OVERVIEW

We are a biotechnology company dedicated to developing BsAb-based therapies to treat cancer-associated complications, cancer and age-related ophthalmologic diseases.

Founded in 2010, we have designed and developed a pipeline of seven clinical-stage drug candidates. As of the Latest Practicable Date, five of our seven clinical-stage drug candidates were BsAbs designed for cancer treatment or cancer-associated complications such as MA and MPE. In particular, we have been focusing on the development of the T cell-engaging BsAbs, including M701, M802 and Y150, and the development of the TME-targeted BsAbs, including Y101D and Y332. Our Core Product, M701, is a recombinant BsAb that targets human EpCAM-expressing cancer cells and human CD3-expressing T cells. We completed a Phase I clinical trial of M701 in treating MA in January 2022. We are currently conducting a Phase II clinical trial to evaluate the efficacy of M701 monotherapy in combination with systematic treatment (including targeted therapy, immunotherapy or chemotherapy) in MA patients. In addition, we commenced a Phase Ib/II clinical trial of M701 in treating MPE in China in November 2022. We are developing M701 primarily as a palliative care for MA and MPE, which are severe complications of cancer where fluids build up in the belly or chest cavity of cancer patient, and not for the treatment of cancer itself.

WE MAY NOT BE ABLE TO SUCCESSFULLY DEVELOP OR MARKET OUR CORE PRODUCT OR ANY OF OUR PIPELINE PRODUCTS.

Our Platforms

Equipped with our platform technologies and R&D capability, we are discovering and developing drug candidates for the treatment of cancer and age-related ophthalmologic diseases. We have developed four technology platforms, including self-developed YBODY® platform, Check-BODY platform, and Nano-YBODY™ platform, and UVAX® platform developed in collaboration with WIV.

- Our YBODY® platform is a BsAb platform that focuses on the development of asymmetric human immunoglobulin G (IgG)-like BsAbs with the structure of single-chain variable fragment – antigen-binding fragment – crystallizable fragment (scFv-Fab-Fc structure). The BsAbs with scFv-Fab-Fc structure developed by the YBODY® platform have the following features, including (i) favorable safety profile with low cytokine release syndrome-related toxicity due to their reduced affinity to human immune cells, (ii) high drug product purity of 99%, (iii) minimized mispairing between the heavy chains and light chains of BsAbs, (iv) favorable pharmacokinetics (PK) and pharmacodynamics (PD) profile, and (v) high stability. Based on YBODY® platform, we have developed three T cell-engaging BsAbs, namely M701, M802 and Y150. There were one drug applying for renewal of marketing authorization and six pipelines of innovative drugs under clinical development globally that were specifically developed for the treatment of MA or MPE, including two BsAbs, three cell therapy pipelines and one polypeptide

pipeline and one pipeline of other proteins according to public information; and Y150 is the only CD38-targeting and T cell-engaging BsAb that has entered into clinical development in China.

- Our Check-BODY platform is designed to develop symmetric tetravalent BsAbs. Both Fab and Fv fragments of a Check-BODY molecule show high affinity to the targets. Due to the symmetric structure of these molecules, the purification process of Check-BODY molecules is similar to that of IgG-like monoclonal antibodies (mAbs) and therefore is easier to achieve. We are able to develop Check-BODY molecules with consistent high quality in multiple batches, and can easily scale up the production of Check-BODY molecules. We have discovered and developed Y101D, a PD-L1 × TGF-β BsAb, based on the technologies of our Check-BODY platform.

- Our Nano-YBODY™ platform is designed to develop symmetric tetravalent BsAbs based on single-domain antibodies. The structure enables Nano-YBODY™ molecules to achieve higher binding affinity, better stability, lower immunogenicity and higher production yield than other BsAbs. We have discovered and developed Y400 and Y332 based on the technologies of our Nano-YBODY™ platform. As a testament to our R&D capability, we have transferred all the rights and assets of Y400 to CMS Vision. We are entitled to receive an upfront payment, milestone payments upon the occurrence of certain pre-agreed milestone events, and tiered royalties based on net sales. We have received the full upfront payment of US$5 million for Y400. For more details, please refer to the paragraphs headed "– Collaboration Agreements – Collaboration with CMS Vision" in this section.

- Our UVAX® platform is an immunogen preparation platform for the development of recombinant protein vaccines, which is designed leveraging our BsAb engineering technologies. We utilize our UVAX® platform to form subunit dimers of coronavirus and produce immunogens of the vaccine through high-yield CHO expression and antibody-like purification systems. We have discovered and developed Y2019 based on the technologies of the UVAX® platform.

These platforms serve as an engine for our continuous endeavor to deliver new drug candidates, potential drug candidates we may develop in the future utilizing the molecular structures and CMC processes of the platforms. To protect our proprietary technologies and maintain our competitive advantages, we have built a comprehensive patent portfolio for our platforms. Leveraging our platform technologies, we are able to design and generate different antibody structures, and therefore can quickly expand our pipeline to include additional BsAbs that direct toward a wide range of targets and signaling pathways.

Our Business Model

All of our drug candidates and platform technologies are in-house developed, except for Y2019 and UVAX® platform which we develop in collaboration with Wuhan Institute of Virology, Chinese Academy of Sciences (WIV). Our core business model is to in-house discover, develop and commercialize BsAb-based therapies to treat cancer-associated complications, cancer and age-related ophthalmologic diseases.

Commitment on BsAb-based Therapies

We have been dedicated to developing BsAb-based therapies since our inception in 2010. As of the Latest Practicable Date, five of our seven pipeline drug candidates were BsAbs designed for the treatment of some of the most significant cancer types as well as cancer-associated complications such as MA and MPE.

We carefully select potential targets for our BsAbs, and have adopted a differentiated clinical development strategy for our drug candidates. In particular, we have been focusing on the development of the T cell-engaging BsAbs, including M701, M802 and Y150. We initiated the R&D for M802 back to 2012 and obtained China's first IND approval for in-house developed BsAb for M802. The R&D of our Core Product, M701, commenced in 2013, and we obtained China's second IND approval for in-house developed BsAb for M701. We have also been focusing on the development of the tumor microenvironment (TME)-targeted BsAbs, and are developing Y101D and Y332.

For more details about our key development milestones for BsAbs for cancer treatment, please refer to the paragraphs headed "History, Development and Corporate Structure – Milestones" in this document.

During the Track Record Period, we have invested a significant portion of our efforts and financial resources in the development of BsAbs designed for cancer treatment. In 2021, 2022 and the five months ended May 31, 2023, the R&D expenses attributable to the five BsAbs for the treatment of cancer and its complications in our pipeline amounted to RMB58.2 million, RMB78.5 million and RMB49.4 million, respectively.

R&D Capabilities Fueled by Technology Platforms

Our ability to design and develop BsAbs is largely driven by our technology platforms, namely YBODY®, Check-BODY and Nano-YBODY™. M701, Y150 and M802 were designed and generated by YBODY®, Y101D was designed and generated by Check-BODY, while Y332 and Y400 were generated by Nano-YBODY™. Leveraging our platform technologies, we are able to design and generate different antibody structures.

For more details about our R&D capability and technology platforms, please refer to the paragraphs headed "– Our R&D Platform" in this section.

Strategic Collaborations

To complement our internal efforts, we have entered into collaboration arrangements with third parties in relation to the development of our drug candidates. For details, please refer to the paragraphs headed "– Collaboration Agreements" in this section. In the future, we will continue to seek strategic collaborations with resourceful partners and form additional strategic alliances or other collaborations. We are not currently engaged in negotiations with third parties on strategic collaborations.

Business Strategies to Navigate Pricing Pressure and Competition

We will face pricing pressure for our BsAb drug candidates due to fierce competition in the market. Furthermore, we will also face pricing pressure for our BsAb drug candidates to be included in the National Reimbursement Drug List (NRDL) in China due to their high costs of development and manufacturing. For a pharmaceutical product to be included on the NRDL, a ceiling of such product's reimbursable amount under the national medical insurance will be determined, based on negotiation with the government. In addition, we may face competition from international and Chinese biopharmaceutical conglomerates who may operate on lower margins based on their economies of scale. Accordingly, we will take into consideration clinical demands by MA and MPE patients, clinical value of M701, our market share, the competitive landscape and the price level of other available treatment options for MA or MPE in the relevant market in forming the pricing strategy for M701.

To navigate such pricing pressure and competition, we (i) develop our Core Product, M701, with differentiated market positioning for the treatment of MA and MPE, (ii) maintain clinical dosages of our drug candidates at the microgram or milligram level, ensuring that each treatment course requires minimal medication quantities, thus lowering costs of treatment of our drug candidates and balancing patient affordability with our profitability, (iii) develop stable, high-yield processes under our technology platforms, including YBODY®, Check-BODY and Nano-YBODY™, to produce high-purity BsAb, and (iv) seek strategic collaborations and contract part of our manufacturing process to CMOs/CDMOs to reduce upfront investment costs.

Pipeline of Drug Candidates

We have designed and developed a pipeline of seven clinical-stage drug candidates. In particular,

- We have focused on the development of the T cell-engaging BsAbs. We have developed three T cell-engaging BsAbs, namely M701, M802 and Y150;

- We have adopted the therapeutic strategy towards the efficient targeting of TME. TME plays a critical role in tumor initiation, development and progression, and therefore is becoming an emerging treatment target for cancer. We are developing two drug candidates targeting TME, namely Y101D and Y332; and

- We are developing Y400, a targeted therapy for the treatment of age-related ophthalmologic diseases.

The following pipeline chart summarizes the development status of our selected drug candidates:

Candidate[1]	Target	Technology Platform	Type	Regimen	Indication	Pre-clinical	IND	Phase I		Phase II	Phase III/ Pivotal	Commercial Rights	Current Status/ Upcoming Milestone
								Phase Ia	Phase Ib				
★ **M701**	EpCAM×CD3	YBODY®	BsAb	Mono	Malignant ascites							Global	Phase II commenced in Dec 2021; Expect to initiate Phase III/pivotal trial in Q1 2024 and submit the BLA in Q1 2025
					Malignant pleural effusion							Global	Phase Ib/II commenced in Nov 2022; Expect to initiate Phase III/pivotal trial in Q3 2024 and submit the BLA in Q4 2025
					Solid tumor							Global	Expect to file IND application in Q1 2024 and initiate Phase I/II in Q2 2024
Y101D	PD-L1×TGF-β	Check-BODY	BsAb	Mono	Solid tumors							Global	Phase I commenced in Aug 2021; Expect to complete Phase I in Q4 2023
				Combo with gemcitabine and albumin paclitaxel	Pancreatic cancer							Global	Phase Ib/II commenced in Feb 2023; Expect to complete Phase Ib/II in Q3 2024 and initiate Phase III in Q4 2024
				Combo with bevacizumab	Hepatocellular carcinoma and other advanced solid tumors							Global	Phase Ib/II commenced in Mar 2023; Expect to complete Phase Ib/II in Q2 2025
				Combo with chemotherapy[2]	Small cell lung cancer							Global	Expect to file IND application in Q1 2024
Y150	CD38×CD3	YBODY®	BsAb	Mono	Relapse or refractory multiple myeloma							Global	Phase I commenced in Aug 2021; Expect to complete Phase I in Q2 2024
				Combo with lenalidomide	Relapse or refractory multiple myeloma							Global	Expect to file IND application after the completion of the Phase II portion of Phase II/III clinical trial of Y150 monotherapy for rrMM
Y2019[3]	SARS CoV-2 RBD homodimer	UVAX®	Vaccine	Mono	COVID-19							Global	Completed Phase Ia
M802	HER2×CD3	YBODY®	BsAb	Mono	HER2-positive solid tumors							Global	Completed Phase I
Y332	VEGF×TGF-β	Nano-YBODY™	BsAb	Mono	Solid tumors							Global	IND application approved in Apr 2023; Expect to initiate Phase I in Q3 2023
Y400	VEGF×ANG2	Nano-YBODY™	BsAb	Mono	wAMD, DME and other ocular neovascularization related diseases							Global[4] ***CMS Vision***	IND application approved in Apr 2023

★ **Core Product** **Clinical Stage** **Pre-clinical Stage**

Notes:

(1) Except for Y2019, all of our drug candidates are in-house developed.

(2) Specific combination drug(s) of the trial will be decided prior to the commencement of the trial.

(3) We completed a Phase Ia clinical trial for Y2019 in China in August 2022 which evaluates the safety and tolerability of Y2019 in healthy adults, and obtained ethical committee approval for the Phase IIa clinical trial. Along with the relaxation of the preventative measures for the COVID-19 epidemic and the increasing number of individuals gaining immunity due to COVID-19 infection in China in late 2022, there are uncertainties surrounding the market demand for the COVID-19 vaccine, hence we will deprioritize the clinical development of Y2019 and currently have no immediate plans to initiate the Phase IIa clinical trial for Y2019.

(4) We have transferred all the rights and assets of Y400 to CMS Vision. We are entitled to receive an upfront payment, milestone payments upon the occurrence of certain pre-agreed milestone events, and tiered royalties based on net sales. We have received the full upfront payment of US$5 million and US$1 million milestone for Y400. We, at our own cost, are responsible for all the pre-clinical studies of Y400 that are necessary for (i) the IND application and (ii) the Phase I clinical trial, if any, in accordance with the standards and requirements set by the CDE. Furthermore, if requested by CMS Vision, we will also be responsible for, at CMS Vision's cost, non-clinical toxicology studies of Y400 that are necessary in the Phase II and Phase III clinical trials and CMC studies in Phase III clinical trials in China. For more details, please refer to the paragraphs headed "– Collaboration Agreements – Collaboration with CMS Vision" in this section.

* Three preclinical drug candidates Y180, Y224, and Y229 for the treatment of solid tumors, cachexia, and hematologic malignancy, respectively, are not included in the pipeline chart as they are currently at the early preclinical stage. We plan to continue the preclinical studies of these drug candidates and progressively apply for IND approvals for them in the next few years.

Abbreviations: Mono refers to monotherapy; Combo refers combination therapy; EpCAM refers to epithelial cell adhesion molecule; CD3 refers to cluster of differentiation 3; PD-L1 refers to programmed death ligand 1; TGF-β refers to transforming growth factor-β; CD38 refers to cluster of differentiation 38; COVID-19 refers to coronavirus disease 2019; RBD refers to recombinant receptor-binding domain; HER2 refers to human epidermal growth factor receptor 2; VEGF refers to vascular endothelial growth factor; ANG2 refers to angiopoietin-2; wAMD refers to wet age-related macular degeneration; DME refers to diabetic macular edema.

M701

M701, our Core Product, is a recombinant BsAb that targets EpCAM-expressing cancer cells and T cell surface antigen CD3. We are currently developing M701 primarily as a palliative care for the treatment of MA and MPE which are sever complications of cancer, instead of cancer itself. The M701 intraperitoneal infusion takes approximately one hour and it is in line with the industry standard.

The market size of MA therapies grew from RMB9.9 billion in 2018 to RMB10.8 billion in 2022 and is expected to grow and reach RMB12.6 billion in 2026 and RMB14.4 billion in 2030, and the market size of MPE therapies grew from RMB10.9 billion in 2018 to RMB11.7 billion in 2022 and is expected to grow and reach RMB13.5 billion in 2026 and RMB15.1 billion in 2030.

We are currently conducting a Phase II clinical trial to evaluate the efficacy of M701 monotherapy in combination with systematic treatment (including targeted therapy, immunotherapy or chemotherapy) for MA. In this clinical trial, subjects receive systematic treatment for the treatment of cancer. As these subjects are suffering from MA as a result of their cancer, they are designed to receive M701 monotherapy for the treatment of MA. As advised by our PRC Legal Advisor, pursuant to the "Clinical Trial Technical Guidance Principles for Combination Therapy of Anticancer Drugs" (《抗腫瘤藥物聯合治療臨床試驗技術指導原則》) issued by the CDE, clinical trials for combination therapy should gather evidence of superior efficacy for a particular indication/tumor type relative to any monotherapies within that combination therapy for the same indication/tumor type. This implies that different monotherapies within a combination therapy should be designed for the treatment of the same indication. As M701 and the systematic treatment target different indications (i.e., systematic treatment is used to treat cancer, while M701 is designed to treat MA), this trial is not a study of the combination therapy of M701 and systematic treatment, but rather a study for the monotherapy of M701 for MA. We also expect to commence a pivotal/Phase III clinical trial of M701 in treating MA in the first quarter of 2024. The expected BLA submission time will be in the first quarter of 2025 and the expected commercial launch time will be in the fourth quarter of 2025. In addition, we commenced a Phase Ib/II clinical trial of M701 in treating MPE in China in November 2022. We also expect to commence a pivotal/Phase III clinical trial of M701 in treating MPE in the third quarter of 2024. The expected BLA submission time will be in the fourth quarter of 2025 and the expected commercial launch time will be in the second quarter of 2026. Furthermore, we expect to commence a Phase I/II clinical trial for treatment of solid tumor in the second quarter of 2024.

Y101D

Y101D, a recombinant anti-PD-L1 and anti-TGF-β humanized BsAb, is being developed for the treatment of solid tumors.

According to the CDE and the ClinicalTrials.gov websites, Y101D is the only PD-L1 × TGF-β symmetric tetravalent BsAb that has entered into clinical development globally. There are 16 PD-1/PD-L1 × TGF-β targeted pipelines under clinical trials in China, among which Y101D is the only PD-L1 × TGF-β BsAb and the other 15 pipelines are PD-1/PD-L1 × TGF-β targeted bifunctional antibody-receptor fusion proteins. There is no evidence that BsAbs offer any significant clinical advantages compared to fusion proteins. For a comparative analysis between BsAb and fusion protein, please refer to the paragraphs headed "Industry Overview – Global and China Antibody Drug Market – Overview" in this document. Based on our pre-clinical studies, the anti-TGF-β fragment of Y101D has better stability and biological activity than TGF-β trap *in vivo*. Y101D is designed to simultaneously inhibit the PD-1/PD-L1 axis and the TGF-β signaling pathways, thus having the potential to unleash a synergistic anti-tumor activity and relieve drug resistance. We are currently evaluating Y101D in a Phase I clinical trial for the treatment of metastatic or locally advanced solid tumors, and interim results of this Phase I clinical study show an encouraging safety and efficacy profile for Y101D. We also commenced a Phase Ib/II clinical trial of Y101D in combination therapy for the treatment of advanced/metastatic pancreatic cancer in February 2023. We have commenced the patient enrollment for the Phase II portion of this Phase Ib/II clinical trial in July 2023. We commenced for a Phase Ib/II clinical trial of Y101D in combination therapy for the treatment of HCC and other advanced solid tumors in March 2023. In addition, we plan to submit IND application for Y101D for the treatment of SCLC in the first quarter of 2024.

Y150

Y150 is a recombinant anti-CD38 and anti-CD3 humanized BsAb. We are developing Y150 for the treatment of rrMM in a Phase I clinical trial. We plan to commence a Phase II/III clinical trial of Y150 monotherapy in China for the treatment of rrMM. We also plan to initiate a Phase Ib/II clinical trial for Y150 in combination with lenalidomide as second-line treatment for rrMM after the completion of Phase II portion of Phase II/III clinical trial of Y150 monotherapy for rrMM.

According to the CDE website, Y150 is the only CD38-targeting and T cell-engaging BsAb that has entered into the clinical development in China. As of the Latest Practicable Date, there were 22 and nine CD38 targeted antibody drug candidates or fusion proteins for the treatment of MM under clinical development globally (excluding China) and in China, respectively. There is no evidence that BsAbs offer any significant clinical advantages compared to fusion proteins. For a comparative analysis of BsAb and fusion protein, please refer to the paragraphs headed "Industry Overview – Global and China Antibody Drug Market – Overview" in this document. Y150 is well-designed to bind to both CD38 on multiple myeloma (MM) tumor cells and CD3 on T cells, inducing the activation of the T cells, improving the targeting of activated T cells, and allowing the activated T cells to attack the target tumor cells.

Y2019

Y2019 is a recombinant receptor-binding domain (RBD)-dimer subunit SARS-CoV-2 vaccine candidate for COVID-19.

We completed a Phase Ia clinical trial for Y2019 in China in August 2022 which evaluated the safety and tolerability of Y2019 in healthy adults aged 18 years or older, and have obtained satisfactory 7-day and 90-day safety data post immunization. Along with the relaxation of the preventative measures for the COVID-19 epidemic and the increasing number of individuals gaining immunity due to COVID-19 infection in China in late 2022, there are uncertainties surrounding the market demand for the COVID-19 vaccine, hence we will deprioritize the clinical development of Y2019 and currently have no immediate plans to initiate the Phase IIa clinical trial for Y2019.

M802

M802 is an anti-HER2 and anti-CD3 humanized BsAb. We are developing M802 for the treatment of HER2-positive solid tumors.

We have completed a Phase I clinical trial for M802 in China. We will consider exploring potential out-licensing opportunities of M802 in the global market. M802 displays significant cytotoxicity to some Herceptin-resistant breast cancer cells (JIMT-1, MDA-MB-231), indicating an emerging treatment for HER2-positive and/or Herceptin-resistant breast cancer patients. M802 binds to HER2 with high affinity, and binds to CD3 receptor with lower affinity, which reduces the toxicity of cytokine release syndrome caused by the activation of T cells. Data obtained from the Phase I clinical trial of M802 also indicates that M802 has a favorable safety profile.

Y332

Y332, a recombinant anti-VEGF and anti-TGF-β BsAb, is being developed for the treatment of a variety of solid tumors. We received IND approval for Y332 for metastatic or locally advanced solid tumors in April 2023.

In pre-clinical studies, Y332 shows high affinity to both VEGF and TGF-β, favorable bioactivity and stability, and demonstrates encouraging anti-tumor effects. Y332 can also be used in combination of immune checkpoint inhibitors to deliver an enhanced anti-tumor effect. There is currently only one VEGF × TGF-β antibody fusion protein, namely ZGGS18, that has entered into clinical development in China. Based on our internal pre-clinical studies, Y332 shows favorable bioactivity and stability.

Y400

Y400 is a recombinant anti-VEGF and anti-ANG2 BsAb. The CMC studies for Y400 have been completed and the CDE approved the IND application for Y400 in April 2023.

In our *in vitro* experiment, Y400 has shown an encouraging efficacy profile. Y400 also has a high concentration formulation which is an important factor for the success of such ophthalmic drugs.

As a testament to our R&D capability, we have transferred all the rights and assets of Y400 to CMS Vision. For more details, please refer to the paragraphs headed "– Collaboration Agreements – Collaboration with CMS Vision" in this section.

We aim to treat cancer-associated complications, cancer and age-related ophthalmologic diseases. According to the WHO website, cancer is the second-leading cause of death globally. The oncology drug market in China has expanded significantly in the past several years, primarily driven by increasing cancer incidences, improving affordability of marketable drugs and technological progress in the treatment paradigm. According to the Global Cancer Observatory (GLOBOCAN), International Agency for Research on Cancer (IARC) and National Central Cancer Registry of China (NCCR), the annual cancer incidence in China is expected to increase from approximately 4.8 million in 2022 to approximately 5.8 million in 2030. Our current pipeline drug candidates address some of the most significant cancer types, as well as cancer-associated complications such as MA and MPE. Therefore, we believe we are well-positioned to capture the market opportunities in the PRC oncology drug market.

According to the National Bureau of Statistics of China, the population of senior people aged at or above 65 years old in China is expected to increase from approximately 210 million in 2022 (approximately 15% of all China's population) to approximately 273 million in 2030 (approximately 22% of all China's population). China has one of the fastest-growing aging populations in the world, resulting in an increasing clinical demand for preventive and therapeutic drugs for age-related ophthalmologic diseases.

To fulfill our mission to discover and develop innovative drugs for the healthier lives of patients, we are committed to the continuous development and commercialization of BsAb-based therapies. By advancing the R&D of our drug candidates, we strive to deploy our innovation engine in the fight against cancer and age-related ophthalmologic diseases for the benefit of patients to improve their quality of life and survival rate.

OUR STRENGTHS

Focusing on the development of BsAbs in China

We are focusing on the development of BsAbs in China. We have developed YBODY®, a BsAb platform that focuses on the development of asymmetric IgG-like BsAbs with scFv-Fab-Fc structure. M701, our Core Product, is an EpCAM × CD3 BsAb that focuses on the treatment of MA and MPE. According to public information, as of the Latest Practicable Date, there were one drug applying for renewal of marketing authorization and six pipelines of innovative drugs under clinical development globally that were specifically developed for the treatment of MA or MPE, including two BsAbs, three cell therapy pipelines and one polypeptide pipeline and one pipeline of other proteins; and Y150, the only CD38-targeting and T cell-engaging BsAb to have entered into clinical development in China, according to the CDE website. As of the Latest Practicable Date, there were 22 and nine CD38 targeted antibody drug candidates or fusion proteins for the treatment of MM under clinical development globally (excluding China) and in China, respectively. There is no evidence that BsAbs offer any significant clinical advantages compared to fusion proteins. For a comparative analysis of BsAb and fusion protein, please refer to the paragraphs headed "Industry Overview – Global and China Antibody Drug Market – Overview" in this document.

We built our pipeline to focus on the development of new BsAb drugs. In recent years, BsAbs have attracted increasing interest in scientific and clinical research for the treatment of cancer. Multiple signaling pathways are involved in tumor cell development. Even if a mutationally activated pathway can be blocked by an inhibitor, tumor cells may evade the inhibitor by activating other pathways. Therefore, through targeting two different antigen binding sites to block two different signaling pathways, or through enhanced binding affinity to prevent the tumor immune escape, BsAbs can deliver potent and tumor-specific killing effect. The therapeutic effect of BsAbs, such as T cell engaging BsAbs, are 100- to 1,000-fold stronger than that of mAbs. Furthermore, BsAbs have a wide range of applications in tumor immunotherapy. However, the safety and efficacy of BsAbs in treating cancer and its complications compared to the current treatments for these diseases remain to be substantiated in clinical applications. In addition to cancer treatment, BsAbs also have potential in treating other diseases, such as ophthalmology and hemophilia.

We carefully select potential targets for our BsAbs, and have adopted a differentiated clinical development strategy for our drug candidates. We have focused on the development of the T cell-engaging BsAbs, including M701, M802 and Y150 that can destruct tumor cells through T cell activation. T cell-engaging BsAb is a new class of therapeutic agents designed to simultaneously bind to T cells and tumor cells via tumor-cell specific antigens in immunotherapy. In addition, we are also focusing on the development of the TME-targeted BsAbs, including Y101D and Y332. TME plays a critical role in tumor initiation, development and progression, and therefore is becoming an emerging treatment target for cancer.

Our ability to design and develop BsAbs is largely driven by our technology platforms, namely YBODY®, Check-BODY and Nano-YBODY™. The design and production of BsAbs present a unique set of challenges due to the presence of BsAb-specific byproducts, such as mispaired products, undesired fragments and higher levels of aggregates, that are otherwise absent or present in lower levels in mAb cells. Leveraging our platform technologies, we are able to overcome these technical difficulties and have made the following achievements in developing BsAbs:

- *Minimum mismatches and high purity*. The main challenge in the development of BsAbs is that there are two types of chains, heavy and light, and it is difficult yet critical to prevent mismatches. We have successfully addressed this challenge by utilizing optimized technologies in the design of our BsAbs. For instance, we introduced the Knobs-into-Holes and salt-bridge technologies in the Fc modification to disfavor the formation of homodimers and achieve the desired heterodimeric BsAbs. Furthermore, by utilizing the proprietary design of the scFv segment, we are able to completely avoid the mismatch of heavy chains and light chains for YBODY® molecules. We can achieve 99% product purity of the YBODY® molecules by (a) achieving over 90% accurate pairing of heavy chains based on the technologies of the YBODY® platform and (b) eliminating those less than 10% mismatches in heavy chains by applying the traditional protein purification process techniques.

- *High stability*. BsAbs are engineered artificial antibodies, and thus are more unstable than mAbs. We utilize antibody engineering technologies to design the optimized structure of our BsAbs and effectively achieve high stability of these BsAbs.

- *Minimum immunogenicity*. With an increasing number of BsAbs entering into clinical development, recent data highlights immunogenicity as an emerging challenge in the development of such biologics. Repetitive administration of these protein-based therapeutics to immunocompetent patients elicit immune responses in the form of anti-drug antibodies, which in turn impact their pharmacological properties and may trigger adverse events. We have implemented a drug-specific immunogenicity risk assessment strategy to minimize immunogenicity risks in our drug candidates. Through *in vitro* and *in vivo* experiments, we selectively choose the candidates with lowest level of immunogenicity risks for next-step research and development.

- *Effective target selection and binding*. We conduct thorough evaluations for various targets, and select the optimized targets with clinical and commercial potentials in developing our BsAbs. For instance, one of our focuses on the BsAb development is to develop the T cell-engaging BsAbs, which has potential in treating both hematological malignancies and solid tumors. The dual-targeting mechanism of these BsAbs enable them to target both TAAs on tumor cells and the CD3 receptor on the surface of T cells, bridging them together and activating T cells to kill the cancer cells.

With the increasing trend of population aging and growing cancer incidences in China, it is expected that the clinical demands for effective oncology drugs will increase significantly. The market size of the PRC oncology market has increased from approximately RMB157.5 billion in 2018 to approximately RMB233.6 billion in 2022, and is expected to reach approximately RMB586.6 billion in 2030. In particular, due to the encouraging efficacy and manageable safety profile, the market size of PRC therapeutic antibody drugs has increased from approximately RMB16.0 billion in 2018 to RMB75.9 billion in 2022, and is expected to reach RMB479.3 billion in 2030.

Technology platforms fueling the research and development of drug candidates

Our core technology platforms enable us to effectively select innovative targets, optimize molecule structure design and accelerate the drug development process. We have successfully built four technology platforms, including self-developed YBODY®, Check-BODY and Nano-YBODY™ platform, and UVAX® platform developed in collaboration with WIV. Leveraging the technologies of these platforms, we are able to design and generate different antibody structures. As such, we can select targets and signaling pathways with clinical and commercial value and design and modify the structure of our BsAbs to bind such targets. Therefore, we are able to quickly expand our pipeline to include additional BsAbs that direct toward a wide range of targets and signaling pathways, optimize the use of our resources and expertise, and achieve the maximized value of our pipeline candidates.

YBODY® Platform

Our in-house developed YBODY® platform is a BsAb platform that focuses on the development of asymmetric human IgG-like BsAbs with scFv-Fab-Fc structure. The features of our YBODY® platform enable us to discover and develop BsAbs to target both TAAs of a variety of tumor cells and the receptors on the surface of human immune cells (such as T cells, NK cells and macrophages). We have discovered and developed three T cell-engaging BsAbs, including M701 (an EpCAM × CD3 BsAb), M802 (a HER2 × CD3 BsAb) and Y150 (a CD38 × CD3 BsAb), based on the technologies of our YBODY® platform.

YBODY® has an IgG-like structure, so it can provide good pharmacokinetics and pharmacodynamics. The well-designed structure of the asymmetrical YBODY® molecules features moderate affinity to human immune cells, which reduces the toxicity of cytokine release syndrome caused by the activation of T cells. The proprietary design of the scFv structure of YBODY® molecules is applied to avoid mispairing of heavy chains and light chains. Furthermore, we can easily identify the misassembled impurities of BsAbs through the asymmetry of the molecular weight and thus remove the impurities through the asymmetry of the molecular charge. In this way, we improve the efficiency of the desired dimerization and formation of YBODY® molecules.

Check-BODY Platform

Our in-house developed Check-BODY platform, an immune checkpoint platform, is designed to develop symmetric tetravalent BsAbs to direct toward the most prevailing targets, including dual immune checkpoints, immune checkpoint and cytokine, as well as the immune checkpoint and tumor microenvironment target. We have discovered and developed Y101D based on the technologies of our Check-BODY platform.

A Check-BODY molecule is composed of three segments: two Fab fragments from antibody A to target TAAs, two variable fragments from antibody B to target and activate the T cells to kill the tumor cells, and Fc fragments from human IgG with or without modification. We apply the genetic engineering technology to use protein linkers to connect the Fab fragments with Fv fragments and the Fc fragments, respectively, to achieve the ultimate symmetric tetravalent BsAb products. Both Fab and Fv fragments of a Check-BODY molecule show high affinity to the targets. Due to the symmetric structure of these molecules, the purification process of Check-BODY molecules is similar to that of IgG-like mAbs and therefore is easier to achieve. Therefore, the product purity of Check-BODY molecules can reach over 90% by the one-step affinity chromatography.

Nano-YBODY™ Platform

Our in-house developed Nano-YBODY™ platform is designed for the development of symmetric tetravalent BsAbs based on single-domain antibodies. We have discovered and developed two IND-enabling drug candidates, namely Y400 and Y332, based on the technologies of the Nano-YBODY™ platform. We apply genetic engineering technology to connect the heavy chain of an IgG mAb with the variable domain of a heavy chain (VHH) of a single domain antibody to achieve the ultimate symmetric tetravalent BsAbs with an IgG-$(VHH)_2$ structure. Nano-YBODY™ molecules show high affinity to both targets. These molecules also have favorable performance in production expression, purification yield, liquid formulation concentration, stability, solubility and shelf life.

UVAX® Platform

Our UVAX® platform, developed in collaboration with WIV, is an immunogen preparation platform for the development of recombinant protein vaccines, which is designed leveraging our BsAb engineering technologies. We utilize our UVAX® platform to form subunit dimers of coronavirus efficiently and produce immunogens of the vaccine through reliable, safe and high-yield CHO expression and antibody-like purification systems. We have discovered and developed Y2019 based on the technologies of the UVAX® platform. The immunogen of Y2019 is a homodimerized protein of which two RBD monomers are linked covalently by an interdomain disulfide bond at the C terminus of the RBD of the S protein. According to the design, the SARS-CoV-2 RBD gene (319–541 amino acid) is fused with the Fc gene of human IgG, and the DNA of the genes are constructed into the vector to express the RBD-Fc fusion protein. The Fc fragment of the fusion protein is then removed by thrombin digestion and purification to obtain the RBD homodimer protein as the immunogen of the vaccine. Therefore, UVAX® vaccines have high production expression, purification yield and stability.

Comprehensive Patent Protection

To protect our proprietary technologies and maintain our competitive advantages, we have built a patent portfolio for our core technology platforms. In particular, as of the Latest Practicable Date, (a) we filed two PCT applications for our YBODY® Platform, and had entered into national phase in major markets, including seven granted patents in China, Canada, the U.S. and Japan, and six pending patent applications in China, Canada, Europe, Japan and South Korea; (b) we filed one PCT application for our Check-BODY Platform, and entered into national phase in major markets, including one granted patent in China, and six pending patent applications in China, the U.S., Canada, South Korea, Europe and Japan, and (c) we filed one PCT application for our general Fc mutation technology, and entered into national phase in major markets, including one granted patent in China, three pending patent applications in the U.S., Europe and Japan. We will continue to seek patent protections for our core technology platforms and drug candidates.

A pipeline of drug candidates with market potential developed under our differentiated clinical development strategies

We have adopted a differentiated clinical development strategy to maximize the clinical and commercial value of our drug candidates. We select potential targets for our drug candidates.

T cell-engaging BsAbs

We have developed three T cell-engaging BsAbs, namely M701, M802 and Y150. Although CD3-targeted BsAbs have shown promising effects in treating hematological tumors, such BsAbs have certain limitations in treating solid tumors. Our well-designed T cell-engaging BsAbs can overcome such limitations. The dual-targeting mechanisms of these BsAbs enable them to target both TAAs on solid tumor cells and the CD3 receptors on the surface of T cells, bridging them together and activating T cells to kill the cancer cells.

M701 – a potentially standard palliative treatment option for MA and MPE

M701, our Core Product, is an EpCAM × CD3 BsAb currently being developed as a palliative care primarily for the treatment of MA and MPE, which are sever complications of cancer, instead of cancer itself. According to public information, as of the Latest Practicable Date, there were one drug applying for renewal of marketing authorization and six pipelines of innovative drugs under clinical development globally that were specifically developed for the treatment of MA or MPE, including two BsAbs, three cell therapy pipelines and one polypeptide pipeline and one pipeline of other proteins. We are evaluating M701 for the treatment of MA in a Phase II clinical trial and MPE in a Phase Ib/II clinical trial. MA and MPE occur in association with a variety of cancer types and raise significant treatment challenges.

The currently available treatment options include a multitude of different procedures with limited efficacy and a certain degree of risks. For example, according to the literature, diuretic therapy is only less than 50% effective in treating MA. Patients who fail to respond to diuretic therapy and nutritional support needed to undergo laparotomy for fluid release. Around 90% of patients have symptomatic relief, but this is maintained for an average of only approximately 10 days and generally needs to be repeated. Repeated massive puncture drainage carries the risk of reduced effective circulating blood volume, hyponatremia, renal dysfunction and hypoproteinaemia. Local chemotherapeutic drug therapy has an efficiency of only 40%-60% in treating MA. Closed drainage of the pleural cavity with a chest tube is only 11%-40% effective for 30 days to control MPE. The incidence of complications from pleural cavity atresia is up to more than 40%. Therefore, there remains a medical demand of MA and MPE patients for an effective therapy. As of the Latest Practicable Date, no BsAb has been approved for the treatment of MA or MPE in China, according to the CDE website. We believe that M701 has the potential to capture this market opportunity and address the medical demands.

Both MA and MPE are commonly found in various cancer types. To effectively address the challenges in treating MA and MPE and embrace the market opportunities, we have selected EpCAM as the target on tumor cells. Abnormal EpCAM expression is regularly found in cancer patients who tend to develop MA and MPE, according to relevant research papers. EpCAM expression is highly tumor-specific as normal cells in the peritoneal compartment do not express EpCAM on their surface. According to relevant research papers, such as Went, P., et al. "Frequent high-level expression of the immunotherapeutic target EpCAM in colon, stomach, prostate and lung cancers." British journal of cancer, high EpCAM expression is observed in approximately 90% of gastric cancer, approximately 60% of lung cancer, over 50% of ovarian cancer and approximately 50% of breast cancer. Therefore, EpCAM is deemed a particular suitable target for treating MA and MPE. With a clear mechanism of actions, and encouraging clinical results, we believe M701 has potential to become a standard treatment option for MA and MPE.

Y150 – a candidate with innovative mechanism for rrMM patients

We are developing Y150, a CD38 × CD3 BsAb, for the treatment of rrMM. We are evaluating Y150 in a Phase I clinical trial. Despite the introduction of multiple therapies, MM remains incurable, and patients experience multiple relapses and/or become refractory to current standard-of-care treatments. CD38 is highly expressed in MM cells, making it a desirable target for innovative therapeutic antibodies. The MM incidence in China increased from 20.1 thousand in 2018 to 22.4 thousand in 2022, and is expected to further reach 27.6 thousand in 2030. The MM patients generally have a longer overall survival period, and thus need different therapies with diversified mechanisms of actions due to drug resistance, representing a need for new classes of therapies with innovative mechanisms of action. According to the CDE website, Y150 is the only CD38-targeting and T cell-engaging BsAb to have entered into clinical development in China. As of the Latest Practicable Date, there were 22 and nine CD38 targeted antibody drug candidates or fusion proteins for the treatment of MM under clinical development globally (excluding China) and in China, respectively. Outside of China, there is only one CD38 × CD3 BsAb, namely ISB-1342 of Ichnos Sciences, under

development in a Phase I clinical trial. Besides that, SAR442257, an anti-CD38/CD28/CD3 antibody being developed by Sanofi, is also under clinical development, evidencing the therapeutic potentials of CD38 and CD3. There is no evidence that BsAbs offer any significant clinical advantages compared to fusion proteins. For a comparative analysis of BsAb and fusion protein, please refer to the paragraphs headed "Industry Overview – Global and China Antibody Drug Market – Overview" in this document.

M802 – targeting HER2-positive solid tumors to meet significant demands for second-line treatments

We are developing M802, a HER2 × CD3 BsAb, initially for the treatment of HER2-positive solid tumors. We have completed a Phase I clinical trial for M802. We will consider exploring potential out-licensing opportunities of M802 in the global market. The breast cancer incidence in China increased from approximately 320.7 thousand in 2018 to approximately 341.0 thousand in 2022, and is expected to further reach approximately 370.6 thousand in 2030. Patients with breast cancer generally have a longer overall survival period, and therefore need to receive multiple second-line treatments with different and innovative mechanism of actions. Furthermore, HER2 is also frequently observed in bladder cancer, pancreatic cancer, ovarian cancer and gastric cancer, representing a huge market with demands.

Drug candidates targeting TME

We are adopting innovative therapeutic strategies towards an efficient targeting of tumor microenvironment (TME). The tumor mass consists of not only a heterogeneous population of cancer cells but also a variety of resident and infiltrating host cells, secreted factors and extracellular matrix proteins, collectively known as the TME. TME plays a pivotal role in tumor initiation, progression and therapeutic resistance by creating a dynamic interaction with cancer cells.

We are developing two drug candidates targeting TME, namely Y101D and Y332.

Y101D – overcoming the limitations of anti-PD-L1 antibodies

We are developing Y101D, a PD-L1 × TGF-β BsAb, for the treatment of solid tumors. We are evaluating Y101D in a Phase I clinical trial. Therapeutic antibodies that target PD-1/PD-L1 axis induce potent and durable anti-tumor responses in multiple types of solid tumors. However, only a subset of patients benefit from anti-PD-1/PD-L1 therapies. For instance, among various PD-1/PD-L1 approved indications, the overall response rate (ORR) for head and neck squamous cell carcinoma and liver cancer is less than 35% (i.e. over 65% of patients are primary refractory). Microsatellite stable type colorectal cancer, pancreatic cancer, and biliary cancer are less likely to benefit from and are not approved for PD-1/PD-L1 treatment; the median progression-free survival (PFS) for non-squamous and squamous lung cancer is 8-9 months; the median PFS for small cell lung cancer is only 5.2 months; and the median PFS for esophageal squamous cell carcinoma is only 6.9 months, indicating that these patients will develop resistance after treatment for 5-9 months. Y101D is designed to simultaneously inhibit

the PD-1/PD-L1 axis and the TGF-β signaling pathways, and has the potential to unleash a synergistic anti-tumor activity and relieve drug resistance. By simultaneously inhibiting the PD-1/PD-L1 axis and the TGF-β signaling pathways, Y101D restores the dysregulated anti-tumor immunity of cancer patients and establishes an immuno-supportive TME.

Y332 – unlocking the therapeutical potential for both VEGF and TGF-β pathways

Y332 is a VEGF × TGF-β BsAb for the treatment of solid tumors. By simultaneously targeting VEGF and TGF-β, Y332 unlocks the therapeutical potential of blockades for both pathways, synergistically transforming the immuno-suppressive TME of cancer patients and restoring their dysregulated anti-tumor immunity. We received IND approval for Y332 for metastatic or locally advanced solid tumors in April 2023. Y332 can also be used in combination with immune checkpoint inhibitors to deliver an enhanced anti-tumor effect.

Focusing on increasing age-related ophthalmologic diseases

We have focused on the development of drug candidates to address the rapidly growing age-related ophthalmologic diseases. In particular, we have taken a collaborative approach to develop Y400, a VEGF × ANG2 BsAb. The CDE approved the IND application for Y400 in April 2023. VEGF and ANG2 are two important targets that can promote the proliferation and leakage of new blood vessels, as well as the formation of abnormal vascular structure, which will eventually lead to vision loss. As a BsAb simultaneously targeting VEGF and ANG2, Y400 is an emerging prospect for the treatment of wAMD, DME and other ocular neovascularization-related diseases when compared to currently prevailing anti-VEGF therapies. wAMD and DME patient incidence reached approximately 4.0 million and 7.3 million in China in 2022, accounting for approximately 1.9% and 3.5% of senior people aged at or above 65 years old in China.

A GMP-compliant CMC platform

We have established a GMP-compliant chemistry, manufacturing and control (CMC) platform to leverage our experience in the CMC for BsAbs with various structures. We believe such platform will serve as a foundation for our large-scale commercial production in the future. CMC refers to activities to properly define methods for manufacturing processes, product characteristics and testing, product storage and release to clinical usage in order to ensure that a pharmaceutical product is safe, effective and consistent among different batches. Although the discovery and protein engineering techniques of BsAbs are now relatively advanced, the development of BsAbs still faces many challenges in the CMC comparing to the development of typical mAb drugs, including low expression titer of the target BsAbs, more impurities to remove, less stability of the intermediates, and hurdles in process scale-up. Therefore, the execution of an appropriate CMC development strategy is vital to the success of the overall drug development program.

Our CMC strategies include evaluating the stability of the candidate BsAb molecules at the early development stage, choosing the monoclonal cells with high titer and high purity for BsAb production, tailoring purification methods fit for the molecule characteristics, and using sustainable scale-up strategies for large-scale production.

- *High expression level in cell line development.* We leverage the world's leading CHO GS-KO expression system to design and produce various types of BsAbs with different structures. As such, we are able to obtain stable cell lines at high expression level.

- *High expression level in upstream process development*. To improve the titers of target BsAbs, we optimize the manufacturing process by adopting the Fed-Batch mode. With the optimized techniques, we are able to achieve the average expression level for Check-BODY molecules and Nano-YBODY™ molecules of approximately 6.0g/L and 8.0g/L, respectively, far beyond the industry average in China.

- *High purity in downstream development*. Through downstream development and optimization, we are able to achieve high purity of our BsAbs, which has led to a favorable safety profile of our candidates. The total yield of BsAbs in our purification process can reach 75%, and the purity of the drug substance can reach 99%, with low levels of impurities.

- *High concentration formulations development*. We are able to produce different types of formulation products, such as liquid and lyophilized dosage forms. Through the formulation screening and optimization, our BsAb formulations are able to reach a concentration rate of 140mg/ml with low product viscosity and great stability, exceeding the industry average in China.

- *Established analytical methods to expediate the CMC process*. We have developed more than 30 platform analytical methods to support our drug development. At the early stages of drug development, we apply these analytical methods to analyze molecular properties and characterize molecular structures, which can expedite sample testing and improve our development efficiency. At the CMC stage, the analytical methods are fine-tuned by us to accommodate projects involving different BsAbs. As such, we are able to efficiently support and accelerate our product development and manufacturing process.

- *Compliance with global regulatory standards.* As drug development moves from concept to commercialization, the breadth and depth of CMC documentation required in regulatory submissions increases in parallel. Equipped with our CMC platform, we are able to comply with GMP requirements and consistently deliver BsAbs in compliance with the requirements of the NMPA, the FDA and the EMA. Our CMC capabilities to meet global regulatory standards are evidenced by our receipt of NMPA and FDA IND approvals for our drug candidates, namely M701, M802, Y150 and Y101D.

- *Established and expanding manufacturing facility.* As of the Latest Practicable Date, we had a manufacturing base of approximately 1,400 square meters with a scale of 500L (two 200L bioreactors and two 50L bioreactors) for antibody production. While we already have sufficient manufacturing capability to meet the demands for Phase I to Phase II clinical development, we plan to continue to enhance our manufacturing capability.

Execution-driven management and R&D teams

Our core management team is composed of industry veterans with an average of more than ten years of experience and a track record of discovery, development and commercialization of innovative drugs. We, as one team led by our senior management, strive to deliver innovative drugs with aligned aspirations to address large medical demands. Leveraging our team's capability to consistently advance the development of our drug candidates, implement differentiated yet effective clinical development strategy, expediate the CMC process and achieve stable and high-quality manufacturing, we believe we are able to continuously develop innovative drugs and achieve our mission.

Our co-founder, Dr. Zhou Pengfei, has over 33 years of extensive experience in the healthcare and pharmaceutical industries, focusing on oncology treatment and innovative drug development. Dr. Zhou worked for a number of leading MNCs, including Schering-Plough Corporation, Crown Bioscience (Beijing) Co., Ltd., and Pfizer-Crown Asian Cancer Research Center. Dr. Zhou also has over eight years of experience serving as a physician. Dr. Zhou has obtained a Ph.D. in molecular immunology from McMaster University, served as a visiting scholar for clinical research at McMaster University School of Medicine, and received post-doctoral training in immunology from Stanford University. Dr. Zhou has filed over 80 patent applications including 15 PCT applications, and has been granted with over 40 issued patents. He has published over 50 research papers. In addition, Dr. Zhou is the leader of the Major Science and Technology Special Project for "Significant New Drugs Development" ("重大新藥創制"科技重大專項) under the 12th Five-Year Plan and the 13th Five-Year Plan. Dr. Zhou also received the honor as a leader leading our Company as one of the "Key Overseas Chinese Entrepreneurial Teams (重點華僑華人創業團隊)" in 2015 recognized by the Overseas Chinese Affairs Office of the State Council (國務院僑務辦公室).

We have attracted a large number of talents. Our team comprises experts with extensive global drug development experience in the pharmaceutical industry. Our department heads and other key technical personnel have served various roles in leading multinational pharmaceutical companies, having complementary experience covering various stages of the entire development lifecycle of drug products, including pre-clinical studies, clinical development, manufacturing and commercialization.

We have developed a cohesive and vibrant corporate culture that inspires and encourages innovation, which we believe helps us to attract, retain and motivate an aspiring team to drive our fast growth. We strive to build a young, yet experienced team with extensive drug development experience, complementary skillsets, and synergies in working style. As of the Latest Practicable Date, we have built a team of 129 members, including 104 R&D personnel, 43.4% of which have a master's degree or higher.

We believe our dedicated team with its deep industry expertise is the core pillar of our Company and will drive us toward success.

OUR STRATEGIES

To achieve our mission and to further strengthen our market position, we plan to implement the following strategies:

Accelerate the development of our drug candidates

The acceleration of our R&D progress for our drug candidates is our top priority. We will continue to rapidly advance the development of our drug candidates and invest more resources in the following areas: (a) clinical development advancement of our clinical-stage drug candidates to maximize their clinical and commercial potentials; (b) exploration of the potentials of our drug candidates in combination therapy with chemotherapy, radiotherapy and immunotherapy to achieve enhanced efficacy with a favorable safety profile; (c) advancement of the clinical development of M701 for MA to bring M701 to the market in an accelerated pace, and active advancement the clinical development of M701 for other indications, including MPE in multi-center clinical trials; (d) advancement of the clinical development of Y101D, particularly for indications for which no immunotherapy has been approved, including microsatellite stable colorectal cancer, pancreatic cancer, biliary tract cancer, inoperable advanced breast cancer, endometrial cancer, central nervous system tumors, sarcomas (including osteosarcomas), prostate cancer, and neuroendocrine tumors; (e) the further development of our pre-clinical drug candidates, with the aim to advance additional new candidates into clinical development, and (f) the active pursuit of opportunities to develop our drug candidates in major overseas markets.

Continue to expand our pipeline through in-house R&D efforts and collaborations

We believe continuous innovation is critical to our competitiveness and sustainable growth. We will continue to dedicate ourselves to the in-house discovery and development of innovative drug candidates in their respective classes. We endeavor to optimize our drug development process to accelerate the bench-to-bedside translation and improve R&D cost-effectiveness as we maintain our high success rate. We plan to further invest in our core technology platforms, design and generate different antibody structures to bind different targets, and further expand our pipeline to include additional BsAbs that direct toward a wide range of targets and signaling pathways. We will continue to focus on addressing medical demands in oncology and aging-related ophthalmologic disease areas to enrich our pre-clinical and clinical pipeline to include candidates that pinpoint targets in these areas in order to capture market opportunities. Furthermore, we will continue to design and implement an efficient and cost-conscious clinical development plan to shorten the time-to-market phase of our drug candidates.

In addition, we will continue to work closely with our existing strategic partners, WIV and CMS Vision, to help advance our collaborative programs. Our dedicated team will also continue to explore additional or expand strategic relationships and opportunities with multinational pharmaceutical companies and domestic companies to derive further value from our platforms and fully exploit the potentials of our pipeline candidates. Given the breadth of opportunities that our technologies and platforms provide, we plan to continue to adopt a flexible approach to pursuing various types of partnerships, including co-development and licensing arrangements. Leveraging our partners' complementary resources and expertise, we believe we are able to further enrich our pipeline, advance the development of our existing candidates, and maximize the commercial value of our pipeline.

Continue to enhance our manufacturing capabilities

We will continue to enhance our manufacturing capabilities for our BsAbs to leverage our CMC capabilities. We plan to further improve our techniques to ensure the consistent high quality of our drug candidates, and to lower the product costs to effectively compete with other market players.

We plan to further enhance our CMC and manufacturing capabilities through procurement of new machinery, instrument and equipment to improve the efficiency of our production and the quality of our products. This includes: (a) acquiring perfusion systems, fully automatic ultrafiltration systems, small-scale bioreactors, and other equipment to improve antibody expression per unit time and volume of our production line, thereby increasing the efficiency of formulation development sample preparation, (b) procuring automated filling equipment to improve filling efficiency, (c) procuring biomolecular mass spectrometers, high-performance liquid chromatography, capillary electrophoresis, and other analytical quality control equipment to conduct more comprehensive and in-depth characterization of product quality attributes, thereby streamlining product quality control process, and (d) upgrading the corresponding water systems, cold storages to optimize the compatibility of the water system with our current production site.

We will also recruit more professionals in CMC and other technicians. With enhanced manufacturing capabilities, we believe we will be able to deliver our drugs to meet the potential increasing demands for our drugs in the future.

Continue to build our commercialization capabilities

To continue advancing the potentials of our clinical-stage candidates, we will continue to build our commercialization capabilities. We plan to build our own commercialization team in China with an initial focus on the sales and marketing of our Core Product M701. We intend to market M701 as well as our other drug candidates primarily through a physician-targeted marketing strategy, focusing on direct and interactive communication with key opinion leaders and physicians in the respective therapeutic areas to promote the differentiating clinical aspects of our drug candidates, and to increase the brand awareness and recognition of our Company and our drugs.

We also plan to collaborate with qualified and experienced CSOs to promote and market other drug candidates upon approval in China. Leveraging the CSOs' experience and sales network in China, we should rapidly achieve wide market coverage of our drugs. We also plan to explore the potential of our drugs in overseas markets, mainly through out-licensing arrangements and/or collaborations with local partners in the future.

Continue to attract, nurture and retain skilled talent

We place a high priority on selecting, nurturing and retaining top talents. Leveraging our position in the development of BsAbs as well as our brand recognition in China, we have been able to, and will continue to, attract skilled talents. We are committed to providing our team with career development and learning opportunities, trainings and mentorship from our team leaders, competitive compensation, and a supportive and dedicated work environment.

To support our continuous growth, we will continue to retain top talent as we enlarge our talent pool. With more of our drug candidates advancing into the clinical stage, in the near term we intend to strengthen our team by attracting talent with extensive experience in clinical development, regulatory affairs and commercialization in China.

OUR DRUG CANDIDATES

As a biotechnology company, we have developed all of our pipeline candidates in-house by utilizing our proprietary and integrated R&D platforms. We have designed and developed a pipeline of seven clinical-stage drug candidates targeting therapeutic areas with market potentials. The following pipeline chart summarizes the development status of our selected drug candidates:

Candidate[1]	Target	Technology Platform	Type	Regimen	Indication	Pre-clinical	IND	Phase I		Phase II	Phase III/ Pivotal	Commercial Rights	Current Status/ Upcoming Milestone
								Phase Ia	Phase Ib				
★ **M701**	EpCAM×CD3	YBODY®	BsAb	Mono	Malignant ascites							Global	Phase II commenced in Dec 2021; Expect to initiate Phase III/pivotal trial in Q1 2024 and submit the BLA in Q1 2025
					Malignant pleural effusion							Global	Phase Ib/II commenced in Nov 2022; Expect to initiate Phase III/pivotal trial in Q3 2024 and submit the BLA in Q4 2025
					Solid tumor							Global	Expect to file IND application in Q1 2024 and initiate Phase I/II in Q2 2024
Y101D	PD-L1×TGF-β	Check-BODY	BsAb	Mono	Solid tumors							Global	Phase I commenced in Aug 2021; Expect to complete Phase I in Q4 2023
				Combo with gemcitabine and albumin paclitaxel	Pancreatic cancer							Global	Phase Ib/II commenced in Feb 2023; Expect to complete Phase Ib/II in Q3 2024 and initiate Phase III in Q4 2024
				Combo with bevacizumab	Hepatocellular carcinoma and other advanced solid tumors							Global	Phase Ib/II commenced in Mar 2023; Expect to complete Phase Ib/II in Q2 2025
				Combo with chemotherapy[2]	Small cell lung cancer							Global	Expect to file IND application in Q1 2024
Y150	CD38×CD3	YBODY®	BsAb	Mono	Relapse or refractory multiple myeloma							Global	Phase I commenced in Aug 2021; Expect to complete Phase I in Q2 2024
				Combo with lenalidomide	Relapse or refractory multiple myeloma							Global	Expect to file IND application after the completion of the Phase II portion of Phase II/III clinical trial of Y150 monotherapy for rrMM
Y2019[3]	SARS CoV-2 RBD homodimer	UVAX®	Vaccine	Mono	COVID-19							Global	Completed Phase Ia
M802	HER2×CD3	YBODY®	BsAb	Mono	HER2-positive solid tumors							Global	Completed Phase I
Y332	VEGF×TGF-β	Nano-YBODY™	BsAb	Mono	Solid tumors							Global	IND application approved in Apr 2023; Expect to initiate Phase I in Q3 2023
Y400	VEGF×ANG2	Nano-YBODY™	BsAb	Mono	wAMD, DME and other ocular neovascularization related diseases							Global[4] ***CMS Vision***	IND application approved in Apr 2023

★ **Core Product** **Clinical Stage** **Pre-clinical Stage**

Notes:

(1) Except for Y2019, all of our drug candidates are in-house developed.

(2) Specific combination drug(s) of the trial will be decided prior to the commencement of the trial.

(3) We completed a Phase Ia clinical trial for Y2019 in China in August 2022 which evaluates the safety and tolerability of Y2019 in healthy adults, and obtained ethical committee approval for the Phase IIa clinical trial. Along with the relaxation of the preventative measures for the COVID-19 epidemic and the increasing number of individuals gaining immunity due to COVID-19 infection in China in late 2022, there are uncertainties surrounding the market demand for the COVID-19 vaccine, hence we will deprioritize the clinical development of Y2019 and currently have no immediate plans to initiate the Phase IIa clinical trial for Y2019.

(4) We have transferred all the rights and assets of Y400 to CMS Vision. We are entitled to receive an upfront payment, milestone payments upon the occurrence of certain pre-agreed milestone events, and tiered royalties based on net sales. We have received the full upfront payment of US$5 million and US$1 million milestone for Y400. We, at our own cost, are responsible for all the pre-clinical studies of Y400 that are necessary for (i) the IND application and (ii) the Phase I clinical trial, if any, in accordance with the standards and requirements set by the CDE. Furthermore, if requested by CMS Vision, we will also be responsible for, at CMS Vision's cost, non-clinical toxicology studies of Y400 that are necessary in the Phase II and Phase III clinical trials and CMC studies in Phase III clinical trials in China. For more details, please refer to the paragraphs headed "– Collaboration Agreements – Collaboration with CMS Vision" in this section.

** Three preclinical drug candidates Y180, Y224, and Y229 for the treatment of solid tumors, cachexia, and hematologic malignancy, respectively, are not included in the pipeline chart as they are currently at the early preclinical stage. We plan to continue the preclinical studies of these drug candidates and progressively apply for IND approvals for them in the next few years.*

Abbreviations: Mono refers to monotherapy; Combo refers combination therapy; EpCAM refers to epithelial cell adhesion molecule; CD3 refers to cluster of differentiation 3; PD-L1 refers to programmed death ligand 1; TGF-β refers to transforming growth factor-β; CD38 refers to cluster of differentiation 38; COVID-19 refers to coronavirus disease 2019; RBD refers to recombinant receptor-binding domain; HER2 refers to human epidermal growth factor receptor 2; VEGF refers to vascular endothelial growth factor; ANG2 refers to angiopoietin-2; wAMD refers to wet age-related macular degeneration; DME refers to diabetic macular edema.

M701 (EpCAM × CD3 BsAb) – Our Core Product

M701 is a recombinant BsAb that targets human epithelial cell adhesion molecule (EpCAM)-expressing cancer cells and human cluster of differentiation 3 (CD3)-expressing T cells. M701 is designed to kill tumor cells by different mechanisms of action such as T cell activation, antibody-dependent cell-mediated cytotoxicity (ADCC), and complement-dependent cytotoxicity (CDC). According to relevant research paper published on *Frontiers in Immunology*, EpCAM is one of the most frequently and most intensely expressed tumor-associated antigens, and thus is an attractive target for antibody therapy of oncology, particularly carcinomas of various origins. We are currently developing M701 primarily as a palliative care for the treatment of MA and MPE which are sever complications of cancer, instead of cancer itself.

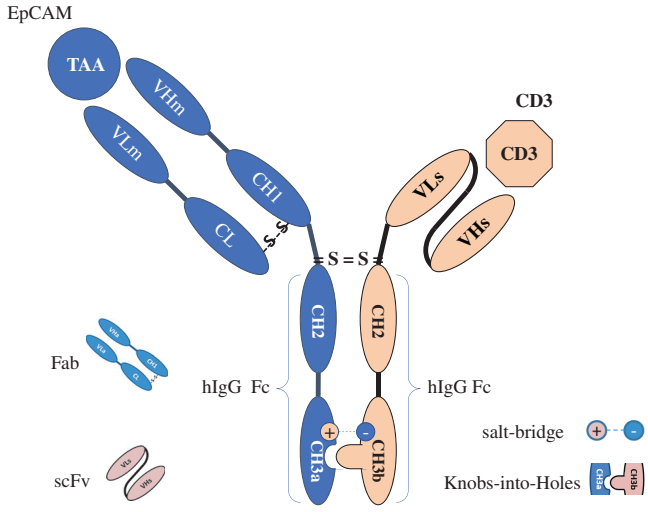
According to public information, as of the Latest Practicable Date, there were one drug applying for renewal of marketing authorization and six pipelines of innovative drugs under clinical development globally that were specifically developed for the treatment of MA or MPE, including two BsAbs, three cell therapy pipelines and one polypeptide pipeline and one pipeline of other proteins. We completed a Phase I clinical trial of M701 monotherapy for the treatment of MA in patients with EpCAM-positive carcinomas in China in January 2022. We are currently conducting a Phase II clinical trial of M701 monotherapy in combination with systematic treatment (including targeted therapy, immunotherapy or chemotherapy) for MA in patients with EpCAM-positive carcinomas in China. We also expect to commence a pivotal/Phase III clinical trial of M701 in treating MA in the first quarter of 2024. The expected BLA submission time will be in the first quarter of 2025 and the expected commercial launch time will be in the fourth quarter of 2025. In addition, we commenced a Phase Ib/II clinical trial of M701 in treating MPE in China in November 2022. We also expect to commence a pivotal/Phase III clinical trial of M701 in treating MPE in the third quarter of 2024. The expected BLA submission time will be in the fourth quarter of 2025 and the expected commercial launch time will be in the second quarter of 2026. Furthermore, we expect to commence a Phase I/II clinical trial for treatment of solid tumor in the second quarter of 2024.

We are developing M701 in-house and own its global IP and commercial rights. As of the Latest Practicable Date, we owned two PCT applications in relation to M701, including one PCT applications that are generally applicable to our YBODY® molecules, including M701 and M802, and one PCT application specifically relating to M701. As of the same date, one PCT application had entered into national phase in major markets, including five granted patents in China, Canada, the U.S. and Japan, and one pending patent applications in China; and the other PCT application was published.

We are developing M701 for the treatment of MA and MPE. Preliminary clinical trial results suggest that M701 demonstrates clinical efficacy for MA and MPE (which are the results of cancerous deposits in the peritoneal and pleural space) as well as the underlying cancers. We plan to file BLA submission for M701 in treating MA in the first quarter of 2025. Even though M701 is designed to treat MA and MPE (instead of the underlying cancer that cause MA or MPE), our ability to receive a BLA approval for M701 will not be adversely impacted. As advised by the PRC Legal Advisor, according to the "Guidelines for the Clinical Development of Anticancer Drugs Guided by Clinical Value" (《以臨床價值為導向的抗腫瘤藥物臨床研發的指導原則》) issued by the CDE, the clinical trial endpoint should respond to patient-oriented research questions, and the "Technical Guidelines for the Clinical Trial Endpoint of Advanced Non-Small Cell Lung Cancer" (《晚期非小細胞肺癌臨床試驗終點技術指導原則》) further specifies that regulatory authorities can approve new drugs based on significant symptom improvement (such as control of malignant effusion, improvement of cancer-related fatigue, and improvement of bone-related events). In addition, the protocol for the Phase II clinical trial of M701 for MA in patients with EpCAM-positive carcinomas, approved by the CDE, uses puncture-free survival (PuFS) as the primary endpoint, an indicator of the efficacy of M701 for MA (instead for the underlying cancer). Based on the foregoing regulations, whether M701 demonstrates efficacy in clinical trials on the underlying cancer that causes MA or MPE is not mandatory to issue a BLA approval for M701 in treating MA or MPE, and therefore will not impact the BLA approval for M701 in treating MA or MPE.

Mechanism of Action

M701 is a recombinant BsAb expressed using genetically engineered Chinese hamster ovary (CHO) cells. M701 is designed based on the molecular structure YBODY® and is mainly comprised of anti-EpCAM heavy chain, anti-EpCAM light chain, and anti-CD3 single chain. The following diagram illustrates the structure of M701:



Source: Company data

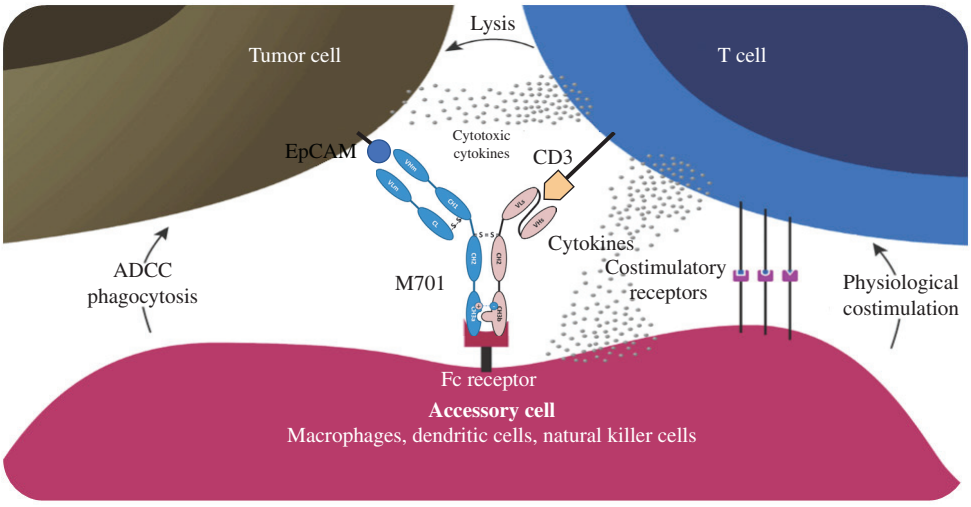
EpCAM is a type I transmembrane glycoprotein. EpCAM plays a role in epithelial carcinogenesis and is involved in various biological functions, such as cell cycle progression, cell proliferation, differentiation, migration, and immune evasion. In normal tissues, EpCAM is only expressed baso-laterally and is shielded by tight junctions that limit its accessibility. However, EpCAM is also expressed on the whole cell surface in tumor cells, and thus is more easily available for binding.

CD3 is expressed on all human T cells. Together with the T cell antigen recognition receptor (TCR), CD3 forms a TCR/CD3 complex and mediates the intracellular transduction of activation signals produced by TCR to activate T cells and perform effector functions.

M701 binds to both tumor cells and T cells by using EpCAM as the target on tumor cells and CD3 as the target on T cells, respectively. M701 contains the constant region of human IgG1 as the structural framework, whose Fc fragment can trigger ADCC and CDC. It also improves the tumor-targeting ability of T cells and their immune killing effect on tumor cells. M701 binds to EpCAM and blocks the downstream signal of EpCAM to inhibit tumor growth. By binding to T cell surface antigen CD3, M701 promotes T cell activation and proliferation and the release of cytokines, such as TNFα, IFN-γ, perforin and granzyme B to kill tumor cells. In addition, M701 shows cytotoxicity against tumor cells through ADCC and CDC.

M701, as an asymmetrical BsAb that leverages the technology of YBODY® platform, features moderate affinity to human immune cells, which reduces non-specific activation of T cells and the toxicity of cytokine release syndrome, an adverse event commonly seen in some CD3-based antibodies. In a preclinical study involving *in vivo* experiments, it was found that reducing the CD3-arm binding affinity of bispecific antibodies (bsAbs) still allows for a potent antitumor response while limiting systemic cytokine levels (Scientific Reports volume 11, Article number: 14397 (2021)). Another preclinical study demonstrated that compared to bsAbs with high CD3 affinity (<1 nM), the HER2xCD3 bsAb with low CD3 affinity (50 nM) could avoid being captured by circulating T cells, decrease its distribution in tissues rich in T cells such as spleen and lymph nodes, and be more enriched in tumor tissues with high HER2 expression, thereby reducing off-target toxicity (Mol Cancer Ther; 17(4) April 2018). Moreover, it was revealed in the Multi-Disciplinary Review and Evaluation for BLA applications submitted to the FDA that the CD3 affinities of the bsAbs teclistamab and mosunetuzumab were 28.03 nM and 40 nM, respectively, which indicates a moderated CD3 affinity. These findings clearly indicate that a lower CD3 affinity of CD3 bsAbs does not impair efficacy but can significantly improve safety by reducing cytokine release and off-target toxicity.

The following diagram illustrates the mechanism of action of M701:



Source: Company data

Market Opportunities and Competition

EpCAM is one of the most frequently and most intensely expressed tumor-associated antigens. Due to its frequent overexpression in carcinomas, EpCAM has been widely studied as a target for cancer diagnostics and treatment.

EpCAM-positive tumors

EpCAM overexpression is widely observed in many carcinomas. According to relevant research papers, such as Went, P., et al. "Frequent high-level expression of the immunotherapeutic target EpCAM in colon, stomach, prostate and lung cancers." British journal of cancer, high EpCAM expression is observed in approximately 90% of gastric cancer and colorectal cancer, approximately 80% of prostate cancer, approximately 60% of lung cancer, over 50% of ovarian cancer, approximately 50% of breast cancer and kidney cancer, and approximately 10% to 15% of hepatocellular carcinoma (HCC).

MA and MPE

MA and MPE are the end-stage manifestation of tumors. MA is the accumulation of fluid in the peritoneal cavity resulting from the growth of primary or metastatic malignant neoplasms in the peritoneum. The most common etiologies for MA are ovarian cancer, HCC, pancreatic cancer, gastric cancer, esophageal cancer, colorectal cancer and breast cancer. The incidence of MA in China has grown from approximately 547.6 thousand in 2018 to approximately 606.9 thousand in 2022, representing a CAGR of 2.6%. It is expected that the prevalence will increase to approximately 667.2 thousand in 2026 and 726.6 thousand in 2030, at a CAGR of 2.4% and 2.2% from 2022 to 2026 and from 2026 to 2030, respectively.

MA often leads to abdominal pain and swelling, dyspnea, nausea, vomiting, malnutrition and anorexia. The causes of MA are independent of the origin of the primary tumor. Tumor-secreted factors lead to tumor neovascularization and increased capillary permeability, resulting in increased plasma inflow into the peritoneal cavity. Tumor cells obstruct lymphatic drainage, leading to decreased fluid efflux from the peritoneal cavity. MA has the characteristics of stubbornness, recurrence, and large volume, which brings huge pain to patients.

MPE is the collection of fluid in the pleural cavity resulting from malignant disease. Malignant pleural effusions often contain free floating malignant cells. The most common etiologies for MPE are lung cancer, breast cancer, lymphoma, ovarian cancer and gastric cancer. MPE is observed on approximately 45% of lung cancer patients, 2% to 11% of breast cancer patients, 41.6% of lymphoblastic lymphoma patients, and 33% of ovarian cancer patients. The incidence of MPE in China has grown from approximately 553.1 thousand in 2018 to approximately 624.1 thousand in 2022, representing a CAGR of 3.8%. It is expected that the prevalence will increase to approximately 699.4 thousand in 2026 and 775.4 thousand in 2030, at a CAGR of 2.2% and 2.6% from 2022 to 2026 and from 2026 to 2030, respectively.

Current treatment and limitations

Around 17.7% MA patients and around 21.3% MPE patients may choose to forgo treatment. Among the MA/MPE patients who are willing to receive any treatment (i.e., MA/MPE treating patients), approximately 10% with mild symptoms of MA/MPE only need systematic cancer therapies to control their tumor growth and indirectly control the MA/MPE complications caused by tumor. For the other approximately 90%, the systematic treatment aiming only to control tumors usually is not able to control the MA/MPE. Therefore, approximately 90% of the MA/MPE treating patients require local therapies for the treatment of MA/MPE in addition to systematic cancer therapies.

Current local therapies for MA and MPE

Paracentesis serves as the basis for local therapy for MA/MPE. Upon thoroughly evacuating accumulated fluids in the thoracic and abdominal cavities through paracentesis, MA/MPE patients may further accept intraperitoneal or intrapleural infusions of (a) chemotherapy drugs, (b) anti-angiogenic drugs, (c) immunosuppressants, or (d) innovative drugs specifically developed for the treatment of MA and MPE, including M701, to manage MA/MPE. Furthermore, patients may also resort to diuretics on top of paracentesis to alleviate symptoms of MA/MPE. Diuretics is a relatively cheap treatment option with limited efficacy.

The use of the four types of medications (chemotherapy drugs, anti-angiogenic drugs, immunosuppressants, innovative drugs) on top of paracentesis is not mutually exclusive. After receiving an infusion of a particular drug following paracentesis, patients can opt for another drug to enhance efficacy.

Paracentesis is the only therapy recommended by clinical guidelines for managing MA/MPE. However, given that paracentesis offers only short-term symptom relief, paracentesis necessitates frequent hospital admissions. It requires frequent repetition, often weekly to biweekly, which can exacerbate nutritional deterioration and risk acute circulatory failure or renal failure due to large drainage volumes. Additionally, paracentesis carries several issues, including procedural pain, protein loss leading to hypovolemia, infection risk, peritonitis, and bowel perforation. Therefore, clinicians tend to opt for supplemental medications (chemotherapy drugs, anti-angiogenic drugs, and immunosuppressants, with innovative drugs under development) on top of paracentesis to amplify its effects and mitigate side effects. After receiving chemotherapy drugs, anti-angiogenic drugs, immunosuppressants, or innovative drugs on top of paracentesis, patients with MA/MPE may have a prolonged interval before their need for the next paracentesis. In other words, the frequency of their required paracentesis may decrease, which is an indication of successful control of their MA/MPE symptoms.

Intraperitoneal or intrapleural infusions of chemotherapy drugs, anti-angiogenic drugs, or immunosuppressants on top of paracentesis have neither been approved nor recommended by any clinical guidelines for the treatment of MA/MPE. They fall under the category of off-label use of therapies in clinical practice. Among them, chemotherapy drugs are priced lower, costing several thousand yuan annually, while both anti-angiogenic drugs and immunosuppressants are priced higher, costing annually approximately RMB30,000 and RMB10,000, respectively. Despite the high cost of anti-angiogenic drugs and immunosuppressants, a considerable proportion of patients still choose these two therapies due to their potential improved efficacy compared to paracentesis alone. Nevertheless, literature indicates that the effectiveness of anti-angiogenic drugs and immunosuppressants in controlling MA/MPE is limited.

Innovative drugs for MA and MPE

As of the Latest Practicable Date, there were one drug applying for renewal of marketing authorization and six pipelines of innovative drugs under clinical development globally that were specifically developed for the treatment of MA or MPE on top of paracentesis, including two BsAbs, three cell therapy pipelines and one polypeptide pipeline and one pipeline of other proteins. The intraperitoneal administration of M701 on top of paracentesis potentially provides the advantage of targeted immunotherapy against EpCAM tumor cells in the peritoneal cavity, the primary cause of MA/MPE. Clinical data of catumaxomab (the BsAb drug with the same targets and mechanism of actions as the M701 approved in Europe in 2009, withdrew from market in 2017 due to commercial reasons, and applied for renewal of the marketing authorization in 2022) demonstrate that the intraperitoneal infusion of catumaxomab, along with paracentesis, significantly slows down ascites accumulation and extends puncture-free survival (the length of period when paracentesis is not necessary) compared to paracentesis alone.

Competitive landscape

According to public information, as of the Latest Practicable Date, there were one drug applying for renewal of marketing authorization and six pipelines of innovative drugs under clinical development globally that were specifically developed for the treatment of MA or MPE, including two BsAbs, three cell therapy pipelines and one polypeptide pipeline and one pipeline of other proteins, as illustrated below.

Global Pipeline

Product	Developer	Highest Clinical Stage	Indication	Region	Drug Type	Target	First Posted Date[(1)]
Catumaxomab	TRION Pharma GmbH and Neovii Biotech GmbH	Approved in Europe in 2009, Canada in 2012, Israel in 2011 and Russia in 2013, withdrew from market in 2017, applied for renewal of the marketing authorization in Europe in 2022	MA	Initially approved in Europe, Canada, Israel and Russia, applied for renewal of the marketing authorization in Europe	BsAb	EpCAM, CD3	–
	LintonPharm Co., Ltd.	Phase III	Stomach Neoplasms, Advanced Gastric Carcinoma With Peritoneal Metastasis	China	BsAb	EpCAM, CD3	2020/07/17
		Phase I/II	Non-Muscle-Invasive Bladder Cancer	China	BsAb	EpCAM, CD3	2021/04/12
	LINDIS Biotech	Phase I	Urinary Bladder Neoplasms	Germany	BsAb	EpCAM, CD3	2020/07/07
ENDOSTAR™	Jiangsu Simcere Pharmaceutical Co., Ltd.	Phase III	MPE, Malignant Peritoneal Effusion	China	Other Protein	Endostatin	2021/05/27
M701	the Company	Phase II	MA	China	BsAb	EpCAM, CD3	2021/07/23
M701	the Company	Phase Ib/II	MPE	China	BsAb	EpCAM, CD3	2022/08/08
GAIA-102	Gaia BioMedicine Inc; Kyushu University Hospital	Phase II	MA, Stomach Neoplasms, Pancreatic Neoplasms, Carcinoma, NSCLC	Japan	Cell Therapy	–	2021/11/19
RSO-021	RS Oncology LLC	Phase I/II	MPE, Malignant Pleural Mesothelioma, Mesothelioma, Solid Tumor	United Kingdom	Polypeptide	–	2022/02/07
VAK	Wuhan Binhui Biotechnology Co., Ltd.	Phase I	MPE, Malignant Peritoneal Effusion	China	Cell Therapy	–	2022/09/29

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

(1) "First Posted Date" in terms of global clinical trials refers to the date when the study corresponding to the global highest clinical phase (except China) was first available on ClinicalTrials.gov after the National Library of Medicine has concluded its quality control review; "First Posted Date" in the context of China clinical trials refers to the date when the study corresponding to the highest clinical phase in China was first available on chinadrugtrials.org.cn after the Center for Drug Evaluation (CDE) has concluded its review. The CDE is an affiliated institution of the NMPA.

Among them, catumaxomab (developed by TRION Pharma GmbH and Neovii Biotech GmbH) is the world's first marketed BsAb and has two targets identical to M701 which was approved in 2009 for the treatment of MA. Upon the initial commercial launch of catumaxomab in 2009, based on public information, the medical community's understanding of immunotherapy and BsAb was not fully developed, which limited the comprehension of the mechanism of actions of catumaxomab, resulting in a relatively cautious approach towards the clinical application of the drug. Moreover, based on public information, the developers of catumaxomab fell short in formulating a market-oriented marketing strategy for catumaxomab, which led to poor sales performance after its launch and its subsequent withdrawal from the market in 2017. Catumaxomab was approved and marketed in Europe, Canada, Israel, and Russia for the treatment of MA only and the withdrawal of catumaxomab impacted the MA market in relevant jurisdictions. Unlike the humanized M701, catumaxomab is a murine-derived antibody. Studies indicate that a murine-derived antibody, when compared to a humanized antibody, generally exhibits higher immunogenicity and carries a greater risk of inducing Human Anti-Mouse Antibody (HAMA) responses, an allergic reaction to the mouse antibodies that can range from a mild form, like a rash, to a more extreme response, such as kidney failure. M701 demonstrated manageable immunogenicity profile in Phase I clinical trial. For details, please refer to paragraphs headed "- M701 (EpCAM × CD3 BsAb) – Our Core Product – Summary of Clinical Trial Results – Completed Phase I clinical trial of M701 monotherapy for the treatment of MA in patients with EpCAM-positive carcinomas in China – Immunogenicity results" in this section. As the world's first BsAb drug, the withdrawal of catumaxomab did impact the overall perception of BsAbs within the medical community for a period of time. However, this perception has gradually improved with the increase in marketed BsAb drugs and their clinical use. Therefore, the developers of catumaxomab applied for the renewal of the EMA marketing authorization of the drug for the treatment of MA in August 2022, which is currently under review.

In addition, LintonPharm Co., Ltd., a Guangzhou-based clinical-stage biopharmaceutical company, is evaluating catumaxomab in a Phase III clinical trial for stomach neoplasms, advanced gastric carcinoma with peritoneal metastasis, and a Phase I/II clinical trial for non-muscle-invasive bladder cancer in China. LINDIS Biotech, a research partner with LintonPharm Co., Ltd., is also evaluating catumaxomab in a Phase I clinical trial for urinary bladder neoplasms in German. In this Phase I clinical trial, 6 participants received catumaxomab achieved a complete response, with the duration of response lasting 9.5 months. Catumaxomab is expected to be available in China and Europe upon successful commercialization.

Moreover, peer products targeting identical molecular targets as M701 are under clinical development. According to public information, the following table sets forth BsAb pipelines targeting EpCAM and CD3 and mAb, antibody fusion protein and CAR-T pipelines targeting EpCAM currently under clinical development globally.

Product	Developer	Drug Type	Target	Highest Clinical Phase	Region	First Posted Date	Indication
A-337	ITabMed Ltd.	BsAb	EpCAM, CD3	I	China	8/2/2023	Solid Tumors
BA3182	BioAtla	BsAb	EpCAM, CD3	I	United States	4/1/2023	Advanced Adenocarcinoma
M701	the Company	BsAb	EpCAM, CD3	II Ib/II	China China	7/23/2021 8/8/2022	MA MPE
Catumaxomab	LintonPharm Co., Ltd.	BsAb	EpCAM, CD3	III	China	7/17/2020	Stomach Neoplasms Advanced Gastric Carcinoma With Peritoneal Metastasis
Catumaxomab	LintonPharm Co., Ltd.	BsAb	EpCAM, CD3	I/II	China	4/12/2021	Non-Muscle-Invasive Bladder Cancer
Catumaxomab	LINDIS Biotech	BsAb	EpCAM, CD3	I	Germany	7/7/2020	Urinary Bladder Neoplasms
AM-928	AcadeMab Biomedical	mAb	EpCAM	I	United States	1/7/2023	Solid Tumors
VB4-845	Qilu Pharmaceutical Co., Ltd.	Antibody fusion protein	EpCAM	III	China	4/13/2021	Non-Muscle Invasive Bladder Cancer
TM4SF1- positive chimeric antigen receptor T-cell therapy, EpCAM- positive chimeric antigen receptor T-cell therapy	Shanghai Biomedunion Biotechnology Co., Ltd.	CAR-T	EpCAM, TM4SF1	NA	China	10/29/2019	Solid Tumors

Source: ClinicalTrials.gov, Frost & Sullivan Analysis

In addition to the above pipelines, Amgen Inc. commenced a multicenter Phase I clinical trial of solitomab, a bispecific EpCAM×CD3 T-cell engager BsAb in patients with refractory solid tumors in 2008. According to public information, Amgen Inc. has removed solitomab from its pipeline update since 2015, indicating that it may have suspended the clinical development plan for the drug candidate. We have not learned from public information that solitomab has safety or effectiveness issues. Amgen's suspension of this pipeline may be due to strategic considerations.

Limitations and imminent risks on the market potential of M701

We face the following limitations and imminent risks on the market potential of M701:

- MA and MPE, the intended indications of M701, are complications of the tumor. The continual refinement of early tumor detection methods, preventive measures, non-drug treatment options, along with the relentless innovation in tumor treatment methodologies, will reduce tumor prevalence and improve early-stage tumor cure rates, subsequently decreases the occurrence of MA and MPE as complications of the tumor.

- Systematic therapies for primary and metastatic cancers, including but not limited to systematic chemotherapy, targeted therapies, and immunotherapies, while not directly targeting MA and MPE, can help control these complications. Approximately 10% of MA/MPE treating patients with mild symptoms only need these cancer systematic therapies to control their tumor growth, and therefore indirectly control the MA/MPE complications caused by tumor. Compared to such systematic treatments that have a curative effect on cancer, M701 is primarily used to improve symptoms and complications of cancer. These therapies for cancer thereby indirectly limit the market size for M701.

- Current treatment methods for MA/MPE includes paracentesis, intraperitoneal/intrapleural infusions of (a) chemotherapy drugs, (b) anti-angiogenic drugs, (c) immunosuppressants on top of paracentesis, and diuretics. For more details, please refer to the paragraphs headed "Industry Overview – CD3 Targeted Bispecific Antibody Market – EpCAM x CD3 Targeted BsAB – Treatment Paradigm for MA and MPE in China" in the document. As an innovative therapy, we develop M701 on top of paracentesis with an aim to improve the effectiveness and reduce side effects of the current treatment methods for MA and MPE. However this method will also be more expensive than most of the current treatment methods, including paracentesis, diuretics and intraperitoneal/intrapleural infusions of chemotherapy drugs and immunosuppressants on top of paracentesis and approximately equally expensive as infusions of anti-angiogenic drugs and may not be affordable by some patients.

- The market size for MA and MPE is relatively limited when compared to the oncology drug market. Comparing with the rapid growth of the oncology drug market in China, the overall growth rate for the China market size of MPE and MA therapies is comparatively stable, which could further limit the market potential of M701.

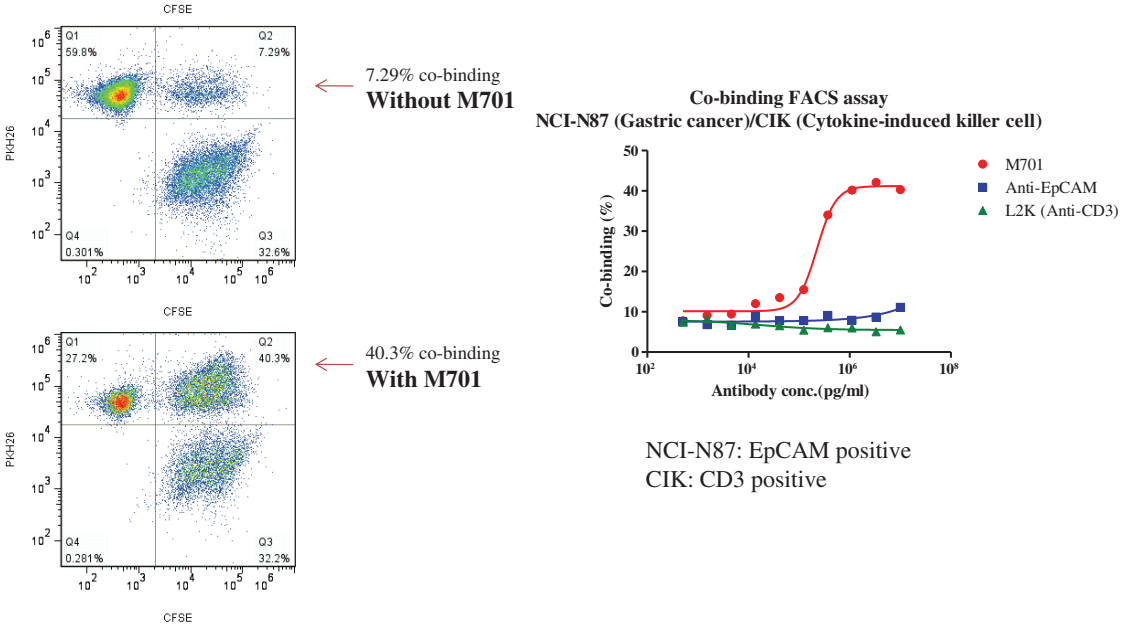
Competitive Advantages of M701

Optimized structure designed to bind both EpCAM and CD3

M701 is designed based on the molecular structure YBODY® and is mainly comprised of anti-EpCAM heavy chain, anti-EpCAM light chain, and anti-CD3 single chain. M701 can specifically bind to EpCAM, an antigen highly expressed in tumors on the one hand, and, on the other hand, to human T cell surface antigen CD3. EpCAM is an antigen highly expressed in tumors, and lowly expressed in normal human epithelial tissues. Therefore, M701 causes a very limited biological effect when binding to EpCAM in normal cells. CD3 is a surface antigen on normal human T cells that are distributed almost all over the body. M701 is able to quickly bind to human T cells' surface antigen CD3 in humans, resulting in a rapid decline of plasma concentration of free M701; T cell activations induce various biological effects, such as T cell proliferation and cytokine release, which causes systemic and transient cytokine release syndrome.

M701 has demonstrated high affinity and specificity to EpCAM in pre-clinical studies. The proprietary structure of M701 enables it to bind EpCAM with high affinity and CD3 with moderate affinity. Furthermore, M701 mediates the linkage of CD3-positive cells with EpCAM-positive tumor cells, but not with EpCAM-negative tumor cells, indicating that M701-mediated linkage is EpCAM-dependent and that M701 can redirect the CD3-positive immune cells to the targeted EpCAM-positive tumor cells, as shown below:

Compared to the control mAbs, M701 mediates association between tumor cells and immune cells



NCI-N87: EpCAM positive
CIK: CD3 positive

Source: Company data

Abbreviation: FACS refers to fluorescence activated cell sorter.

Anti-EpCAM, an mAb against EpCAM, and L2K, an mAb against CD3, and M701 were assessed in the above co-binding FACS assay. Among the three molecules, only M701 is able to mediate the interaction between tumor cells NCI-N87 and immune cells CIK, with a maximum co-binding percentage of 42.1%. Neither of the other two mAbs are able to mediate the interaction between the tumor cells and immune cells. The table below sets forth the results of the above co-binding FACS assay.

Sample	Co-binding (%)	EC50 (ng/mL)
M701	42.1	226.8
Anti-EpCAM	11.1	–
L2K	9.5	–

Source: Company data

Abbreviation: EC50 refers to half maximal effective concentration, the concentration of a drug, antibody or toxicant which induces a response halfway between the baseline and maximum.

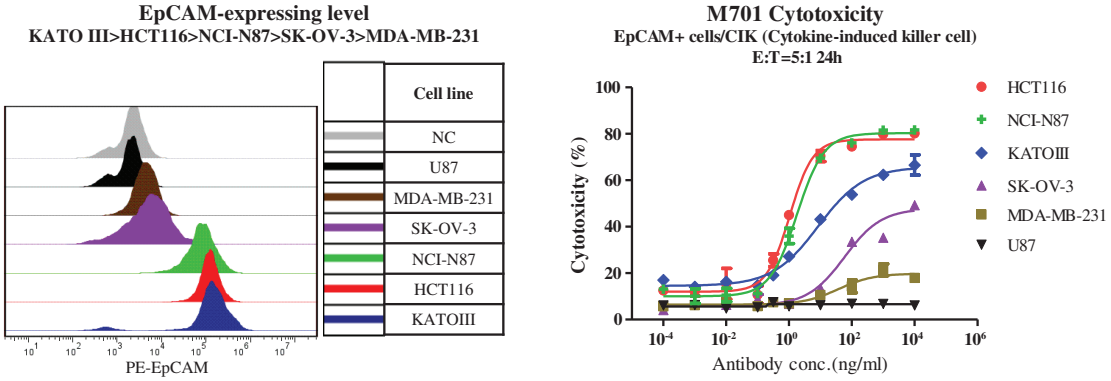
Encouraging ascites controlling capability activity

M701 has demonstrated a strong killing activity to all tested EpCAM-positive cells in a dose-dependent manner *in vitro* and *in vivo* studies.

In the *in vitro* pharmacodynamic studies, EpCAM-positive cells, including HCT116 (a colorectal cancer cell line), OVCAR3 (an ovarian cancer cell line), and KATOIII (a gastric cancer cell line), were used as the target cells, and the peripheral blood mononuclear cells (PBMCs), cytokine-induced killer cells (CIKs), or T cells were used as the effector cells. A

primary glioblastoma cell line U87 was used as EpCAM-negative controls. M701-mediated killing activity of effector cells on the tumor cells was examined both *in vitro* and *in vivo*. *In vitro* studies have shown that M701 demonstrates a strong killing activity to all tested EpCAM-positive cells in a dose-dependent manner. *In vitro* mechanism studies have shown that M701 mediates the linkage of EpCAM-positive cancer cells and CD3-positive T cells, mediates ADCC and CDC activities on some cancer cells, and induces cancer cell apoptosis. Most importantly, M701 activates T cells, thereby largely increasing the expression levels of activation markers on T cells and inducing the secretion of cytokines, including IFN-γ, TNFα, perforin and granzymes, which lead to the killing of cancer cells.

Cytotoxicity of M701 to various cancer cells with different EpCAM expression level



Source: Company data

The table below sets forth the maximum lysis percentage and the EC50 value of M701 on different tumor cells with descending levels of EpCAM expression, in the presence of CIKs. As shown below, EpCAM over-expressing cell lines HCT116 (colon cancer) NCI-N87 (gastric cancer) and KATOIII (gastric cancer) were significantly more sensitive to M701-mediated killing (as demonstrated by the low-level of EC50) than the low-level expressing cell line SK-OV-3 (ovarian cancer), MDA-MB-231 (breast cancer) and U87 (glioma), as demonstrated by high-level of EC50.

EpCAM expressed cancer cell	Maximum lysis (%)	EC50 (ng/ml)
KATOIII (gastric cancer)	66	8.5
HCT116 (colon cancer)	78	1.1
NCI-N87 (gastric cancer)	80	1.8
SK-OV-3 (ovarian cancer)	48	58.7
MDA-MB-231 (breast cancer)	20	37.8
U87 (glioblastoma, negative control)	6	–

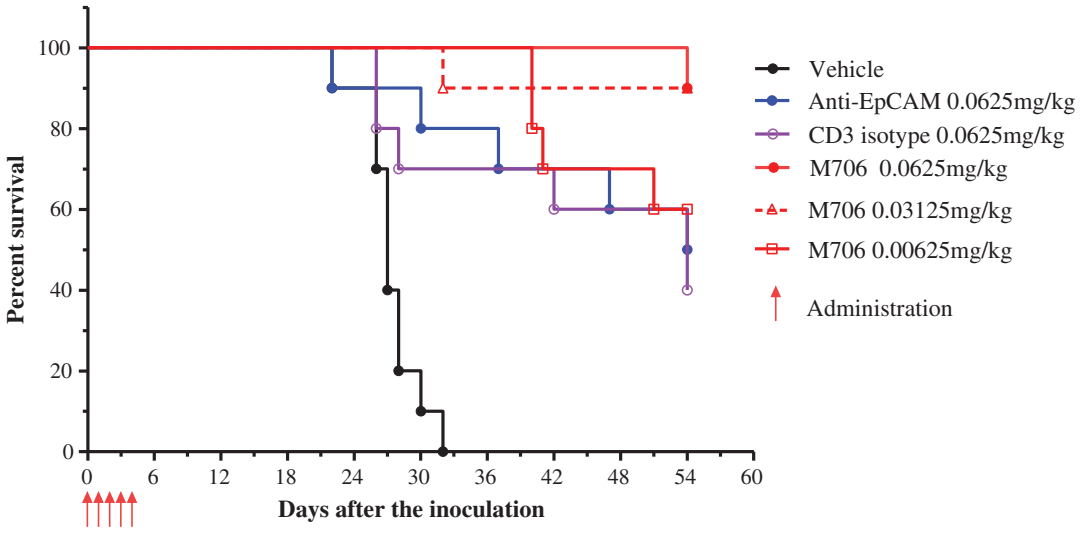
Source: Company data

Abbreviation: EC50 refers to half maximal effective concentration, the concentration of a drug, antibody or toxicant which induces a response halfway between the baseline and maximum.

As shown below, the survival rate of mice treated with anti-EpCAM mAb after 54 days post-inoculation was 50%, whereas the survival rate of mice treated with CD3 isotype was 40%. In contrast, the survival rate of mice treated with the same dosage (0.0625 mg/kg) of M706 (EpCAM × murine CD3 BsAb, the mouse surrogate of M701) was 90%, and the survival

rate of mice treated with a lower dose of 0.03125 mg/kg of M706 was also 90%. In addition, the survival rate of mice treated with the lowest dose of 0.00625 mg/kg of M706 was 60%. These results indicate that the efficacy of M706 is dose-dependent and significantly superior to the mAb control group.

In the CT26-hEpCAM ascites tumor model
The efficacy of the surrogate M706 was significant and dose-dependent



Source: Company data

The table below shows the survival rates of mice treated with anti-EpCAM mAb, CD3 isotype and different doses of M706 at 54 days post-inoculation in the CT2-hEpCAM ascites tumor model.

Sample	Dosage(mg/kg)	Survival rates of mice at 54 days post-inoculation
Vehicle	0	0
anti-EpCAM mAb	0.0625	50%
CD3 isotype	0.0625	40%
M706	0.0625	90%
M706	0.03125	90%
M706	0.00625	60%

Source: Company data

The advantages of the structure design of M701 have also translated into clinical benefits. Among 18 patients who have completed the core treatment period, three patients reached complete response (CR), which means the complete disappearance of ascites for at least four weeks, and eight patients reached partial response (PR), which means at least a 50% reduction in the volume of ascites for at least four weeks. Therefore, the clinical trial results showed an

ORR of approximately 61.1% (11/18). Furthermore, among the 18 patients who have received at least four times of treatment during the dose-escalation phase, the median overall survival (mOS) reached 151.5 days in this clinical trial.

Manageable safety profile

Data obtained from this Phase I clinical trial for the treatment of MA shows that M701 monotherapy is well tolerated and safe up to 400μg. Only two subjects with DLT were observed at cohort 7 (with an initial dose level at 100μg and a maintenance dose level at 600μg). Therefore, MTD was determined at the dose level of cohort 6 (with an initial dose level at 50μg and a maintenance dose level at 400μg). 15 out of 35 enrolled subjects did not experience any TRAE, and only 5 patients experienced Grade 3 TRAEs during the trial, indicating the manageable safety profile of M701. For more details, please refer to the paragraphs headed "– M701 (EpCAM × CD3 BsAb) – Our Core Product – Summary of Clinical Trial Results" in this section.

Leading development progress in China

EpCAM is one of the most frequently and most intensely expressed tumor-associated antigens. As a result, EpCAM becomes an attractive target for antibody therapy of oncology, particularly carcinomas of various origins. According to public information, as of the Latest Practicable Date, there were one drug applying for renewal of marketing authorization and six pipelines of innovative drugs under clinical development globally that were specifically developed for the treatment of MA and MPE, including two BsAbs, three cell therapy pipelines and one polypeptide pipeline and one pipeline of other proteins. Currently, patients with MA and/or MPE have limited treatment options and poor prognoses. Therefore, we believe M701 has potential to address the medical needs.

Summary of Clinical Trial Results

We received an IND approval from the NMPA for the Phase I, II and III clinical trials of M701 on February 12, 2018. We commenced a Phase I clinical trial of M701 monotherapy for the treatment of MA in patients with EpCAM-positive carcinomas in China in January 2019, and completed this clinical trial in January 2022. We are currently conducting a Phase II clinical trial of M701 monotherapy in combination with systematic treatment (including targeted therapy, immunotherapy or chemotherapy) for MA in patients with EpCAM-positive carcinomas in China. As of July 31, 2023, a total of 85 subjects were enrolled in this Phase II clinical trial.

Completed Phase I clinical trial of M701 monotherapy for the treatment of MA in patients with EpCAM-positive carcinomas in China.

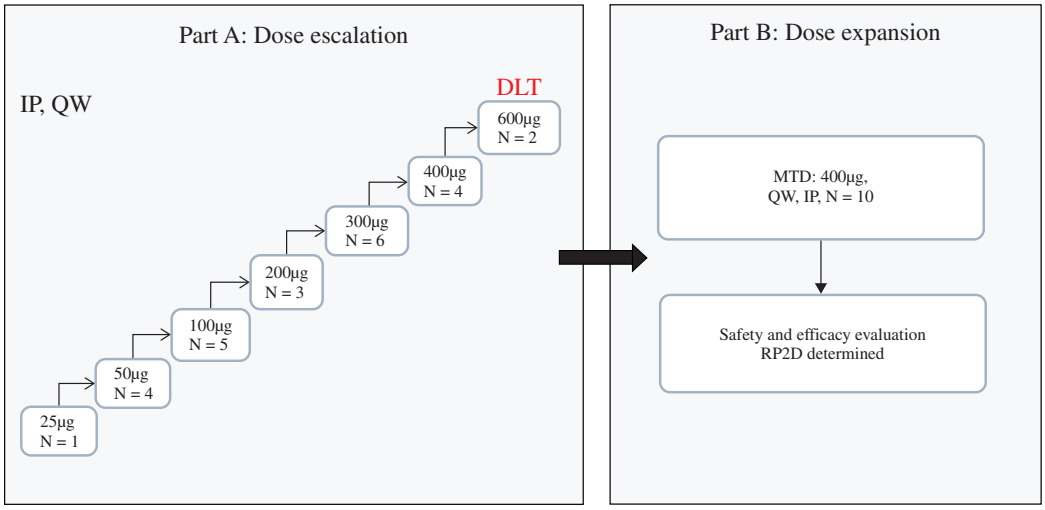
Trial design

This is a Phase I, multicenter, open-label, multiple-ascending dose study of M701 monotherapy. This trial has enrolled a total of 35 subjects who have failed the standard treatment and require therapeutic paracentesis. Subjects who meet the inclusion criterion of "failed standard treatment and require therapeutic paracentesis" are individuals who have completed at least one systemic standard treatment regimen but failed to control the generation and accumulation of ascites. These individuals may present with symptoms such as abdominal pain, distension, poor appetite and intestinal obstruction. A clinical physician has determined that these symptoms require the use of paracentesis for relief. Additionally, the investigator must determine that the patient does not have an effective systemic treatment option available, or that the patient has refused systemic treatment, or that the patient requires immediate paracentesis to alleviate symptoms.

Given that paracentesis offers only short-term symptom relief, paracentesis necessitates frequent hospital admissions. It requires frequent repetition, often weekly to biweekly, which can exacerbate nutritional deterioration and risk acute circulatory failure or renal failure due to large drainage volumes. Additionally, paracentesis carries several issues, including procedural pain, protein loss leading to hypovolemia, infection risk, peritonitis, and bowel perforation. Therefore, we investigate the efficacy and safety of M701 on top of paracentesis to address the issues with paracentesis alone. After receiving chemotherapy drugs, anti-angiogenic drugs, immunosuppressants, or innovative drugs (including drugs specifically developed for MA and MPE, such as M701) on top of paracentesis, patients with MA/MPE may have a prolonged interval before their need for the next paracentesis. In other words, the frequency of their required paracentesis may decrease, which is an indication of successful control of their MA/MPE symptoms. Therefore, we investigate the efficacy and safety of M701 on top of paracentesis to address the issues with paracentesis alone.

Patients are scheduled to undergo a 2-week screening period and a 4-week core treatment period (treatment received once weekly for 4 weeks). Following completion of the core treatment period, patients who demonstrate good tolerance and do not exhibit progression of ascites or systemic tumor as evaluated by imaging, and who also express willingness may continue to enter into the extended treatment period (treatment received once weekly for 4 weeks) until disease progression or toxicity intolerance.

In the dose escalation phase, 25 subjects received M701 intraperitoneal injections after paracentesis once weekly across seven cohorts with 1, 4, 5, 3, 6, 4 and 2 subjects enrolled and received maintenance dose level at 25 μg, 50 μg, 100 μg, 200 μg, 300 μg, 400 μg and 600 μg, respectively, in the corresponding cohort. In the dose expansion phase, ten subjects received M701 intraperitoneal injections after paracentesis once weekly with dose level at 400 μg where the safety and preliminary efficacy of M701 were evaluated and RP2D were determined. Further details are illustrated in the diagram below.



Source: Company data

Abbreviations: IP refers to intraperitoneal injections; QW refers to once weekly; DLT refers to dose-limiting toxicity; MTD refers to maximum tolerable dose; RP2D refers to recommended Phase II dose.

The primary objectives of this Phase I clinical trial were to evaluate the safety and tolerability of M701, while the secondary objectives were to evaluate PK, PD, and immunogenicity and to preliminarily assess the efficacy in treating ascites and tumors in patients. The primary endpoints include DLT, MTD, and incidence of AEs, among others. The secondary endpoints include PK, PD, immunogenicity and preliminary efficacy.

Trial status

We commenced this trial in January 2019 and completed it in January 2022 with a total of 35 subjects enrolled. The following table sets forth the number of subjects enrolled in this Phase I clinical trial of M701 by cancer type.

Cancer types	Number of subjects enrolled for the Phase I clinical trial
Ovarian cancer	14
Colorectal cancer	7
Gastric cancer	6
Primary peritoneal carcinoma	4
Other types of cancer	4
Total	35

Safety results

Data obtained from this trial shows that M701 monotherapy is well-tolerated and safe up to 400μg. Only two subjects with DLT were observed at cohort 7 (with an initial dose level at 100μg and a maintenance dose level at 600μg). Therefore, MTD was determined at the dose level of cohort 6 (with an initial dose level at 50μg and a maintenance dose level at 400μg). DLT, or dose-limiting toxicity, refers to the occurrence of Grade 3 or above AEs as specified in the clinical trial protocol, which is considered to be possibly or definitely related to the medication during the dose escalation phase of a Phase I clinical trial. Typically, when DLT occurs, the study investigators will expand the cohort of participants at that dose level to further evaluate the toxicity risk or determine that the dose is not tolerable. MTD, or maximum tolerated dose, refers to the highest dose cohort in which no DLT are observed in a Phase I clinical trial. It is the highest dose of the medication that can be tolerated by the study participants. The MTD observed in this trial (at cohort 6 with a maintenance dose level at 400μg) is considered to be manageable and meets the expectations of the researchers vis-à-vis accepted medical standards adopted as industry norm.

The following table sets forth the number of patients experiencing TRAEs by different cohorts. 15 out of 35 enrolled subjects did not experience any TRAE, and only 5 patients experienced 6 Grade 3 TRAEs during the trial, indicating the manageable safety profile of M701.

	Grade 1 TRAEs	**Grade 2 TRAEs**	**Grade 3 TRAEs**
Cohort 1	1	0	0
Cohort 2	1	1	2
Cohort 3	3	1	0
Cohort 4	1	0	0
Cohort 5	2	1	1
Cohort 6	8	5	1
Cohort 7	1	1	2
Total	17	9	6

Source: Company data

Note: Each patient in the trial may experience multiple incidences of TRAEs in different grades. For example, a patient experienced both Grade 1 and Grade 2 TRAEs will be counted toward the number of Grade 1 and Grade 2 TRAEs at the same time. Therefore, although only 20 patients experienced TRAEs in this trial, the number of patients experiencing TRAEs is presented as 31 in this table.

The following table presents the symptoms of TRAEs by different cohorts.

	Symptoms
Grade 1 TRAEs	Hypoalbuminemia, decrease in platelet count, decrease in white blood cell count, anemia, hypokalemia, lactic acidosis, fever, abdominal pain, increase in neutrophil, anorexia, fatigue, etc.
Grade 2 TRAEs	Hypochloremia, elevation of alanine transaminase, anemia, chest tightness, tachycardia, abdominal distention, constipation, abdominal pain, cytokine release syndrome, etc.
Grade 3 TRAEs	Elevation of aspartate transaminase, hypertension, anemia, intestinal obstruction and general fatigue.

Source: Company data

The symptoms for Grade 3 TRAEs in cohorts 2, 5 and 6 are elevation of aspartate transaminase, hypertension and anemia. None of these symptoms resulted in a patient withdrawal in this trial. However, two patients in cohort 7 experienced general fatigue and intestinal obstruction, and subsequently withdrew from this trial. Therefore, the Cohort 7 dose level (with an initial dose level at 100μg and a maintenance dose level at 600μg) was determined as the DLT dose level. As a result, MTD was determined at the dose level of cohort 6 (with an initial dose level at 50μg and a maintenance dose level at 400μg). We have reported to the CDE on the TRAEs occurred in this trial and CDE did not raise any concern in this regard.

Efficacy results

The data obtained from this trial shows preliminary clinical efficacy of M701 monotherapy. Of the 35 enrolled patients, 18 of them have completed the 4-week core treatment period in the escalation phase, with treatment received once weekly for 4 weeks. Reasons for patients not completing the 4-week core treatment period in the escalation phase primarily is patient withdrawal, and secondarily are disease progression, AEs, and recommendation from the investigators. Failure for certain subjects to complete treatment in a clinical trial is common in the industry. Among these 18 patients, three patients reached CR, which means complete disappearance of ascites for at least four weeks based on CT evaluation, and eight patients reached PR, which means at least a 50% reduction in the volume of ascites for at least four weeks based on CT evaluation. The use of CT evaluation for evaluating M701's preliminary efficacy in treating MA is in line with WHO guidelines. There, the clinical trial results show an ORR of approximately 61.1% (11/18). The ORR is a measure of the proportion of study participants who show a complete or partial remission (CR or PR) of ascites, as evaluated by imaging or other objective methods, according to the imaging criteria specified in the clinical trial protocol. ORR is a specific numerical value and do not necessarily indicate the efficacy of a treatment on its own. Rather, it must be compared to the corresponding values of current standard treatment options or to the expectations of the researchers or reviewers. If

the results show a statistically significant increase, the new therapy is considered superior. If the results are not statistically significant, the new therapy is considered similar in efficacy to the current standard treatment but may be approved due to its advantages in terms of safety or convenience. In the case of M701, a treatment therapy for MA, there is currently no standard treatment option to be compared with. Thus, evaluation of its ORR vis-à-vis accepted medical standards is done by comparing it to the expectations of the researchers. M701's ORR data surpass the researchers' expectations formed based on historical data from other treatments for MA in the literature including Bevacizumab, cisplatin chemotherapy, cisplatin chemotherapy in combination with Endostar™, and Recombinant Tumor Necrosis Factor (rTNF) treatment and their own clinical treatment experience, indicating the preliminary efficacy for M701.

The main purpose of the Phase I study of M701 is to evaluate the safety profile of M701. The preliminary claim of efficacy of M701 based on the Phase I data only relies on a limited number of patients and may not be indicative of future clinical results.

The following table sets forth the ORR results by different cohorts.

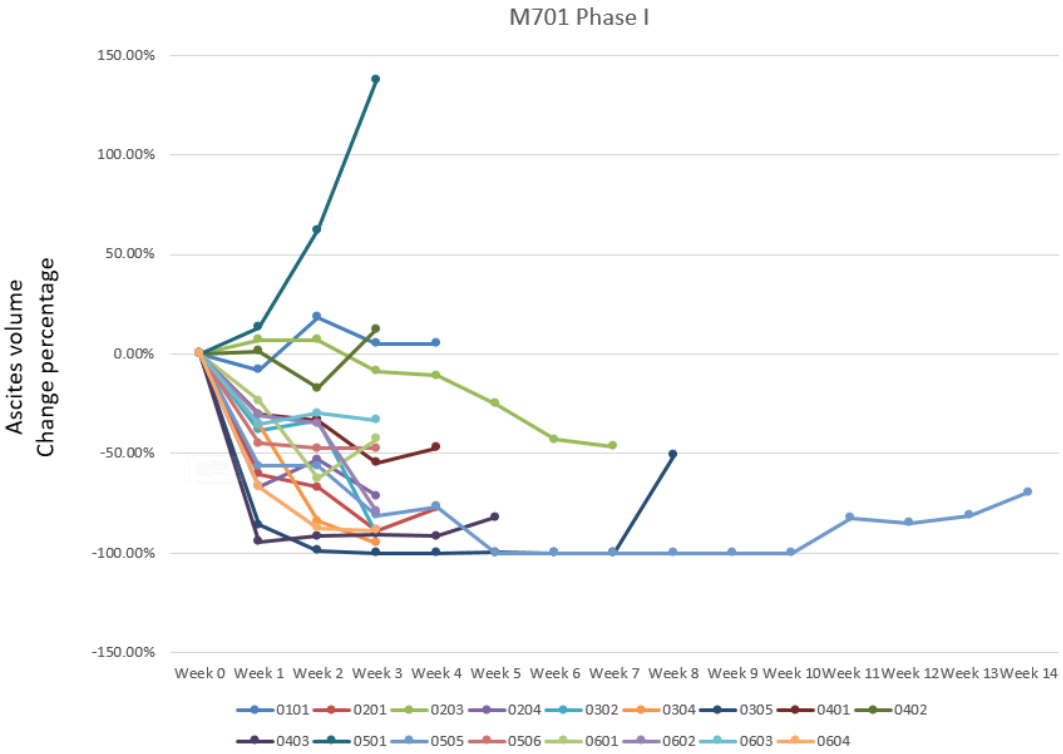
Cohort	Subjects completing the 4-week core treatment period	PR	CR	ORR
Cohort 1	1	0	0	0
Cohort 2	3	2	0	66.70%
Cohort 3	3	2	1	100%
Cohort 4	3	2	0	66.70%
Cohort 5	4	0	2	50%
Cohort 6	4	2	0	50%
Total	18	8	3	61.10%

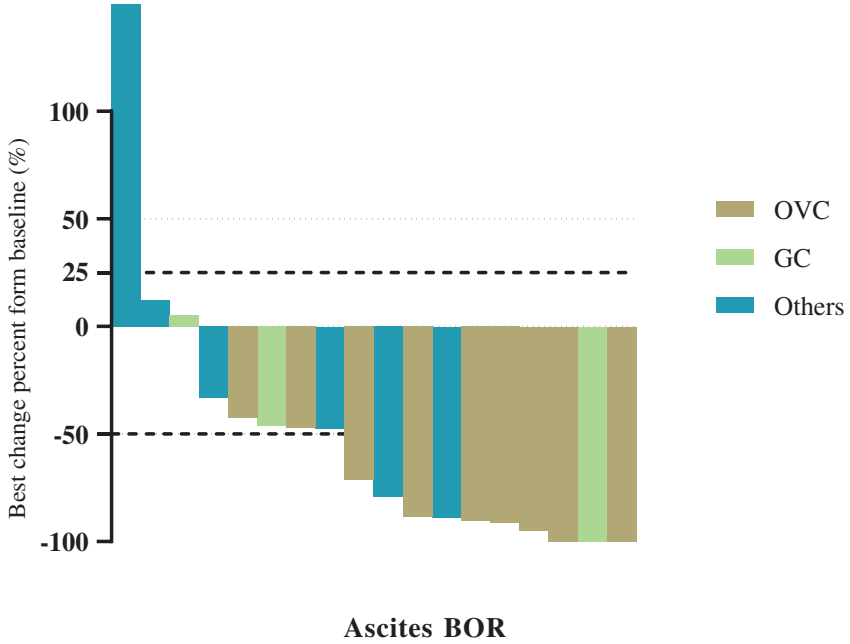
Source: Company data

Abbreviations: PR refers to partial response; CR refers to complete response; ORR refers to objective response rate

Out of 18 patients who have completed the 4-week core treatment period in the escalation phase, 9 patients entered the extended treatment period. The main reason for certain patients not entering the extended treatment period was tumor progression, followed by AEs and patient withdrawal. Patients who enter the extended treatment period will continue to receive M701 treatment without a fixed completion date. Throughout the course of the trial, many patients experienced cancer progression or deterioration in their overall health, necessitating the resumption of systematic treatment for the tumor, rendering them unable to complete the trial or move into the extended treatment period according to the trial protocol.

The following two diagrams show the efficacy results of patients who have completed the 4-week core treatment period in the escalation phase:





Ascites BOR

Source: Company data

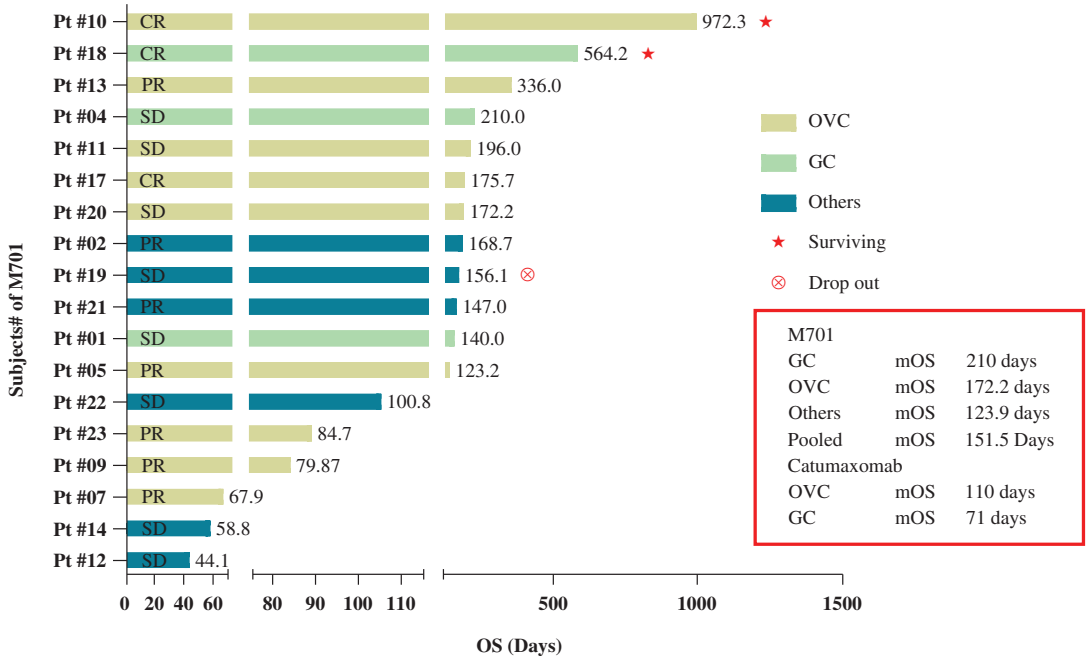
Abbreviation: BOR refers to best of response; GC refers to gastric cancer; OVC refers to ovarian cancer

Best objective response (BOR) is the best response that is recorded over the course of the trial, from the start of treatment until the progression or relapse of the disease, based on the imaging or other objective evaluation criteria stated in the clinical trial protocol. As there is currently no standard treatment option for MA to be compared with, the evaluation of the BOR of M701 vis-à-vis accepted medical standards is done by comparing it to the expectations of the researchers. M701's BOR data surpass the researchers' expectations formed based on historical data from other treatments for MA in the literature and their own clinical treatment experience, indicating the efficacy of M701.

Furthermore, among the 18 patients who have received at least four times of treatment during the dose-escalation phase, the median overall survival (mOS) reached 151.5 days in this clinical trial. The mOS is the median of all subjects' overall survival time which is the interval of time from the participation to death or loss to follow-up for a subject. As there is currently no standard treatment option for MA to be compared with, the evaluation of the mOS of M701 vis-à-vis accepted medical standards is done by comparing it to the expectations of the researchers. M701's mOS data surpass the researchers' expectations formed based on historical data from other treatments for MA in the literature and their own clinical treatment experience, indicating the preliminary efficacy for M701.

The following diagram shows the overall survival days for such 18 patients as of October 31, 2022.

Overall Survival



Source: Company data; publicly available data

Abbreviations: Pt refers to patient; OVC refers to ovarian cancer; GC refers to gastric cancer.

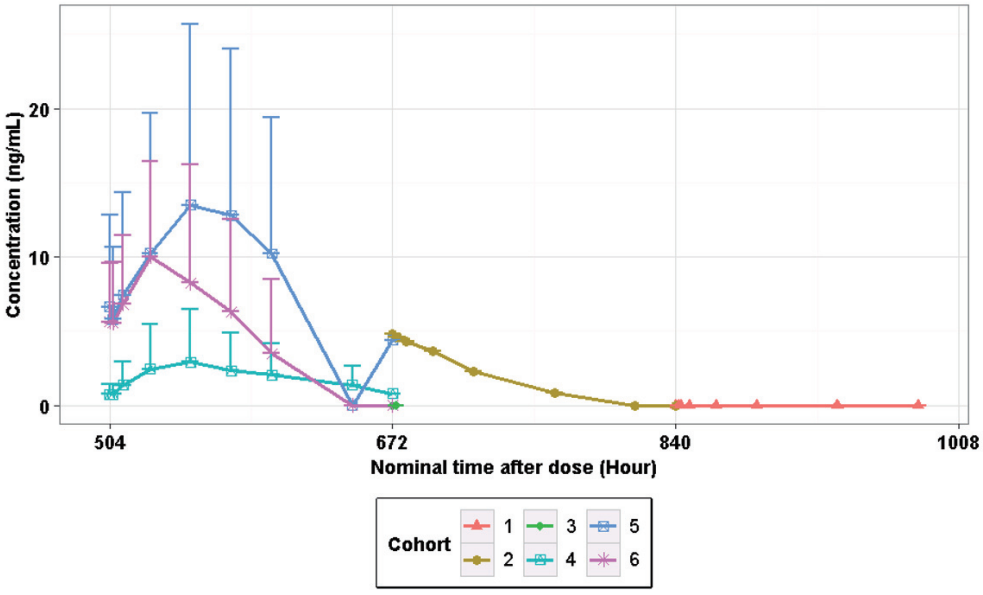
PK/PD results

PK results

The following is a summary of the PK results of M701 in blood samples and ascites samples. The data is presented in the form of a diagram, with the x-axis representing the "nominal time after dose" and the y-axis representing the "concentration of M701." The diagram below provides a visual representation of the overall PK profile of M701 in blood and ascites samples over time.

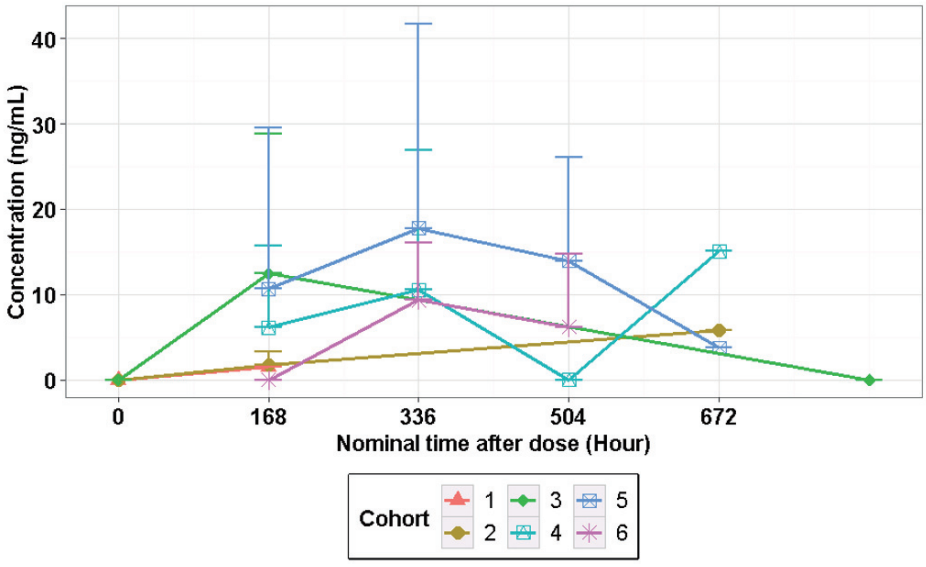
PK Results of M701 in Blood Samples

Mean Serum Concentration of M701 – Time Curve after Continuous Intraperitoneal Infusion in Subjects of Different Cohorts



PK Results of M701 in Ascites Samples

Mean Ascites Concentration of M701 – Time Curve of M701 after Intraperitoneal Infusion in Subjects of Different Cohorts



Cellular PD results

After intraperitoneal administration of the drug, there was a brief decline in the percentage and count of lymphocytes, followed by a rapid recovery, with significant inter-individual variation. There was no significant correlation between the percentage and count of lymphocytes and the dose of the drug administered. Similarly, there was also a brief decline in the percentage and count of monocytes, followed by a rapid recovery, with significant inter-individual variation and no significant correlation between the percentage and count of monocytes and the dose of the drug administered. Additionally, there was a brief increase in the percentage and count of neutrophils, followed by a rapid recovery, with significant inter-individual variation and no significant correlation between the percentage and count of neutrophils and the dose of the drug administered.

The following table presents the cellular PD results of M701 in its Phase I clinical trial by different cohorts.

Cohort (dosage)	Cellular PD results
Cohort 1 (2-5-10-25μg)	After the first dose, the relative lymphocyte count significantly decreased but recovered to baseline before the next dose. Subsequent changes were stable.
Cohort 2 (25-50μg)	After the first dose, the relative lymphocyte count significantly decreased but recovered to baseline before the next dose. Subsequent changes were stable.
Cohort 3 (50-100μg)	After the first dose, the relative lymphocyte count significantly decreased but recovered to baseline before the next dose. Subsequent changes were stable.
Cohort 4 (50-200μg)	After the first dose, the relative lymphocyte count did not significantly decrease, but recovered to baseline before the next dose. After the second dose, the lymphocyte count did not significantly decrease, but recovered to baseline again. Subsequent changes were stable.
Cohort 5 (50-300μg)	After the first dose, the relative lymphocyte count did not significantly decrease, but recovered to baseline before the next dose. After the second dose, the lymphocyte count did not significantly decrease, but recovered to baseline again. Subsequent changes were stable.
Cohort 6 (50-400μg)	After the first dose, the relative lymphocyte count did not significantly decrease, but recovered to baseline before the next dose. After the second dose, the lymphocyte count did not significantly decrease, but recovered to baseline again. Subsequent changes were stable.

Cytokine PD results

Furthermore, we also analyzed the levels of several cytokines such as IFNγ, TNFα, and IL-6. We observed significant inter-individual variation in the levels of these cytokines. After drug administration, there was a brief decline in the levels of IFNγ and TNFα, followed by a rapid recovery. Additionally, the levels of IFNγ and TNFα were higher in the higher dose cohorts (3-6) compared to lower dose cohorts (1-2). However, there was no significant correlation between the levels of these cytokines and the dose of the drug administered. Also, there was a brief decline in the levels of IL-6, followed by a rapid recovery, with no significant correlation between the levels of IL-6 and the dose of the drug administered.

The following table presents the cytokine PD results of M701 in its Phase I clinical trial by different cohorts.

Cohort (dosage)	Cytokine PD results
Cohort 1 (2-5-10-25μg)	No significant changes in IFNγ and TNFα after administration; a transient downward trend in IL-6 after the second administration, followed by a rapid recovery and a smooth subsequent change.
Cohort 2 (25-50μg)	No significant changes in IFNγ after administration; a transient downward trend in TNFα after the first administration and after the second administration, followed by rapid recovery and smooth subsequent changes; a transient downward trend in IL-6 after the first administration, followed by rapid recovery and smooth subsequent changes.
Cohort 3 (50-100μg)	Elevated IFNγ after the first dose, followed by recovery to baseline and smooth subsequent changes; transient downward trend of TNFα after the first and second doses, followed by rapid recovery and smooth subsequent changes; transient downward trend of IL-6 after the first dose, followed by rapid recovery and smooth subsequent changes.
Cohort 4 (50-200μg)	IFNγ showed a transient decrease after the second administration, followed by a recovery to baseline and a smooth subsequent change. TNFα showed a transient downward trend after the second administration, followed by a rapid recovery and a smooth subsequent change; IL-6 showed a transient downward trend after the first administration, followed by a rapid recovery and a smooth subsequent change.
Cohort 5 (50-300μg)	Elevated IFNγ after the second administration, followed by recovery to baseline and smooth subsequent changes; transient downward trend of TNFα after the second administration, followed by rapid recovery and smooth subsequent changes; transient downward trend of IL-6 after the first administration, followed by rapid recovery and smooth subsequent changes.
Cohort 6 (50-400μg)	Elevated IFNγ after the second administration, followed by recovery to baseline and smooth subsequent changes; a transient downward trend of TNFα after the second administration, followed by rapid recovery and smooth subsequent changes; a transient downward trend of IL-6 after the first administration, followed by rapid recovery and smooth subsequent changes.

Source: Company data

Immunogenicity results

The following table presents the immunogenicity results of M701 in different cohorts. Although there are 23 ADA positive events across 7 cohorts, these events have little impact on the concentrations of M701 in blood and ascites samples over time which means that the presence of ADA have limited influence on M701's ability to reach its target sites. For more details of the PK results of M701 in blood and ascites samples, please refer to the paragraphs headed "– M701 (EpCAM × CD3 BsAb) – Our Core Product – Summary of Clinical Trial Results – Completed Phase I Clinical Trial of M701 Monotherapy for the Treatment of MA in Patients with EpCAM-positive Carcinomas in China – PK/PD Results – PK Results" in this section.

Cohort (dosage)	The number of subjects evaluable for ADA	The number of subjects who tested positive for ADA (and as a percentage of the number of subjects evaluable for ADA)	The number of subjects who tested negative for ADA (and as a percentage of the number of subjects evaluable for ADA)
Cohort 1 (25 μg)	1	1 (100%)	0 (0)
Cohort 2 (50 μg)	4	3 (75%)	1 (25%)
Cohort 3 (100 μg)	4	3 (75%)	1 (25%)
Cohort 4 (200 μg)	3	2 (66.7%)	1 (33.3%)
Cohort 5 (300 μg)	4	4 (100%)	0 (0)
Cohort 6 (400 μg)	11	9 (81.8%)	2 (18.2%)
Cohort 7 (600 μg)	1	1 (100%)	0 (0)
Total	28	23 (82.1%)	5 (17.9%)

Source: Company data

Abbreviation: ADA refers to anti-drug antibodies

Ongoing Phase II clinical trial of M701 monotherapy in combination with systematic treatment for MA in patients with EpCAM-positive carcinomas in China

Trial design

This is a multicenter, randomized, open-label, controlled Phase II clinical trial to evaluate the efficacy of M701 monotherapy in combination with systematic treatment (including targeted therapy, immunotherapy or chemotherapy) for MA in patients with EpCAM-positive carcinomas in China. In this clinical trial, subjects receive systematic treatment for the treatment of cancer. As these subjects are suffering from MA caused by their cancer, they are designed to receive M701 monotherapy for the treatment of MA. As advised by our PRC Legal

Advisor, pursuant to the "Clinical Trial Technical Guidance Principles for Combination Therapy of Anticancer Drugs" (《抗腫瘤藥物聯合治療臨床試驗技術指導原則》) issued by the CDE, clinical trials for combination therapy should gather evidence of superior efficacy for a particular indication/tumor type relative to any monotherapies within that combination therapy for the same indication/tumor type. This implies that different monotherapies within a combination therapy should be designed for the treatment of the same indication. As M701 and the systematic treatment target different indications (i.e., systematic treatment is used to treat cancer, while M701 is designed to treat MA), this trial is not a study of the combination therapy of M701 and systematic treatment, but rather a study for the monotherapy of M701 for the single indication of MA. We plan to enroll a total number of 91 to 111 subjects (a) who are advanced ovarian cancer/primary peritoneal carcinoma patients resistant to cisplatin, or advanced gastric cancer or colorectal cancer patients who have failed first-line treatment and second-line treatment, and (b) who have EpCAM-positive ascites with a volume of at least 1L based on a CT evaluation.

To specify the inclusion criteria of "advanced gastric cancer or colorectal cancer patients who have failed first-line treatment and second-line treatment" above, the following table sets forth the standard first-line treatment and second-line treatment for the gastric cancer and colorectal cancer patients.

Cancer Type	First-line treatment	Second-line treatment
Gastric cancer	(1) FOLFOX/XELOX in combination with a PD-1 inhibitor; (2) Oxaliplatin/cisplatin plus fluoropyrimidine; (3) Irinotecan/irinotecan plus fluoropyrimidine; (4) Herceptin in combination with oxaliplatin/cisplatin plus fluorouracil/ capecitabine (only for HER2-positive patients).	(1) Single agent chemotherapy (paclitaxel, irinotecan, or vismodegib); (2) For MSI-H patients, pembrolizumab monotherapy.
Colorectal cancer	FOLFOX/CAPEOX/FOLFIRI chemotherapy with or without bevacizumab or cetuximab.	(1) PD-1/PD-L1 inhibitors; (2) Combination of different chemotherapy regimens such as ixabepilone, with or without bevacizumab or satuximab as additional treatment

Source: Company data

Patients will be randomized into two groups (treatment arm and control arm) at the ratio of 1:1, and each go through two treatment cycles. The first treatment cycle lasts for 18 days with the treatment arm to receive four paracenteses plus intra-peritoneal (IP) M701 infusions at an initial dose at 50μg and a maintenance dose at 400μg in combination with systematic treatment, and the control arm to receive four paracenteses in combination with systematic treatment on days 1, 4, 8, and 18. The following table sets forth the treatment regime in the treatment arm and the control arm for the first treatment cycle on days 1, 4, 8, and 18:

Tumor types	Control arm	Treatment arm
Advanced gastric cancer	Paracentesis in combination with systematic treatment	Paracentesis plus M701 IP infusion in combination with systematic treatment
Advanced colorectal cancer	Paracentesis in combination with systematic treatment	Paracentesis plus M701 IP infusion in combination with systematic treatment
Advanced ovarian cancer/ primary peritoneal carcinoma	Paracentesis in combination with systematic treatment	Paracentesis plus M701 IP infusion in combination with systematic treatment

Source: Company data

We expect that, after receiving four infusions of M701 in the first treatment cycle, patients in the treatment arm will have good, sustainable control over MA compared to the control arm, which we intend to observe in the second treatment cycle where (i) patients in treatment arm will receive biweekly infusion of M701 to maintain the efficacy of the drug in combination with systematic treatment, (ii) patients in control arm will receive only systematic treatment, and (iii) patients in both treatment arm and control arm will not receive any further paracentesis until the researcher determines that the ascites in the patients in either the treatment or control arm have progressed to the point where paracentesis intervention is needed. The criteria for requiring paracentesis include patients experiencing noticeable intolerable symptoms (including anorexia, nausea, vomiting, abdominal distention, abdominal pain, difficulty breathing, shifting dullness, fluid thrill, dullness on abdominal percussion, etc.), and the discovery of a large amount of ascites through ultrasound or CT scans. A determination of intolerance to ascites is made after comprehensive evaluation by the researchers. At this point, the patients will undergo paracentesis, and the researchers will record the time of the patients' puncture-free survival (PuFS).

Details of drugs used in the systematic treatment are as follows:

Tumor types	Drugs used in the systematic treatment	Drug types
Advanced gastric cancer	Apatinib mesylate	Targeted therapy
	Nivolumab (provided that nivolumab will only be used in anti-PD-1 antibody naïve patients)	Immunotherapy
Advanced colorectal cancer	Regorafenib	Targeted therapy
	Fruquintinib	Targeted therapy
Advanced ovarian cancer/ primary peritoneal carcinoma	Paclitaxel	Chemotherapy
	Doxorubicin hydrochloride liposome	Chemotherapy

Source: Company data

The primary objective of this trial is to evaluate the puncture-free survival (PuFS) in MA treatment, while the secondary objectives are to evaluate other efficacy indicators, safety, PK and immunogenicity. The primary endpoint is puncture-free survival (PuFS). The secondary endpoints include ORR, PFS, OS, quality of life, adverse events, PK and immunogenicity.

Trial status

We commenced this trial in December 2021 with CDE confirmation and ethic committee approval. As of July 31, 2023, a total of 85 subjects were enrolled. The following table sets forth the number of subjects enrolled in this Phase II clinical trial of M701 by cancer type as of July 31, 2023.

Cancer types	Number of subjects enrolled for the Phase II clinical trial as of July 31, 2023
Gastric cancer	43
Ovarian cancer (including fallopian tube cancer)	30
Colorectal cancer	11
Primary peritoneal carcinoma	1
Total	85

Interim safety results

As of December 31, 2022, the safety data showed that M701 was well tolerated combined with the systematic treatment. Most of the AEs were Grade 1 or Grade 2 AEs. The incidences of Grade 3 or above TEAEs were 38.9% in M701 arm, in a similar level to that of 38.5% in control arm. The Grade 3 or above TEAEs in M701 arm included hypoalbuminemia, anemia, nausea, hypokalemia, decreased appetite and vomiting. There were only three SAEs related to M701 arm and two of them caused the cessation of treatment. These M701 related SAEs included anorexia, intestinal obstruction and multiple organ dysfunction syndrome.

Ongoing Phase Ib/II clinical trial of M701 monotherapy in combination with systematic treatment for advanced non-small cell lung cancer patients with MPE in China

Trial design

This is a multicenter, open-label Phase Ib/II clinical trial to evaluate the PK/PD, safety, tolerability, and preliminary efficacy of M701 monotherapy in combination with systematic treatment of MPE in advanced non-small cell lung cancer (NSCLC) patients in China. The regimen of the systematic therapy will be decided by the investigators among chemotherapy, targeted therapy, and immunotherapy. In this clinical trial, subjects receive systematic treatment for the treatment of cancer. As these subjects are suffering from MPE as a result of their cancer, they are designed to receive M701 monotherapy for the treatment of MPE. As advised by our PRC Legal Advisor, pursuant to the "Clinical Trial Technical Guidance Principles for Combination Therapy of Anticancer Drugs" (《抗腫瘤藥物聯合治療臨床試驗技術指導原則》) issued by the CDE, clinical trials for combination therapy should gather evidence of superior efficacy for a particular indication/tumor type relative to any monotherapies within that combination therapy for the same indication/tumor type. This implies that different monotherapies within a combination therapy should be designed for the treatment of the same indication. As M701 and the systematic treatment target different indications (i.e., systematic treatment is used to treat cancer, while M701 is designed to treat MPE), this trial is not a study of the combination therapy of M701 and systematic treatment, but rather a study for the monotherapy of M701 for MPE. We plan to enroll 22 to 36 subjects for the Phase Ib portion and 60 subjects for the Phase II portion.

The Phase Ib portion consists of a dose-escalation phase and a cohort-expansion phase. The dose-escalation phase will include four cohorts. Cohort 1 will follow the "1+5" design, and cohort 2 to cohort 4 will follow the standard "3+3" design. Subjects in each cohort will undergo a 28-day DLT observation period, receiving an initial dosage of M701 at 25μg on day 1, and escalating dosages of M701 at 50μg, 100μg, 200μg and 400μg for cohort 1, cohort 2, cohort 3 and cohort 4 on day 4, day 7 and day 10, respectively. We plan to enroll 10 to 24 patients in the dose-escalation phase. After determining the RP2D in the dose-escalation phase, the RP2D cohort will be expanded to include an additional three groups (groups A, B and C) of subjects with four subjects in each group. Subjects in groups A, B and C will receive one dosage of M701 every three days for a total of three, four and six dosages, respectively.

The primary objectives of the Phase Ib portion are to evaluate the safety and tolerability of M701, and to determine the RP2D and appropriate dosage frequency of M701 monotherapy in combination with systematic treatment in advanced NSCLC patients with MPE.

In the Phase II portion, patients will be randomized into two groups (treatment arm and control arm) at the ratio of 1:1. The treatment arm will receive M701 intra-pleural infusion plus thoracentesis at RP2D in combination with systematic treatment. The control arm will receive thoracentesis only or thoracentesis and thoracic perfusion chemotherapy, both in combination with systematic treatment.

The primary objective of the Phase II portion is to evaluate the efficacy of M701 monotherapy in combination with systematic treatment in treating MPE for patients with advanced NSCLC.

Trial status

We commenced this trial in November 2022. As of July 31, 2023, a total of 11 subjects had been enrolled for this trial. We expect to complete this trial in the third quarter of 2024.

Clinical Development Plan

MA

We completed a Phase I clinical trial of M701 in monotherapy in treating MA in China in January 2022. We initiated a Phase II clinical trial of M701 monotherapy in combination with systematic treatment in treating MA in China in December 2021. We expect to complete this Phase II trial in the fourth quarter of 2023. For more details, please refer to the paragraphs headed "– Our Drug Candidates – M701 (EpCAM × CD3 BsAb) – Our Core Product – Summary of Clinical Trial Results – Ongoing Phase II Clinical Trial of M701 monotherapy in Combination with Systematic Treatment for MA in Patients with EpCAM-positive Carcinomas in China" in this section. After the completion of this Phase II trial, we plan to commence a pivotal/Phase III trial for M701 in treating MA in China in the first quarter of 2024 and file BLA submission in the first quarter of 2025. We expect to receive the BLA approval for M701 monotherapy for the treatment of MA following such submission.

We also received FDA IND approval for our clinical investigation for MA in patients with EpCAM-positive carcinomas in October 2019. We currently have no immediate plan to initiate clinical trial for M701 in the U.S. We plan to leverage our clinical results of Phase II and pivotal/Phase III clinical trials in China to conduct late-stage clinical development of M701 in the U.S. in the future.

We believe it is feasible for us to leverage clinical results of M701 in China to conduct late-stage clinical development of M701 in the U.S. because FDA has released a "Guidance for Industry and FDA Staff/FDA Acceptance of Foreign Clinical Studies Not Conducted Under an IND Frequently Asked Questions" which provides guidance for the industry and the FDA staff

on the acceptance of results generated from foreign clinical studies. This guidance clarifies that sponsors and applicants can demonstrate compliance with the requirements of 21 CFR 312.120 by submitting information evidencing that a foreign clinical study is conducted in accordance with Good Clinical Practice (GCP). As we have been, and will continue to, conduct the clinical trials of M701 in accordance with GCP, we believe the clinical trial results of M701 in China can be used for the application of FDA IND approvals.

Additionally, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guideline "Ethnic Factors in the Acceptability of Foreign Clinical Data E5 (R1)" also supports the use of foreign clinical data as a basis to support the approval of an IND application in a new jurisdiction, without the need to repeat the entire clinical drug development program in the new jurisdiction.

Furthermore, the approval of Zebutinib (developed by BeiGene) by FDA in 2019 primarily based on data from a pivotal Phase II clinical trial conducted in China, as well as data from a global Phase I/II clinical trial, provides a precedent for the acceptance of clinical data generated from clinical trials conducted in China by the FDA.

There have been recent examples of the FDA declining to approve China-tested drugs mainly based on the clinical data generated in China, including sintilimab, a lung cancer drug candidate and surufatinib, a pancreatic and extra-pancreatic neuroendocrine tumor drug candidate. Sintilimab has not undergone any clinical trials in the U.S., while surufatinib has only been tested in a small-scale bridging trial in the U.S. Neither drug has been evaluated in pivotal clinical trials involving diverse populations in the U.S., nor have their pivotal clinical trial protocols been reviewed or approved by the FDA.

After completing the Phase II clinical trial of M701 and the Phase Ib/II clinical trials of Y101D in China, we plan to leverage the clinical results generated in China to support the late-stage clinical development in the U.S. We plan to collaborate with overseas partners to confirm the design of late-stage clinical trials with FDA and conduct such clinical trials in the U.S., which will enable us to obtain efficacy data encompassing multiple ethnicities and form the basis for us to obtain regulatory approvals to commercialize M701 in the U.S. and some other overseas markets. However, we cannot guarantee that the FDA will accept our clinical results generated in China to support pivotal clinical trials in the U.S., and we may face difficulties and incur additional costs thereof. For details, please refer to the paragraphs headed "Risk Factors – Risks Relating to Commercialization of Our Drug Candidates – We may face difficulties in leveraging the clinical results of our drug candidates in China for late-stage clinical development in other jurisdictions" in this document.

MPE

We commenced a Phase Ib/II clinical trial of M701 for advanced NSCLC patients with MPE in China in November 2022. This trial is designed to evaluate M701 in treating MPE instead of NSCLC. We expect to complete this Phase Ib/II trial in the third quarter of 2024. For more details, please refer to the paragraphs headed "– Our Drug Candidates – M701 (EpCAM

× CD3 BsAb) – Our Core Product – Summary of Clinical Trial Results – Ongoing Phase Ib/II Clinical Trial of M701 Monotherapy in Combination with Systematic Treatment for Advanced Non-Small Cell Lung Cancer Patients with MPE in China" in this section. Following the completion of this Phase Ib/II trial, we plan to commence a pivotal/Phase III trial for M701 for the treatment of MPE (instead of NSCLC) in China in the third quarter of 2024 and file BLA submission in the fourth quarter of 2025. We expect to receive the BLA approval for M701 monotherapy for the treatment of MPE (instead of NSCLC) following such submission. We have internally drafted a summary of the design of this pivotal/Phase III clinical trail and plan to submit a consultation with CDE regarding the design in the third quarter of 2024. We expect the speed of subject enrollment for this Phase III trial to be faster than that of the Phase II clinical trial of M701 for MA due to (i) the confirmed dosage and frequency for the Phase III clinical trial, eliminating the need for time-consuming exploration, and (ii) the significantly larger number of clinical trial centers involved in Phase III compared to Phase II.

Solid tumor

We plan to file an IND application with the NMPA in the first quarter of 2024 and expect to receive the IND approval in the second quarter of 2024. We plan to initiate and sponsor a Phase I/II clinical trial of M701 for the treatment of solid tumor in the second quarter of 2024 in China. We expect to conduct a pivotal/Phase III clinical trial and receive the BLA approval for M701 monotherapy for the treatment of solid tumor following the pivotal/Phase III clinical trial and BLA submission for M701 monotherapy for solid tumor.

Licenses, Rights and Obligations

As we internally discovered and developed M701, we maintain the global rights to develop and commercialize this drug candidate.

Material Communications with Competent Authorities

The material communications with the relevant competent authorities in respect of M701 are as follows:

- We filed the IND application for M701 for MA with the NMPA on August 9, 2016 and received the umbrella IND approval from the NMPA for the Phase I, II and III clinical trials of M701 for MA on February 12, 2018. This IND approval authorized the design of the Phase I clinical trial of M701 monotherapy for the treatment of MA in patients with EpCAM-positive carcinomas in China. The IND approval stipulates that at the time when we plan to conduct a Phase III clinical trial, we should consult with CDE regarding the design of such Phase III clinical trial.

- We filed the IND application for M701 for MA with the FDA on October 2, 2019 and received the IND approval for M701 for MA from the FDA on October 29, 2019.

- We submitted the consultation to the CDE in respect of a Phase II clinical trial of M701 monotherapy in combination with systematic treatment for MA on December 14, 2020. During this consultation, we submitted the interim safety and efficacy data as of November 30, 2020 in the Phase I clinical trial of M701 for the treatment of MA. We received the confirmation from the CDE for the trial design and commencement of this Phase II clinical trial on January 8, 2021. As M701 and the systematic treatment target different indications (i.e., systematic treatment is used to treat cancer, while M701 is designed to treat MA) in this Phase II trial, this trial is not a study of the combination therapy of M701 and systematic treatment, but rather a study for the monotherapy of M701 for MA. For more details regarding the design of this Phase II clinical trial of M701 monotherapy, please refer to the paragraphs headed "– Our Drug Candidates – M701 (EpCAM × CD3 BsAb) – Our Core Product – Summary of Clinical Trial Results – Ongoing Phase II Clinical Trial of M701 Monotherapy in Combination with Systematic Treatment for MA in Patients with EpCAM-positive Carcinomas in China" in this section. In addition to the above communications with the relevant competent authority, on May 28, 2021, we submitted to the ethic committee the interim safety and efficacy results as of May 8, 2021 from the Phase I clinical trial of M701 for MA, and we received the ethic committee approval for the design and commencement this Phase II clinical trial on June 23, 2021. According to the Measures for the Administration of Drug Registration (《藥品註冊管理辦法》), each phase of clinical drug trials shall be examined and approved by the ethics committee before being carried out. We had sufficient clinical basis to commence this Phase II clinical trial for MA prior to the completion of the Phase I clinical trial of M701 for MA, based on the initial safety and efficacy data as of May 8, 2021 of the Phase I clinical trial of M701 for MA, primarily as the main purpose of Phase I trial of M701 for MA is to confirm the safety profile of M701 and determine the RP2D. By May 8, 2021, we have received sufficient safety data to the satisfactory of the ethic committee and the RP2D for the Phase II clinical trial. As advised by Frost & Sullivan, it is not uncommon to commence a Phase II clinical trial prior to the completion of a prior Phase I clinical trial.

- We submitted the IND application for M701 for MPE with the NMPA on April 19, 2022 and received the IND approval from the NMPA for the Phase Ib/II, Phase III clinical trials of M701 for MPE on July 4, 2022. This IND approval authorized the design of the Phase Ib/II clinical trial of M701 monotherapy in combination with systematic treatment for advanced NSCLC patients with MPE in China. As M701 and the systematic treatment target different indications (i.e., systematic treatment is used to treat cancer, while M701 is designed to treat MPE) in this Phase Ib/II trial, this trial is not a study of the combination therapy of M701 and systematic treatment, but rather a study for the monotherapy of M701 for MPE. For more details regarding the design of this Phase Ib/II trial of M701 monotherapy for MPE, please refer to the paragraphs headed "– Our Drug Candidates – M701 (EpCAM × CD3 BsAb) – Our Core Product – Summary of Clinical Trial Results – Ongoing Phase Ib/II Clinical Trial of M701 Monotherapy in Combination with Systematic Treatment for Advanced Non-Small Cell Lung Cancer Patients with MPE in China" in this section.

The intended indications of M701 include MA, MPE and solid tumor, which are regarded as three independent indications (instead of indication expansions) mainly due to (a) different administration method (for example, intraperitoneal infusions for MA while intrathoracic infusions for MPE), and (b) different dosing level and schedule designed for each indication. Notwithstanding the foregoing, the safety data, PK/PD data in a clinical trial for one indication of M701 can be leveraged and used as reference in a clinical trial for another indication of M701. However, the efficacy of M701 in different indications will be evaluated independently in different clinical trials.

Therefore, we expect to receive three independent BLA approvals from the NMPA for M701 with respect to each of MA, MPE and solid tumor. With respect to clinical trials for M701 in treating MA, notwithstanding that the Phase I clinical trial evaluated M701 monotherapy in treating MA while the Phase II clinical trial is evaluating M701 monotherapy in combination with systematic treatment for MA, these are regarded as the same clinical program covered by the umbrella IND approval from the NMPA for the Phase I, II and III clinical trials for the study of M701 monotherapy in treating MA, as elaborated above. Therefore, we will only submit one BLA application for M701 monotherapy for MA, and will be able to receive a BLA approval for MA if all the application criteria are met.

We plan to commence a pivotal/Phase III trial for M701 in treating MA in China in the first quarter of 2024 and file BLA submission in the first quarter of 2025. We expect to receive the BLA approval for M701 monotherapy for the treatment of MA following such submission. The BLA approval for M701 for MA will be limited to the cancer types to be evaluated in the pivotal/Phase III trial of M701 for MA. Based on the cancer types that we evaluated in Phase I and Phase II clinical trials of M701 for MA, we currently expect to include the following cancer types in the pivotal/Phase III trial for M701 for MA: gastric cancer, ovarian cancer, colorectal cancer and peritoneal carcinoma. Therefore, we expect that the BLA approval for M701 in treating MA will be initially limited to the MA caused by these four cancer types. Notwithstanding the foregoing, after the commercialization of M701, physicians may consider using M701 for MA treatment in other cancer types depending on the clinical efficacy of M701 for MA caused by such other cancer types. In addition, we may also expand the clinical application of M701 for MA in other cancer types through post-launch Phase IV clinical studies or through indication-expansion clinical trials.

As of the Latest Practicable Date, we were not aware of any legal claim or proceeding that may have an adverse effect on our development of M701. We had not received any regulatory agency's concerns or objections to our clinical development plans, completed clinical trial for MA or ongoing clinical trials for MA and MPE as of the Latest Practicable Date, nor did any material unexpected or adverse changes had occurred since the date of issue of relevant regulatory approvals for M701.

Cautionary Statement required by Rule 18A.05 of the Listing Rules of the Hong Kong Stock Exchange:

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET M701 SUCCESSFULLY.

Y101D (PD-L1 × TGF-β BsAb)

Y101D is a recombinant anti-programmed death ligand-1 (PD-L1) and anti-transforming growth factor-β (TGF-β) humanized BsAb. According to the CDE and the ClinicalTrials.gov websites, Y101D is the only PD-L1 × TGF-β symmetric tetravalent BsAb that has entered into clinical development globally. There are 16 PD-1/PD-L1 × TGF-β targeted pipelines under clinical trials in China, among which Y101D is the only PD-L1 × TGF-β BsAb and the other 15 pipelines are PD-1/PD-L1 × TGF-β targeted bifunctional antibody-receptor fusion proteins. There is no evidence that BsAbs offer any significant clinical advantages compared to fusion protein antibodies. For a comparative analysis between BsAb and fusion protein, please refer to the paragraphs headed "Industry Overview – Global and China Antibody Drug Market – Overview" in this document. Therapeutic antibodies targeting PD-1/PD-L1 axis induce potent and durable anti-tumor responses in multiple types of solid tumors. However, only a subset of patients benefits from anti-PD-1/PD-L1 therapies. Y101D is designed to simultaneously inhibit the PD-1/PD-L1 axis and the TGF-β signaling pathways, thus having the potential to unleash a synergistic anti-tumor activity and relieve drug resistance. In our preclinical studies, Y101D has demonstrated potent anti-tumor activity with a favorable safety profile, and the anti-TGF-β moiety of Y101D has better stability and biological activity than TGF-β trap *in vivo*. The interim results of the Phase I clinical study for Y101D in patients with metastatic or locally advanced solid tumors in China also show an encouraging safety and efficacy profile for Y101D.

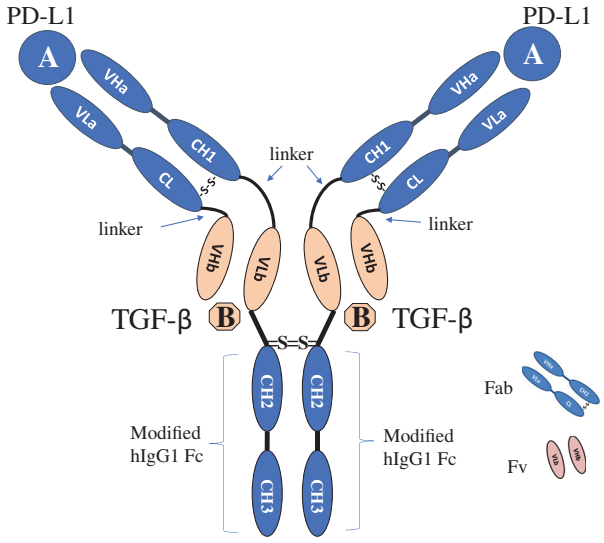
We are currently evaluating Y101D in patients with metastatic or locally advanced solid tumors in a Phase I clinical trial in China. We also commenced a Phase Ib/II clinical trial of Y101D in combination therapy for the treatment of advanced/metastatic pancreatic cancer in February 2023. We have commenced the patient enrollment for the Phase II portion of this Phase Ib/II clinical trial in July 2023. In addition, we commenced a Phase Ib/II clinical trial of Y101D in combination with anti-angiogenesis for the treatment of HCC and other advanced solid tumors in March 2023. In addition, we plan to file the IND application for Y101D in combination with chemotherapy in treating SCLC in the first quarter of 2024.

We are developing Y101D in-house and own its global IP and commercial rights.

Mechanism of Action

Y101D is a recombinant IgG-like BsAb, which has two identical short chains and two identical long chains, in which short-long chains paired and long-long chains paired. The short chain of Y101D consists of three domains: VLa, CL, and VHb, where CL and VHb are connected through a linker. The VLa domain is from the VL of an anti-PD-L1 antibody. The

VHb domain is from the VH of an anti-TGF-β antibody. The long chain of Y101D consists of five domains: VHa, CH1, VLb, CH2, and CH3, where CH1 and VLb are connected through a linker. The VHa domain is from the VH of the anti-PD-L1 antibody, and the VLb domain is from the VL of the anti-TGF-β antibody. The Fc of Y101D consists of CH2 and CH3 modified from hIgG1 Fc to eliminate the binding to Fc gamma receptors (FcγRs). The diagram below illustrates the molecule structure of Y101D.



Source: Company data

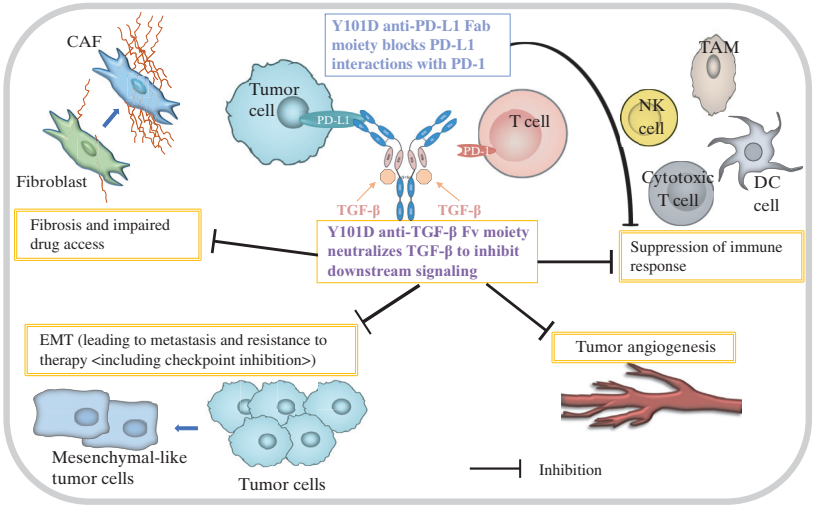
PD-1 is an inhibitory cell surface receptor expressed on T cells. The binding of PD-1 to its ligand PD-L1 transmits a negative signal that suppresses T cell activity. The normal function of PD-1 is to modulate T cell-mediated immune response in order to prevent the immune system from attacking normal healthy tissue in the body. However, this safeguarding mechanism is often exploited by cancer cells to evade immune surveillance. Many solid tumor cells produce a large amount of PD-L1 to circumvent T cell assaults.

As a versatile cytokine, TGF-β is usually overexpressed in advanced tumors and is related to poor prognoses of the diseases. The role of TGF-β is context-dependent. For pre-malignant cells, TGF-β acts as a tumor suppressor by inhibiting cell proliferation, inducing cell apoptosis, and suppressing inflammation. However, for advanced cancers, TGF-β promotes distant metastasis, drug resistance, and immune escape. TGF-β can regulate the functions of multiple immune cells, such as reducing the cytotoxicity of T cells and natural killer cells (NK cells), inducing the differentiation of regulatory T cells (Tregs), and suppressing the antigen presentation activity of dendritic cells (DCs). TGF-β also restricts the infiltration of immune cells by facilitating peritumoral collagen generation.

Y101D binds to PD-L1 and prevents it from binding to PD-1, thereby restoring the blocked anti-tumor immune response of T cells. Y101D also antagonizes TGF-β, thereby enhancing the tumor-killing activity of multiple immune cells, promoting T cell infiltration by restraining cancer-associated fibroblast (CAF) and collagen generation, counteracting

epithelial-mesenchymal transition (EMT), and suppressing tumor angiogenesis. Therefore, by simultaneously inhibiting the PD-1/PD-L1 axis and the TGF-β signaling pathways, Y101D restores the dysregulated anti-tumor immunity of cancer patients and establishes an immuno-supportive tumor microenvironment (TME).

The following diagram illustrates the mechanism of action of Y101D:



Source: Company data

Abbreviation: TAM refers to tumor-associated macrophage.

Market Opportunities and Competition

We are developing Y101D as a monotherapy for the treatment of various types of solid tumors, as well as in combination therapy for the treatment of pancreatic cancer, HCC and other advanced solid tumors.

The incidence of pancreatic cancer in China has grown from approximately 104.9 thousand in 2018 to approximately 120.0 thousand in 2022, and is expected to increase to approximately 137.1 thousand in 2026 and approximately 155.2 thousand in 2030. According to the NCCR and GLOBOCAN, HCC ranked fifth in terms of patient incidence in China in 2021. The incidence of HCC in China has grown from approximately 360.2 thousand in 2018 to approximately 397.5 thousand in 2022, and is expected to further increase to approximately 435.5 thousand in 2026 and 472.3 thousand in 2030.

Therapeutic antibodies that target the PD-1/PD-L1 axis induce potent and durable anti-tumor responses in multiple types of solid tumors. However, only a subset of patients benefits from anti-PD-1/PD-L1 therapies. The response rate of anti-PD-1/PD-L1 mAb in overall patients is far from satisfactory, and most patients show primary or acquired resistance to these immune checkpoint inhibitors. For instance, among various PD-1/PD-L1 approved indications, the overall response rate (ORR) for head and neck squamous cell carcinoma and liver cancer is less than 35% (i.e. over 65% of patients are primary refractory). Microsatellite

stable type colorectal cancer, pancreatic cancer, and biliary cancer are less likely to benefit from and are not approved for PD-1/PD-L1 treatment; the median progression-free survival (PFS) for non-squamous and squamous lung cancer is 8-9 months; the median PFS for small cell lung cancer is only 5.2 months; and the median PFS for esophageal squamous cell carcinoma is only 6.9 months, indicating that these patients will develop resistance after treatment for 5-9 months. As a negative regulator of anti-tumor immunity, TGF-β impairs the efficacy of anti-PD-1/PD-L1 drugs and induces resistance. In the TME with hyperactive TGF-β signaling, the effect of anti-PD-1/PD-L1 therapy is limited. Moreover, after receiving anti-PD-1/PD-L1 treatments, the TGF-β1 gene expression is higher in the tumor tissues of non-responders, resulting in elevated TGF-β levels in their TME, thus forming a vicious cycle.

Correspondingly, the dual blockade of PD-L1 and TGF-β enhances the effect of anti-PD-1/PD-L1 therapies and relieves drug resistance that can benefit patients who (i) are not eligible for PD-1/PD-L1 monotherapy, (ii) failed or developed resistance to PD-1/PD-L1 monotherapy, or (iii) are sensitive to PD-1/PD-L1 yet whose tumors have high levels of TGF-β. Furthermore, anti-PD-L1 and anti-TGF-β BsAbs unleash a synergistic anti-tumor activity, and therefore have the potential to be more efficacious than PD-1/PD-L1 monotherapies, and may replace them as first-line treatment for solid tumors.

Competitive Landscape

No PD-1/PD-L1 × TGF-β BsAb drug is marketed either globally or in China. There are 16 PD-1/PD-L1 × TGF-β targeted pipelines under clinical trials in China, among which Y101D is the only PD-L1 × TGF-β BsAb and the other 15 pipelines are PD-1/PD-L1 × TGF-β targeted bifunctional antibody-receptor fusion proteins, according to the CDE and the ClinicalTrials.gov websites. There is no evidence that BsAbs offer any significant clinical advantages compared to fusion protein antibodies. For a comparative analysis between BsAb and fusion protein, please refer to the paragraphs headed "Industry Overview – Global and China Antibody Drug Market – Overview" in this document.

The following table summarizes the status of PD-1/PD-L1 × TGF-β pipelines under clinical trials in China as of the Latest Practicable Date:

China Pipeline

Product	Developer	Target	Drug Type	Indication	Highest Clinical Phase	First Posted Date[1]
M7824	Merck & Co., Inc.	PD-L1, TGF-β	Fusion Protein	Advanced solid tumor (including, NSCLC, cholangiocarcinoma, cervical cancer)	III	2022/4/21
SHR-1701	Jiangsu Hengrui Medicine Co Ltd, Shanghai Hengrui Pharmaceutical Co Ltd, Suzhou Suncadia Biopharmaceuticals Co Ltd	PD-L1, TGF-β	Fusion Protein	Advanced solid tumor (including, NSCLC, cervical cancer, gastric cancer)	III	2021/11/17
PM-8001	Biotheus Inc	PD-L1, TGF-β	Fusion Protein	Advanced solid tumor	I/II	2020/6/24
TQB2858	Nanjing Jun Xin Pharmaceutical Co., Ltd.	PD-L1, TGF-β	Fusion Protein	Advanced malignant tumor	I	2021/3/25
JS-201	Shanghai Junshi Biosciences Co Ltd	PD-1, TGF-β	Fusion Protein	Advanced solid tumor	I	2021/5/21
QLS31901	Qilu Pharmaceutical Co., Ltd.	PD-L1, TGF-β	Fusion Protein	Advanced solid tumor	I	2021/6/2
Y101D	the Company	PD-L1, TGF-β	BsAb	Metastatic or locally advanced solid tumors; HCC; PC	Ib/II	2022/12/05
BR102	Hisun Biopharmaceutical Co., Ltd.	PD-L1, TGF-β	Fusion Protein	Advanced malignant tumor	I	2021/9/13
LBL-015	Nanjing Leads Biolabs Co., Ltd.	PD-1, TGF-β	Fusion Protein	Advanced solid tumor	I	2021/9/22
TQB-2868	Nanjing Shunxin Pharmaceuticals Co, Ltd of Chiatai Tianqing Pharmaceutical Group	PD-1, TGF-β	Fusion Protein	Advanced malignant tumor	I	2022/2/14
BJ-005	Boji Biomedical Technology (Hangzhou) Co Ltd	PD-L1, TGF-β	Fusion Protein	Advanced solid tumor; advanced lymphadenoma	I	2022/3/9
GT-90008	Kintor Pharmaceutical (Guangdong) Co., Ltd.	PD-L1, TGF-β	Fusion Protein	Advanced solid tumor	I	2022/5/31
TST-005	Mabspace Biosciences (Suzhou) Co, Limited	PD-L1, TGF-β	Fusion Protein	Metastatic or locally advanced solid tumors (e.g. HPV positive, NSCLC)	I	2022/7/1
HB-0028	Huabo Biopharm Co Ltd	PD-L1, TGF-β	Fusion Protein	Advanced solid tumor	I	2022/8/9
LY01019	Shandong Boan Biotechnology Co. Ltd	PD-L1, TGF-β	Fusion Protein	Advanced solid tumor	I	2022/8/30
6MW3511	Mabwell (Shanghai) Bioscience Co., Ltd.	PD-L1, TGF-β	Fusion Protein	Advanced solid tumor	I	2022/9/1

Source: NMPA, CDE, Frost & Sullivan Analysis

(1) "First Posted Date" in the context of China clinical trials refers to the date when the study corresponding to the highest clinical phase in China was first available on chinadrugtrials.org.cn after the Center for Drug Evaluation (CDE) has concluded its review. The CDE is an affiliated institution of the NMPA.

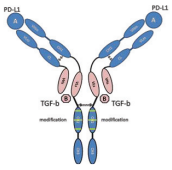
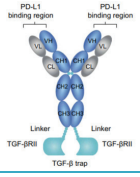
For additional information on the market opportunities and competitive landscape of this drug candidate, please refer to the paragraphs headed "Industry Overview – PD-1/PD-L1 × TGF-β Targeted Drugs Market – Competitive Landscape of PD-1/PD-L1 × TGF-β Targeted Drugs" in this document.

Competitive Advantages

Optimized structural design to target both PD-L1 and TGF-β

In the TME with hyperactive TGF-β signaling, the effect of anti-PD-1/PD-L1 therapy is limited. With the treatment of anti-PD-1/PD-L1 therapy, the TGF-β1 gene expression is higher in the non-responder's tumor tissues. Correspondingly, the dual blockade of PD-1/PD-L1 and TGF-β has a synergistic anti-tumor activity. Given the independent and complementary immunosuppressive effects of the PD-1/PD-L1 axis and TGF-β, it is rational to block the TGF-β signal to enhance the efficacy of anti-PD-1/PD-L1 to overcome treatment resistance. To optimize the anti-tumor activity of anti-PD-1/PD-L1 therapies, we have developed Y101D, which can simultaneously block the PD-1/PD-L1 and TGF-β pathways.

As shown in the table below, Y101D is a BsAb, whose moiety of anti-TGF-β is from the Fv moiety of an anti-TGF-β antibody, while other PD-1/PD-L1 × TGF-β candidates in clinical trials such as M7824 are bifunctional antibody-receptor fusion proteins whose moieties of binding TGF-β are excellular domains of TGF-βRII. The diagram below lists Company data of Y101D and publicly available data of M7824, and is not a head-to-head study of Y101D and M7824.

	the Company Y101D[1]	Merck M7824[2]
Format		
Technology	$(Fab)_2$-$(Fv)_2$-Fc, symmetric tetravalent BsAb with modified Fc of hIgG1	IgG-trap, bifunctional antibody-receptor fusion protein with Fc of wild-type hIgG1
Molecular weight	~200kDa	~180kDa
Affinity	PD-L1: EC50=0.40nM, cell binding TGF-ß1: EC50=0.73nM, ELISA TGF-ß2: EC50=0.56nM, ELISA TGF-ß3: EC50=0.72nM, ELISA	PD-L1: EC50=0.27nM, cell binding TGF-ß1: EC50=1.20nM, ELISA TGF-ß2: EC50=0.14nM, ELISA TGF-ß3: EC50=3.62nM, ELISA
FcγRs binding	No	Yes
Number of glycosylations	1 pair	4 pairs
Stability	Stable at 2-8°C for 27 months and the assessment is continuing	Not available

Source: (1) Company data;

(2) the reference "Lan et al., Sci. Transl. Med. 10, eaan5488 (2018)"

Abbreviation: EC50 refers to half maximal effective concentration.

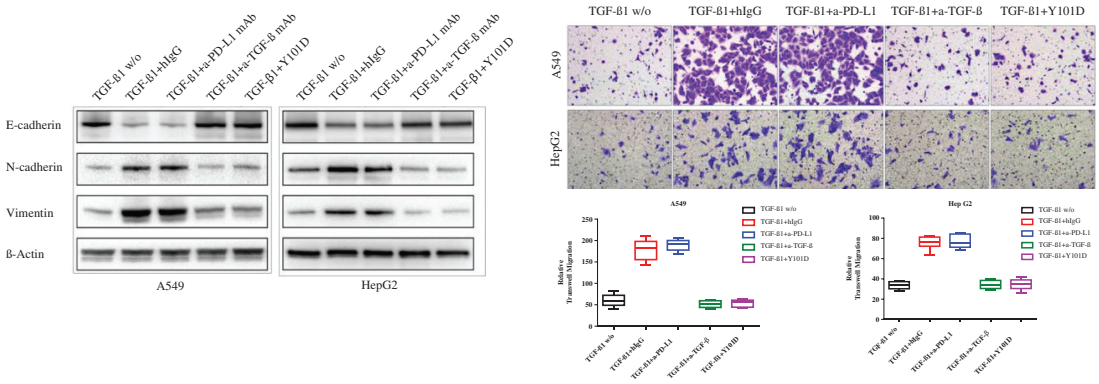
Effectively counteracted the biological effects of TGF-β pathway

In vitro experiments show that Y101D can effectively counteract the biological effects of TGF-β pathways, including inducing EMT, and immunosuppression.

Y101D can inhibit TGF-β-induced EMT and cell migration. TGF-β enhances the movement capability and promotes EMT in cancer cells. Consistent with previous observations, TGF-β1 decreases epithelial markers as it increases the expression of

mesenchymal markers in A549 (human lung cancer cell) and HepG2 (human HCC cell) cells. Y101D effectively antagonizes the TGF-β1-induced EMT in A549 and HepG2 cells: upregulating the epithelial marker (E-cadherin) and downregulating mesenchymal markers (N-cadherin and Vimentin). At the same time, an anti-PD-L1 antibody does not affect the EMT in cancer cells.

Y101D inhibits TGF-β1-induced EMT and cell migration



Source: Company data

Abbreviation: w/o refers to without.

The study also shows that Y101D inhibits the migration of A549 and HepG2 cancer cells enhanced by TGF-β1. The following table shows the migration rates of A549 and HepG2 cancer cells induced by various test samples:

Sample	A549 cells migration rate (%)	HepG2 cells migration rate (%)
TGF-β1 w/o	59.83	33.50
TGF-β1+hIgG	178.83	75.83
TGF-β1+anti-PD-L1 mAb	189.83	76.83
TGF-β1+anti-TGF-β mAb	51.33	34.17
TGF-β1+Y101D	54.33	34.50

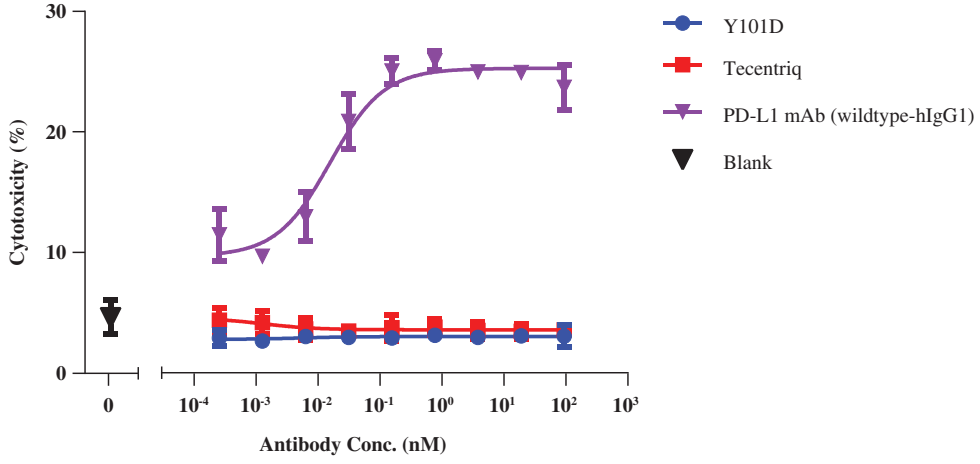
Source: Company data

Y101D can also reverse the TGF-β caused immunosuppression. TGF-β cooperates with IL-2 to induce Foxp3 expression and promotes the conversion of naïve T cells to Tregs. Tregs are immune-suppressive T cells. Y101D blocks the negative effects of TGF-β1 on T cells: it reversed proliferation inhibition, decreased the ratio of G1, and counteracted cell apoptosis. Furthermore, TGF-β1 substantially reshaped the cytokine pattern during T cell activation. Most cytokines, such as Th1-associated (IL-2) and pro-inflammatory cytokines (IFN-γ), are downregulated by exogeneous TGF-β1. Y101D almost completely antagonizes the TGF-β1-caused changes in the cytokine release.

No ADCC activity on PD-L1 expressing T cells

Normally, the Fc region of an antibody binds to FcR, which is generally expressed at high levels on NK cells. As PD-L1 is also expressed on activated T cells, an anti-PD-L1 antibody can also lead to the killing of these activated T cells in a tumor via ADCC as it can bind to PD-L1 on T cells and FcγRs on NK cells simultaneously. To address this issue, we have introduced several mutations to the Fc region of Y101D to disable its binding to the FcγRs. Leveraging this well-designed structure, Y101D does not elicit ADCC, antibody-dependent cell-mediated phagocytosis (ADCP) or CDC activity on PD-L1 expressing T cells. As shown in the diagram below, the Fc region of Y101D is modified to remove the binding to FcγRs and the ADCC function. In addition, the killing activities mediated by FcγRs via other cells such as macrophage are also eliminated.

The Fc of Y101D is modified to remove the binding to FcγRs and the ADCC function



Source: Company data

The following table shows the Fc-mediated ADCC effect (measured by the maximum lysis percentage and the EC50 value) of samples on PD-L1 positive H358 cells with NK cells used as effector cells.

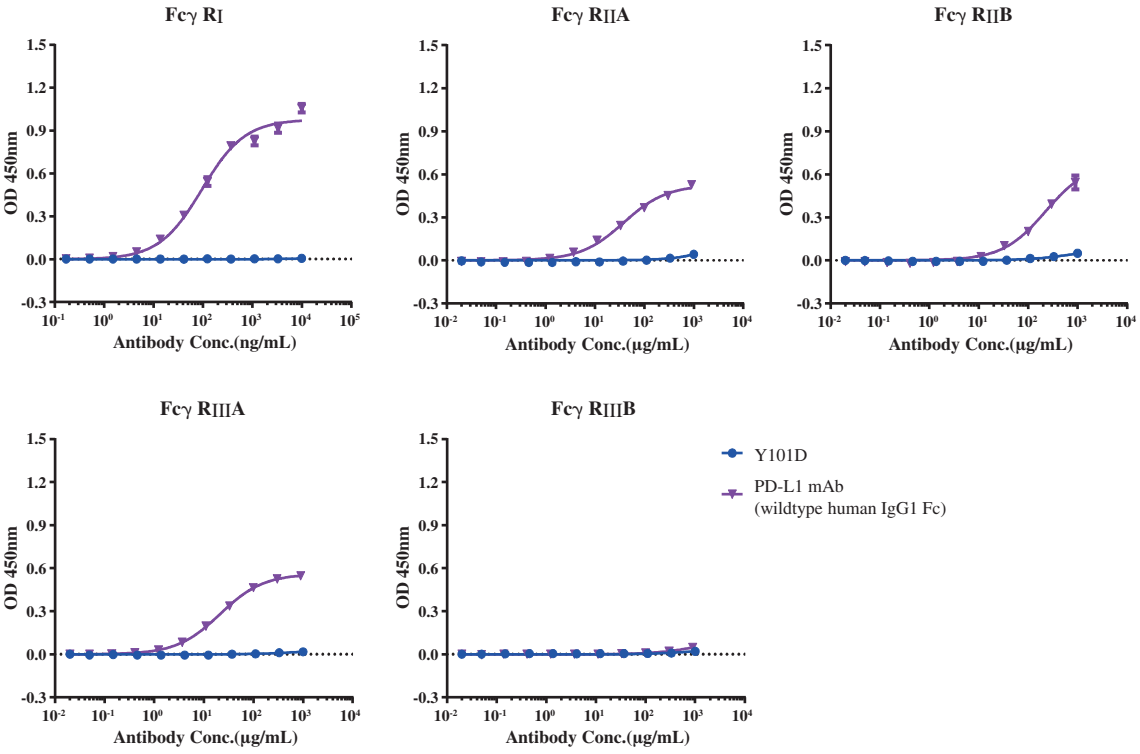
Sample	Maximum lysis (%)	EC50 (nM)
Y101D	2.9	–
Tecentriq	3.5	–
PD-L1 mAb	25.1	0.01604

Source: Company data

Abbreviation: EC50 refers to half maximal effective concentration, the concentration of a drug, antibody or toxicant which induces a response halfway between the baseline and maximum.

In an *in vitro* study to detect the Fc-mediated effector function of Y101D, Y101D does not bind to any of the following five FcγRs: FcγRI, FcγRIIA, FcγRIIB, FcγRIIIA, and FcγRIIIB in ELISA. Also, it does not induce ADCC activities to PD-L1 positive cell line H358.

The following graphs and table show the binding effect of the Fc of Y101D and PD-L1 mAb on FcγR.



Sample	FcγRI	FcγRIIA	FcγRIIB EC50	FcγRIIIA	FcγRIIIB
Y101D	–	–	–	–	–
PD-L1 mAb	95.4ng/mL	38.3μg/mL	225.5μg/mL	21.27μg/mL	–

Source: Company data

Abbreviation: EC50 refers to half maximal effective concentration, the concentration of a drug, antibody or toxicant which induces a response halfway between the baseline and maximum.

Dual blockade of TGF- β and PD-1/PD-L1 which lead to potent anti-tumor effect

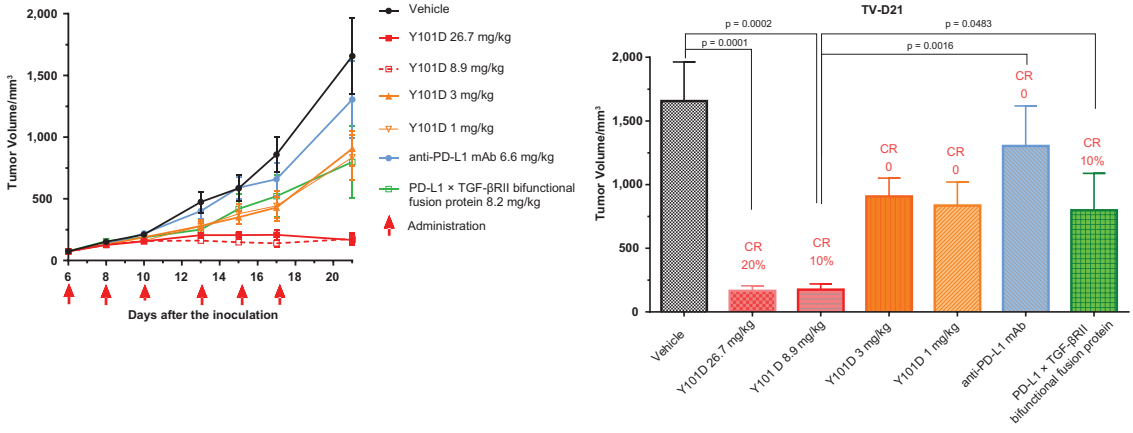
The immune normalization strategy aims to recover the blocked anti-tumor immune response. For certain patients, normalizing a single vital pathway such as PD-1/PD-L1 is sufficient to trigger the reshape of the TME. However, for most patients, immune deficiency or dysregulation in the TME is often multifaceted and correcting other defects might be necessary to overcome the resistance to anti-PD-1/PD-L1 therapy. Based on the fact that TGF-β is the dominant inhibitory pathway, the dual blockade of TGF-β and PD-1/PD-L1 by Y101D can effectively alter the "cancer-immunity set point," converting immune tolerance to activated T cell immunity.

In vivo experiment indicates that, in the EMT-6 breast orthotopic tumor model, the anti-tumor activity of Y101D is superior to that of anti-PD-L1 monotherapy and PD-L1 × TGF-βRII bifunctional fusion protein. We compared the anti-tumor effect of Y101D (8.9 mg/kg) with other controls, including vehicle, anti-PD-L1 mAb (6.6 mg/kg) and PD-L1 ×

TGF-βRII bifunctional fusion protein (8.2 mg/kg). In the EMT-6 orthotopic tumor model, the anti-PD-L1 antibody does not exhibit a significant anti-tumor effect, the anti-tumor activity of Y101D is superior to vehicle (p = 0.0002), the anti-PD-L1 antibody (p = 0.0016), and PD-L1 × TGF-βRII bifunctional fusion protein (p = 0.0483). The higher dose of Y101D had better efficacy. In particular, Y101D (26.7mg/kg) treatment led to 20% CR.

The diagrams and table below present the efficacy of anti-PD-L1 mAb, PD-L1 × TGF-βRII bifunctional fusion protein, and different doses of Y101D in suppressing tumor growth in the EMT-6 breast orthotopic tumor model 21 days after inoculation.

In the EMT-6 breast orthotopic tumor model
The efficacy of Y101D was better than that of
PD-L1 × TGF-βRII bifunctional fusion protein



Source: Company data

Drug	Dose (mg/kg)	CR	The average tumor volume (mm^3)	Tumor growth inhibition rate	P-value (compared with the vehicle)
Vehicle	–	0%	1,656.54	0.00%	–
Y101D	26.7	20%	166.17	89.97%	0.0001
Y101D	8.9	10%	175.40	89.41%	0.0002
Y101D	3	0%	907.20	45.23%	0.0405
Y101D	1	0%	835.40	49.57%	0.0343
Anti-PD-L1 mAb	6.6	0%	1,304.12	21.27%	0.4343
PD-L1 × TGF-βRII bifunctional fusion protein	8.2	10%	798.31	51.81%	0.0574

Source: Company data

Favorable safety profile

As of December 31, 2022, data obtained from the Phase I study demonstrated that Y101D was well-tolerated. MTD was not reached up to 30 mg/kg. Most of the AEs were Grade 1 or Grade 2 AEs. Only two SAEs have been observed (both were bleeding) in two patients, and such patients have recovered.

Summary of Clinical Trial Results

We initiated a Phase I clinical trial for Y101D in patients with metastatic or locally advanced solid tumors in China in August 2021. This trial is currently ongoing.

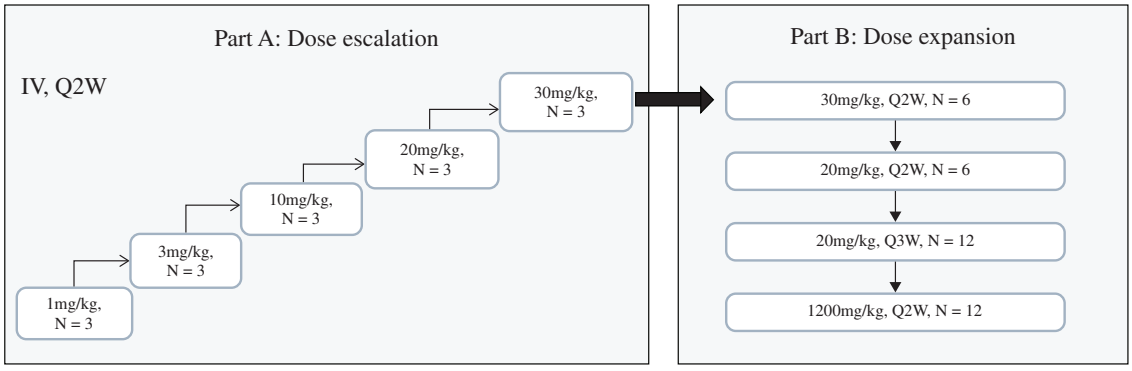
Trial design

This is a multicenter, open-label, dose-escalation Phase I trial. The primary objectives of this trial are to evaluate the safety and tolerability of Y101D (including observing DLT, and determining MTD and RP2D). The secondary objectives are to evaluate the PK/PD profile, immunogenicity, and preliminary efficacy of Y101D. The primary endpoints include safety and tolerability, and secondary endpoints include PK/PD profile, immunogenicity, ORR, time in therapeutic range, DCR, DOR, PFS, and OS.

This trial consists of a dose-escalation phase and a cohort-expansion phase. The dose-escalation phase followed the standard "3+3" protocol, with five escalating dose levels set at 1 mg/kg, 3 mg/kg, 10 mg/kg, 20 mg/kg, and 30 mg/kg, respectively. Each cohort includes three subjects. Subjects in each cohort will receive a biweekly dosage for a four-week DLT observation period. Subjects who complete the four-week DLT observation period may, at the discretion of the investigator, enter an extended treatment period until disease progression or intolerable toxicity is observed. We plan to enroll 15 to 30 patients in the dose-escalation phase.

After determining the MTD in the dose-escalation phase, the MTD cohort will be expanded to include an additional three to six subjects. If the MTD is not observed at cohort five (30 mg/kg), the investigator may decide to continue with the dose-escalation and explore higher dose levels, or expand the cohort at certain dose levels. In addition, if the investigator observes clinical benefits for subjects in certain cohort(s), the investigator may expand such cohort(s) to include subjects with one to three different tumor types, provided that each expanded cohort will not exceed 30 subjects.

The following diagram illustrates the design of Y101D Phase I clinical trial:



Source: Company data

Abbreviations: IV refers to intravenous injection; Q2W refers to every two weeks.

Trial status

We initiated this Phase I clinical trial in August 2021. As of July 31, 2023, a total of 48 patients have been enrolled in the dose-escalation phase and the cohort-expansion phase. We expect to complete this Phase I clinical trial in the fourth quarter of 2023.

Interim safety results

As of December 31, 2022, data obtained from the Phase I study demonstrated that Y101D was well-tolerated. MTD was not reached up to 30 mg/kg. MTD, or maximum tolerated dose, refers to the highest dose cohort in which no Grade 3 or above AEs as specified in the clinical trial protocol which is considered to be possibly or definitely related to the medication (DLT) are observed in the Phase I clinical trial. It is the highest dose of the medication that can be tolerated by the study participants. This trial is still in its dose escalation phase, and the MTD has not been decided yet.

Most of the AEs were Grade 1 or Grade 2 AEs. Only two SAEs have been observed (both are bleeding) in two patients, and such patients have recovered.

The following table sets forth the number of patients experiencing TRAEs by different cohorts as of December 31, 2022.

	Grade 1 TRAEs	**Grade 2 TRAEs**	**Grade 3 TRAEs**
Cohort 1	1	1	0
Cohort 2	2	1	0
Cohort 3	1	2	0
Cohort 4	3	2	0
Cohort 5	8	5	2
Total	15	11	2

Source: Company data

Note: Each patient in the trial may experience multiple incidences of TRAEs in different grades. For example, a patient experienced both Grade 1 and Grade 2 TRAEs will be counted toward the number of Grade 1 and Grade 2 TRAEs at the same time. Therefore, although only 18 patients experienced TRAEs in this trial, the number of patients experiencing TRAEs is presented as 28 in this table.

The following table presents the symptoms of TRAEs by different cohorts as of December 31, 2022.

	Symptoms
Grade 1 TRAEs	Oral mucositis, disseminated rash, gingival bleeding, thyrotoxicosis, elevation of lipase, diarrhea, dry mouth, proteinuria, epistaxis, muscle pain, elevation of alkaline phosphatase, elevation of thyroxine, increase in fatigue, nausea, poor appetite, etc.
Grade 2 TRAEs	Rash, hyperthyroidism, elevated levels of lipase, prolonged QTc interval, decreased platelet count, anemia that worsens, low sodium levels, increased levels of alanine aminotransferase, urticaria-associated pruritus, epistaxis, etc.
Grade 3 TRAEs	Elevated levels of gamma-glutamyl transpeptidase, nosebleed.

Source: Company data

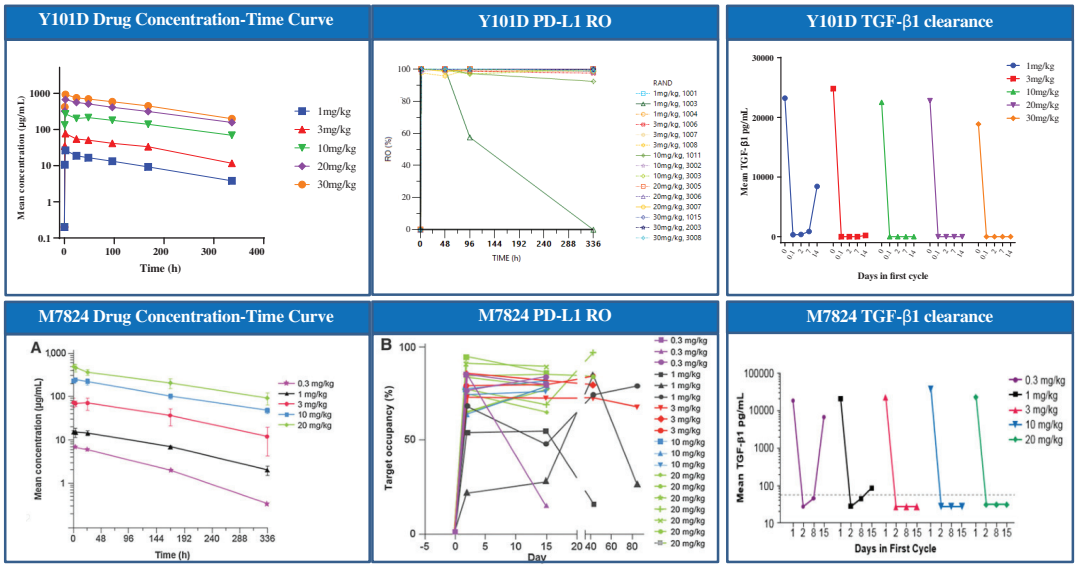
Interim efficacy results

As of December 31, 2022, one refractory Peritoneal Mesothelioma patient has reached a progression-free survival (PFS) of 13 months, showing the preliminary antitumor activity of Y101D. PFS is the total duration of time from the start of treatment until the progression or relapse of the disease, as determined by imaging or other objective evaluation criteria specified in the clinical trial protocol. As there is currently no standard treatment option for metastatic or locally advanced solid tumors to be compared with, the evaluation of the PFS of Y101D vis-à-vis accepted medical standards is done by comparing it to the expectations of the researchers. Y101D's PFS data surpass the researchers' expectations formed based on historical data from other treatments for metastatic or locally advanced solid tumors in the literature and their own clinical treatment experience, indicating the preliminary efficacy for Y101D.

Interim PK/PD results

As of December 31, 2022, data obtained from the Phase I study shows a favorable PK/PD profile of Y101D. The Cmax and the $t_{1/2}$ are as shown below diagram. Y101D can occupy the PD-L1 epitope for 100% and completely (100%) eliminate the TGF-β1/2/3 at 3mg/kg.

The following diagram shows the PK/PD characters of Y101D and M7824.



Source: (1) Company data;
(2) Published M7824 phase I clinical data (Clin Cancer Res. 2018 Mar 15;24(6):1287-1295.)

Abbreviation: RO refers to receptor occupancy.

The following table presents the immunogenicity results of Y101D in different cohorts as of December 31, 2022.

Cohort (dosage)	The number of subjects evaluable for ADA	The number of subjects who tested positive for ADA (and as a percentage of the number of subjects evaluable for ADA)	The number of subjects who tested negative for ADA (and as a percentage of the number of subjects evaluable for ADA)
Cohort 1 (1mg/kg)	3	2 (66.67%)	1 (33.33%)
Cohort 2 (3mg/kg)	3	3 (100%)	0 (0)
Cohort 3 (10mg/kg)	3	1 (33.33%)	2 (66.67%)
Cohort 4 (20mg/kg)	3	1 (33.33%)	2 (66.67%)
Cohort 5 (30mg/kg)	8	2 (25%)	6 (75%)
Total	20	9 (45%)	11 (55%)

Source: Company data

Abbreviation: ADA refers to anti-drug antibodies

Clinical Development Plan

Y101D as a monotherapy in patients with metastatic or locally advanced solid tumors in China

We expect to complete the Phase I clinical trial for Y101D in patients with metastatic or locally advanced solid tumors in China in the fourth quarter of 2023. We will continue to explore the potentials of Y101D as a monotherapy.

Y101D in combination with gemcitabine and albumin paclitaxel as the first-line treatment for advanced/metastatic pancreatic cancer patients

We obtained the ethic committee and IND approvals for a Phase Ib/II clinical trial of Y101D in combination with gemcitabine and albumin paclitaxel as the first-line treatment for advanced/metastatic pancreatic cancer patients in China in November and December 2022, respectively. We commenced this trial in February 2023 and expect to complete this trial by the first quarter of 2025. We have commenced the patient enrollment for the Phase II portion of this Phase Ib/II clinical trial in July 2023. As of July 31, 2023, we have enrolled 22 subjects for the Phase Ib portion of this trial and 6 subjects for the Phase II portion of this trial. Following the completion of this Phase Ib/II clinical trial, we also plan to commence a Phase III clinical trial in the fourth quarter of 2024 and expect to complete this trial by the second quarter of 2026.

This is a multicenter, open-label Phase Ib/II clinical trial to evaluate the safety, tolerability, and preliminary efficacy of Y101D in combination with gemcitabine and albumin paclitaxel as the first-line treatment for advanced/metastatic pancreatic cancer patients in China. The Phase Ib portion consists of a dose-escalation phase and a cohort-expansion phase. The dose-escalation phase includes two cohorts, both of which follow the standard "3+3" design to receive (a) two escalating dose levels of Y101D at 20 mg/kg and 30 mg/kg (Day 1, Q3W), respectively, and (b) gemcitabine (manufactured by Hansoh Pharmaceutical Group Company Limited with a selling price of RMB210/g) at 1,000mg/m^2 (Day 1, Day 8, Q3W) and albumin paclitaxel (manufactured by CSPC Ouyi Pharmaceutical Co., Ltd. with a selling price of RMB700/100mg) at 125mg/m^2 (Day 1, Day 8, Q3W). Subjects in each cohort will undergo a three-week DLT observation period. After completing the safety assessment for cohort 1 and cohort 2, the investigator may decide to conduct dose-expansion studies for one or two cohorts. We plan to enroll 12 to 36 subjects for the Phase Ib trial.

Y101D in combination with bevacizumab in treating HCC and other advanced solid tumors in China

We obtained the ethic committee and IND approvals for a Phase Ib/II clinical trial of Y101D in combination with bevacizumab in treating HCC and other advanced solid tumors in China in December 2022. We commenced this trial in March 2023 and expect to complete this trial by the second quarter of 2025. As of July 31, 2023, we have enrolled eight subjects for this trial. Following the completion of this Phase Ib/II clinical trial, we also plan to commence a Phase III clinical trial.

This is a multicenter, open-label Phase Ib/II clinical trial to evaluate the safety and preliminary efficacy of Y101D in combination with bevacizumab in treating HCC and other advanced solid tumors in China. The Phase Ib portion consists of a dose-escalation phase and a cohort-expansion phase. The dose-escalation phase will include three cohorts, with each cohort following the standard "3+3" design. Subjects in these three cohorts will receive (a) escalating dose levels of Y101D at 10mg/kg, 20 mg/kg and 30 mg/kg Q3W, respectively, and (b) bevacizumab at 15mg/kg (Q3W). Subjects in each cohort will undergo a three-week DLT observation period. After determining MTD in the dose-escalation phase, the investigator may decide to conduct dose-expansion studies for HCC patients for one or two cohorts. We plan to enroll 29 to 38 subjects in the Phase Ib portion, including 20 subjects in the cohort-expansion phase. The RP2D of Y101D determined in the Phase Ib portion will be used in the Phase II portion. The Phase II portion includes a screening period of 28 days, a treatment period, and a follow-up period. We plan to enroll 47 to 82 subjects for the Phase II portion.

The primary objectives of the Phase Ib portion are to evaluate the safety and tolerability of Y101D in combination with bevacizumab (manufactured by Roche with a selling price of RMB2,050/100mg) in treating HCC and other advanced solid tumors, and to determine the RP2D. The primary objective of the Phase II portion is to evaluate the efficacy of Y101D in combination with bevacizumab in treating HCC.

Y101D in combination with chemotherapy in treating SCLC

We plan to file an IND application with the NMPA in the first quarter of 2024. The specific combination drug of the trial will be decided prior to the commencement of the trial.

FDA IND approval

In addition, we received FDA IND approval for our clinical investigation of Y101D for solid tumors in January 2021. We currently have no immediate plan to initiate clinical trial for Y101D in the U.S. We plan to leverage our clinical results of Y101D in China for further clinical development of Y101D in the U.S. in the future.

We believe it is feasible for us to leverage clinical results of Y101D in China to conduct late-stage clinical development of Y101D in the U.S. because (i) FDA has released a "Guidance for Industry and FDA Staff/FDA Acceptance of Foreign Clinical Studies Not Conducted Under an IND Frequently Asked Questions" which provides guidance for the industry and the FDA staff on the acceptance of results generated from foreign clinical studies; and (ii) the ICH guideline "Ethnic Factors in the Acceptability of Foreign Clinical Data E5 (R1)" which supports the use of foreign clinical data as a basis to support the approval of an IND application in a new jurisdiction, without the need to repeat the entire clinical drug development program in the new jurisdiction.

There have been recent examples of the FDA declining to approve China-tested drugs mainly based on the clinical data generated in China, including sintilimab, a lung cancer drug candidate and surufatinib, a pancreatic and extra-pancreatic neuroendocrine tumor drug candidate. Sintilimab has not undergone any clinical trials in the U.S., while surufatinib has

only been tested in a small-scale bridging trial in the U.S. Neither drug has been involved in pivotal clinical trials involving diverse populations in the U.S., nor have their pivotal clinical trial protocols been reviewed or approved by the FDA.

After completing the Phase II clinical trial of M701 and the Phase Ib/II clinical trials of Y101D in China, we plan to leverage the clinical results generated in China to support the late-stage clinical development in the U.S. We plan to collaborate with overseas partners to confirm the design of late-stage clinical trials with FDA and conduct such clinical trials in the U.S., which will enable us to obtain efficacy data encompassing multiple ethnicities and form the basis for us to obtain regulatory approvals to commercialize M701 in the U.S. and some other overseas markets. For more details, please refer to the analysis in the paragraphs headed "– Our Drug Candidates – M701 (EpCAM × CD3 BsAb) – Our Core Product – Clinical Development Plan". However, we cannot guarantee that the FDA will accept our clinical results generated in China to support pivotal clinical trials in the U.S., and we may face difficulties and incur additional costs thereof. For details, please refer to the paragraphs headed "Risk Factors – Risks Relating to Commercialization of Our Drug Candidates – We may face difficulties in leveraging the clinical results of our drug candidates in China for late-stage clinical development in other jurisdictions" in this document.

Licenses, Rights and Obligations

As we internally discovered and developed Y101D, we maintain the global rights to develop and commercialize this drug candidate.

Material Communications with Competent Authorities

The material communications with the relevant competent authorities in respect of Y101D are as follows:

- We filed the IND application for Y101D for solid tumors with the NMPA on February 24, 2021 and received the umbrella IND approval from the NMPA for the Phase I, II and III clinical trials of Y101D for solid tumors on May 18, 2021.

- We filed the IND application for Y101D for solid tumors with the FDA on December 23, 2020 and received the IND approval for Y101D for solid tumors from FDA on January 21, 2021.

- We submitted the IND application for Y101D for advanced/metastatic pancreatic cancer in combination therapy with gemcitabine and albumin paclitaxel with the NMPA on September 9, 2022 and received the umbrella IND approval from the NMPA for the Phase Ib/II, Phase III clinical trials of Y101D for advanced/metastatic pancreatic cancer in combination therapy with gemcitabine and albumin paclitaxel on December 5, 2022.

- We submitted the IND application for Y101D for HCC and other advanced solid tumors in combination therapy with bevacizumab with the NMPA on October 19, 2022 and received the umbrella IND approval from the NMPA for the Phase Ib/II, Phase III clinical trials of Y101D for HCC and other advanced solid tumors in combination therapy with bevacizumab paclitaxel on December 29, 2022.

We had not received any regulatory agency's concerns or objections to our clinical development plans or any ongoing clinical trial as of the Latest Practicable Date, nor did any material unexpected or adverse changes had occurred since the date of issue of relevant regulatory approvals for Y101D.

Cautionary Statement required by Rule 18A.05 of the Listing Rules of the Hong Kong Stock Exchange:

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET Y101D SUCCESSFULLY.

Y150 (CD38 × CD3 BsAb)

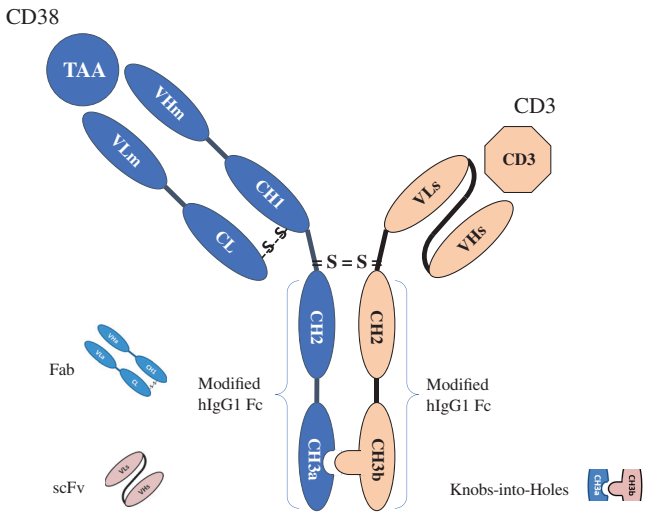
Y150 is a recombinant BsAb based on our YBODY® platform that consists of a fully human anti-CD38 Fab-Fc moiety and a humanized anti-CD3 scFv-Fc moiety. According to the CDE website, Y150 is the only CD38-targeting and T cell-engaging BsAb that has entered into clinical development in China. As of the Latest Practicable Date, there were 22 and nine CD38 targeted antibody drug candidates or fusion proteins for the treatment of MM under clinical development globally (excluding China) and in China, respectively. There is no evidence that BsAbs offer any significant clinical advantages compared to fusion protein antibodies. For a comparative analysis of BsAb and fusion protein, please refer to the paragraphs headed "Industry Overview – Global and China Antibody Drug Market – Overview" in this document. Y150 simultaneously binds CD38 antigen on target tumor cells and the CD3 antigen on T cells, bringing them into spatial proximity, allowing activated T cells to attack target tumor cells.

We are currently evaluating Y150 in a Phase I clinical trial in rrMM in China. We will further explore the clinical efficacy of Y150 monotherapy in treating rrMM patients as well as its potentials in combination therapy. We plan to commence a Phase II/III clinical trial of Y150 monotherapy in China for the treatment of rrMM. We also plan to initiate a Phase Ib/II clinical trial for Y150 in combination with lenalidomide as second-line treatment for rrMM after the completion of Phase II portion of Phase II/III clinical trial of Y150 monotherapy for rrMM.

We are developing Y150 in-house and own its global IP and commercial rights.

Mechanism of Action

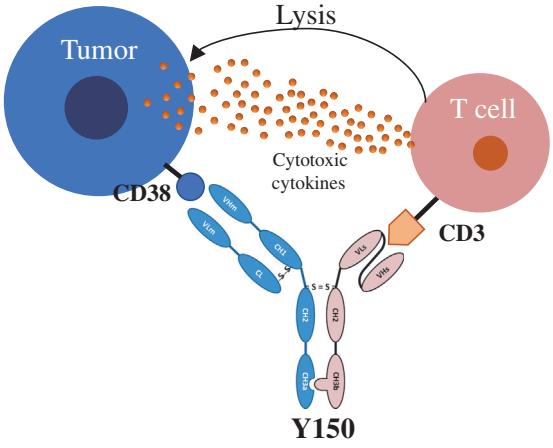
Y150 is a recombinant, IgG1-like BsAb consisting of a fully human anti-CD38 Fab-Fc and a humanized anti-CD3 scFv-Fc, with the Fc region of Y150 modified to eliminate binding to FcγRs. The diagram below illustrates the molecule structure of Y150.



Source: Company data

CD38 is expressed at low levels on normal healthy tissues, while at high levels on multiple myeloma (MM) and lymphoma cells, suggesting its potential as a tumor target to treat hematological malignancies, especially MM. CD3 is a protein complex and T cell co-receptor that directly activates cytotoxic T cells and T helper cells, in association with T cell antigen recognition receptor (TCR).

Y150 is designed to simultaneously target CD38 antigen on tumor cells and CD3 antigen on T cells. Upon binding, the antibody bridges the effector and the target cells, bringing them together into spatial proximity to activate T cells, allowing for the activated T cells to attack the target cells and enhance their anti-cancer activities. The following diagram illustrates the mechanism of action of Y150:



Market Opportunities and Competition

MM is a cancer of the plasma cells in the bone marrow. Plasma cells are antibody-producing white blood cells that are critical to the immune system. Myeloma begins when healthy plasma cells become cancerous and grow out of control. MM often results in extensive skeletal destruction with osteolytic lesions, osteopenia, and/or pathologic fractures.

The incidence of MM in China exhibits a much faster growth trend partly due to the fast-growing aging population in China. The incidence of MM increased from 20.1 thousand in 2018 to 22.4 thousand in 2022 at a CAGR of 2.8%. With the increasing aging population in China, the incidence of MM is expected to grow to 25.0 thousand in 2026 at a CAGR of 2.8% from 2022 and further to 27.6 thousand in 2030 at a CAGR of 2.5% from 2026. The diagnostic rate of MM in China is relatively low due to the complicated diagnostic process and lack of accessibility to effective diagnostic methods.

Current treatment and limitations

The prognosis of an MM patient is very heterogeneous and is subject to various factors, such as genetics, performance status and stage of disease, which in turn can determine the treatment and management of the disease. Current treatment regimens can prolong patient survival; however, MM remains incurable, and patients will eventually relapse and succumb to their disease, and for most of the patients, MM will eventually develop into rrMM. As a result, patients may require continuous treatment in order to manage MM as a chronic disease and treatment regimens with convenient administration would be preferred. Existing treatment options with different mechanisms of action are usually exhausted early on in the treatment, as patients are treated with doublet and triplet combination regimens in early treatment lines. Therefore, new classes of therapy with innovative mechanisms of action are required for patients who relapse or who are refractory to the current classes of drugs. There are a few new classes of MM therapy, for example, the antibody drug conjugate that targets the B cell maturation antigens, which can reach an ORR of 31% as a third or later-line treatment, and 73% of the patients who responded to the treatment continued to respond at month six, and selective inhibitors of nuclear exports such as selinexor. However, such new classes of MM therapies may not be able to completely cure MM. In recent years, the clinical application of Thalidomide, Lenalidomide, Bortezomib and CD38 mAbs has greatly improved the remission rate of multiple myeloma, however, these drugs cannot completely avoid the relapse caused by minimal residual disease. Those patients still do not have effective drug to use.

Given that approximately 16.2 thousand and 117.1 thousand deaths were caused by MM in China and globally in 2020, respectively, there remains a need for patients whose disease has relapsed after, or is refractory to, available MM therapies. We believe Y150, leveraging its well-designed structure to simultaneously target CD38 antigen on tumor cells and CD3 antigen on T cells, has the potential to serve as a therapy for the treatment of MM patients who relapse or otherwise become refractory to the existing therapies.

Competitive landscape

CD38 is an emerging target for the treatment of MM. As a result, there are multiple CD38 targeted antibodies being developed for the treatment of MM. As of the Latest Practicable Date, there were 22 and nine CD38 targeted antibody drug candidates or fusion proteins for the treatment of MM under clinical development globally (excluding China) and in China, respectively.

The development of CD38 targeted BsAb is still at its emerging stage. However, there is no evidence that BsAbs offer any significant clinical advantages compared to fusion protein antibodies. For a comparative analysis of BsAb and fusion protein, please refer to the paragraphs headed "Industry Overview – Global and China Antibody Drug Market – Overview" in this document. The following table sets forth the competitive landscape of CD38 targeted BsAbs for the treatment of MM globally as of the Latest Practicable Date:

Global Pipeline

Product	Developer	Target	Drug Type	Indication	Highest Clinical Phase		First Posted Date[(1)]
Y150	the Company	CD38, CD3	BsAb	Multiple myeloma	Global	FDA IND Approval	\
					China	I	2021/5/28
ISB 1442	Ichnos Sciences SA	CD38, CD47	BsAb	Multiple myeloma	Global	I/II	2022/6/14
ISB 1342	Ichnos Sciences SA, Glenmark Pharmaceuticals S.A.	CD38, CD3	BsAb	Multiple myeloma	Global	I	2017/10/04
SG2501	Hangzhou Sumgen Biotech Co., Ltd.	CD38, CD47	BsAb	Relapsed or Refractory Hematological Malignancies and Lymphoma	Global	I	2022/3/01
VP301	Virtuoso Therapeutics	CD38, ICAM1	BsAb	Multiple myeloma Lymphoma Solid Tumors	Global	I	2022-12-12
IGM-2644	IGM Biosciences	CD38, CD3	BsAb	Multiple myeloma	Global	I	2023-05-26

Source: NMPA, CDE, ClinicalTrial.gov, FDA, Frost & Sullivan Analysis

(1) "First Posted Date" in terms of global clinical trials refers to the date when the study corresponding to the global highest clinical phase (except China) was first available on ClinicalTrials.gov after the National Library of Medicine has concluded its quality control review; "First Posted Date" in the context of China clinical trials refers to the date when the study corresponding to the highest clinical phase in China was first available on chinadrugtrials.org.cn after the Center for Drug Evaluation (CDE) has concluded its review. The CDE is an affiliated institution of the NMPA.

Several competing molecules of Y150 target CD47 in addition to CD38. Both CD38 and CD47 are highly expressed on MM cells and serve as negative regulators of immune cells. However, CD38 has enzymatic activity, modulating the immune system and transmitting signals through its metabolites, while CD47 is an immune checkpoint and inhibits macrophage phagocytosis and immune response through its interaction with macrophages.

For additional information on the market opportunities and competitive landscape of this drug candidate, please refer to the paragraphs headed "Industry Overview – CD3 Targeted Bispecific Antibody Market – CD38 × CD3 Targeted BsAbs" in this document.

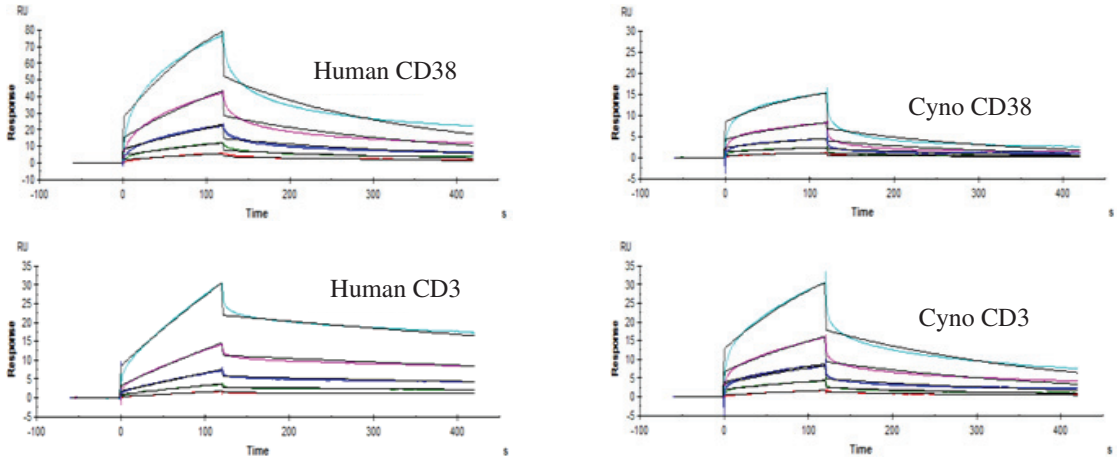
Competitive Advantages

Well-designed structure to avoid inducing on-target but off-tumor toxicity

Targets for tumor recognition such as CD38 are not only highly expressed on tumor cells but are also ubiquitously detected on healthy tissues. Consequently, highly potent T cell-engaging BsAbs bear the risk of inducing on-target, but off-tumor toxicity by attacking normal healthy cells, limiting the achievement of dose levels needed for optimal anti-tumor activity.

Y150 is a bispecific monoclonal antibody that consists of a fully human anti-CD38 Fab-Fc and a humanized anti-CD3 scFv-Fc, with the Fc region modified from hIgG1. Knobs-into-Holes (KIH) mutations are introduced into the Fc region to maximize heterodimer formation. In order to avoid non-specific immune activation, we also introduce mutations into the Fc region to reduce the FcγRs' binding activity. In addition, we specifically modifies the CD38-binding domain of Y150 to equip it with reduced CD38 affinity, allowing it to selectively recognize CD38-positive tumor cells without attacking normal healthy cells with low CD38 expression.

Y150 has monkey species cross-reactivity and binds to both human and cynomolgus monkey antigens CD38 and CD3 with moderate affinity



Source: Company data

The table below presents the binding affinities of Y150 towards human and monkey CD38 and CD3 using a surface plasmon resonance (SPR) assay. The results show that Y150 exhibits moderate binding affinities towards both human and monkey CD38 and CD3, with binding constant of 100nM.

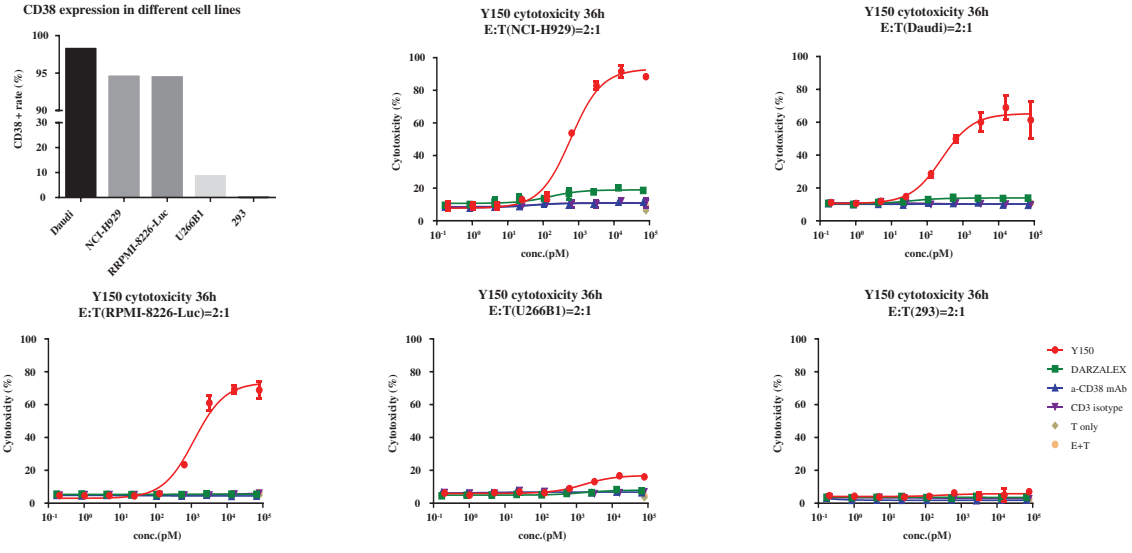
Antibody	Antigen	k_a (1/Ms)	k_d (1/s)	K_D (M)
Y150	Human CD38	9.447E+04	1.119E-02	1.184E-07
Y150	Human CD3	5.161E+04	9.544E-03	1.849E-07
Y150	Cynomolgus CD38	3.064E+04	4.568E-03	1.491E-07
Y150	Cynomolgus CD3	1.058E+04	3.451E-03	3.262E-07

Source: Company data

Abbreviation: k_a refers to the association rate constant, the rate at which the analyte binds to the ligand, measured in inverse milliseconds (1/Ms); k_d refers to the dissociation rate constant, the rate at which the analyte dissociates from the ligand, measured in inverse seconds (1/s); K_D refers to the equilibrium dissociation constant, the ratio of the dissociation constant to the association constant, measured in molar (M).

As shown below, the study has demonstrated significant cytotoxicity of Y150 against high-expressing CD38 cell lines such as RPMI-8226-Luc cells, Daudi and NCI-H929 cells with the maximum killing potential of 73.5%, 65.3% and 93.2%, respectively. The cytotoxicity of Y150 against the low-CD38 expressing U266B1 line was low with a maximum killing potential of 16.9%. Y150 did not mediate any significant cell death effect in CD38 negative HEK293 cells. These results have demonstrated that Y150 may stimulate T cell mediated cytotoxicity of CD38-expressing cells in a dose-dependent manner. The susceptibility of cancer cells to Y150 correlates with the surface expression levels of CD38.

Y150-mediated cytotoxicity to various target cells with different CD38 expression levels



Source: Company data

The table below presents the Y150-mediated cytotoxicity to various target cells with descending CD38 expression levels in our head-to-head pre-clinical studies:

Sample	Daudi		NCI-H929		RPMI-8226-Luc		U266B1		293	
	Maximum lysis (%)	EC50 (pM)	Maximum lysis (%)	EC50 (pM)	Maximum lysis (%)	EC50 (pM)	Maximum lysis (%)	EC50 (pM)	Maximum lysis (%)	EC50 (pM)
Y150	65.3	258.3	93.16	607.2	73.53	1,189	16.92	1,641	5.781	–
DARZALEX	13.94	–	18.97	156.4	5.572	–	7.966	1,481	3.506	–
Anti-CD38 mAb	10.21	–	10.79	–	4.422	–	6.818	4.339	1.817	–
CD3 isotype	10.28	–	11.05	–	7.154	–	–	–	2.908	–

Source: Company data

Abbreviation: EC50 refers to half maximal effective concentration, the concentration of a drug, antibody or toxicant which induces a response halfway between the baseline and maximum.

Potent in vitro and in vivo efficacy

A series of *in vitro* studies were conducted to fully elucidate the binding and relevant functional characteristics of Y150 that contribute to its ability of T cell activation and cytotoxicity. These studies demonstrate that, among others, (a) Y150 has the ability to promote CD3-positive cell-to-CD38-positive cell association, followed by a significant increase in the subpopulations of activated cytotoxic T cells; (b) Y150 exhibits a cytotoxic effect in the presence of CD3-positive effectors and various types of CD38-positive cancer cells; and (c) Y150 can induce its cytotoxic effect through T cell activation rather than through ADCC, ADCP, CDC or PCD mechanisms of cytotoxicity.

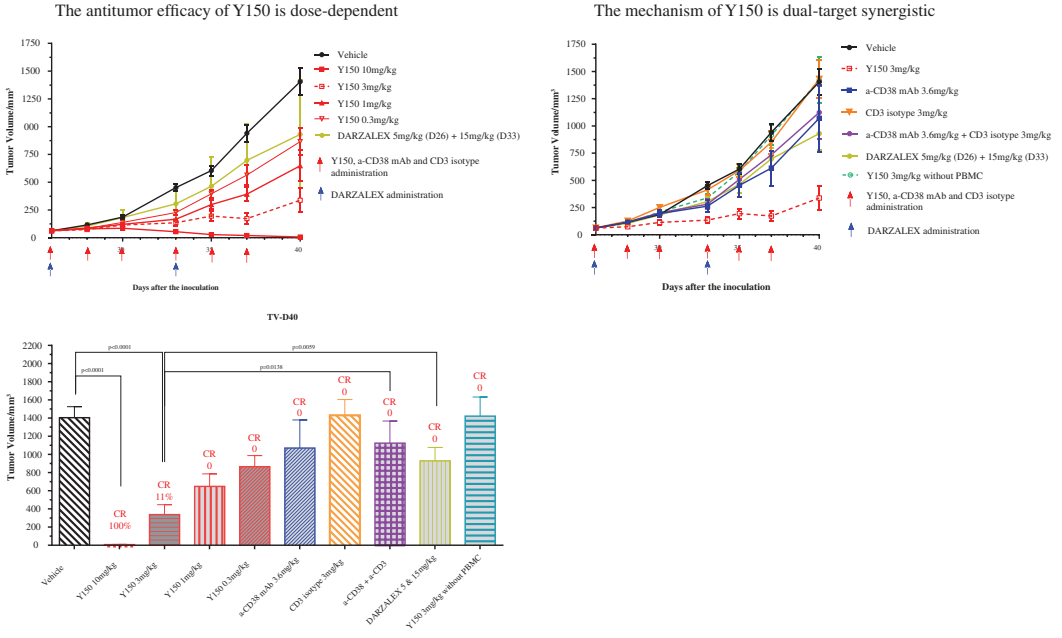
These mechanisms of Y150 are further demonstrated in *in vivo* efficacy experiments in xenograft murine models of human malignancies, in which Y150 is able to inhibit the growth of pre-established human Burkitt's lymphoma and multiple myeloma tumors in a dose-dependent manner.

In the *in vivo* efficacy experiment to evaluate the growth inhibition effect of Y150 against pre-established CD38-positive human Burkitt's lymphoma Daudi cells in immunocompromised NPG mice that were reconstituted with human PBMCs, dose-dependent tumor growth inhibition is observed in the Y150 treated groups. On study day 40, the rate of tumor growth inhibition reaches 38%, 54%, 76% and 100% in animals received 0.3mg/kg, 1mg/kg, 3mg/kg and 10 mg/kg of Y150, respectively. Moreover, the CR of the Y150 (10mg/kg) treated group is 100%. Treatment with $\geq$ 3 mg/kg Y150 is more efficacious than Darzalex (a CD38 antibody developed by Janssen Biotech), 3.6 mg/kg of an anti-CD38 mAb, 3 mg/kg of CD3 isotype, or a combination of an anti-CD38 mAb and a CD3 isotype, all of which suggests the physical closeness of activated T cells to CD38-positive target cells is important.

The diagram and table below present the efficacy of different doses of Y150, anti-CD38 mAb, CD3 isotype, anti-CD38+CD3 isotype and DARZALEX in suppressing tumor growth in the Daudi subcutaneous tumor model 40 days after inoculation in our head-to-head pre-clinical studies:

In the human Burkitt's lymphoma Daudi subcutaneous tumor model

The efficacy of Y150 was better than that of Darzalex in our head-to-head pre-clinical studies



Source: Company data

Drug	Dose (mg/kg)	CR	The average tumor volume (mm^3)	Tumor growth inhibition rate	P-value (compared with the vehicle)
Vehicle	N/A	0%	1,404.92	0%	N/A
Y150	10	100%	6.74	100%	<0.0001
Y150	3	11%	337.6	76%	<0.0001
Y150	1	0%	648.26	54%	0.0006
Y150	0.3	0%	865.6	38%	0.0061
Anti-CD38 mAb	3.6	0%	1,070.3	24%	0.2936
CD3 isotype	3	0%	1,430.85	-2%	0.9037
Anti-CD38+CD3 isotype	3.6+3	0%	1,123.78	20%	0.3142
DARZALEX	5+15	0%	930.19	34%	0.0215
Y150 w/o PBMC	3	0%	1,421.09	-1%	0.9444

Source: Company data

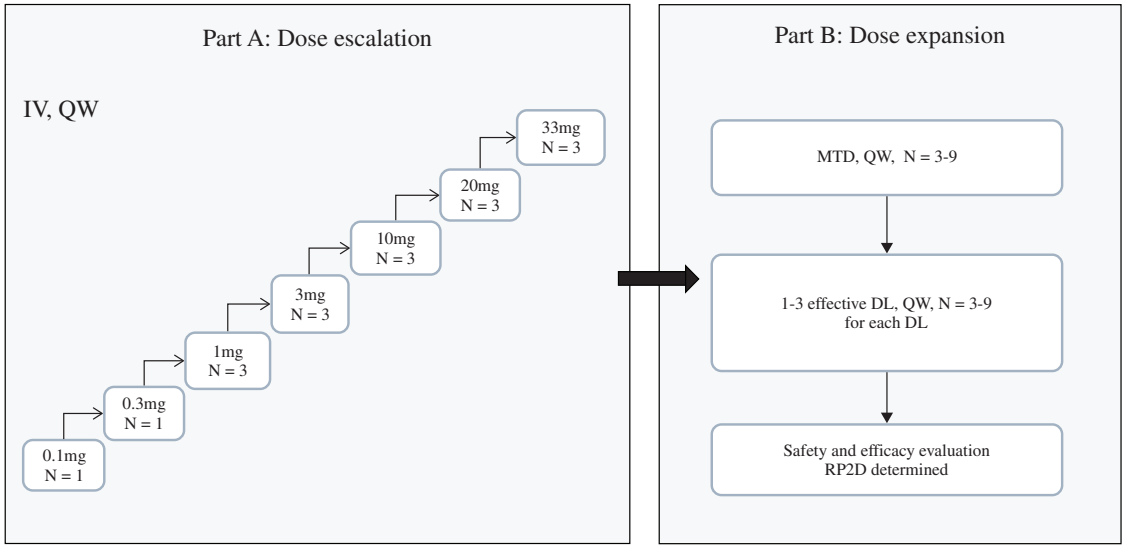
Summary of Clinical Trial Results

We initiated a Phase I clinical trial of Y150 in rrMM in China in August 2021. We are currently enrolling patients.

Trial design

This is a multicenter, open-label, dose-escalation Phase I trial to evaluate the safety, tolerability, pharmacokinetic, immunogenicity and preliminary efficacy of Y150 in subjects with rrMM. We plan to enroll a total number of 23 to 78 patients in this study. This trial includes a dose-escalation phase and a cohort-expansion phase. The dose-escalation phase consists of an accelerated titration phase and a traditional "3+3" dose-escalation phase. In the accelerated titration phase, patients will be enrolled in two cohorts to receive escalating dose levels from 0.1mg to 0.3mg. In the traditional "3+3" dose-escalation phase, patients will be enrolled in five dose cohorts (at maximum dose level of 1mg, 3mg, 10mg, 20mg and 33 mg, respectively). If the MTD is not reached, the maximum administered dose (MAD) will be 33mg. Once the MTD or MAD is reached, the RP2D will be determined. An additional 3-9 subjects might be enrolled at MTD/MAD to ensure that at least 9 patients are in the cohort.

The primary endpoints include safety and tolerability, and the determination of MTD and RP2D. Secondary endpoints include PK/PD profile, efficacy evaluation, and immunogenicity. The following diagram shows the design of Y150 Phase I clinical trial:



Source: Company data

Abbreviations: IV refers to intravenous injection; QW refers to once every week.

Trial status

We initiated this Phase I clinical trial for Y150 in August 2021. As of July 31, 2023, a total of 20 patients had been enrolled in the first five cohorts of the dose-escalation phase. We expect to complete this Phase I clinical trial in the first quarter of 2024.

Interim safety results

As of December 31, 2022, data obtained from the Phase I study demonstrated that Y150 was generally well tolerated. Only one subject with DLT was observed at 1mg and had recovered without treatment. Y150 is well tolerated among the other 13 subjects enrolled. The MTD was not reached up to 3 mg. MTD, or maximum tolerated dose, refers to the highest dose cohort in which no Grade 3 or above AEs as specified in the clinical trial protocol which is considered to be possibly or definitely related to the medication (DLT) are observed in a Phase I clinical trial. It is the highest dose of the medication that can be tolerated by the study participants. This trial is still in its dose escalation phase, and the MTD has not been decided yet. The majority of TRAEs observed were Grade 1 and 2.

The following table sets forth the number of patients experiencing TRAEs by different cohorts as of December 31, 2022.

	Grade 1 TRAEs	**Grade 2 TRAEs**	**Grade 3 TRAEs**	**Grade 4 TRAEs**
Cohort 1	1	1	0	0
Cohort 2	1	1	1	0
Cohort 3	6	6	4	3
Cohort 4	3	3	2	1
Total	11	11	7	4

Source: Company data

Note: Each patient in the trial may experience multiple incidences of TRAEs in different grades. For example, a patient experienced both Grade 1 and Grade 2 TRAEs will be counted toward the number of Grade 1 and Grade 2 TRAEs at the same time.

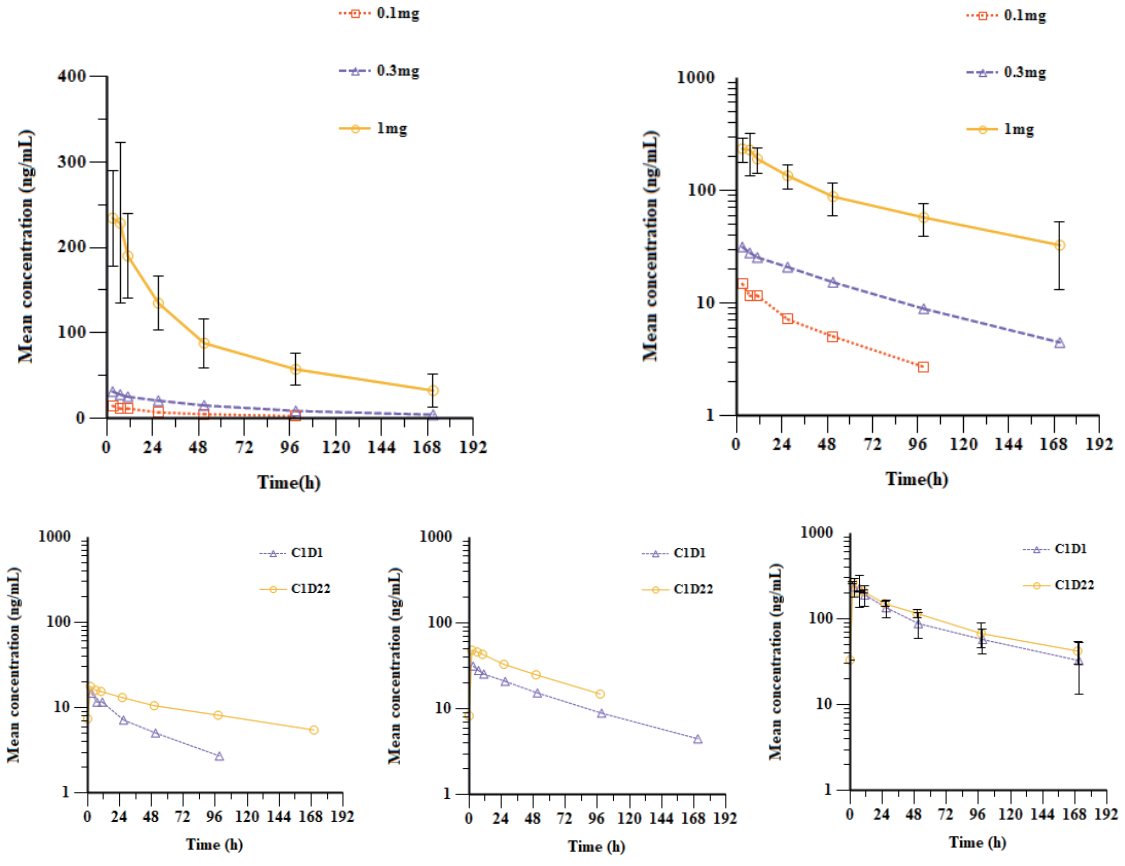
The following table presents the symptoms of TRAEs by different cohorts as of December 31, 2022.

	Symptoms
Grade 1 TRAEs	Biliary colic, nausea, abdominal mass, prolonged activated partial thromboplastin time, local edema, prolonged prothrombin time, vomiting, insomnia, decreased appetite, elevation of aspartate transaminase, elevation of bilirubin, decrease in fibrinogen, decrease in white blood cell count, difficulty breathing, etc.

	Symptoms
Grade 2 TRAEs	Gastrointestinal distention, biliary colic, elevation of bilirubin, decrease in fibrinogen, epistaxis, tachycardia, coughing, decrease in platelet count, hypoproteinemia, decrease in neutrophil count, decrease in white blood cell count, anemia, fever, pain, etc.
Grade 3 TRAEs	Decreased appetite, decrease in platelet count, hypertension, hypokalemia, decrease in white blood cell count, anemia, elevation of aspartate transaminase, heart failure, hypoproteinemia, decrease in fibrinogen, decrease in neutrophil count.
Grade 4 TRAEs	Myocarditis, decrease in white blood cell count, decrease in platelet count, decrease in neutrophil count, decrease in platelet count.

Source: Company data

The following Y150 semi-logarithmic mean concentration-time curves for single and multiple doses of Y150 present the interim PK results of the Y150 over time in its Phase I clinical trial.



The following table presents the interim PD results of Y150 in its Phase I clinical trial by different cohorts.

Cohort (dosage)	Cytokine PD results
Cohort 1 (0.1mg)	After the first administration, there was a 1-2 fold increase in IL-6, IL-8, and IL-10 levels compared to baseline. These levels began to increase 8 hours after administration, reached a peak at 24 hours, and returned to baseline by 48 hours. The second administration of the drug resulted in a 2-3 fold increase in IL-6 and IL-8 levels compared to baseline. These levels began to increase 4-8 hours after administration, reached a peak at 24-48 hours, and returned to baseline by 24-48 hours. Activation of CD69+ T cells was not significant, but there was an abnormal increase in the proportion of CD38+ B cells.
Cohort 2 (0.3mg)	After first administration, IL-6, IL-8, and IL-10 levels increased 1-2 fold compared to baseline. These levels began to increase 0-4 hours after administration, reached a peak at 24-48 hours, and returned to baseline by 24-48 hours. Activation of CD69+ T cells increased 24-48 hours after administration, and the proportion of CD38+ B cells decreased 24-48 hours after administration.
Cohort 3 (1mg)	In one patient, IL-6 levels reached a maximum of 40,000 pg/ml (1280 times the baseline level), while in the other three patients, IL-6 levels peaked at 700-1000 pg/ml (235 times the baseline level). In the remaining 3 patients, IL-6 levels increased 3-6 fold. There was significant individual variability. Cell factors were most significantly released after the first administration of the drug, with a transient release that peaked 4 hours after the end of the administration and returned to baseline by 24-48 hours. Activation of CD69+ T cells increased significantly 24-48 hours after administration, and the proportion of CD38+ B cells decreased significantly 24-48 hours after administration, with significant individual variability.
Cohort 4 (3mg)	The peak of cytokine IL-6 was between 1420-3035pg/ml (around 150-fold baseline). In one patient, IL-6 peak was at 8150pg/ml (880-fold baseline), and the activation was obvious. After the 1st drug administration, the cytokine reached peak level at 8-24h, then released transiently, and gradually recovered at 48h. Subpopulation of CD69+T lymphocytes had a significantly activation at 24h after drug administration, while the proportion of CD38+B cells decreased significantly at 24-48h after drug administration with large individual differences.

Source: Company data

The following table presents the immunogenicity results of Y150 in different cohorts.

Cohort (dosage)	The number of subjects evaluable for ADA	The number of subjects who tested positive for ADA (and as a percentage of the number of subjects evaluable for ADA)	The number of subjects who tested negative for ADA (and as a percentage of the number of subjects evaluable for ADA)
1 (0.1mg)	1	0 (0)	1 (100%)
2 (0.3mg)	1	0 (0)	1 (100%)
3 (1 mg)	4	1 (25%)	3 (75%)
Total	6	1 (16.7%)	5 (83.3%)

Source: Company data

Abbreviation: ADA refers to anti-drug antibodies

The results show that the incidence of ADA is low across all the evaluated cohorts, and no significant difference in the incidence of ADA were observed between the different cohorts. These results suggest that Y150 is well tolerated and has a low immunogenic potential, which is a favorable characteristic for a therapeutic BsAb.

Clinical Development Plan

We expect to complete the Phase I clinical trial of Y150 in rrMM in China in the first quarter of 2024. We will further explore the clinical efficacy of Y150 monotherapy in treating rrMM patients as well as its potentials in combination therapy. We plan to commence a Phase II/III clinical trial of Y150 monotherapy in China for the treatment of rrMM. We plan to file an IND application with the NMPA in the second quarter of 2024 and expect to receive the IND approval in the third quarter of 2024. In addition, we also plan to initiate a Phase Ib/II clinical trial for Y150 in combination with lenalidomide as second-line treatment for rrMM after the completion of Phase II portion of Phase II/III clinical trial of Y150 monotherapy for rrMM. Specific manufacturer(s) of the combination drug lenalidomide will be decided prior to the commencement of the trial.

Furthermore, we received FDA IND approval for our clinical investigation of Y150 for rrMM in August 2020. We currently have no immediate plan to initiate clinical trial for Y150 in the U.S. We plan to leverage our clinical results of Y150 in China for further clinical development of Y150 in the U.S. in the future.

We believe it is feasible for us to leverage clinical results of Y150 in China to conduct late-stage clinical development of Y150 in the U.S. because (i) FDA has released a "Guidance for Industry and FDA Staff/FDA Acceptance of Foreign Clinical Studies Not Conducted Under an IND Frequently Asked Questions" which provides guidance for the industry and the FDA staff on the acceptance of results generated from foreign clinical studies; and (ii) the ICH

guideline "Ethnic Factors in the Acceptability of Foreign Clinical Data E5 (R1)" which supports the use of foreign clinical data as a basis to support the approval of an IND application in a new jurisdiction, without the need to repeat the entire clinical drug development program in the new jurisdiction. For more details, please refer to the analysis in the paragraphs headed "– Our Drug Candidates – M701 (EpCAM × CD3 BsAb) – Our Core Product – Clinical Development Plan" in this section.

Licenses, Rights and Obligations

As we internally discovered and developed Y150, we maintain the global rights to develop and commercialize this drug candidate.

Material Communications with Competent Authorities

The material communications with the relevant competent authorities in respect of Y150 are as follows:

- We filed the IND application for Y150 for rrMM with the NMPA on November 17, 2020 and received the umbrella IND approval from the NMPA for the Phase I, II and III clinical trials of Y150 for rrMM on January 18, 2021.

- We filed the IND application for Y150 for rrMM with the FDA on July 12, 2020 and received the IND approval for Y150 for rrMM from FDA on August 12, 2020.

We had not received any regulatory agency's concerns or objections to our clinical development plans or any ongoing clinical trial as of the Latest Practicable Date, nor did any material unexpected or adverse changes had occurred since the date of issue of relevant regulatory approvals for Y150.

Cautionary Statement required by Rule 18A.05 of the Listing Rules of the Hong Kong Stock Exchange:

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET Y150 SUCCESSFULLY.

Y2019 (RBD-dimer Subunit SARS-CoV-2 Vaccine)

Y2019 is a recombinant receptor-binding domain (RBD)-dimer subunit SARS-CoV-2 vaccine candidate for COVID-19.

We completed a Phase Ia clinical trial for Y2019 in China in August 2022 which evaluated the safety and tolerability of Y2019 in healthy adults aged 18 years or older, and have obtained satisfactory 7-day and 90-day safety data post immunization. Along with the relaxation of the preventative measures for the COVID-19 epidemic and the increasing number of individuals

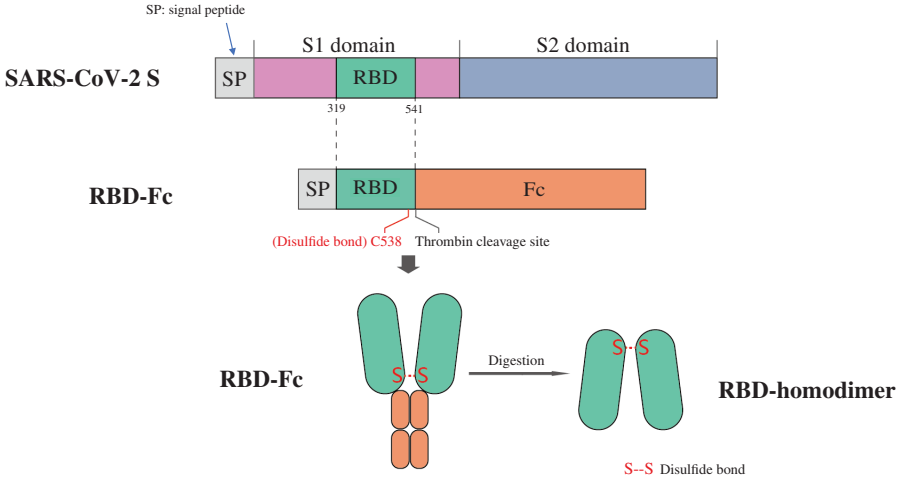
gaining immunity due to COVID-19 infection in China in late 2022, there are uncertainties surrounding the market demand for the COVID-19 vaccine, hence we will deprioritize the clinical development of Y2019 and currently have no immediate plans to initiate the Phase IIa clinical trial for Y2019.

Mechanism of Action

The main target for vaccine development for SARS-CoV-2 is the spike (S) protein of the virus, responsible for attachment and cell entry via the cellular receptor human ACE2. Therefore, the goal for all COVID-19 vaccines is to induce high titers of neutralizing antibodies to the S protein to reduce the incidences of infection.

Y2019 consists of an RBD homodimer protein and an aluminum hydroxide adjuvant (AL). RBD is the core region of the SARS-CoV-2 S protein that binds to the receptor, human angiotensin-converting enzyme II (hACE2) on the surface of the host cells and mediates the viral invasion process. In the development of RBD homodimers, the RBD of the S protein was fused with the Fc fragment of immunoglobulin G (IgG) to produce RBD dimers with an Fc tag and the Fc fragment was then removed through thrombin digestion and repeated affinity chromatography to obtain the desired stable RBD homodimers. Adjuvants are pharmacological or immunological substances that can be added to a specific protein in a vaccine to help boost the immune response triggered by the vaccine.

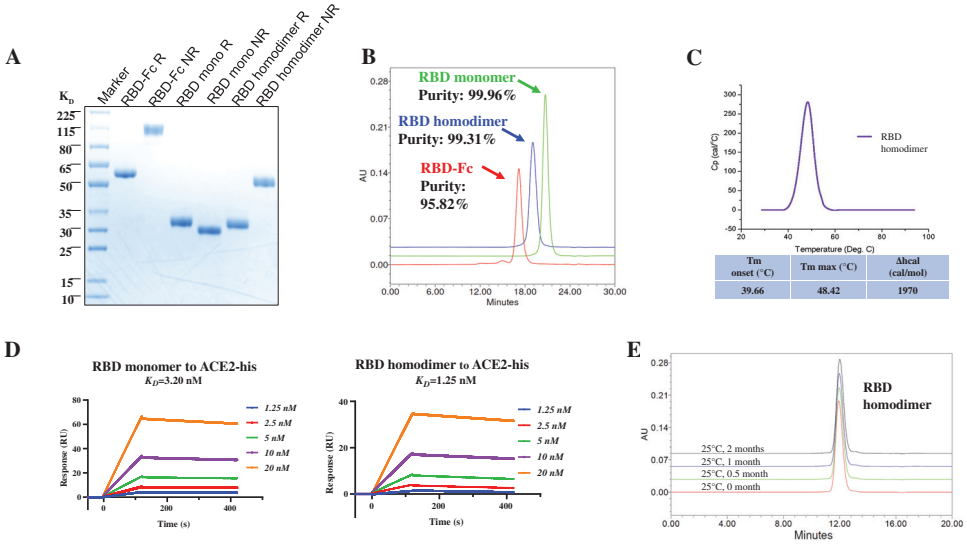
The following diagram illustrates the structure of Y2019:



Source: Company data

As shown below, RBD homodimer has disulfide bonds between both RBD monomers. The purification process meets the medicinal standard of high purity of RBD homodimer. The thermal stability of the RBD homodimer is good at room temperature. The affinity (K_D) of RBD homodimer to hACE2 was 1.25 nM, which is slightly better than the K_D of the monomer RBD (3.20 nM).

The RBD-homodimer showed high purity, a high affinity for hACE2, and good stability



Source: Company data

Market Opportunities and Competition

COVID-19 is associated with high transmission rates and, without adequate and effective treatment, a significant number of patients experience respiratory distress, which threatens to overwhelm global healthcare capacity.

According to the CDE and WHO websites, as of the Latest Practicable Date, 15 COVID-19 vaccines had received marketing approvals in the PRC, consisting of five inactivated vaccines, three recombinant adenovirus viral vector-based, six recombinant subunit protein vaccines and one mRNA vaccine. As of the same date, 32 clinical-stage COVID-19 pipeline candidates in the PRC were being developed, including nine using the recombinant subunit protein route.

The chart below illustrates the marketed recombinant subunit protein COVID-19 vaccines under development in China as of the Latest Practicable Date:

China Marketed Products

Product	Company	Medicine	Indication	Approval Time
智克威得	Anhui Zhifei Longcom Biopharmaceutical Co.,Ltd	Recombinant Subunit Protein Vaccine(CHO Cell)	COVID-19	2022/3/1
麗康V-01	Lizhu Pharmaceutical Group Co., JoincarePharmaceutical Group Industry Co., Ltd.	Recombinant Subunit Protein Vaccine (CHO Cell)	COVID-19	2022/9/14
SCTV01C	Sinocelltech Group Limited	Recombinant Subunit Protein Vaccine	COVID-19	2022/12/4 (for emergency use)
威克欣	WestVac Biopharma Co.,Ltd, West China Hospital of Sichuan University	Recombinant Subunit Protein Vaccine (Sf9 Cell)	COVID-19	2022/12/2 (for emergency use)
SCB-2019	Sichuan Clover Biopharmaceuticals Co., Ltd., GlaxoSmithKline Pharmaceuticals	Recombinant Subunit Protein Vaccine (CHO Cell)	COVID-19	2022/12/5 (for emergency use)

Source: Annual Reports of Listed Medical Companies, NMPA, CDE, Frost & Sullivan Analysis

(1) "First Posted Date" in the context of China clinical trials refers to the date when the study corresponding to the highest clinical phase in China was first available on chinadrugtrials.org.cn after the Center for Drug Evaluation (CDE) has concluded its review. The CDE is an affiliated institution of the NMPA.

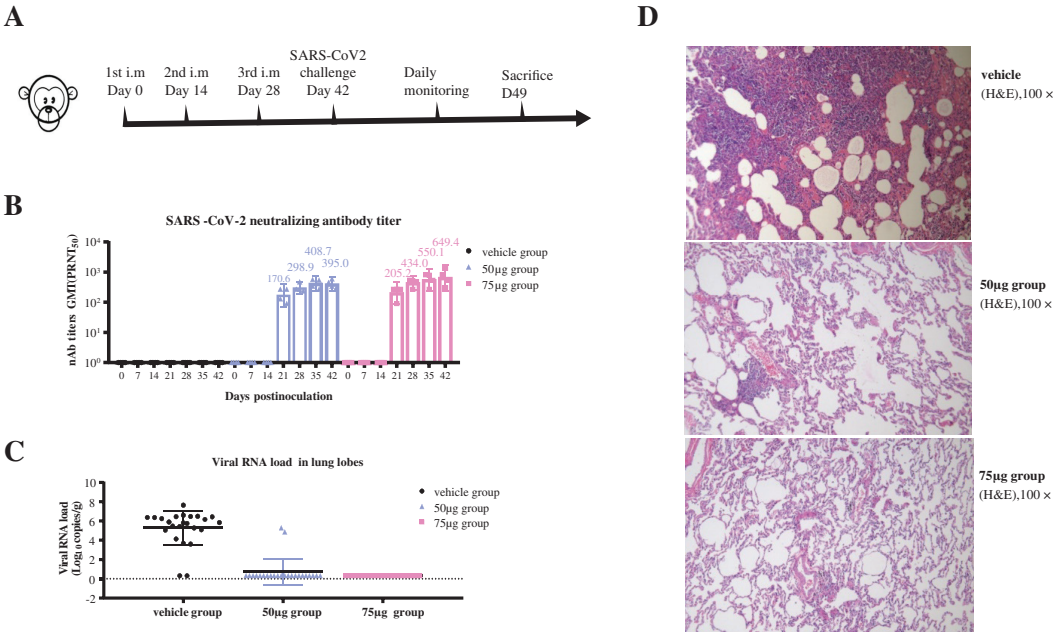
However, the yields of these vaccines are still too low to meet the worldwide need. For details, please refer to the paragraphs headed "Industry Overview – China's COVID-19 Vaccine Market" in this document.

Competitive Advantages

Encouraging immunogenicity and efficacy in infection prevention in vivo

Based on our pre-clinical studies, Y2019 can induce high-level immune responses *in vivo* and prevent SARS-CoV-2 infection in non-human primates.

Y2019 vaccine protected rhesus monkeys from pneumonia caused by SARS-CoV-2 infection



Source: Company data

As shown above, the pre-clinical study in rhesus macaques (RMs) has demonstrated encouraging immunogenicity and efficacy of Y2019. The titers of neutralizing antibodies began to increase on day 14 after the first immunization in RMs and reached a high level on day 35 ($PRNT_{50}$ GMT 408.7 and 550.1). The neutralizing antibody titers remained at high level until day 42 after the first immunization in RMs ($PRNT_{50}$ GMT 395.0 and 649.4). Our pre-clinical data suggests that Y2019 elicits a strong immune response in non-human primates, and vaccinated individuals experienced a significant reduction in viral load in their lungs after infection. Moreover, Y2019 significantly improves the pulmonary pathology in RMs

vaccinated with Y2019, compared to RMs from the control group, evidenced by the reduced severity of lesions in the lung tissues of the RMs vaccinated with Y2019. Taken together, the neutralizing antibody stimulated by Y2019 vaccination conferred protection against SARS-CoV-2 infection to immunized RMs.

Favorable safety profile

Data obtained from the Phase Ia clinical trial of Y2019 indicates that Y2019 is generally safe and well-tolerated. As of June 27, 2022, most of the ADRs were Grade 1 or Grade 2 ADRs. The observed incidences of ADRs mainly included solicited local ADRs, such as pain, swelling, induration and pruritus, and solicited systemic ADRs, such as fever and fatigue. We obtained the ethic committee approval in July 2022 to proceed with a Phase IIa clinical trial of Y2019 based on satisfactory seven-day safety data post immunization of Y2019 obtained from this Phase Ia clinical trial.

In pre-clinical studies, we performed an *in vivo* safety evaluation of Y2019. No material changes associated with Y2019 vaccination were observed in rhesus macaques (RMs) after intramuscular injection at the doses of 50μg and 150μg RBD proteins, indicating that the Y2019 vaccination has no obvious effects on cardiovascular and respiratory systems of RMs.

Highly stable

The favorable stability profile of the Y2019 makes it suitable for storage and transportation. The results of the stability tests show that Y2019 remains stable for at least 30 days at room temperature and for at least six months in refrigerated conditions, making it suitable for long-term storage and long-distance transportation.

Summary of Clinical Trial Results

We initiated a Phase Ia clinical trial of Y2019 in China in April 2022 and have obtained satisfactory seven-day and 90-day safety data post immunization. We completed this Phase Ia clinical trial in August 2022. We expect to complete the follow-up site visit for all enrolled subjects in January 2024.

Trial design

This is a randomized, double-blinded, placebo-controlled Phase Ia clinical trial of Y2019 in China. We plan to enroll 100 healthy subjects aged 18 years or older, including 50 healthy subjects aged between 18 to 59 years old (adult subjects) and 50 healthy subjects aged 60 years or older (elderly subjects). Each subject will receive one dose intramuscular injection on day 0, day 21 and day 42 in the deltoid muscle of the upper arm. The subjects will be randomized into four groups, as illustrated below:

Age Group	Dose Level	Test Vaccine Group Subjects	Placebo Group Subjects	Subtotal	Total
Adult subjects	25μg/0.25mL (Low-dose group)	20	5	50	100
	50μg/0.5mL (High-dose group)	20	5		
Elderly subjects	25μg/0.25mL (Low-dose group)	20	5	50	
	50μg/0.5mL (High-dose group)	20	5		

Source: Company data

The primary objectives of this clinical trial are to evaluate the safety and tolerability of different doses of Y2019 in healthy people aged 18 years or older. The secondary objective of this clinical trial is to evaluate the immunogenicity of different doses of Y2019 in healthy people aged 18 years or older. The primary endpoint is the occurrence of AEs within seven days after injection of each dose of Y2019.

Trial status

We commenced this Phase Ia clinical trial in April 2022 and completed this trial in August 2022. All of the 100 healthy subjects were enrolled in the clinical trial and all three doses of vaccination of Y2019 were completed. We have completed the three-month preliminary evaluation of the safety and efficacy of Y2019 and obtained certain data for the evaluation of the immunogenicity of live virus neutralizing antibodies. We will conduct a 14-month follow-up site visit for each subject and expect to complete such follow-up site visit in January 2024.

Safety results

The safety results indicate that Y2019 is generally safe and well tolerated. As of June 27, 2022, most of the Adverse Drug Reactions (ADRs) were Grade 1 or Grade 2 ADRs. The observed incidences of ADRs mainly included solicited local ADRs, such as pain, swelling, induration and pruritus, and solicited systemic ADRs, such as fever and fatigue. Fourteen incidences of Grade 3 or above ADRs were observed. The incidence rate of Grade 3 or above ADRs in the high-dose and low-dose groups was 7.5% (3 subjects, 9 incidences) and 7.5% (3 subjects, 5 incidences), respectively. The symptoms were:

- swelling at the site of inoculation, high dose (7.5%, 3 incidences) and low dose group (7.5%, 3 incidences)

- induration at the inoculation site was observed in high dose (5.0%, 2 incidences) and low dose group (2.5%, 1 incidence)

- pruritus at the inoculation site, high dose (2.5%, 1 incidence)

- redness at the inoculation site was observed in high dose (5.0%, 2 incidences) and low dose group (2.5%, 1 incidence)

- rash at the site of inoculation, high dose (2.5%, 1 incidence)

Observations of ADRs in vaccine clinical trials adhere to stricter standards compared to observations of AEs in drug clinical trials. The relevant standards clearly outline the solicited ADRs that must be observed in vaccine clinical trials. Specifically, the standards list solicited local ADRs, such as swelling and pruritus, and solicited systemic ADRs, such as fever and fatigue, that must be observed. These milder reactions are often not considered as AEs in drug clinical trials. As such, the ADR rate in vaccine clinical trials should not be compared to the AE rate in drug clinical trials. As illustrated above, Grade 3 or above ADRs of Y2019 mainly include tolerable syndromes such as swelling, induration or pruritus at the site of inoculation. The Grade 3 or above ADR rate in the Phase Ia clinical trial of Y2019 is comparable to those of the COVID-19 vaccines approved in China.

Immunogenicity evaluation results

The results of immunogenicity of live virus neutralizing antibodies showed that the serum conversion rate in the low-dose groups (25μg/0.25mL/dose of Y2019) was 100% (4-fold increase of neutralizing antibody) on day 7 and day 30 post immunizations. The serum conversion rate of live virus neutralizing antibodies in the high-dose groups (50μg/0.5mL/dose of Y2019) reached 95% on day 7 and day 30 post immunizations.

The Y2019 vaccine-induced antibodies, as measured by the geometric mean titer (GMT), exhibit a temporal dependence. In a virus neutralization assay, the GMT reached its peak (109.2) 30 days post-final vaccination. Analysis of the geometric mean increment (GMI) reveals a consistent trend of temporal dependence in the Y2019 vaccine-induced antibodies. The GMI reached its peak (45.157) 30 days post-final vaccination in the virus neutralization assay.

Clinical Development Plan

We completed a Phase Ia clinical trial for Y2019 in China in August 2022 and obtained ethical committee approval for the Phase IIa clinical trial. Along with the relaxation of the preventative measures for the COVID-19 epidemic and the increasing number of individuals gaining immunity due to COVID-19 infection in China in late 2022, there are uncertainties surrounding the market demand for the COVID-19 vaccine, hence we will deprioritize the clinical development of Y2019 and currently have no immediate plans to initiate the Phase IIa clinical trial for Y2019.

Licenses, Rights and Obligations

We have entered into an agreement to collaborate with the Wuhan Institute of Virology, Chinese Academy of Sciences (WIV) in the research and development of Y2019. For more details, please refer to the paragraphs headed "– Collaboration Agreements – Collaboration with WIV" in this section.

Material Communications with Competent Authorities

The material communications with the relevant competent authorities in respect of Y2019 are as follows:

- We filed IND application for Y2019 with the NMPA and submitted the application documents on a rolling basis from January 8, 2021 to October 26, 2021 and received an umbrella IND approval from the NMPA for the Phase Ia, IIa, IIIa clinical trials of Y2019 for adults and Phase Ib, Phase IIb, Phase IIIb clinical trials of Y2019 for children and adolescent aged from 3 to 17 on December 10, 2021.

- We submitted a consultation to the CDE regarding the Phase IIa clinical trial for Y2019 on April 21, 2022, and received a response from the CDE on July 7, 2022, accepting our protocol for the Phase IIa clinical trial and recommending that in the Phase IIa clinical trial, (1) we clearly define the primary immunogenic markers as the neutralizing antibody levels against the current prevalent strains of live viruses, particularly Omicron sub-variants; (2) we conduct a comparison of (a) antibody level against VOCs in the experimental group and against ancestral strain of virus in the control group and (b) antibody levels against VOCs in both the experimental group and the control group post-immunization. These recommendations by the CDE reflect their recognition of the ability of Y2019 to resist mutating VOCs.

- In addition to the above material communications with the relevant competent authorities, we also obtained the ethic committee approval to proceed with the Phase IIa clinical trial of Y2019 in healthy people aged 18 years or older in July 2022. According to the Measures for the Administration of Drug Registration (《藥品註冊管理辦法》), each phase of clinical drug trials shall be examined and approved by the ethics committee before being carried out.

We had not received any regulatory agency's concerns or objections to our clinical development plans or any completed or ongoing clinical trial as of the Latest Practicable Date, nor did any material unexpected or adverse changes had occurred since the date of issue of relevant regulatory approvals for Y2019.

Cautionary Statement required by Rule 18A.05 of the Listing Rules of the Hong Kong Stock Exchange:

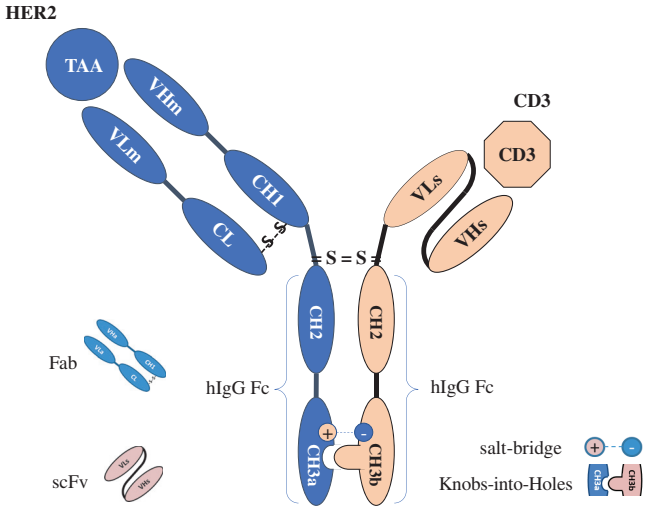
WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET Y2019 SUCCESSFULLY.

M802 (HER2 × CD3 BsAb)

M802 is a HER2 × CD3 BsAb. We completed a Phase I clinical trial of M802 for patients with HER2-positive solid tumor in China in May 2022. We will consider exploring potential out-licensing opportunities of M802 in the global market.

Mechanism of Action

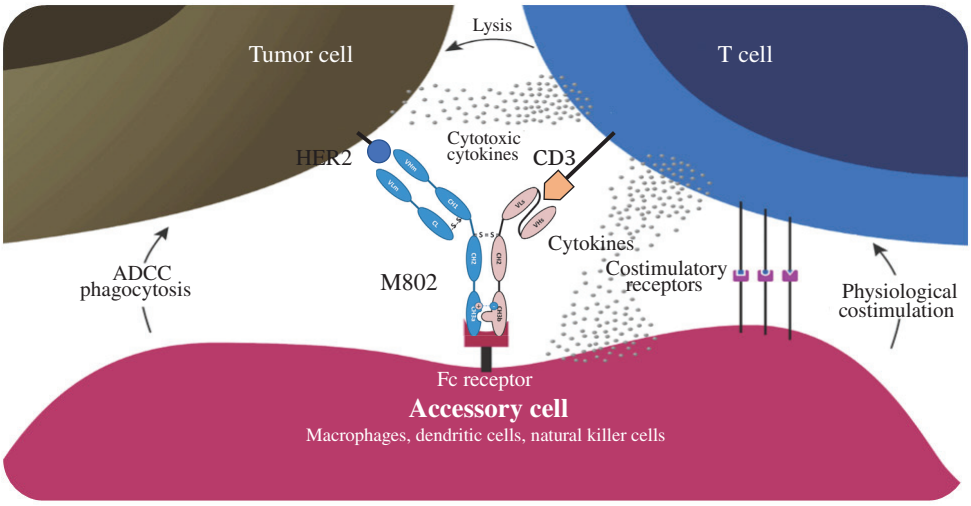
M802 is a recombinant anti-HER2 and anti-CD3 humanized BsAb that consists of a monovalent unit specifically binds to HER2 and a single chain unit which binds to CD3. The monovalent unit consists of Fab and Fc1, and the single chain unit consists of scFv and Fc2, where the Fc1 and Fc2 are from hIgG1 and mutated to form salt-bridge and KIH. The following diagram illustrates the structure of M802:



Source: Company data

HER2 plays an important role in cell proliferation, survival, differentiation, angiogenesis, cellular migration, metastatic growth, and invasion of cancer cells. Amplification of the HER2 gene or overexpression of the HER2 protein plays an important role in the development of malignant cancers. With the affinity of its monovalent unit to HER2, M802 can preferentially bind to HER2-positive tumor cells. It regulates the tumorigenesis signal pathways of tumor cells, which inhibits the proliferation and promotes the apoptosis in HER2-positive tumor cells. By binding to CD3 through its single chain unit, M802 can recruit and redirect T cells to target HER2-positive tumor cells, and further activate T cells to kill the tumor cells.

The following diagram illustrates the mechanism of actions of M802:



Market Opportunities and Competition

HER2 overexpression is prevalent in many cancer types, such as breast cancer, gastric cancer, bladder cancer, pancreatic cancer and ovarian cancer. The incidence of breast cancer, gastric cancer, bladder cancer, pancreatic cancer and ovarian cancer in China reached approximately 341.0 thousand, 498.6 thousand, 91.5 thousand, 120.0 thousand and 57.0 thousand in 2022, respectively, and is expected to increase to approximately 370.6 thousand, 619.6 thousand, 117.2 thousand, 155.2 thousand and 62.4 thousand in 2030, respectively.

HER2 antibodies, such as Trastuzumab, have been used as the standard treatment for HER2-positive breast cancer and gastric cancer in combination with chemotherapy. Despite the current treatment options, there is a huge need for treatment of HER2-positive solid tumors, since patients face multiple problems, such as limited treatment options, high recurrence rates, and resistance to current treatment. Patients who have developed progression subsequently have very limited treatment options.

Moreover, according to relevant research paper published on *Journal of Practical Oncology*, patients with HER2-low expression do not respond to HER2 antibodies in general. Although HER2 antibody-drug conjugates (ADCs) are shown to be active in certain HER2-low expressing tumors in clinical trials, they are often associated with severe adverse effects, such as interstitial lung disease, and can sometimes be fatal. In addition, Trastuzumab (trade name Herceptin), a recombined humanized anti-HER2 mAb developed by Roche, was approved by the FDA for the treatment of HER2-positive advanced breast cancer. However, approximately 70% of patients develop resistance to Herceptin, and some patients present with primary resistance. This suggests a clear need to develop novel therapeutics with a better efficacy-safety balance for patients with HER2-low expressing cancers and Trastuzumab-resistant cancers.

HER2 is an emerging target for cancer treatment. As of the Latest Practicable Date, there were ten HER2-targeted BsAb pipelines under clinical development globally (excluding China), and 13 HER2-targeted BsAb pipelines under clinical development in China. The

development of HER2 × CD3 BsAbs represents an emerging trend. As of the Latest Practicable Date, there were four HER2 × CD3 BsAbs under clinical development globally, including M802, RG6194, EX 101 Injection and AMX 818, as illustrated in the table below:

Global Pipeline

Product	Developer	Target	Drug Type	Indication	Highest Clinical Phase		First Posted Date(1)
Runimotamab (RG6194)	Genentech, Inc.	HER2, CD3	BsAb	Advanced or Metastatic HER2-Expressing Cancers	Global	I	2018/2/27
M802	the Company	HER2, CD3	BsAb	Advanced HER2-Expressing Solid Tumors	Global China	FDA IND Approval I	\ 2018/7/26
EX101 Injection	Guangzhou AI Simai Biomedical Technology Co., Ltd.	HER2, CD3	BsAb	HER2-positive advanced solid tumors	China	I	2021/09/15
AMX 818	Amunix Pharmaceuticals	HER2, CD3	BsAb	Locally Advanced or Metastatic HER2-Expressing Cancers	Global	I	2022/5/2

Source: NMPA, CDE, ClinicalTrial.gov, FDA, Frost & Sullivan Analysis

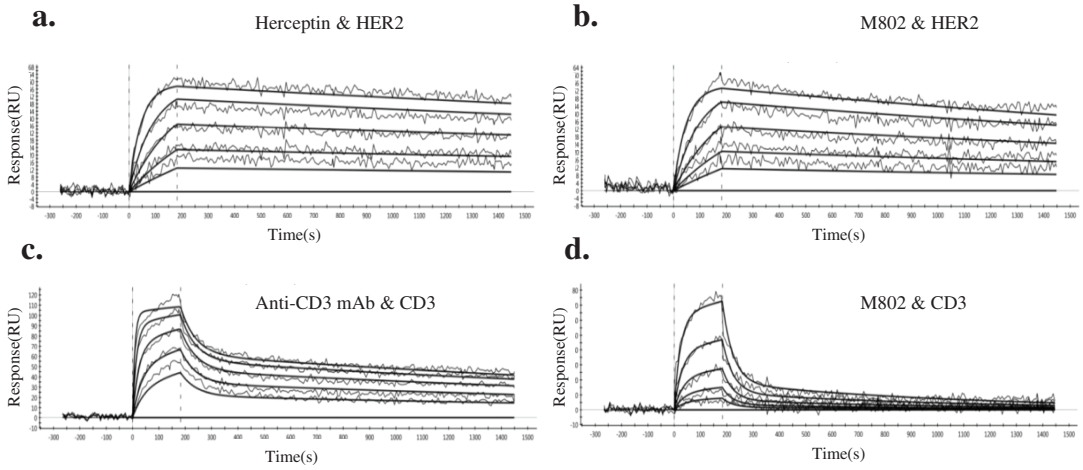
(1) "First Posted Date" in terms of global clinical trials refers to the date when the study corresponding to the global highest clinical phase (except China) was first available on ClinicalTrials.gov after the National Library of Medicine has concluded its quality control review; "First Posted Date" in the context of China clinical trials refers to the date when the study corresponding to the highest clinical phase in China was first available on chinadrugtrials.org.cn after the Center for Drug Evaluation (CDE) has concluded its review. The CDE is an affiliated institution of the NMPA.

Competitive Advantages

Well-designed structure to target both HER2 and CD3

Compared with monospecific antibodies, the ability to bind two different antigens or epitopes simultaneously gives BsAbs potential advantages by blocking different signaling pathways. The single chain of M802 binds to CD3 and thus can recruit T cells to target HER2-positive tumor cells and induce HER2-dependent T cell activation and cytokine release.

The affinity of M802 for HER2 is high and for CD3 is moderate



Affinity measurements of antibodies

	k_a, 1/Ms	k_d, 1/s	K_D, M
M802 and HER2 interaction	(4.29±0.17) E+05	(2.48±0.15)E-04	(5.78±0.12)E-10
Herceptin and HER2 interaction	(1.12±0.035) E+06	(1.27±0.23)E-04	(1.14±0.23)E-10
M802 and CD3 interaction	(3.45±0.191) E+05	(2.45±0.18)E-02	(7.12±0.91)E-08
Anti-CD3 mAb and CD3 interaction	(1.07±0.072) E+07	(1.31±0.19)E-02	(1.23±0.18)E-09

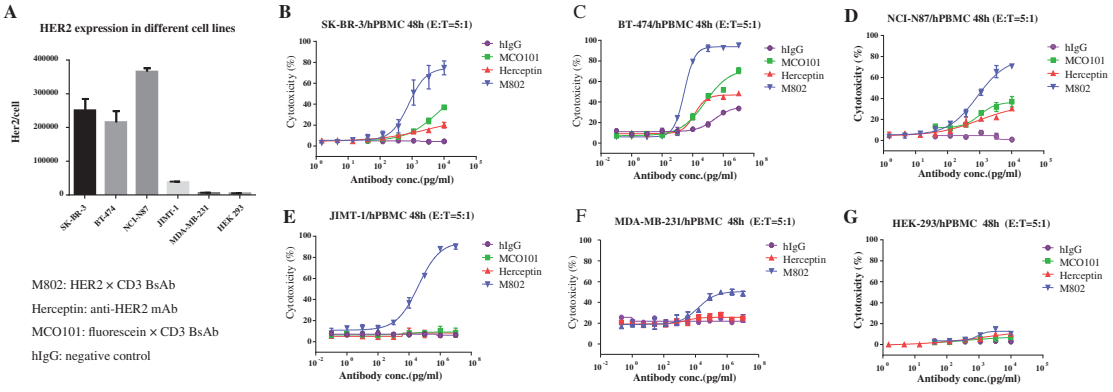
The association rate constant (k_a) and the dissociation rate constant (k_d) were measured with PriteOn. The equilibrium dissociation constant K_D was calculated as $K_D = K_d/K_a$.

Source: Company data and published in "Yu et al. Journal of Experimental & Clinical Cancer Research (2019) 38:355"

Potent anti-tumor effect

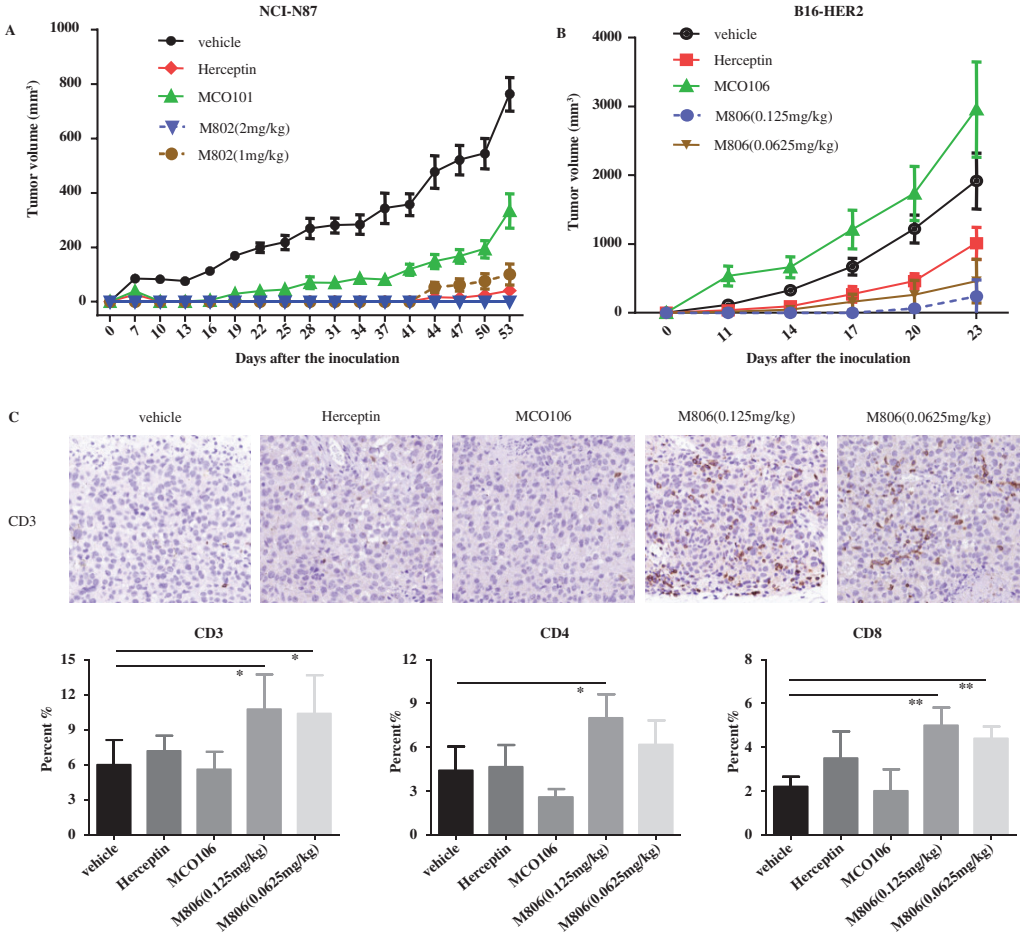
Our experiments indicate that M802 exhibits potent antitumor efficacy *in vitro* and *in vivo*. Our *in vitro* experiments suggest that M802 have remarkable cytotoxic effects against HER2-positive tumor cells, including certain Herceptin-resistant tumor cells. M802 also shows an obvious dose-dependent effect on growth inhibition of human breast cancer cells and promotes apoptosis in certain human breast cancer cells. Furthermore, M802 displays significant cytotoxicity to some Herceptin-resistant breast cancer cells (JIMT-1, MDA-MB-231).

M802-mediated cytotoxicity to various target cells with different HER2 expression levels



Source: Company data and published in "Yu et al. Journal of Experimental & Clinical Cancer Research (2019) 38:355"

In the animal models, M802 and M806 exhibited superior efficacy on inhibition of human gastric cancer (NCI-N87) and mouse melanoma (B16-HER2)



Source: Company data and published in "Yu et al. Journal of Experimental & Clinical Cancer Research (2019) 38:355"

As shown above, M802 exhibits superior efficacy on inhibition of human gastric cancer cells (NCI-N87) in NOD/SCID mice compared with control antibodies (as shown in A above). BsAb M806 targets human HER2 and murine CD3 on immunocompetent C57BL/6 mice. The results showed that M806 (0.125 mg/kg and 0.0625 mg/kg) significantly inhibited the growth of B16-HER2 tumors *in vivo* (as shown in B above) and recruited T lymphocytes to tumor tissues (as shown in C above). MCO101 and MCO106 are human and murine CD3 isotypes, respectively.

Favorable safety profile

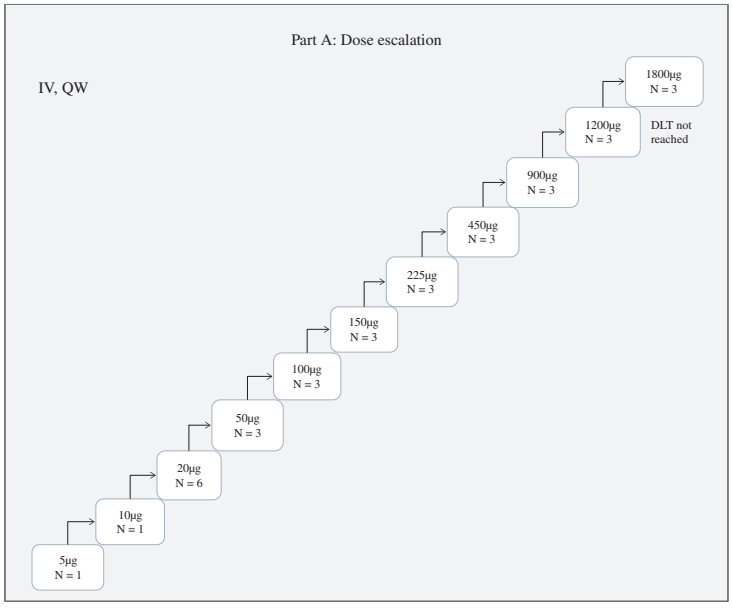
M802 binds to CD3 receptor with reduced affinity, which reduces the toxicity of cytokine release syndrome caused by the activation of T cells. In pre-clinical studies, M802 is well-tolerated and generally safe. Data obtained from the Phase I clinical trial of M802 also indicates that M802 is generally safe and well tolerated.

Summary of Clinical Trial Results

We completed a Phase I clinical trial of M802 for patients with HER2-positive solid tumors in China. We commenced this Phase I clinical trial in September 2018. A total of 34 subjects were enrolled. We completed this clinical trial in May 2022.

This is a multi-center, open-label, dose-escalation Phase I clinical trial to evaluate the safety and tolerability of M802 in patients with HER2-positive solid tumors in China. Subjects are randomly assigned to 11 cohorts, and receive M802 on day 1, day 8, day 15 and day 22. The leading dose of M802 on day 1 ranges from 2μg in cohort 1 to 100μg in cohort 11, and starting from day 8, subjects will receive the maintenance dose of M802 ranging from 5μg in cohort 1 to 1,800μg in cohort 11. The primary endpoints are the safety and tolerability of different doses of M802 in patients with HER2-positive solid tumors, including DLT, AEs, SAEs, laboratory values, PK, and biomarkers, among others, as the basis for the RP2D. The secondary endpoints are MTD, PK, PD, immunogenicity, and efficacy parameters.

Data obtained from the Phase I clinical trial of M802 indicates that M802 is generally safe and well-tolerated. The MTD was not reached in this Phase I clinical trial. The following diagram shows the subjects enrolled in M802's Phase I clinical trial:



Source: Company data

Clinical Development Plan

We completed a Phase I clinical trial in China with M802 alone for patients with HER2-positive solid tumors.

We also received FDA IND approval for our clinical investigation for HER2 positive solid tumors in August 2019. We will consider exploring potential out-licensing opportunities of M802 in the global market.

Licenses, Rights and Obligations

As we internally discovered and developed M802, we maintain the global rights to develop and commercialize this drug candidate.

Material Communications with Competent Authorities

We had not received any regulatory agency's concerns or objections to our clinical development plans or any completed clinical trial as of the Latest Practicable Date, nor did any material unexpected or adverse changes had occurred since the date of issue of relevant regulatory approvals for M802.

Cautionary Statement required by Rule 18A.05 of the Listing Rules of the Hong Kong Stock Exchange:

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET M802 SUCCESSFULLY.

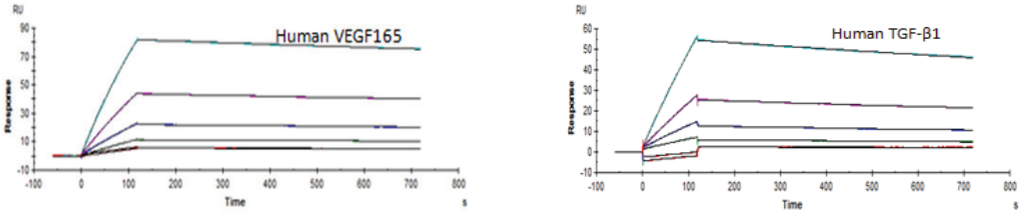
Y332 (VEGF × TGF-β BsAb)

Y332 is a VEGF × TGF-β BsAb for the treatment of solid tumors. We received IND approval for Y332 for metastatic or locally advanced solid tumors in April 2023. We plan to commence a Phase I clinical trial in the third quarter of 2023 and following the completion of this Phase I clinical trial, we plan to commence a Phase Ib/II clinical trial of Y332.

VEGF is a growth factor overexpressed in most solid tumors and a key driver of angiogenesis, the process that leads to the formation of new blood vessels within and around tumors. Through the blockade of VEGF/VEGF receptor signaling, Y332 inhibits the angiogenesis process, disrupting the vascular supply and starving the tumor of nutrients and oxygen. In addition to stimulating tumor angiogenesis, VEGF plays a negative role in tumor immunity via various mechanisms within the TME. TGF-β also negatively regulates multiple immune cells, facilitates the generation of CAF and stimulates the EMT process of tumor cells that restricts T cell infiltration. By simultaneously targeting VEGF and TGF-β, Y332 unlocks the therapeutical potential of blockades for both pathways, synergistically transforming the immuno-suppressive TME of cancer patients and restoring their dysregulated anti-tumor immunity. In addition, the TGF-β signaling pathway and the TGF-β-induced hypoxic TME condition promote the expression of VEGF in tumor cells. Therefore, by blocking TGF-β, Y332 downgrades tumor cells' expression of VEGF, hence amplifying its own VEGF-inhibiting effect.

In pre-clinical studies, Y332 demonstrates high affinity to both VEGF and TGF-β, and shows noticeable anti-tumor effects, as shown in a diagram below.

High affinities of Y332 for both VEGF and TGF-β



Affinity measurements of antibodies

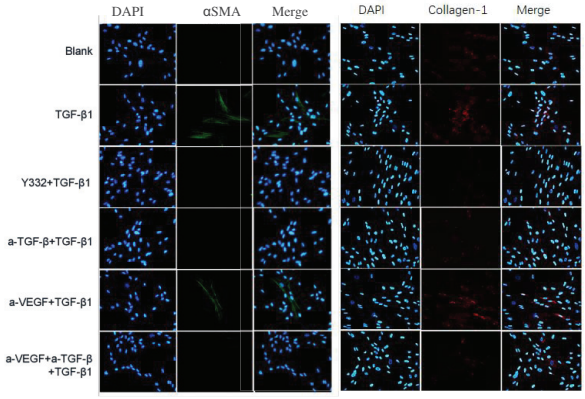
	k_a, 1/Ms	k_d, 1/s	K_D, M
Y332 and VEGF interaction	8.363E+05	1.476E-04	1.764E-10
Y332 and TGF-β1 interaction	6.904E+05	4.883E-04	7.072E-10

The association rate constant (k_a) and the dissociation rate constant (k_d) were measured with PriteOn in inverse seconds (1/s) or inverse milliseconds (1/Ms). The equilibrium dissociation constant K_D was calculated as $K_D = K_d/K_a$, measured in molar (M).

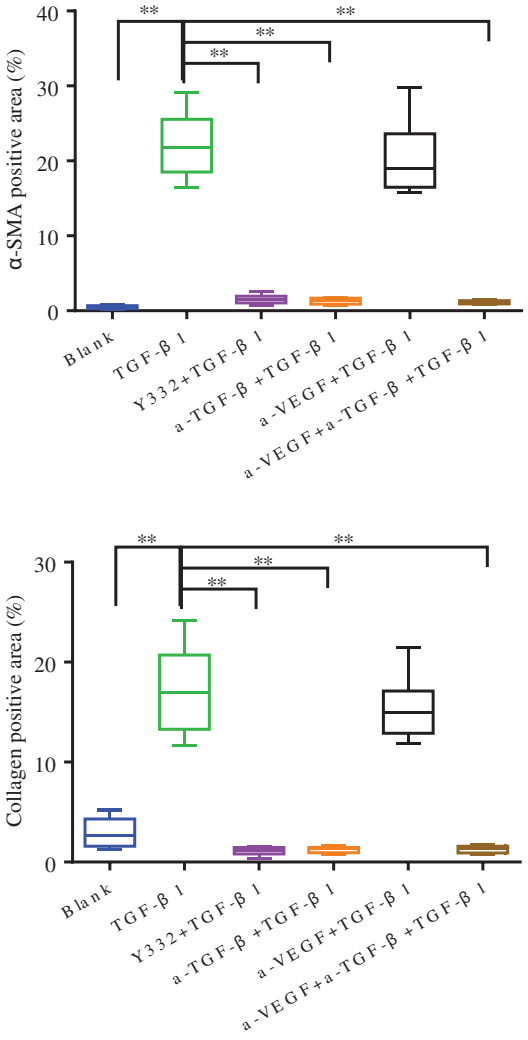
Source: Company data

As shown in the diagram below, Y332 inhibits TGF-β1-induced cancer-associated fibroblasts:

Y332 inhibits TGF-β1-induced cancer-associated fibroblasts (CAFs) activation



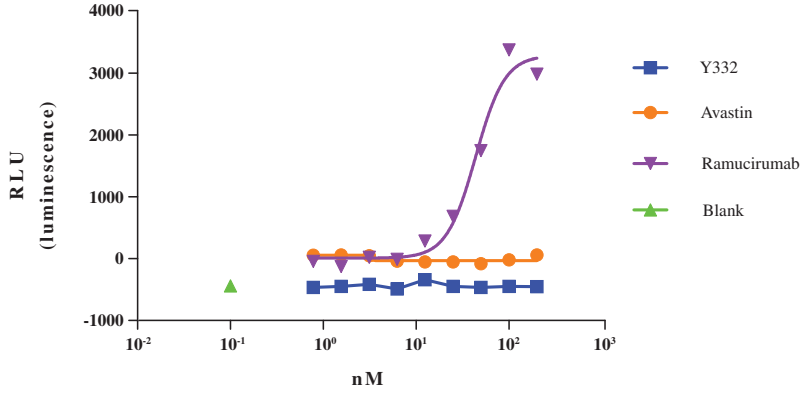
*Note: Both αSMA and Collagen - 1 are biomarkers of fibroblasts; **: p<0.01*



Source: Company data

As shown in the diagram below, the Fc of Y332 is modified to remove ADCC effects:

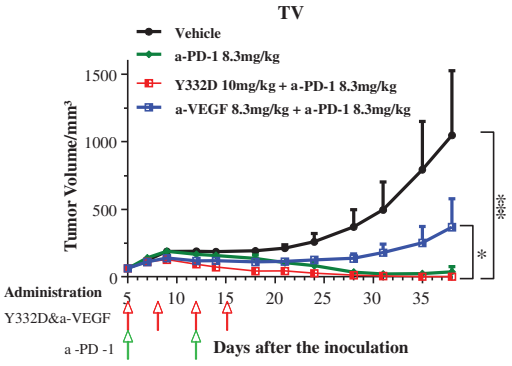
The Fc of Y332 is modified to remove ADCC function
(Jurkat - FcγRIIIα : HUVEC = 3:1)



Source: Company data

Y332 could also be used in combination of immune checkpoint inhibitors to deliver an enhanced anti-tumor effect. As shown in the diagram below, in the EMT-6-hPD-L1 orthotopic tumor model (TV≈100mm^3 at the time of first dose), the efficacy of the Y332D, a murine surrogate of Y332, in combination with an anti-PD-1 antibody (CR: 100%) is better than that of an anti-VEGF antibody in combination with an anti-PD-1 antibody (CR: 14.3%) and the anti-PD-1 monotherapy (CR: 85.7%).

Breast cancer EMT-6-hPD-L1 orthotopic model
Significant anti-tumor efficacy of Y332D + anti-PD-1 combination



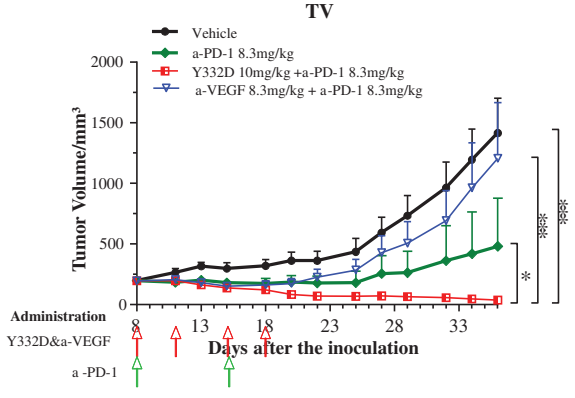
Y332D：Y332 surrogate, anti-murine VEGF and TGF-β
EMT-6-hPD-L1：mouse breast cancer cell
The mean tumor volume at the time of the first dose was 100mm^3

*: p<0.05
***: p<0.001

Source: Company data

In the EMT-6-hPD-L1 orthotopic large tumor model (TV≈200mm^3 at the time of first dose), the efficacy of the Y332D in combination with an anti-PD-1 antibody (CR: 42.9%) is better than that of an anti-PD-1 monotherapy (CR: 28.6%) and an anti-VEGF antibody in combination with an anti-PD-1 antibody (CR: 14.3%).

Breast cancer EMT-6-hPD-L1 orthotopic model
Significant anti-tumor efficacy of Y332D + anti-PD-1 combination



The mean tumor volume at the time of the first dose was 200mm^3

*: p<0.05
***: p<0.001

Source: Company data

Clinically, anti-VEGF mAbs have demonstrated an acceptable safety and efficacy profile, and anti-TGF-β-mAbs have shown little toxicity but negligible effectiveness. Leveraging the complementary and amplifying effect of both targets, Y332 could potentially be significantly more effective than the anti-VEGF or the anti-TGF-β mAbs while maintaining a comparable safety profile.

As of the Latest Practicable Date, no VEGF × TGF-β targeted drugs were marketed either globally or in China. As of the same date, one VEGF × TGF-β targeted BsAb and one PD-L1 × VEGF × TGF-β fusion protein were at clinical stage globally.

Global Pipeline

Product	Developer	Target	Drug Type	Indication	Highest Clinical Phase		First Posted Date[1]
PM8003	Biotheus Inc.	PD-L1, VEGF, TGF-β	Fusion protein	Advanced Solid Tumor	China	I	2021/7/30
ZGGS18	Suzhou Zelgen Biopharmaceuticals Co., Ltd..	VEGF, TGF-β	BsAb	Advanced Solid Tumor	Global China	FDA IND Approval I/II	\ 2022/10/20

Source: NMPA, CDE, FDA, Frost & Sullivan Analysis

(1) "First Posted Date" in terms of global clinical trials refers to the date when the study corresponding to the global highest clinical phase (except China) was first available on ClinicalTrials.gov after the National Library of Medicine has concluded its quality control review; "First Posted Date" in the context of China clinical trials refers to the date when the study corresponding to the highest clinical phase in China was first available on chinadrugtrials.org.cn after the Center for Drug Evaluation (CDE) has concluded its review. The CDE is an affiliated institution of the NMPA.

We internally discovered and developed Y332 and maintain the global rights to develop and commercialize this drug candidate.

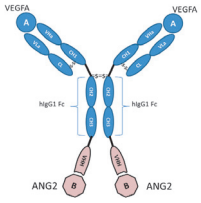
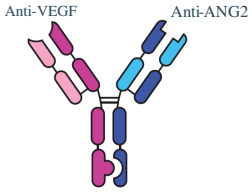
Cautionary Statement required by Rule 18A.05 of the Listing Rules of the Hong Kong Stock Exchange:

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET Y332 SUCCESSFULLY.

Y400 (VEGF × ANG2 BsAb)

Y400 is an anti-VEGF and anti-angiopoietin-2 (ANG2) BsAb. The CMC studies for Y400 have been completed and the CDE approved the IND application for Y400 in April 2023.

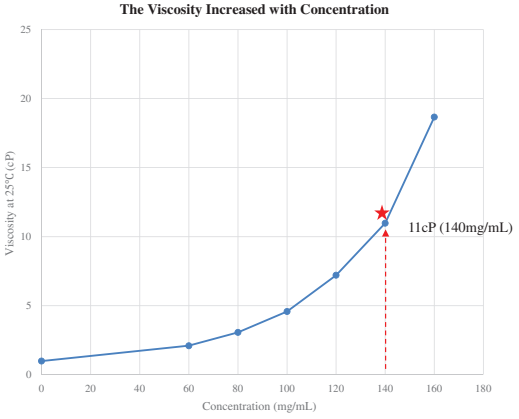
In our *in vitro* experiment, Y400 has shown an encouraging efficacy profile. Y400 has a high concentration formulation which is an important factor for the success of such ophthalmic drugs. The diagram below lists Company data of Y400 and publicly available data of Faricimab, and is not a head-to-head study of Y400 and Faricimab.

	the Company Y400 [1]	Roche Faricimab [2]
Format		
Technology	IgG-(VHH)2, single-domain antibody	Cross-mAb, Knobs-into-Holes
Valencies	Both anti-VEGF and anti-ANG2 moieties are bivalent	Both anti-VEGF and anti-ANG2 moieties are monovalent
Concentration	140mg/ml	120mg/ml
Molecular weight	~175kDa	~145kDa
Affinity	To VEGF: 0.03nM, SPR To ANG2: 0.22nM, SPR	To VEGF: 3.5nM, SPR To ANG2: 22nM, SPR

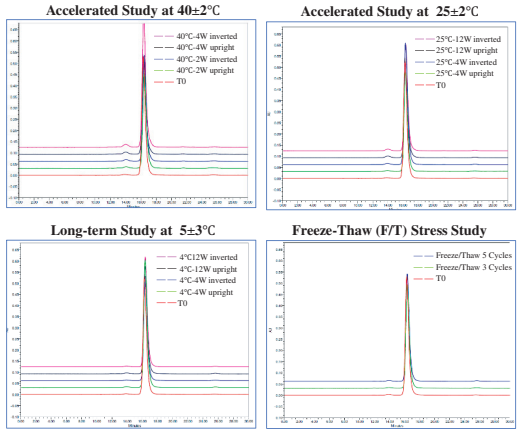
Source: (1) Company data;
(2) EMBO Mol Med (2016)8:1265-1288

Y400 is a BsAb developed based on Nano-YBODY™ technology with high-quality pharmaceutical properties, including high solubility, low viscosity, and favorable molecular stability, as shown below:

The performance of high concentration formulation of Y400 in injectability and stability



 # The viscosity of finished product (140mg/mL) is lower than 15 cP.
The drug product with high concentration had good injectability

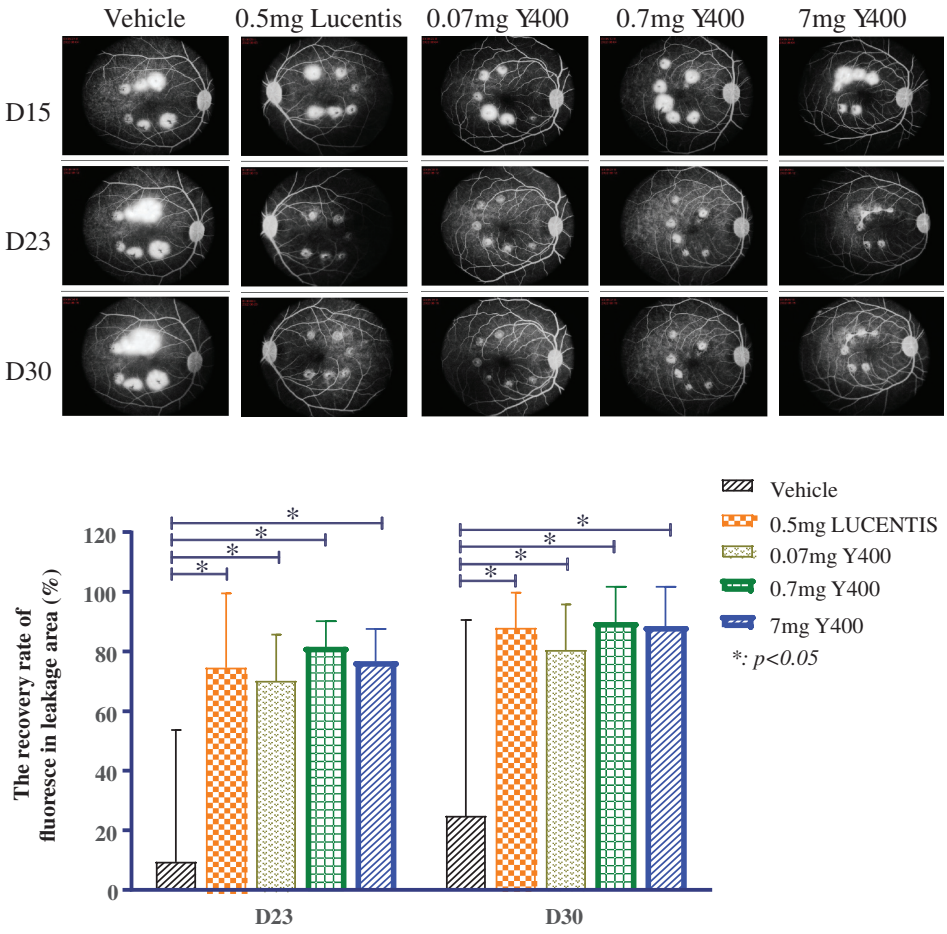


 # All the results remained well within the finished product specifications.
The drug product had a good stability performance

Source: Company data

As shown below, in the monkey model, the results of fluorescein fundus angiography (FFA) suggest that all doses of Y400 (0.07, 0.7, 7mg/eye) and LUCENTIS® (0.5 mg/eye) effectively inhibit the fluorescein leakage on Day 23 and Day 30, and the effects of all doses of Y400 are significant.

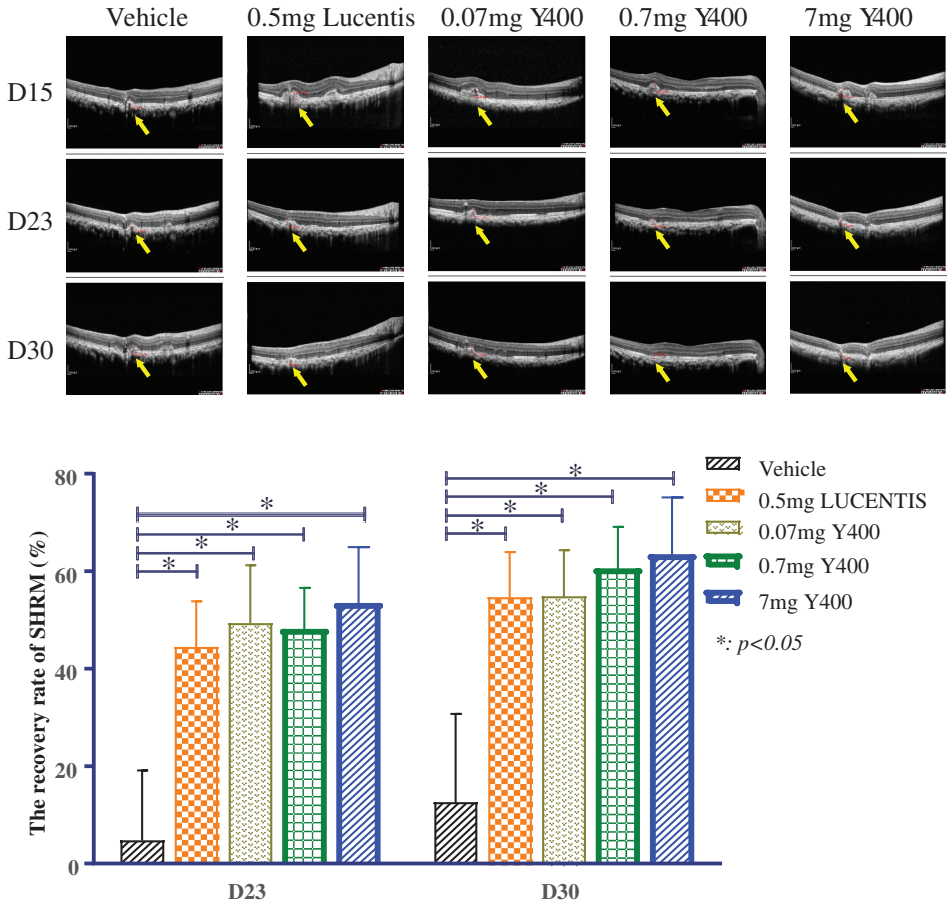
The recovery rate of leakage area of grade 4 lesion in Y400 groups were significantly greater than that in vehicle control group and similar to that in lucentis group



Source: Company data

As shown below, in the monkey model, the results of optical coherence tomography (OCT) suggest that all doses of Y400 (0.07, 0.7, 7 mg/eye) and LUCENTIS® (0.5 mg/eye) effectively decrease the thickness of SHRM on Day 23 and Day 30, and the effects of all doses of Y400 are significant.

The recovery rate of subretinal hyperreflective material (SHRM) of grade 4 lesion in Y400 groups were significantly greater than that in vehicle control group and similar to that in lucentis group



Source: Company data

As a testament to our R&D capability, we have out-licensed the global rights of Y400 to Shenzhen Kangzhe Vision Pharmaceutical Development Co., Ltd., a subsidiary of China Medical System Holdings Limited (0867.HK). For further details, please refer to the paragraphs headed "– Collaboration Agreements – Collaboration with CMS Vision" in this section.

Age-related macular degeneration (AMD) is an irreversible medical condition of partial or complete vision loss caused by degenerative lesions of the retinal pigment epithelium and neuronal retina. AMD can be classified as dry (atrophic) AMD and wAMD. DME is a serious eye complication characterized by abnormal swellings (edema) in the central part of the retina caused by tiny bulges protruding from the vessel walls, leaking, or oozing fluid and blood into the retina.

In wAMD, DME and other ocular neovascularization-related diseases, abnormal blood vessel growth stimulated by vascular endothelial growth factor (VEGF) under the macula causes blood and fluid to seep into the retina. Anti-VEGF therapy improves vision in patients with wAMD, DME and other ocular neovascularization-related diseases by inhibiting the

proliferation and leakage of new blood vessels. However, anti-VEGF therapy has limited ability in ablating vessel growth. Therefore, there are medical needs for drugs with multiple pro-angiogenetic targets among patients who have had an incomplete response to anti-VEGF therapy. Angiopoietin-2 (ANG2) promotes vascular leakage, leading to hypotension and abnormal vascular structure. Antibodies against ANG2 inhibit neovascularization and leakage and lessen the inflammatory response.

As a BsAb that simultaneously targets VEGF and ANG2, we believe Y400 has the prospect for the treatment of wAMD, DME and other ocular neovascularization-related diseases. wAMD and DME patient prevalence reached approximately 4.0 million and 7.3 million in China in 2022, accounting for approximately 1.9% and 3.5% of senior people aged at or above 65 years old in China. Y400 has a high expression level in the upstream process and the downstream process with high purity and stable quality. Leveraging our CMC capabilities, we would also achieve a high product purity of approximately 99% in Y400 formulation, with a product concentration of 140mg/ml.

As of the Latest Practicable Date, there were seven VEGF targeted antibody drugs or fusion proteins approved for the treatment of wAMD and DME globally (excluding China) and three approved in China. As of the same date, there were 56 and 16 VEGF targeted antibody or fusion protein drug candidates for the treatment of wAMD and DME under clinical development globally (excluding China) and in China, respectively. Among the 16 VEGF targeted antibody or fusion protein drug candidate pipelines for wAMD and DME under clinical development in China, eight were in Phase III clinical trials, three were in Phase II clinical trials and five were in Phase I clinical trials. In addition to VEGF targeted antibody or fusion proteins, there are three drug candidates in China utilizing different methods in treating wAMD and DME under clinical development, including chemical drugs and gene treatments.

Among all the VEGF targeted drugs, VEGF × ANG2 drug candidates represent an emerging trend. As of the Latest Practicable Date, there were four VEGF × ANG2 drug candidates for treating neovascular eye diseases under clinical development in China:

China Pipeline

Product	Drug Name	Developer	Target	Drug Type	Indication	Highest Clinical Phase	First Posted Date[1]
Y400	Y400	the Company	ANGPT2, VEGF	BsAb	Neovascular age-related macular degeneration	I/II	2023/04
Faricimab Injection	Faricimab	F. Hoffmann-La Roche Ltd	ANG2, VEGF	BsAb	DME, macular edema secondary to branch RVO, wAMD, CRVO or hemi retinal vein occlusion secondary to macular edema, polypoidal choroidal vasculopathy	III	2021/7/6
IBI324	IBI324	Innovent Biologics (Suzhou) Co. Ltd.	VEGF, ANG2	BsAb	DME	I	2022/6/17
ASKG-712	ASKG-712	Suzhou Aosaikang Biopharmaceutical Co., Ltd.	ANG2, VEGF	Fusion Protein	wAMD	I	2022/7/29

Source: NMPA, CDE, Frost & Sullivan Analysis

Abbreviations: RVO refers to retinal vein occlusion; CRVO refers to central retinal vein occlusion.

(1) "First Posted Date" in the context of China clinical trials refers to the date when the study corresponding to the highest clinical phase in China was first available on chinadrugtrials.org.cn after the Center for Drug Evaluation (CDE) has concluded its review. The CDE is an affiliated institution of the NMPA.

As Y400 received the IND approval in April 2023, it is still at very early clinical development stage when compared to other VEGF targeted therapies and ANG2 targeted therapies, and face fierce competition for the treatment of wAMD and DME.

Cautionary Statement required by Rule 18A.05 of the Listing Rules of the Hong Kong Stock Exchange:

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET Y400 SUCCESSFULLY.

OUR R&D PLATFORM

We believe that in-house research and development capabilities are critical to our success. We have built an integrated research and development platform that encompasses three main functions: drug discovery and pre-clinical development function, CMC function and clinical development function. With collaboration among such functional groups, we are able to bring our pipeline of innovative drugs from inception through development, manufacturing and commercialization.

We are dedicated to enhancing our pipeline by leveraging our in-house research and development capabilities, from early-stage drug discovery to clinical development. As of the Latest Practicable Date, our research and development team consisted of 104 employees, 43.4% of which have a master's degree or higher and 24 are our key R&D staff. We also work with CROs to support our pre-clinical and clinical studies in China. Our research and development team members have extensive pre-clinical and clinical development experience, focusing on oncology and immunology. In 2021, 2022 and the five months ended May 31, 2023, our total research and development expenses were RMB112.9 million, RMB157.3 million and RMB63.7 million, respectively, and the research and development expenses attributable to our Core Product, M701, amounted to RMB9.9 million, RMB23.5 million and RMB25.5 million, representing approximately 8.7%, 15.0% and 40.1% of the total research and development expenses for the same years, respectively. In 2021, 2022 and the five months ended May 31, 2023, our total research and development expenses accounted for approximately 78.2%, 88.5% and 90.3% of our operating expenses (being the research and development expenses and administrative expenses) for the same years/periods, respectively. For details about our research and development expenses in relation to M701 for different indications and the remaining drug candidates, respectively, and the explanation of fluctuations of our research and development expenses, please refer to the paragraphs headed "Financial Information – Descriptions of Selected Components of Consolidated Statements of Profit or Loss and Other Comprehensive Income – Research and Development Expenses" in this document.

Our key R&D staff have an average of 13 years of relevant experience working in the biopharmaceutical industry, and remained employed during the Track Record Period and up to the Latest Practicable Date. Many of them have worked on biotechnology and/or biopharmaceutical research at renowned research institutions (such as the University of Texas M.D. Anderson Cancer Center and the Institute of Biophysics of the Chinese Academy of Science) and corporations (such as Becton, Dickinson and Company and WuXi Biologics Co., Ltd.) and have accumulated profound experience in drug discovery, pre-clinical and clinical development, process development and manufacturing, quality control and assurance, and registration management. More than 85% of our key R&D staff have a master's degree or higher in relevant fields, including, but not limited to, medicine, cancer biology, molecular biology, microbiology, biotechnology, chemical technology, biochemistry and immunology. More than 90% of our key R&D staff have engaged in the projects in relation to the R&D of M701. Approximately 80% of these key R&D staff have engaged in the projects in relation to the R&D of Y332 and Y400. and approximately 60% of the key R&D staff have engaged in the projects in relation to the R&D of Y101D and Y150.

Compared to mAbs, BsAb production poses greater challenges in terms of upstream expression, downstream purification yield and product stability. We have achieved breakthroughs in the following areas through our technical accumulation and project development.

- *Expression*. The expression level of BsAbs in production is generally low. Leveraging our technology platforms, we have optimized the vector construction, cell line screening and cell culture process in BsAb production and can reach an expression level of over 8.0g/L for Nano-YBODY™ molecules, which has enhanced the competitiveness of our products for industrialization.

- *Purity and yield*. Another great challenge in manufacturing BsAbs is generally low purity and yield. We are dedicated to the combination and optimization of downstream purification strategies and have developed a high-purity and high-yield purification process. The total yield of BsAbs in our purification process can reach 75%, and the purity of the drug substance can reach 99% with low levels of impurities.

- *Stability*. The stability of BsAbs poses a challenge in its production. We are able to meet stability requirements in storage and transportation of different products through substantial prescription screenings and optimizations. The final formulation products remain stable for over three years.

Drug Discovery and Pre-clinical Development

Our drug discovery and pre-clinical development function is led by Dr. Zhou Pengfei and Mr. Zhang Jing. Dr. Zhou has over 33 years of experience in the healthcare and pharmaceutical industries. He obtained a bachelor's degree in pediatrics and a master's degree in pediatric surgery (oncology) from Tongji Medical University (currently known as Tongji Medical College of Huazhong University of Science and Technology) in the PRC. He also obtained a doctorate in medicine from McMaster University in Canada. For more details about Dr. Zhou's background and credentials, please refer to the paragraphs headed "Directors, Supervisors and Senior Management – Directors – Executive Director" in this document. Mr. Zhang has relevant working experience of almost 15 years in the biopharmaceutical industry. He obtained a bachelor's degree in biotechnology from Wuhan University and a master' degree in biochemistry and molecular biology from the Graduate School of the Chinese Academy of Science (currently known as the University of Chinese Academy of Science). For more details about Mr. Zhang's background and credentials, please refer to the paragraphs headed "Directors, Supervisors and Senior Management – Supervisors" in this document. As of the Latest Practicable Date, our drug discovery and pre-clinical development function consisted of 22 members.

Our drug discovery and pre-clinical development function comprises three divisions, namely, antibody engineering division, early discovery and research division and pharmacodynamics, pharmacokinetics and toxicology division.

- The antibody engineering division focuses on the discovery, sequence optimization, structure design, small preparation and early stability assessment of antibodies.

- The early discovery and research division is responsible for target research and scientific cooperation to initiate research and development projects.

- The pharmacodynamics, pharmacokinetics and toxicology division evaluates the *in vivo* efficacy and mechanisms of action of the antibodies, explores toxicity, and reviews the protocols of formal safety evaluation experiments.

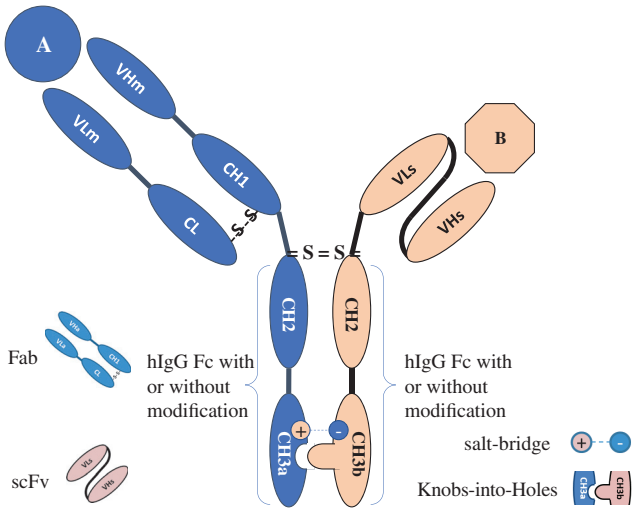
Our Technology Platforms

We have successfully built four platforms, including the self-developed YBODY®, Check-BODY and Nano-YBODY™ platform, and the UVAX® platform developed in collaboration with WIV. These platforms serve as an engine for our continuous endeavor to deliver new drug candidates, including potential drug candidates we may develop in the future utilizing the molecular structures and CMC processes of the platforms.

YBODY® Platform

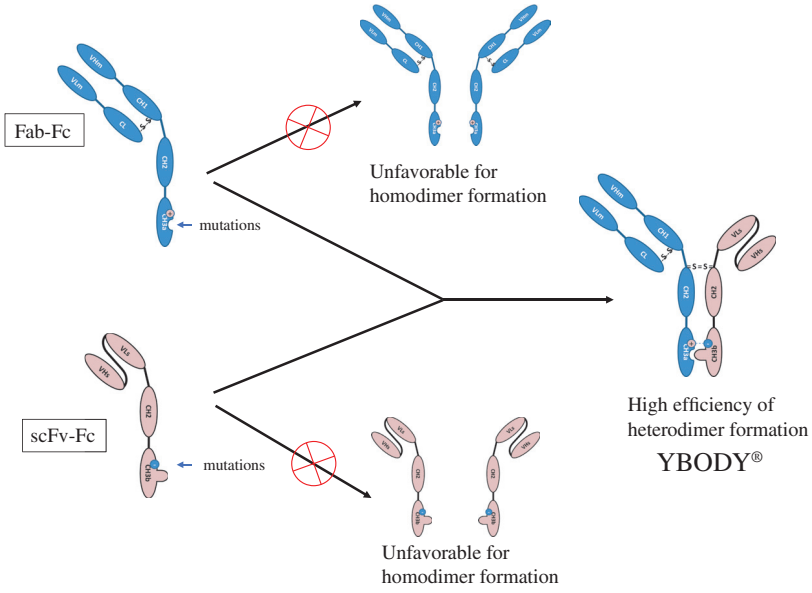
YBODY® platform is our first in-house developed asymmetrical BsAb platform. YBODY® platform is an innovative BsAb platform that focuses on the development of asymmetric human IgG-like BsAbs with scFv-Fab-Fc structure. We have discovered and developed M701, M802 and Y150 based on the technologies of the YBODY® platform. By binding both tumor-associated antigens (TAAs) and human immune cells, molecules being developed leveraging YBODY® platform can recognize, inhibit and kill tumor cells. They can also stimulate human immune system, increase cytotoxicity towards tumor cells, and inhibit tumor relapse and dissemination.

A YBODY® molecule is composed of three polypeptide chains, a heavy chain, a light chain, and a single chain, to form three segments, as illustrated in the diagram below. The first moiety is a Fab fragment that targets antigen A, such as TAAs. The second moiety is a scFv fragment that targets antigen B, such as immune-associated antigen. The third moiety is a Fc region with or without modification to retain or eliminate the binding to FcγRs.



Source: Company data

As illustrated by the diagram below, with respect to the anti-TAA Fab-Fc and anti-CD3 scFv-Fc, we utilize the KIH and salt-bridge technologies in the Fc mutations to disfavor the formation of homodimers and achieve the desired heterodimeric BsAbs. The proprietary design of the scFv is also applied to avoid mispairing of the heavy chains and the light chains. Furthermore, we can easily identify the misassembled impurities of BsAbs through the asymmetry of the molecular weight and thus remove the impurities through the asymmetry of the molecular charge. The integration of these technologies ensures the favorable formation of the desired heterodimeric BsAbs in CHO cells and downstream purification of the desired YBODY® products by conventional chromatography.

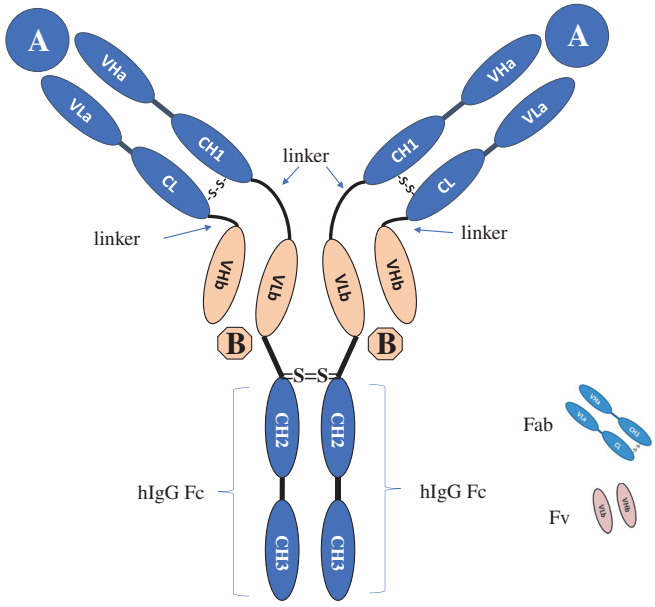


Source: Company data

The well-designed structure of the asymmetrical BsAbs that leverages the YBODY® platform features moderate affinity to human immune cells, which reduces the toxicity of cytokine release syndrome caused by the activation of T cells. The misassembled impurities can be easily identified through the asymmetry of the molecular weight of the BsAbs and removed through the asymmetry of the molecular charge, which improves the efficiency of the desired dimerization and formation of YBODY® molecules. Based on the high performance of our well-developed CMC platform, we are able to develop BsAbs with consistent high quality in multiple batches and easily scale up the manufacturing of YBODY® molecules. The stability and expression level of our YBODY® molecules are close to those of common mAbs. Our YBODY® molecules were found to remain stable for over three years in the stability assessment, which is comparable to the marketed anti-CD3 BsAbs around the world.

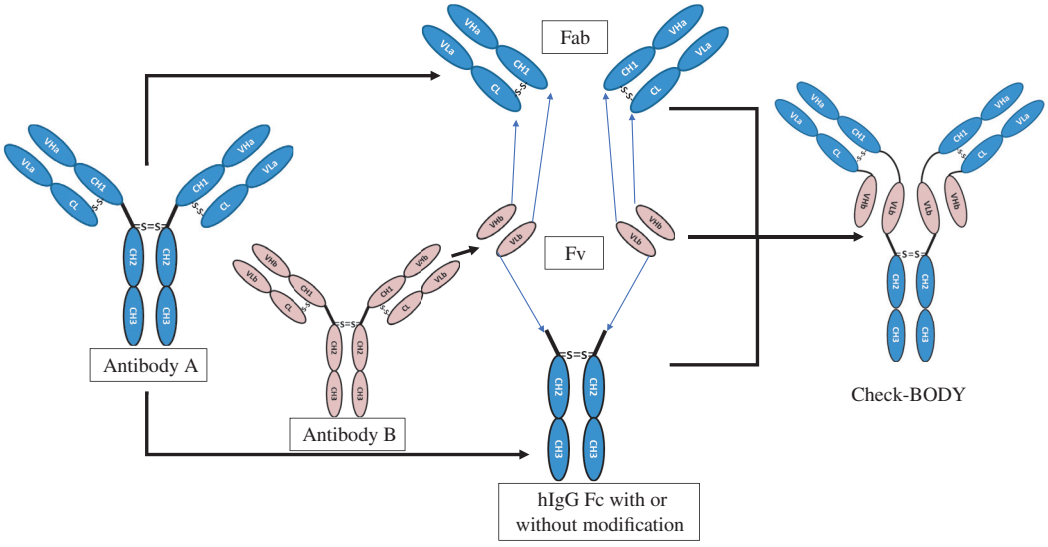
Check-BODY Platform

Our in-house developed Check-BODY platform is designed for the development of symmetric tetravalent BsAbs. We have discovered and developed Y101D based on the technologies of the Check-BODY platform. A Check-BODY molecule is composed of three segments, as illustrated in the diagram below: (i) two Fab fragments from antibody A to target antigen A, (ii) two variable fragments (Fv) from antibody B to target antigen B, and (iii) Fc fragments from human IgG with modification or not.



Source: Company data

We apply the genetic engineering technology to use protein linkers to connect the Fab fragments with Fv fragments and the Fc fragments, respectively, and therefore achieve the ultimate symmetric tetravalent BsAb products, the Check-BODY molecules.

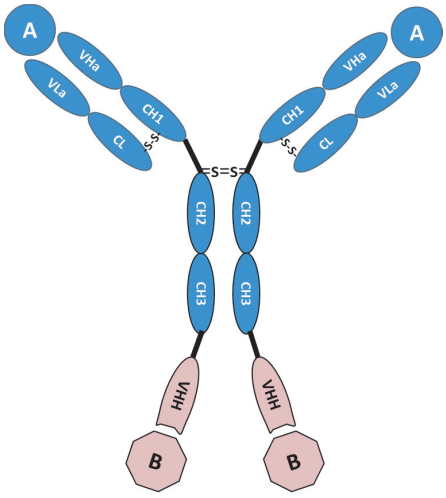


Source: Company data

Both Fab and Fv moieties of a Check-BODY molecule show high affinity to the respective targets. Due to the symmetric structure of these molecules, the purification process of Check-BODY molecules is similar to that of IgG-like mAbs and therefore is easier to achieve. We are able to develop Check-BODY molecules with consistent high quality in multiple batches. The average expression level for Check-BODY molecules is nearly 6.0g/L in the Fed-Batch mode with the yield rate higher than 50%.

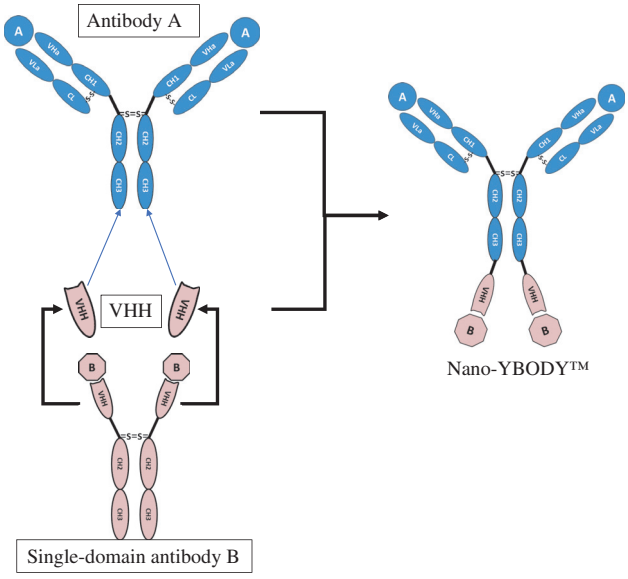
Nano-YBODY™ Platform

Our in-house developed Nano-YBODY™ platform is designed for the development of symmetric tetravalent BsAbs. We have discovered Y400 and Y332 based on the technologies of the Nano-YBODY™ platform. A Nano-YBODY™ molecule is composed of the following, as illustrated in the diagram below: (i) a typical IgG antibody with two Fab moieties, and (ii) the two variable domains of a heavy chain (VHH) of a single-domain antibody (sdAb).



Source: Company data

We apply the genetic engineering technology to use protein linkers to connect each of the two heavy chains of an IgG antibody with each of the two VHH fragments from an sdAb, as illustrated below.

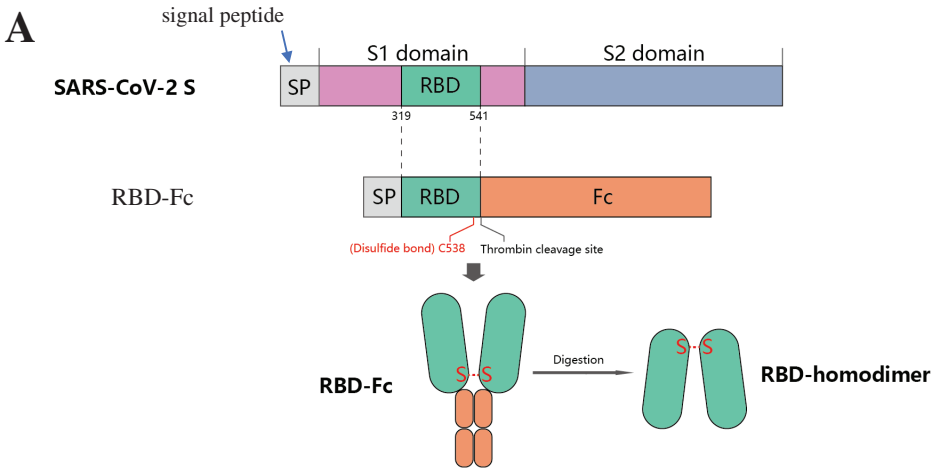


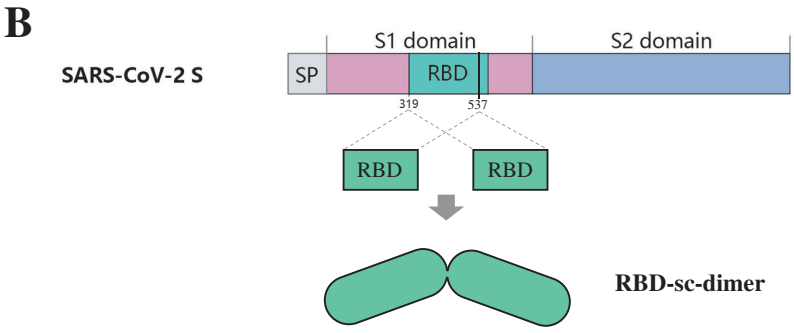
Source: Company data

Both the Fab and the VHH moieties of a Nano-YBODY™ molecule show high affinity to the respective targets. The Nano-YBODY™ molecules have demonstrated a superior performance in expression level, purification yield, solubility, and stability. The average expression level for Nano-YBODY™ molecules is greater than 8.0g/L with recovery rate over 70%. We have developed Nano-YBODY™-based molecules at a superiorly high concentration up to 140 mg/mL for intravitreal injection with the product purity of approximately 99%.

UVAX® Platform

Our UVAX® platform, developed in collaboration with WIV, is a unique immunogen preparation platform for the development of recombinant protein vaccines, which is designed leveraging our proprietary BsAb engineering technologies. We utilize our UVAX® platform to form subunit dimers of coronavirus efficiently and produce immunogens of the vaccine through reliable, safe and high-yield CHO expression and antibody-like purification systems. The platform enables us to make significant progress in the development of coronavirus vaccine Y2019. Y2019 is a homodimerized protein, of which two RBD monomers are linked covalently by an interdomain disulfide bond at the C terminus of the RBD of the S protein. According to the design, the SARS-CoV-2 RBD gene (319–541 amino acid) is fused with the Fc gene of human IgG, and the DNA of the genes are constructed into the vector to express the RBD-Fc fusion protein. The Fc fragment of the fusion protein is then removed by thrombin digestion and purification to obtain the RBD homodimer protein as the immunogen of the vaccine. The structure of our RBD-homodimer is illustrated in the diagram below (A), and it is similar to the marketed vaccine ZF2001 (Zhifei Longcom) of which structure is RBD-sc-dimer (B):





Source: A, Company data and published in "Pan et al. Cell Discovery (2021) 7:82";
B, the reference "Dai et al., 2020, Cell 182, 722–733"

Our RBD-homodimer is produced in an industry-standard CHO cell system. We have two 200L production lines and are able to produce about 40 million doses at 50μg per dose annually. The production of our RBD-homodimer can be rapidly scaled up. Moreover, based on our UVAX® platform, the vaccines to the VOCs for SARS-CoV-2 can be rapidly prepared within three months.

Clinical Development

Clinical Development Team

Our clinical development team is led by Dr. Huang Shaoyi. Dr. Huang Shaoyi has relevant working experience of almost ten years in clinical research and product development. He obtained a bachelor's degree in biotechnology and a master's degree in microbiology from Wuhan University, and a doctorate in cancer biology from the University of Texas Health Science Center at Houston and the University of Texas M.D. Anderson Cancer Center in the United States. For more details about Dr. Huang's background and credentials, please refer to the paragraphs headed "Directors, Supervisors and Senior Management – Senior Management" in this document. As of the Latest Practicable Date, our clinical development team consisted of 18 members.

The clinical development team is mainly responsible for clinical trial design, document preparation, trial operations (including subject enrollment), clinical data monitoring, project management, data analysis and safety management.

Clinical Trial Design and Implementation

As of the Latest Practicable Date, seven of our drugs have entered into clinical development stage. Our clinical trial design is mainly based on the characteristics of our drug candidates and the market demand, including the MOA and applicable targets of our drug candidates, the current clinical treatment status of targets and the selection of appropriate indications. We also consider the opinions of researchers and CROs engaged in the clinical trials. We take into account the target cancers of our clinical trials and select the most suitable

research centers and patients to be engaged to accelerate our clinical trials as much as possible. We also maintain a good safety and efficacy profile of our drug candidates to ensure the willingness and efficiency of the subject enrollment.

All of the clinical trial designs need to be approved by the head of the clinical development team, the head of our quality center and Dr. Zhou Pengfei, our chief executive officer. Both a hard copy and an electronic version of the relevant documents are required for record. We have executed an adaptive clinical development strategy. A practical design of clinical trials, including with respect to the number of subjects to be enrolled for our clinical trials, is important to our clinical trial implementation. The number of subjects to be enrolled for our clinical trials is determined based on the anticipated trial designs, as well as various factors influencing these designs.

The following table sets forth the methodologies for determining the number of subjects to be enrolled for different types of our clinical trials.

Our clinical trials	Methodologies applied
Single-arm Phase I/Phase Ib trials (Phase Ib portions of Phase Ib/II trials and a Phase I portion of a Phase I/II trial) of (a) M701 for MPE and solid tumor, (b) Y101D for metastatic or locally advanced solid tumors, advanced/metastatic pancreatic cancer (in combination with gemcitabine and albumin paclitaxel), HCC and other advanced solid tumors (in combination with bevacizumab), and SCLC (in combination with chemotherapy), (c) Y150 for rrMM in monotherapy and in combination with lenalidomide, and (d) Y332 for solid tumors in monotherapy and in combination therapy.	The number of subjects to be enrolled for these trials depends on: (a) the number of cohorts in the dose-escalation stage of these trials, influenced by the initial dose, expected MTD, and dose escalation gradient between cohorts, (b) the likelihood of encountering a DLT in any cohort which typically causes the enrollment of additional subjects to that cohort in the dose-escalation stage, and (c) the number of subjects for the cohort-expansion stage, dictated by the depth of insight we aim to acquire regarding the safety and preliminary efficacy of a drug candidate before proceeding to Phase II.
Controlled Phase II trial of M701 for MA and controlled Phase II portion of Phase Ib/II trial of M701 for MPE.	These trials comprise a control arm and a treatment arm each enrolling equal number of subjects, with the CDE recommending a minimum of 30 subjects to be enrolled in each arm to prevent statistical bias.

Our clinical trials	Methodologies applied
Single-arm Phase II trials (Phase II portion of Phase I/II trial or Phase II portions of Phase Ib/II trials) of (a) M701 for solid tumor, (b) Y101D for advanced/metastatic pancreatic cancer (in combination with gemcitabine and albumin paclitaxel), HCC and other advanced solid tumors (in combination with bevacizumab), and SCLC (in combination with chemotherapy), (c) Y150 for rrMM in combination with lenalidomide, and (d) Y332 for solid tumors in combination therapy.	The number of subjects to be enrolled for these trials depends on our plan to study the efficacy of our drug candidates in different tumor subtypes or different tumor cell gene expression subtypes within the same tumor indication. We typically recruit 25-30 subjects for each subtype we plan to study in these trials to minimize statistical bias. We plan to conduct subtype studies in (a) a Phase II portion of Phase I/II trial of M701 for solid tumor, (b) a Phase II portion of Phase Ib/II trial of Y101D for SCLC (in combination with chemotherapy), and (c) a Phase II portion of Phase Ib/II trial of Y150 for rrMM in combination with lenalidomide. For the Phase II trials that do not involve subtype studies, we plan to enroll 30-50 subjects each to avert statistical bias.
Controlled Phase III trials of (a) M701 for MA and MPE, and (b) Y101D for advanced/metastatic pancreatic cancer (in combination with gemcitabine and albumin paclitaxel), and HCC and other advanced solid tumors (in combination with bevacizumab).	The estimated number of subjects to be enrolled for these trials is determined according to the statistical requirement to validate the superiority of the drug candidates in the treatment arm relative to the control arm. Statistically, the less significant the superiority of the treatment arm is compared to control arm, the greater influence random disturbances would have on this subtle advantage, and the more subjects should be enrolled to mitigate the impact of the random disturbances and to achieve statistical significance results. The requirement of CDE to enroll at least 300 subjects receiving the RP2D dose across all clinical trial phases and indications to evaluate the safety profile of a drug candidate is also considered in determining the estimated number of subjects to be enrolled for these trials.

Our clinical trials	Methodologies applied
Single-arm Phase II/III trial of Y150 for rrMM.	For rare indications lacking effective therapies such as rrMM, the CDE does not require a minimum of 300 subjects to receive the RP2D dose before approving a drug candidate. Therefore, we plan to enroll around 200 subjects in our Phase II/III trial of Y150 for the treatment of rrMM to expedite the trial process.

We abide by the requirements of the NMPA/CDE in determining the number of subjects to be enrolled for our planned clinical trials, specifically:

(a) The NMPA/CDE does not specify a minimum number of subjects to be enrolled in Phase I trials, Phase Ib/II trials, Phase I/II trials, or Phase II trials.

(b) The CDE typically requires a total of no less than 300 subjects receiving the RP2D dose across all clinical trial phases and indications of a cancer drug candidate for safety evaluation before approval for marketing. We plan to enroll more subjects for our four controlled Phase III clinical trials than this minimum requirement, with an aim to meeting statistical demands to validate the superiority of the drug candidates compared to control treatment.

(c) For rare indications lacking effective therapies, such as rrMM, the CDE does not require a minimum of 300 subjects to receive the RP2D dose before approving a drug candidate. We plan to enroll around 200 subjects in the Phase II/III trial of Y150 for the treatment of rrMM to expedite the trial process, which is in line with CDE requirements.

The expected number of subjects to be enrolled for each type of our clinical trials is in line with that of similar drug candidates in similar clinical stages developed by the industry peers in China.

Collaboration with CROs, SMOs, CMOs/CDMOs, and Other Third Parties

In line with the practice in the pharmaceutical industry, we engage CROs, SMOs, CMOs/CDMOs and third-party research centers (i.e., hospitals and laboratory centers) to conduct and support our preclinical studies and clinical trials. We closely supervise the activities of these third party collaborators. We have selected these institutions by weighing various factors, such as their qualifications, expertise, experience, reputation, and costs.

The following table sets forth the number of CROs, SMOs, CMOs/CDMOs, hospitals and laboratory centers we engaged during the Track Record Period:

	For the Years Ended December 31,		For the Five Months Ended May 31,
	2021	2022	2023
CRO	28	27	16
SMO	12	22	19
CMO/CDMO	3	1	2
Hospital	33	37	57
Laboratory Center	7	13	14

The following table sets forth the background of our key CROs, SMOs, CMOs/CDMOs, hospitals and laboratory centers engaged by us, as well as their involvement and contributions in the research and development and clinical trials:

	Background	Involvement
CRO 1	A China-based non-clinical CRO primarily engaging in drug safety assessment	Provision of preclinical safety assessment and detection work of clinical samples
CRO 2	A China-based pharmaceutical company primarily engaging in R&D of new drug and technology	Provision of pre-clinical and clinical CRO work, including but not limited to clinical operation, medical supervision, statistics and drug alert services
SMO 1	A China-based biotechnology company primarily engaging in providing technology development, transfer and consulting services in pharmaceutical industry	Provision of SMO work, including but not limited to project approval, start-up, screening and coordination services for clinical trials in certain laboratory centers

	Background	Involvement
SMO 2	A China-based biotechnology company primarily engaging in providing technology development, transfer and consulting services in medical and clinical medical technology industry	Provision of SMO work, including but not limited to project approval, start-up, screening and coordination services for clinical trials in certain laboratory centers
CDMO	A China-based biomedical company primarily engaging in providing one-stop services for biomacromolecules drugs	Provision of production of clinical samples
CMO	A China-based biotechnology company primarily engaging in pharmaceutical production, pharmaceutical commissioned production and medical device production	Provision of formulation production of clinical samples
Hospital	A China-based Class III-A hospital integrating clinical, scientific research, teaching and training functions	Provision of clinical research
Laboratory Center	A China-based drug research company primarily engaging in providing technical testing and medical technology promotion services	Provision of detection work for clinical samples

In the process of product development, we are responsible for the molecular design and selection of all the drug candidates and engage CROs to complete the animal immunization and antibody discovery for some pipeline as well as the preclinical safety and pharmacokinetics assessment for all the pipeline. We also engage CMOs/CDMOs to complete the production and supply of clinical samples and some testing work when our production capacity and testing capacity are over-loaded or some non-crucial testing project capabilities have not been built. In terms of clinical research, we are responsible for the clinical research protocols and strategies as well as the supervision of clinical implementation quality, and CROs, SMOs, hospitals and laboratory centers are responsible for the clinical operation related work. We engage the CROs, SMOs, CMOs/CDMOs, hospitals and laboratory centers on a project-by-project basis. We have taken several initiatives to make sure that these institutions perform their duties to a standard in compliance with applicable laws and regulations, as well as in line with our quality control procedures, protocols and industry benchmark to safeguard the

integrity of the data collected from the trials and studies. We will inspect their qualifications in advance to ensure that they have the corresponding capabilities for the trials or studies. For those institutions engaging in clinical trials, we provide them with the final clinical trial protocols and a series of trainings to ensure their familiarity with the trials. They conduct the clinical trials based on our protocols, and we designate internal personnel to supervise the implementation phase. We also engage an external independent third-party company to regularly monitor our clinical trials, which is required to timely identify and supervise rectification of any non-compliance in the implementation.

The service fees we paid to our CROs, SMOs, CMOs/CDMOs, hospitals and laboratory centers during the Track Record Period were primarily based on market prevailing standards and determined through arm's length negotiations with reference to the service scope, clinical trial type as well as the number of subjects enrolled at such site, among others.

Below is a summary of the key terms of an agreement we typically enter into with our CROs, SMOs, CMOs/CDMOs, hospitals and laboratory centers:

- *Services*. Our cooperating partner provides the high-quality research and development and technical services to us, including but not limited to the implementation and management of a preclinical or clinical research project, pre-clinical safety evaluation and PK/PD research, as specified in the agreement.

- *Term*. Our cooperating partner is required to perform its services and complete the preclinical or clinical research project within the prescribed time limit set out in each agreement, or until the cooperation agreement is terminated by both parties after negotiation.

- *Payments*. We are required to make payments to our cooperating partner in accordance with the payment schedule agreed by the parties.

- *Intellectual property rights*. We own all intellectual property rights arising from the preclinical or clinical research project.

- *Confidentiality*. Our cooperating partner is obligated to keep confidential all the data, information or contents we distributed to our cooperating partner related to the project specified in the agreement, and such obligation may survive the termination of the cooperation agreement.

- *Risk allocation*. The risk allocation between the parties and indemnification are subject to further negotiation between the parties.

Chemistry, Manufacturing, and Controls (CMC)

CMC Team

Our CMC team provides support throughout the drug development process. The team is mainly responsible for upstream and downstream process development, formulation development, analytical development, process characterization and validation, pilot manufacturing, quality study, product analysis, quality control (QC) and quality assurance (QA).

Our manufacturing center was led by Dr. Yang Bin, the vice president of the manufacturing center. Dr. Yang has over ten years of experience in CMC processes management and drug development. He obtained a bachelor's degree in pharmacy from Wuhan University, a master' degree in microbiology and biochemical pharmacy from Shenyang Pharmaceutical University, and a doctorate in biology (biomedicine) from Jinan University. For more details about Dr. Yang's background and credentials, please refer to the paragraphs headed "Directors, Supervisors and Senior Management – Senior Management" in this document. As of the Latest Practicable Date, our manufacturing center consisted of 28 members.

We also have a registration management team mainly responsible for the management of R&D projects, registration filings, applications for governmental research projects, as well as management of intellectual properties. Our registration management team is led by Mr. Li Si. Mr. Li has over 15 years of experience in R&D project management and registration filings. He obtained a bachelor's degree in veterinary medicine from Huazhong Agricultural University. As of the Latest Practicable Date, our registration management team consisted of seven members.

CMC Activities and Capabilities

CMC refers to activities to properly define methods for manufacturing processes, product characteristics and testing, product storage and release to clinical usage in order to ensure that a pharmaceutical product is safe, effective and consistent between batches. Because of the complexity of therapeutic antibody, CMC is essential for antibody drug development from cell line development to cell culture process development to purification and formulation.

Although the discovery and protein engineering techniques of BsAbs are now relatively advanced, the development of BsAbs still faces many challenges in CMC comparing to the development of typical mAb drugs, including low expression titer of the target BsAbs, more impurities to remove, less stability of the intermediates, and hurdles in process scale-up.

Therefore, in addition to the specific efforts made with molecular design, the execution of an appropriate CMC development strategy is vital to the success of the overall drug development program. Our CMC strategies include evaluating the stability of the candidate BsAb molecules at the early development stage, choosing the monoclonal cells with high titer and high purity for BsAb production, tailoring purification methods fit for the molecule characteristics, and using sustainable scale-up strategies for large-scale production.

We have extensive experience in the CMC process for the development of different BsAbs in various structures and have established CMC capabilities.

Process development

The process development for BsAbs can be generally divided into the upstream and downstream process development. The upstream process development, including, among others, cell line development and clone selection, media optimization, development of process strategies, and optimization of bioreactor systems, focus on generating products with a high product titer, high productivity and high quality. Meanwhile, the downstream process development focus on the production yield, process capacities and productivity, and product purity as well, using different chromatographic and non-chromatographic technologies to improve the efficiency of purification.

Built on our platform technologies, our process development capability ensures the delivery of stable and high-quality BsAbs for our pre-clinical studies and clinical trials:

- *Cell line development*. Leveraging the world's leading CHO GS-KO expression system, our CMC team is able to design and produce various types of BsAbs with different structures to obtain stable cell lines at high expression level for pre-clinical studies and clinical trials.

- *Upstream process development*. Our CMC team ensures stable and high quality products in the scale-up production. To improve the titers of target BsAbs, we optimize the manufacturing process by adopting the Fed-Batch mode to maintain a semi-continuous and semi-open cultivation system in the reactors where the nutrients are supplied aseptically. After the optimization, the average expression level for Check-BODY antibodies is nearly 6.0g/L and the average expression level for Nano-YBODY™ antibodies can reach approximately 8.0g/L, far beyond the industry average in China.

- *Downstream development*. Our CMC team improves the purity of BsAbs and assures safety. The total yield of BsAbs in our purification process can reach 75%, and the purity of the drug substance can reach 99% with low levels of impurities.

Formulations development

Our drug formulation development team supports the development of drug product formulations and processes. Our capabilities include the development of liquid and lyophilized dosage forms. We have successfully manufactured three types of BsAb formulations for intravenous injection, intraperitoneal injection, and intravitreal injection, respectively. Through the formulation screening and optimization, the concentration of our BsAb formulations can reach 140mg/ml, with low product viscosity and great stability, exceeding the industry average in China.

Analytical development

We have developed more than 30 platform analytical methods to support our drug development. The analytical methods based on the requirements under the Chinese and U.S. Pharmacopoeias include, among others, physicochemical analysis, analysis of protein content, purity and impurity, and safety assessment. The analytical methods developed based on the liquid chromatography–mass spectrometry technology include, among others, the analysis of molecular weight, glycosylation, disulfide bonds, and peptide mapping. These analytical methods are used to analyze molecular properties and characterize molecular structures at the early stages of drug development, expediting sample testing and improving our development efficiency. At the CMC stage, we optimize the analytical methods to accommodate projects involving different BsAbs. Combined with our other developed specific analytical methods, such as charge variants analysis, isoelectric point, binding activity and biological activity, we are able to efficiently support and accelerate our product development from drug discovery to process development and manufacturing process.

GMP-compliant manufacturing

With the efforts of our quality center, we have established a GMP-compliant quality system and strictly implemented the requirements under the GMP, Chinese and U.S. Pharmacopoeias and other relevant regulations and guidelines in our product manufacturing process. As a result, we obtained the approvals by both the NMPA and FDA to conduct the clinical trials for our drug candidates M701, M802, Y150 and Y101D.

Manufacturing Facility and Collaboration with CMOs/CDMOs

As of the Latest Practicable Date, we maintained a manufacturing base of approximately 1,400 square meters with a scale of 500L (two 200L bioreactors and two 50L bioreactors) and a maximum annual production of 20-24 batches with single bioreactor to accommodate the manufacturing demands for our pre-clinical studies and earlier phases of clinical trials prior to the pivotal clinical trials for a majority of our drug candidates, including M701, Y150, Y332, and our preclinical candidates. In 2021 and 2022, the utilization rate of our manufacturing base in terms of number of days in use was approximately 69.9% and 84.4%, respectively. Unlike commercial production lines that schedule production based on continuous orders, our

production plans are mainly determined by the periodic requirements of our clinical and pre-clinical pipelines. Due to the intermittent nature of production demand for pre-clinical studies and clinical trials, our manufacturing capacity may not be fully utilized throughout each point of the year.

Besides manufacturing conducted at our own facilities, we currently also engage third-party CMOs/CDMOs for (i) the production for pivotal clinical trials of M701, (ii) the manufacturing for pre-clinical studies and clinical trials of Y101D, which require larger production volumes. We are responsible for the development of manufacturing process of our drug candidates, and CMOs/CDMOs are responsible for the manufacturing. We selected our CMOs/CDMOs by carefully reviewing and considering various factors, including their manufacturing capacity, qualifications, geographic proximity, expertise, reputation, and costs. We have adopted procedures to ensure that the team qualifications, facilities and processes of CMOs/CDMOs comply with the relevant regulatory requirements and our internal quality management system.

We expect to engage third-party CMOs/CDMOs to manufacture certain of our products after they are commercialized. M701 and Y101D, the drug candidates that we expect to be firstly commercialized, will be initially manufactured by CDMOs upon marketing approval and later transferred to our own expanded manufacturing facility upon approval by competent regulatory authorities. We currently expect that the annual production capacity of M701 after commercialization would be around one million formulations.

While our current manufacturing capacity, in conjunction with our current plan of manufacturing outsourcing to CMOs/CDMOs, can meet the manufacturing needs for clinical trials and commercial launch of our drug candidates, we plan to further enhance our CMC and manufacturing capabilities through new machinery, instrument and equipment to improve the efficiency of our production and the quality of our products. This includes: (a) acquiring perfusion systems, fully automatic ultrafiltration systems, small-scale bioreactors, and other equipment to improve antibody expression per unit time and volume of our production line, thereby increasing the efficiency of formulation development sample preparation, (b) procuring automated filling equipment to improve filling efficiency, (c) procuring biomolecular mass spectrometers, high-performance liquid chromatography, capillary electrophoresis, and other analytical quality control equipment to conduct more comprehensive and in-depth characterization of product quality attributes, thereby streamlining product quality control process, and (d) upgrading the corresponding water systems, cold storages to optimize the compatibility of the water system with our current production site.

Manufacturing Process

Our manufacturing process has three stages, namely, the cell culture stage, purification stage and drug product manufacturing stage, as set out below.

Cell culture

The cell culture stage is divided into cell recovery, cell expansion and cell cultivation, which generally takes 25 to 32 days.

- *Cell recovery*. Resuscitation of cells that are cryopreserved in liquid nitrogen.

- *Cell expansion*. We thaw the cells and transfer the seed cell culture from shaker flasks to larger vessels till bioreactors to reach the number of viable cells needed for production.

- *Cell cultivation*. We cultivate the cells to produce the target protein.

Purification

The purification stage is generally divided into four steps which takes seven to ten days.

- *Depth filtration*. The cell culture is further processed by removing cells and cell debris through depth filtration and filtration. Depth filtration primarily removes cells from the culture solution, and filtration primarily removes smaller cell debris and controls bioburden during the harvest.

- *Multi-step chromatography and viral inactivation*. Impurities are removed through multi-step chromatography. Leveraging our protein engineering expertise and platforms, our BsAb candidates are stable during the purification process, so the general chromatographic steps for our BsAb candidates are similar to conventional mAbs. Viruses are inactivated by altering the pH, temperature, and other conditions.

- *Nanofiltration and ultrafiltration*. Viruses of all sizes are filtered and removed by passing through nanometer-sized pores on a nanofiltration membrane. For products requiring relatively highly concentrated antibody solutions, ultrafiltration is used after nanofiltration to reach the final desired product concentration. Most of our product candidates require ultrafiltration.

- *Bul*k. Drug substances after ultrafiltration are filled into drug substances container for final product manufacturing.

Drug product manufacturing

The drug product manufacturing stage is generally divided into two steps.

- *Preparation*. Drugs are produced using predetermined formulations. Some formulations may require adding buffer solutions.

- *Fill and finish*. The final product will undergo aseptic filtration, filling, stoppering, capping, inspection, labelling and packaging.

Quality Management

QC and QA are crucial to us. We are committed to ensuring the quality of our products through a comprehensive quality management system in accordance with the regulations of NMPA, FDA, ICH Q8 and other applicable regulations, including GMP and the standards of the Chinese and American Pharmacopoeia. The regulations cover all aspects of our operations, including process development, procurement, product manufacturing, and product storage and transportation.

Our quality management function was led by Dr. Yi Jizu, the senior vice president of the quality center. Dr. Yi has over 25 years of relevant experience in the biopharmaceutical industry. Before he joined our Group, Dr. Yi served as a chief scientist at Becton, Dickinson and Company, one of the largest global medical technology companies in the world, for over ten years. Dr. Yi obtained a bachelor's degree in analytical chemistry and a master's degree in physical chemistry from Central South University in China, and obtained a doctorate in biochemistry from Rutgers the State University in the United States. For more details about Dr. Yi's background and credentials, please refer to the paragraphs headed "Directors, Supervisors and Senior Management – Supervisors" in this document. As of the Latest Practicable Date, our quality center consisted of 29 members.

We have established QC and QA procedures for monitoring operations to ensure that they meet relevant regulatory and internal quality requirements. We implement QC measures for the entire production process, mainly including control and inspection of raw materials, control of production process, inspection of intermediate and products, establishment of internationalized product release standards, research on product stability, management of deviations, changes and risks evaluation during product development and manufacturing.

Quality Control: Our QC team is mainly responsible for quality inspection of GMP-compliant manufacturing, analytical method validation, product quality standard establishment, product release testing, and stability assessment. Our QC team also inspects raw materials, intermediate products, raw liquids, finished products, and decides whether to release such materials for manufacturing.

Quality Assurance: Our QA team is mainly responsible for managing experimental documents, overseeing manufacturing site and final products for clinical usage, compliance assessment, and the inspection and audit of our outsourced vendors. We implement strict procedures for the receiving and releasing of the raw materials used in the production, intermediate products, raw liquids and buffers, and finished products.

We have established a series of internal procedures and protocols including standard operating procedures for quality management of manufacturing process, product release and stability study. We also have standard operating procedures in place to ensure that the finished production meets the process requirements by relevant regulatory authorities. Such procedures ensure the high quality of our products used for clinical trials.

COMMERCIALIZATION

We plan to recruit capable marketing professionals and develop our capabilities of commercialization. As our current pipeline of drug candidates comes to the market, we will build an in-house commercialization team with medical and scientific background to maximize the reach of our product offering and expedite market acceptance of our products in China. We plan to seek collaboration and out-licensing opportunities to promote our drug candidates and brand in the overseas markets.

Our in-house commercialization team will initially focus on the marketing and sales of M701 once it is approved for commercialization. We plan to contract a 300-person contract sales organization (CSO) team in China with experience in selling oncology drugs and establish an in-house sales team of approximately 20 employees to meet the sales demands for M701 upon its commercialisation. We also plan to further scale up our sales team in line with increasing sales demand of M701 in the future. We plan to initiate negotiations for CSO engagement in the first half of 2024 and enter into a partnership agreement with CSO within that year. Prior to the commercial launch of M701, the CSO and our sales team will carry out pre-launch academic promotion, market access, key opinion leader maintenance, and other preparatory work, ensuring that M701 can swiftly enter the market and achieve sales upon its commercial launch. We will consider seeking inclusion of M701 into the National Reimbursement Drug List (NRDL) and other reimbursement programs to rapidly penetrate the market for the treatment of MA or MPE in China. M701 has been selected for the "National Major New Drug Innovation" program under the 12th Five-Year Plan, which we believe could be an advantage for its future inclusion into the NRDL. Leveraging the expertise and industry connections of our commercialization team, we plan to market M701 through a physician-targeted marketing strategy, focusing on direct and interactive communication with key opinion leaders and physicians to promote the clinical use of M701. We intend to identify a number of hospitals, clinics and physicians that specialize in in the treatment of MA or MPE, and to visit the sites and physicians in person for pre-launch training and contact.

We also plan to cooperate with established CSOs to promote other drug candidates, especially those facing fierce market competition from approved and late clinical-stage drug candidates that focus on similar indications and subpopulations. Moreover, we believe academic-oriented marketing efforts will be beneficial for improving alignment of expert opinions on, and promoting clinical use of, our drug candidates after they become available for sale. We have actively participated in and will continue to attend and organize academic conferences and seminars to publicize the clinical data and research results in relation to our drug candidates in order to raise our brand awareness and recognition. We also consider supporting leading experts to report the results of their research at international and domestic conventions, symposia and other notable events to promote our brand at the foreground of the industry.

COLLABORATION AGREEMENTS

We actively seek to form strategic collaborations with resourceful partners to support the development and maximize the commercial value of our drug candidates. These collaborations allow us to utilize clinical, financial, and commercial resources of our partners, and provide us with opportunities to explore innovative modalities and therapies that employ new mechanisms through cooperation with other innovative drug developers.

Collaboration with CMS Vision

On July 26, 2022 (the "Effective Date"), we entered into an asset transfer agreement (the "CMS Agreement") with Shenzhen Kangzhe Vision Pharmaceutical Development Co., Ltd. (深圳市康哲維盛醫藥發展有限責任公司) (formerly known as Kangzhe Pharmaceutical Research and Development (Shenzhen) Limited (深圳康哲醫藥發展有限公司)) ("CMS Vision"), a wholly-owned subsidiary of China Medical System Holdings Limited (0867.HK) (together with its subsidiaries, the "CMS Group"), to transfer all the rights and assets relating to Y400 to CMS Vision. CMS Group is a platform company linking pharmaceutical innovation and commercialization with strong product lifecycle management capability, which has been deeply engaged in several therapeutic fields, including cardio-cerebrovascular, gastrointestinal, central nervous system, dermatology and medical aesthetics, ophthalmology and pediatrics etc.

Governance

The parties shall establish a joint steering committee ("JSC") with an equal number of representatives from each party. All decisions of the JSC shall be made by unanimous vote with each party's representatives collectively having one vote. In case of any disagreement that cannot be resolved by negotiations, CMS Vision shall have the final decision-making authority over all matters relating to the development, manufacturing and commercialization of Y400 in the Territory (as defined below).

Detailed Arrangement of Asset Transfer

Pursuant to the CMS Agreement, we agree to, subject to certain special arrangement with respect to United States, Europe and Japan (the "Special Arrangement"), transfer all the rights and assets relating to Y400 for any indication worldwide (the "Territory") to CMS Vision, including but not limited to: (i) all the rights, proprietary technologies, regulatory approvals and assets (tangible and intangible) that are necessary to use, develop, register, make, have made, sell, distribute, promote and commercialize Y400; (ii) all the intellectual property rights (including trademarks, patents, know-how and applications thereof) relating to Y400 (the "Transferred IP Rights"); and (iii) all the cell bank, data, materials, information, filings and records relating to Y400, as well as all the rights obtained or otherwise generated from all the pre-clinical and clinical studies and experiments conducted for the purpose of applying and receiving regulatory approvals and intellectual property rights for Y400, that are currently owned or controlled by, or will be owned or controlled by, us and our affiliates. We also agree to grant a non-exclusive sublicense to CMS Vision with respect to an upstream cell line which we have sublicensed from a third party relating to Y400.

We have agreed to a Special Arrangement with CMS Vision with respect to the rights to Y400 in Europe, the United States, and Japan. Within 24 months upon the receipt of IND approval of Y400 in China (the "Two-year Period"), we and CMS Vision have the joint right to dispose Y400 in these jurisdictions. If we and CMS Vision agree to license, sublicense, transfer or otherwise dispose our rights to Y400 in the United States, Europe or Japan to a third party (the "Disposal Arrangement"), we and CMS Vision will equally share the gains generated from such arrangement. In this case, CMS Vision is no longer responsible to pay the corresponding milestone payments and royalties in the applicable jurisdiction. However, if a Disposal Arrangement has not been agreed and reached in any of the United States, Europe and Japan market within the Two-year Period, then the Special Arrangement will be terminated, and CMS Vision will enjoy the rights to Y400 in the corresponding jurisdiction (s) (i.e., the United States, Europe and/or Japan, as the case may be) as if such rights to Y400 were transferred to CMS Agreement since the execution date of the CMS Agreement, on the condition that they pay the corresponding milestone payments and royalties under the CMS Agreement.

Intellectual Property Arrangements

We shall transfer all the intellectual property rights specifically related to Y400, if any, that arise from the activities related to Y400 under the CMS Agreement to CMS Vision within a reasonable period requested by CMS Vision. Such intellectual property rights, if transferred, shall be treated as the Transferred IP Rights.

CMS Vision, at its own cost, is responsible for the maintenance of the Transferred IP Rights, and we will provide necessary support and assistance.

R&D

We, at our own cost, are responsible for all the pre-clinical studies of Y400 that are necessary for (i) the IND application and (ii) the Phase I clinical trial, if any, in accordance with the standards and requirements set by the CDE. These studies include, but not limited to, pharmacology, PK, toxicology, pharmacy, CMC studies and quality and process studies for active pharmaceutical ingredients and formulations. Furthermore, if requested by CMS Vision, we will also be responsible for, at CMS Vision's cost, non-clinical toxicology studies of Y400 that are necessary in the Phase II and Phase III clinical trials and CMC studies in Phase III clinical trials in China.

CMS Vision, at its own cost, is responsible for filing and obtaining the INDs, and conducting clinical trials of Y400 in the Territory, and we will provide necessary support and assistance.

The IND application for Y400 has been filed with the NMPA in January 2023 and the CDE approved the IND application for Y400. As of May 31, 2023, we incurred costs and expenses of approximately RMB30.1 million for our R&D activities in connection with the CMS Agreement.

Manufacturing

We have two batches of pilot-production products of Y400 and placebos in our inventories. We will deliver the two batches of Y400 and placebos to be used for Phase I and Phase II clinical trials in China to CMS Vision free of charge when the relevant clinical trials start. CMS Vision is entitled to manufacture Y400 for clinical use, use in regulatory approval or in commercial sales by itself or engage us/a CMO. If CMS Vision decides to manufacture Y400 by itself or through a CMO, we will conduct a technology transfer ("Tech Transfer") for all the technologies and know-how relating to the manufacturing of Y400. If CMS Vision decides to engage us to manufacture Y400, parties will negotiate an agreement for the relevant rights and obligations.

Regulatory Filing and Commercialization

CMS Vision, at its own cost, is responsible for (i) filing and obtaining the regulatory approvals and marketing authorizations of Y400 in the Territory, and (ii) commercialization of Y400 in the Territory. CMS Vision will use commercially reasonable efforts to commercialize Y400 in the Territory. We will provide necessary support and assistance.

Payments

We are entitled to receive upfront, milestone and royalty payments under the CMS Agreement. CMS Vision shall pay us an upfront payment of US$5 million, which we have received in full. Furthermore, CMS Vision is obligated to pay us:

(i) development milestone payment:

  (a) in an aggregate amount of US$9 million in the PRC, upon the receipt of the first IND approval in the PRC, the completion and delivery of a clinical study report for a Phase III clinical trial for the first indication and the receipt of the marketing approval for the first proposed indication; and

  (b) assuming the Special Arrangement is terminated, in an aggregate amount of US$16 million in the United States, upon the receipt of the first IND approval in the United States, the completion and delivery of a clinical study report for a Phase III clinical trial for the first indication and the receipt of the marketing approval for the first proposed indication;

(ii) sales milestone payment: subject to the Special Arrangement, up to US$190 million upon the achievement of certain net sales thresholds ranging from US$300 million to US$2 billion of Y400 in the Territory in a given calendar year; and

(iii) royalties at single-digit percentage of the annual net sales of Y400 in the Territory.

Non-compete Covenant

We covenant that we will not conduct any Competing Activity directly or indirectly in the Territory, or provide any funding, technical, or commercial assistance, service or advice for any Competing Activity. For the purpose of CMS Agreement, Competing Activity refers to any research, development, manufacturing and/or commercialization of any drug that targets both VEGF and ANG2 in any indication (excluding Y400), or targets either VEGF or ANG2 in ophthalmology.

Termination and Dispute Resolution

The CMS Agreement will continue to be in full force and effect unless terminated due to customary termination events, including but not limited to material breach of the CMS Agreement. Any dispute relating to the CMS Agreement that is not resolved by good faith negotiation may be resolved by the Shenzhen Court of International Arbitration. As of the Latest Practicable Date, we had no disputes with CMS Vision or CMS Group.

Collaboration with WIV

We entered into an agreement and a supplemental agreement thereof with Wuhan Institute of Virology, Chinese Academy of Sciences (WIV), for our collaboration in the research and development of an RBD protein subunit COVID-19 vaccine, i.e., Y2019, against the

SARS-CoV-2 virus in July 2020 and January 2023, respectively. Founded in 1956, WIV has been dedicated to conducting scientific research on the prevention and control of emerging infectious diseases in China and providing technology support to ensure the national biosafety.

Pursuant to our agreement with WIV, we are responsible for leading the clinical trials of Y2019, and the filing of IND and NDA submissions under the names of both parties. We completed the Phase Ia clinical trial of Y2019 on our own and at our cost.

Upon mutual agreement by the parties, WIV will conduct the antibody activity assay and animal studies during the clinical development of Y2019 and we will provide reimbursements for such activities. In the pre-clinical studies of Y2019, we, by ourselves or through a CRO, conducted the efficacy evaluation in mice (other than the evaluation involving live SARS-CoV-2 virus), the efficacy evaluation in rhesus macaques and the safety evaluation. We also manufactured and supplied the vaccines used for the pre-clinical studies. WIV, at our cost, conducted the efficacy evaluation in mice involving live SARS-CoV-2 virus, the *in vitro* efficacy evaluation in rhesus macaques (other than the evaluation we conducted) and the immunogenicity evaluation involving live SARS-CoV-2 virus in the pre-clinical studies of Y2019. We paid RMB0.7 million and RMB0.5 million to WIV in 2021 and 2022, respectively, for its contribution to the pre-clinical studies of Y2019 during the same year.

Pursuant to our agreement with WIV, we shall be the sole applicant and sole owner of a patent application filed on August 14, 2020 that is specifically related to Y2019. We and WIV shall jointly own other intellectual property rights of Y2019 arising from this collaboration. If parties intend to utilize the research results arising from this collaboration to make any publication, file any patent application, apply for any governmental subsidies, or apply for any research project, the parties shall jointly do so and jointly own the rights arising therefrom. We and WIV shall jointly share the rights and interests related to the research results and achievements of Y2019 arising from our collaboration. If the IND approval, NDA approval and/or jointly-owned intellectual property rights were transferred or licensed to third parties, we and WIV are entitled to 80% and 20% of the revenue derived thereof, respectively. Upon the commercialization of Y2019, WIV is entitled to 4% of annual sales revenue.

Our agreement with WIV shall be effective until terminated upon mutual agreement. If any disputes arise during the performance of the collaboration agreement between us and WIV, they shall be resolved through negotiations and mediation. If the disputes cannot be resolved through negotiations and mediation, any party is entitled to file a lawsuit with the court where the plaintiff resides. As of the Latest Practicable Date, we had no disputes with WIV.

INTELLECTUAL PROPERTY

Our intellectual property is an important component of our business. We rely on a combination of patent and other intellectual property, as well as confidentiality procedures, non-disclosure agreements, employee invention assignment agreements, and other contractual restrictions to establish and protect our commercially important technologies, inventions and know-how related to our business. While we believe our intellectual property rights and applications in the aggregate are important to our competitive position, no single intellectual property right or application is material to our business as a whole.

As of the Latest Practicable Date, we owned (i) 21 issued patents in the PRC, (ii) eight issued patents in the United States, (iii) four issued patents in other jurisdictions, and (iv) 45 patent applications, including 15 pending PRC patent applications, five pending U.S. patent applications, five pending PCT patent applications which have not entered into national phases, and 20 pending applications in other jurisdictions. We believe there is no material legal impediment for us to obtain the approvals for these pending patent applications. As of the Latest Practicable Date, we self-owned all of our material patents as well as patent applications. We owned two PCT applications in relation to M701, including one PCT application that is generally applicable to our YBODY® molecules, including M701 and M802, and one PCT application specifically relating to M701. One PCT application had entered into national phase in major markets, including five granted patents in China, Canada, the U.S. and Japan, and one pending patent applications in China; and the other PCT application was published.

We have extensive patent protection for our key platform technologies and drug candidates. The following table sets forth the portfolio of patents and patent applications for our platform technologies and our clinical-stage drug candidates that are material to our business operations as of the Latest Practicable Date (for each drug candidate and technology platform, all the counterparts in its related patent family are set forth in the following table):

Technology Platform/Drug Candidate	Title of Invention	Scope of Patent Protection	Inventors[4]	Jurisdiction[3]	Patent Application Number	Status	Patent Expiration
YBODY® Platform; M802; M701; Y150	Bispecific Antibody	Structure of YBODY including light-heavy chain pairs targeting tumor cells or microbe, and scFv-Fc targeting immune cells, preparation method, and uses thereof	Zhou Pengfei, Zhang Jing, Yan Yongxiang	PCT	PCT/CN2012/084982	Nationalized[1]	N/A
				China	201280065551.5	Granted	2032.11.21
				China	202010703147.2	Pending	N/A
				United States	14/119,179	Granted	2032.11.21
				Japan	2015543227	Granted	2032.11.21
				United States	14/209,708	Granted	2032.11.21
				Canada	2892059	Granted	2032.11.21
	CD3 antigen binding fragment and application thereof	Invention of humanized antibody targeting CD3 and uses thereof	Zhang Jing, Fang Lijuan, Yan Yongxiang, Zeng Liang, Zhou Pengfei	PCT	PCT/CN2019/075901	Nationalized[1]	N/A
				China	201980050849.0	Granted	2039.02.22
				China	202211447908.8	Pending	N/A
				United States	17/432,892	Granted	N/A
				Europe	19915848.6	Pending	N/A
				Japan	2023-70901	Pending	N/A
				South Korea	10-2021-7030408	Pending	N/A
				Canada	3131036	Pending	N/A

Technology Platform/Drug Candidate	Title of Invention	Scope of Patent Protection	Inventors[4]	Jurisdiction[3]	Patent Application Number	Status	Patent Expiration
Check-BODY Platform; Y101D	Tetravalent symmetric bispecific antibody	Structure of Check-BODY including two identical fused heavy chains and two identical fused light chains, and uses thereof	Zhang Jing, Fang Lijuan, Yan Yongxiang, Zeng Liang, Zhou Pengfei	PCT	PCT/CN2019/095603	Nationalized[1]	N/A
				China	201980050120.3	Granted	2039.07.11
				China	202111190335.0	Pending	N/A
				United States	17/573,559	Pending	N/A
				Canada	3146381	Pending	N/A
				South Korea	10-2022-7004772	Pending	N/A
				Europe	19936731.9	Pending	N/A
				Japan	2022-501314	Pending	N/A
Fc mutation technology; Y150; Y101D; Y332	Modified Fc fragment, antibody comprising same, and application thereof	Fc fragment with Fc function elimination effect and uses thereof	Zhang Jing, Fang Lijuan, Yan Yongxiang, Zeng Liang, Zhou Pengfei	PCT	PCT/CN2019/075881	Nationalized[1]	N/A
				China	201980003210.7	Granted	2039.02.22
				United States	17/432,705	Pending	N/A
				Europe	19915620.9	Pending	N/A
				Japan	2021-549474	Pending	N/A
M701	Bispecific antibody and application thereof	Sequence of M701 and uses thereof	Fang Lijuan, Zhang Jing, Hua Shan, Zhou Pengfei	PCT	PCT/CN2021/131804	Accepted[2]	N/A
Y101D	Tetravalent symmetric bispecific antibody	Sequence of Y101D and uses thereof	Zhang Jing, Fang Lijuan, Yan Yongxiang, Zeng Liang, Zhou Pengfei	China	202111191003.4	Pending	N/A
Y150	Modified Fc fragment, antibody comprising same, and application thereof	Invention of antibody targeting CD38 × CD3, which includes Fc fragment with Fc function elimination effect and uses thereof	Zhang Jing, Fang Lijuan, Yan Yongxiang, Zeng Liang, Zhou Pengfei	China	202010977832.4	Granted	N/A
				South Korea	10-2021-7030413	Pending	N/A
				Canada	3131033	Pending	N/A

Technology Platform/Drug Candidate	Title of Invention	Scope of Patent Protection	Inventors[4]	Jurisdiction[3]	Patent Application Number	Status	Patent Expiration
Y2019	Novel coronavirus RBD fusion protein	Structure and sequence of RBD fusion protein and RBD dimer, preparation method, and uses thereof	Fang Lijuan, Zhang Jing, Shi Jian, Wang Xin, Luo Fang, Zhou Chi*, Lei Chuanfei*, Zhou Pengfei, Xiao Gengfu, Pan Xiaoyan, Gong Rui, Zhang Zhe	PCT	PCT/CN2020/109295 202080104145.X	Nationalized[1] Pending	N/A N/A
M802	Construction and application of a bispecific antibody HER2 x CD3	Structure and sequence of M802, preparation method, and uses thereof	Zhou Pengfei, Wang Tao*, Fang Lijuan, Yang Jinxia*, Ma Yingying*, Li Na*	China	201510029954.X	Granted	2035.01.21
			Zhou Pengfei, Zhang Jing, Hu Lingli*, Wang Rui*, Zhou Xiang*, Fan Kesuo*	United States United States	14/803,278 15/449,656	Granted Granted	2034.07.21 2034.07.21

Notes:

(1) Nationalized represents the status of a PCT patent application that it has entered into corresponding countries for subsequent national examination and the patent in specific jurisdiction come from the nationalization of the PCT patent.

(2) Accepted represents the status of a patent application that the application has been accepted by the applicable patent examination authorities for subsequent examination.

(3) In respect of two patents granted under the same jurisdiction, they correspond to the parent patent and the divisional patent, which come from the same PCT patent application, have the same original disclosure while differ in the scope of protection.

(4) Except for Xiao Gengfu, Pan Xiaoyan, Gong Rui and Zhang Zhe, all inventors of our material patents and patent applications are our current or previous R&D team members and all the patents are granted to us under relevant agreements. Xiao Gengfu, Pan Xiaoyan, Gong Rui and Zhang Zhe are investigators dedicating to research on the prevention and control of emerging infectious diseases and they provided us with support during the clinical development of Y2019. Throughout the collaboration, our in-house R&D team took the leading role in the clinical trials, filing of IND and NDA submission. Each of them confirmed that we are the sole applicant and sole owner of, and they will not challenge our right to exercise, any intellectual property rights arising from such patent.

(5) This table only lists the main jurisdictions into which the PCT applications have been entered, including China, United States, Europe, Japan, South Korea and Canada.

* our previous employees

Our drug candidates are developed based on the technologies of our key technology platforms. The structure and certain technical aspects of such drug candidates are derived from the technology platforms. Therefore, certain patents or patent applications with claims covering structure and sequence of antibody molecule and uses thereof are applicable to both certain drug candidates and technology platform. The term of individual patents may vary based on the countries in which they are obtained. In most countries in which we file patent applications, including China and the U.S., the term of an issued patent is generally 20 years from the filing date of the earliest non-provisional patent application on which the patent is based in the applicable country. In the U.S., a patent's term may be lengthened in some cases by a patent term adjustment, which extends the term of a patent to account for administrative delays by the United States Patent and Trademark Office ("**USPTO**"), in excess of a patent applicant's own delays during the prosecution process, or may be shortened if a patent is terminally disclaimed over a commonly-owned patent having an earlier expiration date.

In addition, with respect to any issued patents in the U.S., China as well as certain other foreign jurisdictions, we may be entitled to obtain an extension of the patent's term provided we meet the applicable requirements for obtaining such patent term extensions. For example, in the U.S., we may apply for a patent term extension of up to five years as compensation for the patent term lost during clinical trials and the U.S. FDA regulatory review process under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The exact duration of the extension depends on the time we spend in clinical studies, as well as getting a BLA approval from the FDA. However, a patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, a patent may be extended only once, and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Furthermore, a reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. Furthermore, in China, the PRC Patent Law introduces patent extensions to patents of new drugs that launched in the PRC, which may enable the owner of the patent for an innovative new drug that has been granted the marketing authorization in China to submit applications for a patent term extension of up to a maximum length of five years, in order to compensate the time required for the regulatory approval for the commercialization of such innovative new drug; provided that, the patent term of such innovative new drug shall not exceed a total of 14 years. In certain other foreign jurisdictions, similar extensions as compensation for regulatory delays are also available.

The actual protection afforded by a patent varies on a claim-by-claim and country-by-country basis and depends upon many factors, including the type of patent, the scope of its coverage, the availability of any patent term extensions or adjustments, the availability of legal remedies in a particular country and the validity and enforceability of the patent. We cannot provide any assurance that patents will issue with respect to any of our owned or licensed pending patent applications or any such patent applications that may be filed in the future, nor can we provide any assurance that any of our owned or licensed issued patents or any such patents that may be issued in the future will be commercially useful in protecting our drug candidates and methods of manufacturing the same.

We may rely, in some circumstances, on trade secret and/or confidential information to protect aspects of our technology. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with consultants, scientific advisors and contractors, and invention assignment agreements with our employees. We have entered into confidentiality agreements and non-competition 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.

These agreements may not provide sufficient protection of our trade secret and/or confidential information. These agreements may also be breached, resulting in the misappropriation of our trade secret and/or confidential information, and we may not have an adequate remedy for any such breach. In addition, our trade secret and/or confidential information may become known or be independently developed by a third party, or misused by any collaborator to whom we disclose such information. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to or successfully copy aspects of our products or to obtain or use information that we regard as proprietary without our consent. As a result, we may be unable to sufficiently protect our trade secrets and proprietary information.

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. Despite any measures taken to protect our data and intellectual property, unauthorized parties may attempt to or successfully gain access to and use information that we regard as proprietary. For more details, please refer to the paragraphs headed "Risk Factors – Risks Relating to Our Intellectual Property Rights" in this document.

We also own a number of registered trademarks and pending trademark applications. We have registered trademarks for our corporate logo in China and are seeking trademark protection for our corporate logo in the jurisdictions where available and appropriate.

We enter into collaboration agreements and other relationships with pharmaceutical companies and other industry participants to leverage our intellectual property and gain access to the intellectual property of others. For more details, please refer to the paragraphs headed "– Collaboration Agreements" in this section.

Our IP Legal Advisor conducted the freedom-to-operate searches and analyses on our Core Product and major pipeline products and litigation searches, and is of the view that there is no legal, arbitral or administrative proceedings in respect of infringement of third parties' IP rights involving the Group during the Track Record Period and up to the Latest Practicable Date. Taking into account the views of the IP Legal Advisor, our Directors confirmed that, 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 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 drug candidates in which we may be a claimant or a respondent.

The Sole Sponsor has performed the following due diligence work in relation to the intellectual property rights of the Group and no particular findings has caused or casted doubt on the Directors' confirmation above: (i) discussed with the management of the Company on the "freedom-to-operate" analysis and any infringement of third parties' IP rights by the Group; (ii) conducted due diligence interview with the IP Legal Advisor, and reviewed the intellectual property due diligence report on the Company issued by the IP Legal Advisor which contains freedom-to-operate analysis and litigation search in relation to intellectual property rights. Nothing has come to the attention of the Sole Sponsor that would cause it to cast doubt on the IP Legal Advisor's view above; (iii) reviewed the PRC legal opinion issued by the PRC legal advisor to the Company which contains intellectual property, litigation and compliance information of the Group, and no instance of litigation, arbitration or administrative penalty of infringement of third parties' IP rights by any member of the Group has been identified during the Track Record Period and up to the Latest Practicable Date in the PRC legal opinion; (iv) engaged background search agent to conduct background search and litigation search on the Group, and no findings suggested that the Group was involved in any litigation, non-compliance or negative news in relation to infringement of third parties intellectual property rights; and (v) together with Merits & Tree Law Offices, the PRC legal advisor to the Sole Sponsor, conducted desktop search on the Company and no instance of infringement of third parties intellectual property rights by the Company has been identified.

DATA PRIVACY AND PROTECTION

We routinely receive, collect, generate, store, process, transmit and maintain medical data treatment records and other personal details of the subjects enrolled in our clinical trials, along with other personal or sensitive information. As such, we are subject to the relevant local, state, national and international data protection and privacy laws, directives regulations and standards that apply to the collection, use, retention, protection, disclosure, transfer and other processing of personal data in the various jurisdictions in which we operate and conduct our clinical trials, as well as contractual obligations.

We have established procedures to protect the confidentiality of patients' data. We maintain policies requiring our personnel to be trained to collect and safeguard personal information and require our CROs to have data protection clauses in our agreements with them. They are responsible for safeguarding data in their possession. According to the GCP and relevant regulations, access to clinical trial data has been strictly limited to authorized personnel.

Additionally, we require external parties and internal employees involved in clinical trials to comply with confidentiality requirements. Data are to be used only for the intended use, as agreed by the patients and consistent with the Informed Consent Form (the "ICF"). We will obtain consent from patients if any use of data falls outside the scope of ICF.

We have a number of ongoing or planned clinical studies in China and may in the future, conduct clinical trials the United States. Any transfer of clinical trial data in connection with our product development efforts and regulatory communications is subject to the applicable local data and privacy protection laws, including those in China and the United States. Together with our CROs and other collaboration partners, we have implemented controls and arrangements designed to ensure a data management and transfer plan is developed and implemented to govern the transfer of all clinical trial data or other potentially sensitive information. Related measures include, as applicable, ensuring that the cross-border transfer of this clinical data and information is permitted, any requisite approvals are properly obtained, and applicable filings are made, in each case, with the competent authorities and in accordance with relevant laws and regulations (particularly in the case of any transfer between China and the United States). Our Directors confirm that we were not subject to any material claims, lawsuits, penalties or administrative actions relating to non-compliance with applicable PRC laws and regulations for data privacy and protection as of the Latest Practicable Date.

COMPETITION

The markets for biopharmaceutical industry and BsAbs are evolving and highly competitive. While we believe that our research and development capabilities enable us to establish a favorable position in the industry, we encounter competition from international and domestic biopharmaceutical companies, specialty pharmaceutical and biotechnology companies of various sizes, academic institutions and research institutions. For more information on the competitive landscape of our drug candidates, please refer to the section headed "Industry Overview" in this document and the paragraphs headed "– Our Drug Candidates" in this section.

We believe the primary competitive factors in our markets are identification of potential targets, mechanisms and pathways for drug development, molecule screening and design, efficacy and safety of drug candidates, manufacturing efficiency and commercialization development. We expect the competition will become more intensive in the future as additional players enter into the segments. Any drug candidates that we successfully develop and commercialize will compete with existing drugs or any new drugs that may become available in the future. For potential impact of market competition, please refer to the paragraphs headed "Risk Factors – Risks Relating to the Research and Development of our Drug Candidates – We face substantial competition and our competitors may discover, develop or commercialize competing drugs faster or more successfully than we do" in this document.

RAW MATERIALS AND SUPPLIERS

During the Track Record Period, our purchases mainly included third-party contracting services for preclinical evaluation and clinical trials of our drug candidates, raw materials, consumables, machines, and equipment.

Our inventory consists of raw materials and consumables used for our drug candidates' development. We regularly monitor our inventories and endeavor to keep an optimal inventory level in line with the expected usages in the near term. We have established an inventory management system which records inventory data. Our Directors confirmed that our inventory control system and policies had been effective and we did not experience any material shortage in supply or overstock of inventories during the Track Record Period and up to the Latest Practicable Date.

Our major suppliers primarily consist of CROs, CDMOs, CMOs, and suppliers of equipment, devices, and consumable items located in China.

We select our suppliers by considering their product/service quality, costs, delivery standards, industry reputation and compliance with relevant regulations and industry standards.

For the years ended December 31, 2022 and 2021, and the five months ended May 31, 2023, the aggregate purchases attributable to our five largest suppliers in each year were RMB68.0 million, RMB24.5 million and RMB16.5 million, respectively, representing 48.4%, 37.7% and 29.7% of our total purchases for the same years/periods, respectively. Purchases attributable to our single largest supplier in each year were RMB50.0 million, RMB9.0 million and RMB5.4 million, accounting for 35.3%, 13.8% and 9.6% of our total purchases for the same years/periods, respectively. We believe that we maintain stable relationships with our major suppliers.

The following table sets forth details of our five largest suppliers for the five months ended May 31, 2023:

Ranking	Supplier	Supplier Background	Products/ Services Purchased	Years of Business Relationship	Credit Term Granted	Purchase Amount	% of Total Purchase
						(RMB in thousands)	
1	Supplier A	A China-based biomedical company primarily engaging in providing one-stop services for biomacromolecule drugs	Manufacture services	Since 2020	5 business days	5,371	9.6%
2	Supplier B	An integrated pharmaceutical R&D service platform	Clinical research services	Since 2022	15 to 20 business days	3,648	6.6%
3	Supplier C	A China-based clinical trial center	Clinical research services	Since 2021	20 business days	2,647	4.8%
4	Supplier D	A China-based medical company primarily engaging in technology promotion and application services	Clinical research services	Since 2022	10 business days	2,448	4.4%
5	Supplier E	A China-based Class III hospital	Clinical research services	Since 2020	N/A*	2,408	4.3%
Total						**16,522**	**29.7%**

* *Credit terms are not specified under the relevant contracts.*

The following table sets forth details of our five largest suppliers for the year ended December 31, 2022:

Ranking	Supplier	Supplier Background	Products/ Services Purchased	Years of Business Relationship	Credit Term Granted	Purchase Amount	% of Total Purchase
						(RMB in thousands)	
1	Supplier F	A China-based non-clinical CRO primarily engaging in drug safety assessment	Preclinical drug metabolism and toxicological evaluation, and clinical testing services	Since 2014	7 to 30 days	49,666	35.3%
2	Supplier G	A China-based medical company primarily engaging in technology promotion and application services	Clinical outsourcing services	Since 2020	20 business days	5,873	4.2%
3	Supplier H	A U.K.-based company primarily engaging in providing testing and production services	Cell bank assay and virus inactivation removal process validation services	Since 2018	30 days	4,640	3.3%
4	Supplier I	A China-based clinical trial site	Clinical research services	Since 2022	14 days	4,021	2.9%
5	Supplier A	A China-based biomedical company primarily engaging in providing one-stop services for biomacromolecule drugs	Manufacture services	Since 2020	5 business days	3,848	2.7%
Total						**68,048**	**48.4%**

The following table sets forth details of our five largest suppliers for the year ended December 31, 2021:

Ranking	Supplier	Supplier Background	Products/ Services Purchased	Years of Business Relationship	Credit Term Granted	Purchase Amount	% of Total Purchase
						(RMB in thousands)	
1	Supplier J	A China-based biotechnology company primarily engaging in large animal experiments, new drug research and evaluation	Preclinical drug metabolism and toxicological evaluation services	Since 2018	10 business days	8,961	13.8%
2	Supplier K	A Switzerland-based chemical and biotechnology company primarily engaging in providing product development services	Raw materials (host cells)	Since 2018	30 days	4,344	6.7%
3	Supplier L	A China-based biomedical company primarily engaging in providing one-stop services for biopharmaceutical industry	Manufacture services	Since 2021	30 days	4,228	6.5%
4	Supplier M	A China-based pharmaceutical company primarily engaging in R&D of new drug and technology	Clinical outsourcing services	Since 2018	22 business days	4,045	6.2%
5	Supplier H	A U.K.-based company primarily engaging in providing testing and production services	Cell bank assay and virus inactivation removal process validation services	Since 2018	30 days	2,930	4.5%
Total						**24,508**	**37.7%**

Supplier J, with purchase amount of RMB9.0 million in 2021, was our largest supplier for the same year, primarily due to the fact that supplier J is located in Wuhan and is able to supply adequate materials necessary for our research and development at lower price when certain imported materials necessary for our research and development became scarce due to the impact of the COVID-19 pandemic. Since late 2021, with the COVID-19 related pandemic control measures gradually lifted domestically and globally, we resumed and renewed collaborations with suppliers based on our R&D progress. We entered into an agreement with supplier F in late 2021 for their services in 2022. Accordingly, the purchase amount attributable to supplier F was RMB50.0 million in 2022 and supplier F was the largest supplier for the same year.

Relationship with Supplier M

Supplier M is indirectly wholly-owned by CSPC through its subsidiary as of the Latest Practicable Date, and is regarded as our related party and a connected person. Supplier M was selected as our CRO for its relatively stable relationship with major research centers and the collaboration was determined after arm's length negotiations. Under our collaboration agreement, we owned all intellectual property and trial results and supplier M must maintain strict confidentiality with respect to the information it acquired from us during clinical trials. For the years ended December 31, 2021 and 2022, the aggregate purchases attributable to supplier M were RMB4.0 million and RMB2.2 million, respectively. The CRO collaboration with supplier M has ended in 2022 and the Company has no intention to continue such collaboration after the [**REDACTED**]. In order to proceed with relevant clinical research using the original database, the Company entered into service agreements with supplier M in September 2022 and October 2022, respectively, based on arm's length negotiations. Pursuant to such service agreements, the Company shall pay supplier M service fees on a quarterly basis for using the databases and other ancillary services provided by supplier M. One corresponding agreement has expired in June 2023 and the other agreement will expire in November 2023. The Company has no intention to renew such agreements upon their expiration. For the year ending December 31, 2023, the aggregate service fees under such agreements are expected to be approximately RMB0.3 million. Except for the aforesaid transactions with supplier M, we did not have other historical and, as of the Latest Practicable Date, do not have intention to enter into any transactions with CSPC and/or its associates. Our Directors confirm that the relationship adjustment with supplier M did not and will not have a material adverse impact on our business operations and financial performance.

During the Track Record Period, except for supplier M, none of our five largest suppliers was our related parties. Except for supplier M, none of our Directors or their associates or, to the knowledge of our Directors, any Shareholder with over 5% of the share capital of our Company has any interest in any of our five largest suppliers during the Track Record Period.

In addition, we believe that adequate alternative sources for such supplies exist, and we have developed alternative sourcing strategies for these supplies. We will establish necessary relationships with alternative sources based on supply continuity risk assessment. Other than the agreements with certain CROs and CMOs, we order supplies and services on a purchase order basis and do not enter into long-term dedicated capacity or minimum supply arrangements. We generally have credit periods of nil to 90 days.

EMPLOYEES

As a biotechnology company, our employees are our valuable resource. As of the Latest Practicable Date, we had a total of 129 full-time employees, all of whom were in China. The following table sets forth a breakdown of our employees categorized by function as of the Latest Practicable Date:

Function	Number	Percentage
R&D	104	80.6%
General and Administrative	25	19.4%

We also plan to develop our internal sales and marketing team preparing for the commercialization of our drug candidates in the future.

Employment Agreements with Key Management and R&D Staff

We enter into standard labor, confidentiality and non-compete agreements with our employees. The non-compete restricted period typically expires two years after the termination of employment, and we agree to compensate the employees with a certain percentage of their pre-departure salary during the restricted period. Our standard employment contract, which we used to employ each of our employees, contains an assignment clause, under which we own all the rights to all inventions, technology, know-how and trade secrets derived during the course of such employee's work.

We recruit and retain highly engaged and motivated team players who are driven by our commitment, and are excited to contribute to the development of next-generation immunotherapies leveraging their extensive experience. Our success depends largely on the efforts and expertise of all employees who are an integral part of our business. As we are dedicated to expanding our talent pool to support our future development, our business will not be materially and adversely affected by the departure of any single key management or R&D staff. We believe that we are in a good position to create an equitable, inclusive and diverse workplace while maintaining a good working relationship with our employees. As of the Latest Practicable Date, we had not experienced any major labor disputes.

Training and Development

We offer employees a variety of professional development opportunities and encourage a performance-driven environment. We focus on creating a culture to encourage retention and engagement. Given our emphasis on our integrated in-house research and development capabilities, we attach great importance to internal talent growth. We continually pursue progression opportunities for our staff through various internal and external training and development programs, including pre-job training, on-the-job practice, cross-training, special skills training, and talent echelon development training.

Employee Benefits

We are committed to making sure that working conditions throughout our business network are safe and that employees are treated with care and respect. We believe we offer our employees competitive compensation packages, reflecting our stakeholder-centric ethos which we believe leads to sustainable and durable growth. As required by PRC regulations, we participate in various government statutory employee benefit plans, including social insurances, namely pension insurance, medical insurance, unemployment insurance, work-related injury insurance, maternity insurance, and housing funds. We are required under PRC law to make contributions to employee benefit plans at specified percentages of the salaries, bonuses and certain allowances of our employees, up to a maximum amount specified by the local government regulations from time to time. Our compensation package also comprises year-end bonuses, communication, transport and meal allowances, staff dormitory, paid leaves, and holiday benefits. In addition, we provide career development opportunities and promote an inventive, collaborative, and productive work environment, which we believe fosters long-lasting self-motivation for our employees.

During the Track Record Period, we were not in strict compliance with the requisite contribution requirements in relation to some of our PRC employees, which we believe will not bring any material adverse effect to our operations or financial position. As of the Latest Practicable Date, we had not received any order of correction or any fines or penalties from the competent authority as a result of any such failure. We have obtained certain confirmation letters issued by the relevant competent social insurance and housing provident fund authorities confirming that there is no record of any member of our Group that hires employees being imposed administrative penalties by the relevant authorities for violation of the relevant laws and regulations. As advised by our PRC Legal Advisor, the likelihood that we are subject to centralized collection of historical arrears and any material penalties due to our failure to make full contributions of social insurance premium and housing provident funds for some of our employees during the Track Record Period is remote, based on the interviews with competent authorities.

LAND AND PROPERTIES

Land, Construction-in-Progress and Owned Properties

As of the Latest Practicable Date, we had land use right to one land parcel located in Wuhan, Hubei, with a site area of approximately 25,533.4 square meters. We also had ownership on ten properties with an aggregate gross floor area of 3,772.5 square meters as of the Latest Practicable Date.

We acquired such land parcel in 2012 for the construction of our manufacturing facility pursuant to a land grant contract (the "Land Grant Contract") with Wuhan Municipal Bureau of Natural Resources and Planning, East Lake High-tech Development Zone Branch (the "Wuhan Bureau of Natural Resources and Planning"). Under the Land Grant Contract, the construction work on this parcel should be completed within two years from the date of the Land Grant Contract. However, we experienced certain delays in completing the construction

project on such land parcel, primarily due to the delay in delivery of such land parcel by the Wuhan Bureau of Natural Resources and Planning and our change of manufacturing plan to outsource the manufacturing of M701 to qualified CMOs at this stage, as well as the impact of COVID-19 outbreaks.

Under PRC laws, if a company fails to complete its construction works within the required time frame in the relevant land use right grant contract, the competent PRC authorities may impose liquidated damages on such company from the required construction completion date under the land use right grant contract, and the land parcel may be subject to forfeiture to the PRC government if the construction has not meet relevant capital investment requirement. For more details, please refer to the paragraphs headed "Risk Factors – Risks Relating to Our Operations – The PRC government may impose fines or other penalties on us if we fail to comply with the terms of the land grant contracts" in this document.

We conducted a consultation with the Wuhan Bureau of Natural Resources and Planning on September 21, 2022, with respect to our suspended constructions on such land parcel. During the consultation, the Wuhan Bureau of Natural Resources and Planning confirmed that (i) the land parcel under the Land Grant Contract is not recognized as an idle land, and (ii) after the completion of the [**REDACTED**], if we could complete the construction work on such land parcel in accordance with the construction standards stipulated in the Land Grant Contract, the Wuhan Bureau of Natural Resources and Planning will not impose any penalty to us. As confirmed by our PRC Legal Advisor, the Wuhan Bureau of Natural Resources and Planning is the competent authority to conduct such a consultation. Based on the foregoing, our PRC Legal Advisor is of the view that, after the completion of the [**REDACTED**], if we could complete the construction work on such land parcel in accordance with the construction standards stipulated in the Land Grant Contract, the risks of our being subject to penalty and forfeiture of land parcel with respect to such land parcel is remote.

The following table summarizes the properties we owned as of the Latest Practicable Date:

Location	Use of Property	Gross Floor Area (m^2)
East Lake High-tech Development Zone Wuhan, Hubei Province	Employee Dormitory	81.2
	Employee Dormitory	81.2
	Employee Dormitory	81.2
	Employee Dormitory	81.0
	Leased Out (to an independent third party)	81.0
	Employee Dormitory	136.4
	Office	811.8
	R&D	811.8
	R&D	811.8
	R&D	795.3

Leases

As of the Latest Practicable Date, we leased four properties with a total of approximately 1,295.1 square meters from independent third parties as our office premises and research and development center in the PRC; and one of our subsidiaries leased one property with a total of approximately 3,230.6 square meters from our Company as such subsidiary's office premise and research and development center. 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. We do not anticipate undue difficulty in renewing our leases upon their expiration.

The following table sets forth the details of our leased properties from independent third parties:

Location	Type of Property	Address	Gross Floor Area (m^2)	Lease Term	Expiry Date
Wuhan, Hubei	Office premise and R&D center	Rooms 301-307, 3/F, Block D, Building C1, Biolake Park, No. 666 High-tech Avenue, East Lake High-tech Development Zone Wuhan, Hubei Province	510	13 months	June 9, 2024
Wuhan, Hubei	Office premise	Overhead 1/F, Building C2-3, Biolake Park, No. 666 High-tech Avenue, East Lake High-tech Development Zone Wuhan, Hubei Province	120	One year	December 31, 2023

Location	Type of Property	Address	Gross Floor Area (m^2)	Lease Term	Expiry Date
Nanjing, Jiangsu	Office premise and R&D center	Rooms 903-909, 926-928, Block A, Phase I of Zhongdan Ecology and Life Science Industrial Park, No. 3-1 Xinjinhu Road, Jiangbei New Area, Nanjing, Jiangsu Province	565	Three years	December 19, 2025
Nanjing, Jiangsu	Office premise	Room 635, Block A, Phase I of Zhongdan Ecology and Life Science Industrial Park, No. 3-1 Xinjinhu Road, Jiangbei New Area, Nanjing, Jiangsu Province	100	One year	March 5, 2024

The lessor who leased us the property with gross floor area of approximately 120 square meters in Wuhan, Hubei, has not provided us with its property ownership certificate or any other documentation proving its right to own or lease the property. As advised by our PRC Legal Advisor, the lack of such documentation may invalidate our lease agreements with such lessor. We believe that such defect will not have a material and adverse impact on our business operations considering that there are sufficient alternative locations for us to choose from and the relocation is convenient.

Pursuant to the applicable PRC laws and regulations, both lessors and lessees are required to file the lease agreements with relevant authorities for record and obtain property leasing filing certificates for their leases. As of the Latest Practicable Date, six of our leases had not been filed with the governmental authorities. For one of such six leases, our Company is the lessor and one of our subsidiaries is the lessee. The failure to file and obtain property leasing filing certificates for such six leases, as required under PRC laws, may subject us to a fine ranging from RMB1,000 to RMB10,000 for each agreement not filed. If such fines are imposed, the maximum penalty we may be required to pay would be approximately RMB70,000. For details of the risk associated with the unregistered lease agreements, please refer to the paragraphs headed "Risk Factors – Risks Relating to Our Operations – We are subject to risks associated with leasing space" in this document. During the Track Record Period and up to the Latest Practicable Date, we had not been subject to any penalties arising

from the non-registration of our lease agreements, and had not experienced any dispute arising out of, or in relation to, our leased properties. As advised by our PRC Legal Advisor, the non-registration of our lease agreements does not affect the validity of such agreements, and we believe such non-compliance is unlikely to have a material adverse effect on our business operations and financial performance. We will take all practicable and reasonable steps to ensure that the unregistered leases are registered.

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, 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 require a valuation report with respect to all our interests in land or buildings, for the reason that, as of May 31, 2023, we had no single property with a carrying amount of 15% or more of our consolidated total assets.

Upon expiration of our leases, we will need to negotiate for renewal of the leases or relocate. There are sufficient alternative locations for us to choose from, but we may incur additional costs in relation to the potential relocation. During the Track Record Period, we did not experience any dispute arising out of our leased properties.

AWARDS AND RECOGNITIONS

We have received various awards and qualifications for our projects and entities. The following table sets forth the key selected awards and qualifications for which we received government grants as of the Latest Practicable Date:

Year of Grant	Award/Recognition	Issuing Authority
2023	Second Prize of Science and Technology Progress Award of Hubei Province	People's Government of Hubei Province
2022	"Specialized and Innovative" Small Giant Enterprise of Hubei Province	Department of Economy and Information Technology of Hubei Province
2022	National Science and Technology Small and Medium Enterprise	Ministry of Science and Technology of the PRC

Year of Grant	Award/Recognition	Issuing Authority
2021	"Gazelle Enterprise"	Science and Technology Bureau of Wuhan East Lake High-tech Development Zone
2021	Strategic Innovation and Entrepreneurship Team of Hubei Province	Department of Science and Technology of Hubei Province
2020	Hubei Provincial Intellectual Innovation Demonstration Base	Department of Science and Technology of Hubei Province
2018	Postdoctoral Research Station	Ministry of Human Resources and Social Security of the PRC
2018	Top Ten Innovative Enterprise	Biolake of Wuhan East Lake High-tech Development Zone
2017	Hubei Immunological Targeted Antibody Engineering Technology Research Center	Department of Science and Technology of Hubei Province
2016	Hubei Provincial Research Center for Bispecific Antibody Engineering Technology	Development and Reform Commission of Hubei Province
2016	Intellectual Property Pioneer	Intellectual Property Administration of Wuhan East Lake High-tech Development Zone

ENVIRONMENTAL MATTERS AND WORKPLACE SAFETY

We acknowledge our environment protection and social responsibilities and are aware of the environmental, energy, climate-related and workplace safety issues that may impact our Group's business operation. We are committed to complying with environmental, social and governance ("**ESG**") reporting requirements upon [**REDACTED**].

Our Board has overall responsibility for (i) overseeing and determining our Group's environmental, social, and climate-related risks and opportunities that impact our Group, (ii) establishing ESG related targets of our Group, (iii) adopting the ESG related policies, and (iv) reviewing our Group's performance in ESG matters.

Environment Protection

We endeavor to reduce negative impacts on the environment through our commitment to energy saving and sustainable development.

We had not yet commercialized any of our drug candidates and had not started large-scale commercial production as of the Latest Practicable Date. We currently manufacture certain of our existing drug candidates for R&D purposes only. Accordingly, we produce limited air pollution, wastewater, biological solid waste or other hazardous wastes. We have adopted internal policies for environmental risk prevention to ensure compliance with the requirements of the applicable national, industrial and local standards, laws, regulations and policies, including, but not limited to, (i) strict compliance with the GMP regulations and relevant pollutant emissions standards; and (ii) periodic environmental evaluations on exhaust gas detection and emissions, hazardous waste disposals, noise emissions, and waste water detection and emissions.

During the Track Record Period and up to the Latest Practicable Date, we had not received any fines or penalties associated with the breach of any environmental laws or regulations. To the best knowledge and belief of our Directors, we are not subject to material environmental liability risk and will not incur material compliance costs in the future.

We monitor our hazardous wastes on a periodic basis and make continuous efforts in working towards the target of reducing the hazardous wastes discharge. Our wastewater discharge levels in relation to the research and testing decreased from approximately 1.7 tons in 2021 to 0.9 tons in 2022, and the solid waste we transferred to the third parties decreased from 10.9 tons in 2021 to 7.4 tons in 2022, respectively. In the five months ended May 31, 2023, our wastewater discharge level in relation to the research and testing and the solid waste we transferred to the third parties are 0.6 tons and 2.5 tons, respectively. For any potential hazardous wastes we produce from R&D activities, we contract with qualified third parties for the disposal of hazardous materials and wastes. In 2021, 2022 and the five months ended May 31, 2023, we incurred costs of approximately RMB217,333, RMB39,518 and RMB66,450, respectively, in this regard. We require their operational qualifications in accordance with relevant governmental laws and regulations. The third-party waste treatment service providers issue written records for the transfer of hazardous wastes and we keep such records for our internal review and compliance. We will make continuous endeavors to take measures to protect the ecological environment during our business operation, so as to minimize adverse environmental impact.

Resource Consumption

To reach our goal for sustainable development, we oversee our environmental protection performance in various aspects, such as efficiency in the use of resources and energy consumption. We monitor our electricity and water consumption levels and implement measures to improve energy efficiency and water conservation. In 2021, 2022 and the five months ended May 31, 2023, the electricity consumption levels were approximately 1.1 million kWh, 1.1 million kWh and 0.4 million kWh in aggregate, respectively with our water

consumption levels reaching approximately 3.2 thousand tons, 4.4 thousand tons and 1.9 thousands tons in aggregate, respectively. The table below sets forth an analysis of our environmental protection performance with industry average as of the year ended December 31, 2021 and 2022:

	As of/For the year ended December 31	
	2021	**2022**
Our Company		
Number of employees	111	120
Electricity consumption (kWh)	1,052,334	1,070,588
Per employee electricity consumption (kWh)	9,480	8,922
Water consumption (tons)	3,153	4,422
Per employee water consumption (tons)	28	37
Industry Peers*		
Electricity consumption (kWh)	5,165,192	6,172,679
Per employee electricity consumption (kWh)	18,164	10,759
Water consumption (tons)	41,258	50,294
Per employee water consumption (tons)	83	97

Source: Annual Reports or ESG Reports of Listed Biotech Companies under Chapter 18A of the Listing Rules as of the Latest Practicable Date

Following the ESG evaluation system standards in China and the market practice of industry pioneers, we aim to avoid or reduce the adverse impact on the environment caused by our operations and services, formulate environmental management plans to continuously improve our energy consumption efficiency and ensure all of our operations comply with governmental environment-related regulations and requirements. Our current target is to establish a comprehensive ESG governance mechanism and system for our Company and the historical energy consumption levels during the Track Record Period will serve as a foundation for developing more relevant energy reduction strategies and settling appropriate reduction targets for us in the future. We intend to reduce our per employee electricity and water consumption by 10% in 2026 with a view of balancing our R&D and manufacture progress in the next three years, and our environmental commitment to maximize electricity utilization and reduce water waste in our daily operation through process optimization.

To achieve our goals, we have already implemented the following environmentally friendly measures:

- encouraging all staff to reduce the production of paper waste, reduce consumption of water resources and electrical appliances by posting water-saving or power-saving signs in eye-catching areas to cultivate our employees' awareness of environment protection;

- encouraging our employees to avoid printing hard copies and requiring double-sided printing whenever possible;
- encouraging teleconferences as opposed to physical meetings to reduce travel;
- reducing the usage of air conditioning, including requirements on lowest temperature;
- regularly conducting inspections of our laboratory equipment in order to check for abnormal conditions, and make prompt report to avoid potential damages;
- carrying out manual check after shift to eliminate unnecessary lighting;
- promoting recycling schemes, seeking alternative ways of disposing of and reducing waste in environmental-friendly ways; and
- strictly complying with and fully implementing all relevant environmental laws and regulations.

During the Track Record Period, we complied with the relevant environmental laws and regulations in all material aspects and we did not have any incidents or complaints which had a material and adverse effect on our business, financial condition or results of operations.

Climate Change

In view of the nature of our business, to the best knowledge of our Directors, the climate change will not have any major impact on our business operation. In the case of extreme natural weather, we will actively respond to the relevant policies of local government, make contingency plans in addition to the life insurance contributed by our Group to ensure the safety of our staff. In the case of acute physical risks such as direct damage to assets and indirect impacts from supply chain disruption as a result of extreme weather events, we will make corresponding contingency and disaster preparedness plans, and we believe that we have the ability to deal with climate crisis. During the Track Record Period and up to the Latest Practicable Date, we had not experienced any material impact on our business operations, strategies or financial performance as a result of environmental, social and climate-related issues.

Potential transition risk may result from a lower-carbon economy, which entails climate-related regulations and policy change and reputational risk. Currently, the National Development and Reform Commission and the Ministry of Ecology and Environment have jointly issued the Opinions on Further Strengthening the Cleanup of Plastic Pollution, laying out a five-year roadmap to restrict the use, production and sale of plastic products by 2020, 2022, and 2025, respectively. Our Group will work with the suppliers to comply with such regulations, and we will monitor the scope to ensure our works meet the expectations of the regulators.

Workplace Safety

We commit to promoting work-life balance and create a positive workplace for all of our employees.

We have adopted and maintained a series of rules, standard operating procedures, and measures, including those required under the GMP standards, to maintain our employees' health and we emphasize providing a safe working environment for our employees as well as our clinical trial participants. We implement safety guidelines to set out information about potential safety hazards, safe practices, accident prevention and accident reporting as core aspects, and we ensure that clinical trial participants properly acknowledge their understanding of safety matters at the time of enrollment and on an ongoing basis as necessary. We ensure safe storage and handling of flammable and corrosive materials used in our manufacturing process. We also have safety equipment and instruments in place, and we periodically inspect our utility equipment and fire services to ensure the safety of our employees.

Additionally, we have established an environmental, health and safety ("**EHS**") community in charge of safety and emergency issues consisting of nine employees mainly responsible for identifying and mitigating safety risks, improving the safety production policies and procedures, supervising the implementation of such policies and procedures, making emergency plans and providing trainings in respect of production safety to our employees. In addition, we provide our employees with training in various areas to improve their knowledge and skills. In addition, we conduct safety inspections of our laboratories and manufacturing facilities on a regular basis and new employees are required to participate in safety training to familiarize themselves with the relevant safety rules and procedures. In particular, we conduct training sessions on fire control safety and regularly perform emergency evacuation drills to reduce risks associated with potential fire accidents. Furthermore, we have taken measures in relation to the occupational health and monitoring management, as an effort to protect the health and rights of our employees, prevent occupational diseases, and provide proper placement and compensation for employees diagnosed with occupational diseases.

We are also dedicated to providing fair and equal treatment and career opportunities to all of our employees. We prohibit any form of discrimination based on gender, family origin, disability, religious beliefs, or race throughout our recruiting process. To the best knowledge of our Directors and during the Track Record Period, we did not encounter any significant workplace safety incidents.

Manufacturing and Clinical Trial Safety

Our environmental, health and safety protection measures in relation to manufacturing include: (i) implementing safety guidelines with respect to employee health and safety, environmental protection and operational and manufacturing safety in laboratories and manufacturing facilities, and closely monitor internal compliance with these guidelines; (ii) complying with the GMP qualification requirements and relevant pollutant emissions standards

during our production process to reduce pollutant emissions of air and wastewater, among others; and (iii) engaging qualified third parties for the disposal of hazardous waste for all of our research and development manufacturing activities in accordance with applicable laws and regulations.

We comply with relevant regulations once our drugs are approved and emphasize product quality and clinical trial safety. In order to enhance our clinical trial safety, we have adopted a series of measures:

- establishing and enforcing internal policies and procedures on clinical trial safety;
- regularly checking regulatory developments and updates;
- developing clinical trial protocols with reference to the latest regulations and guidelines on clinical trial safety;
- communicating with relevant employees and CROs on the regulatory compliance update and the enforcement of clinical trial protocols;
- revising protocols, investigators' brochures and informed consent forms and re-evaluating the safety risks periodically;
- monitoring adverse events of drugs and drug candidates from literature, social media, reports and clinical trials as well as creating safety management plans and recording properly and accurately the clinical trial safety events for each clinical trial;
- conducting comprehensive analysis on the collected adverse events and evaluating the safety risks; and
- reporting serious adverse events and potential serious safety risks to regulatory authorities promptly.

We endeavor to provide safe products to the society through a comprehensive quality management system. We have an experienced quality management team, consisting of 29 personnel as of the Latest Practicable Date. Dr. Yi Jizu, our senior president of the quality center, has extensive experience in quality control, quality assurance, and preclinical safety studies of biological products. All of our quality management team members have received professional training in regulations, GMP standards and quality control analysis methods. All of our manufacturing facilities are designed and maintained, and we implement quality standards, in conformity with GMP standards adopted by NMPA, the EMA, the FDA and related ICH guidelines. We will also collect adverse events of our product candidates from clinical trials, including following the relevant regulations on the collection of adverse events once our product candidates are approved and monitoring adverse events of drugs from literature, social media and reports in order to provide safe products to the public.

We are committed to developing high-quality drugs that are accessible and affordable to patients. In the sales process in different markets, we take into account various factors in formulating product marketing plans. After the launch of innovative drugs such as our Core Product M701, we will promptly promote the drugs to various hospitals through the established and continuously strengthened marketing team in advance and the cooperative CSO. At the same time, before the innovative products are covered by the medical insurance, we plan to carry out short-term and medium-term preferential activities in order to provide competitive prices and charitable drug donations to increase the accessibility and affordability of related tumor patients, taking into account that some patient's family may not be able to afford long-term medication. Surely, we will also seek cooperation with insurance companies through active negotiations with the National Healthcare Security Administration, and promote our innovative drugs to be covered by national medical insurance or commercial insurance in a timely manner, making it easier for the public to obtain treatment for related diseases.

INSURANCE

We maintain insurance policies that we consider to be in line with market practice and adequate for our business to safeguard against risks and unexpected events. Our insurance policies cover adverse events in our clinical trials. We maintain insurance for our employees in accordance with relevant PRC laws and regulations. We believe that our insurance coverage is adequate to cover our key assets, facilities, and liabilities.

PERMITS, LICENSES AND OTHER APPROVALS

Our PRC Legal Advisor has advised that as of the Latest Practicable Date, we have obtained all material licenses, permits, approvals and certificates from the relevant government authorities that are material for the business operations of our Group.

RISK MANAGEMENT AND INTERNAL CONTROL

We have devoted ourselves to establishing and maintaining risk management and internal control systems consisting of policies and procedures that we consider to be appropriate for our business operations, and we are dedicated to continuously improving these systems.

Risk Management

We are exposed to various risks in our business operations and we recognize that risk management is critical to our success. For more details, please refer to the section headed "Risk Factors" in this document. We are also exposed to various market risks currency and interest rate risks, credit risks, and liquidity risks that arise in the normal course of our business. For more details, please refer to the paragraphs headed "Financial Information – Market Risk Disclosure" in this document.

To monitor the ongoing implementation of our risk management policies and corporate governance measures after the [**REDACTED**], we have adopted or will continue to adopt, among other things, the following risk management measures:

- establish an audit committee to review and supervise our financial reporting process and internal control system;
- adopt various policies to ensure compliance with the Listing Rules, including but not limited to aspects related to risk management, connected transactions, and information disclosure;
- provide anti-bribery compliance training periodically to our senior management and employees to enhance their knowledge and compliance with applicable laws and regulations.

We consider that our Directors and members of our senior management possess the necessary knowledge and experience in providing good corporate governance oversight in connection with risk management and internal control.

Internal Control

Our Board is responsible for establishing our internal control system and reviewing its effectiveness. We have engaged an internal control consultant (the "Internal Control Consultant") to perform certain agreed-upon procedures (the "Internal Control Review") in connection with the internal control of our Company in certain aspects, including entity-level controls, financial reporting and disclosure controls, sales and collection management, purchase and payment management, inventory management, fixed assets management, human resources and payroll management, general controls of IT system and other procedures of our operations. The Internal Control Consultant performed the Internal Control Review, identified internal control deficiencies and provided recommendation accordingly. We have adopted the corresponding remediation actions to improve the effectiveness of internal control system. The Internal Control Consultant performed a follow-up review with regard to those actions taken by us and there are no further material findings identified in the process of the follow up Review. As of the Latest Practicable Date, there were no material outstanding issues relating to our Company's internal control.

After considering the remedial actions we have taken, our Directors are of the view that our internal control system is adequate and effective for our current operations.

We plan to provide various and continuing trainings to update our Directors, senior management, and relevant employees on the latest PRC laws and regulations from time to time with a view to proactively identify any concerns and issues relating to any potential non-compliance.

LEGAL PROCEEDINGS AND COMPLIANCE

As of the Latest Practicable Date, there was no litigation, arbitration or administrative proceedings pending or threatened against the Company or any of our Directors which could have a material and adverse effect on the research and development of our drug candidates, our financial condition or results of operations. Potential future litigation or any other legal or administrative proceeding, regardless of the merit or outcome, is likely to result in substantial costs, diversion of our resources, and have a negative impact on our reputation and brand image, which in turn, would have negative impact on our business, financial condition, and results of operations. For potential impact of legal or administrative proceedings on us, please refer to the paragraphs headed "Risk Factors – Risks Relating to Our Operations – We may become involved in lawsuits or other legal proceedings, which could adversely affect our business, financial conditions, results of operations and reputation" in this document.

We are of the view that, during the Track Record Period and up to the Latest Practicable Date, we had complied, in all material respects, with all relevant laws and regulations in the jurisdictions we operate in, our Directors confirmed that, during the Track Record Period and up to the Latest Practicable Date, we had not been and were not involved in any 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 Group's business operations. For potential impact of certain non-compliance incidents on us, please refer to the paragraphs headed "Risk Factors – Risks Relating to Our Operations – We are subject to risks associated with leasing space" and "Business – Employees – Employee Benefits" in this document.