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OVERVIEW

Who We Are

Founded in 2017, we are a clinical-stage biotech company focused on the development of T-cell engager (“TCE”) therapy. TCEs are bispecific or multispecific antibodies engineered to redirect and activate T cells by simultaneously binding tumor-associated antigens (“TAAs”) on tumor cells and receptors on T cells to induce targeted cytotoxicity. We identified early on the differentiated potential of TCE, a new generation of immunotherapy designed to harness and direct the body’s immune system against cancer. Possessing deep insights and innovative capabilities in a high-growth industry, we translate these insights into clinical-stage products, driving our progress from concept to development. We have developed masked TCEs, which can be selectively activated in tumors, for the treatment of solid tumors. As a rapidly evolving therapeutic modality in oncology, the global TCE market reached approximately US\$3.0 billion in 2024 and is expected to reach US\$121.1 billion by 2035 at a CAGR of 40.0%. China’s TCE market reached approximately RMB0.7 billion in 2024 and is expected to reach RMB159.6 billion by 2035 at a CAGR of 62.9%.

Immunotherapy has the potential to cure cancer. Unlike conventional therapies, immunotherapy harnesses the body’s immune system to target and eliminate cancer cells, offering the possibility of durable, long-term responses. TCEs have gained significant attention due to their ability to address cytokine release syndrome (“CRS”), a key challenge in immunotherapy. By precisely activating T-cells against tumor cells while minimizing immune overactivation, our TCEs provide a solution to control CRS and open new opportunities for treating solid tumors, establishing TCEs as a novel treatment modality with a potential for clinical application. TCEs have evolved from early 1+1 (one TAA and one T-cell binding domain) bispecific designs to masking, multifunctional, logic-gated formats, while steadily expanding indications from hematologic malignancies to solid tumors. We have strategically focused on applying the TCE technology, especially our proprietary TCE masking technology, to the treatment of solid tumors, a therapeutic area that has presented tremendous challenges in oncology. To date, most TCE drugs approved or under development target hematologic malignancies, which account for less than 10% of total cancer cases, compared with more than 90% for solid tumors, according to Frost & Sullivan.

TCEs are expected to enter an innovation stage driven by artificial intelligence (“AI”)-assisted design in the future. Supported by advances in AI-assisted molecular design and data-driven structural optimization, TCEs are evolving toward safer, more precise, and durable immunotherapies with expanding potential beyond oncology. The prolonged duration of efficacy of TCEs is expected to address a major pain point in the anti-cancer drug industry. The development of TCEs has reached an inflection point of transforming into a backbone cancer therapy.

Recognizing the transformative potential of this modality, we have focused our research and development efforts on advancing TCEs that achieve precise and sustained activation of T cells while maintaining a favorable safety profile. From establishing antibody libraries to developing proprietary engineering technologies, we have built the know-how and infrastructure to support our pipeline of TCE candidates. The key prerequisites for a backbone cancer therapy include upstream immune activation, zero-order cytotoxicity, and a favorable safety profile, all of which are inherent in our TCEs. Leveraging the upstream immune-activation mechanism of our TCE therapy, our candidates are designed to enable zero-order immune cytotoxicity, whereby activated T cells can kill tumor cells at a steady rate, regardless of the amount of tumor cells or tumor antigens engaged by the TCEs. Achieving the zero-order immune cytotoxicity requires toxicity control, precise tumor recognition, conditional TCE activation, prevention of T cell exhaustion and synergy of different anti-tumor mechanisms — the masking and multifunctional designs of TCEs are well suited to realize these functions. By optimizing T-cell affinity and applying our masking technology, we seek to improve the precision of T-cell activation, thereby achieving better control of immune-related side effects and reducing on-target off-tumor toxicity. Furthermore, our multifunctional TCEs are designed with an OR-gated dual-targeting format, which can activate T cells upon recognizing either one or both TAAs on the tumor cell surface, thereby improving tumor recognition and

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contributing to the prevention of tumor relapse. Collectively, these features position our TCEs with a potential to serve as backbone therapies in future immuno-oncology treatment regimens and to establish a differentiated foothold in this fast-growing global market.

We have advanced four product candidates into clinical development. Each of our drug candidates is developed through our dedicated R&D platforms, including our Multichannel Antibody Discovery Platform, H-shape Bispecific TCE Platform (“**H-BiTE Platform**”), Protease-activatable Bispecific TCE Platform (“**Pro-BiTE Platform**”) and Multifunctional/Logic-gated TCE Platform.

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The following chart summarize the development of our pipeline product candidates as of the Latest Practicable Date.

Platform	Code	Target	Modality	Indication	Administration	Competent Authority	Regimen	Phase				Upcoming Milestone	Commercial Rights
								Pre-Clinical	Phase 1	Phase 2	Phase 3		
TCM	★ DNV3	LAG-3	Monospecific Antibody	Malignant Melanoma ⁽¹⁾	Intravenous Infusion	China NMPA	Combo with PD-1 + Chemo		Phase II Ongoing in China Expect to complete in 2026 Q4			Initiate Phase III Trial in China in 2027 Q3	Global
				NSCLC ^(1,2)					Phase II will initiate in China			Initiate Phase II Trial in China in 2026 Q3	Global
				Solid Tumors and Lymphomas ⁽²⁾					Phase I Completed in China in March 2022			Advance clinical trials for combination therapies	Global
				ESCC ⁽³⁾					Phase IIIa Ongoing in China Expect to complete in 2027 Q2			Initiate Phase III Trial in China in 2027 Q4	Global
TCE	★ SMET12	EGFR/CD3	Bispecific Antibody	TNBC ⁽⁴⁾	Intravenous Infusion	China NMPA & U.S. FDA*	Monotherapy		Phase I Completed for EGFR-positive solid tumors in China in February 2023			Initiate Phase IIa Trial in China in 2026 Q4	Global
				EGFR-positive Solid Tumors ⁽⁵⁾					Patient enrollment for Phase IIIa is temporarily suspended in China			No Specific Plan	Global
				Hepatocellular Carcinoma ⁽⁶⁾					Phase IIIa Ongoing in China Expect to complete in 2027 Q4			Initiate Phase III Trial in China in 2028	Global
				Solid Tumor ⁽⁷⁾					Phase IIIa Ongoing in China Expect to complete in 2027 Q4			Initiate Phase III Trial in China in 2028	Global
				Solid Tumor								Submit IND in China in 2027 Q4 & in U.S. in 2028	Global
				Solid Tumor								Submit IND in China in 2028 in U.S. in 2029	Global

Note:

★ are Core Products.

☞ refers to masking peptide. The masking peptide is a short protein sequence designed to temporarily block the active site or binding region of a therapeutic protein, preventing it from interacting with its target, especially in healthy tissues, thereby reducing side effects.

All products are innovative drugs and are self-developed by the Company.

(1) Locally advanced unresectable or metastatic melanoma

(1.1) Advanced treatment-naïve non-small cell lung cancer

(2) Advanced/metastatic solid tumors and lymphomas

(3) EGFR-positive advanced esophageal cancer

(4) EGFR-positive advanced triple-negative breast cancer

(5) EGFR-positive advanced solid tumors

(6) Advanced hepatocellular carcinoma

(7) EGFR-positive advanced solid tumors (such as non-small-cell lung cancer, colorectal cancer, urothelial carcinoma, head and neck squamous cell carcinoma, and pancreatic cancer)

* While SMET12, CMD011, and CMDE005 have obtained clinical trial approvals from the U.S. FDA, we do not currently have plans to launch clinical operations in the U.S. for the three product candidates.

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Our Pipeline

As of the Latest Practicable Date, we had four in-house, clinical-stage innovative drug candidates, including one TCM and three TCEs:

Core Product DNV3: an advanced T-cell modulator (“TCM”) targeting lymphocyte activation gene 3 (“LAG-3”), an inhibitory receptor highly expressed by exhausted T cells in the TME. DNV3 validates our proprietary high-capacity fully human IgM phage display antibody library as a foundation of our product candidates. DNV3 demonstrated a favorable safety profile and broad potential for combination therapy, with no recorded Grade 3 or higher CRS in our clinical trials. As of the Latest Practicable Date, DNV3 was under a Phase II clinical trial of DNV3 in combination with an anti-PD-1 antibody and chemotherapy targeting locally advanced unresectable or metastatic melanoma. We completed the Phase I clinical trial of DNV3 monotherapy targeting advanced/metastatic solid tumors and lymphomas in March 2022. According to Frost & Sullivan, DNV3 ranked second globally and in China by stage of clinical development among anti-LAG-3 antibody drug candidates for melanoma treatment as of the Latest Practicable Date.

Core Product SMET12: an innovative intravenous EGFR×CD3 TCE. SMET12 validates our TCE structural design capabilities and sets a benchmark for our broader TCE pipeline. As of the Latest Practicable Date, SMET12 was under a Phase IIa clinical trial targeting EGFR-positive advanced solid tumors including esophageal cancer in China. SMET12 received FDA’s IND approval in November 2021. We completed the Phase I clinical trial of SMET12 targeting EGFR-positive advanced solid tumors in China in February 2023. According to Frost & Sullivan, SMET12 ranked first globally and in China by stage of clinical development among EGFR×CD3 TCE drug candidates as of the Latest Practicable Date.

CMD011: an advanced GPC3×CD3 TCE, which together with SMET12 validates our TCE molecular-format engineering and demonstrate the plug-and-play property of our TCE technology platforms. As of the Latest Practicable Date, CMD011 was under a Phase I clinical trial in China for advanced hepatocellular carcinoma (“HCC”). CMD011 received FDA’s IND approval in February 2025. According to Frost & Sullivan, CMD011 ranked within the top two globally by stage of clinical development among GPC3×CD3 TCE drug candidates, as of the Latest Practicable Date.

CMDE005: an innovative EGFR×CD3 masked TCE, which validates our protease-activated masking technology. CMDE005 is a patient-focused drug development initiative aimed at minimizing the safety risks associated with immunotherapy, particularly by reducing CRS. As of the Latest Practicable Date, CMDE005 was under a Phase I clinical trial in China for the treatment of various EGFR-positive advanced solid tumors. CMDE005 received FDA’s IND approval in April 2025. According to Frost & Sullivan, CMDE005 was the first and only in China and ranked among the top two globally incorporating masking peptide technology that has entered the clinical stage among the EGFR×CD3 TCE drug candidates, as of the Latest Practicable Date.

OUR STRENGTHS

Leveraging Our TCE Platform Technologies for the Development of Solid Tumor Therapies

Since our inception, we have strategically focused on applying TCE to the treatment of solid tumors. From establishing antibody libraries to developing proprietary engineering technologies, we have built the know-how and infrastructure to support our pipeline of TCE candidates.

As a rapidly evolving therapeutic modality in oncology, the global TCE market reached approximately US\$3.0 billion in 2024 and is expected to reach US\$121.1 billion by 2035 at a CAGR of 40.0%. China’s TCE market reached approximately RMB0.7 billion in 2024 and is expected to reach RMB159.6 billion by 2035 at a CAGR of 62.9%.

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To date, most TCE drugs approved or under development target hematologic malignancies, which account for less than 10% of total cancer cases, compared with more than 90% for solid tumors, according to Frost & Sullivan. Despite a larger patient population and greater medical needs, only two TCE drugs for solid tumors had been approved globally as of the Latest Practicable Date. The number of TCE drugs in pipeline for the treatment of solid tumors has been growing at a faster pace than hematologic malignancies. Solid-tumor biology presents significant challenges for the development for TCE drugs, including the TME and physical barriers, which demands more advanced innovation in drug design.

Our TCE technologies are specifically designed to address the major challenges of TCE solid-tumor treatment, including CRS, limited tissue penetration, the lack of predictive biomarkers and acquired resistance. Among these, CRS has been recognized across the industry as a critical barrier for effective dosing, underscoring the importance of widening the therapeutic window. Our TCE masking technology is specifically engineered to achieve this objective. By employing an protease-activatable system, our TCEs remain inactive in healthy tissues and are selectively activated in tumors with high protease activity, thereby minimizing on-target off-tumor toxicity, reducing the risk of CRS while preserving potent anti-tumor efficacy. This enables higher effective dosing from the first infusion and supports a “first-dose stage power killing” effect, delivering strong and immediate tumor clearance while laying the foundation for durable clinical benefit.

In addition, our TCEs have the potential to mitigate tumor resistance, as they can redirect T cells to tumor cells through antigen recognition, a mechanism independent of MHC antigen presentation or tumor mutational status. Provided that the target antigen continues to be expressed on the tumor cell surface, TCEs may retain activity even in tumors harboring resistance-associated mutations such as EGFR or RAS mutations, while bispecific or multispecific designs can further reduce the risk of antigen escape. We believe these innovations position us at the forefront of TCE development and support the creation of transformative therapies with the potential to become backbone therapies in oncology.

As of the Latest Practicable Date, we had four in-house developed, clinical-stage drug candidates, including (i) DNV3, an advanced TCM targeting LAG-3, which validates our proprietary high-capacity IgM antibody library as a foundation of our TCE product candidates, (ii) SMET12, an innovative intravenous EGFR×CD3 TCE, (iii) CMD011, an advanced GPC3×CD3 TCE, which together with SMET12 validates our TCE molecular-format engineering and demonstrates the plug-and-play functionality of our TCE technology platforms, and (iv) CMDE005, an innovative EGFR×CD3 masked TCE, which validates our protease-activatable masking technology. In addition, we have two preclinical-stage drug candidates for multifunctional/logic-gated TCE, CMDE101 and CMDE102, which are trispecific masked TCEs targeting FOLR1×PD-L1×CD3 and PSMA×PD-L1×CD3, respectively. Each of our drug candidates is developed through our dedicated R&D platforms, including our Multichannel Antibody Discovery Platform, H-BiTE Platform, Pro-BiTE Platform and Multifunctional/Logic-gated TCE Platform.

Our product candidates not only represent important therapeutic opportunities, but also serve to validate our R&D system, demonstrating the strength of our capabilities in drug discovery, molecular-format engineering and clinical translation. These achievements grant us a competitive position in the TCE area. The global innovative drug market, especially in China, is experiencing rapid growth, with innovative Chinese biopharmaceutical companies increasingly attracting international collaboration and investment. As China-originated innovation gains wider recognition, future licensing opportunities may enable Chinese companies to play a larger role in pricing.

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TCE and TCM Pipeline with Significant Global Market Potential

Core Product DNV3, an Advanced Anti-LAG-3 TCM

DNV3 is an innovative anti-LAG-3 TCM. DNV3 has validated our high-capacity fully human IgM phage display antibody libraries and demonstrated a favorable safety profile in our clinical trials. With no recorded Grade 3 or higher CRS, DNV3 demonstrates a broad potential for combination therapy. As of the Latest Practicable Date, DNV3 was under a Phase II clinical trial of DNV3 in combination with an anti-PD-1 antibody and chemotherapy targeting locally advanced unresectable or metastatic melanoma. We completed the Phase I clinical trial of DNV3 monotherapy targeting advanced/metastatic solid tumors and lymphomas in March 2022. According to Frost & Sullivan, DNV3 ranked second globally and in China by stage of clinical development among anti-LAG-3 antibody drug candidates for melanoma treatment, as of the Latest Practicable Date.

As a TCM, DNV3 restores T-cell function by blocking the inhibitory LAG-3 pathway, thereby enhancing T-cell activation and anti-tumor immune responses. LAG-3 is an inhibitory receptor highly expressed by exhausted T cells in the TME. By binding to MHC class II and other ligands, LAG-3 transmits inhibitory signals that impair T-cell function, making LAG-3 a key target for cancer immunotherapy. Acting upstream in the immune response, LAG-3 has the potential to modulate multiple pathways, while also offering a favorable safety profile. Both LAG-3 and PD-1 are co-expressed on intratumoral T cells in various cancers, where they may synergistically promote T-cell exhaustion that limits effective anti-tumor immune responses. Dual PD-1 and LAG-3 blockade has shown enhanced anti-tumor effects compared to PD-1 or LAG-3 monotherapy. Additionally, in mouse studies, DNV3 exhibited a significantly higher binding capacity towards both T cells and B cells than existing comparable therapy (20% higher for T cells and over ten times higher for B cell), indicating its potential to address challenging indications where enhanced immune activation is required.

DNV3 is positioned to address the significant unmet medical needs in solid tumors, such as melanoma. Melanoma is among the five most common malignancies worldwide. According to Frost & Sullivan, the incidence was 388.5 thousand globally and 27.3 thousand in China in 2024, and is expected to grow to 441.6 thousand and 37.0 thousand, respectively, by 2035, representing a CAGR of 1.2% globally and 2.8% in China from 2024 to 2035. Due to the heterogeneity of melanoma subtypes, no therapy currently addresses all subtypes. For example, in cutaneous melanoma, there is no standard second-line therapy, leaving significant unmet medical needs.

In the ongoing Phase II clinical trial, the combination of DNV3 with an anti-PD-1 antibody and chemotherapy achieved an objective response rate (“**ORR**”) of 44.4% in 18 mucosal melanoma patients previously treated with PD-(L)1 inhibitors, approximately three times higher than that of existing comparable therapies based on publicly available information (without head-to-head comparison in clinical trials), offering new option for patients resistant to first-line PD-1 treatment. In cutaneous melanoma, investigator-initiated trial (“**IIT**”) and Phase II trial data showed an ORR of 66.7% in 12 cutaneous melanoma patients with the same combination therapy, which is over five times higher than that achieved by existing comparable therapies based on publicly available information (without head-to-head comparison in clinical trials). These results underscore DNV3’s therapeutic potential in addressing the low response rates of current immuno-oncology therapies. Moreover, DNV3 in combination with an anti-PD-1 antibody reached an ORR of 38.5% and medium PFS of 7.4 months in 13 melanoma patients with liver metastasis (medium size was 77.4mm), for whom there is currently no effective treatment option. DNV3 has also showed synergistic efficacy with reduced CRS when combined with our TCEs in preclinical studies.

As of the Latest Practicable Date, only one anti-LAG-3 antibody (opdualag: a combination of nivolumab and relatlimab) had been approved worldwide and none has been approved in China, highlighting the market opportunity for DNV3. According to Frost & Sullivan, DNV3 ranked second globally and in China by stage of clinical development among anti-LAG-3 antibody drug candidates for melanoma treatment, as of the Latest Practicable Date. Additionally, as of the Latest

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Practicable Date, no combination therapy of PD-1 and LAG-3 inhibitors had been approved in China, highlighting the substantial combination value and market potential of LAG-3 antibodies. The global anti-LAG-3 antibody drug market reached US\$0.6 billion in 2023. The market grew to US\$0.9 billion in 2024. And it is expected to grow to US\$5.7 billion in 2030 with a CAGR of 35.4% from 2024 to 2030. By 2035, the overall market is expected to reach US\$11.5 billion. In China, the anti-LAG-3 antibody drug market is expected to reach RMB0.8 billion in 2027. And it is expected to grow to RMB3.1 billion in 2030 with a CAGR of 59.0% from 2024 to 2030. By 2035, the overall market in China is expected to reach RMB6.9 billion.

DNV3 forms the foundation of our product pipeline, validating our fully human IgM phage display antibody libraries and exemplifying our strategy to achieve differentiation in a highly competitive market through innovations in drug design, molecular engineering, and rational clinical development. As a TCM with a favorable safety profile, DNV3 has a potential for use in combination with a broad range of therapies, including PD-1/PD-L1 inhibitors and other immuno-oncology therapies. By enhancing T-cell activity, DNV3 may complement and strengthen the efficacy of these therapies, supporting its potential to serve as an important therapy in immuno-oncology.

Core Product SMET12, an Innovative Intravenous EGFR×CD3 TCE

SMET12 is a fully human TCE targeting EGFR on tumor cells and cluster of differentiation 3 (“CD3”) on T cells. SMET12 is the world’s first EGFR-targeting TCE that has entered the Phase II stage, has the potential to become the world’s first intravenous EGFR×CD3 bispecific antibody and is the first in China to receive clinical trial approval from the NMPA, according to Frost & Sullivan. As of the Latest Practicable Date, SMET12 was under a Phase IIa clinical trial targeting EGFR-positive advanced solid tumors including esophageal cancer in China. SMET12 has received FDA’s IND approval in November 2021. We completed the Phase I clinical trial targeting EGFR-positive advanced solid tumors in China in February 2023. SMET12 has a potential for expansion into indications such as NSCLC and colorectal cancer. According to Frost & Sullivan, SMET12 ranked first globally and in China by stage of clinical development among EGFR×CD3 TCE drug candidates as of the Latest Practicable Date.

EGFR is a transmembrane receptor tyrosine kinase whose mutations or overexpression are frequently observed in cancers, leading to persistent downstream signaling that drives uncontrolled tumor growth and metastasis. CD3 is a critical component of the T-cell receptor (“TCR”) complex, responsible for transmitting antigen-recognition signals to activate T cells. Tumors often create an immunosuppressive microenvironment that exhausts T cells and enables immune evasion. By simultaneously binding EGFR on tumor cells and CD3 on T cells, SMET12 may overcome such immunosuppression and mediate potent tumor-killing activity. Besides, the binding activities of SMET12 are not dependent on specific EGFR mutations, allowing it to effectively target all tumor types that express EGFR.

Most TCE therapies face significant challenges in the treatment of solid tumors, such as the risk of CRS and the difficulty with tumor penetration. SMET12 has a well-defined anti-tumor mechanism to address these challenges.

- *Innovative Format Design and Engineering.* We incorporated a complete Fc fragment in the TCE format to achieve an optimal TCE half-life. To address mispairing issues for asymmetric bispecific antibodies, we proprietarily developed a monomeric Fc technology which has practically minimized the homodimeric by-products formation. To ensure best TME penetration, the molecular weight was maintained around 120kDa, smaller than IgG monoclonal antibody.
- *Managing CRS Risk and EGFR Safety Profile by Spatial Hindrance.* A key concern for TCE therapies is CRS, which can cause serious side effects and restrict feasible routes of administration. This brings challenges to the design of a bispecific antibody that

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simultaneously binds EGFR and CD3. Such a design process requires careful control. The binding of CD3, if too strong, can trigger cytokine storms and reduce efficacy, and the immune activity related to the Fc region of the bispecific antibody may further raise the CRS risk. To address these issues, SMET12 uses an engineered Fc design that extends half-life and limits unwanted immune activation, and its structure has been tuned to balance CD3 binding to avoid over-activation. With these innovations, SMET12 enables safer dosing and greater clinical feasibility even including outpatient settings. In addition to CRS, EGFR-targeted therapies are often associated with skin toxicities, such as rash and dermatitis. As of the Latest Practicable Date, SMET12 had demonstrated no typical EGFR-related toxicities (such as skin rash) in our pre-clinical and clinical studies, underscoring its differentiated safety profile. Also, in our completed Phase I and ongoing Phase IIa clinical trials of SMET12, all of CRS events observed were Grade 1 or 2 and recovered within two weeks.

- *Improving Tumor Penetration.* Many TCEs are too large to penetrate solid tumor stroma, thereby limiting their effectiveness. SMET12 is smaller than monoclonal IgG antibodies (*i.e.*, around 120 kDa for SMET12 vs 150 kDa for monoclonal IgG antibodies) and has an optimized structure, enabling better penetration into the solid tumor stroma. This design supports more efficient delivery to the tumor cells and stronger therapeutic activity.
- *Broad Applicability.* SMET12 targets tumors based on EGFR expression rather than relying on specific EGFR mutations. This is different from the functioning of many targeted therapies, which requires the presence of specific mutations in the target protein or tumor-type-specific biomarkers in the patient body. Such requirements may limit the applicability of target therapies across diverse patient populations. The targeting mode of SMET12 allows it to work effectively in tumors regardless of the EGFR mutation status, broadening its potential clinical use and improving treatment options for patients across different tumor types.
- *Enhancing Commercialization Potential.* Earlier TCEs often rely on continuous infusion pumps and inpatient monitoring, which increase costs and limit patient acceptance. SMET12 is the world’s first EGFR×CD3 bispecific antibody designed for direct intravenous infusion. It is also the first intravenous EGFR×CD3 bispecific antibody in China to receive clinical trial approval from the NMPA. SMET12 can be combined with PD-1 inhibitors, a combination already shown to produce clear synergistic effects in IITs. Together, these features not only enhance efficacy but also improve acceptance by physicians and patients, supporting broader adoption.
- *Manufacturing Efficiency.* SMET12 has demonstrated high chemical stability, low mispairing rate and high heterodimer yield with simplified manufacturing process via quality by design, thereby significantly improving manufacturing efficiency.

In preclinical studies, SMET12 demonstrated clear advantages from its innovative target combination and molecular design. It showed up to 40-fold greater affinity for CD3 in the presence of tumor cells compared with the absence of tumor cells, leading to significant tumor growth inhibition at doses as low as 20 µg/kg. Consistent antitumor activity was also observed across other EGFR-high mouse models. In the Phase I clinical trial, SMET12 showed superior safety at the dosage of 10-120µg, with no dose-limiting toxicity recorded. Investigator-initiated trial data showed that for tyrosine kinase inhibitor (“TKI”) resistant EGFR mutation-positive non-small-cell lung carcinoma (“NSCLC”) patients, the ORR was 41.7% (5/12), disease control rate (“DCR”) was 100%, and the median PFS was 7.2 months (95% CI: 5.0, 14). According to Frost & Sullivan, our median PFS marks a clear improvement over the median PFS of approved leading treatments for patients with at least one prior line of treatment, and is within the same range to leading candidates currently under development for patients with at least one prior line of treatment.

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Bispecific antibodies for the treatment of solid tumors represent one of the most active areas in oncology research and development. By bringing T cells and tumor cells together, TCE bispecific antibodies produce synergistic tumor killing with reduced resistance, thereby achieving a “1+1 > 2” therapeutic effect. Among them, the EGFR×CD3 combination is considered a promising TCE format due to its mechanistic advantages and potential for synergistic activity. As of the Latest Practicable Date, no EGFR×CD3 TCE product has been approved. The global EGFR TCE drug market is expected to reach US\$0.9 billion in 2030 and to US\$6.8 billion in 2035. In China, the EGFR TCE drug market is expected to reach RMB3.0 billion in 2030 and RMB8.5 billion in 2035.

SMET12 is our TCE candidate designed with an innovative target combination and molecular structure. This design has exhibited a therapeutic potential in solid tumors and created broad opportunities for combination with PD-1 and other immuno-oncology therapies. SMET12 validates our TCE structural design capabilities, sets a benchmark for our broader TCE pipeline, and accelerates the iteration of our subsequent pipeline assets.

CMD011, an Advanced GPC3×CD3 TCE

CMD011 is a fully human TCE targeting glypican-3 (“GPC3”) on tumor cells and CD3 on T cells. As of the Latest Practicable Date, CMD011 was under Phase I clinical trial in China for HCC and received FDA’s IND approval in February 2025. CMD011 also has a potential for expansion into other indications such as renal cell carcinoma. CMD011, together with SMET12, validates our TCE molecular-format engineering and demonstrates the plug-and-play property of our TCE technology platforms. This capability allows for the rapid generation of therapeutically viable candidates targeting different TAAs. According to Frost & Sullivan, CMD011 ranked within the top two globally by stage of clinical development among GPC3×CD3 TCE drug candidates, as of the Latest Practicable Date.

GPC3 has emerged as a promising target in oncology, particularly in liver cancer. It is characterized by high expression in tumor tissues and minimal expression in normal tissues in adults, making it an ideal target for the development of HCC therapies. By combining GPC3 with CD3, CMD011 provides precise tumor targeting via GPC3 while engaging CD3 to activate T cells to kill tumor cells.

Many GPC3-directed therapies under development continue to face safety challenges, particularly CRS. CMD011, developed on our proprietary H-BiTE Platform, incorporates an innovative molecular design to address these issues.

- *Innovative Format Design and Engineering.* We incorporated a complete Fc fragment in the TCE format to achieve an optimal TCE half-life. To address mispairing issues for asymmetric bispecific antibodies, we proprietarily developed a monomeric Fc technology which has practically minimized the homodimeric by-products formation. To ensure best TME penetration, the molecular weight was maintained around 120kDa, smaller than IgG monoclonal antibody.
- *Managing CRS Risk by Spatial Hindrance.* We have designed CMD011 to minimize homodimer formation (a common byproduct in the preparation of asymmetric bispecific antibodies), which could otherwise trigger excessive T-cell activation and non-specific toxicity. Also, the structure of CMD011 has been tuned to balance CD3 binding to avoid over-activation. This innovative molecular design reduces the risk of CRS, improving safety while maintaining potent antitumor activity.

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- *Outstanding Toxicological Profile.* Through our innovative structure design of CMD011 and target TAA selection, the product shows a prominent safety profile in comparison with similar products from competitive companies. The good laboratory practice (“GLP”) toxicology study has determined that the highest non-severely toxic dose (“HNSTD”) is 5mg/kg, which proximately corresponds to a fixed clinical dose of 96 mg for humans.
- *Ensuring Strong Antitumor Activity.* Through molecular design innovation and target selection, we have demonstrated robust antitumor activity for CMD011 in preclinical mouse models, achieving efficacy at doses as low as approximately 100 µg/kg. This demonstrates the potential of CMD011 as a therapeutic option for liver cancer, with the possibility of addressing the significant medical need for safer and more effective treatments.
- *Convenient Intravenous Administration.* Unlike the commonly used transarterial chemoembolization treatment for liver cancer (which delivers the drugs directly into the arteries feeding a liver tumor), CMD011 supports intravenous administration, offering a more convenient option. This makes CMD011 suitable for outpatient settings or long-term treatment, significantly improving patient adherence to the treatment regimen.

CMD011 has shown good tolerability in humans in its ongoing Phase I clinical trial in HCC patients. No Grade 2 or above CRS occurred in patients that received CMD011 from 10µg to 30mg once every two weeks, demonstrating the high specificity of the GPC3 targeting by CMD011 and a favorable safety profile at high doses. A decrease in the level of alpha-fetoprotein (“AFP”), a liver tumor biomarker, and stable disease (“SD”) have been observed in some patients, with the longest PFS being nearly 11 months, significantly extending the PFS achieved by existing standard of care treatments for advanced HCC. These findings suggest that CMD011 has the potential to overcome the limitations of traditional HCC treatments.

HCC is one of the most prevalent malignancies globally, with approximately 80% of patients diagnosed at intermediate or advanced stages where treatment options are limited and prognosis is poor. The five-year survival rate for HCC is only approximately 21% in the United States and 12.1% in China. According to Frost & Sullivan, the incidence of HCC reached 818.1 thousand globally and 344.5 thousand in China in 2024, and is expected to grow to 1,067.7 thousand and 412.2 thousand, respectively, by 2035, at a CAGR of 2.5% globally and 1.6% in China from 2024 to 2035, respectively. Current therapies are predominantly chemotherapy-based, while available targeted drugs remain constrained by short PFS, immunosuppressive TME, immune barriers and low tumor mutational burden. Global HCC drug market is estimated to increase from US\$2.3 billion in 2020 to US\$4.5 billion in 2024, with a CAGR of 17.9%. In the future, the global HCC drug market will further increase to US\$11.5 billion in 2030 and US\$18.3 billion in 2035, with a CAGR of 16.9% from 2024 to 2030 and 9.8% from 2030 to 2035. In China, HCC drug market is estimated to increase from US\$1.0 billion in 2020 to US\$2.1 billion in 2024, with a CAGR of 18.7%. In the future, the China HCC drug market will further increase to US\$4.2 billion in 2030 and US\$6.1 billion in 2035.

CMD011 has the potential to address critical shortcomings of current HCC treatments and is emerging as a breakthrough therapy. Its advancement also demonstrates the plug-and-play engineering capabilities of our TCE technology platforms, enabling efficient development of differentiated products across multiple indications.

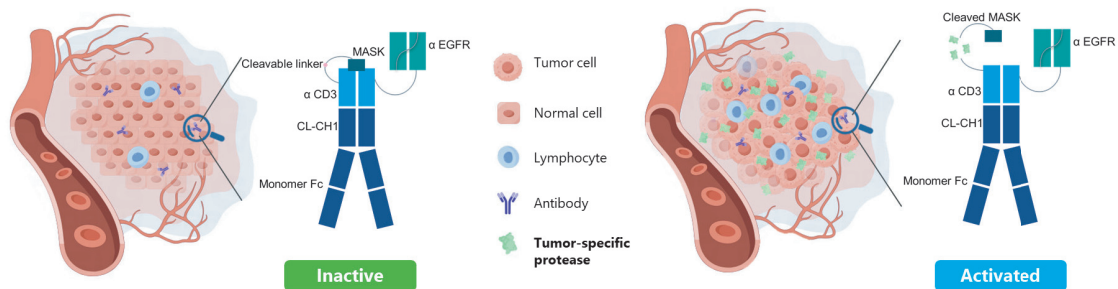
Advanced TCE Masking Technology, Exemplified by Our Product CMDE005 Ranking Among the World’s Top Two Masked TCEs

Leveraging our extensive expertise in TCE technologies, we developed the Pro-BiTE Platform for the TCE masking technology. Through a breakthrough protease-activatable system, the platform enhances the ability of bispecific antibodies to accumulate more effectively in the tumor tissue. The platform’s masking peptide design ensures that the drug remains inactive in normal tissues and

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peripheral circulation, where protease levels are low, while being selectively activated by tumor-specific proteases. This mechanism significantly expands the therapeutic window, addressing both resistance and safety challenges in solid tumor treatment. According to Frost & Sullivan, we are the only company globally to achieve one-step activation in masked EGFR×CD3 TCEs, demonstrating leadership in masking efficiency, a key parameter for minimizing on-target off-tumor toxicity and broadening the therapeutic window. The one-step activation refers to activating the therapeutic effect of TCE only in one step cleavage of the masking peptide.

We developed CMDE005, a protease-activatable EGFR×CD3 bispecific antibody. As of the Latest Practicable Date, CMDE005 was under a Phase I clinical trial in China for the treatment of various EGFR-positive advanced solid tumors, and received FDA’s IND approval in April 2025. According to Frost & Sullivan, CMDE005 was the first and only in China and ranked among the top two globally incorporating masking peptide technology that has entered the clinical stage among the EGFR×CD3 TCE drug candidates, as of the Latest Practicable Date.



Source: Company information

CMDE005 validates our strategic goal of demonstrating the clinical utility of masked peptide design.

- **Innovative Format Design and Engineering.** The Pro-BiTE Platform for masked TCEs was developed based on the H-BiTE Platform. Besides the structural features inherited from the H-BiTE Platform, CMDE005 is added with a masking peptide located at the N-terminus of its heavy chain, which could specifically interact with the CD3 binding site, leading to the blockade of binding of CD3 receptor to CMDE005. To minimize the non-specific activation of T cells in the peripheral circulation, the antibody-dependent cellular cytotoxicity and complement-dependent cytotoxicity were abolished by introducing LALA substitutions to CMDE005’s Fc region. The molecular weight of CMDE005 was restricted to 128kDa vs 150 kDa for monoclonal IgG antibodies, ensuring optimal TME penetration.
- **Controllable Side Effect.** CMDE005 was engineered using our Pro-BiTE Platform to achieve superior masking efficiency, with a novel masking peptide sequence introduced at the CD3 binding site. In normal tissues, CD3 binding is blocked, while protease cleavage in the TME restores CD3 activity. In pre-clinical studies, CMDE005 demonstrated a 10,000-fold reduction in CD3 binding in non-tumor tissues, while a competing product JANX008 achieved a 1,000-fold reduction based on publicly available information. With that, CMDE005 is expected to minimize on-target off-tumor activation, reduce CRS risk, and widen the therapeutic window.
- **Activation Efficiency.** Upon unmasking in the tumor, CMDE005 potently activates T cells through a one-step process. This design enables efficient tumor-directed cytotoxicity while avoiding peripheral T-cell overactivation. CMDE005 is able to

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preserve EGFR in an "open" state. With that, CMDE005 ensures high tumor specificity and effective engagement of T cells in the TME. The one-step activation approach significantly enhances enrichment of active molecules in the TME.

- *Effective Infiltration.* Many TCEs are too large to penetrate solid tumor stroma, limiting their effectiveness. CMDE005 is smaller than monoclonal IgG antibodies (*i.e.*, 128 kDa for CMDE005 vs. 150 kDa for monoclonal IgG antibodies) and has an optimized structure, enabling better penetration into tumor tissue. This design supports more efficient delivery to tumor cells and stronger therapeutic activity.
- *Scalability.* Supported by our robust CMC capabilities, CMDE005 has achieved titer of 4 g/L with purity exceeding 99.3%. This enables process scalability and manufacturability for clinical and future commercial supply.
- *Anti-resistance.* CMDE005 targets EGFR based on receptor expression rather than mutational status, allowing applicability across a broad range of EGFR-expressing tumors. As such, CMDE005 is expected to overcome tumor resistance associated with EGFR mutations.
- *Reliable Biomarkers.* For many TCEs, there is a lack of biomarkers to clearly show which patients may benefit from the TCE treatment or how the treatment is working. CMDE005 uses a protease-dependent masking design that enables activation only in the TME. Because this activation depends on uPA, a protease often overexpressed in many cancers and measurable in patients, uPA may serve as a intrinsic biomarker to help identify the right patients for CMDE005 and track treatment response.
- *Convenience to Use.* CMDE005 supports intravenous administration, offering a more convenient option. This makes it suitable for outpatient settings or long-term treatment, significantly improving patient adherence to the treatment regimen.

In preclinical studies, CMDE005 achieved potent dose-dependent antitumor activity. In the HT1080 xenograft mouse model, near-complete tumor elimination was observed at the highest tested dose (120 µg/kg). In the ACHN renal carcinoma model, CMDE005 also demonstrated strong dose-dependent efficacy. The ongoing Phase I clinical trial results for CMDE005 demonstrated good tolerability in humans, with no dose-limiting toxicities ("DLT") recorded in patients that received CMDE005 at 10 µg to 3mg once every two weeks, and no grade 3 or higher adverse events ("AEs") or serious adverse events observed at doses up to 3 mg. All treatment-related adverse events ("TRAEs") were mild (Grade 1-2), manageable, and resolved completely. Additionally, preliminary signs of efficacy were observed in patients with NSCLC. Some patients in the low-dose group had recorded SD and shrinkage of the target lesions, suggesting potential therapeutic benefit. CMDE005 exhibited a dose-dependent immune response and efficacy profile, with controllable side effects.

A large population of patients with EGFR-expressing or EGFR-resistant tumors, both globally and in China, continue to face limited treatment options. Sequential therapies following resistance to TKI, a type of EGFR-targeted therapy, often show only modest efficacy and carry significant development risks. Leveraging our TCE masking technology, CMDE005 represents a paradigm shift in overcoming TKI resistance, with substantial clinical and commercial potential.

Our TCE masking technology represents a major innovation in TCE development, with a limited number of companies worldwide having demonstrated the expertise and capabilities required to advance this approach. We have established this technology as a central focus of our TCE pipeline. Leveraging our proprietary know-how and accumulated experience, we have become a global leader in masking peptide TCE research and development, both in terms of technological strength and stage of advancement. According to Frost & Sullivan, we are the only company globally to achieve one-step activation in masked EGFR×CD3 TCEs, demonstrating leadership in

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masking efficiency, a key parameter for broadening the therapeutic window. According to Frost & Sullivan, CMDE005 was the first and only in China and ranked among the top two globally incorporating masking peptide technology that has entered the clinical stage among the EGFR×CD3 TCE drug candidates, as of the Latest Practicable Date.

CMDE005 is our flagship TCE candidate. With its masking peptide design, CMDE005 has the potential to become a backbone cancer therapy. As the anchor for our TCE pipeline, CMDE005 positions us to continue developing innovative masked and multi-mechanism formats to address the substantial medical needs in solid tumor treatment. Using our protease-activatable masking technology, we have developed two preclinical-stage drug candidates for multifunctional/logic-gated TCE, CMDE101 and CMDE102, which are trispecific protease-activatable TCEs targeting FOLR1×PD-L1×CD3 and PSMA×PD-L1×CD3, respectively.

TCE Technology Platforms Driving Innovation with Advanced R&D and CMC Capabilities

We have established an innovation engine built upon our proprietary TCE antibody development system. Backed by a strong R&D team and extensive CMC expertise, this system forms a solid foundation for our advancement toward commercialization.

Our TCE antibody development system is built to address the key challenges of TCE therapy and unlock its full potential. We emphasize the control of side effects by improving the management of CRS for a broader therapeutic window. To enhance efficacy, we improve T-cell activation efficiency and support efficient infiltration, enabling stronger tumor penetration, and a first-dose stage power killing effect that can help turn “cold” tumors into “hot” ones and sustain immune attack. At the same time, we focus on scalability to ensure stable, cost-effective manufacturing, embed anti-resistance strategies to preserve durable activity across genetically diverse tumors, and apply predictive biomarkers, such as measurable protease activity, to guide patient selection and treatment monitoring. Together, these approaches provide a framework that underpins our innovation engine and advance the development of TCE therapies.

Our TCE antibody development system consists of four technology pillars, covering target and sequence discovery, antibody engineering, and functional validation. This is one of the most comprehensive “zero-to-one” discovery and development platforms for TCEs:

- *TCE Antibody Discovery — Multichannel Antibody Discovery Platform.* Our multichannel antibody discovery platform includes fully human IgM phage display antibody libraries and multi-species immunized libraries. With capacities of 10^{11} - 10^{13} antibody sequences, our fully human IgM phage display antibody libraries are significantly larger than the industry average of 10^9 - 10^{10} . This capacity and diversity enable rapid identification of high-quality, high-affinity lead antibodies, establishing a strong foundation for our drug discovery. With these libraries, we are able to perform high-throughput screening and rapid identification of high-affinity antibodies in just 1-2 weeks. Because these libraries are fully human, the identified antibodies need not go through the humanization process and carry minimized immunogenicity risks. Further, compared to IgG libraries, our IgM libraries offer greater diversity. This enables the selection of multiple epitopes with varying affinities targeting the same antigen. In addition to the fully human IgM phage display antibody libraries, we have established the discovery platform of hybridoma and multi-species immunized antibody libraries using mouse or rabbit B cells. These multi-species immunized antibody libraries are able to avoid the limitations of traditional hybridoma technology, including the long-cycle low-throughput screening for antibody sequences and the stability issues with antibody-encoding genes. They enable higher throughput and prevent the loss of genes during cloning, preserving antibody diversity. Finally, we utilize light chain shuffling technology to further improve antibody sequence diversity and affinity, enhancing the foundation for drug discovery.

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- *TCE Format — H-BiTE Platform.* Our proprietary bispecific antibody platform may optimize pharmacological properties to overcome two traditional challenges in bispecific antibody development, *i.e.*, druggability and high toxicity. The platform utilizes a unique dual-target architecture that attenuate CD3 binding affinity through steric hindrance, ensuring the minimal CD3+ T-cell activation in peripheral circulation. By optimizing the affinity for both CD3 and the target antigen, the platform improves the therapeutic efficacy of TCEs. Furthermore, the design features Fc modifications and a monovalent Fab structure, preventing light and heavy chain mispairing. With that, the platform generates 100% heterodimeric bispecific antibodies, avoiding the toxicity associated with the homodimeric byproducts for asymmetric bispecific antibodies. The Fc engineering features may also reduce cytokine release, thus improving safety profiles. With minimal substitutions (only two amino acids) in the Fc region, the platform reduces immunogenicity compared to other bispecific antibody platforms. These innovations make the H-BiTE platform one of the most competitive bispecific antibody platforms globally, offering significant advantages in clinical application and drug development.
- *TCE Masking — Pro-BiTE Platform.* Our Pro-BiTE platform leverages a protease-activatable bispecific antibody design to enable tumor-selective activation. By taking advantage of the differential expression of proteases in tumors and normal tissues, the platform introduces a masking peptide near the antibody’s target-binding site. This peptide remains intact in normal tissues and circulation, but is cleaved by tumor-specific proteases, such as uPA and MMP, upon accumulation in the TME. This mechanism significantly enhances both the safety and therapeutic window, allowing the antibody to target tumors effectively while minimizing on-target off-tumor toxicity.
- *Multifunctional/Logic-gated TCE Platform.* Our Multifunctional/Logic-gated TCE platform enhances T-cell activation, prevents T-cell exhaustion, and increases tumor-killing power by launching a synergistic targeted attack on tumors by both blocking the immune checkpoint and activating the T cells. Our multifunctional TCEs are designed with an OR-gated dual-targeting format, which can activate T cells upon recognizing either one or both TAAs on the tumor cell surface, thereby improving tumor recognition and contributing to the prevention of tumor relapse. This approach effectively addresses challenges such as antigen loss, mutations, and tumor heterogeneity, ensuring sustained and effective tumor clearance over time.

We are also developing TCENet, an AI-driven, end-to-end database designed to enhance the efficiency and precision of our TCE antibody discovery and development. By systematically integrating data across research, process development, and clinical stages, TCENet is expected to strengthen our capability to identify, design, evaluate, and optimize TCE candidates for solid tumors.

We have accumulated extensive expertise in process development and manufacturing control, which provides us with a competitive edge in CMC. For CMDE005, we achieved a titer of 4 g/L and a purity level exceeding 99.3%, meeting benchmarks comparable to leading global process standards. These results were achieved through close collaboration with CDMOs and guided by our molecular-level understanding of the TCE biology. We played an active role across the entire development process to ensure scalability, stability and quality. These capabilities provide strong assurance of product consistency from discovery to commercialization.

Our R&D team is multi-tiered, covering the full innovation pathway from discovery through clinical translation. The early-stage research team, led by Dr. XIAO Zuoxiang and Dr. ZHOU Dongwen, has become a key driver of our innovation. Our clinical development team, under the leadership of Dr. XIAO Zuoxiang and Ms. WANG Yanping, combines deep medical expertise with strong operational capabilities to align development with clinical needs. The integration of discovery scientists and clinical specialists enables coordinated oversight across the entire R&D process. Our in-house R&D team consisted of 33 employees as of the Latest Practicable Date, over

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97% of whom had obtained at least bachelor’s degrees, and over 70% members of our R&D team had obtained master’s or higher degrees. With dual R&D centers in the United States and China, we operate an integrated model across time zones, supporting a continuous R&D cycle and efficient platform integration.

We place a strong emphasis on intellectual property protection to secure our technology leadership. As of the Latest Practicable Date, we held 21 patents and five patent applications in connection with our clinical-stage product candidates, including four patents related to DNV3, and eleven patents and one patent application related to SMET12, in China, the U.S. and EU.

Support From Leading Industry Investors, Strong Medical Partnerships, and Robust Clinical Operation Capabilities

We have secured the recognition and support of leading healthcare industry investors, including Betta Pharmaceuticals Co., Ltd., Hangzhou Tigermed Consulting Co., Ltd and MabPlex International Co., Ltd. Their investments reflect confidence in the innovation and differentiated value of our products, while also providing us with financial resources and strategic industry support. Through these partnerships, we have established deep strategic collaborations, enabling access to critical industry resources, joint technological innovation, and expanded market channels. This collaborative model has accelerated the translation of our R&D outcomes and strengthened our competitive position within the TCE industry.

We have also established close collaborations with top-tier hospitals in China. We work with prominent principal investigators (“**PIs**”) to build an efficient, resource-integrated framework for clinical development. As of the Latest Practicable Date, our partner hospitals include among others Cancer Hospital, Chinese Academy of Medical Sciences, Fujian Cancer Hospital, and First Affiliated Hospital of Zhejiang University School of Medicine.

In addition, we have developed strong regulatory communication capabilities in both China and the United States. These capabilities enable the efficient progression of our drug candidates through clinical trials. For example, before submitting the IND application for the DNV3 combination therapy targeting melanoma, we had two rounds of communication with the CDE regarding the planned clinical trial and optimized our trial protocol accordingly. After we submitted the IND application, no major modifications of the trial protocol were requested by the NMPA during the review process, which greatly shortened the wait time from IND submission to IND approval to around two months.

We possess robust clinical operation capabilities. For example, it took only 11 months for us to advance from the GLP safety study to first patient in (“**FPI**”), a timeline significantly shorter than the industry average of 19 months. This demonstrates our execution strength in clinical planning, resource allocation, and team coordination, enabling us to rapidly and efficiently advance our pipeline into clinical development.

Experienced Leadership with a Global Perspective

Our founders and management team have an average of more than 31 years of experience in the biopharmaceutical industry. Their combined expertise in industry knowledge, strategic foresight, and operational execution enables them to work seamlessly across scientific, operational, and organizational aspects to drive our long-term, sustainable growth.

Founder, Chairman and Chief Executive Officer — Dr. XIAO Zuoxiang. Dr. Xiao has more than 30 years of experience in oncology clinical practice, disease mechanism research, and antibody drug development. Dr. Xiao previously served at leading U.S. institutions, including Johns Hopkins Bloomberg School of Public Health, Johns Hopkins School of Medicine, and the U.S. National Cancer Institute (“**NCI**”). Dr. Xiao has published over 30 articles in top journals such as *Cancer Cell*, *Genes & Development*, and *PNAS*, with more than 3,000 citations, marking his internationally

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recognized contributions in tumor biology and drug development. He is also widely regarded as a scientific entrepreneur with both strategic foresight and strong execution. Dr. Xiao obtained his bachelor’s degree in Medicine from Shandong First Medical University (山東第一醫科大學) in the PRC in July 1987 and his master’s degree in Medicine from Shanghai University of Traditional Chinese Medicine (上海中醫藥大學) in the PRC in July 1996 and his doctoral degree in oncology from Zhejiang University (浙江大學) in the PRC in March 2003. From May 2003 to April 2006, Dr. Xiao completed his postdoctoral training at The Johns Hopkins Bloomberg School of Public Health.

Senior Clinical Advisor — Dr. HE Ruyi. Dr. He is one of the most authoritative experts in China in clinical development and global regulatory regimes with more than 30 years of experience. Dr. He joined the U.S. FDA in 1999 as a Medical Officer in charge of new drug clinical evaluation until 2016. Dr. He joined the NMPA as the Chief Scientist, after having worked at the U.S. FDA for more than 17 years. Dr. He led numerous technical meetings, reviewed IND and NDA applications, and contributed to the development of regulatory guidelines across therapeutic areas. Dr. He played a pivotal role in reforming China’s drug review system, drafting technical guidelines, and fostering collaborations between Chinese and U.S. regulatory agencies. Also, Dr. He served as the Chief Medical Officer of RemeGen Co., Ltd. and Chief Scientist of SDIC Fund Management Co., LTD. Dr. He is the first CEO of the Global Health Innovation Institute co-sponsored by Shanghai municipal government and the Gates Foundation. Dr. He received his medical degree from China Medical University. He completed his intern and residency training in Internal Medicine at Howard University Hospital and affiliated hospitals in Washington, DC. and received his clinical and research training at the National Institutes of Health (“NIH”) in Bethesda, Maryland. Dr. He is a licensed, board-certified physician in Internal Medicine in the U.S.

Co-Founder, Senior Vice President and Director — Mr. SHAO Qing. Mr. Shao has extensive cross-border management experience in the pharmaceutical and biotech industries, having held senior executive roles at Porton Pharma Solutions Ltd. and others. Mr. Shao received his master’s degree in education from Virginia Tech in the U.S. in December 1994.

Vice President of R&D — Dr. ZHOU Dongwen. Dr. Zhou has over 20 years of research experience in protein structure-function relations and therapeutic antibody development. He previously served as a scientist at the Blood Research Institute of Wisconsin and as a postdoctoral research fellow at the U.S. NCI/NIH, where he advanced structural and functional studies of multiple proteins with therapeutic relevance. His research has provided important insights into protein biology and contributed to the development of antibody-based therapeutics. Dr. Zhou has published over 20 scientific articles in top academic journals such as *Blood*, *PNAS*, and *Nature Structural & Molecular Biology*. Dr. Zhou has received several notable honors, including the American Crystallographic Association Young Scientist Award, the NIH Postdoctoral Fellowship, and the Medical College of Wisconsin Postdoctoral Travel Award. Dr. Zhou obtained his bachelor’s degree in biochemistry from Anhui University (安徽大學) in the PRC in July 1999 and his doctoral degree in biochemistry and molecular biology from the University of Science and Technology of China (中國科學技術大學) in the PRC in June 2008.

Chief Financial Officer, Company Secretary and Board Secretary — Mr. LI Shu Pai. Mr. Li has over 20 years of distinguished work experience at a top audit firm, as well as various top financial institutions and public companies. Since 2014, he served as chief financial officer and director of multiple public companies before joining us in March 2026. Mr. Li obtained his bachelor’s degree in business administration from City University of Hong Kong (香港城市大學) in November 2001 in Hong Kong. He received his master’s degree in business administration from The Hong Kong University of Science and Technology (香港科技大學) in June 2014 in Hong Kong. Mr. Li was admitted as a Certified Public Accountant and a fellow member of the Hong Kong Institute of Certified Public Accountants in October 2004 and February 2012, respectively. He was also admitted as a fellow member of Association of Chartered Certified Accountants in July 2017.

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Chief Operating Officer — Ms. WANG Yanping. Ms. Wang has over ten years of experience in antibody drug research and development and has contributed to multiple novel antibody therapies with several U.S. patent filings. Ms. Wang oversees our U.S. operations and played a key role in the early development of the TCENet platform and antibody discovery. Earlier in her career, as a research fellow at the NIH, she worked on the development and scale-up of humanized monoclonal antibodies (scFv, Fab, and IgG) expressed in both prokaryotic and eukaryotic systems, applying purification strategies tailored to antibody properties. Ms. Wang obtained a Bachelor of Science degree in biotechnology from Nankai University (南開大學) in the PRC in June 2004.

OUR STRATEGIES

Advance Our Pipeline Products to Market Leadership for Global Clinical Development, Regulatory Approvals and Commercialization

DNV3. Both preclinical and clinical data support the potential of DNV3 to overcome tumor resistance to PD-1/PD-L1 inhibitors. Although PD-1/PD-L1 therapies are widely used, many patients eventually develop treatment-resistance, limiting long-term efficacy. DNV3 is designed to address this challenge and offer a new treatment option for PD-1/PD-L1 treatment-resistant patients. Our clinical development is currently focused on melanoma, one of the largest and most significant indications in immuno-oncology with substantial market potential. We completed the Phase I clinical trial of DNV3 monotherapy targeting advanced/metastatic solid tumors and lymphomas in March 2022. As of the Latest Practicable Date, DNV3 was under a Phase II clinical trial of DNV3 in combination with an anti-PD-1 antibody and chemotherapy targeting locally advanced unresectable or metastatic melanoma. The clinical trial is expected to complete in the fourth quarter of 2026. We plan to initiate a Phase III clinical trial of DNV3 in combination with an anti-PD-1 antibody and chemotherapy in the third quarter of 2027.

SMET12. SMET12 is the world’s first EGFR-targeting TCE that has entered the Phase II stage, has the potential to become the world’s first intravenous EGFR×CD3 bispecific antibody and is the first in China to receive clinical trial approval from the NMPA. As of the Latest Practicable Date, SMET12 was under Phase IIa clinical trial in China targeting EGFR-positive advanced solid tumors including esophageal cancer and received FDA’s IND approval in November 2021. We completed the Phase I clinical trial targeting EGFR-positive advanced solid tumors in China in February 2023. We expect to complete the Phase IIa clinical trial targeting esophageal cancer in the second quarter of 2027 and initiate a Phase III clinical trial in the fourth quarter of 2027. We also expect to initiate a Phase IIa clinical trial targeting TNBC in the fourth quarter of 2026. Depending on the results of the Phase II clinical trial of SMET12, we may consider initiating a Phase II clinical trial of SMET12 in combination with an anti-PD-1 antibody targeting selected EGFR-positive solid tumors.

CMD011. As of the Latest Practicable Date, CMD011 was under a Phase I clinical trial in China for HCC and received FDA’s IND approval in February 2025. CMD011 also has a potential for expansion into other indications such as renal cell carcinoma. We expect to complete the Phase I/IIa clinical trial in the fourth quarter of 2027 and initiate a Phase III clinical trial in 2028.

CMDE005. As of the Latest Practicable Date, CMDE005 was under a Phase I clinical trial in China targeting EGFR-positive advanced solid tumors and received FDA’s IND approval in April 2025. We expect to complete the Phase I/IIa clinical trial in the fourth quarter of 2027 and initiate a Phase III clinical trial in 2028.

Preclinical Drug Candidates. We expect to submit an IND application for CMDE101 to the NMPA in the fourth quarter of 2027 and to the FDA in 2028. We expect to submit an IND application for CMDE102 to the NMPA in 2028 and to the FDA in 2029.

Our pipeline reflects the breadth and strength of our technology platforms and the strong execution of our strategic priorities. We advance differentiated molecular designs, target high-value indications, and develop combination strategies to overcome resistance, building a portfolio that

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combines scientific innovation with strong clinical applicability. As our pipeline progresses through clinical development, we are reinforcing our leadership in the area of TCE, which we believe has the potential to become a backbone therapy for cancer treatment, and will position us to capture future opportunities for sustainable growth.

Continue to Expand Our Pipeline by Upgrading Our TCE Platforms and TCE Database TCENet

We will continue to enhance our TCE technology platforms, strengthening their capacity to generate highly selective and multifunctional/logic-gated TCEs. These platforms form the foundation of an antibody discovery and development engine aimed at addressing major clinical needs. In particular, we are working to overcome two longstanding challenges in bispecific antibody development: limited druggability and toxicities. Leveraging our proprietary animal model platforms for antibody indication screening, we plan to expand R&D investment and accelerate the progression of our drug candidates from preclinical research into clinical trials and subsequent biologics license application (“BLA”). This approach is expected to improve efficiency and shorten development timelines. We are also refining processes across the entire R&D process from target selection and drug design to regulatory filings to enhance overall productivity and ensure steady advancement of our pipeline toward key clinical milestones.

We also intend to further improve the capacity and quality of our antibody libraries, while continuing to refine our H-BiTE Platform to support the development of more competitive candidates. We are also investing in emerging technologies such as AI-assisted antibody design. By applying machine learning to identifying new targets, optimizing antibody structures, and guiding molecular design, we aim to enhance precision and increase the likelihood of success.

Looking forward, we plan to develop our proprietary TCE database, TCENet, into the central innovation engine of our R&D and focus on building a full-cycle innovation system from algorithms, data, pipeline development to commercialization. As part of this effort, we have built the world’s largest fully human IgM phage display antibody libraries (approximately 10^{13}) together with cross-species antibody discovery and screening capabilities, which is establishing high industry barriers. At the same time, we are standardizing our TCENet platform into a replicable solution that integrates algorithm models, molecular design tools, and data analysis modules. This transformation enables TCENet to function as a turnkey R&D platform that lowers development barriers and expands access to advanced TCE innovation across the industry.

Collaborate to Unlock the Clinical and Commercial Potential of Our Pipeline

We are committed to establishing strategic partnerships with domestic and international biopharmaceutical companies to fully unlock the clinical and commercial potential of our drug candidates. For early-stage projects, we may pursue licensing and co-development agreements to leverage external resources and accelerate R&D progress. By collaborating with a diverse range of stakeholders, we aim to expedite the development of high-potential candidates. For later-stage clinical projects, we will actively seek commercialization partnerships, leveraging our partners’ established market channels and sales capabilities to accelerate product launches and enhance commercialization efforts. Additionally, we will explore licensing-out opportunities with major global pharmaceutical companies to mitigate development risks and generate significant cash flow from licensing agreements. We are currently considering potential license out opportunities for our Core Products, but we have not established any concrete licensing arrangement.

Enhance International Clinical Development and Expand Market Presence

We are committed to strengthening our international clinical development capabilities and expand market presence across key regions. Our strategy focuses on building a comprehensive, multi-regional clinical development system and tailoring market entry strategies to meet the specific needs of different regions. We plan to establish clinical development centers in major

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pharmaceutical markets, including North America, Europe, and the Asia-Pacific region. Our goal is to assemble clinical teams with extensive international experience and design global, multi-center clinical trials that meet the standards of leading regulatory authorities such as the FDA, EMA and NMPA. We will prioritize the early-stage clinical development of CMD011 and CMDE005 in the U.S. and European markets, aligning progress with that in China to shorten the global commercialization timeline.

We will also adopt a differentiated approach to market access based on regional characteristics. In markets such as the U.S. and Europe, our focus will be on innovative therapies, seeking priority review status through self-submission or by partnering with renowned local pharmaceutical companies, thereby expediting both product approval and market entry. In emerging markets, including Southeast Asia and the Middle East, we will leverage our cost and efficacy advantages through strategies such as technology transfer and local manufacturing collaborations to broaden market coverage and accelerate adoption.

Leverage Top Talents as Our Core Competitive Advantage, Ensuring Sustainable Success through Strategic Talent Development

We are committed to attracting and nurturing top talent with a global perspective, specializing in drug discovery, clinical development and commercialization. By continuously expanding our talent pool, we aim to drive the advancement of our pipeline and TCE platforms, which are critical to enhancing our capabilities and supporting sustainable growth. Additionally, we will provide ongoing training and development programs for our employees to enhance their technical expertise and keep them aligned with the latest industry trends. This investment in talent development will strengthen our workforce and enable us to stay at the forefront of the rapidly evolving biopharmaceutical sector.

OUR PRODUCT PIPELINE

We are a clinical-stage biotech company focused on the development of TCE through an antibody discovery and development engine. Since our founding in 2017, we are strategically focused on TCE antibody therapeutics. Driven by clinical needs, we are committed to developing TCE-related therapies for cancer and autoimmune diseases.

As of the Latest Practicable Date, we had four in-house, clinical-stage drug candidates, including (i) DNV3, an advanced TCM targeting LAG-3, which validates our proprietary high-capacity fully human IgM phage display antibody library, (ii) SMET12, an innovative intravenous EGFR×CD3 TCE, (iii) CMD011, an advanced GPC3×CD3 TCE, which together with SMET12 validate our TCE molecular-format engineering, and (iv) CMDE005, an innovative EGFR×CD3 masked TCE, which validates our protease-activatable, masking technology. In addition, we have two preclinical stage drug candidates for multifunctional and logic-gated TCE, CMDE101 and CMDE102, which are trispecific masked TCEs targeting FOLR1×PD-L1×CD3 and PSMA×PD-L1×CD3, respectively. All these drug candidates are self-developed.

Core Product DNV3: an Advanced TCM Targeting LAG-3

Overview

DNV3 is an anti-LAG-3 TCM developed from our proprietary high-capacity IgM antibody libraries. LAG-3 represents a promising ICI beyond PD-1/PD-L1.

As of the Latest Practicable Date, there was one anti-LAG-3 antibody combination therapy (opdualag), which was mainly used for first-line treatment of unresectable or metastatic melanoma. In 2024, the total sales of opdualag reached US\$928 million. In China, there was no approved

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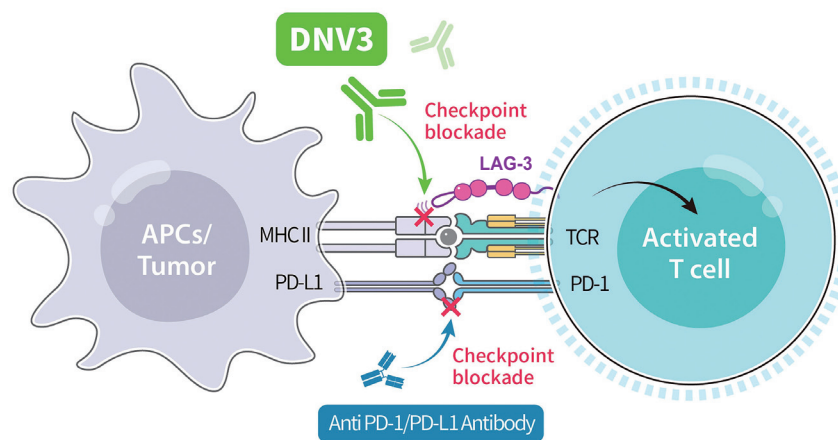
anti-LAG-3 antibody drug. According to Frost & Sullivan, DNV3 ranked second globally and in China by stage of clinical development among anti-LAG-3 antibody drug candidates for melanoma treatment, as of the Latest Practicable Date.

In the ongoing Phase II clinical trial, the combination of DNV3 with an anti-PD-1 antibody and chemotherapy achieved an ORR of 44.4% in 18 mucosal melanoma patients previously treated with PD-(L)1 inhibitors, approximately three times higher than that of existing comparable therapies based on publicly available information (without head-to-head comparison in clinical trials), offering new option for patients resistant to first-line PD-1 treatment. In cutaneous melanoma, IIT and Phase II trial data showed an ORR of 66.7% in 12 cutaneous melanoma patients with the same combination therapy, which is over five times higher than that achieved by existing comparable therapies based on publicly available information (without head-to-head comparison in clinical trials). These results underscore DNV3's therapeutic potential in addressing the low response rates of current immuno-oncology therapies. Also, DNV3 demonstrated a favorable safety profile in our clinical trials, with no recorded Grade 3 or above CRS. Moreover, DNV3 in combination with an anti-PD-1 antibody and chemotherapy reached an ORR of 38.5% and medium PFS of 7.4 months in 13 melanoma patients with liver metastasis (medium size was 77.4mm), for whom there is currently no effective treatment option.

We developed DNV3 internally and hold the global rights for its use, manufacture, and commercialization. We expect to be the market authorization holder of DNV3 in any jurisdiction. We started the R&D of DNV3 in 2017 by screening for and optimizing the sequences of the anti-LAG-3 antibody based on the Multichannel Antibody Discovery Platform. We then performed preliminary druggability assessment, *in vitro* and *in vivo* pharmacological and efficacy evaluations for DNV3. Thereafter, we retained MabPlex, a CDMO, to conduct CMC development. With these efforts, we obtained the first IND approval of DNV3 from the NMPA in August 2020.

Mechanism of Action

LAG-3-MHCII interaction blockade by DNV3 restores T cell activation



Source: Company information

As a TCM, DNV3 restores T-cell function by blocking the inhibitory LAG-3 pathway, thereby enhancing T-cell activation and anti-tumor immune responses. LAG-3 is an inhibitory receptor that is highly expressed by exhausted T cells in the TME. LAG-3 transmits inhibitory signals to T cells upon binding to MHC class II and other ligands, rendering T cells dysfunctional. Acting upstream in the immune response, LAG-3 has the potential to modulate multiple pathways, while also offering a favorable safety profile. Consequently, LAG-3 is a major target for cancer immunotherapy.

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LAG-3 is the third immune checkpoint inhibitory receptor to be exploited in human anti-cancer immunotherapies, and it is considered a potential cancer immunotherapy target in human therapy, right next to PD-1 and CTLA-4. LAG-3 and PD-1 are co-expressed on intratumoral T cells in various human tumors and mouse models of cancer. Previous studies have shown that PD-1 and LAG-3 may synergistically promote T-cell exhaustion while restraining clonal expansion and downstream autocrine signaling responses to IFN- γ . Dual PD-1 and LAG-3 blockade may synergistically limit tumor growth compared to monotherapy alone.

DNV3, an anti-LAG-3 antibody, is designed to block LAG-3’s inhibitory activity, thereby enhancing anti-cancer immune responses by T cells. Moreover, LAG-3 blockade has been shown to effectively alleviate the patient’s tolerance to PD-1 ICIs. Hence, synchronous LAG-3 and PD-1 inhibition may be a potential new strategy for tumor immunotherapy.

Market Opportunity and Competition

The near-term target market of DNV3 is China. We have no near-term commercialization or clinical development plan for DNV3 in the U.S. From a long-term perspective, in addition to China, the target jurisdictions for clinical trials and registration filing of DNV3 include the U.S., Europe and Australia, primarily in view of relatively high incidence of cutaneous melanoma in such markets. As of the Latest Practicable Date, there was one approved anti-LAG-3 antibody combination therapy (opdualag), which was mainly used for first-line treatment of unresectable or metastatic melanoma. As of the same date, for anti-LAG-3 antibody drugs targeting melanoma globally, one was in the Phase III stage, one was in the Phase II stage (DNV3), and others were in the Phase I/II stage. According to Frost & Sullivan, DNV3 ranked second globally and in China by stage of clinical development among anti-LAG-3 antibody drug candidates for melanoma treatment, as of the Latest Practicable Date. For details, see “Industry Overview—Overview of LAG-3—Global Competitive Landscape of LAG-3-Targeting Antibody Drugs for Melanoma.”

Competitive Advantages

Clinical Leadership. As of the Latest Practicable Date, only one anti-LAG-3 antibody combination therapy (opdualag) was approved globally, and none in China.

Enhanced Mechanism of Action. DNV3 restores T-cell function by blocking the inhibitory LAG-3 pathway, thereby enhancing T-cell activation and anti-tumor immune responses. LAG-3 is an inhibitory immune checkpoint receptor highly expressed by exhausted T cells in the TME. By binding to MHC class II and other ligands, LAG-3 transmits inhibitory signals that impair T-cell function, making it a key target for cancer immunotherapy. Acting upstream in the immune response, LAG-3 has the potential to modulate multiple pathways, while also offering a favorable safety profile. Preclinical studies have shown that DNV3 can effectively block LAG-3 binding to both MHC II and to fibrinogen-like protein 1 (“FGL-1”), thereby further augmenting immune responses. In addition, DNV3 has demonstrated a potential to enhance the antigen presenting and antibody production functions of B cells in preclinical studies, with a clinical potential to generate effective anti-tumor effects even with insufficient T cells.

Encouraging Efficacy. Clinical results indicate that DNV3 can overcome PD-1/PD-L1 drug resistance and achieve a high response rate. In the ongoing Phase II clinical trial, the combination of DNV3 with an anti-PD-1 antibody and chemotherapy achieved an ORR of 44.4% in 18 mucosal melanoma patients previously treated with PD-(L)1 inhibitors, approximately three times higher than that of existing comparable therapies (without head-to-head comparison in clinical trials). In cutaneous melanoma patients previously treated with PD-(L)1 inhibitors, investigator-initiated trial data showed an ORR of 66.7% with the same combination therapy, which is over five times higher than that achieved by existing comparable therapies (without head-to-head comparison in clinical trials). In an ongoing Phase II clinical trial, DNV3 in combination with an anti-PD-1 antibody and chemotherapy reached an ORR of 38.5% and medium PFS of 7.4 months in 13 melanoma patients

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with liver metastasis (medium size was 77.4mm), for whom there is currently no effective treatment option. These results underscore DNV3’s therapeutic potential in addressing the low response rates of current immuno-oncology therapies.

Production Efficiency. DNV3 demonstrates a high yield of up to 6.8g/L with a simple and stable manufacturing process, thereby significantly increasing the production efficiency.

However, as of the Latest Practicable Date, only certain IITs and a Phase I clinical trial with 11 patients had been completed for DNV3. The number of enrolled patients and follow-up period in these trials are limited.

Summary of Clinical Trials

The following sets forth an overview of the key clinical trials of DNV3.

Trial number	Phase	Study design	Sites	Subjects	Status	Patient enrollment
N/A	IIT	Evaluate the efficacy and safety of DNV3 in combination with toripalimab and chemotherapy	China	Patients with advanced melanoma	Completed	27 (Actual)
CTR20202356	I	Evaluate the safety, tolerance and pharmacokinetics of DNV3	China	Patients with advanced/metastatic solid tumors and lymphomas	Completed	11 (Actual)
CTR20243964	II	Evaluate the efficacy and safety of DNV3 in combination with toripalimab and chemotherapy	China	Patients with locally advanced unresectable or metastatic melanoma following failure of prior treatment with immune checkpoint inhibitors	Ongoing	60 (Expected)

An IIT of DNV3 plus toripalimab and chemotherapy in advanced melanoma in China sponsored by us

Trial design. The IIT enrolled 27 patients with advanced melanoma, who received nab-paclitaxel (initial dose 260 mg/m², reduced to 200 mg/m²), cisplatin (25 mg/m²), DNV3 (3 mg/kg), and toripalimab (240 mg) every 3 weeks for 6 cycles, followed by maintenance immunotherapy. The primary endpoint was ORR. The secondary endpoints included safety, PFS, DoR, DCR and OS.

Safety data. Initial nab-paclitaxel 260 mg/m² caused Grade 3 or above TRAEs in 55.6%, leading to dose reduction (200 mg/m²) which reduced Grade 3 or above TRAEs to 22.2%. Immune-related toxicities (Grade 3 or above immune-related AEs in 22.2%) were manageable without fatal events.

Efficacy data. The combination therapy showed 44.4% ORR (85.2% DCR) in the 27 patients which was further elevated to 54.5% in the subgroup of 11 patients with hepatic metastases. Notably, it also demonstrated substantial efficacy in anti-PD-(L)1-resistant cases, with a 42.9% ORR and a median PFS of 7.36 months. Among treatment-naïve mucosal melanoma, the ORR reached 50%. The median PFS for the total cohort (n = 27) was 7.29 months (95% CI: 4.96–10.28).

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In patients with liver metastases (n = 11), PFS was 4.96 months (95% CI: 1.38–NE). In patients previously exposed to anti-PD-(L)1 therapy (n = 21), PFS was 7.36 months (95% CI: 4.96–10.28). Treatment-naïve mucosal melanoma cases (n = 6) exhibited a median PFS of 5.78 months.

Data/IP ownership. We own the data and intellectual property relating to the IIT.

CTR20202356: A Phase I clinical trial to evaluate the safety, tolerance and pharmacokinetics of DNV3 in patients with advanced/metastatic solid tumors and lymphomas in China sponsored by us

Overview. This is an open and multi-site Phase I clinical trial of safety, tolerance and pharmacokinetics in patients with advanced/metastatic solid tumors and lymphomas.

The primary objective is to evaluate the safety and tolerability of DNV3 injection in patients with advanced/metastatic solid tumors and lymphomas. The secondary objectives are to evaluate the pharmacokinetics (“**PK**”), immunogenicity and anti-tumor activity of DNV3 in patients with advanced/metastatic solid tumors and lymphomas.

Trial design. The Phase I clinical trial enrolled 11 patients, who were treated with DNV3 once every two weeks in 28-day treatment cycles. Patients were assigned to sequentially escalating dose groups at doses of 0.1mg/kg, 0.3 mg/kg, 1 mg/kg, 3 mg/kg and 10 mg/kg. The first two dose groups (0.1 mg/kg and 0.3 mg/kg) used an accelerated titration method. One subject was initially enrolled in the 0.1 mg/kg dose group. If this subject experienced Grade 2 or above drug-related toxicity within 28 days of the first dose, the dosing method would switch to the traditional “3+3 design” method. If the subject did not experience Grade 2 or above drug-related toxicity within 28 days of the first dose, it would proceed to the next dose group (0.3 mg/kg). The 0.3 mg/kg dose group followed the same procedure as the 0.1 mg/kg dose group. The remaining three dose groups (1 mg/kg, 3 mg/kg, and 10 mg/kg) would use the traditional “3+3” method for dose escalation. The treatment period was 28 days to 24 months, and the follow-up period was at least 2 years.

The primary endpoints included DLT, AE and SAE. The secondary endpoints included PK, anti-drug antibody (“**ADA**”), ORR, duration of response (“**DoR**”), DCR, OS and PFS.

Trial status. We initiated the Phase I clinical trial in June 2021 and completed the trial in March 2022.

Safety data. 81.8% (9/11) of the enrolled patients experienced AEs. 45.5% (5/11) of the enrolled patients experienced TRAEs. Most of the AEs were Grade 1 or 2. 18.2% of the enrolled patients experienced Grade 3 or above AEs. No DLTs, SAEs, adverse events of special interest (“**AESI**”) or infusion reactions were reported.

CTR20243964: A Phase II clinical trial to evaluate the efficacy and safety of DNV3 in combination with toripalimab and chemotherapy in patients with locally advanced unresectable or metastatic melanoma following failure of prior treatment with immune checkpoint inhibitors sponsored by us in China

Overview. This is an open-label, multicenter, single-arm Phase II clinical trial to assessing the efficacy and safety of DNV3 in combination with toripalimab self-purchased by us and chemotherapy in patients with locally advanced unresectable or metastatic melanoma following failure of prior treatment with immune checkpoint inhibitors. The primary objective is to evaluate the efficacy of DNV3 in combination with toripalimab and chemotherapy in patients with locally advanced unresectable or metastatic malignant melanoma following failure of prior treatment with immune checkpoint inhibitors. The secondary objectives are to evaluate (i) the durability of response to DNV3 in combination with toripalimab and chemotherapy; (ii) the safety and tolerability of DNV3 in combination with toripalimab and chemotherapy; (iii) the pharmacokinetics profile of DNV3 in combination with toripalimab and chemotherapy; (iv) the immunogenicity of DNV3 in combination with toripalimab and chemotherapy.

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Trial design. The trial expects to enroll 60 patients. The combined therapy will be administered once every 3 weeks, and each administration will constitute a treatment cycle of 3 weeks (21 days). Chemotherapy drugs will be administered in the first 4-6 treatment cycles. The specific chemotherapy cycles and doses will be determined by the researchers based on the subject's disease condition and chemotherapy tolerance.

On the first day of each treatment cycle, nab-paclitaxel will be administered intravenously, followed by cisplatin, followed by DNV3, and finally toripalimab. Cisplatin is administered on days 1-3 of each treatment cycle; if carboplatin is used, the administration time is day 1 of each treatment cycle. After the chemotherapy regimen is completed, an interval of at least 30 minutes should be maintained before administering DNV3 combined with toripalimab. The dosage for each administration of the test drugs will be as follows: DNV3 3mg/kg; toripalimab 240mg; nab-paclitaxel 200mg/m²; cisplatin 25mg/m²; carboplatin AUC=5. The treatment period will be 21 days to 2 years, and the follow-up period will be at least 28 days. The primary endpoint is ORR. Secondary endpoints include DoR, RFS, OS, the incidence rate and severity of TEAEs, abnormal laboratory test values, physical examination, vital sign parameters, PK and ADA.

Trial status. We initiated the trial in November 2024 and expect to complete the trial in the fourth quarter of 2026. As of the Latest Practicable Date, the trial recruited 66 patients.

Clinical Development Plan

Between March 2022 and August 2024, we explored several different combination therapies of DNV3. In April 2022, we submitted IND applications for (1) a Phase I/IIa clinical trial of DNV3 in combination with toripalimab in patients with advanced/metastatic solid tumors and lymphomas, and (2) a Phase I/IIa clinical trial of DNV3 in combination with toripalimab in patients with recurrent/metastatic rare skin tumors. The IND applications included the clinical study report for the Phase I clinical trial of DNV3 monotherapy. Based on the Phase I clinical trial results, the NMPA approved the Phase I/IIa clinical trials of DNV3 in combination with toripalimab in June 2022. We conducted the two Phase I/IIa clinical trials, with an exploratory purpose, until 2024 and determined to focus on melanoma as the key indication for DNV3 combination therapy for further clinical development. Based on the results of the two Phase I/IIa clinical trials, we designed the trial protocol and obtained NMPA IND approval for a different DNV3 combination therapy with additional components (DNV3 in combination with an anti-PD-1 antibody and chemotherapy), which is expected to demonstrate greater synergistic targeted attack on tumors. Ultimately, we intend to seek marketing approval from the NMPA for DNV3 in combination with an anti-PD-1 antibody and chemotherapy.

We do not intend to initiate a Phase IIa clinical trial of DNV3 monotherapy. Instead, we expect to complete the Phase II clinical trial of DNV3 in combination with toripalimab (an anti-PD-1 antibody) and chemotherapy in the fourth quarter of 2026. We expect to conduct an end-of-Phase-II-meeting with the NMPA and then initiate a Phase III clinical trial of DNV3 in combination with toripalimab and chemotherapy targeting locally advanced unresectable or metastatic melanoma in the third quarter of 2027. We expect to initiate a Phase II clinical trial of DNV3 in combination with toripalimab and chemotherapy targeting advanced treatment naive NSCLC in the third quarter of 2026 and a Phase III clinical trial of the combination therapy targeting the same indication in 2028.

We have not initiated a clinical trial for DNV3 in the U.S., and we do not have a concrete clinical development plan for DNV3 in the U.S. We currently prioritize the clinical development of DNV3 in China and, based on cost-benefit considerations, are considering establishing collaboration arrangements for the overseas clinical development of DNV3. As of the Latest Practicable Date, we had not yet established any such collaboration arrangement.

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We have not established any collaboration arrangement with a third party for the use of toripalimab in our clinical trials for the combination therapy of DNV3. We procure toripalimab from an authorized distributor of Shanghai Junshi Biosciences Co., Ltd. (the MAH of toripalimab) in China.

Material Communications with Competent Authorities

We submitted to the NMPA the IND application to conduct a Phase I/IIa clinical trial of DNV3 monotherapy for advanced/metastatic solid tumors and lymphomas in May 2020 and received the NMPA's IND approval in August 2020. The IND approval recommended reducing the initial dosage level of DNV3 to be lower than 0.3 mg/kg in the Phase I clinical trial, and we accordingly set the initial dosage level to be 0.1 mg/kg. Also, the IND approval recommended that we obtain a certain amount of clinical data of DNV3 monotherapy before submitting an IND application for the combination therapy of DNV3 and an anti-PD-1 antibody. In addition, the IND approval required us to investigate the potential ADA responses in human trials of DNV3, in light of the immunogenicity and ADA responses of DNV3 observed in its preclinical animal studies. We initiated the Phase I clinical trial in June 2021 and completed the trial in March 2022 as we reached primary endpoints for the Phase I clinical trial. Our communications with the NMPA indicate that the Phase I clinical trial of DNV3 monotherapy was a standalone clinical trial. The trial protocol for the Phase I clinical trial, as a standalone clinical trial separate from the Phase IIa clinical trial, was clearly reflected in our IND applications for the Phase I/IIa clinical trial of DNV3 monotherapy, which was approved by the NMPA in August 2020. After completing the Phase I clinical trial of DNV3 monotherapy, we submitted the clinical study report for the trial to the NMPA, in the IND applications for the Phase I/IIa clinical trials of DNV3 in combination with toripalimab, which the NMPA approved in June 2022. The clinical study report marked the completion of the Phase I clinical trial, and the NMPA did not object to the clinical study report, further demonstrating the NMPA's recognition of the completeness of the Phase I clinical trial as a standalone trial. We initiated the Phase I/ IIa clinical trials of DNV3 in combination with toripalimab in October 2022 and completed the trials in November 2025.

We submitted to the NMPA the IND application to conduct a Phase II clinical trial of DNV3 in combination with toripalimab and chemotherapy targeting melanoma in August 2024 and received the NMPA's IND approval in October 2024. The IND application for the Phase II clinical trial included the clinical study report of the Phase I/IIa clinical trials of DNV3 in combination with toripalimab in patients with advanced/metastatic solid tumors and lymphomas and patients with recurrent/metastatic rare skin tumors. We initiated the Phase II clinical trial in November 2024 and expect to complete the trial in the fourth quarter of 2026.

The IND approvals we received for clinical trials of DNV3 in combination with toripalimab did not include any requirement on the source of toripalimab used in such trials. Separate approvals are not required if we were to use alternative suppliers of toripalimab. There are multiple alternative suppliers of toripalimab in China from which we may procure toripalimab to ensure consistent supply in our clinical trials.

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A detailed chronology of the material communications regarding DNV3 is shown below.

Time	Type of communication	Competent Authority	Scope	Basis of IND approval	Proposed/recommended protocol amendment
May 2020 . . .	IND application submission	NMPA	Phase I/IIa clinical trial of DNV3 monotherapy for advanced/metastatic solid tumors and lymphomas in China	N/A	N/A
August 2020 . .	Grant of IND approval	NMPA	Phase I/IIa clinical trial of DNV3 monotherapy for advanced/metastatic solid tumors and lymphomas in China	The non-clinical test (pharmacology, PK and toxicology) and quality study results of DNV3	The NMPA recommended reducing the initial dosage level of DNV3 to be lower than 0.3mg/kg in the Phase I clinical trial cki. We accordingly set the initial dosage level to be 0.1mg/kg.
August 2024 . .	IND application submission	NMPA	Phase II clinical trial of DNV3 in combination with toripalimab and chemotherapy targeting melanoma in China	N/A	N/A
October 2024 .	Grant of IND approval	NMPA	Phase II clinical trial of DNV3 in combination with toripalimab and chemotherapy targeting melanoma in China	Results of Phase I clinical trial of DNV3 monotherapy for advanced/metastatic solid tumors and lymphomas in China, as well as the Phase I/IIa clinical trials of DNV3 in combination with toripalimab in patients with advanced/metastatic solid tumors and lymphomas and patients with recurrent/metastatic rare skin tumors in China	N/A

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET DNV3 SUCCESSFULLY.

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Core Product SMET12: an Innovative Intravenous EGFR×CD3 TCE

Overview

SMET12 is a fully human bispecific antibody (TCE) targeting EGFR on tumor cells and CD3 on T cells. Developed based on our proprietary antibody screening library and bispecific antibody platform, it is the world’s first EGFR-targeting TCE that has entered the Phase II stage, with the potential to become the world’s first intravenous EGFR×CD3 bispecific antibody, and is the first in China to receive clinical trial approval from the NMPA, according to Frost & Sullivan.

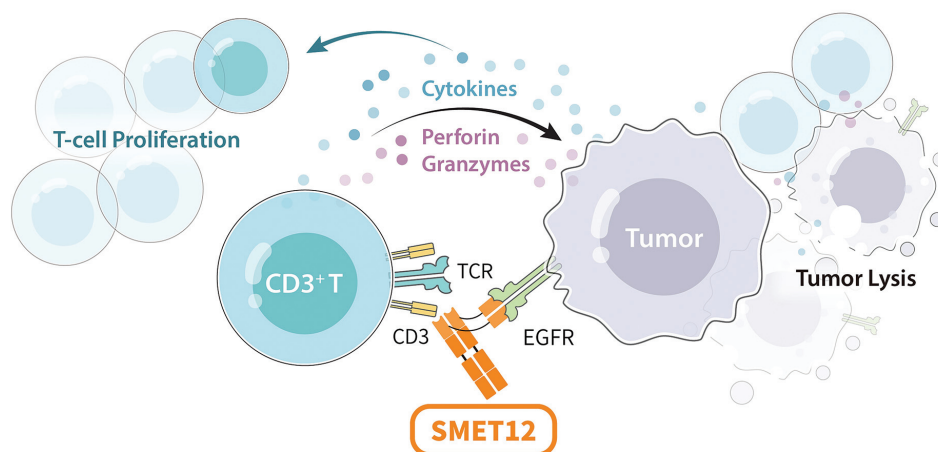
SMET12 is able to recruit and activate T cells to release cytotoxic molecules, such as granzymes, directly killing tumor cells. Moreover, SMET12 has demonstrated a favorable safety profile. A key concern for TCE therapies is CRS, which can cause serious side effects and restrict feasible routes of administration. Designing a molecule that brings EGFR and CD3 together is challenging and requires careful control. Strong CD3 binding can trigger cytokine storms and reduce efficacy, and Fc-related immune activity may further raise the CRS risk. To address these issues, SMET12 uses an engineered Fc design that extends half-life and limits unwanted immune activation, and its structure has been tuned to balance CD3 binding and avoid over-activation. In addition to CRS, EGFR-targeted therapies are often associated with skin toxicities, such as rash and dermatitis. As of the Latest Practicable Date, SMET12 had demonstrated no typical EGFR-related toxicities (such as skin rash) in our pre-clinical and clinical studies, and no Grade 3 or above CRS had been recorded. Therefore, SMET12 is expected to address clinical needs in oncology, offering significant social benefits and market potential.

We submitted the IND application to conduct the Phase I/IIa clinical trial of SMET12 monotherapy for EGFR-positive advanced solid tumors in June 2021 and received the NMPA IND approval in August 2021, making SMET12 the first NMPA-approved EGFR×CD3 bispecific antibody for clinical development. According to Frost & Sullivan, SMET12 ranked first globally and in China by stage of clinical development among EGFR×CD3 TCE candidates as of the Latest Practicable Date.

We developed SMET12 internally and hold the global rights for its use, manufacture and commercialization. We expect to be the market authorization holder of SMET12 in any jurisdiction. We started the R&D of SMET12 in 2017 by screening and optimizing the sequences of the EGFR×CD3 bispecific antibody based on the Multichannel Antibody Discovery Platform. With such sequences, we constructed the TCE structure for SMET12 base on the H-BiTE Platform. We then performed preliminary druggability assessment, *in vitro* and *in vivo* pharmacological and efficacy evaluations for SMET12. Thereafter, we retained MabPlex, a CDMO, to conduct CMC development. With these efforts, we obtained the first IND approval of SMET12 from the NMPA in August 2021.

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Mechanism of Action



Source: Company information

SMET12 is a bispecific antibody that can target both CD3 and EGFR. EGFR is a transmembrane receptor tyrosine kinase whose mutations or overexpression are frequently observed in cancers, leading to persistent downstream signaling that drives uncontrolled tumor growth and metastasis. CD3 is a critical component of the TCR complex, responsible for transmitting antigen-recognition signals to activate T cells. Tumors often create an immunosuppressive microenvironment that exhausts T cells and enables immune evasion. SMET12 has a well-defined anti-tumor mechanism. SMET12 binds to EGFR-positive tumor cells and CD3-positive T cells simultaneously. This dual binding mediates potent tumor-killing activity. Through the unique design of our H-BiTE Platform, SMET12 avoids toxicity caused by homodimerization and aggregation, while possesses optimal EGFR×CD3 affinity.

Market Opportunity and Competition

First-generation EGFR targeting monospecific antibodies, such as cetuximab and panitumumab, had been investigated in the treatment of ESCC and TNBC. Although certain studies demonstrated preliminary anti-tumor activity, these antibodies generally failed to show significant survival benefits, reflecting limitations of conventional EGFR monospecific antibodies in patient selection, resistance mechanisms, and immune activation. However, EGFR remains a valid drug target for cancer treatment. MOA innovation has enabled clinical breakthroughs against the same target. For example, amivantamab, a bispecific antibody that targets EGFR and mesenchymal-epithelial transition factor, was approved by the FDA in 2024 for the treatment of NSCLC, demonstrating that differentiated MOAs can substantially improve clinical outcomes. TCE represents another MOA that is different from traditional monospecific antibodies which function by targeting only the EGFR signaling pathway. Through CD3-mediated T-cell recruitment and redirection, TCEs may induce more direct and potent tumor cell killing. Clinical validation of TCEs in solid tumors has been shown in the FDA approval of tarlatamab (a TCE that targets CD3 and delta-like ligand 3) for treating small cell lung cancer in 2024.

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The near-term target markets of SMET12 are China. We have no near-term commercialization or clinical development plan for SMET12 in the U.S. As of the Latest Practicable Date, there was one EGFR-targeting TCE (SMET12) in Phase II clinical stage and one unmasked EGFR-targeting TCE in Phase I globally. For details, see “Industry Overview—Overview of EGFR/CD3 BsAbs—Global Competitive Landscape of EGFR-Targeting Antibody Drugs.”

Competitive Advantages

Clinical Leadership. SMET12 is the world’s first EGFR-targeting TCE that has entered the Phase II stage and first EGFR×CD3 bispecific antibody designed for direct intravenous infusion. It is also the first intravenous EGFR×CD3 bispecific antibody in China to receive clinical trial approval from the NMPA. SMET12 is designed with optimized T-cell affinity to mitigate the CRS risk associated with many conventional TCEs, and it is thus able to achieve systemic delivery via direct intravenous infusion.

Encouraging Efficacy. Many TCEs are too large to penetrate solid tumor stroma, limiting their effectiveness. SMET12 is smaller than IgG monoclonal antibodies (*i.e.*, around 120 kDa for SMET12 vs 150 kDa for monoclonal IgG antibodies) and has an optimized structure, enabling better penetration into tumor tissue. This design supports more efficient delivery to TME and stronger therapeutic activity. Clinical results indicate that SMET12 in combination with an anti-PD-1 antibody drug has shown significant efficacy in patients who had previously failed chemotherapy or targeted therapy. In NSCLC patients that had failed targeted therapy, SMET12 in combination with an anti-PD-1 antibody drug achieved DCR of 100.0%, ORR of 41.7% and PFS up to 18 months in an IIT.

Favorable Safety Profile for Outpatient Settings. A key concern for TCE therapies is CRS, which can cause serious side effects and restrict feasible routes of administration. Strong CD3 binding can trigger cytokine storms and reduce efficacy, while Fc-related immune activity may further raise the CRS risk. To address these issues, SMET12 uses an engineered Fc design tuned to balance CD3 binding and avoid over-activation, which not only limits unwanted immune activation but also extends half-life, and its structure has been tuned to balance CD3 binding and avoid over-activation. With these innovations, SMET12 enables safer dosing and greater clinical feasibility even including outpatient settings. In addition to CRS, EGFR-targeted therapies are often associated with skin toxicities, such as rash and dermatitis. As of the Latest Practicable Date, SMET12 had demonstrated no skin toxicities typically observed with EGFR-targeting therapies in our pre-clinical and clinical studies, underscoring its differentiated safety profile. Also, in our completed Phase I and ongoing Phase IIa clinical trials of SMET12, all of CRS events observed were Grade 1 or 2 and recovered within two weeks.

Convenience of Use. Earlier TCEs often rely on continuous infusion pumps and inpatient monitoring, which increase costs and limit patient acceptance. SMET12 is the world’s first EGFR×CD3 bispecific antibody designed for direct intravenous infusion. It is also the first intravenous EGFR×CD3 bispecific antibody in China to receive clinical trial approval from the NMPA. The administration of SMET12 by standard intravenous infusion is expected to improve its acceptance by physicians and patients.

Broad Applicability. Many targeted therapies require activating mutations or tumor-type-specific biomarkers, limiting their use across diverse patient populations. SMET12 targets tumors based on EGFR expression rather than relying on specific EGFR mutations, allowing it to work effectively in tumors regardless of the EGFR mutation status. Also, SMET12 maintains a high targeting efficiency at both high and low levels of EGFR expression. Most types of solid tumors are EGFR-positive and thus may be targeted by SMET12. Among them, certain tumor types (*e.g.*, esophageal cancer and TNBC) have a low expression of TME-specific proteases (*e.g.*, uPA). For treating such tumors, a masking peptide cannot be added to the therapeutic antibody (*e.g.*, TCE), because the masking peptide cannot be removed within the TME to allow activation of the antibody — in that case, the antibody will remain inactive within the TME and thus cannot exert its tumor

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killing function. SMET12, which has no masking peptide, is designed to address the types of solid tumors with a low expression of TME-specific proteases. Such solid tumors, which affect over 20 million and over 4.5 million people globally and in China, respectively, represent a significant market of over US\$160 billion globally and US\$25 billion in China. Thus, SMET12 has broad potential clinical use and may become improved treatment options for patients across different tumor types.

Manufacturing Efficiency. SMET12 has demonstrated high chemical stability, low mispairing rate and high heterodimer yield with simplified manufacturing process via quality by design, thereby significantly improving manufacturing efficiency.

However, as of the Latest Practicable Date, only certain IITs and a Phase I clinical trial with 16 patients had been completed for SMET12. The number of enrolled patients and follow-up period in these trials are limited.

Summary of Clinical Trials

The following sets forth an overview of the key clinical trials of SMET12.

<u>Trial number</u>	<u>Phase</u>	<u>Study design</u>	<u>Site</u>	<u>Subjects</u>	<u>Status</u>	<u>Patient enrollment</u>
CTR20212374	I	Evaluate the safety and PK characteristics of SMET12	China	Patients with EGFR-positive advanced solid tumors	Completed	16 (Actual)
CTR20212374	Ila	Evaluate the safety and PK characteristics of SMET12	China	Patients with EGFR-positive advanced solid tumors	Ongoing	80-150 (Expected)
CTR20231358	I/Ila	Evaluate the safety, tolerability, PK characteristics and preliminary efficacy of SMET12 in combination with toripalimab	China	Patients with EGFR-positive advanced solid tumors	Temporarily suspended	99-192 (Expected)

CTR20212374: A Phase I clinical trial to evaluate the safety and PK characteristics of SMET12 in patients with EGFR-positive advanced solid tumors in China sponsored by us.

Overview. This is an open, single-arm, dose escalation Phase I clinical trial assessing the efficacy and safety of SMET12 in patients with EGFR-positive advanced solid tumors.

The primary objective is to evaluate the safety and tolerability of SMET12 in patients with EGFR-positive advanced solid tumors. The secondary objectives are to evaluate the DLT, maximum tolerated dose (“**MTD**”), PK, pharmacodynamics (“**PD**”) and immunogenicity of SMET12 in patients with EGFR-positive advanced solid tumors.

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Trial design. The Phase I part enrolled 16 patients, who were treated with SMET12 once every two weeks in 28-day treatment cycles. A traditional “3+3 design” was adopted for the dose escalation schedule. Patients were assigned to sequentially escalating dose groups at doses of 10 µg, 30 µg, 60 µg, 100 µg and 120 µg, with at least 3 patients enrolled at each dose level. The treatment period was at least 6 weeks, and the follow-up period was at least 28 days.

The primary endpoints include the incidence rate and severity of TEAEs, abnormal laboratory test values, physical examination, vital sign parameters, and electrocardiogram. The secondary endpoints include DLT, PK, PD and ADA.

Trial status. We initiated the Phase I part in December 2021 and completed it in February 2023.

Safety data. 93.8% (15/16) of the enrolled patients experienced AEs, 43.8% (7/16) of the enrolled patients experienced Grade 3 or above AEs, and 81.3% (13/16) of the enrolled patients experienced TRAEs. 37.5% (6/16) of the enrolled patients experienced SAEs, and 18.8% (3/16) of the enrolled patients experienced TRSAEs. 43.8% (7/16) of the enrolled patients experienced AESI, which were all CRS. All of the AESIs were Grade 1 or 2 and were recovered within two weeks. No DLTs or infusion reactions were reported.

Efficacy data. The DCR for the 16 enrolled patients reached 43.7%. Among them, one NSCLC patient recorded a 29.8% reduction of the target tumor lesion, and one esophageal cancer patient recorded a 26% reduction of the target tumor lesion.

CTR20212374: A Phase IIa clinical trial to evaluate the safety and PK characteristics of SMET12 in patients with EGFR-positive advanced solid tumors in China sponsored by us.

Overview. This is an open, single-arm, dose expansion Phase IIa clinical trial assessing the efficacy and safety of SMET12 in patients with EGFR-positive advanced solid tumors.

The primary objective is to evaluate the anti-tumor activity of SMET12 in patients with EGFR-positive target indications. The secondary objectives are to evaluate the safety and tolerability of SMET12 in patients with EGFR-positive target indications, and the impact of SMET12 on the TME.

Trial design. The Phase IIa part expects to enroll 80-150 patients with multiple solid tumors.

The patients will be treated with SMET12 at a tentative exploratory dose of 120 µg every 2 weeks until death, loss to follow-up, pregnancy, disease progression as assessed by imaging (patients may continue treatment if clinically stable during confirmation of first disease progression), loss of clinical benefit, unacceptable toxicity, withdrawal of informed consent, and a maximum of 24 months (96 weeks) after the first dose, or the end of the trial, whichever occurs first. During the trial, if the investigator determines that the 120 µg dose is too high (for example, if multiple patients cannot tolerate this dose), the dosage level may be adjusted, for example, to 100 µg or another dose deemed appropriate by the investigator. The treatment period will be 28 days to 24 months, and the follow-up period will at least 8 weeks.

The primary endpoint is OS. The secondary endpoints include ORR, DoR, DCR, PFS, the incidence rate and severity of TEAEs, abnormal laboratory test values, physical examination, vital sign parameters, and electrocardiogram.

Trial status. We initiated the Phase IIa clinical trial in August 2025 and expect to complete it in the second quarter of 2027. As of the Latest Practicable Date, the trial recruited 25 patients.

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CTR20231358: A Phase I/IIa clinical trial to evaluate the safety, tolerability, PK characteristics and preliminary efficacy of SMET12 in combination with toripalimab in patients with EGFR-positive advanced solid tumors in China sponsored by us.

Overview. This is an open, multi-center Phase I/IIa clinical trial that involved both dose escalation and dose expansion. The trial consists of two parts: Part A for dose escalation and Part B for dose expansion.

For Part A, the primary objective is to evaluate the safety and tolerability of SMET12 in combination with toripalimab in patients with EGFR-positive advanced solid tumors; the secondary objectives are to evaluate the PK, immunogenicity and anti-tumor activity of SMET12 in patients with EGFR-positive advanced solid tumors. For Part B, the primary objective is to evaluate the anti-tumor activity of SMET12 in combination with toripalimab in patients with EGFR-positive advanced solid tumors; the secondary objectives are to evaluate the safety, PK and immunogenicity of SMET12 in patients with EGFR-positive advanced solid tumors.

Trial design. Part A expects to enroll 9-12 patients. A traditional “3+3 design” is adopted for the dose escalation schedule. Patients will be assigned to two escalating dose groups: one group will receive 30 µg SMET12 and 3mg/kg toripalimab once every two weeks; the other group will receive 60 µg SMET12 and 3mg/kg toripalimab once every two weeks. The treatment period will be four weeks. Primary endpoints include MTD, OBD, incidence rate and severity of AEs/SAEs, abnormal laboratory test values, physical examination, vital sign parameters, ECOG score and electrocardiogram. Secondary endpoints include PK, ADA, NAb, ORR, DoR, DCR, PFS and OS.

Part B expects to enroll 90-180 patients. The dosing scheduled will be determined based on the clinical data collected in Part A, after completion of the DLT assessment of the last patient in Part A. Primary endpoint is ORR. Secondary endpoints include PK, ADA, NAb, DoR, DCR, PFS, OS, abnormal laboratory test values, physical examination, vital sign parameters, ECOG score and electrocardiogram.

The follow-up period for the trial will be at least 28 days.

Trial status. We initiated the trial in June 2023 and temporarily suspended it in April 2025, to prioritize the clinical development of SMET12 monotherapy. As of the Latest Practicable Date, Part A recruited 7 patients, and Part B recruited 24 patients.

Clinical Development Plan

We expect to complete the Phase IIa clinical trial of SMET12 targeting esophageal cancer in the second quarter of 2027 and initiate a Phase III clinical trial of SMET12 in the fourth quarter of 2027. We expect to initiate a Phase IIa clinical trial targeting TNBC in the fourth quarter of 2026. Depending on the results of the Phase II clinical trial of SMET12, we may consider continuing the Phase I/IIa clinical trial of SMET12 in combination with an anti-PD-1 antibody (toripalimab) targeting selected EGFR-positive solid tumors. A Phase I clinical trial of the combination therapy or a Phase IIa clinical trial of SMET12 monotherapy is not required to be completed before the initiation of a Phase IIa of the clinical trial of the combination therapy.

We have not initiated a clinical trial for SMET12 in the U.S., and we do not have a concrete clinical development plan for SMET12 in the U.S. We currently prioritize the clinical development of SMET12 in China and, based on cost-benefit considerations, are considering establishing collaboration arrangements with multinational corporations for the overseas clinical development of SMET12. As of the Latest Practicable Date, we had not yet established any such collaboration arrangement.

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As SMET12 remains in clinical development and its current clinical data are primarily focused on safety, tolerability, and preliminary anti-tumor activity, the ultimate clinical positioning of SMET12 (including treatment line, combination strategy, and target patient population) remains to be determined based on the overall results from ongoing and future clinical trials. Current data are primarily focused on safety, tolerability, and preliminary anti-tumor activity. SMET12 is designed to target multiple EGFR-positive solid tumors. We intend to select the types of EGFR-positive solid tumors with the most favorable efficacy results as the intended indications of SMET12.

Material Communications with Competent Authorities

We submitted the IND application to conduct the Phase I/IIa clinical trial of SMET12 monotherapy for EGFR-positive advanced solid tumors in June 2021 and received the NMPA IND approval in August 2021. The Phase I and the Phase IIa clinical trials of SMET12 thus approved are two standalone clinical trials. The IND approval authorizes the conduct of both trials without stipulating any additional approval requirements from the NMPA. Also, the IND approval recommended adopting the traditional "3+3 design" in the dose escalation schedule in the Phase I clinical trial, and we accordingly adopted the "3+3 design" in the Phase I protocol. We initiated the Phase I clinical trial in December 2021 and completed it in February 2023 as we reached primary endpoints for the Phase I clinical trial. We had a pre-Phase-IIa communication with the CDE and received no objection from the CDE in August 2025. Thereafter, we initiated the Phase IIa clinical trial in August 2025 and expect to complete the trial in the second quarter of 2027. We expect to conduct an end-of-Phase-IIa-meeting with the NMPA and then, if allowed by the NMPA, initiate a Phase III clinical in the fourth quarter of 2027. In addition, we obtained the IND approval to conduct a Phase I/IIa clinical trial of SMET12 in combination with an anti-PD-1 antibody (toripalimab) in March 2023, based on the Phase I clinical trial results of SMET12 monotherapy. The IND approval did not include any requirement on the source of toripalimab used in the trial.

We submitted the IND application to conduct clinical trials of SMET12 for advanced solid tumors with high EGFR expression in the U.S. in October 2021 and received FDA's IND approval in November 2021. The IND approval covered an open-label, dose escalation Phase I clinical trial to evaluate the safety, tolerability, PK and preliminary efficacy of SMET12 in patients with advanced solid tumors with high EGFR expression.

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A detailed chronology of the material communications regarding SMET12 is shown below.

Time	Type of communication	Competent Authority	Scope	Basis of IND approval	Proposed/recommended protocol amendment
June 2021 . . .	IND application submission	NMPA	Phase I/IIa clinical trial of SMET12 monotherapy for EGFR-positive advanced solid tumors in China	N/A	N/A
August 2021 . .	Grant of IND approval	NMPA	Phase I/IIa clinical trial of SMET12 monotherapy for EGFR-positive advanced solid tumors in China	The non-clinical test (pharmacology, PK and toxicology) and quality study results of SMET12	The NMPA recommended adopting the traditional “3+3 design” in the dose escalation schedule in the Phase I clinical trial. We accordingly adopted the “3+3 design” in the Phase I protocol.
December 2022	IND application submission	NMPA	Phase I/IIa clinical trial of SMET12 in combination with toripalimab for EGFR-positive advanced solid tumors in China	N/A	N/A
March 2023 . .	Grant of IND approval	NMPA	Phase I/IIa clinical trial of SMET12 in combination with toripalimab for EGFR-positive advanced solid tumors in China	Results of Phase I clinical trial of SMET12 monotherapy for EGFR-positive advanced solid tumors in China	N/A
October 2021 .	IND application submission	FDA	Phase I clinical trial of SMET12 for advanced solid tumors with high EGFR expression in the U.S.	N/A	N/A
November 2021	Grant of IND approval	FDA	Phase I clinical trial of SMET12 for advanced solid tumors with high EGFR expression in the U.S.	The non-clinical test (pharmacology, PK and toxicology) and quality study results of SMET12	N/A

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET SMET12 SUCCESSFULLY.

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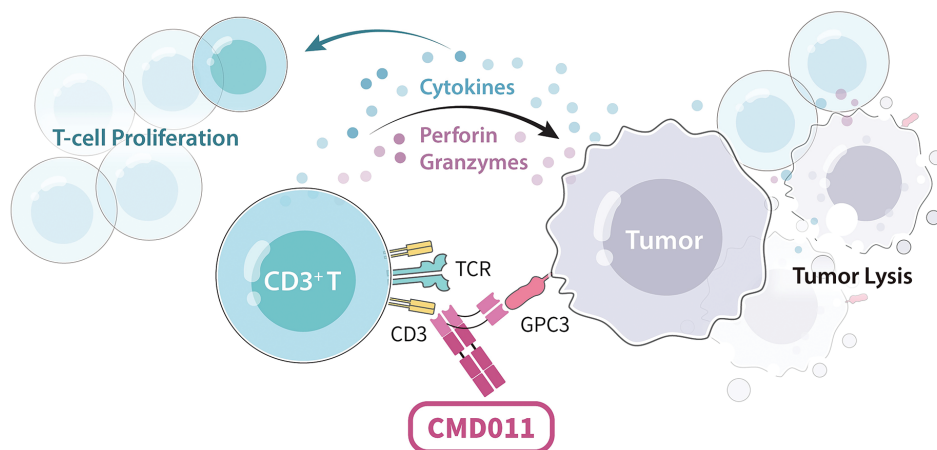
CMD011: an Advanced GPC3×CD3 TCE

CMD011 is a fully human bispecific antibody (TCE) targeting GPC3 on tumor cells and CD3 on T cells. It is intended for the treatment of advanced HCC, with a potential for expansion into other indications such as renal cell carcinoma. CMD011 is able to provide precise tumor targeting via GPC3 while engaging CD3 to activate T cells to kill tumor cells.

In February 2025, the FDA granted IND approval for CMD011, making it the third GPC3×CD3 bispecific antibody globally to secure FDA clinical trial approval. According to Frost & Sullivan, CMD011 ranked within the top two globally by stage of clinical development among GPC3×CD3 TCE drug candidates, as of the Latest Practicable Date.

We developed CMD011 internally and hold the global rights for its use, manufacture, and commercialization. We expect to be the market authorization holder of CMD011 in any jurisdiction.

Mechanism of Action



Source: Company information

GPC3 is specifically expressed in HCC tumor cells and has negligible presence in normal tissues, making it an ideal target for GPC3×CD3 bispecific antibody development. CMD011 exhibits a well-defined antitumor mechanism: by simultaneously binding GPC3-positive tumor cells and CD3-positive T cells, it activates T cells to eliminate tumors. Moreover, CMD011 is able to activate all major subsets of T cells, including CD8+ and CD4+ T cells, thereby eliciting broad T-cell responses to eliminate the tumor cells. This design also ensures balanced T-cell activation and maximizes efficacy.

Market Opportunity and Competition

As of the Latest Practicable Date, no GPC3-targeting antibody was commercialized globally. For GPC3-targeting TCE drugs, three were in Phase I/II clinical stage and two were in Phase I globally as of the same date. For details, see “Industry Overview—Overview of GPC3×CD3 BsAbs—Global Competitive Landscape of GPC3-targeting Antibody Drugs.”

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Competitive Advantages

Clinical Leadership. As of the Latest Practicable Date, no GPC3×CD3 TCE bispecific antibody was approved globally. CMD011 is among the first wave of such product candidates in clinical development worldwide. According to Frost & Sullivan, CMD011 ranked within the top two globally by stage of clinical development among GPC3×CD3 TCE drug candidates, as of the Latest Practicable Date.

Target Specificity. CMD011 targets GPC3, an antigen that is highly expressed in HCC cells but shows minimal expression in normal tissues. This enables more precise tumor targeting with improved safety and tolerability.

Encouraging Clinical Data. Through our molecular innovation and target selection, we have demonstrated robust antitumor activity for CMD011 in preclinical mouse models, achieving efficacy at doses as low as approximately 100 µg/kg. The Phase I clinical data demonstrated that CMD011 at 150 µg (low dose) achieved disease control in patients receiving therapeutic doses and significant anti-tumor activity. These results demonstrate the potential of CMD011 as a therapeutic option for liver cancer, with the possibility of addressing the significant medical need for safer and more effective treatments.

Comprehensive Activation Profile. We engineered CMD011 to efficiently activate multiple T-cell subsets, expanding immune engagement and enhancing its therapeutic potential. This design ensures balanced T-cell activation and maximizes efficacy.

Favorable Safety Profile. Through innovative structural design and target TAA selection, CMD011 achieved a prominent safety profile in comparison with peer products. The GLP toxicology study in cynomolgus monkeys showed a HNSTD of 5 mg/kg, which approximately corresponded to a fixed clinical dose of 96 mg for humans. The Phase I clinical results demonstrated that CMD011 was well tolerated in the HCC patients. Most TRAEs were mild (Grade 1-2), and all TRAEs were manageable and fully resolved.

Convenience of Use. Unlike the commonly used transarterial chemoembolization treatment for liver cancer, CMD011 supports intravenous administration, offering a more convenient option. This makes it suitable for outpatient settings or long-term treatment, significantly improving patient adherence to the treatment regimen.

Efficient Manufacturing. CMD011 demonstrates high chemical stability, low mispairing rate and high heterodimer yield with simplified manufacturing process, thereby significantly improving manufacturing efficiency.

Summary of Clinical Trials

CTR20233880: A Phase I/IIa clinical trial to assess the safety, pharmacokinetics and tolerability of CMD011 in patients with advanced HCC in China sponsored by us.

Overview. This is an open-label, single-arm, multi-center Phase I/IIa clinical trial to assess the safety, pharmacokinetics and tolerability of CMD011 in patients with advanced HCC who experienced disease progression after undergoing at least one systemic treatment. The trial consists of two parts. The Phase I part is for dose escalation, and the Phase II part is for dose expansion.

Phase I part

The primary objective is to evaluate the safety and tolerability of CMD011 in patients with advanced HCC. The secondary objectives are to evaluate the PK, PD, immunogenicity and anti-tumor activity of CMD011 in patients with advanced HCC.

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Trial design. The Phase I part expects to enroll 19-31 patients, who will be treated with CMD011 once every two weeks in 28-day treatment cycles. Patients will be assigned to sequentially escalating dose groups at doses of 10 µg, 50 µg, 150 µg, 450 µg, 750 µg, 1 mg, 3 mg, 10 mg and 30 mg. The treatment period will be at least 28 days, and the follow-up period will be at least 12 weeks.

The primary endpoints include DLT, optimal biological dose (“**OB**D”), AE and SAE. The secondary endpoints include PK, ADA, neutralizing antibody (“**NA**b”), ORR, DoR, DCR and PFS.

Phase IIa part

The primary objective is to assess the anti-tumor activity of CMD011 in patients with advanced HCC. The secondary objectives are to evaluate the safety, tolerability, PK, PD and immunogenicity of CMD011 in patients with advanced HCC.

Trial design. The Phase IIa part expects to enroll 30-60 patients, who will be treated with CMD011 whose dosing schedule will be determined by the safety review committee. The treatment period will be at least 14 days, and the follow-up period will be at least 12 weeks.

The primary endpoint is ORR. The secondary endpoints include PK, ADA, NAb, DoR, DCR, PFS and OS.

Trial status. We initiated the Phase I/IIa clinical trial in December 2023 and expect to complete trial in the fourth quarter of 2027.

Interim results. The Phase I part demonstrated good tolerability of CMD011 in humans. No CRS occurred in patients that received CMD011 from 10µg to 30mg once every two weeks, demonstrating the high specificity of the GPC3 targeting by CMD011 and a favorable safety profile at high doses. In the 150 µg cohort, disease progression was effectively controlled in all patients, showing significant antitumor efficacy. A decrease in the level of AFP, a liver tumor biomarker, and SD have been observed in some patients, with the longest PFS being nearly 11 months, significantly extending the PFS achieved by existing standard of care treatments for advanced HCC. These findings suggest that CMD011 has the potential to overcome the limitations of traditional HCC treatments.

Clinical Development Plan

We expect to complete the Phase I/IIa clinical trial of CMD011 in the fourth quarter of 2027 and initiate a Phase III clinical trial in 2028.

Material Communications with Competent Authorities

We submitted the IND application to conduct the Phase I/IIa clinical trial of CMD011 in China in July 2023 and received NMPA’s IND approval in October 2023. The IND application included the non-clinical test (pharmacology, PK and toxicology) and quality study results of CMD011. The IND approval recommended that the first human study enroll patients with advanced HCC who had disease progression after standard treatment or for whom there was no standard treatment option.

We submitted the IND application to conduct the Phase I/IIa clinical trial of CMD011 in the U.S. in January 2025 and received FDA’s IND approval for CMD011 in February 2025. The IND application included the non-clinical test (pharmacology, PK and toxicology) and quality study results of CMD011. The FDA did not raise any clinical hold issues in the IND approval.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET CMD011 SUCCESSFULLY.

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CMDE005: an Innovative Protease-Activatable EGFR×CD3 TCE as a Backbone Therapy

Overview

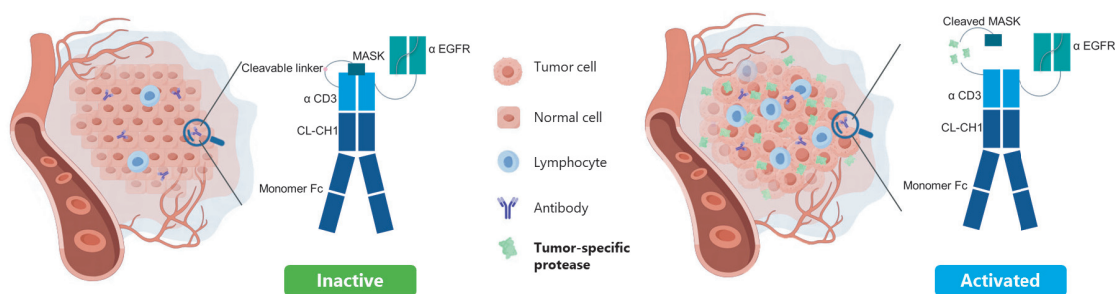
CMDE005 is recombinant humanized anti-EGFR-CD3 protease-activatable bispecific antibody (TCE) as a backbone therapy. CMDE005 incorporates the protease-activatable feature using our Pro-BiTE Platform. The key prerequisites for a backbone cancer therapy include upstream immune activation, zero-order cytotoxicity, and a favorable safety profile, all of which are inherent in our CMDE005, positioning it with a potential to serve as backbone therapies.

The Pro-BiTE Platform represents a breakthrough protease-activatable system, which adds a masking peptide design to the TCE to achieve precise targeting of tumors while minimizing on-target off-tumor activation and peripheral toxicity. The masking peptide can be selectively cleaved by proteases highly expressed in malignant tumors. As such, the platform enhances the ability of bispecific molecules to accumulate more effectively in tumor tissue. The masking peptide design ensures that the TCE remains inactive in normal tissues and peripheral circulation, where protease levels are low, while being selectively activated by tumor-specific proteases. This mechanism significantly expands the therapeutic window by addressing both resistance and safety challenges in solid tumor treatment. With that, CMDE005 holds promise for the treatment of various EGFR-positive advanced solid tumors. As of the Latest Practicable Date, no protease-activatable bispecific antibody product had been approved globally.

In September 2024, CMDE005 was approved for clinical trials by the NMPA for the treatment of various EGFR-positive advanced solid tumors. As of the Latest Practicable Date, CMDE005 was under an ongoing Phase I clinical trial in China. In April 2025, the FDA granted IND clearance for CMDE005. According to Frost & Sullivan, CMDE005 was the first and only in China and ranked among the top two globally incorporating masking peptide technology that has entered the clinical stage among the EGFR×CD3 TCE drug candidates, as of the Latest Practicable Date. CMDE005 represents a disruptive TCE and validates our strategic goal of demonstrating the clinical utility of masking peptide design.

We self-developed CMDE005 and hold the global rights for its use, manufacture and commercialization. We expect to be the market authorization holder of CMDE005 in any jurisdiction.

Mechanism of Action



Source: Company information

CMDE005 is a bispecific antibody that can target both CD3 and EGFR. It has a well-defined anti-tumor mechanism. By simultaneously binding EGFR-positive tumor cells and CD3-positive T cells, CMDE005 mediates potent tumor-killing activity.

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CMDE005 is a protease-activatable antibody. It utilizes a “masking peptide” to block CD3 binding activity. In the peripheral blood and normal tissues, the anti-CD3 arm of CMDE005 remains inactive. Upon reaching the TME, tumor-specific proteases (such as uPA) cleave specific linkers on CMDE005. This cleavage releases the masking peptide, unblocking the CD3 binding activity and converting CMDE005 into its active EGFR×CD3 bispecific antibody state. This mechanism enables targeted anti-tumor activity while minimizing on-target off-tumor toxicity against normal tissues, resulting in high tumor specificity.

Market Opportunity and Competition

As of the Latest Practicable Date, three EGFR-targeting masked TCEs were in active clinical trials. For details, see “Industry Overview—Overview of EGFR/CD3 BsAbs—Global Competitive Landscape of EGFR-Targeting Antibody Drugs.”

Competitive Advantages

Protease-Activatable Design. Incorporated with a protease-cleavable masking peptide into the EGFR×CD3 TCE, CMDE005 remains inactive in normal tissues and circulation, and is selectively activated in the TME by tumor-specific proteases. In normal tissues, CD3 binding is blocked, while protease cleavage in the TME restores the CD3-binding activity of CMDE005. With that, CMDE005 showed a 10,000-fold reduction in CD3 binding in non-tumor tissues compared to unmasked molecules, while a competing product JANX008 achieved a 1,000-fold reduction based on publicly available information. This enhanced masking efficiency minimizes on-target off-tumor activation and peripheral toxicity.

Clinical Leadership. Globally, no enzymatically activatable TCE bispecific antibody has yet been approved, and most remain in the Phase I/II clinical stage. CMDE005 is the first protease-activatable TCE candidate that has entered clinical trials in China, positioning it within the top two globally by stage of clinical development.

One-step Activation. According to Frost & Sullivan, we are the only company globally to achieve one-step activation in masked EGFR×CD3 TCEs, demonstrating leadership in masking efficiency, a key parameter for broadening the therapeutic window. The one-step activation approach significantly enhances enrichment of active molecules in the TME.

Preserved Tumor Targeting Ability. CMDE005 was designed to preserve EGFR binding, keeping the receptor in an “open” state to ensure high tumor targeting ability. The innovation of the masking strategy expands the therapeutic window and enables administration of higher effective doses and first-dose stage power-killing.

Encouraging Efficacy. In preclinical studies, CMDE005 achieved potent dose-dependent antitumor activity. In the HT1080 xenograft mouse model, near-complete tumor elimination was observed at the highest tested dose (120 µg/kg). In the ACHN renal carcinoma model, CMDE005 also demonstrated strong dose-dependent efficacy. CMDE005 exhibited a dose-dependent immune response and efficacy profile, with controllable side effects.

Favorable Safety Profile. In a Phase I clinical trial, CMDE005 was well tolerated at doses up to 3 mg with no dose-limiting toxicities, Grade 3 or above adverse events, or serious adverse events reported. All TRAEs were mild (Grade 1-2), manageable and fully resolved. This mechanism significantly expands the therapeutic window by 100-fold, addressing both resistance and safety challenges in solid tumor treatment.

Convenience to Use. CMDE005 supports intravenous administration, offering a more convenient option. This makes it suitable for outpatient settings or long-term treatment, significantly improving patient adherence to the treatment regimen.

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Efficient Manufacturing. CMDE005 demonstrates high chemical stability, low mispairing rate and high heterodimer yield. Using simplified manufacturing process, our robust CMC capabilities support a demonstrated titer of 4 g/L and purity exceeding 99.3%, thereby significantly improving manufacturing efficiency.

Summary of Clinical Trials

CTR20243706: A Phase I/IIa clinical trial to assess the safety, pharmacokinetics and efficacy of CMDE005 in patients with EGFR-positive advanced solid tumors in China sponsored by us.

Overview. This is an open-label, single-arm Phase I/IIa clinical trial to assess the safety, pharmacokinetics, and efficacy of CMDE005 in patients with EGFR-positive advanced solid tumors (including NSCLC and CRC). The trial consists of two parts. The Phase I part is for dose escalation, and the Phase IIa part is for dose expansion.

Phase I part

The primary objective is to evaluate the safety of CMDE005 in patients with EGFR-positive advanced solid tumors. The secondary objectives are to evaluate the PK, PD, immunogenicity and anti-tumor activity of CMDE005 in patients with EGFR-positive advanced solid tumors.

Trial design. The Phase I part expects to enroll 19-37 patients, who will be treated with CMDE005 once every two weeks in 28-day treatment cycles. Patients will be assigned to sequentially escalating dose groups at doses of 10 µg, 50 µg, 150 µg, 300 µg, 400 µg, 500 µg, 1 mg, 3 mg, 6 mg, 10 mg and possibly higher doses. The treatment period will be at least 28 days, and the follow-up period was at least 12 weeks.

The primary endpoints include DLT, OBD, recommended Phase II dose (“**RP2D**”), AE and SAE. The secondary endpoints include PK, ADA, NAb, ORR, DoR, DCR and PFS.

Phase IIa part

The primary objective to is assess the efficacy of CMDE005 in patients with EGFR-positive advanced solid tumors. The secondary objectives are to evaluate the safety, PK, PD and immunogenicity of CMDE005 in patients with EGFR-positive advanced solid tumors.

Trial design. The Phase IIa part expects to enroll 75-150 patients who are EGFR-positive with the following tumors: NSCLC, pancreatic cancer, urothelial carcinoma, renal cell carcinoma and others. The patients will be treated with CMDE005 once every two weeks in 28-day treatment cycles. The dosing schedule will be determined based on the results of the Phase I part.

The primary endpoint is ORR. The secondary endpoints include PK, ADA, NAb, DoR, DCR, PFS, OS, ECOG score, physical examination, vital signs, laboratory tests, electrocardiogram and echocardiography.

Trial status. We initiated the Phase I/IIa clinical trial in October 2024 and expect to complete it in the fourth quarter of 2027.

Interim results. CMDE005 demonstrated good tolerability in humans, with no DLT recorded in patients that received CMDE005 at 10 µg to 3mg once every two weeks, and no Grade 3 or higher AEs or SAEs observed at doses up to 3 mg. All TRAEs were mild (Grade 1-2), manageable, and resolved completely. Additionally, preliminary signs of efficacy were observed in patients with NSCLC: the medium prior line of treatment for enrolled patients was 3.5; one out of one patient in the 0.4 mg group recorded SD, one out of two patients in the 1 mg group recorded shrinkage of target lesions, and two out of three patients in the 3 mg group recorded SD. We are currently dosing

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the 6 mg group and expect to further increase the dosage due to the broad therapeutic window potential of CMDE005. CMDE005 exhibited a dose-dependent immune response and efficacy profile, with controllable side effects.

Clinical Development Plan

We expect to complete the Phase I/IIa clinical trial of CMDE005 in the fourth quarter of 2027 and initiate a Phase III clinical trial of CMDE005 in 2028. In the future clinical trials of CMDE005, we intend to recruit patients with the intended indications of CMDE005, which are EGFR-positive advanced solid tumors, such as NSCLC, CRC, urothelial carcinoma, head and neck squamous cell carcinoma, and pancreatic cancer.

Material Communications with Competent Authorities

We submitted the IND application to conduct clinical trials of CMDE005 in China in July 2024 and received NMPA’s IND approval in September 2024. The IND application included the non-clinical test (pharmacology, PK and toxicology) and quality study results of CMD011. The IND approval indicated that, if we plan to investigate a combination therapy of CMDE005, we will need to evaluate the scientific validity and rationality of the combination therapy study plan after obtaining the clinical data of CMDE005 monotherapy, and then we will need to submit a clinical trial application for the combination therapy.

We submitted the IND application to conduct the Phase I/IIa clinical trial of CMDE005 in U.S. in March 2025 and received FDA’s IND approval in April 2025. The IND application included the non-clinical test (pharmacology, PK and toxicology) and quality study results of CMD011. The FDA did not raise any clinical hold issues in the IND approval.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET CMDE005 SUCCESSFULLY.

Our Preclinical Stage Trispecific Protease-activatable TCE Candidates

We have two preclinical stage drug candidates, CMDE101 and CMDE102, which are trispecific protease-activatable TCEs targeting FOLR1×PD-L1×CD3 and PSMA×PD-L1×CD3, respectively. The two candidates were developed from our Multifunctional/Logic-gated TCE Platform.

CMDE101 and CMDE102 are trispecific protease-activatable TCEs that simultaneously recognize and bind to three targets: CMDE101 targets FOLR1, PD-L1 and CD3; and CMDE102 targets PSMA, PD-L1 and CD3. They are currently under preclinical development as a potential treatment for multiple solid tumors. FOLR1 and PSMA are overexpressed in a number of solid tumors, such as ovarian cancer, NSCLC, TNBC and prostate cancer, and implicated in tumorigenesis. CMDE101 and CMDE102 are expected to enhance the antitumor immune response by launching a synergistic targeted attack on tumors by both blocking the immune checkpoint activating the T cells. By setting up OR-gated targeting of TAA and PD-1, multifunctional TCEs can address several key challenges in cancer treatment, including antigen loss where cancer cells may hide their identifying markers from the immune system, mutations that help tumors evade detection, and tumor heterogeneity, where different tumor cells within the same patient express varying antigens. We expect to submit an IND application for CMDE101 to the NMPA in the fourth quarter of 2027 and to the FDA in 2028. We expect to submit an IND application for CMDE102 to the NMPA in 2028 and to the FDA in 2029.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET CMDE101 and CMDE102 SUCCESSFULLY.

BUSINESS

OUR TECHNOLOGY PLATFORM

TCE Antibody Discovery — Multichannel Antibody Discovery Platform

Our Multichannel Antibody Discovery Platform includes four ultra-large fully human IgM phage display antibody libraries and multi-species immunized libraries.

The fully human IgM phage display antibody libraries have capacities of 10^{11} - 10^{13} antibody sequences, significantly larger than the industry average of 10^9 - 10^{10} . They are also featured with Fab and domain antibodies ("dAb") formats with industry-leading diversity. This scale and diversity enable rapid identification of high-quality, high-affinity lead antibodies, establishing a strong foundation for antibody discovery, setting the foundation for TCE development. The libraries allow high-throughput screening and rapid identification of high-affinity antibodies just 1-2 weeks. Because these libraries are fully human, the identified antibodies need not go through the humanization process and have minimized immunogenicity risks. Further, our fully human IgM phage display antibody libraries provide broader sequence diversity than IgG phage display antibody libraries, thereby enabling simultaneous identification of multiple antibody candidates with different epitopes and affinities for the same target. Our fully human IgM phage display antibody libraries also enable direct discovery of dAbs, which, due to their small size, can penetrate solid tissues such as epidermis and solid tumors and target hidden epitopes, with greater ease of subsequent engineering. These libraries are crucial for drug target selection in our early-stage preclinical research.

In addition, we have established multi-species immunized libraries, developed from mouse, rabbit and other species. Some of our multi-species immunized libraries are built upon mouse B cells immunized with multiple antigens, which enable high-throughput screening. Compared with the traditional hybridoma methods for generating monoclonal antibodies, our multi-species immunized libraries can overcome several limitations of the traditional methods, including the long-cycle low-throughput screening for antibody sequences, as well as the stability issues with antibody-encoding genes.

Finally, we utilize the light chain shuffling technology to further increase the antibody diversity and obtain higher quality antibodies. Together, these complementary libraries enhance the efficiency and diversity of our early-stage preclinical antibody discovery.

We developed the Multichannel Antibody Discovery Platform internally without involvement of third parties. The platform development started in 2017. We established the ultra-large fully human IgM phage display antibody libraries in 2018 and multi-species immunized libraries in 2021.

TCE Format — H-BiTE: H-shape Bispecific TCE Platform

The H-BiTE Platform is characterized by three distinguishing features: shielding CD3 through steric hindrance, preventing light and heavy chain mispairing, high yield and stable production.

The H-BiTE Platform is designed to overcome poor druggability and toxicity challenges of traditional bispecific antibodies. The platform's structural engineering improves tumor targeting, broadens the therapeutic window, and simplifies manufacturing. The platform adopts a unique bispecific architecture that shields CD3 through steric hindrance, ensuring it is not exposed prematurely. By optimizing the affinity for both CD3 and the target antigen, the platform improves therapeutic efficacy. Furthermore, the design features Fc modifications and a monovalent Fab structure, preventing light and heavy chain mispairing and ensuring product stability. The platform generates 100% heterodimeric bispecifics, avoiding the toxicity associated with homodimeric and oligomeric products for asymmetric BsAbs. It also reduces cytokine release, improving safety profiles. With minimal mutations (only two amino acids) in the Fc region, the platform reduces immunogenicity compared to other bispecific platforms. Besides, the platform enables high-yield and stable production through conventional protein A purification, significantly simplifying process

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development and improving manufacturing efficiency. These features and innovations make the H-BiT E Platform one of the most competitive bispecific antibody platforms globally, offering significant advantages in clinical application and drug development. Several bispecific antibody candidates generated from our platform have demonstrated favorable developability, further validating its potential to support innovative therapeutic development.

We developed the H-BiT E Platform internally without involvement of third parties. The development of the H-BiT E Platform started in 2017, and the platform was established in 2018, when SMET12, the first product derived from the platform, entered CMC development.

TCE Masking — Pro-BiT E: Protease-Activatable TCE Platform

The Pro-BiT E Platform incorporates masking peptides containing protease-cleavable linkers near the target-binding sites of the antibody. These peptides effectively block the antibody’s activity in normal tissues and the peripheral circulation. When the antibody accumulates in the TME, tumor-specific proteases — such as uPA and MMP — recognize and cleave specific sites between the masking peptide and the antibody molecule. Cleavage releases the masking peptide, restoring the antibody’s target-binding activity and its anti-tumor function. This design significantly reduces on-target off-tumor toxicity caused by non-specific killing of normal tissues, conferring high tumor-targeting specificity. This mechanism dramatically improves the safety profile and therapeutic window of TCEs, offering a potential major breakthrough in solid tumor treatment and addressing significant unmet medical needs.

CMDE005 is the first product derived from this platform. It features convenient clinical administration (direct intravenous infusion) and broad-spectrum anti-tumor activity. As an immunotherapy, CMDE005 has the potential to improve the depth and duration of responses in responding patients compared to existing standard treatments, potentially enhancing overall survival benefit. Preclinical studies of CMDE005 demonstrated a blocking efficiency of over 10,000-fold and an expansion of the therapeutic window by more than 100-fold compared with SMET12, highlighting the high tumor specificity and the substantially reduced on-target off-tumor toxicity achieved by our enzymatically activatable Pro-BiT E design.

We developed the Pro-BiT E Platform internally without involvement of third parties. The development of the Pro-BiT E Platform started in 2017, and the platform was established in 2022, when CMDE005 entered CMC development.

Multifunctional/Logic-gated TCE Platform

As an industry leader with years of deep expertise in TCE development, we have established our Multifunctional/Logic-gated TCE Platform which enables the development of multifunctional TCEs designed to use a dual or multi-target approach to simultaneously target TAAs and T-cell receptors. Our TCE Multifunctional/Logic-gated platform enables the enhancement of T-cell activation, which is crucial for the immune system’s ability to recognize and destroy cancer cells. Our multifunctional TCEs are designed with an OR-gated dual-targeting format, which can activate T cells upon recognizing either one or both TAAs on the tumor cell surface, thereby improving tumor recognition and contributing to the prevention of tumor relapse. In addition to activating T-cells, the platform prevents T-cell exhaustion, a major challenge in cancer immunotherapy where immune cells become ineffective over time. By launching a synergistic targeted attack on tumors by both blocking the immune checkpoint and activating the T cells, our platform enhances the tumor-killing capacity of T cells, ensuring a more robust and durable immune response. This approach also addresses several key challenges in cancer treatment, including antigen loss where cancer cells may hide their identifying markers from the immune system, mutations that help tumors evade detection, and tumor heterogeneity, where different tumor cells within the same patient express varying antigens. By overcoming these obstacles, our Multifunctional/Logic-gated TCE platform ensures sustained and effective tumor clearance, improving the potential for long-term therapeutic success.

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We developed the Multifunctional/Logic-gated TCE Platform internally without involvement of third parties. The development of the Multifunctional/Logic-gated TCE Platform started in 2023, and the platform was established in 2025.

RESEARCH AND DEVELOPMENT

R&D Team

Our R&D team is multi-tiered, covering the full innovation pathway from discovery through clinical translation. The early-stage research team, led by Dr. XIAO Zuoxiang and Dr. ZHOU Dongwen, has become a key driver of our innovation. Our clinical development team, under the leadership of Dr. XIAO Zuoxiang and Ms. WANG Yanping, combines deep medical expertise with strong operational capabilities to align development with clinical needs. The integration of discovery scientists and clinical specialists enables coordinated oversight across the entire R&D process. With dual R&D centers in the United States and China, we operate an integrated model across time zones, supporting a continuous R&D cycle and efficient platform integration.

Our in-house R&D team consisted of 33 employees as of the Latest Practicable Date, over 97% of whom held at least bachelor’s degrees, and over 70% members of our R&D team held master’s or higher degrees. Our R&D team is led by a team of seasoned scientists with years of drug development experience. The following table sets forth a breakdown of the number of R&D team by function as of the Latest Practicable Date.

Functions	Number of R&D employees
Drug Discovery and Pre-clinical Development	17
Clinical Development	16
Total	33

The following table sets forth the identities, background and expertise of our core/key R&D personnel for the R&D of our product candidates. All of these core/key R&D personnel have been full-time employees since our commencement of the R&D work on such product and remained employed by the Group during the Track Record Period and up to the Latest Practicable Date.

Identity	Background	Expertise	Involvement and contributions to the R&D activities	Time of joining our Group
Dr. XIAO Zuoxiang . .	Obtained bachelor’s degree in medicine from Shandong First Medical University, master’s degree in medicine from Shanghai University of traditional Chinese medicine, doctoral degree in oncology from Zhejiang University	More than 30 years of experience in oncology clinical practice, disease mechanism research, and antibody drug development	Sequence screening and vector development for DNV3 and SMET12	July 2017

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Identity	Background	Expertise	Involvement and contributions to the R&D activities	Time of joining our Group
Ms. WANG Yanping . . .	Obtained a bachelor of science degree in biotechnology from Nankai University	Over ten years of experience in antibody drug research and development and having contributed to multiple novel antibody therapies with several U.S. patent filings	Antibody expression, purification and functional assessment for DNV3 and SMET12	August 2018
Dr. ZHOU Dongwen . . .	Obtained bachelor’s degree in biochemistry from Anhui University and doctoral degree in biochemistry and molecular biology from the University of Science and Technology of China	Over 20 years of research experience in protein structure-function relations and therapeutic antibody development	Antibody expression, purification and functional assessment for DNV3; sequence screening, structural optimization and functional assessment for SMET12; team management, molecular design and patent application for CMD011 and CDME005	November 2018
Mr. MIAO Hangbin . . .	Obtained master’s degree in marine biology from Xiaman University		<i>In vitro</i> and <i>in vivo</i> functional assessment for DNV3; <i>in vitro</i> and <i>in vivo</i> pharmacological efficacy studies for SMET12; sequence screening and preliminary functional assessment for CMD011 and CDME005	November 2017
Mr. LIN Jinxiong . . .	Obtained master’s degree in pharmacology from Zhejiang Chinese Medical University		<i>In vitro</i> and <i>in vivo</i> functional assays for CMD011 and CDME005	July 2019

All key R&D personnel involved in the development of the Core Products and our other product candidates remained employed by us during the Track Record Period and as of the Latest Practicable Date. The departed senior management and R&D personnel do not own any material assets of and technical know-how pertinent to the Group and in particular with the Core Products, including intellectual property.

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Drug Discovery and Pre-clinical Development

Our drug discovery and pre-clinical development is led by Dr. XIAO Zuoxiang and Dr. ZHOU Dongwen. We believe the size of our current R&D team, together with the engagement with scientific consultants, external advisors and CROs, is sufficient in managing our existing demand for clinical development in China and the United States.

Clinical Development

Clinical Development Team

Our clinical development team is led by Dr. XIAO Zuoxiang and Ms. WANG Yanping. As of December 31, 2025, our clinical development team consisted of 14 members, including professionals with strong drug development experience, who participate in clinical development strategy development, clinical trial protocol design, clinical trial operation organization, drug safety monitoring, and clinical trial quality control. Many of our clinical development team members had extensive relevant work experience. Among our clinical development team members as of December 31, 2025, over 25% held post-graduate degrees. Our clinical development team is generally responsible for the clinical development of our Core Products and other pipeline products.

Clinical Trial Design and Implementation

Our clinical development team manages all stages of clinical trials, from protocol design to overseeing the operations and conduct of clinical trials. Our rapid trial advancements are driven by (i) our strategic decision to initiate clinical trials based on preclinical results that are assessed as promising, (ii) optimized trial design, enabled by our rigorous quantitative analysis of integrated data, and whole-process oversight, and (iii) long-term partnership with various hospitals and principal investigators from different regions to achieve smooth execution.

Our clinical development team is also responsible for the selection of trial sites. Our site selection criteria include the site’s overall experience, understanding of the disease state, access to relevant experts and patients, geographical coverage, regulatory and quality management, range of services, staff proficiency, and technology. We have collaborated with numerous hospitals and PIs located in China that can support our clinical trials of different indications. The selection of these hospitals and PIs is guided by their specialized knowledge, access to suitable patient pools, and operational capacity. The scale and diversity of our partner network provide us with an advantage in implementing large-scale clinical trials and enable us to conduct multiple clinical trials concurrently. With the support of our partner hospitals, we are capable of recruiting participants from specific populations for trials that would otherwise be difficult to fulfill enrollment.

Our clinical development strategy is guided by the goal of addressing unmet clinical needs since the target selection stage. We do not intend any single clinical trial to be a one-time validation of the efficacy or safety of drug candidates. Rather, the design of clinical trials represents a continuous iterative process that starts with the underlying mechanism and is driven by the gradual accumulation of clinical data, to determine the safety, efficacy, and clinical positioning of drug candidates for specific indications. Also, safety is always a priority consideration for any clinical trial design.

For example, safety was the primary consideration in designing our clinical trials for CD3 targeting bispecific antibodies. CD3 targeting bispecific antibodies function by redirecting T cells to kill tumor cells by simultaneously binding to specific membrane proteins on the surface of tumor cells and CD3 on the surface of T cells. Such a mechanism dictates that the CD3 targeting bispecific antibodies not only possess potent immune activation capabilities, but also carry a higher risk of immune-related toxicity. As a result, we adopt a phased, incremental dosing strategy to gradually explore the acceptable dose range, administration method and therapeutic window of CD3 targeting bispecific antibodies. For early-stage clinical trials, we employ a dose-escalation design, which

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incorporates an initial dosing, observation periods between dose increases, and strict criteria for determining dose-limiting toxicity. Such a design aims to reduce the risks associated with cytokine release syndrome, immune effector cell-associated neurotoxicity syndrome, and other related adverse events.

In the selection of indications, decisions of clinical trial design are primarily made based on the underlying biology and risk-benefit balance. On the one hand, priority is given to advanced solid tumors with a high expression level of or strong dependence on the target protein, and for which standard treatment options are limited, such as EGFR-positive solid tumors or GPC3-positive hepatocellular carcinoma that have failed multiple lines of treatment. Patients with such solid tumors are expected to benefit most from the drug candidate. On the other hand, it is important to avoid enrolling patients who are expected to experience potentially unacceptable toxicity or insufficient clinical benefit in the early stages of clinical trials. Through exploratory studies in patients with different tumor types and varying levels of target protein expression, we aim to gradually identify the most promising target indications that are likely to demonstrate clear clinical benefit from the drug candidate.

In terms of safety and efficacy, we emphasize simultaneous assessment and dynamic balance. Regarding safety, the clinical trial design incorporates not only routine adverse event monitoring, but also a focus on recording immune-related toxicity and target-related toxicity. Clear rules for preparation before treatment, supportive care, and dose adjustment or discontinuation will be established. With that, safety signals are expected to be promptly identified through intensive early-stage monitoring. Regarding efficacy, early-stage clinical trials typically use objective response rate, disease control rate, and duration of response as primary or key secondary endpoints. Combining these endpoints with pharmacokinetic, pharmacodynamic, and biomarker analyses, early-stage clinical trials are designed to verify the association between T-cell activation and antitumor activity. After safe dosages and preliminary efficacy signals are thus established, late-stage clinical trials will gradually shift to more indication-focused investigation and confirmatory endpoints, to systematically evaluate the overall risk-benefit profile of drug candidates in the target patient population.

Relationship with CROs

During the Track Record Period, we engaged CROs to perform certain R&D tasks. We select CROs based on various factors including qualifications, experiences, industry reputation, adequacy of clinical trial equipment and data management capability. The CROs we collaborate with are able to offer comprehensive services across the entire product development lifecycle, from preclinical to clinical stages. Their expertise spans across various stages and fields related to research and development of product candidates, such as preclinical toxicology, quantitative pharmacological analysis, FDA registration, clinical data management and analysis. Our clinical development department closely supervises and monitors the performance of CROs to ensure they conduct clinical trials in accordance with our protocols and GCP requirement. CROs are typically responsible for facilitating in the selection of investigators, locating trial sites, local vendors, making local regulatory filings with our review and approvals, purchasing equipment and materials, engaging other third parties to further facilitate the clinical trials, enrolling qualifying trial participants, routine trial site monitoring, and trial data management and analysis.

We have adopted a management system for suppliers in evaluating the qualifications and capabilities of CROs and signing contracts with CROs that specify the quality requirements for each project milestone. We also regularly monitor the quality of the project implementation process of CROs through specific data and schedule management plans that we developed.

We engaged two and two CROs, namely CRO A and CRO B, in 2024 and 2025, respectively. CRO A is a leading dual-listed Chinese company, primarily engaging in CRO services and providing clinical operation support services globally. We incurred expenses of RMB2.8 million and RMB3.3 million in 2024 and 2025 for CRO A. CRO B is a leading dual-listed Chinese company, primarily

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engaging in CRO services globally, including drug R&D and data analysis services. We incurred expenses of RMB160 thousand and RMB2.3 million in 2024 and 2025 for CRO B. All of the CROs we engaged in each year during the Track Record Period were Independent Third Parties. According to Frost & Sullivan, there are numerous CROs in Chinese Mainland market that provide similar services. Therefore we do not have any material reliance on current CROs.

Regulatory Affairs

Our regulatory affairs team is responsible for the regulatory process of our product candidates, including assembling application dossiers for IND and BLA, addressing inquiries from relevant authorities and monitoring our R&D projects to ensure their compliance with relevant regulations. Our regulatory affairs team manages the regulatory submission process, which generally requires filings to be made to and approved by the regulatory authorities before clinical trials and commercialization of our products can be initiated. The regulatory affairs team prepares and manages regulatory filings by coordinating filing dossiers drafting, addressing regulatory questions and conducting CMC assessments for our product candidates. We possess extensive knowledge and experience in regulatory filings. Leveraging our expertise and established presence in the industry, we are able to design clinical trials that maximize regulatory alignment and operational efficiency.

CHEMISTRY, MANUFACTURING & CONTROLS (“CMC”)

CMC Team

As of December 31, 2025, our CMC team consisted of six professionals with extensive experience in process development, production and quality management mostly from well-known biopharmaceutical and pharmaceutical companies. Our CMC team members are led by Dr. ZHOU Dongwen, a decorated industry scientist with over 20 years’ experience. Our CMC team specialized in antibody drug process development, toxicology and pharmacokinetics study, and IND enabling throughout the drug development process. The CMC function in our Company plays a critical role in drug development. It is responsible for developing safe, robust, and economically sound production processes for our innovative drugs, and ensuring their quality meets regulatory requirements.

Manufacturing and Collaboration with CDMOs

For manufacturing of our product candidates, we currently outsource such production to a limited number of highly reputable CDMOs. These CDMOs engaged by us are specialized third parties that collectively provide us with various services in the manufacturing process of drug candidates. During the Track Record Period, we collaborated with CDMOs who have significant experience in supporting biotech companies, with research centers, test facilities, and a solid history of supporting various projects. The CDMOs we collaborate with have over ten years of R&D experience and are based in China. They possess extensive experience in the development and manufacturing of biopharmaceuticals, including antibody drugs and other large-molecule drugs, and are capable of providing services such as process development and GMP manufacturing. Teams we work with provide services like manufacturing, quality assurance, and quality control, ensuring reliable results for cell and gene therapies, antibody proteins, and other biotechnological products. We commission these CDMOs to manufacture active drug products to support our clinical development. We do not have in-house manufacturing facilities and capabilities, and we have no concrete plan to establish the same.

We did not experience any material product quality issues in respect of the products manufactured by our CDMO partners during the Track Record Period. Under our agreement with our CDMO partners, the CDMO partners are required to perform their services according to the prescribed time frame as set out in the agreement. Usually, we pay the CDMO partners in installments, with a specified credit period. Our CDMO partners are responsible for manufacturing our required products in accordance with certain product specifications, in compliance with cGMP

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requirements (where applicable), our quality standards and other applicable laws and regulations. We retain all the intellectual property rights and grant our CDMO partners the right to use our intellectual property rights for such manufacturing and packaging activities during the contract period. We are entitled to inspect and audit our CDMO partner’s manufacturing process. We mainly determine the service fees paid to the CDMOs in accordance with market prices of similar services, the number of products manufactured, and the quality and contents of the services provided. We do not share our IPs, know-hows and trade secrets with CDMOs.

We have adopted a management system for suppliers in evaluating the qualifications and capabilities of CDMOs and signing contracts with CDMOs that specify the quality requirements for each project milestone. We also regularly monitor the quality of the project implementation process of CDMOs through specific data and schedule management plans that we developed.

We engaged two CDMOs in the year ended December 31, 2024, namely CDMO A and CDMO B, for which we incurred expenses of RMB5.1 million. And we engaged three CDMOs in the year ended December 31, 2025, namely CDMO A, CDMO B and CDMO C, for which we incurred expenses of RMB3.2 million. CDMO A is a private company incorporated in China, engaging in CDMO services for large molecules and biopharmaceuticals, providing CDMO services for CMDE005. CDMO B is a leading private company incorporated in China, primarily engaging in CDMO services globally, focusing on development and manufacturing of biopharmaceuticals, providing CDMO services for DNV3, SMET12 and CMD011. CDMO C is a private company incorporated in China, providing CDMO services for process development and manufacturing of CMDE101. All of the CDMOs engaged in each year during the Track Record Period were Independent Third Parties. Our Directors confirm that our collaboration with CDMOs were all at preclinical stages, and any change of CDMOs would not have a material impact on our business. According to Frost & Sullivan, there are numerous CDMOs in Chinese Mainland market that provide similar services. Therefore we do not have any material reliance on current CDMOs.

COMMERCIALIZATION, MARKETING AND BUSINESS DEVELOPMENT

Given the development status of our product candidates, we had not established a sales and marketing team as of the Latest Practicable Date. As we advance the clinical development of our product candidates to a later stage, we will evaluate their respective form of commercialization, taking into account the market condition, competitive landscape and our available resources at the material time. For both DNV3 and SMET12, we place primary emphasis on market size when selecting target markets for commercialization, including the size and growth potential of the relevant therapeutic market and the diagnosed patient population. For details, see “Industry Overview.” For DNV3, we will adopt a dual-track commercialization strategy, i.e., direct sales in China and international partnerships for global markets. The pricing considerations for DNV3 in Chinese Mainland and overseas markets include: (1) cost (R&D, production, and sales costs); (2) market competition (clinical value-oriented pricing, in light of the price, indications, and efficacy of Opdualag); (3) reimbursement policy (differentiated pricing based on the varying health insurance policies of different countries; (4) affordability (purchasing power of consumers in different jurisdictions). Other than the aforesaid considerations, its price will also be benchmarked against opdualag, the only approved anti-LAG-3 antibody combination therapy. In the overseas market, we plan to actively pursue competitive pricing with similar therapies, government reimbursement, and coverage of commercial insurance policies. In China, we plan to leverage our production cost control advantages in the pricing of DNV3. We may seek pursuing inclusion of DNV3 in the NRDL based on consideration of multiple factors, including market changes, government policy adjustments, and shareholder interests. The commercialization of SMET12 will follow a similar dual-track strategy. We plan to collaborate with experienced commercialization partners in overseas markets, with pricing and reimbursement strategies aligned with those of major players in the U.S. and Europe (pharmaceutical companies with competing products, such as Amgen, Johnson & Johnson and AstraZeneca), aiming to ensure patient access and secure favorable commercial returns. The above-mentioned four major pricing considerations in determining DNV3 will likewise be taken into account in pricing of SMET12. In the future, we intend to build our own

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sales team and network in preparation of the commercialization of our product candidates in China. For the commercialization of our product candidates in the overseas market, we plan to identify and collaborate with top pharmaceutical companies with significant global or local presence.

In view that market acceptance of our drug products depends on consistent clinical benefits across studies, indications and patient populations, we adopt risk mitigation strategies, dose optimization approaches and longer-term development plans for our Core Products to support manageable and predictable safety profiles and alignment with standard treatment pathways. In terms of risk mitigation strategies, we adopt measures across key stages of clinical development, including patient screening, trial quality control, adverse event management and clinical site operations, to safeguard patient safety and ensure reliable clinical data for regulatory review and future clinical use. We also adopt dose optimization approaches by conducting stepwise dose exploration and subgroup-specific dose assessment based on pharmacokinetic, efficacy and safety data. These approaches are designed to determine appropriate therapeutic doses and dose adjustment principles, with a view to balancing clinical benefit and tolerability and supporting standardized dosing for future clinical use. For longer-term development plans of our Core Products and other pipeline products, following confirmation of clinical benefits in pivotal studies, we plan to continue pursuing indication expansion, combination therapy development and real-world studies to further accumulate evidence across different lines of therapy and patient populations. We also intend to leverage our pipeline products to build a broader treatment portfolio covering different stages of disease, with a view to supporting inclusion in authoritative clinical guidelines and facilitating broader clinical adoption after approval.

OUR SUPPLIERS

We mainly procure R&D and clinical-related services from third party suppliers. We maintain stable relationships with our suppliers to ensure the stability of material supply and delivery. In 2024 and 2025, the aggregate purchase amount from our top five suppliers was RMB18.2 million and RMB15.6 million, representing 53.7% and 58.1% of our total purchase amount, respectively. In 2024 and 2025, purchase amount to our largest supplier was RMB7.4 million and RMB4.1 million, representing 21.7% and 15.3% of our total purchase amount, respectively. The following table sets forth details of our five largest suppliers in each year of the Track Record Period:

Suppliers	Products or Services Purchased	Background	Business Relationship Since	Purchase Amount	Percentage of Our Total Purchase
				RMB'000	%
<i>Year ended December 31, 2024</i>					
Supplier C	R&D and clinical-related services, specially preclinical toxicology and pharmacokinetic studies for CMD011 and CMDE005	A leading Chinese company listed in Shanghai Stock Exchange, primarily engaging in CRO services globally, including preclinical toxicology and pharmacokinetic studies.	2018	7,373	21.7
Supplier E	Property leasing services	A private company incorporated in China, primarily engaging in property services in China.	2019	2,904	8.6

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Suppliers	Products or Services Purchased	Background	Business Relationship Since	Purchase Amount <i>RMB'000</i>	Percentage of Our Total Purchase <i>%</i>
Supplier F	R&D and clinical-related services, specifically the assignment of clinical research coordinators to assist PIs with non-medical tasks in clinical studies for DNV3, SMET12 and CDM011	A leading Chinese company listed in both Shenzhen Stock Exchange and Hong Kong Exchanges, primarily engaging in CRO services and providing clinical operation support services for global customers.	2019	2,778	8.2
Supplier B	R&D and clinical-related services, specifically R&D and manufacturing services for CMDE005	A private company incorporated in China, primarily engaging in CDMO services for large molecules and biopharmaceuticals in China.	2022	2,669	7.9
Supplier A	R&D and clinical-related services, specifically R&D and manufacturing services for clinical trial samples of DNV3, SMET12 and CMD011	A leading private company incorporated in China, primarily engaging in CDMO services globally, focusing on the development and manufacturing of biopharmaceuticals for clinical trial samples.	2018	2,468	7.3
Total				<u>18,192</u>	<u>53.7</u>
<i>Year ended December 31, 2025</i>					
Supplier G	R&D and clinical-related services, particularly clinical studies involving patients for DNV3, SMET12 and CMDE005	A Chinese hospital, primarily engaging in clinical trial and research services in China.	2022	4,114	15.3
Supplier F	R&D and clinical-related services, specifically the assignment of CRCs to assist PIs with non-medical tasks in clinical studies for DNV3, SMET12 and CDM011	A leading Chinese company listed in both Shenzhen Stock Exchange and Hong Kong Exchanges, primarily engaging in CRO services and providing clinical operation support services globally.	2019	3,338	12.4
Supplier E	Property leasing services	A private company incorporated in China, primarily engaging in property services in China.	2019	3,092	11.5

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Suppliers	Products or Services Purchased	Background	Business Relationship Since	Purchase Amount <i>RMB'000</i>	Percentage of Our Total Purchase <i>%</i>
Supplier A	R&D and clinical-related services, specifically R&D and manufacturing services for clinical trial samples of DNV3, SMET12 and CMD011	A leading private company incorporated in China, primarily engaging in CDMO services globally, focusing on the development and manufacturing of biopharmaceuticals for clinical trial samples.	2018	2,638	9.8
Supplier H	R&D and clinical-related services, specifically including data management, statistical analysis and pharmacovigilance services for DNV3, SMET12, CMD011 and CMDE005	A Chinese company listed in both Shanghai Stock Exchange and Hong Kong Exchanges, primarily engaging in CRO services globally, including drug R&D and data analysis services.	2021	2,449	9.1
Total				<u>15,631</u>	<u>58.1</u>

To the best of our knowledge, during the Track Record Period and up to the Latest Practicable Date, all of our five largest suppliers were Independent Third Parties. During the Track Record Period, we purchased R&D and clinical-related services in our ordinary course of business from Hangzhou Tigermed and MabPlex, who were among our five largest suppliers, and such transactions were conducted on an arm’s length basis. As of the Latest Practicable Date, to the best of our knowledge, save for Hangzhou Tigermed and our Non-executive Director, Wang Yanbing, who held an equity interest below 1% in MabPlex, none of our Directors, their respective close associates or any Shareholder who owned more than 5% of our issued share capital had any interest in any of our five largest suppliers in each year during the Track Record Period.

CUSTOMERS

During the Track Record Period, we did not have a customer or generate revenue from a customer.

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INTELLECTUAL PROPERTY

As of the Latest Practicable Date, we held 21 patents and five patent applications in connection with our clinical-stage product candidates, including four patents related to DNV3, and eleven patents and one patent application related to SMET12. As of the Latest Practicable Date, we had not received any material concerns or inquiries from relevant competent authorities that makes us to believe that any of the pending patent applications will be rejected. The following table sets forth an overview of our material granted patents and filed patent applications in connection with our product candidates as of the Latest Practicable Date.

Related Product ⁽¹⁾	Name of Patent ⁽²⁾	Owner ⁽³⁾	Inventors ⁽⁴⁾	Jurisdiction	Status	Filing Date	Grant Date	Expiration Date ⁽⁵⁾
SMET12. . .	Monomeric human IgG1 Fc and bispecific antibodies	Zhejiang Shimai ⁽⁶⁾	Chen Weizao, Xiao Zuoxiang, Fu Tao	Chinese Mainland	Issued	February 1, 2018	November 9, 2021	February 1, 2038
SMET12. . .	Monomeric human IgG1 Fc and bispecific antibodies	Zhejiang Shimai ⁽⁶⁾	Chen Weizao, Xiao Zuoxiang, Fu Tao	EU	Issued	February 1, 2018	December 11, 2024	February 1, 2038
SMET12. . .	Monomeric human IgG1 Fc and bispecific antibodies	Zhejiang Shimai ⁽⁶⁾	Chen Weizao, Xiao Zuoxiang, Fu Tao	Macau	Issued	February 1, 2018	January 24, 2022	February 1, 2038
SMET12. . .	Protease cleavable bispecific antibodies and uses thereof	Zhejiang Shimai	Chen Weizao, Xiao Zuoxiang, Fu Tao	Chinese Mainland	Issued	December 20, 2019	July 12, 2022	December 20, 2039
SMET12. . .	Protease cleavable bispecific antibodies and uses thereof	Zhejiang Shimai	Chen Weizao, Xiao Zuoxiang, Fu Tao	Hong Kong	Issued	December 20, 2019	December 2, 2022	December 20, 2039
SMET12. . .	Protease cleavable bispecific antibodies and uses thereof	Zhejiang Shimai	Chen Weizao, Xiao Zuoxiang, Fu Tao	Macau	Issued	December 20, 2019	October 27, 2022	December 20, 2039
SMET12. . .	Protease cleavable bispecific antibodies and uses thereof	Zhejiang Shimai	Chen Weizao, Xiao Zuoxiang, Fu Tao	U.S.	Issued	December 20, 2019	June 10, 2025	December 20, 2039
SMET12. . .	Protease cleavable bispecific antibodies and uses thereof	Zhejiang Shimai	Chen Weizao, Xiao Zuoxiang, Fu Tao	EU	Pending	December 20, 2019	N/A	N/A
DNV3 . . .	Human monoclonal antibodies against LAG3 and uses thereof	Zhejiang Shimai	Chen Weizao, Xiao Zuoxiang, Fu Tao	Chinese Mainland	Issued	May 9, 2018	November 9, 2021	May 9, 2038
DNV3 . . .	Human monoclonal antibodies against LAG3 and uses thereof	Zhejiang Shimai	Chen Weizao, Xiao Zuoxiang, Fu Tao	U.S.	Issued	May 9, 2018	May 24, 2022	May 9, 2038
DNV3 . . .	Human monoclonal antibodies against LAG3 and uses thereof	Zhejiang Shimai	Chen Weizao, Xiao Zuoxiang, Fu Tao	EU	Issued	May 9, 2018	September 18, 2024	May 9, 2038
DNV3 . . .	Human monoclonal antibodies against LAG3 and uses thereof	Zhejiang Shimai	Chen Weizao, Xiao Zuoxiang, Fu Tao	Macau	Issued	May 9, 2018	January 24, 2022	May 9, 2038
CMD011 . . .	Antibodies against GPC3 and uses thereof	Zhejiang Shimai	Xiao Zuoxiang, Peng Jiaping, Zhou Dongwen, Zhou Wei, Miao Hangbin, Wang Guannv	Chinese Mainland	Issued	December 23, 2021	July 7, 2023	December 23, 2041

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Related Product ⁽¹⁾	Name of Patent ⁽²⁾	Owner ⁽³⁾	Inventors ⁽⁴⁾	Jurisdiction	Status	Filing Date	Grant Date	Expiration Date ⁽⁵⁾
CMD011 . .	Antibodies against GPC3 and uses thereof	Zhejiang Shimai	Xiao Zuoxiang, Peng Jiaping, Zhou Dongwen, Zhou Wei, Miao Hangbin, Wang Guannv	Hong Kong	Issued	December 23, 2021	September 22, 2023	December 23, 2041
CMD011 . .	Antibodies against GPC3 and uses thereof	Zhejiang Shimai	Xiao Zuoxiang, Peng Jiaping, Zhou Dongwen, Zhou Wei, Miao Hangbin, Wang Guannv	Macau	Issued	December 23, 2021	September 13, 2023	December 23, 2041
CMD011 . .	Antibodies against GPC3 and uses thereof	Zhejiang Shimai	Xiao Zuoxiang, Peng Jiaping, Zhou Dongwen, Zhou Wei, Miao Hangbin, Wang Guannv	U.S.	Pending	December 23, 2021	N/A	N/A
CMD011 . .	Antibodies against GPC3 and uses and compositions thereof	Zhejiang Shimai	Xiao Zuoxiang, Peng Jiaping, Zhou Dongwen, Zhou Wei, Miao Hangbin, Wang Guannv	Chinese Mainland	Issued	December 23, 2021	November 14, 2023	December 23, 2041
CMD011 . .	Antibodies against GPC3 and uses and compositions thereof	Zhejiang Shimai	Xiao Zuoxiang, Peng Jiaping, Zhou Dongwen, Zhou Wei, Miao Hangbin, Wang Guannv	Hong Kong	Issued	December 23, 2021	February 2, 2024	December 23, 2041
CMD011 . .	Antibodies against GPC3 and uses and compositions thereof	Zhejiang Shimai	Xiao Zuoxiang, Peng Jiaping, Zhou Dongwen, Zhou Wei, Miao Hangbin, Wang Guannv	Macau	Issued	December 23, 2021	February 26, 2024	December 23, 2041
CMDE005 . .	Protease cleavable recombinant bispecific antibodies and compositions and uses thereof	Zhejiang Shimai	Xiao Zuoxiang, Peng Jiaping, Zhou Dongwen, Zhou Wei	Chinese Mainland, U.S., EU	Pending	November 28, 2022	N/A	N/A

Notes:

- (1) All the patents and patent applications listed as relating to SMET12 and CMDE005 in the table are also the material patents and patent applications that relate to our technology platforms.
- (2) Unless otherwise indicated, the name of patents and patent applications within the same family is the same and is therefore disclosed once. The name of the patent reflects its scope of coverage.
- (3) All of these inventors were the employees of the Group before filing the corresponding patent applications.
- (4) The Group is the sole owner of all the patents and patent applications listed in the table.
- (5) The patent expiration date is estimated based on current filing status, without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity and other government fees.
- (6) All patents and patent applications listed in the table were self-developed. No third parties were involved in, or had contributed to, the Group’s patents or patent applications.

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Three patent applications relating to SMET12, CMD011 and CMDE005 remain unapproved as of the Latest Practicable Date, as disclosed in the below table.

Application No.	Related Product	Jurisdiction	Current Status	Reason for Pendency >3 Years ¹	Expected Grant Timeline ²
EP19900194.2	SMET12	Europe	Substantive examination started; first office action issued on Feb 12, 2025, response filed on Jun 04, 2025	Complex technical subject-matter; EPO examination backlog; normal for pharmaceutical-related inventions to undergo multiple rounds of examination	2-3 years from current date
US18/691,036	CMD011	America	Awaiting substantive examination	PCT entry date (Mar 11 2024) is recent; USPTO examination backlog; average pendency for pharmaceutical patents is 3-5 years from national-phase entry	3-5 years from entry date (i.e., ~2027-2029)
CN202280005740.7 . .	CMDE005	China	Awaiting substantive examination	CNIPA examination backlog; complex technical subject-matter; average pendency for pharmaceutical patents is 4-6 years from national-phase entry	4-6 years from entry date (i.e., ~2027-2029)

We have not identified any substantive legal impediments that would prevent the above patent applications from proceeding to grant. We are actively managing the patent applications and will address any office actions in a timely manner.

Regarding EP19900194.2 and CN202280005740.7, non-approval of the two patent applications has no material adverse impact on the commercialization of the Core Products and other product candidates. EP19900194.2 does not cover Core Products and other product candidates. The Core Products DNV3 and SMET12 are already covered by other granted patents. Although CN202280005740.7 covers CMDE005, we already hold granted Chinese patent ZL201880009333.7, which also covers CMDE005 and can provide patent protection for the product candidate.

Notes:

- (1) In all three major patent offices (EPO, USPTO, CNIPA), it is common for pharmaceutical-related patent applications to remain pending for more than three years after filing or national-phase entry. This is due to (i) high volume of applications and corresponding backlogs, (ii) technical complexity requiring multiple prior-art searches and examination rounds, and (iii) for PCT-based applications, the time required for translation, formalities review, and assignment to an examiner. The pendency periods for the above applications are within normal ranges for the respective jurisdictions.
- (2) The above estimates are based on typical prosecution timelines for pharmaceutical inventions in the respective jurisdictions and assume no substantive objections that would significantly prolong prosecution. The Company is actively managing these cases to avoid unnecessary delays.

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Regarding US18/691,036, non-approval of this patent application will affect market exclusivity of the related product, CMD011. Without a granted patent in the U.S., we would lack the statutory right to exclude others from making, using, selling, or importing the product in the U.S. Competitors could launch generic versions immediately upon regulatory approval, eroding our market share and pricing power. However, as advised by our IP counsel, the probability of ultimate non-approval is very low in view of the examination history of other applications in the patent family of this U.S. patent application and originality of the antibody sequences they cover under the U.S. patent law. We are actively managing this patent application and will take necessary steps, where appropriate, to secure a granted patent that adequately covers the relevant product.

We may rely, in some circumstances, on trade secret and/or confidential information to protect aspects of our product candidates. We have entered into confidentiality agreements with our senior management and key members of our R&D team and other employees who have access to trade secrets or confidential information about our business. Our standard employment contract, which we used to employ each of our employees, provides that we own all the rights to all inventions, technology, know-how and trade secrets derived during the course of such employee’s work.

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

According to the freedom-to-operate searches and analyses (“**FTO Analysis**”) conducted by our IP counsel in China in relation to our clinical-stage product candidates and in the U.S. in relation to SMET12, CMD011 and CMDE005 for which we have obtained FDA’s IND approval, our Directors confirm that no substantial risk of infringement had been identified from the FTO Analysis in relation to our clinical-stage product candidates. Our Directors confirmed, as supported by our IP counsel’s view, that our patents and patent applications sufficiently cover all material aspects of the Core Products and/or their associated technologies.

We conduct our business under the brand name of “CentryMed” and/or “時邁藥業”. As of the Latest Practicable Date, we held 13 registered trademarks in Chinese Mainland and three registered trademarks in Hong Kong. We are also the owner of two domain names.

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

COMPETITION

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, competition and a strong emphasis on proprietary drugs. While we believe our pipeline of clinical and preclinical stage proprietary assets, R&D capability, technology platforms and seasoned management team provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing drugs and new drugs that may become available in the future.

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We focus on leveraging our industry experience and established R&D capabilities for the in-house discovery and development of TCE therapies for the treatment of solid tumors. We face fierce competition from existing products and product candidates under development in the market. See “Industry Overview” for more details on the competitive landscape of the various markets in which we compete. We face uncertainties in clinical trial development which are subject to a variety of factors, including satisfactory safety and efficacy results from clinical trials, successful enrollment of patients, and performance of CROs and other parties involved in clinical trial development and others.

INSURANCE

We maintain insurance policies that we consider to be in line with market practice and adequate for our business. Our principal insurance policies cover auto insurance and liability insurance for clinical trials. We currently do not maintain insurance for environmental liability or property loss. See “Risk Factors—Risks Relating to our Business and Industry—We have limited insurance coverage, and any claims beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources.” We consider that the coverage from the insurance policies maintained by us is adequate for our present operations and is in line with the industry norm. During the Track Record Period, we had not made or been the subject of any material insurance claims.

EMPLOYEES

As of December 31, 2025, we had 51 employees in total. The following table sets forth the number of our employees categorized by function as of December 31, 2025.

Functions	Number of employees by function	Percentage
Drug Discovery and Preclinical Development	16	31.4%
Clinical Development	15	29.4%
General and Administrative	20	39.2%
Total	51	100.0%

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

To maintain our workforce’s quality, knowledge, and skill levels, we provide continuing education and training programs, including internal training, to improve their technical, professional or management skills. We also provide training programs to our employees from time to time to ensure their awareness and compliance with our policies and procedures in various aspects. Furthermore, we provide various incentives and benefits to our employees, including competitive salaries, bonuses and share-based payment, particularly our key employees.

Our employees’ remuneration comprises salaries, bonuses, provident funds, social security contributions, and other welfare payments. We have made contributions to our employees’ social security insurance funds (including pension plans, medical insurance, work-related injury insurance, unemployment insurance and maternity insurance) and housing funds pursuant to applicable laws and regulations. During the Track Record Period and as of the Latest Practicable Date, we did not make full contribution to the social insurance and housing funds for our employees in accordance with the relevant PRC laws and regulations, and the amount of outstanding contribution was RMB0.6 million and RMB0.7 million in 2024 and 2025, respectively. No provision was made for outstanding contributions based on the considerations that (i) the credit

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reports obtained from the relevant authority confirmed that we did not have any record of violation of laws and regulations with respect to social insurance and housing funds; (ii) no employee had raised any material disputes against us regarding social insurance and housing funds matters, and we had not received any litigation documents related to material labor disputes; and (iii) the amount of social insurance and housing funds contributions required to be made up as directed by the relevant authorities due to our past underpayment is not material to our operation and accordingly, the Directors are of the view that such non-compliance would not have a material adverse effect on our business as a whole. See “—Risk Factors—We are subject to risks in relation to our social insurance and housing provident fund contributions.”

To prevent any future recurrences, we have implemented the following internal control measures: (i) we will prepare and maintain regular reports in respect of our payment of social insurance premium and housing provident funds for our employees for review by our Board and the head of our human resources department; (ii) we will regularly communicate with the relevant competent authorities and, where necessary, consult with our PRC Legal Adviser, to ensure that our calculation and payment methods are in compliance with the relevant laws and regulations; (iii) we will regularly consult with our PRC Legal Adviser to understand whether we are at risk of non-compliance with the relevant laws and regulations; and (iv) we will provide regular internal trainings to our Directors, senior management personnel and other responsible staff on the relevant laws and regulations and consult with our PRC Legal Adviser, where necessary, on the updates thereof.

Workplace Safety

We have adopted and maintained a series of rules, standard operating procedures, and measures to maintain our employees’ healthy and safe environment. We implement safety guidelines to set out information about potential safety hazards and procedures. We require employees to participate in safety training to familiarize themselves with the relevant safety rules and procedures. Also, we have policies in place and have adopted relevant measures to ensure the hygiene of our work environment and the health of our employees. During the Track Record Period and up to the Latest Practicable Date, we did not experience any fatal occupational accidents. Our PRC Legal Advisor has confirmed that, during the Track Record Period and up to the Latest Practicable Date, we had not been subject to any material penalty in relation to health, work safety, social and environmental protection in China.

PROPERTIES

As of Latest Practicable Date, we did not own any real properties. We leased one property in China with an aggregate GFA of approximately 3,110 sq.m. We also leased one property in Maryland, U.S., with an aggregate GFA of approximately 279 sq.m. We believe our current facilities are sufficient to meet our near-term needs, and additional space can be obtained on commercially reasonable terms to meet our future needs. As of the Latest Practicable Date, our lease agreement for property in China has been registered with relevant authorities.

As of the Latest Practicable Date, none of our leased properties had a carrying amount equal to or exceeding 15% of our consolidated total assets. Therefore, according to Chapter 5 of the Listing Rules and section 6(2) of the Companies (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice (Cap. 32L of the Laws of Hong Kong), this Document is exempted from compliance with the requirements of section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance in relation to paragraph 34(2) of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance, which requires a valuation report with respect to our Group’s interests in land or buildings.

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PERMITS, LICENSES AND OTHER APPROVALS

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

AWARDS AND RECOGNITIONS

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

Year	Award/Recognition	Issuing Authority
2018	2018 High-level Returned Overseas Personnel (Teams) Entrepreneurial Innovation Project in Hangzhou (2018年度高層次留學回國人員(團隊)在杭創業創新項目)	Hangzhou Municipal Human Resources and Social Security Bureau; Hangzhou Science and Technology Bureau
2019	2019 Hangzhou Leading Entrepreneurial Team (2019年度杭州市領軍型創業團隊)	Hangzhou Science and Technology Bureau; Talent Office of the CPC Hangzhou Municipal Committee
2020	First Prize in the 9th China Innovation and Entrepreneurship Competition Zhejiang Division and the 7th Zhejiang Province “Torch Cup” Innovation and Entrepreneurship Competition (第九屆中國創新創業大賽浙江賽區暨第七屆浙江省“火炬杯”創新創業大賽總決賽一等獎)	Zhejiang Provincial Department of Science and Technology
2021-2025 .	Hangzhou Quasi-Unicorn Company (杭州準獨角獸企業)	Hangzhou Venture Capital Association; Welian
2021	First Prize in Zhejiang Province in the 6th “Maker in China” Contest (第六屆“創客中國”浙江省一等獎)	Zhejiang Provincial Department of Economy and Information Technology
2021	Second Prize in National Finals of the 6th “Maker in China” Contest (第六屆“創客中國”全國總決賽二等獎)	Ministry of Industry and Information Technology; Ministry of Finance
2022	Shandong Antibody Drug Innovation and Entrepreneurship Community Subsidy Fund (山東省抗體藥物創新創業共同體補助資金)	Yantai Rongchang Biomedical Industry Technology Research Institute Co., Ltd.
2022	The 1st KPMG China’s Top 50 Bioinnovation Companies (畢馬威中國首屆生物科技創新50企業)	KPMG
2022	2022 Zhejiang Province Specialized, Refined, Special, and New Small and Medium Enterprises (2022年度浙江省專精特新中小企業)	Economy and Information Technology Department of Zhejiang
2023	National Disruptive Technological Innovation Competition Final Excellence Award (全國顛覆性技術創新大賽總決賽優秀獎)	Torch Center, Ministry of Science and Technology

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Year	Award/Recognition	Issuing Authority
2023	Third Prize in HICOOL 2023 Global Entrepreneurship Competition (HICOOL 2023全球創業大賽三等獎)	People’s Government of Beijing Municipality
2023	2023 Hangzhou Biopharmaceutical Industry High-Quality Development Special Preclinical Drug R&D Project (2023年杭州市生物醫藥產業高質量發展專項“臨床前藥物研發項目”)	Hangzhou Municipal Bureau of Economy and Information Technology
2023	Zhejiang’s Most Valuable Innovative Enterprises for Investment TOP50 for 2023 (2023浙江最具投資價值創新企業TOP50)	Economy and Information Technology Department of Zhejiang; Zhejiang Venture Capital Association
2024	Project establishment for the 2024 “Leading Goose” R&D Programs of Zhejiang Province (浙江省2024年度“尖兵領雁+X”研發攻關計劃項目立項)	Zhejiang Provincial Department of Science and Technology
2024	2024 Zhejiang Province Leading Innovation and Entrepreneurship Team (2024年度浙江省領軍型創新創業團隊)	Zhejiang Provincial Department of Science and Technology
2025	Project establishment for Zhejiang Province 2025 Annual “Pioneer Leading Goose+X” Science and Technology Plan (2025年度浙江省“尖兵領雁+X”科技計劃項目立項)	Zhejiang Provincial Department of Science and Technology
2025	“Innovative Binjiang New Force Enterprise TOP10” List	Hangzhou High-Tech Zone (Binjiang) Government
2025	2025 China Future Unicorn TOP100 (2025中國未來獨角獸TOP100)	China Investment Promotion Association; Welian

ENVIRONMENTAL, SOCIAL AND GOVERNANCE

ESG Governance Structure

The Board fully recognizes the importance of Environmental, Social, and Governance (“ESG”) management in achieving our green, compliance, and sustainability realization. Throughout our management and operation processes, the Board promotes the implementation of ESG principles and integrates them into our governance framework.

As the highest decision-making authority on ESG matters, the Board of Directors bears ultimate responsibility for defining the direction, setting the strategy and objectives, overseeing performance, and ensuring transparent reporting on our sustainable development. We have established an ESG working group to report to the Board of Directors no fewer than twice a year regarding policy formulation directions, strategic implementation progress, achievement of objectives, and other ESG matters. The ESG Working Group shall report to the Board and shall be responsible for, among others, the following matters: formulating our ESG strategies and objectives, identifying and managing ESG-related risks and opportunities, and advising the Board accordingly; maintaining communication with stakeholders such as investors, media, and government authorities to identify, assess, and monitor ESG topics of concern, and providing timely recommendations to the Board in response to changes or potential risks; establishing ESG-related policies, systems, and work plans, and reporting progress and results to the Board on a regular basis; coordinating the management and implementation of ESG initiatives, monitoring execution, and collecting, consolidating, and reporting the progress and performance of responsible departments; reviewing ESG disclosure content and providing recommendations to the Board; providing ESG-related training and materials to the Board.

The Board of Directors shall maintain oversight of all matters related to sustainable development with the support of this working group.

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Material ESG Topics

In accordance with the “Materiality” principle in the Hong Kong Stock Exchange’s “Environmental, Social and Governance Reporting Guidelines” and the management requirements for material issues in the Global Reporting Initiative “Sustainability Reporting Guidelines,” while also referring to the list of materialities in the pharmaceutical industry in the Stock Exchange of Hong Kong’s “Environmental, Social and Governance Reporting Guidelines,” SASB Health Cared Materiality Map, and leading companies materiality issues in this sector, and considering our actual situation, we have preliminarily identified the following key ESG matters.

Issues of importance	Importance	Potential risks/opportunities	Some quantitative indicators
Business ethics and anti-corruption . . .	very important	Good business ethics can establish a positive corporate image	Number of hours per person trained in anti-corruption (hours/person)
Product quality and safety	very important	Product quality assurance is the key to enterprise revenue	Percentage (%) of the total number of products sold or shipped that must be recovered for safety and health reasons
Data privacy and security	very important	Violations of confidentiality may result in compensation for litigation	Total number of incidents (items) in violation of customer privacy protection regulations and voluntary guidelines
Greenhouse gas emission	very important	Exceeding emissions limits can result in fines	Total greenhouse gas emissions (tons)
Development and training	very important	Talent is the cornerstone of enterprise development	Employee training coverage (%)
Employee health and safety	very important	Talent is the cornerstone of enterprise development	Number of working days lost due to work-related injury (days)
Risk management . . .	relatively important	Timely identification and response to risks can reduce losses	Number of major risk events (items)
Research and development and innovation	relatively important	It is the embodiment of enterprise competitiveness	The ratio of R&D amount to operating revenue (%)
Intellectual property right	relatively important	It is the embodiment of enterprise competitiveness	Number of intellectual property rights held (items)
Hazardous waste . . .	relatively important	Exceeding emissions limits can result in fines	Hazardous waste discharge (tons)
Supply chain management	relatively important	A stable supply chain to ensure timely delivery	Number of suppliers (households)
Equal employment . .	relatively important	Talent is the cornerstone of enterprise development	The proportion of female employees is (%)
Climate change	relatively important	Refer to Climate Change	Losses due to climate change (ten thousand yuan)
Customer relations . .	relatively important	Customer satisfaction supports the long-term development of enterprises	Received customer complaint handling completion status (%)
Community contribution	moderately important	The embodiment of corporate social responsibility	Social public welfare investment (ten thousand yuan)

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Following our [REDACTED], the ESG Working Group will continue to review material issues and maintain active communication with stakeholders through multiple channels. Stakeholder feedback will be systematically consolidated and submitted to the Board of Directors, enabling the Board of Directors to assess the significance of each issue to both stakeholders and us in a timely and informed manner. Such feedback will be integrated into the materiality assessment process and, where appropriate, reflected in our strategic planning to ensure the development of a more relevant and stakeholder-responsive materiality matrix.

Business Ethics

We place strong emphasis on upholding business ethics and are committed to establishing a sound ethical governance framework. We strictly comply with applicable laws and regulations, including the Company Law of the PRC, the Anti-Unfair Competition Law of the PRC, and the Opinions on Several Issues Concerning the Application of Law in Handling Criminal Cases of Commercial Bribery. We adopt a zero-tolerance approach to corruption, bribery, extortion, fraud, and money laundering. This policy is uniformly applicable to all activities involving our employees (including staff and directors), third-party representatives (such as agents, consultants, and joint venture partners), suppliers, clients, government officials, and healthcare professionals. To ensure the effective implementation of business ethics standards, we have established regular anti-bribery audit mechanisms, strengthened whistleblower protection systems, and integrated compliance criteria into its partner evaluation processes — thereby consistently fostering a clean, transparent, and compliant business environment.

Environmental Protection

We understand the significance and attach great attention to principles of green chemistry across our research, testing, and production processes. We are committed to ensuring the safety of pharmaceutical raw materials, minimizing the environmental impact of reaction products, continuously enhancing our processes, reducing the use of hazardous chemicals and waste generation, and safeguarding environmental and public health. We strictly adhere to pharmaceutical industry standards for biosafety and chemical management in laboratory systems, implementing green chemical design and complying with experimental waste disposal guidelines to protect the environment as well as the physical and mental well-being of employees. We will continue to enhance our energy management system, establish robust internal environmental risk assessment mechanisms, and develop comprehensive wastewater and exhaust gas treatment systems, thereby fulfilling our social responsibility in energy conservation and emission reduction. Specific requirements are as follows:

Waste Discharge and Management

Solid Waste. We continuously and consistently oversight our practices to comply with applicable laws and regulations in all jurisdictions where it operates, and implements full lifecycle management for hazardous wastes, including laboratory waste liquids, waste organic solvents, spent activated carbon, wastewater treatment sludge, biological waste, and medical/pharmaceutical waste. These wastes are managed in accordance with regulatory requirements from generation to final disposal, encompassing standardized production controls, secure storage, professional transportation, and compliant disposal procedures. During the storage phase, we rigorously enforce classification, labeling, and record-keeping systems, and engages qualified third-party institutions to perform safe and compliant disposal, thereby minimizing environmental risks and upholding our corporate environmental responsibilities.

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In 2024 and 2025, the total amount of waste generated by us is:

	For the year ended December 31,	
	2024	2025
Hazardous waste (tons)	0.07	0.04
General waste (tons)	5.0	5.2

Exhaust Gas. We strictly enforce our emission control system, ensuring compliance with regulatory standards while continuously improving the effectiveness of emission reduction through multi-stage treatment processes. We utilize technologies including adsorption, supported by high-efficiency exhaust treatment systems. Additionally, fume hoods and universal exhaust systems are deployed within enclosed systems to effectively control fugitive emissions. Through a combination of technological innovation and rigorous operational management, we are committed to minimizing exhaust emissions and mitigating environmental impact.

In 2024 and 2025, the total amount of pollutants emitted by us is:

	For the year ended December 31,	
	2024	2025
Total exhaust gas emission (kg)	0.5	0.5

Wastewater. We have established a stringent wastewater classification and treatment system, applying differentiated control measures based on the types of laboratory-generated waste liquids. These waste liquids are classified into four categories: general solutions, strong acids and alkalis, heavy metal solutions, and organic solutions. General solutions are diluted to meet discharge standards, while the other types are strictly segregated and stored in designated waste liquid tanks. All wastewater is handled by professionally qualified third-party institutions to ensure standardized treatment, full compliance with national environmental protection regulations, and to prevent any direct discharge into natural water bodies.

In 2024 and 2025, the discharge of wastewater by us is as follows:

	For the year ended December 31,	
	2024	2025
Waste water (tons)	556.0	522.6

Regarding waste emissions, we set the target to “strive to reduce the generation and discharge of pharmaceutical waste by 5% by 2028, with 2025 as the baseline year.” To this end, we have implemented a series of optimization measures: by refining R&D plans, strengthening operational training, and improving experimental success rates, we actively control the generation of waste liquids, waste reagent bottles, and medical waste.

Additionally, domestic sewage is pretreated in septic tanks before being discharged into the municipal sewage network. Experimental wastewater is collected and disinfected with sodium dichloroisocyanurate before being discharged via the pipeline. Organic exhaust gases are collected and treated through activated carbon adsorption, then emitted through the DA001 exhaust stack at a height of 60 meters.

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Resource Consumption and Carbon Emissions

We consider resource conservation and efficient utilization as a key foundation of sustainable development. Through the establishment of a green management framework across research and development, production, and operational processes, we systematically enhance the efficiency of energy and material utilization, continuously reduces resource consumption intensity per unit of output, and maximizes resource value.

In 2024 and 2025, the total amount and intensity of consumption of various resources are as follows:

Water consumption:

	For the year ended December 31,	
	2024	2025
Amount (ton)	668.6	626.8
Intensity (tons/person)	13.4	13.3

Power consumption:

	For the year ended December 31,	
	2024	2025
Amount (kilowatt-hour)	324,113	362,026
Intensity (MWh/person)	6.4	7.7

Goals and Strategies

Based on an in-depth analysis of the macro-environment, active alignment with national “Dual Carbon Goals” strategic directives, integration of industry trends and our own developmental context, and through prudent evaluation and benchmarking against peers, we have systematically developed and established the following ESG objectives.

We aim to implement energy-saving measures to ensure full compliance with environmental regulations. We set the target to “reduce per capita electricity consumption by 5% compared to the baseline year of 2024 by 2029.” To achieve this, we strictly enforce energy-saving measures in office areas, such as turning off lights and computers when leaving. For office equipment like water dispensers and printers, we require that their power be completely cut off during non-working hours such as nights and weekends to reduce standby energy consumption.

We have set the target to “reduce per capita water consumption by 3% compared to the baseline year of 2024 by 2029.” To this end, we have established a rapid response mechanism requiring immediate reporting of water leaks to property management, with repairs completed as soon as possible, aiming to address all potential leaks on the same day to prevent waste at the source. Additionally, we have posted prominent reminders such as “Conserve Water” in all water-use areas, including restrooms, pantries, and sinks, to continuously reinforce water-saving awareness among employees. Furthermore, we display paper-saving tips in visible locations, actively promote double-sided and black-and-white printing, and strive to enhance the efficient use of office resources by reducing unnecessary printing and increasing waste paper utilization.

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Based on prudent assessment, the CRO we contracted did not generate hazardous materials or waste in the course of their operations. Meanwhile, we have conducted compliance qualification verification for other relevant contractors and reviewed the waste disposal and management documentation they provided, ensuring that their handling of hazardous materials and waste complies with legal and regulatory requirements.

In relation to the outsourced CMC projects, we entered into a quality agreement with the cooperating CDMO, clearly stipulating that the CDMO is responsible for the compliant disposal of project-generated waste, including hazardous waste, as well as the handling of related environmental procedures, thereby ensuring compliance with national and local environmental regulations. As the project progresses and our business develops, we will also establish and improve an independent EHS management department and system framework, implementing control measures in phases. Specific measures include (1) setting up a dedicated EHS organizational structure, assigning professional personnels with clearly defined roles and responsibilities, (2) enhancing internal EHS control systems to cover the entire process of waste management and on-site audits, (3) strengthening the evaluation of the CDMO’s waste disposal qualifications and establish a dynamic review mechanism and (4) conducting routine on-site inspections and records checks to solidify the compliance responsibilities of the cooperating party and prevent environmental risks.

We also pay close attention to Scope 3 emissions and plan to launch an assessment of upstream and downstream carbon sources. Reduction strategies include, but are not limited to: (i) placing water and energy conservation signage in visible areas to raise environmental awareness; (ii) promoting double-sided printing and electronic documentation to support a paperless office; (iii) encouraging teleconferencing to reduce non-essential travel; and (iv) advocating public transportation use for commuting and business travel. We will regularly evaluate our progress and adjust our strategies based on actual business developments.

The Board of Directors is responsible for identifying, assessing, and managing ESG-related risks, and for overseeing sustainability opportunities and strategic objectives. In light of our expanding business scale, we anticipate a phased increase in total resource inputs and environmental impacts, despite efforts to optimize resource utilization. We are committed to enhancing environmental performance throughout the value chain — covering office operations, supplier selection, raw material procurement, laboratory processes, and waste management.

Carbon Dioxide Emissions

	For the year ended December 31,	
	2024	2025
Total greenhouse gas emissions (tons of CO ₂ equivalent)	201.4	235.9
Scope 1	2.5	3.2
Scope 2	172.0	192.1
Scope 3	26.9	40.6

Note: The increase in Scope 2 greenhouse gas emissions from 2024 to 2025 was mainly due to an increase in our electricity consumption. The increase in in Scope 3 greenhouse gas emission during the same period was mainly due to a rise in business demand, resulting in an increase in business travel, particularly in air traveling by employees.

We are committed to continuously reducing compliance costs related to environmental and safety regulations through proactive compliance initiatives, while expanding our positive contribution to sustainability. We set the target to reduce per capita Scope 1 and Scope 2 greenhouse gas emissions by 4% from the 2025 baseline level by 2029. Through measures such as energy

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conservation, consumption reduction, and standardized vehicle use, we ensure a steady decline in both the total greenhouse gas emissions from Scope 1 and Scope 2, as well as the per capita greenhouse gas emission intensity. The Board of Directors will implement an annual target review mechanism to dynamically adjust ESG measures, ensuring their continued relevance and confirming that existing systems do not cause material disruption to business operations.

Climate Change and Risk Management

We are committed to long-term climate resilience and actively follow the Task Force on Climate-related Financial Disclosures guidance, conduct ongoing climate risk assessments, and implement mitigation and adaptation measures across our business. We have established a robust risk management and internal control system. Regarding ESG-related risks, the ESG Working Group identifies and manages such risks and opportunities and reports to the Board accordingly.

Employee Rights

We recognize employees as our most valuable asset and are committed to ensuring that all individuals are treated with dignity and respect. We strictly comply with applicable labor and employment laws in all jurisdictions where we operate. We actively promote work-life balance and strive to foster a supportive and inclusive work environment for all employees.

Labour Standards

We respect internationally recognized human rights and labor standards, including the rights to freedom of expression, publication, assembly, association, and peaceful demonstration. Workers are employed without discrimination based on ethnicity, race, gender, or religious belief. All employees are entitled to equal employment rights, regardless of gender. We strictly prohibit all forms of sexual harassment in the workplace. Victims have the right to file complaints through internal reporting channels or with relevant authorities.

We adhere to the principles of open recruitment, fair competition, merit-based selection, and internal promotion prioritization. Both the hiring department and the Human Resources Department conduct comprehensive candidate evaluations based on qualifications, competencies, character, experience, health status, and role suitability. Additional emphasis is placed on the candidate's values, behavior, and alignment with our strategic direction, business needs, and corporate culture.

We comply with all applicable labor laws and prohibit any form of forced labor, including coercion, threats, or unlawful restrictions on personal freedom. We do not withhold employees' identification documents, nor do we require employees to provide guarantees or collect property under any pretense.

Talent Development

Guided by the core philosophy of “Global Value, Global Talent”, we have established a talent development system based on Tiered Empowerment and Shared Responsibility. We introduced the VAPP Value-Oriented Matrix as the core framework for employee incentives, achieving deep alignment between personal growth and our R&D strategy, patient well-being, and shareholder value. VAPP Matrix forms a full-cycle incentive loop:

Value (Value Orientation). Employees are incentivized to focus on “dual value creation” — on the one hand, concentrating on the essence of innovative drug R&D to generate social value through technological breakthroughs, clinical progress, and improved patient access; on the other hand, creating sustainable commercial value for us and shareholders via compliant operations, efficiency optimization, and commercialization. This aligns individual contributions closely with the social mission of the innovative drug industry and our strategy;

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Action (Action Empowerment). Fully considering the high uncertainty and necessity of trial-and-error in innovative drug R&D, we encourage the employees to conduct breakthrough explorations under compliance — including cutting-edge technology R&D, clinical protocol optimization, and interdisciplinary collaborative innovation. A supporting mechanism featuring “error tolerance, review, and iteration” is established to break down innovation barriers and stimulate vitality in our R&D and business operations;

Position (Frontline Endeavors). Emphasizing the practical value of being “close to the frontline,” we encourage the employees to proactively engage in core frontline roles. Resources and incentives are tilted toward “frontline leaders” who directly address technological challenges, patient needs, and market demands, enhancing problem-solving capabilities and efficiency;

Performance (Result Orientation). Quantifiable and verifiable results serve as the core basis for incentives. These include key milestones as well as long-term value outcomes — achieving a balanced incentive for both short-term breakthroughs and long-term development.

The VAPP Matrix is not an isolated incentive tool. It is deeply integrated with the our three-tier talent development system:

Foundation Tier. Through workplace skills and general competency training, we help our employees build a solid foundation in “value identification” and “compliant action”;

Professional Tier. Through training on cutting-edge industry knowledge, we help our employees enhance their capability in frontline roles (Position) and the professionalism of their actions (Action);

Strategic Tier. We cultivate leaders with “strategic vision + social responsibility” to drive their teams toward higher-dimensional value (Value) creation and performance (Performance) breakthroughs.

We embed the VAPP incentive indicators into the entire process of talent development, promotion, and compensation & benefits. This ensures the implementation of incentive principles — safeguarding the compliance and professionalism of innovative drug R&D while attracting and retaining top global talents through targeted incentives, thereby providing core impetus for us to continuously overcome R&D bottlenecks for TCE and achieve sustainable development.

Employee Welfare

We comply with applicable compensation and benefits regulations in all jurisdictions where we operate and have established a comprehensive and competitive remuneration system offering flexible benefit combinations, including commercial health insurance, annual medical checkups, and various additional benefits.

Welfare of Trial Subjects

In the design and implementation of clinical trials, we adhere to the latest GCP requirements, assess and control risks that may affect the safety of trial subjects, and rationally develop trial protocols, dosing and discontinuation criteria. We have established a comprehensive system for collecting, evaluating, and reporting adverse events. In the event of significant safety risks, the investigator’s brochure, trial protocol, and informed consent documents will be updated promptly. Through continuous monitoring, quality management, and corrective and preventive actions, we ensure that the protection measures for subject safety are effectively implemented throughout the entire trial cycle.

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As for the preclinical animal studies, they are performed by CROs retained by us. The use and welfare of subject animals in these studies have received accreditation from the Association for Assessment and Accreditation of Laboratory Animal Care International. Also, the CROs we retained have obtained the requisite experimental animal use licenses issued by the regulatory authorities, and the animal studies are operated in accordance with Good Laboratory Practice guidelines.

LEGAL PROCEEDINGS AND NON-COMPLIANCE

Legal Proceedings

During the Track Record Period and up to the Latest Practicable Date, we were not a party to any actual or threatened legal or administrative proceedings that could, individually or in the aggregate, have a material adverse effect on our business, financial condition or results of operation.

Legal Compliance

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

RISK MANAGEMENT AND INTERNAL CONTROL

Risk Management

We are exposed to various risks in our business operations, and we believe that risk management is important to our success. For more details, see “Risk Factors—Risks Relating to Our Business and Industry” in this Document. Our Directors oversee and manage the overall risks associated with our operations. We have prepared written terms of reference in compliance with Rule 3.21 of the Listing Rules and the Corporate Governance Code and Corporate Governance Report as set out in Appendix C1 to the Listing Rules.

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; 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

We have employed an independent internal control consultant to assess our internal control system in connection with the [REDACTED]. The internal control consultant has conducted a review procedure on our internal control system in certain aspects, including financial reporting and disclosure controls, corporate level controls, information system control management and other procedures for our operations. We have improved and refined our internal control system by adopting and implementing corresponding enhanced internal control measures. For the remaining deficiencies under rectification, we plan to complete the corrective actions before the [REDACTED]. Going forward, we will continue to regularly review and improve these internal control policies, measures and procedures.

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We have also appointed external legal counsel to advise us on compliance matters, such as compliance with the regulatory requirements on clinical R&D, which is also monitored by our legal compliance team. Under our whistle blowing policy, we make our internal reporting channel open and available for our employees to report, on an anonymous basis, any non-compliance incidents and acts, including bribery and corruption. Reported incidents and persons will be investigated and appropriate measures will be taken in response to the findings. We have also established anti-bribery guidelines and compliance requirements. After considering the remedial actions we have taken, our Directors are of the view that our internal control system is adequate and effective for our current operations.

We plan to provide our Directors, senior management, and relevant employees with continuous training programs and updates regarding the relevant laws and regulations regularly to proactively identify any concerns and issues relating to any potential non-compliance.

Anti-bribery

We maintain a strict code of conduct and anti-corruption policies among our employees. We believe we will be less affected by the increasingly stringent measures taken by the PRC government to correct corruptive practices in the pharmaceutical industry. We strictly prohibit bribery or other improper payments in our business operations. This prohibition applies to all business activities, anywhere globally, whether involving government officials or healthcare professionals. Improper payments prohibited by this policy include bribes, kickbacks, excessive gifts or entertainment, or any other payment made or offered to obtain an undue business advantage. We will also ensure that future commercialization team personnel comply with applicable promotion and advertising requirements, including restrictions on promoting drugs for unapproved uses or patient populations and limitations on industry-sponsored scientific and educational activities.

We have adopted comprehensive internal control measures for anti-corruption and anti-bribery by (i) monitoring books, records and accounts with respect to supplier management, tendering and bidding process management and financial payment management to identify any false, misleading or undisclosed entries; (ii) establishing whistle-blowing mechanisms and encouraging all employees, suppliers, customers and other third parties to report suspicious activities and violations of the policies.

Conflict of Interest and Non-Competition

Our code of conduct clearly defines the scope of conflicts of interest, including supplier and customer relationships, hospitality and gifts, financial interests and personnel matters. Our employees, including but not limited to our Directors and R&D team members, may not have or be suspected of having a personal interest in business dealings with our suppliers, customers, competitors or distributors; accept monetary, financial or other benefits from our suppliers, customers, competitors or distributors. At the same time, employees shall keep confidential information strictly confidential and agree on the definition of confidential information, the content covered, the use of intellectual properties, including but not limited to any transfer of know-how, acquisition of technologies, and potential breach liabilities.

Our employee agreements have included non-competition clauses, which prohibit employees from engaging in or directly or indirectly assisting any third party to engage in the same, similar and competitive business activities as ours for a period of two years from the date of termination of employment. Any of our employees shall not, without our prior written approval, own, manage, operate or control any other entity that competes with us.

Data Privacy Protection

We have established procedures to protect the confidentiality of patients' data. We implement strict internal policies to govern the collection, handling, storage, retrieval of, and access to our patients' personal data and medical records and protect the security and confidentiality of personal information to ensure compliance with all applicable national or international rules and regulations on data protection and privacy. We usually require our personnel to collect and safeguard personal information in their possession. Typically, data are entered by investigators into the electronic data

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capture system and may be accessed and reviewed by authorized project team members after appropriate access rights are granted. Our information technology network is configured with multiple layers of protection to secure our databases and servers. Upon completion of relevant clinical trial, the database will be locked after confirmation and sign-offs by the principal investigators of each study site, after which the data management personnel will export all trial data and transfer them to the sponsor in accordance with applicable procedures. We have also implemented a variety of protocols and procedures to safeguard our data assets and prevent unauthorized access to our network. According to the GCP and relevant regulations, access to clinical trial data has been strictly limited to authorized personnel. In order to strengthen the management of our database, ensure the normal and effective operation of the database, and ensure the security of the database, we have designated database administrator to carry out the responsibilities of daily maintenance, authority control, security protection and other management of the database. Additionally, we require external parties and internal employees involved in clinical trials to comply with confidentiality requirements. Data are to be used only for the intended use, as agreed by the patients and consistent with the informed consent form.

In the clinical trial, the personal information of trial subjects will be removed from the collected clinical data before they are entered into the electronic data capture system of the clinical center. After the trial is completed, such data (without the personal information) will be stored by us and used in statistical analysis to support regulatory submissions. We will retain the data for five years after the test drug in the clinical trial is launched.

All subjects participating in our trials are required to sign an informed consent form approved by the Institutional Ethics Committee before their participation. When a new circumstance arises that may affect a subject's participation in the trial, the informed consent form will be updated, and approval of the form will be sought from the Institutional Ethics Committee. The trial subjects will be required to sign the updated informed consent form to continue their participation in the trial.

Furthermore, we enter into confidentiality agreements with our employees who have access to any aforementioned privacy information. The confidentiality agreements provide that, among other things, these employees are legally obligated not to misuse the confidential information while in office, to surrender all confidential information in possession while resigning, and to retain their confidential obligations after they leave office. We also implement a series of measures to ensure our employees' compliance with our data security measures. For instance, we provide training to our employees on relevant data security policies.

During the Track Record Period and up to the Latest Practicable Date, we did not experience any breach of confidential client information or any other client information-related incidents which could cause a material adverse effect on our business, financial condition or results of operations. During the Track Record Period and up to the Latest Practicable Date, we had not been subject to any material penalty in relation to data privacy and had not conducted any cross-border data transfer activities in connection with our clinical trials.