

INDUSTRY OVERVIEW

Certain information and statistics set out in this section have been extracted from various official government publications, available sources from public market data providers and an Independent Third-Party source, China Insights Industry Consultancy Limited. The report prepared by China Insights Industry Consultancy Limited and cited in this document was commissioned by us. We believe that the sources of this information are appropriate sources for such information and have taken reasonable care in extracting and reproducing such information. We have no reason to believe that such information is false or misleading or that any fact has been omitted that would render such information false or misleading. Only information from official government sources has not been independently verified by us, the Joint Sponsors, the Overall Coordinators, [REDACTED], any of the [REDACTED], any of our or their respective directors, officers, employees, agents, or representatives of any of them or any other parties involved in the [REDACTED], and no representation is given as to the accuracy, fairness and completeness of such information from official government sources. For discussion of the risks relating to our industry, see “Risk Factors” in this Document.

OVERVIEW OF CHRONIC KIDNEY DISEASE AND THERAPEUTIC LANDSCAPES

Introduction to Chronic Kidney Disease (“CKD”)

CKD refers to a variety of pathophysiologic conditions in which the kidney is damaged and loses its function, as represented by a persistent reduction in the glomerular filtration rate (“GFR”), an indicator showing how well kidneys remove waste and excess fluids from blood, over a period of 3 months. The kidney function in patients with CKD typically declines over time and may eventually progress to kidney failure. Depending on the status of kidney function as calculated from a blood test called eGFR, CKD can be classified from stage 1 to 5 (*i.e.*, G1 to G5), with G5 being end stage renal disease (“ESRD”) which often requires life-long dialysis or a kidney transplant.

Prevalence of CKD

CKD is the third most prevalent chronic diseases globally. The prevalence of CKD globally reached 788.4 million in 2024, and it is estimated to reach 943.9 million in 2035 corresponding to a CAGR of 1.7% from 2020 to 2024 and 1.6% from 2024 to 2035. China has 123.2 million patients in 2024, and it is estimated to reach 129.4 million in 2035, representing a CAGR of 0.4% from 2020 to 2024 and 0.4% from 2024 to 2035. A detailed breakdown of CKD prevalence by disease stage is as follows.

CKD staging	Definition	GFR (mL/min/1.73m ²)	Global % of total CKD prevalence	The US % of total CKD prevalence	China % of total CKD prevalence
G1-G2	<ul style="list-style-type: none"> Mild kidney damage Kidneys work well or function as normal 	>60	47.7%	60.7%	48.1%
G3a	<ul style="list-style-type: none"> Mild to severe kidney damage Kidneys don't work as well 	45-59	49.0%	36.4%	47.2%
G3b		30-44			
G4	<ul style="list-style-type: none"> Severe kidney damage Kidney close to loss of function 	15-29	2.6%	2.1%	2.8%
G5	<ul style="list-style-type: none"> Most severe kidney damage Kidney close to loss of function or kidney failure 	<15	0.7%	0.7%	1.9%

Source: KDIGO, KDOQI, Chinese Journal of Blood Purification, CIC

INDUSTRY OVERVIEW

The global CKD market is expected to grow from US\$222.6 billion in 2024 to US\$503.9 billion in 2035. In 2024, among CKD drugs, the DKD market accounted for over 70% share, the hyperphosphatemia market accounted for 5% share, and the IgAN market accounted for 3% share.

Unaddressed Clinical Needs of CKD

Because CKD is often asymptomatic in its early stage, it frequently remains undiagnosed. Consequently, many patients are first diagnosed at relatively advanced stages after irreversible damage has occurred. Currently, kidney disease awareness remains low. Worldwide, only 6% of the general population and 10% of the high-risk population are aware of their CKD status.

Current medical interventions for CKD patients are primarily designed to help control different symptoms, reduce complications, and slow down progression of the disease. However, there is a lack of targeted therapeutics or disease-modifying drug for CKD, or effective treatment to halt the progression of CKD. 5%-10% of CKD patients progress to ESRD within five years regardless of the treatment they receive.

The current under-treatment of CKD is partly due to low patient adherence to treatments. Medications aimed at managing CKD symptoms and complications often cause undesired side effects, which can further burden the kidneys, liver, or cardiovascular system, and further limit available treatment options. Additionally, managing multiple CKD complications typically requires patients to take various types of medications, many of which involve high pill burden.

Conditions and Complications of CKD

The conditions of CKD can be divided into three types based on their pathological origins.

Primary kidney disease refers to a category of renal conditions originating directly within kidneys, independent of any systemic conditions. Examples include IgA nephropathy (“**IgAN**,” a chronic glomerular inflammation caused by IgA deposits), focal segmental glomerulosclerosis (“**FSGS**,” a segmental scarring of some glomeruli leading to proteinuria), and membranous nephropathy (“**MN**,” a thickening of the glomerular basement membrane with immune complex deposits).

Secondary kidney disease refers to a kidney damage or loss of function caused by another underlying systemic disease or health condition. Examples include diabetic kidney disease (“**DKD**,” a kidney damage due to chronic high blood sugar and metabolic changes in diabetes) and lupus nephritis (“**LN**,” an autoimmune inflammation of kidneys caused by systemic lupus erythematosus).

Hereditary kidney disease refers to a group of kidney disorders caused by a pathogenic variant or mutation in one or more genes. A primary example is autosomal dominant polycystic kidney disease (“**ADPKD**”), a genetic disorder characterized by progressive development of fluid-filled cysts in both kidneys, leading to enlarged kidneys and gradual loss of kidney function.

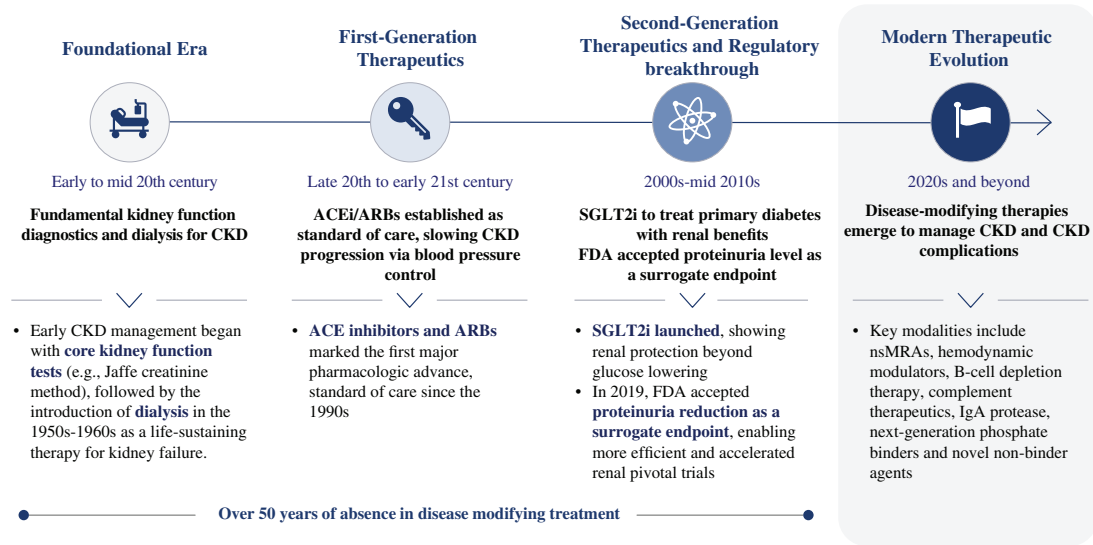
CKD is a complex disease and its progression is associated with multiple serious complications as kidney function deteriorates. Hyperphosphatemia is a common CKD complication is caused mainly by impaired kidney function to excrete excess phosphate. Another common complication of CKD is renal anemia. It is associated with decreased red blood cell formation due to reduced erythropoietin production in the kidney.

Market Opportunities of CKD Drugs

The development and evolution of CKD treatments

The chart below shows the historical timeline of CKD drug development.

INDUSTRY OVERVIEW



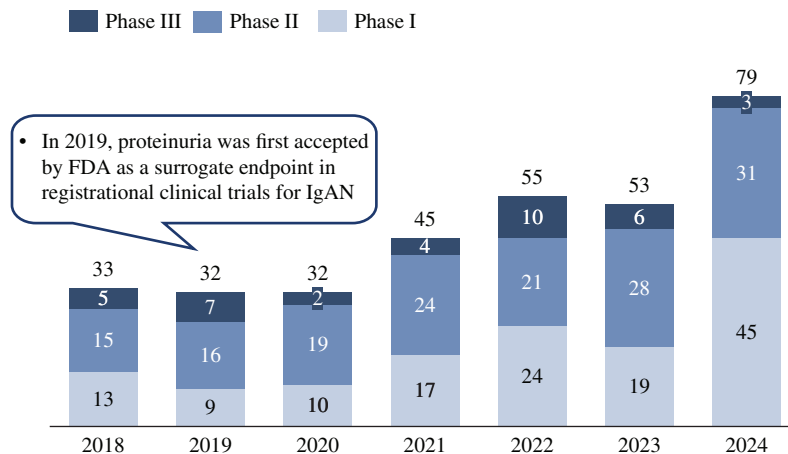
Source: *Seminars in Nephrology, Chinese Journal of Nephrology, CIC*

Increased R&D and Investment Fueled by Favorable Government Policies

Global regulatory support is accelerating the innovation in CKD treatment. In the U.S., the FDA traditionally required evidence of long-term clinical outcome. This usually necessitates large quantities of clinical samples and long-term follow-up periods, which leads to high R&D costs and prolonged development timeline. In 2019, the proteinuria level was accepted by the FDA as a surrogate endpoint for registrational clinical trials targeting IgAN. This regulatory development has significantly boosted the innovation in the CKD drug R&D. Additionally, several CKD drug candidates have received the Fast Track designation. In China, CKD management is incorporated into the “Healthy China 2030” blueprint, which aims to reduce the burden of non-communicable diseases. The NMPA has streamlined the review process of drug candidates addressing urgent clinical needs and included novel renal drugs in the National Reimbursement Drug List (“NRDL”).

The number of newly initiated clinical pipelines in CKD drug development globally has been rapidly increasing in the past few years, as shown in the chart below. However, the number of new clinical pipelines in CKD drug development globally only accounted for less than 2% out of total new global clinical pipelines in 2024, while oncology comprises over 40%, which suggests significant untapped potential for technology innovation and clinical development of CKD therapeutics.

Number of new clinical trials globally in kidney disease drug development



Source: *FDA, CDE, EMA, ClinicalTrials, CIC*

INDUSTRY OVERVIEW

In addition, there is a growing volume of global merger and acquisition (“M&A”) and licensing transactions focused on renal disease therapeutics. As of December 31, 2025, the top 10 transactions in renal therapeutics with multinational companies since 2020 had amounted to an aggregate of US\$85.4 billion.

Top 10 transactions in renal disease therapeutics with MNCs since 2020* (As of Dec. 2025)

Rank	Deal date	Target / Licensor	Acquirer / Licensee	Therapeutic target	Renal indications	Transaction type	Key renal assets	Total transaction value (billion USD)	Upfront payment (million USD)
1	2020-12-12	Alexion Pharmaceuticals	AstraZeneca	C5	IgAN, C3G	M&A	Ravulizumab, eculizumab	39.0	N/A
2	2021-12-14	Vifor	CSL	SLC40A1, KOR	CKD anemia, CKD-ap, hyperkalemia	M&A	FCM, patiromer, difelikefalin	11.7	N/A
3	2021-09-30	Acceleron Pharma	Merck Sharp & Dohme	ACVR2A, ACVR2B	CKD anemia	M&A	sotatercept, lusparcept	11.5	N/A
4	2020-08-19	Momenta Pharmaceuticals	Johnson & Johnson	FcRn	Lupus nephritis	M&A	nipocalimab	6.4	N/A
5	2024-04-10	Alpine Immune Sciences	Vertex	BAFF/APRIL	IgAN	M&A	Povetacicept	4.9	N/A
6	2022-08-04	ChemoCentryx	Amgen	C5AR	C3G	M&A	avacopan	3.7	N/A
7	2020-08-17	Principia Biopharma	Sanofi	BTK	FSGS	M&A	SAR442168, rilzabrutinib, PRN473	3.7	N/A
8	2023-06-12	Chinook Therapeutics	Novartis	EDNRA, APRIL	IgAN	M&A	atrasentan, zigakibart	3.5	3,200
9	2020-06-11	Corvidia Therapeutics	Novo Nordisk	IL6	CKD	M&A	ziltekimab	2.1	725
10	2024-05-22	Human Immunology Biosciences	Biogen	CD38	IgAN, pMN, Lupus nephritis	M&A	felzartamab	1.8	1,150

Note: *The transactions includes various types of deals such as drug-related and enterprise-related transactions. Additionally, deals that have been fully terminated are not included

Source: Company announcement, CIC

Entry Barriers in the CKD Drug Market

R&D Barriers: CKD is a chronic and heterogeneous disease area, involving multiple underlying etiologies, comorbidities and treatment objectives across different stages of disease progression. Companies developing CKD therapies are required to demonstrate clinically meaningful benefits in well-defined patient populations, while taking into account renal function, cardiovascular risk, concomitant medications and long-term safety. As a result, successful R&D in the CKD drug market generally requires disease-specific clinical development capabilities, appropriate endpoint selection, and experience in designing and executing renal-focused clinical trials.

Investment and Resource Barriers: The development of CKD drugs generally requires substantial investment and operational resources. Given the chronic and progressive nature of CKD, clinical programs may involve relatively large patient populations, multi-center trial networks and sustained follow-up periods to evaluate efficacy, safety and tolerability. Patient recruitment and retention can be affected by disease stage, comorbidities, background therapies and eligibility criteria. These factors may increase the complexity, duration and cost of clinical development, regulatory preparation and post-approval evidence generation.

Manufacturing Barriers: Manufacturing requirements for CKD drugs vary by drug type, formulation and mechanism of action. Certain CKD therapies, including phosphate binders and other products with specialized formulation or quality attributes, may require tailored manufacturing processes, robust quality control systems and reliable supply chain management. Other CKD therapies, such as small-molecule agents, may rely on more conventional pharmaceutical manufacturing processes but still require compliance with applicable GMP standards and consistent product quality. Accordingly, manufacturing capability, process control, quality assurance and supply reliability may constitute entry barriers to varying degrees depending on the specific product category.

INDUSTRY OVERVIEW

Product Portfolio Barriers: To establish a competitive advantage in the CKD space, a company needs a broad product portfolio with extensive coverage of CKD-related indications. This allows the company to offer integrated treatment solutions, enhance patient retention, and stabilize market share. Managing such a diverse portfolio requires significant investment in specialized teams to coordinate development, regulatory, and commercialization efforts across indications.

Growth Drivers and Market Trends in CKD Drug Market

Growing Aging Population and Expanding Patient Base: The addressable CKD patient population continues to grow, driven by the global aging demographics and the rising prevalence of diseases that damage kidney function. The expansion of healthcare services to primary care institutions at community and township levels improves early detection and management of CKD, which further broadens the patient base. Stronger insurance coverage and increased reimbursement support enhance the patients’ access to CKD diagnosis and therapies.

Transformation of Clinical Outcomes Fueled by Breakthrough Pharmacotherapies: The introduction of breakthrough therapies may establish a new standard of care for CKD and accelerate the growth of the CKD drug market. For example, AP306 is designed to inhibit multiple phosphate transporters to effectively lower the serum phosphate level in CKD patients. It has the potential of MOA innovation, where new drugs are designed not only to target novel pathways but also to enhance patient convenience and outcomes.

Longitudinal Patient Management Optimized by Specialized Medicine and Integrated Healthcare Pathways: CKD patients often suffer from multiple chronic conditions, including hypertension, diabetes, and cardiovascular disease. This complexity, combined with the rapidly expanding and costly CKD market, is fueling a shift towards transformative therapies that not only address the underlying disease more effectively but also integrate longitudinal care pathways to optimize patient outcomes over time.

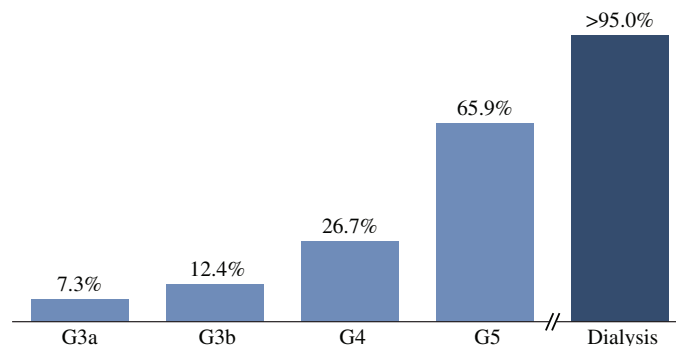
OVERVIEW OF HYPERPHOSPHATEMIA MARKET

Introduction of Hyperphosphatemia

Hyperphosphatemia is a medical condition characterized by elevated level of phosphate in the blood, typically defined as a serum phosphate concentration greater than 4.5 mg/dL, according to KDIGO. It is clinically challenging to bring target serum phosphorous level below 4.5 mg/dL. The target serum phosphorus level for dialysis patients is 3.5-5.5 mg/dL, according to K/DOQI guidelines. Excessive level phosphate can lead to serious complications. Impaired kidney function, especially in patients with CKD, is the leading cause of hyperphosphatemia.

The incidence of hyperphosphatemia increases significantly with the progression of CKD. For non-dialysis patients, the serum phosphate level is usually manageable by dietary interventions and pharmacological treatment. For dialysis patients, the serum phosphate level is markedly elevated and difficult to control.

Prevalence of hyperphosphatemia by different CKD stages

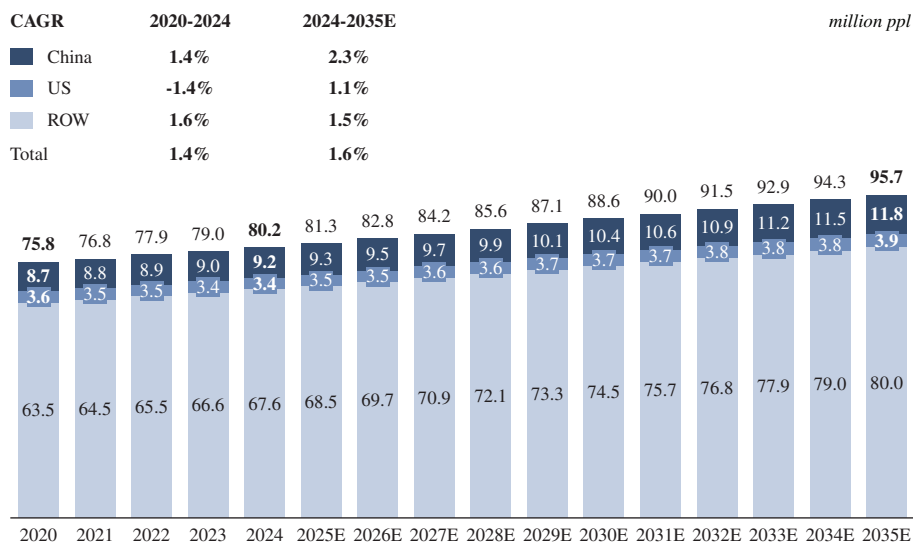


Source: Chinese Journal of Blood Purification, CIC

INDUSTRY OVERVIEW

In current clinical practice, phosphate-lowering agents are routinely prescribed for patients with late-stage CKD, while the management of earlier-stage CKD primarily relies on lifestyle modification, reflecting the absence of effective novel therapies. Phosphate binders represent a major class of phosphate-lowering agents. They act within the gastrointestinal tract by binding dietary phosphorus and reducing its absorption into the bloodstream. Phosphate binders may be broadly categorized based on their active components and binding mechanisms. Calcium-based formulations utilize divalent calcium cations to initiate ionic precipitation, yielding insoluble calcium-phosphate salts within the gastrointestinal tract; lanthanum-based agents leverage trivalent lanthanum to establish high-affinity ionic bonds with phosphate ions across a broad physiological pH spectrum, forming non-absorbable lanthanum phosphate complexes; iron-based binders achieve phosphate capture through ligand exchange or surface adsorption mechanisms localized to oxyhydroxide cores.

The chart below shows the global prevalence of hyperphosphatemia.



Source: CNRDS, JAMA, Chinese Journal of Nephrology, CIC

The hyperphosphatemia patients could be broken down into G3~G5 ND-CKD patients (patients who are not on dialysis) and DD-CKD patients (patients who are on dialysis). Globally, the DD-CKD patients consisted of <10% of the hyperphosphatemia population in 2024, and among G3~G5 ND-CKD patients, G3 ND-CKD, G4 ND-CKD, G5 ND-CKD accounted for approximately 55%, 25% and 25%, respectively, of the total global hyperphosphatemia population. The DD-CKD patients consisted of 15% of the hyperphosphatemia population in 2024 in China, and among G3~G5 ND-CKD patients, G3 ND-CKD, G4 ND-CKD, G5 ND-CKD accounted for 60%, 10% and 15%, respectively, of the total China hyperphosphatemia population.

Current Treatment Paradigm and Medical Needs for Hyperphosphatemia

The current clinical practice guidelines and practices for the standard of care treatments of hyperphosphatemia are as follows.

INDUSTRY OVERVIEW

Guideline	Jurisdiction	Eligible population	Treatment goal	Non-pharmacological interventions		Pharmacological treatment recommendations	
				Dietary interventions	Dialysis management	Calcium-based binders	Calcium-free agents
KDIGO CKD-MBD 2017	Global	CKD G3a–G5D including both non-dialysis and dialysis patients	<ul style="list-style-type: none"> Lower elevated phosphate levels toward the normal range 	<ul style="list-style-type: none"> limiting dietary phosphate intake in the treatment of hyperphosphatemia alone or in combination with other treatments 	<ul style="list-style-type: none"> For patients with CKD G5D (on dialysis) with persistent hyperphosphatemia, increasing dialytic phosphate removal is suggested 	<ul style="list-style-type: none"> In adult patients receiving phosphate-lowering treatment, it is suggested to restrict the dose of calcium-based binders, broadening the restriction compared to the 2009 guideline 	<ul style="list-style-type: none"> –
K/DOQI guidelines 2003	US	CKD G3a–G5D including both non-dialysis and dialysis patients	<ul style="list-style-type: none"> Maintenance of normal serum levels of phosphorus in CKD patients 	<ul style="list-style-type: none"> restricting dietary phosphorus to 800–1,000 mg/day (adjusted for protein needs) when serum phosphorus is elevated 	<ul style="list-style-type: none"> For patients with serum phosphorus >7.0 mg/dL, the guideline indicates that more frequent dialysis should also be considered 	<ul style="list-style-type: none"> Calcium-based phosphate binders should not be used in dialysis patients who are hypercalcemic (corrected serum calcium >10.2 mg/dL), or Have PTH <150 pg/mL on two consecutive measurements 	<ul style="list-style-type: none"> Calcium-free agents are preferred in dialysis patients with severe vascular and/or other soft-tissue calcifications
Chinese expert consensus (2025 edition)	China	CKD G3a–G5D including both non-dialysis and dialysis patients	<ul style="list-style-type: none"> To lower serum phosphorus to the normal range Regular monitoring is required 	<ul style="list-style-type: none"> Daily phosphate intake should be restricted to < 1,000 mg, and protein intake control is needed 	<ul style="list-style-type: none"> Ensure adequate dialysis, and adjust frequency if needed 	<ul style="list-style-type: none"> Calcium-Based Binders are suggested specifically for patients with hypocalcemia 	<ul style="list-style-type: none"> Calcium-free agents are prioritized for CKD G3a–G5D patients to avoid calcium loading

Source: KDIGO, KDOQI, Chinese Journal of Blood Purification, CIC

Currently, commonly used phosphate binders include calcium-based binders, lanthanum carbonate, and Sevelamer, with Sevelamer being the most widely used in clinical practice. However, about 76% and 52% of dialysis patients in China and U.S., respectively, suffer from an uncontrolled serum phosphorus level after medications. Also, existing phosphate binders generally suffer from frequent GI side effects, high pill burden, systemic absorption and negative impact on normal physiological functions. As a result, the clinical adoption of phosphate binders remains at a low level.

Dietary phosphate restriction and, where applicable, dialysis remain foundational components of phosphate control and should not be viewed as interchangeable with pharmacotherapy. Clinical guidelines emphasize that phosphate-lowering treatment is typically based on a combination of measures, including dietary modification, phosphate-lowering agents and, in patients with CKD on dialysis, dialysis-based phosphate removal. This is particularly important outside the dialysis setting, where dietary management remains a core intervention and dialysis is not available to compensate for ongoing phosphate burden. At the same time, pharmacotherapy continues to play an important complementary role, particularly for patients whose serum phosphate remains persistently elevated despite dietary measures alone or, in the dialysis population, despite background dialysis treatment, as drug therapy may help further reduce intestinal phosphate absorption and improve overall phosphate control.

Underpenetrated Status of Phosphate Control in China

In China, approximately 76% of dialysis patients fail to achieve the target serum phosphorus levels between 3.5-5.5 mg/dL based on K/DOQI guidelines, which is significantly higher than that in the U.S. (approximately 52%) and Japan (approximately 39%). This gap in the control rate for serum phosphate level is mainly due to the following reasons:

Lower Penetration Rate for Dialysis: Dialysis penetration among ESRD patients in China remains low at about 27%, compared to about 72% in the U.S. and to about 98% in Japan. This gap is primarily due to the limited availability of dialysis centers (over 80% concentrated in tertiary or secondary hospitals) and inadequate reimbursement coverage for dialysis in China.

Lack of Novel Therapeutic Options: The therapeutic landscape for phosphate control in China is characterized by a dominance of off-patent drugs, with novel therapies occupying only a negligible market share.

Lower Duration of Treatment: In China, the average duration of treatment for non-calcium phosphate binders is about 100 days, significantly lower than the U.S. (about 200 days) and Japan (about 250 days). The discrepancy is largely attributable to patients’ access to novel treatments and consequent compliance issue due to high pill burden and side effects.

INDUSTRY OVERVIEW

Market Opportunities of Hyperphosphatemia Drugs

Development History of Hyperphosphatemia Drugs

The chart below shows the historical evolution of phosphate binders.

Agents	Al/Mg /Ca-based	Sevelamer/Lanthanum	Velphoro® <i>1st gen. iron-based</i>	AP301 <i>Next gen. iron-based</i>
Improvement	<i>Phasing-out or restricted use</i>	<ul style="list-style-type: none"> Improved phosphate-lowering efficiency Less CV and all-cause death 	<ul style="list-style-type: none"> Improved GI safety profile Less pill numbers 	<ul style="list-style-type: none"> Further improved phosphate-lowering efficiency Well tolerated, good overall safety profile No systemic absorption
Remaining Concerns		<ul style="list-style-type: none"> Suboptimal serum phosphate control rate GI side effects (e.g., nausea (~20%), vomiting (~20%) and constipation (~8%)) Compromised patient adherence due to high dosing burden Accumulation in liver (lanthanum) 	<ul style="list-style-type: none"> Suboptimal serum phosphate control rate High daily dose weight Need to chew before use, leading to high discontinuation rate and suboptimal patient adherence 	<ul style="list-style-type: none"> Diarrhea

Source: Drug labels, Company announcements, CIC

Pan-phosphate transporter inhibitor represents an emerging, novel type of hyperphosphatemia treatment other than phosphate binders. It is expected to function by pan-inhibiting all major types of active phosphate transporters, so as to reduce the active transcellular uptake of phosphate in the gut, thereby lowering the serum phosphate level.

Market Size of Hyperphosphatemia Drugs

The introduction of Sevelamer, first approved by the FDA in 1998 under the trade name Renegel® (Sevelamer hydrochloride) and then approved by the FDA in 2000 under the trade name Renvela® (Sevelamer carbonate), led to a rapid market expansion starting in the 2000s. The launch of Velphoro®, approved by the FDA in 2013, further fueled global market growth. These approved drugs are all phosphate binders.

In 2014, the patent that covers Sevelamer expired, and the drug faced a loss of exclusivity (“LoE”). As a result, multiple generic versions of the drug entered the market in 2017, which caused a sharp drop in sales of the branded drug. The size of the global market for hyperphosphatemia drugs had significantly declined since 2018.

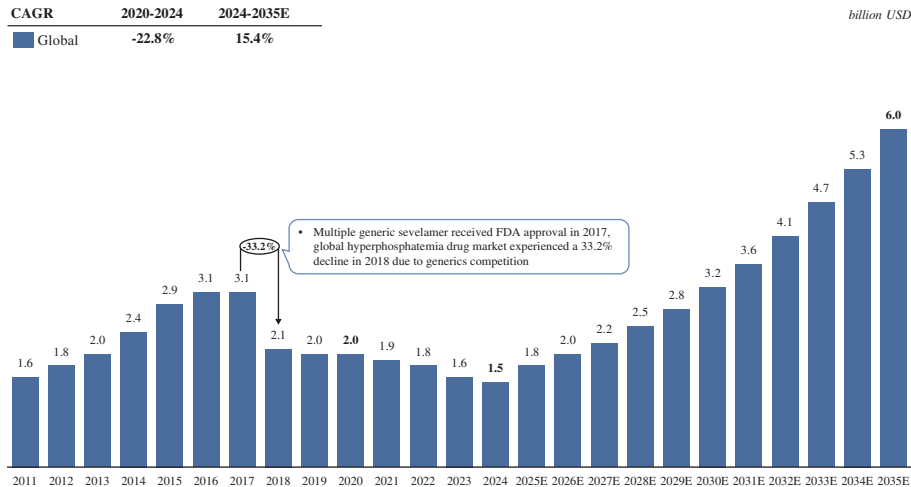
The global market experienced continued decline from 2020 to 2024, primarily due to the COVID-19 pandemic-related disruptions, including a reduction in medical procedures and increased mortality among ESRD patients. Although healthcare delivery normalised after 2023, the hyperphosphatemia drug market in 2024 continued to reflect lagged effects of pandemic-era ESRD patient mortality, slower recovery of the dialysis population, and sustained generic-driven pricing pressure, resulting in a temporary but slowed decline in market size.

In 2025, the global market saw a robust recover. It was mainly driven by the strong revenue growth of Velphoro® in the U.S. market following its inclusion in the TDAPA (Transitional Drug Add-on Payment Adjustment), a Medicare payment mechanism for new renal dialysis drugs and biological products under the ESRD Prospective Payment System.

INDUSTRY OVERVIEW

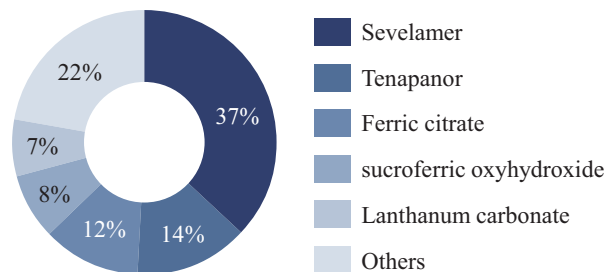
The global market is expected to continue growing from 2025 onwards, driven by the launch of new therapies with improved efficacy, tolerability and lower pill burden. The growth is further supported by the rising prevalence of CKD, improving long-term disease management and reimbursement conditions. For example, the U.S. Centers for Medicare & Medicaid Services (“CMS”) has incorporated oral-only drugs (including phosphate binders) into the ESRD Prospective Payment System bundled payment beginning from January 1, 2025. The CMS has specified the TDAPA treatment for phosphate binders and provided payment details for 2025, including an additional fixed amount added to TDAPA for monthly claims that include phosphate binders.

Global market trend of hyperphosphatemia drugs, 2011-2035E



Source: *Clinical Kidney Journal, Nephrology, CIC*

The aforementioned drivers for the historical and future growth of the hyperphosphatemia drug market also apply to that of phosphate binders, which account for a vast majority share of the hyperphosphatemia drug market both globally and in China. In 2024, the global sales of phosphate binders reached US\$1,306.9 million, accounting for about 86% of the hyperphosphatemia drug market, while NHE3 inhibitor amounted to US\$212.8 million, representing about 14% of the market. In the total hyperphosphatemia drug market, DD-CKD patients contributed to 95% of the total market size. Among phosphate binders, in 2024, iron-based binders accounted for 7% of the total hyperphosphatemia market, and non iron-based binders accounted for 79% of the total hyperphosphatemia market. In China, phosphate binders recorded total sales of RMB2,422.2 million, representing 100% of the market, whereas transporter inhibitors generated no sales as no such drugs had been approved. In China’s total hyperphosphatemia drug market, DD-CKD patients contributed to 90% of the total market size. Iron-based binders accounted for approximately 2% of the total hyperphosphatemia market, and non iron-based binders accounted for 98% of the total hyperphosphatemia market. Globally, the top five hyperphosphatemia drugs in terms of market share in 2024 are presented as follows.

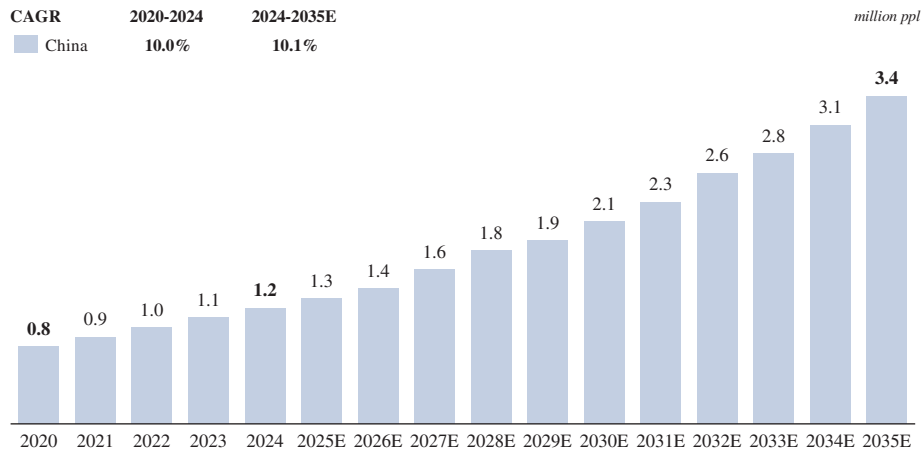


Source: *KDIGO, KDOQI, Chinese Journal of Blood Purification, CIC*

INDUSTRY OVERVIEW

In 2024, the recorded sales of the global top five hyperphosphatemia drugs were as follows: (1) Sevelamer US\$562.3 million, (2) Tenapanor US\$212.8 million, (3) Ferric citrate US\$182.4 million, (4) Sucroferric oxyhydroxide US\$121.6 million, and (5) Lanthanum carbonate US\$106.4 million.

In China, the number of ESRD patients receiving dialysis treatment has been rapidly increasing, as shown in the chart below.

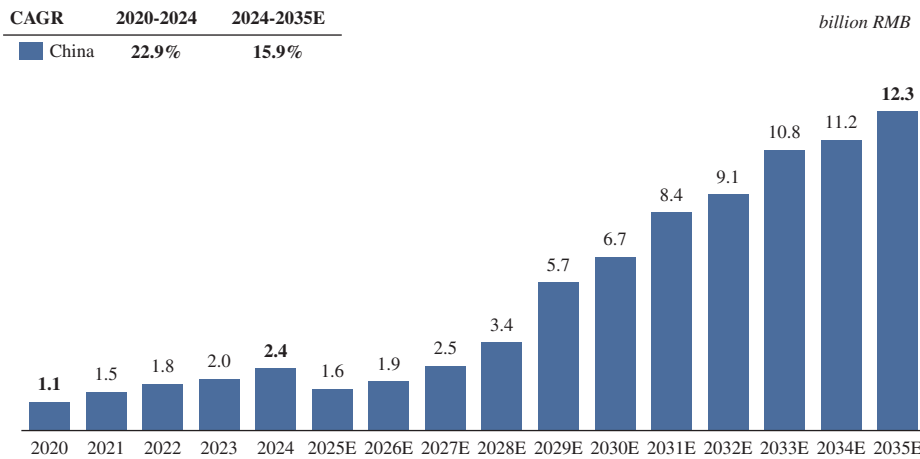


Source: NIDDK, CK-NET, CN-CNRDS, USRDS, DOPPS, CIC

The market size for hyperphosphatemia drugs in China was historically driven by the launch of new drugs, including the first approval of Sevelamer in 2013. Since phosphate binders were included in NRDL in 2017, the market has experienced substantial expansion, as shown in the chart below. The market is expected to experience a contraction in 2025, due to the volume-based procurement (“VBP”) of lanthanum carbonate in 2023 and Sevelamer in 2024. However, the market for hyperphosphatemia drugs in China is expected to rebound from 2025 onwards, primarily fueled by the improving penetration rate of dialysis and phosphate binder treatments, the introduction of new hyperphosphatemia drugs and the consequent increase in the treatment duration. Specifically, by 2026, the impact from VBP of lanthanum carbonate and sevelamer is expected to largely flatten, as the major rounds of price adjustment are substantially absorbed by the market. In parallel, tenapanor was included in the NRDL in 2025, with reimbursement implementation commencing in 2026. It is expected to expand treatment uptake and partially offset prior pricing pressure from legacy phosphate binders. As a result, the hyperphosphatemia drug market is expected to stabilise and return to a growth trajectory from 2026 onwards. In addition, the inclusion of the serum phosphorus control rate in China’s 2024 *National Medical Quality and Safety Improvement Goals* announced by the NHC marks the first time hyperphosphatemia management has been elevated to a national-level quality metric, creating a strong incentive for hospitals and physicians to standardize treatment and improve ESRD patient outcomes. This policy directive is expected to directly accelerate the adoption of phosphorus-lowering therapies, fueling market growth.

INDUSTRY OVERVIEW

China market size of hyperphosphatemia drugs, 2020-2035E



Source: Clinical Kidney Journal, Nephrology, CIC

Competitive Landscape of Hyperphosphatemia Drug Market

As of the Latest Practicable Date, there were seven drug types approved as phosphate lowering agents, including six non-calcium phosphate lowering molecules (tenapanor, ferric citrate, sucroferriic oxyhydroxide, bicalomer, lanthanum carbonate, sevelamer) and calcium-based phosphate binders. In the U.S., all the drug types except bicalomer were approved as phosphate lowering agents. In China, all the drug types except bicalomer and ferric citrate were approved as phosphate lowering agents. The chart below shows the approved non-calcium phosphate-lowering molecules for use by CKD patients with hyperphosphatemia (the target patient cohort) globally as of the Latest Practicable Date.

INN ¹	Brand name	Company	FDA Approval date	NMPA Approval date	MoA	Therapy type	Daily dosage mass ²	Daily cost ³	Safety and Efficacy	Patent expiry status	Number of generics
Calcium acetate	PHOSLO [®]	Pfizer Medical Care	• 1990-10	• /	Non iron-based PB	• Mono	• -8 g	• -8 USD	• SP control rate ~50% • Hypercalcemia ~17.5%	Expired	• Global: >20 • China: 20
Sevelamer	Renvela [®] Renegel [®]	Sanofi	• 1998-10	• 2013-01	Non iron-based PB	• Mono	• -9.6 g	• -35 USD	• SP control rate <50% • Nausea 21%, diarrhea 19%, vomiting 12%	Expired	• Global: >40 • China: 15
Bicalomer ⁴	Kiklin [®]	Astellas	• /	• /	Non iron-based PB	• Mono	• -7.5g	• /	• SP control rate <50% • Constipation 21%	2027	• /
Lanthanum carbonate	FOSRENOL [®]	Takeda	• 2004-10	• 2012-02	Non iron-based PB	• Mono	• -9 g	• -36 USD	• SP control rate ~50% • Nausea 11%, Vomiting 9%	Expired	• Global: >20 • China: 16
Sucroferriic oxyhydroxide	Velphoro [®]	Renal Pharma	• 2013-11	• 2023-02	Iron-based PB	• Mono	• -8.3 g	• -70 USD	• SP control rate <50% • Diarrhea 24%, Discolored feces 16%, nausea 7%	2029-05	• /
Ferric citrate	Auryxia [®]	Akebia Therapeutics	• 2014-09	• /	Iron-based PB	• Mono	• -9 g	• -44 USD	• SP control rate <50% • Diarrhea 21%, Discolored feces 19%, nausea 11%, constipation 8%	2026-04	• /
Tenapanor	XPHOZAH [®]	Ardelys/ Fosun Pharma	• 2023-10	• 2025-02	NHE3i	• Add-on to PBs	• -400 mg + 10 g ⁵	• -150 USD ⁵	• SP control rate <50% • Diarrhea 43-53%, Severe diarrhea 5%, Abdominal pain 4%	2033-08	• /

Notes: 1 International Nonproprietary Name; 2 Daily dose mass refers to total weight of drug formulation intake for a day instructed by their labels; 3 Daily cost calculated based on US WAC, if WAC not available, price based on retail price from public sources; 4 Bicalomer is only approved in Japan and was launched in 2012, with no clinical trials active in the US or China; 5 Tenapanor is indicated as an add-on therapy to binders, daily cost represent overall phosphate-lowering pill burden and cost burden of patients

Source: NMPA, FDA, EMA, PMDA, Company website, CIC

The chart below shows clinical-stage molecules in pipeline for hyperphosphatemia with active global trials as of the Latest Practicable Date.

Drug Name	Target	Sponsor	Phase	First Posted Date	Trial Number	Trial Location
AP301	Phosphate binder	Alebund	III	2023/05/30	NCT07030595; CTR20231624 (Completed)	China
				2025/04/18	NCT06933472; CTR20252745	China; US
AP306	NaPi-IIb, PiT-1, PiT-2	Alebund, R1 Therapeutics	II	2023/01/30	NCT05764590; CTR20230189 (Completed)	China
				2024/11/27	NCT06712654	Global

INDUSTRY OVERVIEW

In addition, in January 2026, the FDA accepted the NDA for oxylanthanum carbonate, an oral phosphate binder for the treatment of hyperphosphatemia in patients with CKD on dialysis.

The chart below compares AP301 and AP306 with other currently available phosphate-lowering agents.

	Non-binder agents		Phosphate binder-based therapy ³			Calcium-based binders
Key agents	AP306	AP301	Velphoro	Sevelamer	Tenapanor + Binders	
SP control rate ¹	• >85% ²	• >65% ²	• <50% ³	• <50% ⁴	• <50% ⁵	Restricted Use under KDIGO recommendations
Daily dose mass	• ~300 mg	• ~7.5 g	• ~8.3 g	• ~9.6 g	• ~400 mg + 10 g	
Side effect	• GI symptoms, well tolerated	• Well-tolerated, good overall safety profile	• GI symptoms	• GI symptoms	• GI symptoms	
Pill burden	• 2-3 small tablets	• 6-9 soft capsules	• 3-5 Chewable tablets	• 8-12 large tablets	• 2 small tablets + full weight PBs	
Generic drug status	• /	• /	• /	• Generics launched	• /	
Patient access in China	• /	• /	• Included in NRDL • Not yet covered in VBP	• Included in NRDL • Covered in VBP	• Tenapanor not yet included in NRDL	
Evaluation	• Significant phosphate-lowering efficacy than sevelamer in ph2 active control trials	• A lower daily dose option, smaller capsule provides better patient compliance	• Non-calcium option, GI effects common, needs chewing	• Moderate efficacy, high pill burden	• Effective phosphate control, but high dosage burden under add-on regimen	

Notes: 1 SP control = Serum phosphorus between 3.5-5.5 mg/dL, with non-head-to-head comparison; 2 Estimated based on data from early clinical trials; 3 Currently, approved therapy choices of hyperphosphatemia are limited to phosphate binders.

Source: FDA, ClinicalTrials.gov, Nephrology Dialysis Transplantation, Company website, CIC

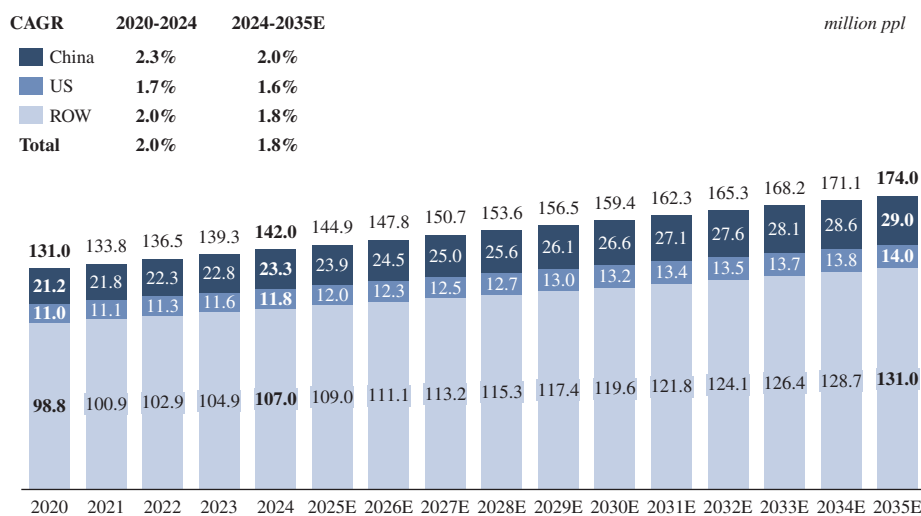
OVERVIEW OF DIABETIC KIDNEY DISEASE (“DKD”) MARKET

Introduction to DKD

DKD is a type of kidney disease caused by diabetes. It is almost asymptomatic in the early stage. Clinically, DKD is mainly characterized by persistent albuminuria and/or a progressive decline in GFR. DKD is a leading cause of ESRD worldwide. Also, DKD markedly increases the risk of cardiovascular disease (“CVD”) and CVD-related death in patients with diabetes.

Prevalence of DKD

The chart below shows the global prevalence of DKD.

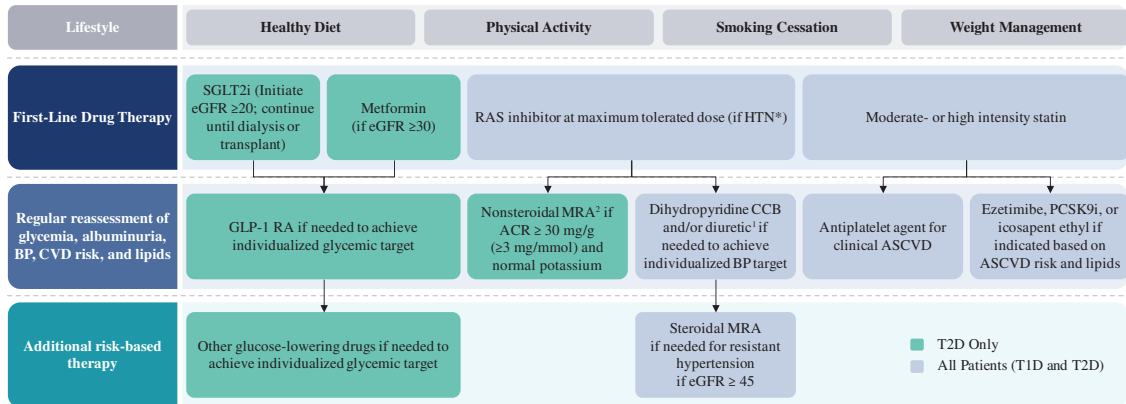


Source: CNRDS, JAMA, Chinese Journal of Nephrology, CIC

INDUSTRY OVERVIEW

Current Treatment Paradigm and Medical Needs

The chart below shows the treatment pathway for DKD.



Notes: 1 Angiotensin-converting enzyme inhibitor (ACEi) or angiotensin II receptor blocker (ARB) should be first-line therapy for hypertension (HTN) when albuminuria is present, otherwise dihydropyridine calcium channel blocker (CCB) or diuretic can also be considered; all 3 classes are often needed to attain blood pressure targets. 2 Finerenone is currently the only nonsteroidal mineralocorticoid receptor antagonist (MRA) with proven clinical kidney and cardiovascular benefits

Source: KDIGO, CIC

However, current treatment paradigms for DKD are subject to limitations in efficacy. Several novel therapies under development have shown the potential to fulfill the unmet medical needs for effective DKD treatment. The key therapies for DKD can be classified according to their MOAs, as shown in the chart below.

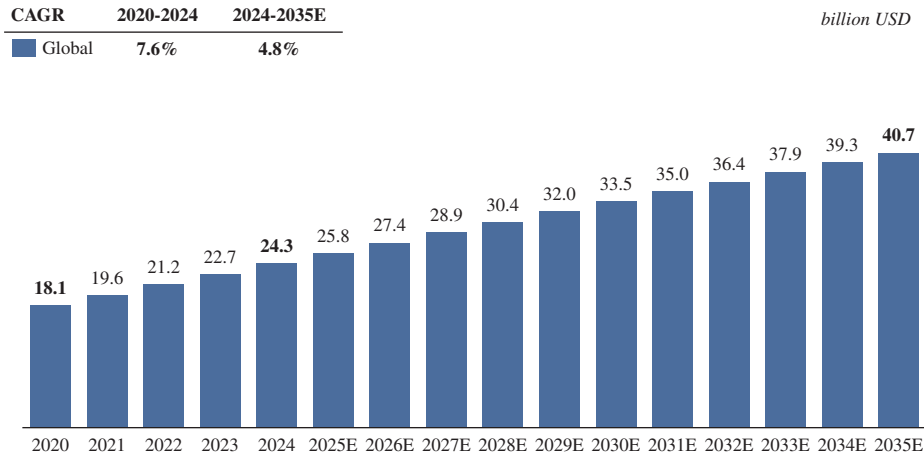
Candidate	AP303	Dapagliflozin	Semaglutide	Finerenone
Drug class	PPAR agonists	SGLT2 inhibitors	GLP-1R agonists	non-steroidal mineralocorticoid receptor antagonists
Decrease intraglomerular pressure Correct hemodynamic adaptation	√√√	√√	-	-
UACR/UPCR reduction independent to GFR change Anti-inflammation, heparinase inhibition, and others	√√√	-	√√	√
Restore tubular energy supply Fatty acid oxidation	√√√	√	-	-

Source: Expert Opinion on Investigational Drugs, Company website, CIC

Market Opportunities of DKD Drugs

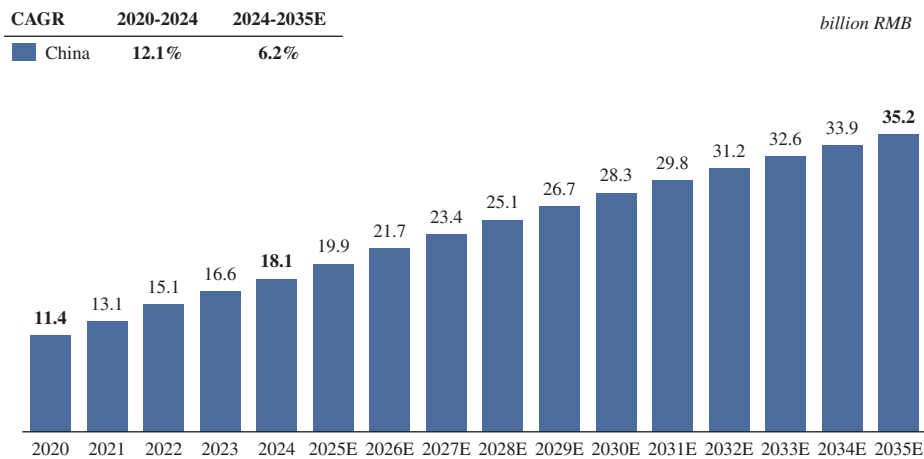
The chart below shows the global market size for DKD drugs.

INDUSTRY OVERVIEW



Source: *Clinical Kidney Journal, Nephrology, CIC*

The chart below shows China’s market size for DKD drugs.



Source: *Clinical Kidney Journal, Nephrology, CIC*

Competitive Landscape of DKD Drug Market

As of the Latest Practicable Date, there were seven approved drugs for DKD globally, six of which had been approved in China.

Overview of approved drugs for DKD globally

INN ¹	Brand name	Company	FDA Approval date	NMPA Approval date	Target	Dosage	Monthly cost ²
losartan	COZAAR®	MSD	• 1995-04	• 1997-01	• ARB	• 50 mg PO QD	• ~USD140
Irbesartan	AVAPRO®	Sanofi	• 1997-09	• 2000-01	• ARB	• 300 mg PO QD	• ~USD270
Canagliflozin	INVOKANA®	Johnson & Johnson	• 2019-09	• 2022-06	• SGLT2	• 100–300 mg PO QD	• ~USD600
Dapagliflozin	FARXIGA®	AstraZeneca	• 2021-04	• 2022-09	• SGLT _i	• 10mg PO QD	• ~USD600
Finerenone	KERENDIA®	Bayer	• 2021-07	• 2022-06	• MR	• 20mg PO QD	• ~USD660
Empagliflozin	JARDIANCE	Eli Lilly	• 2023-09	• 2023-11	• SGLT2	• 10mg PO QD	• ~USD600
Semaglutide	OZEMPIC®	Novo Nordisk	• 2025-01	• 2025-07	• GLP1R	• 0.5mg SC QW	• ~USD670

INDUSTRY OVERVIEW

Notes: 1 International Nonproprietary Name; 2 Monthly cost calculated based on US WAC (WAC price represents the manufacturer’s published catalog or list price for a drug product to wholesalers as reported to third-party drug pricing publishers)

Source: NMPA, FDA, EMA, PMDA, Company website, CIC

As of the Latest Practicable Date, there were less than 10 drug candidates in the Phase II clinical trial stage or beyond targeting DKD with active global trials. In addition, AP303 from Alebund will soon enter the Phase II stage.

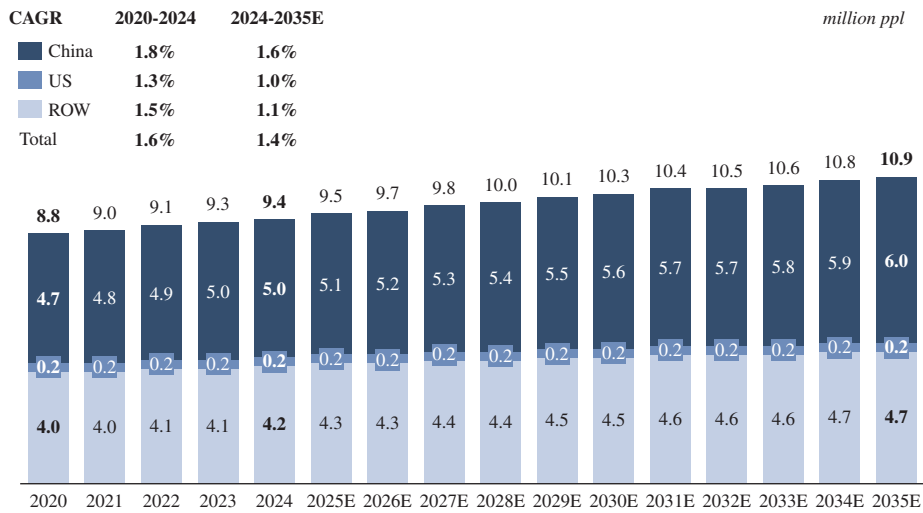
OVERVIEW OF IgA NEPHROPATHY (“IgAN”) MARKET

Introduction of IgAN

IgAN is the most prevalent primary glomerulonephritis worldwide. It is characterized by the deposition of immunoglobulin A (“IgA”) antibodies in the glomeruli — the kidney’s filtering units — leading to inflammation and kidney damage. IgAN often manifests with microscopic hematuria (blood in urine) and may progress to severe proteinuria (excess protein in urine), edema (swelling), and hypertension. IgAN is one leading cause of glomerulonephritis and renal failure: 25%-30% of IgAN patients develop ESRD within 20-25 years of the first onset of the disease.

Prevalence of IgAN

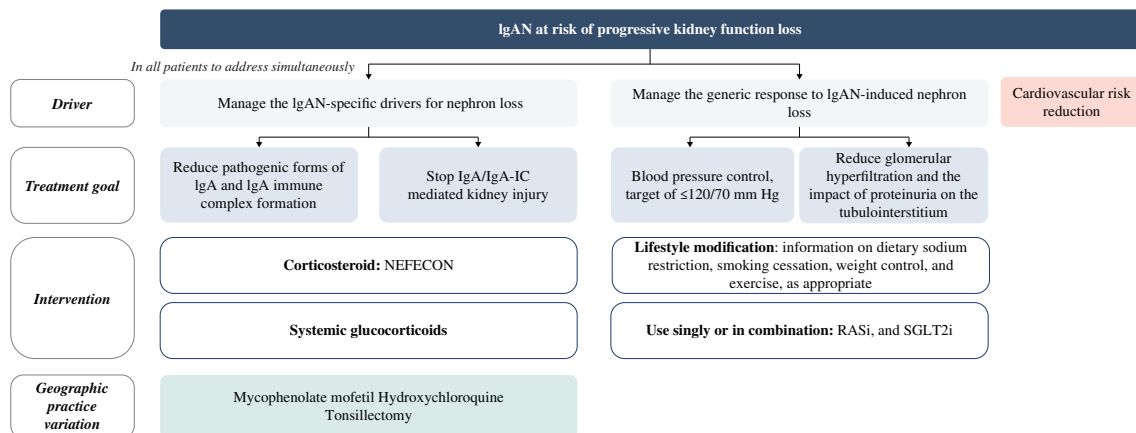
The chart below shows the global prevalence of IgAN.



Source: CNRDS, JAMA, Chinese Journal of Nephrology, CIC

Current Treatment Paradigms and Medical Needs

The chart below shows the current treatment paradigm for IgAN.



INDUSTRY OVERVIEW

Note: RASi: renin-angiotensin system inhibitors, DEARA: dual endothelin angiotensin receptor antagonism
Source: KDIGO 2025, CIC

However, the diagnosis and treatment of IgAN are subject to a lack of non-invasive diagnosis and monitoring; poor risk stratification and lack of personalized treatments; a lack of safe, effective and targeted treatments; and challenges with the management of high-risk and refractory patients.

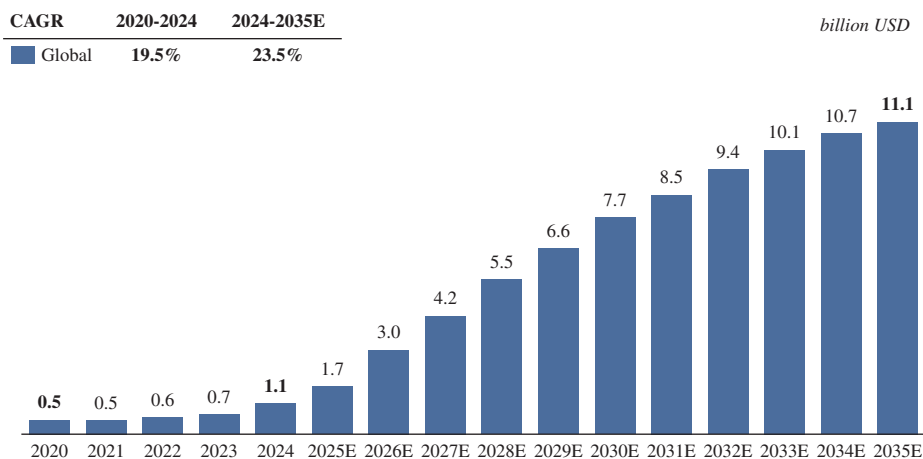
Market Opportunities of IgAN Drugs

Emerging Novel Therapies for IgAN

- *B-cell depletion*, which targets gut-associated B cells to reduce production of pathogenic IgA1 antibodies and prevent disease initiation. Main potential targets under this MOA include B-cell survival factors (e.g., a proliferation-inducing ligand (“**APRIL**”) and B-cell activating factor (“**BAFF**”)) and CD38;
- *Inhibition of complement activation*, which blocks key complement components to suppress inflammation and immune-mediated kidney damage. Main potential targets under this MOA include Factor B, Factor D, C3 and C5;
- *Clearance of pathogenic IgA1 and immune complexes*, which removes or degrades harmful IgA1 and immune complexes, to prevent glomerular deposition and inflammation. Potential drug candidates adopting this MOA could be IgA protease fusion proteins, immune complex clearance agents, and anti-FcαRI antibodies. This novel MOA has a paradigm shifting potential for IgAN treatments, because of the multifaceted therapeutic benefits it can achieve, including prevention of kidney damage, reduction of inflammatory cascade, prevention of auto-amplification, and the potential to halt disease progression. Moreover, patient reaction can be achieved within weeks of treatment, and it has the potential to be the first line treatment;
- *Overall renal protection*, which improves renal blood flow and reduces fibrosis by modulating vascular tone and promoting tissue regeneration. Main potential targets under this MOA include endothelin receptor, angiotensin receptor, dual PPAR agonist. Currently, approved drugs adopting this MOA include atrasentan (endothelin receptor antagonist) and sparsentan (endothelin and angiotensin II receptor antagonist).

Market Size of IgAN Drugs

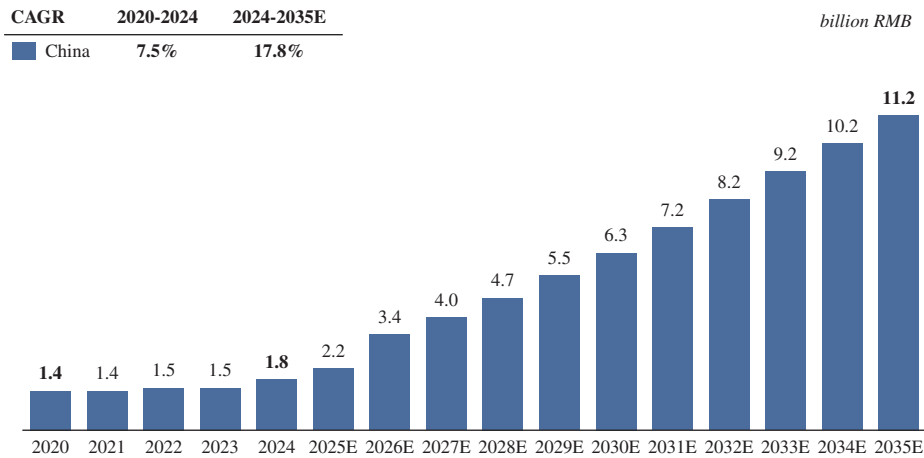
The chart below shows the global market size for IgAN drugs.



Source: Clinical Kidney Journal, Nephrology, CIC

INDUSTRY OVERVIEW

The chart below shows China’s market size for IgAN drugs.



Competitive Landscape of IgAN Drug Market

As of the Latest Practicable Date, there were four approved drugs for IgAN globally, three of which were approved in China, as set forth in the table below.

INN/ Drug Name	Brand name	Company	FDA approval date	NMPA approval date	Target	Dosage	24h uPCR reduction ³ from baseline	Monthly cost ²
Atrasentan	Vanravia®	Novartis	• 2025-04	• 2025-08	• EDNRA	• 0.75 mg PO QD	• -36% (36w)	• ~14,000 USD
Iptacopan	Fabhalta®	Novartis	• 2023-12	• 2025-09	• CFB	• 200 mg PO BID	• -38% (36w)	• ~45,000 USD
Sparsentan	Filspari®	Traverse Therapeutics	• 2023-02	• /	• ENDRA/ AT1R	• 200-400 mg PO QD	• -35% ⁴ (36w)	• ~12,000 USD
Budesonide	Tarpeyo® /Nefecon®	Asahi Kasei/ Everest Medicines	• 2021-12	• 2023-11	• /	• 16 mg PO QD	• -27% (9 months)	• ~18,000 USD

Notes: 1. International Nonproprietary Name; 2. Monthly cost based on US wholesale acquisition cost; 3. placebo-adjusted 24h uPCR reduction data from drug labels; 4. positive control (irbesartan) adjusted uPCR reduction data from PROTECT study

Source: NMPA, FDA, EMA, PMDA, Drug labels, CIC

As of the Latest Practicable Date, there were eight drug candidates in the Phase III stage or beyond for IgAN with active global trials, as set forth in the table below. The MOA of those drug candidates primarily include B-cell depletion and inhibition of complement activation.

Pipelines of clinical phase III or above for IgAN globally

Drug Name	Target	Sponsor	Phase	First Posted Date	24h uPCR reduction ¹ from baseline	Trial Location
Sibeprenlimab	APRIL	Otsuka Pharmaceutical	NDA	2022/02/21	• -51.2% (ph3, 9 months)	China; US; Others
Telitacicept	APRIL; BAFF	Remegen Co., Ltd.	NDA	2025/10/14	• -55% (ph3, 39w)	China
Atacicept	APRIL; BAFF	Vera Therapeutics	NDA	2025/11/07	• -42% (ph3, 36w)	China; US
Sefaxersen	CFB	Roche	III	2023/04/04	• -44% ² (ph2, 29w)	China; US; Others
Zigakibart	APRIL	Chinook/SanReno Novartis	III	2023/05/10	• -34.2% ² (ph1/2, 28w)	China; US; Others
Ravulizumab	C5	Alexion Pharmaceuticals AstraZeneca	III	2024/03/04	• -29.5% (ph2, 26w)	China; US; Others
Povetacicept	APRIL; BAFF	Alpine Immune Sciences Vertex	III	2024/08/21	• -66% ² (ph2, 48w)	China; US; Others
Felzartamab	CD38	Human Immunology Biosciences Biogen	III	2025/04/20	• -39.1% (ph2a, 9 months)	China; US; Others
Mezagitamab	CD38	Takeda	III	2025/05/09	• -54.1% ² (ph1b, 48w)	China; US; Others

INDUSTRY OVERVIEW

Notes: 1. Placebo adjusted 24h uPCR (Urine Protein Creatinine Ratio) reduction from baseline; 2. Single-arm trial, not adjusted for placebo

Source: *Clinicaltrials.gov, CDE, CIC*

As of the Latest Practicable Date, there was no IgA protease drug candidate for IgAN in the clinical development stage, and AP308 was the only IgA protease that will soon enter clinical development.

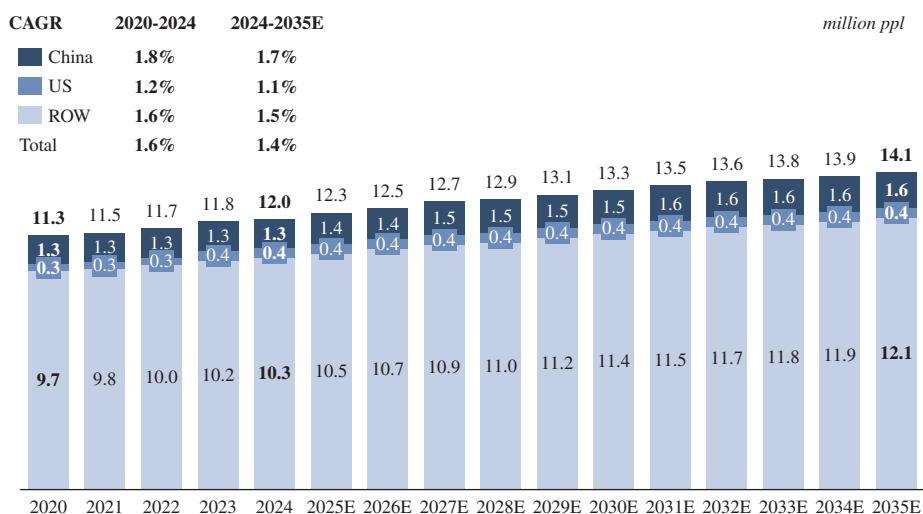
OVERVIEW OF AUTOSOMAL DOMINANT POLYCYSTIC KIDNEY DISEASE (“ADPKD”) MARKET

Introduction to ADPKD

ADPKD is a hereditary kidney disorder, primarily caused by mutations in two genes, PKD1 and PKD2. These mutations may lead to the loss of intracellular inhibitory signaling and progressive enlargement of renal cysts, and eventually result in the renal function impairment.

Prevalence of ADPKD

The chart below shows the global prevalence of ADPKD.



Source: *American Journal of Kidney Diseases, Journal of Human Genetics, Kidney Diseases, Kidney360, CIC*

Current Treatment Paradigms and Medical Needs

Current management and treatment methods for ADPKD include dietary and lifestyle interventions, drug therapy aiming to slow ADPKD progression, pharmacological control of ADPKD’s symptoms, as well as patient education and psychological care. However, there is currently no curative treatment for ADPKD. Besides, there is a lack of therapies that directly target the mechanisms of ADPKD development and cyst growth.

Competitive Landscape of ADPKD Drug Market

As of the Latest Practicable Date, tolvaptan was the only approved drug for ADPKD globally. Since its first FDA approval in 2018 for ADPKD, tolvaptan has generated substantial sales globally, reaching over US\$1.5 billion in 2023. Historically, there has been limited research and development of novel ADPKD treatments. As of the Latest Practicable Date, four drug candidates for ADPKD were in the Phase II stage or beyond with active global trials. AP303 developed by our Company, is expected to enter the Phase II clinical trials soon.

INDUSTRY OVERVIEW

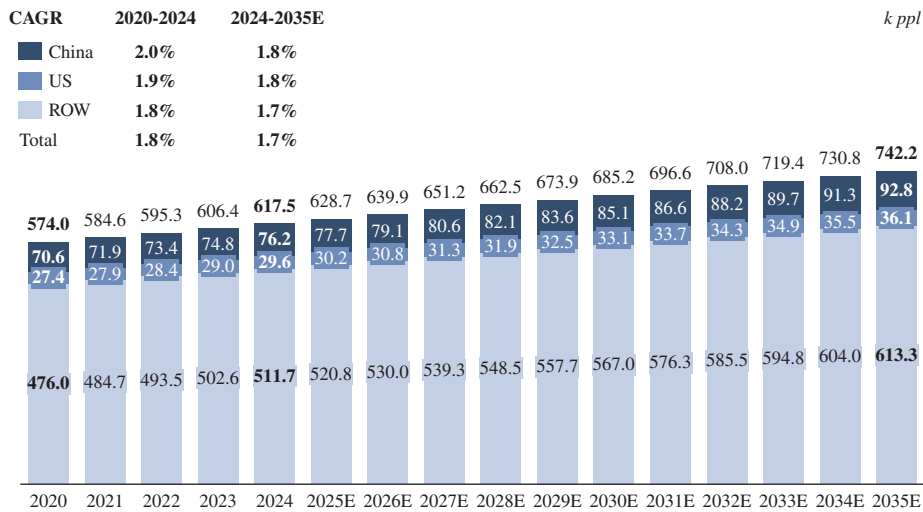
OVERVIEW OF FOCAL SEGMENTAL GLOMERULOSCLEROSIS (“FSGS”) MARKET

Introduction to FSGS

FSGS is a disease in which the scar tissue develops on the glomeruli. The injury of podocytes (a key component of the glomerular filtration barrier) is considered a primary cause of FSGS. FSGS commonly manifests with nephrotic-range proteinuria and edema, and may eventually develop into ESRD. FSGS can be divided into three types based on etiology. Primary FSGS, also known as idiopathic FSGS, has no known cause for the disease conditions. Secondary FSGS is caused by adaptive responses (e.g., obesity), drugs and infections. Genetic FSGS is caused by hereditary mutations in podocyte-related genes.

Prevalence of FSGS

The chart below shows the global prevalence of FSGS.



Source: American Journal of Kidney Diseases, Journal of Human Genetics, Kidney Diseases, Kidney360, CIC

Current Treatment Paradigms and Medical Needs

For primary FSGS patients with the nephrotic syndrome (a collection of symptoms due to kidney damage), glucocorticoid is the major treatment. For steroid-resistant primary FSGS patients, calcineurin inhibitor (“CNI”) is the major treatment. Cyclophosphamide, rituximab and mycophenolate mofetil are used for FSGS patients with CNI failure, intolerance or contraindications.

However, the current treatment methods for FSGS are subject to multiple safety, efficacy and accessibility issues. Long-term exposure to glucocorticoids may lead to resistance, drug dependence or other side effects. The use of CNI can be costly and cause nephrotoxicity that accelerates CKD progression, and the efficacy of CNI is limited in patients with interstitial fibrosis or vascular lesions. Cyclophosphamide can temporarily lower the blood level of white blood cells, thereby increasing the chance of getting an infection. Rituximab may cause infusion-related reactions, which can be life-threatening and require immediate medical attention. Mycophenolate mofetil may weaken the immune system and increase the risk of developing rare and serious virus infections.

Competitive Landscape of FSGS Drug Market

As of the Latest Practicable Date, Sparsentan was approved by the FDA for reducing proteinuria in patients aged eight years and older with FSGS without nephrotic syndrome in April 2026. As of the same date, there were over ten FSGS drug candidates in the Phase II stage or beyond globally. In addition, AP303 from Alebund will soon enter the Phase II stage, which is expected to fulfill the large unmet medical needs in this area.

INDUSTRY OVERVIEW

In May 2025, Travere announced the FDA’s acceptance of sNDA for sparsentan in FSGS based on its phase III pivotal trial which used proteinuria as a surrogate endpoint. FDA may consider potentially using proteinuria level as a surrogate endpoint for FSGS.

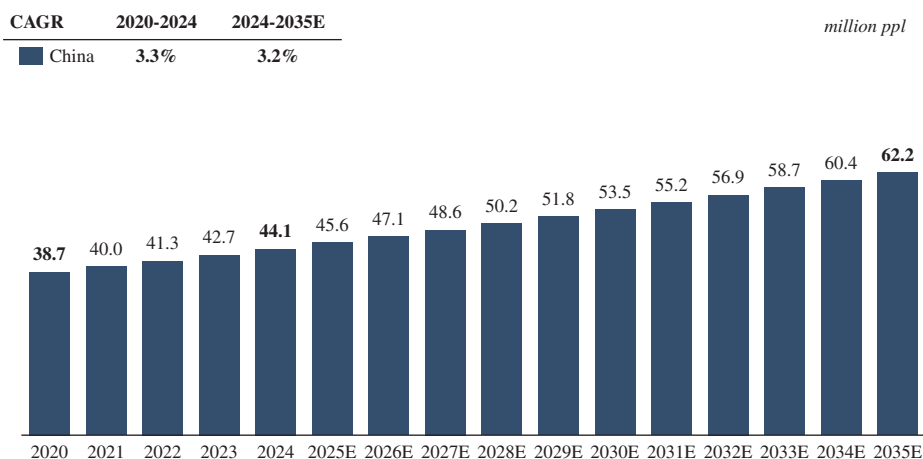
OVERVIEW OF RENAL ANEMIA MARKET

Introduction to Renal Anemia in CKD Patients

Renal anemia is a common complication of CKD, where CKD patients have red blood cell count that is lower than normal level.

Prevalence of Renal Anemia

The chart below shows the prevalence of renal anemia in China.



Source: NIDDK, USRDS, The lancet, JAMA, Clinical and Experimental Nephrology, CIC

Current Treatment Paradigm

Current treatment approaches to renal anemia include injectable erythropoiesis-stimulating agents (“**ESAs**”), intravenous (“**IV**”) or oral administration of iron, as well as oral hypoxia-inducible factor prolyl hydroxylase (“**HIF-PH inhibitors**”). ESAs function by stimulating the production of red blood cells; IV or oral administration of iron works by replacing iron stores directly; and HIF-PH inhibitors act by stimulate the production of endogenous erythropoietin. ESAs are prescribed with individualized dose adjustments to maintain hemoglobin within the target range. IV or oral irons are prescribed based on the iron status in patients. For ESA-hyporesponsive patients, HIF-PH inhibitors may be considered after risk-benefit evaluation.

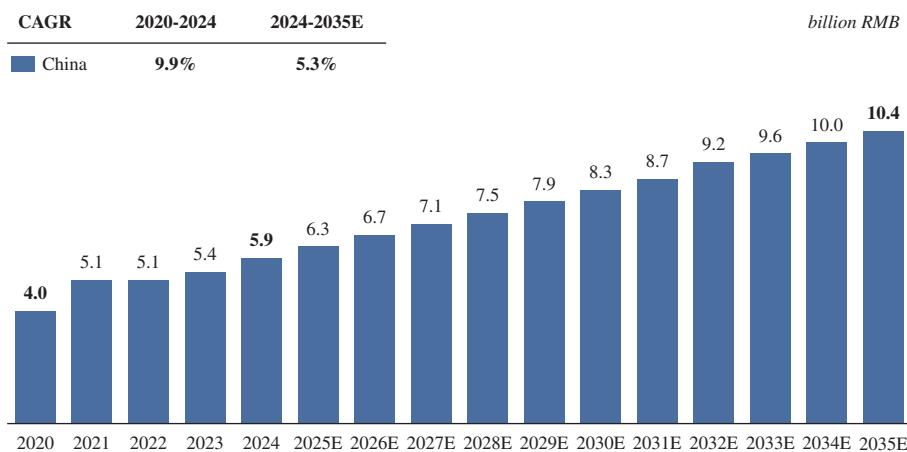
HIF-PH inhibitors have emerged as an oral treatment option for renal anemia, in addition to ESAs. Compared with ESAs, HIF-PH inhibitors may offer greater convenience through oral administration and may improve iron utilization by regulating the hypoxia-inducible factor pathway. However, their use remains subject to patient characteristics, dialysis status, safety profile, reimbursement coverage and physician judgment. In China, roxadustat was approved in December 2018 for anemia in dialysis-dependent CKD patients and in August 2019 for anemia in non-dialysis-dependent CKD patients. Enarodustat was approved in June 2023 for anemia in adult non-dialysis CKD patients, and its indication was expanded in September 2025 to adult dialysis CKD patients. Roxadustat was also included in China’s eleventh round of national volume-based procurement in 2025, which may improve affordability and access while increasing price competition in this class.

INDUSTRY OVERVIEW

Among all the available treatment approaches, ESA is recommended as first-line therapy for CKD-related anemia with clear advantages over the others, as ESA can significantly reduce the need for transfusion and anemia-related symptoms in CKD patients. IV or oral administration of iron is subject to potential infusion reactions, GI intolerance, slow hemoglobin correction, reduced absorption of iron in CKD patients, and need of avoiding interactions with certain drugs/food. For HIF-PH inhibitors, though they are comparable or superior to ESAs in raising the hemoglobin level, there are concerns about cardiovascular outcomes, thrombotic events, and tumor progression. Such concerns have prevented HIF-PH inhibitors from being widely approved for clinical use. Also, the long-term safety of HIF-PH inhibitors has not been fully demonstrated yet.

Market Size of Renal Anemia Drugs in China

The chart below shows the market size of renal anemia drugs in China. In China, long-acting ESAs represented less than 5% of the market in 2024, compared with approximately 50% in the U.S. and 80% in Japan.



Source: Clinical Kidney Journal, Nephrology, CIC

Competitive Landscape of Renal Anemia Drug Market

As of Latest Practicable Date, there were four approved long-acting ESAs for the treatment of renal anemia, all of which have been approved in China, as set forth in the table below. MIRCERA[®] is the first approved once monthly long-acting EPO.

Overview of approved long-acting ESA for renal anemia in China

INN ¹	Brand name	Company	Approval date	MoA	Target	Dosage	Monthly cost ²	NRDL status ³
Methoxy Polyethylene Glycol-Epoetin Beta	MIRCERA [®] 美信羅 [®]	Roche/Alembund	• NMPA: 2018-07	• EPO	• EPOR	• 0.6 µg/kg SC/IV QM	• ~460 RMB	• NRDL listed
Darbepoetin alfa	ARANESP [®] 耐斯寶 [®]	Amgen/Kyowa Kirin	• NMPA: 2020-06	• EPO	• EPOR	• 20 µg SC/IV QW or 40 µg SC/IV Q2W	• ~460 RMB	• NRDL listed
Pegmolsatide	聖羅萊 [®]	Hansoh	• NMPA: 2023-06	• PEG-EMP	• EPOR	• 0.04 mg/kg SC Q4W	• ~780 RMB	• NRDL listed
Recombinant erythropoiesis stimulating protein injection	新比澳 [®]	3S Bio	• NMPA: 2026-03	• EPO	• EPOR	• 5-150 µg SC Q2W	• /	• /

INDUSTRY OVERVIEW

Notes: 1 International Nonproprietary Name; 2 Monthly cost calculated based on NRDL price 3 refers to whether the underlying indications of a drug is included in NRDL in China

Source: NMPA, FDA, EMA, PMDA, Company website, CIC

REPORT COMMISSIONED BY CHINA INSIGHTS CONSULTANCY

In connection with the [REDACTED], we have engaged China Insights Industry Consultancy Limited (“CIC”) to conduct a detailed analysis and to prepare an industry report on the major markets for which our drug candidates are positioned (the “CIC Report”). CIC is an independent global market research and consulting company founded in 2014 and is based in China. We have agreed to pay CIC a total fee of approximately RMB810,000 for the preparation of the CIC Report, and we believe that such fee is consistent with the market rate. The payment of such amount was not contingent upon our successful [REDACTED] or on the content of the CIC Report. Except for the CIC Report, we did not commission any other industry report in connection with the [REDACTED]. We confirm that after taking reasonable care, there has been no adverse change in the market information since the date of the report prepared by CIC which may qualify, contradict or have an impact on the information set forth in this section in any material respect.

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