OVERVIEW

We are a renal-focused biopharmaceutical company with the broadest drug candidates in terms of renal indication coverage globally, according to CIC. Our product portfolio in clinical and preclinical stages consists of one Core Product AP301 and six other product candidates, including one late-clinical-stage product candidate AP306, one early-clinical-stage product candidate (AP303), and four preclinical product candidates (AP308, AP304, AP305, and AP307) as of the Latest Practicable Date.

Our sole Core Product, AP301 (full global rights acquired from Vidasym in 2021), is classified as a Class 1 new chemical drug in China. AP301, is a distinctive phosphate binder for the treatment of hyperphosphatemia, one of the most prevalent complications of CKD with large medical needs. AP301 completed a China registrational Phase III trial with near-term NDA submission expected and is currently undergoing a global Phase III pivotal MRCT in the U.S. and China.

We run a dedicated team aiming to deliver quality products. We target the largest renal indications globally with novel and effective therapeutics and achieve early PoC by striving to satisfy global regulatory requirements with our preclinical and clinical evidence. Coupled with our deep clinical know-how, this approach enables us to pursue simultaneous global development and regulatory submission through MRCTs and to accelerate clinical development through disciplined execution. We have built manufacturing facilities to support global expansion and maximize commercial value by establishing in-house sales team in key markets and forming strategic partnerships with leading players. Together, these efforts accelerate innovation and delivery of renal therapeutics with broad applicability and impact. We also had one commercialized product, Mircera®.

Our Pipeline

We have implemented a renal-focused pipeline strategy focusing on both therapeutics with reduced risks and novel mechanisms of action. As of the Latest Practicable Date, our portfolio consisted of seven product candidates (including three clinical-stage product candidates) and one commercialized product. Our Core Product, AP301, is a distinctive phosphate binder for the treatment of hyperphosphatemia, one of the most prevalent complications of CKD with large unmet medical needs. AP301 completed a China registrational Phase III trial with near-term NDA submission expected (based on the result of China registrational Phase III trial) and is currently undergoing a global pivotal Phase III MRCT in the U.S. and China. AP306 is a novel pan-phosphate transporter inhibitor for hyperphosphatemia that we acquired from Chugai and received BTD from the NMPA. AP303 is a novel disease-modifying agent to delay or halt the progression of CKD and received the FDA ODD for ADPKD. AP308 is a novel engineered recombinant IgA protease aiming for functional cure of IgAN that we licensed from PUFH. Our commercialized product, Mircera®, developed by Roche, is an effective EPO approved for the treatment of anemia associated with CKD. All of our products are designed as first-line treatment in CKD patients. The diagram below summarizes the development status of our portfolio as of the Latest Practicable Date.

Program	MoA[2]	Category[3]	Indications	Preclinical/ IND-Enabling	Phase I	Phase II	Phase III	NDA	Marketed	Regulatory Authority (ies)	Trial Location	Upcoming Milestones[6]	Source	Commercial Rights
AP301 ★	Phosphate Binder	Chemical Drug	Hyperphos-phatemia	Completed China PhIII in June 2025						China NMPA		China NDA submission in Q2 2026	Acquired (Vidasym)	Global^
				Initiated global PhIII MRCT in July 2025						U.S. FDA		Global Phase III MRCT completion expected in Q2 2027[7] NDA submission in Q3 2027		
										EU EMA		Phase III trial initiation expected in 2028		
AP306	Pan-phosphate Transporter Inhibitor	Chemical Drug	Hyperphos-phatemia	IND cleared for global PhIIb						U.S. FDA China NMPA		Global Phase IIb MRCT completion expected in Q2 2027[8]	In-licensed (Chugai)	Greater China (Alebund) Ex-China (R1 Therapeutics)[13]†
AP303	Dual PPAR Agonist	Chemical Drug	DKD with high proteinuria	IND cleared for global PhII						U.S. FDA China NMPA[5]		A basket Phase II trial for DKD and IgAN patients with high proteinuria is expected to be initiated in Q3 2026[9] Additional Phase II trials for ADPKD and FSGS are expected to be initiated in Q4 2026 and Q1 2027, respectively PoC data expected in 2027	Self-developed	Global
			IgAN with high proteinuria	IND cleared for global PhII						U.S. FDA China NMPA[5]				
			FSGS	Global PhII planned[4]						U.S. FDA China NMPA[5]				
			ADPKD	Global PhII planned[4]						U.S. FDA China NMPA[5]				
AP308	IgA Protease	Biologics	IgAN							U.S. FDA China NMPA		IND submission in Q3 2026 Phase I completion expected in Q2 2027 PoC data expected in 2027H1	Collaboration[12] (PUFH)	Global
AP304	Serine Protease	Biologics	AKI & AIS							/	/	IND submission in 2027	Self-developed	Global
AP305	CFB Inhibitor	Chemical Drug	IgAN & others							/	/	IND submission in 2027	Self-developed	Global
AP307	Complement Pathway Inhibitor	Chemical Drug	MPGN							/	/	/[10]	Self-developed	Global
AP601 (MIRCERA®)[1]	Long-acting EPO	Biologics	Anemia associated with CKD							China NMPA	/	/[11]	Partnered (Roche)	China[14]*

★ Core Product U.S. FDA Orphan Drug Designation China NMPA Breakthrough Therapy Designation

Notes: Abbreviations: MoA = Mechanism of Action, IND = Investigational New Drug, NDA = New Drug Application, NMPA = National Medical Products Administration of the PRC, FDA = U.S. Food and Drug Administration, MRCT = Multi-Regional Clinical Trial, PPAR = Peroxisome Proliferator-activated Receptor, DKD = Diabetic Kidney Disease, PoC = Proof of Concept, IgA = Immunoglobulin A, IgAN = IgA Nephropathy, FSGS = Focal Segmental Glomerulosclerosis, ADPKD = Autosomal Dominant Polycystic Kidney Disease, AKI = Acute Kidney Injury, AIS = Acute Ischemic Stroke, CFB = Complement Factor B, MPGN = Membranoproliferative Glomerulonephritis, EPO = Erythropoietin

(1) As calculated based on NRDL prices, MIRCERA® 's monthly cost is approximately RMB460; (2) All of Alebund's products / product candidates are orally administered, except for AP308 and AP304 (intravenous or subcutaneous) and AP601 (subcutaneous); (3) All of Alebund's products / product candidates are first line therapies and Class 1 New Drugs, except for AP601 which is an Original Imported Drug; (4) Phase II trial planned, and no confirmation from competent authorities to proceed has been received yet; (5) Phase I trials for AP303 were conducted in China and Australia, and upcoming Phase II trials will be conducted in the U.S. and China; (6) Alebund acts as sponsor for all clinical trials of its product candidates; (7) The FDA's grant of IND clearance for the Phase III MRCT was based on the results of the Phase II clinical trial of AP301 in China and the Phase I clinical trial of AP301 in Australia; (8) Alebund plans to leverage AP306's global Phase IIb MRCT data to directly support China NDA submission, potentially eliminating the need for a separate China Phase III trial; (9) Pharmacokinetic bridging studies demonstrated no ethnic differences, and Phase Ib data confirmed AP303's renal hemodynamic effect, supporting the initiation of an exploratory Phase II study directly in the patient population; (10) IND application date not yet confirmed; (11) All clinical development milestones have been achieved; (12) AP308 is internally engineered by Alebund based on a prototype licensed from PUFH; (13) Alebund directly owns the rights of AP306 in Chinese Mainland, Hong Kong, Macau and Taiwan; (14) Instead of Alebund, Roche is the marketing authorization holder of MIRCERA® in Chinese Mainland

^ Alebund has partnered with Vidasym and obtained the full China and global rights relating to AP301 in 2018 and 2021, respectively, with no future royalty obligations from Vidasym via a series of transactions (low double digit million of U.S. dollars paid in total)

† Alebund has partnered with Chugai and has the exclusive right to develop, manufacture, and commercialize AP306 (formerly EOS789) globally. Under the agreement, Chugai is entitled to receive an upfront license payment and milestone payments up to a single-digit millions of U.S. dollars based on achievement of certain predetermined milestones relating to regulatory approval and commercial sales, with additional royalty payments linked to annual net sales of AP306 after its expected launch

* Alebund has partnered with Roche and has the exclusive right to commercialize Roche's MIRCERA® (methoxy polyethylene glycol-epoetin beta) in China. Under the agreement, Roche is entitled to receive an upfront payment of single-digit millions of RMB, as well as milestone payments up to double-digit millions of RMB based on achievement of certain predetermined milestones relating to NRDL and commercial sales

Chronic Kidney Disease Complications Management Portfolio

We have developed a synergistic portfolio addressing the most prevalent and critical complications of CKD, in particular hyperphosphatemia and anemia, creating a near-term commercial foundation.

AP301

AP301, our Core Product, stands out due to its consistent phosphate-lowering capacity and safety profile. In the Phase III clinical trial, AP301 reduced the serum phosphorus level by 2.22 mg/dL in CKD patients receiving maintenance dialysis with hyperphosphatemia, compared to 2.17 mg/dL for sevelamer carbonate at week 12. Moreover, AP301 achieved a higher serum phosphate response rate in the AP301 arm (66.7%) compared to the sevelamer carbonate arm (58.6%) at Week 52, suggesting its long-term therapeutic effect. Importantly, AP301 does not release or allow systemic absorption of iron, as the iron is irreversibly bound by the acacia scaffold. The most common AEs were GI disorders, mainly diarrhea, which were resolved without intervention. Together with AP306 and Mircera®, AP301 forms a synergistic and complementary portfolio that addresses key CKD complications.

AP306

In our completed Phase II trial, AP306 demonstrated a mean serum phosphate reduction of 2.51 mg/dL, with nearly 95% of patients had their serum phosphate levels controlled at less than 5.5 mg/dL by Week 7-8. This significantly outperforms classic binders like Sevelamer, which brought around 50% of patients to the serum phosphate level at less than 5.5 mg/dL by Week 7-8 in the same clinical trial. Also, AP306 was able to lower the average serum phosphate level to between 3.5 and 4.5 mg/dL, a target few phosphate binder can reach. In the same Phase II trial, the most common AEs were GI disorders, mainly diarrhea. The discontinuation rate due to AEs was less than 5%. Moreover, AP306 significantly reduces pill burden, requiring only 2-3 small tablets, a significant contrast to 6-12 tablets daily typically needed for traditional phosphate binders. We are currently preparing a Phase IIb MRCT in the U.S. and China.

Mircera®

Mircera® is a proven commercial anchor for renal anemia solution. Mircera® stimulates erythropoiesis by interacting with the erythropoietin receptor on progenitor cells in the bone marrow, thereby helping the patients reach the target hemoglobin ("**Hb**") level of 110g/L. Mircera® can maintain a stable Hb level with a favorable safety profile, and it is the first-line recommended medication by global anemia treatment guidelines. We are commercializing Mircera® as our first marketed product in China to establish a scalable renal dedicated sales team and distribution channel. By building direct relationships and distribution channels with hospitals through Mircera®, we aim to create an infrastructure that supports market access and medical education across nephrologists, physicians and hospitals. This commercial infrastructure is designed to synergize with our future renal therapeutics, accelerating subsequent launches and enabling efficient portfolio promotion. As of the Latest Practicable Date, Mircera® was listed in over 300 hospitals in China.

CKD Disease-Modifying Portfolio

We have also developed a pipeline for CKD treatment aimed at significantly slowing or halting CKD progression, positioning us to drive a paradigm shift in overall CKD treatment.

AP303

As a dual PPAR agonist, AP303 is designed to deliver broad renal protection across a wide spectrum of high-value indications, including among others, DKD, IgAN, ADPKD and FSGS. In the completed Phase I trials in Australia and China, AP303 was safe and well tolerated in healthy volunteers and there was clear and robust dose-related PD signal. We completed Phase Ib study in

DKD patients in China in September 2025 and have received positive feedback and clear guidance from the FDA and the NMPA for all indications in the pre-IND communication regarding Phase II MRCTs in U.S. and China with respect to DKD, IgAN, ADPKD, and FSGS. A basket Phase II clinical trial targeting DKD and IgAN patients with high proteinuria is expected to be initiated in the third quarter of 2026. Two additional Phase II trials, targeting ADPKD and FSGS, are expected to be initiated in the fourth quarter of 2026 and the first quarter of 2027, respectively.

AP308

AP308 acts as "molecular scissors" to remove the IgA and IgA complex in circulatory system as well as IgA complex deposited in the kidneys, directly targeting the underlying pathology of IgAN. This mechanism represents a novel approach to treating IgAN. We expect to obtain IND clearance and enter clinical development stage in China and the U.S. in the third quarter of 2026.

Our Market Opportunity — Renal, A Vast but Underserved Market

According to CIC, the global burden of CKD represents one of the most critical unmet medical needs of our time, affecting 788.4 million individuals globally in 2024 and ranking third among global chronic diseases in 2024. China has the largest prevalence of CKD with approximately 123.2 million patients in 2024. 5-10% of CKD patients progress to ESRD within five years regardless of the treatment they receive, where their life quality is significantly limited due to the need for either renal replacement therapy or transplantation, placing substantial burden on patients and their families. The global CKD market is expected to grow from US$222.6 billion in 2024 to US$503.9 billion in 2035, representing substantial market potential.

Within the CKD market, hyperphosphatemia is one of the most common CKD complications. Its global prevalence steadily increased in the past four years to approximately 80.2 million patients in 2024. The prevalence of hyperphosphatemia in China reached 9.2 million in 2024, accounting for 11.5% of total hyperphosphatemia patients globally. Moreover, the incidence of hyperphosphatemia increases significantly with the progression of CKD. Almost all ESRD patients undergoing dialysis require phosphate-lowering therapy. However, despite the widespread use of phosphate binders, 76% and 52% of dialysis patients in China and U.S., respectively, suffer from an uncontrolled serum phosphorus level. 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. For details regarding the MOA of different types of phosphate binders, please refer to "Industry Overview — Overview Of Hyperphosphatemia Market." The dialysis population in China reached 1.2 million in 2024 and is projected to expand rapidly to 4.3 million patients in 2035, representing a CAGR of 10.1%. This rapid growth, combined with the large patient group of uncontrolled hyperphosphatemia, highlights a substantial and expanding market opportunity for phosphate management solutions.

The vast unmet medical demands highlight the critical need for therapeutics that can significantly delay or halt CKD progression. However, over the past two decades, few innovative renal therapeutics were approved. The failure of certain large, global Phase III trials prompted many multinationals companies to withdraw investments in innovative renal therapeutics. In 2019, the FDA accepted proteinuria reduction as the surrogate endpoint for approvals in IgAN. This marked a revitalization of renal R&D, drawing many multinational companies back to the field. The number of newly initiated clinical pipelines in CKD drug development globally has been rapidly increasing since 2019, reaching 79 new clinical pipelines in total in 2024, more than double of that in 2019. The revitalization of renal R&D is also evidenced by the growing momentum of global 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. In this regulatory and market backdrop, the renal therapeutics industry is well positioned for substantial growth in the years to come.

Nevertheless, the novel renal therapeutics reaching the market remain limited, underscoring the high development challenge and significant entry barriers. Successful development demands a clear, comprehensive understanding of renal diseases and unmet medical needs. Novel renal therapeutics that offer superior efficacy, better safety, and reduced medical burden covering the full spectrum of renal diseases will lead the future market.

To address these profound unmet needs, we are building a novel and effective portfolio targeting renal disease: We have established a comprehensive portfolio of drug candidates for CKD complication management to address its most prevalent complications and secure a near-term commercial foundation. Concurrently, we are advancing a pipeline for CKD treatment aimed at slowing or halting disease progression. For details, see "— Our Product Pipeline." With a renal-focused portfolio that offers superior efficacy, unparalleled safety and better patient compliance, we aim to address the unmet medical needs.

OUR STRENGTHS

A Renal-Focused Biopharmaceutical Company with End-to-End Capabilities

We are a renal focused biopharmaceutical company with the broadest drug candidates in terms of renal indication coverage globally, according to CIC. We focus on innovation in renal therapeutics to address a broad spectrum of renal diseases for patients worldwide, aiming to establish new standard of care and address major clinical gaps in the current renal therapeutics. We have, since our inception, developed vertically integrated capabilities, spanning across research and development, manufacturing and commercialization. By capturing the entire value chain, these capabilities enable us to reduce reliance on external partners, mitigate potential supply chain risks and ensure faster, and more tailored commercialization of renal therapeutics in China's evolving CKD market.

Research and Development Capabilities

Our research and development capabilities enable us to build a pipeline targeting unmet needs, prioritizing novel and effective therapeutics. This strategy drives leadership in hyperphosphatemia with AP301 and AP306 and expands access in renal anemia via Mircera®, translating unmet need into patient impact and market leadership. In addition, we are able to identify high-impact targets by dissecting complex disease pathology, and then design molecules with unparalleled precision. This capability spans small and large molecules (e.g., dual PPAR agonist AP303 and re-engineered IgA-targeting protease AP308) and bridges academic concepts to viable drug candidates with distinct advantage. AP306's BTD from the NMPA and AP303's ODD from the FDA for ADPKD underscore our commitment to delivering novel and differentiated renal therapeutics to patients worldwide.

Our research and development capabilities also enable us to excel in pipeline progression that combines study design, operational efficiency, disciplined cross-region execution and effective regulatory communication. Regarding study design, the planned AP308 Phase Ib study incorporates specific markers to rapidly generate PoC data; regarding operational efficiency, in China, AP301's pivotal Phase III enrolled 474 participants across 50 centers in nine months, and AP306 progressed from IND clearance to first patient enrollment in three months; regarding cross-region execution, we coordinate studies in the U.S. and China — AP301's Phase III MRCT and AP306's Phase IIb MRCT are enrolling in both regions — to address regional requirements in parallel; and regarding regulatory communication, we engage early, constructive dialogues with regulatory authorities to accelerate paths to approval, and notably, the FDA accepted a single global Phase III MRCT for AP301's U.S. registration, streamlining development.

Manufacturing Capabilities

We have completed the construction of a world-class facility in Yangzhou, supporting commercial-scale production of both drug substance and drug product for our product candidates at the same site. The designed annual capacity will reach approximately 200 metric tons for AP301. Civil construction has been completed with built-in scalability reserved for future production needs of AP306 and other portfolio programs. Our self-owned manufacturing infrastructure brings the following advantages.

Supply Chain Reliability: For high-volume, lifelong therapeutics such as phosphate binders, CDMOs often cannot scale to the volumes required to meet market demand with reasonable supply price given the dedicated production lines and complexity of manufacturing procedures. Our in-house manufacturing ensures stable supply quality and quantity with pricing flexibility, which is critical for patient access.

Pricing Flexibility. In-house manufacturing enables us to tightly monitor materials as well as manufacturing costs. This cost advantage translates into higher margins and a clear competitive edge in terms of pricing flexibility in the hyperphosphatemia drug market.

Quality Control & Compliance. Direct oversight ensures stringent quality control throughout the manufacturing process. Our internal quality system is designed to meet global standards, ensuring consistent product quality.

Commercialization Capabilities

We have built a strong in-house sales team to maximize the value of our portfolio in China, while actively pursuing strategic partnerships with influential players to support successful global commercialization at the same time.

Recognizing the unique structure of China's renal market — where diagnosis and treatment are centralized in hospital nephrology departments — we are establishing our own in-house sales team that engages physicians, nephrologists and hospitals directly. We focus on "scientific-driven promotion" as a core competitive edge in commercialization. This involves academic engagement, tailored scientific discussions with physicians, and participation in medical conferences, designed to build trust and differentiate our therapeutics. This approach ensures our breakthroughs are understood and adopted. Our experienced team of 37 professionals as of December 31, 2025 has demonstrated strong market insight and execution, as evidenced by the successful launch of Mircera® in China. Mircera® was included in the 2023 NRDL and was listed in over 300 hospitals as of the Latest Practicable Date.

Building an in-house, renal-dedicated sales team in China creates powerful synergies: it aligns our broad CKD pipeline with unified nephrology sales and distribution networks, concentrates promotional efforts within the same hospital nephrology departments, and maximizes commercialization efficiency. By launching and scaling Mircera® first, we recruited and trained a high-performing team, strengthened relationships with physicians, hospitals, and payors, expanded market access and distribution, and could then leverage this backbone to accelerate sales and maximize impact for subsequent commercialization of our renal portfolio.

In wider global markets, we will actively explore partnerships to advance commercialization of our existing pipeline in select markets with differentiated strategies tailored for each market. For instance, unlike China, patients in U.S. receive dialysis in specialized dialysis centers, which often operate independently from hospitals. We will pursue a focused U.S. commercialization strategy by partnering with leading dialysis center chains to build deep collaborations and rapidly, cost-effectively reach patients receiving dialysis. For other global regions, depending on the commercial policies and target patient behaviors in the region, we intend to advance commercialization through partnerships with local healthcare institutions.

Complementary Portfolio of Novel and Effective Therapeutics in CKD Complications Management with High Commercialization Prospects

AP301 Stands as a Foundational Therapy in Hyperphosphatemia

AP301 is poised to become the new foundational therapy in hyperphosphatemia. It stands out with its consistent efficacy and safety. Key clinical progress and validation for AP301 underscore an accelerated path to approval and launch with reduced risk. We successfully completed the registrational Phase III trial in China confirming its consistent efficacy and safety profile. This pivotal achievement showcased our execution capability. Building on the results of our clinical studies, we reached an agreement with the FDA such that only one pivotal study is required for U.S. approval, reducing the requirement to a single additional global Phase III MRCT. That MRCT is

already underway and is expected to enroll 264 patients and being conducted across the U.S. and China. This transpacific trial design not only minimizes costs but significantly expedite the overall timeline and maximize our time-to-market advantage globally. Beyond dialysis patients, we will also explore clinical development of AP301 on serum phosphorous control in non-dialysis dependent patients with hyperphosphatemia.

AP306 Stands as the Breakthrough Therapy Reshaping Phosphate Control with a Novel Mechanism

AP306 is the first and only orally administered inhibitor targeting all three key intestinal phosphate transporters: phosphate transporter type IIb ("NaPi-IIb"), phosphate transporter-1 ("PiT-1"), and phosphate transporter-2 ("PiT-2"). Unlike existing binders that physically trap phosphate in the gut lumen, AP306 functions as a biological "valve" — it directly and vastly blocks the cellular pathways of active phosphate absorption. This novel mechanism offers a more efficient and effective approach to phosphate control, representing a paradigm shift in hyperphosphatemia treatment. By inhibiting the absorption itself, AP306 achieves deep and durable phosphate control, especially beneficial for patients whose hyperphosphatemia remains uncontrolled despite heavy use of binders.

Mircera® (AP601), The Proven Commercial Anchor As A Long-Acting Agent For Renal Anemia Solution

Mircera® is a strategic pillar of our portfolio addressing CKD complication management, establishing us as a key player in treating anemia in China. Mircera® is a preferred treatment due to their convenience and more stable efficacy. Its key advantage lies in providing exceptionally stable erythropoiesis. Unlike short-acting agents that cause significant peaks and troughs in hemoglobin levels, Mircera®'s advanced molecular structure ensures a continuous and steady stimulation of red blood cell production, leading to more consistent anemia control and potentially reducing the risk of cardiovascular complications associated with hemoglobin variability. Furthermore, Mircera® transforms the patient experience by significantly extending the dosing schedule to once monthly, a major improvement over competitors that requires injections three times per week. This significant reduction in treatment burden enhances patient quality of life and adherence, and lowers the operational burden on healthcare providers, cementing Mircera®'s position as the preferred standard of care for anemia.

Expanded Portfolio of CKD Treatment Paves Way for Sustainable Growth

AP303 — A Novel Disease-Modifying Agent to Halt the Progression of CKD

AP303 is designed to deliver broad renal protection across a spectrum of high-value indications, including, DKD, IgAN, ADPKD, and FSGS. Current therapeutic options only slightly slow disease progression, leaving a huge unmet medical need for disease-modifying agents that can further delay or halt kidney function decline. AP303 is an orally administered, dual PPAR agonist. With its novel and unique MOA, AP303 may achieve synergistic effects when used in combination with other renal disease treatments. For instance, AP303 may synergize with GLP-1R agonists or SGLT2 inhibitors to achieve greater renal protection.

AP308 — A Novel Engineered Recombinant IgA Protease Aiming for Functional Cure for IgAN

Unlike current and emerging IgAN therapeutics that focus on modulating the immune response (e.g., through B-cell modulation by APRIL or APRIL/BAFF) in slowing down new deposits, AP308 acts as a "molecular scissor" to directly remove the existing, disease-causing immune complexes from the kidney's mesangium. In our PD models, AP308 was observed to directly act on the kidney and cleave the IgA complexes and C3 deposits, confirming its highly direct mechanism of action. Based on its direct-acting mechanism, AP308 is projected to deliver a therapeutic effect that is both faster and deeper than any existing or pipeline therapy for IgAN. Our internal assessment, based on early observations, is to achieve an approximately 80-90% reduction in proteinuria within four weeks of treatment. This stands in contrast to current therapeutics and drug candidates, which typically achieve a 30-50% reduction over six to nine months.

Experienced Leadership Team with a Proven Track Record and Expertise in Renal Disease Drug Innovation

We have formed a renal-focused leadership team with deep expertise across the biopharmaceutical value chain and an unwavering focus on kidney disease — a hard-to-replicate talent pool. With decades of experience at leading global pharmaceutical and biotechnology companies, this team creates an unparalleled moat: our experts span the full continuum from discovery, research and development to regulatory approval, manufacturing and commercialization, combining unmatched scientific insight, clinical acumen, regulatory intelligence, manufacturing experience, and go-to-market execution.

Dr. Gavin Xia, our chief executive officer and co-founder, and Dr. Huading Zhang, our chief operating officer, bring decades of experience in healthcare, investments and pharmaceutical industry. Dr. Gavin Xia is a seasoned entrepreneur and venture capitalist with over 15 years in healthcare. Dr. Zhang brings over 15 years of experience across Pfizer, Roche, Baxter, and Amgen and integrates our operations from discovery to commercialization. Together, their strategic foresight, ability to translate scientific innovation into operational excellence, and decisive leadership skills continue to propel our growth and cement our strong position in renal therapeutics.

We place great importance on building our research and development capabilities. Jin Tian, M.D., our chief medical officer and co-founder, is a board-certified nephrologist with over 15 years of clinical practice, bringing a rare patient-centric perspective that has shaped our clinical strategy and real-world relevance. He led the development and approval of Mircera® in China while at Roche and led early clinical development of AP301. Dr. Shen Xiao, our chief scientific officer, also a nephrologist by training, spent over 20 years at the FDA in nephrology and cardiology, providing unparalleled regulatory insight and ensuring our global R&D strategy is aligned with regulatory expectations. Dr. Shu Chutian, our chief technology officer, brings over 15 years of CMC expertise from Boehringer Ingelheim, Novartis, and startups, with blockbuster drug experience that underpins our manufacturing capabilities. Under his leadership, our Yangzhou facility enables efficient, scalable production of our current and future renal-focused portfolio.

Our other executive team members also possess industry experience that is pivotal in supporting our rapid and efficient operations. Mr. Feng Jun, our head of commercialization, has over 25 years in sales leadership experience at Novartis, AstraZeneca, Sandoz, and Fresenius Kabi, giving him deep insight into renal market dynamics, KOL engagement, distribution, and patient access. Ms. Yun Wang, our chief of staff, brings over 15 years of experience in multinational healthcare companies specializing in organizational development, talent management, and compensation strategy. Her leadership cultivates a high-performing team and ensures the stability and efficiency of our end-to-end capabilities, across research and development, manufacturing, and commercialization functions.

Beyond our core management, our strategic direction and scientific rigor are strengthened by our experienced scientific advisery board. This highly distinguished panel comprises globally recognized experts and KOLs across the full spectrum of nephrology. Our scientific advisery board brings unparalleled influence across CKD indications and complications, and the global standards that guide clinical and regulatory development. Collectively, they lead and author cornerstone guidelines (including KDIGO CKD-MBD), shape the FDA and other regulatory policy (persuading the FDA to use proteinuria as a surrogate endpoint in IgAN), and have designed and executed landmark trials across DKD, IgAN, ADPKD and other CKD. They sit on steering committees of major international trials and research organizations, review and edit for top journals such as NEJM, JAMA, JASN, and AJKD, and advise leading nephrology societies and foundations.

OUR STRATEGIES

Expand R&D Capabilities and Accelerate Clinical Development of Existing Pipeline Globally

We are focused on developing novel and effective therapeutics. We will continue to strengthen our R&D capabilities to expand and deepen our renal-focused pipeline. Our renal-focused R&D engine has also enabled close relationships and strategic partnerships with leading research institutions. Recently, we established a joint laboratory with the Department of Nephrology at Peking University First Hospital, a global leader in renal disease research. This partnership facilitates shared access to research resources, accelerates the translation of scientific discoveries into therapies, and, importantly, grants us priority review rights to incorporate early discovery projects into our proprietary R&D pipeline. Going forward, we plan to implement differentiated R&D strategies to advance our product pipeline.

Advancing Clinical Development of AP301 and AP306 Towards Approval and Commercialization

AP301 and AP306 are currently in the most advanced clinical stages worldwide with promising clinical profile. We will rapidly advance AP301 and AP306 towards regulatory approvals:

AP301. We plan to engage in meetings with regulatory authorities, targeting the formal submission of NDA to the NMPA in the second quarter of 2026. We are conducting a global pivotal Phase III MRCT in the U.S. and China and plan to submit NDA to the FDA in the third quarter of 2027. We are actively preparing for regulatory communications with the EMA regarding registrational trials design and may explore strategic collaborations with potential partners to advance clinical registrations in the EU markets. In other global regions, we plan to leverage the potential FDA approval and establish partnerships, such as forming joint ventures, with leading local healthcare institutions to complete clinical registration of AP301 in select markets. We believe AP301 is on track to obtain the NMPA approval in China in 2027 and the FDA approval in the U.S. in 2028, while clinical development advances in parallel across the rest of the world. We also intend to initiate registrational trials for hyperphosphatemia in non-dialysis CKD patients both in China and globally.

AP306. We plan to initiate a Phase IIb MRCT in the U.S. and China and complete the trial by the second quarter of 2027, and to initiate global Phase III trials in 2027. Outside of China, we have formed joint ventures with qualified business partners with established market presence and industry knowhow to advance clinical development and registration of AP306 in select markets. We also intend to initiate registrational trials for hyperphosphatemia in non-dialysis CKD patients both in China and globally, to fully capture the market opportunities across life cycle of renal disease patients who have developed hyperphosphatemia.

Expanding Expertise in Major CKD Indications to Drive Global Renal Innovation

We will accelerate the delivery of our therapeutics to patients across broader CKD indications.

AP303. We have received positive feedback and clear guidance from the FDA and the NMPA regarding three Phase II studies in DKD/IgAN basket trial, ADPKD, and FSGS. We expect to initiate the first Phase II basket MRCT for DKD and lgAN patients with high proteinuria in the third quarter of 2026.

AP308. We expect to obtain IND clearance and enter clinical development stage in the third quarter of 2026.

We will also advance the development of multiple preclinical renal drug candidates, including AP304, AP305 and AP307, into clinical stage.

Expedite Entry into Markets with Tailored Commercialization Strategies for Our Portfolio

In China, as we advance AP301 and AP306 towards regulatory approvals and commercialization, we plan to methodically expand our marketing team to accelerate penetration into leading hospitals in major cities in China that have strong nephrology presence and medical capabilities. Given the interdisciplinary nature of renal diseases, patients are concentrated in comprehensive hospitals in China. By concentrating on the nephrology department within a target hospital, we expect to maximize the sales force efficiency. For broader expansion into other lower-tier markets, we may pursue a capital-efficient strategy via partnerships with CSOs. Given AP301's more advanced stage of development relative to AP306, our near-term commercialization strategy will prioritize bringing AP301 to market in China.

In wider global markets, we will actively explore partnerships to advance commercialization of our existing pipeline in select markets with differentiated strategies tailored for each market. For instance, the majority of the ESRD patients in the US will receive dialysis treatment in the dialysis centers managed by leading chain operators. Hence, we will partner with leading dialysis center chains to build deep collaborations in the U.S. and rapidly, cost-effectively reach patients receiving dialysis. For other global regions, depending on the commercial policies and target patient behaviors in the region, we intend to advance commercialization through partnerships with local healthcare institutions.

As for AP306 and other pipeline drugs that expect regulatory approvals at a later stage, we will fully leverage on the sales channels and promotional advantages established by the commercialization of AP301. Meanwhile, we will proactively explore commercialization opportunities through a range of partnership models, including JV, CSO, and out-licensing.

Enhance Our Manufacturing Capabilities towards A Full-fledged Biopharmaceutical Company

We have established and are ready to scale up our in-house manufacturing capacity to ensure sufficient production capacity to meet global market demand, enhance cost control and maintain pricing flexibility, as well as exert better oversight of production quality.

AP301: Production capacity is critical to the successful commercialization of AP301, given the complexity of manufacturing procedure of the molecule. The phase I construction of Yangzhou facility has been completed. It is currently in the phase of pilot-scale production and scale-up preparation. We may also scale up the capacity by establishing and upgrading production lines in the future, to accommodate the growing demand as AP301 continues to be commercialized in the global markets.

AP306 and other pipeline drugs: Civil construction has been completed with built-in scalability reserved for future production needs of AP306 and other drugs. Subsequent production capacity planning and investment will be determined based on the global phase II clinical trials results of AP306 as well as market demand. We will also actively consider further expanding capacity for other pipeline products in the future in coordination with their clinical development plans.

We plan to expand our production and quality control team by primarily recruiting team members with GMP industrial production experience, as well as personnel with quality control and assurance experience. We will also formulate comprehensive supply chain management system and quality control system to maintain high production efficiency, reliability and consistency as well as to exercise control over the whole manufacturing process from raw material procurement and monitoring, rigorous quality checks to final product delivery.

Proactively Explore Value Accretive Partnerships and Alliances

We plan to explore in-licensing opportunity of the best renal therapeutics across different development stages to achieve synergies with our existing portfolio and introduce these products into the China market. Meanwhile we will continue to scout for novel and effective drug candidates in broader CKD indications and complications. We will also proactively seek strategic partners to jointly advance the clinical development and, ultimately, achieve commercial success in major markets outside China such as the U.S. Depending on the clinical stage of each product, we will actively evaluate different modes of external partnerships, including potential joint venture, CSO or out-licensing arranagements, and find the most suitable approach tailored for each partnership. We are currently exploring global commercial and development partnerships to maximize the global market potential of AP301 and AP306.

Scale up Our Organization by Attracting, Training and Retaining Talents Globally in the Renal Therapeutic Fields and Expand Coloration with Renal-Focused Experts

We are committed to recruiting and retaining top talents globally in the renal therapeutic research and discovery, clinical development, manufacturing and commercialization to continuously enhance our end-to-end capabilities. In addition, we will also offer systematic training and career development programs for employees to continuously enhance their industry expertise, enabling them to remain at the forefront of industry dynamics and trends. Meanwhile, we closely collaborate with — experts in the nephrology space. For example, our scientific advisery board brings together expertise in the renal therapeutic fields.

OUR PRODUCT PIPELINE

AP301: Our Core Product, A Distinctive Oral Phosphate Binder for the Treatment of Hyperphosphatemia

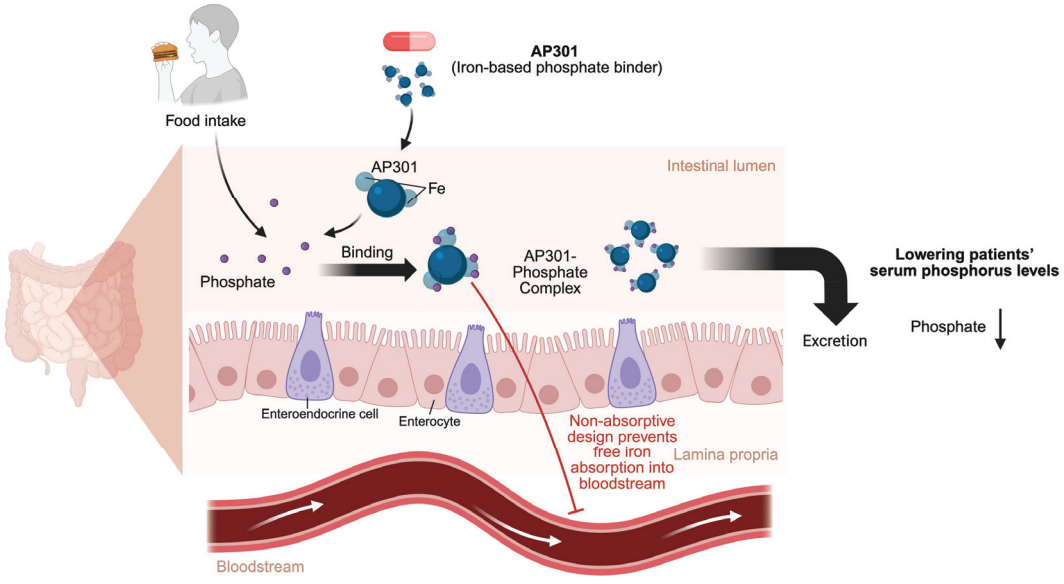
Overview

Our Core Product AP301 is under clinical development for the treatment of hyperphosphatemia, standing out due to its consistent phosphate-lowering capacity and safety profile. We hold the global rights for the development, manufacture and commercialization of AP301.

Mechanism of Action

The primary avenue of phosphate intake in human is through food and the primary avenue of phosphate excretion is via urine. Many CKD patients (especially ESKD patients) require dialysis, and due to their impaired renal function, excess phosphate cannot be excreted from urine and results in elevated serum phosphorus level, known as hyperphosphatemia. There is an established correlation between elevated serum phosphorus level with increased mortality risk.

AP301 is a complex consisting of acacia and ferric oxyhydroxide. It binds phosphate in the GI tract and facilitates its excretion via feces, effectively reducing phosphorus absorption without releasing iron, thereby maintaining phosphorus homeostasis in renal failure patients. We developed AP301 using a precisely controlled chemical process to irreversibly bind specific metal ions (*i.e.,* iron) to pharmaceutical grade functional fibers (*i.e.,* acacia). This transforms water-soluble fibers into a structurally stable, water-insoluble, high-density product with therapeutic potential. The new product may maintain its integrity throughout physiologically relevant pH values in the GI tract and may act as a highly effective chelator that binds to and removes overage of phosphate in the GI tract in a targeted manner. In the discovery of AP301, numerous polysaccharide and metal ion combinations were screened to identify an optimal pairing of the two components for a phosphate binder. Eventually, acacia was selected because it is a safe pharmaceutical-grade material with a unique structure, which ensures stable iron binding and maximal phosphate-binding efficiency without systemic absorption.



Market Opportunity and Competition

The global market of hyperphosphatemia drugs reached US$1.5 billion in 2024 and is estimated to reach US$6.0 billion in 2035. The market of hyperphosphatemia drugs in China reached RMB2.4 billion in 2024 and is estimated to reach RMB12.5 billion in 2035.

As of the Latest Practicable Date, there were seven drug types approved as phosphate lowering agents, namely tenapanor, ferric citrate, sucroferric oxyhydroxide, bixalomer, lanthanum carbonate, sevelamer, and calcium-based phosphate binders. In the U.S., there were six drug types approved as phosphate lowering agents, namely tenapanor, ferric citrate, sucroferric oxyhydroxide, lanthanum carbonate, sevelamer, and calcium-based phosphate binders. In China, there were five drug types approved as phosphate lowering agents, namely tenapanor, sucroferric oxyhydroxide, lanthanum carbonate, sevelamer, and calcium-based phosphate binders.

As of the Latest Practicable Date, there were five approved non-calcium phosphate-lowering molecules for hyperphosphatemia globally. As of the Latest Practicable Date, there were only two clinical-stage assets in pipeline for hyperphosphatemia with active global trials, according to CIC. For more details, see "Industry Overview — Overview of Hyperphosphatemia Market."

Competitive Advantages

Consistent Phosphate-Lowering Capacity

AP301 is highly potent at binding phosphate in the GI tract. Unlike Sevelamer whose phosphate binding capability functions optimally only at neutral pH, AP301's phosphate-binding activity remains potent throughout physiologically relevant pH values in the GI tract. In a Phase II clinical trial in China, AP301 achieved a mean reduction in serum phosphorus level in CKD patients receiving maintenance hemodialysis of 2.01 mg/dL after a six-week dose titration. Moreover, AP301 achieved phosphate control with lower pill weight of a median daily dose of approximately 5.11g. The same effect was achieved by the daily dosage of approximately 7.0g for Velphoro (sucroferric oxyhydroxide) and approximately 8.25g for Sevelamer in Velphoro's Phase III trial (without a head-to-head comparison with AP301).

In the Phase III clinical trial, AP301 reduced the serum phosphorus level by 2.22 mg/dL in CKD patients receiving maintenance dialysis with hyperphosphatemia, compared to 2.17 mg/dL for sevelamer carbonate at week 12. Moreover, AP301 achieved persistent serum phosphate reduction over 52 weeks, suggesting its long-term therapeutic effect. It also showed a higher serum phosphate response rate in the AP301 arm (66.7%) compared to the sevelamer carbonate arm (58.6%) at Week 52, and with a lower mean daily dose exposure (6.52 g/day in AP301 versus 7.56 g/day in sevelamer carbonate).

Superior Safety with Minimal GI Side Effects

AP301 delivers a consistent GI safety profile, effectively preventing bloating, constipation and discomfort common with prior generations of phosphate binders, as evidenced by a pooled patient TEAE related dropout rate of < 5%. Importantly, the body will not absorb the iron component in AP301, as the iron is tightly bound by AP301's acacia scaffold. Also, the volume of AP301 remains stable and insoluble across the physiologically relevant pH range in the GI tract. These properties effectively limit the iron absorption by the body from AP301. Moreover, compared with Sevelamer, the volume of AP301 experiences much lower expansion when exposed to the gastric fluid present in the GI tract. This significantly reduces the incidence of GI adverse events such as nausea, vomiting, constipation, and obstruction. Lastly, AP301 does not disrupt the body's internal balance regarding water and electrolyte. The superior safety profile of AP301 has received endorsement from the FDA, which granted AP301 a waiver for a 2-year rodent carcinogenieity study noting a general lack of systemic absorption from the gastro-intestinal tract with the majority of AP301 being excreted in feces and the observation that AP301 did not induce pre-neoplastic changes in a 26-week rat toxicity study.

Convenience of Use

AP301 is orally administered in the capsule form, which is more convenient to swallow than tablets. It is tasteless, odorless, and does not require chewing. Also, AP301's high phosphate binding capacity lowers the pill burden and thus improves patient compliance. Compared with traditional phosphate binders, which require 7.5 to 14 grams of total mass for daily administration, the needed daily dosage of AP301 is expected to be much lower. Moreover, AP301 enhances GI motility, potentially alleviating constipation in the hyperphosphatemia patients.

Summary of Clinical Trials

The following sets forth an overview of the key clinical studies of AP301.

Study number	Phase	Study design	Sites	Subjects	Status	Patient enrollment
VDKDL001 . . .	I	Evaluate the tolerability, safety and efficacy of AP301	Australia	End stage renal disease patients undergoing hemodialysis	Completed	10 (Actual)
AP301-HP-01 . .	II	Evaluate the tolerability, safety and efficacy of AP301 to treat hyperphosphatemia	China	CKD patients receiving maintenance hemodialysis	Completed	158 (Actual)
AP301-HP-02 . .	III	Evaluate the efficacy and safety of AP301 on serum phosphorus control	China	CKD patients receiving hemodialysis and peritoneal dialysis	Completed	474 (Actual)
AP301-HP-03 . .	III	Evaluate the efficacy and safety of AP301 on serum phosphorus control	China and the U.S.	CKD patients receiving maintenance dialysis with hyperphosphatemia	Ongoing	264 (Expected)

All dosage levels indicated in the trial design refer to the dosage of the active moeity of AP301 and comparator.

VDKDL001: A dose escalation Phase I clinical trial of AP301 to evaluate the tolerability, safety and efficacy in end stage renal disease patients undergoing hemodialysis sponsored by Vidasym in Australia

Overview. This was a single-arm, dose escalation Phase I clinical trial of AP301. Its objective was to evaluate the tolerability, safety and efficacy of AP301 when given with meal for 8 weeks to hemodialysis patients with hyperphosphatemia.

Trial design. The trial enrolled 10 subjects. AP301 was orally administered with meal for 8 weeks. The starting dose was 1.50 g per day, and the dose was elevated step wise from 1.50 g to 2.25 g, 4.50 g and 6.75 g per day based on the safety assessment and plasma phosphorus level every 2 weeks during the 8-week treatment period. The primary endpoint was plasma inorganic phosphorus change from baseline to end of treatment.

Trial status. The trial was initiated in July 2015 and completed in June 2016. We acquired the protocol and results of the Phase I clinical trial from Vidasym, pursuant to the 2018 Vidasym Agreement.

Efficacy data. AP301 was demonstrated to be effective to hemodialysis patients with hyperphosphatemia. A significant difference of plasma inorganic phosphorus was found between baseline and end of treatment ($p<0.0001$), with a mean reduction of 2.40 mg/dL (95% CI: 1.68, 3.13).

Safety data. AP301 was demonstrated to be safe and well-tolerated to hemodialysis patients with hyperphosphatemia. The overall incidence of TEAEs was 70%. The incidence of drug related AEs was observed in 4 subjects (40%), which were mild or moderate in intensity. SAE occurred in 2 subjects. One subject died by SAE during the study. The investigators considered that all of the SAEs had no relationship to AP301.

AP301-HP-01: A dose-escalation and dose-ranging Phase II clinical trial to evaluate the tolerability, safety and efficacy of AP301 to treat hyperphosphatemia in CKD subjects receiving maintenance hemodialysis sponsored by us in China.

Overview. This is a multi-center, open-label, two-part, active-controlled Phase II clinical trial to evaluate the tolerability, safety and efficacy of various dosages of AP301 when given orally with meal for 6 weeks to treat hyperphosphatemia in CKD subjects receiving maintenance hemodialysis.

The trial consisted of two parts. Part 1 was a single-arm, multicenter, open-label, dose-escalation study to evaluate the tolerability and preliminary efficacy of AP301 for the treatment of hyperphosphatemia in CKD patients receiving maintenance hemodialysis. The primary objective of Part 1 was to assess the tolerability of escalating AP301 doses in patients. The secondary objectives were to: assess the association between the dose of AP301 and the reduction of serum phosphorus; assess the effects of AP301 on serum phosphorus, serum calcium, calcium phosphorus product and intact parathyroid hormone levels during dose escalation.

Part 2 was a multicenter, open-label, parallel-group, active-controlled, dose-ranging study to assess the safety and efficacy of different fixed doses of AP301 for the treatment of hyperphosphatemia in CKD patients receiving hemodialysis (including both hemodialysis and hemodiafiltration). The primary objective of Part 2 was to assess the efficacy of different fixed doses of AP301 in reducing serum phosphorus. The secondary objectives were to: assess the effects of different doses of AP301 and sevelamer carbonate on serum P, serum phosphorus, serum calcium, calcium phosphorus product and intact parathyroid hormone levels; assess the overall safety and tolerability of AP301 in the subjects.

Trial status. We initiated the Phase II clinical trial in October 2020 and completed the trial in April 2022.

Trial design. This trial enrolled 158 patients in total.

Part 1 enrolled 25 patients. All patients in Part 1 received a starting dosage of AP301 of 2.25 g/day. At the end of every two weeks, the dosage was escalated sequentially to 4.50 and 9.00 g/day based on the safety assessment and serum phosphorus levels. The primary endpoint was change of serum phosphorus from baseline to end of treatment in different fixed dose groups. The secondary endpoint included: change in serum phosphorus levels over time from baseline to the end of treatment; time to serum phosphorus response (defined as serum phosphorus level decreased at least 1 mg/dL and dropped below 5.5 mg/dL); proportion of subjects with serum phosphorus levels of 3.5-5.5 mmol/L at the end of treatment; change in serum calcium level from baseline to the end of treatment; change in calcium phosphorus product from baseline to the end of treatment; change in intact parathyroid hormone level from baseline to the end of treatment.

Part 2 enrolled 133 patients, which were randomized into the four experimental arms that received various dosages of AP301 (1.50, 2.25, 4.50 or 6.75 g/day) and one active control arm that received Sevelamer carbonate (4.80 g/day), an approved drug for hyperphosphatemia. The primary endpoint was change of serum phosphorus from baseline to end of treatment in different fixed dose groups. The secondary endpoint included: change in serum phosphorus levels over time from baseline to the end of treatment; time to serum phosphorus response (defined as serum phosphorus level decreased at least 1 mg/dL and dropped below 5.5 mg/dL); proportion of subjects with serum phosphorus levels of 3.5-5.5 mmol/L at the end of treatment; change in serum calcium level from baseline to the end of treatment; change in calcium phosphorus product from baseline to the end of treatment; change in intact parathyroid hormone level from baseline to the end of treatment.

Inclusion criteria included: male or female aged 18 years and above; on a stable hemodialysis treatment 3 times per week for more than 12 weeks before the screening and throughout the study period; serum phosphorus level > 6 mg/dL but 10 mg/dL at the screening visit (if the patient was not taking any phosphate binder at screening visit) or at the end of the washout period (if the patient was taking phosphate binder(s) at the screening visit).

Exclusion criteria included: renal transplant patient or scheduled renal transplant, or change to peritoneal dialysis/home hemodialysis, or plan to change the dialysis regimen or relocate to another hemodialysis center during the study period; serum phosphorus level of patients who were on phosphate binder(s) was lower than 4.0 mg/dL or higher than 7.5 mg/dL at screening, and serum phosphorus level was above 10 mg/dL once during laboratory tests within 3 months before screening (including test as screening); serum calcium level was lower than 8 mg/dL or higher 11 mg/dL; serum intact parathyroid hormone level was >800 pg/mL at screening.

Efficacy data. In Part 1, serum phosphorus significantly improved (mean change -2.0 mg/dL; 95% confidence interval -2.7, -1.4) after AP301 dose escalation. In Part 2, serum phosphorus significantly and dose-dependently improved in all AP301 arms, with clinically meaningful reductions with AP301 4.50 and 6.75 g/day, and Sevelamer carbonate 4.80 g/day (mean change at -1.6 (-2.2, -1.0), -1.8 (-2.4, -1.2) and -1.4 (-2.2, -0.5) mg/dL, respectively). In both parts, serum phosphorus reductions occurred within 1 week of AP301 initiation.

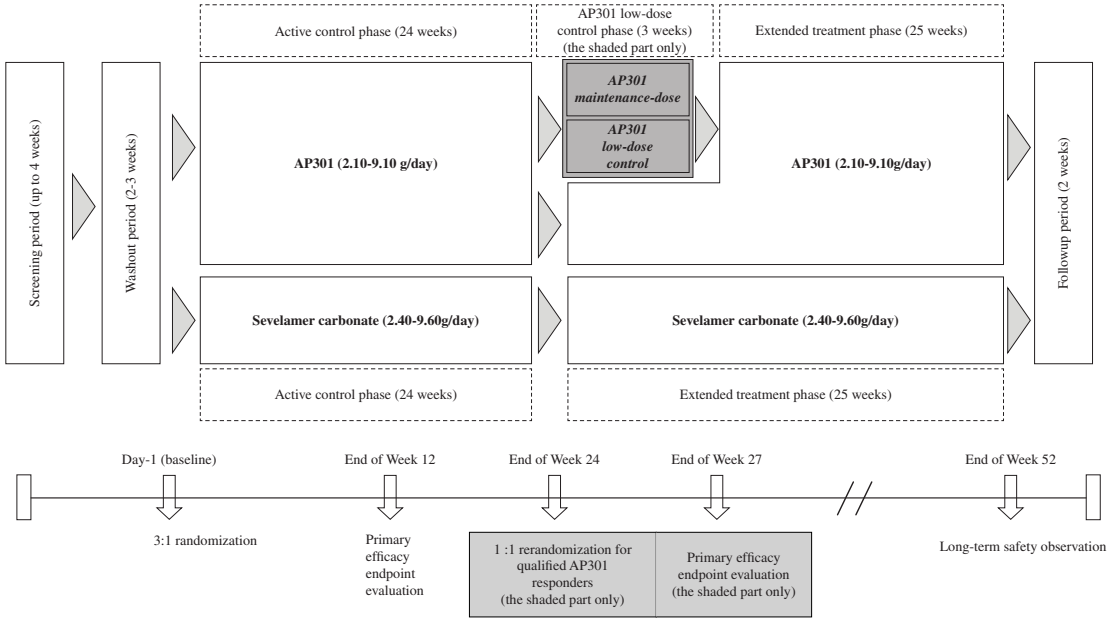
Safety data. AP301 was well tolerated with a manageable safety profile. Most patients reported one or more TEAE. Most TEAEs were mild in severity. All SAEs were assessed as not associated with drug related. The most common AEs were GI disorders, mainly feces discolored (63.5%) and diarrhea (16.5%; generally during Weeks 1-2 of treatment). Most GI disorders resolved without intervention.

AP301-HP-02: A Phase III clinical trial to evaluate the efficacy and safety of AP301 for controlling serum phosphorus in CKD patients receiving hemodialysis and peritoneal dialysis with hyperphosphatemia sponsored by us in China.

Overview. This is a randomized, open-label, multi-center, Phase III clinical trial to evaluate the efficacy and safety of AP301 on serum phosphorus control in chronic kidney disease patients receiving maintenance dialysis with hyperphosphatemia. This trial has two primary objectives: (i) the superiority of maintenance dose versus ineffective low dose of AP301; and (ii) the non-inferiority of AP301 versus Sevelamer carbonate on serum phosphorus control. The secondary objectives were to assess: overall efficacy of AP301 in controlling serum phosphorus in dialysis patients with hyperphosphatemia; effect of AP301 on serum calcium, calcium phosphorus product and intact parathyroid hormone levels in dialysis patients with hyperphosphatemia; safety and tolerability of AP301 in dialysis patients with hyperphosphatemia.

Trial status. We initiated the Phase III clinical trial in June 2023 and completed the trial in June 2025. The trial met its primary endpoint, demonstrating a statistically significant and clinically meaningful improvement in serum phosphorus control with AP301. The safety profile of AP301 was favorable and consistent with previous studies.

Trial design. A total of 474 patients were enrolled in this trial. The trial consisted of four periods: (i) a screening period of up to 4 weeks; (ii) a washout period of 2 to 3 weeks; and (iii) a treatment period of 52 weeks containing a 24-week active control phase, a 3-week AP301 low dose control phase, and a 25 or 28-week extension treatment phase; and (iv) a follow up period of 2 weeks after the participants' completion or discontinuation of the study treatment. Below is a general illustration of the trial design.



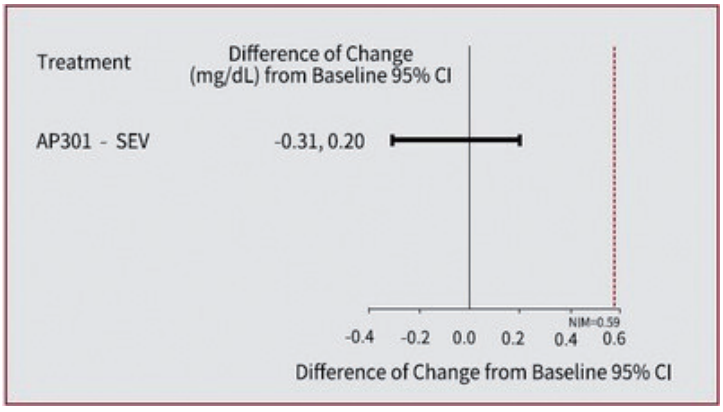
The primary endpoints included: (i) the change in serum phosphorus levels between patients with hyperphosphatemia who responded to AP301 and continued on the AP301 maintenance dose and the low-dose AP301 control group from Week 24 to Week 27 or the end of the low-dose control period (whichever occurred first), and (ii) the changes in serum phosphorus levels from baseline to the end of Week 12 or the end of treatment (whichever occurred first), in the AP301 group and the Sevelamer carbonate group.

Secondary endpoints included the achievement rate of serum phosphorus in the target range (3.5-5.5 mg/dL); changes in serum calcium; changes in serum phosphorus; changes in serum calcium times phosphorus product; changes in intact parathyroid hormone; and the time to reach the first serum phosphorus response.

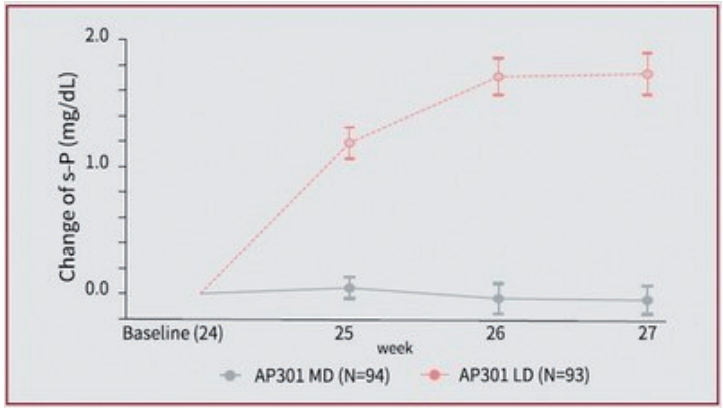
Inclusion criteria were: male or female aged 18 years and above; on hemodialysis treatment for at least 3 months before the screening and throughout the study period; serum phosphorus level 3.5 mg/dL but < 8 mg/dL at the screening visit and serum phosphorus level 6 mg/dL but < 10 mg/dL at the end of the washout period, if the patient receives phosphate binders; serum phosphorus level 6 mg/dL but < 10 mg/dL at the screening visit, if the patient has not received phosphate binders for at least two consecutive weeks before the screening visit.

Exclusion criteria were: history or plan of kidney transplantation; history of parathyroid intervention 6 months before signing the informed consent form or planned parathyroid intervention; serum calcium < 7.6 mg/dL or > 11 mg/dL at screening; serum intact parathyroid hormone > 1000 pg/mL at screening.

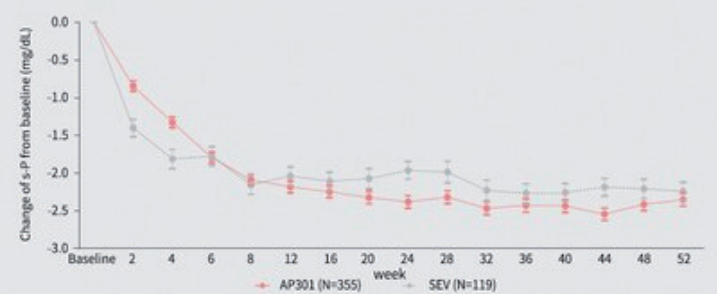
Efficacy data. At week 12, AP301 demonstrated non-inferiority to Sevelamer carbonate: the least squares mean ("LSM") reduction from baseline was 2.22 mg/dL for AP301, compared to 2.17 mg/dL for Sevelamer carbonate. The LSM difference was -0.06 mg/dL (95% CI: -0.31, 0.20).



At week 27, AP301 maintenance dose showed a clinically and statistically significant superiority on serum phosphate control over an ineffective AP301 low dose in the low dose control phase. The LSM difference was -1.8 mg/dL (95% CI: –2.1, –1.5; P <0.001).



AP301 achieved persistent serum phosphate reduction over 52 weeks, suggesting its long-term therapeutic effect. It also showed a numerically higher serum phosphate response rate in the AP301 arm (66.7%) compared to the Sevelamer carbonate arm (58.6%) at Week 52, and with a lower mean daily dose exposure (6.52 g/day in AP301 versus 7.56 g/day in Sevelamer carbonate).



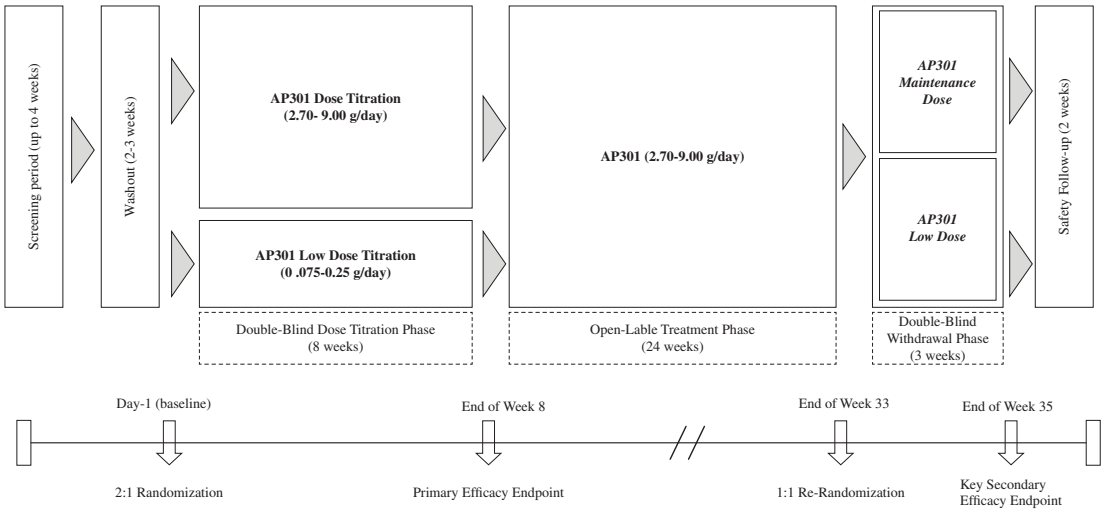
Safety data. Most participants experienced at least one AE (96.3% in AP301 and 90.8% in Sevelamer carbonate). Diarrhea was the most common AE leading to study discontinuation in the AP301 arm (2/355, 0.6%), typically occurring within the first 2–4 weeks and predominantly mild in severity.

AP301-HP-03: A Phase III clinical trial to evaluate the efficacy and safety of AP301 on serum phosphorus control in CKD patients receiving maintenance dialysis with hyperphosphatemia sponsored by us in multiple regions (including China and the U.S.).

Overview. This is a double-blind, randomized, multi-regional, Phase III clinical trial to evaluate the efficacy and safety of AP301 on serum phosphorus control in chronic kidney disease patients receiving maintenance dialysis with hyperphosphatemia. The primary objective is to evaluate the superiority of AP301 versus AP301 low dose (ineffective dose) on serum phosphorus control during the double-blind dose titration phase in dialysis patients with hyperphosphatemia. The key secondary objective is to evaluate the superiority of AP301 maintenance dose versus AP301 low dose (ineffective dose) on serum phosphorus control during the double-blind randomized withdrawal phase in dialysis patients with hyperphosphatemia. Other secondary objectives include assessing the effects of AP301 on changes in serum calcium, calcium phosphorus product, and intact parathyroid hormone levels and the effect of AP301 treatment on health-related quality of life in dialysis patients with hyperphosphatemia in China.

Trial status. We initiated the Phase III clinical trial in July 2025 and expect to complete the trial in the second quarter of 2027.

Trial design. The trial will consist of four periods: (i) a screening period of up to 4 weeks; (ii) a washout period of 2 to 4 weeks; and (iii) a treatment period of 35 weeks; and (iv) a follow up period of 2 weeks after the participants' completion or discontinuation of the study treatment. The treatment period will contain a dose titration phase, a treatment phase and a withdrawal phase. Below is a general illustration of the trial design.



The primary endpoint will be change in serum phosphorus levels from baseline to the end of dose titration phase, between the AP301 and AP301 low dose in hyperphosphatemia patients. The secondary endpoint will be change in serum phosphorus levels from the end of open-label treatment phase to the end of withdrawal phase, between the maintenance dose of AP301 and low dose of AP301 in hyperphosphatemia patients previously treated with AP301. Safety endpoints include number (percentage) of participants with TEAEs and SAEs.

Inclusion criteria were: aged 12 years and above; on hemodialysis treatment for at least 3 months before the screening and throughout the study period; treated with phosphate lowering products for hyperphosphatemia over 4 weeks and whose serum phosphate level 3.5 mg/dL but < 8 mg/dL at the screening visit and serum phosphorus level 6 mg/dL but < 10 mg/dL at the end of the washout period, with increase of serum phosphate level from screening after washout.

Exclusion criteria were: history of kidney transplantation (except for allograft failure), or plan to receive kidney transplantation, change of dialysis modality, or plan to relocate to another non-participating dialysis center during the study period; history of parathyroid intervention 6 months before signing the informed consent form or planned parathyroid intervention; serum calcium < 7.6 mg/dL or > 11 mg/dL at screening; serum intact parathyroid hormone > 1200 pg/mL at screening.

Clinical Development Plan

In China, based on the satisfactory efficacy and safety results obtained from the Phase II clinical trial and subsequent completion of the Phase III China clinical trial, we expect to file an NDA for AP301 with the NMPA in the second quarter of 2026. Separately, following communications with the FDA regarding the regulatory requirements for a direct marketing application in the U.S., we initiated a Phase III MRCT of AP301 in July 2025, and we expect to complete the Phase III MRCT of AP301 in the second quarter of 2027 and file an NDA with the FDA in the third quarter of 2027. We conduct the Phase III MRCT solely for the purpose of obtaining direct marketing application with the FDA. The inclusion of China as one of the clinical trial sites in the Phase III MRCT, together with the U.S., is not mandated by the competent authorities. Rather, it reflects our assessment that conducting part of the MRCT in China is operationally efficient and enables timely patient recruitment under a unified clinical protocol, while maintaining compliance with applicable regulatory requirements. Both China and the U.S. are the primary trial locations for the Phase III MRCT, all participating sites in the Phase III MRCT are conducted under the same clinical protocol, including consistent trial objectives and endpoints. The Phase III MRCT is independent from, has no reliance on the results of the China Phase III clinical trial (AP301-HP-02), and is unrelated to the planned NDA for AP301 to the NMPA. We plan to include the Phase III MRCT results (in both the U.S. and China) in the NDA for AP301 to the FDA. In the EU, we expect to initiate a Phase III clinical trial of AP301 in 2028.

Material Communications with Competent Authorities

We submitted the IND application to conduct a Phase II clinical trial of AP301 in China (AP301-HP-01) in October 2019, based on results of Phase I clinical trial of AP301 in Australia, and received IND clearance from the NMPA in January 2020. The details of the Phase II clinical trial stipulated in the submitted IND application are as follows.

Indication	Hyperphosphatemia
Therapy type	Monotherapy
Stage of treatment	First-line
Patient cohort	CKD patients receiving maintenance hemodialysis

The stipulated primary and secondary objectives, primary and secondary endpoints, and inclusion and exclusion criteria are as set forth in the above disclose of the trial design of AP301-HP-01.

After completion of the Phase II clinical trial, we submitted the IND application to conduct a Phase III clinical trial of AP301 in China (AP301-HP-02) in December 2022 and received IND clearance from the NMPA in March 2023. The NMPA IND clearance was based on the results of Phase I clinical trial of AP301 in Australia and Phase II clinical trial of AP301 in China. The details of the Phase III clinical trial stipulated in the submitted IND application are as follows.

Indication	Hyperphosphatemia
Therapy type	Monotherapy
Stage of treatment	First-line
Patient cohort	CKD patients receiving hemodialysis and peritoneal dialysis

The stipulated primary and secondary objectives, primary and secondary endpoints, and inclusion and exclusion criteria are as set forth in the above disclose of the trial design of AP301-HP-02.

Both the FDA and the NMPA have independently reviewed and approved the trial plan of the Phase III MRCT (AP301-HP-03). We submitted to the FDA the IND application to conduct a Phase III MRCT (AP301-HP-03) in June 2024 and received the IND clearance from the FDA in July 2024. We submitted to the NMPA the IND application to conduct a Phase III MRCT (AP301-HP-03) in April 2025 and received the IND clearance from the NMPA in June 2025. The IND clearances from the FDA and the NMPA were both based on the results of Phase I clinical trial of AP301 in Australia and Phase II clinical trial of AP301 in China. The details of the Phase III MRCT stipulated in the submitted IND applications are as follows.

Indication	Hyperphosphatemia
Therapy type	Monotherapy
Stage of treatment	First-line
Patient cohort	CKD patients receiving maintenance dialysis

The stipulated primary and secondary objectives, primary and secondary endpoints, and inclusion and exclusion criteria are as set forth in the above disclose of the trial design of AP301-HP-03.

Licenses, Rights and Obligations

AP301 was initially discovered and developed by Vidasym, which is a U.S.-based clinical-stage drug discovery and development company with a focus on CKD complications and osteoporosis. Dr. Jin Tian, our co-founder and chief medical officer was heavily involved in Vidasym's early-stage research and clinical development. Dr. Tian is no longer an employee or consultant of Vidasym since 2019. We have no competition with Vidasym as it focuses on a different therapeutic area. Vidasym completed a Phase I clinical trial of AP301 in Australia. We in-licensed the full China right and later acquired global rights relating to AP301 in 2018 and 2021, respectively, with no future milestone and royalty obligations from Vidasym following the close of the below transactions. Led by Dr. Jin Tian, we have solely designed and independently conducted the clinical trials of AP301 except the Phase I clinical trial in Australia (VDKDL001). Led by Dr. Shu Chutian, our chief technology officer, we independently established a proprietary manufacturing process for AP301 and constructed an in-house facility in Yangzhou for the manufacturing of AP301. For more details, please refer to "Business — Major Collaboration Arrangements — Collaboration Arrangement with Vidasym, Inc."

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET AP301 SUCCESSFULLY.

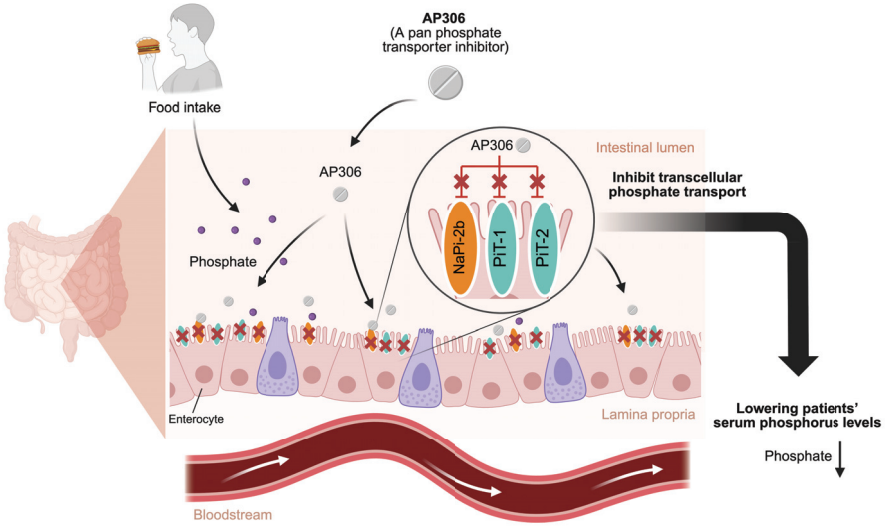
AP306: A Novel Pan-Phosphate Transporter Inhibitor

Overview

AP306 is the world's first and, as of the Latest Practicable Date, the only pan-phosphate transporter inhibitor in clinical development for the treatment of hyperphosphatemia. We hold the global rights for the development, manufacture and commercialization of AP306.

Mechanism of Action

Hyperphosphatemia can potentially be treated by reducing intestinal absorption of phosphate. Two different mechanisms — passive paracellular transport via tight junctions and active transcellular transport — contribute to the intestinal absorption of phosphate. The active transport of phosphate involves the sodium-dependent NaPi-IIb, PiT-1, and PiT-2. The inhibition of these transporters is able to control hyperphosphatemia.



AP306 is an oral pan-phosphate transporter inhibitor (NaPi-IIb, PiT-1 and PiT-2). It inhibits the active phosphate transport in the intestine and has the potential to inhibit active phosphate absorption with a much lower pill burden as compared to phosphate binders.

Market Opportunity and Competition

AP306 targets hyperphosphatemia. For details, see "— AP301: Our Core Product, A Distinctive Oral Phosphate Binder for the Treatment of Hyperphosphatemia — Market Opportunity and Competition."

Competitive Advantages

Novel MOA

AP306 is the first pan-phosphate transporter inhibitor developed clinically. This novel mechanism offers a more efficient and effective approach to phosphate control, representing a paradigm shift in hyperphosphatemia treatment. By targeting the absorption itself, AP306 is able to achieve deep and durable control of serum phosphate level, which is especially beneficial for patients with refractory hyperphosphatemia or those requiring optimal and aggressive phosphate management.

Outstanding Efficacy

With this novel MOA, AP306 exhibits outstanding efficacy. In our Phase II clinical trial, AP306 demonstrated a mean serum phosphate reduction of 2.51 mg/dL, and nearly 95% of patients had their serum phosphate levels controlled at less than 5.5 mg/dL by Week 7-8. This efficacy significantly outperforms classic binders such as Sevelamer, which brought around 50% of patients to the serum phosphate level at less than 5.5 mg/dL by Week 7-8 in the same clinical trial. Also, AP306 was able to lower the average serum phosphate level to between 3.5 and 4.5 mg/dL, a target few phosphate binder can reach. This outstanding efficacy further indicates AP306's potential to expand its indication to non-dialysis dependent CKD patients.

Favorable Safety Profile

AP306 demonstrated a favorable safety profile. In the Phase II clinical trial, the most common adverse events were GI disorders and diarrhea, and any observed diarrhea was mild and manageable. The discontinuation rate due to AEs was less than 5%, and there was no premature discontinuation due to GI adverse effects.

Convenience of Use

AP306 offers a significant reduction in pill burden, requiring only 2-3 small tablets, a significant contrast to 6-12 tablets daily typically needed for traditional phosphate binders.

Summary of Clinical Trials

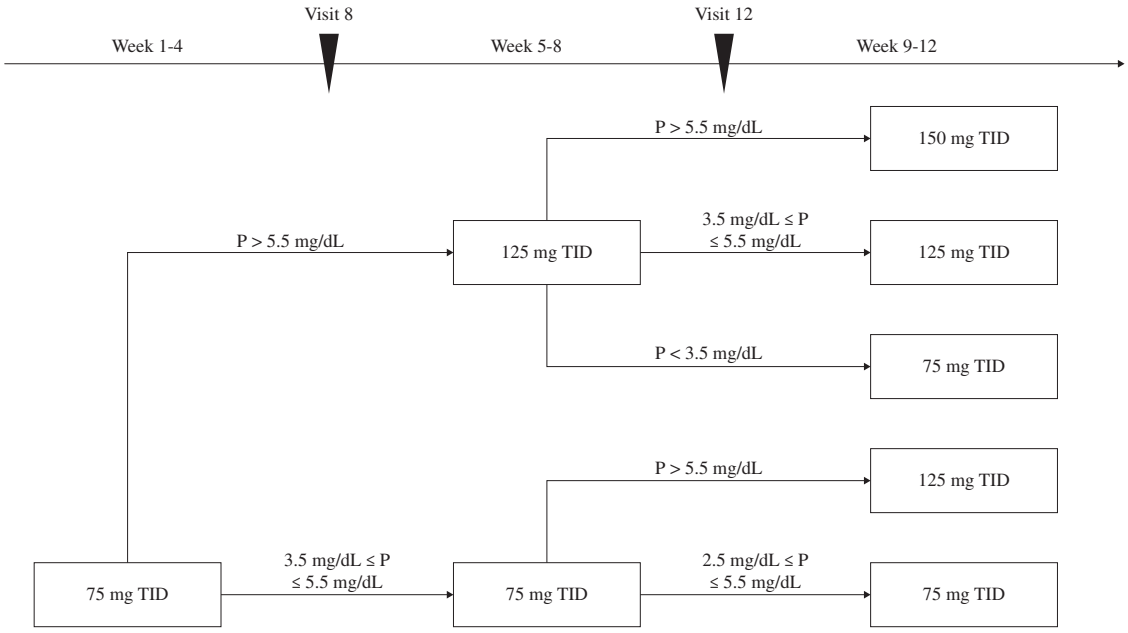
AP306 has completed the Phase II clinical trial stage in China and expects to initiate a Phase IIb MRCT in the second quarter of 2026. All dosage levels indicated in the trial design refer to the dosage of the active moeity of AP306 and comparator.

AP306-HP-01: A Phase II clinical trial to evaluate the safety and serum phosphorus lowering effect of AP306 in chronic kidney disease patients receiving maintenance hemodialysis with hyperphosphatemia in China sponsored by us.

Overview. This is a randomized, open-label, active-controlled, multicenter Phase II clinical trial to evaluate the safety and serum phosphorus lowering effect of AP306 in chronic kidney disease patients receiving maintenance hemodialysis with hyperphosphatemia. The goal of this clinical trial is to evaluate the efficacy (assessed by blood phosphorus lowering), safety and tolerability of AP306 in the patients receiving maintenance hemodialysis with elevated blood phosphorus.

Trial status. We initiated the Phase II clinical trial in March 2023 and completed the trial in October 2023. The results of the trial were presented through the Focused Oral at the 61st ERA Congress in 2024.

Trial design. The trial enrolled 55 patients, who were randomized into two groups. The experimental group, which included 27 patients, received AP306 for 12 weeks. The active comparator group, which included 28 patients, received Sevelamer carbonate for 12 weeks. The dose of AP306 and Sevelamer was adjusted every 4 weeks to keep serum phosphate in the target range of 3.5 to 5.5 mg/dL. The investigational dose of AP306 was initiated at 75 mg and increased stepwise to 125 mg, and 150 mg three times a day with meals. The dosing schedule of AP306 is illustrated below.



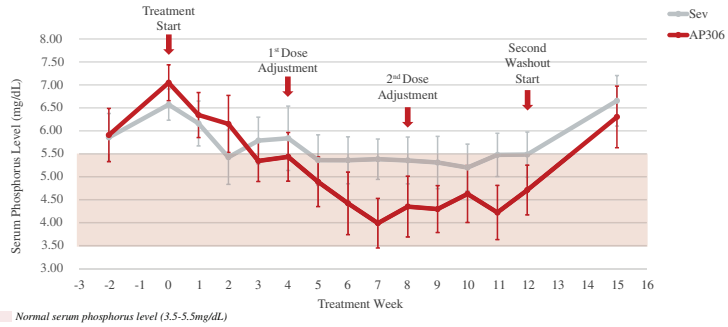
Abbreviations: P: serum phosphorus; TID: three times a day

The primary endpoint was defined as the mean changes in serum phosphate from baseline to the end of treatment. Secondary endpoints included: time to first occurrence of serum phosphate ≤5.5 mg/dL; change in serum phosphate from baseline over time; the proportion of patients with serum phosphate concentration between 2.5 and 4.5 mg/dL over time.

Efficacy data. The AP306 and sevelamer groups achieved decrease in serum phosphate of -2.51 mg/dL (95% confidence interval: -3.07, -1.92) and -1.08 mg/dL (95% confidence interval: -1.58, -0.59), respectively. The proportions of patients achieving the recommended range as per the KDIGO guidelines (2.5-4.5 mg/dL) were about 20% higher in AP306 than in Sevelamer, starting from treatment week 5.

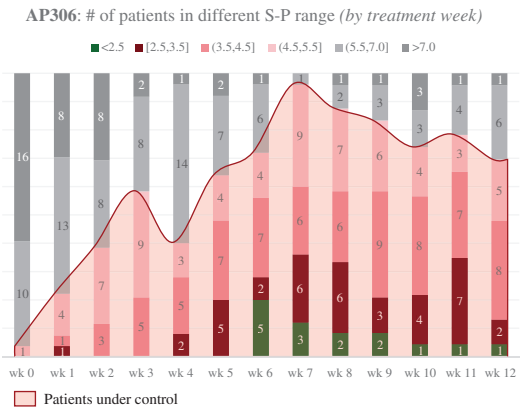
Serum phosphate concentrations in both groups decreased after the first week of treatment, and this reduction was maintained until the end of the 12-week treatment period. The magnitude of this reduction was more pronounced in the experimental group that received AP306. Serum phosphate concentrations returned to near baseline values 3 weeks after discontinuation of AP306 and Sevelamer carbonate in the experimental group and the active comparator group, respectively. The proportion of patients with serum phosphate concentrations between 2.5 and 4.5 mg/dL (the normal serum phosphate level) was consistently higher among those randomized to the AP306 group after 5 weeks of treatment (48% vs. 25%) and was maintained until the end of the 12-week treatment period (44% vs. 21%).

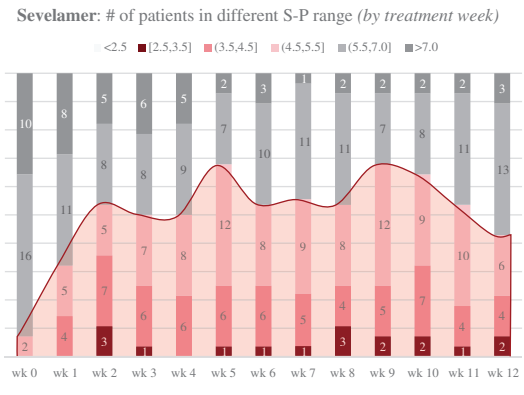
Regarding actual exposure to treatment in the trial, the daily doses of AP306 were significantly lower than Sevelamer. The mean daily dose (± SD) of AP306 was 288 ± 82 mg after two dose level adjustments, while that of Sevelamer was 4,651 ± 1,899 mg. Notably, the daily dose of AP306 was stabilized below 300 mg after two dose level adjustments, suggesting that no more than 3 tablets daily would be required in clinical practice, assuming a formulation of tablets containing 100 or 150 mg of AP306. The figure below shows the change of serum phosphate concentration of over time in the enrolled patients.



	AP306	Sevelamer
Subject (N)	27	28
Baseline: Serum P	7.06 mg/dL	6.57 mg/dL
End of treatment: Serum P	4.55 mg/dL	5.48 mg/dL
Primary Endpoint *(Change from BL to wk 12)*	**-2.51 mg/dL** (95% CI -3.07, -1.92)	-1.08 mg/dL (95% CI -1.58, -0.59)
Avg. Dose during the third 4-week treatment	**98.0 mg TID**	1571.4 mg TID
End of wk16	6.29 mg/dL	6.66 mg/dL

The figures below show the change of proportion of enrolled patients within designated target ranges over time.





Total Pt. #	27	27	26	26	25	25	25	25	24	24	23	23	23
Avg. dose (mg)		75.0	75.0	75.0	75.0	105.0	105.0	105.0	104.2	100.0	98.9	98.9	96.7
Response % (<=5.5 mg/dL)	3.7%	22.2%	38.5%	58.3%	40.0%	64.0%	72.0%	**96.0%**	**87.5%**	83.3%	73.9%	78.3%	**69.6%**

Total Pt. #	28	28	28	28	28	28	28	28	28	28	28	28	28
Avg. dose (mg)		914.3	914.3	914.3	914.3	1,314.3	1,314.3	1,303.7	1,314.3	1,571.4	1,571.4	1,571.4	1,571.4
Response % (<=5.5 mg/dL)	7.4%	33.3%	55.6%	51.9%	51.9%	**66.7%**	55.6%	53.8%	55.6%	70.4%	66.7%	55.6%	**44.4%**

Safety data. AP306 demonstrated a favorable safety profile. Over the 12-week treatment period, 78% and 57% of the patients in the experimental and active control groups, respectively, experienced at least one treatment related TEAE. Most of the reported TEAEs were assessed as Grade 1 or 2. The most reported AEs associated with AP306 were GI disorders, most of which were mild to moderate diarrhea (44.4%).

Clinical Development Plan

We and R1 expect to initiate a Phase IIb MRCT of AP306 in the second quarter of 2026 and complete the trial in the second quarter of 2027. R1 is in negotiation with the FDA and coordinating with us to finalize the protocol for the Phase IIb MRCT, aiming to meet the FDA's expectation to count the Phase IIb MRCT as a pivotal clinical trial for AP306 to support a direct marketing application of AP306 to the FDA. Another pivotal clinical trial of AP306 for supporting the marketing application with the FDA is expected to be a Phase III MRCT, which is expected to commence in 2027.

In China, we plan to leverage the data of the Phase IIb MRCT and the Phase III MRCT to support a direct marketing application of AP306 to the NMPA, thereby potentially obviating the need to conduct a separate Phase III clinical trial in China. We intend to request an end-of-phase-II meeting with NMPA in 2027, to seek the NMPA's confirmation of the aforementioned plan regarding the marketing application of AP306. If, however, the NMPA determines that we must conduct a separate Phase III clinical trial of AP306 in China for the marketing application of AP306, instead of leveraging the Phase IIb MRCT and Phase III MRCT data, then we expect to initiate a separate China Phase III clinical trial and then submit an NDA for AP306 with the NMPA in 2029.

Material Communications with Competent Authorities

We submitted to the NMPA an IND application to conduct a Phase II clinical trial of AP306 in August 2022, based on results of Phase 1 clinical trail of AP306 in Japan, and received the IND clearance in December 2022. The scope of the IND clearance covered the AP306-HP-01 Phase II clinical trial.

In October 2024, we submitted to the FDA an IND application to conduct a Phase IIb clinical trial of AP306 and received the FDA IND clearance in November 2024. In November 2024, we submitted to the NMPA an IND application to conduct a Phase IIb clinical trial of AP306 and received the NMPA IND clearance in February 2025. The FDA and NMPA IND clearances were both based on results of Phase I clinical trial of AP306 in Japan and Phase II clinical trial of AP306 in China. The Phase I clinical trial of AP306 in Japan and the U.S. was completed by Chugai.

In August 2025, we submitted to the FDA and the NMPA a protocol amendment of the planned Phase IIb MRCT, by shortening the treatment period from 12 weeks to 8 weeks. Neither the FDA nor the NMPA has raised any objection or concern to the amendment.

Licenses, Rights and Obligations

AP306 was initially discovered and developed by Chugai, which completed a Phase I clinical trial of AP306 in Japan and the U.S. and shared with us the results of the Phase I clinical trial. Founded in 1925, Chugai is one of Japan's leading research-based pharmaceutical companies. Chugai, based in Tokyo, specializes in prescription pharmaceuticals and is listed on the Tokyo Prime Stock Exchange. We obtained the global development and commercialization rights for AP306. We have independently conducted the Phase II clinical trial of AP306. For more details, please refer to "Business — Major Collaboration Arrangements — Collaboration Arrangement with Chugai Pharmaceutical Co., Ltd."

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET AP306 SUCCESSFULLY.

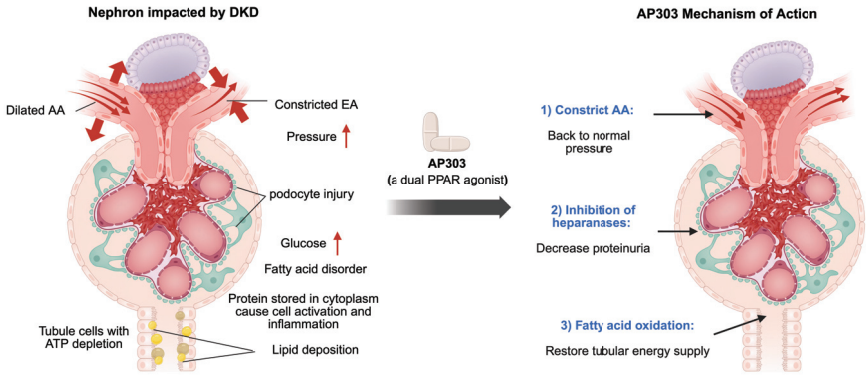
AP303: A Novel Dual PPAR Agonist for Broad Renal Protection

Overview

AP303 is a small molecule dual PPAR agonist. It is developed as a potential treatment for a broad spectrum of high-value indications, including among others, DKD, IgAN, ADPKD and FSGS. We self-discovered and internally developed AP303 and hold the global rights for its development, manufacture and commercialization. Dr. Tian led our internal development of AP303.

Mechanism of Action

AP303 is an orally administered, dual PPAR agonist. PPARs are nuclear receptors that mediate diverse metabolic and cellular functions. Lipid and glucose metabolism, energy homeostasis, and inflammation in organisms are all regulated by PPARs transcription. PPARs have been demonstrated to have broad therapeutic potential by coordinately modulating multiple pathological processes such as inflammation, oxidative stress, and mitochondria abnormalities in kidney disease. PPAR activation may protect the kidneys in CKD by regulating lipid metabolism and attenuating fibrosis. AP303 is designed to simultaneously target the three core pathological pillars of CKD progression: (i) aberrant intraglomerular pressure, (ii) podocyte dysfunction or loss, inflammation and fibrosis, and (iii) tubular metabolic dysfunction. Further, AP303 is designed to have a balanced PPAR activity ratio.



Market Opportunity and Competition

As of the Latest Practicable Date, globally there were seven approved drugs for DKD, four approved drugs for IgAN, one approved drug for ADPKD, and no approved drug specifically for FSGS. For more details, see "Industry Overview."

Competitive Advantages

Novel MOA

AP303 is designed to simultaneously target the three core pathological pillars of CKD progression. Current standards of care, such as ACE inhibitors and ARBs, primarily address one or two of the three pathological pillars.

Potential Synergy with Other Renal Disease Treatments

AP303 may achieve synergistic effects when used in combination with other renal disease treatments. For instance, AP303 may synergize with GLP-1 receptor agonists or SGLT2 inhibitors to achieve greater renal protection. This ability to enhance existing therapies significantly expands its clinical utility and market potential, positioning AP303 as the indispensable "plus" in the emerging combination paradigm.

Diverse Potential Indications

AP303 is designed to deliver broad renal protection across a broad spectrum of high-value indications, including among others, DKD, IgAN, FSGS and ADPKD. AP303 has received ODD from the FDA for ADPKD, underscoring its potential to transform the renal treatment landscape. AP303's mechanism offers the potential for a more profound and durable treatment effect. In preclinical models, AP303 demonstrated significant reductions in proteinuria across multiple nephropathy mouse models (including DKD, IgAN, and FSGS), alongside improved TKV and renal survival in various ADPKD mouse models. Compared with renal protective agents such as SGLT2i and GLP-1 RA, AP303 can significantly reduce patients' risk of progressing to dialysis and delay disease progression.

Summary of Clinical Trials

The following sets forth an overview of the key clinical studies of AP303.

Study number	Phase	Study design	Sites	Subjects	Status	Patient enrollment
AP303-PK-01	I	Assess the safety, tolerability, and pharmacokinetics of AP303	Australia	healthy adult subjects	Completed	62 (Actual)

Study number	Phase	Study design	Sites	Subjects	Status	Patient enrollment
AP303-PK-02	I	Assess the safety, tolerability, PK and PD of AP303	China	healthy adult subjects	Completed	18 (Actual)
AP303-PK-03	Ib	Assess the safety, tolerability, PK and PD of AP303	China	DKD patients with renal impairment	Completed	18 (Actual)

AP303-PK-01: A Phase I clinical trial to assess the safety, tolerability, and pharmacokinetics ("PK") of AP303 in healthy adult subjects in Australia sponsored by us.

Overview. This is a single-center, randomized, double-blind, placebo-controlled, first-in-human Phase I clinical trial in which the safety, tolerability, and PK of orally administered AP303 were assessed in healthy adult subjects. The primary objectives were to: (i) assess the safety and tolerability of single dose and multiple doses of AP303 when administered orally to healthy subjects, and (ii) characterize the single-dose and multiple-dose PK of AP303 in healthy subjects. The secondary objective was to explore the effect of food on the PK of AP303 after single dose administration.

Trial status. We initiated the Phase I clinical trial in December 2022 and completed the trial in July 2023.

Trial design. The trial enrolled 62 subjects. It consisted of two parts: Part A was a single ascending dose ("**SAD**") phase enrolling a total of 4 cohorts of healthy subjects; Part B was a multiple ascending dose ("**MAD**") phase enrolling 3 cohorts of healthy subjects.

Part A enrolled 38 subjects, who were sequentially enrolled into 1 of 4 planned SAD cohorts. The dose escalation sequence was 50 μg, 150 μg, 300 μg and 600 μg. The subjects were confined to a clinical research unit ("**CRU**") on Day 1 and discharged on Day 4. On Day 1, subjects were administered a single oral dose of AP303 or placebo under the fasting conditions. Food effect was evaluated for Cohort 2.

Part B enrolled 24 subjects, which were divided into 3 cohorts. The subjects were confined to a CRU on Day 1 and discharged on Day 17. On Days 1 through 14, the subjects received once daily doses of AP303 or placebo at 50μg, 150μg and 300μg for Cohorts 1, 2 and 3, respectively.

Primary endpoints included incidence and severity of AEs, laboratory, ECG, vital sign changes and PK characteristics. Secondary endpoint was the effect of food on PK characteristics.

Safety data. The safety results indicated that AP303 was safe and well tolerated in the enrolled healthy subjects.

AP303-PK-02: A Phase I clinical trial to assess the safety, tolerability, PK and PD of AP303 in healthy Chinese adult participants in China sponsored by us.

Overview. This is a randomized, double-blind, placebo-controlled, multiple-ascending-dose Phase I clinical trial to investigate the safety, tolerability, PK and PD of AP303 following 2-week oral administration in healthy Chinese participants. The primary objectives were to: (i) assess the safety and tolerability of multiple-ascending-dose of AP303 when administered orally to healthy Chinese participants, and (ii) characterize the single and multiple-ascending-dose PK of AP303 in healthy Chinese participants. The secondary objective was to evaluate the pharmacodynamic effect of multiple oral doses of AP303 in healthy Chinese participants.

Trial status. We initiated the Phase I clinical trial in March 2024 and completed the trial in May 2024, as marked by the Phase I database lock. Thereafter, we conducted clinical data analysis and finalized the clinical study report of the China Phase I clinical trial in August 2024.

Trial design. The trial enrolled 18 participants, who were randomized into one of the two dose cohorts. Each cohort included 9 participants randomized to receive AP303 and placebo at 2:1 ratio (i.e., 6 on AP303 and 3 on placebo). The starting dose of AP303 was 150 μg and 300 μg once daily for the first and second cohorts, respectively. AP303 or placebo was administered on Day 1 and Days 3 to 14 of the 14-day treatment period. Primary endpoints included incidence and severity of AEs, incidence of laboratory abnormalities, ECG, vital signs, physical examination, body weight and PK characteristics. Secondary endpoint was the change in certain blood metabolic and biochemistry parameters from baseline to end of treatment and 14±1 days after the last dose of each cohort.

Safety data. The safety results indicated that AP303 was safe and well tolerated in healthy Chinese participants. All TEAEs were mild and recovered. No SAE, severe TEAE, AESI, or TEAE leading to study discontinuation was reported in this study.

AP303-PK-03: A Phase Ib clinical trial to assess the safety, tolerability, PK and PD of AP303 in DKD patients with renal impairment in China sponsored by us.

Overview. This is a randomized, double-blind, placebo-controlled Phase Ib clinical trial to investigate the safety, tolerability, PK and PD of AP303 following 2-week oral administration in DKD patients with renal impairment. The primary objectives are to: (i) assess the safety and tolerability of multiple oral doses of AP303 in DKD patients with renal impairment, and (ii) characterize the PK of single or multiple oral doses of AP303 in DKD patients with renal impairment. The secondary objective is to evaluate the PD of multiple oral doses of AP303 in DKD patients with renal impairment.

Trial status. In preparation for the Phase Ib clinical trial, we completed the Ethics Committee submission in August 2024 and filing with the Human Genetic Resources Administration of China in October 2024. The clinical site initiation and patient screening for the trial commenced in November 2024, which led to the initiation of the trial in February 2025. We completed the trial in September 2025. The Phase Ib clinical trial was not required by the NMPA.

Trial design. The trial enrolled 18 participants, who were randomized into one of the two dose cohorts. Each cohort included 9 participants randomized to receive AP303 and placebo at 2:1 ratio (6 in the AP303 150 μg group and 3 in the placebo group). AP303 150 μg or placebo was administered orally, once daily, on Day 1 and Days 3 to 14 of the 14-day treatment period. Primary endpoints included incidence and severity of AEs, incidence of laboratory abnormalities, ECG, vital signs, physical examination, body weight and PK characteristics. Secondary endpoint was the change in certain blood metabolic and biochemistry parameters from baseline to end of treatment and 14±1 days after the last dose of each cohort.

Clinical Development Plan

A basket Phase II clinical trial targeting DKD and IgAN patients with high proteinuria, which has received IND clearance in both the U.S. and China, is expected to be initiated in the third quarter of 2026. Two additional Phase II trials, targeting ADPKD and FSGS, are expected to be initiated in the fourth quarter of 2026 in China, Europe and Australia and the first quarter of 2027, respectively. The target markets of AP301 for the indications of ADPKD and FSGS are China, the U.S. and Europe.

Material Communications with Competent Authorities

We submitted to the TGA an IND application to conduct a Phase I clinical trial in Australia in November 2022. We submitted to the NMPA an IND application to conduct a Phase I clinical trial of AP303 in China in October 2023 and received the NMPA IND clearance in January 2024.

In addition, we submitted to the NMPA an IND application for a basket Phase II clinical trial of AP303 targeting DKD and IgAN patients with high proteinuria in February 2025, based on results of Phase I clinical trials of AP303 in Australia and China, and received the NMPA IND clearance in June 2025. We submitted to the FDA an IND application for a basket Phase II clinical trial of AP303 targeting DKD and IgAN patients with high proteinuria in the U.S. in January 2025, based on the results of Phase I clinical trials of AP303 in Australia and China, and received the FDA IND clearance in March 2025.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET AP303 SUCCESSFULLY.

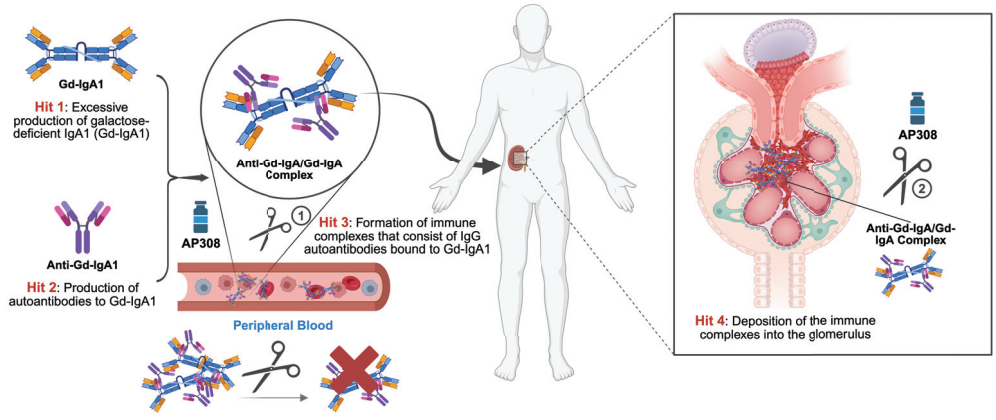
AP308: A Novel Engineered Recombinant IgA Protease Aiming for Functional Cure for IgAN

Overview

AP308 is an engineered recombinant IgA protease able to specifically degrade the circulating IgA and IgA complexes, as well as IgA complexes deposited in the kidney. It is developed as a potential targeted and curative therapeutic for IgAN. We hold the global rights for the development, manufacture and commercialization of AP308.

Mechanism of Action

Current treatments of IgAN, such as renin-angiotensin system ("**RAS**") inhibitors and corticosteroids, focus on symptom control and slowing progression rather than disease modification, and they do not directly target the mechanism of IgAN's pathogenesis. Compared to currently available treatment options for IgAN, AP308 is of a novel MOA and potentially a disease-modifying therapy. It specifically clears the circulating IgA and IgA complexes, as well as IgA complexes deposited in the kidney.



AP308 is chemically modified by a site-directed conjugation process, where a high-molecular-weight polymer, polyethylene glycol ("**PEG**"), is attached to specific sites on a protein. The PEG conjugation results in longer half-life *in vivo*, enhanced stability of the protein and lowered potential immunogenicity.

Market Opportunity and Competition

IgAN is the most common form of primary glomerulonephritis in Asia, and it is responsible for 50% of primary glomerulonephritis in China. The size of the global market for IgAN drugs reached US$1.1 billion in 2024 and is expected to reach US$11.1 billion in 2035, at a CAGR of 23.5% from 2024 to 2035. The market size for IgAN drugs in China reached RMB1.8 billion in 2024 and is expected to reach RMB11.2 billion in 2035, at a CAGR of 17.8% from 2024 to 2035. As of the Latest Practicable Date, there were four approved drugs for IgAN. As of the Latest Practicable Date, there was no IgA protease drug candidate in the clinical development stage, and AP308 was the only IgA protease that would soon enter clinical development. For more details, see "Industry Overview — Overview of IgA Nephropathy ("IgAN") Market."

Preclinical Data

Developed from an IgA protease from commensal bacteria in the GI tract, AP308 exhibited strong enzymatic activity in removing circulating IgA and IgA complexes as well as IgA deposits in pre-clinical models. The strong enzymatic activity remained after repeated dosing up to nine times. In addition, in the analysis of pooled samples from healthy donors and patients, no pre-existing anti-AP308 antibody was detected. These evidence supports AP308 as a potential IgA protease in a human use setting.

Clinical Development Plan

We expect to submit to the NMPA and the FDA an IND application for AP308 and initiate a Phase I clinical trial in the third quarter of 2026. We expect to complete the Phase I clinical trial in the second quarter of 2027.

Licenses, Rights and Obligations

We independently designed and applied site-directed PEG modification process for AP308. The original IgA protease based on which AP308 was created was developed by and licensed from the Peking University First Hospital ("**PUFH**"). In January 2022, we entered into a license agreement with the PUFH, which granted us an exclusive and irrevocable license to research, develop, and commercialize globally the IgA protease. For more details, please refer to "Business — Major Collaboration Arrangements — Collaboration Arrangement with the Peking University First Hospital." Such in-licensing of certain components for subsequent drug development is a common practice in the biopharmaceutical industry, according to CIC.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET AP308 SUCCESSFULLY.

Mircera® (AP601): A New Choice for Chinese CKD Patients with Anemia

Mircera® (methoxy polyethylene glycol-epoetin beta) is a long-acting EPO used for the treatment of anemia associated with CKD. It is the first EPO approved for once-monthly administration worldwide. Mircera® is not a biosimilar drug. As of the Latest Practicable Date, Mircera® enjoyed market exclusivity, fortified by the absence of approved biosimilars. Globally, Mircera® is a leading erythropoiesis-stimulating agent, distinguished by an effective clinical profile. In 2024, Mircera® accounted for approximately 30% share of the global renal anemia drug market, and in China, its market share was less than 5%.

Anemia, characterized by a deficiency in red blood cells or hemoglobin, is a common and serious complication of CKD. It results from impaired erythropoietin production due to kidney dysfunction. While conventional treatments include EPOs and iron supplementation, many patients, particularly those on hemodialysis or peritoneal dialysis, fail to achieve target hemoglobin ("**Hb**") levels after receiving conventional treatments. Mircera® stimulates erythropoiesis by interacting with the erythropoietin receptor on progenitor cells in the bone marrow, thereby helping the patients reach the target Hb level of 110g/L. Mircera® can maintain a stable Hb level with a favorable safety profile, and it is the first-line recommended medication by global anemia treatment guidelines. Its once-monthly dosing also improves patient adherence and treatment convenience.

Mircera® was developed by Roche Pharmaceuticals Inc. ("**Roche**"). It is marketed globally. In 2018, the NMPA granted marketing approval of Mircera® in China. In October 2023, we entered into a supply and marketing agreement with Roche, under which we shall exclusively promote Mircera® in China. For more details, please refer to "Business — Major Collaboration Arrangements — Collaboration Arrangement with Roche Holding AG." We secured inclusion of Mircera® in the 2023 NRDL of China right after obtaining the commercialization rights in China.

Other Preclinical Stage Product candidates

We are advancing the development of additional product candidates at the preclinical stage. AP304 is a product candidate targeting acute kidney injury ("**AKI**") and acute ischemic stroke ("**AIS**"). AP305 is a complement factor B inhibitor developed for the treatment of IgAN and other immune-mediated renal diseases. AP307 is a product candidate targeting membranoproliferative glomerulonephritis ("**MPGN**"), a kidney disorder where immune system defects lead to the deposition of antibodies and complement components in the kidney, causing inflammation and changes to kidney cells. We expect to file IND applications for AP304 and AP305 in 2027.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET AP304, AP305 and AP307 SUCCESSFULLY.

MAJOR COLLABORATION ARRANGEMENTS

Collaboration Arrangement with Vidasym, Inc.

AP301 was initially developed by Vidasym, which is a U.S.-based clinical-stage drug discovery and development company with a focus on CKD complications and osteoporosis. It was co-founded by Jin Tian, M.D., our co-founder and chief medical officer. Vidasym completed a Phase I clinical trial of AP301. We in-licensed the full China right and later acquired the full global rights relating to AP301 in 2018 and 2021, respectively, with no future milestone and royalty obligations from Vidasym following the close of the below transactions. We have solely conducted the Phase II and Phase III clinical trials of AP301.

In May 2018, we entered into an Assignment and License Agreement (the "**2018 Vidasym Agreement**") with Vidasym, Inc. ("**Vidasym**") regarding AP301.

- *Obligations, Responsibilities, and Intellectual Properties.* Pursuant to the 2018 Vidasym Agreement, we acquired from Vidasym its entire right, title and interest in patent applications relating to AP301 in Chinese Mainland, Hong Kong, Macau and Taiwan, as well as the inventions described therein. Also, we acquired from Vidasym (i) an exclusive license to exploit additional patents or patent applications in multiple jurisdictions, as well as know-how, of Vidasym relating to AP301, in Chinese Mainland, Hong Kong, Macau and Taiwan, and (ii) a non-exclusive license to exploit the said patents, patent applications and know-how in regions outside Chinese Mainland, Hong Kong, Macau and Taiwan.

  We shall use commercially reasonable efforts to develop and seek regulatory approvals for at least one product containing AP301 in at least one indication and in at least one regulatory jurisdiction in Chinese Mainland, Hong Kong, Macau and Taiwan. The 2018 Vidasym Agreement did not provide a joint steering committee.

- *Payments.* Vidasym shall receive from us a one-time payment of a low single-digit hundred thousand of RMB. No milestone payment or royalties were provided in the 2018 Vidasym Agreement. In addition, Vidasym will obtain, in a nominal value reasonably acceptable to the parties, certain equity interest of us. As of the Latest Practicable Date, we have fulfilled our payment obligations with Vidasym under the 2018 Vidasym Agreement. The total consideration of the 2018 Vidasym Agreement included the aforementioned one-time payment and equity interest to be received by Vidasym.

- *Dispute Resolution.* Any dispute or claim arising out of or in connection with the 2018 Vidasym Agreement, shall be referred to and finally resolved by arbitration administered by the Hong Kong International Arbitration Centre.

- *Termination.* Unless terminated earlier, the 2018 Vidasym Agreement shall expire on the last to occur of: (1) expiration of the last-to-expire valid claim in the patent applications assigned to us pursuant to the 2018 Vidasym Agreement relating to AP301 in Chinese Mainland, Hong Kong, Macau and Taiwan; and (2) the expiration of, on a product-by-product and jurisdiction-by-jurisdiction basis, any exclusive marketing rights or data exclusivity rights conferred by any regulatory authority with respect to any product containing AP301 in a jurisdiction within Chinese Mainland, Hong Kong, Macau and Taiwan. We may terminate without cause upon prior written notice to Vidasym or if the assigned patent titles are acquired by a government authority, while either party may terminate for the other party's material breach or bankruptcy.

In connection with the 2018 Vidasym Agreement, Shanghai Alebund shall issue certain equity interest equivalent to the parties involved, including Vidasym. Accordingly, in 2018, Shanghai Alebund issued 37.5% of its equity stake to Vidasym. This percentage was set at arm's length among our founder, investors, and Vidasym, reflecting AP301's market potential in Greater China. The ratio was fixed in the joint venture agreement in connection with the establishment of Shanghai Alebund, not as part of the 2018 Vidasym Agreement. When such issuance of equity interest occurred, the key business activity of Shanghai Alebund was to conduct R&D of AP301 and serve as the IP holding company for AP301 in China. The aforementioned one-time payment and equity interest received by Vidasym in connection with the 2018 Vidasym Agreement were based on our evaluation of the market value of the Greater China rights of AP301 at the time of the transaction as well as the valuation of Shanghai Alebund based on consensus between external investors and us. For details, see "History, Development and Corporate Structure — Corporate Development and Major Shareholding Change — (1) Establishment and Historical Corporate Reorganization" and "History, Development and Corporate Structure — Pre-[**REDACTED**] Investments."

In November 2019, we entered into an Equity Transfer Agreement (the "**2019 Vidasym Agreement**") with Vidasym. Pursuant to the 2019 Vidasym Agreement, Vidasym: (i) sold 37.5% of the of the equity interests it held in Shanghai Alebund to a wholly-owned subsidiary of Alebund Cayman and (ii) granted us an exclusive option to acquire Vidasym's global rights in the intellectual property regarding AP301, in exchange for our payment of a low single-digit millions of U.S. dollars with the intention to realize immediate economic benefits. The pricing was based on our evaluation of the market value of the Greater China rights of AP301 as well as the post-money valuation of Shanghai Alebund after the May 2018 Investment. Such low single-digit millions of U.S. dollars were paid in full and as of the Latest Practicable Date, there was no outstanding payment obligations under the 2019 Vidasym Agreement. Following the execution of the 2019 Vidasym Agreement, Vidasym was no longer our shareholder. In September 2020, we entered into an Amendment to Equity Transfer Agreement, pursuant to which the end date of exercising the exclusive option was amended to June 30, 2022.

In June 2021, we entered into an Assignment Agreement (the "**2021 Vidasym Agreement**") with Vidasym regarding AP301, as an exercise of the exclusive option granted to us in the Equity Transfer Agreement in November 2019. Pursuant to the 2021 Vidasym Agreement, we acquired from Vidasym the full global rights regarding AP301, in exchange for our payment of low double-digit millions of U.S. dollars, which had been fully paid.

Vidasym had not been involved in and will not further contribute to the clinical development and indication expansion of AP301 beyond the completed Phase I clinical trial (VDKDL001). Vidasym does not retain any right of, nor there exists any, revenue-sharing arrangement for AP301 after the 2021 Vidasym Agreement and going forward.

Collaboration Arrangement with Chugai Pharmaceutical Co., Ltd.

Chugai Agreement

In July 2021, we entered into an option and license agreement (the "**Chugai Agreement**") with Chugai Pharmaceutical Co., Ltd. ("**Chugai**") regarding AP306. Founded in 1925, Chugai is one of Japan's leading research-based pharmaceutical companies. Chugai, based in Tokyo, specializes in prescription pharmaceuticals and is listed on the Tokyo Prime Stock Exchange (TSE: 4519). We obtained the global development and commercialization rights for AP306.

Obligations and Responsibilities

Under the Chugai Agreement, Chugai granted us an option to acquire a global exclusive sublicensable license to develop, manufacture, and commercialize AP306. Also, Chugai allowed us to conduct an early-stage efficacy clinical trial to further evaluate AP306. If we exercise the option, Chugai shall grant us an exclusive license to develop, manufacture, and commercialize AP306 for all indications worldwide. In October 2023, we exercised the option, and we now own the global development and commercialization rights for AP306.

After our exercise of the option under the Chugai Agreement, Chugai shall grant to us an exclusive license for all patents and know-how that are controlled by Chugai and necessary or useful to exploit AP306, for us to exploit AP306 globally. The Chugai Agreement did not limit such patents and know-how to a specified group of patents or know-how. After our exercise of the option under the Chugai Agreement, we shall have the sole responsibility and control, at our sole costs and expense, for all development and commercialization activities for AP306.

In addition, the parties shall establish a joint steering committee of four committee members, consisting of two senior representatives designated by each party. The purpose of the joint steering committee is to address and oversee the development, registration and commercialization activities, as well as any other issue, in connection with the Chugai Agreement.

Intellectual Property

Chugai retains ownership of the patents relating to AP306 prior to execution of the Chugai Agreement. We shall own all data, inventions, discoveries and know-how, whether patentable or not, and any intellectual property rights thereof, acquired or developed by us upon or after our exercise of the option under the Chugai Agreement.

Payments

Chugai shall receive from us an upfront payment of a middle single-digit hundred thousand of U.S. dollars upon executing the Chugai Agreement. In addition, if we exercise the option under the Chugai Agreement, Chugai shall receive from us an upfront license payment of a low double-digit million of U.S. dollars as well as milestone payments up to a low single-digit hundreds of millions of U.S. dollars based on achievement of certain predetermined milestones relating to regulatory approval and commercial sales, and royalty payment of a middle single-digit to teens percentage of annual net sales of AP306 after its expected launch.

Dispute Resolution

The parties shall negotiate in good faith to settle the disputes in connection with the Chugai Agreement. Any dispute shall be referred to senior management of each party for attempted resolution. In the event senior management are unable to resolve the dispute, the dispute shall be settled by arbitration administered by the Singapore International Arbitration Centre.

Termination Clause

Unless terminated earlier, the Chugai Agreement shall continue in full force and effect until the expiration of the royalty term for AP306 under the Chugai Agreement. The royalty term for AP306 will expire in a country upon the latter of: (a) expiration of the last-to-expire patent that has a valid claim covering AP306 in the country and (b) the tenth anniversary of the first commercial sale of AP306 in the country.

Collaboration Arrangement with Roche Holding AG

Roche Agreement

In October 2023, we entered into a supply and marketing agreement (the "**Roche Agreement**") with Roche Hong Kong, Ltd. ("**Roche**," a subsidiary of Roche Holding AG) regarding Mircera®. Founded in 1896 in Switzerland, Roche Holding AG is a world leading biotechnology company and a global leader in *in-vitro* diagnostics.

Obligations and Responsibilities

The Roche Agreement granted us an exclusive license to sell, distribute or otherwise commercialize Mircera® in China (not including Hong Kong, Macau and Taiwan). Roche shall supply Mircera® to us pursuant to an annual purchase schedule and price terms provided in the Roche Agreement. Roche shall obtain and maintain the drug registration certificate and its appendices of Mircera® in China at its own expense. We shall obtain and maintain all permits and registrations required for the marketing and promotion of Mircera® in China at our own expense. The Roche Agreement did not provide a joint steering committee.

Intellectual Property

The Roche Agreement did not provide for any transfer or concession of intellectual property rights relating to Mircera® between Roche and us.

Payments

Roche shall receive from us an upfront payment of a middle single-digit millions of RMB, as well as milestone payments up to a low double-digit millions of RMB based on achievement of certain predetermined milestones relating to NRDL and commercial sales.

Dispute Resolution

The parties shall amicably settle any controversy or claim relating to the Roche Agreement. For any controversy or claim relating to supply of Mircera® that cannot be amicably settled, either party shall submit such controversy or claim to Hong Kong International Arbitration Center. For any controversy or claim relating to promotion of Mircera® that cannot be amicably settled, either party shall submit such controversy or claim to Shanghai International Arbitration Center.

Termination Clause

The Roche Agreement shall remain in force for ten years, unless terminated earlier, and shall be automatically renewed for another five-year period, unless either party notices the other party in writing of its intent not to renew in advance. Roche may terminate the Roche Agreement without cause. Each party may also terminate the Roche Agreement upon a material breach by the other party, the dissolution, liquidation, or bankruptcy of the other party, or inability to sell Mircera® legally in China due to reasons not attributable to any party's fault.

Collaboration Arrangement with the Peking University First Hospital

PUFH Agreement

In January 2022, we entered into a license agreement (the "**PUFH Agreement**") with PUFH to discover, develop, manufacture and commercialize an IgA protease. Founded in 1915, PUFH is a large comprehensive Grade 3A hospital in China, integrating medical services with teaching and research.

Obligations and Responsibilities

Under the PUFH Agreement, PUFH granted us an exclusive and irrevocable license to research, develop, and commercialize an IgA protease globally, with the right to grant sublicenses. In addition, we commissioned PUFH to perform non-clinical studies regarding the medical application of the licensed IgA protease. Under the PUTH Agreement, we shall, at our own decision and cost, be responsible for the IND application, clinical research, regulatory activities, manufacture, sales and promotion relating to the IgA protease. We shall own the IND approval, marketing authorization, trademark and promotion materials relating to the IgA protease.

Intellectual Property

PUFH retains ownership of the patents filed prior to execution of the PUFH Agreement. Any intellectual property, including patents and know-how, developed by PUFH under the said commissioned studies regarding the licensed IgA protease shall be jointly owned by the parties.

Payments

PUFH shall receive from us an upfront payment of a low single-digit millions of RMB. PUFH also shall receive from us development milestone payments up to a low single-digit hundreds of millions of RMB based on achievement of certain predetermined milestones relating to clinical trial progress and commercial launch, as well as commercial milestones payments up to a low single-digit hundreds of millions of RMB based on the annual net sales amount of the product incorporating the licensed IgA protease after the commercial launch. In addition, PUFH shall receive from us royalty payment of a low single-digit percentage of annual net sales of the product incorporating the licensed IgA protease after the commercial launch.

Dispute Resolution

The parties shall strive to resolve the disputes arising from the PUFH Agreement. In the event the parties are unable to resolve the dispute, the dispute shall be resolved by arbitration administered by the China International Economic and Trade Arbitration Commission in Beijing.

Termination Clause

Unless terminated earlier, the PUFH Agreement shall continue in effect until the last to occur of, on a country-to-country basis: (1) expiration of the last-to-expire valid claim of the patents covering the sequence of the licensed IgA protease in that country; and (2) ten years from the first commercial sale of the product incorporating the licensed IgA protease in that country. We may terminate the PUFH Agreement if research, development, or commercialization of the licensed IgA protease or the product incorporating the same constitutes an infringement of a third party's patents, such that the product incorporating the same no longer has commercial viability. Each party may also terminate the PUFH Agreement upon occurrence of one of the following events: (1) the other party's material breach of the PUFH Agreement, and (2) bankruptcy of the other party.

Chugai, Roche and PUFH are Independent Third Parties.

Collaboration Arrangement with R1 Therapeutics

R1 Agreement

In December 2025, we entered into a collaboration and license agreement (the "**R1 Agreement**") with R1 Therapeutics, Inc., a corporation organized and existing under the laws of State of Delaware with respect to AP306. R1 Therapeutics, Inc. ("**R1**") is a newly established biotechnology company backed by major global dialysis service providers and a syndicate of leading global life sciences investors. R1 focuses on the research, development, and commercialization of innovative biopharmaceutical products for the treatment of kidney diseases and related complications and other chronic conditions.

In connection with the R1 Agreement, we entered into common stock issuance agreements with R1. Subsequently, R1 entered into stock purchase agreement with certain investors in connection with its financing. Upon closing of these agreements, we held a significant equity stake (minority stake), with anti-dilution protection mechanisms designed to maintain such percentage ownership.

We selected R1 as our partner based on the following considerations: (i) R1's dedicated strategic focus on renal diseases; (ii) the strategic industrial backing from well known global life science investors which provides valuable commercial insights and market access capabilities; (iii) R1's financial position secured through R1's subsequent financing to support the Phase IIb MRCT and subsequent development of AP306; and (iv) the deal structure which allows us to retain an equity interest in R1 and enjoy future dividend, thereby capturing the long-term upside of AP306's global success. Other than AP306, R1 currently does not hold other products in development in its pipelines. In addition, R1 does not acquire the ownership of any existing AP306-related patent through the R1 Agreement.

Obligations and Responsibilities

We granted R1 an exclusive license to develop, manufacture, and commercialize AP306 in the territory outside Chinese Mainland, Hong Kong, Macau and Taiwan (the "R1 Territory"), while we retain full rights and control over the asset in our core market of Greater China. R1 assumes the primary financial responsibility for the global clinical development of AP306 in the R1 Territory. Specifically, for the planned MRCTs of AP306, R1 has agreed to bear the majority of the total trial costs as the U.S. arm of the trial will be conducted by R1. Accordingly, we and R1 will each conduct the Phase IIb MRCT and the subsequent Phase III clinical trial for AP306 in their respective territories, with we responsible for Greater China and R1 responsible for R1 Territory. R1 and us will act as co-sponsors, and each is responsible for clinical trial execution and regulatory submissions in its respective territory, while providing the other party with relevant data and necessary support for regulatory purposes. This structure allows us to leverage R1's capital to fund the global data generation required for our own China regulatory filings, reducing our R&D burn rate while retaining full upside in our home market. Pursuant to the R1 Agreement, R1 owned and controlled the full rights specified under the R1 Agreement with respect to AP306 in R1 territory.

R1 assumes and directly bears the financial obligations owed to our upstream licensor, Chugai, related to the R1 Territory. This includes the responsibility for the tiered royalties and the commercial milestone payments payable to Chugai, thereby removing these financial liabilities from our balance sheet for the R1 Territory. R1 also assumes responsibility for all regulatory activities and filings in the R1 Territory. We are only obligated to provide necessary technical transfer and existing regulatory materials, primarily data, information and regulatory communications regarding registrational clinical trial conducted, to enable R1's activities, thereby minimizing our operational burden for overseas markets.

In addition, the parties shall establish a joint steering committee to coordinate and discuss the development and commercialization of AP306 by each party. The joint steering committee will be composed of an equal number of representatives from each party and a minimum of three representatives of each party. A representative of R1 and a representative of us will co-chair the

joint steering committee. The joint steering committee will make decisions as to matters within its jurisdictions unanimously. If the joint steering committee is unable to resolve any matter unanimously, then (a) if such matter is solely related to matters in Chinese Mainland, Hong Kong, Macau and Taiwan, such matters shall be finally decided by us, and (b) all other matters shall be finally decided by R1, subject to certain restrictions.

Development Technology Transfer and Assistance

We will deliver our knowhows, mainly clinical and regulatory materials, to R1, and thereafter, each calendar quarter during the term, both parties will exchange any additional knowhows, with translations into English as needed and reasonable technical assistance provided at cost. To the extent permitted by applicable laws, we will also transfer and assign regulatory materials obtained from authorities in the R1 Territory to R1.

Intellectual Property

R1 will solely own all rights, title and interests in and to all know-hows developed, conceived or reduced to practice during the term of the R1 Agreement solely by or on behalf of R1 or any of R1's affiliates' or sublicensees' (excluding us and certain preferred shareholders) employees, independent contractors, or consultants, in the course of conducting activities under the R1 Agreement, and any related patent rights. Subject to the exclusive licenses granted under the R1 Agreements, we will solely own all rights, title and interests in and to all know-how developed, conceived, or reduced to practice during the term solely by or on behalf of us or any of our affiliates or licensees' (other than R1) employees, independent contractors, or consultants, in the course of conducting activities under the R1 Agreement and any related patent rights.

Financial Provision

We hold a minority equity stake in R1 pursuant to common stock issuance agreements separately entered into with R1 with anti-dilution protection mechanisms designed to maintain our percentage ownership at a specified level through subsequent financing rounds.

We are eligible to receive from R1 milestone payments up to low triple-digit millions of U.S. dollars in total based on achievement of certain predetermined regulatory and commercial milestones, such as, among others, submission of marketing authorization in the E.U. or U.K. in the U.S., receipt of marketing approvals in the U.S., and commencement of commercial sales in the E.U. or U.K., the U.S. and in Japan, and will share in the economics of AP306's global success through tiered royalty payments. Milestone and royalty payments owed to Chugai defined in the Chugai Agreement shall be passed through from R1 to Chugai either through us or directly. For details on payment to Chugai, see "— Collaboration Arrangement with Chugai Pharmaceutical Co., Ltd." In addition, we will also receive tiered royalty payment linked to annual net sales of AP306 after its expected launch, ranging from 1% to 4% depending on the amount of annual net sales exceeding US$1.0 billion. As of the Latest Practicable Date, no conditions for milestone and royalty payments were reached.

Dispute Resolution

The parties shall negotiate in good faith to settle disputes in connection with the R1 Agreement. Any dispute shall be referred to senior management of each party for attempted resolution. If senior management are unable to resolve the dispute, the dispute shall be settled by arbitration administered by the International Centre for Dispute Resolution in New York City.

Termination

Unless terminated earlier due to material breach, insolvency, patent challenge, cessation of activities or failure to fund, the R1 Agreement shall continue in full force and effect until upon the expiration of the royalty term for AP306 under the R1 Agreement.

RESEARCH AND DEVELOPMENT

We have built our research and development ("**R&D**") capabilities as the core of our mission to contribute to renal therapeutics and serve the needs of renal patients globally. Integrating deep insights into renal disease biology, we serve varied clinical needs and enable the building of a pipeline targeting salient needs in CKD and its complications, prioritizing novel and effective therapeutics. Our R&D team comprises seasoned scientists with decades of experience from leading global pharmaceutical companies and regulatory bodies, driving innovations across small molecules, biologics, and enhancing our end-to-end capabilities. Our entire R&D philosophy, led by our chief medical officer, Jin Tian, M.D., chief technology officer, Dr. Shu Chutian, and our chief scientific officer, Dr. Shen Xiao, is therefore anchored in addressing pressing needs of patients and their nephrologists.

R&D Team

Our in-house R&D team consisted of 63 employees as of the Latest Practicable Date, with 73.0% members of our R&D team holding master's or PhD degrees, including 15.9% members with doctorate degrees. Our core R&D personnel consists of three members who have been working in the pharmaceutical industry for an average of over 20 years with substantial expertise in preclinical and clinical development. During the Track Record Period and up to the Latest Practicable Date, we had 46 R&D personnel involved in the development of our Core Product and 17 R&D personnel responsible for the development of our other product candidates. As of the Latest Practicable Date, 97.9% of our R&D personnel involved in the development of the Core Product as of December 31, 2025 remain employed by us. The following table sets forth a breakdown of the number of R&D team by function as of December 31, 2025:

Functions	Number of employees by function	Employees responsible for the development of AP301	Employees responsible for the development of other technological capabilities
Drug Discovery and CMC Development	28	18	10
Pre-clinical Development and Regulatory	15	7	8
Clinical Development	19	18	1
Portfolio Management and Quality	4	4	0
Total	**66**	**47**	**19**

The following table sets forth the identities, positions, expertise of our core R&D personnel.

Identity	Position	Expertise	Involvement and contributions to the R&D activities	Date of joining our Group
Jin Tian, M.D.	Chief medical officer and co-founder	Board-certified physician in internal medicine and nephrologist, with 15 years' experience in academic and clinical practice and over 20 years' experience in the biopharmaceutical industry	Establish clinical-stage program portfolio, conduct communications with regulatory authorities, and implement clinical trials. Lead scientific evaluation of in-licensed products.	April 2018
Dr. Shu Chutian	Chief technology officer	Substantial manufacturing expertise based on over 15 years' CMC experience in the biopharmaceutical industry	Refine the CMC aspects of our pipeline products to advance drug development, optimize cost and ensure consistent quality.	July 2019

Identity	Position	Expertise	Involvement and contributions to the R&D activities	Date of joining our Group
Dr. Shen Xiao . . .	Chief scientific offer	In-depth regulatory insight based on over 20 years' experience with FDA	Lead preclinical strategy design, target discovery, evaluation and global development. Before his full-time employment, Dr. Xiao acted as our key advisor, drawing on his deep expertise gained from his tenure at the FDA to formulate the regulatory road map for AP301. Upon joining us, he immediately took charge of executing our global strategy, leading constructive dialogues with the FDA and other authorities for AP301 and other early-stage product candidates.	April 2025

Scientific Advisory Board

There are 6 members in our scientific advisory board, all of whom are nephrologists holding more than 30 years' practical experience in nephrology clinics. They led or co-led major clinical studies in the renal space, such as clinical studies related to CKD, DKD, IgAN, polycystic kidney disease, FSGS and Alport Syndrome. Their major contribution includes but is not limited to: (1) advocating "reduction level of proteinuria" as a surrogate endpoint for IgAN/FSGS in series discussions with the FDA and other authorities; (2) leading KDIGO guideline updates in CKD-MBD, glomerular diseases, DKD, etc.; (3) guiding global research network and/or patient advocate groups for kidney diseases such as, among others, IgAN, ADPKD and FSGS.

For the years ended December 31, 2024 and 2025, we recorded research and development expenses of RMB235.4 million and RMB372.6 million, respectively, with research and development expenses of RMB139.8 million and RMB205.6 million attributable to our Core Product, respectively, representing 59.4% and 55.2% of our R&D expenses. We anticipate continuing to make significant investments in our R&D efforts, since we plan to expand the indications and continue the clinical development of our product candidates, advance more pipeline candidates along clinical trials and conduct additional preclinical studies.

The following table sets forth a breakdown of our research and development expenses by Core Product and other product candidates, in an absolute amount and as a percentage of our total research and development expenses, for the years indicated.

	For the Year Ended December 31,			
	2024		2025	
	RMB	*%*	*RMB*	*%*
	(RMB in thousands, except for percentages)			
Core Product	**139,800**	**59.4**	**205,600**	**55.2**
Other product candidates . . .	**95,567**	**40.6**	**166,974**	**44.8**
AP303	30,205	12.8	38,568	10.4
AP304	1,177	0.5	1,238	0.3
AP305	4,631	2.0	1,618	0.4
AP306	39,450	16.8	58,016	15.6

	For the Year Ended December 31,			
	2024		2025	
	RMB	*%*	*RMB*	*%*
	(RMB in thousands, except for percentages)			
AP308	20,104	8.5	67,529	18.1
Others	0	0.0	4	0.0
Total	**235,367**	**100.0**	**372,574**	**100.0**

Drug Discovery and CMC Development

Our drug discovery work is led by Dr. Shu Chutian (our chief technology officer) and Dr. Shen Xiao (our chief scientific officer). In early discovery and development, we leverage our R&D expertise alongside growing collaborative interest from leading research institutions to foster innovation and expand our renal disease portfolios.

Our CMC team consists of professionals with extensive experience in process development, manufacturing and quality management from well-known biopharmaceutical and pharmaceutical companies. Our CMC team members have on average approximately 12 years' of experience. Our CMC team is responsible for develop, scale up, and characterize the manufacturing process to support pre-clinical and clinical studies and future commercial use. It is also responsible for preparing pharmaceutical related regulatory files and interactions with the health authorities on the related subjects.

Clinical Development

Clinical Development Team

Our clinical development team is led by Jin Tian, M.D., our co-founder and chief medical officer. As of December 31, 2025, our clinical development team consisted of 19 members, including professionals with strong drug development experience, who participate in clinical development strategy development, clinical trial protocol design, clinical trial operation organization, drug safety monitoring, and clinical trial quality control.

Further, we have established a scientific advisery board which brings unparalleled influence across CKD indications and complications, and the global standards that guide clinical and regulatory development. Collectively, they lead and author cornerstone guidelines (including KDIGO CKD-MBD), shape the FDA and other regulatory policy (persuading the FDA to use proteinuria as a surrogate endpoint in IgAN), and have designed and executed landmark trials across DKD, IgAN, ADPKD and other CKD. They sit on steering committees of major international trials and research organizations, review and edit for top journals such as NEJM, JAMA, JASN, and AJKD, and advise leading nephrology societies and foundations, providing invaluable and substantive input to ensure our portfolio aligns with the most current academic discovery and policy frameworks.

Clinical Trial Design and Implementation

Our clinical development team manages all stages of clinical trials, from protocol design to overseeing the operations and conduct of clinical trials. Our clinical development team is also responsible for the selection of trial sites. Our site selection criteria include the site's overall experience, understanding of the disease state, access to relevant experts and patients, geographical coverage, regulatory and quality management, range of services, staff proficiency, and technology. We have collaborated with numerous hospitals and PIs that can support our clinical trials of different indications, at different stages and in different jurisdictions. To the best of our knowledge, none of our collaborating PIs have any past or present relationships with our Group, our Directors, Shareholders, senior management or any of their respective associates. The PIs are responsible for conducting site-level clinical research activities according to our trial protocols and in accordance

with laws, regulations, and the GCP guideline, a quality standard for the overall conduct of the clinical trial. Each trial has a leading PI with primary responsibility to ensure compliance with trial protocol and GCP over the entire trial.

Relationship with CROs

During the Track Record Period, we engaged 79 and 89 CROs in the years ended December 31, 2024 and 2025, respectively. All of our top five major CROs engaged in each year during the Track Record Period are Independent Third Parties. We engaged CROs to support our clinical trials in line with the industry norm. We select CROs based on qualifications, experiences, industry reputation, adequacy of clinical trial equipment and data management capability. Our clinical development team closely supervises and monitors the performance of CROs to ensure they conduct clinical trials in accordance with our protocols and GCP requirements. CROs are typically responsible for facilitating the selection of investigators, locating trial sites, local vendors, making local regulatory filings with our review and approvals, purchasing equipment and materials, engaging other third parties to further facilitate the clinical trials, enrolling qualifying trial participants, routine trial site monitoring, and trial data management and analysis.

Regulatory Affairs

Our regulatory affairs team is responsible for the regulatory process of our product candidates, including assembling application dossiers for IND and NDA, addressing inquiries from relevant authorities and monitoring our R&D projects to ensure their compliance with relevant regulations. Our regulatory affairs team manages the regulatory submission process in China, the U.S., Australia and other regions where we may conduct clinical development. We consistently initiate early and constructive dialogues with regulatory authorities, which has significantly accelerated our pipeline progression. For AP301, our discussions with the FDA secured a single clearance for a multi-regional Phase III clinical trial that included the U.S. and China. For AP306, our communications with the NMPA led to the receipt of BTD for the treatment of hyperphosphatemia in patients with CKD that enables expedited regulatory review of AP306. For AP303, our communications with the FDA led to the receipt of ODD for the ADPKD indication.

MANUFACTURING

As of December 31, 2025, our manufacturing team consisted of 28 members. We have completed the construction of an in-house manufacturing facility in Yangzhou, China, which has completed the pilot manufacturing with commercial operation expected half a year after the commercial launch of AP301, subject to final regulatory approval of AP301. As of the Latest Practicable Date, the manufacturing facility was in the phase of pilot-scale production and scale-up preparation. The designed annual capacity of AP301 will reach over 200 metric tons at full operation, equivalent to approximately 285.7 million capsules of AP301, assuming a 700 mg per capsule. The manufacturing facility has been designed, constructed and operated in accordance with PRC GMP requirements and international cGMP standards, and we have obtained a Drug Manufacturing License (Category B) issued by the Jiangsu Provincial Drug Administration. It is expected to support the commercial-scale production of both drug substance and drug product for our product candidates such as AP301 and AP306.

For manufacturing of our product candidates for preclinical and clinical study, we currently outsource such production to a number of CDMOs. Under our oversight, we did not experience any material product quality issues in respect of the products manufactured by our CDMO partners during the Track Record Period. Under our agreement with our CDMO partners, the CDMO partners are required to perform their services according to the prescribed time frame as set out in the agreement. Usually, we pay the CDMO partners in installments, with a specified credit period. Our CDMO partners are responsible for manufacturing our required products in accordance with certain product specifications, in compliance with cGMP requirements (where applicable), our quality standards and other applicable laws and regulations. We retain all the intellectual property rights and grant our CDMO partners the right to use our intellectual property rights for such manufacturing and packaging activities during the contract period. We are entitled to inspect and

audit our CDMO partner's manufacturing process. We mainly determine the service fees paid to the CDMOs in accordance with market prices of similar services, the number of products manufactured, and the quality and contents of the services provided. We do not share our IPs, know-how and trade secrets with CDMOs.

COMMERCIALIZATION, MARKETING AND BUSINESS DEVELOPMENT

We plan to build our commercialization capabilities through a combination of an in-house sales team for China and strategic external partnerships with industry leading players tailored for global markets, in particular, the U.S., respectively.

We have assembled a renal specialized in-house sales team with 37 members led by Mr. Feng Jun, our head of commercialization, as of December 31, 2025. Mr. Feng Jun has over 25 years of experience in the biopharmaceutical industry, with extensive experiences in sales management roles. Currently, our sales team is focused on promoting the sales of Mircera® in China. We plan to expand the team to support the expected commercialization of AP301 and other product candidates. We expect that our future market access team will engage in negotiations regarding insurance and pricing and seek to include our approved products in the NRDL.

For commercialization in overseas markets, we actively pursue diversified global business development opportunities, to maximize the commercial potential and improve the development efficiency of our product candidates. Our business development efforts are led by Dr. Gavin Xia, our chief executive officer and co-founder. Going forward, we will proactively explore commercialization opportunities through a range of partnership models, including forming associates with qualified business partners leveraging their local know-how and insight, engaging CSO for oversea commercialization efforts, and exploring other out-licensing arrangements. We will select potential collaborators based on the brand awareness of the potential collaborators, their R&D capabilities and/or commercialization networks, the track records of successfully developing and/or commercializing pharmaceutical products, where applicable. We will also seek such potential collaborators with pipelines, R&D and commercialization capabilities, as well as monetary resources that could bring potential synergies to us and our pipelines.

Pricing

As of the Latest Practicable Date, we had one commercialized product in the market, Mircera®. We sell our commercialized product to a third-party distributor in China, who is our direct customer and responsible for subsequently delivering our products to hospitals, medical institutions and pharmacies, where we are responsible for sales efforts.

As for our other product candidates, only AP301 is in late clinical development stage with NDA submission to NMPA (based on the result of China registrational Phase III trial) expected in the second quarter of 2026 and to FDA (based on the result of Phase III MRCT in China and the U.S.) expected in the third quarter of 2027.

AP301 Commercialization Strategy

With respect to commercialization strategy in China, we will submit NDA for AP301 in the second quarter of 2026 and subject to timely regulatory approval, expect to commercially launch AP301 in China in 2028. We plan to commercialize AP301 in China through our own in-house sales and marketing team. We believes this approach is appropriate given the concentration of AP301's target patient population in public hospitals in China and our connection and network established during commercialization of Mircera®.

With respect to commercialization strategy outside China, we currently prioritize the U.S. as the principal overseas market for AP301. Subject to timely completion of the Phase III MRCT and regulatory approval by the FDA, we currently expect to commercially launch AP301 in the U.S. in 2029. We intend to collaborate with contract sales organizations, or CSOs, in the U.S. to maximize the commercial value of AP301. As of the Latest Practicable Date, we had neither entered into any definitive agreement nor identified any business partner for commercialization of AP301 outside China.

In China, we expect to include AP301 in NRDL and price AP301 by considering the historical pricing of other domestic innovative product. In the U.S., we expect to include AP301 in TDAPA and price AP301 similar to historical pricing of other innovative product as well.

Distributorship

During the Track Record Period, we sold our commercialized drug Mircera® in China to a third-party distributor, which has registered capital of RMB2 billion and is wholly owned by a major state-owned enterprise listed on the Hong Kong Stock Exchange with a national distribution network for medicinal products in China. Our distributor is primarily engaged in the trading and distribution of pharmaceutical products. It is also our direct customer responsible for delivering Mircera® to its sub-distributors, who subsequently delivered to hospitals and medical institutions. Such arrangement is necessary because under PRC regulations, sales to public hospitals must be conducted through entities holding a Good Supply Practice (GSP) License. As we do not currently possess a GSP License, we engaged such distributor to facilitate compliant sales into public hospitals. Meanwhile, our sales team is responsible for the promotion of Mircera® to hospitals in China. Furthermore, the channels and expertise developed through Mircera®'s commercialization have equipped us with the requisite infrastructure and capabilities to launch its other renal programs. We believe this distribution model helps extend our coverage in a cost-effective mannerwhile retaining proper control over our sales distribution network and enhancing our core commercialization capabilities through direct engagement with downstream hospitals. Our distribution model is in line with the industry norm in the pharmaceutical industry, according to CIC.

As of the Latest Practicable Date, Mircera®'s distribution network through our distributor covered over 50 cities in China. During the Track Record Period, all of our revenue was generated from sales to our distributor in China. Such revenue is recognized when control of the goods is transferred to the distributor, generally on delivery of the goods. To the best knowledge of our Directors, our distributor during the Track Record Period and up to the Latest Practicable Date was an Independent Third Party. Also, during the Track Record Period and up to the Latest Practicable Date, our distributor was not controlled by our former or current employees, did not use our brand or name, and did not receive any material advance or financial assistance from us.

We chose our distributor based on its demonstrated distribution capabilities, knowledge of the respective markets, financial stability, creditworthiness, and operational scale. We regularly monitor our inventory to ensure timely supply of our products and reduce the risk of overstocking. Individual sales contracts or purchase orders are generally separately entered into or placed for each purchase. The following sets forth salient terms of our distribution agreement:

- *Designated distribution area*. Our distributor is allowed to import, store, sell and distribute our commercialized drug Mircera® in China (not including Hong Kong, Macau and Taiwan).

- *Term*. The duration of the distribution agreement is two years and can be renewed for another year under the same terms.

- *Sub-distributors*. We do not prohibit our distributor from engaging second-tier or other sub-distributors subject to the compliance with certain specified requirements and clauses in the distribution agreement, including obtaining all the required licenses and permits in its respective designated area for storing, selling and distributing the product. Generally, we do not have contractual relationships with or revenue recognized from sub-distributors engaged by our distributor and we do not manage or monitor such sub-distributors directly. We typically rely on our distributor to supervise its respective sub-distributors. However, we retain a right to select sub-distributors and disqualify particular sub-distributors for failure to meet the specified requirements and clauses in the distribution agreement applicable to the sub-distributors.

- *Delivery and acceptance.* Upon receiving the delivery notice, the distributor is responsible for accepting the product, handling customs clearance, and transporting the relevant goods to the consignment warehouse. The products in the consignment warehouse remain our property.
- *Transfer of ownership.* After both parties sign the purchase order, we will issue an invoice. Once the invoice is issued, the products may be transferred from the consignment warehouse to the distributor's own warehouse, and title to the products will also pass to the distributor.
- *Sales target and minimum purchase requirement*. Our distribution agreement does not specify an agreed annual sales target or minimum annual purchase amount. Our distribution agreement does not mandate selling prices to sub-distributors or end-customers.
- *Return of products*. Our distributor is required to inspect the products on delivery. In line with market practice, return of products are generally not allowed except for limited circumstances, such as, among others, defective or expired products, return requests from medical institutions, or other specific requests approved by us.

OUR SUPPLIERS

During the Track Record Period, our suppliers are mainly comprised of service providers and equipment and consumables suppliers. Although we primarily use a limited number of suppliers, there are alternate suppliers available for our needs for services, equipment and consumables. To the best knowledge of our Directors, there was no material breach of procurement agreements with our suppliers during the Track Record Period. Our Directors believe that we would not experience any material difficulties in procuring our major consumables. For the years ended December 31, 2024 and 2025, purchases from our five largest suppliers in aggregate accounted for 57.0% and 46.4% of our total purchases, respectively. Our purchases from our largest supplier in each year during the Track Record Period amounted to RMB110.5 million and RMB31.4 million, representing 21.9% and 11.2% of our total purchases for the respective year. All of our five largest suppliers during the Track Record Period are Independent Third Parties. None of our Directors or Shareholders who, to the knowledge of our Directors, own more than 5% of our issued share capital immediately following completion of the [**REDACTED**] nor any of their respective close associates had any interest in any of our five largest suppliers during the Track Record Period.

The charts below set forth details regarding purchases from our five largest suppliers for the years indicated:

Supplier	Background	Major Purchases	Credit Terms	Commencement of Business Relationship (Since)	Purchase Amount	% of Total Purchases for the Period
					(RMB in million)	
			For the year ended December 31, 2024			
Supplier A . . .	Founded in China in 1958, it is a general contractor for construction projects	Construction services	60 days	2022	110.5	21.9%
Supplier B . . .	Founded in China in 1989, it is a general contractor for mechanical and electrical equipment installation and housing construction	Construction services	60 days	2022	99.8	19.8%
Supplier C . . .	Founded in China 2010, it is a CRO company that provides clinical research services for the development of drugs and services	CRO services	20 days	2023	37.3	7.4%

Supplier	Background	Major Purchases	Credit Terms	Commencement of Business Relationship (Since)	Purchase Amount	% of Total Purchases for the Period
					(RMB in million)	
			For the year ended December 31, 2024			
Supplier D . . .	Founded in China in 2000, it is a global leading CRDMO platform listed on Shanghai Stock Exchange and the Hong Kong Stock Exchange, providing integrated and end-to-end pharmaceutical development and manufacturing services.	CRO services	30 days	2018	22.2	4.4%
Supplier E . . .	Founded in China in 2021, it is a trading company specializing in the import, export, and distribution of industrial and commercial products, with a focus on providing supply chain solutions and procurement service	Equipment purchase	60 days	2023	17.0	3.4%
Total					286.8	57.0%

Supplier	Background	Major Purchases	Credit Terms	Commencement of Business Relationship (Since)	Purchase Amount	% of Total Purchases for the Year
					(RMB in million)	
			For the year ended December 31, 2025			
Supplier F . . .	Founded in 1985, it is a CRO platform, provides preclinical new drug discovery services for global customers	CMC services	60 days	2022	31.4	11.2
Supplier G . . .	Founded in 2005, it is a global CRO that provides clinical development and patient access solutions for pharmaceutical, biotechnology and medical device companies.	CRO services	30 days	2025	28.5	10.2
Supplier H . . .	Founded in 1968, it is a global CRO that provides clinical development services for the life sciences industry	CRO services	30 days	2025	27.2	9.7
Supplier C . . .	Founded in China 2010, it is a CRO company that provides clinical research services for the development of drugs and services	CRO services	20 days	2023	22.2	7.9
Supplier I. . . .	Founded in 1896, it is a public-listed multinational biotech company engaged in the development of new medicines, diagnostics and digital health solutions	Medical products	45 days	2023	20.7	7.4
Total					130.0	46.4

OUR CUSTOMER

During the Track Record Period, our revenue was generated from a single customer, which is our distributor for Mircera® in China. The single customer was established in 2003. For further details, please see "Business — Commercialization, Marketing and Business Development — Distributorship." Our credit term with the the customer was 30 days during the Track Record Period. We started to sell and recognize revenue from Mircera® in June 2024. In 2024 and 2025, our revenues deriving from our single customer were RMB6.5 million and RMB30.6 million, respectively. Our single customer in the respective periods during the Track Record Period is an Independent Third Party. During the Track Record Period and up to the Latest Practicable Date, to the knowledge of our Directors, none of our Directors or any Shareholder who owns more than 5% of our share capital had any interest in any of our customers. Our customer, including its shareholders, directors, senior management or any of its respective associates, has no past or present relationship (family, employment, trust, financing or otherwise) with us, our subsidiaries, our Shareholders, Directors, senior management or any of their respective associates.

During the Track Record Period, our customer in each period of the Track Record Period was not one of our suppliers, and none of our five largest suppliers in each period of the Track Record Period was also our customer.

INTELLECTUAL PROPERTY

As of the Latest Practicable Date, we held 151 patents and patent applications, among which 24 were related to our Core Product (including four granted patents in China, two granted patents in the U.S., one granted patent in Europe, three granted patents in Taiwan, two granted patents in each of Hong Kong, Macau, Australia, Canada, Japan and New Zealand, as well as two pending patent applications in China). As of the Latest Practicable Date, we had not received any material concerns or inquiries from relevant competent authorities that make us believe that any of the pending patent applications will be finally rejected. The following table sets forth an overview of our material granted patents and filed patent applications in connection with our Core Product as of the Latest Practicable Date:

Product Candidate	Name of Patent[1]	Type	Owner	Jurisdiction	Status	Inventor	Filing Date	Granted Date	Patent Expiration[2]
AP301. .	Iron-fiber composition, preparation and uses thereof	Invention	The Group	Chinese Mainland, U.S., Japan, Australia, Canada, New Zealand, Taiwan	Granted	Jinshyun Ruth Wu-Wong[3]	October 12, 2012	Chinese Mainland: October 5, 2016 U.S.: February 14, 2017 Japan: August 10, 2017 Australia: May 14, 2015 Canada: July 21, 2020 New Zealand: May 27, 2016 Taiwan: July 1, 2017	October 12, 2032

Product Candidate	Name of Patent[1]	Type	Owner	Jurisdiction	Status	Inventor	Filing Date	Granted Date	Patent Expiration[2]
AP301. .	Metal ion-functional fiber component complex compositions, preparation and uses thereof	Invention	The Group	Chinese Mainland, Hong Kong, Macau, Australia, Canada, EU, Japan, New Zealand	Granted	Jinshyun Ruth Wu-Wong[3]	March 4, 2014	Chinese Mainland: November 20, 2018/October 26, 2021 Hong Kong: March 6, 2020/February 11, 2022 Macau: April 25, 2019/February 16, 2022 Australia: August 2, 2018 Canada: May 3, 2022 EU: April 24, 2019 Japan: October 12, 2018 New Zealand: March 24, 2017	March 4, 2034
AP301. .	Metal ion-functional fiber component complex compositions, preparation and uses thereof	Invention	The Group	Taiwan	Granted	Jinshyun Ruth Wu-Wong[3]	March 6, 2014	April 11, 2020/July 11, 2022	March 6, 2034
AP301. .	Metal ion-functional fiber component complex compositions, preparation and uses thereof	Invention	The Group	U.S.	Granted	Jinshyun Ruth Wu-Wong[3]	March 4, 2014	October 24, 2017	October 12, 2032
AP301. .	A dissolution test system and test method	Invention	The Group	Chinese Mainland	Pending	Xiaoming Zheng; Yuanyuan Gu; Bin Tian[4]	September 23, 2024	N/A	N/A
AP301. .	A dissolution test system	Utility Model	The Group	Chinese Mainland	Granted	Xiaoming Zheng; Yuanyuan Gu; Bin Tian[1]	September 23, 2024	July 29, 2025	September 23, 2034

Product Candidate	Name of Patent[1]	Type	Owner	Jurisdiction	Status	Inventor	Filing Date	Granted Date	Patent Expiration[2]
AP301. .	Pharmaceutical Composition Comprising Iron–Gum Arabic Complex and Method for Preparing the Same	Invention	The Group	Chinese Mainland	Pending	Haixia Zhao; Dongying Liu; Bin Tian; Jialiang Li; Chutian Shu; Fang Li; Feng Wang (All of these inventors were the employees of the Group before filing this patent application).	February 9, 2026	N/A	N/A

1 Unless otherwise indicated, the names of the patents and/or patent applications within the same family is the same and is therefore listed once.

2 The patent expiration date is estimated based on current filing status, without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity and other government fees.

3 This inventor has executed an assignment to assign her rights to Vidasym.

4 All of these inventors were the employees of the Group before filing this patent application.

We may rely, in some circumstances, on trade secret and/or confidential information to protect aspects of our product candidates. We seek to protect our proprietary product candidates and processes, in part, by entering into confidentiality agreements with consultants, scientific advisers and contractors, and invention assignment agreements with our employees. We have entered into confidentiality agreements with our senior management and key members of our R&D team and other employees who have access to trade secrets or confidential information about our business. Our standard employment contract, which we used to employ each of our employees, contains an assignment clause, under which we own all the rights to all inventions, technology, know-how and trade secrets derived during the course of such employee's work.

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems.

As of the Latest Practicable Date, we held six registered trademarks in Chinese Mainland and three registered trademarks in Hong Kong. We are also the owner of one domain name.

During the Track Record Period and up to the Latest Practicable Date, (i) we were not involved in any legal, arbitral or administrative proceedings in respect of, and we had not received notice of any material claims of infringement, misappropriation or other violations of, third-party intellectual property; and (ii) we were not involved in any proceedings in respect of any intellectual property rights that may be threatened or pending and that may have an influence on the research and development for any of our product candidates in which we may be a claimant or a respondent.

A freedom-to-operate searches and analyses ("**FTO Analysis**") has been conducted in China, the United States and Europe in relation to AP301 (our Core Product), and in China and the United States in relation to AP306 and AP303. With the support of the FTO Analysis, our Directors were not aware of any material infringement risk of third parties' patent rights in relation to AP301 (our Core Product), AP306 and AP303 in China and the U.S. up to the Latest Practicable Date. In addition, our Directors confirm, with the support of the our IP adviser's view, that the Group's patents and patent applications sufficiently cover the material aspects of AP301 and/or its associated technologies in China and the U.S.

COMPETITION

We face competition from existing products and product candidates under development in the market. See "Industry Overview" for more details on the competitive landscape of the various markets in which we compete. To stay competitive in such a dynamic environment, we will continue to focus on leveraging our industry experience, established R&D capabilities and collaboration network for the discovery and development of differentiated therapeutics in the field of kidney diseases. Also, we will implement differentiated R&D strategies to advance our product pipeline. See "Business — Our Strategies" for more details on our strategies for product pipeline development.

INSURANCE

We maintain insurance policies that we consider to be in line with market practice and are adequate for our business. Our principal insurance policies cover employee benefits liability, adverse events in clinical trials and property loss for our manufacturing facility in Yangzhou. We currently do not maintain insurance for environmental liability. Please refer to "Risk Factors — Risks Relating to Our Operations — We have limited insurance coverage, and any claims beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources." in this Document. During the Track Record Period, we had not made or been the subject of any material insurance claims.

EMPLOYEES

As of December 31, 2025, we had 162 employees in total. The following table sets forth the number of our employees categorized by function as of December 31, 2025.

Functions	Number of employees by function	Percentage/%
Research and Development	66	40.8
Commercialization and Sales	37	22.8
Business Strategy and Corporate Development	5	3.1
General and Administrative	26	16.0
Manufacturing	28	17.3
Total	162	100.0

We enter into individual employment contracts with our employees covering salaries, bonuses, employee benefits, workplace safety, confidentiality and non-competition, work product assignment clause and grounds for termination.

We have made contributions to our employees' social security insurance funds (including pension plans, medical insurance, work-related injury insurance, unemployment insurance and maternity insurance) and housing funds pursuant to applicable laws and regulations. We have complied with all statutory social security insurance fund and housing fund obligations applicable to us under the laws and regulations in China in all material aspects during the Track Record Period

and as of the Latest Practicable Date. Please refer to the section headed "Risk Factors — Risks Relating to Doing Business in the Jurisdictions Where We Operate — We are subject to risks in relation to our social insurance and housing provident fund contributions" in this Document.

During the Track Record Period, our shortfall in social insurance and housing provident fund contributions amounted to approximately RMB1.5 million. According to our PRC Legal Adviser, under the relevant PRC laws and regulations, (i) if the outstanding amounts of social insurance shortfall are not paid in a timely manner, we may be subject to fines of one to three times the outstanding amounts; and (ii) for any shortfall in the housing provident fund, the relevant authorities may direct us to make up the shortfall within a stipulated period and we may be subject to the court for enforcement if it remains unpaid after the deadline. As of the Latest Practicable Date, we had not been subject to any administrative penalties due to insufficient payment of employee social insurance or housing provident fund. We had also not received any significant complaints or reports from employees regarding such payments, nor any notifications from relevant authorities requesting us to make up payments, conduct investigations, or accept penalties. Based on relevant regulatory policies and facts above, our PRC Legal Adviser is of the opinion that the likelihood of being pursued by the relevant authority for unpaid amounts or facing administrative fines due to historical shortfall is remote. In consideration of the above, our Directors believe that past non-compliance issues are unlikely to have a significant adverse impact on our business, financial conditions or future compliance and we had thus not made any provision for the shortfall in our social insurance and housing provident fund contributions during the Track Record Period and up to the Latest Practicable Date.

According to the Interpretation (II) for Trial of Labor Dispute Cases, if the employer and laborer agree or the laborer promises that social insurance premiums need not be paid, the people's court shall deem such agreement or promise invalid. During the Track Record Period, we had reached such agreement with only one employee. Considering the limited number of employee involved, our PRC Legal Adviser and Reporting Accountant are of the view that the Interpretation (II) for Trial of Labor Dispute Cases will not have a material and adverse impact on our business operations.

We have enhanced our internal control measures requiring social insurance and housing provident fund contributions to be made in compliance with relevant PRC laws and regulations. We plan to regularly review and monitor the reporting and contributions of social insurance and housing provident fund and consult our PRC legal counsel on a regular basis to keep us abreast of relevant regulatory developments. In particular, (i) our human resources department has inspected the consequences and reason for engaging a third-party human resources agency to make social insurance and housing provident fund contributions. We will, based on business development and employee needs, reasonably control the number and proportion of employees whose contributions are handled by third-party agencies; (ii) we will prepare and maintain regular reports in respect of our payment of social insurance premium and housing provident funds for our employees for review by our Board and the head of our human resources department; (iii) we will regularly consult with PRC Legal Adviser to assess and mitigate our level of risk of non-compliance with the relevant laws and regulations; and (v) we will provide regular internal trainings to our Directors, senior management personnel and other responsible staff on the relevant laws and regulations and consult with PRC Legal Adviser, where necessary, on the updates thereof.

Workplace Safety

We have adopted and maintained a series of rules, standard operating procedures, and measures to maintain our employees' healthy and safe environment. We require employees to participate in safety training to familiarize themselves with the relevant safety rules and procedures. Our PRC Legal Adviser has confirmed that, during the Track Record Period and up to the Latest Practicable Date, we had not been subject to any material penalty in relation to health, work safety, social and environmental protection.

PROPERTIES

As of December 31, 2025, we owned our manufacturing facility in Yangzhou. We leased six properties in Chinese Mainland with an aggregate GFA of approximately 3,331.13 sq.m. We did not own or lease any properties overseas. We believe our current facilities are sufficient to meet our near-term needs, and additional space can be obtained on commercially reasonable terms to meet our future needs.

As of the Latest Practicable Date, our interests in two leased properties may be defective, as the ownership certificates or other similar proof of certain leased properties have not been provided to us by the relevant lessors. Our PRC Legal Adviser believes that this will not have a material and adverse impact on our business operations. As of the Latest Practicable Date, six of our lease agreements for properties in China had not been registered with relevant authorities in China. Our PRC Legal Adviser has advised us that the non-registration of lease agreements will not affect the validity of the lease agreements, but the relevant local housing administrative authorities can require us to complete registrations within a specified timeframe and if we fail to so rectify, we may be subject to a fine of between RMB1,000 and RMB10,000 for each of these leasing properties. We believe additional and/or substitutional space can be obtained on commercially reasonable terms to meet our future needs. We do not expect to experience any material difficulty or incur material cost in relocating any of the foregoing facilities if necessary, and our Directors and our PRC Legal Adviser believe that this will not have a material adverse impact on our business operations and financial performance. We plan to comply with the lease agreement registration requirement regarding our lease agreements. However, as the filing of the lease agreements requires the coordination of both lessors and lessees, the lessors may not cooperate and complete the registration in a timely manner. For further details, see "Risk Factors — Risks Relating to Doing Business in the Jurisdictions Where We Operate — We are subject to risks associated with our leased properties."

The Property Valuation Report from AVISTA Valuation Advisory Limited, an independent property valuer, set out in Appendix III of this Document, sets out details of our property interests as of March 31, 2026. AVISTA Valuation Advisory Limited valued our property interests at an amount of RMB422.8 million as of March 31, 2026. Except for the property interests set forth in the property valuation report, no single property interest that forms part of our non-property activities had a carrying amount representing 15% or more of our total assets as of December 31, 2025.

PERMITS, LICENSES AND OTHER APPROVALS

As of the Latest Practicable Date, we had obtained all requisite licenses, approvals and permits from relevant authorities that are material to our operations in the PRC and such licenses, permits and certifications all remain in full effect. For more details regarding the laws and regulations to which we are subject, see "Regulatory Overview" in this Document. We had not experienced any material difficulty in renewing such licenses, permits, approvals and certificates during the Track Record Period and up to the Latest Practicable Date, and we currently do not expect to have any material difficulty in renewing them when they expire, if applicable. During the Track Record Period and up to the Latest Practicable Date, we had not been penalized by any government authorities for any non-compliance relating to maintenance and renewal of our material licenses, permits, approvals and certificates.

The following table sets forth the details of our material licenses, permits and approvals as of the Latest Practicable Date:

License/Permit	Issuing Authority	Grant Date	Expiration Date
Drug Clinical Trial Approval Notice (Phase II trial for VS-505 pills).	NMPA	January 16, 2020	N/A

License/Permit	Issuing Authority	Grant Date	Expiration Date
Drug Clinical Trial Approval Notice (Phase III trial for AP301 pills)	NMPA	March 10, 2023	N/A
Drug Clinical Trial Approval Notice (Phase III trial for AP301 pills)	NMPA	March 20, 2023	N/A
Drug Clinical Trial Approval Notice (Phase III trial for AP301 pills)	NMPA	July 5, 2024	N/A
Drug Clinical Trial Approval Notice (for AP303 tablets)	NMPA	January 5, 2024	N/A
Drug Clinical Trial Approval Notice (Phase II trial for AP303 tablets)	NMPA	March 7, 2025	N/A
Drug Clinical Trial Approval Notice (Phase II trial for AP303 tablets)	NMPA	June 6, 2025	N/A
Drug Clinical Trial Approval Notice (Phase II trial for AP306 pills)	NMPA	December 16, 2022	N/A
Drug Clinical Trial Approval Notice (Phase II trial for AP306 tablets)	NMPA	November 21, 2024	N/A
Drug Clinical Trial Approval Notice (Phase II trial for AP306 tablets)	NMPA	February 27, 2025	N/A
Drug Manufacturing License Category B	Jiangsu Provincial Drug Administration	February 9, 2026	February 8, 2031

ENVIRONMENTAL, SOCIAL AND GOVERNANCE

Corporate Governance

ESG Governance Structure

Our Board of Directors fully recognizes the importance of environmental, social, and corporate governance to achieve green, compliant, and sustainable development. To support our long-term sustainable development strategy, we have formulated the ESG Policy and regularly review and evaluate the effectiveness of relevant policies and management systems.

We have established an ESG Working Group under direct supervision of the Board of Directors. The Board of Directors, as our highest decision-making body for ESG matters, bears the ultimate responsibility for our overall direction, strategies, objectives, performance, and reporting on sustainable development. The Board of Directors is responsible for reviewing and supervising our ESG vision, policies, and objectives, and it assesses and confirms our material ESG risks and opportunities at least once a year to ensure proper responses. The Board of Directors works closely with the ESG Working Group to jointly identify and assess ESG-related risks and opportunities, approve relevant business strategies, and continuously optimize our ESG management measures. In addition, the Board of Directors also adopts resolutions on relevant issues proposed by the ESG Working Group, formulates specific action plans, and assigns tasks to relevant departments or work units for implementation, so as to ensure the effective achievement of ESG goals.

The ESG Working Group has one leader, who shall be our Executive Director, CEO. Members of the Working Group are composed of heads of various functional departments, including human resources, pre-clinical R&D, CMC, administration and quality control. The leader of the ESG Working Group shall coordinate our ESG work, guide the development of ESG initiatives, organize communication meetings, and assess the implementation of ESG work.

The Board of Directors provides overall ESG oversight by approving our sustainability mission, values and objectives; ensuring resources for ESG strategy implementation; validating material ESG risks and opportunities; monitoring performance against key indicators; and reviewing and approving ESG disclosures. The ESG Working Group — formed with diversity in mind — drives execution by developing ESG strategy, targets and mid- to long-term plans, delivering the annual ESG work plan, assessing risks/opportunities and mitigation actions, engaging stakeholders, maintaining ESG policies, providing training, and consolidating data to prepare the annual ESG report for Board review and approval.

The Board of Directors and all employees have learned about ESG and are actively putting ESG concepts into practice. Looking ahead, we will also consider engaging external experts to provide professional ESG training to the Board of Directors and all employees. This initiative aims to ensure that our Board of Directors continuously updates and maintains the timeliness of its ESG-related knowledge, thereby possessing sufficient expertise to support the company's decision-making in the ESG field. After [**REDACTED**], we will further improve our ESG governance framework in accordance with the requirements of the ESG Code.

Business Ethical Values

We emphasise integrity and compliance and comply with applicable PRC laws, including the PRC Company Law and the PRC Anti-Unfair Competition Law. We maintain zero tolerance for misconduct such as corruption, bribery, extortion, malpractice and money laundering, and have implemented internal policies (including our Compliance Policy and Employee Handbook) prohibiting such conduct in all business operations. All employees receive compliance training, and relevant third parties are required to provide integrity undertakings or have anti-bribery and compliance obligations included in their contracts. We also maintain reporting channels for suspected fraud or non-compliance, accept reports on an identified, confidential or anonymous basis, and protect whistleblowers and related information with strict confidentiality.

Information Security and Data Privacy Protection

We comply with applicable PRC laws and regulations on cybersecurity and personal information protection, including the PRC Cybersecurity Law and the PRC Personal Information Protection Law. Based on our operational needs, we have established internal mechanisms and policies (including data security management and personal information protection assessment procedures) and require all employees to sign confidentiality agreements and comply with our information security controls.

In accordance with GCP and applicable requirements, access to clinical trial data is restricted to authorised personnel under a hierarchical access control framework, and data is used only for the purposes consented to by trial subjects and consistent with the informed consent form. We impose confidentiality obligations on clinical trial service providers and manage personal information in line with applicable laws, ethics committee-approved protocols and informed consent requirements. We collect only data necessary for research objectives, apply coding/de-identification and access restrictions, and primarily use trial data rather than direct identifiers. We also maintain retention and deletion/anonymisation procedures, under which data is deleted or anonymised upon expiry of the retention period, or retained where required by applicable laws and regulations.

Product Responsibility

Product Quality and Safety

We have established a quality and safety management system covering the entire process of drug research and development, registration, clinical trials, contract manufacturing, and promotion, strictly in accordance with the requirements of laws and regulations such as the Drug Administration Law of the People's Republic of China, the Measures for the Administration of Adverse Drug Reaction Reporting and Monitoring, the Good Clinical Practice for Drug Clinical Trials, and the Good Pharmacovigilance Practices. We have formulated a series of management systems, including the "Quality Standards", "Procedures for Entrusted Drug Production Management", "Procedures for Entrusted Inspection Management", and "Procedures for Entrusted Production Process Monitoring Management", to comprehensively regulate drug production, inspection, and transportation from an institutional level. This ensures that drugs are safe, effective, and of controllable quality throughout the entire production and circulation process, thereby guaranteeing that the manufactured drugs fully comply with their intended use and registration standards.

In terms of supplier quality management, we consider multiple factors when selecting suppliers, such as their company size, production experience, and financial capability. We regularly audit and inspect suppliers to verify that their processes comply with our quality requirements and regulatory standards.

Protecting Intellectual Property Rights

We strictly abide by the Patent Law of the People's Republic of China, the Trademark Law of the People's Republic of China, and other laws and regulations, and have established effective mechanisms for intellectual property and trade secret protection. To avoid infringement, we strictly implement a duplicate checking and review process during intellectual property applications, while strengthening employees' compliance awareness and explicitly prohibiting fraud or plagiarism of others' achievements.

Supply Chain Management

We strictly abide by the Bidding Law of the People's Republic of China and other laws and regulations, standardize procurement practices and procedures, and promote green procurement and transparent procurement to enhance the sustainable management of our supply chain, committed to establishing long-term win-win partnerships with suppliers. We integrate ESG concepts throughout the entire supply chain management process, continuously promoting the development of a responsible supply chain. We have formulated supply chain ESG management standards to ensure that partners' management systems comply with our requirements for compliance, safety, and sustainability.

In the selection and cooperation process, we not only focus on suppliers' qualifications, quality, and delivery capabilities but also considers their performance in areas such as energy conservation and emission reduction, occupational health, safe production, protection of employee rights, and business ethics. For partners involved in R&D, production, and clinical stages (such as CROs, CDMOs, etc.), we also monitor the implementation of their environmental, social, and governance management policies, as well as the standardization of their production measures and management procedures, to ensure that entrusted production and related activities align with our sustainable development goals.

Protection of Employees' Rights and Interests

Compliance in Employment

We strictly observe laws and regulations such as the Labor Law of the People's Republic of China, the Labor Contract Law of the People's Republic of China, and the Special Provisions on Labor Protection for Female Employees, and formulates and implements internal rules and regulations such as the Employee Handbook and ESG Policy, explicitly prohibiting any form of discrimination, firmly opposing forced labor, harassment, and abuse, and strictly prohibiting the use

of child labor. We have committed to treating all employees fairly in all aspects of employment, remuneration and benefits, promotion, dismissal, and retirement, without discrimination based on nationality, race, gender, religious beliefs, or cultural background, striving to create a diverse and inclusive work environment.

Training and Development

We attach great importance to improving employees' capabilities and qualities, supports employee growth through a sound training system, empowers employees at all stages of their careers, enables employees to grow and develop rapidly, enhances job competency, and provides every employee with open, fair, and just opportunities and platforms for self-development. The training content covers various areas, including new employee onboarding training, general competency training, professional skills training, and leadership training.

Health and Safety

We regard employee health and safety as a key responsibility and comply with applicable PRC laws and regulations, including the Work Safety Law, the Law on Prevention and Treatment of Occupational Diseases, the regulations on hazardous chemicals safety management and work-related injury insurance. We have established and continue to enhance our safety and occupational health management systems, with clearly defined departmental safety responsibilities and role-specific duties and health objectives across production and operations to safeguard employees. We also strengthen laboratory safety through risk-based emergency plans, enhanced day-to-day control of reagents and hazardous materials, adequate firefighting and emergency equipment, and spill prevention measures in chemical collection and storage areas.

Environment

Use of Resources

We comply with the Energy Conservation Law of the People's Republic of China, the Circular Economy Promotion Law of the People's Republic of China and other laws and regulations, and is committed to minimizing resource consumption through various measures:

- Electricity consumption: Install smart lighting, energy-saving air conditioners, variable frequency motors, and other energy-saving products in office areas and other premises, and carry out energy-saving renovation or regular upgrades for high-energy-consuming equipment; encourage employees to develop energy-saving habits, such as turning off lights and computers, and reasonably setting air conditioning temperatures.

- Water: Continuously optimize water resource management, carry out water conservation campaigns, post water-saving slogans, and enhance all employees' awareness of water conservation; promote water-saving technologies and facilities, such as water-saving toilets, induction faucets, and rainwater harvesting systems, optimize water usage in production processes, and improve water recycling rates; regularly inspect water supply equipment and pipelines, promptly repair and replace old equipment, and eliminate phenomena such as running, overflowing, dripping, and leakage.

Our main resources consumed are electricity, steam, and water. We do not own corporate vehicles, so we do not involve the consumption of direct energy such as gasoline and diesel. For the years ended 2024 and 2025, the total consumption and intensity of various resources are as follows:

	For the Year Ended December 31,	
	2024	2025
Water consumption		
Total water consumption (ton)	149,324.4	135,978.9
Consumption intensity* (tons/employee)	1,131.3	839.4

	For the Year Ended December 31,	
	2024	2025
Indirect energy consumption		
Purchased electricity (kWh)	4,495,223.2	6,121,548.1
Purchased steam (tons)	4,927.6	10,199.6
Integrated energy consumption		
Total energy consumption (tons of standard coal)	935.2	1,714.6
Energy consumption intensity (tons of standard coal/employee)	7.1	10.6

Note:

* The high water consumption intensity was primarily due to the construction of our manufacturing facility in Yangzhou, which required significant water consumption. As the construction progresses toward completion and the facility transitions to regular operations, the water consumption intensity is expected to return to normal levels in subsequent years.

Pollutant emissions

We comply with applicable PRC laws and regulations and those of our operating locations, including the PRC laws on the prevention and control of atmospheric pollution, water pollution and environmental pollution by solid waste. We have established an environmental management system covering the handling of air emissions, wastewater and hazardous waste, conduct regular inspections of environmental protection equipment, and engage qualified testing agencies to carry out periodic monitoring of wastewater and air emissions to ensure compliance with applicable discharge standards and the standardised management of solid waste.

Our waste mainly comprises (i) hazardous waste generated from laboratory R&D and (ii) general solid waste and domestic waste arising from daily operations. General solid waste is regularly transferred to qualified recyclers or disposal parties, and domestic waste is collected and transported by property management or municipal sanitation service providers. Hazardous waste is collected and stored in designated, properly labelled areas in accordance with applicable requirements and is transferred to contracted, qualified third-party contractors for centralised disposal. We also maintain a hazardous waste register to record, among others, the type, quantity, movement, storage and disposal of hazardous waste.

Our hazardous waste quantities in 2024 and 2025 are set out below:

	For the Year Ended December 31,	
	2024	2025
Hazardous waste (tons)	3.0	18.05
Hazardous waste discharge intensity (tons/employee)		
Non-hazardous waste (tons)	0.02	0.11
Discharge density of non-hazardous waste (ton/employee)	23.3	28.05

The exhaust gas produced by us mainly comes from emissions generated during the R&D process. For the waste gas generated by the laboratory, it is collected through a fume hood, treated by an activated carbon adsorption device on the roof, and then discharged up to standard through a 63-meter-high exhaust chimney. For waste gas generated from production, after being treated by the medium-efficiency filter and two-stage activated carbon at the outlet of the air conditioning ventilation system, it is discharged up to standard through a 30-meter high exhaust chimney.

In 2024 and 2025, the exhaust gas emissions generated by us were as follows:

	For the Year Ended December 31,	
	2024	2025
Total airborne emissions (kg)	122.1	79.52

Our wastewater primarily arises from R&D activities, production and domestic use. R&D and production wastewater is treated by the park's centralised wastewater treatment facilities to meet applicable standards and is then discharged to the municipal wastewater network together with domestic sewage. In accordance with licensing requirements, we have installed online monitoring devices at the production wastewater discharge point and connected them to the municipal environmental monitoring system, and we engage qualified monitoring agencies to conduct regular testing of wastewater discharges and report results to the local Ecology and Environment Bureau. As our business grows and drug candidates progress toward commercialisation, resource consumption and emissions may increase; nevertheless, we will continue to enhance resource efficiency and reduce emissions, and seek to improve environmental performance across our value chain, including office operations, supplier management, laboratory activities and waste management.

Greenhouse Gas Emissions

We have not yet purchased any fuel-powered official vehicles, so Scope 1 GHG emissions are not currently involved. In the future, when purchasing official vehicles, we will prioritize new energy vehicles or pure electric vehicles to further reduce the carbon footprint of its operations and promote green and low-carbon travel.

Scope 2 carbon emissions from purchased electricity and purchased steam are the main sources of our carbon emissions. Therefore, we formulate a series of environmental management plans to continuously improve our resource consumption efficiency and ensure all of our operations comply with governmental environment-related regulations and requirements, aiming to avoid or reduce the adverse impact of our operations on the environment. We continue to reduce daily office electricity consumption through various measures such as green lighting control, power-saving settings for office equipment, energy-saving settings for air conditioning, and meeting room usage management.

Our carbon dioxide emissions in 2024 and 2025 were as follows:

	For the Year Ended December 31,	
	2024	2025
Scope 1 emissions (tCO_2e)	0	0
Scope 2 emissions (tCO_2e)	3,101.78	6,081.78
Scope 3 emissions (tCO_2e)	78.23	73.40
Greenhouse gas emissions (tCO_2e)	3,180.00	6,155.18
Greenhouse gas emission intensity ((tCO_2e)/employee)	28.2	37.99

Notes:

(1) According to Appendix II of the HKEX's How to Prepare an ESG Report, Scope 2 GHG emissions refer to emissions from our consumption of purchased or acquired electricity and steam.

(2) Scope 3 GHG emissions mainly include GHG emissions from waste generated in operations (Category 5) and business travel (Category 6).

Addressing Climate Change

We monitor the impacts of climate change on the pharmaceutical sector and our operations and, with reference to the ISSB S2 disclosure framework, assess and implement climate risk management measures to enhance long-term resilience. Climate-related risks and opportunities are reviewed at least annually by the ESG Working Group, with the EHS Department leading strategy development, coordinating related work and reporting key issues to the Board. We also provide annual climate-related training to the Board and may engage external experts to share relevant developments.

Based on our current business profile, we do not expect climate change to have a material impact on our operations in the near term. However, we may be exposed to physical risks (acute and chronic), such as typhoons, floods and rising temperatures, which could damage assets and disrupt operations and supply chains. We seek to mitigate these risks through measures including property insurance, contingency planning and enhanced supply chain management. We may also face transition risks arising from tighter environmental regulation and market expectations, including higher energy and raw material costs, increased waste and pollutant treatment costs, investment in low-emission technology upgrades (such as green chemistry R&D), and potential demand shifts from customers. We address these risks through strengthened compliance and disclosure, stakeholder engagement, talent development and supply chain management, while promoting green chemistry innovation and improving energy efficiency through energy-saving and consumption-reduction initiatives.

Goals and Strategies

The Board of Directors is responsible for assessing and managing ESG-related risks, opportunities, and objectives. As our business expands, we anticipate an increase in our overall resource consumption and emissions. We are committed to improving the environmental performance of the entire value chain, including office operations, supplier selection, raw material inflow, experimental processes, and waste management, to control resource consumption intensity and waste levels. Based on our historical energy consumption levels and average of industry peers, we have set the following specific ESG-related targets:

In the next three years, we will continue to optimize our energy structure and energy conservation management, striving to control our greenhouse gas emissions and energy consumption intensity between 90% and 150% of the base year of 2025. Taking into account the periodic fluctuations that may be brought about by the commissioning of new projects, this goal aims to steadily improve energy efficiency while ensuring the development of our business.

	Indicators	2025 (Actual)	Goals for the Next Three Years
GHG reduction . . .	GHG (tCO_2e/employee)	37.99	Control the emission intensity at 90% to 150% of the 2025 level for each of the next three years
Energy efficiency .	Energy consumption intensity (tons of standard coal/employee)	10.58	Maintain energy consumption intensity at 90% to 150% of the 2025 level for each of the next three years

We have not yet set short-term water efficiency targets as water usage remains volatile during the construction of our Yangzhou manufacturing facility; targets will be set once operations stabilise based on actual data.

We have completed data collection for certain Scope 3 categories and have adopted measures to reduce Scope 3 emissions and resource use, including office energy and water-saving initiatives, paperless practices, remote meetings to reduce travel, greener commuting and business travel, improved recycling and reuse in production, and supplier environmental assessment and engagement, while continuing to focus on supply chain and transportation emissions. Using 2024 as the base year, we target a 10% reduction in water intensity in China and a 100% compliant hazardous waste disposal rate by 2030, and will review progress regularly and refine actions as appropriate.

The Board will periodically review performance against ESG objectives and adjust measures where material deviations are identified, and our Directors do not expect these measures to have a material adverse impact on our operations.

LEGAL PROCEEDINGS AND NON-COMPLIANCE

Legal Proceedings

During the Track Record Period and up to the Latest Practicable Date, we were not a party to any actual or threatened legal or administrative proceedings.

Legal Compliance

During the Track Record Period and up to the Latest Practicable Date, we had complied with all material applicable laws and regulations in all jurisdictions. Specifically, according to our PRC Legal Adviser, during the Track Record Period and up to the Latest Practicable Date, we had not been and were not involved in any material non-compliance incidents that led to fines, enforcement actions or other penalties that could, individually or in the aggregate, have a material adverse effect on our business, financial condition or results of operation. Our Directors confirmed that we had complied with all material applicable laws and regulations for our operations in the PRC and the United States and we were not involved in any material or systemic non-compliance incidents in the PRC and the United States.

RISK MANAGEMENT AND INTERNAL CONTROL

Risk Management

To monitor the ongoing implementation of our risk management policies and corporate governance measures after the [**REDACTED**], we have adopted or will continue to adopt, among other things, the following risk management measures: establish an Audit Committee to review and supervise our financial reporting process and internal control system; adopt various policies to ensure compliance with the Listing Rules, including but not limited to aspects related to risk management, connected transactions and information disclosure; provide anti-corruption and anti-bribery compliance training periodically to our senior management and employees to enhance their knowledge and compliance with applicable laws and regulations; and attend training sessions by our Directors and senior management in respect of the relevant requirements of the Listing Rules and duties of directors of companies listed in Hong Kong.

Internal Control

We have engaged an independent internal control consultant to assess our internal control system in connection with the [**REDACTED**]. The internal control consultant has conducted a review procedure on our internal control system in certain aspects, including financial reporting and disclosure controls, corporate level controls, information system control management and other procedures for our operations. We had improved our internal control system by adopting and implementing the corresponding enhanced internal control measures. Going forward, we will continue to regularly review and improve these internal control policies, measures and procedures.

We have also appointed external legal counsel to advise us on compliance matters, such as compliance with the regulatory requirements on clinical R&D, which is also monitored by our legal compliance team. We have also established anti-bribery guidelines and compliance requirements. After considering the remedial actions we have taken, our Directors are of the view that our internal control system is adequate and effective for our current operations. We plan to provide our Directors, senior management, and relevant employees with continuous training programs and updates regarding the relevant laws and regulations regularly to proactively identify any concerns and issues relating to any potential non-compliance.

Anti-bribery

We maintain a strict code of conduct and anti-corruption policies among our employees and distributors. We strictly prohibit bribery or other improper payments in our business operations. This prohibition applies to all business activities, anywhere globally, whether involving government officials or healthcare professionals. We will also ensure that commercialization team personnel comply with applicable promotion and advertising requirements, including restrictions on promoting drugs for unapproved uses or patient populations and limitations on industry-sponsored scientific and educational activities.

We have adopted comprehensive internal control measures for anti-corruption and anti-bribery by (i) providing regular anti-corruption and anti-bribery compliance training for senior management and employees, including daily compliance team meeting, annual compliance training and other ad hoc compliance training sessions, to enhance their knowledge and compliance with applicable law and regulations; (ii) monitoring books, records and accounts with respect to supplier management, tendering and bidding process management and financial payment management to identify any false, misleading or undisclosed entries; (iii) establishing whistle-blowing mechanisms and encouraging all employees, suppliers, customers and other third parties to report suspicious activities and violations of the policies.

Conflict of Interest and Non-Competition

Our code of conduct clearly defines the scope of conflicts of interest, including supplier and customer relationships, hospitality and gifts, financial interests and personnel matters. Our employees may not have or be suspected of having a personal interest in business dealings with our suppliers, customers, competitors or distributors; accept monetary, financial or other benefits from our suppliers, customers, competitors or distributors; have close relatives who work for our suppliers, customers, competitors or distributors; serve as a consultant or director in an association or company in the same market or industry. At the same time, employees shall keep confidential information strictly confidential and agree on the definition of confidential information, the content covered, the use of intellectual properties, including but not limited to any transfer of know-how, acquisition of technologies, and potential breach liabilities.

Data Privacy Protection

The data collected by us mainly includes de-identified personal information of patients participating in clinical trials and other clinical trial data provided by Clinical Trial Sites. We use Electronic Data Capture systems established by CROs for the storage and management of trial data. We process the patients' personal information in accordance with the informed consent forms agreed by the patients, in which we have established specific personal information processing terms, and retain s patients' personal information in accordance with legal requirements and the duration agreed upon by each patient. All personal information we obtain from patients has been de-identified and cannot directly identify any individual, thereby meeting the requirements of GCP for subject data in clinical trials. To the best of our knowledge, we believe that all the personal information of patients generated in our clinical trials has been de-identified to the extent necessary. We do not and will not use the patients' personal information for any purposes other than the clinical trial objectives. We establish and implement personal information protection and deletion mechanism, to ensure that the personal information of the patients is retained in accordance with legal requirements, including retention for five years after database lock, for the duration necessary

to achieve the purposes outlined in the informed consent form, or until five years after the investigational drug receives marketing approval. Personal information will be retained within the scope of the informed consent. Up to the Latest Practicable Date, we are only involved in providing one commericialized product, but we do not sell it directly to users, nor do we collect users' personal information through this product. We have established procedures to protect the confidentiality of patients' data. We implement strict internal policies to govern the collection, handling, storage, retrieval of, and access to our patients' personal data and medical records and protect the security and confidentiality of personal information to ensure compliance with all applicable PRC rules and regulations on data protection and privacy, including the Research Center Management and Supervision Measures, Research and Development Records and Data Management Procedures, Data Security Management System, Data Classification and Grading Management Measures, Data Security and Education Training System, and Personal Information Protection Impact Assessment System. Access to clinical trial data has been strictly limited to authorized personnel. Additionally, we require external parties and internal employees involved in clinical trials to comply with confidentiality requirements. Data are to be used only for the intended use, as agreed by the patients and consistent with the informed consent form.

We enter into confidentiality agreements with our employees who have access to any aforementioned privacy information. The confidentiality agreements provide that, among other things, these employees are legally obligated not to misuse the confidential information while in office, to surrender all confidential information in possession while resigning, and to retain their confidential obligations after they leave office. Furthermore, we have set up a Data Security Management Committee, which is fully responsible for our data security governance. In terms of operational measures, our collaboration with the CRO is governed by a data processing agreement. We require the CROs to utilize systems compliant with Level 2 of the national Cybersecurity Classified Protection scheme for specific clinical trial data management. As confirmed by our PRC Legal Adviser, the internal controls and technical measures we have implemented fully comply with all currently applicable data security and privacy protection laws and regulations in all material aspects.

During the Track Record Period and up to the Latest Practicable Date, we did not experience any breach of patient personal information or any other patient personal information-related incidents which could cause a material adverse effect on our business, financial condition or results of operations. Our PRC Legal Adviser has confirmed that, up to the Latest Practicable Date, we had not been subject to any material penalty in relation to data privacy, and have been in compliance with the relevant PRC laws and regulations in all material aspects in this regard.

AWARDS AND RECOGNITIONS

The following table sets out the major awards and recognitions we have received.

Year	Award/Recognition	Issuing Authority
2024	Special Project on "Research on Prevention and Treatment of Common and Frequently-occurring Diseases" under the National Key R&D Program (國家重點研發計畫"常見多發病防治研究"重點專項) (for AP308 and related research)	Ministry of Science and Technology/National Health Commission
2024	ODD (孤兒藥認定) (to AP303 for ADPKD indication)	U.S. FDA
2024	BTD (突破性療法認定) (to AP306)	NMPA
2024	"Double Entrepreneurship Plan" Entrepreneurial Team ("雙創計畫"創業團隊)	Jiangsu Provincial Department of Industry and Information Technology