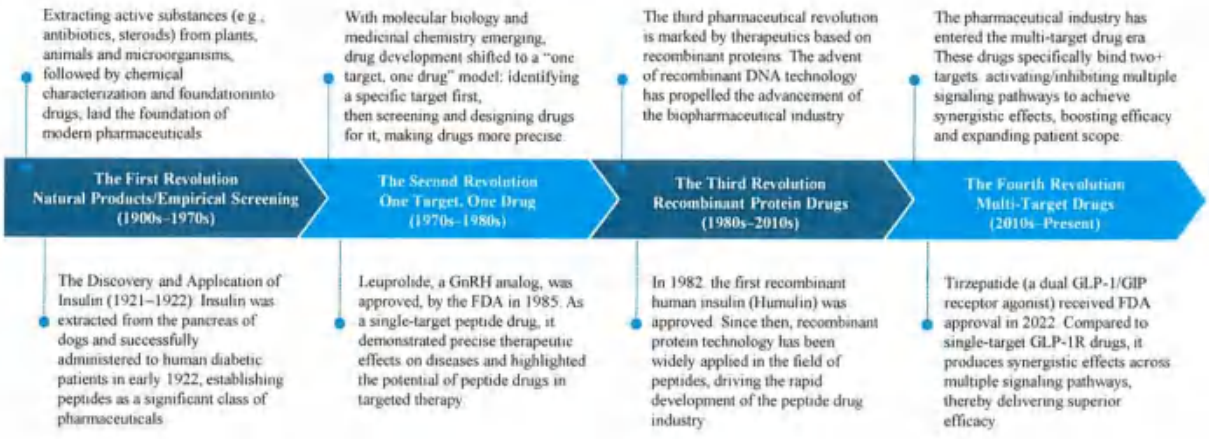
The Revolution in the Pharmaceutical Industry and the Development of Peptide Drugs

- The modern pharmaceutical industry has undergone several revolutions in the past century: initially, there were drugs made from extracted active substances with unknown targets; then came small-molecule chemical drugs and biological agents targeting a single target; followed by drugs acting on specific targets developed via recombinant DNA technology; and in recent years, multispecific drugs have become the mainstream direction of drug development. With the advancement of pharmaceutical industry technologies, peptide pharmaceutical technology has become increasingly mature, gradually entering the era of multi-target peptide drugs. In this process, the application of peptide drugs is no longer limited to the treatment of endocrine and metabolic fields in the early stage; their clinical applications have expanded to multiple areas such as cardiovascular diseases, tumors, and immune regulation. In addition to achieving multi-target synergy and expanding therapeutic fields, peptide pharmaceutical technology has also continuously made breakthroughs in formulation innovation, among which long-acting formulations and oral formulations have become important directions for the future development of peptide drugs.



Source: Literature Review, Frost & Sullivan Analysis

Key Characteristics of Peptide Drug

- 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 (mimicking) or antagonists of endogenous peptides or proteins, exerting their therapeutic effects through high-affinity and high-specificity binding to biological targets.

- **High Target Affinity and Potency:**

Peptide drugs exhibit exceptional affinity for their biological targets (e.g., specific receptors, enzymes, or signaling proteins) due to their structural similarity to endogenous peptides (such as hormones, neurotransmitters, or growth factors). This structural mimicry allows them to bind tightly to target sites — often with nanomolar to picomolar binding affinity — enabling potent modulation of biological pathways at low doses.

- **High Selectivity and Low Off-Target Toxicity:**

Peptide drugs exhibit exceptional affinity for their biological targets (e.g., specific receptors, enzymes) due to their structural similarity to endogenous peptides. This structural mimicry allows them to bind tightly to target sites, which enables low doses of potent modulation of biological pathways.

- **Relatively Low Immunogenicity:**

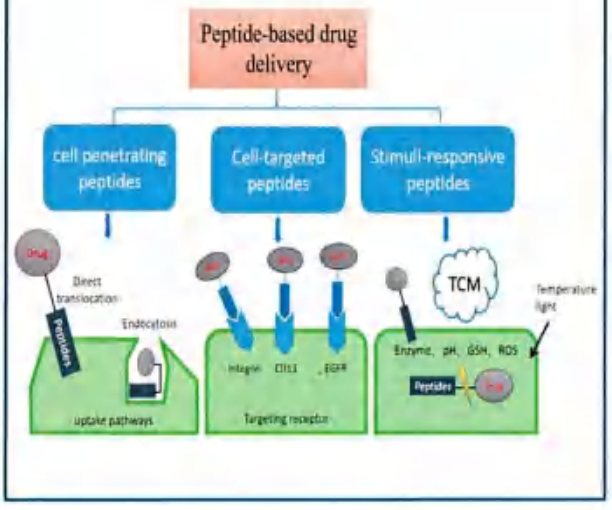
Unlike large-molecule biologics, most peptide drugs have relatively low immunogenicity and they are less likely to trigger an immune response in the human body. Peptides are often derived from endogenous human sequences or designed to avoid recognition by the immune system.

Source: Frost & Sullivan Analysis

Target Distribution of Peptide Drug

- From the perspective of drug delivery, the target distribution strategy of peptide drugs reflects a high degree of design and intelligence, which can be mainly divided into three categories, aiming to accurately deliver drugs to the site of action.

Target Distribution of Peptide Drugs



1. **The first type** is cell penetrating peptides, which target the cells themselves. These peptides do not rely on specific receptors and can carry multiple drug molecules into the cell through direct transport or endocytosis. This makes it a widely used delivery tool that can effectively overcome the physical barriers of cell membranes.

2. **The second type** is targeted peptides, which target receptors highly expressed on specific cell surfaces. These peptides are designed to recognize and bind to specific molecular targets, such as integrins, CD13, EGFR, etc. Through this precise molecular navigation, they can guide coupled drugs to target cells, thereby achieving precise drug delivery. While improving efficacy, it also enhances drug targeting and safety.

3. **The third type** is stimulus responsive peptides, which target specific conditions of the lesion microenvironment. This type of peptide is an intelligent delivery system that remains stable in a normal physiological environment, but is activated by specific stimulation signals when it reaches a site with special pathological features, such as the tumor microenvironment.

Source: Literature Review, Frost & Sullivan Analysis

Clinical Applications and Advantages of Peptide Drug

- Peptide drugs achieve the therapeutic goal of "reducing toxicity and increasing efficiency" in precision medicine due to their strong structural designability, high target specificity, and strong biological activity. Its natural amino acid composition brings good metabolic safety, while targeting protein interaction interfaces that are difficult to cover with traditional small molecules, providing differentiated solutions for multiple unmet clinical fields. The core advantages of peptide drug stem from their high specificity and potency. Peptides also demonstrate unique value in some of the most challenging areas of modern drug development.

mimic the body's own regulatory mechanisms

- By forming precise three-dimensional structures, peptides can establish multi-point, high-affinity interactions with their targets, enabling potent biological effects at very low concentrations while significantly reducing off-target toxicity.
- Therefore, the core advantage of peptide drug stem from their high specificity and potency.
- This characteristic is particularly in the fields of metabolic and endocrine diseases — including obesity and its complications, as well as metabolic disorders associated with chronic kidney disease (CKD).

effectively target protein-protein interaction (PPI) interfaces

- Their molecular size and structure allow them to effectively target protein-protein interaction (PPI) interfaces, which are difficult for traditional small molecules to bind. This provides a potential solution for engaging targets previously considered undruggable.
- Therefore, the advantage of peptide drug is the ability to target "untreatable" targets.

their metabolites are non-toxic, endogenous amino acids

- Peptides possess a superior safety profile — their metabolites are non-toxic, endogenous amino acids. This, combined with their unique pharmacokinetic properties such as rapid onset of action and short half-life, makes them ideal therapeutic choices in scenarios requiring acute intervention, such as metabolic homeostasis regulation during short-term weight loss therapy for obese patients, and correction of electrolyte and metabolic disorders in CKD patients before and after dialysis.
- Therefore, the advantage of peptide drug possess a superior safety profile.

Source: Literature Review, Frost & Sullivan Analysis

Growth 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 CKD and osteoporosis. According to literature published in The Lancet, the prevalence and burden of CKD continue to rise in tandem with global population aging. Osteoporosis disrupts calcium and phosphorus metabolism and may induce or worsen secondary hyperparathyroidism (CKD-SHPT), further driving corresponding treatment demand and 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.

Source: Frost & Sullivan Analysis

Drivers of Peptide Drug Market

Vast and unmet rigid 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, precisely 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. Compared to single-target drugs, dual- or triple-target GLP-1 agonists demonstrate a 30-50% improvement in weight loss efficacy. This significant therapeutic advantage has attracted greater attention from both patients and clinicians, thereby expanding market demand for these peptide-based medications.
Innovation in oral formulation development	Peptide drugs have long been constrained by injection administration, which reduces patient compliance and limits market expansion for certain potential indications. In recent years, Research and development of oral formulations has achieved certain progress, becoming a key focus area for the industry. Innovations in oral formulation development have liberated peptide drugs from limitations to freeze-dried powders and injectable formulations, enhancing patient convenience and compliance.
Breakthroughs in key platform technologies have resolved the core bottlenecks	Long-acting technologies, such as fatty acid modification and PEGylation, have successfully extended the dosing frequency of peptides from multiple times a day to once a week or even longer, dramatically improving patient compliance. Moreover, the commercial success of oral delivery technologies, exemplified by the SNAC absorption enhancer, has broken the technological barrier of oral peptide administration and validated its commercial viability. This has, in turn, spurred major pharmaceutical companies worldwide to invest heavily in the development of next-generation oral peptides or small-molecule alternatives.
Investment in the peptide drug sector has continued to grow	The robust market expansion in peptide drug market has spurred increasing R&D investment and corporate acquisition from international pharmaceutical companies. Recently, a series of large-value transactions have also emerged in the peptide field. In March 2025, Syneron Bio entered into a strategic cooperation with AstraZeneca. Under the agreement, AstraZeneca will pay an upfront fee of USD75 million, with a total transaction value of up to USD3.4 billion, and the two parties will join hands to develop first-in-class macrocyclic peptide drugs for chronic diseases. These deals demonstrate that innovative peptide drugs possess significant commercial potential and investment value in the global pharmaceutical market.

Source: Frost & Sullivan Analysis

Entry Barriers of Peptide Drug Market

Technical design and intellectual property barriers	➢ Successful development of peptide drugs not only requires the discovery of new molecular sequences, but also relies on complex chemical modification techniques such as lipidation and PEGylation to optimize stability and half-life to meet clinical needs. ➢ In addition, converting peptides from traditional injectable forms to oral, inhaled, or long-acting release formulations is a recognized core technical challenge in the industry; Having a mature delivery technology platform constitutes a strong competitive advantage. ➢ In addition, the intensive patent layout in this field places higher demands on the innovation capabilities and differentiated design strategies of new entrants.
Large scale production and cost control barriers	➢ Scaling up peptide production from the gram level in the laboratory to the commercial hundred kilogram or even ton level involves an extremely complex CMC (Chemical, Production, and Control) process. Among them, large-scale solid-phase or liquid-phase synthesis and high-performance liquid chromatography (HPLC) purification are recognized as technical bottlenecks, and the control requirements for impurity mass spectrometry are extremely strict. ➢ Core technical talents and high-end equipment (such as large-scale purification media) are still scarce resources. More importantly, due to the expensive starting materials and numerous process steps, the cost of sale (COGS) of peptides is much higher than that of small molecule drugs.

Source: Frost & Sullivan Analysis

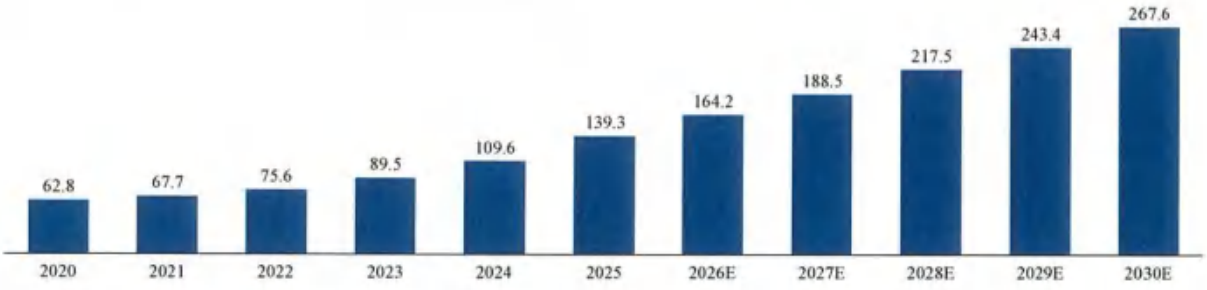
Global Peptide Drug Market Size, 2020-2030E

- The global peptide drug market has grown from USD62.8 billion in 2020 to USD139.3 billion in 2025 with a CAGR of 17.3%, and is estimated to reach USD267.6 billion by 2030, at a CAGR of 13.9%. Given the advantages of peptide drugs, their clinical applications will further expand to multiple areas such as cardiovascular diseases, tumors, and immune regulation.

Global Peptide Drug Market Size, 2020-2030E

Period	CAGR
2020-2025	17.3%
2025-2030E	13.9%

Billion RMB



Source: Frost & Sullivan analysis

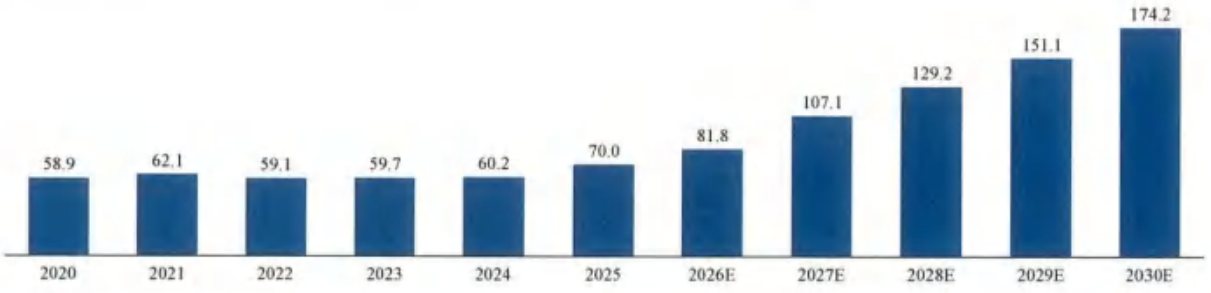
Peptide Drug Market Size in China, 2020-2030E

- 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 RMB58.9 billion in 2020 to RMB70.0 billion in 2025, at a CAGR of 3.5%, and is estimated to reach RMB174.2 billion by 2030, at a CAGR of 20.0% during this period. Driven by aging populations, rising chronic disease rates and advances in costly innovative therapies, cost containment has become a key trend in global healthcare. Under fiscal pressure, governments and third-party payers (public and commercial insurers) are controlling surging medical spending by limiting coverage and adjusting reimbursement for specific drugs. Although healthcare cost control has become a global norm, this trend has also driven structural optimization of healthcare payment systems, channeling limited public healthcare funds and commercial insurance resources to prioritize coverage for innovative drugs with differentiated clinical value — specifically those featuring novel target combinations, new mechanisms of action and the ability to effectively address unmet clinical needs

Peptide Drug Market Size in China, 2020-2030E

Period	CAGR
2020-2025	3.5%
2025-2030E	20.0%

Billion RMB



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Introduction of Chronic Kidney disease (CKD)

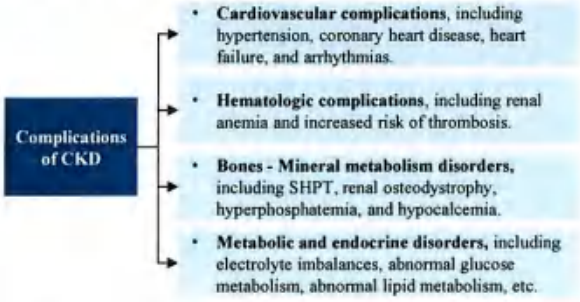
- Chronic kidney disease (CKD) is a group of chronic diseases centered on abnormalities in renal structure or function. Its diagnostic criteria are renal damage or a decrease in glomerular filtration rate (GFR) lasting for 3 months or longer. Its diagnostic criteria are renal damage or a decrease in 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.

Stages of chronic kidney disease

Stages	GFR level	Characteristics
1	≥90	Normal or elevated kidney function, but with confirmed kidney damage.
2	60–89	Mildly reduced kidney function, often accompanied by evidence of kidney damage.
3	30–59	Moderately reduced renal function. Symptoms gradually manifest.
4	15–29	Severely reduced renal function. Complications significantly worsen.
5	<15	Severe loss of renal function. Requires dialysis or kidney transplantation to sustain life, frequently presenting with uremic symptoms.

- 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.

Complications of chronic kidney disease.



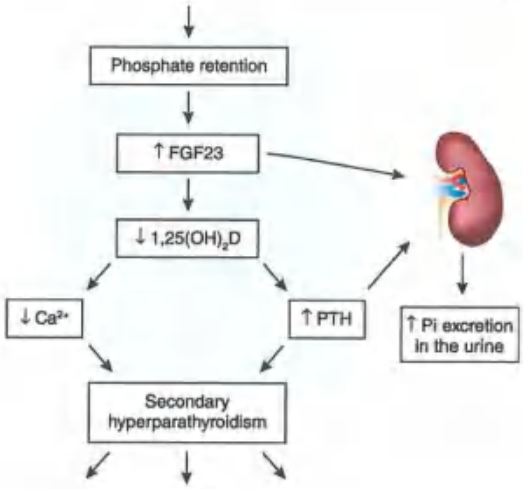
- CKD not only affects the kidneys themselves but also causes systemic multisystem complications, such as renal anemia, secondary hyperparathyroidism (CKD-SHPT), and cardiovascular diseases (e.g., heart failure, arteriosclerosis). Among these, CKD-SHPT is particularly common in patients with CKD in middle and advanced stages, seriously endangering patients' quality of life and lifespan.

Source: Literature Review, Frost & Sullivan Analysis

Introduction of Secondary Hyperparathyroidism (SHPT)

- CKD-SHPT is a common and severe complication in patients with CKD, particularly those with end-stage renal disease receiving dialysis, and represents one of the core manifestations of CKD-mineral and bone disorder. Its pathogenesis mainly arises from impaired phosphorus excretion caused by progressive renal function decline, leading to hyperphosphatemia, insufficient synthesis of active vitamin D and hypocalcemia; abnormalities in regulatory pathways including the calcium-sensing receptor and vitamin D receptor continuously stimulate excessive secretion of parathyroid hormone by the parathyroid glands, which further results in diffuse or nodular hyperplasia of the parathyroid glands and forms a vicious cycle of autonomous hypersecretion of PTH.

Mechanisms of SHPT



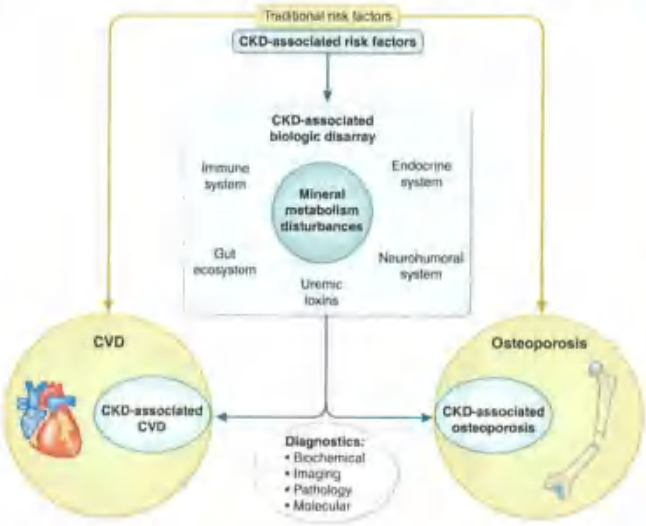
- In patients with CKD-SHPT, long-term, sustained excessive secretion of parathyroid hormone (PTH) over-activates osteoclast-mediated bone resorption and inhibits osteoblast-mediated bone formation, resulting in a rate of bone resorption that far exceeds bone formation. This causes continuous dissolution of hydroxyapatite crystals in bone and massive mobilization of calcium and phosphorus minerals into the bloodstream. The massive loss of bone calcium, combined with hyperphosphatemia caused by CKD-SHPT itself, significantly increases the calcium-phosphorus product beyond the normal threshold, leading to ectopic deposition of calcium-phosphate complexes in blood vessel walls, heart valves and other soft tissues. Consequently, CKD-SHPT may give rise to renal osteodystrophy, vascular and soft tissue calcification and other disorders, clinically manifesting as bone pain, increased bone fragility, pathological fractures, vascular stiffness and increased cardiovascular burden, and significantly increases the risk of adverse cardiovascular events and mortality among affected patients

Source: Literature Review, Frost & Sullivan Analysis

Introduction of Chronic kidney disease-mineral and bone disorder (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.

Biological systems affected by CKD-MBD and potential complications



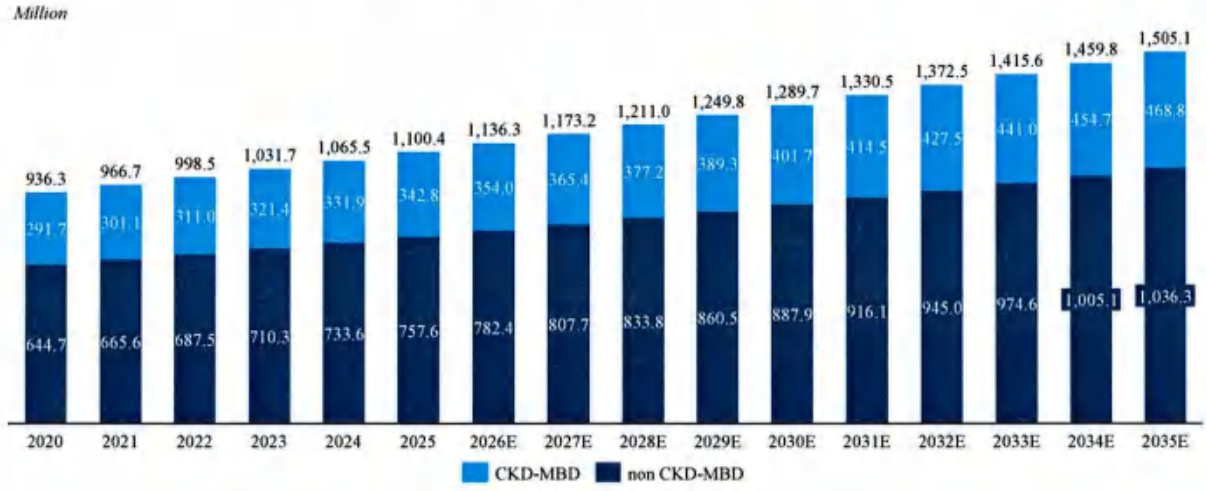
- **Potential risks associated with CKD-MBD**
- Patients with CKD-MBD may experience bone pain, deformities, and increased fracture risk in the skeletal system, while children may also exhibit growth retardation. The cardiovascular system experiences accelerated atherosclerosis and elevated blood pressure 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 ≥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.

Source: Literature Review, Frost & Sullivan Analysis

Global Prevalence of Chronic Kidney Disease (CKD), 2020-2035E

- The global prevalence of CKD grew from 936.3 million in 2020 to 1,100.4 million in 2025, and is projected to reach 1,289.7 million by 2030 and 1,505.1 million by 2035.
- The global prevalence of CKD-MBD grew from 291.7 million in 2020 to 342.8 million in 2025, and is projected to reach 403.0 million by 2030 and 470.3 million by 2035.

Global Prevalence of Chronic Kidney Disease , 2020-2035E

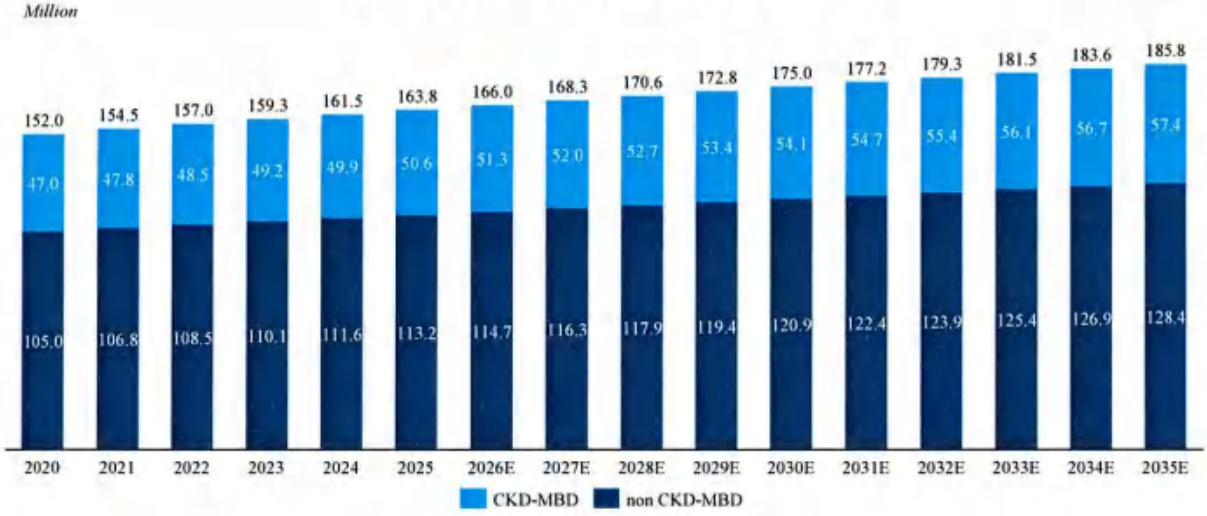


Source: Frost & Sullivan analysis

Prevalence of Chronic Kidney Disease (CKD) in China, 2020-2035E

- In China, the prevalence of CKD grew from 152.0 million in 2020 to 163.8 million in 2025, and is projected to reach 175.0 million by 2030 and 185.8 million by 2035.
- The prevalence of CKD-MBD in China grew from 47.0 million in 2020 to 50.6 million in 2025, and is projected to reach 54.1 million by 2030 and 57.4 million by 2035.

Prevalence of Chronic Kidney Disease in China, 2020-2035E

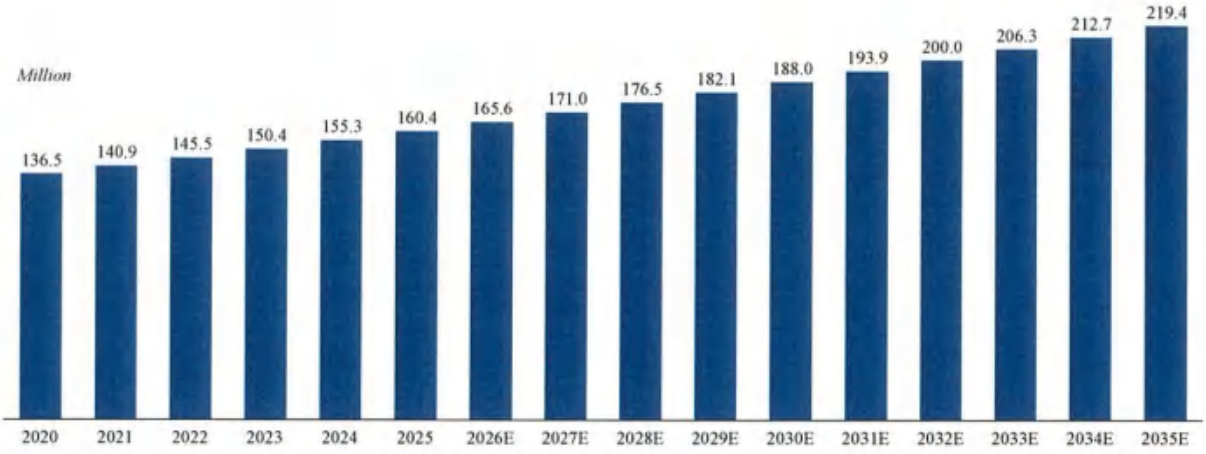


Source: Frost & Sullivan analysis

Global Prevalence of CKD-SHPT, 2020-2035E

- The global prevalence of CKD-SHPT grew from 136.5 million in 2020 to 160.4 million in 2025, and is projected to reach 188.0 million by 2030 and 219.4 million by 2035. The global population of patients with Stage 5 CKD complicated by SHPT expanded from 5.0 million in 2020 to 5.9 million in 2025. This cohort is projected to reach 6.9 million by 2030 and 8.1 million by 2035.

Global Prevalence of CKD-SHPT, 2020-2035E

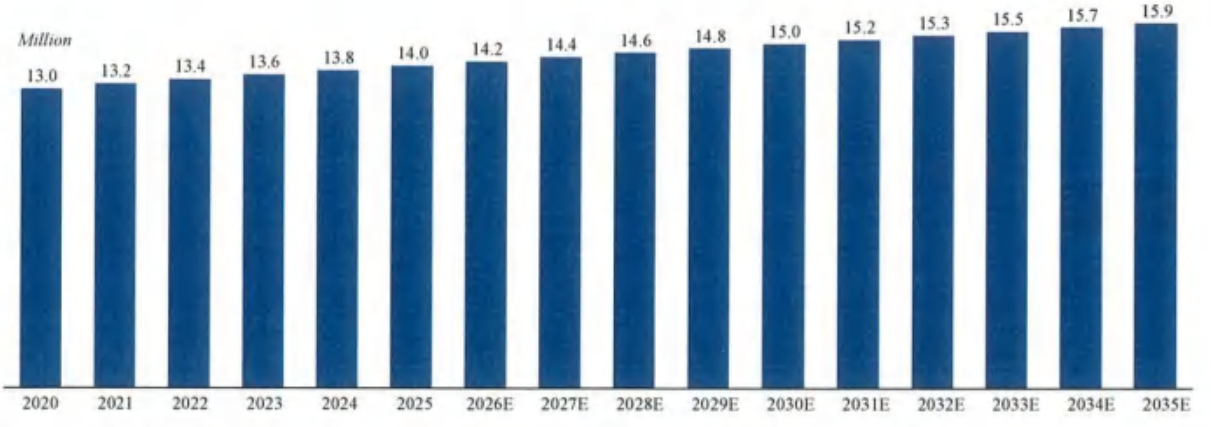


Source: Frost & Sullivan analysis

Prevalence of CKD-SHPT in China, 2020-2035E

- The prevalence of CKD-SHPT in China grew from 13.0 million in 2020 to 14.0 million in 2025, and is projected to reach 15.0 million by 2030 and 15.9 million by 2035. Concurrently, the patient population with Stage 5 CKD complicated by SHPT in China grew from 0.60 million in 2020 to 0.65 million in 2025, and is forecasted to hit 0.69 million by 2030 and 0.73 million by 2035.

Prevalence of CKD-SHPT in China, 2020-2035E



Source: Frost & Sullivan analysis

Main treatment of Secondary Hyperparathyroidism (SHPT)

- In the field of CKD-SHPT treatment, there is no concept of first-line, second-line, or other sequential therapies. The choice of a specific treatment regimen depends entirely on whether the patient meets the eligibility criteria for the medication. In the early stages, CKD-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 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.

Main Treatment of SHPT	*Mechanism*	*Main drugs/surgery*
Main treatment of SHPT → **Phosphorus binder**	Hyperphosphatemia is a key pathogenic factor in SHPT, reducing serum phosphorus levels by decreasing intestinal phosphorus absorption or increasing phosphorus excretion, thereby diminishing stimulation of PTH.	Calcium-phosphorus binders, non-calcium-phosphorus binders
Active vitamin D and its analogues	Supplementation with active vitamin D directly increases intestinal calcium absorption and elevates serum calcium levels, while simultaneously inhibiting parathyroid cell proliferation and PTH gene expression, thereby reducing PTH synthesis and secretion.	Calcitriol Alfacalcidol Paricalcitol
CaSR agonist therapy	Directly activates calcium-sensitive receptors (CaSR) on the surface of parathyroid cells, enhancing their sensitivity to serum calcium levels, thereby inhibiting parathyroid hyperplasia and the synthesis and secretion of parathyroid hormone (PTH).	Evocalcet Etelcalcetide Cinacalcet
Surgery	By excising excessively hyperplastic parathyroid tissue, this procedure directly reduces the synthesis and secretion of parathyroid hormone (PTH), making it suitable for severe secondary hyperparathyroidism (SHPT) unresponsive to medical therapy.	Total parathyroidectomy with autologous grafting

- 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 CKD-SHPT, with parathyroidectomy being the main surgical procedure.

Source: Literature Review, Frost & Sullivan Analysis

Treatment diagrams 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 CKD-SHPT, but it tends to cause hypocalcemia and gastrointestinal symptoms. Surgical treatment is targeted at patients with severe CKD-SHPT refractory to medical therapy, which can 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:

Clinical Symptoms	*Eligibility Criteria*	*Appropriate treatment methods*
CKD-MBD → **Hyperphosphatemia**	Serum phosphorus > target value	**Calcium-free phosphate binders:** Sevelamer, Lanthanum carbonate **Calcium-containing phosphate binders:** Calcium carbonate
SHPT	iPTH > target value	**Active vitamin D analogs:** Calcitriol, Paricalcitol, Alfacalcidol
	Serum calcium & iPTH & serum phosphorus > target values	**CaSR agonist:** Cinacalcet, Etelcalcetide, Evocalcet
	Failure of drug therapy	**Parathyroidectomy:** Total parathyroidectomy, subtotal parathyroidectomy, total parathyroidectomy with autotransplantation
Vitamin D deficiency	25(OH)D < 30 ng/mL	**Vitamin D:** Cholecalciferol (Vitamin D_3) **Active vitamin D:** Calcitriol
Hypercalcemia	Serum calcium > 2.75 mmol/L	**Calcium-lowering agents:** Calcitonin **Bisphosphonates:** Zoledronic acid

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

Efficacy and Safety Profile of Standard Treatment for CKD-MBD

Standard Treatment (Representative Drug)	Recommended Indicated Patient	Global and Chinese Indicated Patients in 2025	Efficacy	Safety Profile
Phosphate Binders (Lanthanum Carbonate)	Patients with Stage 3-5 CKD complicated with hyperphosphatemia	Global: 60.0 million China: 5.2 million	Potently reduces serum phosphorus levels, lowers the risk of vascular calcification, and serves as an adjuvant therapy to stabilize patients' PTH levels	The core adverse reactions are gastrointestinal reactions, with favorable tolerability and safety profile for long-term use
Phosphate Binders (Calcium Carbonate)	Patients with Stage 3-5 CKD complicated with hyperphosphatemia	Global: 60.0 million China: 5.2 million	Binds to phosphate to reduce its absorption and lower serum phosphorus levels, while supplementing calcium to correct hypocalcemia and inhibit excessive PTH secretion from the parathyroid glands, with a rapid onset of action	It may cause hypercalcemia; long-term excessive use may accelerate calcification of blood vessels and soft tissues, and gastrointestinal adverse reactions are common
Active Vitamin D (Calcitriol)	Patients with Stage 5 CKD complicated with SHPT	Global: 5.9 million China: 0.6 million	Directly acts on the vitamin D receptors of the parathyroid glands, potently inhibits the synthesis and secretion of PTH, and rapidly reduces serum PTH levels	The core adverse reactions include hypercalcemia and hyperphosphatemia. Excessively high dosage may induce over-inhibition of PTH, resulting in adynamic bone disease
Active Vitamin D Analogues (Paricalcitol)	Patients with Stage 5 CKD complicated with SHPT	Global: 5.9 million China: 0.6 million	With high targeting specificity to the vitamin D receptors of the parathyroid glands, it potently inhibits the synthesis and secretion of PTH with a minimal impact on serum calcium and phosphorus levels	It has a significantly lower incidence of hypercalcemia and hyperphosphatemia, with a superior safety profile and favorable long-term tolerability
CaSR agonist (Cinacalcet)	Patients with Stage 5 CKD complicated with SHPT	Global: 5.9 million China: 0.6 million	Activates the CaSR to enhance the sensitivity of the receptors to serum calcium. It potently inhibits the synthesis and secretion of PTH without increasing serum calcium, while simultaneously reducing serum phosphorus levels	The core adverse reaction is dose-dependent hypocalcemia, with common mild to moderate gastrointestinal reactions
Bisphosphonates (Alendronate Sodium)	Patients with CKD complicated with osteoporosis	Global: 121.3 million China: 10.8 million	Binds to bone mineralization sites with high affinity, specifically inhibits osteoclast activity and reduces bone resorption, significantly increases bone mineral density, lowers the risk of fragility fractures, and delays bone mass loss	It has a favorable safety profile in patients with Stage 1-3 CKD; for patients with Stage 4-5 CKD, cautious use with dose reduction is required to avoid exacerbation of renal impairment
Calcium-lowering Agents (Calcitonin)	Patients with CKD complicated with osteoporosis	Global: 121.3 million China: 10.8 million	For patients with osteoporosis, it reduces bone calcium loss and relieves bone pain, with a rapid onset of action. However, it provides no long-term prognostic improvement	Short-term use has no risk of elevated serum calcium and phosphorus, with a favorable safety profile. Long-term use may cause dose-dependent hypocalcemia, and there is a risk of immunogenicity

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

Market drivers of CKD drugs market

Synergistic Effects of Increasing Prevalence and Population Aging

- The prevalence of 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. AI 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.

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.

Source: Frost & Sullivan Analysis

Entry barriers of CKD drug market

Technical Barriers	• CKD features a complex pathogenesis, and drug R&D 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 R&D 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.

Source: Frost & Sullivan Analysis

Mechanism of CaSR and OGP agonist

- Calcium-sensitive receptor (CaSR) is a G protein-coupled receptor distributed in parathyroid glands, kidneys, and other tissues, and its core function is to sense changes in extracellular calcium ion concentration and regulate the secretion of parathyroid hormone (PTH) through negative feedback to maintain calcium metabolism homeostasis.

Mechanism of CaSR

- Calcium-sensing receptor (CaSR) is a G protein-coupled receptor distributed in parathyroid glands, kidneys, and other tissues, and its core function is to sense changes in extracellular calcium ion concentration and regulate the secretion of parathyroid hormone (PTH) through negative feedback to maintain calcium metabolism homeostasis. CaSR agonists enhance their sensitivity to extracellular calcium by binding to CaSR, which can activate the CaSR signaling pathway and directly inhibit the secretion of PTH by parathyroid master cells even when blood calcium levels are not high; at the same time, prolonged use of these agents reduces the proliferation of parathyroid cells and slows down the process of glandular hyperplasia. This mechanism can not only reduce the blood PTH level, but also indirectly improve the calcium and phosphorus metabolism disorder, thus alleviating the complications of bone pain, fracture and vascular calcification caused by CKD-SHPT.

Development history of CaSR agonist

- The first generation of CaSR receptor agonists is cinacalcet, as the firstapproved drug, which is used to treat calcium metabolism disorders such as CKD-SHPT in chronic kidney disease by activating calcium-sensitive receptors to inhibit PTH secretion, but it has significant drawbacks, including a high incidence of gastrointestinal side effects, susceptibility to hypercalcemia, and limited effects on severe parathyroid hyperplasia and requires daily dosing. The second generation of drugs includes Evocalcet and Etelcalcetide, of which Evocalcet reduces the risk of gastrointestinal reactions and drug interactions through structural optimization, and Etelcalcetide avoids oral side effects and has a stronger activation effect due to intravenous injection, which improves the safety of the first generation as a whole, but there are still shortcomings to be solved, such as an increased incidence of hypocalcemia, and severe hypocalcemia still requires emergency intervention, and the insufficient efficacy for severe parathyroid hyperplasia requires combination therapy, and the convenience of drug administration is not easy. Combination therapy is needed for severe parathyroid hyperplasia, and the convenience of drug administration needs to be improved.

Mechanism of OGP

- Osteogenic growth peptide (OGP) is an active peptide involved in the regulation of bone metabolism, which can promote the proliferation of osteoblasts, enhance osteogenic activity, stimulate the synthesis of collagen and the formation of bone matrix, and regulate the process of bone formation. OGP has the potential to combat the symptoms of excessive bone resorption activity and inhibited bone formation caused by CKD-SHPT. By promoting bone formation, it can reduce the excessive release of calcium from bones, facilitate the deposition of calcium and phosphorus to bone tissue, and indirectly stabilize the levels of blood phosphorus and blood calcium — thereby alleviating the stimulation to the parathyroid glands caused by calcium loss from bones. Although no OGP-targeting drugs have been approved, OGP's bone metabolism regulation mechanism holds therapeutic promise for CKD-MBD-related conditions.

Source: Literature Review, Frost & Sullivan Analysis

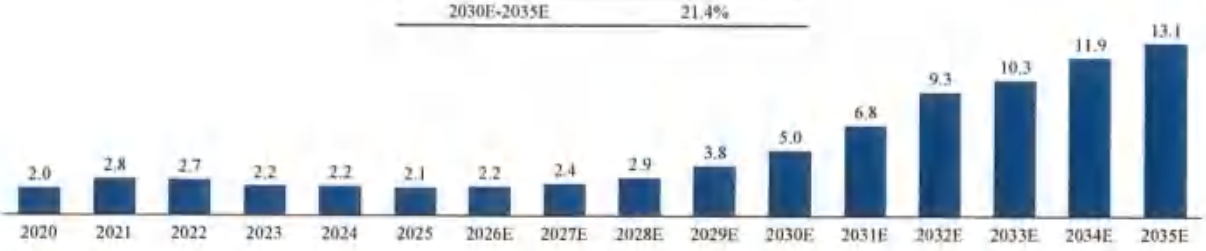
Market size and forecast of SHPT drugs in China, 2020-2035E(1/2)

- Between 2020 and 2025, core drugs for the treatment of CKD-SHPT in China have fully completed generic substitution and been successively included in the national volume-based procurement, resulting in a significant decline in the overall average selling price of the market. As of the end of 2025, all mainstream CKD-SHPT treatment drugs are small-molecule drugs, including oral CaSR agonist cinacalcet, vitamin D analog paricalcitol, traditional vitamin D drug calcitriol, and phosphate binders lanthanum carbonate and sevelamer, have been included in the national or local centralized drug procurement programs, leading to a substantial drop in the overall average selling price. Between 2020 and 2025, the average selling price of CKD-SHPT drugs declined by approximately 80%. The aforementioned mainstream CKD-SHPT drugs were all included in the NRDL at an early stage, and the implementation of volume-based procurement has further significantly reduced the financial burden on patients and greatly improved drug accessibility. Meanwhile, with the continuous increase in the dialysis rate of patients with CKD in China and the improvement in CKD-SHPT disease screening and diagnosis capabilities, the number of CKD-SHPT patients receiving standardized pharmacotherapy has achieved rapid growth. Between 2020 and 2025, annual sales volume of CKD-SHPT drugs increased by 3 to 5 times. The significant decline in the average selling price of CKD-SHPT drugs and the rapid growth in their sales volume have offset each other, resulting in a minimal growth of only 0.7% in the market size of CKD-SHPT drugs in China Mainland from 2020 to 2025, increasing from RMB2.0 billion to RMB2.1 billion.

Market size of SHPT drugs in China, 2020-2030E

Billion RMB

Period	CAGR
2020-2025	0.7%
2025-2030E	18.7%
2030E-2035E	21.4%



Source: Frost & Sullivan analysis

Market drivers of CKD-SHPT drug market

Multiple peptide-based CaSR agonists will be launched successively and included in the NRDL, improving drug accessibility	• Etelcalcetide was approved by NMPA in May 2023 and has not yet been included in the NRDL. In addition, two other peptide-based CaSR agonists (MT1013 and SHR6508) are in Phase III clinical trials and nearing approval for launch. As most other drugs in the CKD-SHPT treatment field have already been included in the NRDL, all three drugs are expected to be successively included in the NRDL through national medical insurance negotiations within the next 2 to 3 years, enhancing their accessibility and achieving commercial volume expansion.
The treatment cost of peptide-based CKD-SHPT drugs will be significantly higher than that of small-molecule SHPT drugs, driving up the average treatment cost of CKD-SHPT drugs	• Currently, the monthly treatment cost of mainstream small-molecule CKD-SHPT drugs is less than RMB100, while the monthly treatment cost of peptide-based CaSR agonists exceeds RMB2,000. Even after being included in the NRDL, the projected monthly treatment cost of peptide-based CaSR agonists will still be more than 10 times that of the existing post-procurement small-molecule CaSR agonist cinacalcet, which will raise the overall average treatment cost of CKD-SHPT drugs.
The small-molecule CaSR agonist cinacalcet is constrained by high incidence of gastrointestinal adverse reactions and poor patient treatment compliance, which hinders the improvement of its market penetration and expansion of its market space.	• Cinacalcet features a relatively high incidence of gastrointestinal adverse reactions, leading numerous patients to discontinue treatment due to intolerance to such reactions. Meanwhile, as an oral formulation, it comes with stringent administration requirements coupled with prominent side effects, further resulting in frequent missed doses, arbitrary dosage adjustment and even premature treatment cessation among patients, thus resulting in unsatisfactory overall treatment compliance. The aforesaid gastrointestinal adverse reactions and compliance issues not only constrain the market penetration of cinacalcet, but also restrict the overall treatment rate of CKD-SHPT patients, ultimately forming a bottleneck that curbs further growth of its market size.
Peptide-based CaSR agonists avoid the common adverse reactions of small-molecule CaSR agonists and expand the eligible patient population	• Peptide-based CaSR agonists are administered intravenously and directly enter the blood circulation, avoiding the severe gastrointestinal adverse reactions commonly associated with oral cinacalcet, enabling a large number of patients who were previously unable to tolerate oral treatment to receive standardized therapy. They also carry a lower risk of causing hypercalcemia and hyperphosphatemia, and their indication scope can be extended to patients with all stages of CKD-SHPT.
Peptide-based CaSR agonists can be administered concurrently with dialysis, compared to small-molecule CaSR agonists, can significantly improve patient treatment adherence	• These agents can be directly administered by medical staff through dialysis lines during patients' routine dialysis sessions, completely resolving the common problems of missed doses, self-medication reduction, and treatment discontinuation associated with oral drugs, and significantly improving patient treatment adherence.

Source: Frost & Sullivan Analysis

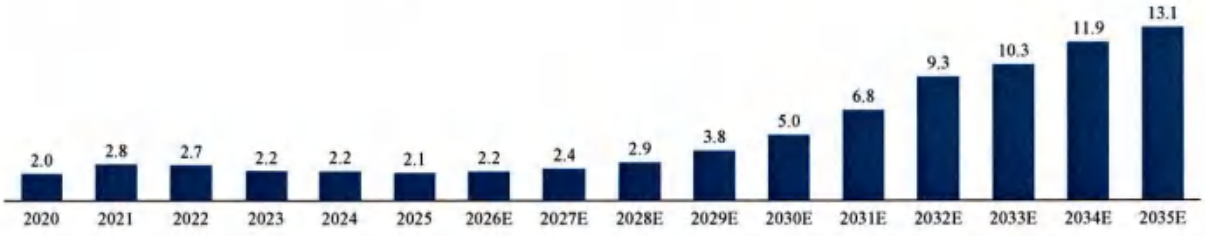
Market size and forecast of SHPT drugs in China, 2020-2035E(2/2)

- With the approval and launch of peptide-based CaSR agonists, the domestic CKD-SHPT drug market is poised for rapid growth. Driven by the continuous increase in market penetration resulting from improved accessibility following the commercial launch and NRDL inclusion of peptide-based CKD-SHPT drugs, the rise in overall patient treatment rate and expansion of the eligible patient population brought about by their superior safety and treatment adherence advantages, as well as their higher treatment costs compared to small-molecule CKD-SHPT drugs, both the sales volume and average treatment cost per patient of CKD-SHPT drugs will be simultaneously boosted, thereby propelling the rapid expansion of the domestic CKD-SHPT drug market. It is projected that the market size will reach RMB5.0 billion by 2030 and RMB13.1 billion by 2035, representing CAGRs of 18.7% and 21.4% respectively during the corresponding periods.

Market size of SHPT drugs in China, 2020-2030E

Period	CAGR
2020-2025	0.7%
2025-2030E	18.7%
2030E-2035E	21.4%

Billion RMB



Source: Frost & Sullivan analysis

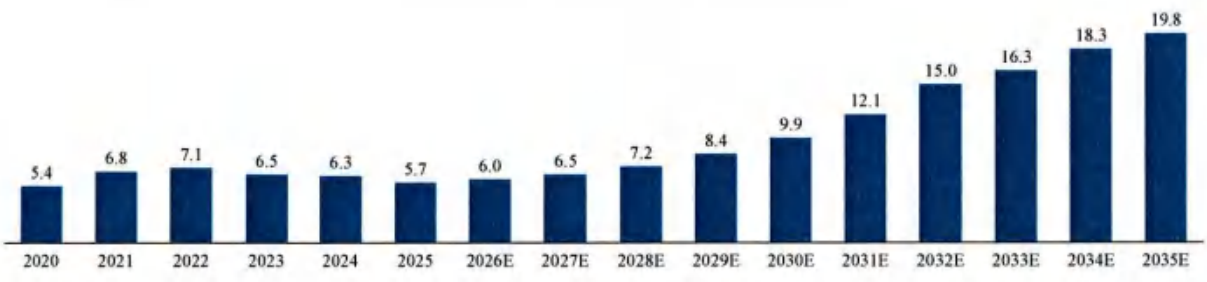
Market size of CKD-MBD drugs in China, 2020-2035E

- In 2025, the market size of CKD-MBD drugs in China reached RMB5.7 billion. It is estimated that the market size will reach RMB9.9 billion by 2030 and RMB19.8 billion by 2035, with the CAGR of 11.7% and 14.8%, respectively, during the period.

Market size of CKD-MBD drugs in China, 2020-2035E

Period	CAGR
2020-2025	1.3%
2025-2030E	11.7%
2030E-2035E	14.8%

Billion RMB

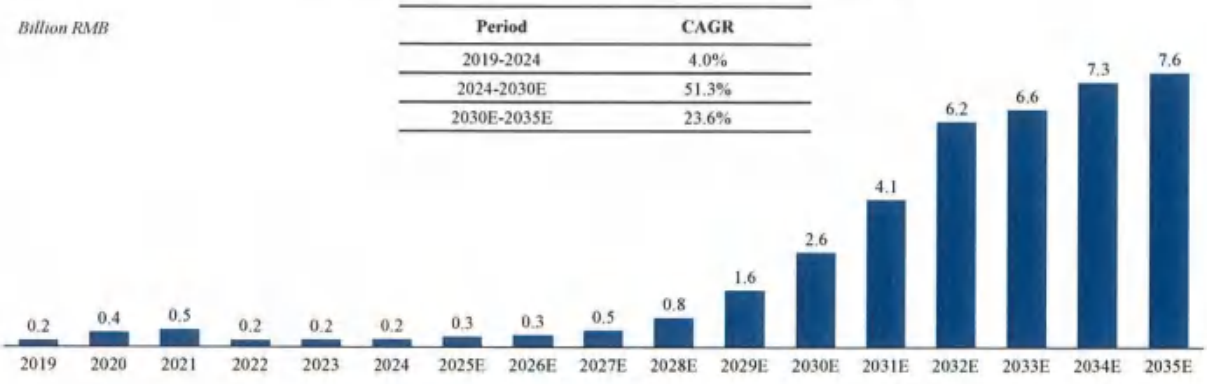


Source: Frost & Sullivan analysis

Market size and forecast of CaSR agonist drugs in China, 2019-2035E

- Since the approval of cinacalcet in China in 2014, the Chinese CaSR agonist drug market has experienced rapid growth as the penetration rate of cinacalcet for the treatment of SHPT patients has gradually increased. However, following the approval of generic cinacalcet in 2020, the CaSR agonist drug market saw a significant decline before stabilizing at a relatively steady growth rate. By 2024, the Chinese CaSR agonist drug market size reached to RMB 0.2 billion.
- Due to the narrow patient population applicable to cinacalcet and its adverse reactions such as hypocalcemia and gastrointestinal reactions, the therapeutic penetration rate and patient compliance rate of small-molecule CaSR agonist drugs remain low. In contrast, peptide CaSR agonist drugs offer more convenient administration routes, fewer adverse reactions, faster onset of action, and broader applicability across patient groups. With the gradual market launch of peptide CaSR agonist drugs and their subsequent inclusion in the NRDL, the therapeutic penetration rate and patient compliance rate of CaSR agonist drugs will fursther increase, driving rapid growth in China's CaSR agonist drug market. It is estimated that the market size will reach RMB 2.6 billion by 2030 and RMB 7.6 million by 2035, with the CAGR of 51.3% and 23.6%, respectively, during the period.

Market size and forecast of CaSR agonist drugs in China, 2019-2035E



Source: Frost & Sullivan analysis

Global competitive landscape of CaSR agonist drugs

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

Target	Drug Name	Brand Name	Company	Indication	Dosage Form	Regulatory Authorities	Approval Date
CASR	Evocalcet	Orkedia	Kyowa Kirin	SHPT	Oral	NMPA	2024-07-30
CASR	Etelcalcetide	Parsabiv	Amgen	SHPT	Injection	FDA	2017-02-07
						NMPA	2023-05-06
CASR	Cinacalcet	Sensipar	Amgen	SHPT, Hypercalcemia	Oral	FDA	2004-03-08
						NMPA	2014-08-21

As of June 1 2026

Source: FDA, NMPA, Frost & Sullivan Analysis

Global competitive landscape of CaSR agonist pipelines

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

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	Injection	NMPA	Phase III	2025-10-09
				FDA	Phase I	2022-07-29
CASR	SHR-6508	Henrui Pharmaceutical	Injection	NMPA	Phase III	2025-12-27
CASR	ASP7991	Astellas Pharma	Oral	FDA	Phase II	2024-11-06

As of June 1 2026

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

Future Trends of SHPT drug market

Combination therapy with CaSR agonist

- The combination of CaSR agonist with other drugs has become a core strategy for optimizing SHPT therapy. The use of CaSR agonist in combination with active vitamin D analogs in patients who do not achieve compliance with monotherapy synergistically lowers PTH and balances calcium and phosphorus metabolism, improving compliance and reducing the risk of hypercalcemia. Combination with phosphorus-binding agents improves calcium-phosphorus multiplication and delays vascular calcification. Combination therapy with CaSR agonist is becoming an important treatment for SHPT.

Emergence of multi-targeted CaSR agonists

- Traditional CaSR agonists have a single target, which is insufficient to regulate parathyroid hyperplasia, resulting in poor efficacy, dose-dependent side effects and gastrointestinal reactions. Multi-target CaSR agonists can act on both the CaSR and other targets related to the pathological mechanism of SHPT. They can not only synergistically enhance the PTH-lowering effect, reduce adverse reactions caused by single-target activation, and improve safety and tolerability, but also address the multiple pathological issues of SHPT.

Rising treatment rate of SHPT patients

- With the popularization of medical screening and advancement of testing technology, the diagnosis rate of SHPT has increased significantly, and more potential patients have been identified at an early stage. The development and launch of domestic innovative drugs is expected to further break the bottleneck of drug accessibility, which, combined with the application of early intervention strategies and digital management tools, will promote more patients to receive standardized treatment.

Source: Frost & Sullivan Analysis

Growth drivers of SHPT drug market

Unmet clinical needs	• Influenced by the aging population and the high prevalence of underlying diseases such as diabetes mellitus and hypertension, the incidence of chronic kidney disease (CKD) is on the rise worldwide. With the progression of CKD, the prevalence of SHPT in CKD patients has gradually increased. According to Relationship between Secondary Hyperparathyroidism and Hypertension in Chronic Kidney Disease, the prevalence of SHPT can reach more than 80% in end-stage renal disease (ESRD) patients. Along with the growth of the number of CKD patients, the number of SHPT patients is also growing. CKD-MBD has a complex pathogenesis and currently lacks effective treatment options, presenting a significant unmet clinical need.
Increased diagnostic rate of SHPT	• In recent years, testing technology has been advancing, with third-generation PTH testing gradually replacing traditional methods, and combined with ultrasound, nuclide imaging and other imaging methods, the accuracy of evaluating the function and morphology of the parathyroid glands has been improved. Regular clinical monitoring of CKD patients and the promotion of multidisciplinary collaboration models have enabled more SHPT patients to be diagnosed promptly.
Drug R&D Innovation	• Existing CKD-SHPT therapies face critical clinical limitations. Active vitamin D analogs are excluded from non-dialysis guidelines due to risks of hypercalcemia and accelerated cardiovascular calcification. Conversely, oral CaSR agonists often trigger hypocalcemia and gastrointestinal adverse effects (e.g., nausea), compromising long-term patient compliance and resulting in a comprehensive target achievement rate of approximately 7.5%. This suboptimal efficacy underscores an urgent medical need for next-generation therapeutics with enhanced safety profiles to reduce mortality. Consequently, R&D has shifted toward innovative modalities like multi-target agonists, driving the growth of the CKD-SHPT drug market.

Source: Frost & Sullivan Analysis

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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 (m2). According to international standards set by the World Health Organization and the National Institutes of Health, a BMI of 25 kg/m2 or higher is considered overweight, while a BMI of 30 kg/m2 or higher defines obesity. In China, the official guidelines suggest that a BMI between 24 kg/m2 and 28 kg/m2 indicates overweight, while a BMI of 28 kg/m2 or higher indicates obesity.

Main factors of overweight and obesity

- **Dietary Factors:** Excessive intake of high-sugar, high-fat, and high-energy-density foods; imbalanced dietary composition.
- **Lack of Exercise:** Sedentary lifestyles reduce energy expenditure, while decreased muscle mass further lowers basal metabolic rate.
- **Genetics and Physiology:** Certain genes may increase susceptibility to obesity; endocrine disorders can also cause abnormal weight gain.
- **Environment and Psychology:** Widespread availability of processed foods, excessive stress, insufficient sleep, and other factors.

The relationship between major non-communicable diseases(NCD) and BMI

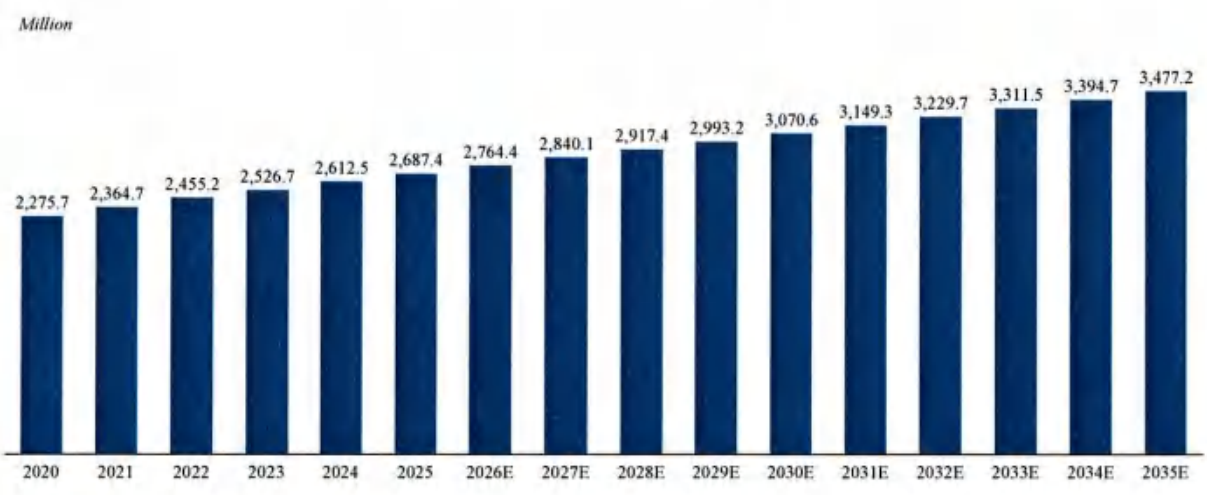
NCDs	Risk factor rank for premature deaths	High BMI as % of deaths	Risk factor rank for adult years living with ill health	High BMI as % of ill health
Cancers	4	9%	2	16%
Ischemic heart diseases	6	16%	8	14%
Stroke	11	7%	8	9%
Type 2 Diabetes	2	55%	2	55%

Source: Literature Review, Frost & Sullivan Analysis

Global Prevalence of obesity and overweight, 2020-2035E

- The global prevalence of overweight and obesity patients grew from 2,275.7 million in 2020 to 2,687.4 million in 2025, and is projected to reach 3,070.6 million by 2030 and 3,477.2 million by 2035.

Global Prevalence of obesity and overweight, 2020-2035E

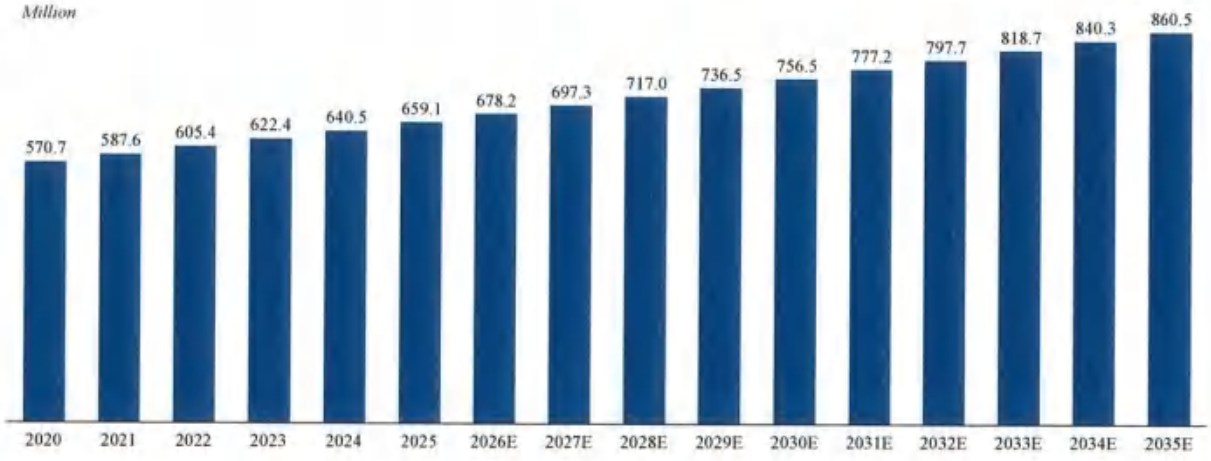


Source: Frost & Sullivan analysis

Prevalence of obesity and overweight in China, 2020-2035E

- In China, the prevalence of overweight and obesity increased from 570.7 million in 2020 to 659.1 million in 2025, and is projected to reach 756.5 million by 2030 and 860.5 million by 2035

Prevalence of obesity and overweight in China, 2020-2035E



Source: Frost & Sullivan analysis

Main treatment of overweight and obesity

- Current treatments for overweight and obesity focus on weight loss, weight maintenance, and managing related diseases, employing differentiated approaches based on obesity severity. Among these, GLP-1 receptor agonists serve as first-line therapies due to their dual efficacy in blood glucose control and weight reduction.
- The primary GLP-1 drugs globally include semaglutide and tirzepatide. While both demonstrate significant weight loss effects, they each have limitations.

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.

Limitations of approved GLP-1R drugs

- 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 highly significant weight-loss effects, they still face numerous limitations in clinical application. 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.

Source: Literature Review, Frost & Sullivan Analysis

Overview of CKD with Proteinuria

- CKD with proteinuria refers to the condition where patients with CKD have excessive protein in their urine. This usually indicates kidney damage and is associated with an increased risk of cardiovascular disease. The pathological core lies in the damage to the glomerular filtration barrier or impairment of renal tubular reabsorption. Persistent proteinuria activates intrarenal inflammatory responses, promotes glomerulosclerosis and renal tubulointerstitial fibrosis — which not only accelerates the progression to end-stage renal disease (ESRD) but also increases the risk of cardiovascular events by 2-3 times. Without intervention, most patients will require dialysis or renal transplantation for survival within 10-20 years.
- In China, the prevalence of CKD with proteinuria grew from 74.6 million in 2019 to 80.8 million in 2024 at a CAGR of 1.6% and is projected to reach 87.5 million by 2030 and 92.9 million by 2035.

Limitation of the treatment of CKD with proteinuria

- The treatment of CKD with proteinuria focuses on reducing proteinuria and delaying renal progression; however, current treatment approaches still have certain limitations. Basic lifestyle interventions serve only as adjuvant measures, primarily due to poor patient compliance and their effectiveness being limited to mild proteinuria. SGLT2 inhibitors exert both hypoglycemic and renoprotective effects, yet their application is restricted to specific patient groups, and they carry a risk of genitourinary tract infections. RAS inhibitors can lower blood pressure and reduce proteinuria, though the reduction in proteinuria rarely exceeds 50%; additionally, they may cause an increase in serum creatinine or hyperkalemia, and are contraindicated in patients with bilateral renal artery stenosis. Newer non-steroidal mineralocorticoid receptor antagonists (MRAs) can provide additional proteinuria reduction, but they are associated with a high risk of hyperkalemia, are expensive, and lack sufficient data on long-term use. When the disease progresses to end-stage renal disease (ESRD), dialysis or kidney transplantation becomes necessary. Dialysis can only replace 10%-15% of normal renal function and is associated with high risks of cardiovascular events and infections. In contrast, kidney transplantation faces challenges such as a shortage of donors and the need for long-term post-transplant use of immunosuppressants—which carry risks of rejection and malignancy. The shortcomings of existing treatments mean that significant unmet clinical needs remain in the field of CKD with proteinuria.

Source: Literature Review, Frost & Sullivan Analysis

Overview of MASH

- Metabolic Associated Steatohepatitis (MASH) is a severe subtype of Metabolic Associated Fatty Liver Disease (MASLD), and its core pathological feature is excessive fat accumulation in the liver accompanied by chronic inflammation and fibrosis. This disease is highly associated with metabolic disorders such as obesity and type 2 diabetes. In the early stage, MASH may only manifest as fatigue and impaired liver function; however, it can progress gradually to cirrhosis and hepatocellular carcinoma, while significantly increasing the risk of cardiovascular diseases—imposing a dual burden on patients' health and the social healthcare system.
- In China, the prevalence of MASH grew from 37.1 million in 2019 to 44.0 million in 2024 at a CAGR of 3.5% and is projected to reach 53.7 million by 2030 and 63.1 million by 2035.

Limitation of the treatment of MASH

- At present, the treatment of MASH is centered on basic interventional therapy and precision targeted therapy, which mainly includes three types of approaches: firstly, lifestyle intervention, which reduces liver fat through a healthy diet and exercise-induced weight loss and is regarded as a first-line treatment strategy; secondly, pharmacological therapy—In 2024, the FDA approved resmetirom, a thyroid hormone receptor beta agonist, as the first targeted drug for patients with non-cirrhotic MASH and moderate-to-severe fibrosis, while GLP-1R agonists have become the preferred option for obese patients or those with diabetes complicated by MASH due to their effects on weight loss and metabolic regulation; thirdly, end-stage intervention, where liver transplantation may be considered for patients with cirrhosis but its clinical application is limited.
- However, the existing treatments have significant limitations: for one thing, lifestyle intervention requires long-term and strict behavioral changes, leading to low patient compliance, and some weight loss methods may even cause muscle loss; for another, pharmacological therapy has limited coverage—for example, resmetirom is contraindicated in cirrhotic patients, and most drugs are still in the clinical trial phase, with no approved therapies for advanced cirrhosis yet; additionally, issues such as unclear disease mechanisms and unstandardized evaluation criteria for liver biopsy further hinder the advancement of drug development and precision treatment.

Source: Literature Review, Frost & Sullivan Analysis

Mechanism of GLP1R, GCCR, MASR agonist

- GLP1R, GCGR, and MASR are respectively distributed in different parts of the body. When activated, they exert effects by regulating glucose and lipid metabolism, etc. Their agonists can be used to treat metabolism-related diseases such as type 2 diabetes mellitus and obesity, and can also improve cardiovascular risk and complications.

Mechanism of GLP1R

- GLP1R is a G protein-coupled receptor distributed in the pancreas and central part of the body. When activated by GLP-1, GLP1R promotes insulin secretion, inhibits glucagon, reduces food intake and delays gastric emptying, and participates in the regulation of glucose and lipid metabolism; by mimicking the above effects, GLP-1R agonists lower blood glucose, reduce fat accumulation, and are used in the treatment of metabolic disorders, such as type 2 diabetes mellitus and obesity, and also reduce cardiovascular risk.

Mechanism of GCGR

- GCGR is mainly expressed in the liver, and when activated by glucagon, it promotes hepatic glycogenolysis and gluconeogenesis to maintain blood glucose homeostasis, and when metabolism is abnormal, over-activation will exacerbate hyperglycemia; GLP1R/GCGR dual-targeted agonists are used to treat metabolic disorders, such as type 2 diabetes mellitus and non-alcoholic fatty liver disease, by moderately regulating hepatic glucose output, promoting lipolysis, and synergistically improving insulin sensitivity.

Mechanism of MASR

- MASR is a G protein-coupled receptor of the renin-angiotensin system, distributed in blood vessels and kidneys, etc. After activated by Ang (1-7), it can relax blood vessels, anti-inflammatory and regulate metabolism, such as promoting water and sodium excretion, improving fat and liver metabolism; MASR agonists can lower blood pressure and improve insulin resistance through activating the receptor, which can be used to assist in the treatment of metabolic syndrome and diabetes mellitus complications.

Source: Literature Review, Frost & Sullivan Analysis

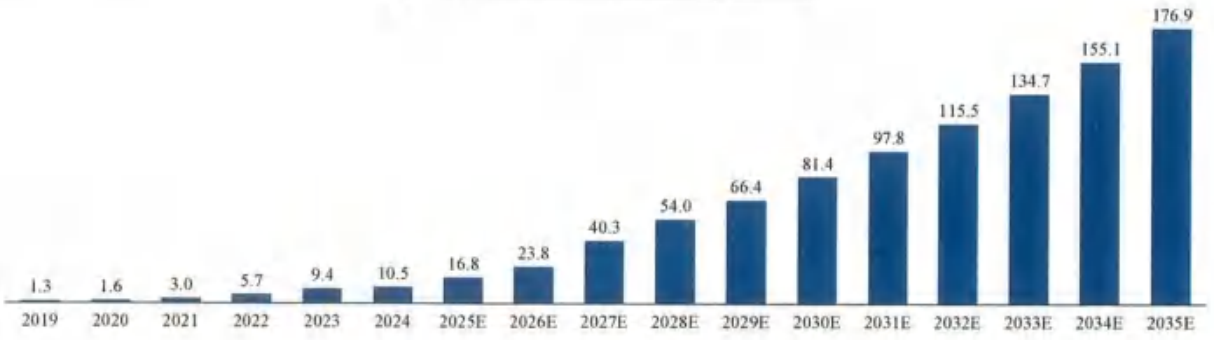
Market size and forecast of GLP1R peptide drugs in China, 2019-2035E

- With the approval of China's first GLP-1R drug for the treatment of obesity and overweight in 2023, the penetration rate of GLP-1R drugs has grown rapidly. In 2024, the GLP1R peptide drug market in China is RMB 10.5 billion. It is estimated that the GLP1R peptide drug market in China will grow to RMB 81.4 billion in 2030 and RMB 176.9 billion in 2035, with a CAGR of 40.6% from 2024 to 2030 and 16.8% from 2028 to 2035 respectively.

Market size and forecast of GLP1R peptide drugs in China, 2019-2035E

Period	CAGR
2019-2024	52.3%
2024-2030E	40.6%
2030E-2035E	16.8%

Billion RMB



Source: Frost & Sullivan analysis

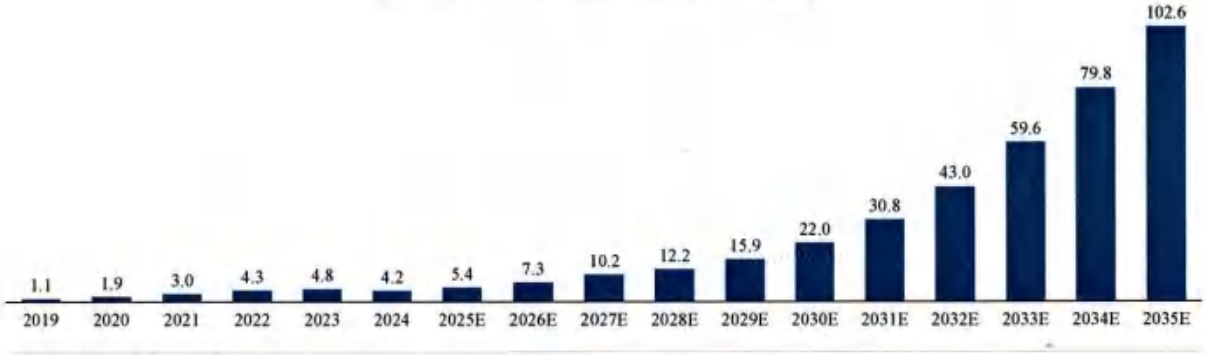
Market size and forecast of overweight and obesity drugs in China, 2019-2035E

- In 2024, the overweight and obesity drug market in China is RMB 4.2 billion. It is estimated that the overweight and obesity drug market in China will grow to RMB 22.0 billion in 2030 and RMB 102.6 billion in 2035, with a CAGR of 31.8% from 2024 to 2030 and 36.1% from 2028 to 2035 respectively.

Market size and forecast of overweight and obesity drugs in China, 2019-2035E

Period	CAGR
2019-2024	31.4%
2024-2030E	31.8%
2030E-2035E	36.1%

Billion RMB



Source: Frost & Sullivan analysis

Market size and forecast of overweight and obesity drugs in China, 2020-2035E

- Historically, treatment options for overweight and obesity in China were relatively limited. The mismatch between existing treatment regimens and clinical needs has unlocked immense market opportunities for GLP-1 receptor agonists. The research and development of long-acting GLP-1 drugs can reduce dosing frequency and enhance patient compliance, which is expected to lift the penetration level of GLP-1 therapeutics. This will broaden the patient base and further raise market penetration of GLP-1 drugs, especially against the backdrop of sustained growth in China's overweight and obese population. In addition, numerous GLP-1 receptor agonist candidates for the treatment of overweight and obesity are currently in clinical development across China. In view of the limited availability of existing therapies, the launch of such novel GLP-1 receptor agonists is expected to significantly fuel the rapid growth of China's overweight and obesity drug market. In 2025,the overweight and obesity drug market in China is RMB 5.7 billion. It is estimated that the overweight and obesity drug market in China will grow to RMB 23.5 billion in 2030 and RMB 107.3 billion in 2035, with a CAGR of 32.9% from 2025 to 2030 and 35.5% from 2030 to 2035 respectively.

Market size of overweight and obesity drugs in China, 2020-2035E

Period	CAGR
2020-2025	24.4%
2025-2030E	32.9%
2030E-2035E	35.5%

Billion RMB

Source: Frost & Sullivan analysis

Global competitive landscape of GLP1R peptide drugs pipeline

- To date, there are eight triple-target GLP1R peptide drug candidates in the clinical stage globally.

Target	Drug Code	Company	Indication	Clinical Stage	Latest update date
GLP1R, GCGR, GIPR	retatrutide	Eli Lilly	Overweight & Obesity, Diabetes Type 2, Chronic Low Back Pain, ASCVD, CKD, Obstructive Sleep Apnea, Osteoarthritis	Phase III	2026-05-22
	LY4086940		Overweight & Obesity, Diabetes Type 2	Phase I	2026-05-12
	efocipegtrutide	Hanmi Pharmaceutical	NASH	Phase II	2025-11-19
			Overweight & Obesity, NAFLD	Phase I	2025-02-06
	HM15275		Overweight & Obesity	Phase II	2026-05-26
	MWN109	Lepu Medical Technology	Overweight & Obesity	Phase I	2025-11-20
	SAR441255	Sanofi	Overweight	Phase I	2025-09-22
GLP1R, GIPR, AMYR	NN9662	Novo Nordisk	Overweight & Obesity, Diabetes Type 2	Phase II	2026-05-19
GLP1R, GIP, NPY2R	BI 3034701	Boehringer Ingelheim	Overweight & Obesity	Phase I	2025-11-21

As of June 1 2026

Source: ClinicalTrials.gov, Frost & Sullivan Analysis

Competitive landscape of GLP1R peptide drugs pipeline in China

- To date, there are 12 triple-target GLP1R peptide drug candidates in the clinical stage in China.

Target	Drug Code	Company	Indication	Clinical Stage	Latest Update Date
GLP1R, GCGR, MASR	XTL6001	Shaanxi Micot Pharmaceutical Technology	Overweight & Obesity, CKD with proteinuria	Phase I	2026-05-09
GLP1R, GCGR, GIPR	Retatrutide	Eli Lilly	MASLD	Phase III	2026-05-08
	LY4086940		Overweight & Obesity	Phase I	2024-07-08
	UBT251	Federal Biotechnology	Overweight & Obesity, Type 2 diabetes, MASH, CKD with proteinuria	Phase II	2026-04-24
	ZX2021	Jiangsu Kanion Pharmaceutical	Overweight & Obesity	Phase II	2025-06-18
	DYX116	Jiangsu Deyuan Pharmaceutical	Type 2 diabetes, Overweight & Obesity	Phase II	2026-05-18
	MWN101	Lepu Medical Technology	Type 2 diabetes, Overweight & Obesity	Phase II	2025-01-23
	MWN109		Type 2 diabetes, Overweight & Obesity	Phase II	2026-05-30
	HEC-007	HEC Pharmaceutical	Type 2 diabetes, Overweight & Obesity	Phase I	2026-04-12
	HRS-4729	Hengrui Pharma	Overweight & Obesity	Phase I	2026-05-07
GLP1R, GCGR, FGF21	MWN105	Lepu Medical Technology	Overweight & Obesity	Phase II	2025-09-05
			Type 2 diabetes, Overweight & Obesity	Phase I	2024-12-27
	DR10624	Huadong Medicine	MAFLD, Hypertriglyceridemia	Phase II	2026-02-14

As of June 1 2026

Source: CDE, Frost & Sullivan Analysis

Global competitive landscape of GLP1R peptide drugs pipeline

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	2026-05-09
			Overweight & Obesity	FDA	IND	2024-12-20
	Retatrutide	Eli Lilly	Overweight & Obesity, Diabetes Type 2, Chronic Low Back Pain, ASCVD, CKD, Obstructive Sleep Apnea, Osteoarthritis	FDA	Phase III	2026-05-22
			MASLD	NMPA	Phase III	2026-05-08
	LY4086940		Overweight & Obesity, Diabetes Type 2	FDA	Phase I	2026-05-12
			Overweight & Obesity	NMPA	Phase I	2024-07-08
	Efocipegtrutide	Hanmi Pharmaceutical	NAFLD	FDA	Phase II	2025-11-19
			Overweight & Obesity	FDA	Phase I	2025-02-06
	HM15275		Overweight & Obesity	FDA	Phase II	2026-05-26
GLP1R, GCGR, GIPR	UBT251	Federal Biotechnology	Overweight & Obesity, Type 2 diabetes, MASH, CKD with proteinuria	NMPA	Phase II	2026-04-24
		Novo Nordisk	Overweight & Obesity	FDA	Phase II	2026-02-17
	ZX2021	Jiangsu Kanion Pharmaceutical	Overweight & Obesity	NMPA	Phase II	2025-06-18
	DYX116	Jiangsu Deyuan Pharmaceutical	Type 2 diabetes, Overweight & Obesity	NMPA	Phase II	2026-05-18
	MWN101	Lepu Medical Technology	Type 2 diabetes, Overweight & Obesity	NMPA	Phase II	2025-01-23
	MWN109		Type 2 diabetes, Overweight & Obesity	NMPA	Phase II	2026-05-30
			Overweight & Obesity	FDA	Phase I	2025-11-20
	SAR441255	Sanofi	Overweight	FDA	Phase I	2025-09-22
	HEC-007	HEC Pharmaceutical	Type 2 diabetes, Overweight & Obesity	NMPA	Phase I	2026-04-12
	HRS-4729	Hengrui Pharma	Overweight & Obesity	NMPA	Phase I	2026-05-07
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	DR10624	Huadong Medicine	MAFLD, Hypertriglyceridemia	NMPA	Phase II	2026-02-14
GLP1R, GIPR, AMYR	NN9662	Novo Nordisk	Overweight & Obesity, Diabetes Type 2	FDA	Phase II	2026-05-19
GLP1R, GIP, NPY2R	BI 3034701	Boehringer Ingelheim	Overweight & Obesity	FDA	Phase I	2025-11-21

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

Future Trends of GLP1R peptide drugs market

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 proteinuria and MASH. Among CKD patients in China, nearly 50% exhibit proteinuria abnormalities. 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.

Domestic substitution

- Although overseas GLP-1 peptide drugs occupy nearly 90% of the global market share, domestic innovative drugs are realizing breakthrough through differentiated technology. Domestic GLP-1 innovative drugs have demonstrated superior efficacy in clinical trials compared with marketed imported GLP-1 peptide drugs, have differentiated target combination design, and have completed some overseas licensing deals, showing that domestic GLP-1 innovative drugs have the potential to replace imported GLP-1 drugs.

Source: Frost & Sullivan Analysis

Growth drivers of GLP1R peptide drugs market

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. According to the China Public Weight Management and Nutrition Awareness Survey Report (2026), 91.7% of the public recognizes the importance of weight management. In particular, the younger generations, who are increasingly impacted by obesity and overweight, are showing a greater willingness to engage in weight management treatments.
Favorable government policies	• The Chinese government has implemented a number of policies to support effective and innovative therapies for obesity and weight management. For instance, in 2024, National Health Commission and 16 other departments launched the "Weight Management Year" initiative, which focuses on creating supportive environments for weight management and increasing public awareness about obesity and overweight treatments. Such government-led efforts are spurring demand for weight management medications and contributing to the market growth.

Source: Frost & Sullivan Analysis

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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. In a broader definition, pan-vascular diseases also encompass small vessel, microvascular, and venous disorders, as well as vasculopathies associated with cancer, diabetes, and immune-mediated mechanisms. 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). PAD specifically includes lower extremity artery disease (LEAD), supra-aortic artery disease (encompassing carotid, vertebral, and subclavian arteries), and visceral artery disease (involving renal, mesenteric, and other visceral arteries), etc. Antithrombotic therapy is a cornerstone of management for pan-vascular diseases, primarily consisting of antiplatelet therapy and anticoagulant therapy.

Antithrombotic Therapy for Pan-Vascular Diseases

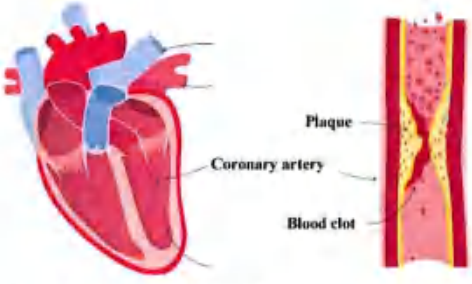
Therapy	Mechanism	Representative drugs	Applicable disease areas
Anticoagulant Therapy	Inhibiting the activity of certain coagulation factors in the blood to prevent and treat thrombotic diseases	Heparin, Warfarin, Novel Oral Anticoagulants (e.g., Rivaroxaban, Dabigatran)	• **Cardiovascular diseases**: atrial fibrillation, post-heart valve replacement, acute coronary syndrome; • **Venous diseases**: deep vein thrombosis (DVT), pulmonary embolism (PE), thrombophlebitis; • **Other high-risk conditions**: hereditary thrombophilia, cancer-associated thrombosis, long-term immobilization, post-major surgery
Antiplatelet Therapy	Primarily targeting arterial thrombosis by inhibiting platelet aggregation and preventing platelet-rich thrombus formation	Aspirin, Clopidogrel, Ticagrelor…	• Coronary artery disease/angina, post-myocardial infarction, stroke prevention, post-coronary stenting

Source: Literature Review, Frost & Sullivan Analysis

Overview of ACS and 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.

Acute Coronary Syndrome (ACS)



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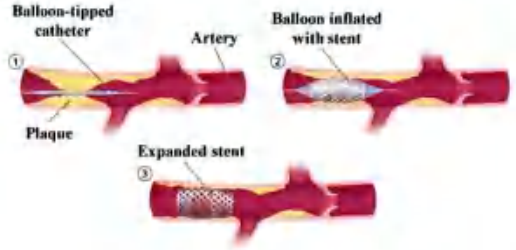
Percutaneous coronary intervention (PCI)



- 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.

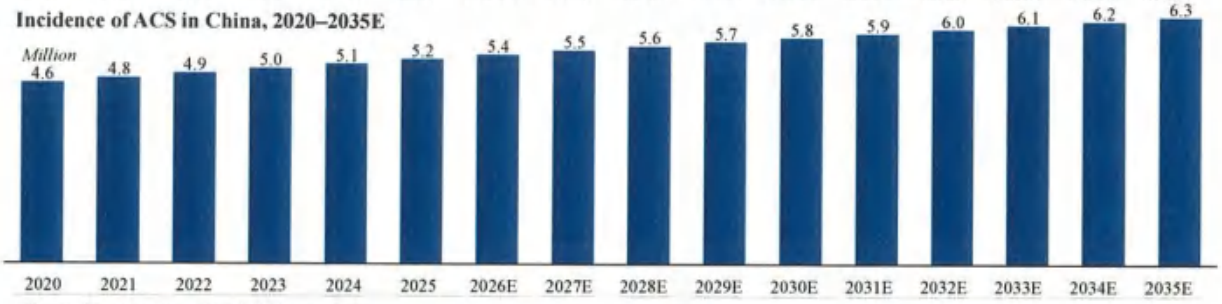
Source: Literature Review, Frost & Sullivan Analysis

Global Incidence of ACS, 2020–2035E

- From 2020 to 2025, the incidence of ACS worldwide increased from 23.8 million to 26.6 million. It is estimated that by 2030 and 2035, the incidence of ACS worldwide will reach 29.1 million and 31.4 million, respectively.
- From 2020 to 2025, the incidence of ACS in China increased from 4.6 million to 5.2 million. It is estimated that by 2030 and 2035, the incidence of ACS in China will reach 5.8 million and 6.3 million, respectively.

Global Incidence of ACS, 2020–2035E

Incidence of ACS in China, 2020–2035E

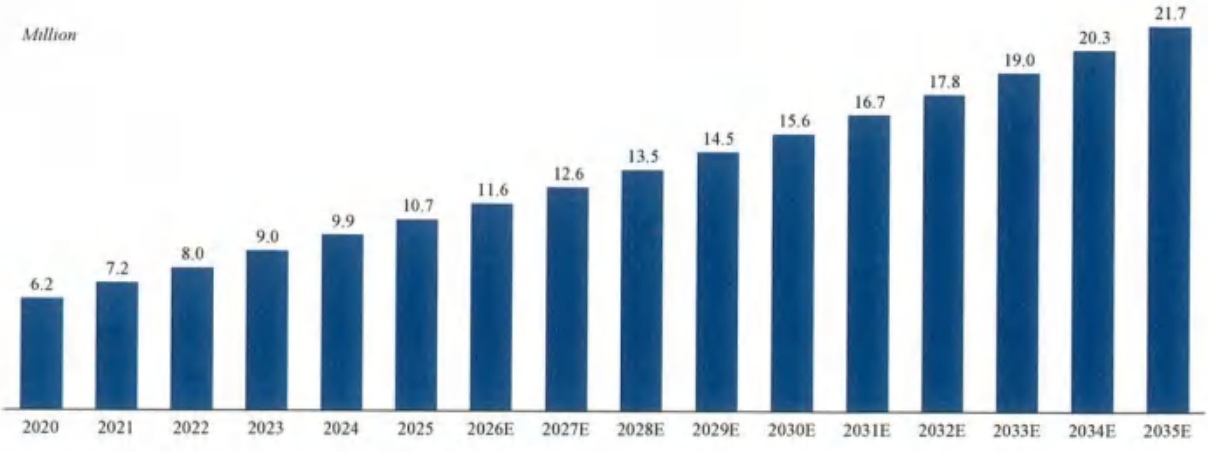


Source: Expert interview, Frost & Sullivan analysis

Global PCI Procedure Volume, 2020–2035E

- From 2020 to 2025, the volume of PCI procedures worldwide increased from 6.2 million to 10.7 million. It is estimated that by 2030 and 2035, the volume of PCI procedures worldwide will reach 15.6 million and 21.7 million, respectively.

Global PCI Procedure Volume, 2020–2035E

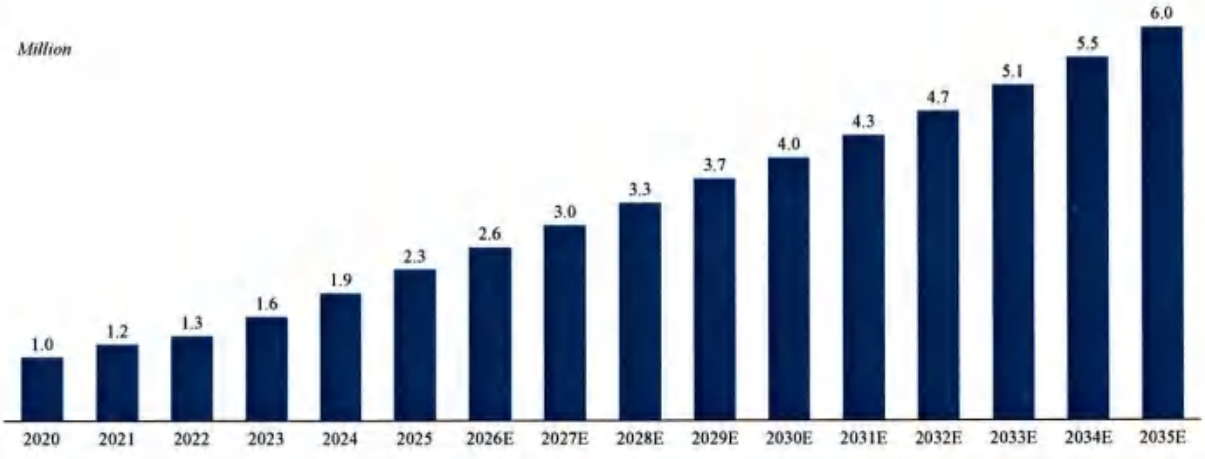


Source: Frost & Sullivan analysis

Procedure Volume in China, 2020–2035E

- From 2020 to 2025, the volume of PCI procedures in China increased from 1.0 million to 2.3 million. 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.

Procedure Volume in China, 2020–2035E



Source: Frost & Sullivan analysis

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.

Antiplatelet Therapy

- Clinically used antiplatelet agents include oral medications such as aspirin, and the $P2Y_{12}$ receptor antagonists clopidogrel, ticagrelor, and prasugrel, as well as intravenously administered **glycoprotein IIb/IIIa inhibitors (GPIs)** such as tirofiban and eptifibatide. Currently, GPIs are indicated exclusively for patients with high intraoperative thrombus burden, concomitant coronary slow flow or no-reflow phenomena, or those experiencing in-stent thrombosis.

Anticoagulant Therapy

- For all patients with ACS, anticoagulant therapy should be initiated immediately upon diagnosis. Whether undergoing primary PCI for ACS or elective PCI for chronic coronary syndrome (CCS), intraoperative anticoagulation with heparin is required. Available anticoagulant agents include unfractionated heparin (UFH), low-molecular-weight heparin (LMWH), fondaparinux, and bivalirudin. Following emergency or elective PCI, routine post-procedural anticoagulation is generally not required. However, continued anticoagulation may be indicated in high-risk or complex PCI cases, or in the presence of complications such as no-reflow phenomenon, or when there are concurrent clinical conditions necessitating anticoagulation. These conditions include atrial fibrillation, prior mechanical heart valve implantation, lower extremity deep vein thrombosis, pulmonary embolism, or intracardiac thrombus formation. Additionally, in patients who are immobilized for prolonged periods, prophylactic-dose anticoagulation may be warranted. Suitable agents for long-term or prophylactic anticoagulation include warfarin or non-vitamin K antagonist oral anticoagulants (NOACs) such as apixaban, rivaroxaban, edoxaban, or dabigatran.

Source: Frost & Sullivan analysis

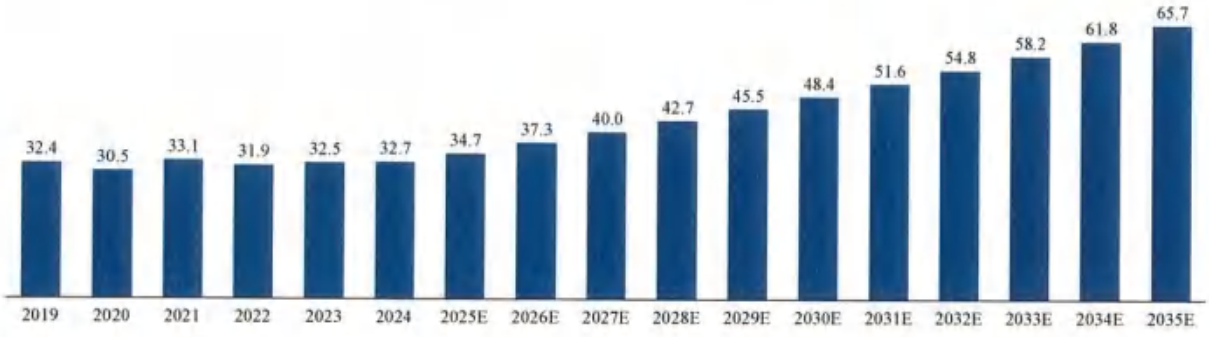
Market Size and Forecast of Antithrombotic Drugs in China, 2019-2030E

- In 2024, the antithrombotic drugs market in China reached RMB 32.7 billion. It is estimated that the antithrombotic drugs market in China will grow to RMB 48.4 billion in 2030 and RMB 65.7 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

Period	CAGR
2019-2024	0.2%
2024-2030E	6.7%
2030E-2035E	6.3%

Billion RMB



Source: Expert interview, Frost & Sullivan analysis

Market size and forecast of antithrombotic drugs in China, 2020-2035E

- China is witnessing accelerated population aging alongside a growing elderly population, and the morbidity rate of thromboembolic diseases rises progressively with age, forming the core demand group for antithrombotic drugs. Meanwhile, there exists a substantial patient base suffering from chronic illnesses including cardiovascular diseases, and the heavy socioeconomic and medical burden imposed by such ailments fuels sustained clinical treatment needs. The continuous refinement of national clinical diagnosis and treatment guidelines has facilitated the standardization and normalization of antithrombotic therapy, thereby further unlocking unmet clinical demand. Leveraging superior efficacy, favourable safety profiles and higher administration convenience, novel antithrombotic drugs are rapidly substituting conventional alternatives and reshaping the market structure. In addition, patients afflicted with thromboembolic diseases generally require long-term or even lifelong medication use, which underpins steady repeat purchasing demand. Collectively, the aforesaid factors drive the steady expansion of China's antithrombotic drug market
- In 2025, the antithrombotic drugs market in China reached RMB 34.5 billion. It is estimated that the antithrombotic drugs market in China will grow to RMB 47.2 billion in 2030 and RMB 61.8 billion in 2035, with a CAGR of 6.4% from 2025 to 2030 and 5.6% from 2030 to 2035, respectively.

Market size of antithrombotic drugs in China, 2020-2030E

Period	CAGR
2020-2025	2.5%
2025-2030E	6.4%
2030E-2035E	5.6%

Billion RMB

Source: Frost & Sullivan analysis

Growth Drivers of the Antithrombotic Drug Market

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.
Heightened Risk of Thrombosis in Interventional Therapies	• The continuous development and widespread adoption of cardiovascular interventional procedures have significantly improved the treatment outcomes for patients with CVDs. Nevertheless, these interventions are associated with a heightened risk of thrombosis during and after the procedures. According to Complications and Management of Coronary Artery Injury During Emergency PCI, the overall incidence of thrombotic events during PCI is 7.7%, 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.
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.

Source: Frost & Sullivan Analysis

Future Trends 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 $P2Y_{12}$ 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.
Expansion of Treatment Fields	• With advancing disease understanding, evolving clinical needs, and optimized drug properties, the application scope of antithrombotic therapies has expanded beyond traditional core indications. This includes extension from cardiovascular diseases to cerebrovascular disorders, peripheral artery disease, and cancer-associated thrombosis, as well as a shift from treating established thrombosis to preventing thrombotic complications in underlying conditions such as metabolic syndrome and autoimmune diseases. The therapeutic focus has further transitioned from acute thrombus management to comprehensive risk prevention across the entire disease course, and from single-disease treatment to integrated management of multimorbidity.
Precision and Personalization in Antithrombotic Therapies	• Conventional antithrombotic agents historically targeted broad physiological pathways, limiting specificity. Advances in thrombosis mechanism research have driven drug development toward precise molecular targets. For example, novel oral anticoagulants (NOACs) directly modulate specific factors within the coagulation cascade—direct thrombin inhibitors selectively target thrombin, enabling more precise regulation of haemostasis while reducing bleeding risks. In antiplatelet therapy, emerging agents directed against platelet-specific receptors (e.g., $P2Y_{12}$ receptors, glycoprotein IIb/IIIa receptors) demonstrate enhanced capacity to selectively inhibit platelet activation and aggregation. These innovations not only improve antithrombotic efficacy but also elevate treatment safety profiles, collectively advancing the field toward precision medicine in thrombosis management.

Source: Frost & Sullivan Analysis

Global 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.

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	Piano 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 Angioplasty

*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

As of June 1 2026

Source: NMPA, FDA, Frost & Sullivan Analysis

Global Competitive Landscape of PCI Drugs Pipeline

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

Target	Drug Code	Company	Indication	Regulatory Authorities	Clinical Stage	Latest Update Date
GPFactor II, GPIIb/IIIa	MT1002	Shaanxi Micot Pharmaceutical Technology	• Anticoagulation therapy and antithrombotic therapy for ACS patients undergoing PCI; • ACS patients undergoing PCI with HIT or HITT	NMPA	Phase II	2024-05-11
			• ACS patients undergoing PCI	FDA	Phase I	2019-08-08
	Vicagrel	Jiangsu vcare pharmaceutical	• Patients with ACS undergoing PCI	FDA	Phase III	2024-10-01
	DT678	Beijing SL Pharmaceutical	• Antiplatelet therapy in patients following PCI	NMPA	Phase II	2026-01-04
	PRT060128	Portola Pharmaceuticals	• Non-urgent PCI	FDA	Phase II	2023-08-08
P2RY12	HY-022619	Hefei medical and Pharmaceutical	• Antiplatelet therapy in the perioperative treatment of PCI in patients with ACS	NMPA	Phase I	2026-01-28
	CG-0255	Shanghai CureGene Pharmaceutical	• Antiplatelet therapy in the perioperative treatment of PCI in patients with ACS	NMPA	Phase I	2026-03-04
	Cangrelor	Jiangsu Aosaikang Pharmaceutical	• Antithrombotic therapy in the perioperative treatment of PCI in patients with ACS	NMPA	Phase I	2019-07-30
LIAS、LIPT1、SLC5A6	CMX-2043	Ischemix, LLC	• Patients undergoing PCI and Peri-operative reperfusion treatment	FDA	Phase II	2011-06-20
CDH5	FX06	Biopure Corporation	• Ischemia reperfusion injury in patients undergoing PCI	FDA	Phase II	2007-12-04
/	SBK009	Chengdu Shibeikang Biopharmaceutical	• Antiplatelet therapy in the perioperative treatment of PCI in patients with ACS	NMPA	Phase I	2025-12-23

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

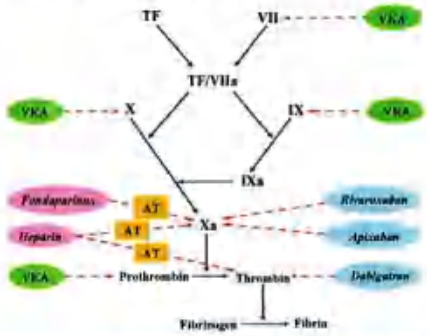
As of June 1 2026

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

Overview and Mechanism of Factor II and GPIIb/IIIa Targets

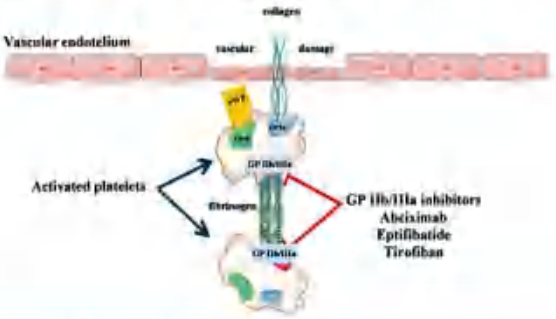
- Coagulation factor II, namely thrombin (a serine protease in plasma), is generated by activation of the liver-synthesized precursor prothrombin (the precursor of coagulation factor II).
- Glycoprotein IIb/IIIa (GP IIb/IIIa) inhibitors prevent platelet aggregation by blocking glycoprotein IIb/IIIa receptors on their platelet's plasma membrane and inhibiting fibrinogen binding. The available GP IIb/IIIa inhibitors include tirofiban and eptifibatide. These agents, along with aspirin, are used in patients with unstable angina with PCI within 24 hours.

Function and Mechanism of Factor II



- Coagulation factor II, namely thrombin (a serine protease in plasma), is generated by activation of the liver-synthesized precursor prothrombin (the precursor of coagulation factor II). It is a key enzyme in the coagulation cascade (a series of enzymatic reactions leading to blood clot formation) that converts fibrinogen (a plasma protein converted by thrombin into fibrin) into an insoluble fibrin mesh. It also promotes platelet (cell fragments involved in hemostasis and thrombosis) activation and the activation of other coagulation factors (enzymes and proteins involved in hemostasis), representing a critical step in the formation of stable thrombus.

Function and Mechanism of GPIIb/IIIa Target



- GPIIb/IIIa (integrin αIIbβ3, an integrin receptor on the platelet membrane) is the primary integrin receptor on the platelet surface. Upon activation of platelets by ADP (adenosine diphosphate, a platelet activator), TXA2 (thromboxane A2, a platelet-secreted pro-aggregatory substance), and vWF (von Willebrand factor, a glycoprotein mediating platelet adhesion), this receptor undergoes a conformational change enabling it to bind fibrinogen (fibrinogen, a plasma protein involved in thrombus formation) or vWF, bridging multiple platelets to form aggregates — this is the core mechanism of white thrombus formation (particularly arterial thrombosis).

Source: Literature review, Frost & Sullivan analysis

Overview of Dual-Target Antagonist of Factor II and GPIIb/IIIa

- The dual-target antagonist of coagulation Factor II and GPIIb/IIIa is a bifunctional antagonist indicated for antithrombotic and anticoagulant therapy in patients with ACS undergoing PCI. Clinical studies have demonstrated that the use of anticoagulants or antiplatelet agents as monotherapy is associated with a high incidence of bleeding complications or treatment failure. The dual-target antagonists simultaneously exert specific, reversible direct inhibition of Factor II and GP IIb/IIIa, thereby delivering synergistic antithrombotic effects through dual mechanisms of action. By targeting both pathways concurrently, it addresses the challenges associated with combination drug dosing and reduces the risk of haemorrhagic adverse events.

Advantages of dual-target antagonist of coagulation Factor II and GPIIb/IIIa

Synergistic antithrombotic mechanism

- Thrombus formation fundamentally results from the combined action of platelet adhesion and aggregation and fibrin cross-linking driven by thrombin. The dual-target antagonist simultaneously inhibits thrombin activity and blocks the key steps of platelet aggregation, generating complementary antithrombotic effects. Unlike single-target antithrombotic agents which often require high-dose administration to achieve sufficient efficacy, thereby increasing the risk of adverse effects. The synergistic interaction of dual-target inhibition enables comparable or superior antithrombotic potency at lower individual doses, significantly improving therapeutic efficiency while minimizing off-target toxicity.

Simplify the treatment regimen and optimise therapeutic compliance

- In contemporary clinical practice, patients undergoing PCI for ACS routinely require combination therapy with multiple pharmacological agents, including dual antiplatelet therapy and adjunctive anticoagulants. However, this polypharmacy approach is associated with significant clinical challenges, including complex drug-drug interactions that may amplify adverse effects, difficulties in individualized dose titration, and suboptimal patient adherence due to high pill burden and cumulative side effects. The dual-target antagonist integrates both anticoagulant and antiplatelet functionalities within a single molecular entity, simultaneously targeting thrombin-mediated fibrin generation and glycoprotein IIb/IIIa receptor-dependent platelet aggregation. By eliminating the need for concurrent administration of separate anticoagulant and antiplatelet agents, this therapeutic class streamlines the treatment regimen, minimizes the risk of drug-drug interactions, and simplifies clinical decision-making for dose optimization. These advantages collectively enhance long-term therapeutic adherence and contribute to greater stability in treatment efficacy, particularly for patients with complex comorbidities or heightened susceptibility to adverse drug reactions.

Source: Literature review, Frost & Sullivan analysis

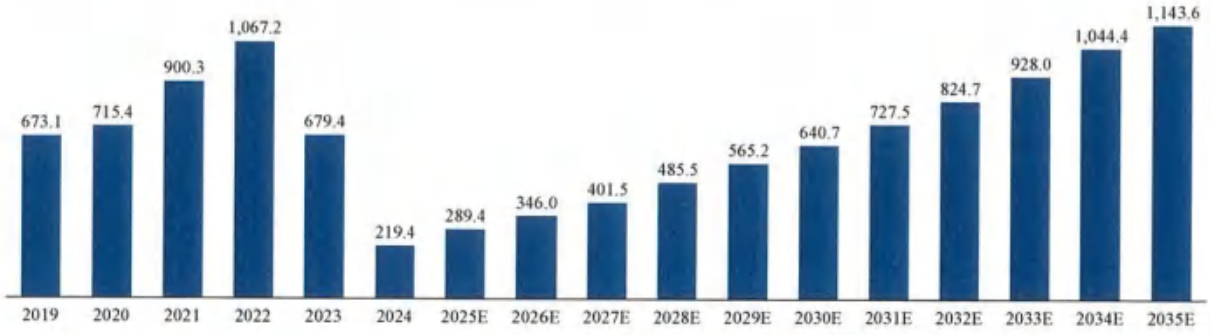
Market Size and Forecast of GPIIb/IIIa Antagonist in China, 2019-2030E

- In 2024, the GPIIb/IIIa antagonist market in China reached RMB 219.4 million. It is estimated that the GPIIb/IIIa antagonist market in China will grow to RMB 640.7 million in 2030 and RMB 1,143.6 million in 2035, with a CAGR of 19.6% from 2024 to 2030 and 12.3% from 2030 to 2035, respectively.

Market Size and Forecast of GPIIb/IIIa Antagonist in China, 2019-2030E

Period	CAGR
2019-2024	-20.1%
2024-2030E	19.6%
2030E-2035E	12.3%

Million RMB



Source: Frost & Sullivan analysis

Global Competitive Landscape of GPIIb/IIIa Antagonist Approved by NMPA

- Currently, there are no dual-target antagonist of coagulation factor II and GPIIb/IIIa drugs that have been approved for marketing globally. To date, there are 3 GPIIb/IIIa antagonist drugs approved by NMPA.

GPIIb/IIIa Antagonist Approved by NMPA

Target	Drug Name	Brand Name	Company	Indication	NMPA Approval date
GPIIb/IIIa	Tirofiban	Aggrastat	Merck	ACS, MI, angina pectoris, ischemia	2003-06-13
GPIIb/IIIa	Eptifibatide*	NA	Hansoh Pharmaceutical etc.	Unstable angina, ACS, MI	2012-10-30
GPIIb/IIIa	Bevifibatide	Betagrin	Bio-Thera	Perioperative antithrombotic therapy for PCI	2024-06-25

*Note. Currently, eptifibatide is only approved in China as a generic drug, with approved manufacturers including Hybio Pharmaceutical Co., Ltd., Beijing SL Pharmaceutical Co., Ltd., Shenyang Shuangding Pharmaceutical Co., Ltd., among others

As of September 5th, 2025

Source: NMPA, Frost & Sullivan Analysis

Global Competitive Landscape of GPIIb/IIIa Antagonist Approved by FDA

- To date, there are 2 GPIIb/IIIa antagonist drugs approved by FDA.

GPIIb/IIIa Antagonist Approved by FDA

Target	Drug Name	Brand Name	Company	Indication	FDA Approval date
GPIIb/IIIa	Tirofiban	Aggrastat	Medicure	ACS, MI, angina pectoris, ischemia	1998-05-14
GPIIb/IIIa	Eptifibatide*	Eptifibatide	TEVA Pharms	Unstable angina, ACS, MI	2015-06-12

*Note: The original drug of Eptifibatide (Integrilin) discontinued manufacturing based on a supply issue with eptifibatide, the active pharmaceutical ingredient in Integrilin.

As of September 5th, 2025

Source: FDA, Frost & Sullivan Analysis

Global Competitive Landscape of GPIIb/IIIa Antagonist Pipeline

- To date, there are 3 GPIIb/IIIa antagonist drug candidates for in the clinical stage globally.

Global Competitive Landscape of GPIIb/IIIa Antagonist Drugs Pipeline

Target	Drug Code	Company	Indication	Clinical Stage	Latest update date
GPIIb/IIIa	CSL511	CSL Behring	Acquired fibrinogen deficiency	Phase III	2025-05-28
GPIIb/IIIa	Zalunfiban	CeleCor Therapeutics	ST-elevation myocardial infarction	Phase III	2025-06-29
GPIIb/IIIa	BT-524	Biotext AG	Congenital afibrinogenemia, congenital hypofibrinogenemia	Phase III	2025-06-13

As of September 5th, 2025

Source: ClinicalTrials.gov, Frost & Sullivan Analysis

Competitive Landscape of GPIIb/IIIa Antagonist Pipeline in China

- To date, there are 2 GPIIb/IIIa antagonist drug candidates for in the clinical stage in China.

Competitive Landscape of GPIIb/IIIa Antagonist Drugs Pipeline in China

Target	Drug Code	Company	Indication	Clinical Stage	Latest update date
Factor II, GPIIb/IIIa	MT1002	Shanxi Micot Pharmaceutical	ACS: non-ST elevation myocardial infarction (NSTEMI), ST-elevation myocardial infarction (STEMI), Unstable angina (UA)	Phase II	2024-05-11
GPIIb/IIIa	HYC11395	Nanjing Heqi Pharmaceutical	Short-term antiplatelet therapy for patients with coronary ischemic syndrome undergoing percutaneous coronary angioplasty or coronary intravascular atherectomy during the perioperative period	Phase I	2018-11-28

As of September 5th, 2025

Source: CDE, Frost & Sullivan Analysis

Overview of Stroke

- Cerebrovascular disease refers to transient or permanent neurological dysfunction caused by one or more cerebrovascular lesions due to various etiologies, with acute onset being the most common clinical presentation. The acute manifestation of cerebrovascular disease is known as stroke, which is a general term for brain disorders characterized by sudden focal or diffuse neurological deficits resulting from circulatory disturbances. Stroke mainly includes ischemic stroke, intracerebral haemorrhage, and subarachnoid haemorrhage.

Prevalence of Stroke

- Stroke has become the leading cause of death and disability in China, posing a significant threat to the health of residents as a major chronic disease. In China, the prevalence of stroke grew from 28.2 million in 2019 to 36.0 million in 2024 at a CAGR of 5.0% and is projected to reach 45.8 million by 2030 and 55.4 million by 2035.

Treatment Analysis and Unmet Needs

- The pharmacological treatment of stroke aims to control the progression of the disease by targeting its diverse etiologies, risk factors, and complications, thereby reducing mortality, disability rates, and recurrence. Currently, the main categories of medications include specific therapeutic drugs such as thrombolytics, antiplatelet drugs, anticoagulants, and neuroprotective agents, as well as non-specific therapeutic agents including lipid-lowering drugs, antihypertensive drugs, and hypoglycemic agents.
- Nevertheless, existing pharmacotherapies still exhibit certain limitations in treatment efficacy. Therefore, there is an urgent need to develop novel therapeutic targets and drug strategies that enable more precise pharmacological management of cerebrovascular disease patients across varying degrees (e.g., high-risk populations, acute cerebrovascular events, secondary prevention) and different disease stages (e.g., ultra-acute phase, acute phase, stable phase). Additionally, the development of thrombolytic agents with longer half-lives and lower haemorrhagic transformation rates remains a critical priority.

Source: Literature Review, Frost & Sullivan Analysis

Overview of Anticoagulation Therapy for Hemodialysis

- Chronic kidney disease (CKD) is a progressive loss of glomerular function caused by a long-standing renal parenchymal disease. End-stage renal disease (ESRD) is the last stage (stage five) of CKD and has become a growing global public health concern, imposing a substantial economic burden on both families and society. The main treatment modalities for patients with ESRD include haemodialysis (HD), peritoneal dialysis (PD), and kidney transplantation (KT). Among these, HD is the predominant treatment approach. HD plays a role in clearing toxins, removing excess water, maintaining electrolyte and acid-base balance, and providing temporary renal replacement therapy through diffusion, convection, and other methods, and is becoming increasingly widely used in clinical practice.

The number of Patients Receiving HD Treatment

- The number of patients receiving HD treatment worldwide increased from 3.1 million in 2019 to 3.7 million in 2024. It is projected to reach 4.6 million by 2030 and 5.5 million by 2035. In China, the number of patients receiving HD treatment grew from 0.6 million in 2019 to 1.0 million in 2024 at a CAGR of 10.2% and is projected to reach 1.8 million by 2030 and 2.8 million by 2035.

Treatment Analysis and Unmet Needs

- Safe and effective anticoagulation is a prerequisite for ensuring the smooth progress of haemodialysis. Adequate anticoagulation is crucial in maintaining the flow of blood in the extracorporeal circulation during HD, avoiding blood loss caused by extracorporeal coagulation and inducing thromboembolic diseases. There are many types of anticoagulants, and currently commonly used in clinical practice include unfractionated heparin, low-molecular-weight heparin, argatroban, sodium citrate, and naprolimus mesylate.
- However, due to platelet adhesion and aggregation dysfunction in patients with renal failure, the incidence of bleeding is high. Currently available mainstream pharmaceuticals are associated with common adverse reactions such as bleeding, heparin-induced thrombocytopenia (HIT), and may lead to severe side effects including shock and dyspnoea. These drugs are contraindicated in patients with severe liver failure, a high risk of bleeding, or HIT. There is an urgent clinical need to develop innovative, targeted therapeutic agents with fewer side effects, improved safety, and enhanced efficacy.

Source: Literature Review, Frost & Sullivan Analysis

Overview of HD with Heparin-platelet Factor 4 Complex (HD-PF4)

- HIT is one of the major adverse effects associated with commonly used anticoagulants in dialysis. Type II HIT occurs when heparin forms a complex with platelet factor 4 (PF4), inducing conformational changes that trigger the production of autoantibodies. These antibodies lead to platelet activation, aggregation, and consumption, and may also damage the vascular endothelium, resulting in arterial and venous thrombosis, which is heparin-induced thrombocytopenia and thrombosis, (HITT). The incidence of Type II HIT following initial heparin exposure ranges from 3% to 5%, making it a potentially life-threatening and severe complication.

Treatment Analysis and Unmet Needs

- Heparin drugs are not suitable for patients with type II HIT or HD patients with heparin-platelet factor 4 complex. Commonly used anticoagulants such as low molecular weight heparin are contraindicated in the treatment of Type II or as alternative anticoagulants due to their potential for cross-reactivity with heparin-PF4 antibodies. Currently available therapeutic agents do not fully meet clinical needs. Consequently, the development of novel anticoagulant agents for HD, featuring reduced bleeding risk, minimal complications, and a lower incidence of dialyzer clotting, has emerged as a key priority in new drug research and development.

Source: Literature Review, Frost & Sullivan Analysis

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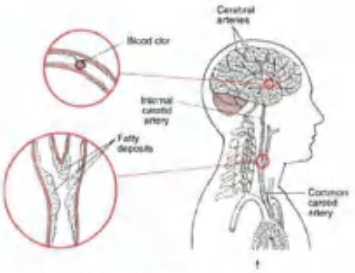
Introduction of ischemic stroke

- 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.

Ischemic stroke



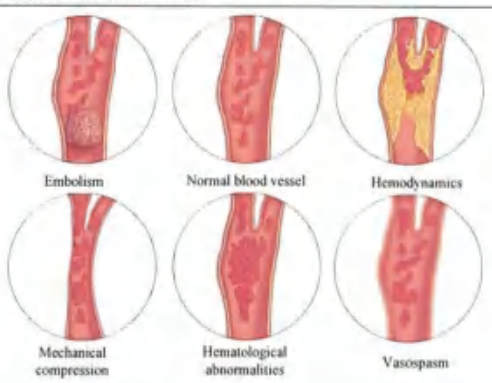
The major causes of acute ischemic stroke:

- Atherosclerosis-induced blood clots blocking large intracranial blood vessels (cerebral arteries)

Arteries mainly involved in chronic arterial stenosis:

- Cerebral artery, internal carotid artery, common carotid artery

Pathogenesis of ischemic stroke



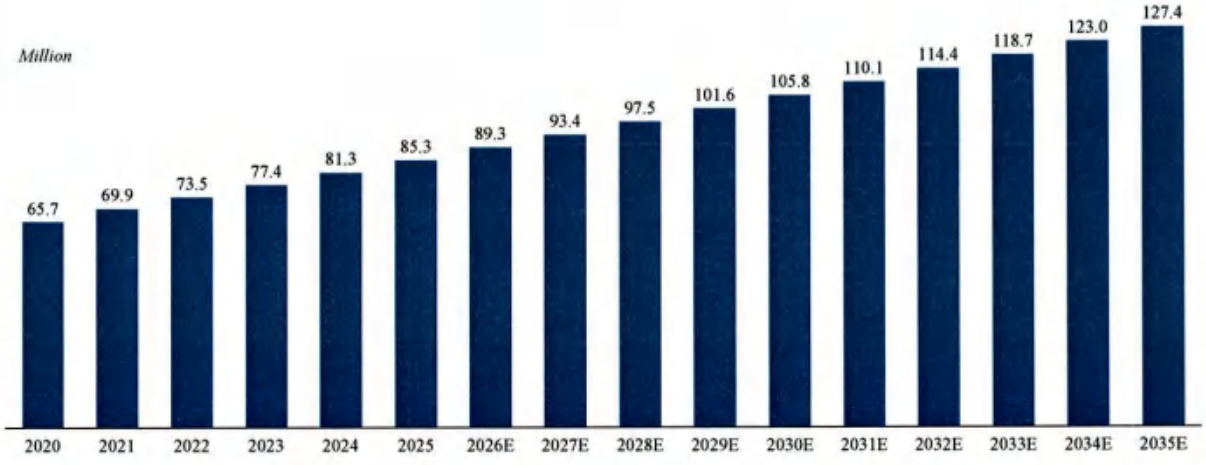
- The main mechanisms of ischemic stroke pathogenesis are embolic and hemodynamic mechanisms, in addition to vasospasm, mechanical compression, and hematological abnormalities.

Source: Literature Review, Frost & Sullivan Analysis

Global Prevalence of ischemic stroke, 2020-2035E

- The global prevalence of ischemic stroke grew from 65.7 million in 2020 to 85.3 million in 2025, and is projected to reach 105.8 million by 2030 and 127.4 million by 2035.

Global Prevalence of ischemic stroke, 2020-2035E

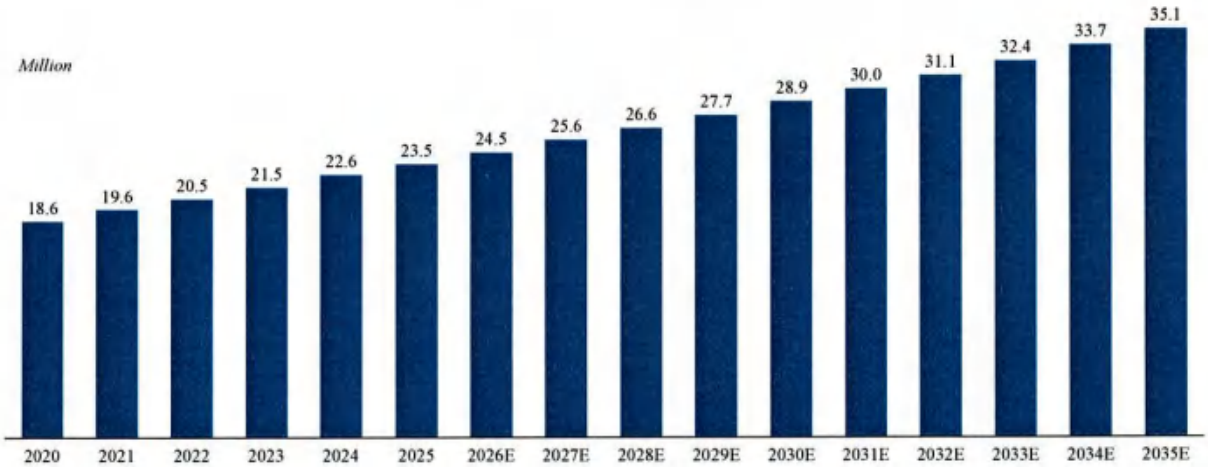


Source: Frost & Sullivan analysis

Prevalence of ischemic stroke in China, 2020-2035E

- In China, the prevalence of ischemic stroke grew from 18.6 million in 2020 to 23.5 million in 2025, and is projected to reach 28.9 million by 2030 and 35.1 million by 2035.

Prevalence of ischemic stroke in China, 2020-2035E

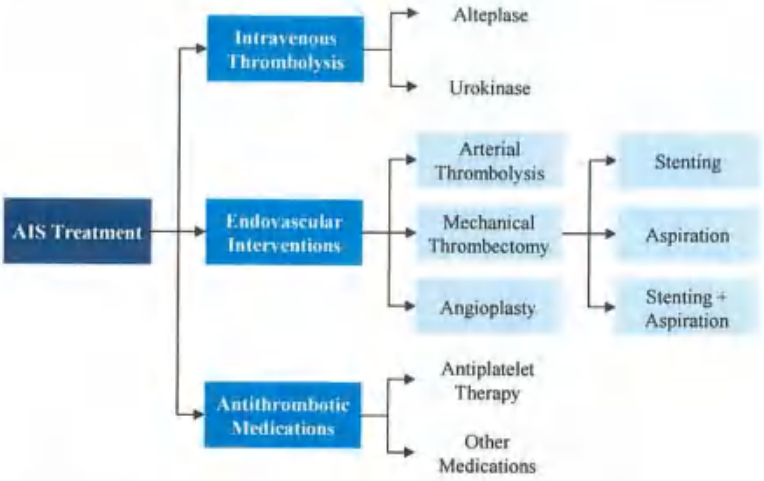


Source: Frost & Sullivan analysis

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.

Primary treatment options for acute ischemic stroke



Neuroprotection in Ischemic Stroke

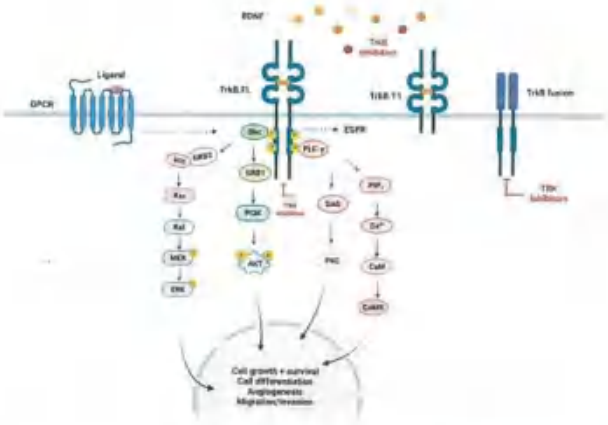
- However, brain cell damage brought about during cerebral ischemia and the fact that reperfusion can make neutrophils more likely to recruit toward the ischemic area, triggering more severe immune inflammation, can have a significant negative impact on stroke prognosis. Neuroprotectants reduce necrosis 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.

Source: Literature Review, Frost & Sullivan Analysis

Mechanism of TrKB agonist

- TrKB receptor is a transmembrane receptor with tyrosine kinase activity in the Trk family, which mainly binds to brain-derived neurotrophic factor and neurotrophin-4/5. After binding to ligands, TrKB receptor activates the downstream signaling pathways such as PI3K/Akt, MAPK/ERK, and PLCγ by dimerization, and regulates neuronal survival, proliferation and differentiation, axonal dendritic development, and synaptic plasticity, which is essential for the development of the nervous system. It is a core molecule in the development of the nervous system, maintenance of function and repair of damage.

TrkB signaling Pathway



- **TrKB receptor agonist binds to TrKB and exerts neuroprotective effects through multiple mechanisms:** activating the PI3K/Akt pathway to inhibit neuronal apoptosis and reduce ischemic or toxic injury; promoting axonal regeneration and synaptic reconstruction via the MAPK/ERK pathway to facilitate the repair of the neural network; enhancing the regulation of PLCγ-mediated calcium signaling to improve synaptic transmission and alleviate cognitive impairment; down-regulating proinflammatory drugs; and down-regulating the calcium signaling pathway to improve synaptic transmission and alleviate cognitive impairment. It also enhances PLCγ-mediated calcium signaling and improves synaptic transmission to alleviate cognitive deficits; down-regulates the pro-inflammatory pathway to inhibit glial over-activation and reduce inflammatory damage; and stimulates neurogenesis in the hippocampus and other regions to facilitate functional recovery.

- These potential multiple therapeutic mechanisms make TrKB agonists have the potential to treat stroke, neurodegenerative diseases, depression and other neurological disorders. Comparison of neuroprotective agents.

Source: Literature Review, Frost & Sullivan Analysis

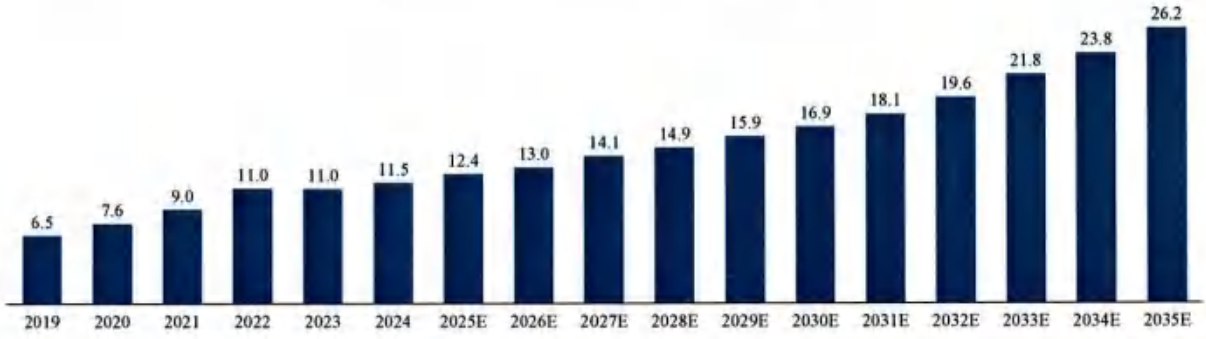
Market size and forecast of neuroprotective agent in China, 2019-2035E

- In 2024, the neuroprotective agent market in China reached RMB 11.5 billion. It is estimated that the neuroprotective agent market in China will grow to RMB 16.9 billion in 2030 and RMB 26.2 billion in 2035, with a CAGR of 6.5% from 2024 to 2030 and 9.2% from 2030 to 2035 respectively.

Market size and forecast of neuroprotective agent in China, 2019-2035E

Period	CAGR
2019-2024	12.1%
2024-2030E	6.5%
2030E-2035E	9.2%

Billion RMB



Source: Frost & Sullivan analysis

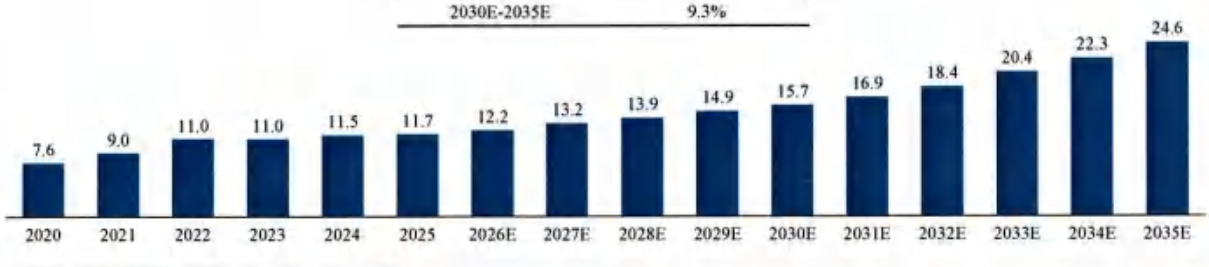
Market size and forecast of neuroprotective drugs in China, 2020-2035E

- The patient population suffering from stroke in China continues to expand. The accelerating aging of the population, the simultaneous increase in incidence and prevalence rates, and the trend of younger onset have laid a solid foundation for the rigid demand for neuroprotective drugs. The nationwide construction of stroke centers and the implementation of the hierarchical medical system have significantly improved the diagnosis rate and standardized treatment rate of stroke at primary medical institutions, releasing a large amount of potential demand for medication. Core neuroprotective drugs have been included in the NRDL, which has greatly reduced the financial burden on patients and enhanced clinical accessibility and penetration rates. The launch of multi-target innovative drugs and optimized dosage forms has enriched clinical treatment options and extended the medication cycle for patients. Meanwhile, the growing popularity of stroke rehabilitation concepts has promoted the expansion of drug application scenarios from the traditional acute phase to the recovery phase and home-based treatment, all of which are driving the steady growth of China's neuroprotective drug market.
- In 2025, the neuroprotective drugs market in China reached RMB 11.7 billion. It is estimated that the neuroprotective drugs market in China will grow to RMB 15.7 billion in 2030 and RMB 24.6 billion in 2035, with a CAGR of 6.2% from 2025 to 2030 and 9.3% from 2030 to 2035, respectively.

Market size of neuroprotective drugs in China, 2020-2030E

Period	CAGR
2020-2025	8.8%
2025-2030E	6.2%
2030E-2035E	9.3%

Billion RMB



Source: Frost & Sullivan analysis

Growth drivers of neuroprotective agent market

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.
National Policy Support	• The Chinese government has strengthened the prevention and control of stroke by building a primary healthcare service system; included the prevention and treatment of neurological diseases in the "14th Five-Year Plan" national key R&D program and opened a priority review channel for innovative drugs; and included various neuroprotectants in the medical insurance catalog to enhance drug accessibility, which has boosted the development of the market in a multi-dimensional way.
R&D Innovation	• Neuroprotective agent 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.

Source: Frost & Sullivan Analysis

Future Trends of neuroprotective agent market

Clinical application scenarios continue to expand	• The clinical application scenarios of neuroprotective agents 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 protection against neurological impairment in the brain. Preclinical data demonstrate that TrKB receptor agonists possess more than 40 times stronger free radical-scavenging activity than first-line drugs, and exert a significant therapeutic effect on cerebral ischemia-reperfusion injury. In addition, NAD + 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.
Combination therapies become the main treatment mode	• The combination of neuroprotective agents with other treatments has become an important trend. In the field of acute stroke, the combined use with thrombolysis and thrombectomy has improved the prognostic effect and reduced the risk of injury. In neurodegenerative diseases, combination therapies have diversified, including combining with gene therapy and brain-computer interface technology to enhance the efficacy by dynamically adjusting the treatment program.

Source: Frost & Sullivan Analysis

Competitive landscape of neuroprotective agent in China approved by NMPA

- To date, there are 3 neuroprotective agent drugs approved by NMPA.

Target	Drug Name	Brand Name	Company	Indication	NMPA Approval date
/	Edaravone+L(-)-borneol	先必新	Simcere 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:
As of June 1 2026

Source: NMPA, Frost & Sullivan Analysis

Competitive landscape of neuroprotective agent pipeline in China

- To date, there are 11 neuroprotective agent drug candidates for neuroprotection in acute ischemic stroke in the clinical stage in China.

Target	Drug Code	Company	Clinical Stage	Latest update date
NRF2, mTOR, AMPK	Nitrone Triazine injection	Guangzhou magpie Pharmaceuticals	Phase III	2025-11-15
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 Apeloa Medical	Phase III	2022-01-01
NTRK2	MT200605	Shaanxi Micot Pharmaceutical	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

As of August 15 2025

Source: CDE, Frost & Sullivan Analysis