

## BUSINESS

### OVERVIEW

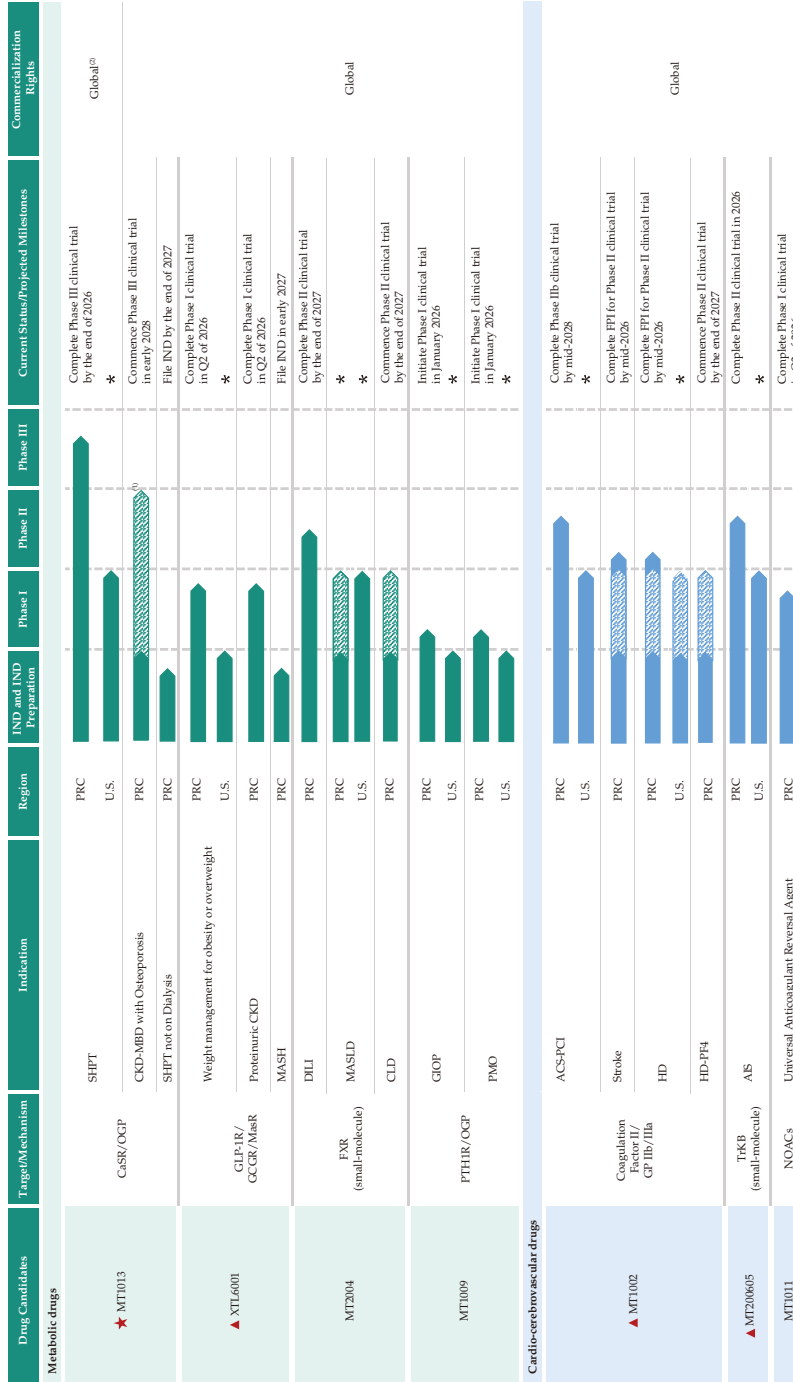
#### Who We Are

We are a biotechnology company specializing in the discovery, development and commercialization of bi-/multi-specific peptide drugs for the treatment of metabolic diseases as well as cardiovascular and cerebrovascular diseases, with our Core Product in Phase III clinical trials.

We are committed to advancing peptide drugs as cornerstone therapies across multiple disease areas. Leveraging over a decade of experience in peptide drug research and development, we have established a fully integrated platform supporting the innovation and industrialization of bi-/multi-functional peptide drug candidates. As of the Latest Practicable Date, we had developed a globally leading pipeline of bi-/multi-functional peptides and innovative drug candidates, including: (i) our Core Product, MT1013, the world's first-in-class peptide drug targeting both CaSR and OGP receptors, primarily developed for the treatment of SHPT, with the potential to be further developed for additional indications such as CKD-MBD with Osteoporosis and SHPT not on Dialysis; and (ii) three Key Products, namely XTL6001, MT1002 and MT200605, as well as other product candidates.

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The chart below summarizes the development status of our seven clinical-stage product candidates:



★ Core product ▲ Key product ■ Directly proceed to the next stage ■ Currently assessing the competitive landscape and formulating future clinical development plan.  
▲ MASH: Metabolic Dysfunction-associated Steatosis; ▲ SHPT: Serum Phosphorus; ■ HD: Hemodialysis; ■ PP4: Protein phosphatase 4; ■ NOACs: Novel Oral Anticoagulants  
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Notes:

- (1) We have completed Phase II clinical trial of the relevant product for the indication of SHPT, and plan to leverage data collected from respective trials to seek IND approvals from competent regulatory authorities to conduct Phase III clinical trial of the relevant product for the expanded indication of CKD-MBD with Osteoporosis.
- (2) Researched and developed in-house. We have granted Everest an exclusive right to sell, commercialize and promote MT1013 for SHPT in Chinese Mainland, Hong Kong, Macau and Taiwan as well as Asia-Pacific (excluding Japan) (the "Territory"). We reserved the rights to (i) research, develop and manufacturing MT1013 globally; (ii) commercialize MT1013 for any indications outside Territory; and (iii) commercialize MT1013 in the Territory for any indications other than SHPT. For more information, see "Business — Commercialization".

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### MT1013

Our Core Product, MT1013, is the world's first-in-class dual-targeting receptor agonist polypeptide that simultaneously targets the CaSR and the OGP receptor. It is designed for the treatment of SHPT, CKD-MBD with Osteoporosis and SHPT not on Dialysis. MT1013's clinical studies have demonstrated its significant improvement in comprehensive control rate of iPTH/serum calcium/serum phosphorus levels, fast-acting, and strong and sustained efficacy in lowering iPTH, cardiovascular benefit potential, enhanced bone mineral density and metabolism, and a favorable safety and tolerability profile.

- **Market and Clinical Needs:** The market size of SHPT drugs in the PRC is estimated to reach RMB5.5 billion by 2030 and RMB14.1 billion by 2035. Currently, the clinical management of SHPT primarily relies on single-target drugs, which may present limitations such as suboptimal efficacy in severe cases with significantly elevated iPTH levels, inadequate improvement in bone metabolism abnormalities, and safety concerns such as the risk of hypocalcemia and gastrointestinal adverse reactions.
- **Promising Clinical Data:**
  - MT1013 demonstrated significant improvement in the comprehensive control rate of iPTH/serum calcium/serum phosphorus levels. In a Phase II head-to-head comparison with Etelcalcetide, MT1013 showed superior efficacy in achieving simultaneous control of these indicators.
  - MT1013 showed fast-acting, and strong and sustained efficacy. Results from a Phase II clinical trial showed its significant improvement in iPTH levels within three weeks of treatment and stable efficacy by week nine.
  - MT1013 exhibited cardiovascular benefit potential. Clinical studies showed that MT1013 effectively controls iPTH, serum calcium and phosphorus levels, significantly reducing FGF23, a biomarker for cardiovascular risk in SHPT population, thereby reducing cardiovascular risk in SHPT patients.
  - MT1013 have favorable safety and tolerability profile, with no severe hypocalcemia observed in all of its clinical trials.
  - MT1013 enhanced bone mineral density and metabolism. A phase II clinical study showed that MT1013 significantly improved high bone turnover in SHPT patients, enhanced bone metabolism and improved bone remodeling balance.
- **Clinical Progress:** MT1013 completed its Phase II clinical trials (MT1013-II-C01 and MT1013-II-C03) for the treatment of SHPT and has entered a Phase III clinical trial using Cinacalcet as the active comparator, which is expected to be completed by the end of 2026. The Pre-NDA submission is planned in late 2026, followed by the NDA submission in early 2027.

### XTL6001

Our Key Product, XTL6001, is a GLP-1R/GCGR/MasR tri-target agonist. The introduction of MasR, an innovative target, into the target panel of GLP-1R/GCGR represents the world's first among current GLP-1 drugs, with potential applications in the treatment of diseases such as Chronic Weight Management in Obese or Overweight Populations, Proteinuric CKD, and MASH. XTL6001's preclinical studies have demonstrated its ability to preserve muscle mass, achieve weight loss through enhanced energy metabolism-driven mechanisms and deliver multi-organ protection.

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- **Market and Clinical Needs:** The global population affected by metabolic diseases continues to rise, with obesity becoming an increasingly severe issue. The overweight and obesity drug market in the PRC is expected to reach RMB22.0 billion in 2030 and RMB102.6 billion in 2035, with a CAGR of 36.1% from 2030 to 2035. Current GLP-1-based therapies face clinical limitations including muscle loss and gastrointestinal adverse reactions, highlighting the urgent need for safer and more effective treatment options.
- **Preclinical and Clinical Data:** The introduction of MasR, an innovative receptor target, into the GLP-1R/GCGR panel provides additional benefits. In terms of muscle preservation, XTL6001 activates renal MasR receptors to promote protein synthesis and has demonstrated a breakthrough effect of "fat loss without muscle loss" in DIO mouse models. In terms of tolerability, the tri-agonist synergy enables weight loss without significant appetite suppression, suggesting a lower risk of gastrointestinal adverse events compared to GLP-1-based drugs that primarily act by delaying gastric emptying. Phase I clinical trial results further suggest that XTL6001 reduces body weight and waist circumference, improves lipid profiles, and lowers serum uric acid levels.
- **Clinical Progress:** XTL6001 had obtained IND approvals in both the PRC and the United States for the treatment of Chronic Weight Management in Obese or Overweight Populations. As of the Latest Practicable Date, the Phase I clinical trial of XTL6001 in the PRC had completed the LPLV and the database lock. We are also exploring its potential in other metabolic diseases. A Phase II clinical trial for the treatment of Proteinuric CKD is expected to commence in mid 2027, and an IND application for the treatment of MASH is expected to be submitted in early 2027.

### MT1002

Our key product, MT1002, is the world's first coagulation factor II and GP IIb/IIIa dual-targeting peptide antagonist, primarily designed for clinical needs in anticoagulation and anti-thrombosis for indications such as ACS-PCI, Stroke, HD and HD-PF4. MT1002's clinical studies have demonstrated its potential to address the bleeding and ischemia balance in ACS-PCI, with a fast onset of action, rapid recovery after discontinuation, stable pharmacokinetic profile, and favorable population adaptability.

- **Market and Clinical Needs:** The global population of ACS patients continues to grow, accompanied by a steady increase in the volume of PCI procedures. The antithrombotic drugs market in the PRC is estimated to reach RMB48.4 billion in 2030 and RMB65.7 billion in 2035. The current standard of care involves a combination of anticoagulants and antiplatelet agents, which may lead to challenges such as complex drug-drug interactions and an increasing risk of bleeding. MT1002, administered via intravenous bolus followed by continuous infusion is intended for use in emergency PCI settings especially when oral antiplatelet agents are not yet effective or cannot be administered.
- **Clinical Data:** Results from the Phase II clinical trials of MT1002 showed that all subjects successfully completed PCI procedures under the anticoagulant and antiplatelet effect of MT1002 without thrombotic events or major bleeding. No deaths, SAEs or early withdrawals due to TEAEs were observed, and all adverse events were mild or moderate in severity, supporting the favorable safety and efficacy profile of MT1002.
- **Clinical Progress:** As of the Latest Practicable Date, MT1002 had completed Phase I clinical trials in both the PRC and the United States for the treatment of ACS-PCI. A Phase II clinical trial is underway in the PRC. Upon completion, we plan to initiate an EOP II meeting with the CDE and proceed to a confirmatory Phase III clinical trial. We have also obtained Phase II clinical trial approvals in the PRC for additional indications, including Stroke, HD and HD-PF4, and plan to complete FPI for the Phase II clinical trials of Stroke and HD in the PRC by mid-2026, and to initiate the Phase II clinical trial of HD-PF4 in the PRC by the end of 2027.

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### MT200605

Our Key Product, MT200605, is a neuroprotectant for injection. Its core breakthrough lies in a dual synergistic mechanism of action — by simultaneously activating the TrkB receptor and eliminating oxygen radicals, it blocks the post-AIS pathological cascade via dual pathways. MT200605's clinical studies have demonstrated its favorable safety and tolerability profile, as well as dual-pathway synergistic neuroprotective effects, offering an innovative therapeutic option for patients.

- **Market and Clinical Needs:** In the PRC, the market size of neuroprotective drugs is estimated to reach RMB16.9 billion in 2030 and RMB26.2 billion in 2035. Existing neuroprotective agents may face limitations such as single mechanisms of action, modest efficacy and low blood-brain barrier penetration rates which may hinder their ability to comprehensively address the complex cascade of neural damage following an ischemic event.
- **Clinical Data:** MT200605 promotes neuronal repair by activating the p-TrkB signaling pathway and exerts antioxidant radical effects by enhancing SOD and GSH-Px activities, thereby reducing neuronal cell death. Clinical studies have shown that MT200605 was safe and well tolerated in healthy subjects, with all TEAEs related to MT200605 being Grade 1 in severity. No SAEs or withdrawals due to adverse events were reported, and all TEAEs were reversible or resolved.
- **Clinical Progress:** MT200605 has completed Phase I clinical studies in both the PRC and the United States. A Phase II clinical trial is currently underway in the PRC to evaluate its neuroprotective effect in patients with AIS, which is expected to be completed in 2026.

### *Other Clinical-Stage Pipeline Candidates*

We have established a diversified pipeline focused on metabolic diseases (particularly renal-related) and cardiovascular and cerebrovascular diseases. As of the Latest Practicable Date, in addition to our Core Product and Key Products, we have been developing three other clinical-stage drug candidates, including MT2004 for DILI, MASLD and CLD; MT1009 for GIOP and PMO; and MT1011 for anticoagulant reversal therapy. Leveraging differentiated mechanisms, these candidates are designed to provide innovative therapeutic options for diseases with limited effective treatments. See “— Our Drug Candidates” for more information.

### **R&D System and Technology Platforms**

We have established four core technology platforms covering the full R&D cycle of multi-functional peptide drugs, including (i) Bi-/Multi-specific Peptide and Peptide-based Macromolecule Technology Platform, which adopts a multi-target synergistic design to precisely identify targets and optimize drug structures, extending half-life, enhancing metabolic stability, improving specificity and reducing adverse effects through fusion protein engineering and related techniques; (ii) Computer-aided Peptide Design Platform, which leverages AI algorithms to accelerate molecular design and optimization, thereby enabling an intelligent R&D workflow from molecular generation to druggability evaluation; (iii) Oral Peptide Delivery Platform, which is being developed to overcome the limitations of injectable peptide therapies with the aim of enhancing patient convenience and improving treatment adherence; and (iv) Druggability Evaluation Platform, which supports the selection of clinical candidates from target validation by leveraging approximately 100 animal models and completing numerous in vivo and in vitro evaluations annually.

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### Clinical Development and CMC Capability

We have adopted a self-operated model for clinical development in the PRC, under which our in-house professional team is responsible for protocol design, management and execution oversight, with the aim of improving the quality, cost-effectiveness and efficiency of clinical development. This model ensures closer alignment between trial design and R&D objectives while enhancing data quality and regulatory compliance. We have established an integrated CMC platform covering API, formulation and sustained-release development, with in-house capabilities to conduct process development. Our CMC R&D center is equipped to support core process development and optimization from the preclinical to clinical stages without reliance on third-party partners in process development.

### Management Team

Our sustained progress in R&D and commercialization is driven by an experienced management team with a global perspective. Led by our founder, Chairman and Chief Executive Officer Dr. Wang Bing, we have achieved significant milestones. Dr. Wang has over 20 years of experience in the biopharmaceutical industry, underpinned by a solid academic foundation and scientific expertise. He has served in key industry roles, including as a review expert for the National Major New Drug Innovation Program (“重大新藥創制專項”), and has a proven track record of professional recognition. Our senior management team possesses expertise spanning the full drug development lifecycle, from preclinical research to clinical execution. The team members bring extensive experience at global pharmaceutical companies and research institutions, and possess strong capabilities in drug development, regulatory submission and commercialization.

### OUR STRENGTHS

#### 1. Scientific Insights Facilitating Our Innovation in Developing Next-Generation Bi-/Multi-Specific Peptide Drugs

Compared with small-molecule chemical drugs, peptide drugs offer higher biological activity and specificity; and compared with protein-based drugs, they provide superior stability, higher purity and lower manufacturing costs. As such, peptide drugs combine the advantages of both modalities and address treatment across various therapeutic areas. Globally, the peptide drug industry is gaining momentum, with several blockbuster products already approved, such as Semaglutide (USD29.3 billion), Dulaglutide (USD5.3 billion), Tirzepatide (USD16.5 billion) and Pegcetacoplan (USD0.8 billion) in sales in 2024. Their clinical application has expanded from metabolic diseases to a broad range of indications, including cardiovascular, CNS, endocrine, gastrointestinal, hematological, ophthalmic and orthopedic diseases.

Driven by continued innovation, the global peptide drug market is expected to grow from USD109.6 billion in 2024 to USD233.8 billion in 2030, representing a CAGR of 13.5%. The peptide drug market in the PRC is also experiencing rapid growth, with its market size projected to increase from RMB60.2 billion in 2024 to RMB165.2 billion in 2030, representing a CAGR of 18.3%. Given their superior precision, safety and broad therapeutic potential, peptide drugs are well positioned to address significant unmet medical needs, underpinning their strong growth trajectory.

Against this backdrop, bi-functional and multi-functional peptides have emerged as one of the most promising innovation directions in the peptide drug field, offering substantial competitive barriers. Such peptides are designed to selectively modulate two or more molecular targets through a single compound. For complex and multi-etiological diseases, including cardiovascular and cerebrovascular diseases, metabolic disorders, central nervous system diseases and immune-related conditions, bi- or multi-specific peptides are capable of simultaneously targeting interrelated disease pathways, thereby producing synergistic therapeutic effects and achieving superior clinical outcomes.

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As a key innovator in the peptide-based therapeutic field in the PRC, we have established a differentiated portfolio of bi/multi-functional peptide drug candidates, particularly in the non-GLP-1 segment, where we have built strong technical barriers and unique competitive advantages. Our clinical-stage multifunctional peptide assets include MT1013, XTL6001, MT1002, MT1009 and MT1011. For more information of efficacy and advantages of these clinical-stage assets, see "— Our Drug Candidates" in this section. Leveraging our expertise and proprietary know-how accumulated through the development of these clinical-stage assets, we are accelerating the identification of differentiated targets based on unmet clinical needs and expanding our coverage to a broader range of indications through the synergistic advantages of bi-functional peptides.

### **2. Core Product MT1013 as the World's First-in-Class Bi-functional Peptide Agonist Targeting CaSR and OGP Receptor, with Demonstrated Improvements in Comprehensive Control Rate and Patient Survival Benefits**

MT1013 is a dual-targeting receptor agonist polypeptide that concurrently targets the CaSR of the parathyroid gland and OGP. Through our in-house development efforts, MT1013 is primarily designed for the treatment of SHPT, with potential for expansion into additional indications such as CKD-MBD with osteoporosis and SHPT not on Dialysis.

#### *Significant improvement in comprehensive control rate of iPTH/serum calcium/serum phosphorus levels*

MT1013 has demonstrated a significant advantage in improving the comprehensive control rate of iPTH/serum calcium/serum phosphorus levels. In a head-to-head Phase II clinical trial against Etelcalcetide, after 26 weeks of treatment, the proportion of subjects in the MT1013 group achieving simultaneous control of iPTH, serum calcium and serum phosphorus was approximately 2.5 times that of Etelcalcetide. A higher triple-target attainment rate is indicative of a substantial reduction in all-cause mortality, more effective prevention of vascular calcification, comprehensive bone protection and improved patient quality of life.

#### *Fast-acting, and strong and sustained efficacy*

MT1013 has demonstrated fast-acting, strong and sustained efficacy in reducing iPTH levels. Results from the Phase II clinical trials showed significant improvement in iPTH levels shortly after treatment initiation and sustained efficacy with continued treatment. In a head-to-head clinical trial against Etelcalcetide, MT1013 showed superior efficacy in achieving the target iPTH range.

#### *Cardiovascular benefit potential*

FGF23, a key biomarker of vascular calcification and cardiovascular risk, has been shown to correlate with improved cardiovascular outcomes when reduced. In the head-to-head Phase II clinical trial against Etelcalcetide, MT1013 achieved superior efficacy in both absolute FGF23 reduction and the proportion of subjects with a reduction of more than 30%, consistent with its higher attainment rates of iPTH, calcium and phosphorus, suggesting potential to substantially reduce cardiovascular events and mortality risk.

#### *Enhanced bone mineral density and metabolism*

MT1013 has shown favorable effects on bone health. Results from the Phase II clinical trials showed that MT1013 can effectively improve the high-turnover bone status frequently in SHPT patients, promote bone metabolic balance, and establish a more favorable bone remodeling profile. These results support the clinical potential of MT1013 in treating CKD-MBD-related bone disorders.

#### *A favorable safety and tolerability profile*

The most common adverse events associated with existing calcimimetics are hypocalcemia and gastrointestinal reactions. No severe hypocalcemia was observed in any of the clinical trials of MT1013. In addition, only a small number of subjects experienced gastrointestinal adverse reactions, such as nausea and vomiting during long-term treatment, with incidence rates lower than those observed with existing calcimimetics. These results support the favorable safety and tolerability profile of MT1013.

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### *Broad potential for indication expansion*

The Phase II clinical trials of MT1013 observed improvement in bone mineral density. To fully leverage the therapeutic potential of MT1013, we have been actively expanding its indications to include CKD-MBD with Osteoporosis and SHPT not on Dialysis. See “— Our Drug Candidates” for more information of MT1013’s clinical results.

### **3. Differentiated Pipeline Targeting High-Potential Areas with Significant Unmet Clinical Needs**

We focus on addressing significant unmet clinical needs in metabolic (especially renal-related) and cardiovascular diseases, aiming to offer superior treatment options globally. Beyond our Core Product MT1013, we have advanced several Key Products with differentiated mechanisms to expand innovative treatment pathways.

#### *Chronic Weight Management in Obese or Overweight Populations*

The obesity and weight management therapeutics market presents substantial growth opportunities, driven by the continuously rising prevalence of obesity and associated complications. The overweight and obesity drug market in the PRC is expected to reach RMB22.0 billion in 2030 and RMB102.6 billion in 2035, with a CAGR of 36.1% from 2030 to 2035. The GLP1R polypeptide drug market in the PRC is estimated to reach RMB81.4 billion in 2030 and RMB176.9 billion in 2035, with a CAGR of 16.8% from 2030 to 2035.

Against this backdrop, we are developing XTL6001, a long-acting tri-agonist peptide drug candidate intended for the treatment of obesity, Proteinuric CKD and MASH. Existing anti-obesity therapies face multiple limitations, including gastrointestinal adverse events, hepatic toxicity, and impaired absorption of fat-soluble vitamins during clinical use. GLP-1-based therapies primarily induce weight loss by delaying gastric emptying, but are frequently associated with gastrointestinal side effects such as nausea and vomiting, resulting in limited patient tolerance. Leveraging its differentiated mechanism of action, XTL6001 is designed to enhance basal metabolic rate while potentially addressing key challenges observed with single- or dual-agonist therapies, including muscle loss, severe gastrointestinal adverse reactions, and weight rebound following drug discontinuation. In addition, XTL6001 offers potential liver- and kidney-protective benefits beyond weight reduction, targeting the complex comorbidity profile commonly seen in obese patients.

#### *ACS-PCI*

ACS is an acute manifestation of CAD, continues to demonstrate a progressively increasing incidence trend. It is estimated that by 2030 and 2035, the incidence of ACS in China will reach 5.8 million and 6.3 million, respectively. The volume of PCI procedures in China will reach 4.0 million and 6.0 million, respectively. The antithrombotic drugs market in the PRC is estimated to reach RMB48.4 billion in 2030, and RMB65.7 billion in 2035, with a CAGR of 6.3% from 2030 to 2035.

MT1002 is the first domestically developed dual-functional antithrombotic peptide drug with both anticoagulant and antiplatelet activities. It simultaneously targets coagulation factor II and GPIIb/IIIa, exerting dual anticoagulant and antiplatelet effects. Unlike conventional anticoagulants used during PCI procedures, MT1002 does not require combination therapy and is designed to reduce both bleeding risk and the incidence of in-stent thrombosis. It may serve as an alternative to heparin while avoiding HIT, and addresses the unmet clinical need in emergency PCI procedures for patients who are unresponsive to antiplatelet agents or unable to take oral medications. Results from the Phase II clinical trial have demonstrated favorable safety and dual activity in thrombin inhibition and platelet aggregation suppression.

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### AIS

AIS is the acute phase of ischemic stroke. The global prevalence of ischemic stroke is projected to reach 127.4 million by 2035, while in the PRC it is projected to reach 35.1 million. The neuroprotective drugs market in the PRC is estimated to reach RMB16.9 billion in 2030 and RMB26.2 billion in 2035.

MT200605 is the first flavonoid-based small molecule compound that acts as an agonist of the TrkB receptor. MT200605 promotes neural regeneration through TrkB receptor activation and reduces free radical-induced neuronal damage via its antioxidant effects, thereby forming a dual protective mechanism. Preclinical studies have shown that MT200605 demonstrates good brain tissue distribution, the ability to cross the blood-brain barrier, and superior efficacy in improving stroke-related behavioral outcomes and reducing infarct volume compared with existing neuroprotective agents, supporting its therapeutic potential and future development prospects.

### *Other Indications*

We are advancing a tiered pipeline of innovative product candidates addressing unmet clinical needs to accelerate translation and capture market opportunities. Our product candidates include MT2004 for DILI, MASLD and CLD, MT1011 for anticoagulant reversal therapy, and MT1009 for GIOP and PMO, which collectively strengthen and expand our portfolio in metabolic diseases (particularly renal-related) and cardiovascular and cerebrovascular diseases. See "— Our Drug Candidates" for more information.

#### **4. Integrated End-to-End Platform Covering the Full Value Chain from Discovery to Commercialization, Enabling Accelerated Global Expansion**

We have established a fully integrated system covering early target discovery, preclinical research, clinical development and CMC process development. Our R&D and operations headquarters is located in Xi'an, clinical and regulatory center in Beijing and large molecule development platform in Shanghai. This structured and collaborative innovation network enables end-to-end capabilities from laboratory research to commercial translation.

### *Platform Development*

We have established four core technology platforms that operate in a coordinated manner, encompassing our entire R&D process and establishing an integrated drug R&D system that spans from molecular design to clinical translation. Leveraging our four technology platforms, we have generated and developed multiple drug candidates that have entered various stages of preclinical and clinical development, further demonstrating the maturity and translational capability of our platforms.

- *Bi-/Multi-specific Peptide and Peptidebased Macromolecule Technology Platform*

The core advantage of the platform lies in its ability to address limitations associated with traditional single-function peptides, including restricted target engagement and limited therapeutic outcomes. Centered on a peptide-based modular architecture, our platform enables the integration of precise target binding, multi-target synergistic pharmacological regulation and optimized pharmacokinetics into a single molecular entity, making it well-suited to address the long-term treatment needs of chronic diseases, such as reducing adverse effects and improving patients' quality of life. To address the limitations of peptide drugs in metabolic stability and biological half-life, particularly in chronic diseases requiring long-term administration, we have established a macromolecule platform based on functional peptides as an extension of our Bi-/Multi-functional Peptide Platform.

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- *Computer-aided Peptide Design Platform*

The core advantage of our platform lies in its ability to accelerate early-stage peptide drug discovery through the synergistic application of homology modeling, molecular dynamics simulation and virtual screening modules. This enables precise prediction of peptide–target binding conformations, thereby shortening the discovery cycle and reducing the cost of screening.

- *Oral Peptide Delivery Platform*

The core advantage of this platform lies in its application of solid dosage technologies, including solid dispersion, inclusion complexation, dry granulation and direct compression. To enhance absorption of protein and peptide drugs, the platform employs permeation enhancers and inclusion techniques to modulate local pH, inhibit enzymatic degradation and molecular aggregation, stabilize the microenvironment at the administration site, preserve the active conformation of the drug, improve mucosal permeability and enhance overall formulation stability.

- *Drugability Evaluation Platform*

The core advantage of this platform lies in its comprehensive animal model coverage tailored to our pipeline and a standardized evaluation system for safety, efficacy and pharmacokinetics. It enables in vitro studies such as target selectivity and plasma protein binding, and in vivo assessments including PK, PD and toxicology, supporting full-spectrum developability evaluation in-house. The candidate molecules evaluated through this platform have demonstrated a high success rate in clinical trial applications.

For more information on our technology platforms and the drug candidates derived from these platforms, see “— Our Technology Platforms” in this section.

### *Pipeline Development*

We have established a clinical development and registration system covering both the PRC and the United States, with full-process execution capabilities for international multi-regional clinical trials (MRCTs). Adopting a “dual China-U.S. filing and global commercialization” model, we aim to accelerate the global time-to-market of our drug candidates. We have established collaborations with clinical trial centers in China, the United States and other regions to support registration trials. For our core pipeline programs, we have generally adopted a dual China-U.S. filing strategy. As of the Latest Practicable Date, seven innovative drug candidates had entered clinical trials in China and/or the United States, and six had completed dual regulatory filings in both jurisdictions. We have built a fully functional clinical operations team and collaborate with leading international principal investigators (PIs) and academic institutions to ensure data integrity and registration efficiency. We have implemented a self-operated clinical trial management model, which has demonstrated advantages in execution efficiency, data quality and cost control, particularly in multi-program parallel settings, and has laid a solid foundation for future multi-regional clinical development.

### *CMC Capability and Commercialization Strategy*

We have established in-house R&D capabilities covering API and formulation development, and are able to conduct process development without reliance on third-party partners. As of the Latest Practicable Date, we had developed manufacturing processes and quality standards for multiple APIs and formulations, including a cost-effective, environmentally friendly and scalable synthetic process for the API of our Core Product MT1013, and a scalable manufacturing process for its injectable formulation. We have continued to optimize key steps such as solution preparation and lyophilization to enhance product quality and consistency, while improving cost efficiency to support future commercial production.

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For commercialization, we intend to pursue a dual-track strategy combining external partnerships and internal sales team development to gradually support product launches. For more information of our commercialization strategy, see "Business — Commercialization". We believe that our integrated capabilities and experience across product development, regulatory filings and CMC Capability will continue to support the successful translation of our innovative drug candidates and drive the ongoing expansion of our business scale and market competitiveness.

### **5. Management Team Comprised of Experts in Peptide Drug Development and Industry Veterans**

We are led by a management team with proven track record, which consists of visionary professionals from leading pharmaceutical companies both in China and overseas, boasting strong academic backgrounds in the peptide industry and comprehensive experience across the entire drug development chain — from research and clinical development to commercialization. Several members have led the development and commercialization of multiple globally successful blockbuster drugs, providing solid support for our sustained innovation.

Our founder, Dr. Wang Bing, holds a Ph.D. in pharmacology and has over 20 years of experience in peptide-based drug research, with profound academic and scientific expertise in the field. Dr. Wang focuses on the pathological mechanisms of cardiovascular, cerebrovascular, metabolic, anti-inflammatory, and analgesic diseases, as well as the R&D of novel peptide drugs. His work includes the development of a key technology platform for bispecific peptide new drugs and related product candidates, along with sustained-release technologies and products for macromolecular peptide/protein-based drugs. He has published 35 papers, 15 of which were included in SCI journals, and has applied for and obtained 13 patents, one of which was awarded the First Prize of Shaanxi Provincial Patent Award in 2002–2003.

Our management team consists of visionary professionals with extensive industry experience. Our Executive Director and Senior Vice President, Dr. Yu Weiping, has over 40 years of experience in pharmaceutical R&D and senior management and is primarily responsible for our Group's CMC and quality control. Our Chief Medical Officer, Ms. Wang Xiangling, has nearly 20 years of experience in the pharmaceutical industry and oversees all clinical development and related functional operations. Our Chief Financial Officer, Mr. Zou Ran, has more than 17 years of experience in corporate finance, management, and equity investments, and is responsible for formulating our Group's financial and development strategies, as well as overall financial management and corporate development.

In addition, we have also received strong support from a number of well-known institutional and industrial investors, including Northern Light Venture Capital, NRL Capital and TASLY Group, reflecting the capital market's strong confidence in our future prospects.

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### OUR STRATEGIES

#### 1. Accelerate Clinical Development and Commercialization of Our Product Candidates

We plan to accelerate the clinical development of our Core Product and Key Product candidates to expedite their registration in priority indications and enable commercialisation. In parallel, we intend to leverage existing clinical and mechanistic data to explore their potential applications in other related disease areas, with a view to extending product lifecycle and expanding market opportunities. Specifically, we have formulated the following development plans:

- For MT1013, we plan to pursue our first marketing approval for the treatment of SHPT Undergoing Maintenance Hemodialysis and we expect to submit the pre-NDA in late 2026 and the NDA in early 2027. Furthermore, we are developing new indications for MT1013 as set forth below:
  - (i) CKD-MBD with Osteoporosis: We have completed Phase II clinical trial of MT1013 for the indication of SHPT, and plan to leverage data collected from respective trials to seek IND approvals from competent regulatory authorities to conduct Phase III clinical trial of MT1013 for the expanded indication of CKD-MBD with Osteoporosis. We expect to initiate the Phase III trial for this indication in early 2028.
  - (ii) SHPT not on Dialysis: we plan to submit the IND application by the end of 2027.

For more information of our future development plans, see "Business — Our Drug Candidates — Our Core Product MT1013 — Clinical Development Plan".

- For XTL6001, we plan to advance XTL6001 primarily for the treatment of Chronic Weight Management in Obese or Overweight Populations, while also exploring its potential in other metabolic diseases. We plan to initiate a Phase II clinical trial for the treatment of Proteinuric CKD in mid 2027, and to submit an IND application for the treatment of MASH in early 2027.

For more information of our future development plans, see "Business — Our Drug Candidates — Our Key Product — XTL6001 — Clinical Development Plan".

- For MT1002, following the completion of the China Phase II (MT1002-II-C04) study, we plan to initiate an EOP II meeting with the CDE and proceed to a confirmatory Phase III clinical trial with NACE and MACE events as primary efficacy endpoints to support subsequent NDA submission. We have also obtained Phase II clinical trial approvals in the PRC for additional indications, including stroke, HD and HD-PF4, and plan to complete FPI for the Phase II clinical trials of Stroke and HD in the PRC by mid-2026, and to initiate the Phase II clinical trial of HD-PF4 in the PRC at the end of 2027.
- For MT200605, we plan to complete the Phase II clinical trial of MT200605 in the PRC in 2026. This study is a randomized, double-blind, placebo-controlled, multi-center trial designed to evaluate the efficacy, safety and pharmacokinetic profile of MT200605 in patients with AIS. As of the Latest Practicable Date, enrollment of 360 subjects has been completed.

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### **2. Focus on Clinical Needs and Advance Peptide Drug Candidates with Innovative Mechanisms and Commercialisation Potential**

Leveraging our deep industry knowledge in the peptide field, extensive R&D experience, and forward-looking product strategy, we will continue to focus on major disease areas such as metabolic disorders (particularly renal-related) and cardiovascular and cerebrovascular diseases to develop innovative treatment solutions with differentiated advantages.

### **3. Deepen Strategic Collaborations to Unlock the Clinical and Commercial Potential of Our Product Candidates**

With a portfolio of assets advancing rapidly in global clinical development, we have been actively seeking collaboration opportunities to accelerate their clinical progress and commercialization. In the PRC, we are rapidly advancing the clinical studies of our pipeline candidates, while also planning to establish partnerships to expedite development and expand into major international markets.

We intend to form strategic collaborations with industry participants both domestically and overseas to drive commercialization and enhance our global market potential. In addition, we will continue to explore and evaluate external collaboration models such as license-out, co-development and the establishment of new joint ventures (NewCo). For more information of our commercialization strategy, see "Business — Commercialization".

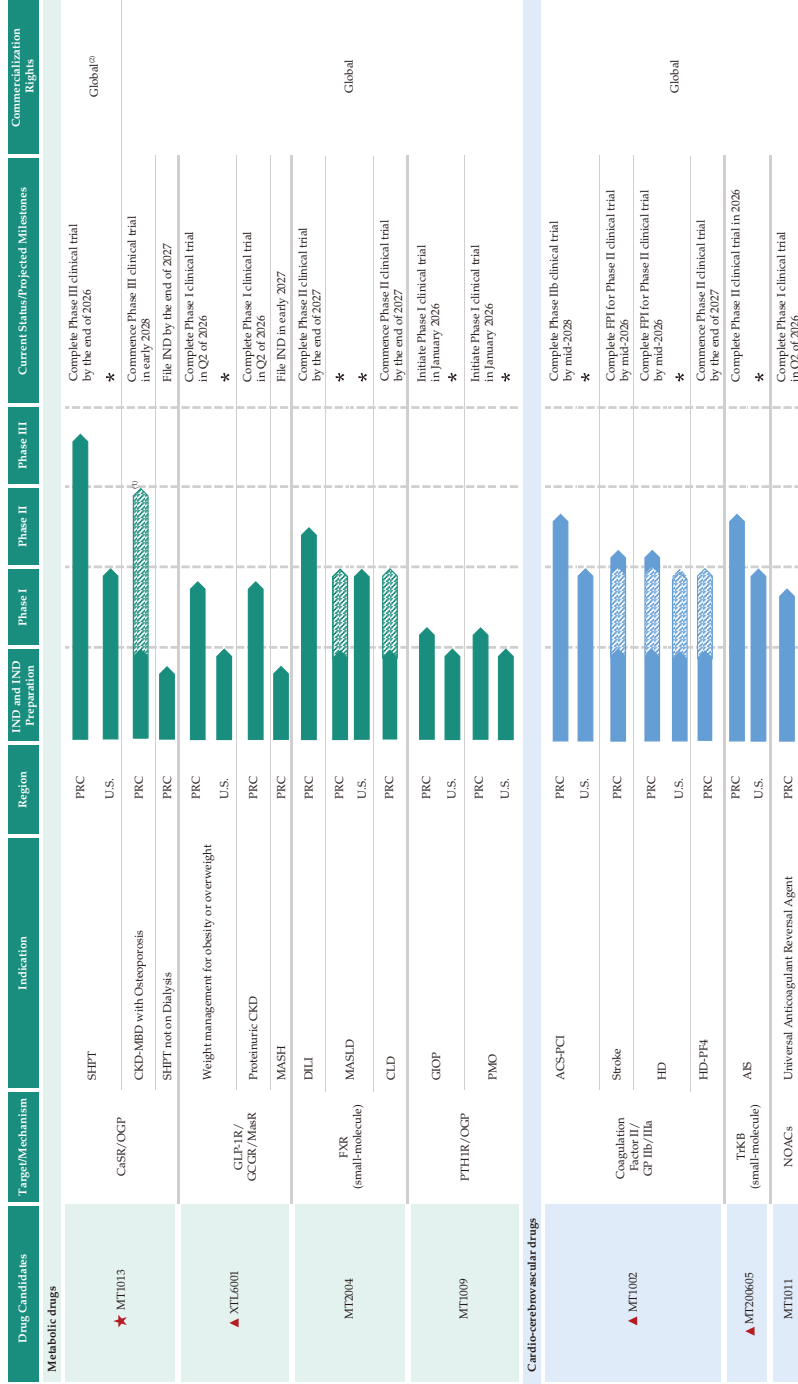
### **4. Recruit and Retain Talent to Promote Systematic Training and Sustainable Development.**

The majority of our Board members possess extensive backgrounds in the medical field and substantial industry experience, and place strong emphasis on the selection and development of professional talent. Leveraging experienced team leadership and deep expertise in drug development, we have successfully attracted and retained outstanding professionals who are passionate about building careers in the biopharmaceutical industry. To further enhance our market competitiveness, we will continue to bring in additional experts specialized in drug research, clinical development, commercialization, and other critical functions, injecting renewed vitality into our Company's long-term growth. For our existing team, we regularly organize systematic training programs designed to align individual career development with our Company's future objectives, ensuring mutual growth and consistent progress.

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OUR DRUG CANDIDATES

Leveraging our expertise in innovative polypeptide therapies and relying on our four major technology platforms, we independently develop dual-target and multi-target specific polypeptide drugs. As of the Latest Practicable Date, we have established an extensive pipeline of drugs under development. The diagram below summarises the development progress of our clinical-stage drug candidates:



★ Core product ▲ Key product [Green bar] Directly proceed to the next stage [Blue bar] Currently assessing the competitive landscape and formulating future clinical development plan. [Red bar] Currently conducting Phase I clinical trial. [Yellow bar] Currently conducting Phase II clinical trial. [Light blue bar] Currently conducting Phase III clinical trial. [Dark blue bar] Currently conducting Phase IV clinical trial. [Pink bar] Currently conducting Phase V clinical trial. [Purple bar] Currently conducting Phase VI clinical trial. [Light purple bar] Currently conducting Phase VII clinical trial. [Light green bar] Currently conducting Phase VIII clinical trial. [Light orange bar] Currently conducting Phase IX clinical trial. [Light pink bar] Currently conducting Phase X clinical trial. [Light blue-gray bar] Currently conducting Phase XI clinical trial. [Light teal bar] Currently conducting Phase XII clinical trial. [Light cyan bar] Currently conducting Phase XIII clinical trial. [Light magenta bar] Currently conducting Phase XIV clinical trial. [Light yellow-green bar] Currently conducting Phase XV clinical trial. [Light lavender bar] Currently conducting Phase XVI clinical trial. [Light lime green bar] Currently conducting Phase XVII clinical trial. [Light peach bar] Currently conducting Phase XVIII clinical trial. [Light mint green bar] Currently conducting Phase XIX clinical trial. [Light salmon bar] Currently conducting Phase XX clinical trial. [Light turquoise bar] Currently conducting Phase XXI clinical trial. [Light lavender-blue bar] Currently conducting Phase XXII clinical trial. [Light seafoam green bar] Currently conducting Phase XXIII clinical trial. [Light steel blue bar] Currently conducting Phase XXIV clinical trial. [Light powder blue bar] Currently conducting Phase XXV clinical trial. [Light sky blue bar] Currently conducting Phase XXVI clinical trial. [Light cornflower blue bar] Currently conducting Phase XXVII clinical trial. [Light blue-gray bar] Currently conducting Phase XXVIII clinical trial. [Light steel blue bar] Currently conducting Phase XXIX clinical trial. [Light powder blue bar] Currently conducting Phase XXX clinical trial.

Notes:

- (1) We have completed Phase II clinical trial of the relevant product for the indication of SHPT, and plan to leverage data collected from respective trials to seek IND approvals from competent regulatory authorities to conduct Phase III clinical trial of the relevant product for the expanded indication of CKD-MBD with Osteoporosis.
- (2) Researched and developed in-house. We have granted Everest an exclusive right to sell, commercialize and promote MT1013 for SHPT in Chinese Mainland, Hong Kong, Macau and Taiwan as well as Asia-Pacific (excluding Japan) (the "Territory"). We reserved the rights to: (i) research, develop and manufacturing MT1013 globally; (ii) commercialize MT1013 for any indications outside Territory; and (iii) commercialize MT1013 in the Territory for any indications other than SHPT. For more information, see "Business — Commercialization".

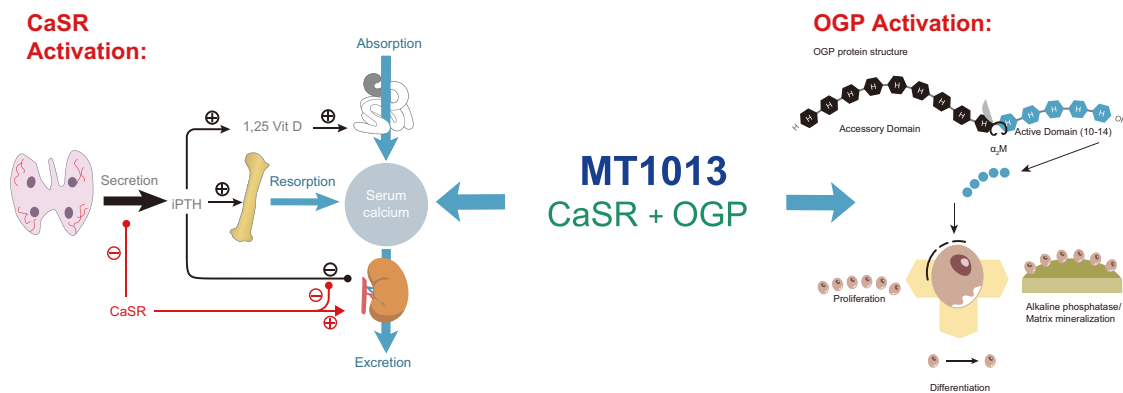
## BUSINESS

### Our Core Product — MT1013

Our Core Product, MT1013, is a first-in-class dual-targeting receptor agonist polypeptide that targets both the CaSR and OGP. Representing a completely innovative, next-generation drug design, it targets two key pathogenic links of CKD-SHPT/CKD-MBD by acting on the CaSR in the parathyroid gland and concurrently on disease-related OGP. It simultaneously regulates the two key metabolic pathways of calcium and phosphorus, demonstrating a significant advantage in regulating the key indicators of calcium and phosphorus metabolism, thereby achieving the dual synergistic benefits of both calcimimetic and pro-osteogenic effects. This distinguishes it from traditional single-target calcimimetics, which directly regulate iPTH but lack a direct pro-osteogenic effect. MT1013 is primarily developed for the treatment of SHPT, with planned expansion to indications such as CKD-MBD with Osteoporosis and SHPT not on Dialysis.

### Mechanism of Action

MT1013 exerts a dual effect by simultaneously activating the CaSR and mimicking the OGP mechanism, thereby targeting and controlling SHPT and related bone disorders. On one hand, by activating the CaSR on the surface of parathyroid cells, MT1013 mimics the action of calcium ions to inhibit the synthesis and secretion of iPTH, thus lowering iPTH levels to counteract the damage to bone and kidneys caused by high iPTH; reducing Ca reabsorption in the renal tubules and increasing urinary Ca excretion. On the other hand, its OGP-like structure promotes the proliferation and differentiation of osteoblasts, enhances alkaline phosphatase activity, and facilitates bone matrix mineralization, which helps to ameliorate osteoporosis and treat renal osteodystrophy. Through this synergistic CaSR+OGP mechanism, MT1013 can achieve comprehensive regulation of iPTH, serum calcium, and serum phosphorus in SHPT patients, resulting in a higher comprehensive control rate and providing cardiovascular protection benefits; improving bone metabolism and addressing the challenge of the lack of effective treatment for renal osteodystrophy in patients with CKD (G5D) and concomitant SHPT.



Source: Company data

CaSR is a G protein-coupled receptor distributed in parathyroid glands, kidneys, and other tissues, and its core function is to sense changes in extracellular calcium ion concentration and regulate the secretion of iPTH through negative feedback to maintain calcium metabolism homeostasis. In SHPT, the abnormal decrease in extracellular calcium concentration due to impaired phosphorus excretion and decreased calcium absorption caused by chronic kidney disease will weaken the CaSR's ability to sense calcium, making it unable to effectively inhibit iPTH secretion; at the same time, long-term calcium-phosphorus disorders will stimulate the proliferation of parathyroid glands, which will further reduce the sensitivity of the CaSR, forming a iPTH. At the same time, long-term calcium and phosphorus disorders will stimulate parathyroid hyperplasia, further reducing CaSR sensitivity, forming a vicious cycle of "iPTH over-secretion — parathyroid hyperplasia", aggravating bone metabolism abnormalities and cardiovascular damage.

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OGP is an active peptide involved in the regulation of bone metabolism, which can promote the proliferation of osteoblasts, enhance osteogenic activity, stimulate the synthesis of collagen and the formation of bone matrix, and regulate the process of bone formation. OGP has the potential to counteract the symptoms of SHPT-induced bone resorption hyperactivity and inhibition of bone formation, and indirectly stabilizes the blood calcium level by reducing the excessive release of calcium from the bone through the promotion of bone formation, thus alleviating the stimulation of parathyroid gland by the loss of calcium from the bone.

*Source:*

- (1) Bab, I.; Gazit, D.; Chorev, M.; Muhrad, A.; Shteyer, A.; Greenberg, Z.; Namdar, M.; Kahn, A. Histone H4-related osteogenic growth peptide (OGP): a novel circulating stimulator of osteoblastic activity. *EMBO J* 1992, 11, 1867-1873
- (2) Pigossi SC, Medeiros MC, Saska S, Cirelli JA, Scarel-Caminaga RM. Role of Osteogenic Growth Peptide (OGP) and OGP(10-14) in Bone Regeneration: A Review. *Int J Mol Sci.* 2016 Nov 22;17(11):1885.

### ***Market Opportunities and Competition***

#### *SHPT*

SHPT is a parathyroid dysfunction caused by disorders in calcium, phosphorus, and vitamin D metabolism, characterized by parathyroid hyperplasia and excessive secretion of iPTH. SHPT is particularly common in patients with CKD in middle and advanced stages, seriously endangering patients' quality of life and lifespan. In 2024, the global number for SHPT patients reached 157 million, and is expected to increase to 190 million by 2030. As of the Latest Practicable Date, there are two CaSR agonist drugs approved by FDA and three CaSR agonist drugs approved by NMPA. In addition, there are five CaSR agonist drug candidates for SHPT in the clinical stage globally, including MT1013 (currently in Phase III). For more information, see "Industry Overview — Main treatment of Secondary Hyperparathyroidism (SHPT)" and "Industry Overview — Competitive landscape of CaSR agonist."

#### *CKD-MBD with Osteoporosis*

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

#### *SHPT not on Dialysis*

The global prevalence of SHPT not on hemodialysis grew from 130.2 million in 2019 to 153.2 million in 2024. It is projected to reach 185.3 million by 2030 and 216.2 million by 2035. In China, the number of SHPT patients not on hemodialysis grew from 12.1 million in 2019 to 12.8 million in 2024, and is projected to reach 13.1 million by 2030.

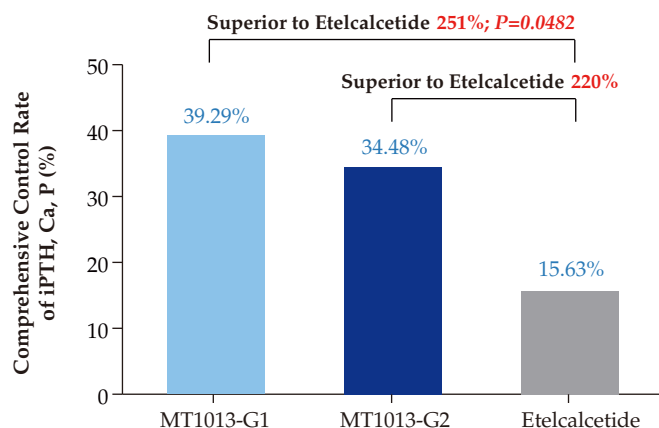
### ***Competitive Advantages***

- (1) *Significant improvement in comprehensive control rate of iPTH/serum calcium/serum phosphorus levels*

Numerous studies suggest that when targets for the three indicators of iPTH, serum calcium, and serum phosphorus are simultaneously met, the risks of hospitalisation due to cardiovascular disease, cardiac death and all-cause mortality are significantly lower for patients compared to when targets for only two or one of these indicators are met. In a Phase II head-to-head clinical study against Etelcalcetide, MT1013 demonstrated that after 26 weeks of treatment, it not only potentially lowered iPTH and maintained serum calcium within the normal range, but also significantly reduced serum phosphorus, outperforming Etelcalcetide (MT1013 groups: 11.2%-11.6% vs. Etelcalcetide: 5.3%), with a phosphorus-lowering effect 2.1 to 2.2 times greater. Consequently, the proportion of subjects achieving the simultaneous targets for the three indicators of iPTH, serum calcium, and serum phosphorus (iPTH: 2-9 times the upper limit of normal (130-586 pg/mL); serum calcium: 2.10-2.50 mmol/L; serum phosphorus: 1.13-1.78 mmol/L) was

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superior to the existing single-target calcimimetic Etelcalcetide (MT1013 groups: 34.48%-39.29% vs. Etelcalcetide: 15.63%), with the comprehensive control rate for the two MT1013 dose groups being 220%-251% of that of the single-target calcimimetic Etelcalcetide. A higher comprehensive control rate suggests a significant reduction in all-cause mortality, effective prevention of vascular calcification, comprehensive maintenance of skeletal health, and improved quality of life for patients. For more information of the clinical results, see "— Clinical Trial Overview of MT1013" below in this section.



**Figure: Comprehensive Control Rate of iPTH, Serum Calcium (Ca), and Serum Phosphorus (P) by Group during Weeks 20-27 (%)**

*Comprehensive Control Rates: Week 20-27,  
iPTH: 2-9 times the upper limit of normal (130-586 pg/mL);  
serum calcium: 2.10-2.50 mmol/L; Serum Phosphorus: 1.13-1.78 mmol/L  
Note: EAP treatment group N=28-32/group*

(2) *Fast-acting, and strong and sustained efficacy in reducing iPTH*

The iPTH-lowering effect of MT1013 is characterised by rapid onset, potent achievement of targets, and long-lasting, stable efficacy; therefore, earlier use by patients leads to earlier benefits. Based on the results of two clinical studies (II-C01/C02), it was observed that after 3 weeks of treatment, iPTH levels in one-third of the subjects had decreased by over 30%; after 9 weeks of treatment, a stable state of efficacy was achieved, with nearly 80% of patients showing an iPTH reduction of over 30%. After 26 and 52 weeks of continuous treatment, the proportion of patients with an iPTH reduction of >30% reached 80%-90%, and the proportion with an iPTH reduction of >50% reached 65%-70%.

Based on the results of a dual-controlled clinical study with placebo and Etelcalcetide as the active comparator (MT1013-II-C03), a head-to-head comparison showed that 54.8%–56.7% of subjects in the MT1013 groups achieved the ideal iPTH standard ( $150 \leq \text{iPTH} \leq 300$  pg/ml), which was superior to the 43.8% in the Etelcalcetide group. Furthermore, MT1013 demonstrated greater advantages in patients with severe SHPT (baseline iPTH >600 pg/ml). MT1013 group 2 reduced iPTH by 69.6% from a baseline mean of 938.5 pg/ml to a mean of 274.2 pg/ml (within the guideline-recommended ideal target range of 150-300 pg/ml), which was significantly superior to Etelcalcetide (a 61.8% reduction from a baseline mean of 912.5 pg/ml to 350.7 pg/ml), which did not reach the guideline-recommended ideal target range of 150-300 pg/ml). For more information of the clinical results, see "— Clinical Trial Overview of MT1013" below in this section.

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### (3) *Cardiovascular benefit potential*

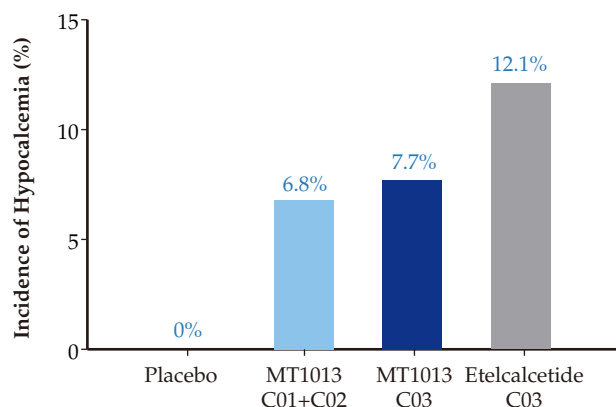
High iPTH, hypercalcemia, and hyperphosphatemia are significantly associated with the risks of cardiovascular events, fractures, and mortality, and have become one of the major risk factors for complications in CKD-MBD patients. In clinical studies, MT1013 has demonstrated excellent comprehensive control of high iPTH, hypercalcemia, and hyperphosphatemia within target ranges. This suggests the potential to reduce the risk of cardiovascular events in SHPT patients, thereby achieving potential cardiovascular protection benefits. FGF23, an indicator of vascular calcification recommended by the 2017 KDIGO CKD-MBD guidelines, is also a key indicator for assessing cardiovascular risk. The EVOLVE study demonstrated that a >30% reduction in FGF-23 from baseline in the target population is associated with improved cardiovascular outcomes (reduced risk of cardiovascular mortality, heart failure, and sudden death). In the head-to-head study between MT1013 and Etelcalcetide, it was observed that MT1013 was superior to Etelcalcetide in both the absolute reduction of FGF-23 and the proportion of subjects with a >30% reduction in FGF-23. This trend is consistent with its superior composite endpoint achievement rate for iPTH/serum calcium/serum phosphorus compared to Etelcalcetide. This indicates that MT1013 has the potential to significantly reduce the incidence of cardiovascular events and the risk of mortality. For more information of the clinical results, see “— Clinical Trial Overview of MT1013” below in this section.

*Source:*

- (1) Tentori F, Blayney MJ, Albert JM, Gillespie BW, Kerr PG, Bommer J, Young EW, Akizawa T, Akiba T, Pisoni RL, Robinson BM, Port FK. Mortality risk for dialysis patients with different levels of serum calcium, phosphorus, and iPTH: the Dialysis Outcomes and Practice Patterns Study (DOPPS). *Am J Kidney Dis.* 2008 Sep;52(3):519-30
  - (2) Block GA, Kilpatrick RD, Lowe KA, Wang W, Danese MD. CKD-mineral and bone disorder and risk of death and cardiovascular hospitalization in patients on hemodialysis. *Clin J Am Soc Nephrol.* 2013 Dec;8(12):2132-40
  - (3) Kidney Disease: Improving Global Outcomes (KDIGO) CKD-MBD Update Work Group. KDIGO 2017 Clinical Practice Guideline Update for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease-Mineral and Bone Disorder (CKD-MBD). *Kidney Int Suppl* (2011). 2017 Jul;7(1):1-59
  - (4) Moe SM, Chertow GM, Parfrey PS, Kubo Y, Block GA, Correa-Rotter R, Drüeke TB, Herzog CA, London GM, Mahaffey KW, Wheeler DC, Stolina M, Dehmel B, Goodman WG, Floege J; Evaluation of Cinacalcet HCl Therapy to Lower Cardiovascular Events (EVOLVE) Trial Investigators\*. Cinacalcet, Fibroblast Growth Factor-23, and Cardiovascular Disease in Hemodialysis: The Evaluation of Cinacalcet HCl Therapy to Lower Cardiovascular Events (EVOLVE) Trial. *Circulation.* 2015 Jul 7;132(1):27-39
- (4) *A favorable safety and tolerability profile with no new safety signals observed beyond those associated with calcimimetics.*

The most common adverse events associated with existing calcimimetics are hypocalcemia and gastrointestinal adverse reactions: (i) No severe hypocalcemia occurred in any of the MT1013 clinical trials; (ii) In the MT1013-II-C01 and C02 studies, after receiving MT1013, as iPTH levels decreased, the hypercalcemic state of subjects improved, and Ca levels gradually declined. After 52 weeks of continuous treatment, the mean corrected calcium levels of the subjects remained consistently within the normal range; (iii) In the head-to-head study with Etelcalcetide, the incidence of hypocalcemia in the MT1013 groups was significantly lower than in the Etelcalcetide group (7.7% vs. 12.1%); (iv) In the head-to-head study with Etelcalcetide, the incidence of adverse reaction leading to temporary drug discontinuation in the MT1013 group was superior to that of the Etelcalcetide group (MT1013: 27.7% vs. Etelcalcetide: 33.3%); and (v) In the MT1013-II-C01 and C02 studies, a total of 133 subjects were treated for up to 52 weeks. The incidences of the gastrointestinal adverse reactions of nausea (1.5%) and vomiting (1.5%) were both significantly lower than those of existing calcimimetics.

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**Figure: Incidence of Hypocalcemia in Each Group of MT1013-II-C01/C02 and MT1013-II-C03 Studies (%)**

MT1013-II-C01+C02 : MT1013 N=133

MT1013-II-C03: MT1013 group 1/33 subjects, MT1013 group 2/32 subjects, etelcalcetide/33 subjects, placebo group/16 subjects

Source: Company data

For more information of the clinical results, see “— Clinical Trial Overview of MT1013” below in this section.

(5) *Enhanced bone mineral density and metabolism*

In the Phase II study (II-C01), subjects with baseline bone mass reduction/osteoporosis showed a significant increase in lumbar spine and femoral neck bone mineral density after 24 and 52 weeks of treatment with MT1013 (at 52 weeks of treatment, lumbar spine increased by 1.65% and femoral neck by 4.44% from baseline). Bone turnover markers (b-ALP, OC, PINP, CTX, TRAP-5b) in all subjects were significantly reduced relative to baseline (at week 53, ALP decreased by 27.06% and TRAP-5b by 45.55%), indicating that MT1013 significantly ameliorated the high bone turnover state in SHPT patients, improved bone metabolism, and established better bone balance. This demonstrates its promising clinical application prospects in the field of CKD-MBD-related bone diseases. For more information of the clinical results, see “— Clinical Trial Overview of MT1013” below in this section.

**Summary of Clinical Trial Results**

The table below sets out a summary of the completed and ongoing clinical trials for MT1013:

Study ID	Study Phase	Location	No. of (Planned) Subjects	Dosing Period	Primary Study Design	Status
MT1013-I-A01 . . . . .	Phase I	U.S.	40	Single dose	Healthy Subjects SAD: 2.5 mg, 5 mg, 10 mg, 15 mg, 20 mg	Completed
MT1013-I-C02 . . . . .	Phase I	PRC	44	Single dose	Healthy Subjects SAD: 1.25 mg, 2.5 mg, 5 mg, 10 mg, 15 mg, 20 mg	Completed
MT1013-I-C03 . . . . .	Phase I	PRC	4-6	Single-dose administration on Day 1; continuous dosing from Week 6 for 3 weeks.	Patients with SHPT Undergoing Maintenance Hemodialysis in the PRC; A single-center, non-randomized, open-label study design	Ongoing

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Study ID	Study Phase	Location	No. of (Planned) Subjects	Dosing Period	Primary Study Design	Status
MT1013-II-C01 . . . . .	SAD	PRC	40	Single dose	Patients with SHPT Undergoing Maintenance Hemodialysis SAD: 5mg, 10 mg, 20 mg, 40 mg, 60 mg	Completed
	MAD		24	2w/4w	Patients with SHPT Undergoing Maintenance Hemodialysis MAD: 5 mg (2w), 10 mg (4w), 20 mg (4w)	Completed
	Long-term cohort		33	52w	Patients with SHPT Undergoing Maintenance Hemodialysis, single-arm; titrated dosing	Completed
MT1013-II-C02 . . . . .	Supportive Phase III, registered as IIb	PRC	350	52w	Patients with SHPT Undergoing Maintenance Hemodialysis, single-arm; titrated dosing; safety as the primary endpoint; efficacy as the secondary endpoint	Ongoing
MT1013-II-C03 . . . . .	Phase II	PRC	114	26w	Patients with SHPT Undergoing Maintenance Hemodialysis, randomized, active comparator (Etelcalcetide) and placebo-controlled, titrated dosing; efficacy as the primary endpoint	Completed
MT1013-III-C01 . . . . .	Phase III	PRC	424	26w	Patients with SHPT Undergoing Maintenance Hemodialysis; multicenter, randomized, double-blind, double-dummy, with cinacalcet as the active comparator	Ongoing

**Clinical Trial Overview**

*MT1013-I-A01 U.S. Phase I Study*

**Overview:** This study was a Phase I clinical study with single ascending doses conducted in healthy subjects in the U.S. The primary objective was to evaluate the safety and tolerability, and the secondary objective was to characterize the pharmacokinetics and pharmacodynamics of MT1013.

**Trial design:** A single-center, randomized, placebo-controlled, double-blind, single ascending dose study, comprising five dose cohorts with dose levels of 2.5, 5, 10, 15, and 20 mg, respectively. Each subject received a single-dose administration. Cohorts received treatment sequentially in an ascending dose manner, with each cohort comprising 8 subjects (6 subjects receiving the active investigational drug and 2 subjects receiving a matching placebo). Subjects underwent a follow-up visit on Day 8 (±1 day).

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A total of 40 subjects were enrolled in the US in this trial. The key inclusion criteria included, among others: (1) male or female non-smokers aged between 18 and 55 years, with a body mass index (BMI) greater than 18.0 kg/m<sup>2</sup> and less than 30.0 kg/m<sup>2</sup>, and a body weight of no less than 45.0 kg; and (2) healthy subjects without clinically significant medical history or conditions. The key exclusion criteria included but were not limited to: (1) any clinically significant abnormalities identified during physical examination at medical screening, including abnormal laboratory test results, or positive findings for HIV, hepatitis B virus (HBV), hepatitis C virus (HCV) or Treponema pallidum antibody; (2) positive results in urine drug screening, urinary cotinine test, or breath alcohol test at screening; (3) positive pregnancy test result at screening; and (4) other clinically significant abnormalities identified during screening, including abnormalities in ECG, vital signs or laboratory findings.

**Trial status:** The Phase I clinical trial was conducted in the United States, with the first subject receiving the first dose in June 2021 and the last subject completing the last visit in October 2021.

**Pharmacokinetics (PK) results:** The geometric mean values of PK exposure parameters for each dose level were as follows: AUC<sub>0-t</sub> were 205.87, 435.43, 714.29, 1328.67, and 1602.78 h\*ng/mL, respectively; AUC<sub>0-inf</sub> were 211.97, 447.68, 729.02, 1340.27, and 1625.27 h\*ng/mL, respectively; C<sub>max</sub> were 197.20, 425.70, 576.72, 1128.90, and 1218.03 ng/mL, respectively, with the mean T<sub>max</sub> ranging from 0.114 to 0.181 hours. Results from a power model analysis indicated that exposure increased proportionally with the dose in the 2.5–20 mg range.

**Safety data:** In healthy subjects, single intravenous (IV) administration of MT1013 in the dose range of 2.5 mg to 20 mg was well tolerated. Among the 40 subjects who received any dose of MT1013 or placebo, 3 subjects (7.5%) reported a total of 4 TEAEs. Among the 30 subjects who received any dose of MT1013, 2 subjects (6.66%) reported 3 TEAEs, and among the 10 subjects who received placebo, 1 subject (10%) reported 1 TEAE. A total of 3 subjects (7.5%) reported headache, and 1 subject reported nausea. All TEAEs reported during the study were mild in severity. No moderate or severe TEAEs were reported. Of these 4 TEAEs, 3 were considered unrelated, and 1 (headache) was considered related to MT1013. No drug-related SAEs were reported. No life-threatening AEs occurred, nor did any AE lead to patient withdrawal or study discontinuation.

**Efficacy data:** At different doses from 2.5 to 20 mg, MT1013 significantly reduced serum iPTH, with maximum inhibition rates of 32.1%, 19.8%, 66.6%, 63.0%, and 74%, respectively. The reduction was reversible, with levels gradually recovering after 6 hours. The preliminary pharmacodynamic effect lasted for 24 - 48 hours. In the placebo group, iPTH levels ranged from 11.70 to 98.50 pg/ml. For MT1013, at different doses and time points, iPTH levels ranged from 5.30 to 82.90 pg/ml.

### *MT1013-I-C02 PRC Phase I Study*

**Overview:** This study was a Phase I clinical study with single ascending doses in healthy adult subjects in the PRC. Its objective was to evaluate the safety, tolerability, pharmacokinetics, and preliminary pharmacodynamics of MT1013.

**Trial design:** A single-center, randomized within each dose group, placebo-controlled, double-blind, single ascending dose study. Six dose groups were designed within the 1.25 mg to 20 mg range. Group A1 consisted of 4 subjects (investigational drug: placebo = 3:1), and groups A2-A6 each consisted of 8 subjects (investigational drug: placebo = 6:2). The trial proceeded from the lowest dose group to the highest. Subjects underwent a safety assessment on Day 3 and were discharged from the study thereafter.

A total of 44 subjects were enrolled in the PRC in this trial. The key inclusion criteria included: (1) male or female healthy subjects of Chinese nationality with an appropriate gender ratio; (2) aged between 18 (inclusive) and 45 (inclusive) years; and (3) body weight of no less than 50.0 kg for male subjects and no less than 45.0 kg for female subjects, with a body mass index (BMI) between 19.0 kg/m<sup>2</sup> and 26.0 kg/m<sup>2</sup> (inclusive). The key exclusion criteria included but were not limited to: (1) subjects with clinically significant abnormalities in cardiovascular, hepatic, renal, endocrine, metabolic, gastrointestinal, hematologic or respiratory laboratory findings as determined by the investigator, or with

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a confirmed diagnosis of any of the above diseases, or with a history of infections, malignancy or psychiatric disorders; (2) subjects with a history of clinically significant ECG abnormalities or long QT syndrome, or a history of epileptic seizures; and (3) subjects with clinically significant abnormalities in physical examination, vital signs, laboratory tests or ECG results, as determined by the investigator.

**Trial status:** The Phase I clinical trial was initiated in January 2022 and completed in June 2022.

**Pharmacokinetics (PK) results:** For the 1.25 mg to 20 mg MT1013 dose groups, the geometric mean  $C_{max}$  values were 129.28, 284.91, 537.21, 1038.90, 1570.64, and 2264.62 ng/mL, respectively; the geometric mean  $AUC_{0-t}$  values were 97.75, 194.04, 350.78, 709.75, 1110.29, and 1723.16 ng · h/mL, respectively; and the geometric mean  $t_{1/2}$  values were 1.18, 1.30, 1.13, 1.16, 1.29, and 1.47 h, respectively. A power model was used for linear pharmacokinetic analysis of blood PK parameters ( $C_{max}$ ,  $AUC_{0-t}$ ,  $AUC_{0-\infty}$ ), which met the criteria for linear pharmacokinetics.

**Safety data:** MT1013 demonstrated good safety and tolerability. The number of subjects with adverse reactions (and incidence rates) in the MT1013 1.25 mg, 2.5 mg, 5 mg, 10 mg, 15 mg, 20 mg, and placebo groups were 1 (33.3%), 4 (66.7%), 4 (66.7%), 5 (83.3%), 4 (66.7%), 6 (100.00%), and 6 (54.5%), respectively. There was no significant association between AE incidence or severity and the administered dose. No drug-related TEAEs of Grade 3 or above were observed, and no drug-related SAEs were reported. No life-threatening AEs occurred, nor did any AE lead to patient withdrawal or study discontinuation.

**Efficacy data:** In the MT1013 1.25 mg to 20 mg groups, serum parathyroid hormone levels began to decrease after intravenous bolus injection of MT1013, reaching a nadir approximately 6 hours post-injection. At this time point, the percentage change from baseline in serum parathyroid hormone concentration for the placebo group and the various dose groups were -36.42(16.80)%, -46.42(19.12)%, -39.99(17.75)%, -52.65(7.96)%, -68.51(7.07)%, -71.51(5.74)%, and -80.35(5.98)%, respectively. Serum parathyroid hormone levels reached their nadir 6 hours after a single intravenous bolus injection of MT1013. This pharmacodynamic effect lasted for up to 24 hours and returned to baseline by 48 hours.

### *MT1013-I-C03 PRC Phase I Mass Balance Study*

**Overview:** This is an in vivo mass balance study conducted in the PRC in patients with SHPT Undergoing Maintenance Hemodialysis. Its objective was to quantitatively analyze the total radioactivity and radioactive metabolite profile in excreta, as well as the pharmacokinetic parameters and safety, after intravenous injection of [ $^{14}C$ ]MT1013.

**Trial design:** A single-center, non-randomized, open-label study design. During the first week, a single intravenous dose of [ $^{14}C$ ]MT1013 (comprising 10 mg of non-labeled MT1013 and approximately 50  $\mu$ Ci of radiolabeled compound) was administered after the first hemodialysis session. Beginning from Week 6, MT1013 was administered intravenously after each of the three weekly hemodialysis sessions for a total duration of three weeks, with the final dose given after the first hemodialysis session in Week 9, at a dose of 5 mg per administration. Subjects entered a follow-up period of one week thereafter. The study is planned to enroll 4-6 participants in the PRC with SHPT Undergoing Maintenance Hemodialysis.

The key inclusion criteria included: (1) male or postmenopausal female participants aged 18 years or above who were clearly diagnosed with SHPT; (2) BMI between 18.0 kg/m<sup>2</sup> and 35.0 kg/m<sup>2</sup> (based on pre-dialysis body weight); (3) subjects who had received adequate and regular hemodialysis for at least 12 weeks prior to screening and had undergone sufficient dialysis within four weeks prior to screening; and (4) subjects whose pre-dialysis serum calcium level during screening (measured before hemodialysis and corrected for serum albumin <40 g/L) was no less than 8.4 mg/dL (2.1 mmol/L). The key exclusion criteria included but were not limited to: (1) subjects who had undergone parathyroidectomy within six months prior to screening, or who planned to undergo parathyroidectomy, ablation, radiation or other related procedures during the study period; (2) subjects with a history of gastrointestinal bleeding or peptic ulcer within six months prior to screening; (3) subjects who had experienced myocardial infarction or

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undergone percutaneous coronary intervention or coronary artery bypass grafting within six months prior to screening; (4) subjects with a history of NYHA class III or IV heart failure within three months prior to screening, or with symptomatic arrhythmia within six months prior to screening, or with a history of torsades de pointes.

**Trial status:** The trial was initiated in July 2025. As of the Latest Practicable Date, enrollment of all six subjects in the PRC had been completed, and the LPLV is expected to occur by April 2026.

### *MT1013-II-C01 Phase II Single- and Multiple-Ascending Dose and 52-week Long-term Treatment Study in the Target Population*

**Overview:** This was a Phase II clinical study conducted in patients with SHPT Undergoing Maintenance Hemodialysis, aiming to evaluate the safety, efficacy and pharmacokinetics of MT1013 after a single dose, continuous dosing for 2-4 weeks, and long-term continuous dosing for 52 weeks in HD subjects with SHPT. Safety evaluation was the primary objective of the SAD and MAD studies, while the efficacy evaluation was the primary objective of the long-term cohort.

**Trial design:** A multi-center, Phase II, randomized, double-blind, SAD and MAD study, as well as a single-arm clinical study to evaluate the long-term efficacy and safety of MT1013. The study population comprised patients with SHPT Undergoing Maintenance Hemodialysis. The SAD study included 5 cohorts with doses of 5, 10, 20, 40, and 60 mg. The MAD study included 3 cohorts with doses of 5, 10, and 20 mg. Each cohort in the SAD and MAD studies included 8 subjects (6 subjects received the active investigational drug and 2 subjects received matching placebo) and were conducted sequentially. All subjects in the long-term dosing cohort underwent hemodialysis 3 times a week and were administered the drug once after each hemodialysis session for a duration of 52 weeks. Subjects in the SAD study underwent a follow-up visit on Day 8 ( $\pm 1$  day), subjects in the MAD study underwent a follow-up visit within one week after the last dose, and subjects in the long-term dosing cohort underwent follow-up for a total period of 52 weeks.

The key inclusion criteria included: (1) male subjects aged 18 years or above and below 80 years, and female subjects who were non-pregnant and non-lactating; (2) patients who had received adequate hemodialysis and maintained stable treatment for more than three months prior to screening; (3) subjects with an iPTH level of at least 300 pg/mL; (4) subjects with serum calcium (corrected for albumin  $< 40$  g/L) of no less than 2.25 mmol/L (9.0 mg/dL); and (5) subjects with hemoglobin levels of at least 8.0 g/dL. The key exclusion criteria included but were not limited to: (1) subjects with a history of severe ventricular arrhythmia, symptomatic ventricular arrhythmia at screening, or QTc interval  $> 470$  ms for males or  $> 480$  ms for females at screening; (2) subjects with NYHA class II or V heart failure symptoms at screening; (3) subjects with a history of myocardial infarction, percutaneous coronary intervention or coronary artery bypass grafting within six months prior to screening; (4) subjects with a history of epileptic seizures or who had received treatment for seizures; and (5) subjects who had undergone parathyroidectomy.

**Trial status:** SAD and MAD studies: The first subject signed the informed consent form on April 7, 2023, and the last subject completed the trial on December 17, 2023. A total of 65 subjects were actually enrolled (64 were randomized for dosing). Long-term dosing cohort: The first subject signed the informed consent form on February 27, 2024, and the last subject completed the trial on May 12, 2025. A total of 33 subjects were actually enrolled.

**Pharmacokinetics results:** After intravenous bolus injection of MT1013 in the 5, 10, 20, 40, and 60 mg dose groups of the single ascending dose (SAD) study, the geometric mean  $C_{max}$  values of MT1013 were 434.2, 1008.8, 1544.9, 3311.3, and 4580.5 ng/mL, respectively; the geometric mean  $AUC_{0-t}$  values were 362.710, 856.968, 1529.749, 3329.690, and 4281.925 ng  $\cdot$  h/mL, respectively; and the geometric mean  $t_{1/2}$  values were 1.492, 1.567, 1.857, 2.062, and 2.164 h, respectively. After intravenous bolus injection of MT1013 in the 5, 10, and 20 mg dose groups of the multiple ascending dose (MAD) study, the geometric mean  $C_{max}$  values of MT1013 at the last dose were 441.5, 1115.8, and 1896.4 ng/mL, respectively; the geometric mean  $AUC_{0-t}$  values at the last dose were 373.110, 830.400, and 1654.778 ng  $\cdot$  h/mL, respectively; and the geometric mean  $t_{1/2}$  values at the last dose were 1.131, 1.896, and 2.175 h, respectively. Regression analysis using a power model showed that the in vivo pharmacokinetic processes of dose and exposure in the

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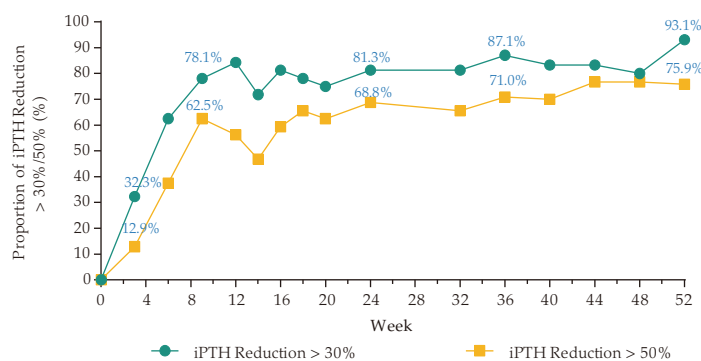
single-dose 5 mg to 60 mg groups and the multiple ascending dose 5 mg to 20 mg groups exhibited linear pharmacokinetic characteristics. No significant accumulation of exposure was observed after multiple doses.

**Safety data:** MT1013 demonstrated good safety and tolerability in target population following treatment with single doses (5-60 mg) and multiple doses (5-20 mg, for 2-4 weeks). The most common (observed in >2 subjects) adverse events related to the investigational product were blood calcium decrease associated with the pharmacodynamic effect of MT1013 (incidence of 30.0% in the SAD study and 38.9% in the MAD study), hypocalcemia (incidence of 16.7% in the MAD study), and QT interval prolongation (incidence of 16.7% in the MAD study). One participant permanently discontinued due to a TEAE of moderate hypocalcemia in the MAD 20 mg cohort, which did not meet the criteria for severe intensity, nor SAE.

In the long-term dosing (52-week) cohort, the most common (≥10%) adverse events related to the investigational product were blood calcium decrease associated with the pharmacodynamic effect of MT1013 (29 cases, 87.9%) and hypocalcemia (5 cases, 15.2%). No severe TEAEs related to MT1013, no SAEs related to MT1013, no deaths related to MT1013, and no adverse events leading to permanent drug discontinuation occurred during the trial. In the long-term treatment (starting dose of 5 mg or 10 mg, titrated, for 52 weeks) of patients with SHPT on hemodialysis, MT1013 demonstrated good overall safety with manageable risks.

**Efficacy data:** After treatment with MT1013 in the target population, the SAD study showed a significant decrease in serum parathyroid hormone in dose groups of 5 mg and above compared to the placebo group, with the most significant effects observed in the 40 mg dose group (percentage change from baseline: -79.114%) and the 60 mg dose group (percentage change from baseline: -75.950%). In the MAD study, the number (proportion) of patients with a >30% reduction from baseline in mean serum iPTH for the 5 mg to 20 mg groups and the placebo group were 3 (50.0%), 4 (66.7%), 5 (100%), and 2 (33.3%), respectively. Dose groups of 5 mg and above showed a significant decrease in serum parathyroid hormone compared to the placebo group, with the most significant effect observed in the 20 mg dose group. A comprehensive analysis showed that iPTH, serum corrected calcium, and serum phosphorus decreased from baseline in all dose groups. Furthermore, as the dose increased, iPTH and serum corrected calcium gradually decreased, showing a clear dose-response relationship.

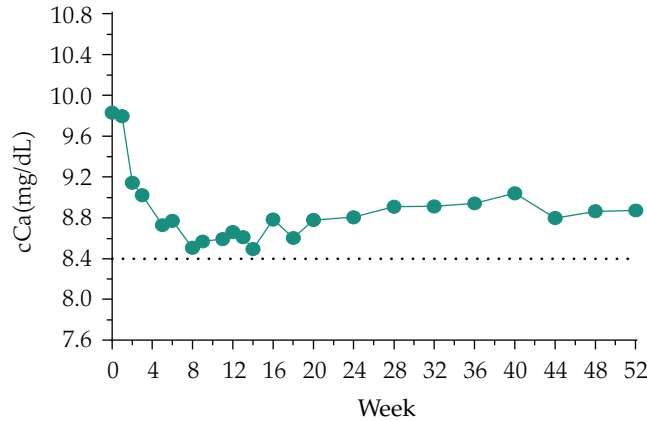
The trial results indicated that patients with SHPT on maintenance hemodialysis received clinical benefits from a relatively long-term treatment of 52 weeks with MT1013. In the long-term dosing cohort, among SHPT patients treated with MT1013, from week 9 onwards, the mean reduction in iPTH from baseline reached 50%, the proportion of subjects with a >30% reduction reached 80%, and the proportion with a >50% reduction reached 60%. By week 52, these metrics were 57.2%, 93.1%, and 75.9%, respectively. The proportion of subjects with iPTH <300 pg/mL was 65.6%, and the proportion achieving the target range of 150-300 pg/mL was 53.1%. The study results demonstrated that SHPT patients could generally achieve a stable pharmacodynamic state after 9 weeks of MT1013 treatment and continued to benefit from long-term therapy.



**Figure: Proportion of Subjects with >30% and >50% iPTH Reduction at Each Visit Point in MT1013-II-C01 (%)**  
N=33

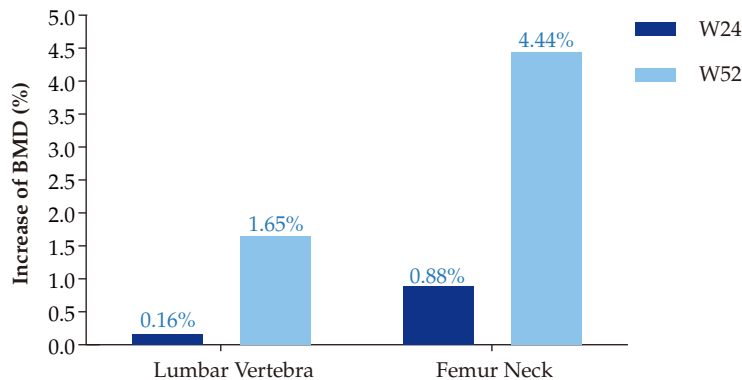
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The trial results showed that serum corrected calcium (cCa) decreased to its lowest level at week 9 of MT1013 administration, then slowly recovered and began to stabilize, decreasing from a relatively high calcium level to within the normal range and remaining stable long-term, demonstrating that treatment can improve high calcium levels to the physiological normal range with long-term stable benefits.



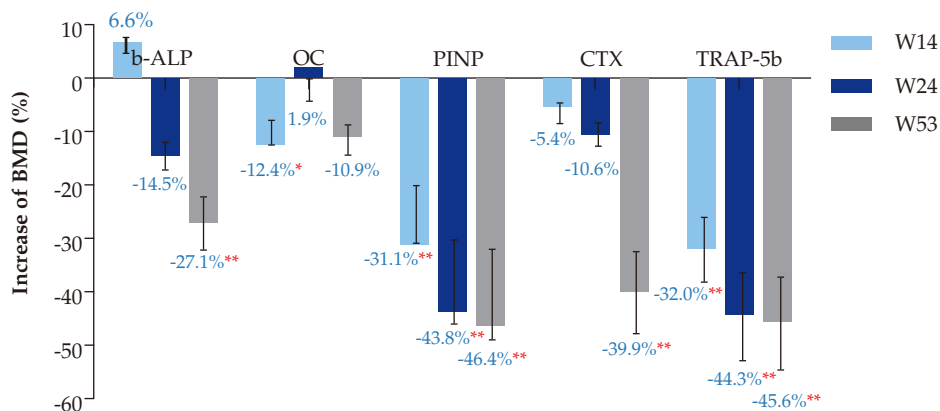
**Figure: Mean Change in Serum Corrected Calcium (cCa) at Each Visit Point in MT1013-II-C01 (mg/dL)**  
N=33

The efficacy data showed that after long-term treatment with MT1013, bone turnover markers shifted from a high-turnover state to a low-turnover state and remained relatively stable long-term, which corroborates and aligns with the conclusion of stable iPTH improvement after long-term MT1013 treatment. The bone mineral density examination results further suggested potential bone benefits after a relatively long-term treatment of 52 weeks, corroborating and aligning with the conclusion of bone marker benefits suggested by the bone marker results.



**Figure: Change in Lumbar Spine and Femoral Neck Bone Mineral Density (BMD) in Subjects with Baseline Osteoporosis in MT1013-II-C01 (%)**  
N=33

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**Figure: Change from Baseline (%) in Bone Turnover Markers in Subjects of MT1013-II-C01**

N=33, compared with baseline, \*P<0.05, \*\*P<0.01

Source: Company data

*MT1013-II-C02 PRC Long-Term Dosing Study (Supportive Phase III Clinical Study)*

**Overview:** This is a Phase IIb clinical study (supportive Phase III clinical study) of MT1013 for injection for the treatment of patients with SHPT Undergoing Maintenance Hemodialysis. Its primary objective was to evaluate the safety, and the secondary objective was to evaluate the efficacy and improvement in bone mineral density of MT1013.

**Trial design:** A multi-center, open-label, single-arm clinical study in a population of patients with SHPT Undergoing Maintenance Hemodialysis. It is planned to enroll 350 subjects who undergo hemodialysis 3 times a week or 5 times every two weeks. They will receive MT1013 at the end of each hemodialysis session for 52 consecutive weeks. After completing the aforementioned dosing, subjects will enter an extended treatment period to continue receiving MT1013 until the trial sponsor decides to terminate the study. Subjects will undergo a safety follow-up assessment 7 days ( $\pm 3$  days) after the last dose.

A total of 350 subjects are planned to be enrolled in this trial. The key inclusion criteria included, among others: (1) male or female subjects aged 18 years or above at the time of signing the informed consent form; (2) subjects who had received maintenance hemodialysis three times per week or five times every two weeks for at least three months prior to screening; (3) subjects whose dialysate calcium concentration was no less than 2.5 mEq/L (1.25 mmol/L), maintained at a stable level for at least four weeks prior to the laboratory assessments during the screening period, and required to remain at no less than 2.5 mEq/L (1.25 mmol/L) throughout the study; (4) subjects diagnosed with SHPT and with an iPTH level of more than 300 pg/mL at screening; for subjects who were receiving cinacalcet, etelcalcetide, MT1013 or other calcimimetics prior to screening, the pre-dialysis iPTH level measured during screening was required to be greater than 100 pg/mL. The key exclusion criteria included but were not limited to: (1) subjects with primary hyperparathyroidism; (2) subjects who refused to discontinue cinacalcet, etelcalcetide or other calcimimetics during the study; (3) subjects who had received denosumab or other receptor activator of nuclear factor kappa-B ligand (RANKL) inhibitors within six months prior to screening; (4) subjects with a history of gastrointestinal bleeding or peptic ulcer within six months prior to screening.

**Trial status:** The Phase II clinical trial was initiated in March 2024. As of the Latest Practicable Date, enrollment of all 350 subjects had been completed.

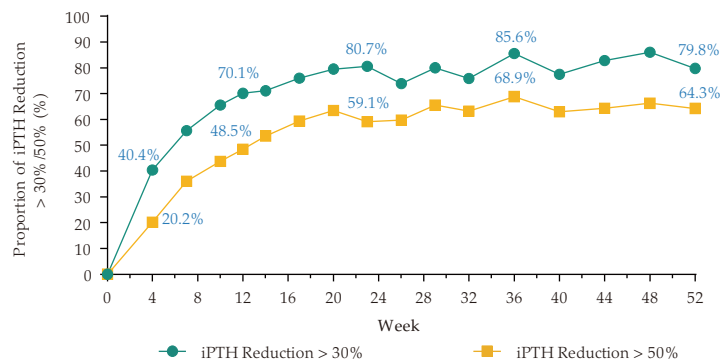
**Safety data:** An interim analysis of the 52-week data from the first 100 subjects in this study showed that the most common adverse events related to the investigational product were blood calcium decrease associated with the pharmacodynamic effect of MT1013 (229 cases, 80%) and hypocalcemia (4 subjects, 4%). There were no cases of severe or serious hypocalcemia. In the adverse reaction, the incidences of nausea (2 cases, 2%)

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and vomiting (2 cases, 2%) were low. No severe TEAEs related to MT1013, no SAEs related to MT1013, no deaths related to MT1013, and no adverse events leading to patient withdrawal or permanent drug discontinuation occurred during the trial. In the long-term treatment (starting dose of 5 mg or 10 mg, titrated, for 52 weeks) of patients with SHPT on hemodialysis, MT1013 demonstrated good overall safety with manageable risks, and no unexpected safety signals or risks were identified.

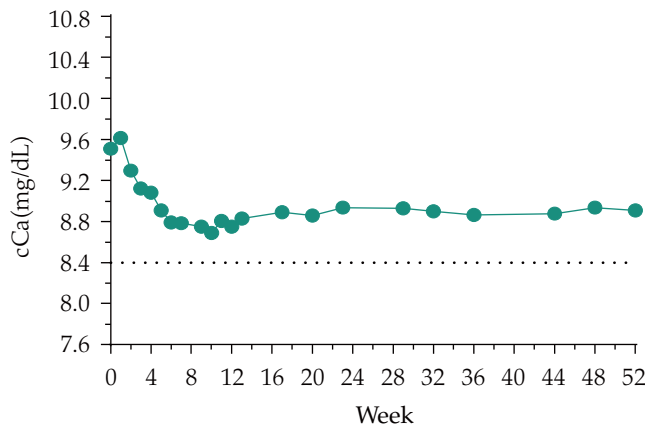
**Efficacy data:** An interim analysis of the 52-week data from the first 100 subjects in this study showed that, regardless of prior use of calcimimetics, the proportion of SHPT patients achieving a >30% reduction in iPTH from baseline after 52 weeks of MT1013 treatment reached 79.8%, and the proportion achieving a >50% reduction reached 64.3%. The proportion achieving the target iPTH range of 150-300 pg/mL was 45.6%. Patients' relatively high calcium levels were reduced to within the normal range and remained stable long-term. In summary, the study results demonstrated that, regardless of whether patients were previously using calcimimetics, over 80% of patients experienced further improvement in iPTH after using MT1013, and high calcium levels were significantly improved and maintained within the physiological normal range long-term.

**iPTH Reduction Profile:**



**Figure: Proportion of Subjects with >30% and >50% iPTH Reduction at Each Visit Point in MT1013-II-C02 (%)**  
N=100

**Corrected Serum Calcium Profile:**



**Figure: Mean Change in Serum Corrected Calcium (cCa) at Each Visit Point in MT1013-II-C02 (mg/dL)**  
N=100

Source: Company datae

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### MT1013-II-C03

**Overview:** A Phase II clinical study of MT1013 for injection for the treatment of patients with SHPT Undergoing Maintenance Hemodialysis, with continuous dosing for 26 weeks to evaluate the efficacy, safety, immunogenicity and pharmacokinetic of MT1013. Efficacy evaluation was the primary objective of the study.

**Trial design:** A multi-center, randomized, active-controlled, and placebo-controlled clinical study in a population of patients with SHPT Undergoing Maintenance Hemodialysis. It is planned to enroll 112 subjects, who will be randomly assigned in a 2:2:1:1 ratio to MT1013 Group 1, MT1013 Group 2, the Etelcalcetide group, and the placebo group. Stratified randomization will be performed based on the mean iPTH level during the screening period (mean of two pre-dialysis measurements on different days within 14 days before randomization) of  $\leq 800$  pg/ml or  $> 800$  pg/ml. The drug was administered via intravenous injection through the venous line of the dialysis circuit after each hemodialysis session, three times a week, for 26 consecutive weeks. Subjects will undergo a safety follow-up assessment within one week (+3 days) after the last dose.

A total of 114 subjects were enrolled in this trial. The key inclusion criteria included, among others: (1) subjects who fully understood and voluntarily agreed to participate in the study and signed the informed consent form; (2) male or female subjects aged 18 years or above at the time of signing the informed consent form; (3) subjects who had received regular maintenance hemodialysis three times per week for at least three months prior to screening, and had undergone adequate dialysis within four weeks prior to screening, defined as a single-pool Kt/V (spKt/V)  $\geq 1.2$  or urea reduction ratio (URR)  $\geq 65\%$ ; and (4) subjects diagnosed with SHPT with dialysate calcium concentration and pre-dialysis serum iPTH level meeting the study requirements as specified in the protocol. The key exclusion criteria included but were not limited to: (1) subjects who had undergone parathyroidectomy within six months prior to screening or who planned to undergo parathyroidectomy, ablation, radiation or other related treatments during the study period; (2) subjects with a history of gastrointestinal bleeding or peptic ulcer within six months prior to screening; (3) subjects with a history of myocardial infarction, percutaneous coronary intervention or coronary artery bypass grafting within six months prior to screening; (4) subjects with NYHA class III or IV heart failure symptoms within three months prior to screening, or with symptomatic arrhythmia within six months prior to screening, or with a history of torsades de pointes.

**Trial status:** The Phase II clinical trial was initiated in November 2024 and completed in March 2026.

**Safety data:** In this study, MT1013 demonstrated good overall safety and tolerability, with no unexpected safety signals or risks identified. There was no difference in SAEs between groups, which were comparable to placebo. No severe TEAEs or SAEs related to the investigational product were observed in the study. The incidence of temporary drug discontinuation due to adverse reactions was higher in the Etelcalcetide group (33.3%) than in the MT1013 groups (27.7%). No patients permanently discontinued the drug due to adverse events. Regarding the incidence of hypocalcemia, a pharmacodynamic effect of special concern for calcimimetics, the rate was significantly lower for MT1013 (7.7%) compared to Etelcalcetide (12.1%), with no cases of severe or serious hypocalcemia in either group. The MT1013 group showed a lower incidence of gastrointestinal TRAEs compared with the Etelcalcetide group. Specifically, the incidences of vomiting, nausea, diarrhea and abdominal discomfort were each 1.54% in the MT1013 group, as compared with 6.06%, 3.03%, 0% and 3.03%, respectively, in the Etelcalcetide group, suggesting that MT1013 may have a more favorable gastrointestinal tolerability profile.

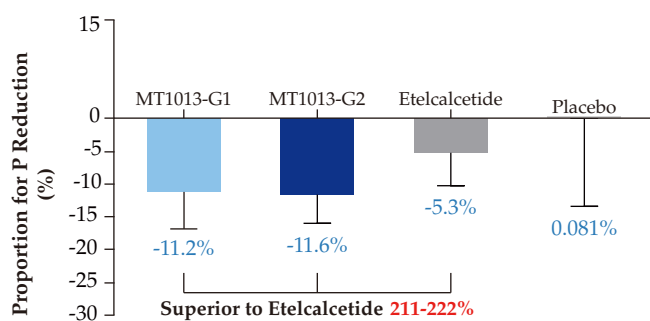
Two subjects (both in the Placebo group) withdrew from the study due to TEAEs, including one case of weakness and one case of arthralgia.

**Efficacy data:** After 26 weeks of treatment in the target population, the number (proportion) of patients with a  $>30\%$  reduction from baseline in mean serum iPTH during the EAP period for MT1013 Group 1, MT1013 Group 2 and the Etelcalcetide group was 25 (80.65%), 28 (93.33%) and 29 (90.63%), respectively. The number (proportion) of patients with a  $>50\%$  reduction was 23 (74.19%), 24 (80.0%), and 24 (75%), respectively. For patients with severe SHPT (baseline iPTH  $>600$  pg/mL), MT1013 showed greater improvement in

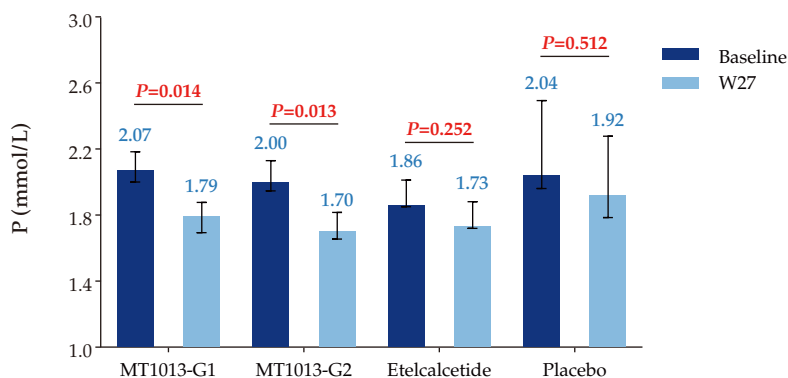
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iPTH compared to Etelcalcetide: during the EAP period, the number (proportion) of patients with a >30% reduction from baseline in mean serum iPTH was 17 (85.0%), 19 (100%), and 18 (85.71%) for MT1013 Group 1, MT1013 Group 2, and the Etelcalcetide group, respectively. The number (proportion) of patients with a >50% reduction was 15 (75.0%), 16 (84.21%), and 15 (71.43%), respectively. The iPTH achievement rate (150-300 pg/mL) during the EAP period was superior for MT1013 compared to Etelcalcetide (54.8% for MT1013 Group 1, 56.7% for Group 2, and 43.8% for the Etelcalcetide group).

During the course of treatment, the proportion of patients whose serum calcium was controlled within the normal range was slightly better in the MT1013 groups compared to the Etelcalcetide group (71% for MT1013 Group 1, 80% for Group 2, and 68.8% for the Etelcalcetide group). In terms of serum phosphorus control, MT1013 was superior to Etelcalcetide in lowering serum phosphorus (percentage reduction in serum phosphorus from baseline at Week 27: 11.2% for MT1013 Group 1, 11.6% for Group 2, and 5.3% for the Etelcalcetide group). In terms of achieving the composite endpoint for all three indicators (iPTH: 2-9 times the upper limit of normal (130-586 pg/mL); serum calcium: 2.10-2.50 mmol/L; serum phosphorus: 1.13-1.78 mmol/L), MT1013 was also superior to Etelcalcetide (34.48%-39.29% for MT1013 groups vs. 15.63% for Etelcalcetide). The composite endpoint achievement rates for the two MT1013 dose groups were 220%-251% of that of Etelcalcetide.



**Figure: Reduction Rate (%) of Serum P from Baseline in Each Group at W27**  
*Treatment groups at W27 N=32-38/group, placebo group N=9*



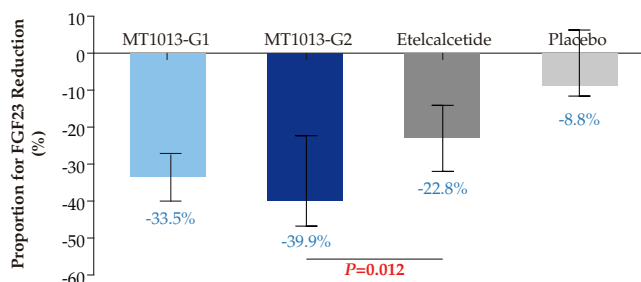
**Figure: Change in Serum P (mmol/L) in Each Group Before and After Treatment (Mean±SEM)**

*Note: treatment groups/38-32 subjects, placebo group/9 subjects*

*Source: Company data*

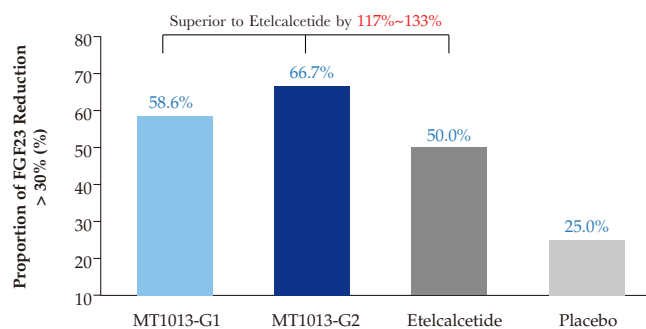
The efficacy data showed that MT1013 was superior to Etelcalcetide both in terms of absolute reduction in FGF-23 and the proportion of subjects with a > 30% reduction in FGF-23 (statistical difference was not achieved due to the small sample size). This trend is consistent with the trend of superior composite achievement rate of iPTH/serum calcium/serum phosphorus over Etelcalcetide. Showing that MT1013 has the potential to significantly reduce the incidence of cardiovascular events and the risk of death.

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**Figure: Reduction Rate (%) of FGF23 from Baseline in Each Group at W27 (Mean±SEM)**

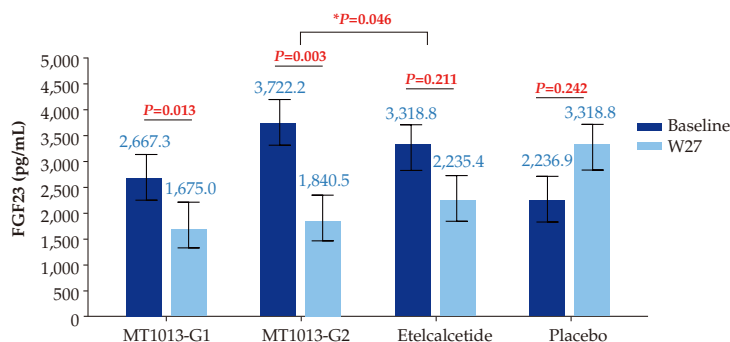
Notes: Treatment groups at W27 N=27-30/group, placebo group N=8



**Figure: Proportion of Subjects (%) with > 30% Reduction in FGF-23 from Baseline in Each Group at W27**

Note: W27: treatment groups N=27-30 per group; placebo group N=8

Source: Company Data



**Figure: Change in FGF23 (pg/mL) in Each Group Before and After Treatment (Mean±SEM)**

Treatment groups at W27 N=27-30/group, placebo group N=7. \*P=0.046: For the log value of change from baseline at W27, MT1013 was significantly superior to etelcalcetide

Source: Company data

**MT1013-III-C01**

**Overview:** This is a Phase III clinical study of MT1013 for injection for the treatment of patients with SHPT Undergoing Maintenance Hemodialysis, aiming to evaluate the safety and efficacy of MT1013. The primary endpoint 1 was the proportion of subjects achieving a reduction of >50% in serum iPTH from baseline during the EAP with MT1013 compared to Cinacalcet. The primary endpoint 2 was the proportion of subjects achieving a reduction of > 30% in serum iPTH from baseline during the EAP with MT1013 compared to Cinacalcet.

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**Trial design:** A multi-center, randomized, double-blind, double-dummy clinical study with cinacalcet as the active comparator. The study population comprises subjects with SHPT Undergoing Maintenance Hemodialysis. It is planned to enroll 424 subjects, randomized 1:1 into the MT1013 group and the cinacalcet group, to receive either MT1013 + cinacalcet placebo or cinacalcet + MT1013 placebo, respectively. MT1013/MT1013 placebo: Subjects undergo regular hemodialysis three times a week. After each dialysis session, MT1013 is administered directly through the venous line of the dialysis circuit or intravenously after the full flush is complete, for 26 consecutive weeks. Cinacalcet/cinacalcet placebo: Except for the post-dialysis dose on D1, subjects take cinacalcet orally with or after a meal once a day (QD). It is recommended to take the medication at the same time each day, ensuring an interval of  $\geq 12$  hours before iPTH blood sampling, for 26 consecutive weeks. Subjects will enter a 4-week safety follow-up period after the last dose.

A total of 424 subjects are planned to be enrolled in this trial. The key inclusion criteria included, among others: (1) subjects who fully understood and voluntarily agreed to participate in the study and signed the informed consent form; (2) male or female subjects aged 18 years or above at the time of signing the informed consent form, with BMI between 18 kg/m<sup>2</sup> and 35 kg/m<sup>2</sup>, calculated based on post-dialysis body weight; (3) subjects who had been receiving regular maintenance hemodialysis three times per week for at least 12 weeks prior to screening, and had undergone adequate dialysis within four weeks prior to screening, defined as a urea clearance index (Kt/V)  $\geq 1.2$  or urea reduction ratio (URR)  $\geq 65\%$ , with each dialysis session lasting 3 to 4.5 hours (inclusive). The key exclusion criteria included but were not limited to: (1) subjects who had undergone parathyroidectomy within six months prior to screening or who planned to undergo parathyroidectomy, ablation, radiation or other related treatments during the study period; (2) subjects with a history of gastrointestinal bleeding or peptic ulcer within six months prior to screening; (3) subjects with a history of myocardial infarction, percutaneous coronary intervention or coronary artery bypass grafting within six months prior to screening.

**Trial status:** The Phase III clinical trial was initiated in July 2025 and as of the Latest Practicable Date, a total of 392 subjects had been enrolled.

### *Clinical Development Plan*

In May 2025, MT1013 completed the Phase II-C01 clinical study for SHPT in the PRC and has entered a Phase III clinical study with cinacalcet as a comparator. It is the world's first and only dual-functional polypeptide drug to have completed Phase II clinical studies. The ongoing Phase III clinical trial, in addition to evaluating the primary efficacy endpoints, also places special focus on changes in bone metabolism-related parameters. We plan to seek marketing approval for MT1013 with the treatment of SHPT Undergoing Maintenance Hemodialysis. We expect to submit a Pre-NDA in late 2026, and an NDA in early 2027.

Concurrently, we are actively expanding the indications for our Core Product MT1013 into areas such as CKD-MBD with Osteoporosis and SHPT not on Dialysis. MT1013 not only demonstrates outstanding performance in controlling mineral levels such as iPTH, serum calcium, and serum phosphorus, but the results of the phase-II clinical trial also show a positive effect on improving bone mineral density, particularly significant in high-risk patients with osteopenia. For more information of the clinical results, see "Business — Clinical Trial Overview of MT1013". This clinical benefit not only validates the potential clinical value of MT1013 in the treatment of bone diseases related to mineral metabolism disorders but also lays the foundation for its development for broader indications within CKD-MBD. We plan to leverage data collected from the phase II clinical trials to seek IND approvals from competent regulatory authorities to conduct Phase III clinical trial of MT1013 for the expanded indication of CKD-MBD with Osteoporosis.

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The table below sets out our clinical development plan:

Indication	Current Status/Trial Phase	Location	Upcoming Milestones
SHPT . . . . .	MT1013-I-C03 PRC Phase I Mass Balance Study	PRC	Expected to complete by mid-2026
	MT1013-II-C02 PRC Phase IIb Long-Term Dosing Study (Supportive Phase III Clinical Study)	PRC	Expected to complete by end of 2026
	MT1013-III-C01 Confirmatory Phase III Study with Cinacalcet as Active Comparator	PRC	Expected to complete by the end of 2026; Expected to submit Pre-NDA in late 2026, and NDA in early 2027.
CKD-MBD with Osteoporosis . . .	IND in preparation	PRC	Expected to commence Phase III clinical trial in early 2028
SHPT not on Dialysis . . . . .	IND in preparation	PRC	Expected to file IND by the end of 2027

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**Material Communications**

As of the Latest Practicable Date, we had not received any objection from any relevant regulatory authorities to our clinical development plans.

The table below sets out our key regulatory communications with regulatory authorities regarding the development of MT1013 for the treatment of SHPT:

Study	Study number	Phase	Competent authorities	Study sites	Details of communications	Status
SHPT	MT1013-I-A01	I	FDA	US	<p>(i) In January 2021, we filed IND application with the FDA for MT1013 for the treatment of SHPT. The FDA subsequently initiated the technical review of the IND submission and did not raise any further comments on the clinical trial protocol during the review process.</p> <p>(ii) In March 2021, the FDA issued Study May Proceed Letter to allow us to proceed the Phase I clinical study to evaluate the safety, tolerability, pharmacokinetics and preliminary pharmacodynamics of MT1013 in healthy subjects.</p>	Completed: we achieved each objective set out in the clinical trial overview on June 21, 2022.
	MT1013-I-C02	I	NMPA	PRC	<p>(i) In April 2021, we filed an IND application with the NMPA for the clinical development of MT1013 for the treatment of SHPT, and the NMPA accepted our IND application in the same month.</p> <p>(ii) In July 2021, the NMPA issued an umbrella IND approval for Phase I, Phase II and Phase III clinical studies of MT1013 for the treatment of SHPT, and required us to (1) revise the Phase I clinical trial protocol under this application with particular attention to the starting dose, which was recommended to be set with at least a tenfold safety margin; (2) closely monitor the potential risks of the product and strictly implement the risk management plan; (3) closely track the development progress of drugs with similar targets and, based on the existing non-clinical and clinical data of the product, evaluate its efficacy and safety profile and ensure adequate risk control and subject protection; and (4) apply for a communication meeting with the CDE upon the completion of Phases I and II clinical trials before commencing the Phase III clinical trial.</p>	Completed: we achieved each objective set out in the clinical trial overview on September 24, 2022.
	MT1013-I-C03 <sup>(1)</sup>	I	NMPA	PRC	<p>(i) In March 2025, we submitted a communication meeting application to the CDE for the mass balance study of MT1013.</p> <p>(ii) In August 2025, we reached a consensus with the CDE on the clinical trial protocol of the mass balance study.</p>	Ongoing (enrollment of all six subjects has been completed as of the Latest Practicable Date) and is expected to be completed by mid-2026.

**BUSINESS**

Study	Study number	Phase	Competent authorities	Study sites	Details of communications	Status
	MT1013-II-C01	II	NMPA	PRC	<p>(i) In September 2022, the initial clinical study report (CSR) of MT1013-I-C02 was issued, marking the completion of the Phase I clinical trial. In October 2022, we submitted an application to the CDE for an end-of-Phase I (EOP1) communication meeting to seek guidance on the initiation of the Phase II clinical trial of MT1013.</p> <p>(ii) In January 2023, based on the results of our Phase I clinical study (MT1013-I-C02), the CDE, in its written feedback, had no objection for the Company to proceed with the Phase II clinical study to further evaluate the efficacy and safety of MT1013 in patients with SHPT, with a view to providing a basis for determining the dosing regimen and dosage for the confirmatory Phase III clinical study.</p>	Completed: we achieved each objective set out in the clinical trial overview for the SAD and MAD studies on April 8, 2025, and for the long-term cohort on August 25, 2025.
	MT1013-II-C02	IIb <sup>(2)</sup>	NMPA	PRC		Ongoing <sup>(3)</sup> (enrollment of all 350 subjects completed as of the Latest Practicable Date) and is expected to be completed by the end of 2026.
	MT1013-II-C03	II	NMPA	PRC	<p>(i) In February 2024, upon completion of the single-ascending-dose and multiple-ascending-dose Phase II clinical studies (MT1013-II-C01), we submitted the first end-of-Phase II (EOP2) communication meeting application to the CDE to seek guidance on the initiation of the Phase III clinical trial of MT1013.</p> <p>(ii) In July 2024, based on the results of the existing Phase II clinical studies, the CDE recommended conducting a small-scale comparative study of MT1013 in comparison with Etelcalcetide and placebo to further justify the rationale of the starting dose, titration scheme and dose adjustment, and to provide supportive data for the subsequent confirmatory Phase III clinical study.</p> <p>(iii) In July 2024, we initiated the MT1013-II-C03 study based on the recommendation of the CDE.</p>	Completed: we achieved each objective set out in the clinical trial overview in March 2026.

**BUSINESS**

Study	Study number	Phase	Competent authorities	Study sites	Details of communications	Status
	MT1013-III-C01	III	NMPA	PRC	(i) In May 2025, upon completion of the Phase II clinical study (MT1013-II-C01) and obtaining part of the key data from the MT1013-II-C02 and MT1013-II-C03 studies, we submitted another end-of-Phase II (EOP2) communication meeting application to the CDE to seek guidance on the initiation of the Phase III clinical trial of MT1013.	Ongoing and is expected to be completed by the end of 2026.
					(ii) In June 2025, based on the Phase II study results of MT1013, which demonstrated efficacy comparable to the marketed calcimimetics, the CDE had no objection for the initiation of the confirmatory Phase III clinical trial and specified certain key elements of the Phase III clinical trial protocol. Further, a consensus was reached with the CDE that, if the Phase III clinical trial of MT1013 achieves the expected results, the subject exposure level would be sufficient to support the subsequent NDA submission and approval.	

*Notes:*

- (1) The ongoing Phase I clinical trial (MT1013-I-C03) is a mass balance study designed to quantitatively analyze the total radioactivity, radioactive metabolite profiles, pharmacokinetic parameters and safety following intravenous administration of [<sup>14</sup>C] MT1013. This mass balance study is a supportive pharmacokinetic study primarily intended to supplement the completeness of the new drug registration dossier and does not involve efficacy validation or dose determination. Accordingly, it will not affect the validity of the results of clinical studies conducted thereafter. As confirmed by Frost & Sullivan, such supplementary mass balance studies are commonly undertaken in the industry and are considered optional pharmacokinetic-supportive studies that are not necessarily required for registration and are conducted on a discretionary basis. Additionally, the Directors confirm that consensus on the study design was reached with the CDE during the communication meeting, and that such study arrangement complies with regulatory requirements and is consistent with industry practice.
- (2) The MT1013-II-C02 trial is a Phase IIb study designed to evaluate the safety and efficacy of MT1013. In the event that such study is not completed as scheduled or the study results are not satisfactory, it would not affect the validity of the existing Phase III clinical trial data. Nevertheless, the Company will continue to summarize and submit the interim safety and efficacy data in accordance with the clinical trial protocol to support the completeness of the new drug registration dossier.
- (3) The MT1013-II-C02 trial was initiated in March 2024 and enrollment of all 350 subjects was completed as of the Latest Practicable Date. The relatively extended enrollment period was mainly due to the increase in the planned sample size, as the study initially planned to enroll approximately 100 subjects and, based on the feedback from the CDE during the EOP2 communication, the Company increased the number of subjects by approximately 250 to achieve the required patient exposure level, resulting in a total sample size of approximately 350 subjects.

Based on the completion of the Phase I clinical trial (MT1013-I-C02) for the treatment of SHPT in the PRC, and CDE having no objection for the Company to proceed into Phase II clinical trials, the Company's clinical development demonstrates that for SHPT, MT1013 has been developed beyond concept stage and is eligible as Core Product.

**WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET MT1013 SUCCESSFULLY**

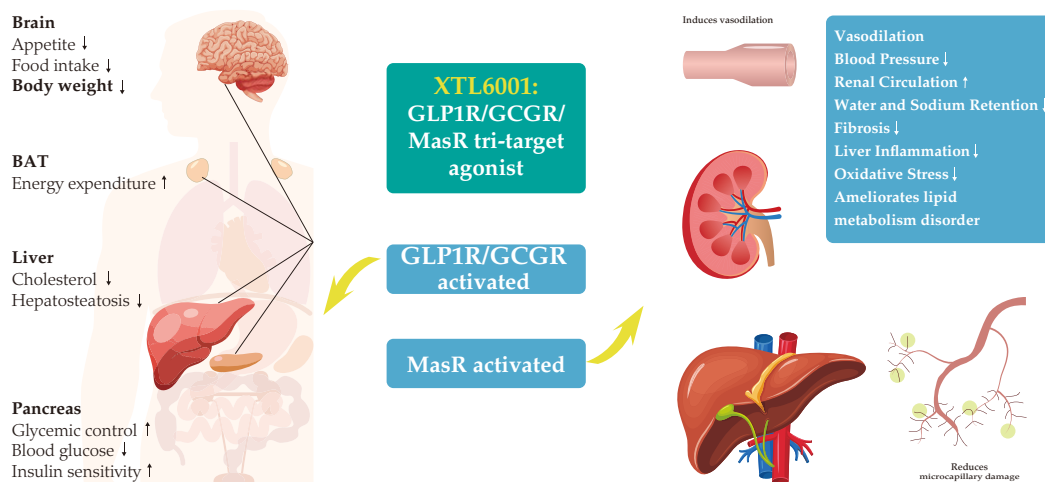
## BUSINESS

### Our Key Product — XTL6001

Our Key Product, XTL6001, is a GLP-1R/GCGR/MasR triple-agonist that has received IND approval in both the PRC and the US and has entered the clinical trial stage, with potential applications in the treatment of diseases such as obesity, chronic kidney disease (CKD) with proteinuria, and MASH. Through its innovative mechanism, XTL6001 is expected to address issues associated with current GLP-1 weight-loss drugs, such as muscle loss, appetite suppression or GI side effect, and rebound after drug withdrawal, offering a new multi-organ protective therapeutic option for metabolic diseases.

#### Mechanism of Action

XTL6001 is a recombinant tri-target peptide-Fc fusion protein that activates GLP-1R, GCGR and MasR to exert pharmacological effects.



#### • Effect of XTL6001 on Chronic Weight Management in Obese or Overweight Populations

GLP-1R activation can slow down gastric emptying, and increase satiety signals to reduce food intake; Upon activation, GCGR acts on the liver to inhibit insulin secretion and stimulate hepatic gluconeogenesis and glycogenolysis, promoting fatty acid oxidation, regulating purine metabolism, and stimulating lipid catabolism and metabolic processes to reduce body fat. The energy expenditure effect from GCGR activation and the food intake reduction effect from GLP-1 receptor activation can synergistically reduce body weight. Activation of MasR also promotes brown adipose tissue mass, improves thermogenesis, reduces lipid droplets, promotes lipolysis, reduces inflammation, improves overall thermogenesis, and increases muscle mass. Upon activation, renal MasR leads to vasodilation, lowers blood pressure, improves renal circulation, reduces water and sodium retention, ameliorates liver and kidney inflammation, reduces fibrosis, and alleviates oxidative stress.

Therefore, the GLP-1R, GCGR, and MasR triple-agonist XTL6001, through multi-target synergy promotes lipolysis, increases muscle mass (fat reduction and muscle gain), thereby potentially achieving sustained weight loss.

#### Source:

- (1) Proença AB, et al. Adipose tissue plasticity mediated by the counterregulatory axis of the renin-angiotensin system: Role of Mas and MrgD receptors. *J Cell Physiol*. 2024 Jun;239(6):e31265
- (2) Gironacci MM, et al. Unraveling the crosstalk between renin-angiotensin system receptors. *Acta Physiol (Oxf)*. 2024 May;240(5):e14134
- (3) Passos-Silva DG, Verano-Braga T, Santos RA. Angiotensin-(1-7): beyond the cardio-renal actions. *Clin Sci (Lond)*. 2013 Apr;124(7):443-56. doi: 10.1042/CS20120461. PMID: 23249272

## BUSINESS

- *Effect of XTL6001 on Proteinuric CKD*

XTL6001 exerts synergistic effects after multi-target activation. It can simultaneously regulate glomerular hemodynamics and protect mechanically sensitive podocytes, directly targeting the pathophysiological mechanisms of CKD onset and progression to protect renal function. It directly improves hemodynamics by activating MasR and GLP-1R, reducing glomerular capillary pressure and protecting the filtration barrier; It exerts stronger anti-inflammatory and anti-fibrotic effects by activating MasR and GLP-1R, reducing glomerular and tubulointerstitial damage; Activation of MasR can combat oxidative stress, directly protect podocytes, inhibit podocyte apoptosis and nephrin loss, and repair the filtration barrier; In addition, GCGR/GLP-1R/MasR activation can reduce weight and improve insulin resistance, inhibit uric acid synthesis, and promote uric acid excretion, thereby ameliorating the hyperuricemia common in CKD patients and further protecting renal function by mitigating kidney damage caused by high uric acid; Other indirect effects stem from its potential beneficial effects on blood glucose, lipids, and blood pressure.

Source:

- (1) Kanbay M, Copur S, Bakir CN, Covic A, Ortiz A, Tuttle KR. Glomerular hyperfiltration as a therapeutic target for CKD. *Nephrol Dial Transplant.* 2024 Jul 31;39(8):1228-1238
- (2) Simões E Silva AC, Teixeira MM. ACE inhibition, ACE2 and angiotensin-(1-7) axis in kidney and cardiac inflammation and fibrosis. *Pharmacol Res.* 2016 May;107:154-162
- (3) Barroso LC, Silveira KD, Lima CX, Borges V, Bader M, Rachid M, Santos RA, Souza DG, Simões E Silva AC, Teixeira MM. Renoprotective Effects of AVE0991, a Nonpeptide Mas Receptor Agonist, in Experimental Acute Renal Injury. *Int J Hypertens.* 2012;2012:808726
- (4) Lu J, Chen G, Shen G, Ouyang W. Ang-(1-7) attenuates podocyte injury induced by high glucose in vitro. *Arch Endocrinol Metab.* 2023 Jun 19;67(6):e000643

- *Effect of XTL6001 on MASH*

XTL 6001 combines the extrahepatic benefits of GLP-1 receptor agonism (glycemic control, appetite reduction, and weight loss) with the direct hepatic effects of glucagon receptor agonism (increased energy expenditure, lipolysis, and hepatic fat mobilization), creating a powerful synergy of complementary advantages. Activation of Ang1-7/MasR can activate AMP-activated protein kinase (AMPK), inhibit HSC activation, and accelerate HSC apoptosis, thereby inhibiting and blocking the pathogenesis and progression of liver fibrosis. Therefore, the GLP-1R, GCGR, and MasR triple-agonist XTL6001, through synergistic effects, is expected to comprehensively improve MASH and block its progression.

Source:

- (1) Spezani R, Mandarim-de-Lacerda CA. The current significance and prospects for the use of dual receptor agonism GLP-1/glucagon. *Life Sci* 2022;288:120188
- (2) Valdecantos MP, Pardo V, Ruiz L, Castro-Sánchez L, Lanzón B, Fernández-Millán E, García-Monzón C, Arroba AI, González-Rodríguez A, Escrivá F, Alvarez C, Rupérez FJ, Barbas C, Konkar A, Naylor J, Hornigold D, Santos AD, Bednarek M, Grimsby J, Rondinone CM, Valverde AM. A novel glucagon-like peptide 1/glucagon receptor dual agonist improves steatohepatitis and liver regeneration in mice. *Hepatology.* 2017 Mar;65(3):950-968
- (3) Wu Y, Yin AH, Sun JT, Xu WH, Zhang CQ. Angiotensin-converting enzyme 2 improves liver fibrosis in mice by regulating autophagy of hepatic stellate cells. *World J Gastroenterol.* 2023 Sep 7;29(33):4975-4990

### **Market Opportunities and Competition**

#### *Overweight and Obesity*

Overweight and obesity are chronic diseases characterized by excessive fat accumulation that poses risks to health. These conditions are the major contributors to various other health issues, such as diabetes and cardiovascular diseases. The global prevalence of overweight and obesity patients is projected to reach 3,070.6 million by 2030 and 3,477.2 million by 2035, while in the PRC it is projected to reach 756.5 million by 2030 and 860.5 million by 2035. As of the Latest Practicable Date, there are 13 triple-target GLP-1R peptide drug candidates for overweight and obesity in the clinical stage globally.

**BUSINESS**

Among these, 11 drug candidates target GLP-1R,GCGR and GIPR, while one drug targets GLP-1R,GCGR and FGF21. XTL6001, our GLP-1R drug candidate, is the only triple-target GLP-1R peptide drug candidate targeting GLP-1R, GCGR and MasR. Agonizing MasR can increase protein synthesis and preserve muscle mass. XTL6001 holds the potential to eliminate the side effect of muscle loss associated with GLP-1R agonists during weight loss. For more information, see "Industry Overview — Main treatment of Overweight and Obesity" and "Industry Overview — Competitive landscape of GLP1R polypeptide drugs."

*Proteinuric CKD*

In the PRC, the prevalence of CKD with proteinuria grew from 74.6 million in 2019 to 80.8 million in 2024 at a CAGR of 1.6% and is projected to reach 87.5 million by 2030 and 92.9 million by 2035. For more information on the treatment of Proteinuric CKD, see "Industry Overview — Overview of CKD with Proteinuria."

*MASH*

In the PRC, the prevalence of MASH grew from 37.1 million in 2019 to 44.0 million in 2024 at a CAGR of 3.5% and is projected to reach 53.7 million by 2030 and 63.1 million by 2035. For more information on the treatment of MASH, see "Industry Overview — Overview of MASH."

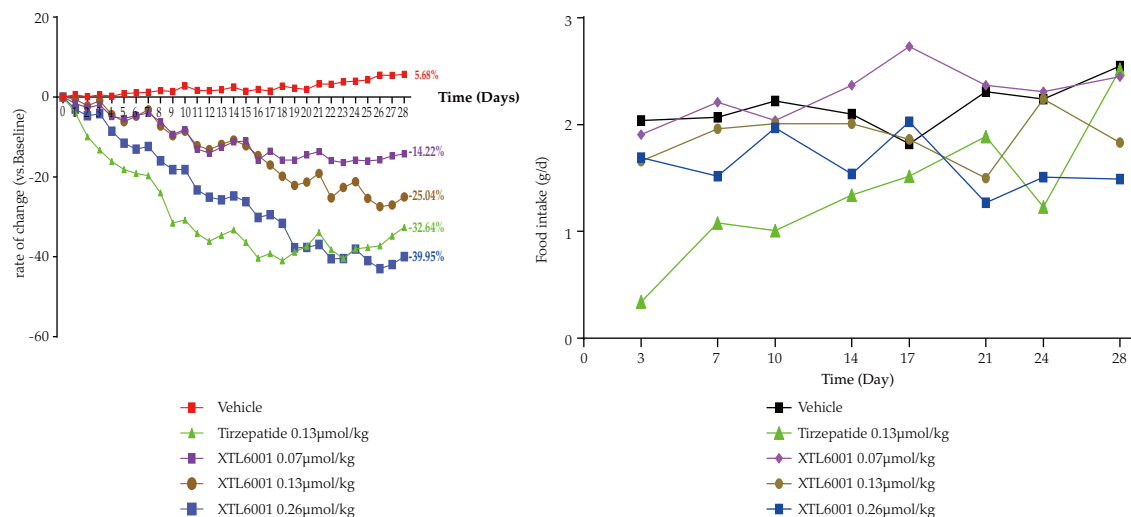
*Competitive Advantages*

*Chronic Weight Management in Obese or Overweight Populations*

- (1) Focus on a weight-loss mechanism through enhanced energy metabolism

XTL6001 achieves weight loss primarily by increasing energy expenditure rather than by strongly suppressing appetite. Compared to other GLP-1 class drugs that primarily rely on delaying gastric emptying, XTL6001 has the potential to significantly reduce gastrointestinal adverse reactions while achieving weight loss.

Preclinical studies have shown that XTL6001 can progressively, dose-dependently, and significantly reduce the body weight of diet-induced obesity (DIO) mice without significantly affecting food intake, attributable to its mechanism of promoting energy expenditure to achieve weight control, which may improve tolerability and treatment adherence while achieving weight reduction.



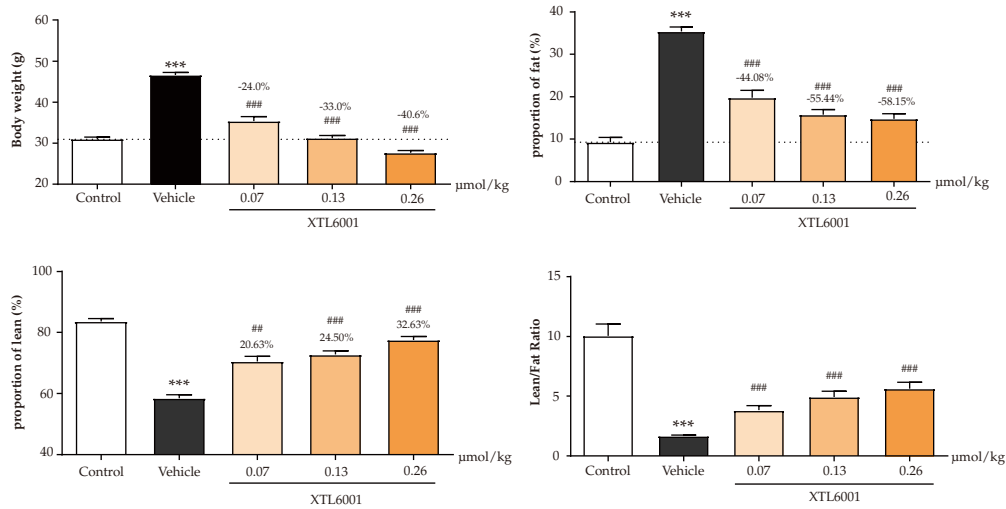
**Effects of XTL6001 vs. Tirzepatide on body weight and food intake in a DIO mouse model (n=12)**

Source: Company data

**BUSINESS**

(2) Precise fat reduction and effective prevention of muscle loss

The preclinical study has shown that XTL6001 dose-dependently reduces body weight and total fat mass, increases total lean body mass, and raises the total lean mass/fat mass ratio to normal levels in DIO mice.



**Effect of XTL6001 on total lean body mass and fat mass (MRI) (n=10)**

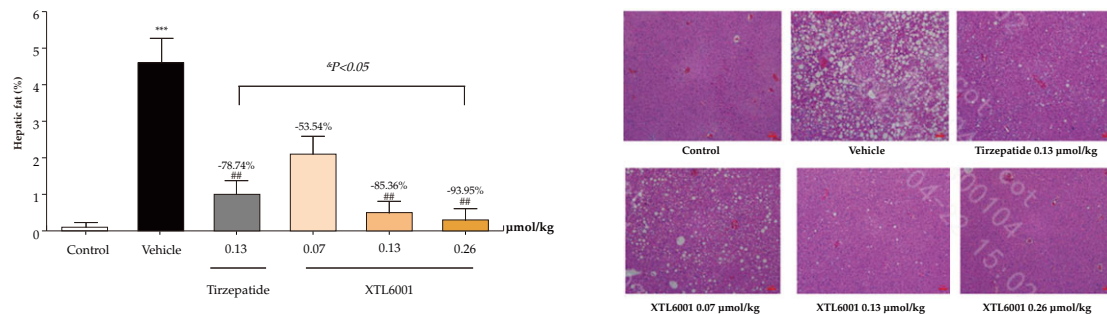
\*\*\*P<0.001 vs. Control; ##P<0.01; ###P<0.001 vs. Vehicle

Source: Company data

Phase I clinical trial results further suggest that XTL6001 may reduce waist circumference and waist-to-hip ratio (WHR), with effects observed to persist following treatment discontinuation. For more information, see “— Clinical Trial Overview of XTL6001” below in this section.

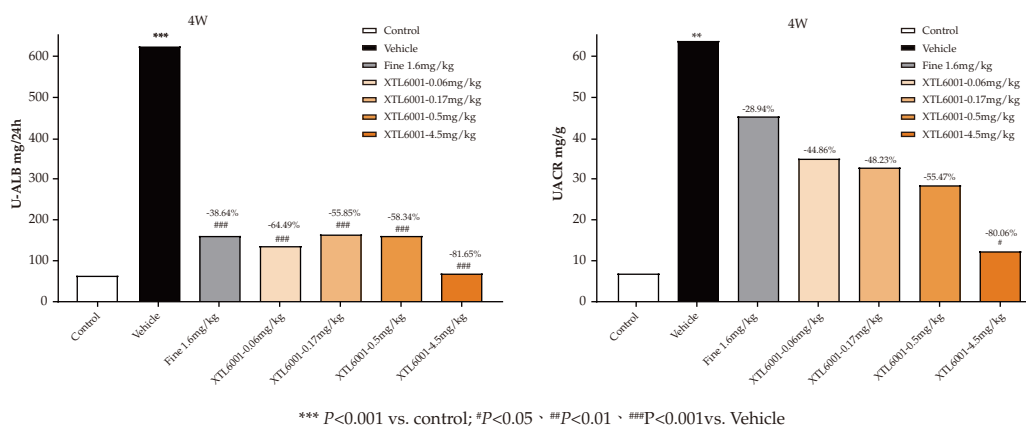
(3) Significantly lowers blood lipids, hepatic lipids, and uric acid; reverses fatty liver; reduces proteinuria; and addresses obesity-related organ damage

Preclinical studies have shown that compared to Tirzepatide, XTL6001 is superior in reversing fatty liver (reducing hepatic fat by over 93.95%) (Figure 1). In comparison with Finerenone, XTL6001 reduced urinary albumin-to-creatinine ratio (UACR) by an additional 15% to 50% (Figure 2).



**Figure 1: Effect of XTL6001 on hepatic fat in DIO obese mice (vs. Tirzepatide, n=12)**

**BUSINESS**



**Figure 2: In a rat model of diabetic nephropathy with proteinuria induced by alloxan combined with unilateral nephrectomy, the reduction rate of UACR by XTL6001 was 15% to 50% higher than that of finerenone. (n=12)**

Source: Company data

Phase I clinical trial results further suggest that XTL6001 may improve lipid profiles and reduce serum uric acid levels, with increases in uric acid clearance observed. For more information, see “— Clinical Trial Overview of XTL6001” below in this section.

(4) Favorable safety and potential for long-acting administration

Phase I study results showed that XTL6001 exposure increases with dose escalation, and once-weekly dosing maintained effective plasma drug concentrations for over one week. Safety data showed that XTL6001 has a good overall safety profile, with no serious adverse events (SAEs) occurring. Apart from the expected pharmacodynamically-related gastrointestinal adverse reactions (which were transient and dose-dependent) associated with GLP-1 class drugs at high doses, no other significant safety signals were observed. For more information of the clinical results, see “— Clinical Trial Overview of XTL6001” below in this section.

**Clinical Trial Overview of XTL6001**

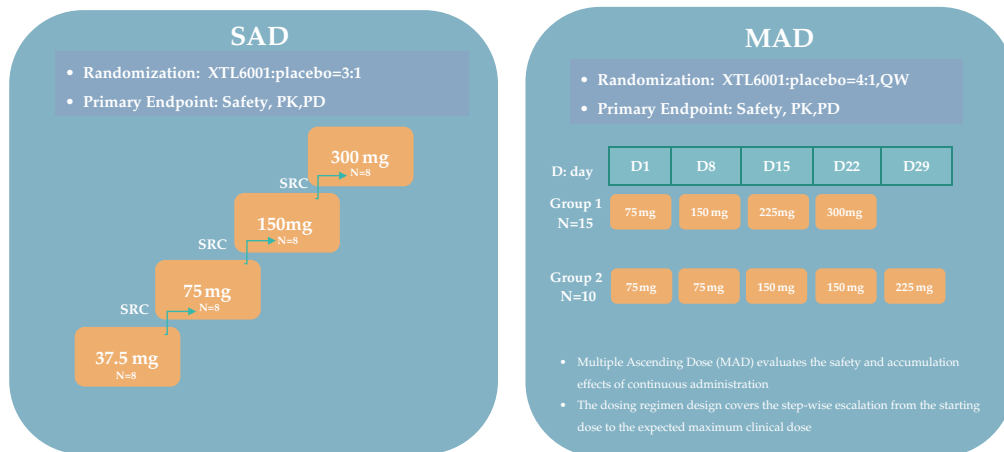
*XTL6001-I-C01 PRC Phase I Clinical Study*

**Overview:** This is a randomized, double-blind, placebo-controlled Phase I clinical trial involving single ascending dose (SAD) and multiple ascending dose (MAD) in healthy and obese subjects. Its primary objective was to evaluate the safety and tolerability, and the secondary objective was to characterize the pharmacokinetics, pharmacodynamics and immunogenicity of XTL6001, to inform optimal dose selection and dosing regimen for Phase II studies.

**BUSINESS**

**Trial design:**

**A randomized, double-blind, SAD and MAD Phase I clinical study in healthy volunteers**



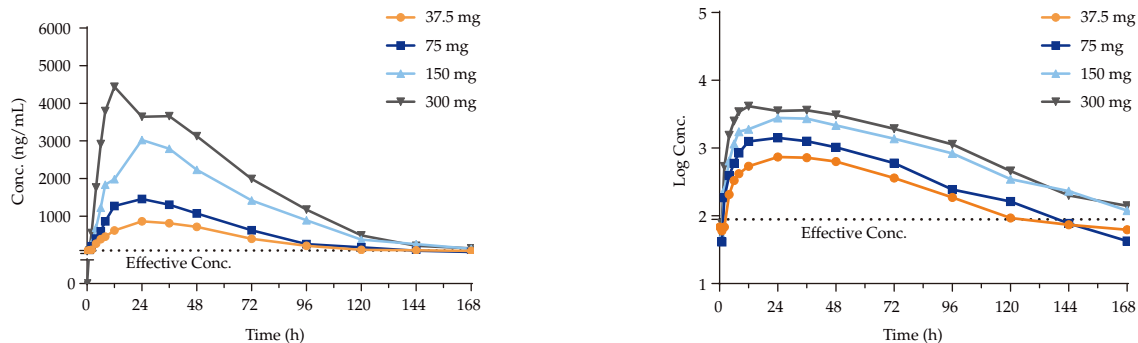
A total of 57 subjects are planned to be enrolled in this trial. The key inclusion criteria included: (1) subjects aged 18 years or above and below 65 years at the time of screening; (2) subjects with BMI of no less than 18.5 kg/m<sup>2</sup> and below 40.0 kg/m<sup>2</sup>; and (3) subjects with a body weight of no less than 50.0 kg for males and no less than 45.0 kg for females at screening. The key exclusion criteria included but were not limited to: (1) subjects with a history of type I or type II diabetes mellitus, or with glycated hemoglobin (HbA1c) > 6.5% or fasting plasma glucose > 7.0 mmol/L at screening; (2) subjects who had used prescription or over-the-counter (OTC) medications known to cause weight loss within three months prior to screening; (3) subjects with known clinically significant gastric emptying disorders, chronic use of medications that directly affect gastrointestinal motility, severe chronic gastrointestinal diseases, or who had undergone gastrointestinal surgery; (4) subjects with a history of acute or chronic pancreatitis, symptomatic gallbladder disease, malignancy within five years prior to screening, medullary thyroid carcinoma, or multiple endocrine neoplasia syndrome type 2A or type 2B.

**Trial status:** The Phase I clinical trial was initiated in June 2025. As of the Latest Practicable Date, the LPLV had occurred and the database lock had been completed.

**Safety data:** XTL6001 demonstrated an overall favorable safety profile. No serious adverse events were reported. Gastrointestinal adverse events were all Grade 1-2, with no treatment discontinuation due to such events, and were dose-related. The incidence of such adverse events may be reduced with a prolonged dose titration period.

**Efficacy data:**

**PK profile:** XTL6001 exposure increases with dose escalation; Peak concentration is reached 20-30 hours post-dose, with an elimination half-life of approximately 30 hours, showing no significant differences between dose cohorts:



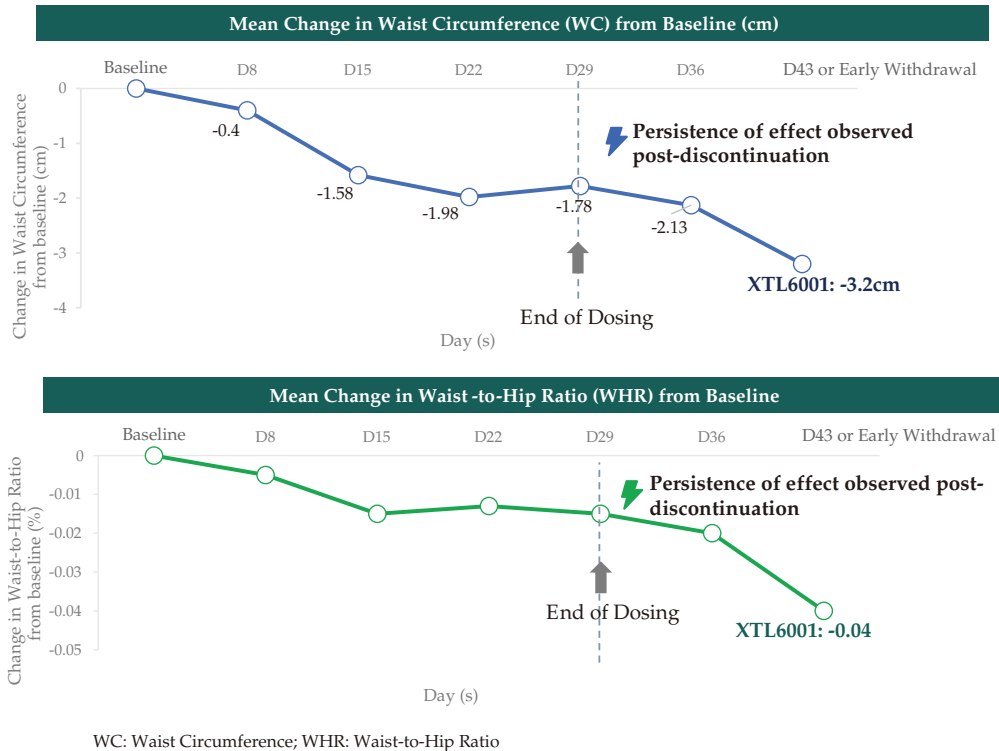
*Drug Time-Concentration and Semi-logarithmic Plots of XTL6001-I-C01 SAD Study (N=6/group)*

**BUSINESS**

**Effective drug concentration maintained for >1 week:** doses  $\geq 150$  mg can maintain this effective concentration for over 168 hours (7 days), meeting the requirement for once-weekly administration.

Reductions in Waist Circumference and Waist-to-Hip Ratio: in the MAD cohort, after 4-5 weeks of treatment, subjects with BMI  $< 28$  kg/m<sup>2</sup> achieved a body weight reduction of 2.06% to 2.21%. In obese subjects (BMI  $\geq 28$  kg/m<sup>2</sup>), waist circumference decreased by approximately 2 cm, and waist-to-hip ratio (WHR) decreased by 0.015. The reductions were sustained after treatment discontinuation: at two weeks following the last dose, the total reduction reached 0.04 in WHR and 3.2cm in waist circumference.

The results indicate that XTL6001 leads to a substantially greater reduction in waist circumference (visceral fat) compared to changes in hip circumference (subcutaneous fat and muscle mass).

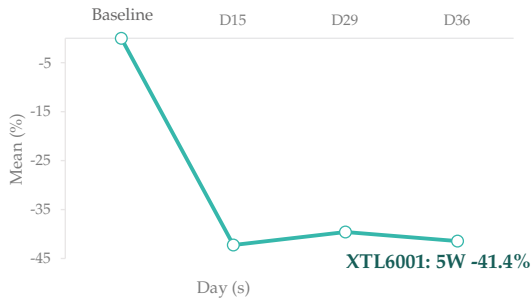


Source: Company data

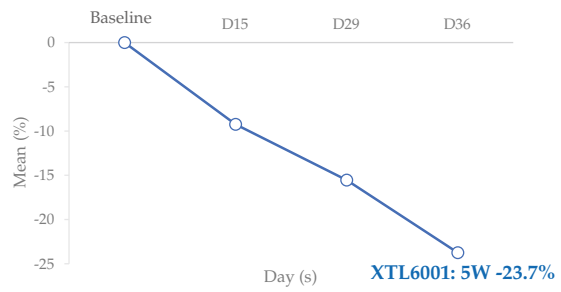
Reductions in Atherogenic Lipid Parameters: Compared with baseline, in obese subjects, XTL6001 reduced triglycerides (TG) by 41.4%, low-density lipoprotein cholesterol (LDL-C) by 30%, and apolipoprotein B (ApoB) by 26.6% at Week 5, suggesting a rapid and robust lipid-lowering effect.

**BUSINESS**

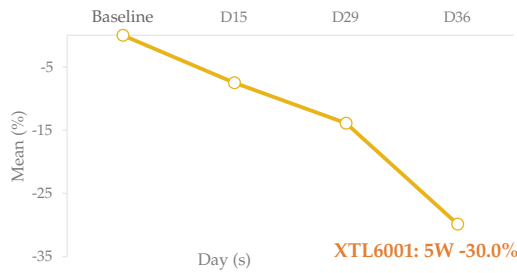
**TG (Triglycerides) %:**



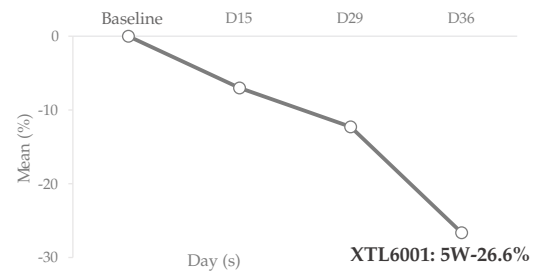
**TC (Total Cholesterol) %**



**LDL-C (Low-Density Lipoprotein Cholesterol) %**



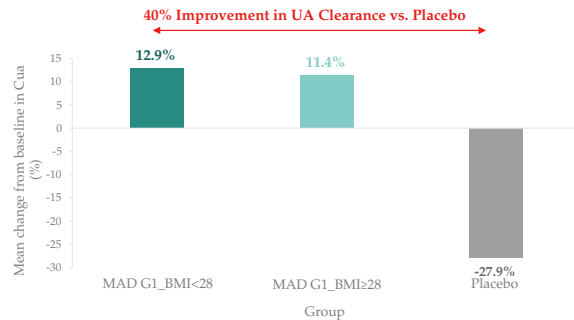
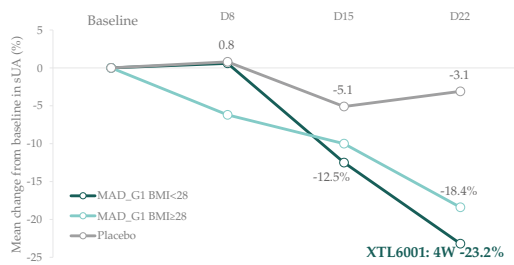
**ApoB (Apolipoprotein B) %**



MAD Group 2 (BMI ≥ 28) | Mean Percent Change from Baseline (%), N=8

*Note:* The potent lipid-lowering signals observed in healthy volunteers with normal baseline levels

**Reduction in Serum Uric Acid (sUA) Levels:** Compared with baseline, after four weeks of treatment with XTL6001, sUA levels in all subjects decreased by 18.4% to 23.2%, as compared to a reduction of 3.1% in the placebo group. Uric acid clearance increased by approximately 40% compared with placebo. These results suggest that XTL6001 may reduce sUA levels by decreasing uric acid production and promoting its excretion.



Source: Company data

**BUSINESS**

***Clinical Development Plan***

The following table sets forth the planned clinical studies and plans for XTL6001 for the treatment of obesity/weight loss, CKD with proteinuria, and MASH:

Indication	Clinical Trial	Location	Upcoming Milestones
Chronic Weight Management in Obese or Overweight Populations . . . . .	A randomized, double-blind, controlled Phase II clinical trial to evaluate the efficacy, safety, and pharmacokinetics of XTL6001 for injection in obese/overweight subjects. Sample size of approximately 240 subjects.	PRC	The trial is planned to be initiated in the third quarter of 2026 and is expected to be completed in the third quarter of 2027.
Proteinuric CKD . . . .	A randomized, double-blind, controlled Phase II clinical trial to evaluate the efficacy, safety, and pharmacokinetics of XTL6001 for injection in subjects with chronic kidney disease and proteinuria. Sample size of approximately 150 subjects	PRC	The trial is planned to be initiated in mid 2027 and is expected to be completed in the fourth quarter of 2027.
MASH . . . . .	IND preparation stage	PRC	IND application expected in early 2027

***Material Communications***

As of the Latest Practicable Date, we had not received any objection from any relevant regulatory authorities to our clinical development plans.

The following table sets forth our important regulatory communications with regulatory authorities regarding the development of XTL6001 for the treatment of obesity/weight loss and CKD with proteinuria:

Indication	Time	Regulatory Authority	Details
Chronic Weight Management in Obese or Overweight Populations . . . . .	2024.5	FDA	IND Submission
	2024.12.20	FDA	IND Approval
	2025.2.12	NMPA	IND Submission
	2025.4.22	NMPA	IND Approval
Proteinuric CKD . . .	2025.4.21	NMPA	IND Submission
	2025.6.30	NMPA	IND Approval

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET XTL6001 SUCCESSFULLY

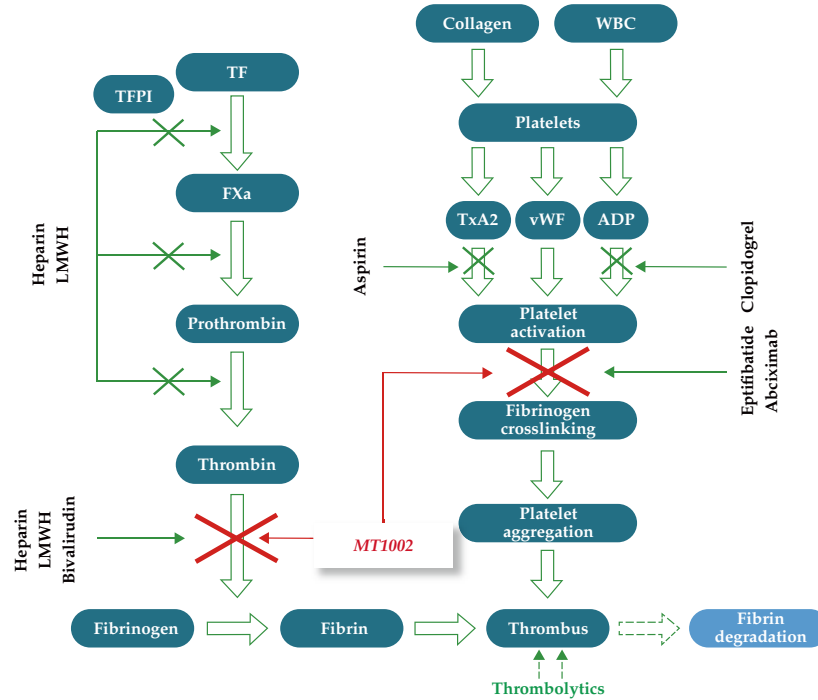
**Our Key Product — MT1002**

Our Key Product, MT1002, is the world’s first dual antagonist of coagulation factor II and the GP IIb/IIIa receptor, primarily targeting clinical needs in anticoagulation and anti-thrombosis for indications such as ACS-PCI, Stroke, HD and HD-PF4.

**BUSINESS**

**Mechanism of Action**

MT1002 simultaneously antagonizes coagulation factor II and GPIIb/IIIa, possessing dual effects of anticoagulation and anti-platelet aggregation. It inhibits thrombosis through dual pathways and has clinical advantages such as rapid onset, convenient administration, no need for frequent monitoring, no dose adjustment required in patients with hepatic or renal impairment, and rapid recovery of parameters after discontinuation without affecting normal coagulation and platelet function.



Source: Company data

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

GPIIb/IIIa (integrin  $\alpha$ Ib $\beta$ 3, an integrin receptor on the platelet membrane) is the primary integrin receptor on the platelet surface. Upon activation of platelets by ADP (adenosine diphosphate, a platelet activator), TXA<sub>2</sub> (thromboxane A<sub>2</sub>, a platelet-secreted pro-aggregatory substance), and vWF (von Willebrand factor, a glycoprotein mediating platelet adhesion), this receptor undergoes a conformational change enabling it to bind fibrinogen (fibrinogen, a plasma protein involved in thrombus formation) or vWF, bridging multiple platelets to form aggregates — this is the core mechanism of white thrombus formation (particularly arterial thrombosis).

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### *Market Opportunities and Competition*

#### *ACS-PCI*

ACS, a type of CHD, refers to a group of conditions that include ST-elevation myocardial infarction (STEMI), non-ST elevation myocardial infarction (NSTEMI), and unstable angina. ACS is related to sudden reduced blood flow to the heart. PCI is a non-surgical, invasive procedure with a goal to relieve the narrowing or occlusion of the coronary artery and improve blood supply to the ischemic tissue. From 2019 to 2024, the volume of PCI procedures worldwide increased from 6.7 million to 9.9 million, at a CAGR of 8.1%. It is estimated that by 2030, the volume of PCI procedures worldwide will reach 15.6 million. From 2019 to 2024, the volume of PCI procedures in China increased from 1.0 million to 1.9 million, at a CAGR of 13.7%. It is estimated that by 2030, the volume of PCI procedures in China will reach 4.0 million.

PCI drugs are primarily used in patients with ACS who are scheduled to undergo PCI. As of the Latest Practicable Date, there were three drugs with an indication for PCI approved by the NMPA and three drugs with an indication for PCI approved by the FDA. In addition, there were nine PCI drug candidates in the clinical stage globally, including MT1002 (currently in Phase II).

#### *Stroke*

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

#### *HD*

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

#### *HD-PF4*

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

### *Competitive Advantages*

- (1) *A direct thrombin + GP IIb/IIIa dual-target antagonist addresses the challenge of balancing bleeding and ischemia in ACS-PCI.*

Unfractionated heparin has a high bleeding risk and large inter-individual variability, and some patients are intolerant to heparin treatment, leading to heparin-induced thrombocytopenia; Certain existing anticoagulants may have a high risk of acute in-stent thrombosis, increasing ischemic risk; Combination therapy (e.g., an anticoagulant plus a GP IIb/IIIa inhibitor) tends to increase bleeding risk, and without an established dosing basis for combined use, it is difficult to balance the risks of bleeding and ischemia. As a "direct thrombin + GP IIb/IIIa dual-target antagonist," MT1002's dual-function polypeptide design may address the challenge of balancing bleeding and ischemia in ACS-PCI. It has demonstrated a favorable efficacy and safety profile in ACS-PCI patients, and has the potential to overcome the limitations of conventional anti-thrombotic regimens.

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In the Phase II clinical trials in the U.S. and the PRC, MT1002 has shown good efficacy and safety at various dose levels. In the U.S. trial, all 6 enrolled patients in the 0.90 mg/kg + 1.8 mg/kg/h × 4 hours dose group successfully completed the PCI procedure without any MACE or major bleeding events. In the PRC trial, all 15 subjects who underwent PCI successfully completed the procedure without any MACE or major bleeding events. Combining the results of both trials, all subjects, under the effect of MT1002's anticoagulant and antiplatelet targets, successfully completed the PCI procedure without any thrombotic or major bleeding events. There were no deaths, SAEs, or early withdrawals due to TEAEs. All adverse events were mild or moderate, fully validating its good safety and efficacy.

- (2) *MT1002 demonstrates dose-dependent anticoagulant and antiplatelet activity with rapid onset and quick recovery after discontinuation. It can fill the therapeutic need in emergency PCI where antiplatelet drugs have not taken effect or patients are unable to take oral medication, while ensuring a good safety profile.*

In the U.S. Phase II clinical trial, the treatment regimen of 0.90 mg/kg + 1.8 mg/kg/h × 4 hours for MT1002 was able to stably maintain the clinical anticoagulation target during the procedure. In the PRC Phase II clinical trial, the pharmacodynamic effect showed anticoagulant activity closely related to the administered dose, taking effect within 5 minutes of administration. PD indicators rapidly returned to near-normal levels within 2 hours after discontinuation, validating MT1002's characteristics of rapid onset and quick recovery after withdrawal. For more information of the clinical results, see "— Clinical Trial Overview of MT1002" below in this section.

- (3) *Stable pharmacokinetic properties and good population adaptability*

MT1002 has demonstrated consistent and stable pharmacokinetic and pharmacodynamic profiles across different populations. The Phase II clinical study showed that the in vivo exposure (C<sub>max</sub> and AUC) of MT1002 in ACS patients increased with dose, demonstrating good dose dependency. The PK curve was consistent with the Phase I results, showing no significant difference at the same dose levels, which supports its stable pharmacokinetic characteristics. PK/PD modeling results further showed that the typical values of ACT and APTT and their 95% confidence intervals were highly consistent between the PRC and U.S. populations under the same dosing regimen, verifying its good comparability across different ethnic groups. Furthermore, MT1002 is primarily metabolized via plasma enzymatic hydrolysis, consistent with the characteristics of a typical polypeptide drug. It is not affected by ethnic differences and demonstrates good population adaptability.

### *Clinical Trial Overview of MT1002*

#### *MT1002-I-C01 U.S. Phase I Clinical Study*

**Overview:** This is a randomized, open-label, sequential parallel-group, single-dose escalation study. Its primary objective was to evaluate the safety and tolerability, and the secondary objective was to characterize the pharmacokinetics and pharmacodynamics of MT1002 in healthy subjects.

**Trial design:** 6 subjects were enrolled in each of the 5 cohorts (a total of 30 subjects) to receive different bolus + infusion doses of MT1002. The total infusion time was 4 hours. Pharmacokinetic and pharmacodynamic parameters were measured at different time points after administration to assess the pharmacokinetic and pharmacodynamic characteristics, while also evaluating the safety and tolerability of MT1002 in healthy subjects. Subjects underwent follow-up until Day 8 from the initiation of dosing. No additional administration was provided during the follow-up period.

A total of 30 healthy subjects were enrolled in this trial. The key inclusion criteria included: (1) male or female subjects aged between 18 and 60 years; (2) provision of written informed consent; (3) BMI between 18.0 and 34.0 kg/m<sup>2</sup>; (4) abstinence from xanthine-, quinine- or caffeine-containing beverages and avoidance of prolonged intense physical activity during the study period (from 72 hours prior to dosing to the last visit). The key exclusion criteria included: (1) presence of any medical condition, abnormal clinical laboratory findings or other circumstances that, in the opinion of the investigator or designee, would render the subject unsuitable for the study; (2) inability to tolerate

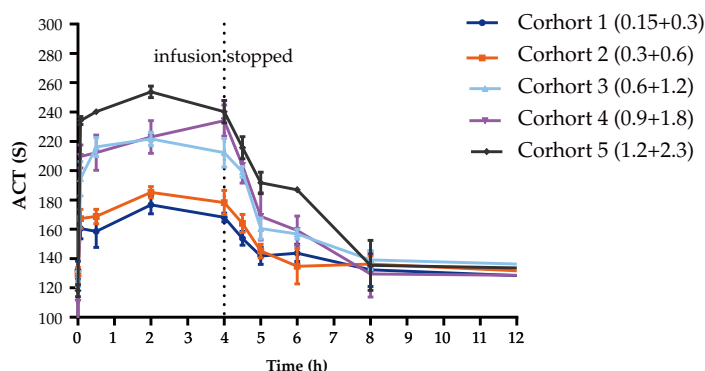
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venipuncture or poor venous access; (3) participation in another investigational drug study and receipt of study treatment within 30 days or five half-lives (whichever is longer) prior to the screening visit, or concurrent participation in another clinical trial; (4) occurrence of acute illness within 14 days prior to the screening visit; and (5) known hypersensitivity to MT1002 for injection.

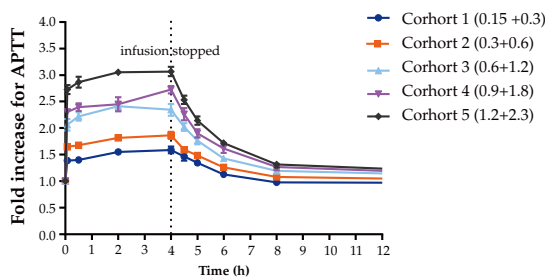
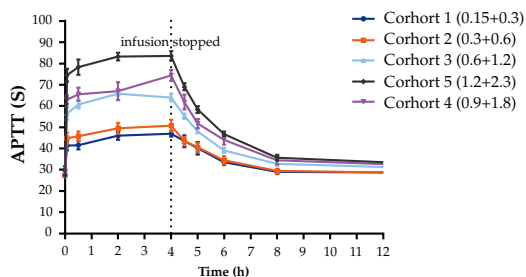
**Trial status:** The Phase I clinical trial was initiated in April 2019 and is completed in August 2019. A total of 30 healthy subjects completed the study drug administration in 5 dose groups. In a dose-escalation design, the safety and tolerability of MT1002 in healthy individuals were explored across 5 dose groups (6 subjects per group).

**Safety data:** MT1002 for injection showed good safety and tolerability. No SAEs were reported. No life-threatening AEs occurred, nor did any AE lead to patient withdrawal or study discontinuation. All TEAEs were Grade 1 in severity with mild symptoms, none of which required clinical intervention, and all subjects fully recovered/resolved in a short period.

**Efficacy data:**



**Effect of MT1002 on anticoagulant indicator ACT**  
(N=6/group, dose unit: mg/kg + mg/kg/h)

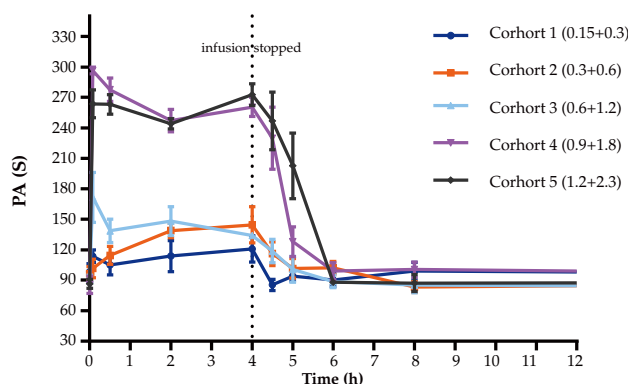


**Effect of MT1002 on anticoagulant indicator APTT and the fold of its prolongation**  
(N=6/group, dose unit: mg/kg + mg/kg/h)

Source: Company data

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**Anticoagulant effect:** MT1002 demonstrated a dose-dependent anticoagulant activity by prolonging APTT, ACT, INR, PT, and TT. These parameters rapidly returned to the normal range after discontinuation, with no impact on the human coagulation function.



### Effect of MT1002 on the anti-platelet indicator, platelet aggregation (PA) function

*Note:* The PA results for cohort 3 were not accurately obtained as most reported values were >134s due to an equipment malfunction during sample testing.

*Source:* Company data

**Anti-platelet effect:** MT1002 prolonged platelet aggregation time, demonstrating a dose-dependent anti-platelet activity. Platelets were immediately inhibited after administration, and the function rapidly returned to the normal range after discontinuation, with no impact on human platelet function.

Results from the Phase I study demonstrated that MT1002 exhibited a favorable safety profile, with pharmacokinetic and pharmacodynamic parameters showing a consistent correlation. Dose-dependent anticoagulant and antiplatelet activities were observed. Coagulation and platelet function rapidly returned to within normal ranges following treatment discontinuation. The objectives set out in the overview were achieved.

#### MT1002-I-C02 PRC Phase I Clinical Study

**Overview:** This study adopted a single-center, randomized, double-blind, placebo-controlled, single-dose escalation design. Its primary objective was to evaluate the safety and tolerability, and the secondary objective was to characterize the pharmacokinetics and pharmacodynamics of MT1002 for injection in healthy subjects in the PRC.

**Trial design:** The study included a dose escalation/de-escalation study with 2 dose groups. Each group consisted of 10 healthy subjects, with 8 receiving MT1002 and 2 receiving placebo. MT1002 was administered as a bolus injection followed by a continuous 4-hour infusion. Subjects underwent follow-up until Day 7 from the initiation of dosing. No additional administration was provided during the follow-up period.

A total of 20 healthy subjects were enrolled in this trial. The key inclusion criteria included: (1) male or female subjects with an appropriate gender distribution; (2) aged 30 years or above, with children and no plans for future reproduction or sperm/egg donation at the time of signing the informed consent form; (3) body weight not less than 50.0 kg for males and 45.0 kg for females; and (4) BMI within the range of 18.0 to 28.0 kg/m<sup>2</sup>. The key exclusion criteria included: (1) history of severe allergy or known hypersensitivity to any component of the investigational product or its excipients; (2) inability to comply with standardized meals or fasting requirements; (3) intolerance to venipuncture or history of needle/blood phobia; and (4) history or presence of clinically significant cardiovascular, cerebrovascular, hepatic, renal, endocrine, metabolic, gastrointestinal, hematological, respiratory, infectious, oncological or psychiatric disorders, as determined by the investigator.

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**Trial status:** The Phase I clinical trial was initiated in September 2021 and is completed in April 2022. A total of 6 subjects in dose group 1 and 7 subjects in dose group 2 completed the trial. All 4 subjects in the placebo group completed the trial.

**Safety data:** All TEAEs were Grade 1 or 2 in severity, with no clinical symptoms, and did not require corresponding measures. No drug-related SAEs were reported. No life-threatening AEs occurred, nor did any AE lead to patient withdrawal or study discontinuation.

**Efficacy data:** After administration, coagulation indicators and platelet aggregation time showed dose-dependent anticoagulant and anti-platelet activities. These functions rapidly returned to the normal range after discontinuation, with no impact on human coagulation or platelet function.

Phase I results showed good safety, linear pharmacokinetics with dose-proportionality, and a clear PK/PD relationship. The objectives set out in the overview were achieved.

### *MT1002-II-C01 U.S. Phase II Efficacy Study in NSTEMI-PCI Patients*

**Overview:** A dose escalation/de-escalation study was conducted in the U.S. in NSTEMI-PCI patients to evaluate the efficacy and safety of MT1002.

**Trial design:** The target population was patients with non-ST-segment elevation myocardial infarction (NSTEMI) undergoing PCI. A total of 18 patients were planned for enrollment into 3 dose groups of 6 patients each. All patients were to receive MT1002 via bolus injection + 4-hour infusion during the peri-procedural period of PCI. Safety and efficacy endpoints included BARC type 3-5 bleeding events and MACE events. PD endpoints included coagulation-related indicators. Subjects underwent follow-up until Day 30 from the initiation of dosing. No additional administration was provided during the follow-up period.

A total of 6 subjects were enrolled in this trial. The key inclusion criteria included: (1) male or female subjects aged  $\geq 18$  years and  $\leq 85$  years; (2) confirmed diagnosis of NSTEMI; (3) patients who were hospitalized for this episode of NSTEMI and planned to undergo PCI; and (4) ability to understand and voluntarily sign a written informed consent form. The key exclusion criteria included: (1) cardiogenic shock or a history of prolonged cardiopulmonary resuscitation (CPR); (2) active bleeding, bleeding diathesis or coagulopathy; (3) history of intracranial hemorrhage or structural abnormalities in the brain; (4) history of transient ischemic attack (TIA) or stroke within the past six months; and (5) current myocardial infarction (MI) diagnosed as ST-segment elevation myocardial infarction (STEMI) or accompanied by newly diagnosed left bundle branch block (LBBB).

**Trial status:** The Phase II clinical trial was initiated in December 2020 and the study for the first dose group has been completed, with a total of 6 subjects enrolled who received MT1002 via bolus injection + continuous 4-hour infusion. The study was terminated due to commercial considerations.

**Safety data:** Interim results showed that all 6 patients successfully completed the PCI procedure without any thrombotic or major bleeding events. A total of 9 AEs were reported by 2 subjects, the majority (66.7%) of which were mild. No drug-related SAEs were reported. No life-threatening AEs occurred, nor did any AE lead to patient withdrawal or study discontinuation.

**Efficacy data:** Interim results showed that after administration of MT1002, the pharmacodynamic effect was rapidly exerted within 5 minutes, with anticoagulant indicators reaching desired levels. All 6 patients successfully completed the PCI procedure without any thrombotic or MACE events. MT1002 demonstrated rapid-onset characteristics, meeting the urgent need for rapid anticoagulation during the peri-procedural period of PCI and providing timely and reliable protection against thrombosis.

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### *MT1002-II-C04 PRC Phase II Efficacy Study in ACS-PCI Patients*

**Overview:** This is a dose escalation/de-escalation study conducted in the PRC in ACS-PCI patients. Its primary objective was to identify the safe and well-tolerated dose of MT1002, and the secondary objective was to evaluate the safety and tolerability.

**Trial design:** The target population was ACS patients undergoing PCI, including those with ST-segment elevation myocardial infarction (STEMI), non-ST-segment elevation myocardial infarction (NSTEMI), and unstable angina (UA). A total of 53 to 65 patients are planned to be enrolled in six cohorts, including five dose-exploration cohorts and one dose-expansion cohort. All patients are to receive MT1002 via bolus injection + 4-hour infusion during the peri-procedural period of PCI. Safety and efficacy endpoints included BARC type 3-5 bleeding events and MACE events. PD endpoints included indicators related to coagulation and platelet function. Subjects underwent follow-up until Day 30 from the initiation of dosing. No additional administration was provided during the follow-up period.

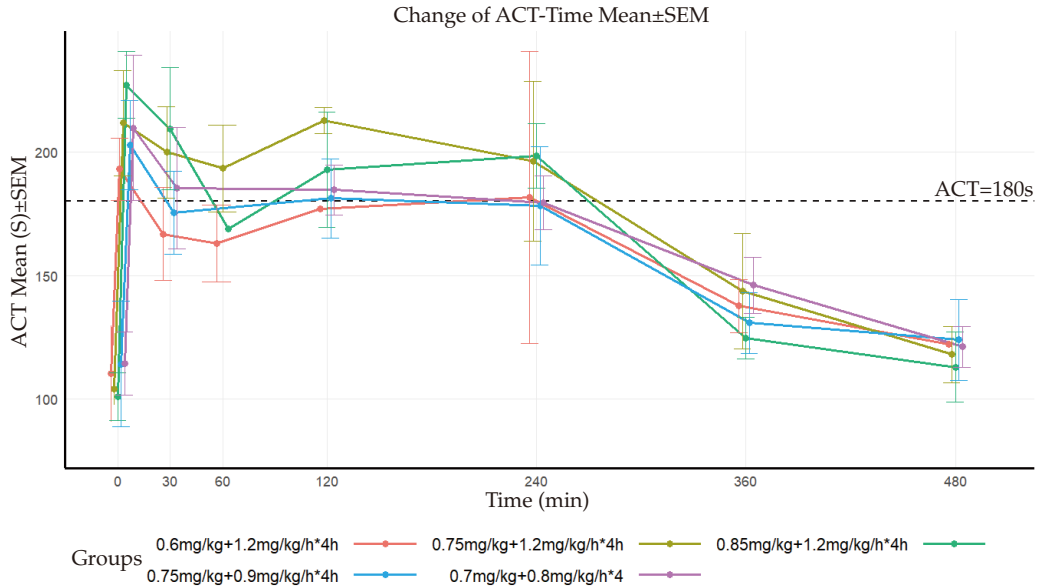
The key inclusion criteria included: (1) male or female subjects aged between 18 and 85 years; (2) subjects diagnosed with ACS who were hospitalized and planned to undergo PCI; (3) subjects who were able to understand and willing to sign a written informed consent form prior to any study-related procedures. The key exclusion criteria included: (1) subjects with cardiogenic shock or those who had undergone CPR; (2) subjects suspected of having aortic dissection, pericarditis or endocarditis; (3) subjects with a history of intracranial hemorrhage or structural abnormalities in the brain; (4) subjects who experienced TIA or stroke within the past six months; (5) subjects with a history of gastrointestinal or genitourinary bleeding within the past month; (6) subjects scheduled to undergo coronary artery bypass grafting (CABG), cardiac valve surgery or other invasive procedures within one month after enrollment.

**Trial status:** The Phase II clinical trial was initiated in February 2024. As of the Latest Practicable Date, studies for five dose groups have been completed. A total of 28 subjects who ultimately underwent the PCI procedure received MT1002 via bolus injection + continuous 4-hour infusion.

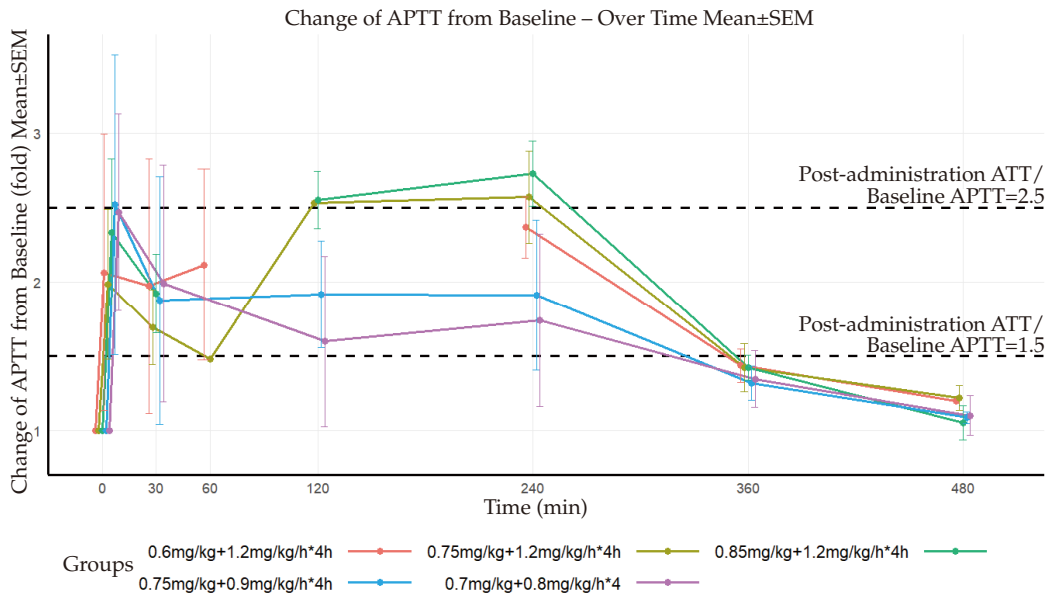
**Safety data:** MT1002 demonstrated good safety and tolerability. As of the Latest Practicable Date, one thrombotic event that was assessed as unrelated to the study drug was reported, and no MACE events, NACE events, or BARC type 3-5 bleeding events occurred. With the exception of one moderate AE unrelated to the study drug, all other AEs were mild.

**Efficacy data:** After administration of MT1002, the pharmacodynamic effect was rapidly exerted within 5 minutes. All 28 subjects successfully completed the PCI procedure without any drug-related thrombotic or MACE events. The study showed that PCI procedures could be successfully completed and thrombotic events prevented even with an ACT of 200s or below, suggesting MT1002's good ability to balance ischemic and bleeding risks. It demonstrates the characteristic of preventing thrombosis at lower ACT levels, thereby avoiding the high risk of major bleeding associated with traditional anticoagulants. Unlike existing standard therapies, the synergistic anticoagulant and anti-platelet effects of MT1002 ensure anti-thrombosis while avoiding the high risk of major bleeding associated with traditional anticoagulants. After exploring the optimal balanced dose in Phase II studies, a large-sample validation will be conducted in a Phase III study.

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**Effect of MT1002 on Activated Clotting Time (ACT)  
in the PRC Phase II Clinical Study**



**Effect of MT1002 on Activated Partial Thromboplastin Time (APTT)  
in the PRC Phase II Clinical Study**

Source: Company data

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***Clinical Development Plan***

For ACS-PCI: We plan to further communicate with the CDE in an EOP II meeting after completing the PRC Phase II MT1002-II-C04 study, to advance a large-sample confirmatory Phase III clinical study with NACE and MACE events as efficacy endpoints, in support of a subsequent NDA filing.

For Stroke: We have obtained the PRC Phase II clinical trial approval and plan to complete FPI for the Phase II clinical trial in the PRC by mid-2026.

For HD: We have obtained the PRC Phase II clinical trial approval and plan to complete FPI for the Phase II clinical trial in the PRC by mid-2026.

For HD-PF4: We have obtained the PRC Phase II clinical trial approval and plan to initiate the PRC Phase II clinical trial by the end of 2027.

***Material Communications***

As of the Latest Practicable Date, we had not received any objection from any relevant regulatory authorities to our clinical development plans.

The table below sets forth our key regulatory communications with regulatory agencies regarding the development of MT1002 for ACS-PCI, Stroke, HD, and HD-PF4:

<u>Indication</u>	<u>Time</u>	<u>Regulatory Authority</u>	<u>Details</u>
ACS-PCI . . . . .	2019.1	FDA	IND Submission
	2019.3.1	FDA	IND Approval
	2021.3.10	NMPA	IND Submission
	2021.6.2	NMPA	IND Approval
	2022.12.27	NMPA	EOP1 Meeting
Stroke . . . . .	2024.8.15	NMPA	EOP2 Meeting
	2023.4.17	NMPA	IND Submission
Stroke . . . . .	2023.6.25	NMPA	IND Approval
	HD . . . . .	2023.10	FDA
2023.11.13		FDA	IND Approval
2023.5.18		NMPA	IND Submission
2023.7.27		NMPA	IND Approval
HD-PF4 . . . . .	2023.3.22	NMPA	IND Submission
	2023.6.6	NMPA	IND Approval

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET MT1002 SUCCESSFULLY

**Our Key Product — MT200605**

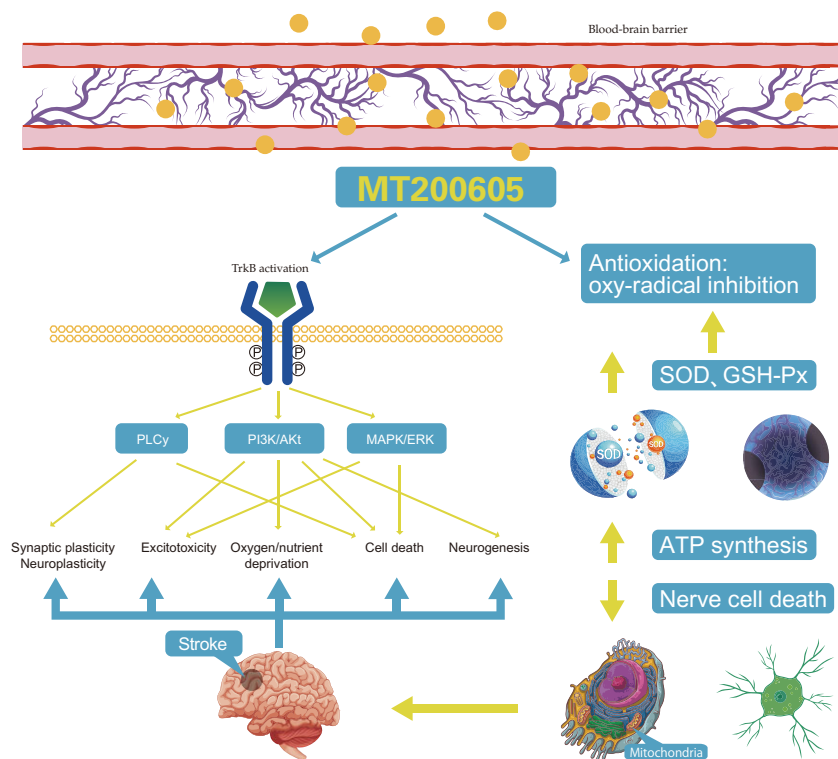
Our Key Product, MT200605, is a neuroprotectant for injection. Its core breakthrough lies in a dual synergistic mechanism of action — by simultaneously activating the TrkB receptor and eliminating oxygen radicals, it blocks the post-acute AIS pathological cascade via dual pathways, offering an innovative therapeutic solution for patients with currently unmet clinical needs.

***Mechanism of Action***

MT200605 has a dual mechanism of action: on one hand, by activating the TrkB receptor, it initiates the BDNF signaling pathway, further activating signaling pathways such as ERK, PI3K/Akt, and PLC. This promotes the growth, repair, and regeneration of neural cells, counteracts damage from toxic substances, enhances learning and memory functions, and demonstrates a significant neuroprotective effect in stroke models. On the other hand, it exerts the anti-oxygen free radical effect of flavonoids. Acute ischemic

## BUSINESS

stroke leads to the release of a large number of reactive oxygen species, triggering inflammatory responses and ischemia-reperfusion injury. Flavonoid compounds possess multiple mechanisms, including directly blocking or scavenging free radicals, inhibiting lipid peroxidation, and chelating with metal ions, thereby exerting antioxidant and neuroprotective effects.



Source: Company data

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

TrkB receptor agonist binds to TrkB and exerts neuroprotective effects through multiple mechanisms: activating the PI3K/Akt pathway to inhibit neuronal apoptosis and reduce ischemic or toxic injury; promoting axonal regeneration and synaptic reconstruction via the MAPK/ERK pathway to facilitate the repair of the neural network; enhancing the regulation of PLC $\gamma$ -mediated calcium signaling to improve synaptic transmission and alleviate cognitive impairment; down-regulating proinflammatory drugs; and down-regulating the calcium signaling pathway to improve synaptic transmission and alleviate cognitive impairment. It also enhances PLC $\gamma$ -mediated calcium signaling and improves synaptic transmission to alleviate cognitive deficits; down-regulates the pro-inflammatory pathway to inhibit glial over-activation and reduce inflammatory damage; and stimulates neurogenesis in the hippocampus and other regions to facilitate functional recovery. These potential multiple therapeutic mechanisms make TrkB agonists have the potential to treat stroke, neurodegenerative diseases, depression and other neurological disorders.

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### Market Opportunities and Competition

AIS is the most common type of stroke, accounting for about 70%-80% of strokes. The global prevalence of ischemic stroke grew from 62.2 million in 2019 to 81.3 million in 2024 at a CAGR of 5.5%, and is projected to reach 105.8 million by 2030 and 127.4 million by 2035. In China, the prevalence of ischemic stroke grew from 17.6 million in 2019 to 22.6 million in 2024 at a CAGR of 5.1%, and is projected to reach 28.9 million by 2030 and 35.1 million by 2035.

As of the Latest Practicable Date, there are three neuroprotective drugs approved by NMPA. In addition, there were a total of 12 neuroprotective drug candidates for AIS in the clinical stage in the PRC, including our Key Product MT200605 (currently in phase II). For more information, see "Industry Overview — Main treatment of Ischemic Stroke" and "Industry Overview — Competitive landscape of neuroprotective drugs."

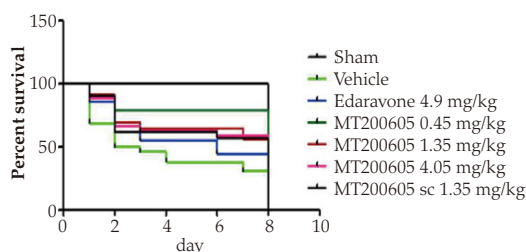
### Competitive Advantages

#### (1) Favorable safety and tolerability profile

MT200605 has successfully completed Phase I clinical studies in both the PRC and the U.S. Study results showed that MT200605 has good safety and tolerability in healthy subjects. All TEAEs related to MT200605 were Grade 1, with no SAEs or events leading to subject withdrawal. All adverse events were resolved or recovered, further validating the safety foundation of MT200605 as a neuroprotective agent for stroke in the early clinical stage. Furthermore, results from the Phase I single and multiple dose studies indicated that the in vivo exposure of MT200605 is clearly linearly correlated with the dose, demonstrating a good dose-exposure relationship. There was no accumulation after multiple administrations, providing support for subsequent dose exploration and clinical application. For more information of the clinical results, see "— Clinical Trial Overview of MT200605" below in this section.

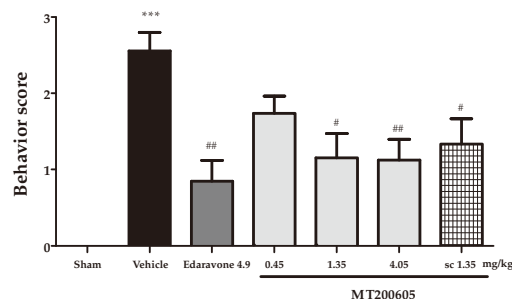
#### (2) Synergistic neuroprotective effect via dual pathways

MT200605 has a well-defined dual mechanism of action, which is supported by existing clinical data. On one hand, the drug promotes neurogenesis by activating the TrkB receptor; on the other hand, it leverages the antioxidant properties of flavonoids to inhibit free radical damage, thereby achieving a synergistic neuroprotective effect. Existing preclinical pharmacodynamic studies (MCAO-CIR rat model) show that MT200605 is well-distributed in brain tissue and has the ability to cross the blood-brain barrier; it is superior to existing neuroprotective agents in improving stroke-related behavioral indicators, increasing brain SOD and GSH-Px content, reducing cerebral infarction volume, prolonging the survival rate of model mice, and delaying the time of animal death, demonstrating significant therapeutic advantages and good development potential.



**MT200605 can significantly prolong the survival rate of model rats and delay the time of death.**

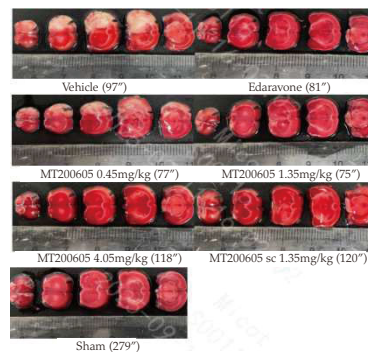
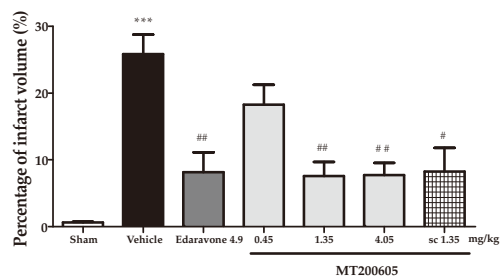
(79.2% vs. Edar 44.8%, n=10~29)



**MT200605 can reduce the behavioral scores of rats in a dose-dependent manner.**

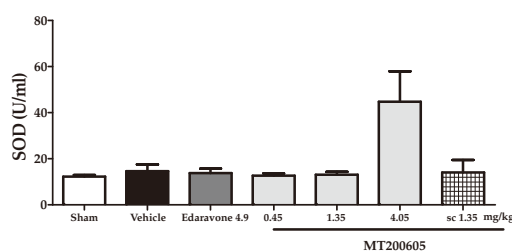
(n=10~29)

**BUSINESS**

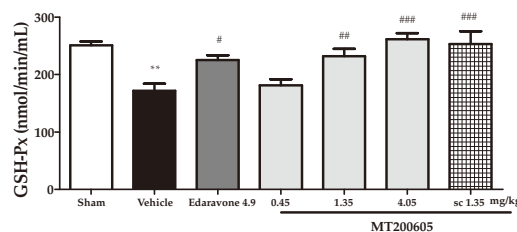


**Effect on the percentage of cerebral infarction volume in rats**  
 (n=10-19) \*\*\*P<0.001 vs. Sham; #P<0.05, ##P<0.01 vs. Vehicle

**Typical photos of cerebral infarction**



**MT200605 increases SOD content**  
 (44.7% vs. Edar 13.7%, n=10~29)



**MT200605 increases GSH-Px content**  
 (52.6% vs. Edar 31.3%, n=10~29)

Source: Company data

**Clinical Trial Overview of MT200605**

**MT200605-I-C01 PRC Phase I Clinical Study**

**Overview:** We conducted a randomized, double-blind, placebo-controlled Phase I clinical trial in healthy subjects in the PRC to evaluate single ascending dose (SAD) and multiple ascending dose (MAD) administration of MT200605 for injection. Its primary objective was to evaluate the safety and tolerability, and the secondary objective was to characterize the pharmacokinetic of MT200605 in healthy individuals in the PRC, and to recommend the optimal dosing regimen and dose for Phase II clinical trials.

**Trial design:** This was a single-center, Phase I, randomized, double-blind, placebo-controlled, sequential-dosing SAD and MAD study. The SAD study consisted of 5 cohorts (MT200605 0.15mg/Kg, 0.3mg/Kg, 0.6mg/Kg, 0.9mg/Kg, and 1.2mg/Kg, single dose). The 4 subjects in the first cohort all received MT200605, while the remaining cohorts each had 8 subjects (6 on MT200605 + 2 on placebo). A total of 36 healthy subjects were enrolled in the entire SAD study. The MAD study comprised 3 cohorts (0.3mg/Kg, 0.6mg/Kg, and 1.2mg/Kg, dosed every 12 hours for 7 consecutive days), with 8 subjects in each cohort (6 on MT200605 + 2 on placebo), for a total of 24 subjects. Subjects in the SAD study will undergo follow-up 11 days after dosing, while those in the MAD study will undergo follow-up 7 days after completion of dosing. The primary endpoint of the study was the safety and tolerability of MT200605 in healthy subjects, with its pharmacokinetic characteristics as a secondary endpoint.

A total of 60 subjects were enrolled in the PRC in this trial. The key inclusion criteria included: (1) subjects aged between 18 and 50 years at the time of screening, with a BMI of no less than 18.0 kg/m<sup>2</sup> and no more than 28.0 kg/m<sup>2</sup>; (2) healthy subjects without clinically significant medical history or conditions; (3) subjects with no plan for conception, sperm donation or egg donation within six months following screening, who voluntarily agree to use effective contraceptive measures, and for female subjects, with a negative serum pregnancy test result; and (4) subjects who are able to understand the study procedures and have signed the informed consent form prior to participation in the study. The key exclusion criteria included but were not limited to: (1) any clinically significant abnormal findings identified during physical examination; (2) any clinically

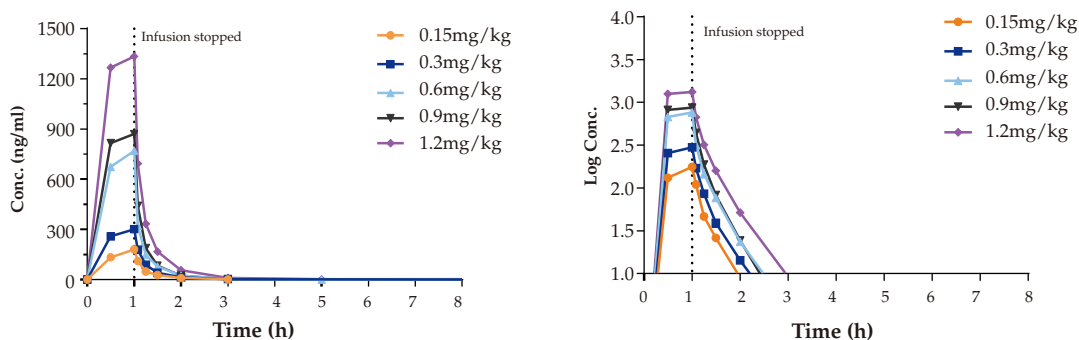
**BUSINESS**

significant abnormalities in laboratory test results at screening, or positive findings for HBsAg, anti-HCV antibody, HIV antibody, serological testing, or active infection; (3) female subjects with a positive pregnancy test result or who are lactating; (4) positive results in urine drug screening or breath alcohol test; and (5) a clinically significant history of allergic reactions, such as anaphylaxis, hypersensitivity or angioedema, as determined by the investigator.

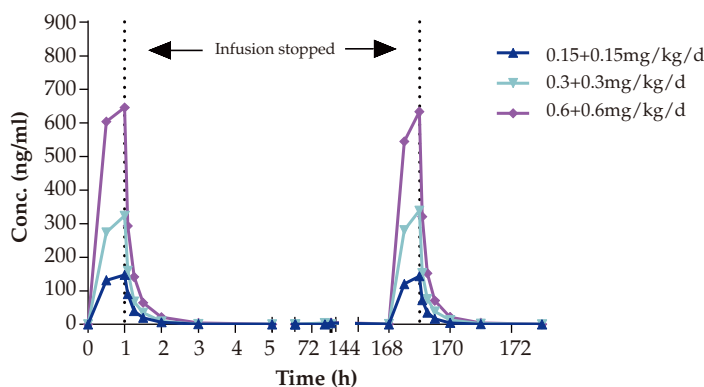
**Trial status:** The Phase I clinical trial was initiated in July 2023 and completed in December 2023 with 60 subjects enrolled in the PRC.

**Safety data:** The PRC Phase I clinical study showed a good safety profile. No drug-related TEAEs of Grade 3 or above were observed, and no drug-related SAEs were reported. No life-threatening AEs occurred, nor did any AE lead to patient withdrawal or study discontinuation. The objective set out in the overview was achieved.

**Pharmacokinetic data:** The SAD study showed that within the 0.15mg/kg to 1.2mg/kg range, the pharmacokinetic (PK) characteristics of both total MT200605 and free MT200605 showed a clear positive dose-exposure correlation, and the main pharmacokinetic parameters followed linear kinetic characteristics. The MAD study showed that within the 0.3mg/kg to 1.2mg/kg range, there was no significant accumulation after multiple doses of MT200605, and steady state trough concentration was reached on day 5. The main pharmacokinetic parameters of free MT200605 followed linear kinetic characteristics, while the increase in exposure (AUC<sub>0-t,ss</sub>) of total MT200605 was slightly higher than dose-proportional (approximately 1.85-fold).



**Time-Concentration and Semi-logarithmic Plots of MT200605 Parent Drug in Each Dose Group of the MT200605 SAD Study (N=6/group)**



**Time-Concentration Plots of MT200605 Parent Drug in Each Dose Group of the MT200605 MAD Study (N=6/group)**

Source: Company data

Results from the Phase I study demonstrated a favorable safety profile of MT200605, with pharmacokinetic parameters showing a linear correlation with the administered dose. The objectives set out in the overview were achieved.

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### *MT200605-101-US U.S. Phase I Clinical Study*

**Overview:** We conducted a randomized, double-blind, Phase I clinical trial in the U.S. to evaluate the safety, tolerability, and pharmacokinetics of single ascending doses (SAD) of MT200605 for injection in healthy subjects. Its primary objective was to evaluate the safety and tolerability, and the secondary objective was to characterize the pharmacokinetic of MT200605 in healthy subjects in the U.S., and to recommend the optimal dosing regimen and dose for Phase II clinical trials.

**Trial design:** The U.S. Phase I clinical study included 2 cohorts (MT200605 0.1mg/Kg and 0.3mg/Kg), both with single-dose administration. Each cohort comprised 8 subjects (6 on MT200605 + 2 on placebo). Subjects will undergo a safety follow-up assessment 7 days after dosing. A total of 16 healthy subjects were enrolled in the study.

A total of 16 subjects were enrolled in the US in this trial. The key inclusion criteria included: (1) male or non-childbearing potential female,  $\geq 18$  and  $\leq 65$  years of age with BMI  $\geq 18.0$  and  $\leq 32.0$  kg/m<sup>2</sup> at screening; (2) healthy subject without clinically significant medical history or conditions; (3) female subjects of non-childbearing potential; (4) female subjects (except for post-menopausal women) must have agreed to use two forms of acceptable non-hormonal methods of contraception, for the duration of the study and for 30 days following the completion of the study; and (5) subjects able to understand the study procedures and provide signed informed consent to participate in the study. The key exclusion criteria included but were not limited to: (1) any abnormalities identified during physical examination (including examination of the administration site); (2) abnormal laboratory test results at screening, or positive findings for hepatitis B surface antigen (HBsAg), anti-hepatitis C virus (HCV) antibody, HIV antigen or antibody, or evidence of active infection; (3) positive pregnancy test result or lactation at screening; (4) positive urine drug screening, positive urinary cotinine test or positive breath alcohol test; and (5) a history of severe allergic reactions (e.g., anaphylaxis, hypersensitivity or angioedema) considered clinically significant by the investigator.

**Trial status:** The Phase I clinical trial was initiated in October 2022 and completed in January 2023 with 16 subjects enrolled in the US.

**Safety data:** The U.S. Phase I clinical study showed a good safety profile. No drug-related TEAEs of Grade 3 or above were observed, and no drug-related SAEs were reported. No life-threatening AEs occurred, nor did any AE lead to patient withdrawal or study discontinuation.

**Pharmacokinetic data:** The increase in pharmacokinetic exposure of free MT200605 was dose-proportional, whereas the increase in pharmacokinetic exposure of total MT200605 was slightly greater than dose-proportional. MT200605 is minimally excreted in urine. At doses of 0.1 mg/kg and 0.3 mg/kg, the percentage of urinary excretion was 0.07% and 0.10% for free MT200605, and 2.46% and 5.39% for total MT200605, respectively.

The Phase I study demonstrated that MT200605 had a favorable safety profile and exhibited linear pharmacokinetic characteristics with dose-proportional exposure. The objectives set out in the overview were achieved.

### *MT200605-II-C01 PRC Phase II Clinical Study*

**Overview:** This is a multi-center, randomized, double-blind, placebo-controlled study in patients with acute ischemic stroke in the PRC. Its purpose is to investigate the efficacy, safety, and pharmacokinetic characteristics of different doses of MT200605 in patients with acute ischemic stroke, and to explore an appropriate dose for the Phase III confirmatory trial. Efficacy evaluation was the primary objective of the study.

**Trial design:** The study will select 360 patients with acute ischemic stroke within 24 hours of onset and an NIHSS score between 6 and 25 (inclusive), including those who have or have not received intravenous thrombolysis or reperfusion therapy. They will be randomized in a 1:1:1:1 ratio into low, medium, and high dose groups of MT200605 and a placebo group, to receive intravenous infusions of MT200605 at 10 mg BID, 20 mg BID, 40 mg BID, or placebo for 14 consecutive days, followed by a follow-up period up to day 90 from the first dose. The primary efficacy endpoint of the study is the proportion of subjects with a modified Rankin Scale (mRS) score of  $\leq 1$  on day 90 after onset. A secondary efficacy endpoint is the change in NIHSS score from baseline within 14 days of treatment.

## BUSINESS

A total of 360 subjects are planned to be enrolled in this trial. The key inclusion criteria included: (1) male or female subjects aged 18 years or above and no more than 80 years; (2) subjects diagnosed with ischemic stroke in accordance with the Guidelines for the Diagnosis and Treatment of Acute Ischemic Stroke in China (2023); (3) subjects whose onset of symptoms and expected administration of the investigational product occurred within 24 hours, including those who had not received reperfusion therapy or who had received intravenous thrombolytic therapy; and (4) subjects who were able to understand and comply with the study procedures and voluntarily signed the informed consent form. The key exclusion criteria included but were not limited to: (1) subjects with intracranial hemorrhagic diseases confirmed by imaging examinations; (2) subjects presenting with significant disturbance of consciousness after onset, defined as a score greater than 1 on item 1a (level of consciousness) of the NIHSS; (3) subjects with TIA; and (4) subjects requiring endovascular therapy for the current acute ischemic stroke, including intra-arterial thrombolysis, mechanical thrombectomy or angioplasty.

**Trial status:** The Phase II clinical trial was initiated in July 2025 and enrollment of 360 subjects has been completed as of the Latest Practicable Date.

### *Clinical Development Plan*

The Phase II study of MT200605 is a randomized, double-blind, placebo-controlled, multi-center Phase II clinical study designed to explore the efficacy, safety, and pharmacokinetic characteristics of MT200605 in patients with acute ischemic stroke. We expect to complete this study and the summary report in 2026.

### *Material Communications*

As of the Latest Practicable Date, we had not received any objection from any relevant regulatory authorities to our clinical development plans.

The table below sets forth our key regulatory communications with regulatory agencies regarding the development of MT200605 for the treatment of ischemic stroke:

<u>Time</u>	<u>Regulatory Authority</u>	<u>Details</u>
2021.11 . . . . .	FDA	IND Submission
2021.12.29 . . . . .	FDA	IND Approval
2023.1.5 . . . . .	NMPA	IND Submission
2023.3.24 . . . . .	NMPA	IND Approval
2025.3.13 . . . . .	NMPA	EOP1 Meeting

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET MT200605 SUCCESSFULLY

### **MT2004**

MT2004 adopts a prodrug design, leveraging concentration gradients inside and outside hepatocytes to achieve targeted delivery to the liver. Non-clinical studies demonstrated that the parent compound MT2004 does not activate FXR, while its metabolite MT2004-met1 significantly activates the FXR receptor, with an efficacy approximately 10 times stronger than chenodeoxycholic acid (CDCA), thereby validating the rationale of its prodrug design.

Following hepatic metabolism by CYP3A4 and CYP3A5 into the active metabolite MT2004-met1, the compound specifically and locally activates hepatic FXR receptors in situ. By modulating bile acid metabolism (inhibiting bile acid synthesis, reducing bile acid reabsorption, and promoting bile acid excretion) as well as glucose and lipid metabolism, MT2004 is designed to alleviate cholestasis and its clinical symptoms, slow disease progression, and repair liver damage. This targeted design avoids the high systemic exposure of FXR agonists in peripheral blood, which has been associated with adverse events, and has the potential to substantially reduce side effects observed with existing FXR agonists in clinical use. As a result, MT2004 may provide a more favorable safety profile and improve patient compliance.

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Preclinical studies have demonstrated therapeutic potential in DILI, NASH, and CLD. MT2004 has obtained IND approval in the United States for the treatment of NASH and in the PRC for the treatment of DILI, MASLD, and CLD. We have completed Phase I clinical trials of MT 2004 in both the United States and the PRC, the clinical data of which has demonstrated favorable safety and tolerability profile, with no pruritus or related adverse events reported. As of the Latest Practicable Date, we were conducting a Phase II clinical trial in the PRC for DILI.

**WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET MT2004 SUCCESSFULLY**

### MT1009

MT1009 is a novel bi-specific fusion peptide with dual functional domains of parathyroid hormone-related peptide (PTHrP) and OGP. MT1009 exerts the effects of PTHrP by enhancing bone formation, activating the PTH1 receptor, and reproducing most of the functions of iPTH, including promoting bone resorption and mobilizing calcium and phosphorus into the bloodstream. In addition, through activation of the OGP pathway, MT1009 increases the number of osteoblasts and stimulates the release of osteogenic growth factors from osteoblasts, thereby further promoting bone formation.

MT1009 is intended for the prevention of glucocorticoid-induced osteoporosis in patients at moderate to high risk with long-term glucocorticoid use, as well as for the treatment of postmenopausal osteoporosis and primary or hypogonadism-induced osteoporosis. Compared with conventional anti-osteoporosis therapies (such as bisphosphonates, teriparatide, and abaloparatide), MT1009 has demonstrated the potential to significantly increase bone mineral density (BMD), improve bone quality (by rebuilding trabeculae, thickening cortical bone, and repairing microfractures), and achieve a more pronounced reduction in fracture risk. As of the Latest Practicable Date, MT1009 has obtained IND approvals in both the PRC and the United States.

**WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET MT1009 SUCCESSFULLY**

### MT1011

MT1011 is a novel synthetic small-molecule broad-spectrum anticoagulant reversal agent targeting both thrombin factor IIa inhibitors and factor Xa inhibitors. MT1011 binds directly to anticoagulant molecules through non-covalent hydrogen bonding without binding to coagulation factors or other plasma proteins. This direct antagonistic mechanism neutralizes the anticoagulant activity and rapidly restores normal coagulation.

MT1011 is intended for use in patients receiving anticoagulant therapy (such as factor Xa inhibitors rivaroxaban or apixaban) who require urgent reversal of anticoagulation due to life-threatening or uncontrolled bleeding. MT1011 addresses the significant unmet clinical need for a broad-spectrum reversal agent by antagonizing all NOACs as well as heparin/enoxaparin in cases of life-threatening or uncontrolled bleeding.

MT1011 demonstrates a favorable safety profile by directly binding to anticoagulants without interacting with coagulation factors or other plasma proteins, thereby avoiding off-target effects. MT1011 also offers a wider therapeutic window, with a significantly lower effective dose for antagonizing factor Xa inhibitors (demonstrating equivalent effects at doses approximately 380 times lower than ciraparantag). As of the Latest Practicable Date, enrollment of all subjects in the PRC Phase I clinical trial has been completed, and the LPLV is expected to occur by the end of March 2026.

**WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET MT1011 SUCCESSFULLY**

## BUSINESS

### OUR NON-PIPELINE PRODUCT CANDIDATES

#### XTL3602

XTL3602 is designed as a tri-agonist targeting GLP-1R, GCGR, and GIPR with balanced activity across the three receptors. The molecule incorporates fatty acid chain modification to achieve an extended half-life for long-acting activity, while maintaining activity and balance across all three targets. XTL3602 is intended for the treatment of metabolic diseases, including obesity, diabetes, and obstructive sleep apnea associated with obesity; non-alcoholic fatty liver disease by reducing hepatic fat deposition through weight loss; secondary prevention of cardiovascular events by exploring the role of weight reduction in lowering cardiovascular risk. We expect to submit an IND application in 2027 to advance XTL3602 into clinical development.

#### XTL3710

XTL3710 is designed as a tri-agonist targeting GLP-1R and GCGR with the introduction of MasR to achieve balanced activity across three receptors. The molecule incorporates fatty acid chain modification to extend half-life and enable once-weekly administration, while maintaining activity and balance across all three targets. XTL3710 is intended for the treatment of metabolic diseases caused by multiple risk factors, including diabetes and diabetic kidney disease (DKD). IND submission is planned in 2026 to advance XTL3710 into clinical development.

#### MT1016

MT1016 is a selective peripheral kappa opioid receptor (KOR) agonist and a long-acting peptide (administered via subcutaneous injection) designed for more effective and safer treatment of pain and pruritus. We expect to submit an IND application in 2027 to advance MT1016 into clinical development. We believe MT1016 has the potential to offer more effective management of visceral pain and promotes faster postoperative gastrointestinal function recovery. MT1016 may also reduce central nervous system-related adverse effects and provides long-acting analgesia, thereby decreasing the need for frequent use of analgesic pumps.

#### XTL1018

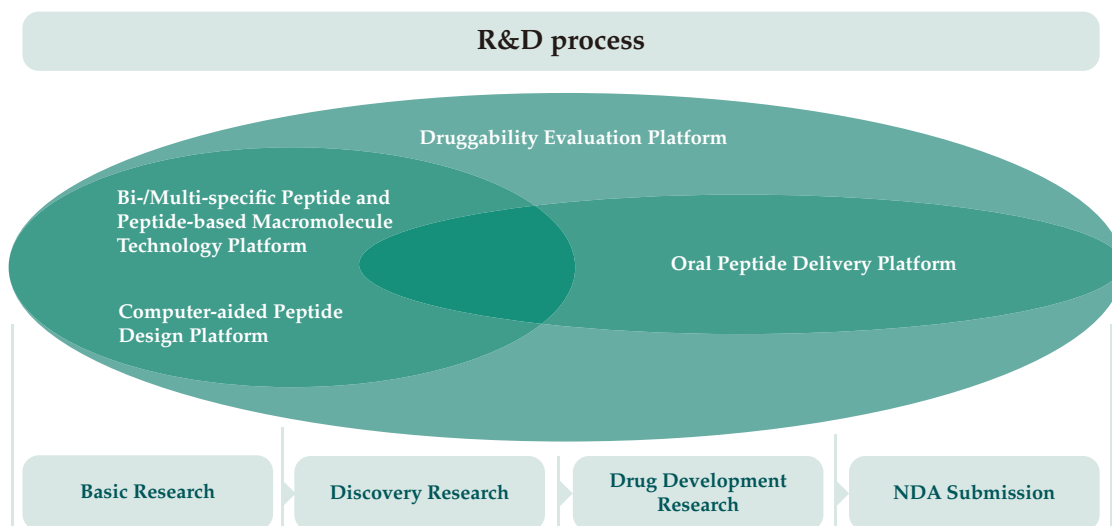
XTL1018 is an innovative bi-specific peptide–drug conjugate (PDC) candidate targeting complement C3 and TrkB. The design links a peptide targeting complement C3 with a small molecule modulator of TrkB, which exerts neuroprotective activity. By inhibiting excessive activation of the complement cascade and suppressing inflammatory responses, while simultaneously modulating the BDNF/TrkB signaling pathway, XTL1018 is expected to exert biological effects that prevent downstream inflammation and cell damage associated with geographic atrophy (GA) and restore impaired neuroprotective signaling in GA. Accordingly, XTL1018 is intended for the treatment of late-stage dry AMD with GA. We expect to submit the IND application for XTL1018 in 2028 to initiate clinical development.

**WE MAY NOT ULTIMATELY BE SUCCESSFUL IN DEVELOPING AND MARKETING OUR NON-PIPELINE PRODUCT CANDIDATES.**

## BUSINESS

### OUR TECHNOLOGY PLATFORMS

We have self-developed four core technology platforms including (i) Bi-/Multi-Specific Peptide and Peptide-based Macromolecule Technology Platform, (ii) Computer-Aided Peptide Design Platform, (iii) Oral Peptide Delivery Platform, and (iv) Druggability Evaluation Platform. These platforms collectively span the entire R&D continuum from basic research, drug discovery research, drug development research to NDA submission and serve as the foundational engine driving the advancement of our differentiated peptide-based pipeline.



#### Bi-/Multi-specific Peptide and Peptide-based Macromolecule Technology Platform

The pathogenesis of diseases often involves the interplay of multiple targets. Unlike the traditional drug development pathway, which typically begins with a single target followed by high-throughput screening to identify hit compounds, optimization into lead compounds, advancement into PCCs, pre-clinical development and ultimately clinical studies, our Bi-/Multi-specific Peptide Platform has established a novel R&D paradigm, covering key stages including target selection, structure-activity relationship analysis, design optimization, computer-based modeling, synthesis and target validation.

**Lead compound design and optimization:** In the design and optimization of lead compounds, we adopt a dual approach. On the one hand, we leverage structural information from reported drugs and clinically validated active compounds and apply classical medicinal chemistry principles in conjunction with computer-aided drug design molecular simulation to rationally construct novel molecules. On the other hand, we conduct screening of our compound list to identify hit or lead compounds with development potential. For the design of bi-/multi-functional peptides, we primarily adopt the following three strategies:

- Linker fusion technology, which involves selecting flexible, rigid, or enzyme-cleavable linkers based on design needs to maximize biological activity, reduce adverse effects, optimize pharmacokinetic profiles, enhance stability, extend half-life, and improve dosage form and patient compliance;
- Chimeric technology, which combines two or more functional fragments, along with single or active amino acid motifs, based on the characteristics of the target indication and the nature of the pharmacological targets, to enhance bioactivity, reduce immunogenicity, and prolong half-life; and
- Conjugation-extension technology, which involves segmenting and recombining different functional domains to construct extended molecular conformations with multiple physiological functions, thereby addressing clinical needs across various therapeutic areas.

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**Diversified molecular entity design to meet druggability requirements:** Starting from clinical application scenarios, we select the most suitable molecular structures by evaluating the characteristics of linear peptides, monocyclic peptides, and bicyclic peptides.

- Linear peptides are linear chain structures formed by amino acids sequentially linked through peptide bonds, without cyclization. They are easy to synthesize and highly amenable to chemical modification, allowing rapid generation of structurally diverse candidate compounds.
- Cyclic peptides demonstrate significant advantages in both pharmacological and pharmacokinetic properties, such as enhanced metabolic stability, improved target specificity and selectivity, as well as favorable biophysical attributes.
- Bicyclic peptides combine cell membrane permeability with a large interaction interface, allowing them to bind to protein targets independently of conventional binding pockets, thereby enabling precise targeting of previously undruggable targets.

**Peptide chemical modification technologies:** We apply strategies such as non-natural amino acid substitution, site-specific mutagenesis, cyclization, PEGylation, and long-chain fatty acid esterification to improve druggability, including enhancing resistance to proteolytic degradation, reducing antigenicity, prolonging in vivo half-life, and increasing bioavailability.

Although peptide-based therapeutics offer high target specificity and favorable safety profiles, their clinical applications are limited by poor metabolic stability and short biological half-life, particularly in indications requiring long-term administration such as chronic diseases, which may affect patient adherence and treatment experience. To address these limitations, we have established a macromolecule platform based on functional peptides as an extension of our Bi-/Multi-Specific Peptide Platform. This platform leverages macromolecular modification to significantly extend the half-life of peptide drugs, improve their metabolic stability, enable targeted delivery, enhance drug specificity and reduce adverse drug reactions.

Based on this technology platform, we have generated and developed a number of clinically promising candidate molecules with diverse molecular formats and mechanisms of action. Among them, four candidates — MT1013, MT1002, XTL6001 and MT1009 have entered clinical development. Another three candidates — XTL3710 and XTL3602 — have completed hit-to-lead validation, and peptide-drug conjugate MT1018 has completed PCC selection.

### Computer-aided Peptide Design Platform

Our Computer-aided Peptide Design Platform integrates multiple functional modules, including virtual screening, molecular dynamics simulation, SAR prediction and ADMET prediction, and is supported by advanced hardware, enabling operation without compromising accuracy to meet our needs in compound virtual screening. Built on the principles of computational chemistry, structural biology and biophysics, and supported by various open-source databases, the platform is operated by an experienced domestic peptide early research team, thereby reducing time and cost, enhancing R&D efficiency and improving the clinical success rate of candidate molecules.

**AI-enhanced peptide molecule design:** One of the key features of this platform is AI-enhanced computer-aided drug design. The platform integrates artificial intelligence-generated content algorithms, enabling the from-scratch design of novel peptide molecules targeting specific biological targets. At the initial screening stage, the platform is capable of producing batches of candidate molecules, which, upon in vitro cell-based validation, demonstrated target activity at the micromolar level.

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***Molecule virtual screening method based on effective activity prediction:*** In the process of molecule virtual screening, we skip the traditional affinity-based screening step and directly predict the more challenging in vitro activity. This method predicts the activity of linear peptides or cyclic peptide compounds at specific targets by analyzing key features such as intermolecular interactions, physicochemical properties of binding pockets and changes in binding free energy, and further guides molecule design and optimization through integration with in vitro activity validation and preliminary pharmacological results. This approach not only reduces manpower, resources and time required for affinity validation, but also lowers the resource consumption associated with validating and optimizing high-affinity molecules.

***Diversified molecule design to improve candidate success rate:*** New drug development is typically characterized by long cycles, high investment and significant risk. Leveraging peptide drug design expertise, this platform conducts multi-form peptide molecule design based on target and binding pocket characteristics, and performs diversified molecular screening through the platform. In candidate selection, in addition to effective activity, druggability is also a critical factor influencing the success rate of Phase I and Phase II clinical trials. This platform is further capable of conducting early ADMET prediction on different forms of peptide molecules, thereby bringing forward the assessment of druggability risks, improving the likelihood of candidates advancing from the pre-clinical stage into clinical trials, and enhancing the overall transition efficiency of PCCs.

Based on this platform, we have advanced multiple candidate molecules into in vitro activity validation, significantly improving molecular design efficiency and early development success rates for several projects, including MT1016, MT1019 and XTL3710. As of the Latest Practicable Date, the candidate molecules of MT1016 and XTL3710 had advanced to the PCC stage and obtained preliminary druggability evaluation data.

### **Oral Peptide Delivery Platform**

Peptide drugs generally suffer from rapid enzymatic degradation and low intestinal absorption, leading low oral bioavailability and long-term reliance on injections, which compromise patient adherence and convenience. The Oral Peptide Delivery Platform we are developing is dedicated to addressing this issue.

Our platform adopts solid-dosage manufacturing processes, including solid dispersion, inclusion complexation, dry granulation and direct compression. To promote the absorption of protein and peptide drugs, we incorporate permeation-enhancement approaches that use permeation enhancers and inclusion complexation to encapsulate the drug and to adjust local pH, thereby suppressing enzymatic degradation and molecular aggregation, stabilizing the microenvironment at the administration site, protecting the active conformation, increasing mucosal permeability and enhancing overall formulation stability.

The platform supports two delivery routes: oral and sublingual. Oral tablets incorporate permeation enhancers, inclusion complexation and stabilizers and are designed to achieve therapeutically relevant systemic exposure following gastrointestinal absorption. Sublingual tablets disintegrate rapidly in the oral cavity and deliver peptides via the oral mucosa, enabling a faster onset while bypassing first-pass metabolism, thereby offering flexible options to accommodate different patient needs.

Based on this platform, we have advanced the oral formulation development of five peptide candidates (XTL3710, XTL3602, MT1013, MT1009 and MT200605), with XTL3710 and MT1013 achieving effective in vivo exposure.

### **Druggability Evaluation Platform**

Our druggability evaluation platform is centered on animal model-based assessments. This platform runs through the entire process of new drug development, from target identification, hit discovery, lead generation and optimization, to the selection of preclinical candidate (PCC) and clinical candidate (CC). Our evaluation system adopts a phased and progressive decision-making mechanism, covering early-stage screening of efficacy, toxicity, metabolism and physicochemical properties, IND-enabling studies such as safety assessment, toxicology, formulation and quality control, as well as clinical-stage

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validation of human efficacy, safety, and evaluation of carcinogenicity and genotoxicity. At each stage, key go/no-go decisions are made based on the compound's druggability, safety and efficacy profile, ensuring scientific, risk-managed advancement of new drug candidates.

**Multi-model evaluation framework with translational focus:** Focusing on metabolic diseases (particularly renal-related) and cardiovascular and cerebrovascular diseases, this platform has established approximately 100 pharmacodynamic animal evaluation models and more than 100 blood and urine biochemical testing capabilities to support the pharmacological assessment needs of its pipeline assets. Model selection is based on the alignment between the drug's mechanism of action and the characteristics of the intended indication, ensuring high relevance and translational value of the results. Building on this, we have developed an integrated evaluation system covering key aspects including in vitro biological studies, in vivo efficacy in disease models, safety evaluation and DMPK. This system provides comprehensive validation support across both in vitro and in vivo stages, facilitating a seamless data transition from animal studies to human trials and enhancing the translational reliability of preclinical findings.

**Infrastructure supporting multidimensional druggability assessment:** We have established a standardized druggability evaluation system, which includes standardized animal facilities (SPF) and a range of research and functional platforms, covering functional laboratories, ex vivo organ and tissue research laboratories, behavioral pharmacology evaluation laboratories, clinical testing laboratories, and pathology diagnostic platforms. Equipped with medical diagnostic and analytical instruments, the system supports a wide range of assessments.

This platform has been continuously optimized and iterated to comprehensively support the druggability evaluation of all our self-developed pipelines. All seven clinical-stage candidates have undergone druggability evaluation via this proprietary platform.

## RESEARCH AND DEVELOPMENT

For the years ended December 31, 2024 and 2025, our R&D expenses amounted to RMB107.0 million and RMB130.1 million, respectively. We have been focusing our in-house R&D efforts on the development of our Core Product, MT1013. For the years ended December 31, 2024 and 2025, we incurred R&D expenses for MT1013 of RMB66.7 million and RMB84.4 million respectively, representing 62.3% and 64.9% of our total R&D expenses for the same period, respectively.

### R&D Team

As of the Latest Practicable Date, we had a team of 103 R&D professionals, representing approximately 78.6% of our total staff count. Among them, over 50.5% held doctoral or master's degrees. Our core R&D personnel consisted of eight members, who collectively possess extensive experience across the entire drug R&D process, including discovery, pre-clinical studies, CMC development, clinical trials and registration, with an average of approximately 19 years of experience in the biopharmaceutical industry. The R&D team is structured into three specialized centers with clear division of functions. The CMC R&D Center focuses on chemistry, manufacturing, and controls, comprising quality management, active pharmaceutical ingredients (API), drug formulation, and pharmaceutical analysis. The Pre-Clinical R&D Center is responsible for pre-clinical research, covering non-clinical quality, early-stage R&D, pharmacokinetics, pharmacology and toxicology. The Clinical R&D Center oversees clinical development, comprising clinical medicine, pharmacovigilance, clinical quality, clinical operations, clinical pharmacology, biometrics and statistics as well as regulatory affairs.

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The following table sets forth a breakdown of the number of R&D team by function as of the Latest Practicable Date:

<u>Function of R&amp;D team</u>	<u>Number</u>
CMC R&D Center . . . . .	32
Pre-Clinical R&D Center . . . . .	13
Clinical R&D Center . . . . .	58
<b>Total . . . . .</b>	<b>103</b>

The following table sets forth the identities, positions, expertise of part of our core R&D personnel and their involvement and contributions to the R&D activities since the discovery of the Core Product and up to the Latest Practicable Date. All the key employees involved in the development of the Core Product MT1013 remained employed by us during the Track Record Period and as of the Latest Practicable Date.

<u>Identities</u>	<u>Positions</u>	<u>Expertise</u>	<u>Involvement and contributions to the R&amp;D activities since the discovery of the Core Product</u>	<u>Date of joining our Group</u>
Dr. Wang Bing (王冰) . . . . .	Chairman of our Board and Executive Director	Over 20-year experience in the medical and pharmaceutical industry	Steered key development directions of the Core Product	December 2019
Dr. Yu Weiping . . . . .	Executive Director, Senior Vice President	Over 40-year experience of drug R&D with a doctoral degree of University of Paris-Sud	CMC of the Core Product	August 2019
Ms. Wang Xiangling (王湘玲). . . . .	Chief Medical Officer	Nearly 20-year experience of drug R&D with education experience in Xiangya School of Medicine and Shantou University Medical College	Clinical trials of the Core Product	October 2024

Ms. Wang Xiangling focused on clinical development and the related functions. Prior to the joining of Ms. Wang Xiangling, the rest of R&D personnel had sufficient experience to support the R&D of our Core Product and had been contributing to the R&D of the Core Product throughout the process under the leadership of Dr. Wang Bing and Dr. Yu Weiping, including but not limited to drug discovery and clinical trial management. For biographies of Dr. Wang Bing, Dr. Yu Weiping and Ms. Wang Xiangling, please see "Directors and Senior Management".

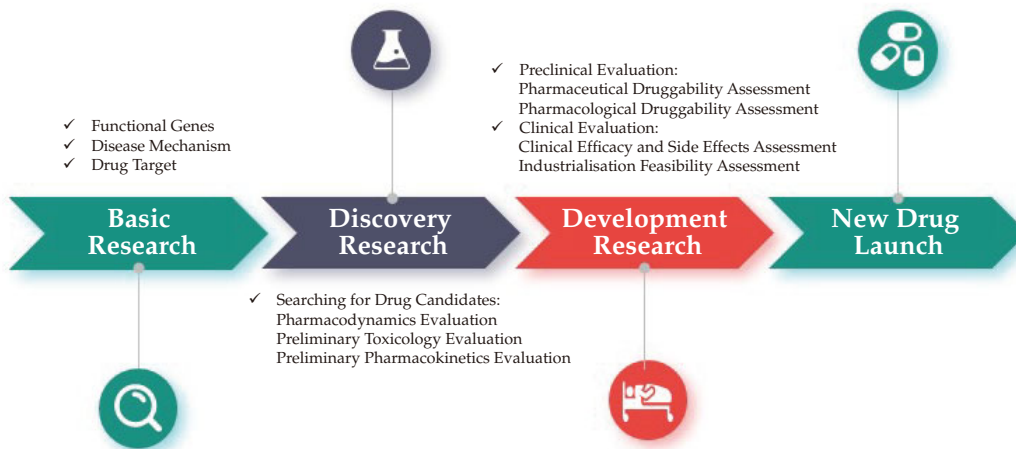
**R&D Facilities**

As of the Latest Practicable Date, our R&D activities were primarily conducted in our headquarters Xi'an in the PRC. Our R&D facilities are equipped with advanced equipment and workspace to facilitate the R&D activities covering basic research, drug discovery, pharmaceutical development as well as regulatory matters.

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### R&D Process

The flowchart below illustrates the key stages of our R&D process, from basic research, drug discovery research, drug development research to NDA submission:



- **Basic Research.** At the basic research stage, efforts are primarily focused on the identification of functional genes, elucidation of disease mechanisms, and discovery of potential drug targets, providing the biological foundation and target rationale for subsequent drug development.
- **Drug Discovery Research.** The drug discovery phase begins with developability assessment, where we conduct iterative cycles of therapeutic indication evaluation, target validation, competitor benchmarking, and risk-benefit analysis to identify promising opportunities. During this critical stage, our early-stage R&D department of Pre-Clinical R&D team focuses on scaffold design and optimization, systematically progressing compounds through hit identification and hit-to-lead-to-candidate optimization. Concurrently, our biology team of early-stage R&D department performs essential target verification along with preliminary assessments of pharmacological activity, pharmacokinetic properties, and toxicity profiles. This multidisciplinary approach ensures we select only the most viable candidates for further development while mitigating potential risks early in the process.
- **Drug Development Research.** The subsequent drug development phase represents a comprehensive druggability evaluation stage where drug candidates undergo extensive preclinical and clinical assessment:
  - Our preclinical evaluations include integrated druggability assessments featuring complete pharmacological characterization, pharmacokinetic/pharmacodynamic studies, and toxicological profiling, as well as pharmaceutical druggability assessment covering process development, quality standard establishment, and early formulation technology assessment.
  - As drug candidates progress, we conduct clinical studies focused on administration route/dose exploration and efficacy/safety profiling, while simultaneously advancing industrialization research to optimize API processes, refine dosage form manufacturing, and enhance quality standards.
- **Application for marketing of new drugs.** If the safety and effectiveness of a drug have been proved in clinical trials. Once the requirements for the manufacturing process, quality control and GMP are met, we can then apply for an NDA with the regulatory authority.

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### Collaboration with Third Parties in R&D

We collaborate with third parties such as SMOs and CROs to conduct and support our preclinical and clinical studies, which is in line with the general practice in the industry. We select our SMO and CRO partners by weighing various factors, such as their qualifications, academic and professional experience, industry reputation and service fees.

In terms of the involvement and contributions of each of the major SMOs and CROs to the development of our drug candidates, the SMO partners provide a comprehensive suite of services to assist us in implementing and managing clinical trials, including trial preparation and trial conduct management. The preclinical CRO partners mainly provide us with services related to preclinical toxicity and safety evaluations, such as animal studies, of our product candidates in accordance with agreed study design and under our supervision. The clinical CRO partners provide us with an array of services necessary for complex clinical trials in accordance with agreed trial design and under our supervision. We carefully supervise our SMO and CRO partners to ensure that they perform their duties in a manner that complies with our protocols and applicable laws and protects the data integrity.

Our cooperative relationship with SMO and CRO partners is based on specific projects, depending on the type of services needed, we enter into service agreements which set out detailed work scope, work plan and technical requirements, deliverables and payment schedule. Key terms of our agreements that we typically enter into with our SMO and CRO partners are set forth below:

#### *Agreements with SMOs*

- **Services.** According to China's GCP common practice, we engage SMOs, working together with trial sites in trial site management, including assisting in recruiting trial participants, coordinating site staff to confirm site process compliance, collecting clinical trial documents and maintaining data integrity at each site.
- **Term.** Our SMO partners are required to perform their services and complete the clinical trial project within the prescribed time limit set out in each agreement, with service fees settled based on actual enrollment.
- **Payments.** We typically make an initial payment within a specified timeframe upon the execution of the agreement and make subsequent payments through monthly or quarterly settlement. We generally settle payments upon receipt of deliverables at the conclusion of project.
- **Intellectual property.** All clinical results, reports, publications, and related rights and interests, including all intellectual property rights in connection with the performance of the agreements, are owned by us.
- **Confidentiality.** SMOs are obligated to keep all non-public information and data from clinical trials confidential.
- **GCP compliance.** We require our SMO partners to coordinate clinical trials in accordance with GCP standards. Typically, we require the clinical research coordinator to have GCP training experience and hold relevant certification.

#### *Agreements with CROs*

- **Services.** Our CRO partners are required to conduct comprehensive implementation, management, and monitoring of clinical trials as specified in the agreement.
- **Term.** Our CRO partners are required to perform their services and complete the clinical trial project within the prescribed time limit set out in each agreement.
- **Payments.** We are required to make payments to CRO partners in accordance with the payment schedule agreed by the parties.
- **Intellectual property rights.** All intellectual property rights arising from preclinical and clinical trials are owned by us.

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- **Confidentiality.** Our CRO partners are required to keep confidential all the data, information or contents we distributed to them related to the project specified in the agreement, and such obligation may survive the termination of the cooperation agreement.
- **GCP compliance.** We require our CRO partners to conduct clinical trials in accordance with GCP standards. Typically, we require the CRO personnel handling our clinical trials to have GCP training experience or hold relevant certification.

We engaged in strategic R&D collaborations with the prestigious university, which provide us with valuable insights into industry trends and emerging technologies, thereby enabling us to focus our current and future R&D efforts more effectively and maintain our competitive edge.

### PRODUCTION

At current stage, as all our manufactured products are investigational drugs for clinical trial use, we arrange production schedules in accordance with clinical development plans and outsource the manufacturing of both APIs and drug products to third-party CDMOs.

### CMC

Our CMC R&D center, comprising the CMC quality department, API department, formulation department and analytical department, provides support throughout the drug development process. Our CMC platform covers the key CMC development stages for APIs, formulations and sustained-release preparations. It encompasses the core capabilities required across the peptide drug development cycle, including process development and optimization from the preclinical to commercial stages, comprehensive quality studies, and technology transfer in support of regulatory submissions. Leveraging this platform, our CMC R&D team is capable of independently conducting key activities including API process development, formulation process development and API scale-up at kilogram level. As of the Latest Practicable Date, our CMC team consisted of 32 members.

Our CMC R&D center is led by Dr. Yu Weiping, an executive Director and Senior Vice President of our Group, who is primarily responsible for CMC and quality management. For more information, see "DIRECTORS AND SENIOR MANAGEMENT" in this document.

### Collaboration with CDMO

As of the Latest Practicable Date, we had not established any manufacturing facility for commercialization scale. We currently collaborate with industry recognized CDMOs in China. Our CDMO partners have established a set of GMP and cGMP-compliant biopharmaceutical R&D and production system which is recognized by the CDE, FDA and EMA. We believe it is cost-effective to engage CDMO for certain manufacturing activities as it reduces the capital expenditure required for setting up and maintaining the necessary production lines and allows us to optimize resource allocation to focus on the drug research and development at current stage. We rigorously select CDMO partners in accordance with our Code of Conduct for Procurement Operations, employing a comprehensive evaluation framework that assesses seven key dimensions: Technology (T), Quality control and after-sales service capabilities (Q), Responsiveness and cooperation willingness (R), Delivery capacity (D), Cost (C), Environment (E), and Social responsibility (S) collectively forming our TQRDCES supplier assessment methodology. To monitor and evaluate the services of our CDMO partners, we have adopted MAH system by entering into manufacturing agreements and quality agreements with our CDMO partners, wherein the respective responsibilities and obligations of all parties are clearly stipulated throughout the entire product lifecycle including manufacturing, quality testing, product release, logistics and end-use applications, ensuring full compliance with applicable regulatory requirements. We did not experience any product quality issues in respect of the products manufactured by our CDMO partners during the Track Record Period.

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Salient terms of our collaboration agreement with our CDMO partners are set forth below:

- **Payments.** We typically make an initial payment within a specified timeframe upon the execution of the agreement. As the CDMO delivers the agreed-upon goods, we will inspect and approve them. After approval, the CDMO will issue invoices based on the delivered quantities. We will make the corresponding payment after receiving the invoice.
- **Intellectual property.** Any new technological documents, product verification (including process and method verification), quality standards, records, technical achievements, and intellectual property (including patents, copyrights, and non-patented technology) generated by the CDMO under this contract will belong to us. This includes all written deliverables provided by the CDMO under this agreement.
- **Term.** The agreement becomes effective immediately upon both parties signing and stamping it.
- **Exclusivity.** The CDMO promises not to develop or manufacture similar or identical products related to this project for themselves, nor will they sell the raw materials or finished products to third parties.

### Quality Assurance and Quality Control

In accordance with applicable pharmaceutical regulatory requirements, we have established a Quality Assurance (QA) Department and a Quality Control (QC) Department to oversee quality management. The QA function is responsible for: (i) establishing, implementing and supervising our quality management system to ensure ongoing compliance with the PRC Drug Administration Law, Good Manufacturing Practices and other relevant regulatory requirements; (ii) managing key quality events and independently performing core functions including product release, supplier audits, CDMO oversight, validation activities and regulatory inspection preparedness; and (iii) carrying out GMP training, regulatory communication, product recall and complaint handling, as well as conducting annual product quality reviews, risk assessments and internal audits. The QC function is responsible for: (i) developing and implementing quality control systems to ensure that our products meet applicable legal and regulatory requirements, industry standards and customer specifications; (ii) overseeing full-process quality testing, including sampling and analysis of raw materials, intermediates and finished products manufactured by third-party CDMOs; and (iii) conducting quality data analysis and risk identification, facilitating continuous improvement, and maintaining a traceable quality data management system.

## COMMERCIALIZATION

### Our Marketing Strategy

Successful commercialization relies on an experienced team with specialized expertise. We have established a robust talent framework and expansion plan, with a dedicated team overseeing commercialization activities. Comprised of industry veterans, this team possesses extensive experience in GMP compliance, large-scale production scheduling, and international regulatory requirements.

As of the Latest Practicable Date, we had not obtained marketing approval for any drug candidates, nor had we generated any revenue from product sales. Anticipating commercialization of our MT1013 in early 2028, we will implement a dual-track commercialization approach: domestically through collaborations with third party Contract Sales Organizations (CSOs) and internationally via license-out partnerships. Considering the potentially significant sales cost, we have not built our internal sales team. Instead, we plan to form cooperation with selected CSO partners to leverage their access to a wide range of pharmacies, clinics and hospitals, to better capture the market potential and maximize the value of our Core Product. In particular, we prioritize CSO partners with: (i) demonstrated success in the nephrology therapeutic area, (ii) established nephrology-focused commercialization teams, and (iii) proven capabilities in hospital network development and coverage.

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In February 2026, we entered into an agreement (the "**Agreement**") with Everest Medicines (China) Co., Ltd. ("**Everest**"), a wholly-owned subsidiary of Everest Medicines Limited (Hong Kong [REDACTED]: 1952), both of which are Independent Third Parties. Pursuant to the Agreement, we granted Everest an exclusive right to sell, commercialize and promote our self-developed drug candidate MT1013 for the treatment of SHPT in Chinese Mainland, Hong Kong, Macau, and Taiwan as well as Asia-Pacific (excluding Japan) (the "**Territory**"). Accordingly, Everest acts as an exclusive CSO responsible for the commercialization of MT1013 for the treatment of SHPT in the Territory, while we reserved the rights to (i) research, develop and manufacturing MT1013 globally; (ii) commercialize MT1013 for any indications outside Territory; and (iii) commercialize MT1013 in the Territory for any indications other than SHPT. The following sets forth the salient terms of the Agreement.

R&D	As MT1013 is our self-developed drug candidate, we retain full responsibility for all development activities for MT1013 in the Territory, including conducting CMC studies and pre-clinical studies, and continuing to conduct and complete the clinical trials for MT1013 in Chinese Mainland for SHPT;
MAH	We shall be responsible for applying for, obtaining, renewing and maintaining the marketing authorization for MT1013 in Chinese Mainland in accordance with applicable laws, and we or our affiliates shall act as the MAH;
IP rights	We shall own all IP rights relating to MT1013 and are responsible for the maintenance and enforcement of such IP rights, including bringing legal actions, infringement proceedings and defending against infringement claims;
Production	We shall be responsible for manufacturing and supplying MT1013, either by ourselves or through third parties, to Everest or its designated distributors.
Commercialization	To facilitate sales and marketing and in line with general practice in the industry, Everest shall be entitled to handle general matters with respect to the routine and day-to-day marketing of MT1013 in the Territory for the treatment of SHPT, including formulating and implementing market access and reimbursement negotiation strategies, while giving good faith consideration our Company's reasonable suggestions. Everest shall also prepare and submit an annual commercialization plan for MT1013 for the treatment of SHPT, subject to our Company's review, and provide periodic reports on its implementation. In addition, Everest shall undertake annual minimum sales target with our Company, which will be subjected to negotiation between our Company and Everest.
Joint steering committee ("JSC")	A JSC shall be established to coordinate and communicate the commercialization activities of MT1013 in the Territory for the treatment of SHPT. The JSC shall consist of four members, with two representatives appointed by each party;
Payment	We are entitled to receive an upfront payment of RMB200 million and potential regulatory and commercial milestone payments of up to RMB1,040 million;

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### Termination

The Agreement may be terminated under certain circumstances, including if Everest fails to achieve a specified percentage of the annual minimum sales target for three consecutive years, in which case we have the right to terminate the Agreement.

We anticipate MT1013, a dual-target polypeptide agonist of CaSR and OGP, will be competitively positioned in the marketplace in light of its multiple clinical benefits. Given that CaSR agonists currently achieve a comprehensive control rate of only approximately 7.5%, there remains an urgent clinical need for innovative varieties capable of achieving higher target rates and reducing mortality risk. In a Phase II head-to-head comparison with Etelcalcetide, after 26 weeks of treatment, the proportion of subjects in the MT1013 group achieving simultaneous control of iPTH, serum calcium and serum phosphorus was approximately 2.5 times that of Etelcalcetide. Clinical results also showed its fast-acting profile, strong and sustained efficacy, potential cardiovascular benefits, favorable safety and tolerability profile, and improvements in bone mineral density and bone mineral metabolism. In particular, upon the marketing approval of our Core Product MT1013, we plan to adopt tailored business strategies at different stages of its commercial cycle. Prior to its inclusion in the NRDL, we aim to increase the accessibility of MT1013 and gradually accumulate the patient base by leveraging our future commercialization partner's sales network and experience and collaborating with the partner to conduct significant promotion activities to improve market awareness and our brand recognition by physicians and patients, and actively seek entry into hospitals and clinics nationwide to broaden our patient base by educating industry participants, including physicians, through presentation of the advantages of MT1013 in various academic and industry conferences. We also believe that for a drug with potentially significant beneficial results, like MT1013, word-of-mouth referrals can also establish a favorable market reputation and increase the patient base and physicians' willingness to prescribe.

In the overseas markets, we plan to unlock the value of our assets through commercialization collaborations with multinational corporations (MNCs), and we plan to seek out-licensing opportunities with such MNCs for the development of our product candidates. We plan to select such MNCs who have proven track record of commercializing products with rich experience in the nephrology franchises, their local presence including clinical access and network coverage as well as brand recognition, to achieve fast market penetration and maximize commercial opportunities of our drug products effectively. We expect such MNCs to share the potentially significant development costs with us and leverage their local network to facilitate various aspects of the clinical development, such as clinical site establishment, patient enrollment, material supplies and regulatory communications. For the overseas market, we generally plan to take a step-wise approach and plan to formulate a more concrete plan after we commercialize MT1013 in the PRC, to ensure we allocate our resources and focus on the most important and imminent milestones.

### Pricing

During the Track Record Period and up to the Latest Practicable Date, we had no commercialized drugs on the market either in China or overseas. We have not formulated any definitive pricing policy for our drug candidates yet. When our drug candidates progress to commercialization in the future, we will determine their prices based on various factors, such as current medical needs, our drugs' pharmacoeconomic evaluation, our production costs, prices of prior line treatment options, competitive landscape and prices of competing drugs, differences in features between our drugs and competing drugs, and health economics in the country to market in. We will conduct extensive market research with KOLs, hospitals, physicians and patients as well as regulatory bodies before pricing our drugs.

Our Core Product, MT1013, is expected to be launched in the PRC first, then in the U.S. and other regions. We will determine the price of MT1013 in the PRC considering the factors including estimated demand, production costs, affordability of patients, and the prices of second generation CaSR agonists, such as Etelcalcetide (with the price of USD2,684 and RMB3,640 per 30-day treatment cycle in the U.S. and China, respectively). We will also take into consideration that MT1013 is the world's first-in-class dual-targeting receptor agonist polypeptide that simultaneously targets the CaSR and the

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OGP receptor, and has demonstrated significant clinical benefits, as shown by clinical studies indicating a marked improvement in the comprehensive control rate of iPTH, serum calcium and serum phosphorus levels. We will further assess the differences in safety and efficacy and respective benefits between MT1013 and any such potential competing drugs. In addition, we will actively negotiate with government authorities for MT1013 to be included in the NRDL to enhance our product affordability. However, inclusion into the NRDL is evaluated and determined by the relevant government authorities and we may face significant competition for successful inclusion. For more information, see "Risk Factors — Risks Relating to Our Business and Operation — If our products are not included in or are removed from national, provincial or other government sponsored medical insurance programs, our business, financial condition, results of operations and prospects could be materially and adversely affected."

### INTELLECTUAL PROPERTY

Intellectual property rights are important to the success of our business, and we are committed to the development and protection of our intellectual properties. As of the Latest Practicable Date, we owned (i) 10 granted patents in the PRC, three granted patents in Hong Kong, 22 granted patents overseas, and (ii) three patent applications in the PRC, three patent applications in Hong Kong, 10 patent applications overseas and one PCT patent application. As of the Latest Practicable Date, with respect to our Core Product MT1013, we owned (i) four granted patents, including one in the PRC, one in Hong Kong, one in Japan and one in Australia, and (ii) four patent applications, including one in the U.S., one in Europe, one in Canada and one in Korea. The following table sets forth the patents and patent applications of our Core Product as of the Latest Practicable Date. For details, see "Appendix IV — Statutory and General Information — Further Information About our Business."

	Title of Invention	Application Number	Jurisdiction	Status	Expiration Date	Patent Holder/ Applicant
1 . . . .	Bispecific fusion polypeptide compound (雙特異性融合多肽化合物)	CN202180014524.4	PRC	Granted	April 20, 2041	Our Company
2 . . . .	Bispecific fusion polypeptide compound	US18044668	U.S.	Pending	N/A	Our Company
3 . . . .	Bispecific fusion polypeptide compound (雙特異性融合多肽化合物)	HK62022059523.0	Hong Kong	Granted	April 20, 2041	Our Company
4 . . . .	二重特異性融合ポリペプチド化合物	JP2022-558554	Japan	Granted	April 20, 2041	Our Company
5 . . . .	Bispecific fusion polypeptide compound	AU2021338639	Australia	Granted	April 20, 2041	Our Company
6 . . . .	Bispecific fusion polypeptide compound	EP21865532.2	Europe	Pending	N/A	Our Company
7 . . . .	Bispecific fusion polypeptide compound	CA3194729	Canada	Pending	N/A	Our Company
8 . . . .	이중특이적용합폴리펩타이드화합물	KR1020237011659	Korea	Pending	N/A	Our Company

As of the Latest Practicable Date, we had 32 registered trademarks in the PRC and six registered trademarks overseas. We are also the registered owner of four domain name. See "Risk Factors — Risks Relating to Our Intellectual Property Rights" for a description of risks related to our intellectual property.

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During the Track Record Period and up to the Latest Practicable Date, we had not been involved in any material proceedings in respect of, and we had not received notice of any material claims of infringement of, any intellectual property rights of third parties that may be threatened or pending. A freedom-to-operate searches and analyses ("FTO Analysis") has been conducted in the PRC and the U.S. in relation to our Core Product and Key Products. Based on the FTO Analysis and as advised by our PRC Intellectual Property Legal Advisor, our Directors are of the view that we have not infringed any valid and enforceable patents or other IP rights of any third parties in the PRC and the U.S.

### SUPPLIERS AND PROCUREMENT

During the Track Record Period, our suppliers primarily consisted of (i) providers of clinical services, including SMO, CRO and CDMO partners, (ii) providers of pre-clinical services, and (iii) providers of administrative and operational management services.

For the years ended December 31, 2024 and 2025, the aggregate purchases attributable to our five largest suppliers in each year during the Track Record Period amounted to RMB31.3 million and RMB26.8 million, respectively, representing 39.5% and 27.6% of our total purchases for the respective periods. Purchases attributable to our single largest supplier amounted to RMB7.6 million and RMB8.6 million for the same years, accounting for 9.6% and 8.9% of our total purchases for the respective periods. We believe that we maintain stable relationships with our major suppliers.

Our suppliers are mainly CROs, CMOs, CDMOs. See "— Collaboration with Third Parties in R&D" and "— Collaboration with CDMO" in this section for key terms of our agreements that we typically enter into with a CRO, CMO, or CDMO partner.

The following table sets forth details of our five largest suppliers in each year during the Track Record Period:

*Year ended December 31, 2024*

Supplier	Background	Products/ Services	Commencement of business relationship	Credit terms	Purchase amount (RMB'000)	% of total purchases for the respective periods
Supplier A . . . . .	A public company founded in 2000 in China with approximately RMB2,933 million in registered capital that mainly engages in new drug research and development, pharmaceutical technology services and medical product wholesale.	CRO services	2019	15-30 days	7,587.8	9.6%
Supplier B . . . . .	A private company founded in 2009 in China with approximately RMB185 million in registered capital that mainly engaged in research and experimental development.	CDMO services, CRO services	2021	10 days	7,242.4	9.1%
Supplier C . . . . .	A private company founded in 2019 in China with USD47 million in registered capital that mainly engages in consulting services, information technology services, bio-energy technology services and medical device circulation.	CRO services	2022	15-30 days	7,027.8	8.9%

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Supplier	Background	Products/ Services	Commencement of business relationship	Credit terms	Purchase amount (RMB'000)	% of total purchases for the respective periods
Thousand Oaks Biologics INC* (澳斯康生物(南通)股份 有限公司) . . . . .	A private company founded in 2017 in China with approximately RMB49 million in registered capital that mainly engages in pharmaceutical manufacturing.	CDMO services	2022	7-15 days	5,333.2	6.7%
Zhejiang Haorecruit Pharmaceutical Technology Co., Ltd.* (浙江好招募醫藥 科技有限公司) . . . . .	A private company founded in 2021 in China with RMB10 million in registered capital that mainly engages in research and experimental development.	Subject recruitment services	2023	10 days	4,144.3	5.2%
Total . . . . .					<u>31,335.5</u>	<u>39.5%</u>

*Year ended December 31, 2025*

Supplier	Background	Products/ Services	Commencement of business relationship	Credit terms	Purchase amount (RMB'000)	% of total purchases for the respective periods
Supplier A. . . . .	Please see above.	CRO services	2019	15-30 days	8,636.8	8.9%
Beijing Fengyi Technology Co., Ltd.* (北京鋒屹科技有限 公司) . . . . .	A private company founded in 2023 in China with approximately RMB5 million in registered capital that mainly engages in technology promotion and application services.	Subject recruitment services	2024	30 days	5,152.7	5.3%
Supplier D. . . . .	A comprehensive Grade III Level A hospital located in Beijing.	Participation in clinical trials	2021	20 days	4,744.8	4.9%
Zhongling Huizhi Technology Service (Xi'an) Co., Ltd.* (中領匯智科技服務(西安) 有限公司) . . . . .	A private company founded in 2015 in China with approximately RMB5 million in registered capital that mainly engages in comprehensive management services, technology and software services, etc.	Clinical monitoring services	2024	30 days	4,395.0	4.5%
Tianjin Wanze Pharmacy Chain Co., Ltd.* (天津萬澤大藥房連 鎖有限公司) . . . . .	A private company founded in 2023 in China with approximately RMB5 million in registered capital that mainly engages in retail industry.	Drug supply services	2024	20 days	3,917.6	4.0%
Total . . . . .					<u>26,846.9</u>	<u>27.6%</u>

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All of our five largest suppliers in each year during the Track Record Period are independent third parties. To the best knowledge of our Directors, none of our Directors, their respective associates or, or any Shareholder with over 5% of our issued share capital as of the Latest Practicable Date has any interest in any of our five largest suppliers in each year during the Track Record Period.

**COMPETITION**

Our industry is highly competitive and subject to rapid and significant change. While we believe that our innovative technology platforms, our drug candidates and our experienced management team provide us with competitive advantages, we face potential competition from many others working to develop therapies targeting the same indications. These include major biopharmaceutical companies, specialty pharmaceutical and biotechnology companies, and academic institutions, government agencies and research institutions. Any drug candidates that we successfully develop and commercialize will compete both with existing drugs and with any new drugs that may become available in the future.

We are committed to the development of innovative drug candidates with a focus on metabolic diseases (particularly renal-related conditions) and cardiovascular and cerebrovascular diseases, targeting indications such as SHPT, CKD-MBD with Osteoporosis, SHPT not on Dialysis, Chronic Weight Management in Obese or Overweight Populations, ACS-PCI and AIS. Our efforts to bring innovative drug to the market for these indications face intense competition from a burgeoning landscape of pharmaceutical companies. For more information on the competitive landscape of our drug candidates, see "Industry Overview" in this document.

**EMPLOYEES**

As of the Latest Practicable Date, we had 131 full-time employees, all of whom were based in China, and approximately 47.3% of whom held doctoral or master's degrees. The following table sets forth the details of our employees by function:

<u>Function</u>	<u>Number</u>	<u>% of Total</u>
R&D . . . . .	103	78.6%
Finance & Legal . . . . .	6	4.6%
Others (Administrative, IP, Procurement & Public Affairs, etc.) . . . . .	22	16.8%
<b>Total</b> . . . . .	<b>131</b>	<b>100%</b>

We enter into individual employment contracts with our employees covering matters such as salaries, bonuses, employee benefits, workplace safety, confidentiality obligations, work product assignment clause and grounds for termination. Our employee contracts specify that employees are obligated to strictly safeguard our commercial and technical secrets. Additionally, any intellectual property created by employees during their employment while performing their duties, other assigned tasks, or through the use of our resources, funding, or technology, will belong to us.

We place a high value on recruiting and training qualified employees. We maintain high standards on selecting and recruiting talent and provide competitive compensation packages. The remuneration package of our employees includes salary and bonus, which are generally determined by their performance review. We also offer share incentives and promotion opportunities to motivate our employees. During the Track Record Period and up to the Latest Practicable Date, we did not experience any material labor disputes or strikes that may have a material and adverse effect on our business, financial condition or results of operations.

During the Track Record Period, we failed to pay social insurance premiums and housing provident funds in full for and on behalf of some of our employees in accordance with applicable PRC laws and regulations. Based on our estimate, the shortfall of our social insurance and housing provident fund contributions during the Track Record

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Period amounted to RMB0.6 million and RMB0.9 million for the year ended December 31, 2024 and 2025, respectively. Our PRC Legal Advisor is of the view that the risk of incurring material administrative penalties issued by the relevant government authorities is remote, provided that there are no significant changes in current policies, regulations, local government supervision, and law enforcement requirements related to social insurance and housing provident fund and based on the following reasons: (i) during the Track Record Period and up to the Latest Practicable Date, we had not received any notification from the relevant government authorities requiring us to settle any payment shortfall; (ii) we had not been subject to any administrative penalties with respect to social insurance premiums and housing provident funds; and (iii) if any notice related to the payment of social insurance and housing provident funds is received from government authorities in the future, we undertake that we will make up the required amount within the stipulated period.

Therefore, our Directors believe that our failure to fully pay social insurance premiums and housing provident funds will not have an adverse impact on our financial condition and business operations.

**INSURANCE**

We maintain insurance policies that are required under PRC laws and regulations as well as based on our assessment of our operational needs and industry practice. Our existing insurance policies cover adverse events in our clinical trials. We maintain insurance for our employees in accordance with relevant PRC laws and regulations. We believe that our insurance coverage is adequate to cover our key assets, facilities, and liabilities. For more information, see "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."

**LAND AND PROPERTIES**

**Owned Land and Properties**

As of Latest Practicable Date, we owned the land use right of one land parcel in Taizhou, the PRC, with an aggregate land area of approximately 28,397 sq.m., which is planned for potential development of production facilities. Our PRC Legal Adviser confirmed that, as of the Latest Practicable Date, we had obtained all relevant land use rights certificates for this property in the PRC.

**Leased Properties**

As of the Latest Practicable Date, we leased four properties for office and R&D uses in the PRC, with an aggregate GFA of approximately 6,727.895 sq. m. The following table sets forth the details of our leased properties as of the Latest Practicable Date.

<u>Usage</u>	<u>Location</u>	<u>GFA (sq.m.)</u>	<u>Lease Term</u>
Office and R&D . . . . .	Xi'an, China	2,958.15	July 1, 2025 to June 30, 2027
Office . . . . .	Beijing, China	221.5	November 1, 2023 to October 31, 2027
Office . . . . .	Shanghai, China	108	April 1, 2024 to April 30, 2026
Office . . . . .	Suzhou, China	3,440.245	May 18, 2021 to May 17, 2026

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As of the Latest Practicable Date, we had not completed the relevant property leasing registration for two of our leased properties. For details of the risk associated with the unregistered lease agreements, please refer to "Risk Factors — Risks Relating to Our Business and Industry — We are subject to risks associated with leasing space." According to the Urban Real Estate Administration Law of the PRC (中華人民共和國城市房地產管理法), and the Commercial Building Leasing Administrative Measures (商品房屋租賃管理辦法), the relevant local governments may require the rectification of the non-registration of lease agreements within a certain period of time. If rectification is not made within the specified time, we may be subject to a fine ranging from RMB1,000 to RMB10,000 for each unregistered lease agreement and the maximum aggregate amount of fines that may be imposed due to such defects is RMB 20,000. According to our PRC Legal Advisor, under the Civil Code of the PRC (中華人民共和國民法典), the non-registration of the lease agreements does not affect the validity and enforceability of the lease agreements. During the Track Record Period and up to the Latest Practicable Date, we had not been subject to any penalties arising from the non-registration of our lease agreement and had not experienced any dispute arising out of, or in relation to, our leased properties. In addition, the unregistered leased properties were solely for the office use, and we can easily find the alternative properties in replacement. Our PRC Legal Advisor has advised us, and our Directors believe, that such non-registration would not materially and adversely affect our business operations.

As of December 31, 2025, none of the properties leased by us had a carrying amount of 15% or more of our consolidated total assets. According to Chapter 5 of the Hong Kong Listing Rules and section 6(2) of the Companies Ordinance (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice, this document is exempt from the requirements of section 342(1)(b) of the Companies (Winding up and Miscellaneous Provisions) Ordinance to include all interests in land or buildings in a valuation report.

**AWARDS AND RECOGNITIONS**

The table below sets forth a summary of the major awards and recognition we received during the Track Record Period.

<u>Year of Grant</u>	<u>Award/Recognition</u>	<u>Issuing Authority</u>
2022 . . . . .	"Top 100 Most Promising Innovative Pharmaceutical Seed Companies in China" (「中國醫藥創新種子企業100強」)	Healthcare Executive Magazine (E藥人經理雜誌)
2023 . . . . .	"2022 Shaanxi Provincial Innovative Small and Medium-sized Enterprise"* (「2022年陝西省創新型中小企業」)	Ministry of Industry and Information Technology of the PRC (中華人民共和國工業和信息化部)
2024 . . . . .	Shaanxi Province "Unique and Innovative Small and Medium-sized Enterprises in Shaanxi Province"* (陝西省「專精特新」中小企業)	Shaanxi Province Industrial and Information Technology Bureau* (陝西省工業和信息化廳)
2025 . . . . .	"Third Prize in the National Finals (Biomedicine Sector) of the 14th China Innovation and Entrepreneurship Competition" (第14屆中國創新創業大賽生物醫藥全國賽三等獎)	Torch High Technology Industry Development Center, Ministry of Industry and Information Technology (工業和資訊化部火炬高技術產業開發中心)

## BUSINESS

### ENVIRONMENTAL, SOCIAL AND GOVERNANCE REPORT

As an innovative pharmaceutical technology company focusing on the research and development of new drugs, our Company is committed to integrating ESG concepts into its corporate strategy and operations, actively responding to the concerns of its stakeholders, and creating long-term value for human health in a sustainable manner.

#### 1. ESG Governance

The Company has established an ESG governance structure with clear responsibilities. The members of the Board of Directors have diversified professional knowledge in areas including medicine, biochemistry, pharmacology, biology, business administration, economics and accounting, and possess the appropriate skills and professional capabilities to understand and oversee the impact of ESG risks and opportunities. They are responsible for coordinating ESG-related matters, undertaking ESG strategic decision-making and supervisory functions, approving key matters such as ESG strategic goals and management policies, and reviewing and publishing ESG reports, to align with the Company's business strategy and development goals. To support the Board of Directors in implementing ESG-related work, the Company has established an ESG working group comprising members from departments such as EHS and human resources. This group is responsible for assisting in the formulation and review of the ESG strategic framework, coordinating the advancement of the entire ESG management process, implementing ESG objectives, data collection, performance evaluation, and cross-departmental coordination, etc. The Board of Directors supervises the related work of the ESG working group. In addition, the Company has established risk identification, assessment and response mechanisms that cover environmental and social dimensions, and fully integrates ESG factors into its daily corporate operations.

We have adopted a board diversity policy, which sets out the objectives and approaches to achieve and maintain diversity on the Board of Directors to enhance its effectiveness. Our Company seeks to achieve diversity among the members of the Board of Directors by considering a number of factors, including but not limited to gender, age, cultural and educational background, professional experience, skills, knowledge and/or length of service. Our Board of Directors currently comprises two female Directors and seven male Directors, with ages ranging from 36 to 67.

Our Company attaches great importance to the expectations and demands of stakeholders and continuously improves its ESG management structure. Currently, our Company has conducted specialized ESG training for all employees (including directors and senior management) and holds regular cross-departmental ESG promotion meetings to strengthen internal consensus and executive synergy. Our Company plans to further optimize its risk identification and assessment mechanisms after [REDACTED], enhance its risk management capabilities, and periodically disclose ESG-related reports in accordance with regulatory requirements, to continuously improve its ESG governance level and sustainable development performance.

#### *ESG Materiality Assessment and Risk Management*

The Company attaches great importance to the materiality assessment and risk management of ESG issues. In accordance with the Environmental, Social and Governance Reporting Guide of the Hong Kong Stock Exchange, and in combination with the industry's characteristics and the Company's actual operating conditions, it systematically identifies ESG issues and related risks that have a substantive impact on the business and are of concern to stakeholders, and continuously optimises relevant management work.

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In terms of material issue identification, the Company has identified key issues that are closely related to the Company's environmental, social and governance performance from two dimensions: importance to sustainable development and importance to stakeholders. These issues are: supply chain management, patents and intellectual property, and climate change, which are incorporated into its ESG management strategy and policies.

- **Supply Chain Management:** At the business operations level, supply chain disruptions or quality instability could lead to delays in the R&D of drug candidates, impede the progress of clinical studies, and halt the production of commercialised products, thereby affecting drug approvals and market supply. Financially, supply disruptions or supplier compliance issues may trigger significant expenditures such as product recalls, liability claims or compliance rectifications, which could have a potential adverse impact on overall profitability and financial condition. The Company incorporates supply chain management into its ESG management and business to enhance the sustainability and risk resilience of its supply chain.
- **Patents and Intellectual Property:** In terms of business operations, patent challenges or invalidation may impede the commercialisation process of drug candidates, resulting in R&D investments failing to yield expected returns; in terms of financial performance, legal disputes such as patent litigation will generate high rights protection costs; the leakage of trade secrets of core technologies will lead to a decline in product competitiveness, affecting revenue and profit margins; in terms of R&D investment, significant intellectual property disputes may render years of R&D investment unrecoverable, resulting in asset impairment losses. The Company diversifies its intellectual property risks by exploring the development of technological diversity and open innovation cooperation, ensuring that its technological innovation capabilities continue to support its business development.
- **Climate Change:** In terms of business operations, the potential impacts of climate change on supply chain logistics efficiency and energy costs have been observed, but as of now, there has been no material disruption to normal operations. At the strategic level, the Company is actively incorporating climate factors into its long-term planning to enhance operational resilience and seize opportunities in the low-carbon transition. In terms of financial performance, although climate change is classified as a highly important issue, based on current assessments, it has not yet had a significant impact on the Company's profitability or financial condition, and its actual financial impact is low.

As of the Latest Practicable Date, the Company had not experienced any material ESG-related risk incidents, nor had it been subject to any penalties for violating ESG-related laws and regulations. We will continue to improve our ESG materiality assessment and risk management mechanisms, maintain dynamic monitoring of potential risks, and ensure continued and stable operations.

## 2. Environment

### 2.1 Environmental Management

Our Company strictly complies with national and local environmental laws and regulations such as the Environmental Protection Law of the People's Republic of China (《中華人民共和國環境保護法》), and continuously optimises its environmental management system with reference to international standard systems. In 2024 and 2025, the expenses incurred by our Company for environmental protection and compliance were RMB78,000 and RMB50,200, respectively. As of the Latest Practicable Date, our Company had not recorded any environmental pollution incidents. When formulating its sustainable development goals, the Company has fully considered its current development status and future operational trends, and has made comprehensive reference to the requirements of international standards such as ISSB, GRI, and SASB, as well as the performance of industry peers. Currently, its measurable targets are at an average level within the industry. Guided by scientific emission reduction, efficient resource utilization, and

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low-carbon transition, and considering our characteristics of the industry and our Company's actual operations, the Company has established the following environmental management goals:

- **Emission Reduction Goals**

Our Company strictly complies with national environmental regulations such as the Law of the People's Republic of China on the Prevention and Control of Atmospheric Pollution (《中華人民共和國大氣污染 防治法》), ensuring that 100% of air pollutants such as nitrogen oxides (NO<sub>x</sub>), sulfur dioxide (SO<sub>2</sub>), and volatile organic compounds (VOCs) generated during its production and operation processes are discharged in compliance with standards. To achieve greater emission reduction benefits, our Company, using its 2024 emission data as a baseline, aims to reduce the total emission of air pollutants by 5% by 2030.

- **Greenhouse Gas Emission Reduction Goals**

In response to the national "dual carbon" strategy (carbon peaking and carbon neutrality), our Company has incorporated the vision of carbon neutrality into its long-term development plan and systematically manages Scope 1, Scope 2, and Scope 3 greenhouse gas emissions in its operations. Our Company has set a target to reduce its greenhouse gas emission intensity by 5% by 2030, using 2024 as the baseline. On this basis, our Company will focus on optimising its energy structure and improving energy efficiency, and is committed to achieving carbon neutrality at the operational level by 2050.

- **Waste Reduction Goals**

Through measures such as promoting green procurement, improving material utilization efficiency, and ensuring end-of-pipe compliant disposal and resource utilization, our Company, using the generation intensity of 2024 as a baseline, aims to reduce the emission intensity of hazardous waste by 3% by 2030; for general waste, the target for the same period is a 5% reduction.

- **Energy Use Efficiency Goals**

Using the energy consumption level of 2024 as a baseline, our Company has set a target to achieve a 5% reduction in electricity consumption by 2030 through measures including phasing out high-energy-consumption equipment, optimizing production scheduling and process flows, reducing no-load and standby energy consumption, raising energy-saving awareness among all employees, and building a comprehensive energy-saving management system.

- **Water Use Efficiency Goals**

Our Company values the sustainable use of water resources. Using its water consumption performance in 2024 as a baseline, our Company has set a target to reduce total water consumption by 3% by 2030.

### 2.2 *Emissions Management*

Our Company strictly complies with laws and regulations such as the Law of the People's Republic of China on the Prevention and Control of Atmospheric Pollution and the Water Pollution Prevention and Control Law of the People's Republic of China (《中華人民共和國水污染防治法》), adheres to the classification standards of the National Catalogue of Hazardous Wastes (《國家危險廢物名錄》), and achieves compliant management throughout the entire process:

- **Waste Generation Stage:** All hazardous and medical waste are temporarily stored in dedicated leak-proof containers. In waste management, our Company strictly distinguishes between hazardous waste and general solid waste, and implements end-to-end control over their classified collection, temporary storage, transfer, and disposal.

**BUSINESS**

- Temporary Storage Stage: Our Company implements partitioned and isolated control in standardized hazardous waste temporary storage rooms, which are equipped with leak-proof trays and air conditioning systems; dedicated refrigerators are installed in medical waste rooms to ensure the temporary storage of animal carcasses.
- Transfer Stage: Our Company entrusts qualified third-party organizations to carry out the transfer of hazardous waste, medical waste, and sharps. All transfer manifests are filed for record and inspection to achieve traceable management.

**2.3 Resource Use Management**

Our Company actively practices the concept of green office, improves energy use efficiency from multiple dimensions, and builds a low-carbon office environment:

- Energy-Saving Lighting and Air Conditioning Management: Our Company has fully adopted LED energy-saving lighting systems. In addition, our Company implements a strict air conditioning temperature control system, effectively reducing the electricity load from air conditioning.
- Water Conservation Management and Efficiency Improvement: Our Company has comprehensively improved water resource utilization efficiency by promoting water-saving appliances and strengthening employees' water conservation awareness. To date, no incidents of water scarcity or wastage have occurred.
- Paperless Office and Double-Sided Printing: Our Company has fully implemented digital office processes to reduce the use of paper documents. For documents that must be printed, a double-sided printing policy is promoted, significantly reducing paper consumption.
- Promoting an Energy-Saving Culture: Our Company advocates for energy-saving behaviors among employees, requires that lighting, water supply equipment, and other electronic facilities be turned off during non-use periods, and continuously conducts environmental training and energy-saving initiatives for employees to foster a culture of resource conservation with full participation.

The table below summarizes the resource use performance of our Company during the Track Record Period:

Metrics	Unit	2024	2025
Electricity Consumption . . . . .	kWh	310,174	388,516
Electricity Consumption Intensity . . . . .	kWh/person	3,737.00	5,550.20
Water Consumption . . . . .	m <sup>3</sup>	643	1,910
Water Consumption Intensity . . . . .	m <sup>3</sup> /person	7.75	27.28

**2.4 Responding to Climate Change**

Our Company has systematically identified the potential impacts of climate change on its operations, including transition risks such as changes in policies and regulations, and physical risks such as disruptions to production and the supply chain from extreme weather events. To this end, our Company will continue to assess climate-related risks and opportunities, ensure its operational resilience, and steadily advance its goals of peaking carbon emissions by 2030 and achieving carbon neutrality by 2050. As of the end of the reporting period, our Company has initially observed the potential impacts of climate change on certain business segments, such as supply chain logistics and energy costs, but these impacts do not yet constitute significant operational or financial risks, and the impact on our existing assets is low.

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The table below lists the relevant risks identified to date:

Risk Type		Specific Impact
Physical Risks	Acute Risks	<ul style="list-style-type: none"> <li>Power outages, network disruptions or physical damage to R&amp;D laboratories or data centres caused by extreme weather events such as heavy rain</li> </ul>
	Chronic Risks	<ul style="list-style-type: none"> <li>Prolonged high temperatures and heat affecting the stability of raw materials during transportation and storage</li> <li>Continuous increase in cooling energy consumption costs to maintain a constant temperature and humidity in the laboratory environment</li> </ul>
Transition Risks	Policy and Legal Changes	<ul style="list-style-type: none"> <li>Stricter requirements for laboratory waste disposal</li> <li>Carbon regulation leading to additional expenses for purchasing carbon allowances and tax payments</li> </ul>
	Market and Technology Risks	<ul style="list-style-type: none"> <li>Low-carbon R&amp;D methods such as green chemistry changing traditional R&amp;D models</li> </ul>

The table below sets out the greenhouse gas (GHG) emissions of our Company during the Track Record Period:

Metrics	Unit	2024	2025
Total Greenhouse Gas Emissions (Scope 1+Scope 2)	tCO <sub>2</sub> e	174.75	219.24
Greenhouse Gas Emissions Intensity (Scope 1+ Scope 2)	tCO <sub>2</sub> e/person	2.11	1.81
Scope 1 GHG Emissions	tCO <sub>2</sub> e	8.31	10.76
Scope 1 GHG Emissions Intensity	tCO <sub>2</sub> e/person	0.10	0.09
Scope 2 GHG Emissions	tCO <sub>2</sub> e	166.44	208.48
Scope 2 GHG Emissions Intensity	tCO <sub>2</sub> e/person	2.01	1.72
Scope 3 GHG Emissions	tCO <sub>2</sub> e	9,562.50	9,932.83
Category 1	tCO <sub>2</sub> e	8,433.81	7,612.02
Category 5	tCO <sub>2</sub> e	7.56	41.3
Category 6	tCO <sub>2</sub> e	1,068.29	2,215.75
Category 7	tCO <sub>2</sub> e	52.85	63.76
Scope 3 GHG Emissions Intensity	tCO <sub>2</sub> e/person	115.21	82.09

*Note: The calculation method for GHG emissions is based on the \*Sixth Assessment Report\* issued by the Intergovernmental Panel on Climate Change (IPCC) and the \*Announcement on the Release of 2022 CO<sub>2</sub> Emission Factors for the Power Grid\* (《關於發佈2022年電力二氧化碳排放因子的公告》) issued by the Ministry of Ecology and Environment.*

### 3. Social

#### 3.1 Employment

Our Company strictly complies with laws and regulations such as the Labour Law of the People's Republic of China (《中華人民共和國勞動法》) and the Labour Contract Law of the People's Republic of China (《中華人民共和國勞動合同法》), has formulated internal management systems such as the Employee Handbook, and resolutely prohibits child labour and forced labour. It also strictly verifies the age information of applicants, communicates fully with employees before they work overtime, and strictly controls the duration of such overtime. As of the Latest Practicable Date, our Company had not had any incidents of child labour or forced labour.

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Our Company is committed to creating a diverse, equal, and inclusive work environment. It avoids discriminatory language and prejudice in recruitment and explicitly states that it does not discriminate against employees in recruitment and actual work based on age, gender, race, disability, marital status, etc., to ensure that employees are free from harassment and illegal discrimination.

Metrics	Unit	2024	2025
Total Number of Employees	Person	83	121
By Gender	Male	36	56
	Female	47	65
By Age	30 years old and under	19	25
	31-50 years old	59	89
	Over 50 years old	5	7

### 3.2 Health and Safety

Our Company regards production safety as the cornerstone of its steady development and strictly complies with relevant laws and regulations such as the Work Safety Law of the People's Republic of China (《中華人民共和國安全生產法》) and the Law of the People's Republic of China on the Prevention and Control of Occupational Diseases (《中華人民共和國職業病防治法》). It has formulated systems such as the \*Environmental, Occupational Health and Safety Management System\*, \*Occupational Health Management\*, and \*Management System for Detecting Occupational Hazard Factors in the Workplace\*, established and improved its work safety responsibility system, and continuously improves its occupational health and safety management system. To protect personnel from harm when in contact with irritating, corrosive and toxic chemical substances (such as pyridine and hydrochloric acid), our Company equips its laboratories with compliant workwear, boots, gloves, masks and protective eyewear to prevent or mitigate chemical damage to their eyes and skin. Our Company strengthens work safety education and training, formulates an annual safety training plan, and conducts safety training in an orderly manner. In 2024 and 2025, the Company did not have any work-related injury accidents, and the number of workdays lost due to work-related injuries was 0.

### 3.3 Development and Training

To effectively help every employee realise their full potential, our Company has established differentiated training courses for employees of different types and from different business departments, created an online learning platform, and offered various categories of training content, such as skills training and specialized training, to comprehensively improve employees' quality, skills and professional knowledge. Our Company safeguards employees' career development paths, providing a dual-track promotion mechanism for management and professional development for employees at different functions and levels, allowing them to grow and advance in a fair and just environment.

Metrics	Unit	2024	2025
Percentage of Trained Employees by Gender	Male	43	45
	Female	57	55
Percentage of Trained Employees by Employment Category	Senior Management	25	26
	Middle Management	34	26
	General staff	41	48
Average Hours of Training of Employees by Gender	Male	1,546	1,771
	Female	1,815	1,992
Average Hours of Training of Employees by Category	Senior Management	504	651
	Middle Management	471	553
	General staff	2,442	2,653

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### **3.4 Clinical Trials**

Our Company always places the rights and safety of subjects at the core of drug clinical trials, complies with the principles of the Declaration of Helsinki of the World Medical Association and relevant ethical requirements, ensures the implementation of ethical review and informed consent procedures, and protects the rights of subjects.

In terms of data protection, our Company is committed to protecting the information of trial participants in accordance with applicable laws, regulations, and industry standards, and properly records, processes, and preserves participants' clinical trial data to ensure the security and confidentiality of their data and privacy. Our Company also imposes data protection requirements on its clinical trial-related suppliers, who must assume strict confidentiality obligations for all documents, data, records, and information provided by our Company or generated by them during the performance of their services. In addition, our Company signs confidentiality agreements with its internal R&D personnel and ensures the security and reliability of clinical trial data and information through multiple layers of protection.

### **3.5 Animal Welfare**

Our Company always conducts animal research with high standards, typically engaging CROs to carry out animal studies, ensuring that all research activities are conducted in breeding environments that comply with national standards. Our Company strictly complies with key laws and regulations concerning animal welfare and is committed to providing experimental animals with humane care, psychological support, and professional veterinary care. Through ethical reviews, personnel training, and full-process compliance supervision, it ensures that every study reflects respect and responsibility for life.

### **3.6 Supply Chain Management**

Our Company has established a comprehensive supply chain management system and formulated management systems such as the "Code of Conduct for Procurement Business" and "Cross-departmental Workflow for Bidding and Tendering by Procurement Expert Group". We are committed to fully integrating environmental, social and governance factors into its supplier screening process. In 2024 and 2025, our Company collaborated with a total of 322 and 409 suppliers, respectively.

Our Company always upholds a "zero tolerance" principle and resolutely prevents any unfair competition and corrupt practices in the procurement and supplier fulfillment processes. Our Company includes anti-commercial bribery clauses in its contracts and requires suppliers to sign a "Supplier Integrity Pledge" to clarify their integrity obligations, working together to build a fair and honest supply chain.

### **3.7 Business Ethics and Anti-corruption**

Our Company strictly complies with laws and regulations such as the Anti-Unfair Competition Law of the People's Republic of China (《中華人民共和國反不正當競爭法》) and the Anti-Money Laundering Law of the People's Republic of China (《中華人民共和國反洗錢法》), and has formulated internal management systems such as the \*Guidelines on Business Gifts and Anti-Commercial Bribery\* to urge employees to adhere to business ethics. In 2024 and 2025, there were no concluded legal proceedings against our Company or its employees in relation to corruption.

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Our Company has established a comprehensive whistleblower protection mechanism, and is committed to strictly protecting the confidentiality of whistleblowers' identities and the content of their reports, and effectively safeguarding their legal rights and interests. Our Company organizes specialized training on professional integrity to enhance the integrity and compliance awareness of all employees, and strengthens the internal consensus on maintaining an atmosphere of integrity and uprightness.

**IMPACT OF THE COVID-19 OUTBREAK**

The outbreak of the COVID-19 and its recurrence had caused temporary disruption to our operations to the extent that certain on-site meetings, deployment and technical support had to be delayed or cancelled. As of the Latest Practicable Date, however, COVID-19 had not had any material adverse impact on our R&D activities, clinical development, daily operation, supply chain and regulatory affairs. Given that the PRC government has substantially lifted its COVID-19 prevention and control policies since December 2022, our Directors are of the view that it is unlikely that the COVID-19 will have a material adverse impact on our business going forward.

**LICENSES AND PERMITS**

Our PRC Legal Advisor has advised that during the Track Record Period and up to the Latest Practicable Date, we have obtained all material licenses, permits, approvals and certificates from the relevant government authorities that are material for the business operations of our Group. There is no material legal impediment in renewing such licenses, permits, approvals and certificates as they expire in the future as long as we are in compliance with applicable laws, regulations and rules.

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

<u>License/Permit</u>	<u>Issuing Authority</u>	<u>Holder</u>	<u>Grant Date</u>	<u>Expiration Date</u>
Certificate for Utilization of Laboratory Animals (SYXK-(陝) 2021-006) (實驗動物使用許可證(編號: SYXK-(陝) 2021-006)) . . . . .	Shaanxi Provincial Department of Science and Technology (陝西省科學技術廳)	The Company	March 23, 2021	March 22, 2026 (renewal application in progress)
Notice of Approval for Clinical Drug Trial (2025LP01688) (藥物臨床試驗批准通知書(編號: 2025LP01688)) . . . . .	NMPA	Shanghai Xitaili Biomedical Technology Co., Ltd.* (上海西泰利生物醫藥科技有限公司)	June 30, 2025	N/A
Notice of Approval for Clinical Drug Trial (2025LP01148) (藥物臨床試驗批准通知書(編號: 2025LP01148)) . . . . .	NMPA	Shanghai Xitaili Biomedical Technology Co., Ltd.* (上海西泰利生物醫藥科技有限公司)	April 21, 2025	N/A
Notice of Approval for Clinical Drug Trial (2025LP01314) (藥物臨床試驗批准通知書(編號: 2025LP01314)) . . . . .	NMPA	Xi'an Biocare Pharma Ltd. (西安奧立泰醫藥 科技有限公司)	February 20, 2025	N/A
Notice of Approval for Clinical Drug Trial (2025LP01315) (藥物臨床試驗批准通知書(編號: 2025LP01315)) . . . . .	NMPA	Xi'an Biocare Pharma Ltd. (西安奧立泰醫藥 科技有限公司)	February 20, 2025	N/A

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<u>License/Permit</u>	<u>Issuing Authority</u>	<u>Holder</u>	<u>Grant Date</u>	<u>Expiration Date</u>
Approval for XTL6001 Clinical Trial for Weight Management. . . . .	FDA	Shanghai Xitaili Biomedical Technology Co., Ltd.* (上海西泰利生物醫藥科技有限公司)	December 20, 2024	N/A
Approval for MT1002 Clinical Trial for HD . . . . .	FDA	The Company	December 13, 2023	N/A
Notice of Approval for Clinical Drug Trial (2023LP01508) (藥物臨床試驗批准通知書(編號: 2023LP01058)) . . . . .	NMPA	The Company	July 27, 2023	N/A
Notice of Approval for Clinical Drug Trial (2023LP01509) (藥物臨床試驗批准通知書(編號: 2023LP01059)) . . . . .	NMPA	The Company	July 27, 2023	N/A
Notice of Approval for Clinical Drug Trial (2023LP01200) (藥物臨床試驗批准通知書(編號: 2023LP01200)) . . . . .	NMPA	The Company	June 25, 2023	N/A
Notice of Approval for Clinical Drug Trial (2023LP01201) (藥物臨床試驗批准通知書(編號: 2023LP01201)) . . . . .	NMPA	The Company	June 25, 2023	N/A
Notice of Approval for Clinical Drug Trial (2023LP01038) (藥物臨床試驗批准通知書(編號: 2023LP01038)) . . . . .	NMPA	The Company	June 6, 2023	N/A
Notice of Approval for Clinical Drug Trial (2023LP01039) (藥物臨床試驗批准通知書(編號: 2023LP01039)) . . . . .	NMPA	The Company	June 6, 2023	N/A
Notice of Approval for Clinical Drug Trial (2023LP00534) (藥物臨床試驗批准通知書(編號: 2023LP00534)) . . . . .	NMPA	Xi'an Biocare Pharma Ltd. (西安奧立泰醫藥科技有限公司)	March 29, 2023	N/A
Notice of Approval for Clinical Drug Trial (2023LP00535) (藥物臨床試驗批准通知書(編號: 2023LP00535)) . . . . .	NMPA	Xi'an Biocare Pharma Ltd. (西安奧立泰醫藥科技有限公司)	March 29, 2023	N/A
Notice of Approval for Clinical Drug Trial (2023LP00489) (藥物臨床試驗批准通知書(編號: 2023LP00489)) . . . . .	NMPA	The Company	March 24, 2023	N/A
Notice of Approval for Clinical Drug Trial (2023LP00341) (藥物臨床試驗批准通知書(編號: 2023LP00341)) . . . . .	NMPA	The Company	March 14, 2023	N/A

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<u>License/Permit</u>	<u>Issuing Authority</u>	<u>Holder</u>	<u>Grant Date</u>	<u>Expiration Date</u>
Notice of Approval for Clinical Drug Trial (2022LP01267) (藥物臨床試驗批准通知書(編號: 2022LP01267)) . . . . .	NMPA	The Company	August 16, 2022	N/A
Notice of Approval for Clinical Drug Trial (2021LP01920) (藥物臨床試驗批准通知書(編號: 2021LP01920)) . . . . .	NMPA	Xi’an Biocare Pharma Ltd. (西安奧立泰醫藥科技有限公司)	November 30, 2021	N/A
Notice of Approval for Clinical Drug Trial (2021LP01921) (藥物臨床試驗批准通知書(編號: 2021LP01921)) . . . . .	NMPA	Xi’an Biocare Pharma Ltd. (西安奧立泰醫藥科技有限公司)	November 30, 2021	N/A
Notice of Approval for Clinical Drug Trial (2021LP01020) (藥物臨床試驗批准通知書(編號: 2021LP01020)) . . . . .	NMPA	The Company	July 6, 2021	N/A
Notice of Approval for Clinical Drug Trial (2021LP00813) (藥物臨床試驗批准通知書(編號: 2021LP00813)) . . . . .	NMPA	The Company	June 2, 2021	N/A
Approval for MT1013 Clinical Trial for SHPT . . . . .	FDA	The Company	March 5, 2021	N/A
Approval for MT2004 Clinical Trial for NASH . . . . .	FDA	Xi’an Biocare Pharma Ltd. (西安奧立泰醫藥科技有限公司)	November 12, 2019	N/A
Approval for MT1002 Clinical Trial for ACS-PCI. . . . .	FDA	The Company	March 1, 2019	N/A
Fixed Pollution Source Discharge Permit (91320505MA228WRPXE001W) (固定污染源排污登記回執(編號: 91320505MA228WRPXE001W)) .	N/A	Micot (Suzhou) Pharmaceutical Co., Ltd. (麥科奧特(蘇州)醫藥有限公司)	September 8, 2023	September 7, 2028

**LITIGATIONS**

We are subject to legal proceedings and claims arising in the ordinary course of our business from time to time. See “Risk Factors — Risks Relating to Our Operations — We may become involved in lawsuits or other legal proceedings, which could adversely affect our business, financial conditions, results of operations and reputation.”

During the Track Record and up to the Latest Practicable Date, our Directors confirmed that we were not involved in any litigation or arbitration proceedings pending or, to the best knowledge of our Directors, threatened against us or any of our Directors that could have a material adverse effect on our business, results of operations or financial condition.

## BUSINESS

### COMPLIANCE WITH LAWS AND REGULATIONS

During the Track Record Period and up to the Latest Practicable Date, we did not commit any material non-compliance of the laws and regulations which individually or in the aggregate, in the opinion of our Directors, would have a material and adverse effect on our business, financial condition or results of operations. As advised by our PRC Legal Advisor, during the Track Record Period and up to the Latest Practicable Date, we had complied with the applicable PRC laws and regulations in all material respects. Our Directors further confirm that, we have complied with all applicable laws and regulations in all jurisdictions in which we had business operations during the Track Record Period and up to the Latest Practicable Date.

### RISK MANAGEMENT AND INTERNAL CONTROL

We have adopted a series of risk management policies which set out a risk management framework to identify, assess, evaluate, and monitor key risks associated with our strategic objectives on an ongoing basis. Risks identified by management will be analyzed based on likelihood and impact and will be properly followed up, mitigated and rectified by our Company and reported to our Directors. Our audit committee, and ultimately our Directors supervise the implementation of our risk management policies.

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;
- formulate the Anti-fraud System and other institutional documents to clarify the concepts and forms of fraud, the attribution of anti-fraud duties, the prevention and control of fraud, the accountability for fraud, remedial measures and penalties;
- 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 [REDACTED] in Hong Kong.

#### Internal Control

Our Board is responsible for establishing our internal control system and reviewing its effectiveness. We have engaged an internal control consultant (the "**Internal Control Consultant**") to perform certain agreed-upon procedures (the "**Internal Control Review**") in connection with the internal control of our Company in certain aspects, including entity-level controls, financial reporting and disclosure controls, purchase and payment management, inventory management, fixed assets management, human resources and payroll management and other procedures of our operations.

The Internal Control Consultant performed the Internal Control Review covering the period from July 2024 to June 2025, identified internal control deficiencies and provided recommendations accordingly. We have adopted the corresponding remediation actions to improve the effectiveness of the internal control system. The Internal Control Consultant performed a follow-up review with regard to those actions taken by us and there are no material findings identified in the process of the follow up review. As of the Latest Practicable Date, there were no material outstanding issues relating to our Company's internal control. 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.

## BUSINESS

### Data Privacy Protection

We have implemented strict internal policies to protect information to ensure compliance with all applicable national or international rules and regulations on data protection and privacy. In accordance with our internal policy, IT department is responsible for the day-to-day management of data security and confidentiality, and all other departments have the responsibility and obligation to strictly observe the data security and confidentiality system. The data and information required to be kept strictly confidential include clinical trial data, personal data of clinical trial participants, other clinical trial data, intellectual property, R&D results, significant investments, etc.

We have implemented hardware-level encryption protocols to protect confidential information. Our confidential information is stored in safe equipment and places, and we limit access to the information according to the level of confidentiality and set up various pre-approval procedures for the use of confidential information. In addition, we adopt measures such as setting up firewalls to restrict access rights and control data transmission paths, and we also ensure that data is not illegally accessed during transmission through permission settings and data encryption. Furthermore, we enter into confidentiality agreements with our employees who have access to any aforementioned privacy information. The confidentiality agreements provide that, among others, these employees are legally obligated not to misuse confidential information while in office, to surrender all confidential information in possession while resigning, and to retain their confidential obligations after they leave office.

During the Track Record Period and up to the Latest Practicable Date, we did not experience any breach of confidential information, any incident of patient data or other personal data leakage, or any material loss that could cause a material adverse effect on our business, financial condition, or results of operations.