OVERVIEW

Founded in 2014, we are a bio-pharmaceutical company with research and development capabilities. We are committed to the development and commercialization of oncology therapies differentiated clinical profile in response to the trend of treating cancer as a chronic disease.

Our core business model is to discover, research, develop and commercialize oncology products and drug candidates by building a pipeline of innovative products and drug candidates with a potential to create significant synergy as combination therapies to address an unmet medical needs through a combination of in-house discovery, co-development and in-licensing. Our management team has extensive industry experience at organizations including FDA and pharmaceutical companies, and has led us to build capabilities from discovery to commercialization with proven track record.

With the increasing incidence and prevalence of cancer patients as well as the increase of the 5-year overall survival rate of cancer in the U.S. and China (67.1% in the U.S. and 40.5% in China), treating cancer as a chronic disease has become a major trend in oncology treatment. Due to the unmet medical needs to prevent progression, recurrence and metastasis of cancer and to improve the quality of life, treating cancer as a chronic disease will further drive the growth of the oncology drug market in China. In addition, there has been recent evolution of oncology treatment from in-hospitals to out-hospitals, which will potentially make oncology drugs more accessible for patients. Leveraging our deep understanding of the oncology market and unmet medical needs across tumor types as well as our business development, clinical development and registration capabilities and scientific insights of mechanism of actions of candidate drug molecules, we are able to identify and secure compounds and proceed with the discovery, research, development, clinical and regulatory processes. Through both in-house discovery and external collaboration, we have assembled and are developing a portfolio of therapies to treat cancer as a chronic disease.

Focusing on the trend of treating cancer as a chronic disease, we have strategically carried out a forward-looking plan for our product and drug candidate pipeline. We have built a pipeline consisting of one Core Product and 11 drug candidates, including a fully validated immuno-oncology monotherapy, innovative drug candidates with mechanisms of action amenable to combination within the pipeline, and pain management assets. Among our product and drug candidates, the Core Product envafolimab (brand name: ENWEIDA, 恩維達®), as our backbone, was approved in November 2021 and commercialized in December 2021, and seven are in clinical stage. Three of these product and clinical-stage drug candidates have entered into Phase II/III pivotal trials, two of which are conducted by our collaboration partners.

Our Core Product envafolimab is a subcutaneously-injectable PD-L1 antibody that has the potential to address an unmet medical need for the treatment of cancer as a chronic disease. We spent only four years moving envafolimab, a new molecular entity, from the IND stage to the BLA stage. On November 24, 2021, we received BLA approval for envafolimab for previously treated microsatellite instability-high (MSI-H)/mismatch repair deficiency (dMMR) advanced

solid tumors from the NMPA and we are the marketing authorization holder (MAH). It has been approved in China for the treatment of previously treated MSI-H/dMMR advanced solid tumors. Furthermore, envafolimab has potential to drive the technological advancement in the field of immunotherapy by offering PD-L1 inhibitor with a more convenient, cost-effective and generally preferred injection method. Compared with the currently approved PD-1/PD-L1 inhibitors, envafolimab is smaller with better stability and higher solubility, which enables high concentration formulation suitable for subcutaneous injection. Due to its subcutaneous formulation, it has the potential to have better patient compliance with increased convenience, wider patient coverage and huge market potential. Envafolimab has been well acknowledged by the Chinese clinical oncology community and recommended by three updated Chinese Society of Clinical Oncology (CSCO) 2022 Guidelines, including: (1) CSCO Guidelines for Gastric Cancer 2022 Version (Class I recommendation, Level 2A evidence); (2) CSCO Guidelines for Colorectal Cancer 2022 Version (Class II recommendation, Level 2A evidence), and (3) CSCO Guidelines for Clinical Application of Immune Checkpoint Inhibitors 2022 Version (Class I recommendation, Level 2A evidence). As of the Latest Practicable Date, our Core Product was approved for the indication of previously treated MSI-H/dMMR advanced solid tumors only, the incidence of which in China reached approximately 146,100 in 2021 and is expected to reach approximately 186,000 in 2030. We may face fierce competition from existing products and potential drug candidates in the entire oncology market and the market opportunities in respect of the Core Product may be small as it targets late line treatment, i.e., second line or later stage of treatment, for most of its targeted indications.

Our peptide cancer vaccine 3D189 (also known as Galinpepimut-S) is currently being evaluated by our partner SELLAS Group in an ongoing Phase III pivotal trial in the U.S. and Europe for the treatment of acute myeloid leukemia (AML). We obtained the IND approval for 3D189 in China in March 2022. Our GAS6 decoy receptor 3D229 (also known as batiraxcept, AVB-500) is being evaluated by our partner Aravive in a Phase III pivotal trial in the U.S. and Europe for the treatment of platinum resistant ovarian cancer (PROC). We completed a Phase I clinical trial in healthy volunteers in China in May 2022 and we obtained the IND approval for a Phase Ib/II clinical trial in patients with NSCLC, RCC and UC in April 2022. We obtained the IND approval for a Phase III clinical trial in patients with PROC in China in July 2021 to participate in the MRCT, and initiated this Phase III clinical trial in China in February 2022. We plan to join both aforementioned advanced trials to expedite our development and commercialization process in China.

We are focused on and have contributed to the development of immuno-oncology therapies. Employing a combination approach, immuno-oncology therapies have improved therapeutic efficacy and life expectancy of patients with a variety of cancer types and have stood out as particularly influential in recent years. Envafolimab can be used in combination with other treatments, including chemotherapy, targeted therapies, and other immunotherapies, which would potentially benefit more patients. Other drug candidates in our pipeline have promising potential to synergize with envafolimab through varied complementary mechanism of actions.

The following chart summarizes the development status of our product, clinical-stage drug candidates and selected pre-clinical stage drug candidates as of the Latest Practicable Date:

Candidate	Target/ Mechanism	Indications/Study Population	Rights	Preclinical Discovery / IND / Phase I / Phase II / Pivotal/Phase III / NDA	Partner
★ Envafolimab*[1]	PD-L1	MSI-H/dMMR advanced cancer (mono, 2L+)	Worldwide	China — *BLA approved*	Alphamab Group, Simcere Group, (CSO)
		Advanced BTC (combo with chemo vs. chemo, 1L)[†]		China — ‡ — Pivotal	
		NSCLC (vs standard treatment)		China[a] — Pivotal	
		NSCLC (combo with chidamide, 2L+)		China	
		UC (mono vs. BSC, 1L maintenance, MRCT)		China, EU, Japan[a] — Pivotal	
		G/GEJ advanced cancer (combo with chemo, 1L)		China	
		TMB-H advanced cancer (mono, 2L+)		China	TRACON*** (Sarcoma, Phase II)
		EC (mono and combo with lenvatinib, 2L+)		China	
		NSCLC, HCC, RCC (combo with lenvatinib)		China	
		HCC, CRC, NSCLC (combo with BD0801)		China	
		Microsatellite stable CRC (combo with cetuximab)		China[b]	
3D189[2]	WT1	Multiple indications	Greater China**	China[c]	SELLAS Group
3D229[3]	GAS6/AXL	Healthy Volunteers	Greater China**	China — *Completed*	Aravive
		NSCLC/RCC/UC		China[b]	
		PROC		China (MRCT) — Pivotal	
3D1001[4]	COX-2	Post-surgical dental pain/cancer pain	China	China	Haihe Biopharma Group
3D1002[5]	EP-4	Cancer pain/osteoarthritis		China[b]	
3D185[6]	FGFR1/2/3	Locally advanced or metastatic solid tumors	Worldwide	China/US	Haihe Biopharma Group & SIMM
◆ 3D011	TKI prodrug	Advanced malignant solid tumors	Worldwide	China	-
3D197[7]	CD47	Multiple indications	Greater China**	China	ImmuneOncia
3D057[8]	CD3+PD-L1	Multiple indications	Greater China** + Worldwide Priority Transfer right	China[d]	Y-Biologics
3D059[9]	WT1	Multiple indications	Greater China**	China[d]	SELLAS Group
◆ 3D060	Sema4D	Multiple indications	Worldwide	China/US[d]	-
◆ 3D062	KRAS	Multiple indications	Worldwide	China/US[d]	-

★ Co-owned Asset ◆ Proprietary Asset ⚑ Pivotal Trial

* Denotes our Core Product
** Greater China includes China, Hong Kong, Macau and Taiwan region.
*** TRACON is a licensee of envafolimab for the U.S., Canada and Mexico.
[a] Preparing for Phase III clinical trial
[b] Preparing for Phase II clinical trial
[c] Preparing for IND filing
[d] Pre-clinical stage

Abbreviations: MSI-H/dMMR = microsatellite instability-high/mismatch repair deficiency; BTC = biliary tract cancer; NSCLC = non-small cell lung cancer; UC = urothelial cancer; BSC = best supportive care; MRCT = multi-regional clinical trial; G/GEJ = gastric or gastroesophageal junction; TMB-H = tumor mutational burden-High; EC = endometrial cancer; HCC = hepatocellular carcinoma; RCC = renal cell carcinoma; CRC = colorectal cancer; PROC = platinum resistant ovarian cancer; IND = investigational new drug application; BLA = biologics license application; 1L = first-line; 2L+ = second-line or later

Notes:

(1) We maintain the rights to develop envafolimab globally in oncology field through our co-development agreement with Alphamab Group. On December 17, 2020, the NMPA accepted the BLA for envafolimab for previously treated MSI-H/dMMR advanced solid tumors, and our BLA was granted priority review. On November 24, 2021, we received BLA approval for envafolimab for the treatment of previously treated MSI-H/dMMR advanced solid tumors. On January 16, 2020, the FDA granted envafolimab with orphan drug designation for the treatment of advanced BTC. On June 28, 2021, the FDA granted envafolimab with orphan drug designation for the treatment of soft tissue sarcoma. The commencement of each of the clinical trials for the treatment of previously treated MSI-H/dMMR advanced solid tumors, advanced BTC and G/GEJ cancer were based on the initial safety and efficacy data across multiple dose levels from the three then-ongoing Phase I clinical trials in advanced solid tumors in China, the U.S., and Japan.

(2) We own the exclusive rights to develop, manufacture and commercialize 3D189 in China, Hong Kong, Macau and Taiwan region for all therapeutic and other diagnostic uses through our exclusive license agreement with SELLAS Group. We obtained the IND approval for 3D189 in China in March 2022 and we plan to join the MRCT with our partner SELLAS Group. 3D189 has been granted fast track and orphan drug designations by the FDA for the treatment of AML.

(3) We own the exclusive rights to develop, manufacture and commercialize products that contain 3D229 as the sole drug substance, for the diagnosis, treatment or prevention of human oncological diseases, in China, Hong Kong, Macau and Taiwan region through our collaboration and license agreement with Aravive. Stanford licensed the technology that is used by Aravive to develop 3D229 and Aravive licensed 3D229 to us. We completed the Phase I clinical trial in healthy volunteers in China in May 2022. In addition, we received the IND approval for 3D229 for a Phase III clinical trial in patients with PROC in China in July 2021 to participate in the MRCT, and we initiated this Phase III clinical trial in China in February 2022.

(4) We own the exclusive rights to develop, manufacture and commercialize 3D1001 in China in the pain indication field through our license agreement with Haihe Biopharma Group.

(5) We own the exclusive rights to develop, manufacture and commercialize 3D1002 in China in the pain indication field through our license agreement with Haihe Biopharma Group.

(6) We own the exclusive rights to develop, manufacture and commercialize 3D185 globally in the oncology and pulmonary fibrosis treatment through our patent license agreements with Haihe Biopharma and Shanghai Institute of Materia Medica, Chinese Academy of Sciences.

(7) We own the exclusive rights to develop, manufacture and commercialize 3D197 in China, Hong Kong, Macau and Taiwan region in respect of oncology indications through our exclusive license agreement with ImmuneOncia.

(8) We own the exclusive rights to develop, manufacture and commercialize 3D057 in China, Hong Kong, Macau and Taiwan region for all therapeutic areas through our license agreement with Y-Biologics.

(9) We own the exclusive rights to develop and commercialize 3D059 in China, Hong Kong, Macau and Taiwan region for all therapeutic and other diagnostic uses through our exclusive license agreement with SELLAS Group. MSK licensed certain know-how relating to 3D059 to SELLAS, which in turn sub-licensed the same to us.

† The study included an interim analysis after the first 100 patients were enrolled (considered to be equivalent to a Phase II clinical trial) in the pivotal Phase III clinical trial for the treatment of advanced BTC, which has been designed with reference to the sufficient regulatory basis as described below. As advised by our PRC Legal Advisers, according to the Technical Guiding Principles of Clinical Trials of Anti-tumor Drugs (抗腫瘤藥物臨床試驗技術指導) effective as of May 15, 2012, the clinical studies of anti-tumor drugs are generally divided into phase I, phase II and phase III clinical trials. The primary objectives of a phase I clinical trial include the preliminary studies of the tolerability and pharmacokinetics profile of the drugs, which provides data support to the dosage regimen design of subsequent studies. A phase II clinical trial is typically an exploratory study, such as the exploration of administration dosage, the exploration of dosage regimen and the exploration of efficacy, and includes the observation of safety. A phase III clinical trial further confirms the benefits for cancer patients on top of the results of the phase II clinical trial, and provide adequate evidence for obtaining marketing approval. However, the phases of the aforementioned clinical studies are not necessarily fixed. For instance, an exploratory study (i.e. phase II clinical trial) may also be a part of a phase III clinical trial. Specifically, a phase III clinical trial requires to generate efficacy data of clinical benefit and the duration of the phase III trial is relatively long. Therefore, a phase III clinical trial may include an element of exploratory research allowing the adjustments of its the clinical trial protocol or conduct pursuant to the interim analysis and accumulated information. In the field of oncology clinical research, the objectives of a traditional phase II study are increasingly commonly achieved through an expanded Phase I study design or by introducing an interim analysis in the phase III study. This approach has enabled a more efficient clinical development of oncology drugs in recent years.

- **Envafolimab (KN035)**: Our envafolimab (brand name: ENWEIDA, 恩維達®) is a subcutaneously-injectable PD-L1 inhibitor for the treatment of tumor-agnostic indications, and it has been approved in China for the treatment of previously treated MSI-H/dMMR advanced solid tumors. Envafolimab is a fusion protein of single domain PD-L1 antibody and we are solely responsible for, and are conducting its clinical development in the oncology field. We initially focused on the indication of MSI-H/dMMR for envafolimab. As it has the potential to create significant synergies with other drug candidates as a result of its broad activity across multiple tumor types, we adopt a forward-looking approach to choose to focus on other indications, some of which have high risk for recurrence and metastasis such as hepatocellular carcinoma (HCC), urothelial carcinoma (UC) and renal cell carcinoma (RCC), which have significant potential for combination therapy. On December 17, 2020, the NMPA accepted the BLA for envafolimab for the treatment of previously treated MSI-H/dMMR advanced solid tumors, and our BLA was granted priority review. On November 24, 2021, we received BLA approval for this indication from the NMPA. In addition, envafolimab has undergone an exploratory Phase II clinical trial in China in advanced gastric or gastroesophageal junction (G/GEJ) cancer, and is currently being evaluated in two ongoing pivotal clinical trials including a Phase III clinical trial in patients with advanced biliary tract carcinoma (BTC) in China, and a Phase II clinical trial in selected types of advanced sarcoma (SC) in the U.S. sponsored by our partner TRACON. On January 16, 2020, the FDA granted envafolimab with orphan drug designation for the treatment of advanced BTC. On June 28, 2021, the FDA granted envafolimab with orphan drug designation for the treatment of soft tissue sarcoma.

- **Galinpepimut-S (3D189)**: Our 3D189 is a peptide cancer vaccine with potential to create synergies in combination with PD-1/PD-L1 therapies including with our envafolimab. 3D189 is currently being evaluated by our partner SELLAS Group in an ongoing Phase III pivotal trial in the U.S. and Europe for the treatment of AML, and has been granted fast track and orphan drug designations by the FDA for the treatment of AML. 3D189 targets the Wilms Tumor 1 (WT1) protein which is present and over-expressed in an array of hematological malignancies and solid tumors. Through combination therapies, 3D189 has potential to target over 20 types of cancers (including lung cancer and CRC) that over-express WT1 and, due to its ability to induce strong T-cell immune response, is designed to prevent or delay relapses (by prolonging the progression-free interval) and potentially prolong survival in these patients. We obtained the IND approval for 3D189 in China in March 2022 and plan to join the MRCT with our partner SELLAS Group.

- **3D229**: Our 3D229 is a GAS6 decoy receptor that is being evaluated by our partner Aravive in a Phase III pivotal trial in the U.S. and Europe for the treatment of PROC. We received the IND approval for Phase I clinical trial in healthy volunteers in China in May 2021 and completed this Phase I clinical trial in May 2022. We obtained the IND approval for a Phase Ib/II clinical trial in patients with NSCLC, RCC and UC in April 2022. We plan to join Aravive's Phase III pivotal trial to

enable BLA submissions across multiple jurisdictions including China, and we obtained the IND approval for 3D229 for a Phase III clinical trial in patients with PROC in China in July 2021 to participate in the MRCT, and we initiated this Phase III clinical trial in China in February 2022. Research has shown GAS6-AXL signaling to be a key molecular pathway that promotes tumor invasion and metastasis, as well as development of resistance to chemotherapy, targeted therapy and immuno-therapy. Through combination therapies including with envafolimab, 3D229 has the potential to address unmet medical needs to treat multiple tumor types including lung cancer, ovarian cancer (OC), renal cell carcinoma (RCC) and UC.

- **3D011**: Our 3D011 is an in-house discovered tyrosine kinase inhibitor (TKI) prodrug that will be developed as monotherapy and in combination with other agents for the treatment of solid tumors. In pre-clinical studies, 3D011 has demonstrated a better safety profile compared to its parent drug while maintaining efficacy, justifying its clinical development in advanced prostate cancer, HCC, and RCC. We received the IND approval from the NMPA in January 2021, and we initiated this Phase I clinical trial in February 2022.

- **3D185**: Our 3D185 is a fibroblast growth factor receptors (FGFR) 1-3 and colony stimulating factor 1 receptor (CSF1R) inhibitor that is expected to both inhibit tumor cells and remodel the tumor microenvironment to synergistically antagonize tumors and delay the development of resistance to FGFR inhibitors alone. The IND approval was obtained from the NMPA in January 2018. We received the IND approval from the FDA in September 2019. We completed the Phase I clinical trial in patients with advanced solid tumors in China and the U.S. in August 2021. As of the Latest Practicable Date, a new formulation of 3D185 was being studied in a Phase I clinical trial. 3D185 has the potential to be used in combination with our envafolimab.

- **3D1001**: Our 3D1001 is a third-generation cyclooxygenase-2 (COX-2) inhibitor with rapid onset of action and prolonged pain relief to patients with post-surgical dental pain in clinical study attributable to a favorable PK profile. The IND approval was obtained from the NMPA in February 2019. We plan to develop 3D1001 for the treatment of post-surgical dental pain and potentially other pain indications, including cancer pain management. We are preparing for a Phase I/II clinical trial for 3D1001 oral solution.

- **3D1002**: Our 3D1002 is an E-type prostanoid receptor 4 (EP4) inhibitor that has the potential for improved safety profile compared to COX1/2 inhibitors. 3D1002 has demonstrated favorable safety profile and promising efficacy results in phase I/II clinical studies. The IND approval was obtained from the NMPA in July 2018. We plan to develop 3D1002 for the treatment of cancer pain and osteoarthritis.

- **3D197**: Our 3D197 is a next-generation fully human anti-CD47 IgG4 monoclonal antibody with potentially better safety profile that is expected to treat hematological malignancies and solid tumors. We obtained the IND approval for 3D197 in China in January 2022.

- **Our Pre-Clinical Stage Drug Candidates**: In addition to our clinical-stage drug candidates, we are also evaluating a number of promising pre-clinical stage drug candidates in our rich pipeline, including, (a) 3D057, our bispecific antibody drug which targets CD3 receptor of T-cells and PD-L1 of tumor cells, (b) 3D059, our next-generation immunotherapeutic which targets the WT1 protein in hematological malignancies and solid tumors, (c) 3D060, our in-house developed monoclonal antibody which targets Semaphorin 4D (Sema4D) of tumor cells, and (d) 3D062, our in-house developed small molecule for patients with KRAS mutation.

We are led by an experienced management team with a proven track record of leadership responsibilities and successful performance at international drug regulatory agencies, pharmaceutical and biotech companies. Our management team has an average of over 20 years of industry and regulatory experience at reputable organizations such as the FDA, BMS, AstraZeneca and Celgene. Our founder, CEO and Chairman, Dr. Gong, has more than 30 years of industry and academic experience leading and participating in the entire process of new drug development at regulatory agency, various pharmaceutical and biotech companies, and institutions. Led by our management team and supported by our full team with strong execution capabilities, we have adopted a highly systematic approach to the process of screening, identifying, evaluating and developing drug candidates that enhances our comprehensive portfolio for chronic cancer treatment. Our pre-clinical and clinical teams work collaboratively to ensure a seamless transition from discovery to clinical development. We apply efficient clinical study design and disciplined trial execution to achieve shortened timeline in a more cost-effective manner.

We plan to continue to accelerate the development and commercialization of our pipeline products, and further promote our comprehensive competitive capabilities. We have been establishing our internal manufacture capability and sales force, and further enhancing our in-house innovative R&D capability. We believe that these efforts will allow us to reinforce our position in innovative pharmaceutic industry. Our continuous R&D commitments will enhance our competitive advantages in the race to discover, develop and commercialize innovative cancer therapies and help us create and capture more opportunities in the chronic cancer market.

OUR STRENGTHS

We believe that the following core competitive strengths form the foundation of our past success and will continue to help us solidify and enhance our position in a rapidly-growing chronic cancer treatment market:

A major market player in the treatment of cancer as a chronic disease

Due to the increase in chronic cancer patients and the rapid development of continued advances in innovative cancer treatment therapies, the size of the chronic cancer treatment market is expected to grow, which is evidenced by the increasing market size and proportion

of oncology drugs sold outside hospital. According to Frost & Sullivan, the market size of oncology drugs sold outside hospital in China increased from RMB8.3 billion in 2016 to RMB30.8 billion in 2020, representing 6.6% and 15.6% of the China oncology pharmaceutical market, respectively. It is expected to further grow to RMB165.7 billion in 2025 and to RMB379.2 billion in 2030, representing 39.8% and 55.5% of the China oncology pharmaceutical market, respectively.

Significant scientific and clinical advances have been made in the oncology therapeutic area so that many types of cancers can now be controlled and managed as chronic diseases for an extended period of time, thus growing a chronic cancer treatment market that abounds with significant needs and opportunities. A strong evidence to show the trend of treating cancer as a chronic disease is the increase of the overall survival rate of cancer patients in China. For example, according to Frost & Sullivan, the 5-year survival rate of cancer patients in China has reached 40.5% in 2015 from 30.9% in 2005. In the early treatment phase of chronic cancer patients, generally during the first to sixth month after initial diagnosis, patients tend to seek and undergo treatment in tertiary hospitals to improve their survival rate. Due to the distribution of medical resources in China, long-distance treatment could incur significant indirect cost. According to Frost & Sullivan, the indirect costs of cancer treatments including transportation expenses, accommodation expenses is more than twice as the direct costs of cancer treatment in 2019, and increasing indirect costs of cancer treatments shifts cancer patients to choose local hospitals instead of famous tertiary hospitals to the extent possible. According to Frost & Sullivan, the annual growth rate of patients with chronic diseases transferring from tertiary and secondary hospitals to community healthcare institutions has been over 10% since 2017.

We are a major market player in the chronic cancer treatment market, according to Frost & Sullivan. Leveraging the insightful understanding by our management team of the trend of treating cancer as a chronic disease, we have built a complementary pipeline of innovative product and drug candidates to cover all different stages of cancer treatment. Our Core Product envafolimab is a subcutaneously-injectable PD-L1 antibody that has the potential to address an untapped and unmet medical need for the treatment of cancer as a chronic disease. In contrast to all of the marketed PD-1/PD-L1 inhibitors that are required to be administered intravenously, our subcutaneously-injectable envafolimab offers the following advantages:

- *Favorable safety and consistent efficacy*. Based on available clinical data, compared to other marketed PD-1/PD-L1 inhibitors, envafolimab has shown favorable safety profile and consistent efficacy results in clinical trials. Based on available clinical data, envafolimab has a low immune-related pneumonitis rate and no infusion-related reactions.

- *Better patient compliance with increased convenience*. According to the phase III HannaH study of Roche's Herceptin Hylecta, intravenous infusion takes a long time, usually 30-60 minutes, with large dose, potential for irritation and increased adverse reactions, while the subcutaneous injection time is much shorter, usually 2-5 minutes for conventional antibodies formulated for subcutaneous injection. In the

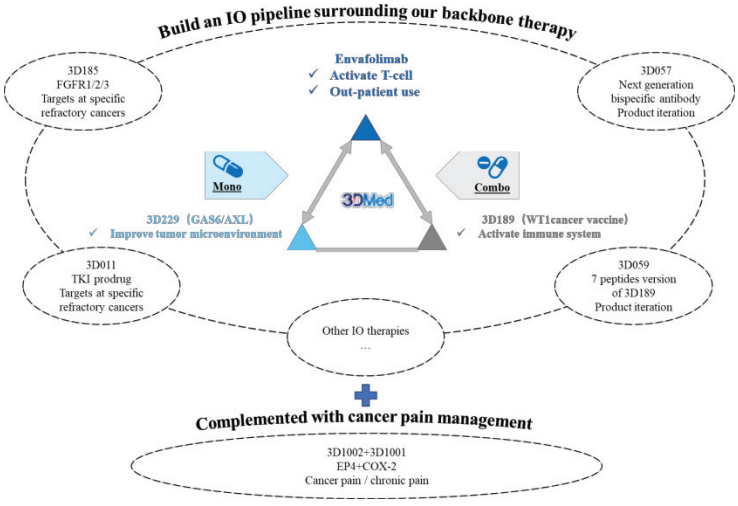
case of envafolimab, the subcutaneous injection takes less than 30 seconds to inject 0.75ml (150 mg). In addition, the observation time for subcutaneous injection is also shorter than for intravenous infusion. Furthermore, while intravenous infusion is usually operated in tertiary hospitals, the subcutaneous injection method allows patients to be injected in outpatient departments and county-level hospitals or community clinics.

- *Wider patient coverage*. According to Ann Emerg Med. 2005 Nov;46(5):456-61. and J Clin Nurs. 2019 Jun;28(11-12):2206-2213, around 10% cancer patients may not be eligible for intravenous formulation due to limited vein access caused by long-term and numerous drug treatments, and subcutaneous injections could be used in patients who are not eligible for intravenous administration to address the unmet medical need.

- *More cost-effective*. In addition to lower production costs, patients would also benefit from lower transportation and accommodation costs as subcutaneous injections can be administered at a wider range of facilities and institutions nearby, such that envafolimab may result in lower indirect cancer treatment cost as a whole.

Therefore, safe and convenient administration of PD-1/PD-L1 subcutaneously is expected to expand application scenarios and further increase the penetration rate among cancer patients, with the potential to expand to the market of oncology drugs sold outside of hospital. Our Core Product envafolimab gives us first mover advantage in the market. Furthermore, we have been building deep entry barriers in the chronic cancer treatment market by focusing on combinational therapies that treat cancer through complementary mechanisms with potential for substantial synergistic effects. We believe this approach will allow us to systemically and effectively tackle tumors, and to significantly improve the response and survival rates of cancer patients.

A multi-mechanism and highly synergetic pipeline of innovative drugs



Our vibrant chronic cancer treatment ecosystem focuses on immuno-oncology therapies which is supported by cancer-related pain management solutions. As we strive to explore and capture oncology market opportunities, through both in-house discovery and external licensing of highly innovative products, we have assembled and are developing a portfolio of therapies for the treatment of cancer as a chronic disease. Over the years since our inception, we have maintained tremendous R&D investment, adopted a forward-looking multi-stream strategy and built cutting-edge technological expertise, thus culminating in a deep pipeline of product and drug candidates that cover multiple therapeutic targets/pathways and employ diverse mechanisms of actions for chronic cancer treatment. In 2020 alone, we have had one BLA accepted, seven clinical trials ongoing, six IND applications submitted, and six drug candidates in-licensed. Our pipeline products not only show differentiated properties in pre-clinical and/or clinical studies, but also have potential for synergy when used in combination with each other, promising broad clinical application prospects and market potential.

Our pipeline is pillared by our fusion protein of single domain PD-L1 antibody envafolimab. Led by envafolimab, our innovative therapeutic pipeline consists of products that are designed and being developed to address critical therapeutic targets and employ diverse validated mechanisms for the treatment of a broad spectrum of cancer indications, and each product and drug candidate can potentially be utilized both as a monotherapy and in combination with other therapies that together may unleash potentially breakthrough efficacy. Our other drug candidates have promising potential to synergize with envafolimab to better guide the human immune system to fight cancer and prolong the survival of cancer patients. 3D189 may potentially create good synergy with envafolimab by increasing the proportion of patients who develop an immune response against their cancer and prolonging the duration of such a response by induction of memory T cells. 3D229 may also potentially achieve good synergy with PD-1/PD-L1 antibodies including envafolimab as it has the potential to treat invasive cancers that are outside the treatment scope of PD-1/PD-L1 and may overcome resistance to PD-1/PD-L1 antibodies. In addition, our in-house developed 3D011 also has the potential to be used in combination with our envafolimab for the treatment of solid tumors.

Furthermore, our R&D investment in safe and effective cancer-related pain management solutions, including 3D1001 and 3D1002, is expected to help us achieve the goal of helping cancer patients live better with reduced cancer related symptom burden.

Successful exploration of innovative oncology therapies with resources consolidation, business development, clinical development and registration capabilities

The global oncology drug market has expanded significantly in the past several years, and is expected to further expand at an accelerated pace. To strategically expand our business in an effective and efficient manner, we have selectively integrated industry resources by exploring innovative oncology therapies through collaboration with strategic partners with complementary resources, and acquired innovative drug candidates that are complementary to our existing product and drug candidates with significant clinical and commercial potential. Leveraging our outstanding R&D capabilities, we have formed collaborations with reputable domestic and multinational pharmaceutical and biotech companies such as Alphamab Group,

Simcere Group, TRACON, SELLAS Group, Aravive, Haihe Biopharma Group, Y-Biologics and ImmuneOncia, and we have also become their trusted partner with respect to research and clinical development. The collaboration with our partners has also allowed us to save costs, minimize risks and strengthen R&D capabilities, which further enables us to deploy sufficient resources to our R&D process.

To ensure maximized commercial value of our product and drug candidates, we have also sought strategic collaboration opportunities worldwide. We have established long-term relationships with industry experts, scholars and regulators through years of endeavors in the R&D of innovative drugs, which enable us to closely follow the latest development in scientific research and clinical practices and the latest changes in applicable regulatory policies. We have worked with reputable PIs to carry out various clinical trials to realize the clinical and commercial value of our product and drug candidates. We have pursued business collaborations with our partners in terms of joint development and commercialization of our product and drug candidates in international markets. For example, we have collaborated with TRACON to carry out clinical trials for envafolimab in patients with soft tissue sarcoma in the U.S., Canada and Mexico, with the majority of the development activities expected to occur in the U.S. Such collaboration is a validation of envafolimab's development strategy as we leverage TRACON's local expertise and efficiently facilitate our market entry in the U.S. While focusing on the Chinese market, we have been committed to realizing the clinical and market potential of our product and drug candidates.

We have carefully considered patient needs as a starting point of our R&D efforts, evaluated the commercialization potential of drug candidates and made product screening decisions based on the mission to treat cancer as a chronic disease. Since inception, we have maintained long-term and effective R&D investment. In 2020, 2021 and for the five months ended May 31, 2022, our R&D expenses reached RMB264.0 million, RMB371.2 million and RMB138.3 million, respectively. As of the Latest Practicable Date, our patent portfolio consisted of 87 patents/patent applications that were owned/co-owned by or licensed to us (including 57 outside of China), including 26 for our Core Product envafolimab. In addition, a large number of publications had been published for our pipeline assets, including 16 publications for our Core Product envafolimab.

Full research and clinical development capabilities with proven track record from discovery to NDA stage

We have a proven track record from discovery to NDA stage, which demonstrates our full research and clinical development capabilities. Our R&D platform has strong molecule screening and design capabilities that increase the possibility of success of moving molecules from pre-clinical studies to market, enable innovative therapeutic approaches and support rich pipeline assets built around key pathways and targets. Our R&D centers in Shanghai and Beijing include large and small molecule platforms, complete cell line screening platforms, high-throughput compound screening platforms and comprehensive animal models. Our strong R&D capabilities can be demonstrated by our in-house developed 3D011 which received the IND approval in January 2021. During the clinical development stage, we manage clinical

trials and carry out a comprehensive suite of clinical development activities in-house, supplemented by CROs as needed, including clinical trial design, medical monitoring, operation, data management, statistics, programming, and pharmacovigilance. As of the Latest Practicable Date, we had obtained 16 IND approvals and implemented 12 Phase II/III clinical studies. We have accumulated comprehensive experience and strong ability to independently complete the entire drug development process from pre-clinical research to clinical development and to NDA/BLA filings.

Our R&D team works collaboratively to ensure a seamless transition from pre-clinical discovery to clinical development. We apply efficient clinical study design and disciplined trial execution to achieve shortened timeline while reducing overall costs. For example, we spent only four years moving envafolimab from the IND stage to the NDA/BLA stage. Historically, innovative oncology drugs like envafolimab took approximately five to six years to move from the IND stage to the NDA/BLA stage, according to Frost & Sullivan. Leveraging trial management and technological expertise of our clinical team, we have successfully enrolled nearly a thousand patients in clinical trials in multiple countries and regions. We are also one of the early pioneers to apply advanced drug discovery and development technologies to minimize false starts and optimize the structure of lead compounds in drug discovery.

Internationally skilled management and R&D team

We are led by an experienced management team with successful performance in the fields of international drug regulatory agencies, pharmaceutical and biotech companies. We specialize in the entire drug R&D process from pre-clinical research to clinical development and to commercialization. Our management team has an average of 20 years of industry experience at reputable organizations such as the FDA, BMS, AstraZeneca and Celgene. Led by Dr. Gong, CEO and Chairman, our outstanding management team has attracted a large number of professionals. As of Latest Practicable Date, our R&D team has a total of 151 employees, 82 of which have a master's degree or higher, including 17 with doctor's degrees. Our drug discovery and translational research function is led by Dr. Yihui Lin, our Head of Translational Medicine Center, and our clinical development team is led by Dr. Dongfang Liu, our Chief Medical Officer. The two functions have been working seamlessly to drive our R&D process.

Our founder, Chairman and CEO, Dr. Gong, has more than 30 years of experience leading and participating in the entire process of new drug development at various pharmaceutical and biotech companies and institutions, including 10 years working at the FDA as a new drug reviewer. Dr. Gong has extensive experience in new drug R&D, including strategic planning, pre-clinical and clinical trial design, Good Laboratory Practice (GLP) and Good Clinical Practice (GCP) regulations, new drug project evaluation, coordination in advancing pre-clinical trials and clinical trials, and risk control and management throughout drug development programs.

Dr. Dongfang Liu, our Chief Medical Officer, has more than 20 years of experience in clinical oncology practice and R&D and has led several clinical development programs resulting in approvals in the U.S., China and Europe, including the approval of nivolumab in China for second-line treatment of non-small cell lung cancer (NSCLC), and the approval of Revlimid plus rituximab (R2) in China, the U.S. and Europe for the treatment of previously treated follicular lymphoma or marginal zone lymphoma.

Dr. Shen Xiao, our Chief Strategic Officer, is responsible for directing and overseeing company strategies and regulatory affairs. He has around 20 years of experiences in FDA where he was primarily responsible for the review and approval of new drug applications. He had led the review of various development stages of hundreds of new drugs and approved more than ten new drugs. Dr. Xiao holds a Ph.D. in kidney physiology and cell biology from West Virginia University in the U.S.

Dr. Yihui Lin, our Head of Translational Medicine Center, has more than 10 years of experience in biomarker validation and translational medicine. Dr. Lin holds a Ph.D. from the Center for Excellence in Molecular Cell Science of Chinese Academy of Sciences.

Led by our management team and supported by our team members, we have adopted a highly systematic approach to the process of screening, identifying, evaluating and developing drug candidates that enhance our comprehensive portfolio for chronic cancer treatment. With the management team's deep industry insights and sound judgment, we have built a synergetic pipeline of innovative product and drug candidates to fully tap the chronic cancer treatment market.

OUR STRATEGIES

We are committed to the discovery, development, and commercialization of safe and effective innovative drugs for chronic cancer treatment, and will further strengthen our position in this market by implementing the following strategies:

Further expand the commercial potential of envafolimab and explore market opportunities

As we already received BLA approval for the treatment of previously treated MSI-H/dMMR advanced solid tumors from NMPA on November 24, 2021, we are leveraging our commercialization resources to quickly penetrate the market and increase our market share, through our collaboration with Simcere Group in connection with the promotion of envafolimab in China. Meanwhile, we will continue to carry out additional clinical studies to expand the addressable indications for envafolimab, such as NSCLC, EC, UC and RCC.

Furthermore, we plan to continue maximizing the commercial value of envafolimab by conducting clinical trials both independently and in collaboration with partners outside of China.

Accelerate the product development to commercialization and further enrich our pipeline

We intend to continue advancing the development of our pipeline drug candidates and fully explore the opportunities for combinational use of pipeline assets in the chronic cancer market. For 3D229, 3D189, and other drug candidates at late clinical stage, we will leverage the clinical data from our partners sponsored clinical trials to advance clinical programs and communicate with regulatory authorities to expedite BLA/NDA submission opportunities in China. For early clinical stage assets, we plan to apply innovative clinical trial designs and efficient clinical strategies to speed up the development process.

Furthermore, our strong business development team will continue conducting foresighted market analysis to seek innovative products that have potential combination synergies with our current pipeline through in-house discovery, licensing or other collaboration arrangements. We also plan to find the most suitable and resourceful partners for strategic collaboration on R&D and commercialization to maximize the clinical and commercial value of innovative therapies and our product and drug candidates.

Further enhance our in-house innovative R&D capability

We intend to further invest in in-house discovery to capture market opportunities and treat cancer patients around the world. The development of novel cancer therapeutics requires industry-leading technologies and know-how that are rapidly upgrading and evolving. Therefore, we will continue to strengthen and optimize our drug discovery and development platforms that integrate cutting-edge technologies and deep know-how in drug design and development, particularly our large molecule platform, small molecule platform and cell line screening platform, which aid our efforts to accelerate the timeline from discovery to approval of innovative products and drug candidates. We currently cooperate with XtalPi and plan to further cooperate with other third parties to further integrate AI-enabled digital drug R&D infrastructure for drug development and efficiency enhancement. We will also continue to leverage our experience from the collaboration with reputable partners to further strengthen our R&D capabilities.

In addition, we will also continue to invest in pre-clinical R&D to identify pipeline assets that cover a wider spectrum of cancer indications, and actively conduct research to evaluate the combination effects of our pipeline candidates. We will continue to screen and design innovative molecules with differentiated characteristics to meet clinical needs by focusing on key targets, pathways and mechanisms of actions. We believe that these R&D commitments will enhance our competitive advantages in the race to discover, develop and commercialize innovative cancer therapies and help us capture more opportunities in the chronic cancer market.

Further establish GMP manufacturing capability and strengthen commercialization capability

We are establishing our internal manufacture capability and continue optimizing management processes to strengthen the operational capabilities of our platform. We have been building manufacturing system and facilities throughout the drug development process, including chemical drugs and biologics, in Xuzhou, Jiangsu Province in compliance with cGMP-standards that cover an area of 65,637.97 square meters. We have obtained the construction permit and started construction of new manufacturing facilities in Xuzhou. We believe optimization of our management process and expansion of our manufacture capabilities will prepare us better for the manufacturing and commercialization of our product and drug candidates.

In addition, we plan to adopt a localized commercial approach, focus on medical-driven promotion strategies, and intend to establish suitable commercialization strategy based on each product or drug candidate's characteristics and market coverage to quickly and efficiently achieve commercial success. For sales of drug candidates in niche but underserved markets, we plan to build our in-house commercial team by recruiting experienced senior-level sales and marketing personnel to support and facilitate the commercialization of our drug candidates. For sales of multi-indication drug candidates in highly competitive markets and drug candidates with extensive patient coverage, we will work with most suitable collaboration partners such as contract sales organizations (CSOs) to leverage their sales and marketing expertise, well-established business networks and experienced teams. For sales of drug candidates outside China, we also intend to seek strategic collaboration opportunities with local expertise for commercialization. We believe these strategic collaborations could expedite commercialization process of potential products and help us capture a substantial share of the chronic cancer treatment market.

Continue to attract, cultivate and retain talents

Our employees are key to our strategy and ability to develop and commercialize innovative drugs, and hence we will continue to recruit, train, promote and retain talents with relevant background and experience in the pharmaceutical and biotech industries. We have established R&D centers in Shanghai and Beijing, and will establish in the U.S. in the future to execute our development strategy and to tap the talent pool of well-trained talents. To fully support our continued growth, we will continue to invest in attracting and retaining top talent in various aspects of our operations around the world, including discovery, research and development, manufacture and commercialization. In addition, in order to ensure our compliance with various standards, such as GLP, GCP and GMP regulations, we will continue to invest in enhancing our talent pool in terms of regulatory compliance.

To attract and retain talent, we are committed to the continued development of a collegial and vibrant corporate culture that inspires and encourages innovation. We will continue to provide our employees with various internal and external training opportunities to help them stay abreast of industry developments and further improve their technical skills. In addition, we

will continue to utilize and optimize our employee incentive schemes to attract and retain highly talented professionals with a passion for building a career in the pharmaceutical and biotech industry. Meanwhile, we will identify leadership talents from an early stage and cultivate them to take on greater responsibilities along with their personal growth through internal training, promotion programs and initiatives. With these measures, we plan to further expand our sustainable talent pool to support our future development.

OUR CORE PRODUCT AND OTHER DRUG CANDIDATES

Our core business model is to discover, research, develop and commercialize oncology products and drug candidates by building a differentiated pipeline of innovative products and drug candidates with a potential to create significant synergy as combination therapies to address global unmet medical needs through a combination of in-house discovery, co-development and in-licensing. Leveraging our strong capabilities in drug discovery, clinical research and development, we have built a pipeline consisting of one Core Product and 11 drug candidates. Among our product and drug candidates, the Core Product envafolimab (brand name: ENWEIDA, 恩維達®), as our backbone, was approved in November 2021 and commercialized in December 2021, and seven are in clinical stage. Three of these product and clinical-stage drug candidates have entered into Phase II/III pivotal trials, two of which are conducted by our collaboration partners. Our Core Product envafolimab, a fusion protein of single domain PD-L1 antibody and fragment crystallizable (Fc), is a subcutaneously injectable single domain PD-L1 antibody. We spent only four years moving envafolimab from the IND stage to the BLA stage. In December 2020, the NMPA accepted our BLA for envafolimab as a monotherapy in the treatment of previously treated MSI-H/dMMR advanced solid tumors based on results from our completed pivotal trials in China, and our BLA was granted priority review. On November 24, 2021, we received BLA approval for this indication from the NMPA, and we are the marketing authorization holder (MAH). It has been approved in China for the treatment of previously treated MSI-H/dMMR advanced solid tumors. Envafolimab is currently being evaluated in two other ongoing pivotal clinical trials including a randomized Phase III clinical trial in combination with gemcitabine and oxaliplatin in patients with advanced biliary tract carcinoma (BTC) in China, and a Phase II clinical trial as monotherapy and in combination with ipilimumab in selected types of advanced sarcoma (SC) in the U.S. sponsored by our partner TRACON.

Our peptide cancer vaccine 3D189 (also known as Galinpepimut-S) is currently being evaluated by our partner SELLAS Group in an ongoing Phase III pivotal trial in the U.S. and Europe for the treatment of acute myeloid leukemia (AML) and we obtained the IND approval in China in March 2022. Our GAS6 decoy receptor 3D229 (also known as batiraxcept, AVB-500) was submitted the IND in March 2021 and received the IND approval in China in May 2021 and is being evaluated by our partner Aravive in a Phase III pivotal trial in the U.S. and Europe for the treatment of platinum resistant ovarian cancer (PROC). We plan to join both aforementioned advanced trials to expedite our development and commercial process in China.

With technologies and industry know-how accumulated by our management team over 20 years, we have established a pharmaceutical discovery and clinical R&D platform which serves as the foundation of our continuous innovations. Leveraging such platform, we have developed a synergetic pipeline of product and drug candidates.

The following chart summarizes the development status of our product, clinical-stage drug candidates and selected pre-clinical stage drug candidates as of the Latest Practicable Date:

Candidate	Target/ Mechanism	Indications/Study Population	Rights	Preclinical Discovery	IND	Phase I	Phase II	Pivotal/Phase III	NDA	Partner
★ Envafolimab*[1]	PD-L1	MSI-H/dMMR advanced cancer (mono, 2L+)	Worldwide	China					*BLA approved*	Alphamab Group, Simcere Group, (CSO)
		Advanced BTC (combo with chemo vs. chemo, 1L)†		China						
		NSCLC (vs standard treatment)		China[a]						
		NSCLC (combo with chidamide, 2L+)		China						
		UC (mono vs. BSC, 1L maintenance, MRCT)		China, EU, Japan[a]						
		G/GEJ advanced cancer (combo with chemo, 1L)		China						
		TMB-H advanced cancer (mono, 2L+)		China						
		EC (mono and combo with lenvatinib, 2L+)		China						TRACON*** (Sarcoma, Phase II)
		NSCLC, HCC, RCC (combo with lenvatinib)		China						
		HCC, CRC, NSCLC (combo with BD0801)		China						
		Microsatellite stable CRC (combo with cetuximab)		China[b]						
3D189[2]	WT1	Multiple indications	Greater China**	China[c]						SELLAS Group
3D229[3]	GAS6/AXL	Healthy Volunteers	Greater China**	China		*Completed*				Aravive
		NSCLC/RCC/UC		China[b]						
		PROC		China (MRCT)						
3D1001[4]	COX-2	Post-surgical dental pain/cancer pain	China	China						Haihe Biopharma Group
3D1002[5]	EP-4	Cancer pain/osteoarthritis		China[b]						
3D185[6]	FGFR1/2/3	Locally advanced or metastatic solid tumors	Worldwide	China/US						Haihe Biopharma Group & SIMM
◆ 3D011	TKI prodrug	Advanced malignant solid tumors	Worldwide	China						-
3D197[7]	CD47	Multiple indications	Greater China**	China						ImmuneOncia
3D057[8]	CD3+PD-L1	Multiple indications	Greater China** + Worldwide Priority Transfer right	China[d]						Y-Biologics
3D059[9]	WT1	Multiple indications	Greater China**	China[d]						SELLAS Group
◆ 3D060	Sema4D	Multiple indications	Worldwide	China/US[d]						-
◆ 3D062	KRAS	Multiple indications	Worldwide	China/US[d]						-

★ Co-owned Asset ◆ Proprietary Asset ⚑ Pivotal Trial

* Denotes our Core Product
** Greater China includes China, Hong Kong, Macau and Taiwan region.
*** TRACON is a licensee of envafolimab for the U.S., Canada and Mexico.
[a] Preparing for Phase III clinical trial
[b] Preparing for Phase II clinical trial
[c] Preparing for IND filing
[d] Pre-clinical stage

Abbreviations: MSI-H/dMMR = microsatellite instability-high/mismatch repair deficiency; BTC = biliary tract cancer; NSCLC = non-small cell lung cancer; UC = urothelial cancer; BSC = best supportive care; MRCT = multi-regional clinical trial; G/GEJ = gastric or gastroesophageal junction; TMB-H = tumor mutational burden-High; EC = endometrial cancer; HCC = hepatocellular carcinoma; RCC = renal cell carcinoma; CRC = colorectal cancer; PROC = platinum resistant ovarian cancer; IND = investigational new drug application; BLA = biologics license application; 1L = first-line; 2L+ = second-line or later

Notes:

(1) We maintain the rights to develop envafolimab globally in oncology field through our co-development agreement with Alphamab Group. On December 17, 2020, the NMPA accepted the BLA for envafolimab for previously treated MSI-H/dMMR advanced solid tumors, and our BLA was granted priority review. On November 24, 2021, we received BLA approval for envafolimab for the treatment of previously treated MSI-H/dMMR advanced solid tumors. On January 16, 2020, the FDA granted envafolimab with orphan drug designation for the treatment of advanced BTC. On June 28, 2021, the FDA granted envafolimab with orphan drug designation for the treatment of soft tissue sarcoma. The commencement of each of the clinical trials for the treatment of previously treated MSI-H/dMMR advanced solid tumors, advanced BTC and G/GEJ cancer were based on the initial safety and efficacy data across multiple dose levels from the three then-ongoing Phase I clinical trials in advanced solid tumors in China, the U.S., and Japan.

(2) We own the exclusive rights to develop, manufacture and commercialize 3D189 in China, Hong Kong, Macau and Taiwan region for all therapeutic and other diagnostic uses through our exclusive license agreement with SELLAS Group. We obtained the IND approval for 3D189 in China in March 2022 and we plan to join the MRCT with our partner SELLAS Group. 3D189 has been granted fast track and orphan drug designations by the FDA for the treatment of AML.

(3) We own the exclusive rights to develop, manufacture and commercialize products that contain 3D229 as the sole drug substance, for the diagnosis, treatment or prevention of human oncological diseases, in China, Hong Kong, Macau and Taiwan region through our collaboration and license agreement with Aravive. Stanford licensed the technology that is used by Aravive to develop 3D229 and Aravive licensed 3D229 to us. We completed the Phase I clinical trial in healthy volunteers in China in May 2022. In addition, we received the IND approval for 3D229 for a Phase III clinical trial in patients with PROC in China in July 2021 to participate in the MRCT, and we initiated this Phase III clinical trial in China in February 2022.

(4) We own the exclusive rights to develop, manufacture and commercialize 3D1001 in China in the pain indication field through our license agreement with Haihe Biopharma Group.

(5) We own the exclusive rights to develop, manufacture and commercialize 3D1002 in China in the pain indication field through our license agreement with Haihe Biopharma Group.

(6) We own the exclusive rights to develop, manufacture and commercialize 3D185 globally in the oncology and pulmonary fibrosis treatment through our patent license agreements with Haihe Biopharma and Shanghai Institute of Materia Medica, Chinese Academy of Sciences.

(7) We own the exclusive rights to develop, manufacture and commercialize 3D197 in China, Hong Kong, Macau and Taiwan region in respect of oncology indications through our exclusive license agreement with ImmuneOncia.

(8) We own the exclusive rights to develop, manufacture and commercialize 3D057 in China, Hong Kong, Macau and Taiwan region for all therapeutic areas through our license agreement with Y-Biologics.

(9) We own the exclusive rights to develop and commercialize 3D059 in China, Hong Kong, Macau and Taiwan region for all therapeutic and other diagnostic uses through our exclusive license agreement with SELLAS Group. MSK licensed certain know-how relating to 3D059 to SELLAS, which in turn sub-licensed the same to us.

† The study included an interim analysis after the first 100 patients were enrolled (considered to be equivalent to a Phase II clinical trial) in the pivotal Phase III clinical trial for the treatment of advanced BTC, which has been designed with reference to the sufficient regulatory basis as described below. As advised by our PRC Legal Advisers, according to the Technical Guiding Principles of Clinical Trials of Anti-tumor Drugs (抗腫瘤藥物臨床試驗技術指導) effective as of May 15, 2012, the clinical studies of anti-tumor drugs are generally divided into phase I, phase II and phase III clinical trials. The primary objectives of a phase I clinical trial include the preliminary studies of the tolerability and pharmacokinetics profile of the drugs, which provides data support to the dosage regimen design of subsequent studies. A phase II clinical trial is typically an exploratory study, such as the exploration of administration dosage, the exploration of dosage regimen and the exploration of efficacy, and includes the observation of safety. A phase III clinical trial further confirms the benefits for cancer patients on top of the results of the phase II clinical trial, and provide adequate evidence for obtaining marketing approval. However, the phases of the aforementioned clinical studies are not necessarily fixed. For instance, an exploratory study (i.e. phase II clinical trial) may also be a part of a phase III clinical trial. Specifically, a phase III clinical trial requires to generate efficacy data of clinical benefit and the duration of the phase III trial is relatively long. Therefore, a phase III clinical trial may include an element of exploratory research allowing the adjustments of its the clinical trial protocol or conduct pursuant to the interim analysis and accumulated information. In the field of oncology clinical research, the objectives of a traditional phase II study are increasingly commonly achieved through an expanded Phase I study design or by introducing an interim analysis in the phase III study. This approach has enabled a more efficient clinical development of oncology drugs in recent years.

1. Our Core Product

a. Envafolimab

Envafolimab (brand name: ENWEIDA, 恩維達®), also known as KN035, a fusion protein of single domain PD-L1 antibody and Fc, is a subcutaneously injectable PD-L1 antibody, and it has been approved in China for the treatment of previously treated MSI-H/dMMR advanced solid tumors. Compared with the other approved PD-1/PD-L1 antibodies, our envafolimab has demonstrated favorable clinical safety profile and consistent clinical efficacy results, and it potentially has better patient compliance with increased convenience, wider patient coverage and may reduce indirect cancer treatment cost for patients. Envafolimab has been well acknowledged by the Chinese clinical oncology community and recommended by three updated Chinese Society of Clinical Oncology (CSCO) 2022 Guidelines, including: (1) CSCO Guidelines for Gastric Cancer 2022 Version (Class I recommendation, Level 2A evidence); (2) CSCO Guidelines for Colorectal Cancer 2022 Version (Class II recommendation, Level 2A evidence), and (3) CSCO Guidelines for Clinical Application of Immune Checkpoint Inhibitors 2022 Version (Class I recommendation, Level 2A evidence). Envafolimab was in pre-clinical stage when the Co-Development Agreements were first entered into between the Company and Alphamab Group in February 2016. Since then, we have independently completed and been independently conducting a number of clinical trials in relation to envafolimab and achieved a number of major R&D milestones on our own and at our own cost, which amounted to approximately RMB614.9 million as of May 31, 2022, and we have significantly increased our R&D team to 151 members as of the Latest Practicable Date. Pursuant to our Co-Development Agreements with Alphamab Group, we are solely responsible for, and are conducting, global clinical development of envafolimab, which has undergone clinical trials for multiple tumor indications in the U.S., China and Japan.

We have completed a Phase II pivotal trial with single agent envafolimab for the treatment of previously treated MSI-H/dMMR advanced cancer and the results of this trial provided data for the initial BLA submission in China. On December 17, 2020, the NMPA accepted the BLA for envafolimab in the treatment of previously treated MSI-H/dMMR advanced solid tumors, and our BLA was granted priority review. On November 24, 2021, we received BLA approval for this indication from the NMPA. In addition, we have completed an exploratory Phase II clinical trial in China with envafolimab in combination with chemotherapy as a first-line treatment in advanced gastric or gastroesophageal junction (G/GEJ) cancer and three Phase I trials with single agent envafolimab conducted in China, the U.S. and Japan, respectively.

We are currently evaluating envafolimab in late-stage clinical trials covering three tumor indications, in an attempt to address the significantly unmet or underserved medical needs in treating cancer, including (i) a randomized Phase III pivotal clinical trial in China as a first-line therapy in combination with chemotherapy for advanced BTC, (ii) a Phase II pivotal trial in the U.S. as monotherapy and in combination with ipilimumab in selected types of advanced SC sponsored by TRACON, and (iii) a Phase II clinical trial in China for the treatment of TMB-H advanced solid tumors. On January 16, 2020, the FDA granted envafolimab with orphan drug designation for the treatment of advanced BTC. On June 28, 2021, the FDA granted

envafolimab with orphan drug designation for the treatment of soft tissue sarcoma. In addition, a number of new clinical studies investigating single agent envafolimab or envafolimab in combination with other agents for a variety of indications are being initiated or ongoing, including non-small cell lung cancer (NSCLC), urothelial carcinoma (UC), endometrial cancer (EC), hepatocellular carcinoma (HCC), renal cell carcinoma (RCC), and colorectal cancer (CRC).

The commencement of each of the clinical trials for the treatment of previously treated MSI-H/dMMR advanced solid tumors, advanced BTC and G/GEJ cancer (the "**Phase II/III Clinical Trials**") were based on the initial safety, efficacy and PK data across multiple dose levels from Phase I clinical trials in advanced solid tumors in China, the U.S., and Japan (the "**Phase I Clinical Trials**").

Clinical Basis

We had sufficient clinical basis to commence the Phase II/III Clinical Trials based on the initial safety, efficacy and PK data of the Phase I Clinical Trials.

The Phase I Clinical Trials were single-arm, open-label, dose escalation and dose expansion Phase I studies of envafolimab as monotherapy. The Phase I Clinical Trials enrolled various tumor types that served as basis for indication selection in subsequent phase II/III studies including but not limited to the previously treated MSI-H/dMMR advanced solid tumors, advanced BTC and G/GEJ. In other words, the previously treated MSI-H/dMMR advanced solid tumors, advanced BTC, and G/GEJ are types of "advanced solid tumors" already covered by the extensive Phase I Clinical Trials in advanced solid tumors. According to the clinical trial protocols of the Phase I Clinical Trials, the primary endpoints of these trials were safety and tolerability and the secondary endpoints of these trials included PK, efficacy, immunogenicity and recommended phase II dose. As of March 20, 2018 (before the commencement of each of the Phase II/III Clinical Trials), 61 subjects were enrolled in these three Phase I Clinical Trials with dose level ranging from 0.01 mg/kg QW to 10.0 mg/kg QW and the follow-up time of the first patient had reached 57 weeks. Prior to the commencement of the Phase II/III Clinical Trials, the initial safety, efficacy and PK data of the Phase I Clinical Trials were as follows:

- Safety: The safety data across the Phase I Clinical Trials were consistent. No dose limiting toxicity (DLT) occurred and no unexpected safety signal was observed. The occurrence of treatment emergent adverse event (TEAE) were consistent with other marketed PD-1/PD-L1 inhibitors and there was no clear dose-response relationship on safety.

- Efficacy: Among 25 subjects who received at least one post-treatment efficacy assessment, 4 subjects achieved partial response (1 subject in 0.3 mg/kg QW, 1 subject in 1.0 mg/kg QW and 2 subjects in 2.5 mg/kg QW). In particular, 1 subject treated at 2.5 mg/kg QW was subject with MSI-H prostate cancer, which served as the basis for our choice of indication.

- PK Profile: The data generated from the trial in China and the U.S. showed favorable PK profile, which supported the dose level of 2.5 mg/kg QW, 150 mg QW and 5.0 mg/kg Q2W were reasonable dosing regimens, which could be used in these subsequent clinical studies.

After obtaining the initial safety, efficacy and PK data of the Phase I Clinical Trials, we had in-depth discussions with principal investigators regarding such initial safety, efficacy and PK data. We and principal investigators were of the view that, based on above initial safety, efficacy and PK data of the Phase I Clinical Trials, the primary and secondary endpoints had been verified in accordance with the study design requirements of clinical trial protocols. Specifically, envafolimab had showed favorable safety and tolerability profile, promising anti-tumor activities and efficacy signal on specific indications. Therefore, we and principal investigators were of the view that such initial safety, efficacy and PK data could support the commencement of next phase of studies of envafolimab.

Accordingly, the following Phase II/III Clinical Trials were proposed and their protocols were well prepared and signed off by us and principal investigators and approved by the respective ethics committees:

- MSI-H/dMMR (pivotal Phase II): Based on initial safety, efficacy and PK data of the Phase I Clinical Trials, we selected 150 mg QW dose regimen (equivalent of 2.5 mg/kg assuming 60 kg body weight) for the pivotal Phase II clinical trial for the treatment of previously treated MSI-H/dMMR advanced solid tumors. On April 17, 2018, the leading principal investigator signed off the protocol (1.0st version) of this trial. On May 15, 2018, this trial was approved by the ethics committee. On July 25, 2018, this trial was duly registered on the registration and information announcement platform for clinical trials of drugs (the "**Information Platform**", http://www.chinadrugtrials.org.cn/) as required under the relevant NMPA regulations. On August 22, 2018, we enrolled the first patient for this trial.

- Advanced BTC (pivotal Phase III): Based on initial safety, efficacy and PK data of the Phase I Clinical Trials, we selected a dose level of 2.5 mg/kg QW for the pivotal Phase III clinical trial for the treatment of advanced BTC. On December 13, 2017, the leading principal investigator signed off the protocol (1.0st version) of this trial. On December 28, 2017, this trial was approved by the ethics committee. On April 9, 2018, this trial was duly registered on the Information Platform as required under the relevant NMPA regulations. On April 23, 2018, we enrolled the first patient for this trial.

- G/GEJ cancer (Phase II): Based on initial safety, efficacy and PK data of the Phase I Clinical Trials, we selected a dose level of 5.0 mg/kg Q2W for the exploratory Phase II clinical trial for the treatment of G/GEJ cancer. On June 6, 2018, the leading principal investigator signed off the protocol (1.0st version) of this trial. On

June 29, 2018, this trial was approved by the ethics committee. On July 24, 2018, this trial was duly registered on the Information Platform as required under the relevant NMPA regulations. On August 31, 2018, we enrolled the first patient for this trial.

Industry Practice

According to Frost & Sullivan, for PD-1/PD-L1 inhibitors, it is a common industry practice to commence the next phase of clinical studies once the primary endpoints of Phase I studies, being safety and tolerability are verified. Specifically, the Phase I dose escalation studies of marketed PD-1/PD-L1 had studied a series of dose levels ranging from 0.1 mg/1.0 mg/kg to 10.0 mg/kg Q2W and the results had shown that the safety and efficacy profile of PD-1/PD-L1 inhibitors would not change significantly once certain dose level (i.e. 0.3 mg/kg) have been reached, which showed a flat exposure-response (E-R) characteristic on both safety and efficacy. Based on this flat E-R characteristic of PD-1/PD-L1 inhibitors, certain marketed PD-1/PD-L1 inhibitors in the industry commenced their phase II/III studies based on the initial results of their Phase I studies.

The Competent Authority had no objection for us to commence each of the Phase II/III Clinical Trials based on the initial safety, efficacy and PK data from the Phase I Clinical Trials

As advised by our PRC Legal Advisers, according to the laws and regulations in relation to drug clinical trials applicable to the development of the Core Product, prior to commencing a clinical trial, an applicant who has obtained an IND approval shall formulate a drug clinical trial protocol and obtain approval from the ethics committee, and the applicant shall also submit the protocol and supporting documents through the Information Platform. The applicable laws and regulations do not require the applicant who has obtained an umbrella IND approval to submit any additional clinical trial application prior to the commencement of phase II or phase III clinical trial, which means that the applicant does not need to obtain any additional IND approval and there is no additional requirement for such applying for such approval.

Prior to obtaining no objection from CDE to commence the Phase II/III Clinical Trials, neither NMPA nor CDE has raised any additional requirements in relation to the Phase I Clinical Trial in China. We have obtained approvals from ethics committee for each of the Phase II/III Clinical Trials (the "**Ethics Committee Approvals**") and have duly registered each of the Phase II/III Clinical Trials on the Information Platform. Neither the Ethics Committee Approvals nor the information registered on the Information Platform contained any additional requirements raised by the ethics committee or the CDE. Furthermore, in the Regulatory Interview, NMPA/CDE did not raise any additional requirements in relation to the Phase I Clinical Trials in China.

As advised by our PRC Legal Advisers, on the basis that (i) the Umbrella IND Approval granted by the NMPA in December 2016 was a one-time umbrella approval for the clinical trials of envafolimab including all phases of Phase I, Phase II and III, which was confirmed by Frost & Sullivan with reference to the industry practice; (ii) we had consulted CDE regarding the Phase I Clinical Trials and each of the Phase II/III Clinical Trials; (iii) each of the Phase II/III Clinical Trials were duly registered on the Information Platform as required by the relevant PRC rules and regulations; (iv) the consents from ethics committees in relation to each of the Phase II/III Clinical Trials were granted; and (v) the interview with a senior officer of NMPA conducted on February 21, 2022 with the attendance of professional parties (the "**Regulatory Interview**") reconfirms, amongst others, that based on the initial safety, efficacy and PK data across multiple dose levels from the Phase I Clinical Trials, that NMPA had no objection for us to commence each of the Phase II/III Clinical Trials, we have obtained all required approvals from the NMPA to proceed with each of the Phase II/III Clinical Trials and no further approval from the NMPA is required for us to commence each of the Phase II/III Clinical Trials.

In the view of our legal advisers as to intellectual property law, we are exclusively entitled to use the patent in the field of oncology or tumor therapy. Besides, we maintain the rights to develop envafolimab globally in oncology field and obtained all the intellectual property rights relating to envafolimab under the Co-Development Agreements. Please refer to the paragraphs headed "Our Collaboration Arrangements – Collaboration with Alphamab Group for Envafolimab" in this section. Under the Co-Development Agreements, with respect to research and development, we are solely responsible for the clinical stage R&D activities in relation to envafolimab. Since the Co-Development Agreements were first entered into in February 2016, we have independently achieved the following major R&D milestones on our own and at our own costs:

- In November 2016, we received the IND approval for envafolimab from FDA for solid tumors;

- In December 2016, we received an umbrella IND approval for Phase I, II and III trials for envafolimab from NMPA;

- In February 2017, we launched (i.e. the first patient was enrolled) a first-in-human Phase I clinical trial of envafolimab in subjects with advanced solid tumors in the U.S.;

- In March 2017, we launched (i.e. the first patient was enrolled) a Phase I clinical trial of envafolimab in subjects with advanced solid tumors in China;

- In May 2017, we received the IND approval for envafolimab from PMDA for solid tumors;

- In October 2017, we launched (i.e. the first patient was enrolled) a Phase I clinical trial of envafolimab in subjects with advanced solid tumors in Japan;

- In April 2018, we launched (i.e. the first patient was enrolled) a randomized Phase III clinical trial of envafolimab for the treatment of advanced BTC in China;

- In August 2018, we launched (i.e. the first patient was enrolled) a pivotal Phase II clinical trial of envafolimab for the treatment of previously treated MSI-H/dMMR advanced solid tumors;

- In August 2018, we launched (i.e. the first patient was enrolled) an exploratory Phase II clinical trial of envafolimab in combination with chemotherapy for the treatment of advanced G/GEJ cancer in China;

- In January 2020, we received orphan drug designation from FDA for envafolimab for the treatment of advanced BTC;

- In April 2020, we completed the Phase I clinical trial of envafolimab in subjects with advanced solid tumors in China;

- In July 2020, we completed the pivotal Phase II clinical trial of envafolimab for the treatment of previously treated MSI-H/dMMR advanced solid tumors;

- In December 2020, we obtained the BLA acceptance from NMPA for envafolimab for the treatment of previously treated MSI-H/dMMR advanced solid tumors;

- In January 2021, the BLA for envafolimab in the treatment of previously treated MSI-H/dMMR advanced solid tumors was publicly announced to be accepted for priority review by NMPA;

- In February 2021, we completed the exploratory Phase II clinical trial of envafolimab in combination with chemotherapy for the treatment of advanced G/GEJ cancer in China;

- In March 2021, we completed the Phase I clinical trial of envafolimab in subjects with advanced solid tumors in Japan;

- In June 2021, we received the IND approval for envafolimab from NMPA for a Phase Ib/II clinical trial in combination with lenvatinib for the treatment of advanced solid tumors;

- In July 2021, we received the IND approval for envafolimab from NMPA for a Phase II clinical trial in combination with chidamide for the treatment of NSCLC;

- In July 2021, we received the IND approval for envafolimab from FDA for a Phase II clinical trial for the treatment of advanced BTC;

- In July 2021, we received the IND approval for envafolimab from NMPA for a Phase II clinical trial in combination with BD0801 for injection with or without chemotherapy for the treatment of advanced solid tumors;

- In September 2021, we received the IND approval for envafolimab from NMPA for a Phase II clinical trial for the treatment of EC;

- In October 2021, we completed the Phase I clinical trial of envafolimab in subjects with advanced solid tumors in the U.S.; and

- In November 2021, we received BLA approval for envafolimab for the treatment of previously treated MSI-H/dMMR advanced solid tumors.

The table below shows the indications for which we are currently evaluating envafolimab in clinical trials:

	Status				
Indication[(1)]	**IND**	**Phase I**	**Phase II**	**Phase III**	**NDA/BLA (Approved)**
China					
Advanced solid tumors[(2)]	●	●			
MSI-H/dMMR	●		● (pivotal)		●
Advanced BTC[(3)]	●			◑ (pivotal)	
G/GEJ	●		●		
NSCLC (combination with chidamide)	●		◑		
NSCLC, HCC, RCC (combination with lenvatinib)	●		◑		
EC (combination with lenvatinib)	●		◑		
TMB-H	●		◑		
HCC, CRC, NSCLC (combination with BD0801)	●		◑		
U.S.					
Advanced solid tumors[(2)]	●	●			
SC (sponsored by TRACON)	●		◑ (pivotal)		
Japan					
Advanced solid tumors[(2)]	●	●			

Abbreviations: MSI-H/dMMR = microsatellite instability-high/mismatch repair deficiency; NSCLC = non-small cell lung cancer; BTC = biliary tract cancer; HCC = hepatocellular carcinoma; RCC = renal cell carcinoma; EC = endometrial cancer; G/GEJ = gastric or gastroesophageal junction cancer; TMB-H = tumor mutational burden-high; CRC = colorectal cancer; SC = sarcoma.

Symbols: ● = complete; ◑ = in progress (a clinical trial is deemed to have been initiated when the first study site is activated)

Notes:

(1) Some indications may not require every phase of the clinical trials indicated on this chart to be completed in the same tumor type prior to the filing of an NDA/BLA.

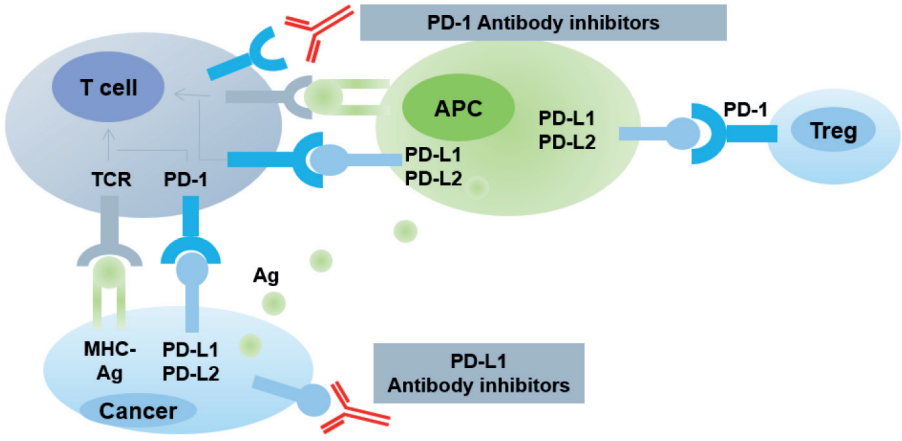
(2) The Phase I clinical trials for advanced solid tumors in China, the U.S., and Japan covered various solid tumor types including the tumor types studied by subsequent clinical trials.

(3) The study included an interim analysis after the first 100 patients were enrolled (considered to be equivalent to a Phase II clinical trial) in the pivotal Phase III clinical trial for the treatment of advanced BTC, which has been designed with reference to the sufficient regulatory basis as described below. As advised by our PRC Legal Advisers, according to the Technical Guiding Principles of Clinical Trials of Anti-tumor Drugs (抗腫瘤藥物臨床試驗技術指導) effective as of May 15, 2012, the clinical studies of anti-tumor drugs are generally divided into phase I, phase II and phase III clinical trials. The primary objectives of a phase I clinical trial include the preliminary studies of the tolerability and pharmacokinetics profile of the drugs, which provides data support to the dosage regimen design of subsequent studies. A phase II clinical trial is typically an exploratory study, such as the exploration of administration dosage, the exploration of dosage regimen and the exploration of efficacy, and includes the observation of safety. A phase III clinical trial further confirms the benefits for cancer patients on top of the results of the phase II clinical trial, and provide adequate evidence for obtaining marketing approval. However, the phases of the aforementioned clinical studies are not necessarily fixed. For instance, an exploratory study (i.e. phase II clinical trial) may also be a part of a phase III clinical trial. Specifically, a phase III clinical trial requires to generate efficacy data of clinical benefit and the duration of the phase III trial is relatively long. Therefore, a phase III clinical trial may include an element of exploratory research allowing the adjustments of its the clinical trial protocol or conduct pursuant to the interim analysis and accumulated information. In the field of oncology clinical research, the objectives of a traditional phase II study are increasingly commonly achieved through an expanded Phase I study design or by introducing an interim analysis in the phase III study. This approach has enabled a more efficient clinical development of oncology drugs in recent years.

i. Mechanism of Action

Under normal conditions, T cells are activated in response to foreign antigens (Ag). Antigen-presenting cells (APCs) process and present Ag to activate T cells through T-cell receptor (TCR) and major histocompatibility complex (MHC) binding. Activated T cells play critical roles in regulating immune response of human body, including recognizing and killing cancer cells. To prevent activated T cells from attacking healthy body tissues, regulatory T cells (Treg) express immune checkpoint receptors, such as PD-1, on their surface to limit overstimulation of the immune system after antigen encounter.

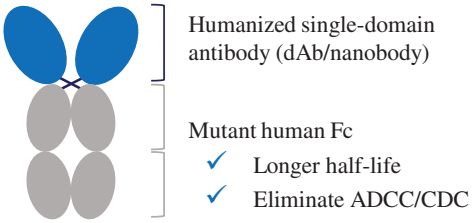
PD-L1 is an important ligand protein that can engage PD-1. The binding of PD-L1, expressed on the surface of normal cells, to PD-1 on the surface of T cells can deliver a negative signal to T-cells, leading to inhibition on immune response. However, it has been found that tumor cells can overexpress PD-L1 to protect themselves from being detected and killed by T cells. A PD-L1 antibody binds to PD-L1 and blocks PD-L1 from binding to PD-1, which allows T cells to kill tumor cells. The diagram below shows the mechanism of action of a PD-L1 antibody:



Abbreviations: Ag = antigen; APC = antigen-presenting cells; TCR = T-cell receptor; MHC = major histocompatibility complex; Treg = regulatory T cell.

Source: American Cancer Society, Front Cell Dev Biol. 2020; 8: 672., Frost & Sullivan Report

Envafolimab is a novel fusion protein consisting of a single-domain antibody (sdAb) fused with a human fragment crystallizable (Fc) region that binds to PD-L1 and blocks PD-L1 from binding to PD-1. As illustrated by the diagram below, as a recombinant fusion protein, envafolimab consists of two identical polypeptide chains linked via a pair of disulfide bonds. Each chain contains a human lgG1 Fc fragment and sdAb, which are obtained from a focused phage library, derived from peripheral blood mononuclear cells (PBMC) of human PD-L1 immunized camel, and humanized afterwards.



Source: Company data

Due to the sdAb format, envafolimab has about half the molecular weight of a full-length conventional antibody with better stability, which enables it to have enhanced tissue penetrability while possessing a full antigen-binding capacity as compared with conventional PD-L1 antibodies. Envafolimab is also more water soluble than a conventional antibody, enabling a convenient subcutaneous injection. In addition, the Fc mediated effector functions are muted in envafolimab to minimize unwanted adverse immune responses.

ii. Market Opportunities and Competition

PD-1/PD-L1 is a clinically-validated immune checkpoint for immuno-oncology therapies. To date, all of the immune checkpoint inhibitors on the market are conventional antibodies administered by intravenous infusion. The introduction of immune checkpoint inhibitors offers breakthrough treatment for certain cancer indications that previously lacked effective therapies. In 2020, the global sales of PD-1/PD-L1 inhibitors reached US$28.6 billion, according to Frost & Sullivan.

As of the Latest Practicable Date, there were a total of 17 approved PD-1/PD-L1 monoclonal antibodies inhibitors in the global market, of which 11 target PD-1 and five target PD-L1. 16 of them are conventional antibodies administered by intravenous infusion. As of the Latest Practicable Date, there were 13 PD-1/PD-L1 inhibitors approved by the NMPA, including nine PD-1 inhibitors and four PD-L1 inhibitors, and seven PD-1/PD-L1 inhibitors approved by the FDA. The following table sets out details of the FDA approved PD-1/PD-L1 inhibitors for MSI-H/dMMR cancer in the U.S. as of the Latest Practicable Date.

Product	Drugs	Company	Immune Checkpoint	2021 Revenue (million)	Price (USD)	2020 Annual Cost (thousand)	Patent Expiration Date	FDA Approved Indications	Injection Methods	Date of Approval
Keytruda	Pembrolizumab	MSD	PD-1	$17,186	25mg/ml 4ml: 5,264.7 8ml: 10,519.8	$168.3	2037-07-18	MSI-H/dMMR solid tumors	Intravenous	May 2017
								First-line MSI-H/dMMR CRC		June 2020
Opdivo	Nivolumab	Bristol Myers Squibb	PD-1	$7,523	10mg/ml 4ml: 1,171.7 10ml: 2,914.9 24ml: 6,982.5	$181.5	2037-06-01	MSI-H/dMMR CRC	Intravenous	August 2017
Jemperli	Dostarlimab-gxly	GlaxoSmithKline	PD-1	$7	500mg/10ml: 10,835.1	$184.2	2036-02-03	dMMR endometrial cancer	Intravenous	April 2021
								dMMR recurrent or advanced solid tumor		August 2021

Abbreviations: MSI-H/dMMR = microsatellite instability-high/mismatch repair deficiency; CRC = colorectal cancer

Note: 2021 Revenue indicates sales revenue for all indications

Source: FDA, Annual Reports of Listed Pharmaceutical Companies, Company Official Websites, NRDL, Frost & Sullivan

Prior to the BLA approval of envafolimab, all of the approved PD-1/PD-L1 inhibitors were required to be administered intravenously. However, intravenous formulation is inconvenient for patients because it requires frequent infusion services and some patients experience infusion reactions. In addition, around 10% cancer patients may not be eligible for intravenous formulation due to limited vein access caused by long-term and numerous drug treatments. Compared to all these approved PD-1/PD-L1 inhibitors, envafolimab can be subcutaneously administered, which is a more convenient administration form for patients that enables improved patient compliance and wider patient coverage. With the indication for previously treated MSI-H/dMMR advanced solid tumors, envafolimab is the first subcutaneously injectable PD-1/PD-L1 inhibitor to receive priority review for a tissue agnostic indication in China and it has been approved in China for the treatment of previously treated MSI-H/dMMR advanced solid tumors.

Subcutaneous formulation is challenging for conventional antibodies due to limited solubility while requiring formulation development. Subcutaneous formulation has been developed for several conventional antibodies by adding hyaluronidase to facilitate subcutaneous absorption. However, these formulations typically require relatively large volume (over 2 mL) and take several minutes to administer. In contrast, full therapeutic dose of envafolimab of 0.75 mL (150 mg) is administered by a single injection in volume less than 1 mL that takes less than 30 seconds to administer. For subcutaneous formulation, the volume for each injection is typically under 2 mL, which is technically challenging for conventional antibodies formulated for subcutaneous injection.

iii. Competitive Advantages

(1) A marketed subcutaneously injectable PD-L1 antibody

Envafolimab is a single-domain antibody with a molecular weight of about 80 kDa, which is smaller compared to other approved PD-1/PD-L1 antibodies. Benefitting from such unique molecular structure, envafolimab has about half the molecular weight of a full-length conventional antibody with better stability and higher solubility, which enables the development of high concentration formulation suitable for subcutaneous injection. Envafolimab is a subcutaneously injectable PD-L1 antibody, and it has been approved in China for the treatment of previously treated MSI-H/dMMR advanced solid tumors. Compared with the other approved PD-1/PD-L1 antibodies, our envafolimab potentially has the following advantages as a result of its subcutaneous injection method:

(a) Envafolimab may achieve better patient compliance with increased convenience. Subcutaneous formulation enables quicker administration and potential for self-injection in the future, which is more convenient for patients in long-term care and enables better patient compliance with the

treatment regimen. It generally only takes less than 30 seconds to subcutaneously inject 0.75 mL (150 mg) of envafolimab. In addition, the observation time for subcutaneous injection is shorter than for intravenous infusion.

(b) Envafolimab may achieve a wider patient coverage. Our envafolimab could be used in patients who are not eligible for intravenous administration, such as elderly patients who are vulnerable to complications of intravenous fluid overload, patients who are heavily treated with chemotherapy resulting in vein shrinkage, or other medical reasons making repeated intravenous infusions not feasible or desired. In addition, envafolimab provides an alternative for patients under the circumstance of public health crisis when they have limited access to hospitals.

(c) Envafolimab may be more cost-effective and better-received by patients. In addition to lower production costs, patients would also benefit from lower transportation and accommodation costs as subcutaneous injections can be administered at a wider range of facilities and institutions nearby, such that envafolimab may result in lower indirect cancer treatment cost as a whole.

(d) Envafolimab may have great potential to expand to the market of oncology drugs sold outside of hospital as a result of its safe and convenient subcutaneous administration method.

(2) First PD-1/PD-L1 inhibitor under priority review for a tissue-agnostic indication in China

In December 2020, the NMPA accepted our BLA for envafolimab as a monotherapy for the treatment of previously treated MSI-H/dMMR advanced solid tumors based on results from our completed pivotal trial in China, and our BLA was granted priority review. On November 24, 2021, we received BLA approval for this indication from the NMPA. Our envafolimab is the first PD-1/PD-L1 inhibitor to receive priority review for a tissue agnostic indication in China, and it has been approved in China for the treatment of previously treated MSI-H/dMMR advanced solid tumors. Therefore, it potentially has substantial competitive advantage and commercial potential in the market, with the potential to create significant synergies with the clinical development of other drug candidates.

(3) Favorable clinical safety profile compared to other marketed PD-1/PD-L1 inhibitors

Based on data collected from our clinical studies, envafolimab has demonstrated a favorable safety profile, compared to other marketed PD-1/PD-L1 inhibitors, in addition to the benefit of no infusion-related reactions. As further illustrated in the table below, a low incidence of immune related pneumonitis (0.5%) and no immune-related colitis was observed based on pooled analyses of our pivotal clinical trial in previously treated MSI-H/dMMR advanced cancer and the Phase I clinical trial in China for envafolimab, and no infusion-related reaction was observed in these studies. Also, due to subcutaneous route of administration of envafolimab, injection site reactions can be observed, and the incidence of injection site reactions with envafolimab is low (~10%) and of mild to moderate severity. Please refer to the paragraphs headed "Our Core Product and Other Drug Candidates – 1. Our Core Product – a. Envafolimab – iv. Summary of Clinical Trials – (1) Pivotal Clinical Trial to Treat Previously Treated MSI-H/dMMR Advanced Cancer in China" in this section. Although these are not head-to-head studies, we believe that helpful insights can nonetheless be obtained from the comparison.

	Anti-PD-1 inhibitors					Anti-PD-L1 inhibitors			
All level AE rate	Nivolumab[1] (N=1994)	Pembrolizumab[2] (N=2799)	Sintilimab[3] (N=540)	Toripalimab[4] (N=598)	Camrelizumab[5] (N=986)	Avelumab[6] (N=1738)	Durvalumab[7] (N=1889)	Atezolizumab[8] (N=2616)	Envafolimab[9] (N=390)
IR-Pneumonitis	3.1%	3.4%	6.9%	1.8%	2.7%	1.2%	5%	2.5%	0.5%
IR-Colitis	2.9%	1.7%	0%	0%	0.2%	1.5%	-	1.0%[10]*	0%
IR-Endocrine disease									
Hypothyroidism	9%	8.5%	8.5%	12.9%	20.5%	5%	11%	4.6%	13.6%
Hyperthyroidism	2.7%	3.4%	4.3%	4.8%	6.7%	0.4%	7%	1.6%	9.0%
IR-Myocarditis	<1%	<1%	0.6%	-	0.3%	<1%	<1%	<1%	0.5%
IR-Hepatitis	1.8%	0.7%	3.5%	3.5%	9.1%	0.9%	12%	9%	3.6%
Infusion reaction	6.4%	3.0%[11]*	-	-	-	25%	2.2%	1.3%	0

* Atezolizumab IR-colitis (1.0%; n=729); Pembrolizumab infusion reaction (3.0%; n=495)

Notes:

The above comparisons are not based on head-to-head clinical trials. The major limitation of the comparisons that are not based on head-to-head clinical trials is that it is not possible to determine if any differences noted between the efficacy measures of different drugs can solely be attributable to the drugs themselves. Instead, the differences may reflect differences in other aspects of the various clinical trials, such as populations, comparators and outcomes. As such, you are cautioned not to place undue reliance on the above cross-trial comparison results.

(1) Nivolumab. HIGHLIGHTS OF PRESCRIBING INFORMATION, Reference ID: 4400635

(2) Pembrolizumab. HIGHLIGHTS OF PRESCRIBING INFORMATION, Reference ID: 4492828

(3) Center for Drug Evaluation of NMPA, Drug Application Technical Review Report of Sintilimab Injection (信迪利單抗注射液申請上市技術審評報告) (March 2019)

(4) Center for Drug Evaluation of NMPA, Drug Application Technical Review Report of Toripalimab Injection (特瑞普利單抗注射液申請上市技術審評報告) (March, 2019)

(5) Center for Drug Evaluation of NMPA, Drug Application Technical Review Report of Camrelizumab for Injection (注射用卡瑞利珠單抗申請上市技術審評報告) (July, 2019)

(6) Avelumab. HIGHLIGHTS OF PRESCRIBING INFORMATION Reference ID: 4433254

(7) Durvalumab. HIGHLIGHTS OF PRESCRIBING INFORMATION Reference ID: 4465139

(8) Atezolizumab. HIGHLIGHTS OF PRESCRIBING INFORMATION Reference ID: 4527935

(9) From KN035-CN-006 (cut-off date: June 19, 2020) and KN035-CN-001 (Sep 2, 2019) studies.

(10) Wang DY, et al, Onco 2017; 6; e1344805

(11) Garon E B, et al, N Engl J Med, 2015, 372 (21)

Source: Company data

(4) Consistent clinical efficacy results compared to other marketed PD-1/PD-L1 inhibitors

In our pivotal clinical trial to evaluate its treatment of previously treated MSI-H/dMMR advanced cancer, envafolimab achieved a confirmed objective response rate (ORR) of 42.7% per BIRC and a 12-month OS of 74.6%, and its efficacy is highly consistent with pembrolizumab and nivolumab. Please refer to the paragraphs headed "– Our Core Product and Other Drug Candidates – 1. Our Core Product – a. Envafolimab – iv. Summary of Clinical Trials – (1) Pivotal Clinical Trial to Treat Previously Treated MSI-H/dMMR Advanced Cancer in China" in this section. Although these are not head-to-head studies, we believe that helpful insights can nonetheless be obtained from the comparison.

iv. Summary of Clinical Trials

As of the Latest Practicable Date, we had evaluated the safety and efficacy profiles of envafolimab in five completed clinical trials and seven ongoing clinical trials, and three clinical studies being initiated with either pre-IND or IND submission completed. We have completed the pivotal trial for the treatment of previously treated MSI-H/dMMR advanced cancer in China, and we have two other ongoing pivotal trials respectively for the treatment of advanced BTC and selected types of advanced SC.

(1) Pivotal Clinical Trial to Treat Previously Treated MSI-H/dMMR Advanced Cancer in China

We have completed a single-arm, multi-center, Phase II pivotal clinical trial to evaluate the efficacy and safety of envafolimab in subjects with previously treated MSI-H/dMMR advanced cancer in China. MSI-H/dMMR results in exceptionally high number of mutations and neoantigens and predicts sensitivity to PD-L1/PD-L1 inhibitor regardless of cancers' tissue of origin. Patients with advanced MSI-H/dMMR cancer who failed standard of care have no satisfactory alternative treatment options and poor prognosis. Pembrolizumab and nivolumab have been approved for the treatment of patients with previously treated MSI-H/dMMR advanced colorectal cancer (CRC). Pembrolizumab was also approved for the treatment of other previously treated advanced tumor types (tissue agnostic

indication). Pembrolizumab was recently approved for first-line treatment of MSI-H/dMMR advanced CRC. JEMPERLI (dostarlimab) was also recently approved by the FDA for the treatment of previously treated advanced dMMR solid tumors.

The efficacy and safety data of this trial was presented at the 2020 European Society for Medical Oncology Asia Virtual Congress in November, 2020. According to the data presented in the 2020 ESMO Asia Virtual Congress (the "**2020 ESMO Asia Presentation**"), 103 subjects with previously treated MSI-H/dMMR advanced cancer were enrolled in this trial from August 22, 2018 to December 5, 2019.

Study purpose. The primary endpoint of this trial was ORR per RECIST v1.1 by blinded independent radiology review (BIRC). The secondary endpoints of this trial were duration of response (DOR), disease control rate (DCR), progression free survival (PFS) and overall survival (OS).

Study design. This trial enrolled subjects who (i) were 18 years or older, (ii) had locally advanced or metastatic solid tumors, (iii) had centrally confirmed MSI-H for CRC, GC and locally confirmed dMMR for other tumors, (iv) had one or more prior line of systemic therapy, (v) ECOG PS between 0 and 1, and (vi) had measurable disease per RECIST v1.1.

Subjects received envafolimab at 150 mg on weekly basis with a single subcutaneous injection at a volume of 0.75 mL using a 1 c.c. syringe. Safety and tolerability would be assessed by monitoring treatment emergent adverse events (TEAEs), physical exams, and laboratory tests. Tumor assessments would be performed every eight weeks based on RECIST version v1.1.

According to the 2020 ESMO Asia Presentation, 103 subjects with previously treated MSI-H/dMMR advanced cancers were enrolled at 25 centers, including 65 subjects with CRC (41 failed $\geq$ 2 lines of prior therapies including fluoropyrimidine, oxaliplatin and irinotecan and 24 failed 1 line prior therapy including fluoropyrimidine and oxaliplatin or fluoropyrimidine and irinotecan), 18 subjects with GC and 20 subjects with other tumor types. As of June 19, 2020, the median follow-up was 11.5 month in the overall population (N=103).

Efficacy. The confirmed ORR per BIRC was 42.7% (95%CI: 33.0%-52.8%) in the overall population, 43.1% (95%CI: 30.8%-56.0%) in CRC, 44.4% (95%CI: 21.5%-69.2%) in GC and 40.0% (95%CI: 19.1%-63.9%) in other tumors. ORRs per investigators were consistent with BIRC assessment.

The median PFS per BIRC was 7.2 months (95% CI: 3.5, NE) for CRC population, and 11.1 months (95% CI: 5.5, NE) for the overall population. Median OS was not reached for any analyzed populations. The 12 month OS rate was 72.9%

(95% CI: 60.1, 82.2) in CRC, 83.3% (95% CI: 56.8, 94.3) in GC, 75.0% (95% CI: 50, 88.7) in other tumors and 74.6% (95% CI: 64.7, 82.1) in overall population. The following tables summarize the efficacy results:

	Advanced CRC (n=65)					
	total (n=65)	≥2 prior therapies* (n=41)	1 prior therapy** (n=24)	Advanced GC (n=18)	Other solid tumors (n=20)	Overall population (n=103)
Best of overall response, per BIRC						
CR	3 (4.6%)	0	3 (12.5%)	0	2 (10.0%)	5 (4.9%)
PR	25 (38.5%)	13 (31.7%)	12 (50.0%)	8 (44.4%)	6 (30.0%)	39 (37.4%)
SD	12 (18.5%)	11 (26.8%)	1 (4.2%)	7 (38.9%)	5 (25.0%)	24 (23.3%)
PD	21 (32.3%)	13 (31.7%)	8 (33.3%)	2 (11.1%)	5 (25.0%)	28 (27.2%)
NE	4 (6.2%)	4 (9.8%)	0	1 (5.6%)	2 (10.0%)	7 (6.8%)
ORR	43.1%	31.7%	62.5%	44.4%	40.0%	42.7%
DCR	61.5%	58.5%	66.7%	83.3%	65.0%	66.0%
DoR≥12 mos.	88.4%	74.6%	100.0%	100.0%	100.0%	92.2%
mPFS, mos.	7.2	4.9	NR	NR	NR	11.1
PFS, % at 12 mos.	43.7%	32.1%	62.5%	58.0%	52.6%	48.5%
OS, % at 12 mos.	72.9%	64.7%	87.1%	83.3%	75.0%	74.6%

Median follow up was 11.5 months in overall population, and 6.5 months for the last subject.

* CRC with ≥2 prior therapies include those patients who were previously treated with fluoropyrimidine, oxaliplatin, and irinotecan containing regimens.

** CRC with 1 prior therapy include those pts who were previously treated with a fluoropyrimidine and oxaliplatin, or a fluoropyrimidine and irinotecan containing regimen.

Source: Efficacy and safety of envafolimab (KN035) in advanced tumours with mismatch-repair deficiency, 2020 European Society for Medical Oncology (ESMO) Asia Virtual Congress

As illustrated in the table below, the efficacy results of envafolimab were comparable to that reported for pembrolizumab and nivolumab monotherapy in similar populations.

	Pembrolizumab			Nivolumab[3][4]	Envafolimab		
	KEYNOTE-164[1]		KEYNOTE-158[2]	CHECKMATE-142	KN035-CN-006		
Study population	CRC-cohort A (3 drugs failed CRC)	CRC-cohort B (overall CRC)	non-CRC (prior≥1 line)	3 drugs failed CRC	3 drugs failed CRC	Overall CRC	Overall population (prior≥1 line)
	Local/central lab verified MSI-H/dMMR	Local/central lab verified MSI-H/dMMR	Local/central lab verified MSI-H/dMMR	Local/central lab verified MSI-H/dMMR	Central lab verified MSI-H	Central lab verified MSI-H	Site/central lab verified MSI-H/dMMR
Sample size	61	63	233	53	41	65	103
ORR, %: IRC	33% (27.9%*)	33% (32%*)	34.3%	28%	31.7%	43.1%	42.7%
mPFS, months	2.3	4.1	4.1	–	4.9	7.2	11.1
6-m PFS rate	(43%*)	(49%*)	–	–	48.8%	53.8%	57.7%
mOS (months)	31.4	not reached	23.5	–	not reached	not reached	not reached
6-m OS rate	(87%*)	(84%*)	–	–	80.5%	84.5%	82.4%
12-m OS rate	72%	76%	60.7%	73%	64.7%	72.9%	74.6%

* KEYNOTE 164 earlier published data[5][6] 3 drugs failed: failed Fluorouracil, and Oxaliplatin and Irinotecan; 2 drugs failed, failed Fluorouracil combined with oxaliplatin or irinotecan

Notes:

The above comparisons are not based on head-to-head clinical trials. The major limitation of the comparisons that are not based on head-to-head clinical trials is that it is not possible to determine if any differences noted between the efficacy measures of different drugs can solely be attributable to the drugs themselves. Instead, the differences may reflect differences in other aspects of the various clinical trials, such as populations, comparators and outcomes. As such, you are cautioned not to place undue reliance on the above cross-trial comparison results.

(1) J Clin Oncol. 2020 Jan 1; 38(1): 11-19

(2) J Clin Oncol. 2020; 38(1): 1-10

(3) Overman MJ, et al. Lancet Oncol. 2017; 18(9): 1182-1191

(4) Opdivo (nivolumab). Highlights of Prescribing Information. Reference ID; 4427750ite.

(5) Annals of Oncology. 2017: 28(S5): 128-129

(6) ASCO 2018 Annual Meeting. 3514

Source: Efficacy and safety of envafolimab (KN035) in advanced tumours with mismatch-repair deficiency, 2020 European Society for Medical Oncology (ESMO) Asia Virtual Congress

Safety. All grade (G) and G3-4 treatment-related adverse events (TRAE) in overall population were 84.5% and 15.5% separately. No G5 TRAE occurred. The most common immune-related TEAEs were hypothyroidism (15.5%) and hyperthyroidism (11.7%). No infusion-related reaction, pneumonitis, or colitis was reported. The occurrence of local injection-site reaction was 8.7% and were all G1-2. The following table summarizes drug related TEAEs in the subjects:

Occurrence≥10% any grade drug related TEAEs	**Overall population (N=103)**		
	Any grade	**Grade 3-4**	**Grade 5**
Drug related TEAE	87 (84.5%)	16 (15.5%)	0
Laboratory test	56 (54.4%)	3 (2.9%)	0
white blood cell count decreased	17 (16.5%)	0	0
Neutrophils count decreased	12 (11.7%)	1 (1.0%)	0
General disease and injection site reactions	29 (28.2%)	0	0
fatigue	17 (16.5%)	0	0
Cutaneous reactions	21 (20.4%)	2 (1.9%)	0
rash	16 (15.5%)	1 (1.0%)	0
Endocrine disorders	21 (20.4%)	0	0
hypothyroidism	16 (15.5%)	0	0
hyperthyroidism	12 (11.7%)	0	0
Blood and lymphatic system disorders	12 (11.7%)	5 (4.9%)	0
anaemia	12 (11.7%)	5 (4.9%)	0

Source: Efficacy and safety of envafolimab (KN035) in advanced tumours with mismatch-repair deficiency, 2020 European Society for Medical Oncology (ESMO) Asia Virtual Congress

Conclusion. According to the 2020 ESMO Asia Presentation, envafolimab demonstrated durable antitumor activity in patients with previously treated MSI-H/dMMR advanced cancer. Safety profile was similar to the marketed PD-(L)1 antibodies but without infusion related reactions and potentially lower rates in pneumonitis or colitis. The data support envafolimab as a new safe and effective treatment option with durable benefit for patients with heavily-previously-treated MSI-H/dMMR advanced cancer.

(2) Phase III Pivotal Clinical Trial to Treat BTC in Combination with Chemotherapy in China

We are conducting a randomized, open-label, parallel, Phase III clinical trial in China. The study plan is to randomize approximately 480 subjects with previously untreated unresectable locally advanced or metastatic BTCs. The primary objective was to compare OS in subjects treated with envafolimab in combination with gemcitabine plus oxaliplatin (GEMOX) chemotherapy versus GEMOX alone. The

first subject in this study was randomized on April 23, 2018. As of July 18, 2022, 472 subjects had been randomized. This trial is ongoing and no unblinded safety or efficacy data is currently available.

(3) Phase II Pivotal Clinical Trial to Treat Selected Types of SC in the U.S.

A multi-center, open-label, randomized, non-comparative, parallel cohort, Phase II pivotal clinical trial of envafolimab or envafolimab combined with ipilimumab in subjects with locally advanced, unresectable or metastatic undifferentiated pleomorphic sarcoma (UPS)/myxofibrosarcoma (MFS) is being conducted in the U.S. and sponsored by TRACON.

The primary endpoint is the ORR. Subjects are assigned at random into one of the two cohorts: cohort A that will receive single agent envafolimab (300 mg every 3 weeks by subcutaneous injection) or cohort B that will receive envafolimab (300 mg every 3 weeks by subcutaneous injection) in combination with ipilimumab (1 mg/kg every 3 weeks intravenously for four doses). Eighty subjects are to be enrolled into each cohort for a total of 160 subjects. The trial was granted the IND approval by the FDA on August 14, 2020. On June 1, 2021, Tracon announced that the Independent Data Monitoring Committee (IDMC) recommended to proceed as planned following the review of safety data from more than 20 patients (more than 10 patients from each arm) enrolled.

(4) Phase II Clinical Trial to Treat Advanced Gastric or Gastroesophageal Junction (G/GEJ) Cancer in Combination with Chemotherapy

We have completed a single-arm, multi-center, Phase II clinical trial to evaluate the safety and tolerability of combining envafolimab with chemotherapy in adult subjects with previously-untreated unresectable locally advanced or metastatic G/GEJ adenocarcinoma cancer in China.

Study purpose. The primary objective was to evaluate the safety and tolerability of envafolimab in combination with standard chemotherapy fluorouracil plus oxaliplatin (FOLFOX) regimen. The secondary objectives were to evaluate the ORR, DOR, DCR, PFS and OS of envafolimab in combination with FOLFOX.

Study design. Eligible subjects received up to eight cycles (two weeks each) of envafolimab plus FOLFOX regimen followed by envafolimab and 5-FU/leucovorin maintenance treatment until progression, death, unacceptable toxicity or withdraw of informed consent, whichever comes first. Envafolimab was administrated subcutaneously at 5 mg/kg on day 1 of each cycle. FOLFOX consisted of 85 mg/m^2 oxaliplatin intravenous infusion on day 1 of each cycle, up to 8 cycles, 400 mg/m^2 5-FU and 400 mg/m^2 leucovorin intravenous infusion on day 1, 2400 mg/m^2 5-FU administered with a 48-hour continuous infusion on day 1 and 2 of each cycle. Tumor was assessed every six weeks per RECIST version 1.1. Safety assessments

included adverse events, ECOG performance status, physical examination, laboratory changes (hematology, blood chemistry, coagulation, thyroid function, urinalysis, and blood pregnancy test), vital signs changes (blood pressure, heart rate, respiratory rate, and temperature), 12-lead ECG, and echocardiography. The severity of AEs was graded using Common Terminology Criteria for Adverse Events version 5.0 (CTCAE v 5.0).

A total of 15 subjects were enrolled and received treatment with envafolimab and FOLFOX regimen. The median age was 56 years, including 11 male subjects; the ECOG performance status score was 1 in 80% (12 subjects) and 0 in the rest subjects. The majority had gastric cancer (80.0%). All 15 (100.0%) subjects had tumors of clinical stage IV at baseline. At the data cutoff of July 15, 2019, the minimum follow-up was 4.0 months.

Efficacy. The confirmed ORR as assessed by investigators was 60% (95% CI: 32.3% – 83.7%) and the unconfirmed ORR was 73.3% (95% CI: 44.9% – 92.2%). The median DOR was not reached (range: 3.98 – 6.93+ months) and 66.7% of responding were ongoing. The DCR was 100%. The median PFS was 6.8 months (95% CI: 4.4-NE), and the median OS was not reached with 3-month, and 6-month OS rates of 100% and 87.5%, respectively.

Safety. As of July 15, 2019, among all 15 treated subjects, the TEAE occurrence was 100% (all grades (G)) and 73.3% (G3-4). The most frequent G3-4 TEAE included neutrophil count decreased 46.7%, white blood cell count decreased 20.0%, anemia 20.0%, and platelet count decreased 20%. No G5 TEAE occurred.

Conclusion. Envafolimab plus FOLFOX as a first-line therapy for advanced G/GEJ cancer demonstrated a manageable safety profile with preliminary promising clinical anti-tumor efficacy.

(5) Phase II Clinical Trial to Treat TMB-H Advanced Solid Tumors in China

We are conducting a single-arm, open-label, multi-center, Phase II clinical trial for the treatment of TMB-H advanced solid tumors in China. As of July 18, 2021, 59 subjects had been enrolled. This trial is ongoing and no safety or efficacy data is currently available.

(6) Phase I Clinical Trials of Envafolimab

As of the Latest Practicable Date, we had completed all three Phase I clinical trials of envafolimab in China, the U.S. and Japan.

The three Phase I clinical trials have exhibited a favorable safety profile in patients with advanced malignancies. Multiple dosing regimens (0.01 mg/kg to 10 mg/kg QW, 2.5 mg/kg to 5.0 mg/kg Q2W, and 300 mg Q4W) were tested across the Phase I studies, and no DLT or MTD was reached in any of the Phase I studies. The efficacy results were also analyzed based on pooled data from the three Phase I clinical trials. The pooled analyses showed that among the 269 subjects who were efficacy evaluable, the ORR (confirmation of response not required) was 12.27%. Responses were observed across multiple tumor types, as summarized in the table below:

Table: ORR per investigator assessment by tumor types based on pooled analyses of efficacy evaluable subjects from three Phase I trials in China, the U.S., and Japan. (only tumor types with subjects ≥ 9 are displayed)

	Responders/ Subjects	ORR	95% CI
Overall	33/269	12.27	(8.60%, 16.80%)
Tumor Histology			
Hepatocellular Carcinoma	3/41	7.32	(1.54%, 19.92%)
Lung Cancer, Non-Small Cell	4/35	11.43	(3.20%, 26.74%)
Biliary Tract Cancer	3/26	11.54	(2.45%, 30.15%)
Colon Cancer	2/24	8.33	(1.03%, 27.00%)
Esophageal Cancer	3/13	23.08	(5.04%, 53.81%)
Melanoma	0/12	0.00	(0.00%, 26.46%)
Neuroendocrine Tumor	2/12	16.67	(2.09%, 48.41%)
Rectal Cancer	0/12	0.00	(0.00%, 26.46%)
Renal Cell Carcinoma	5/10	50.00	(18.71%, 81.29%)
Soft Tissue Sarcoma	2/9	22.22	(2.81%, 60.01%)
Urothelial Carcinoma	2/9	22.22	(2.81%, 60.01%)

Abbreviations: ORR = objective response rate; CI = confidence interval.

Notes:

(1) Proportion with CR or PR, confidence interval based on the Clopper and Pearson method.

(2) Only tumor histology with N≥9 is included.

(3) Subjects completed baseline and at least one post baseline tumor assessment are considered efficacy evaluable.

(4) Database snapshot date: CN001 (2019-09-02), JP001 (2020-03-31), US001 (2019-11-25).

Source: Company data

v. Clinical Development Plan

We collaborate with Alphamab Group on a broad development program targeting a number of strategically selected indications in China, the U.S., Japan and other countries, to support regulatory submissions for multiple indications both in China and other countries.

Under our Co-Development Agreements with Alphamab Group, we are responsible for the clinical development and commercialization of envafolimab. We led the clinical development for envafolimab in multiple countries and regions including China, the U.S. and Japan based on our commercialization strategy. Japan and the U.S. are members of the ICH. A multi-regional clinical trial conducted in ICH member countries is expected to lower operational costs in light of the consistency of general regulatory requirements. Moreover, the subjects in clinical trials conducted in Japan and China are of East Asian ethnicity, and therefore clinical trial data from one country could be leveraged to support clinical trials and accelerate the clinical development process in the other country.

In addition to the ongoing clinical trials that we are conducting, we plan to explore the clinical potential of envafolimab for the treatment of a variety of indications, including NSCLC, HCC, RCC, EC, TMB-H, CRC and UC. Furthermore, we plan to evaluate the potential synergy of envafolimab in combination with our other pipeline drug candidates, including 3D189 and 3D229.

The table below sets forth the details (including the basis) of our clinical development plan for envafolimab:

Indication	Status	(Expected) first patient in date	Expected NDA submission date	Expected number of patients	Location and competent authority
NSCLC (combination with chidamide)[(1)]	Phase II	Q4 2021	Q2 2024	66-69	China and NMPA
NSCLC (vs. standard of care)[(2)]	Phase III	Q2 2023	Q2 2027	400-500	China and NMPA
NSCLC, HCC, RCC (combination with lenvatinib)[(3)]	Phase Ib/II	Q4 2021	Q4 2026	113-170	China and NMPA
EC (monotherapy and combination with lenvatinib)[(4)]	Phase II	Q2 2022	Q4 2024	108	China and NMPA
TMB-H advanced solid tumors[(5)]	Phase II	Q3 2021	Q1 2024	160-200	China and NMPA

Indication	Status	(Expected) first patient in date	Expected NDA submission date	Expected number of patients	Location and competent authority
UC (first line maintenance therapy; MRCT)[6]	Phase III	Q2 2023	Q4 2025	534	China and NMPA Europe and EMA Japan and PMDA
HCC, CRC, NSCLC (combination with BD0801)[7]	Phase II	Q4 2021	Q1 2025	86	China and NMPA
Microsatellite stable CRC (combination with cetuximab)[8]	Phase II	Q2 2023	Q2 2026	50	China and NMPA

Abbreviations: NSCLC = non-small cell lung cancer; HCC = hepatocellular carcinoma; RCC = renal cell carcinoma; EC = endometrial cancer; TMB-H = tumor mutational burden-high; UC = urothelial carcinoma; MRCT = multi-regional clinical trial; CRC = colorectal cancer; Q1 = first quarter; Q2 = second quarter; Q3 = third quarter; Q4 = fourth quarter.

Note:

(1) NSCLC (combination with chidamide): We obtained the IND approval from NMPA in July 2021. We enrolled the first patient for a Phase II clinical trial in China in the fourth quarter of 2021. We expect a potential NDA submission in the second quarter of 2024. As of July 18, 2022, 22 patients were enrolled in this clinical trial.

(2) NSCLC (vs. standard treatment): We had communications with CDE in January 2021, and are still in the process of communicating with CDE regarding the design of the phase III study. Based on the preliminary feedback, we expect that this study will likely enroll the first patient in the second quarter of 2023 with expected NDA submission in the second quarter of 2027. As of July 18, 2022, this clinical trial was still in preparation stage and no patient had been enrolled.

(3) NSCLC, HCC, RCC (combination with lenvatinib): We obtained the IND approval from NMPA in June 2021. We enrolled the first patient for a Phase Ib/II clinical trial in China in the fourth quarter of 2021 to explore the efficacy of envafolimab in combination with lenvatinib across multiple tumor types. The results of this phase Ib/II study will be used to inform the "Go" or "No Go" decision on subsequent registrational phase II or III study/studies. We expect that subsequent pivotal study/studies will enroll the first patient in 2023 with expected NDA submission in the fourth quarter of 2026. As of July 18, 2022, 27 patients were enrolled in this clinical trial.

(4) EC (monotherapy and combination with lenvatinib): We submitted the IND in June 2021 and received the IND approval in September 2021. We enrolled the first patient for this trial in the second quarter of 2022. We expect that the study will fully enroll in the fourth quarter of 2023 with a potential NDA submission in the fourth quarter of 2024. As of July 18, 2022, 12 patients were enrolled in this clinical trial.

(5) TMB-H advanced solid tumors: We enrolled the first patient for this trial in August 2021. We expect that this trial to fully enroll in the first quarter of 2023 with a potential NDA submission in the first quarter of 2024. As of July 18, 2022, 59 patients were enrolled in this clinical trial.

(6) UC (monotherapy vs. best supportive care, first line maintenance therapy): We had communications with CDE in March 2021, and we have completed pre-IND communication with CDE in July 2021. We expect to initiate pre-IND communications with PMDA and EMA in the fourth quarter of 2022. We expect to submit IND in the fourth quarter of 2022 with expected FPI

in the second quarter of 2023. If the interim analysis on the primary endpoint is successful, the NDA submission is expected to occur in the fourth quarter of 2025. As of July 18, 2022, this clinical trial was still in preparation stage and no patient had been enrolled.

(7) HCC, CRC, NSCLC (combination with BD0801): We obtained the IND approval from NMPA in July 2021 and enrolled the first patient for this trial in November 2021. We expect that this study will fully enroll in the first quarter of 2023 with a potential NDA submission in the first quarter of 2026. As of July 18, 2022, 41 patients were enrolled in this clinical trial.

(8) Microsatellite stable CRC (combination with cetuximab): We submitted IND to NMPA in June 2022 with expected FPI in the second quarter of 2023. As of July 18, 2022, this clinical trial was still in preparation stage and no patient had been enrolled.

vi. Licenses, Rights and Obligations

We maintain the rights to develop envafolimab globally in oncology field. We obtained all the intellectual property rights relating to envafolimab from Alphamab Group pursuant to Co-Development Agreements between us and Alphamab Group. Please refer to the paragraphs headed "Our Collaboration Arrangements – Collaboration with Alphamab Group for Envafolimab" in this section.

vii. Material Communications.

The material communications with the relevant competent authorities on all ongoing and completed clinical trials in respect of the Core Product envafolimab are as follows:

- In November 2016, we received the IND approval for envafolimab from FDA for solid tumors;

- In December 2016, we received an umbrella IND approval for Phase I, II and III trials for envafolimab from NMPA;

- In May 2017, we received the IND approval for envafolimab from PMDA for solid tumors;

- In April 2018, we consulted with CDE and received feedback from CDE with respect to the commencement of a Phase III clinical trial of envafolimab for the treatment of advanced BTC in China, which was a "no objection" from CDE for the commencement of this trial, in the view of our PRC Legal Advisers;

- In April 2018, we consulted with CDE and received feedback from CDE with respect to the commencement of a pivotal Phase II clinical trial of envafolimab for the treatment of previously treated MSI-H/dMMR advanced solid tumors in China, which was a "no objection" from CDE for the commencement of this trial, in the view of our PRC Legal Advisers;

- In September 2019, we had a meeting with FDA with respect to the development of envafolimab in combination with axitinib versus sunitinib as first-line treatment of patients with advanced RCC;

- In January 2020, we received orphan drug designation from FDA for envafolimab for the treatment of advanced BTC;

- In May 2020, our partner TRACON had a meeting with FDA with respect to the proposed strategy to initiate pivotal clinical trial of envafolimab in patients with advanced SC;

- In May 2020, we had communications with CDE with respect to a Phase II clinical trial of envafolimab in combination with chidamide for the treatment of NSCLC;

- In July 2020, we consulted the CDE with respect to the submission of BLA of envafolimab for the treatment of previously treated MSI-H/dMMR advanced solid tumors;

- In August 2020, our partner TRACON received the IND approval for envafolimab from FDA for selected types of advanced SC;

- In December 2020, we obtained the BLA acceptance from NMPA for envafolimab for the treatment of previously treated MSI-H/dMMR advanced solid tumors;

- In December 2020, we had communications with CDE with respect to a Phase Ib/II clinical trial of envafolimab in combination with lenvatinib for the treatment of advanced solid tumors;

- In December 2020, we had communications with CDE with respect to a Phase II clinical trial of envafolimab for the treatment of TMB-H advanced solid tumors;

- In January 2021, the BLA for envafolimab for the treatment of previously treated MSI-H/dMMR advanced solid tumors was publicly announced to be accepted for priority review by NMPA;

- In January 2021, we had communications with CDE with respect to a Phase II clinical trial of envafolimab for the treatment of EC;

- In January 2021, we had communications with CDE with respect to a Phase III clinical trial of envafolimab for the treatment of NSCLC;

- In March 2021, we had communications with CDE with respect to a Phase III clinical trial of envafolimab for the treatment of UC;

- In June 2021, we received the IND approval for envafolimab from NMPA for a Phase Ib/II clinical trial in combination with lenvatinib for the treatment of advanced solid tumors;

- In July 2021, we received the IND approval for envafolimab from NMPA for a Phase II clinical trial in combination with chidamide for the treatment of NSCLC;

- In July 2021, we received the IND approval for envafolimab from FDA for a Phase II clinical trial for the treatment of advanced BTC;

- In July 2021, we received the IND approval for envafolimab from NMPA for a Phase II clinical trial in combination with BD0801 for injection with or without chemotherapy for the treatment of advanced solid tumors;

- In September 2021, we received the IND approval for envafolimab from NMPA for a Phase II clinical trial for the treatment of EC;

- In November 2021, we received BLA approval for envafolimab for the treatment of previously treated MSI-H/dMMR advanced solid tumors; and

- In February 2022, we conducted an interview with a senior officer of NMPA with the attendance of professional parties, which reconfirmed, amongst others, that based on the initial safety, efficacy and PK data across multiple dose levels from the Phase I Clinical Trials, that NMPA had no objection for us to commence each of the clinical trials for the treatment of previously treated MSI-H/dMMR advanced solid tumors, advanced BTC and G/GEJ cancer.

We had not received any relevant regulatory agency's objections to our clinical development plans as of the Latest Practicable Date.

Cautionary Statement required by Rule 18A.05 of the Listing Rules of the Hong Kong Stock Exchange: WE MAY NOT BE ABLE TO SUCCESSFULLY DEVELOP AND/OR MARKET OUR CORE PRODUCT ENVAFOLIMAB FOR INDICATIONS OTHER THAN THE APPROVED INDICATION IN PREVIOUSLY TREATED MSI-H/DMMR ADVANCED SOLID TUMORS.

2. Our Other Clinical-Stage Drug Candidates

According to J Immunother Cancer. 2021 Jan;9(1):e001698. Critical Rev Oncology Hematol. 2021 Apr;160:103302, although the emergence of PD-1/PD-L1 inhibitors has brought new treatment for many cancer patients, tumor cells and tumor microenvironment can limit the effect of PD-1/PD-L1 inhibitors, and sizable numbers of cancer patients have limited response to PD-1/PD-L1 inhibitor as monotherapy. These limitations bring the needs to use PD-1/PD-L1 inhibitors in combination with other treatments. More patients benefit when PD-1/PD-L1 antibodies are used in combination with chemotherapy, targeted therapies, or other immune

therapies. According to National Rev Drug Discov. 2021 Mar;20(3):168-169, Chinese Society of Clinical Oncology, PD-1/PD-L1 therapy is currently still a backbone therapy while combination therapy is becoming the mainstream for oncology treatment. Other drug candidates in our pipeline have encouraging clinical results on standalone basis and promising potential to synergize with envafolimab through varied complementary mechanism of actions.

a. 3D189

3D189, also known as galinpepimut-S (GPS), is a peptide cancer vaccine that targets the Wilms Tumor 1 (WT1) protein, which is present and over-expressed in an array of hematological malignancies and solid tumors. We own the exclusive rights to develop, manufacture and commercialize 3D189 in China, Hong Kong, Macau and Taiwan region for all therapeutic and other diagnostic uses through our exclusive license agreement with SELLAS Group. 3D189 has the potential to target over 20 types of cancers (including lung cancer and CRC) that over-express WT1. Due to its strong T-cell immune response, it is designed to prevent/delay relapses (by prolonging the progression-free interval) and eventually potentially prolong survival in these patients, which is evidenced by the encouraging preliminary results in Phase I and II clinical trials performed to date in acute myelocytic leukemia (AML) (after first- and second-line therapy), malignant pleural mesothelioma (MPM) (after first-line therapy), high-risk multiple myeloma (MM) (after upfront therapy including autotransplant), and relapsed ovarian cancer (OC) (after second-line therapy). We obtained the IND approval for 3D189 in China in March 2022. We plan to initiate a Phase I clinical trial in patients with hematological malignancies who have achieved objective response after receiving standard treatment in the second half of 2022. We plan to potentially join SELLAS Group sponsored registration-enabling, randomized, multi-center, pivotal Phase III clinical trial currently ongoing in the U.S. and Europe in patients with AML who have successfully achieved their second complete remission (CR2), subject to our license agreement with SELLAS Group entered into in December 2020. 3D189 (GPS) has been granted fast track and orphan drug designations by the FDA for the treatment of AML, MPM and MM as well as orphan medicinal product designations from the European Medicines Agency (EMA) in AML, MPM, and MM.

The table below shows the indications for which 3D189 is currently being evaluated in clinical trials:

	Status				
Indication[(1)]	**IND (Accepted)**	**Phase I**	**Phase II**	**Phase III**	**NDA/BLA (Filed)**
China					
Hematological malignancies (AML, etc.)	◔	◔		◔	
NSCLC, RCC, UC and other solid tumors	◔	◔	◔		
U.S. (SELLAS Group)					
AML	●	●	●	◑	
MPM	●	●	●		
MM	●	●	●		
OC (combination with PD-1 antibodies)	●	●			
Selected advanced cancers (combination with PD-1 antibodies)	●	◑	◑		

Abbreviations: AML = acute myelocytic leukemia; NSCLC = non-small cell lung cancer; RCC = renal cell carcinoma; UC = urothelial carcinoma; MPM = malignant pleural mesothelioma; MM = multiple myeloma; OC = ovarian cancer.

Symbols: ● = complete; ◑ = in progress (a clinical trial is deemed to have been initiated when the first study site is activated); ◔ = to be initiated

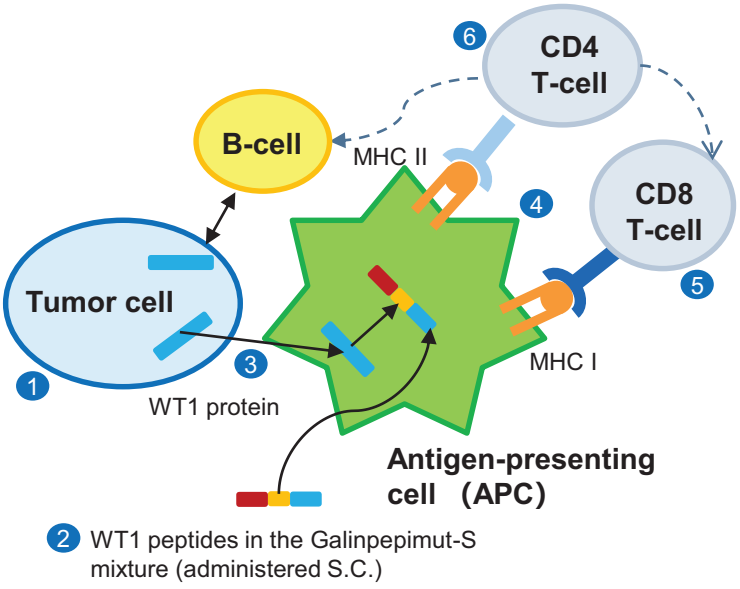
Note:

(1) Some indications may not require every phase of the clinical trials indicated on this chart to be completed prior to the filing of an NDA/BLA.

i. Mechanism of Action

3D189 targets malignancies characterized by an overexpression of the WT1 antigen. The WT1 antigen is one of the most widely expressed cancer antigens in multiple malignancies. It was the top ranked cancer antigen for immunotherapy by the U.S. National Cancer Institute (NCI) in 2009. The WT1 gene encodes for a zinc finger transcription factor that is normally expressed in mesodermal tissues during embryogenesis. The putative role in leukemia biology and the continued low level expression in patients who would otherwise be considered to be without evidence of disease by conventional criteria make WT1 a potential target for therapeutic intervention.

The WT1 immunotherapy 3D189 is comprised of four peptide chains, two of which are modified chains that induce a strong immune response (CD4+/CD8+) against the WT1 antigen and access a broad range of HLA types. When administered to a patient, 3D189's induced immune response has the potential to recognize and destroy cancer cells and provide ongoing support and memory to the immune system so that it can continue to target and destroy recurring tumors and residual cancer cells. 3D189 has the potential to be a highly effective approach to prolonging survival by delaying or preventing relapse/recurrence in patients in complete remission or with low tumor burden. The diagram below shows the mechanism of action for 3D189:



Abbreviations: APC = antigen-presenting cells; MHC = major histocompatibility complex

Source: Biochem J. 2014 Jul 1;461(1):15-32., Frost & Sullivan Report

ii. Market Opportunities and Competition

WT1 immunotherapy has the potential to target various cancers that over-express WT1. As of the Latest Practicable Date, there was no approved WT1 immunotherapy in the world. The following table sets out details of WT1 immunotherapy in clinical development worldwide as of the Latest Practicable Date:

Drug Name	Company	Target	Indications	Status	Location	Date
Galinpepimut-S/3D189	**3DMed/Sellas Life Sciences Group**	**WT1**	**Acute myeloid leukemia; Multiple myeloma; Mesothelioma; CRC; Ovarian cancer; TNBC; SCLC**	**Phase III**	**U.S.**	**2018-12**
TLP0-001	Tella; Wakayama Medical University	WT1	Pancreatic cancer	Phase III	Japan	2017-05
DSP-7888	Sumitomo Dainippon Pharma Oncology Inc	WT1	Glioblastoma; advanced solid tumor	Phase III	MRCT	2017-05
INO-5401	Inovio Pharmaceuticals	WT1	Glioblastoma; Urothelial Carcinoma	Phase I/II	Spain; U.S.	2018-04

Note:

(1) Date denotes the date on which the relevant status was publicly disclosed.

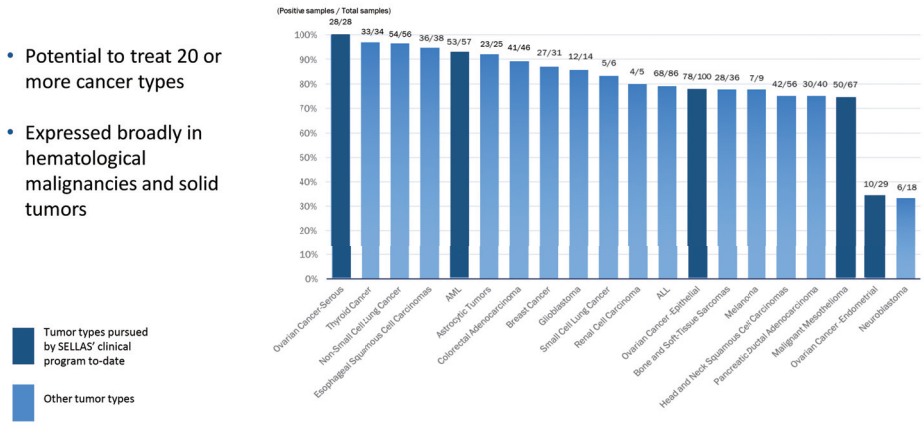
Source: Clinicaltrials.gov, FDA, Frost & Sullivan Report

iii. Competitive Advantages

(1) Targeting WT1, an optimal target for immunotherapy, with a potential to treat various types of cancers and a wide coverage of patients

3D189 is an immunotherapy that targets WT1, which was a top ranked antigen for immunotherapy according to the NCI in 2009. As shown in the figure below, WT1 targeting therapies can potentially treat over 20 cancer types (including lung cancer and CRC), which creates a large potential market with a wide coverage of patients. Specifically, WT1 is broadly detectable in AML, where it is densely and almost universally expressed at 90% to 95% of cases, and it is also expressed in multiple solid tumors and cancer stem cells. Since it is highly expressed and present

in cancer cells, it enables recognition and killing by specifically immunized T-cells, thus potentially preventing and delaying relapses in patients with hematological malignancies and solid tumors.



Source: Memorial Sloan Kettering Cancer Center data (based on review of literature and multiple studies)

(2) Potential synergy with envafolimab

3D189 is an immunotherapy that is able to activate the antigen-presenting cells and elicit T-cell-dependent immune responses against WT1-expressing cancer cells. 3D189 monotherapy has previously shown to be well tolerated and has promising clinical activity in multiple studies, which demonstrated that 3D189 could elicit anti-tumor immune response in the setting of low tumor burden and enhance immune surveillance. Therapies blocking PD-1/PD-L1, such as envafolimab, an anti-PD-L1 single domain antibody, have shown the ability to reduce inhibitory immune signals, thus allowing cytotoxic T cells to infiltrate the tumor and cause tumor regression in an expanding group of human malignancies. The preliminary data from studies of 3D189 in combination with pembrolizumab and nivolumab have displayed encouraging activity in patients with certain WT1-positive advanced solid tumors. Combining 3D189 with envafolimab is hypothesized to increase the proportion of patients who develop an immune response against their cancer and prolong the duration of such a response by induction of memory T cells. In addition, as 3D189 allows for "off the shelf" subcutaneous injection use and requires a simple manufacturing process by lyophilized formulation, it creates potentially good synergy with our envafolimab that is also subcutaneously injectable.

(3) Favorable safety profile with good patient compliance

3D189 is a peptide cancer vaccine consisting of 4 peptide chains, which can stimulate a strong immune response to various types of cancer. Pharmacology studies have reported that 3D189 elicits a strong immune response, yielding cytotoxic T-cells to cancer cells that present the WT1 antigen/peptide.

Based on the Phase I combination study of 3D189 with the anti-PD-1 nivolumab in the treatment of recurrent ovarian cancer patients, 3D189 exhibited highly tolerable safety profile with few significant systemic drug-attributed TEAEs, while its administration leads to mostly grade G1/G2 local skin and subcutaneous tissue inflammatory reactions that are transitory in nature. In addition, across the five completed studies with 3D189 monotherapy, the only Treatment Related Adverse Events (TRAEs) of any grade that occurred in more than 10% of the patients across all studies were injection site reaction in 18.2% of all patients (Grades 1 and 2 only) and fatigue in 14.9% of all patients (Grades 1 and 2 only). None of the Grade 3 or 4 TRAEs were observed in $\geq$ 10% of patients. Grade 3 and 4 TEAEs observed in 5% ~ 10% of patients were hematological (leukopenia, lymphopenia and neutropenia) and they occurred only in patients with hematologic cancers. No TEAE-related deaths occurred in any clinical studies thus far.

(4) Simultaneously boosting CD4+ and CD8+ T-cells using unique technology

3D189's mechanism of action relies on a unique heteroclitic technology to generate a strong anti-tumor immune response. 3D189 consists of four peptides designed for differentiated immunotherapy using the heteroclitic technology for the development of two of the four peptides. Utilizing such unique heteroclitic technology, heteroclitic peptides are engineered to have an artificially introduced single point amino acid sequence mutation, resulting in synthetic peptide analogs with improved immunogenicity by virtue of its higher binding affinity to human leukocyte antigen (HLA) on antigen-presenting cells, thereby breaking tolerance to the native sequence and stimulating a stronger T cell response than the native sequence. In order to broaden immunogenicity over a range of HLA subtypes, 3D189 contains four selected WT1 peptides, with one WT1 heteroclitic peptide to stimulate CD8 responses, two longer WT1 native peptides to stimulate CD4 responses and one longer heteroclitic peptide which could stimulate both CD4 and CD8 cells.

iv. Summary of Clinical Trials

Our partner SELLAS Group is conducting a Phase III pivotal clinical trial in patients in the U.S. and Europe with 3D189 (GPS) in patients with AML who have achieved second hematologic complete remission, with or without thrombocytopenia (CR2/CR2p).

In addition, SELLAS Group has completed several Phase I and II clinical trials including in AML (after first- and second-line therapy), MPM (after first-line therapy), high-risk MM (after upfront therapy including autotransplant), and relapsed OC (after second-line therapy).

Subject to the SELLAS Agreement, we plan to potentially join SELLAS Group's sponsored registration-enabling, randomized, multi-center, Phase III pivotal clinical trial in patients with AML who have successfully achieved their CR2. In addition, we received the IND approval for 3D189 for a Phase I clinical trial in patients with hematological malignancies in China in March 2022.

In January 2020, SELLAS Group commenced the Phase III clinical study of GPS in AML, also known as the REGAL study. The Phase III pivotal REGAL study is a 1:1 randomized, open-label study comparing GPS monotherapy in the maintenance setting to investigators' choice of best available treatment in AML patients who have achieved hematologic complete remission, with or without thrombocytopenia (CR2/CR2p), after second-line antileukemic therapy and who are deemed ineligible for or unable to undergo allogeneic stem-cell transplantation. The study is expected to enroll approximately 116 patients across up to approximately 135 clinical sites primarily in the U.S. and Europe. The primary endpoint is OS from the time of study entry. The Phase II study in AML CR2 patients, which is the same indication as the Phase III REGAL study, showed a median OS of 21.0 months, at a median follow-up of 30.8 months, in patients receiving GPS compared to 5.4 months in contemporaneously treated patients with best standard therapy. Please refer to the paragraphs headed "– Our Core Product and Other Drug Candidates – 2. Our Other Clinical-Stage Drug Candidates – a. 3D189 – iv. Summary of Clinical Trials – (1) AML Phase III Clinical Trial" in this section.

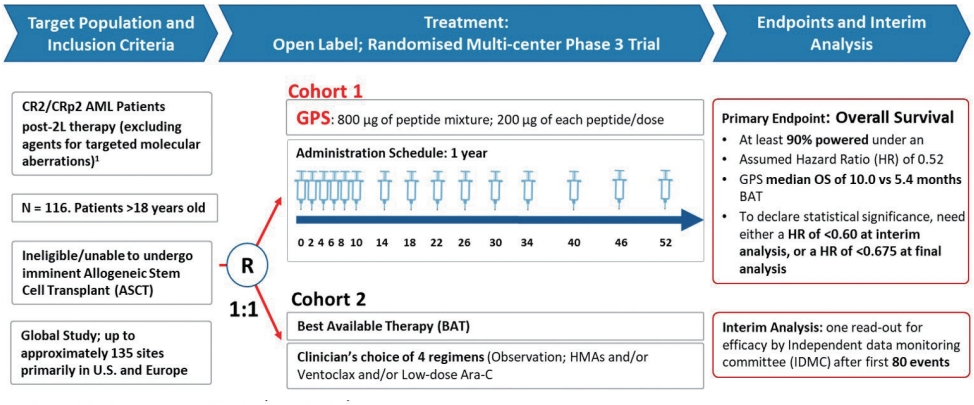
The following summarizes the clinical trials completed and/or being conducted by our partner SELLAS Group with 3D189 (GPS):

(1) AML Phase III Pivotal Clinical Trial

In January 2020, a Phase III pivotal registration-enabling study was commenced for GPS in AML patients in second complete remission, including those in complete remission with incomplete platelet recovery. This study, which is referred to as the REGAL study, is a 1:1 randomized, open-label study comparing GPS in the maintenance setting to investigators' choice of best available treatment, in adult AML patients (age >18 years) who have achieved their second hematologic (morphological) complete remission, with or without thrombocytopenia (CR2/CRp2; with "p" designating platelets), after second-line antileukemic therapy and who are deemed ineligible for or unable to undergo allo-HSCT. The primary endpoint is OS and secondary endpoints include leukemia-free survival rates of achievement of minimal residual disease (MRD) negativity. We plan to potentially join this study by enrolling patients from China in 2022. This study is expected to

be used as the basis for a BLA submission, subject to a statistically significant and clinically meaningful data outcome and agreement with the FDA and other health authorities including NMPA in China.

The key features and schema of this study are shown in the following graphic:



Notes: 1. Excluding agents that should be continued in the maintenance setting after achievement of CR2 with usage of 2L regimens containing such agents (e.g. FLT3 inhibitors); CRp2: CR2 with incomplete platelet recovery, i.e., platelet count of ≥60 x 10^9/L (as defined for this study); PB: peripheral blood; BM: bone marrow

Source: SELLAS's annual report on Form 10-k

(2) AML Phase I/II Clinical Trials

In an initial pilot clinical trial in AML, a total of 10 adult patients of all ages with *de novo* AML were treated with upfront standard chemotherapy and were able to achieve their first complete remission, or CR1. Of the 9 evaluable patients, administration of GPS resulted in a median OS that was at least 35 months from the time of GPS administration. In this study, specifically for patients who were 60 years and older (n=5), median OS was at least 33 months from the time of GPS administration or approximately 43 months from the time of initial AML diagnosis. The mean time of follow-up was 30 months from the time of diagnosis at the time of this analysis for all patients. Of the eight patients tested for immunologic response, seven, or 87.5%, demonstrated a WT1-specific immune response.

In a subsequent Phase II clinical trial in AML, a total of 22 adult patients of all ages with *de novo* AML were treated with upfront standard chemotherapy and were able to achieve CR1. Most patients also received one to four cycles of "consolidation" chemotherapy per standard AML treatment guidelines. GPS was then administered within three months from the completion of the consolidation chemotherapy regimen in up to 12 total doses: six initial doses (priming immunization) followed by six additional "booster" immunizations over a total period of up to nine months to qualifying patients (*i.e.*, patients who were clinically stable and did not show disease recurrence after the first six injections). This Phase II clinical trial met its primary endpoint of an actual OS rate of at least 34%, measured three years into the clinical trial (*i.e.*, percentage of patients alive after

three years of follow-up). An actual OS rate of 47.4% was demonstrated at three years post-GPS treatment, exceeding historical published data of OS of 20% to 25% by 2.4- to 1.9-fold (or 240% to 190%), respectively.

GPS administration was also shown to improve median OS in comparison to historical data in patients in CR1. Administration of GPS resulted in a median OS that was poised to exceed 67.6 months from the time of initial AML diagnosis in patients of all ages, which represents a substantial improvement compared to best standard therapy. Only five of the 22 patients underwent allo-HSCT and an ad hoc statistical analysis failed to show a significant effect of the transplant upon OS (either in median survival times or survival rates at specific landmark time-points). In this study, the patients' median age was 64 years old. The most frequent toxicities were mild to moderate local skin reactions and inflammation, as well as fatigue, which were self-limited and responded to local supportive measures and analgesics. None of the patients developed significant serious or high grade systemic adverse reactions (including anaphylaxis) attributable to GPS. GPS elicited WT1-specific immune responses in 88% of patients, including CD4 and CD8 T-cell responses. Further, the heteroclitic principle was confirmed, in that immune responses were seen against the native version of the two mutated WT1 peptides within the GPS mixture. The results showed a trend in improved clinical outcomes in patients who mounted an immune response with GPS compared to those patients who did not. Importantly, a preplanned subgroup analysis for the cohort of 13 patients within the clinical trial who were 60 years of age or older demonstrated a median OS of 35.3 months from time of initial diagnosis. Comparable historical populations have a median OS ranging from 9.5 to 15.8 months from initial diagnosis, which represents a 2.25 to 3.75-fold improvement in OS associated with GPS therapy in the CR1 maintenance setting as contrasted to these historical cohorts of broadly comparable patients.

An additional Phase II clinical trial of GPS was performed at the H. Lee Moffitt Cancer Center & Research Institute, or Moffitt. This Phase II trial included 10 AML patients who had received first-line therapy for their disease, who then experienced relapse and were subsequently treated with second-line chemotherapy and achieved a CR2. This group of patients had a more advanced disease in comparison to those treated in the Phase II clinical trial in CR1 patients discussed above, and typically demonstrated a historical OS of less than approximately 8 months, even with post-CR2 allo-HSCT. In the Moffitt trial, the efficacy of GPS (measured as median OS, from the time of achievement of CR2 until death from any cause) was compared with that of "watchful waiting" in a cohort of 15 contemporaneously treated (but not matched by randomization) broadly comparable patients treated by the same clinical team at Moffitt. Initial data, at a median follow-up of 19.3 months, showed that GPS administration resulted in a median OS of 16.3 months (495 days) compared to 5.4 months (165 days) from the time of achievement of CR2. This was a statistically significant difference (p=0.0175). Two of 14 AML patients demonstrated relapse-free survival of more than one year. Both

of these patients were in CR2 at time of GPS administration, with duration of their second remission exceeding duration of their CR1, strongly suggesting a potential benefit based on immune response mechanisms. Final data, at a median follow-up of 30.8 months, showed a median OS of 21.0 months in patients receiving GPS therapy compared to 5.4 months in the AML CR2 patients treated with best standard care (not randomized control). This is a statistically significant difference (p-value < 0.02). GPS was well-tolerated in this clinical trial.

(3) MPM Clinical Trials

A randomized, double-blind, placebo-controlled Phase II clinical trial in MPM patients enrolled a total of 41 patients at Memorial Sloan Kettering Cancer Center (MSK) and MD Anderson Cancer Center (MDACC). Data from this Phase II clinical trial was presented in 2016. Based on an initial analysis of 40 patients who were eligible at the time with a median follow-up of 16.3 months, a median OS of 24.8 months was seen for GPS-treated MPM patients, compared to a median OS of 16.6 months for patients in the control arm. In a subsequent analysis for the entire cohort (n=41) in August 2016, with a median follow-up of 17.2 months, a median OS of 22.8 months was observed for GPS-treated MPM patients, compared to a median OS of 18.3 months for patients in the control arm (difference is not statistically significant). In the datasets from both of these analyses, GPS was shown to induce WT1-specific CD8 and CD4 T-cell activation. There were no clinically significant severe adverse events in this study.

(4) MM Clinical Trials

SELLAS Group has reported comprehensive final data from a Phase I/II study for GPS in 19 patients with MM. All non-progression events were confirmed and remained ongoing as of the time of the latest presentation (median follow-up at 20 months for survivors). The data indicate promising clinical activity among MM patients with high-risk cytogenetics at initial diagnosis who also remain MRD(+) after successful frontline therapy (induction regimen followed by ASCT). This subgroup of MM patients, when serially assessed per IMWG criteria, typically relapse/progress within 12 to 14 months after ASCT, even when they receive maintenance therapy with IMiDs such as thalidomide or proteasome inhibitors such as bortezomib. Of note, 18 of the 19 patients received lenalidomide maintenance starting after the first three GPS administrations following ASCT; the remaining single patient received bortezomib under the same schedule. All patients had evidence of at least MRD after ASCT, while 15 of the 19 also had high-risk cytogenetics at diagnosis. Combined, these characteristics typically result in low PFS rates that do not exceed 12 to 14 months following ASCT, even while on maintenance therapy with IMiDs or proteasome inhibitors, which are the current standards of care. At June 2017, median PFS with GPS was 23.6 months, while median OS had not been reached. The results compare favorably with an unmatched cohort of broadly comparable MM patients with high-risk cytogenetics published by

the Spanish PETHEMA group from the PETHEMA Network No. 2005-001110-41 trial. The GPS therapy demonstrated a 1.87-fold increase in median PFS, as well as a 1.34-fold increase in the PFS rate at 18 months compared to the aforementioned historical cohort, which included MM patients with high-risk cytogenetics and MRD(+) post-ASCT and on continuous intensive maintenance with thalidomide +/- bortezomib. The safety profile was devoid of grade 3/4/5 treatment-related adverse events. Immune response data showed that up to 91% of patients had successfully developed T-cell (CD8 or CD4) reactivity to any of the four peptides within the GPS mixture, while up to 64% of patients demonstrated immune response positivity (CD4/CD8) against more than one WT1 peptide (multivalent responses). Moreover, multifunctional cross-epitope T-cell reactivity was observed in 75% of patients to antigenic epitopes against which hosts were not specifically immunized, in a pattern akin to epitope spreading. Further, a distinctive link was shown between the evolution of immune responses and changes in clinical response status (achievement of CR/very good partial response clinical status per IMWG criteria) over time following treatment with GPS, with each patient being used as his or her own control for each longitudinal comparison. This association has not been previously described for a peptide vaccine in MM.

(5) GPS Combination Therapy with PD1 blocker (nivolumab) for Ovarian Cancer

GPS was studied in combination with nivolumab, a PD-1 immune checkpoint inhibitor, in an open-label, non-randomized Phase I/pilot clinical trial, which was independently sponsored by MSK. The aim of the study was to evaluate the safety and efficacy of this combination in patients with WT1-expressing (WT1+) recurrent ovarian, fallopian tube or primary peritoneal cancer who were in second or greater clinical remission (after their successful first or subsequent "salvage" therapy). Eligible patients were devoid of macroscopic residual or recurrent disease, i.e., were free of locally or distantly metastatic deposits detectable by imaging modalities (CT, MRI and/or PET scan). This Phase I/pilot clinical trial enrolled 11 patients with recurrent ovarian cancer who were in second or greater clinical remission at MSK, of whom 10 were evaluable. Patients enrolled in the clinical trial received the combination therapy during the clinical trial's 14-week treatment period. Individuals who had not progressed by the end of this period also received a maintenance course of GPS. In this study, treatment was continued until disease progression or toxicity. Information on the primary endpoint of this clinical trial, which was the safety of repeated GPS administrations, for a total of six doses, in combination with seven infusions of nivolumab was presented at the American Society of Clinical Oncology, or ASCO, 2018 annual meeting. The secondary endpoint of the study was immune response, and the exploratory endpoints included landmark one-year PFS rate compared to historical controls and correlative analyses between clinical and immune responses. Exploratory efficacy interim data from this pilot trial showed that GPS, when combined with a PD-1 inhibitor, in this case nivolumab, demonstrated PFS of 64% at one year in an intent to treat the group of 11 evaluable patients with WT1+ ovarian cancer in second or greater remission. Among patients

who received at least three doses of GPS in combination with nivolumab, PFS at one year was 70% (7/10). The historical rates with best standard treatment do not exceed 50% in this disease setting. The most common adverse events were Grade 1 or 2, including fatigue and injection site reactions. Dose limiting toxicity was observed in one patient, following the second dose of the combination. No additional adverse event burden was observed for the combination as compared to nivolumab monotherapy. The combination induced a high frequency of T- and B-cell immune responses.

Follow-up data now show that three of the 11 patients enrolled in the study have continued to show no signs of disease progression. The mean PFS for these three patients is 35.4 months from the initiation of salvage chemotherapy, or mean PFS of 30.1 months from the first administration of GPS plus nivolumab. Based on this follow-up information, the estimated two-year PFS rate for this study is now 27.3% for the intent-to-treat, or ITT, patients (n=11) and approximately 30% for patients who received greater than two doses of GPS and nivolumab (n=10), as compared to a historical 3% to 10% PFS rate for patients receiving only salvage chemotherapy. No new serious adverse events were noted during the longer follow-up period.

(6) GPS Combination Therapy with PD1 blocker (pembrolizumab)

This clinical study was initiated in December 2018. The tumor type currently being investigated is ovarian cancer (second or third line). In December 2020, it was announced that the first set of evaluable patients (n=8) in the study, diagnosed with 2nd or 3rd line WT1(+) relapsed or refractory metastatic ovarian cancer, demonstrated a disease control rate (the sum of overall response rate and rate of stable disease) of 87.5% with a median follow-up of 9.4 weeks. At the first assessment time-point of 6 weeks post-therapy initiation, 100% of the patients were free of disease progression. Using a validated immunohistochemistry (IHC) assay during the screening period, the rate of WT1 positivity in this ovarian cancer patient population was approximately 70%. Six of the eight evaluable patients are continuing to receive GPS plus pembrolizumab. Enrollment in this arm of the study is continuing with a target of a total of 20 patients.

(7) GPS Combination Therapy with PD1 blocker (nivolumab) for MPM

A single-center, open-label, single-arm, non-randomized investigator-sponsored Phase I trial of concomitant administration of GPS in combination with nivolumab was initiated in February 2020 at MSK in patients with MPM who have previously received treatment with pemetrexed-based chemotherapy and have measurable disease on imaging, either due to residual disease after prior treatment or recurrent disease. SELLAS Group is providing GPS and BMS is providing nivolumab for this study.

The IST is planned to accrue a minimum of 10 patients. Its primary objective is to determine the tolerability of the GPS plus nivolumab combination in patients with previously treated MPM who have documented progression of disease on imaging at the time of study entry, while the secondary objective is to evaluate the immunogenicity of the above combination by assessing the WT1-specific cell-mediated immune response both in peripheral blood and at the tumor site.

In December 2020, it was announced that the first set of evaluable patients (n=3) had a median PFS of at least 10 weeks since therapy initiation. In primary refractory MPM patients, any prolongation of progression-free interval greater than 8 weeks would be considered clinically meaningful, considering the current lack of effective therapies. All patients had the epithelioid variant of MPM, a tumor which is universally expressing WT1. GPS was found to be appropriately immunogenic, leading to the emergence of antigen (WT1)-specific CD4+ T-memory cell responses at three months post-therapy initiation. Additional MPM patients are currently being enrolled.

v. Clinical Development Plan

We plan to join the ongoing Phase III clinical trial in AML sponsored by SELLAS Group. In addition, we plan to conduct an open-label Phase I trial to evaluate the safety, immunogenicity and efficacy of 3D189 in patients with hematological malignancies in China. Following this Phase I trial, we plan to further explore the clinical potential of 3D189 in combination with envafolimab in selected solid tumors, such as NSCLC, RCC, UC and other solid tumors. Depending on initial data, additional tumor types and combination with additional treatments may be studied.

The table below sets forth the details of our clinical development plan in China for 3D189:

Indication	Status	Expected first patient in date	Expected NDA submission date	Expected number of patients	Location and competent authority
HM[(1)]	Phase I	2H 2022	–	15	China and NMPA
NSCLC[(2)]	Phase Ib/II	Q2 2023	–	20	China and NMPA
RCC[(2)]	Phase Ib/II	Q2 2023	–	20	China and NMPA
UC[(2)]	Phase Ib/II	Q2 2023	–	20	China and NMPA
Other solid tumors[(2)]	Phase Ib/II	Q2 2023	–	30	China and NMPA

Abbreviations: HM = hematological malignancies; NSCLC = non-small cell lung cancer; RCC = renal cell carcinoma; UC = urothelial carcinoma; 2H = second half; Q1 = first quarter.

Notes:

(1) This planned clinical trial is based on positive immune response and preliminary efficacy signal from phase I/II studies in AML and MM completed by SELLAS. As of July 18, 2022, this clinical trial was still in preparation stage and no patient had been enrolled. First patient is expected to be enrolled in second half of 2022.

(2) These planned clinical trials are based on over expression of WT1 in NSCLC, RCC, UC etc. and complementary mechanism of action between PD-L1 inhibition and WT1 vaccine. As of July 18, 2022, these clinical trials were still in preparation stage and no patient had been enrolled. First patient is expected to be enrolled in second quarter of 2023.

vi. Licenses, Rights and Obligations

We maintain the exclusive rights to develop, manufacture and commercialize 3D189 in China, Hong Kong, Macau and Taiwan region for all therapeutic and other diagnostic uses. We obtained all the intellectual property rights relating to 3D189 pursuant to an exclusive license agreement between us and SELLAS Group. Please refer to the paragraphs headed "Our Research and Development – Collaboration Agreements – Collaboration with SELLAS Group for 3D189 and 3D059" in this section.

vii. Material Communications

We obtained the IND approval for 3D189 in China in March 2022. We had not received any relevant regulatory agency's objections to our clinical development plans as of the Latest Practicable Date.

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 3D189 SUCCESSFULLY.

b. 3D229

3D229 (also known as batiraxcept, AVB-500), is a high-affinity, soluble Fc-fusion protein designed to bind GAS6 (Growth Arrest Specific 6), intercept the binding of GAS6 to its receptor AXL and block the activation of the GAS6-AXL signaling pathway. We own the exclusive rights to develop, manufacture and commercialize 3D229 in China, Hong Kong, Macau and Taiwan region through our collaboration and license agreement with Aravive. The FDA has permitted our partner Aravive to initiate a Phase III clinical trial to evaluate 3D229 in the U.S. in platinum resistant ovarian cancer (PROC), and Aravive started recruiting patients in the U.S. for this trial in April 2021. Results of a Phase I clinical trial of 3D229 conducted by Aravive in healthy human volunteers showed a favorable safety profile, with no reported serious or dose-limiting adverse events. Moreover, results of this trial showed a dose-related reduction of circulating free GAS6 in serum, which serves as a robust pharmacodynamics marker for 3D229 (batiraxcept, AVB-500). In preclinical studies, GAS6-AXL inhibition has shown activity both as a single agent and in combination with other of anticancer therapies including radiation therapy, immunotherapies, and drugs that affect DNA replication and

repair. We submitted the IND for 3D229 for a Phase I clinical trial in healthy human volunteers in China and obtained the IND approval in China in May 2021. We completed this Phase I clinical trial in May 2022. We obtained the IND approval for a Phase Ib/II clinical trial in patients with NSCLC, RCC and UC in April 2022. Furthermore, we submitted the IND for 3D229 for a Phase III clinical trial in patients with PROC in China in April 2021 to participate in the multi-regional clinical trial (MRCT) and obtained the IND approval for this trial in July 2021, and we initiated this Phase III clinical trial in China in February 2022. Additional feedback from the U.S. FDA regarding standard of care treatment with bevacizumab will be obtained to determine China's participation in the Phase III.

The table below shows the indications for which 3D229 is currently being evaluated by us or our partner Aravive or its collaborators in clinical trials:

	Status					
		Phase I		Phase II	Phase III	NDA/BLA (Filed)
Indication[1]	**IND**	**Ia**	**Ib**			
China						
Healthy human volunteers	●	●				
PROC (MRCT; combination with paclitaxel)	●				◑[2]	
U.S. (Aravive)						
Healthy human volunteers	●	●				
PROC (combination with paclitaxel or pegylated liposomal doxorubicin)	●		●			
PROC (MRCT; pivotal study; combination with paclitaxel)	●				◑	
ccRCC (combination with cabozantinib)	●		◑	◑		
PC (combination with gemcitabine and nab-paclitaxel)	◑		◑	◑		
PROC (combination with durvalumab)[3]	●	◑				
UC (combination with avelumab)[3]	●	◑				
IgA Nephropathy	●			○[4]		

Abbreviations: PROC = platinum-resistant ovarian cancer; MRCT = multi-regional clinical trial; ccRCC = clear cell renal cell carcinoma; PC = pancreatic cancer; UC = urothelial carcinoma.

Symbols: ● = complete; ◑ = in progress (a clinical trial is deemed to have been initiated when the first study site is activated); ◔ = to be initiated; ○ = terminated

Notes:

(1) Some indications may not require every phase of the clinical trials indicated on this chart to be completed prior to the filing of an NDA/BLA.

(2) As of July 3, 2022, four patients have been enrolled to this MRCT in China.

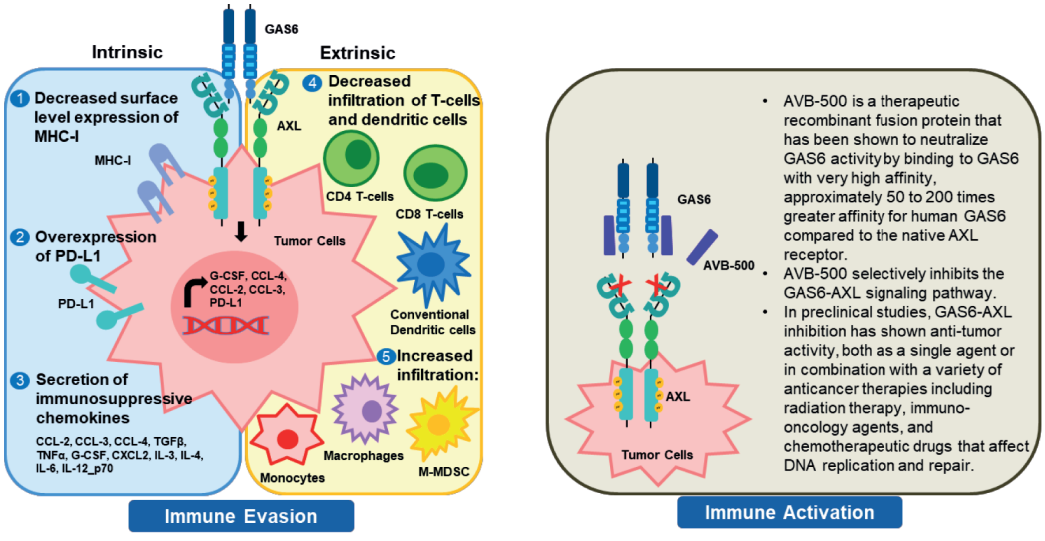
(3) Investigator sponsored trials (IST).

(4) Aravive decided to focus on oncology indications and terminated this study.

i. Mechanism of Action

Activation of the receptor tyrosine kinase AXL by its sole ligand, GAS6, leads to increased cellular adhesion, invasion, migration, pro-tumoral immune response, anti-apoptosis, proliferation, and survival in several cancers. 3D229 is a high affinity GAS6 decoy receptor protein designed by combining an engineered soluble portion of AXL receptor with the Fc region of human IgG1.

AXL is a member of TAM family of tyrosine kinases that include Tyro3, AXL, and Mer (TAMs), and is activated by a single ligand, GAS6. Mer and Tyro3 can be activated by GAS6 and protein S. Upregulated in many cancers, AXL overexpression is linked to metastasis, poor survival, and drug resistance. Research has shown GAS6-AXL signaling to be a key molecular pathway that promotes tumor growth and metastases, as well as immune evasion and resistance to other anticancer agents. AXL and GAS6 expression also correlates with poor prognosis in cancer. Unusually strong binding affinity between GAS6 and AXL of about 30 pM makes development of antibody inhibitors to the pathway challenging. 3D229's affinity to GAS6 is about 200-fold stronger than wild-type AXL receptor and therefore can effectively inhibit the GAS6-AXL signaling pathway. The diagram below shows the mechanism of action for 3D229 (batiraxcept, AVB-500):



Source: Cancers (Basel). 2020 Jul; 12(7): 1850., Frost & Sullivan Report

ii. Market Opportunities and Competition

GAS6-AXL pathway drugs have the potential to impair multiple stages of tumor progression from both neoplastic and host cell axes. Compared to an AXL tyrosine kinase inhibitors, a GAS6 decoy receptor has the potential advantage to selectively inhibit the GAS6-AXL signaling pathway. As of the Latest Practicable Date, there were no approved AXL tyrosine kinase inhibitors that selectively inhibits AXL and a total of eleven GAS6-AXL pathway drugs in clinical development. The following tables sets out details of GAS6-AXL pathway drugs in clinical developments worldwide as of the Latest Practicable Date:

Drug Name	Company	Target	Indications	Status	Location	Date
AVB-S6-500/3D229	**Aravive Biologics; Aravive Inc; 3DMed**	**GAS6/AXL**	**Fallopian tube cancer; Transitional cell carcinoma; Renal cell carcinoma; Ovarian cancer; Peritoneal carcinoma; Ovary epithelial carcinoma; Urothelial Carcinoma; Pancreatic Neoplasms**	**Phase III**	**U.S.; China**	**2018-08**
BA-3011	Bioatla lnc; AstraZeneca PLC	AXL	NSCLC; Osteosarcoma; Melanoma; Synovial sarcoma; Leiomyosarcoma; Sarcoma; Pancreatic cancer; Ewing's sarcoma; Liposarcoma; Solid Tumor; Ovarian Neoplasms	Phase II	U.S.	2018-02
HK-001/ Butylidenephthalide	Everfront Biotech Co Ltd;	AXL	Glioma; Amyotrophic lateral sclerosis	Phase II	China Taiwan region	2017-07
ONO-7475	Ono Pharmaceutical	AXL	Leukemia; Myelodysplastic syndrome; Acute myeloid leukemia; Solid tumors	Phase II	U.S.	2017-06
Dubermatinib/ TP-0903	Sumitomo Dainippon Pharma Oncology Inc	AXL	Chronic lymphocytic leukemia; NSCLC; Melanoma; CRC; Ovarian cancer, AML, Solid Tumor	Phase II	U.S.	2016-04

Drug Name	Company	Target	Indications	Status	Location	Date
Bemcentinib/ BGB324	Bergenbio; Bergenbio Asa; MSD; Rigel Pharmaceuticals Inc	AXL	Myelodysplastic syndrome; Melanoma; Breast cancer; NSCLC; Lung adenocarcinoma. Acute myeloid leukemia; Non-alcoholic fatty liver disease; Idiopathic pulmonary fibrosis; COVID-19; Pancreatic Neoplasms; Brain and Central Nervous System Tumors	Phase II	U.S.; France; Germany; Netherlands; Italy; Norway	2015-07
Enapotamab vedotin	Genmab	AXL	Ovarian Cancer; Cervical Cancer; Endometrial Cancer; Non Small Cell Lung Cancer; Thyroid Cancer; Melanoma; Sarcoma	Phase I/II	Belgium; Denmark; Netherlands; Spain; UK; U.S.	2016-12
BGB-149	Bergenbio	AXL	Ovarian Neoplasms	Phase I	South Korea; UK; Norway; Singapore	2021-05
PF-07265807	Pfizer Inc	AXL	Neoplasm Metastasis	Phase I	U.S.	2020-07
SLC-391/ XZB-0004	Signalchem Lifesciences Co; Xuanzhu Biotechnology	AXL	Solid Tumor	Phase I	Canada	2019-06
CCT301-38	Shanghai PerHum Therapeutics Co., Ltd.	AXL	Relapsed or Refractory AXL Positive Sarcomas	Phase I	China	2021-11

Note:

(1) Date denotes the date on which the relevant status was publicly disclosed.

Source: CDE, FDA, Annual Reports of Listed Pharmaceutical Companies, Frost & Sullivan Report

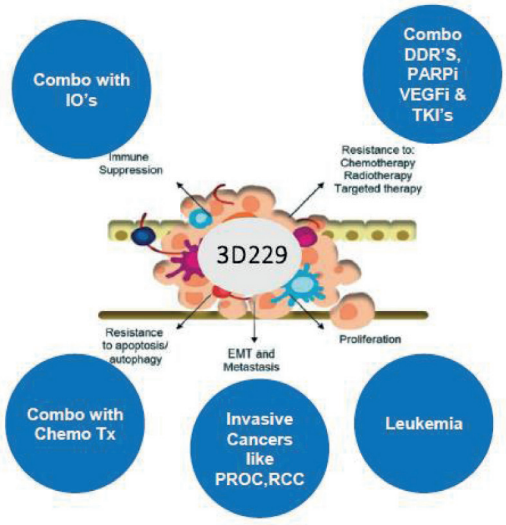
iii. Competitive Advantages

(1) Differentiated product in advanced clinical stage in the world with demonstrated promising effectiveness

3D229 is a differentiated GAS6-AXL signaling pathway inhibitor that selectively binds GAS6 to suppress AXL signaling while other products are tyrosine kinase inhibitors (TKIs) or monoclonal antibody. Please refer to the paragraphs headed "Our Core Product and Other Drug Candidates – 2. Our Other Clinical-Stage Drug Candidates – 3D229 – ii. Market Opportunities and Competition" in this section. Limited selectivity of TKIs likely leads to off-target toxicity and tumor cells often acquire resistance. In addition, monoclonal antibodies likely do not have a high enough affinity to compete effectively with and disrupt the high-affinity GAS6-AXL interaction. The approaches of such other products to target GAS6-AXL signaling pathway have drawbacks which limit their ability to effectively target this pathway.

(2) Good synergy with other immunotherapies with potential in various indications

3D229 has the potential to treat indications such as leukemia and invasive cancers that are outside the treatment scope of PD-1/PD-L1 and may overcome resistance to PD-1/PD-L1 antibodies. It can therefore potentially achieve good synergy with PD-1/PD-L1 antibodies including our envafolimab. In addition, as illustrated in the diagram below, 3D229 has the potential to work in combination with chemotherapy, radiotherapy, and targeted therapies.

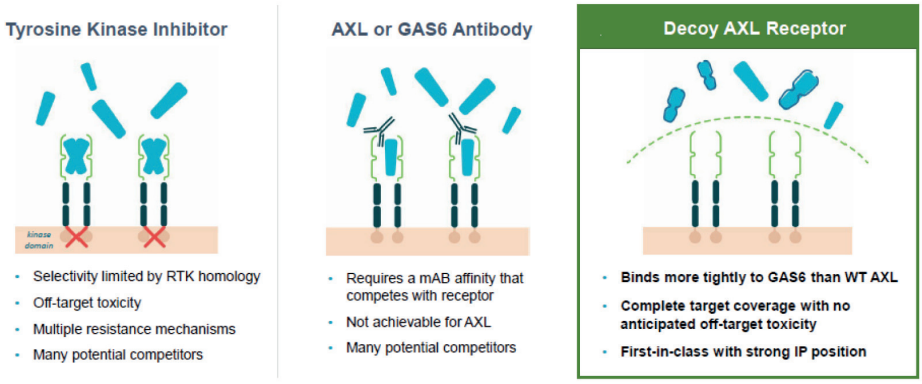


Abbreviations: IO = immune-oncology; DDR = DNA damage response; PARPi = polymerase inhibitor VEGFi = vascular endothelial growth factor receptor inhibitor; TKI = tyrosine kinase inhibitor; PROC = platinum-resistant ovarian cancer; RCC = renal cell carcinoma.

Source: Company data

(3) Promising efficacy due to its advantages in design and mechanism of action

As illustrated by the diagram below, compared to tyrosine kinase inhibitors and AXL or GAS6 antibodies, engineered decoy receptors are potentially the best approach for potently and selectively inhibiting the GAS6-AXL signaling pathway. A GAS decoy receptor can bind more tightly to GAS6 than wild-type AXL with no anticipated off-target toxicity. 3D229 is a high affinity decoy protein that suppresses GAS6 to undetectable levels in early clinical studies and has prolonged target engagement. The safety and tolerability profile of 3D229 in the Phase I clinical trial of 3D229 with healthy volunteers supports its good safety profile and potential for use as a combination and/or maintenance therapy. Please refer to the paragraphs headed "Our Core Product and Other Drug Candidates – 2. Our Other Clinical-Stage Drug Candidates – a. 3D229 – iv. Summary of Clinical Trials – (1) Phase I Clinical Trial in Healthy Volunteers in the U.S." in this section.



Source: Company data

In addition, in the Phase Ib/II clinical trial of 3D229 in combination with pegylated liposomal doxorubicin (PLD) or paclitaxel (PAC) in patients with platinum-resistant recurrent ovarian cancer, as illustrated in the table below, 3D229 in combination with PAC showed ORR of 35% (95% CI of 16% to 58%) while historically, PAC monotherapy has demonstrated an ORR of approximately 10% to 15%. Please refer to the paragraphs headed "Our Core Product and Other Drug Candidates – 2. Our Other Clinical-Stage Drug Candidates – a. 3D229 – iv. Summary of Clinical Trials – (2) Phase Ib/II Clinical Trial for the Treatment of Patients with PROC" in this section. Historically, high sAXL was associated with poor prognosis. However, PAC in combination with 3D229 in this study demonstrated higher response rate with higher sAXL/GAS6 ratio in a post-hoc analysis and will be further explored in future studies. The Phase II portion of this trial was not conducted.

Table: Investigator-Assessed Best Response per RECIST V1.1

	PAC (N=23)	PLD (N=26)
CR	2 (8.7%)	0
PR	6 (26%)	4 (15%)
ORR	**8 (35%)**	4 (15%)
SD	6 (26%)	12 (46%)
CBR	14 (61%)	16 (61.5%)
PD	9 (39%)	10 (38.5%)

Abbreviations: CR = complete response; PR = partial response; ORR = overall response rate; SD = stable disease; CBR = clinical benefit rate; PD = Pharmacodynamic.

Source: Company data

(4) Favorable clinical safety profile

Our partner Aravive has completed a single-blind, randomized, placebo-controlled, Phase I, single ascending-dose (SAD) and repeat-dose (RD), safety and tolerability study of intravenous 3D229 in healthy human volunteers in the U.S. Based on the safety, PK and PD profile of 3D229 in healthy volunteers Phase I clinical trial, 3D229 was well tolerated at all doses levels (1.0, 2.5, 5.0, 10 mg/kg) without clinically significant TEAEs. Please refer to the paragraphs headed "Our Core Product and Other Drug Candidates – 2. Our Other Clinical-Stage Drug Candidates – a. 3D229 – iv. Summary of Clinical Trials – (1) Phase I Clinical Trial in Healthy Volunteers in the U.S." in this section.

iv. Summary of Clinical Trials

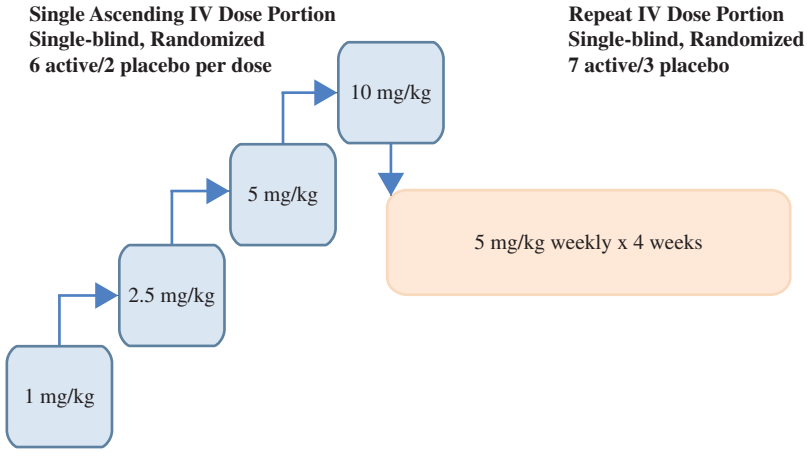
As of the Latest Practicable Date, our partner Aravive had evaluated the safety and efficacy profiles of 3D229 (batiraxcept, AVB-500) in several completed and ongoing clinical trials covering a wide variety of tumor types, including PROC, advanced clear cell renal cell carcinoma (ccRCC). Our partner Aravive is conducting a Phase III clinical trial with of 3D229 in combination with PAC versus PAC alone in patients with PROC in the U.S. and Europe. The first patient was enrolled in the U.S. in April 2021. Aravive initiated this Phase III pivotal clinical trial during the first quarter of 2021. The primary endpoint of the Phase III clinical trial is progression free survival. We submitted the IND for 3D229 in China in April 2021 to participate in the MRCT and obtained the IND approval for this trial in July 2021, and we initiated this Phase III clinical trial in China in February 2022.

The following summarizes the clinical trials completed and/or being conducted by our partner Aravive with 3D229 (batiraxcept, AVB-500):

(1) Phase I Clinical Trial in Healthy Volunteers in the U.S.

In 2018, a Phase I clinical trial with 3D229 (batiraxcept, AVB-500) was completed in 42 dosed normal healthy human volunteers. Subjects in the Phase I trial were given single ascending intravenous, doses and 4 weekly repeat intravenous doses of 3D229 (batiraxcept, AVB-500). The primary objective of the trial was to evaluate the safety and tolerability in healthy subjects of intravenously administered 3D229 (batiraxcept, AVB-500). Secondary objectives were to characterize the pharmacokinetics and pharmacodynamics of intravenously administered 3D229 (batiraxcept, AVB-500) over a range of dose levels and at a single dose level (5mg/kg) for a total of 4 weekly doses.

First Clinical Study in Healthy Volunteers Identified Well-Tolerated and Pharmacologically Active Doses
Data Presented at 2018 EORTC-NCI-AACR



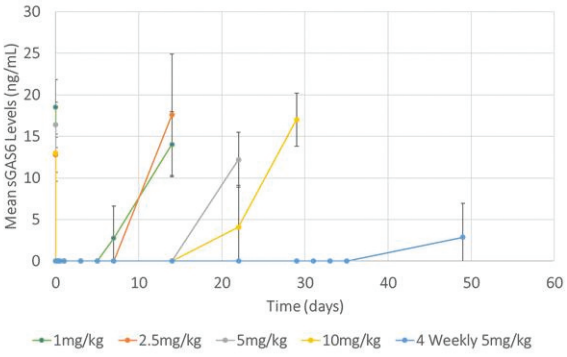
Source: Aravive's annual report on Form 10-k

In this study all laboratory values outside the normal limits as defined in the NCI-CTCAE v4.03 after the first dose of study drug were recorded as adverse events (AEs) whether or not the Investigator deemed them clinically significant. There were no AEs classified as serious and no dose-related AEs. No anti-drug antibodies were noted. As anticipated from preclinical studies, a maximum tolerated dose was not reached and 3D229 (batiraxcept, AVB-500) was well-tolerated across all doses (1, 2.5, 5, 10mg/kg single doses and 4 weekly 5mg/kg doses). The clinical trial met the safety and tolerability endpoints for the trial and demonstrated clinical proof-of-mechanism for 3D229 (batiraxcept, AVB-500) at all doses in neutralizing GAS6, as all doses tested in human subjects suppressed serum GAS6 for at least one week. As shown in the figure below, serum GAS6 levels were suppressed until 22

and 29 days following the 5 mg/kg and 10 mg/kg doses, respectively. Weekly administration of 5mg/kg resulted in suppression of sGAS6 in 4 out of 6 subjects for at least 3 weeks after the fourth dose.

Proof of Mechanism Demonstrated At All Doses

Increased AVB-S6-500 Dose Increased Duration of Abrogation of Serum GAS6



Source: Aravive's annual report on Form 10-k

(2) Phase Ib/II Clinical Trial for the Treatment of Patients with PROC

In December 2018, following a normal healthy volunteer trial that identified a dose of 10mg/kg 3D229 (batiraxcept, AVB-500) as sufficient to suppress serum GAS6 levels for a two-week period, Aravive began treating patients in a Phase Ib clinical trial combining 10mg/kg (administered every 2 weeks) 3D229 (batiraxcept, AVB-500) with standard-of-care therapies (specifically, PAC or PLD) in patients with PROC. The Phase Ib clinical trial was designed, in part, to confirm the dosing regimen predicated on the Phase 1 trial in healthy volunteers and to identify the dose to investigate in later stage trials. The primary objective of the Phase Ib clinical trial was to assess the safety and tolerability of 3D229 (batiraxcept, AVB-500) in combination with PAC or PLD, and secondary objectives were to assess pharmacokinetics and pharmacodynamics or PK/PD (serum GAS6 and soluble AXL (sAXL) levels), efficacy, and potential immunogenicity of 3D229 (batiraxcept, AVB-500). Exploratory objectives included efficacy endpoints in biomarker (GAS6, AXL) defined populations based on expression of those biomarkers in serum and/or tumor tissue. In September 2019, positive data from the initial 12 patients of the Phase Ib clinical trial in a late breaking oral presentation was presented at the European Society for Medical Oncology (ESMO) Congress in Barcelona and based upon the analysis of the data decided to study higher doses of the drug and expanded the Phase Ib trial to study 15 mg/kg and 20 mg/kg dose levels.

On July 23, 2020, a press release was issued to present data from the Phase Ib clinical trial of 3D229 (batiraxcept, AVB-500) combined with standard of care therapies in patients with PROC, the selection of 15 mg/kg as the recommended dose and other results of the trial. The Phase1b clinical trial results are set forth below:

The safety of 3D229 (batiraxcept, AVB-500) has been studied in 84 subjects as of July 2020, including 31 healthy volunteers in a Phase Ia clinical trial and 53 patients with PROC in a Phase Ib clinical trial (40 in 10 mg/kg cohort, 6 in 15 mg/kg cohort, and 7 in 20 mg/kg cohort). The primary objective of the Phase Ib clinical trial was to assess safety of 3D229 (batiraxcept, AVB-500) in combination with PAC or PLD. Secondary endpoints included ORR, CA-125 response, clinical benefit rate, PFS, overall survival, PK profile, GAS6 serum levels, and anti-drug antibody titers.

Safety Data: Analysis of all safety data to date demonstrates that 3D229 (batiraxcept, AVB-500) has been generally well-tolerated with no dose-limiting toxicities or unexpected safety signals. There have been no 3D229 (batiraxcept, AVB-500)-related significant adverse events reported to date. There were two types of adverse events that were considered related to 3D229 (batiraxcept, AVB-500), as determined by an independent medical monitor: infusion reactions and fatigue. A premedication regimen was designed and implemented during the trial to manage potential infusion reactions.

Pharmacokinetics: Prior data analysis of 31 patients from the 10 mg/kg cohort showed that blood trough levels of 3D229 (batiraxcept, AVB-500) demonstrated statistically significant correlation with clinical activity, as patients who achieved minimal efficacious concentration or MEC >13.8 mg/L demonstrated a greater likelihood of response and prolonged PFS. Updated modeling using actual data from all enrolled patients demonstrated that the 20 mg/kg dose is not predicted to improve PFS relative to the 15 mg/kg dose so the dose of 15 mg/kg was selected as the recommended Phase II dose (RP2D) for 3D229 (batiraxcept, AVB-500).

Clinical Activity: While the Phase Ib clinical trial was a safety trial and not powered to demonstrate efficacy, the investigator-assessed best response or RECIST V1.1 to 3D229 (batiraxcept, AVB-500) across all cohorts supports promising clinical activity, as summarized in the table below:

Cohort	Patients Evaluable	Key Findings
10 mg/kg cohort	37 out of 40 patients evaluable	21.6% ORR (8/37) in all evaluable patients, regardless of their MEC or use of PAC or PLD. 33% ORR (5/15) among those treated with 3D229 (batiraxcept, AVB-500) in combination with PAC, with 1 complete response or CR. 50% ORR (4/8), with 1 CR in PAC patients who achieved MEC (13.8mg/L) of 3D229 (batiraxcept, AVB-500). The PFS among those patients treated with 3D229 (batiraxcept, AVB-500) plus PAC who achieved MEC was 7.5 months versus 2.28 months in patients with blood trough levels below MEC (p=0.0062).
15 mg/kg cohort	5 out of 6 patients evaluable	5/5 efficacy evaluable patients in this cohort experienced clinical benefit, with 1 CR, 2 partial responses (PR), and 2 stable disease (SD)
20 mg/kg cohort	7 out of 7 patients evaluable	Of the 7 patients in this cohort, there was 1 PR (with CR of target lesion), 1 SD, and 5 with progressive disease (PD). A post-hoc analysis of tumor expression showed that 4 patients whose best response was PD did not express GAS6 (3) and/or had low amounts of AXL (2) on immunohistopathology of their tumors. While they were enrolled per protocol in the Phase Ib clinical trial, these patients do not appear to be representative of the eventual 3D229 (batiraxcept, AVB-500) target population, as they are mostly rare subtypes of PROC and such patients based on their clinical characteristics will not be eligible for the pivotal trial. The pivotal trial has been designed to only enroll patients with high grade serous ovarian cancer as that is the pathology associated with elevated AXL expression.

Conclusion: 3D229 (batiraxcept, AVB-500) plus PAC appeared to perform better than 3D229 (batiraxcept, AVB-500) plus PLD. Across all cohorts, 3D229 (batiraxcept, AVB-500) plus PAC data show an ORR of 35% (8/23, including 2 CRs) compared to ORR of 15% (4/26) in 3D229 (batiraxcept, AVB-500) plus PLD. 3D229 (batiraxcept, AVB-500) performed well in patients with later lines of therapy and showed improved clinical benefit over published data showing response for patients who were on their third and fourth lines of therapy or who progressed in less than 3 months following their last platinum-containing regimen. 3D229 (batiraxcept, AVB-500) treatment alone demonstrated an ability to maintain tumor response. Three patients' responses were maintained for 3 to 6 months on 3D229 (batiraxcept, AVB-500) following PAC (2 patients) or PLD (1 patient). One was treated at 15 mg/kg had a CR, and 2 patients treated at 10 mg/kg had partial responses (PR). For the 2 patients on maintenance 3D229 (batiraxcept, AVB-500) alone, tumors progressed after missed scheduled 3D229 (batiraxcept, AVB-500) administration.

(3) Phase III Clinical Trial for the Treatment of Patients with PROC

On November 19, 2020, Aravive announced that it had received guidance from the FDA on a registrational Phase III trial design for 3D229 (batiraxcept, AVB-500) in PROC. The FDA feedback received was that this trial, if successful, could support full approval of 3D229 (batiraxcept, AVB-500) for the treatment of PROC. No further preclinical or clinical pharmacology studies are required at this time. The global, randomized, double-blind, placebo-controlled adaptive trial is designed to evaluate efficacy and tolerability of 3D229 (batiraxcept, AVB-500) at a dose of 15 mg/kg in combination with PAC. The Phase III trial was initiated by Aravive in the first quarter of 2021. The pivotal Phase III trial is expected to enroll approximately 350 patients with high-grade serous ovarian cancer who have received one to four prior lines of therapy. This global trial is planned to be conducted at approximately 165 sites in the U.S., China and Europe. The primary endpoint for the trial is PFS, and secondary endpoints include overall survival, objective response rate based on RECIST 1.1, safety and tolerability, duration of response, quality of life, clinical benefit rate, and pharmacokinetic and pharmacodynamic profile. Exploratory biomarkers include serum GAS6, serum sAXL and 3D229 (batiraxcept, AVB-500) drug levels.

In April 2021, Aravive dosed the first patient in its registrational Phase 3 trial of 3D229 (batiraxcept, AVB-500). Aravive projected BLA submission in the second half of 2023 if the ongoing MRCT Phase III is sucessful.

(4) Phase Ib/II Clinical Trial for the Treatment of Patients with ccRCC

This is an open-label Phase 1b/2 study (NCT04300140) of 3D229 (batiraxcept, AVB-500) designed to evaluate the safety and efficacy of 3D229 (batiraxcept, AVB-500) in combination with cabozantinib, 3D229 (batiraxcept, AVB-500) in

combination with cabozantinib and nivolumab, and 3D229 (batiraxcept, AVB-500) monotherapy in subjects with advanced or metastatic clear cell renal cell carcinoma (ccRCC). The trial has a Phase Ib safety portion and a Phase II randomized, controlled portion.

The Phase Ib portion investigates the safety and tolerability of escalating doses (15 mg/kg and 20mg/kg Q2W) of 3D229 (batiraxcept, AVB-500) in combination with cabozantinib (60mg QD) in 26 patients with advanced ccRCC that have progressed after front-line treatment. The primary endpoints for the Phase Ib portion of the clinical trial are safety, PK and PD measurements with secondary endpoints including preliminary activity measures.

As of April 30, 2022, the Phase 1b study completed enrollment with 26 patients (16 patients treated with 15 mg/kg and 10 patients treated with 20 mg/kg 3D229 (batiraxcept, AVB-500) Q2W in combination with cabozantinib 60 mg QD). 3D229 (batiraxcept, AVB-500) 15 mg/kg in combination with cabozantinib 60 mg has a manageable safety profile in previously treated ccRCC. No dose-limiting toxicities have been observed. A similar safety profile was observed across the 15 mg/kg and 20 mg/kg dose cohorts. 3D229 (batiraxcept, AVB-500) given every two weeks suppressed serum GAS6 to below the level of quantitation in 25/26 patients (one patient did not have an assessment), showing a clear PK/PD relationship. 23 out of 26 patients had 3D229 (batiraxcept, AVB-500) trough levels above the minimally efficacious concentration of 13.8 mg/L by Cycle 2. The confirmed and unconfirmed response rate in the total population was 46%, with a 50% confirmed response rate in the 15mg/kg (RP2D) 3D229 (batiraxcept, AVB-500) group. The proportion of patients in the total population who were progression-free at seven months was 71%. The proportion of patients in the total population who had a duration of response of at least seven months was 75%. A baseline biomarker enriched the confirmed response rate in the RP2D (15mg/kg) biomarker high population to 67%, increased the proportion of patients progression-free at seven months to 91%, and increased the proportion of patients who had a duration of response of at least seven months to 80%. 58% (15/26) of the total population achieved a better response on the 3D229 (batiraxcept, AVB-500) trial than they did with their therapy prior to study entry, which was only 23%. This combination's safety and clinical activity with PK/PD data support an RP2D of 15 mg/kg.

The Phase II portion of the clinical trial includes three parts: part A (n=25): 3D229 (batiraxcept, AVB-500) 15 mg/kg Q2W in combination with cabozantinib 60 mg QD for ccRCC subjects who have progressed on or after at least one line of therapy; part B (n=20): 3D229 (batiraxcept, AVB-500) 15 mg/kg Q2W with cabozantinib 40 mg QD and nivolumab (240 mg Q2W or 480 mg Q4W, at the investigator's choice) for first-line treatment of advanced or metastatic ccRCC subjects; and part C (n=10): 3D229 (batiraxcept, AVB-500) 15 mg/kg Q2W monotherapy for subjects with advanced/metastatic ccRCC ineligible for curative intent therapies. The primary objective for each arm is objective response rate by

RECIST v1.1. Secondary objectives include safety, duration of response, clinical benefit rate, progression-free survival by RECIST v1.1, and overall survival. On January 31, 2022, the first patient in the Phase 2 portion was dosed.

(5) Phase Ib/II Clinical Trial for the Treatment of Patients with Pancreatic Cancer

On May 6, 2021, Aravive announced its plans to initiate a Phase 1b/2 clinical trial to investigate 3D229 (batiraxcept, AVB-500) as a first-line treatment in pancreatic cancer.

Aravive plans to expand development of 3D229 (batiraxcept, AVB-500) in a Phase 1b/2 trial as a first-line treatment for pancreatic cancer. The expected design of the trial will evaluate 3D229 (batiraxcept, AVB-500) in combination with gemcitabine and nab-paclitaxel (Abraxane®) in patients with advanced metastatic pancreatic cancer eligible to receive gemcitabine and nab-paclitaxel (Abraxane®) combination therapy. The Phase 1b portion of the clinical trial will assess safety, tolerability, and clinical activity of 3D229 (batiraxcept, AVB-500) in combination with gemcitabine and nab-paclitaxel (Abraxane®). The randomized, controlled Phase 2 portion of the clinical trial will evaluate 3D229 (batiraxcept, AVB-500) in combination with gemcitabine and nab-paclitaxel (Abraxane®) versus gemcitabine and nab-paclitaxel (Abraxane®) alone. The first patient in (FPI) for the Phase 1b portion of the clinical trial was on August 9, 2021.

v. Clinical Development Plan

We completed the Phase I clinical trial in May 2022, and we have expanded the Phase III pivotal trial to China. The results of the Phase III together with Phase I studies in China and the U.S. will be used to support a potential BLA in China. In addition, we plan to conduct Phase Ib/II studies to assess 3D229 in combination with envafolimab in NSCLC, RCC, UC and OC. The inclusion of OC will be initiated if the ongoing Phase III study is successful. If supported by the data from the Phase Ib/II study, we will conduct Phase III studies in these tumor types. Specifically, in the second-line treatment of OC, we plan to evaluate 3D229 in combination with envafolimab versus PAC/PLD if the first PROC Phase III trial is positive, and the Phase II data is supportive. If successful, this will potentially establish a chemotherapy free regimen. In the first-line treatment, we plan to evaluate 3D229 (+/-envafolimab) plus pac/carbo versus pac/carbo if the data from the Phase II study is supportive. For NSCLC, 3D229 will be evaluated in combination with envafolimab in second-line or later subjects who have failed first-line PD-1/PD-L1 treatment and patients who are KRAS mutation positive and have failed chemotherapy. If supported by data, Phase III studies in these NSCLC patient populations will be conducted. If supported by data, we plan to conduct registrational studies of 3D229 for the treatment of RCC and UC, and potentially other tumor types.

The table below sets forth the details of our clinical development plan in China for 3D229:

Indication	Status	(Expected) first patient in date	Expected NDA submission date	Expected number of patients	Location and competent authority
Healthy Volunteers[(1)]	Phase I	Q3 2021 (trial completed)	–	24	China and NMPA
NSCLC[(2)]	Phase Ib/II	Q4 2022	–	60	China and NMPA
RCC[(2)]	Phase Ib/II	Q4 2022	–	60	China and NMPA
UC[(2)]	Phase Ib/II	Q4 2022	–	50	China and NMPA
2L PROC (Aravive sponsored)[(3)]	Phase III	Q2 2022	2024	350	China and NMPA U.S. and FDA Europe and EMA
1L OC[(4)]	Phase III	2H 2023	2026	300-500	China and NMPA
2L OC[(4)]	Phase III	2H 2023	2026	300-500	China and NMPA
NSCLC[(5)]	Phase III	2H 2023	2026	300-500	China and NMPA

Abbreviations: NSCLC = non-small cell lung cancer; RCC = renal cell carcinoma; UC = urothelial carcinoma; PROC = platinum-resistant ovarian cancer; OC = ovarian cancer; 1L = first-line; 2L = second-line; Q1 = first quarter; Q3 = third quarter; 2H = second half.

Notes:

(1) This trial is conducted in healthy volunteers to enable comparison of PK between US and Chinese subjects. The US phase I was completed in healthy volunteers as well. This was made possible due to the favorable safety profile of 3D229. The study was completed in May 2022. The study showed similar PK and safety profiles between Chinese and U.S. subjects.

(2) The reason for choosing NSCLC, RCC and UC were based on pre-clinical and clinical evidence suggesting additivity and synergy between AXL inhibition and PD-(L)1 inhibition as well as role of AXL signaling in immune checkpoint inhibitor (ICI) resistance. We obtained the IND approval for these Phase Ib/II clinical trials in April 2022. As of July 18, 2022, these clinical trials were still in preparation stage and no patient had been enrolled. First patient is expected to be enrolled in the fourth quarter of 2022.

(3) As of July 18, 2022, four patients had been enrolled in this clinical trial in China.

(4) The initiation of Phase III clinical trials in 1L OC and 2L OC will depdend on the positive results from the ongoing Aravive sponsored MRCT Phase III clinical trial.

(5) The initiation of Phase III in NSCLC will depend on the results of the Phase Ib/II clinical trial of NSCLC.

vi. Licenses, Rights and Obligations

We maintain the exclusive rights to develop, manufacture and commercialize products that contain 3D229 as the sole drug substance, for the diagnosis, treatment or prevention of human oncological diseases, in China, Hong Kong, Macau and Taiwan region, pursuant to a collaboration and license agreement between us and Aravive. Please refer to the paragraph headed "Our Research and Development – Collaboration Agreements – Collaboration with Aravive for 3D229" in this section.

vii. Material Communications

We submitted the IND for 3D229 for a Phase I clinical trial in healthy volunteers in China and obtained the IND approval in China in May 2021. We obtained the IND approval for a Phase Ib/II clinical trial in patients with NSCLC, RCC and UC in April 2022. In addition, we submitted the IND for 3D229 for a Phase III clinical trial in patients with PROC in China in April 2021 to participate in the MRCT and obtained the IND approval for this trial in July 2021. We have not received any relevant regulatory agency's objections to our clinical development plans as of the Latest Practicable Date.

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 3D229 SUCCESSFULLY.

c. 3D011

3D011 is an in-house discovered tyrosine kinase inhibitor (TKI) prodrug for the treatment of advanced solid tumors. 3D011 is formed by linking ABT-869 (linifanib), an orally available multi-targeted anti-angiogenesis TKI investigational drug, with a linker (12 carbon chain fatty acid) and a specific 5-peptide (Asp-Glu4). A number of non-clinical studies have been completed for 3D011, including *in vivo* and *in vitro* PD, PK/TK studies, and safety pharmacology studies to support its clinical trials in patients with advanced cancer. Based on such non-clinical data, and the existing clinical data of ABT-869 (linifanib), it is expected that 3D011 can achieve similar or better efficacy than ABT-869 (linifanib) in human trials while reducing its toxicity, which may provide a more effective choice versus available VEGFR multi-TKIs. We received the IND approval from the NMPA in January 2021. We initiated an open-label, single-arm Phase I dose escalation and dose expansion clinical trial in patients with advanced malignant solid tumors in February 2022 and plan to enroll the first patient for this trial in the third quarter of 2022.

The table below shows the indications for which we are currently evaluating 3D011 in clinical trials in China:

Indication[(1)]	Status				
	IND	Phase I	Phase II	Phase III	NDA/BLA (Filed)
China					
Locally advanced, unresectable solid tumors	●	◑			

Symbols: ● = complete; ◑ = in progress (a clinical trial is deemed to have been initiated when the first study site is activated); ◔ = to be initiated

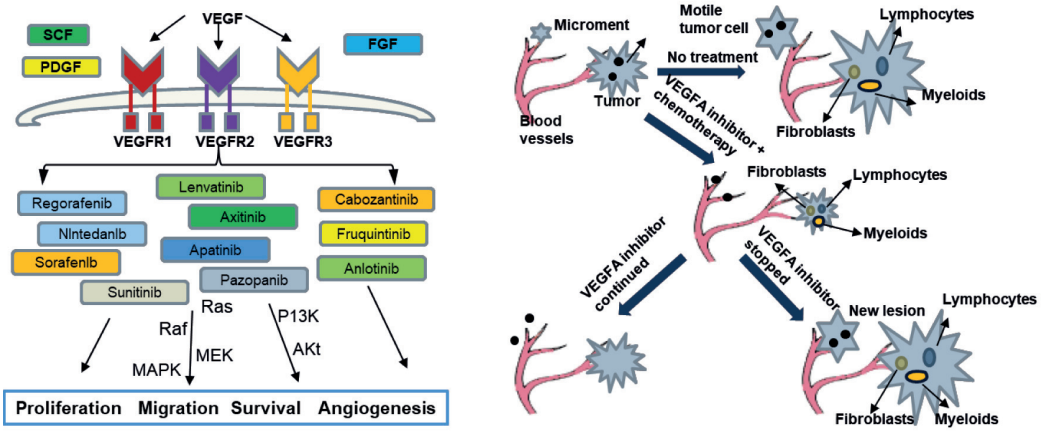
Note:

(1) Some indications may not require every phase of the clinical trials indicated on this chart to be completed prior to the filing of an NDA/BLA.

i. Mechanism of Action

Excessive abnormal angiogenesis is one of the hallmarks of solid tumors. Tumor angiogenesis plays a key role in the occurrence, development and metastasis of malignant solid tumors. Anti-angiogenesis is an important development direction of tumor therapy, and the signaling pathway of vascular endothelial growth factor and its receptor (VEGF/VEGFR) is key to tumor angiogenesis. Besides, PDGFRs and C-KIT pathways also play an important role in tumor angiogenesis. Today, anti-angiogenesis agents represent standard-of-care therapies for multiple types of cancers. As of the Latest Practicable Date, 11 VEGFR targeted anti-angiogenesis TKIs have been approved for cancer treatment by the FDA or the NMPA. The benefits of these anti-angiogenesis agents have proved to be modest, as they provide moderate improvement of overall survival in some indications and delay disease progression without prolonging overall survival in other cancers. Importantly, recent studies demonstrated that anti-angiogenesis therapy not only prunes blood vessel which is essential to cancer growth and metastasis, but also reprograms the tumor immune microenvironment. Anti-angiogenesis induces tumor vessel normalization and improves blood perfusion. Alleviated hypoxia decreases PD-L1 expression on tumor cell while blocked VEGF signal downregulates immune checkpoint expression (e.g. PD-1) on CTL. In the meanwhile, activated immune response-derived inflammatory factors such as interferon-γ (IFN-γ) promotes vessel normalization and regression. Interaction between vessel normalization and immune microenvironment reprogramming could be regulated by anti-angiogenesis agents (bevacizumab or VEGFR-TKI such as axitinib, sorafenib, sunitinib, and vatalanib) and ICI (especially anti-PD-1/PD-L1 mAb). The combination of immunotherapy and anti-angiogenesis agent has

shown more potent anti-tumor effects in multiple tumor types and is now the hotspot in clinical studies.



Source: Angiogenesis. 2010; 13(1): 1-14., Int J Biochem Cell Biol. 1996 Apr;28(4):373-85., Oncotarget. 2017 Feb 28; 8(9): 16052-16074., Drug Des Devel Ther. 2016; 10: 2443-2459., Molecular Cancer volume 21, Article number: 31 (2022), Frost & Sullivan Report

As illustrated in the diagram above, the mechanism of action of multi-targeted small molecule drugs targeting VEGFRs is mainly inhibition of tumor growth by inhibiting tumor angiogenesis. Patients who received anti-angiogenesis therapies are those with advanced-stage disease. They have highly vascularized tumors in the primary organ and/or metastatic sites. In addition, they likely harbor undetected micrometastatic lesions (Micromet). If left untreated, the large tumors will continue to grow and some micromets will develop into new lesions. There are many different cell types in the lesions, which include fibroblasts, lymphocytes, and myeloid cells. Fibroblasts and some myeloid cells may promote tumor growth. When late-stage tumors are treated with VEGFA pathway inhibitors in combination with chemotherapy, vascular pruning occurs. The anti-angiogenesis function of VEGFA pathway antagonists could also prevent micromets from growing into new lesions. VEGFA pathway antagonism has also been shown to increase transendothelial migration of lymphocytes and myeloid cells. After treatment with multiple cycles of VEGFA inhibitor plus chemotherapy, continuation of VEGFR pathway inhibition would exert the antiangiogenesis effect, preventing the regrowth of tumor vasculature and the development of new lesions from micromets. Discontinuation of VEGFA antagonist has been shown to result in the restoration of dense tumor vasculature and the resumption of tumor growth, and may also enable micromets to form new lesions. The exposure of the drug in the body will affect the degree of inhibition of tumor blood vessels.

3D011's parent drug, ABT-869 (linifanib), is an orally available, multi-targeted anti-angiogenesis drug, which has a good inhibitory effect on angiogenesis-related kinases such as VEGFRs, PDGFRs, CSF1R, c-KIT and FLT1/3. 3D011 is formed by linking ABT-869 (linifanib) with a linker (12-carbon chain fatty acid) and a specific

5-peptide (Asp-Glu4). Pre-clinical data has shown that 3D011 is stable *in vitro*, and exert pharmacological activity *in vivo*, potentially by degrading linker and specific 5-peptide via cathepsin and hydrolase systems to release the parent drug ABT-869 (linifanib). In addition, specific 5-peptide have certain tumor targeting properties, which can facilitate preferential distribution of 3D011 to tumor tissues where it is metabolized locally to produce the parent drug ABT-869 (linifanib) to exert its anti-tumor effect.

ii. Market Opportunities and Competition

TKI drugs targeting angiogenesis have the potential to impair multiple stages of tumor progression and reprogram the tumor immune microenvironment. In 2020, the global sales of VEGF/VEGFR targeting TKI reached US$16.0 billion, according to Frost & Sullivan. As of the Latest Practicable Date, 3D011 is the only angiogenesis targeting TKI prodrug in clinical development in China.

iii. Competitive Advantage

(1) Strong demonstration of our *de novo* in-house discovery capabilities

With its unique pro-drug design, 3D011 demonstrates our *de novo* in-house discovery capabilities, from early discovery to clinical stage. The discovery process of 3D011 was initiated in 2016. After comprehensively investigating dozens of drugs that have failed in Phase III clinical trials, we selected an orally available, highly effective drug as the starting compound for systematic development and optimization. After rounds of structure design and optimization, synthesis, optimization of detection assay, our discovery team fully considered and verified the effects of different combinations on the activity and toxicity of the compound, and finally obtained a candidate molecule with well-balanced profiles. In September 2017, our discovery team made a major breakthrough in salt type, which not only greatly improved the water solubility, but also broke through the dilemma of synthesis and purification. And then we managed to obtain gram-level compounds and carry key experiments. We received the IND approval from the NMPA in January 2021.

(2) Potential synergy with PD-L1 inhibitor

3D011 has the potential to be used in combination with our envafolimab for the treatment of solid tumors. There are intricate relationships between angiogenesis and immunity in tumors. Vascular endothelium plays a barrier function and has an important role in activation of immunity by increasing the expression of endothelial cell adhesion molecules that directly interact with macrophages, NK cells, granulocytes, B and T-cells for antigen recognition, rolling, adhesion and extravasation during immune responses. In tumors, vascular endothelial often have abnormal expression of adhesion molecules, including CD34, intracellular cell adhesion molecule-1 (ICAM-1) and vascular cell adhesion molecule-1 (VCAM-1).

Downregulation of these adhesion molecules is in part mediated by angiogenic factors, including VEGF. VEGF also inhibits the maturation of dendritic cells, which suppresses immune activation. Anti-angiogenic treatment with sorafenib, sunitinib or bevacizumab increased PD-L1 expression. PD-L1 is considered to be a target of HIF1- α and the elevation in its expression may be a consequence of anti-angiogenic treatment-induced hypoxia. But other studies have shown that anti-angiogenic treatment could elevate the expression of PD-L1 independently of hypoxia or HIF1-α. In addition, VEGF could increase PD-1 expression on T-cells and mediate "exhaustion" of CD8+ T-cells in tumors.

Preclinical and clinical studies have shown that PD-1/L1 blockade plus anti-angiogenic treatment with axitinib or bevacizumab or lenvatinib reduced Tregs, increased CD8+ T-cells and inhibited the growth of various solid tumors, and demonstrate PFS and/or OS benefit in hepatocellular carcinoma, advanced renal cell carcinoma, and NSCLC cancer patients.

(3) Improved efficacy compared to ABT-869 (linifanib) in preclinical models

The results of preclinical PD studies have shown that applying 3D011 in xenograft tumor-bearing mice model can effectively inhibit the growth of xenotransplanted tumors such as liver cancer, prostate cancer, lung cancer and breast cancer, and the inhibition rate is dose-dependent. Compared with its parent drug ABT-869 (linifanib), 3D011 has better anti-tumor activity at the same molar dose. ABT-869 (linifanib) has shown anti-tumor effect in clinical studies in solid tumors such as hepatocellular carcinoma, renal cell carcinoma, NSCLC, colorectal cancer and breast cancer. Therefore, 3D011 is expected to have better anti-tumor activity in advanced solid tumors.

(4) Better safety and tolerability compared to ABT-869 (linifanib) in preclinical models

The preclinical studies of 3D011 have shown that, compared to its parent drug ABT-869 (linifanib), the its kinase inhibitory activity and cell proliferation inhibitory activity of 3D011 is successfully blocked. In the toxicological research of mice, when administered in equimolar doses (considering the molecular weight of 3D011 is 1,204 and molecular weight of ABT-869 (linifanib) is 375, 3D011 30 mg/kg intravenous infusion once daily (QD) is equivalent to ABT-869 (linifanib) 10 mg/kg oral administration QD), 3D011 had better safety than ABT-869 (linifanib). Based on the findings of preclinical studies, 3D011 is expected to have better safety and tolerability than ABT-869 (linifanib) in clinical studies.

iv. Summary of Clinical Trials

We initiated an open-label, single-arm Phase I dose escalation and dose expansion clinical trial in patients with advanced malignant solid tumors in February 2022 and plan to enroll the first patient for this trial in the third quarter of 2022. No clinical data was available as of the Latest Practicable Date.

v. Clinical Development Plan

We plan to enroll the first patient for a Phase I clinical study of the safety, tolerability, PK and preliminary efficacy of 3D011 monotherapy in human subjects with advanced malignant solid tumors. The trial is designed as an open, single-arm, multi-center Phase I clinical trial, including a dose escalation stage and a dose expansion stage.

The main target population of the dose escalation stage are adult subjects with advanced malignant solid tumors who have no standard treatment or failed standard treatment. It aims to evaluate the safety, tolerability and PK characteristics of 3D011 monotherapy in subjects with advanced malignant solid tumors, as well as preliminary anti-tumor properties to determine RP2D.

The main target population of the dose expansion stage are human subjects with advanced hepatocellular carcinoma and advanced renal cell carcinoma who have failed or refused first-line treatment in the past, and human subjects with metastatic castration-resistant prostate who have failed chemotherapy and/or endocrine therapy. It aims to evaluate the preliminary efficacy, safety, PK and PD characteristics of 3D011 monotherapy of advanced hepatocellular carcinoma, advanced renal cell carcinoma and metastatic castration-resistant prostate cancer in human subjects with RP2D dosing regimen.

We plan to enroll a total of up to 93 patients for this trial, and expect to enroll the first patient in the third quarter of 2022. Following this Phase I trial, we plan to further explore the clinical potential of 3D011 monotherapy or in combination with envafolimab for the treatment of advanced malignant solid tumors.

The table below sets forth the details of our clinical development plan for 3D011:

Indication	Status	Expected first patient in date	Expected NDA submission date	Expected number of patients	Location and competent authority
Advanced malignant solid tumors[(1)]	Phase I	Q3 2022	–	93	China and NMPA

Abbreviations: Q1 = first quarter.

Notes:

(1) The design of this trial is based on the mechanism of action of 3D011 which is a pro-drug of a VEGFR inhibitor, the tumor types chosen are known to be sensitive to VEGFR inhibitors or express enzyme that can covert pro-drug to its active form in the tumor tissue. The site for this clinical trial was activated in first quarter of 2022. Patient enrollment was temporarily delayed due to the control measures taken by the Shanghai government in response to the COVID-19 Recurrences.

vi. Licenses, Rights and Obligations

We internally discovered and developed 3D011, and maintain the global rights to develop and commercialize this drug candidate.

vii. Material Communications

We received the IND approval from the NMPA in January 2021. We had not received any relevant regulatory agency's objections to our clinical development plans as of the Latest Practicable Date.

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 3D011 SUCCESSFULLY.

d. 3D185

3D185, also known as HH185, is a dual FGFR1-3 and CSF-1R inhibitor with high selectivity for the treatment of advanced solid tumors. We own the exclusive rights to develop and commercialize 3D185 globally in the oncology and pulmonary fibrosis treatment through our patent license agreements with Haihe Biopharma and Shanghai Institute of Materia Medica, Chinese Academy of Sciences. Preclinical experiments have observed that 3D185 has an inhibitory effect on tumor cells with FGFR genetic alterations, and its toxicity characteristics are consistent with its expected effect as a selective FGFR inhibitor and are reversible. These results support the clinical study of 3D185 in patients with advanced solid tumors. The IND approval was obtained from the NMPA in January 2018. We received the IND

approval from the FDA in September 2019. We initiated a Phase I clinical trial in patients with locally advanced or metastatic solid tumors in China and the U.S. The FPI in China was December 2018 and the FPI in the U.S. was February 2020. We completed the Phase I clinical trial in August 2021. Clinical investigation of alternative formulation for 3D185 is ongoing.

The table below shows the indications for which we are currently evaluating 3D185 in clinical trials:

	Status				
Indication[(1)]	**IND (Accepted)**	**Phase I**	**Phase II**	**Phase III**	**NDA/BLA (Filed)**
China and the U.S.					
locally advanced or metastatic solid tumors	●	●			

Symbols: ● = complete

Note:

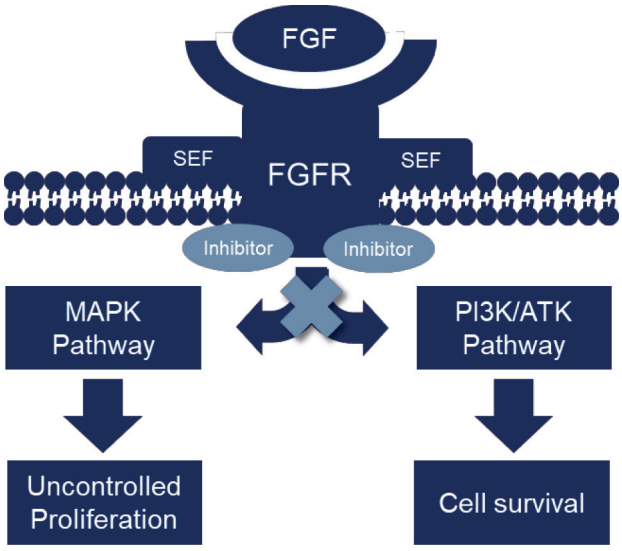
(1) Some indications may not require every phase of the clinical trials indicated on this chart to be completed prior to the filing of an NDA/BLA.

i. Mechanism of Action

3D185 is an orally-administered small molecule adenosine triphosphate (ATP) competitive inhibitor of FGFR, which can selectively inhibit the kinase activity of FGFR1, FGFR2, and FGFR3. 3D185 also inhibits CSF1R.

The oxidative metabolism of 3D185 is mainly catalyzed by the cytochrome P-450 enzyme (CYP) 3A4, and CYP2C8, CYP2D6 and CYP3A5 are also involved to a lesser degree. 3D185 basically has (1) no inhibitory effect on CYP1A2 and CYP3A4; (2) a weak inhibitory effect on CYP2B6, CYP2C9, CYP2C19, CYP2D6 and CYP3A4; and (3) a moderate inhibitory effect on CYP2C8. It has no induction effect on CYP1A2, CYP2B6 and CYP3A4 enzymes. In conclusion, 3D185 has a relatively low potential for drug-drug PK interaction.

3D185, which simultaneously targets FGFR and CSF-1R, is expected to inhibit both tumor cells and remodel the tumor microenvironment to synergistically antagonize tumors and delay the development of resistance to FGFR inhibitors alone. Moreover, 3D185 could inhibit the survival and M2-like polarization of macrophages, reversing the immunosuppressive effect of macrophages on CD8+ T cells. The diagram below shows the mechanism of action for 3D185:



Source: Oncotarget. 2017 Feb 28; 8(9): 16052-16074., Frost & Sullivan Report

ii. Market Opportunities and Competition

FGFR inhibitors can inhibit tumor cells and remodel the tumor microenvironment to synergistically antagonize tumors. In 2020, the global sales of pan-FGFR inhibitors reached US$84.1 million, according to Frost & Sullivan.

As of the Latest Practicable Date, there were a total of three approved pan-FGFR inhibitors in the global market, all of which were in the U.S and one of them was also approved in China. As of the same date, there were one and nine pan-FGFR inhibitor candidates in Phase III and Phase I/II clinical trials worldwide, respectively. As of the same date, there were ten pan-FGFR inhibitor candidates registered with the NMPA, of which there were three in Phase III clinical trials and seven in Phase I/II clinical trial. The following table sets out details of the FDA approved pan-FGFR inhibitors in the U.S. as of the Latest Practicable Date:

Drug Name	Company	Target	Indications	Marketed Location	Date of FDA/NMPA Approval	Price	Annual Cost (thousand)	Patent Expiration Date	2020 Revenue
Pemigatinib	Incyte Corp; Innovent Biologics, Inc.	FGFR1, FGFR2, FGFR3	cholangiocarcinoma	U.S. China	2020-04 2022-04	13.5mg: US$1,351.6	$321.7	2035-01	$26 million
Erdafitinib	Fisher Clinical Services; Janssen Research & Development LLC; Johnson & Johnson Ltd	FGFR1, FGFR2, FGFR3, FGFR4	urothelial carcinoma	U.S.	2019-04	3mg: US$291.1 4mg: US$388.1 5mg: US$485.2	$277.1-311.8	2031-04	N/A
Infigratinib	QED Therapeutics, Inc.	FGFR1, FGFR2, FGFR3	cholangiocarcinoma	U.S.	2021-05	125mg: $534.7	$146.0	2030-12	N/A

Source: FDA, Annual Reports of Listed Pharmaceutical Companies, Frost & Sullivan Report

iii. Competitive Advantages

3D185 has the potential to be used in combination with our envafolimab for the treatment of solid tumors. A preclinical study of combination potential of erdafitinib, a fibroblast growth factor receptor (FGFR) inhibitor under clinical development, with PD-1 blockade in an autochthonous FGFR2K660N/p53mut lung cancer mouse model showed that the erdafitinib and anti-PD-1 combination induced significant tumor regression and improved survival. A decreased fraction of tumor-associated macrophages also occurred but only in combination-treated tumors. Treatment with erdafitinib decreased T-cell receptor (TCR) clonality, reflecting a broadening of the TCR repertoire induced by tumor cell death, whereas combination with anti-PD-1 led to increased TCR clonality, suggesting a more focused antitumor T-cell response.

iv. Summary of Clinical Trials

(1) Phase I Clinical Trial in China and the U.S.

An open-label, global multi-center, dose-escalation Phase I study of safety, tolerability, preliminary PK profile, and preliminary efficacy of 3D185 monotherapy in subjects with advanced solid tumors was completed in China and the U.S. in August 2021. As of December 31, 2020, in the Phase I clinical trial (dose escalation phase), the 25 mg, 50 mg, 100 mg, 150 mg, 200 mg and 250 mg dosing cohorts have been completed, and no DLT event was reported.

Study purpose. The primary objective is to assess the safety and tolerability of 3D185 monotherapy in subjects with advanced solid tumors and explore the maximum tolerated dose (MTD) and the recommended dose for subsequent studies (RP2D) of 3D185 monotherapy in subject with advanced solid tumors. The primary endpoint of this trial is the safety and tolerability of 3D185. The secondary endpoint of this trial is the PK, PD and efficacy of 3D185.

Study design. The starting dose in this dose-escalation study is 25 mg, and the preset 7 dose-escalation cohorts are 25 mg, 50 mg, 100 mg, 150 mg, 200 mg, 250 mg and 300 mg, respectively. This study adopts a combination of accelerated titration and 3+3 for dose escalation. All subjects in each cohort will receive a single oral dose of 3D185, followed by a 7-day washout period (i.e. single-dose PK study period). Then, subjects will receive consecutive daily doses (28 days/cycle) until disease progression, death, unacceptable toxicity, or withdraw of informed consent, whichever comes first. The dose limiting toxicity (DLT) evaluation period includes the single-dose PK study period and the first treatment cycle (within 35 days after the first dose).

Safety. As of December 31, 2020, a total of 15 subjects with advanced malignant solid tumors were enrolled in one of 6 dose cohorts (25 – 250 mg) in this study and received 3D185 tablets monotherapy. Among them, there were 1 subject in each of the 25 mg and 50 mg dose cohorts, 3 subjects in each of the 100 mg, 150 mg, and 200 mg dose cohorts, and 4 subjects in the 250 mg dose cohort. The median treatment days was 37 days (range: 1-256 days). The proportion of subjects who received treatment ≥3 months and 6 months was 13.3% (n=2) and 6.7% (n=1), respectively. The median follow-up time was 2.1 months (range: 0.3-8.5 months). With respect to the primary endpoint, based on the final clinical study report, 3D185 has shown favorable safety and tolerability. No DLT occurred in six dose cohorts (25 to 250 mg) and the TEAE occurrence rate was similar among all dose cohorts. In addition, we completed the studies of secondary endpoint of PK, PD and efficacy in accordance with the protocol.

v. Clinical Development Plan

Following the completion of the Phase I clinical trial, we plan to further explore the clinical potential of 3D185 for the treatment of cholangiocarcinoma, UC and other tumors with FGFR genetic alterations.

The table below sets forth the details of our clinical development plan for 3D185:

Indication	Status	Expected first patient in date	Expected NDA submission date	Expected number of patients	Location and competent authority
Previously treated locally advanced or metastatic cholangiocarcinoma with FGFR2 gene alterations[(1)]	Phase II	1H 2024	1H 2026	50-100	U.S. and FDA China and NMPA
Previously treated advanced UC with FGFR alterations[(1)]	Phase II	2H 2024	2H 2026	50-100	US and FDA China and NMPA

Abbreviations: UC = urothelial cancer; 1H = first half; 2H = second half.

Notes:

(1) Each of these planned clinical trials was based on marketed FGFR inhibitors that have shown activity in these two tumor types with FGFR alterations. As of July 18, 2022, the proposed studies were still on track and these clinical trials are expected to enroll the first patient in 2024.

vi. Licenses, Rights and Obligations

We maintain the exclusive rights to develop, manufacture and commercialize 3D185 for oncology and pulmonary fibrosis treatment globally. We obtained all the intellectual property rights relating to 3D185 pursuant to patent license agreements with Haihe Biopharma and Shanghai Institute of Materia Medica, Chinese Academy of Sciences. Please refer to the paragraph headed "Our Research and Development – Collaboration Agreements – Collaboration with Haihe Biopharma for 3D185" in this section.

vii. Material Communications

The IND approval was obtained from the NMPA in January 2018. We received the IND approval from the FDA in September 2019. We submitted a protocol to FDA on September 6, 2021 for a Phase II clinical trial for 3D185 as monotherapy in subjects with previously treated locally advanced or metastatic cholangiocarcinoma with FGFR2 gene

alterations, but withdrew our submission we decided to establish a RP2D first before we start the Phase II clinical trial. As of the Latest Practicable Date, we were still testing the new formulation in the ongoing Phase I clinical trial, primarily in the dose escalation phase. We had not received any relevant regulatory agency's objections to our clinical development plans as of the Latest Practicable Date.

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 3D185 SUCCESSFULLY.

e. 3D1001

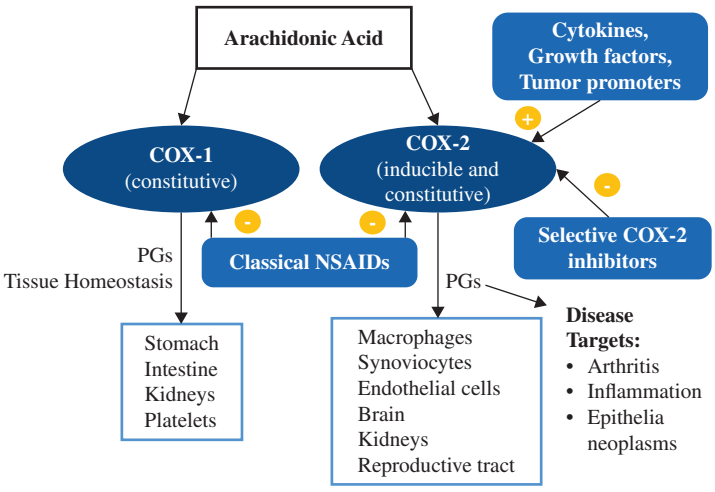
3D1001, also known as RMX1001, is a differentiated COX-2 inhibitor with foreign Phase IIb clinical data. We own the exclusive rights to develop, manufacture and commercialize 3D1001 in China in the pain indication field through our license agreement with Haihe Biopharma Group. According to available data, 3D1001 is a safe and effective non-opioid analgesic with efficacy, rapid onset, long-lasting pain relief and acceptable safety profile. The IND approval for 3D1001 was obtained from the NMPA in February 2019. We plan to develop 3D1001 for the treatment of post-surgical dental pain and potentially other pain indications, including cancer pain management. We are in the preparation stage for the Phase I/II clinical trial for 3D1001 oral solution in China.

i. Mechanism of Action

Cyclooxygenases-2 (COX-2) is an enzyme responsible for the production of prostaglandins, which contribute to inflammation. The role of COX-2 as a target for inflammation and pain has been validated by the clinical effectiveness of selective COX-2 inhibitors. COX-2 inhibitors are a type of nonsteroidal anti-inflammatory drug (NSAID) that selectively targets COX-2, which is responsible for inflammation and pain. Selectivity for COX-2 reduces the risk of peptic ulceration and is the main feature of celecoxib, rofecoxib, and other members of this drug class.

Despite the wide use of NSAIDs over the last century, their mechanism of action was not fully understood until the COX enzyme was identified in 1971. COX-1 and COX-2 are both isoenzymes. Since isoenzymes are genetically independent proteins, the genes in humans for the two enzymes are located on different chromosomes and show different properties. COX-1 is expressed constitutively in many tissues and PGs produced by COX-1 mediate the "housekeeping" functions such as cytoprotection of gastric mucosa, regulation of renal blood flow and platelet aggregation. In contrast, COX-2 is not detected in most normal tissues, but its expression is rapidly induced by stimuli such as proinflammatory cytokines (IL-1b, TNFα), lipopolysaccharides, mitogens and oncogenes (phorbol esters), growth factors (fibroblast growth factor, FGF; platelet-derived growth factor, PDGF; epidermal growth factor, EGF), hormones (luteinizing hormone, LH) and disorders of water-electrolyte hemostasis, resulting in increased synthesis of PGs in

inflamed and neoplastic tissues. Thus, the inducible isozyme has been implicated in pathological processes such as inflammation, pain and cancer pathogenesis. The diagram below shows the mechanism of action for 3D1001:



Source: Best Pract Res Clin Gastroenterol. 2001 Oct;15(5):801-20., National Library of Medicine, Front. Pharmacol., 07 September 2018, Frost & Sullivan Report

ii. Market Opportunities and Competition

COX-2 inhibitors selectively target COX-2, an enzyme responsible for inflammation and pain. Selectivity for COX-2 reduces the risk of peptic ulceration and is the main feature of celecoxib, rofecoxib, and other members of this drug class. In 2020, the China cancer pain drug market reached US$6.8 billion, according to Frost & Sullivan.

As of the Latest Practicable Date, there were a total of seven COX-2 inhibitors were approved for pain management in China. The following table sets out details of approved COX-2 inhibitors for pain management in China as of the Latest Practicable Date:

Drug Name	Company	Immune Checkpoint	Indications	Date of NMPA Approval
Imrecoxib	Hengrui Pharmaceutical	COX-2	Osteoarthritis	2011
Etoricoxib	Merck Sharp & Dohme (Australia) Pty Ltd	COX-2	Osteoarthritis; gouty arthritis; dysmenorrhea	2002
Parecoxib Sodium	Pfizer Europe Ma Eeig	COX-2	Postoperation pain	2002

Drug Name	Company	Immune Checkpoint	Indications	Date of NMPA Approval
Celecoxib	Astellas Pharma Inc.; Dr Reddy's Laboratories; Gdsearle & Co; G.D. Searle Llc; Pfizer; Targeted Therapy Technologies Llc	COX-2	Osteoarthritis; acute pain; rheumatoid arthritis; ankylosing spondylitis	1998
Dexketoprofen Trometamol	Berlin-Chemie AG.Germany; Guangdong Trustever Pharmaceuticals; Shixing Pharmaceuticals; Menarini International Operations Luxembourg Sa	COX-2; COX-1	Migraine; pain	1998
Meloxicam	Baudax Bio Inc; Bidachem Spa; Boehringer Ingelheim Gmbh; CSPC Pharmaceutical Group Limited; Hengrui Pharmaceutical; Shenyang Pharmaceutical University	COX-2	Rheumatoid arthritis; ankylosing spondylitis	1995
Ketorolac Tromethamine	Allergan Inc; Allergan Plc	COX-2; COX-1	Acute pain; allergic conjunctivitis	1989

Source: FDA, Annual Reports of Listed Pharmaceutical Companies, Frost & Sullivan Report

iii. Competitive Advantages

Compared to other marketed COX-2 inhibitors in China, 3D1001 potentially has the competitive advantages of rapid onset and duration of pain relief owing to the rapid absorption and long half-life associated with the oral solution formulation of 3D1001.

iv. Summary of Clinical Trials

The following summarizes the clinical trials completed and/or being conducted with 3D1001:

(1) Phase II Clinical Trial in Patients with Postoperative Dental Pain

A single-dose, double-blind, parallel-group, placebo- and positive-controlled, comparative efficacy study of 3D1001 oral solution in subjects with postoperative dental pain has been completed in the U.S.

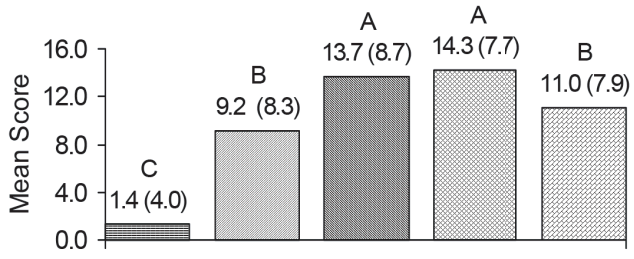
Study purpose. The objectives of the trial are to assess the analgesic efficacy of a single dose of 360 mg 3D1001 compared to ibuprofen 400 mg and placebo in subjects with moderate or severe pain in a post-oral surgery model, to characterize the dose response for 3D1001 in subjects with moderate or severe pain in a post-oral surgery model, and to evaluate the safety and tolerability of single doses of 3D1001.

Study Design. This was a randomized, double-blind, double-dummy (3D1001 in solution; ibuprofen tablets), positive- and placebo-controlled, parallel group study in healthy volunteers undergoing multiple tooth extraction. Subjects who were over 18 years-of-age, in good health, and with a predose pain intensity score (100 mm visual analogue scale (VAS)) over 50 mm and a predose pain intensity score (categorical scale) of 2 (moderate) or 3 (severe) within six hours of oral surgery, were included in the study. Subjects were randomized to receive one of five treatments: solution of 3D1001, at 60, 180, or 360 mg; Ibuprofen (Motrin IB™) 400 mg (two 200 mg tablets); or placebo (to match ibuprofen and 3D1001).

Of the 352 subjects randomized to treatment, 351 subjects completed the study. The majority of subjects were between 18 and 44 years-of-age, with a mean age of approximately 23 years. Seventy-four percent of the subjects (262 subjects) were men and the majority of subjects were white. Sixty-eight percent of the subjects had four molars extracted during the dental surgery. The overall mean pain intensity (on a 0-100 VAS) at baseline (post-surgery/premedication) was 65.4; this score was similar across all treatment groups.

Efficacy. The primary measure for efficacy evaluation was total pain relief through 6 hours (TOTPAR(6)). Secondary measures included pain relief, TOTPAR (8, 12, and 24 hours), pain intensity difference, pain relief intensity difference, summed pain relief intensity difference scores (6, 8, 12, and 24 hours), and summed pain intensity difference (6, 8, 12, and 24 hours). Time to perceptible PR, meaningful PR, onset of analgesia, and time to rescue medication were also analyzed. Subjects completed questionnaires indicating level of satisfaction with study medication.

Subjects treated with 60, 180, and 360 mg of 3D1001 had a significantly higher mean TOTPAR(6) score (improvement) (Categorical Scale, Range 0-4) compared with subjects who received placebo. Subjects treated with 180 and 360 mg 3D1001 had a significantly higher TOTPAR(6) score compared with subjects who were treated with 400 mg ibuprofen. A clear dose response was observed for both primary and secondary endpoints, with 360 mg 3D1001 showing the greatest improvements. The figure below shows the mean TOTPAR(6) score:



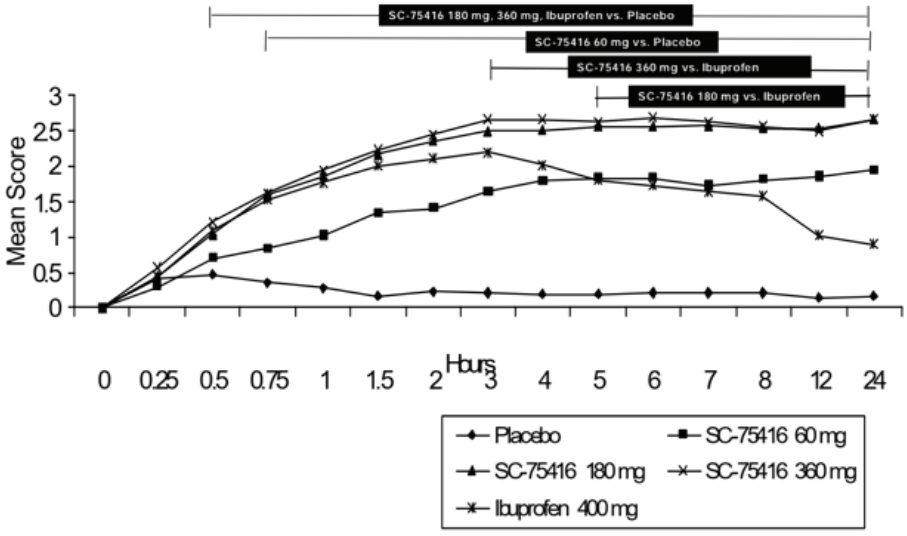
Treatments with the same letter code are not significantly different from each other.
Comparisons are made at 5% level of significance.
Type I error is protected with Fisher's protected LSD.

Placebo SC-75416 60 mg SC-75416 180 mg SC-75416 360 mg Ibuprofen 400 mg

Note: SC-75416 represents 3D1001

Source: Company data

Subjects treated with 60, 180, or 360 mg 3D1001 consistently showed significant improvement in secondary endpoints compared with placebo. Subjects who received 180 mg 3D1001 had significantly greater pain relief from hour 5 through 24 compared with subjects who received 400 mg ibuprofen; subjects treated with 360 mg 3D1001 had significantly greater pain relief from hour 3 through 24 compared with subjects treated with ibuprofen. The following figure shows the mean pain relief (0-24 hours):



Notes:

(1) Positive values signify improvement.

(2) |------| identifies the range of assessment times for which there were significant differences between the active treatment as compared to Placebo and Ibuprofen.

(3) SC-75416 represents 3D1001

Source: Company data

Subjects treated with 360 mg 3D1001 had significantly greater improvement in all secondary endpoints compared to subjects treated with 400 mg ibuprofen. The median time to onset of analgesia was significantly shorter for subjects treated with 360 mg 3D1001 (20 minutes) compared with subjects treated with ibuprofen (28 minutes). The median time to rescue medication was approximately 8.5 hours for ibuprofen subjects compared with >24 hours for 360 mg 3D1001-treated subjects. The subject's global evaluation of study medication on a scale of 1 through 5 (1 = poor, 5 = excellent) resulted in a mean rating of 2.9 for ibuprofen- treated subjects compared with a 3.8 rating for 360 mg 3D1001 treated subjects. In general, efficacy increased with increasing dose of 3D1001.

Safety. 3D1001 was well tolerated. Subjects treated with placebo had the highest incidence of AEs (48%) compared with subjects treated with 60 mg (33%), 180 mg (28%), or 360 mg 3D1001 (32%), or ibuprofen (25%). The most frequently reported AEs during the study were those typically associated with oral surgery, such as dry socket, nausea, vomiting, headache, and dizziness. These events were generally reported in a greater number of placebo- treated subjects. Throat irritation occurred in 4% of subjects treated with 180 mg 3D1001 and 3% of subjects treated with 360 mg 3D1001; throat irritation was not reported by placebo- or ibuprofen-treated subjects. There did not appear to be any relationship between dose of 3D1001 and the incidence of any AE.

There were no withdrawals due to AEs and one ibuprofen-treated subject had four unrelated serious adverse events (SAEs). There were no clinically meaningful changes in laboratory parameters or vital signs.

Conclusion. In subjects with acute pain following oral surgery: (1) a single oral dose of 60, 180, or 360 mg 3D1001 provided significantly ($p < 0.001$) greater analgesic efficacy compared with placebo; (2) a single dose of 360 mg 3D1001 provided significantly greater ($p < 0.001$) analgesic efficacy compared with 400 mg ibuprofen; (3) results confirmed the predictive performance of the PK/PD model; (4) 3D1001 systemic exposure indicates dose proportional extent but highly variable rate of absorption of this oral solution formulation; and (5) 3D1001 was safe and well tolerated; no dose-related safety findings were evident.

(2) Phase I Clinical Trials

Three Phase I clinical studies have been completed for 3D1001 oral solution, which has collectively demonstrated desirably a favorable PK and safety profile of 3D1001 oral solution, as summarized in the table below:

Trial	Design	Sample size	Dose Levels	Key findings
COXD-7577-001 (U.S) (oral solution)	Randomized, Double-Blind, Single Dose Escalating, Safety, tolerability and Pharmacokinetic Study of 3D1001 in Healthy Volunteers	63	0.01, 0.1, 0.5, 2.5, 7.5, 15, 30, and 60 mg	Single doses from 0.01 to 60 mg were well tolerated; PK dose proportionality between 0.1 and 60 mg was observed with half-life ranged approximately from 30-40 hours; 30 and 60 mg dose levels had the potential to selectively inhibit COX-2 while appeared to have no effect on renal safety parameters

Trial	Design	Sample size	Dose Levels	Key findings
A6151001 (U.S) (oral solution)	Randomized, double-blind, placebo-controlled dose escalation study in healthy volunteers	40	1, 10, 20, 40, 60 mg or placebo	Steady state PK are linear from doses of 1 to 60 mg. systemic exposure is dose proportional. t½ ranged from 29.0 to 37.8h, Tmax was 1.8 to 3.0h. Study drug was safe and well-tolerated at doses up to 60 mg/day for 10 days.
A6151010 (U.S) (oral solution)	Randomized, Double-Blind, Placebo-Controlled, Single- and Multiple-Dose Study to Investigate Safety, Tolerability and PK of 3D1001 in Healthy Adults	54	single dose, 60, 120, 180 240, 300, 360 mg or placebo Multiple-dose 60, 120, 180 mg, QD, 10d or placebo	Systemic exposure is dose proportional single and multiple-dose at doses up to 360 mg and 180 mg, respectively. Safe and well-tolerated at all dose levels in the single dose setting. Safe and tolerated in multiple dose setting with the exception of one case with significantly elevated ALT and one case with elevated blood pressure, both of which returned to acceptable level after stopping the study drug. Single- and multiple-dose had similar t½ (single dose: 30.6-36.9; multiple dose: 29.5-35.8 hours) and Tmax (< 2h).

v. Clinical Development Plan

We are preparing for a potential phase I/II clinical trial in China to evaluate the PK, safety and efficacy of 3D1001 in Chinese subjects. If successful, a Phase III clinical trial in this post-surgical dental pain and additional clinical studies in other pain indications will be conducted.

The table below sets forth the details of our clinical development plan for 3D1001 in China:

Indication	Status	Expected first patient in date	Expected NDA submission date	Expected number of patients	Location and competent authority
healthy and post surgical dental pain subjects[(1)]	Phase I/II	1H 2023	–	216	China and NMPA
post-surgical dental pain[(2)]	Phase III	2H 2024	2H 2025	330	China and NMPA

Abbreviations: 1H = first half; 2H = second half.

Notes:

(1) The Phase I portion of the clinical trial is intended to study PK in Chinese healthy volunteers while the phase II portion of the clinical trial will evaluate efficacy and safety of 3D1001 at multiple dose levels versus control in Chinese subjects with post-surgical dental pain. As of July 18, 2022, this clinical trial was still in preparation stage and no patient had been enrolled. First patient is expected to be enrolled in the first half of 2023.

(2) The Phase III clinical trial is based on promising efficacy demonstrated with 3D1001 oral solution in post-surgical dental pain population in a Phase II clinical trial in US patients, which will be further informed by the Phase I/II study to be conducted in China. As of July 18, 2022, the proposed study was still on track and first patient is expected to be enrolled in second half of 2024.

vi. Licenses, Rights and Obligations

We maintain the exclusive rights to develop, manufacture and commercialize 3D1001 in China in the pain indication field. We obtained all the intellectual property rights relating to 3D1001 pursuant to a license agreement between us and Haihe Biopharma Group. Please refer to the paragraph headed "Our Research and Development – Collaboration Agreements – Collaboration with Haihe Biopharma Group for 3D1001 and 3D1002" in this section.

vii. Material Communications

The IND approval for 3D1001 was obtained from the NMPA in February 2019. We had not received any relevant regulatory agency's objections to our clinical development plans as of the Latest Practicable Date.

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 3D1001 SUCCESSFULLY.

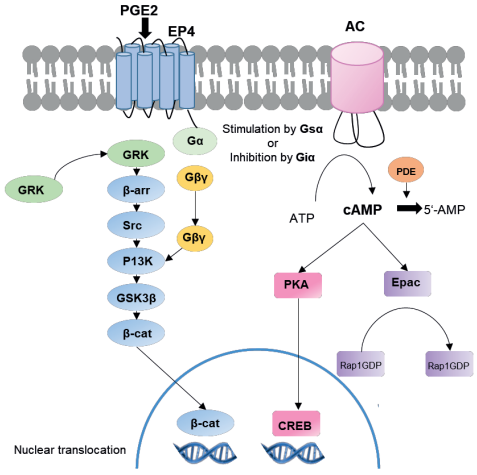
f. 3D1002

3D1002, also known as RMX1002, is an EP4 receptor antagonist. We own the exclusive rights to develop, manufacture and commercialize 3D1002 in China through our license agreement with Haihe Biopharma Group. Its Phase II clinical data in the U.S. has demonstrated an acceptable safety profile and analgesic effect in subjects with osteoarthritis pain. It is expected to become a new pain medication other than COX-2 inhibitor. IND approval for 3D1002 was obtained from the NMPA in July 2018.

i. Mechanism of Action

Prostaglandin E2 (PGE2) is an important pro-inflammatory pain mediator. It is also essential for the homeostasis of many vital organs, including the maintenance of mucosal integrity of the gastrointestinal tract, regulation of bicarbonate secretion in the intestines, modulation of renal sodium and water excretion, and prevention of ischemic cardiomyopathy after acute ischemic events. The physiological activities of PGE2 are mediated by 4 G-protein–coupled receptors identified as E prostanoid receptors 1–4 (EP1–EP4). EP4 has been shown to be the main receptor that mediates pain and inflammatory signaling in animal studies, whereas many of the other activities of PGE2 on physiological homeostasis are mediated by EP1, EP2, and EP3. Data has suggested that an agent that selectively antagonizes the EP4 receptor has the potential to provide an attractive risk/benefit profile in the treatment of painful, inflammatory conditions, such as osteoarthritis and cancer pain.

EP4 is classified as a relaxant type of prostaglandin receptor based on its ability, upon activation, to relax the contraction of certain smooth muscle preparations and smooth muscle-containing tissues that have been pre-contracted by stimulation. EP4 also interacts with Prostaglandin E receptor 4-associated protein (EPRAP) to inhibit a cell's ability to activate nuclear factor kappa B, a transcription factor that controls genes coding for cytokines and other elements that regulate inflammation, cell growth, and cell survival. The diagram below shows the mechanism of action for 3D1002:



Source: Pharmacol Ther. 2013 Jun; 138(3): 485-502., Frost & Sullivan Report

ii. Market Opportunities and Competition

EP4 receptor antagonists demonstrate its rapid onset and long-lasting analgesic effect against osteoarthritis, rheumatoid arthritis and other inflammatory pains based on pre-clinical studies. In 2020, the China cancer pain drug market reached US$6.8 billion, according to Frost & Sullivan.

As of the Latest Practicable Date, there were no approved EP4 receptor antagonists in the global market. As of the Latest Practicable Date, there were one EP4 receptor antagonists candidates registered with the NMPA and was in Phase I clinical trial. The following table sets out details of EP4 receptor antagonists in clinical development worldwide as of the Latest Practicable Date.

Drug Name	Clinical Phase	Company	Active Indications	Targets	Drug type	Therapeutic Strategy	Location	First Posted Date
3D1002/ RMX1002/ Grapiprant	**Phase II**	**3DMed**	**Solid Tumor. Osteoarthritis; Pain**	**PTGER4**	**Chemical drugs**	**Combination therapy**	**China**	**22-Dec-21**
CR-6086	Phase II	Rottapharm	Rheumatoid Arthritis, DMARD-naive and Early Disease Patients	PTGER4	Chemical drugs	Combination therapy	Czechia	23-May-17
YY001	Phase I	Yuyao Biotech; MingMed Biotech	Solid Tumor	PTGER4	Chemical drugs	Monotherapy	China	27-Jun-22
INV-1120	Phase I	Ionova	Solid Tumor	PTGER4	Chemical drugs	Monotherapy/ Combination therapy	China	30-Jul-21
KF-0210	Phase I	Keythera pharm	Advanced CRC, NSCLC, Esophageal squamous cell carcinoma, gastric cancer, bladder cancer, etc.	PTGER4	Chemical drugs	Monotherapy	China	25-Jun-21
AN0025	Phase I	Adlai Nortye	Esophageal cancer	PTGER4	Chemical drugs	Combination therapy	China	25-Jun-21

Drug Name	Clinical Phase	Company	Active Indications	Targets	Drug type	Therapeutic Strategy	Location	First Posted Date
TPST-1495	Phase I	Tempest Therapeutics	Solid Tumor; Colorectal Cancer; Non Small Cell Lung Cancer; Squamous Cell Carcinoma of Head and Neck; Urothelial Carcinoma; Endometrial Cancer; Gastroesophageal Junction Adenocarcinoma; Gastric Adenocarcinoma	PTGER4; PTGER2	Chemical drugs	Combination therapy	US	14-Apr-20
ONO-4578/ BMS-986310	Phase I	BMS; Ono Pharmaceutical	Tumor; Solid tumor	PTGER4	Chemical drugs	Combination therapy	Japan	16-May-17
E-7046/AN0025	Phase I	Adlai Nortye Biopharma Co Ltd; Eisai Co Ltd;	Triple-negative Breast Cancer; NSCLC, Squamous or Non-Squamous; Urothelial Carcinoma of the Bladder; Microsatellite Stable (MSS) Colorectal Cancer (CRC); Cervical Cancer	PTGER4	Chemical drugs	Combination therapy	US; United Kingdom; Poland	15-May-17

Note:

(1) Date denotes the date on which the relevant status was publicly disclosed.

Source: Annual Reports of Listed Pharmaceutical Companies, NMPA, CDE, FDA, ClinicalTrials.gov, Frost & Sullivan Report

iii. Summary of Clinical Trials

The following summarizes the clinical trials completed and/or being conducted with 3D1002:

(1) Phase II Clinical Trial in Patients with Osteoarthritis (OA) Pain for a Period of Two Weeks

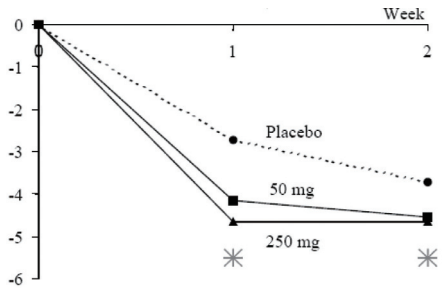
Study design. This was a two-week, randomized, double blind, placebo- and positive-controlled, parallel-group, multi-center study of 3D1002 in patients with osteoarthritis (OA) pain. 201 subjects were enrolled and treated over four dose levels, including 3D1002 50 mg BID, 3D1002 250 mg BID, placebo and rofecoxib.

Efficacy. This was a 2-week, randomized, double-blind, placebo- and positive-controlled, parallel-group, multi-center study of subjects with osteoarthritis pain. It was originally designed to compare 50 and 250 mg BID 3D1002 with placebo and rofecoxib 25 mg QD. However, the rofecoxib group was terminated on October 1, 2004 because rofecoxib was withdrawn from the U.S. market.

Compared with subjects who received placebo, the reduction of pain in subjects treated with 3D1002 (50 and 250 mg BID) was statistically and clinically significant. The primary parameter of efficacy endpoint was the change in the WOMAC (Western Ontario and McMaster Universities Arthritis Index) pain. Therefore, the proof-of-principle of this mechanism was completed. In the primary analysis of WOMAC's average improvement from baseline to week 2, the differences between 50 and 250 mg BID 3D1002 treatment groups and placebo were -0.83 and -0.92, respectively (The larger the number after the minus sign, the better the difference relative to placebo.). Both treatment groups were statistically significant at the level of 0.10 (one sided).

At week 1, the average response for 3D1002 (least squares mean) was greater than placebo response: as of week two, placebo response further improved, narrowing the difference between placebo and 3D1002. At week one, the mean differences between 50 and 250 mg BID treatment groups and placebo was -1.4 and -1.9, respectively, and the difference at week 2 was -0.8 and -0.9 respectively.

The figure below showed the change from baseline in the least squares mean of WOMAC:



Source: Company data

In the primary analysis of WOMAC (full analysis set, mixed-effect model, week 2), the changes from baseline in the placebo group at week 1 and week 2 were -2.7 and -3.7, respectively, which may led to efficacy underestimation (the difference between week 2 and placebo). Notably, despite of considerable placebo responses, the difference was still statistically significant.

Safety. The incidence of AEs was similar among all treatment groups, except for gastrointestinal events. The most frequently reported AEs during treatment were gastrointestinal events and headaches. Gastrointestinal events include abdominal pain, discomfort, bloating, and diarrhea (including loose stools). The most frequently reported treatment-related AEs were gastrointestinal events and headaches.

Conclusion. 3D1002 at the 50 mg BID dose and 250 mg BID dose demonstrated statistically significant and clinically meaningful reductions in OA pain over placebo as measured by WOMAC at Weeks 1 and 2, thus establishing proof of mechanism. 3D1002 at doses of 50 mg BID and 250 mg BID was generally well tolerated during this study.

(2) Phase II Clinical Trial in Patients with Osteoarthritis (OA) Pain for a Period of Four Weeks

Study design. This was a four-week, randomized, double blind, placebo- and positive-controlled, parallel-group, multi-center study of 3D1002 in patients with osteoarthritis pain. 739 subjects were enrolled and treated over seven dose levels, including 3D1002 5 mg QD, 3D1002 5 mg BID, 3D1002 25 mg QD, 3D1002 25 mg BID, 3D1002 75 mg BID, naproxen 500 mg BID and placebo.

Efficacy. The pairwise comparison between 3D1002 and placebo showed that in the following 3D1002 administration group, the change from the baseline to week 4 in WOMAC pain subscale was statistically different from the placebo group: 3D1002 5 mg BID administration group (difference=-1.31, p=0.0116), 3D1002 25 mg QD administration group (difference=-1.36, p=0.0095), 3D1002 25 mg BID administration group (difference=-1.47, p=0.0048) and 3D1002 75 mg BID administration group (difference=-1.81, p=0.0005). The p-value for comparison between naproxen and placebo group was 0.0007 (difference=-1.77), which verified the sensitivity of analysis in this study. The analysis result of ITT (intention-to-treat) population by using LOCF (carrying the last observation forward) method and the analysis result of per-protocol (PP) by using mixed-effects models for repeated-measures confirmed a definite dose-response relationship and demonstrated that the conclusions from primary analysis were robust.

Safety. The percentage of subjects who had AEs was similar among all treatment groups. The percentage of 3D1002 treatment group was between 44.2%-55.6%, naproxen group was 47.6%, and placebo group was 41.5%. In the 3D1002 treatment group, the proportion of subjects who reported AEs after 75 mg BID administration was the lowest, and the incidence of AEs was the highest after 25 mg BID administration. Generally speaking, half of all reported AEs were considered treatment-related. In the 3D1002 treatment group, the proportion of patients who had treatment-related AEs was between 22.4% to 31.5%, 23.8% in the naproxen group and 16.0% in the placebo group. Overall, of all 3D1002 administration groups and placebo group, the most frequently reported AEs was headache.

Conclusion. 3D1002 was efficacious for the treatment of OA pain. Doses over 20 mg per day achieved the target efficacy. 3D1002 was acceptably tolerated in this study.

(3) Phase I Clinical Trials

Five Phase I clinical trials have been completed to assess the safety, tolerability, and pharmacokinetics with 3D1002. The table below summarizes the information of each trial:

Trial	Design	Subjects	Dose Level
RMX1002-1101 (China)	A randomized, double-blind, placebo-controlled, single-dose escalation Phase I clinical study to assess the safety, tolerability and PK characteristics of 3D1002 in healthy Chinese adult subjects	40	25 mg, 100 mg, 300 mg and 600 mg or placebo

Trial	Design	Subjects	Dose Level
A5231003	A randomized, double-blind, placebo-controlled dose escalation study	78 (1 subject was lost to follow up)	1, 3, 10, 30, 100, 300, 600, 1000, 1500 and 2000 mg 3D1002 OPC or placebo
A5231004	A randomized and crossover study to assess the effects of food	12	375 mg tablet (3×125 mg tablet) in the fed and fasted states
A5231009	A randomized, placebo-controlled, sequential parallel group, multiple dose escalation study to assess the safety, tolerability and PK characteristics of 3D1002 tablets in healthy adult subjects and elderly subjects with mild renal impairment	36 (healthy subjects) 21 (elderly subjects)	50, 150 and 300 mg BID or placebo 250 mg BID or placebo
A5231018	A multi-center, randomized, placebo- and positive-controlled study to assess the effect of 3D1002 on the incidence of gastroduodenal endoscopic ulcers in healthy subjects	358	75 mg BID, naproxen 500 mg BID or placebo

3D1002 was well tolerated in single dose ranging from 1 mg to 1000 mg in healthy subjects, as well as in multiple dose for 14 days at doses up to 300 mg BID in healthy adult subjects and at 250 mg BID in elderly subjects with mild renal impairment. Systemic exposure increased in an approximate dose-proportional manner after single and multiple dose. Compared to the fasted condition, a standard high-fat meal decreased the absorption rate of 3D1002 tablets as indicated by a 36% decrease in Cmax and an approximately 3-hour delay in Tmax. The systemic exposure (as measured by AUC) of 3D1002 was not affected by food. There was no significant difference between 3D1002 and placebo in the incidence of gastroduodenal ulcer. There was a significantly lower incidence of ulcers in the 3D1002 group compared to naproxen in the elderly cohort. 3D1002 was well tolerated in healthy Chinese subjects in a single dose of 25 mg to 600 mg.

iv. Clinical Development Plan

We plan to conduct a randomized Phase II clinical trial to evaluate the efficacy, safety and PK of 3D1002 in patients with cancer pain. If the data is supportive, a Phase III clinical trial in this setting will be conducted and other pain indications such as osteoarthritis may be studied.

The table below sets forth the details of our clinical development plan for 3D1002:

Indication	Status	Expected first patient in date	Expected NDA submission date	Expected number of patients	Location and competent authority
cancer pain[(1)]	Phase II	Q4 2022	2H 2025	130-177	China and NMPA

Abbreviations: Q3 = third quarter; 1H = first half.

Notes:

(1) The Phase II clinical trial in cancer pain is based on a potentially improved safety profile for 3D1002 attributable to its novel mechanism of action versus other nonsteroidal anti-inflammatory drugs (NSAIDs). As of July 18, 2022, this clinical trial was still in preparation stage and no patient had been enrolled. First patient is expected to be enrolled in the fourth quarter of 2022.

v. Licenses, Rights and Obligations

We maintain the exclusive rights to develop, manufacture and commercialize 3D1002 in China in the pain indication field. We obtained all the intellectual property rights relating to 3D1002 pursuant to a license agreement between us and Haihe Biopharma Group. Please refer to the paragraph headed "Our Research and Development – Collaboration Agreements – Collaboration with Haihe Biopharma Group for 3D1001 and 3D1002" in this section.

vi. Material Communications

The IND approval was obtained from the NMPA in July 2018. We had not received any relevant regulatory agency's objections to our clinical development plans as of the Latest Practicable Date.

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 3D1002 SUCCESSFULLY.

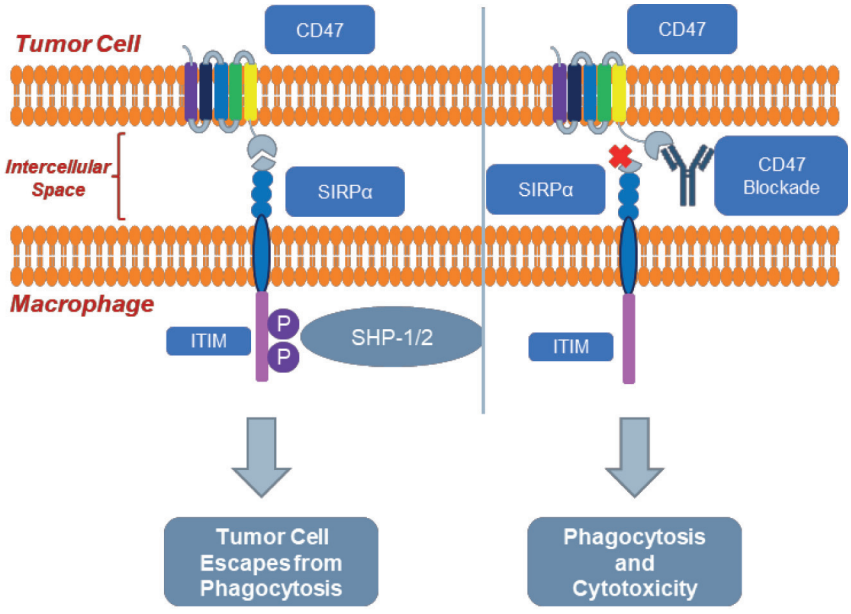
g. 3D197

3D197, also known as IMC-002, is our next-generation fully human anti-CD47 IgG4 monoclonal antibody and designed to block the CD47–SIRPα interaction in order to promote the phagocytosis of cancer cells by macrophages. We own the exclusive rights to develop, manufacture and commercialize 3D197 in China, Hong Kong, Macau and Taiwan region in respect of oncology indications through our exclusive license agreement with ImmuneOncia. According to its pre-clinical results, it binds to human CD47 with an optimal affinity that maximizes efficacy. 3D197 did not cause hemagglutination in vitro nor induced anemia in pre-clinical toxicology studies. It is expected to treat hematological malignancies and solid tumors. We obtained the IND approval for 3D197 for the treatment of advanced malignant tumors in China in January 2022.

i. Mechanism of Action

CD47 is a transmembrane protein expressed on tumor cells that transmits "don't-eat-me" signal to its receptor, signal regulatory protein α (SIRPα), on phagocytes, such as macrophages and dendritic cells. Binding of CD47 to SIRPα induces phosphorylation of the immunoreceptor tyrosine based inhibitory motifs (ITIM) in cytoplasmic domain of SIRPα that recruits Src homology phosphatases 1 and 2 (SHP-1 and SHP-2) and inhibits phagocytic uptake. This inhibitory mechanism is exploited by solid and hematologic malignancies that over-express CD47. Studies showed that blockade of CD47/SIRPα enables cancer cell phagocytosis by macrophages and promoted antitumor activities in various animal models. CD47 blockade also induces anti-tumor T cell responses through cross-presentation of tumor antigens by dendritic cells after engulfing tumor cells. In addition, targeting CD47/SIRPα synergistically enhances anti-tumor responses in combination with other treatments including chemotherapy or immune-modulatory agents, such as anti-PD-1 or PD-L1 antibodies.

3D197 is a fully human anti-CD47 IgG4 monoclonal antibody that blocks the CD47–SIRPα interaction. 3D197 blocks the "don't eat me signal," thereby enhances tumor phagocytosis by macrophage. The diagram below shows the mechanism of action for 3D197:



Source: Front. Immunol., 28 January 2020, Curr Opin Immunol. 2012 Apr; 24(2): 225-232., Journal of Hematology & Oncology volume 13, Article number: 96 (2020), Frost & Sullivan Report

ii. Market Opportunities and Competition

As of the Latest Practicable Date, there has not been any approved CD47 antibody globally. The following table sets forth the details of CD47 mono-antibodies in clinical development in China as of the Latest Practicable Date:

Drug Name	Phase	Company	Indications	Target	Drug Type	Therapeutic strategy	Location	First Posted Date
IBI188	III	Innovent Biologics	Myelodysplastic syndrome, Acute myeloid leukemia, Advanced malignant tumor	CD47	Whole human monoclonal antibody	Monotherapy/ Combination therapy	US; China	2018/11/22
TJ011133 (TJC-4)	II	I-Mab Biopharma	Myelodysplastic syndrome, Recurrent or refractory acute myeloid leukemia, CD20+ lymphoma, advanced solid tumor	CD47	Whole human monoclonal antibody	Monotherapy/ Combination therapy	US; China	2019/12/19
AK117	II	Akesobio	Myelodysplastic syndrome, Lymphoma, Solid tumor, Acute myelogenous leukemia	CD47	Monoclonal antibody	Monotherapy	China	2020/12/29
IMM01	II	ImmuneOnco Biopharm	Myelodysplastic syndrome, Acute myeloid leukemia	CD47	Monoclonal antibody	Monotherapy/ Combination therapy	China	2021/10/26
ZL-1201	I	Zai Lab (Shanghai)	Solid tumor, hematological malignancies	CD47	Monoclonal antibody	Monotherapy	US; China	2020/5/9
MIL95	I	Beijing Mabworks; Beijing Huafang Tianshi; Shanghai Lingyue Bio-tech	Lymphoma, Advanced malignant solid tumors	CD47	Humanized monoclonal antibody	Monotherapy	China	2020/11/27
Kintuzumab	I	Jinsai Pharmaceutical Co., Ltd	Hematological malignant tumor, Advanced malignant solid tumors and lymphomas	CD47	Monoclonal antibody	Monotherapy	China	2021/01/12
TQB2928	I	Chia Tai Tianqing	Advanced Solid Tumor	CD47	Monoclonal antibody	Monotherapy	China	2022/1/4

Drug Name	Phase	Company	Indications	Target	Drug Type	Therapeutic strategy	Location	First Posted Date
BAT7104	I	Bio-thera	Advanced malignant tumor	CD47	Monoclonal antibody	Monotherapy	China	2022/2/22
IMC-002	**I**	**3DMed**	**Locally advanced or metastatic solid tumors and relapsed or refractory hematological tumors**	**CD47**	**Monoclonal antibody**	**Monotherapy**	**China**	**2022/3/9**
F527	I	Shandong Xinshidai	Relapsed or refractory lymphoma	CD47	Humanized monoclonal antibody	Monotherapy	China	2022/4/14

Note:

(1) Date denotes the date on which the relevant status was publicly disclosed.

Source: CDE, Clinicaltrials.gov, Annual Reports of Listed Pharmaceutical Companies, Frost & Sullivan Report

iii. Clinical Development Plan

We plan to conduct a phase I study in China to optimize the dose of single agent 3D197 in Chinese patients. We will subsequently conduct phase Ib/II study to evaluate the combination of 3D197 with envafolimab, azacitidine, rituximab, and other standard agents in solid tumors and hematological malignancies. Phase III study design will be informed by the results of the phase I/II studies.

The table below sets forth the details of our clinical development plan for 3D197:

Indication	Status	Expected first patient in date	Expected NDA submission date	Expected number of patients	Location and competent authority
Advanced tumors[(1)]	Phase I (single agent)	2H 2022	–	escalation phase: 42 expansion phase: 40	China and NMPA
Selected tumor types[(2)]	Phase Ib/II (combination)	2H 2023	–	170	China and NMPA

Abbreviation: 2H = second half.

Notes:

(1) The Phase I clinical trial is based on the design of the ongoing phase I study in the US and South Korea and based on the need to establish a recommended phase II dose (RP2D) in Chinese patients. As of July 18, 2022, this clinical trial was still in preparation stage and no patient had been enrolled. First patient is expected to be enrolled in second half of 2022.

(2) The Phase Ib/II combination clinical trial is based on the published studies showing initial promising efficacy when CD47 antibody is combined with azacitidine or rituximab, and complementary mechanism of action between PD-(L)1 inhibition and CD47 blockade. As of July 18, 2022, the proposed studies were still on track and this clinical trial is expected to enroll the first patient in second half of 2023.

iv. Licenses, Rights and Obligations

We maintain the exclusive rights to develop, manufacture and commercialize 3D197 in China, Hong Kong, Macau and Taiwan region in respect of oncology indications pursuant to our exclusive license agreement with ImmuneOncia. Please refer to the paragraph headed "Our Research and Development – Collaboration Agreements – Collaboration with ImmuneOncia for 3D197" in this section.

v. Material Communications

We obtained the IND approval for 3D197 in China in January 2022. We had not received any relevant regulatory agency's objections to our clinical development plans as of the Latest Practicable Date.

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 3D197 SUCCESSFULLY.

3. Our Pre-Clinical Stage Drug Candidates

In addition to our clinical-stage drug candidates, we are also evaluating a number of pre-clinical stage drug candidates in our rich pipeline. As of the Latest Practicable Date, our pre-clinical stage drug candidates included the following:

- 3D057, also known as YBL-013, our bispecific antibody drug which targets CD3 receptor of T-cells and PD-L1 of tumor cells, which is licensed from Y-Biologics. Please refer to the paragraphs headed "Our Research and Development – Collaboration Agreements – Collaboration with Y-Biologics for 3D057" in this section.

- 3D059, also known as heptavalent galinpepimut-S (GPS+), our next-generation immunotherapeutic which targets the WT1 protein in hematological malignancies and solid tumors, which is licensed from SELLAS Group. Please refer to the paragraphs headed "Our Research and Development – Collaboration Agreements – Collaboration with SELLAS Group for 3D189 and 3D059" in this section.

- 3D060, our in-house discovered monoclonal antibody which targets Semaphorin 4D (Sema4D) of tumor cells.

- 3D062, our in-house discovered small molecule for patients with KRAS mutation.

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 3D059, 3D057, 3D060 and 3D062 SUCCESSFULLY.

OUR RESEARCH AND DEVELOPMENT

Our Platforms

Our R&D platform has strong molecule screening and design capabilities that increase the possibility of success of moving molecules from pre-clinical studies to market, enable innovative therapeutic approaches and support rich pipeline assets built around key pathways and targets. Our R&D centers in Shanghai and Beijing include large and small molecule platforms, complete cell line screening platforms, high-throughput compound screening platforms and comprehensive animal models. Our R&D centers also support a drug activity screening platform, a platform for the study of cellular functions of drugs, a drug biochemical study platform, and a biomolecule detection platform, which can perform common molecular and cellular biology experimental studies such as cell activity detection, ELISA, real-time PCR, western blot, molecular cloning, biochemical enzymology and flow cytometry. Meanwhile, we have hundreds of commercial tumor cell lines from ATCC, ECACC, JCRB and RIKEN, the four largest cell banks in the world. The source of cell tumors covers prevalent tumor types such as lung cancer, liver cancer, colon cancer, gastric cancer, esophageal cancer and breast cancer in the American, European and Asian populations, which can provide broader, more effective and convenient drug candidate screening in early pre-clinical research and development, and these samples also demonstrate notable advantages in the development of tumor biomarkers.

Drug Discovery and Pre-Clinical Research

We believe that R&D is key to maintaining competitiveness in our industry. We have built a platform to enable our R&D in the areas of chronic cancer treatment. Leveraging our proprietary R&D platform, we are able to conduct pre-clinical R&D activities including drug activity screening, studies of cellular functions of drugs, drug biochemical studies and biomolecule detection. We are also fully capable to perform common molecular and cellular biology experimental studies, such as cell activity detection, ELISA, real-time PCR, western

blot, molecular cloning, biochemical enzymology and flow cytometry. Our drug discovery and translational research function is led by Dr. Yihui Lin, our Head of Translational Medicine Center, who holds a Ph.D. from the Center for Excellence in Molecular Cell Science of Chinese Academy of Sciences. As of the Latest Practicable Date, our R&D team had a total of 151 employees, 82 of which have a master's degree or higher, including 17 with doctor's degrees.

During the drug discovery stage, we explore new R&D opportunities, conduct feasibility research and provide evaluation opinion for the opportunities. We also design and prepare new types of chemical compounds, conduct systematic research regarding the manufacturing process and quality management of the new drugs, and develop technology platforms to support, manage and supervise the related technologies. During pre-clinical research stage, we coordinate and accomplish pre-clinical R&D activities in relation to pharmacology, efficacy, toxicology and safety. We conduct extensive early-stage investigation on various drug candidates. We also assist in the registration process of the new drugs by collecting and preparing the required information and materials.

With our pre-clinical research capability, we can find products worldwide that best fit existing pipelines and strategies, and we can efficiently complete target determination, compound design, screening optimization and IND application. We have the experience and ability to independently complete the entire drug development process from drug discovery to pre-clinical research to clinical development and to NDA/BLA application.

Clinical Development

We employ a clinical-demand-oriented and market-driven approach to our clinical research and development efforts. Our clinical development team is composed of scientists and physicians with years of experience in drug development. Our clinical development team carefully customizes clinical development plan for each of our candidate drugs by taking into consideration of unmet medical needs, scientific rationale, and probability of technical and regulatory success, competition, commercial assessment, expert feedback, timeline and cost. We apply state of art clinical trial designs based on our deep understanding of the disease, available evidence, regulatory requirements, feasibility and statistical methods to achieve efficient clinical development of our assets. We demonstrate our clinical capabilities by, for instance, only taking four years to bring a new molecular entity from IND to BLA. Our clinical development team consists of five functions in charge of all aspects of clinical development including clinical research, clinical operation, data management and biostatistics, pharmacovigilance, and drug supply. Our clinical development team is led by Dr. Dongfang Liu, who holds a Ph.D degree from Massachusetts Institute of Technology, a master's degree in pharmaceutical sciences from the University of Toledo, and a bachelor's degree in clinical medicine from Peking University School of Medicine (formerly Beijing Medical University). Dr. Liu is a recognized leader in the field of oncology clinical research and development with a proven track record in developing oncology drugs.

During the clinical development stage, we manage clinical trials and carry out a comprehensive suite of clinical development activities in-house, including clinical trial design, implementation, and the collection and analysis of trial data. We supplement our internal efforts with CROs when necessary to help with operation aspects of selected studies. As of the Latest Practicable Date, we had obtained 16 IND approvals and implemented 12 Phase II/III clinical studies. Our experienced and capable leadership team has led us to differentiate from competitors in both clinical development strategy and execution of the studies as evidenced by being the first to complete the pivotal study in MSI-H/dMMR cancer despite stiff competition from several companies.

COLLABORATION AGREEMENTS

Collaboration with Alphamab Group for Envafolimab

1. Collaboration Agreements and Supplements

In February 2016, we entered into a co-development agreement, as amended, with Alphamab Group for envafolimab (collectively with the subsequent amendments and supplemental agreements thereto, the "**Co-Development Agreements**"). Alphamab Group is a biopharmaceutical company in China, an Independent Third Party of our Group. We became acquainted with Alphamab Group when our founder, CEO and Chairman, Dr. Gong, was introduced to its founder, Dr. Xu Ting in a bio-pharmaceutical development opportunity summit forum in April 2009. Salient terms of the Co-Development Agreements are summarized below:

Allocation of Responsibility

- Under the Co-Development Agreements, we are responsible for, among other things, designing, conducting and monitoring clinical trials, reviewing registration filings, and conducting commercialization of envafolimab globally at our own cost, while Alphamab Group is responsible for, among other things, completing CMC studies and pre-clinical studies and manufacturing envafolimab samples for clinical trials at its own cost. During the clinical stage, Alphamab Group is obligated to supply envafolimab drug samples for free. After envafolimab enters into the commercialization stage, Alphamab Group will supply envafolimab to us on a cost-plus basis. The "cost-plus basis" for the supply of envafolimab by Alphamab Group equals to the production costs times by a certain markup. The markup in the range of 25% to 35% is to cover the depreciation and fixed maintenance cost incurred with Alphamab Group's manufacturing facilities. The commercial rationale for sharing 49% of the profit before tax to Alphamab Group on top of the "cost-plus" payments to Alphamab Group for the supply of envafolimab is that the "cost-plus basis" merely covers both the variable and fixed costs of producing envafolimab whereas the 49% represents the profit sharing of the collaboration between the two parties after deducting relevant costs and expenses.

  We are also entitled to obtain the new drug certificate and would have exclusive commercialization rights for envafolimab worldwide. Alphamab Group is entitled to apply for and obtain the GMP certificate to manufacture envafolimab, and is obligated to manufacture and supply envafolimab to us.

Payment

- Under the Co-Development Agreements, we have the following payment obligations to Alphamab Group: (i) Alphamab Group was eligible to receive an upfront payment of RMB10 million, which we have paid in April 2016; and (ii) upon the approval and commercialization of envafolimab, we would be entitled to 51% while Alphamab Group would be entitled to 49% of the profit before tax generated from the sales of envafolimab in China. We are the marketing authorization holder of envafolimab and we will record 100% of revenue generated from the sales of envafolimab upon commercialization.

Intellectual Property (IP) Arrangements

- Under the Co-Development Agreements, we agreed to co-own with Alphamab Group relevant patents and patent applications in relation to envafolimab (the "**Co-Owned Patents**"). Our ownership interests to the Co-Owned Patents include oncology treatment and may be used for envafolimab or drugs using envafolimab as a component, excluding bispecific antibodies, multi-functional antibodies, fusion proteins and other derivative antibodies. According to the Co-Development Agreements, upon approval of the marketing authorization for envafolimab, we would have 51% while Alphamab Group would be entitled to 49% of the ownership interests to the Co-Owned Patents.

- According to the Co-Development Agreements, we are exclusively entitled to use the Co-Owned Patents in the field of oncology or tumor therapy, such as to manufacture, use, offer for sale, sell and import envafolimab. Without our prior consent, Alphamab Group shall not mortgage or pledge the Co-Owned Patents, or change the patentee, applicant or other matters related to the Co-Owned Patents.

- As further clarified and elaborated in the letter supplemental to the Co-Development Agreements, namely the Alphamab Confirmation Letter (as defined below), amongst others, although both parties will continue to hold co-ownership of the Co-Owned Patents, (i) we will continue to have an exclusive right of use in the field of oncology or tumor therapy which is relevant to the oncology indications of envafolimab, namely the current scope of indications of our Core Product; and (ii) we will continue to be free to independently use the residual rights in the Co-Owned Patents in the future development and commercialization of envafolimab. For more details, please refer to the following sub-paragraph headed "2. Alphamab Confirmation Letter – c. IP Confirmation".

Remedies and Unilateral Right to Transfer the Co-Owned Patents

- Any breach of the foregoing rights and obligations will constitute a breach of the Co-Development Agreements. According to the Co-Development Agreements, a breach of the agreements includes, among other things, (i) Alphamab Group's interference of our exclusive rights to independently use the Co-Owned Patents in the field of oncology and tumor therapy, (ii) Alphamab Group's mortgaging or pledging the Co-Owned Patents without our prior consent, or (iii) Alphamab Group's ceasing the supply of envafolimab products during our commercialization stage.

- According to the Co-Development Agreements, if one party (the breaching party) causes losses to the other party (the non-breaching party) due to its breach of the agreement and fails to indemnify promptly, the non-breaching party shall have a unilateral right to transfer the patents related to envafolimab, and the proceeds from transfer or license shall be first used to compensate the losses of the non-breaching party.

Term and Termination

- The Co-Development Agreements can be terminated in the following situations: (i) if a contracting party breaches the agreements, (ii) if the obligations under the Co-Development Agreements cannot be performed due to force majeure, or (iii) if a party fails to perform its obligations related to the intellectual property rights. Based on the fact that the parties have amicably reached consents on all matters and there have not been any disputes between the parties historically, it is unlikely that either party will breach the Co-Development Agreements.

- The Co-Development Agreements are silent on the duration of the collaboration and which party will own the residual rights in the Co-Owned Patents upon the expiry of the Co-Development Agreements. In the absence of such clause, we and Alphamab Group, as co-owners of the Co-Owned Patents, would retain the residual rights in the Co-Owned Patents under PRC law, in the view of our legal advisers as to the intellectual property law.

Dispute Resolution and Joint Steering Committee (JSC)

- In the event of disagreement over any terms of the agreements, including in respect of the amount of profit before tax to be shared between the parties, the parties should first resolve such disagreement through friendly negotiation. If the disagreement cannot be resolved through negotiation, such disagreement should be resolved by arbitration.

- A joint steering committee (JSC) was established to address matters relating to the development and commercialization of envafolimab. In December 2021, as a mutual agreement, the JSC arrangement was cancelled as part of the arrangement supplemental to the Co-Development Agreements, namely the Alphamab Confirmation Letter (as defined below). For details and reasons on the cancellation, please refer to the following sub-paragraph headed "2. Alphamab Confirmation Letter – b. JSC Cancellation".

2. Alphamab Confirmation Letter

In December 2021, as a supplemental agreement to the Co-Developments, Alphamab Group (through Jiangsu Alphamab Biopharmaceuticals Co., Ltd. ("**Jiangsu Alphamab**")) issued a confirmation letter to us (the "**Alphamab Confirmation Letter**") which mainly concerns (i) cancellation of the JSC (the "**JSC Cancellation**") and (ii) the confirmation of our exclusive right to use the Co-Owned Patents in the field of oncology and tumor therapy without interference from Alphamab Group (the "**IP Confirmation**"). For the avoidance of doubt, as a mutual agreement, we are not subject to any obligations (payment or otherwise) pursuant to the Alphamab Confirmation Letter or otherwise in relation to the cancellation of the JSC Cancellation and the IP Confirmation.

a. Confirmation with Respect to Our Control

According to the Alphamab Confirmation Letter, Alphamab Group confirms and acknowledges that, among other things: (a) during the term of cooperation, we have been undertaking and effectively controlling the global clinical R&D and commercialization of envafolimab in the field of oncology or tumor therapy; (b) we, as the MAH holder, have been solely responsible for the safety, efficacy and quality control of envafolimab throughout the entire process of R&D, manufacture, operation and utilization; (c) Alphamab Group respects and relies on the judgement and advice of us and there has been no inconsistency, conflict or dispute between Alphamab Group and us in terms of the performance and implementation of the Co-Development Agreements since the beginning of the cooperation; and (d) since the beginning of the cooperation, Alphamab Group has never attempted to alter or restrict our ability to effectively control envafolimab in the field of oncology or tumor therapy, and it will not attempt to do so in the future.

b. JSC Cancellation

Given that (i) we have obtained the BLA approval for envafolimab for the treatment of previously treated MSI-H/dMMR advanced solid tumors in November 2021 and we already initiated the commercialization in December 2021, (ii) our expertise has been validated during the development and commercialization of MSI-H/dMMR, which has been also utilized in other indications since the beginning of co-development with Alphamab Group, and (iii) we will undertake the further development of envafolimab and all costs, both parties considered that regular meeting and discussion of the JSC mechanism was no longer necessary and may be onerously burdensome. Hence, the parties cancelled the JSC so that we can make decisions more swiftly and efficiently in relation to envafolimab without having to confer with the JSC.

Furthermore, although the JSC arrangement entailed a voting mechanism, both parties, in actual practice, acted unanimously since the beginning of the cooperation, with Alphamab Group consistently deferring to us for decisions over envafolimab. Given there has never been any inconsistency, conflict or dispute between both parties and none is expected in the future which reasonably mitigates Alphamab Group's concerns over the

development and commercialization of envafolimab, it is reasonably agreed by both parties that the JSC Cancellation will not bring in any material adverse effect over the Co-Development over envafolimab as well as Alphamab Group's interests.

As such, considering (i) previous and existing close and mutual beneficial cooperative business relationship which is critical to us as well as Alphamab Group (for example, under a memorandum of understanding entered into between us and Alphamab in October 2020, we also assist and facilitate Alphamab Group's development of non-oncology indications of envafolimab outside the scope of the Co-Development Agreements by way of a specific arrangement under our subsidiary, 3DMed Sichuan. For details, please refer to the following sub-paragraphs headed "4. A Specific Arrangement in relation to 3DMed Sichuan") and (ii) the reliance upon our expertise and further development of envafolimab (including but not limited to indication expansion), both parties agreed to the JSC Cancellation to further reinforce mutual cooperation and to further enhance our effective control over envafolimab in line with original agreement and actual practice.

c. IP Confirmation

According to the Alphamab Confirmation Letter, with respect to the Co-Owned Patents Alphamab Group confirms and acknowledges the following:

(a) Alphamab Group reaffirms and restates that we have the exclusive right to use the Co-Owned Patents in the field of oncology or tumor therapy, such as to manufacture, use, offer for sale, sell and import envafolimab, and Alphamab Group further commits not to interfere with our independent exercise of such rights.

(b) Alphamab Group reaffirms and restates that, during the cooperation under the relevant Co-Development Agreements, Alphamab Group is obligated to strictly fulfil its obligations in relation to the maintenance of the Co-Owned Patents thereunder and will maintain full communication and coordination with us in this regard. If Alphamab Group fails to fulfil or fails to timely fulfil such obligations, we, as the co-owner of the Co-Owned Patents, have the right to, in our own discretion, carry out relevant maintenance work from time to time, including without limitation the payment of annual fees and other relevant government formalities and safeguarding the Co-Owned Patents in the case of third-party infringement.

(c) Alphamab Group further commits that, in consideration of the long-term cooperation between Alphamab Group and us in relation to envafolimab under the relevant Co-Development Agreements and that there is no specific term of contract, in case of termination or expiration of relevant Co-Development Agreements (if any), we and Alphamab Group will continue to co-own the Co-Owned Patents that will remain valid upon such termination or expiration,

and we, as the co-owner of the Co-Owned Patents, will continue to be entitled to the independently exclusive use of such remaining patents in the field of oncology or tumor therapy, and will continue to be entitled to be responsible for the continued research and development and commercialization of other indications of envafolimab in the field of oncology or tumor therapy.

As advised by our legal adviser as to intellectual property law, the Alphamab Confirmation Letter is a helpful supplement to the Co-Development Agreements by clarifying several issues with respect to the Co-Owned Patents upon any expiration or termination of the Co-Development Agreements: (i) both parties will continue to hold co-ownership of the Co-Owned Patents and we will continue to have an exclusive right of use in the field of oncology or tumor therapy; and (ii) we will continue to be free to independently use the residual rights in the Co-Owned Patents in the future development and commercialization of envafolimab.

3. Effective Control over Core Product under the Co-Development Agreements and the Alphamab Confirmation Letter

Based on the foregoing, we exercised and will continue to maintain effective control over the Core Product in various aspects. In addition, as discussed above, the Alphamab Confirmation Letter (including in particular, the JSC Cancellation) also confirms and acknowledges our control over the Core Product.

a. Intellectual Property Rights in relation to the Core Product

According to the Co-Development Agreements, we are exclusively entitled to use the Co-Owned Patents in the field of oncology or tumor therapy which covers the scope of indications of the Core Product and certain other indications under clinical stage.

According to the Co-Development Agreements and the Fifth Supplement thereto, commencing from the divisional application of PCT/CN/2016/092679 and PCT/CN/2016/092680 in 2016, we and Alphamab Group have been jointly responsible for the prosecution and maintenance of the Co-Owned Patents.

The PCT patent application (PCT/CN/2016/092680) was jointly filed by us and Alphamab Group in 2016 and has been granted to 3DMed Beijing and Alphamab Group as CN107849130B (the "**130B Patent**"). Our legal adviser as to intellectual property law is of the view that we are entitled to maintain and enforce the patent under PRC in the field of oncology or tumor therapy and the use of patent under the arrangement of co-ownership of the patent does not adversely affect our development and commercialization of current scope of oncology indications of envafolimab in China and abroad, including but not limited to our Core Product and several indications which are currently under clinical stage since there is a clear distinction of our Group and Alphamab Group.

i. Our exclusive right to the Co-Owned Patents in the field of oncology and tumor therapy is specified in and protected under both the Co-Development Agreements and the Alphamab Confirmation Letter.

The Co-Development Agreements explicitly provide us the exclusive right to use the Co-Owned Patents in the field of oncology or tumor therapy and as a result, Alphamab Group is not entitled to and has not interfered with our independent exercise of such rights. Alphamab Group further confirms and commits not to interfere with our independent exercise of these rights in the Alphamab Confirmation Letter.

According to our legal adviser as to intellectual property law, the IP Confirmation, which is supplemental to the Co-Development Agreements, reaffirms and restates the provisions under the Co-Development Agreements with respect to: (i) our exclusive right to use the Co-Owned Patents in the field of oncology and tumor therapy, (ii) our right to maintain the Co-Owned Patents, and (iii) our exclusive right of use in the field of oncology and tumor therapy after the expiration or termination of the Co-Development Agreements. Therefore, if Alphamab Group were to breach the Alphamab Confirmation Letter, e.g., by interfering with our exclusive rights or independent exercise of such rights, the breach would itself constitute both a breach of the Alphamab Confirmation Letter and a breach of the Co-Development Agreements. According to the breach of contract provisions of the Co-Development Agreements, in the worst case scenario, were Alphamab Group to commit a breach, we would be entitled to claim for monetary compensation for any losses we incurred and right to request for continued performance of the Co-Development Agreements. If Alphamab Group failed to compensate us for any losses incurred due to its breach of the Co-Development Agreements, we would be further entitled to exercise the unilateral right to transfer the Co-Owned Patents.

If we and Alphamab Group fail to reach an agreement on transferring the Co-Owned Patents, we may file a lawsuit with the competent PRC court to enforce our unilateral transfer right. According to our legal adviser as to intellectual property law, the court is likely to rule in favor of us since it would be relatively simple for us to produce supporting evidence if Alphamab Group interferes with our exclusive rights or independent exercise of such rights. With a judgment in our favor, we could apply to the China National Intellectual Property Administration (CNIPA) to transfer the Co-Owned Patents, according to the Rules for the Implementation of the PRC Patent Law (2010) and the Guidelines for Patent Examination (2010).

ii. The technologies we owned through the Co-Owned Patents are sufficient for us to develop the Core Product.

According to our legal advisers as to intellectual property law, as of the Latest Practicable Date, in relation to the Core Product, the Co-Owned Patents with Alphamab Group covered ten granted patents and ten filed patent applications, and we in-licensed four granted patents and two filed patent applications from Alphamab Group (the "**In-Licensed Patents**"); in total, we co-own or in-license 26 granted patents and patent applications in China and other jurisdictions.

According to our legal adviser as to intellectual property law, the technologies covered by the Co-Owned Patents are sufficient to independently develop the Core Product, a PD-L1 binding protein for preventing and/or treating cancer.

Specifically, in mainland China, the registered Co-Owned Patent of the 130B Patent, granted as of December 31, 2019 and expiring in 2036, is itself sufficient to cover the technologies for independently developing the Core Product.

The 130B Patent has been granted with 22 claims in total, including, among others, coverage of (i) the active pharmaceutical ingredients, (ii) the raw materials for production, (iii) the production method, and (iv) the use in the treatment of cancer indications of the Core Product. According to our legal adviser as to intellectual property law, the technologies under the above listed four areas of the 130B Patent are sufficient for us to independently develop the Core Product.

The Joint Sponsors concur with the views of ours and our legal adviser as to intellectual property law set forth in the preceding paragraphs i and ii.

iii. The in-licensed IP rights serve to mitigate infringement risks.

Given the fact that certain claims of the In-Licensed Patents overlap with those of the Co-Owned Patents, we obtained an exclusive license for the In-Licensed Patents from Alphamab Group, which is intended to mitigate any potential infringement risks against these patents. In patent practice, it is not uncommon to obtain a license, or take transfer, of a target patent for the mere purpose of avoiding any infringement risks against the patent. According to our legal adviser as to intellectual property law, Alphamab Group as the patentee is legally responsible for the prosecution, maintenance and enforcement of the In-Licensed Patents.

Pursuant to the Fifth Supplement to the Co-Development Agreements in December 2018, Alphamab Group agrees to grant us a global, free-of-charge, exclusive license, with the right to sublicense, to freely manufacture, research, use, sell, offer to sell, and import envafolimab in oncology field, based on patent

PCT/CN2016/092679 and patents obtained therefrom in various countries. Salient terms of the in-licensing arrangement with Alphamab Group are summarized below:

Payments	No payment obligations
Intellectual Property (IP) Arrangements	The intellectual property rights of the In-License Patents (including residual rights upon expiration/termination) always vest in Alphamab Group as the patentee.
Term and Termination	The in-licensing arrangement shall remain effective from execution until termination or expiration of the Co-Development Agreements. The Co-Development Agreements can be terminated in the following situations: (i) if a contracting party breaches the agreements, (ii) if the obligations under the Co-Development Agreements cannot be performed due to force majeure, or (iii) if a party fails to perform its obligations related to the intellectual property rights. In the worst case scenario that the Co-Development Agreements are terminated, we might lose the protection afforded by the In-Licensed Patents and potentially be subject to claims of infringement of the In-Licensed Patents for its manufacture, research, use, sale, offer to sell, and importation of envafolimab in the oncology field.

iv. The co-ownership of the Co-Owned Patents and our exclusive right of use survive the termination or expiration of the Co-Development Agreements.

The Alphamab Confirmation Letter particularly specifies that, upon expiration or termination of the Co-Development Agreements: (i) both parties will continue to co-own the Co-Owned Patents and we will continue to have an exclusive right of use in the field of oncology and tumor therapy; and (ii) we will continue to be free to independently use the residual Patent Rights in the future development and commercialization of the Core Product.

Furthermore, the Alphamab Confirmation Letter also clearly states that it shall prevail in the case of any inconsistencies between the Alphamab Confirmation Letter and the Co-Development Agreements.

Based upon the above, the termination or expiration of the Co-Development Agreements will not jeopardize the abovementioned unilateral commitments made by Alphamab Group under the IP Confirmation. In other words, our co-ownership of

the Co-Owned Patents and our exclusive right in the field of oncology and tumor therapy which covers, amongst others, the scope of indications of the Core Product, will survive the termination or expiration of the Co-Development Agreements.

b. R&D and Clinical Trial

We have control over envafolimab's R&D in China and abroad such that we are the responsible party to bring the Core Product from pre-clinical stage to clinical trials and from clinical trial into commercialization. As advised by our PRC Legal Advisers, with respect to research and development, we are responsible for the clinical stage R&D activities in relation to envafolimab under the Co-Development Agreements. Specifically, under the Co-Development Agreements, we are responsible for reviewing new drug application documents and tracking registration progress in China and abroad, designing clinical trial strategy based on precision tumor treatment, implementing and managing clinical trials, managing the collection, reporting and summary of clinical data in China and abroad, arranging clinical and medical specialists to manage the clinical trials, and completing the Phase I clinical development plan and succeeding plans. Furthermore, we received the Umbrella IND Approval in December 2016, completed the China Phase I Clinical Trial and succeeding plans in April 2020 and completed the Pivotal Phase II Clinical Trial in July 2020, all of which occurred after first entering into the Co-Development Agreements in February 2016. To sum up, under the agreed arrangement, we are responsible for the whole clinical stage of R&D activities of envafolimab, while Alphamab Group is mainly responsible for the pre-clinical stage of R&D activities of envafolimab.

Envafolimab was in pre-clinical stage when the Co-Development Agreements were first entered into between us and Alphamab Group in February 2016. Since then, we have independently completed and been independently conducting a number of clinical trials in relation to envafolimab and achieved a number of major R&D milestones on our own and at our own cost, which amounted to approximately RMB614.9 million as of May 31, 2022, and we have significantly increased our R&D team to 151 members as of the Latest Practicable Date.

c. Commercialization and Economic Interests

We have control over envafolimab's commercialization in China and abroad, from contractual, regulatory and accounting perspectives whereas in order to better promote commercialization of envafolimab, our Group may voluntarily choose to cooperate with other partners and leverage its established sales network in China.

In relation to commercialization, we are primarily responsible for envafolimab's worldwide marketing and sales, under the Co-Development Agreements. In addition, under the memorandum with respect to envafolimab's MAH entered into among 3DMed Beijing, Jiangsu Alphamab and Simcere Group dated in October 2020, the parties further agreed that 3DMed Sichuan is the sole MAH with respect to envafolimab and bears sole

responsibility for the marketing and sales of envafolimab in China. According to our PRC Legal Advisers, pursuant to the Drug Administration Law of the PRC (2019 Revision) (中華人民共和國藥品管理法(2019修訂)), a MAH shall be liable for non-clinical study, clinical trial, manufacturing and business operation, post-market launch study, monitoring, reporting and handling of adverse reactions of the drugs, and the legal representative and the key person-in-charge of a MAH shall be fully responsible for the drug quality. Further, 3DMed Beijing retains 100% voting rights at shareholders' meetings and 100% operational management rights over 3DMed Sichuan, and is entitled to 100% economic interests of and 100% nomination right of the director(s), supervisor(s) and senior management of 3DMed Sichuan. Based on the discussion with our management and the facts and circumstances set out by us, our Reporting Accountants concurred with us that, from an accounting perspective, 3DMed Sichuan is a wholly owned subsidiary of our Group, and the sales of envafolimab in China will be recognized on gross basis in our Group's consolidation statement of profit or loss and other comprehensive income.

Furthermore, in order to better promote commercialization of envafolimab and leverage Simcere Group's established sales network in China, we entered into the 3D Alphamab Simcere Agreement with Simcere Group in March 2020 whereby Simcere Group is responsible for preparing a promotion plan and promoting envafolimab in China in accordance with industry standards. Simcere Group is acting as a contract sales organization (CSO) which provides a series of services and solutions related to pharmaceutical marketing and sales activities under contract, and this type of CSO engagement is relatively common in the pharmaceutical industry, according to Frost & Sullivan. The above arrangement with Simcere Group applies to commercialization only in PRC, and we retain authority over envafolimab's worldwide marketing and sales and may choose partner(s) or self-promote envafolimab outside China. For more details, please refer to the paragraphs headed "– Collaboration with Alphamab Group and Simcere Group for Envafolimab" in this section.

d. CMC and Manufacturing

As discussed above, as an allocation of responsibility, we have control and are responsible for the primary aspects of clinical-stage development and commercialization of envafolimab, and is the sole responsible party for the manufacturing and product quality as the MAH for envafolimab, whereas the Alphamab Group is involved to act as a contract manufacturing organization (CMO) by providing drug manufacturing services on a contractual basis including, amongst others, performing CMC research for envafolimab, producing samples for clinical trials and manufacturing envafolimab. We believe that the above arrangement is also in the interests of ours and our Shareholders as a whole since the CMC functions and manufacturing facilities need substantial resources and cost and we elect to focus on the R&D and other functions and aspects of the responsibilities at the moment.

e. Accounting for Our Core Product's Sales

According to the Co-Development Agreements, we obtained exclusive rights to conduct clinical trials and commercialize envafolimab worldwide. Furthermore, under the memorandum of understanding dated October 2020, we and Alphamab Group further agreed that 3DMed Sichuan is the sole MAH with respect to envafolimab and bears sole responsibility for the marketing and sales of envafolimab in China. 3DMed Sichuan in this case acts as a principal in the sales of envafolimab, because it: (i) is the only authorized legal entity to engage in the sales of envafolimab under the Drug Administration Law of the PRC (2019 Revision) (中華人民共和國藥品管理法(2019修訂)) and (ii) controls the goods before goods are transferred to customers. Therefore, according to IFRS15.B35B, 3DMed Sichuan will recognise revenue in gross amount of consideration received for the sales of envafolimab. The profit-share payments represent the consideration to Alphamab Group for the acquisition of the exclusive rights, which is contingent upon the occurrence of successful commercialization of envafolimab. The profit-share payments will be recognised at the time when 3DMed Sichuan is obligated to pay and recorded as expenses.

As disclosed in note 1(g) to the Accountants' Report set out in Appendix I to this document, 3DMed Sichuan is regarded as a wholly owned subsidiary of our Group because (i) 3DMed Beijing retains 100% voting rights at shareholders' meetings over 3DMed Sichuan; (ii) 3DMed Beijing is entitled to 100% economic interests of 3DMed Sichuan; (iii) 3DMed Beijing is entitled to 100% nomination right of the director(s), supervisor(s) and senior management of 3DMed Sichuan; and (iv) 3DMed Beijing retains 100% operational management rights of 3DMed Sichuan. Hence, the operating results of 3DMed Sichuan are included in our Group's consolidated financial statements. We also have the decision-making power over the amount of profit before tax to be shared between the parties.

Based on the discussion with our management and the facts and circumstances set out by us as above, our Reporting Accountants concur that revenue from the sales of envafolimab in China will be recognised on gross basis and the sharing of profit payable to Alphamab Group is recorded as expenses in our Group's consolidated financial statements.

Furthermore, the profit before tax generated from the sales of envafolimab in China takes into account the marketing service fees payable to Simcere Group. We are responsible for the preparation and audit of the financial statement to derive any such profit before tax.

4. A Specific Arrangement in relation to 3DMed Sichuan

As discussed above, considering previous and existing close and mutual beneficial cooperative business relationship which is critical to our Group as well as Alphamab Group, our Group also voluntarily assists and facilitates Alphamab Group's development of non-oncology indications of envafolimab outside the scope of the Co-Development Agreements. Specifically, in October 2020, we entered into a memorandum of understanding with Alphamab Group setting out the terms of the transfer of 49% equity interest in 3DMed Sichuan (which was previously a wholly-owned subsidiary of our Group) to Alphamab Group at a nominal consideration. Under such memorandum of understanding, the parties agreed to designate 3DMed Sichuan as the entity to apply for envafolimab's MAH (for both oncology and non-oncology indications). Considering that the parties' co-ownership of the Co-Owned Patents under the Co-Development Agreements is limited to oncology or tumor therapy and NMPA had historically not granted separate MAH for different indications with respect to one drug at the time of the memorandum of understanding, the parties agreed that 3DMed Beijing would transfer 49% equity interest in 3DMed Sichuan to Jiangsu Alphamab for the higher of RMB1 or book net asset price as a guarantee for the potential interests of non-oncology indications of envafolimab which is outside the scope of the Co-Developments and not relevant to the Core Product. If Alphamab Group could successfully apply for separate MAHs for envafolimab's non-oncology indications, Jiangsu Alphamab would transfer the 49% equity interest in 3DMed Sichuan back to 3DMed Beijing for the higher of RMB1 or book net asset price. Given that NMPA has granted separate MAHs for a drug's different indications since February 2021, it is reasonably expected that Jiangsu Alphamab will potentially transfer the 49% equity interest in 3DMed Sichuan back to 3DMed Beijing for the higher of RMB1 or book net asset price.

To the best of our Directors' knowledge, Alphamab Group has not made any application for separate MAH for envafolimab's non-oncology indications as Alphamab Group's IND application of such non-oncology indications was submitted in March 2019 and is still undergoing evaluation by the NMPA as of the Latest Practicable Date.

In the worst case, if Alphamab Group could not successfully apply for such separate MAH, we would inject additional capital into 3DMed Sichuan equal to royalties generated from envafolimab's non-oncology indications. The commercial rationale for the transfer is that Alphamab Group has no voting rights or economics consolidation rights over 3DMed Sichuan upon the transfer at the nominal consideration and the parties agreed to the above-mentioned double-trigger mechanism whereby further capital could be injected into 3DMed Sichuan if it also becomes the MAH holder for non-oncology indications.

Collaboration with Alphamab Group and TRACON for Envafolimab

In December 2019, we, Alphamab Group and TRACON entered into a collaboration and clinical trial agreement (the "**3D Alphamab TRACON Agreement**") for the development of envafolimab for the treatment of sarcoma in the U.S., Canada, Mexico and each of their dependent territories (the "**TRACON Territory**"). TRACON is a biopharmaceutical company

in the U.S., an Independent Third Party of our Group. We became acquainted with TRACON when our founder, CEO and Chairman, Dr. Gong, had a meeting in San Francisco with its CEO, Dr. Charles Theuer to discuss potential business collaboration in early 2019. Salient terms of the 3D Alphamab TRACON Agreement are summarized below:

Allocation of Responsibility in General	• The 3D Alphamab TRACON Agreement does not specify the respective roles of us and Alphamab Group with respect to envafolimab's development. The two parties shall jointly bear all costs associated with the conduct of the pre-clinical studies and the preparation of chemical, manufacturing and control sections of an IND application for envafolimab. For details of our effective control of envafolimab, please refer to paragraphs headed "– Collaboration with Alphamab Group for Envafolimab – Effective Control over the Various Key Aspect of Our Core Product" in this section.
Allocation of R&D Responsibility	• Pursuant to the 3D Alphamab TRACON Agreement, TRACON is responsible for conducting and will bear the costs of any Phase I, Phase II, and Phase III or post-approval clinical trial in the TRACON Territory for envafolimab in the indications of refractory and first line treatment of sarcoma. We and Alphamab Group are responsible for conducting and will bear the costs of pre-clinical studies (other than those specific to the sarcoma indication) and the preparation of chemical, manufacturing and controls activities sections of an IND application for envafolimab. We and Alphamab Group have agreed to manufacture and supply, or to arrange for a third party manufacturer to manufacture and supply, envafolimab to TRACON at pre-negotiated prices that vary based on clinical or commercial use.

- In light of the 3D Alphamab TRACON Agreement, our Group and the Alphamab Group jointly take responsibilities for the conduct of the pre-clinical studies and the preparing of chemical, manufacturing and control sections of the IND application as set out in the Co-Development Agreements. Under the Co-Development Agreement, we are responsible for the conduct of the pre-clinical studies, which Alphamab Group is responsible for the preparation of chemical, manufacturing and control sections of the IND application. For details, please refer to the paragraphs headed "– Collaboration Agreements – Collaboration with Alphamab Group for Envafolimab – Effective Control over the Various Key Aspects of Our Core Product" in this section.

- With respect to the R&D roles and responsibilities other than the conduct of the pre-clinical studies and the preparing of chemical, manufacturing and control sections of the IND application, TRACON is fully responsible for conducting and will bear the costs of any Phase I, Phase II, and Phase III or post-approval clinical trial in the TRACON Territory for envafolimab in the indications of refractory and first line treatment of sarcoma.

Commercialization and Distribution of Revenue

- TRACON will be responsible for commercializing envafolimab for sarcoma in the TRACON Territory, including booking of sales revenue, unless (a) envafolimab is first approved in the TRACON Territory for an indication other than sarcoma and launched in the TRACON Territory, or (b) envafolimab is first approved in the TRACON Territory for sarcoma and subsequently approved in the TRACON Territory for an additional non-orphan indication and sold commercially by us and/or Alphamab Group, or licensee, in which case we and Alphamab Group will be responsible for commercializing envafolimab for sarcoma in the TRACON Territory, including booking of sales revenue.

- If TRACON has the responsibility for commercialization under the 3D Alphamab TRACON Agreement, we and Alphamab Group will be entitled to tiered double digit royalties on net sales of envafolimab for sarcoma in the TRACON Territory ranging from 15% to 40% depending on whether TRACON is the major stakeholder in the commercialization of envafolimab for sarcoma in the TRACON Territory. Under the 3D Alphamab TRACON Agreement, "net sales" is defined as the gross amounts received for sales or other dispositions by a party or any of its affiliates or licenses to third parties, less certain deductions actually incurred, allowed, paid, accrued or otherwise reasonably allocated in accordance with GAAP. Such royalties shall be split approximately evenly between us and Alphamab Group after accounting for all relevant costs and expenses. If we and Alphamab Group have responsibility for commercialization under the 3D Alphamab TRACON Agreement, TRACON will be entitled to (a) tiered double digit royalties on net sales of envafolimab for sarcoma in the TRACON Territory ranging from 15% to 40% if TRACON has elected to not co-market envafolimab in sarcoma or (b) a 50% on net sales of envafolimab for sarcoma in the TRACON Territory if TRACON has chosen to co-market envafolimab in sarcoma. Payment obligations under the 3D Alphamab TRACON Agreement continue on a country-by-country basis until the last to expire licensed patent covering envafolimab expires.

Intellectual Property (IP) Arrangements

- Pursuant to the 3D Alphamab TRACON Agreement, TRACON was granted an exclusive and non-transferable license to develop and commercialize envafolimab for the treatment of sarcoma in the TRACON Territory.

- We and Alphamab Group retain the right to develop envafolimab in all territories outside of the TRACON Territory as well as within the TRACON Territory for all indications other than sarcoma.

- According to our legal adviser as to U.S. intellectual property law, the completed Phase I clinical trial in the U.S. did not aim at developing treatment for sarcoma and no sarcoma patients were enrolled based on information provided by us. The clinical trial aimed at evaluating the safety and tolerability of envafolimab in advanced and metastatic solid tumors. Under the 3D Alphamab TRACON Agreement, TRACON was given an exclusive license to develop envafolimab in the U.S. for treating sarcoma. Based on the above, it is reasonably concluded that the completed Phase I clinical trial we conducted in the U.S. is not inconsistent with the scope of the exclusive license granted to TRACON pursuant to the 3D Alphamab TRACON Agreement.

Term and Termination

- The term of the 3D Alphamab TRACON Agreement continues until the later of the date the parties cease further development and commercialization of envafolimab for sarcoma in the TRACON Territory or the expiration of all payment obligations. The 3D Alphamab TRACON Agreement may be terminated earlier by a party in the event of an uncured material breach by the other party or bankruptcy of the other party, or for safety reasons related to envafolimab.

To the best of our Directors' knowledge, there is no relationship between Alphamab Group and TRACON other than the contractual relationship under the 3D Alphamab TRACON Agreement.

Collaboration with Alphamab Group and Simcere Group for Envafolimab

In March 2020, we entered into a tripartite collaboration agreement with Alphamab Group and Simcere Group, together with a separate marketing and promotion agreement with Simcere Group in respect of envafolimab (the "**Promotion Agreement**" and collectively, the "**3D Alphamab Simcere Agreements**"). Simcere Group is a company engaged in the R&D, production and commercialization of pharmaceuticals in China, a shareholder and an Independent Third Party of our Group. We became acquainted with Simcere Group when our founder, CEO and Chairman, Dr. Gong, visted Simcere in Nanjing and met with its founder, Dr. Ren Jinsheng, for business collaborations in 2009. Salient terms of the 3D Alphamab Simcere Agreements are summarized below:

Allocation of Responsibility

- The role of Simcere Group under the 3D Alphamab Simcere Agreements is to prepare a promotion plan and promote envafolimab in China in accordance with industry standards for the purpose of increasing its sales. The 3D Alphamab Simcere Agreements are silent on the role of the "distributors introduced by Simcere Group". Once the distributors are introduced by Simcere Group, we work directly with them by entering into agreements and selling envafolimab.

- Pursuant to the 3D Alphamab Simcere Agreement, Simcere Group is mainly responsible for the preparation of promotion plan and promotion of envafolimab in China in accordance with industry standards for the purpose of increasing product sales, and its function is similar to a CSO with no right to exert any control over envafolimab. To facilitate sales and marketing and in line of with general practice in the industry, Simcere Group is entitled to decide on general matters with respect to the routine and day-to-day marketing of envafolimab in China but is not entitled to make any final decisions on specific matters that affect the commercial success of envafolimab such as its initial pricing and availability to centralized procurement or volume purchase catalogue.

- Furthermore, our wholly owned subsidiary, 3DMed Sichuan, is the sole MAH with respect to envafolimab and bears sole responsibility for the marketing and sales of envafolimab in China. For details, please see the paragraphs headed "– Collaboration Agreements – Collaboration with Alphamab Group for Envafolimab – Effective Control over the Various Key Aspects of Our Core Product" in this section. According to our advisers as to PRC law, subject to the 3D Alphamab Simcere Agreement, we therefore have the final decision-making power with respect to all matters of envafolimab granted to MAH holder under PRC law, including the right to select a CSO when carrying out the marketing and sales of envafolimab in China.

- Simcere Group has agreed to undertake annual minimum promotion requirements starting from the fourth year of our collaboration and will re-negotiate such requirements with us and Alphamab Group upon the expiration of each consecutive four-year period thereafter. The "annual minimum promotion requirements" range from RMB200 million to RMB500 million starting from the fourth year of commercialization.

- The reason why annual minimum promotion requirement is set as "starting from the fourth year" of the collaboration is that new drugs are possible to reach peak sales in the fourth year of commercialization, according to Frost & Sullivan, and the minimum promotion requirements setting a floor not only incentivizes Simcere Group to invest in promotion efforts in the first three years for the purpose of maximizing envafolimab's sales potential but also requires Simcere Group to maintain such promotion efforts till envafolimab reaches its peak sales. For the above reasons, there is no minimum promotion requirement for the initial three-year period.

Commercialization and Distribution of Revenue

- Pursuant to the 3D Alphamab Simcere Agreements, Alphamab Group, as the exclusive manufacturer, will be responsible for supplying envafolimab to us at pre-negotiated prices and we will sell envafolimab to the relevant customers through Simcere Group, while Simcere Group will be entitled to receive the marketing service fees on a monthly basis calculated with reference to the total purchases made by distributors through Simcere Group and based on rates stipulated in the 3D Alphamab Simcere Agreements.

- The "rates" of the marketing service fees specified in the 3D Alphamab Simcere Agreements equal to tiered percentage ranging from 55% to 70% with reference to the gross sales revenue minus product costs.

Intellectual Property (IP) Arrangements	•	Under the 3D Alphamab Simcere Agreements, Simcere Group was granted an exclusive promotion right and the rights of first refusal for in-licenses or transfers of envafolimab in respect of oncology indications in China, subject to the terms and conditions of the 3D Alphamab Simcere Agreements.
Right of First Refusal	•	Simcere Group was granted the rights of first refusal for in-licenses or transfers of envafolimab in respect of oncology indications in China under this collaboration because our management team considered that it is in the best interest of us to grant Simcere Group such right of first refusal for the sake of continuous commercialization of envafolimab, given that Simcere Group's strong sales force in the Chinese pharmaceutical market can generate potential synergies with our business and as our existing shareholder, it has a good understanding of the potentials of envafolimab.
Term and Termination	•	The agreement is silent on its duration and can be terminated by a non-breaching party if a breach has occurred but not resolved by negotiation.

In the view of the PRC Legal Advisers, the involvement of such designated distributors does not violate the Two-Invoice System. We intend to expand hospital coverage and promote our products to a larger group of hospitals in a cost-effective manner through the cooperation with Simcere Group. According to the 3D Alphamab Simcere Agreements, Simcere Group is responsible for the marketing and promotion of envafolimab including connecting and coordinating with various drug distributors or pharmacies scattered in different provinces. Our Company, as the MAH of envafolimab, will enter into distribution agreements with the distributors or pharmacies, including Simcere Group (i.e. the "designated distributors"). Our Company will issue invoice to the "designated distributors" as one invoice and the "designated distributors" will issue invoice to the hospitals and other medical service providers as the other invoice. Simcere Group will charge certain promotion service fees as stipulated in the 3D Alphamab Simcere Agreements. As such, our PRC Legal Advisers are of the view that the involvement of such "designated distributors" is not a violation of the "Two-Invoice System."

To the best of our Directors' knowledge, there is no relationship between Alphamab Group and Simcere Group other than the contractual relationship under the 3D Alphamab Simcere Agreement.

Collaboration with MRKDG for Envafolimab

In February 2022, we and Merck Healthcare KGaA ("**MRKDG**") entered into a clinical trial collaboration and supply agreement (the "**3D MRKDG Agreement**") for conducting a Phase II clinical pilot study in Greater China, in which envafolimab and cetuximab (Erbitux®), a monoclonal antibody targeting epidermal growth factor receptor (EGFR) developed by MRKDG, would be dosed in combination (the "**Study**"). MRKDG is a biopharmaceutical company in Germany, an Independent Third Party of our Group. We became acquainted with MRKDG when our founder, CEO and Chairman, Dr. Gong, was introduced to Zezhi Yuan, the head of the oncology division of MRKDG's China bio-pharmaceutical business in 2021. Salient terms of the 3D MRKDG Agreement are summarized below.

Allocation of Responsibility	• Under the 3D MRKDG Agreement, we shall act as the sponsor of the Study and shall at our own cost, among other things, design, conduct and monitor the Study, supply envafolimab for the Study, secure adherence to relevant regulatory standards and communicate with regulatory authorities, and maintain all related reports and documentation. MRKDG shall, among other things, advise on the design of the Study, and supply cetuximab needed for the Study without reimbursement.
Intellectual Property (IP) Arrangements	• All inventions achieved under the Study or through the clinical data relating solely to envafolimab shall be the sole and exclusive property of us, and those relating to cetuximab shall be the sole and exclusive property of MRKDG. Any other inventions shall belong to us while we grant a perpetual, sublicensable, irrevocable, non-exclusive, worldwide, royalty-free, fully paid-up license to use such inventions to MRKDG.
Clinical Data	• All clinical data generated from the Study shall be solely owned by us while we grant a sublicensable, irrevocable, non-exclusive, worldwide and perpetual right to use the clinical data to MRKDG to obtain and maintain the original label or label changes for cetuximab. • Each party grants to the other party a non-exclusive and non-transferable "right of reference" with respect to the results of the Study.

Dispute Resolution

- Each party shall appoint an alliance manager to resolve deadlocks or disputes. If an issue cannot be resolved by the alliance managers, the issue shall be elevated to our CEO (or his delegate) or the Head of Development of MRKDG (or his or her delegate). If failing to reach agreement, we shall have the right to make a final decision except that MRKDG shall have the final decision-making authority with respect to cetuximab -related safety issues and amount of cetuximab to be delivered.

Term and Termination

- The 3D MRKDG Agreement shall continue until the completion of all obligations of parties or terminated by either party.

- Either party may terminate the 3D MRKDG Agreement in the event of (i) material breach by the other party, (ii) reasonable determination of material adverse patient safety impact, (iii) regulatory requirements, (iv) deviation from market forecast of the clinical trials determined by us, and (v) failure to perform obligations or breach of representations and warranties by the other party.

- MRKDG may terminate the 3D MRKDG Agreement if it reasonably and in good faith believes an imminent danger to patients exists in the Study and we fail to incorporate changes or do not address such issue in good faith upon its written notice.

Collaboration with SELLAS Group for 3D189 and 3D059

In December 2020, we entered into an exclusive license agreement with SELLAS Group (the "**SELLAS Agreement**"). SELLAS is a biopharmaceutical company in the U.S., an Independent Third Party of our Group. Salient terms of the SELLAS Agreement are summarized below:

License

- Under the SELLAS Agreement, SELLAS Group granted us a sublicensable, royalty-bearing license, under certain intellectual property owned or controlled by SELLAS Group, to develop, manufacture and have manufactured, and commercialize galinpepimut-S ("**GPS**" or "**3D189**") and heptavalent GPS ("**GPS+**" or "**3D059**") product candidates (the "**SELLAS Licensed Products**"), for all therapeutic and other diagnostic uses (the "**SELLAS Licensed Field**") in China, Hong Kong, Macau and Taiwan region ("**Greater China**"). MSK licensed certain know-how relating to 3D059 to SELLAS, which in turn sub-licensed the same to us. We are not obligated to pay any fee to SELLAS Group for granting sublicense of 3D059 to third parties. The tiered royalties we pay to SELLAS Group are based upon a percentage of the annual net sales of SELLAS Licensed Products in Greater China by us and any of our sublicenses. The license is exclusive, except with respect to certain know-how that has been non-exclusively licensed to SELLAS Group by MSK and is further sublicensed to us on a non-exclusive basis by SELLAS Group.

- We have the right, but not the obligation, to step-in to cure SELLAS' breach in the event it fails to discharge its payment obligations under its license agreement with MSK. The maximum exposure with respect to the payment obligations include (i) running royalties calculated based on worldwide annual net sales, (ii) guaranteed minimum royalties, (iii) milestone payments upon the achievement of certain R&D milestone events, and (iv) share of any sublicensing incomes.

Allocation of Responsibility	• We are responsible for all costs related to developing, obtaining regulatory approval of and commercializing the SELLAS Licensed Products in the SELLAS Licensed Field in Greater China. We are required to use commercially reasonable best efforts to develop and obtain regulatory approval for, and upon receipt of regulatory approval, commercialize the SELLAS Licensed Products in the SELLAS Licensed Field in Greater China. We and SELLAS Group agreed to negotiate in good faith the terms and conditions of a clinical supply agreement, a commercial supply agreement, and related quality agreements pursuant to which SELLAS Group will manufacture or have manufactured and supply us with all quantities of the SELLAS Licensed Product necessary for us to develop and commercialize the SELLAS Licensed Products in the SELLAS Licensed Field in Greater China until we have received all approvals required for us or our designated contract manufacturing organization to manufacture the SELLAS Licensed Products in Greater China.
Intellectual Property (IP) Arrangements	• SELLAS Group retains development, manufacturing and commercialization rights with respect to the SELLAS Licensed Products in the rest of the world.
Royalties	• We agreed to pay tiered royalties based upon a percentage of annual net sales of SELLAS Licensed Products in Greater China ranging from 7% to 12%. The royalties are payable on a SELLAS Licensed Product-by- SELLAS Licensed Product and region-by-region basis commencing on the first commercial sale of a SELLAS Licensed Product in a region and continuing until the latest of (i) the date that is fifteen years from the receipt of marketing authorization for such SELLAS Licensed Product in such region and (ii) the date that is ten years from the expiration of the last valid claim of a licensed patent covering or claiming such SELLAS Licensed Product in such region (collectively, the "**SELLAS Royalty Term**"). The royalty rate is subject to reduction under certain circumstances, including when generic competition for a SELLAS Licensed Product exists in a particular region.

Milestone Payments

- In partial consideration for the rights granted by SELLAS Group, we agreed to pay to SELLAS Group (i) a one-time upfront cash payment of $7.5 million in order to reimburse SELLAS Group for certain expenses incurred with respect to the development of the SELLAS Licensed Products prior to execution of the SELLAS Agreement, and such payment of $7.5 million has been settled in December 2020, and (ii) milestone payments totaling up to $194.5 million in the aggregate upon the achievement of certain technology transfer, development and regulatory milestones, as well as certain net sales thresholds of SELLAS Licensed Products in Greater China in a given calendar year.

- Under the SELLAS Agreement, milestone payments are triggered by two types of events: (i) development milestone events that mark important progress in the research and development of the SELLAS Licensed Products, and (ii) sales milestone events that mark the product reaching net sales thresholds of the SELLAS Licensed Products in Greater China in a given calendar year ranging from $100 million to $2,000 million.

- Under the SELLAS Agreement, development milestone events include (i) approval of the first IND for a SELLAS Licensed Product in China; (ii) agreement on the final version of a plan detailing the transfer of technology from SELLAS Group to us; (iii) completion of the technology transfer; (iv) initiation of the first Phase II clinical trial in Greater China for a SELLAS Licensed Product; (v) initiation of the first Phase III clinical trial in Greater China for a SELLAS Licensed Product; and (vi) approval of a marketing authorization application for a SELLAS Licensed Product by the NMPA for each of the first indication, second indication, third indication, and fourth indication.

Decision-Making

- Under the SELLAS Agreement, a joint steering committee will be established between us and SELLAS Group to coordinate and review the development, manufacturing and commercialization plans with respect to the SELLAS Licensed Products in Greater China. The joint steering committee is initially composed of four representatives, with each of the parties appointing two representatives, and the joint steering committee may change its size from time to time by mutual consent of the parties.

- In the event of deadlock, if the joint steering committee is unable to resolve the dispute within fifteen days, then either SELLAS Group or us may, by written notice to the other, have such matter referred to the President and CEO of the respective party. If such executive officer also fails to resolve such dispute within fifteen days, and provided that such matter (i) raises bona fide safety, efficacy and technical concerns, (ii) is inconsistent with the global development strategy for the SELLAS Licensed Products, or (iii) reasonably could be expected to have an adverse effect on the development or commercialization of any SELLAS Licensed Product outside Greater China, then mutual agreement by SELLAS Group and us will be required to make such decision. If the dispute does not involve any of the abovementioned matters, we shall have the final decision-making authority.

Term and Termination

- The SELLAS Agreement will expire on a SELLAS Licensed Product-by- SELLAS Licensed Product and region-by-region basis on the date of the expiration of all of our payment obligations to SELLAS Group. Upon expiration of the SELLAS Agreement, the license granted to us will become fully paid-up, perpetual and irrevocable. Either party may terminate the SELLAS Agreement for the other party's material breach following a cure period or upon certain insolvency events. SELLAS Group may terminate the SELLAS Agreement if we or our affiliates or sublicensees challenge the validity or enforceability of the licensed patents or if we fail to timely pay the upfront payment. At any time following the two-year anniversary of the effective date, we have the right to terminate the License Agreement for convenience, provided that such termination is made upon (i) six months prior written notice to SELLAS Group if such notice is provided before the first sale to a third party of SELLAS Licensed Products in the China, Hong Kong, Macau or Taiwan; or (ii) twelve months prior written notice to SELLAS Group if such notice is provided after the first sale to a third party of SELLAS Licensed Products in China, Hong Kong, Macau or Taiwan. We may terminate the SELLAS Agreement upon prior notice to SELLAS Group if the grant of the license to us is prohibited or delayed for a period of time due to a change of U.S. export laws and regulations.

- In the event of termination, depending on the reason for the termination, the consequences could be that (i) all licenses and other rights granted by SELLAS Group to us shall terminate, and all of our rights under the intellectual property with respect to the SELLAS Licensed Products shall revert to SELLAS Group; (ii) we shall cease any and all development, manufacture and commercialization activities relating to the SELLAS Licensed Products; (iii) we shall, at our own cost, wind down any of our ongoing clinical trials of the SELLAS Licensed Products or transfer such clinical trials to SELLAS Group.

Right to Remedies

- MSK has the sole right to prosecute and maintain the patents sublicensed by MSK, while SELLAS has the first right to prosecute and maintain each of the licensed patents by SELLAS other than the patents sublicensed by MSK in relation to the SELLAS Agreement. SELLAS agrees to consult with us with respect to the prosecution and maintenance of the abovementioned patents in Greater China. We have the first right, but not the obligation, to enforce the MSK patents and the other licensed patents in the SELLAS Licensed Field in Greater China. Unless the parties otherwise agree in writing, each party shall have the right to defend itself against a suit that names it as a defendant with respect to the defense of claims brought by third parties.

The SELLAS Agreement includes customary representations and warranties, covenants and indemnification obligations for a transaction of this nature.

Collaboration with Aravive for 3D229

In November 2020, we entered into a collaboration and license agreement (the "**Aravive Sub-Licensing Agreement**") with Aravive, whereby Aravive granted us an exclusive sub-license to develop, manufacture and commercialize products that contain 3D229 as the sole drug substance, for the diagnosis, treatment or prevention of human oncological diseases, in Greater China. Please refer to "Risk Factors – If we are unable to obtain and maintain adequate patent protection for our product and drug candidates throughout the world, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties could develop and commercialize products and technologies similar or identical to ours and compete directly against us, and our ability to successfully commercialize any of our future approved products or technologies would be materially adversely affected." in this document for a description of

relevant risks. Stanford licensed the technology that is used by Aravive to develop 3D229 and Aravive licensed 3D229 to us. Aravive is an oncology company in the U.S., an Independent Third Party of our Group. Salient terms of the Aravive Sub-Licensing Agreement are summarized below:

Allocation of Responsibility	• Under the terms and conditions of the Aravive Sub-Licensing Agreement, we will be solely responsible for the development and commercialization of licensed products in Greater China.
Payments	• Under the terms of the Aravive Sub-Licensing Agreement, Aravive received from us cash payments of $12 million, which we have fully paid in November 2020, and is eligible to up to an aggregate of $207 million in clinical development, regulatory and commercial milestone payments. Under the Aravive Sub-Licensing Agreement, milestone payments are triggered by two types of events: (i) development milestone events that mark important progress in the research and development of 3D229, and (ii) sales milestone events that mark the product reaching specific net sales thresholds of 3D229 in Greater China in a given calendar year. There can be no guarantee that any such milestones will in fact be met. Aravive is obligated to make certain payments to The Board of Trustees of the Leland Stanford Junior University ("**Stanford**") based on certain amounts received from us under the Aravive Sub-Licensing Agreement pursuant to the existing exclusive license agreement by and between the Aravive and Stanford, dated January 25, 2012, and as amended to date (the "**Upstream Agreement**").

- Aravive will also be entitled to receive tiered royalties ranging from 10% to 16% on sales in Greater China, if any, of products containing 3D229. Royalties are payable with respect to each jurisdiction in Greater China until the latest to occur of: (i) the last-to-expire of specified patent rights in such jurisdiction in Greater China; (ii) expiration of marketing or regulatory exclusivity in such jurisdiction in Greater China; or (iii) ten (10) years after the first commercial sale of a product in such jurisdiction in Greater China. In addition, royalties payable under the Aravive Sub-Licensing Agreement will be subject to reduction on account of generic competition under certain specified conditions, with any such reductions capped at certain percentages of the amounts otherwise payable during the applicable royalty payment period.

Representations and Warranties

- Under the Aravive Sub-Licensing Agreement, Aravive represented and warranted that it has sufficient legal and/or eneficial title or ownership or license in relation to 3D229.

- We are not entitled or obligated to step-in to cure Aravive's breach in the event Aravive fails to discharge its payment obligations under the Upstream Agreement. Under the Upstream Agreement, if the Upstream Agreement between Aravive and Stanford is terminated, Aravive is obligated to pay the royalties accrued or accruable, and any claim, accrued or to accrue, because of any breach or default by the other party.

Term and Termination

- If either we or Aravive materially breaches the Aravive Sub-Licensing Agreement and does not cure such breach, the non-breaching party may terminate the Aravive Sub-Licensing Agreement in its entirety. Either party may also terminate the Aravive Sub-Licensing Agreement, upon written notice, if the other party files for bankruptcy, is dissolved or has a receiver appointed for substantially all of its property. Aravive may terminate the Aravive Sub-Licensing Agreement if we, our affiliates or our sublicensees challenges the validity or enforceability of any of Aravive's patents covering any of the licensed compounds or products or ceases substantially all development and commercialization of licensed products in Greater China for a specified period, subject to certain exceptions. We may also terminate the Aravive Sub-Licensing Agreement for convenience provided certain notice is provided to Aravive.

- Under the Aravive Sub-Licensing Agreement, in the event of termination (i) all licenses and other rights granted by Aravive to us would terminate, and all of our rights under the licensed intellectual property in relation to 3D229 shall revert to Aravive; and (ii) we would, at our own cost, wind down any ongoing clinical trials for 3D229 or transfer such clinical trials to Aravive, unless the Aravive Sub-Licensing Agreement is terminated by us due to Aravive's material breach or bankruptcy, at Aravive's reasonable request.

Right to Remedies

- Aravive shall have the sole right to prosecute and maintain the patents sublicensed by Aravive in relation to the Aravive Agreement. Aravive shall have the first right, but not the obligation, to enforce the abovementioned patents, with a right for us to join such enforcement action. With respect to third party infringement claims, the party for which the infringement action is brought against shall have the right to direct and control the defense of such infringement action, provided the other party may participate in the defense and/or settlement.

The Aravive Sub-Licensing Agreement contemplates that Aravive will enter in ancillary arrangements with us, including a clinical supply agreement and a manufacturing technology transfer agreement.

Collaboration with Haihe Biopharma for 3D185

In June 2018 and September 2018 respectively, we entered into two patent license agreements with Haihe Biopharma and SIMM with respect to licenses of two patents in relation to 3D185 (the "**Haihe SIMM Collaboration Agreements**"). Haihe Biopharma is a leading innovation-driven biotechnology company in China and SIMM is a comprehensive research institution for drug discovery in China, each of which is an independent third party of our Group. Haihe Biopharma is a biotechnology company in China, an Independent Third Party of our Group. SIMM is a comprehensive research institution for drug discovery in China, also an Independent Third Party of our Group. Salient terms of the Haihe SIMM Collaboration Agreements are summarized below:

Allocation of Responsibility	• The agreement is silent on the relationship between Haihe and SIMM, and the role of SIMM in this collaboration. SIMM therefore has no specified role in this collaboration. • We have rights to manage the clinical development and commercialization of 3D185 at our own discretion and shall retain intellectual property rights for any improvements we made on the licensed patents. Under the Haihe SIMM Collaboration Agreement, we have to manage the clinical development of 3D185 at our own cost.
Intellectual Property (IP) Arrangements	• Under the Haihe SIMM Collaboration Agreement, Haihe and SIMM jointly own the Chinese patents and international patents for 3D185. • Pursuant to the Haihe SIMM Collaboration Agreements, we were granted exclusive licenses of the patents to develop, manufacture and commercialize 3D185 for oncology and pulmonary fibrosis treatment globally.

Payments	• Pursuant to the Haihe SIMM Collaboration Agreements, we fully paid upfront royalty fees of RMB18.75 million in June 2018 for the license, and are obligated to pay further royalty fees subject to achievements of development milestones. We are also obligated to pay 5% of net sales revenue to Haihe Biopharma and SIMM upon successful commercialization of 3D185, and "net sales" refers to the total amount of sale of 3D185 invoiced by us, any of our affiliates or any sublicensee to any third party, less the customary trade discount, refund, return, credit, tax and the costs for transportation, insurance and courier as shown on the aforementioned invoice.
Term and Termination	• The Haihe SIMM Collaboration Agreements will expire upon the later of (a) the 10-year anniversary of the approval of the first indication of the licensed product, and (b) expiration of the licensed patents. The Haihe SIMM Collaboration Agreements may be terminated by us upon a 60-day advance written notice, and may be terminated by either party in the event of material breach by the other party.
Right to Remedies	• We have a right to prosecute and maintain the relevant patents licensed by Haihe in relation to the Haihe SIMM Collaboration Agreements, with an obligation to notify and consult with Haihe Biopharma. The parties shall consult each other with respect to any infringement of third party patents.

Collaboration with Haihe Biopharma Group for 3D1001 and 3D1002

In October 2020 we entered into two patent license agreements (the "**Haihe License Agreement(s)**") with Haihe Biopharma Group for 3D1001 and 3D1002, respectively. Salient terms of the Haihe License Agreement(s) are summarized below:

Allocation of Responsibility

- Pursuant to the Haihe License Agreements, we and Haihe Biopharma Group will establish a coordination committee for each of the Haihe Licensed Products, comprised of representatives of each party, to promote communication and coordination activities between the parties. The coordination committee will meet at least twice a year to discuss matters related to research and development progress and plan, intellectual property, regulatory approval, product labeling and research data. Under the Haihe License Agreements, the coordination committee shall be composed of representatives of each party. In the event of deadlock, the parties shall resolve such matter by lawsuit.

- Under the Haihe License Agreements, we will undertake pre-clinical and clinical trials related to the Haihe Licensed Products. Moreover, we will be responsible for applying for related clinical trials and becoming the Marketing Authorization Holder, with Haihe Biopharma Group using commercially reasonable efforts in providing assistance. We will solely assume the expenses associated with and have the decision-making authority on clinical development and commercialization of the Haihe Licensed Products. Moreover, we will use reasonable efforts in developing Haihe Licensed Products and formulate reasonable development plan.

- Under the Haihe License Agreement, we are not entitled or obligated to step-in to cure Haihe's breach in the event Haihe fails to discharge its payment obligations under the AskAt Agreements. If Haihe fails to discharge its payment obligations under the AskAt Agreements, there will not be any material adverse impact on the development of 3D1001 and 3D1002 because both drug candidates have been fully transferred to us and our subsequent development will not rely on AskAt.

Intellectual Property (IP) Arrangements

- As between the parties, we will be the sole owner of any patents and intellectual property rights that are developed from our new research, data, information and other related technologies created by us while developing the Haihe Licensed Products. We agree to grant Haihe Biopharma Group a royalty-free, permanent and sublicensable license to use such intellectual properties for all uses outside China. Pursuant to the two license agreements entered into between Haihe Biopharma Group and AskAt (the "**AskAt Agreements**"), we will accordingly be granted a royalty-free and permanent license to use intellectual properties newly created by AskAt on AAT-076 and AAT-007. This is because Haihe was granted a royalty free license to the improvements of AAT-076 and AAt-007 within the territory in the AskAt Agreements. Furthermore, according to the Haihe License Agreements, we have been granted a royalty-free and permanent license to use IPs newly created by AskAt on AAT-076 and AAT-007, and as such, in the view of our PRC Legal Advisers, we can enjoy such new IPs.

- We will also have the initial right to enforce or defend the licensed patents against third parties in the Haihe Licensed Field in China, and Haihe Biopharma Group will use reasonable efforts in providing assistance if we so request. Haihe Biopharma Group will also have the step-in right to enforce or defend the licensed patents against third parties, should we fail to do so, and may require us to use our best efforts in joining such enforcement or defense and providing assistance.

License

- Under the Haihe License Agreement(s), Haihe Biopharma Group granted us an exclusive sub-license under specified patents and relevant know-hows to solely develop, manufacture, use, sell, promise to sell and import 3D1001 (a.k.a RMX1001 and AAT-076) and 3D1002 (a.k.a RMX1002 and AAT-007) (the "**Haihe Licensed Products**"), respectively, for the treatment of human pain (including but not limited to chronic or acute pain caused by tumor or inflammation, but excluding injection with respect to 3D1002) (the "**Haihe Licensed Field**") in China, provided that AskAt Inc. ("**AskAt**"), the licensor that originally granted Haihe Biopharma Group the licenses concerning the Haihe Licensed Products, retained the right to develop, manufacture, use and export the Haihe Licensed Products within China for its export towards outside China. Under the Haihe License Agreements, 3D1001 and 3D1002 are out-licensed by AskAt Inc. to Haihe, who in turn sub-licensed 3D1001 and 3D1002 to us. We are granted a sublicense to solely manufacture 3D1001 and 3D1002 on one hand and a right to import the same products on the other hand since Haihe was granted both rights under its agreement with AskAt Inc and we succeed those rights under the Haihe License Agreements. We have never exercised and do not plan to exercise the right to import 3D1001 and 3D1002.

Payments

- Under the Haihe License Agreements, for each of 3D1001 and 3D1002, Haihe Biopharma Group is eligible to receive an upfront payment of RMB500,000 and will be entitled to milestone payments amounting to US$13.1 million plus RMB30 million, upon the achievement of certain development, regulatory and commercial milestones in respect of each of the Haihe Licensed Products. We confirm that the upfront payment of RMB500,000 for each Haihe License Agreement has been settled in January 2021. In addition, Haihe Biopharma Group will be entitled to royalties based upon a single-digit percentage of net sales in the range of 2% to 8% of each of the Haihe Licensed Products, on the basis of each indication, so long as intellectual rights currently held or to be held by Haihe Biopharma Group and AskAt are able to maintain exclusively with respect to the Haihe Licensed Products. Under the Haihe License Agreement, "net sales" refers to the total amount of sale of 3D1001 and 3D1002 invoiced by us, any of our affiliates or any sublicensee to third party, less the customary trade discount, refund, return, credit and tax.

Term and Termination	• The Haihe License Agreements will be effective so long as we are commercializing the Haihe Licensed Products in China, unless terminated earlier or either of the AskAt Agreements is terminated earlier, in which case the respective Haihe License Agreement is deemed terminated simultaneously. The Haihe License Agreements may be terminated by us without cause by providing prior written notice, or by either party because of the other party's uncured material breach of the agreement or bankruptcy events.
Right to Remedies	• In accordance with the Haihe License Agreements, we will have the management right in the approved patents licensed to us, and will be responsible for all matters related to such patents, including but not limiting to administration, preparation, filing, prosecution, maintenance, defense and execution. • We have a right to prosecute and maintain the relevant patents licensed by Haihe in relation to the Haihe License Agreements, with an obligation to notify and consult with Haihe Biopharma. The parties shall consult each other with respect to any infringement of third party patents.

Collaboration with ImmuneOncia for 3D197

In March 2021, we entered into an exclusive license agreement with ImmuneOncia, pursuant to which we were granted an exclusive license for the development, manufacturing and commercialization of 3D197 (also known as IMC-002) in China, Hong Kong, Macau and Taiwan region in respect of oncology indications (the "**ImmuneOncia Agreement**"). ImmuneOncia is an immuno-oncology-centric biopharmaceutical company in South Korea, an Independent Third Party of our Group. Salient terms of the ImmuneOncia Agreement are summarized below:

Payments

- Under the ImmuneOncia Agreement, we shall make to ImmuneOncia an upfront payment of US$8.0 million and, we have paid US$5.0 million in April 2021, and US$1.0 million in July 2021. For the remaining US$2.0 million, we will pay US$1.0 million upon each of the following events: (i) completion of transfer of all the IND submission dossier, data and materials, and approval of the first IND of 3D197 by NMPA; and (ii) completion of the technology transfer pursuant to the technology transfer plan. In addition, ImmuneOncia will be eligible to receive up to US$462.5 million upon the achievement of all future development and commercial milestones, plus tiered royalties up to 10% on annual net sales of 3D197 in China, Hong Kong, Macau and Taiwan region.

- Under the ImmuneOncia Agreement, the 10% royalty rate will be adopted to calculate the royalty payments for the portion of annual net sale of 3D197 in China, Hong Kong, Macau and Taiwan region greater than US$1 billion. "Net sales" means the gross amount received by us, any of our affiliates or any sublicensee for sale of 3D197 to independent third parties less the amounts to the extent actually incurred or paid by the selling party with respect to the sale of 3D197, as determined in accordance with IFRS.

- Under the ImmuneOncia Agreement, milestone payments are made upon two types of events: (i) development milestone events that mark important progress in the research and development of the 3D197, and (ii) sales milestone events that mark the product reaching net sales thresholds of 3D197 in Greater China in a given calendar year ranging from $100 million to $5 billion.

- Development milestone events include (i) initiation of the first Phase Ib clinical trial of 3D197; (ii) initiation of the first Phase II clinical trial or the first pivotal trial of 3D197, whichever occurs first; and (iii) issuance of market authorization application approval of 3D197 in Greater China by the corresponding regulatory authority for each of the first indication, second indication, third indication, and fourth indication."

Term and Termination

- The ImmuneOncia Agreement will remain in effect until the later of (a) 15 years from the first commercial sale of 3D197, (b) 10 years from the expiration of last-to-expire claim of any related patent of ImmuneOncia, and (c) expiration of all applicable regulatory exclusivity period with respect to 3D197. The ImmuneOncia Agreement may be terminated by us upon a 30-day advance written notice, or by ImmuneOncia if we file any patent challenge proceeding against ImmuneOncia. The ImmuneOncia Agreement may also be terminated by either party in the event of the material breach by or insolvency of the other party.

- Under the ImmuneOncia Agreement, in the event of termination, the consequences could be that (i) the license granted by ImmuneOncia to us would terminate; and (ii) we would terminate our ongoing clinical trial for 3D197 or, if ImmuneOncia agrees, transfer such clinical trial to ImmuneOncia.

- Under the ImmuneOncia Agreement, after the expiration of the royalty term for 3D197 in a particular region among China, Hong Kong, Macau and Taiwan region, the licenses granted by ImmuneOncia to us shall continue and shall become non-exclusive, fully paid, royalty free, perpetual and irrevocable in such region.

Right to Remedies	• ImmuneOncia shall have the first right to prosecute and maintain all patents licensed by ImmuneOncia in relation to the ImmuneOncia Agreement, with an obligation to consult with and keep us reasonably informed of the status of the abovementioned patents in Greater China. Unless otherwise agreed by the parties, ImmuneOncia shall have the first right, but not the obligation, to enforce the abovementioned patents, and we have the right to be represented in such action by counsel of our choice at our own expense. The parties shall cooperate with each other in any defense of third party infringement claims by entering into a "common interest agreement" wherein the parties agree to their shared, mutual interest in the outcome of such potential dispute.

Collaboration with Y-Biologics for 3D057

In December 30, 2020, we entered into a license agreement with Y-Biologics with respect to license of 3D057 (also known as YBL-013), a T cell bi-specific engager, pursuant to which we will obtain the exclusive right to develop, manufacture and commercialize 3D057 in therapeutic, palliative, prophylactic and diagnostic applications for all therapeutic areas (the "**Y-Biologics Field**") based on Y-Biologics' Antibody Like Cell Engager (ALiCE) platform technology in China, Hong Kong, Macau and Taiwan region (the "**Y-Biologics Agreement**"). Y-Biologics is a biotech company focusing on the discovery and development of novel antibody therapeutics in South Korea, an Independent Third Party of our Group. Salient terms of the Y-Biologics Agreement are summarized below:

Allocation of Responsibility	• Under the Y-Biologics Agreement, Y-Biologics will bear 50% of the 3D057 IND development costs, and we expect the total CMC costs to be borne by Y-Biologics not to exceed US$4 million.
Intellectual Property (IP) Arrangements	• Y-Biologics shall own the residual intellectual property right in respect of 3D057 arising from the co-development in the ROW Territory and the U.S.

License	• Under the Y-Biologics Agreement, we will obtain the exclusive right to develop, manufacture, and commercialize 3D057 in China, Hong Kong, Macau and Taiwan region for all therapeutic areas and will co-develop 3D057 with Y-Biologic in other regions in the world (excluding China, Hong Kong, Macau, Taiwan region, and Korea). Y-Biologics retains the exclusive right to develop, manufacture and commercialize 3D057 in Korea.
Dispute Resolution	• The dispute resolution authority for the co-development arrangement in other regions in the world is the joint development committee ("**JDC**"), each party is entitled to designate up to three members. If the JDC cannot resolve a matter presented to it despite reasonable discussion, such matter may be escalated by a party to the parties' respective senior management for solution.
	• Under the Y Biologics Agreement, in the event that a matter could not be resolved after escalation to the parties' respective senior management, the matter would be submitted for binding arbitration by the Singapore International Arbitration Centre.
Right of First Refusal	• Under the Y-Biologics Agreement, Y-Biologics has the sole discretion to conduct development and commercialization of 3D057 in all territories of the world other than Greater China, South Korea and the U.S. ("**ROW Territory**"), and if Y-Biologics contemplates to grant a license to a third party to conduct development or commercialization of 3D057 in a country in the ROW Territory, we shall have the right of first refusal.

- If Y-Biologics chooses to pursue the development of 3D057 in the U.S., Y-Biologics shall first approach us with an offer to assist in conducting such development activities. If we and Y-Biologics agree that we shall assist in such development activities, such assistance shall be performed in the name and under the direction of Y-Biologics, and we shall cover all costs and expenses for the co-development in the U.S. We are entitled to tiered percentages, ranging from single digit to twenty, of the Y-Biologics's licensing revenue arising from licensing 3D057 to a third party in the ROW Territory and the U.S. depending on whether we assist in the IND filing or the Phase I clinical trials.

- If we inform Y-Biologics that we are not interested in or we and Y-biologics do not agree on our assistance in the U.S., Y-Biologics has the right to pursue the IND filing and Phase I clinical trials of 3D057 in the U.S. without us. In either case, we shall grant Y-Biologics a perpetual, irrevocable, royalty-bearing, sublicensable and exclusive license to use any intellectual property arising from our development on 3D057 in Greater China for the IND filing and Phase I clinical trials of 3D057 in the U.S. or the ROW Territory accordingly.

Payments

- In addition, Y-Biologics is eligible to receive an upfront payment of US$2 million which we have fully paid in March 2021, and will be eligible to receive up to an additional US$83 million for additional development, regulatory, commercialization and sales milestone payments, and up to 14% royalties on net sales of 3D057 in the authorization regions. Under the Y-Biologics Agreement, milestone payments are made upon two types of milestone events: (i) development and regulatory milestone events that mark important progress in the research and development of the 3D057, and (ii) sales milestone events that mark the product reaching net sales thresholds of 3D057 in Greater China in a given calendar year ranging from $500 million to $1 billion.

- In relation to development and regulatory milestone events, we should make milestone payments upon (i) the start of Phase II clinical trial after regulatory authority's approval; (ii) the start of Phase III clinical trial after regulatory authority's approval; (iii) the NDA approval by NMPA of the first indication of 3D057 in the Y-Biologics Field in Greater China; (iv) additional approval by NMPA of each of the second, third and fourth indication of 3D057 in the Y-Biologics Field in Greater China; and (v) additional approval by NMPA of the fifth or more indications of Licensed Product in the Field in the Territory.

- Under the Y-Biologics Agreement, "net sales" shall mean the gross amount received for sales or other dispositions of 3D057 by us or any of our affiliates or any sublicensee to third parties, less deductions actually incurred, allowed, paid, accrued or otherwise reasonably allocated to 3D057 by the selling party in accordance with IFRS.

Term and Termination

- The Y-Biologics Agreement will remain in effect until the later of (a) 15 years after the first commercial sale by us of 3D057 in the Y-Biologics Field, and (b) 10 years from the expiration of all applicable patents of 3D057 in the Y-Biologics Field, unless prematurely terminated by us or Y-Biologics. The Y-Biologics Agreement may be terminated by either party in the event of material breach by or bankruptcy of the other party. The Y-Biologics Agreement may also be terminated by Y-Biologics if we file any patent action or proceeding against Y-Biologics.

- Under the Y-Biologics Agreement, in the event of termination, the consequences could be that (i) the license granted by the Y-Biologics to us would terminate and revert to Y-Biologics; (ii) unless our activities, rights and benefits under the Y-Biologics Agreement have been adversely affected by Y-Biologics's breach, we would still pay the 50% development costs, upfront payment, milestone payments and royalty payments; and (iii) we would terminate the ongoing clinical trial of 3D057 or transfer such clinical trial to Y-Biologics or its designee.

- Under the Y-Biologics Agreement, upon expiration of the agreement, we will not be granted a perpetual license in respect of 3D057 in the licensed regions as the license granted by the Y-Biologics to us would terminate and revert to Y-Biologics.

Right to Remedies

- Y-Biologics shall be responsible for, and shall have the sole right to prosecute and maintain the relevant patents licensed by Y-Biologics in relation to the Y-Biologics Agreement. We shall have the right to defend the abovementioned patents solely to the extent related to the such patents shall be creditable against the royalties otherwise payable by us to YBiologics, provided that such defence has been approved by Y-Biologics. The parties shall confer in good faith regarding strategy for abating any third party infringement claims, with us having the first right to bring an action for the infringement in Greater China.

Other than as stated above, we confirm that, during the Track Record Period, there is no any other relationship or arrangement (express or implied, formal or informal) with each of Alphamab Group, TRACON, Simcere Group, SELLAS Group, Aravive, Haihe Biopharma, SIMM, ImmuneOncia and Y-Biologics.

Collaboration with CROs

In line with industry practice, we collaborate with contract research organizations (CROs) that manage, conduct and support our clinical trials in China, the U.S. and other jurisdictions. We selected our CROs taking into consideration various factors, such as their qualifications, academic and professional experience, industry reputation and service fees. Except for Simcere, none of our Directors and, to the best knowledge of our Directors, none of our Shareholders who owns more than 5.0% of the Shares in issue, nor any of their respective associates, had any interest in any of our CROs during the Track Record Period.

The CROs provide us with an array of products and services necessary for complex clinical trials. In addition to the scope, depth and quality of their service and product offerings, we place a high value on our CROs' ability to facilitate optimal site selection, timely patient recruitment and efficient conduct of complex clinical trials with high-quality standards. CROs generally provide a comprehensive suite of services to assist us in the implementation and management of clinical trials, including trial preparation, day-to-day site management, clinical safety management, data management, and report preparation.

Generally, we enter into a master service agreement with a CRO under which we execute a separate work order for each clinical research project, or we enter into a research and development contract with a CRO for an individual project. We closely supervise these

third-party service providers to ensure that they perform their duties in a manner that complies with our protocols and applicable laws and regulations, and that protects the integrity of the data resulting from our trials. Below is a summary of the key terms of an agreement that we typically enter into with a CRO:

- **Services**. The CRO provides us with services such as the implementation of a clinical research project as specified in the master agreement or a work order.

- **Term**. The CRO is required to perform its services according to the prescribed timeframe set out in the master agreement or a work order.

- **Payment**. We are required to make payments to the CRO in accordance with the payment schedule agreed by the parties.

- **Confidentiality**. We and the CRO both agree to keep confidential any information in relation to the performance of the master agreement.

- **Intellectual Property**. We own all intellectual property derived from the clinical research project, and we are entitled to apply patent for such intellectual properties.

- **Termination**. Either party is entitled to terminate the agreement in case of a material breach of the other party.

We believe our ability to conduct, and to work closely with CROs to conduct multi-center and high-quality clinical trials enable us to shorten the time required for drug development by generating the requisite data reliably and efficiently.

COMMERCIALIZATION

Our Commercialization Force

We have been establishing our sales and marketing department dedicated to the commercialization of our pipeline products. Since we already received BLA approval for envafolimab for the treatment of previously treated MSI-H/dMMR advanced solid tumors on November 24, 2021, we have been building our qualified and capable sales and marketing department with rich experience in the commercialization of oncology treatment, and to be mainly responsible for product positioning, market strategy, promotional activity planning and patient assistance. As of the Latest Practicable Date, the leadership team of sales and marketing department was in place.

Medical-Driven Marketing

Leveraging the expertise and industry connections of our team, we plan to market our products 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 products. Such marketing efforts have commenced several months before the approval for the commercialization of our product. In preparation for the sales of our future approved products, we are identifying a number of hospitals, clinics and physicians specialized in oncology treatment, and to visit the sites and physicians in person for pre-launch training and liaison. We are also marketing our products directly through introduction of physicians. Through the physician-targeted marketing strategy and utilizing our onsite efforts, we are seeking to get envafolimab marketed to hospitals in major cities in China and constantly improving the commercialization channels to increase the market share of envafolimab.

We plan to sponsor numerous investigator-led clinical trials to generate local clinical data and accumulate relevant clinical experience. With the focus on treating and managing cancer as a chronic disease, we plan to boost the efficiency of promoting envafolimab through academic-oriented marketing channels. We believe that these academic-oriented marketing efforts will be beneficial for improving alignment of expert opinions on, and promoting clinical use of, our product and drug candidates. We will also support leading experts to report the results of their researches at international and domestic conventions, symposia and other notable events to promote our brand at the forefront of the industry and to enhance the opportunities for envafolimab to be included in the relevant clinical guidelines of cancer diagnosis and treatment published by competent research societies. We believe the academic promotional efforts will help convey the advantages of envafolimab over other drug candidates to clinical experts, and lead them to apply envafolimab in the treatment of their patients in a safe and effective manner. Through academic marketing, we aim to educate future leading experts who may engage in determining the NRDL or provincial or local medical insurance catalogues for the National Medical Insurance Program, so as for envafolimab to seek entrance to the NRDL and other relevant catalogues. Moreover, we will actively organize academic conferences and seminars to publicize the clinical data and research results in relation of our product and drug candidates in order to raise our brand awareness and recognition. We expect that we will hold more than 1,000 academic conferences and seminars in 2022 in major cities in China. By hosting seminars and training sessions, presenting exhibitions and sharing our clinical results during such conferences, we are able to enhance physicians' awareness of our products.

Our Sales Operations

We provide our envafolimab to end-users through our collaborations with Simcere Group, and through distributors. We have established a robust sales and distribution network, covering 910 hospitals and 1,562 pharmacies across 201 cities and 30 provinces in China as of the Latest Practicable Date.

The following table sets forth a breakdown of our revenue generated from sales through our collaborations with Simcere Group and through distributors:

	Year Ended December 31, 2021		Five Months Ended May 31, 2022	
	RMB	*%*	*RMB*	*%*
	(in thousands, except for percentages)			
Sales through our collaborations with Simcere Group	60,260	100.0	159,634	99.1
Sales through distributors	–	–	1,428	0.9
Total	60,260	100.0	161,062	100.0

Sales through our collaborations with Simcere Group

As we commercially launched envafolimab in China only after we received BLA approval for envafolimab for the treatment of previously treated MSI-H/dMMR advanced solid tumors in November 2021, we primarily cooperated with Simcere Group with respect to the sales of envafolimab during the Track Record Period and up to the Latest Practicable Date.

We collaborate with Simcere Group in connection with the promotion of envafolimab. In March 2020, we entered into the Promotion Agreement with Simcere Group, together with a tripartite collaboration agreement with Alphamab Group and Simcere Group. Pursuant to the Promotion Agreement, we will sell envafolimab to the relevant customers through Simcere Group, while Simcere Group will be entitled to receive the marketing service fees on a monthly basis calculated with reference to the total purchases made by pharmacy stores and distributors through Simcere Group and based on rates stipulated in the Promotion Agreement. Simcere Group has agreed to undertake annual minimum promotion requirements starting from the fourth year of our collaboration and will re-negotiate such requirements with us and Alphamab Group upon the expiration of each consecutive four-year period thereafter. Please refer to the paragraph headed "Our Research and Development – Collaboration Agreements – Collaboration with Alphamab Group and Simcere Group for Envafolimab" for more details.

In November 2021, we entered into an agreement, as supplemented, with Simcere Group, to further agree on certain matters in connection with the promotion of envafolimab, pursuant to which, Simcere Group, as our business partner, agrees to provide various supports in relation to the sales of envafolimab. As of the Latest Practicable Date, we had just started the commercialization of envafolimab, and we had marketed envafolimab during the Track Record Period to our customers, i.e. pharmacy stores, primarily through our cooperation with Simcere Group.

The price of envafolimab sold by us to pharmacy stores are within a range determined by us after taking into account factors such as our products' costs, prices of competing products, and our target patients' receptiveness to the products, as well as changes in market conditions and the regulatory environment. We also determine the suggested retail prices at which our products are sold by the pharmacy stores to patients. For details, please refer to the paragraph headed "Our Research and Development – Collaboration Agreements – Collaboration with Alphamab Group and Simcere Group for Envafolimab".

We do not enter into long term agreement with pharmacy stores introduced by Simcere Group. The pharmacy stores generally placed orders through Simcere Group. We engage Simcere Group to assist the delivery of our products to the pharmacy stores through qualified vendor, while we, as the owner of the products, bear transportation costs for the delivery. The title and risk of loss for the products transfer from us to the pharmacy stores once the products arrive at the pharmacy stores.

We recognize revenue when the pharmacy stores and distributors receive our products and we grant a collection period of 70 days to Simcere Group who assists us with collecting payment from pharmacy stores and distributors. Our customers generally cannot return products unless that the products have quality defects. During the Track Record Period and up to the Latest Practicable Date, we had not experienced any material customer complaint, disputes or product returns.

Sales through distributors

In addition, we cooperated with distributors who purchase envafolimab from us and resell to their customers, such as certain hospitals and pharmacies, during the Track Record Period and up to the Latest Practicable Date. Our distributors primarily engage in the pharmaceutical drugs distribution business whom we believe have the required qualifications and capabilities and are suited to our strategic marketing model. We have established and maintained resource sharing with our distributors to effectively execute our marketing strategies specifically tailored to each designated geographic location. We believe that our existing distributorship model is consistent with customary industry practice and serves to ensure efficient coverage of our sales network while controlling our cost of distribution.

Upon selecting distributors, we will first evaluate their qualifications. We select our distributors based on their experience in the pharmaceutical industry, particularly in anti-tumor drugs. In addition, they must possess the requisite business licenses and permits to sell drugs in the respective jurisdiction and have established relationships with hospitals, pharmacies and physicians within their designated territory. Before we appoint a distributor, we assess its average annual sales volume, ability to repay its business partners and past incidents of overdue payment, if any, its acceptable payment terms, and its sales staff and management to help ensure that they have the appropriate educational background and professional skills. We may also consult with hospitals or pharmacies regarding our choice of distributors. We perform

annual qualifications of our distributors. During the Track Record Period, none of our distributors had any past or present relationship (business or otherwise) with our Group, our Shareholders, Directors, supervisors, senior management or any of their respective associates.

Rights and obligations relating to the sales of our products

Our agreements with distributors typically include terms such as the term, designated distribution area, rebates, payment and credit terms. The typical principal terms are summarized below.

Duration and option to renew	• The distribution agreements typically have a term of one year and may be renewed upon mutual consent.
Designated geographical regions	• The geographical regions for which a distributor is responsible are designated. Generally, a distributor is prohibited from selling our products outside its designated geographical regions.
Target order amount	• We generally do not set a formal arrangement with our distributors for target order amount. Nevertheless, both us and the distributors agree to commit adequate internal resources to reach a target as discussed by the parties from time to time depending on market conditions.
Payment and credit terms	• We have granted credit terms to some distributors, typically up to 45 to 60 days, and in no event more than 90 days.
Termination	• Both us and our distributors are entitled to terminate the agreement after 30 days of notification of non-fulfillment of the agreement by the other party, bankruptcy and liquidation of the other party, or in the event of *force majeure*, that the other party could not perform its obligations after 90 days.

We conduct annual review of our distributors, based on their business performance and regulatory compliance. Our distributors are generally required to comply with all applicable laws and regulations, such as anti-bribery and anti-kickback laws and regulations, and obtain relevant permits to sell and distribute pharmaceutical products. Distributors' business performance is primarily evaluated based on the distributors' sales performance, breach of payment and credit terms, if any, and feedbacks from the designated hospitals and pharmacies. We also review their compliance with applicable laws and regulations. Our sales and marketing team monitors, manages and supports the activities of our distributors to help ensure that they comply with our guidelines, policies and procedures. We generally do not grant any kinds of cash rebates to our distributors. We may grant different incentive and discount to our distributors on a case by case basis, such as giving discounts to our distributors for products they procured from us if they have, among other things, neither sold our products outside their designated geographical regions, nor made any late payments exceeding the credit terms as agreed. We retain the discretion to adjust their credit terms, renegotiate order price and certain other commercial terms with them based on the review results.

During the Track Record Period, we had maintained effective management and control over our distributors. We regularly communicate and conduct review with our distributors primarily regarding their inventory level, sales amount and marketing activities, as applicable. During the Track Record Period, our distributors did not materially breach our contract terms, and we did not have any disputes with our distributors relating to the settlement of trade receivables. As of the Latest Practicable Date, we were not aware of any potential abuse or improper use of our name by our distributors which could adversely affect our reputation, business operation or financial contribution.

Relationship with distributors

As we had just started the commercialization of envafolimab in December 2021, we began evaluating distributors and entered into agreement with the first distributor in January 2022. As of the Latest Practicable Date, we had signed agreements with a total of 27 distributors. The following table sets forth the changes in the number of our distributors for the periods indicated:

	For the Period From January 1, 2022 to the Latest Practicable Date
As of the beginning of the period	–
Additions of new distributors	27
Termination of existing distributors	–
Net increase (decrease) in distributors	27
As of the end of period	27

Return and Exchanges

Once arrived at the destined place, the distributors shall bear all risks associated with the products. In general, We do not allow distributors to return any unsold products unless there are quality defects. In addition, given the unit price of our envafolimab is considerably high and it imposes strict temperature requirements for storage, our distributors only purchase from us the products they expect to sell to hospitals and pharmacies.

We may consider to allow return or exchange for defective products as ascertained by us, or for a batch of products with short in amount shipped to our distributors, accompanied with valid proof, as assessed on a case-by-case basis. During the Track Record Period and up to the Latest Practicable Date, we had not experienced any material product return from customers, which amounted to less than five units in total.

Pricing

As of the Latest Practicable Date, there was no tender or bidding process or guidance price set by relevant PRC government authorities on our products. For both our sales through our collaborations with Simcere Group and through distributors, we negotiate the price with them on a case-by-case basis. They then sell to hospitals and pharmacies based on suggested prices as mutually agreed with us.

Inventory Management

During the Track Record Period, our inventories consisted of finished products only. We regularly monitor our inventories to reduce the risk of overstocking. Our Core Product envafolimab generally have a shelf life of 18 months. We communicate frequently with Simcere Group and check with our distributors both quarterly and annually to understand the feedback from customers and anticipate their needs. We require Simcere Group and our distributors to provide to us details of the sales volume to customers to assess actual market demand for our products. Our Directors confirm that 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.

During the Track Record Period, We temporarily store all our inventories in Simcere Group's warehouse. As of December 31, 2020, December 31, 2021 and May 31, 2022, we had inventories of nil, RMB13,000 and RMB1.5 million, respectively.

PRODUCTION AND QUALITY CONTROL

Manufacturing

During the Track Record Period and as of the Latest Practicable Date, Alphamab Group manufactured and supplied envafolimab to us pursuant to our collaboration with Alphamab Group. For details of the arrangements with Alphamab Group in connection with the

manufacturing of envafolimab, please refer to the paragraph headed "Our Research and Development – Collaboration Agreements – Collaboration with Alphamab Group for Envafolimab". In addition, we have been establishing our in-house manufacturing capability in Xuzhou, Jiangsu Province and work with qualified CMOs to manufacture and test drug candidates for pre-clinical and clinical supply. In the near future, we plan to continue outsourcing the manufacturing of our product and drug candidates, including commercial-scale manufacturing of our approved drugs, to qualified CMOs/CDMOs. We have adopted, and will continue to implement, robust procedures to ensure that the production qualifications, facilities and processes of our CMOs/CDMOs comply with the applicable regulatory requirements and our internal guidelines and quality standards. We may also engage additional qualified CMOs/CDMOs in the future to ensure that we will have sufficient supply of drug candidates for our clinical trials as well as for the commercial sales of our approved drugs. When selecting CMOs/CDMOs, we will focus on their qualifications, relevant expertise, production capacity, reputation, track record, product quality and production cost.

Quality Assurance and Control

Our quality assurance (QA) and quality control (QC) function oversees the quality of our drug candidates and clinical study management, as well as the quality systems in research and development, manufacturing and commercialization of drug candidates and potential future commercial products. As of the Latest Practicable Date, our QA and QC team had 14 employees. The major responsibilities for our QA and QC function include the following: (i) establishing and maintaining a quality assurance system across the entire business, including document control and quality control evaluations; (ii) qualification of vendors and monitoring the product manufacturing process conducted by CMOs and the execution of clinical studies by the CRO; and (iii) validation of facilities and equipment, which includes laboratory tests to verify that a particular process, method, program, equipment or material works properly.

In-house Production Facilities and Future Expansions

We have been building for our in-house production facilities in Xuzhou, Jiangsu province, with GMP-compliant manufacturing system and facilities throughout the drug development process, including chemical drugs and biologics, to meet stringent standards. In anticipation of large needs of our drugs upon commercialization, we purchased the use right to land in Xuzhou with an aggregate area of 65,637.97 square meters. We have obtained the construction permit and started construction of new manufacturing facilities in Xuzhou. We expect to complete building the facilities and commence operation by 2024. As of the Latest Practicable Date, our manufacturing facilities in Xuzhou did not have production capacity as we are still in the process of construction. We expect that their total production capacity will reach 6,000 L (3x2,000 L) by 2024 and we also plan to further expand the production capacity in the later stage, which will be sufficient to meet commercial manufacturing needs of all our pipeline products in the foreseeable future.

CUSTOMERS

We commercially launched envafolimab in China only after we received BLA approval for envafolimab for the treatment of previously treated MSI-H/dMMR advanced solid tumors in November 2021, and started to generate revenue from the sales of envafolimab to pharmacy stores, which we consider as our customers. As of the Latest Practicable Date, our customers covered 30 provinces and municipalities in China.

As of the Latest Practicable Date, we had just started the commercialization of envafolimab, and we had marketed envafolimab during the Track Record Period to our customers through our cooperation with Simcere Group, and through our distributors. For details of the arrangements with Simcere Group in connection with the commercialization of envafolimab, please refer to the paragraph headed "Commercialization – Our Sales Operations. Our five largest customers in 2021 and for the five months ended May 31, 2022, are China-based pharmaceutical companies. The revenue generated from our five largest customers in 2021 and for the five months ended May 31, 2022, was RMB14.6 million and RMB44.0 million, respectively, which accounted for 24.2% and 27.3% of our total revenue in 2021 and for the five months ended May 31, 2022, respectively. The revenue generated from our largest customer in 2021 and for the five months ended May 31, 2022, was RMB3.9 million and RMB13.7 million, respectively, which accounted for 6.4% and 8.5% of our total revenue in the same periods.

To the best knowledge of our Directors, each of our five largest customers in 2021 and for the five months ended May 31, 2022, is an Independent Third Party. None of our Directors and, to the best knowledge of our Directors, none of our Shareholders who owns more than 5.0% of the Shares in issue, nor any of their respective associates, had any interest in any of our five largest customers in 2021 and for the five months ended May 31, 2022.

Customer	Length of relationship (since)	Customer background and principal business	Products sold	Credit term granted	Sale amount	Percentage of total sale
			For the five months ended May 31, 2022			
			(RMB in thousands, except percentages)			
Customer A	2021	A China-based pharmaceutical company engaged in the sales of drugs	Envofalimab	60 days	13,729.7	8.5%
Customer B	2021	A China-based pharmaceutical company engaged in the sales of drugs	Envofalimab	45 days	11,380.0	7.1%
Customer C	2021	A China-based pharmaceutical company engaged in the sales of drugs	Envofalimab	60 days	7,315.7	4.5%
Customer D	2021	A China-based pharmaceutical company engaged in the sales of drugs	Envofalimab	60 days	5,823.4	3.6%
Customer E	2021	A China-based pharmaceutical company engaged in the sales of drugs	Envofalimab	no credit term	5,791.6	3.6%
Total					**44,040.4**	**27.3%**

Customer	Length of relationship (since)	Customer background and principal business	Products sold	Credit term granted	Sale amount	Percentage of total sale
			For the year ended December 31, 2021			
			(RMB in thousands, except percentages)			
Customer B	2021	A China-based pharmaceutical company engaged in the sales of drugs	Envofalimab	45 days	3,861.10	6.4%
Customer F	2021	A China-based pharmaceutical company engaged in the sales of drugs	Envofalimab	30 days	2,845.00	4.7%
Customer G	2021	A China-based pharmaceutical company engaged in the sales of drugs	Envofalimab	45 days	2,641.80	4.4%
Customer H	2021	A China-based pharmaceutical company engaged in the sales of drugs	Envofalimab	60 days	2,641.80	4.4%
Customer A	2021	A China-based pharmaceutical company engaged in the sales of drugs	Envofalimab	60 days	2,586.70	4.3%
Total					**14,576.40**	**24.2%**

RAW MATERIALS AND SUPPLIERS

During the Track Record Period, we primarily procured raw materials and equipment for the development and manufacture of product and our drug candidates from manufacturers and suppliers around the world. Our purchases mainly include third-party contracting services for research and development of our product and drug candidates and manufacturing of certain drug substances for clinical supply, as well as raw materials, consumables, machines and equipment. We also engage qualified CROs and CMOs to support our internal team in managing and conducting pre-clinical and clinical studies and of our pipeline candidates, as well as the manufacturing activities. During the Track Record Period, our purchases from our five largest suppliers in the aggregate in each year/period accounted for 78.5%, 49.6% and 75.4% of our total purchases (including value added tax), respectively.

To the best of our knowledge, each of our five largest suppliers in each year/period during the Track Record Period is an Independent Third Party. Except for Simcere, none of our Directors and, to the best knowledge of our Directors, none of our Shareholders who owns more than 5.0% of the Shares in issue, nor any of their respective associates, had any interest in any of our five largest suppliers in each year/period during the Track Record Period.

During the Track Record Period, we did not experience any significant fluctuations in raw material prices or delays that had a material impact on our results of operations or financial position. The raw materials for our product and drug candidates to be used in clinical trials as well as materials for our laboratory use are generally readily available in the market through many suppliers. We believe we have alternative sources of suppliers who that can provide us with substitutes with comparable quality and prices. Other than the agreements with certain CROs, we order supplies and services on a purchase order basis and do not enter into long-term dedicated capacity or minimum purchase arrangements. We generally have credit periods of 30 to 60 days and make payments through bank remittance.

The tables below set forth certain information about our five largest suppliers in each year/period during the Track Record Period in terms of purchase amount (in descending order) generated in the same year:

Supplier	Length of relationship (since)	Supplier background and principal business	Services/ Goods sourced	Credit term granted	Purchase amount	Percentage of total purchase
			For the five months ended May 31, 2022 *(RMB in thousands, except percentages)*			
Supplier M	2021	A China-based pharmaceutical company engaged in wholesales of drugs	clinical R&D service, sales and promotion service, channel and delivery service	25 days	97,417.4	40.2%
Supplier N	2021	A China-based company engaged in construction service	construction service (for Xuzhou facility)	7 days	40,809.3	16.8%
Supplier O	2016	A China-based biopharmaceutical company engaged in discovery, development, manufacturing and commercialization of biotherapeutics for cancer treatment	drug manufacture service	no credit term	28,093.4	11.6%
Supplier B	2021	A South Korea-based biopharmaceutical company engaged in drug development and antibody engineering	In-license of drug candidate	30 days	9,605.4	3.9%
Supplier C	2020	A U.S.-based pharmaceutical company engaged in novel cancer immunotherapeutics for a broad range of cancer indications	In-license of drug candidate	30 days	7,015.9	2.9%
Total					**182,941.4**	**75.4%**

Supplier	Length of relationship (since)	Supplier background and principal business	Services/ Goods sourced	Credit term granted	Purchase amount	Percentage of total purchases
			For the year ended December 31, 2021 *(RMB in thousands, except percentages)*			
Supplier A	2020	A U.S.-based pharmaceutical company engaged in the development of treatments designed to halt progression of life-threatening diseases, including cancer and fibrosis	In-license of drug candidate	45 days	58,849.7	17.4%
Supplier M	2021	A China-based pharmaceutical company engaged in wholesales of drugs	clinical R&D service, sales and promotion service, channel and delivery service	25 days	44,901.0	13.3%
Supplier B	2021	A South Korea-based biopharmaceutical company engaged in drug development and antibody engineering	In-license of drug candidate	30 days	38,970.5	11.5%
Supplier C	2020	A U.S.-based pharmaceutical company engaged in novel cancer immunotherapeutics for a broad range of cancer indications	In-license of drug candidate	30 days	12,945.4	3.8%
Supplier N	2021	A China-based company engaged in construction service	construction service (for Xuzhou facility)	7 days	12,301.5	3.6%
Total					**167,968.1**	**49.6%**

Supplier	Length of relationship (since)	Supplier background and principal business	Services/ Goods sourced	Credit term granted	Purchase amount	Percentage of total purchases
		For the year ended December 31, 2020 *(RMB in thousands, except percentages)*				
Supplier A	2020	A U.S.-based pharmaceutical company engaged in the development of treatments designed to halt progression of life-threatening diseases, including cancer and fibrosis	In-license of drug candidate	45 days	78,970.9	36.8%
Supplier C	2020	A U.S.-based pharmaceutical company engaged in novel cancer immunotherapeutics for a broad range of cancer indications	In-license of drug candidate	30 days	49,087.5	22.9%
Supplier D	2017	A China-based company principally engaged in CRO service	CRO (for clinical trial)	60 days	22,188.5	10.3%
Supplier F	2020	A South Korea-based biopharmaceutical company engaged in the discovery & development of novel antibody therapeutics	In-license of drug candidate	90 days	13,049.8	6.1%
Supplier G	2018	A China-based company principally engaged in CRO service	CRO (for clinical trial)	10 days	5,045.0	2.4%
Total					**168,341.7**	**78.5%**

AWARDS AND RECOGNITIONS

We have received various awards and recognitions including:

No.	Awards and Recognitions	Year	Issuer
1.	Small and Medium-Sized Technology Enterprise	2022	Jiangsu Provincial Department of Science and Technology
2.	Small and Medium-Sized Technology Enterprise	2022	Beijing Municipal Commission of Science and Technology
3.	Small and Medium-Sized Technology Enterprise	2022	Sichuan Provincial Department of Science and Technology
4.	Industry Build-Ecological Circle-and-Strengthen-Industry-Chain Leading Enterprise	2022	Communist Party Committee of Jinniu District, Chengdu and People's Government of Jinniu District, Chengdu
5.	Beijing New Technology and New Product (Service)	2021	Beijing Municipal Science and Technology Commission, Beijing Municipal Commission of Development and Reform, Beijing Municipal Commission of Economy and Information, Beijing Municipal Administration of Market Supervision, Beijing Municipal Commission of Housing and Urban-Rural Development, Zhongguancun Management Committee
6.	Innovative Elite of Minhang District, Shanghai	2021	People's Government of Minhang District, Shanghai
7.	Kunpeng Award of China's Biopharmaceutical Industry Chain Innovation List	2020	Nanjing International Summit of Innovative Investment in New Medicine and Life Health Industry
8.	Beijing Small and Medium-sized Technology Enterprise	2020	Beijing Municipal Commission of Science and Technology

No.	Awards and Recognitions	Year	Issuer
9.	Patent Pilot Enterprise of Beijing	2019	Beijing Municipal Intellectual Property Office
10.	State High-tech Enterprise	2019	Beijing Municipal Commission of Science and Technology, Beijing Municipal Finance Bureau, Beijing Municipal Tax Service State Taxation Administration
11.	Enterprise Science Association of Beijing Economic and Technological Development Zone	2019	Association for Science and Technology, Beijing Economic and Technological Development Zone
12.	Member of the Biomedical Industry Center of Beijing Capital Science and Technology Platform	2019	Beijing Municipal Commission of Science and Technology
13.	Beijing Zhongguancun High-tech Enterprise	2018	Zhongguancun Management Committee

PERMITS, LICENSES AND OTHER APPROVALS

During the Track Record Period and up to the Latest Practicable Date, we had obtained all requisite licenses, approvals and permits from relevant authorities that are material to our operations. The table below sets forth the relevant details of the material licenses we hold for our operation in China:

License/Permit	Holder	Issuing Authority	Issue Date	Expiration Date
Drug Manufacturing License (藥品生產許可證)	3DMed Sichuan	Sichuan Medical Products Administration	December 2, 2021	December 7, 2025
Drug Registration Certificate (藥品註冊證書)	3DMed Sichuan	National Medical Products Administration	November 24, 2021	November 23, 2026

RISK MANAGEMENT AND INTERNAL CONTROL

Risk Management

We are exposed to various risks in our business operations and we recognize that risk management is critical to our success. Please refer to the section headed "Risk Factors" for a discussion of various operational risks and uncertainties we face. We are also exposed to various market risks, in particular, credit, liquidity, interest rate and currency risks that arise in the normal course of our business. Please refer to the paragraphs headed "Financial Information – Quantitative and Qualitative Disclosure about Market Risk" in this document for a discussion of these market risks.

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

To monitor the ongoing implementation of 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:

- Our audit committee will oversee and manage the overall risks associated with our business operations, including (i) reviewing and approving our risk management policy to ensure that it is consistent with our corporate objectives; (ii) reviewing and approving our corporate risk tolerance; (iii) monitoring the most significant risks associated with our business operation and our management's handling of such risks; (iv) reviewing our corporate risk in the light of our corporate risk tolerance; and (v) monitoring and ensuring the appropriate application of our risk management framework across our Group.

- Our Board will be responsible for (i) formulating our risk management policy and reviewing major risk management issues of our Company; (ii) providing guidance on our risk management approach to the relevant departments in our Company; (iii) reviewing the relevant departments' reporting on key risks and providing feedbacks; (vi) supervising the implementation of our risk management measures by the relevant departments; and (v) reporting to our audit committee on our material risks.

- The relevant departments in our Company, including but not limited to the finance department, the legal department and the human resources department, are responsible for implementing our risk management policy and carrying out our day-to-day risk management practice. In order to formalize risk management across our Group and set a common level of transparency and risk management performance, the relevant departments will (i) gather information about the risks

relating to their operation or function; (ii) conduct risk assessments, which include the identification, prioritization, measurement and categorization of all key risks that could potentially affect their objectives; (iii) prepare a risk management report annually for our chief executive officer's review; (iv) continuously monitor the key risks relating to their operation or function; (v) implement appropriate risk responses where necessary; and (vi) develop and maintain an appropriate mechanism to facilitate the application of our risk management framework.

- Our R&D department will oversee and manage the overall risks associated with R&D by (i) performing risk assessment beforehand, (ii) setting acceptable indicators, (iii) preparing risk control measures, (iv) monitoring risks on a regular basis, and (v) monitoring the risk of patient safety.

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 independent internal control consultant (the "**Internal Control Consultant**") to perform certain agreed-upon procedures (the "**Internal Control Review**") in connection with the internal control during the period from January 1, 2020 to December 31, 2020 of our Company and our major operating subsidiaries in certain aspects, including entity level control and operation control, such as sales and revenue control, procurement control and payroll control. The Internal Control Consultant performed the Internal Control Review in January 2021 and follow-up reviews in June 2021. As of the Latest Practicable Date, there were no material outstanding issues relating to our Group's internal control.

During the Track Record Period, we regularly reviewed and enhanced our internal control system. Below is a summary of the internal control policies, measures and procedures we have implemented or plan to implement:

- We have adopted various measures and procedures regarding each aspect of our business operation, such as related party transaction, risk management and protection of intellectual property. For more information, please refer to the paragraphs headed "– Intellectual Property." We provide periodic training about these measures and procedures to our employees as part of our employee training program. Our internal audit department will conduct audit field work to monitor the implementation of our internal control policies, reports the weakness identified to our management and audit committee and follows up on the rectification actions.

- Our Directors (who are responsible for monitoring the corporate governance of our Group) with help from our legal advisers, will also periodically review our compliance status with all relevant laws and regulations after the [**REDACTED**].

- We have established an audit committee which (i) makes recommendations to our Directors on the appointment and removal of external auditors; and (ii) reviews the financial statements and renders advice in respect of financial reporting as well as oversees internal control procedures of our Group.

- We have engaged China Securities (International) Corporate Finance Company Limited as our compliance adviser to provide advice to our Directors and management team until the end of the first fiscal year after the [**REDACTED**] regarding matters relating to the Listing Rules. Our compliance adviser is expected to ensure our use of funding complies with the section headed "Future Plans and Use of [**REDACTED**]" in this document after the [**REDACTED**], as well as to provide support and advice regarding requirements of relevant regulatory authorities in a timely fashion.

- 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.

- We intend to maintain strict anti-corruption policies among our sales personnel and distributors in our sales and marketing activities and we believe we will therefore be less affected by the increasingly stringent measures taken by the PRC government to correct corruptive practices in the pharmaceutical industry. We will also ensure that our sales and marketing personnel comply with applicable promotion and advertising requirements, which include restrictions on promoting drugs for unapproved uses or patient populations, also known as off-label use, and limitations on industry-sponsored scientific and educational activities.

- Prior to starting any project proposal for drug candidate or technology development, carrying out technological transformation, or evaluating potential in-licensed drug candidates, we would conduct a thorough search and analysis of public literature in accordance with our internal policy to detect potential IP disputes. We also engage external experts, such as legal advisers, when entering into collaborations to represent us with preparing and negotiating agreements. During the development of in-licensed drug candidates, we also regularly conduct follow-up searches to further mitigate risks of potential IP disputes.

- We have established procedures to protect the confidentiality of patients' personal data. We issued clinical trial testee data protection policy which included personal information definition, confidentiality obligation, response to information leakage, data transfer management. Besides, according to company policy, it is forbidden for us to collect prescription and patient information by paying charges to HCPs.

- Regarding anti-bribery and anti-kickback, we issued anti-bribery and anti-fraud policy which included compliance training for our personnel, adding anti-bribery clause in sales contracts, setting whistle-blowing system for non-compliance behavior and penalties for bribery and fraud cases. In current contract with CSO company, anti-bribery clause has already added in promotional agreement. Meanwhile, we plan to provide compliance training for CSO & distributor which includes specific requirements of laws and regulations and other company compliance requirements in 2022.

INTELLECTUAL PROPERTY

Intellectual property, including patents, trade secrets, trademarks and copyrights, is critical to our business. Our success depends in part on our ability to obtain and maintain proprietary intellectual property protection for our product, drug candidates, novel discoveries, product development technologies, inventions and know-how. Our success also depends in part on our ability to defend and enforce our patents including any patent that we have or may issue from our patent applications, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and proprietary rights of other parties. Our R&D team also regularly conducts patent search and searches of public literature before entering into collaboration or licensing arrangements, and during the course of development of the relevant drug candidates. Specifically, with respect to the collaboration with Alphamab Group, our R&D team conducted thorough patent searches and searches of public literature that are in line with industry practice as part of our due diligence prior to signing the Collaboration Agreement. We did not identify any red flags or risks during our due diligence. Furthermore, as a protective measure for us, Alphamab Group undertakes in the Collaboration Agreements that the Core Product did not infringe any intellectual property. Lastly, throughout the development of the Core Product and as of the date of this submission, we had not received or were aware of any actual, pending or threatened patent infringement claims with respect to the Core Product. Please refer to the paragraphs headed "Risk Factors – Other Risks Relating to Our Business – Risk Relating to Our Intellectual Property Rights" in this document for a description of risks related to our intellectual property.

We have an extensive portfolio of patents to protect our product, drug candidates and technologies. As of the Latest Practicable Date, we owned (including co-owned) (i) ten granted patents in China, (ii) 14 granted patents in other jurisdictions, and (iii) 20 pending patent applications, including five Chinese patent applications, one U.S. patent application and 14 patent applications in other jurisdictions, relating to certain of our product, drug candidates and technologies.

The patent portfolio for our product and clinical-stage drug candidates as of the Latest Practicable Date is summarized below:

- **Envafolimab**: As of the Latest Practicable Date, we co-owned with Alphamab Group one granted Chinese patent, nine granted patents and ten patent applications in other jurisdictions related to envafolimab. As of the Latest Practicable Date, we were licensed by Alphamab Group two granted Chinese patents and, two granted patents and two patent applications in other jurisdiction related to envafolimab.

- **3D189 and 3D059**: As of the Latest Practicable Date, we were licensed by SELLAS Group with one granted Chinese patent, two Chinese patent applications, one granted patent and two patent applications in other jurisdictions related to 3D189 and 3D059.

- **3D229**: As of the Latest Practicable Date, we were licensed by Aravive with one granted Chinese patent, one Chinese patent application, and two granted patents and two patent applications in Hong Kong related to 3D229.

- **3D011**: As of the Latest Practicable Date, we owned two Chinese patent applications, five granted patents and five patent applications in other jurisdictions with respect to 3D011

- **3D185**: As of the Latest Practicable Date, we were licensed by Haihe Biopharma with one Chinese granted patent, 11 granted patents and one patent application in other jurisdictions related to 3D185.

- **3D1001**: As of the Latest Practicable Date, we were sub-licensed by Haihe Biopharma Group with two granted Chinese patents and one Chinese patent application related to 3D1001.

- **3D1002**: As of the Latest Practicable Date, we were sub-licensed by Haihe Biopharma Group with one granted Chinese patent related to 3D1002.

- **3D197**: As of the Latest Practicable Date, we were licensed by ImmuneOncia with one Chinese granted patent, one Chinese patent application and one patent application in other jurisdictions related to 3D197.

- **3D057**: As of the Latest Practicable Date, we were licensed by Y-Biologics with one Chinese patent application and four patent applications in other jurisdictions related to 3D057.

The following table summarizes the details of the material granted patents and filed patent applications owned by us or shared with our collaboration partners in connection with our product, pre-clinical stage and clinical-stage drug candidates:

Product/ Product Candidate	Title	Jurisdiction	Status	Applicant(s)/ Registered Patentee(s)	Patent Type	Date of Application	Date of Approval	Date of Expiration[1]	Our Commercial Rights
Envafolimab[2]	Single domain antibody and derivative proteins thereof against programmed death-ligand (PD-L1)	China	Granted	3DMed Beijing Jiangsu Alphamab	Invention	2016/8/1	2019/12/31	2036/8/1	All rights
		Hong Kong				2016/8/1	2021/1/15	2036/8/1	
		Macau				2016/8/1	2020/5/28	2036/8/1	
		South Korea				2016/8/1	2020/7/21	2036/8/1	
		Australia				2016/8/1	2020/1/23	2036/8/1	
		New Zealand				2016/8/1	2020/1/28	2036/8/1	
		Russia				2016/8/1	2020/3/2	2036/8/1	
		Indonesia				2016/8/1	2021/1/22	2036/8/1	
		Japan				2016/8/1	2021/9/17	2036/8/1	
		Canada				2016/8/1	2022/6/14	2036/8/1	
	Single domain antibody and derivative proteins thereof against programmed death-ligand (PD-L1)	EPO	Pending	3DMed Beijing Jiangsu Alphamab	Invention	2016/8/1	N/A	N/A	All rights
		Singapore				2016/8/1			
		Thailand				2016/8/1			
		Malaysia				2016/8/1			
		Mexico				2016/8/1			
		Philippines				2016/8/1			
		Egypt				2016/8/1			
		Brazil				2016/8/1			
		Vietnam				2016/8/1			
		South Africa				2016/8/1			
3D011	Compound having anti-cancer effect, and preparation method therefor and use thereof	Taiwan region	Granted	3DMed Beijing	Invention	2018/3/6	2021/3/11	2038/3/5	All rights
		Japan				2018/3/6	2020/9/1	2038/3/5	
						2017/11/17	2021/12/27	2037/11/17	
						2017/11/17	2021/12/14	2037/11/17	
		U.S.				2017/11/17	2022/6/7	2038/1/4	
	Compound having anti-cancer effect, and preparation method therefor and use thereof	EPO	Pending	3DMed Beijing	Invention	2017/11/17	N/A	N/A	All rights
						2017/11/17			
		U.S.				2017/11/17			
		China				2017/11/17			
						2017/11/17			
		Thailand				2017/11/17			
						2017/11/17			

Product/ Product Candidate	Title	Jurisdiction	Status	Applicant(s)/ Registered Patentee(s)	Patent Type	Date of Application	Date of Approval	Date of Expiration[1]	Our Commercial Rights
Others	Synthesis and use of anti-tumor drug LQC-Y	China	Granted	3DMed Beijing	Invention	2011/3/9	2014/8/13	2031/3/9	All rights
	Synthesis and use of anti-tumor drug LQC-Y	China	Granted	3D Medicines		2011/3/9	2016/8/31	2031/3/9	
	Compound having anti-tumor effect, and method for preparation thereof and application thereof	China	Granted	3DMed Shanghai; 3D Medicines; 3DMed Beijing		2014/7/1	2018/10/16	2034/7/1	
	Synthesis method and use of anti-tumor drug X-TOA	China	Granted	3D Medicines		2014/10/29	2018/9/28	2034/10/29	
	Triterpenoid derivative TBA-X having anti-tumor effect, and method for preparation thereof and application thereof	China	Granted	3DMed Shanghai; 3DMed Beijing; 3D Medicines		2015/9/1	2018/10/16	2035/9/1	
	Compound having Anti-cancer effect, and method for preparation thereof and application thereof	China	Granted	3DMed Sichuan		2017/1/16	2020/9/1	2037/1/16	
	Compound having Anti-cancer effect, and method for preparation thereof and application thereof	China	Granted	3DMed Sichuan		2016/12/14	2021/1/8	2036/12/14	
	Pyridopyrimidine derivatives as inhibitors of KRAS G12D mutation	China	Pending	3D Medicines		2021/12/2	N/A	N/A	
	Thienopyrimidine derivatives and their use as pan-KRAS mutation inhibitors	China	Pending	3D Medicines; 3DMed Beijing		2022/1/20	N/A	N/A	
	Pan-KRAS inhibitors, preparation and application thereof	China	Pending	3D Medicines		2022/4/8	N/A	N/A	
	Tumor sampling device for easy isolation of tumors	China	Granted	3DMed Xuzhou	Utility Model	2021/8/3	2022/1/18	2031/8/3	
	Effusion sampling device used in oncology	China	Granted	3DMed Xuzhou		2021/5/31	2022/1/14	2031/5/31	

Abbreviation: EPO = Europe Patent Office.

Notes:

(1) Patent expiration date is estimated based on current filing status, without taking into account any possiblepatent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal,annuity and other government fees.

(2) Under the Co-development Agreements, we agreed to co-own the patent rights under a PCT application and its multiple national phase applications (including the ones in China and the U.S.) covering the molecule of envafolimab with Alphamab Group. Please refer to the paragraphs headed "Our Research and Development – Collaboration Agreements – Collaboration with Alphamab Group for Envafolimab" in this section for more details.

The following table summarizes the details of the material granted patents and filed patent applications that licensed to us in connection with our product and clinical-stage drug candidates:

Product/ Product Candidate	Title	Jurisdiction	Status	Applicant(s)/ Registered Patentee(s)	Patent Type	Date of Application	Date of Approval	Date of Expiration[1]	Our Commercial Rights
Envafolimab	Single domain antibody and derivative proteins thereof against programmed death-ligand (PDL1)	China	Granted	Suzhou Alphamab	Invention	2016/8/1	2019/12/31	2036/8/1	All rights
						2016/8/1	2022/2/22	2036/8/1	
		Japan				2016/8/1	2021/4/23	2036/8/1	
		U.S.				2016/8/1	2022/1/18	2036/8/1	
		EPO	Pending			2016/8/1	N/A	N/A	
		Hong Kong				2016/8/1			
3D189 and 3D059	Immunogenic WT-1 peptides and methods of use thereof	China	Granted	MEMORIAL SLOAN KETTERING CANCER CENTER	Invention	2014/1/15	2019/4/2	2034/1/15	Greater China
		Macau				2014/1/15	2019/10/23	2034/1/15	
		China	Pending			2014/1/15	N/A	N/A	
		Hong Kong				2014/1/15			
	Multi-valent immunotherapy composition and methods of use for treating WT1-positive cancers	WIPO	Pending	SLSG LIMITED LLC; MEMORIAL SLOAN KETTERING CANCER CENTER	Invention	2020/4/10	N/A	N/A	
		China				2020/4/10			
3D229	Inhibition of AXL signaling in anti-metastatic therapy	China	Granted	Stanford University	Invention	2011/1/21	2017/3/15	2031/1/21	Greater China
		Hong Kong	Pending			2011/1/21	N/A	N/A	
	Inhibition of AXL signaling in anti-metastatic therapy	Hong Kong	Pending	Stanford	Invention	2011/1/21	N/A	N/A	
	Modified AXL peptides and their use in inhibition of AXL signaling in anti-metastatic therapy	Hong Kong	Granted	Aravive; Stanford	Invention	2013/12/12	2021/10/8	2033/12/12	
	Antifibrotic activity of GAS6 inhibitor	Hong Kong	Granted	Aravive; Stanford	Invention	2015/12/17	2021/4/30	2035/12/17	
	Methods of treating metastatic cancers using axl decoy receptors	China	Pending	Aravive	Invention	2018/11/5	N/A	N/A	

Product/ Product Candidate	Title	Jurisdiction	Status	Applicant(s)/ Registered Patentee(s)	Patent Type	Date of Application	Date of Approval	Date of Expiration[1]	Our Commercial Rights
3D185	Indazole compounds as FGFR kinase inhibitor, preparation and use thereof	China	Granted	Haihe Biopharma; Shanghai Institute of Materia Medica, CAS	Invention	2015/8/19	2019/11/12	2035/8/19	All rights
		U.S.				2015/8/19	2020/2/18	2035/8/19	
		EPO				2015/8/19	2021/10/6	2035/8/19	
		Japan				2015/8/19	2018/12/7	2035/8/19	
		South Korea				2015/8/19	2019/9/11	2035/8/19	
						2015/8/19	2020/10/8		
		Australia				2015/8/19	2018/6/28	2035/8/19	
		Canada				2015/8/19	2021/1/19	2035/8/19	
		Russia				2015/8/19	2020/4/17	2035/8/19	
		Mexico				2015/8/19	2021/4/28	2035/8/19	
		Malaysia				2015/8/19	2021/12/9	2035/8/19	
		Peru				2015/8/19	2022/4/28	2035/8/19	
		Brazil	Pending			2015/8/19	N/A	N/A	
3D1001	Salts and crystal forms	China	Granted	AskAt	Invention	2014/1/6	2017/7/18	2034/1/6	Mainland China
	Pharmaceutical composition	China	Granted		Invention	2012/10/18	2022/5/13	2032/10/18	
	Process for the differential solubility-driven asymmetric transformation of substituted 2h-chromene-3-carboxylic acids	China	Pending		Invention	2020/1/20	N/A	N/A	
3D1002	Crystal forms of an imidazole derivative	China	Granted		Invention	2006/3/1	2010/12/22	2026/3/1	Mainland China
3D197	Antibody therapeutics that bind CD47	China	Granted	SORRENTO THERAPEUTICS, INC.	Invention	2016/3/4	2022/2/8	2036/3/4	Greater China
		Taiwan region	Pending			2016/3/4	N/A	N/A	
		China				2016/3/4			
3D057	Cell engaging binding molecules	China	Pending	Y-BIOLOGICS INC.	Invention	2019/4/9	N/A	N/A	Greater China
		Hong Kong				2019/4/9			
		WIPO				2019/4/9			
	Multispecific fusion protein and use thereof	WIPO	Pending		Invention	2020/10/8	N/A	N/A	
		Taiwan region				2020/10/12			

Note:

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

As to the pending patent applications, the potential legal impediment in obtaining approval and the impact on the development and commercialisation of our drug candidates if we fail to obtain issued patent for each pending patent application are summarized as below:

According to Article 22 of the Patent Law of the People's Republic of China, effective as of June 1, 2021, inventions and utility models for which patent rights are to be granted shall be ones which are novel, creative and of practical use. Lack of or failure to satisfy any of the three requirements of novelty, inventive and practical use would result in rejection of any filed patent applications by the patent administration authorities.

According to our legal advisers as to intellectual property law who have taken a thorough review of the specifications and claims of the filed patent applications and the examination history of the US/EU/CN granted family patents, with the exceptions of CN110292575A, CN111565742A, WO2020210632A1, CN110167917A, and CN110167554A as further described below, there is no legal impediment for each of the filed patent applications in relation to the 10 drug products and candidates in our pipeline (i.e., envafolimab, 3D189, 3D059, 3D229, 3D1001, 3D1002, 3D185, 3D011, 3D057 and 3D197) of being granted, because it can satisfy the requirements of novelty, inventiveness and utility, provided that the examiner cites the same or similar prior arts which have been used in the patent family examination to evaluate the relevant pending claims, or our Company makes appropriate amendments or arguments to the claims where necessary, which is common in patent prosecution practice.

1. CN110292575A in relation to 3D-1001

The likelihood of patent grant for CN110292575A in relation to 3D-1001 is not promising in light of the examination history of its corresponding CN, EU, and US counterparts. However, another patent grant, CN104870431B in relation to 3D-1001, which is stable according to our legal advisers as to intellectual property law, claims the crystal form of a potassium salt and therefore can provide appropriate protection for 3D-1001. Therefore, even if CN110292575A is ultimately rejected, CN104870431B ensures patent protection for 3D-1001.

2. CN111565742A in relation to 3D-229

The likelihood of patent grant for CN111565742A is not promising in light of the examination history of its corresponding WO and EU counterparts. However, another patent grant, CN103154020B in relation to 3D-229, which is stable according to our legal advisers as to intellectual property law, claims a soluble AXL variant polypeptide and therefore can provide appropriate protection for 3D-229. Therefore, even if CN111565742A is ultimately rejected, CN103154020B ensures patent protection for 3D-229.

3. WO2020210632A1 in relation to 3D-059

The likelihood of patent grant for CN111565742A after entering China is not promising in light of the Written Opinion of the International Search Bureau. However, another patent grant, CN105377291B in relation to 3D-059, which is stable according to our legal advisers as to intellectual property law, claims two individual peptides in 3D-059 and therefore can provide appropriate protection for 3D-059. Therefore, even if WO2020210632A1, after entering China, is ultimately rejected, CN105377291B ensures patent protection for 3D-059.

4. CN110167917A and CN110167554A in relation to 3D-011

In light of the disclosure of the patent application documents and the examination history of its corresponding EU and US counterparts, these two patent applications are likely to be granted with narrower scopes, provided that convincing observations and supplementary experimental data demonstrating the beneficial technical effects described in the Description are accepted by the examiner.

In the event that these pending patent applications are ultimately rejected, this would simply mean that the technology intended to be covered by such patent applications is not protected by patent rights. For more details, please refer to "Risk Factors – If we are unable to obtain and maintain adequate patent protection for our product and drug candidates throughout the world, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties could develop and commercialize products and technologies similar or identical to ours and compete directly against us, and our ability to successfully commercialize any of our future approved products or technologies would be materially adversely affected." Practically, however, the loss of patent protection will not hinder us from developing and commercializing the drug candidates by using such technology. Further, as discussed above, there exist other patents which could provide appropriate patent protection for related drug products and candidates. In the absence of patent protection, we may also have extensive know-how in developing the drug products and candidates which enable us to maintain a competitive advantage in the market.

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 U.S. 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. and Europe, 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, only once a patent may be extended, 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. 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 product and drug candidates and methods of manufacturing the same.

We may rely, in some circumstances, on trade secrets 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 or including confidentiality clauses in our agreements with consultants, scientific advisers and contractors, and developing a management system of such proprietary technology and process. We have entered into confidentiality agreements and non-competition agreements, or included confidentiality clauses and non-competition clauses in the employment 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 secrets and/or confidential information. These agreements may also be breached, resulting in the misappropriation of our trade secrets and/or confidential information, and we may not have an adequate remedy for any such breach. In addition, our trade secrets 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. Please refer to the paragraphs headed "Risk Factors – Other Risks Relating to Our Business – Risk Relating to Our Intellectual Property Rights" in this document for a description of risks related to our intellectual property.

We conduct our business under the brand name of "3D Medicines" or "思路迪醫藥." As of the Latest Practicable Date, we had registered 51 trademarks in China, five trademarks in Hong Kong and filed two trademark applications in other jurisdictions, respectively. As of the Latest Practicable Date, we were also the registered owner of one domain name.

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. Please refer to the paragraphs headed "– Our Research and Development – Collaboration Agreements" in this section.

During the Track Record Period and up to the Latest Practicable Date, we were not involved in any proceedings in respect of, and we had not received notice of any claims of infringement of, any intellectual property rights that may be threatened or pending, in which we may be a claimant or a respondent. Our Directors confirm that we were not aware of any instances of infringement of any third parties' intellectual property rights by us during the Track Record Period and up to the Latest Practicable Date.

Please refer to the paragraphs headed "Statutory and General Information – Further Information about Our Business – Intellectual Property Rights" in Appendix IV to this document for further information.

COMPETITION

The pharmaceutical and biopharmaceutical industries are highly competitive and subject to rapid and significant change. While we believe that our pipeline of innovative product and drug candidates in clinical and pre-clinical trials, research and development capability, platform and leadership team provide us with competitive advantages, we face potential competition from many different sources working to develop therapies targeting the same indications against which we develop our products and drug candidates, in particular in the fields of oncology. These include major pharmaceutical companies as well as specialty pharmaceutical and biotechnology companies of various sizes, academic institutions, government agencies and research institutions. Any products and drug candidates that we successfully develop and commercialize will compete both with existing drugs and with any new drugs that may become available in the future. For more information on the competitive landscape of our product and drug candidates, please refer the paragraph headed "– Our Core Product and Other Drug Candidates."

EMPLOYEES

As of the Latest Practicable Date, we had 253 employees in total and the following table sets forth the number of our employees categorized by function:

Function	Number	% of Total
Research and development	151	60%
Quality assurance, quality control and registration	29	11.5%
Commercial, operation and manufacturing	29	11.5%
General, administrative and others	44	17%
Total	253	100.0%

As of the Latest Practicable Date, among the 253 employees, 112 of our employees were stationed in Shanghai, 82 of our employees were stationed in Beijing, and 59 of our employees were based in other cities in China and the U.S. Notably, our R&D has a total of 151 employees, 82 of which have a master's degree or higher, including 17 with doctor's degrees.

We enter into individual employment contracts with our employees covering matters such as salaries, bonuses, employee benefits, workplace safety, confidentiality obligations, work product assignment clause and grounds for termination. We have entered into confidentiality agreements and non-competition agreements, or included confidentiality clauses and non-competition clauses in the employment agreements with our senior management and certain key members of our R&D team and other employees who have access to trade secrets or confidential information about our business.

To maintain the quality, knowledge and skill levels of our workforce, we provide continuing education and training programs, including internal and external training, for our employees to improve their technical, professional or management skills. We also provide trainings programs to our employees from time to time to ensure their awareness and compliance with our policies and procedures in various aspects. Furthermore, we provide various incentives and benefits to our employees, including competitive salaries, bonuses and incentive schemes to our employees, particularly our key employees.

We have complied with the PRC law in all material aspects to make contributions to statutory employee benefit plans (including pension insurance, medical insurance, work-related injury insurance, unemployment insurance, maternity insurance and housing funds) at a certain percentage of our employees' salaries during the Track Record Period and up to the Latest Practicable Date.

None of our Company or any of our subsidiaries have any labor union. We consider our relations with our employees to be good. During the Track Record Period and up to the Latest Practicable Date, we did not experience any strikes or labor disputes which had a material effect on our business.

LAND AND PROPERTIES

Owned Properties

As of the Latest Practicable Date, we owned land use rights to one parcel of land in Xuzhou Economic and Development Area with an area of 65,637.97 square meters, of which we have obtained the property ownership. We have been building our in-house production facilities in Xuzhou, Jiangsu province, with GMP-compliant manufacturing system and facilities throughout the drug development process, including chemical drugs and biologics, to meet stringent standards.

Leased Properties

As of the Latest Practicable Date, we leased 14 properties with an aggregate GFA of approximately 19,050.45 square meters. 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 as of the Latest Practicable Date:

Entity	Location	Type of Property	Gross Floor Area (sq.m.)	Expiry Date
3D Medicines	Shanghai	Office	1,998.89	June 30, 2025
3D Medicines	Shanghai	Laboratories and office	1,975.16	August 31, 2025
3D Medicines	Shanghai	Office	1,811.04	October 31, 2026
3DMed Shanghai	Shanghai	Office	165.18	October 31, 2022
3DMed Shanghai	Guangzhou	Office	304.22	August 31, 2024
3DMed Shanghai	Guangzhou	Office	184.98	August 31, 2024
3DMed Beijing	Beijing	Office and laboratories	5,118	July 31, 2026
3DMed Sichuan	Sichuan	Office	133.32	May 3, 2023
3DMed Xuzhou	Xuzhou	Office	172	June 19, 2023
3DMed Xuzhou	Xuzhou	Office	41	May 23, 2023
Longteng Medicines	Xuzhou	Office and manufacturing factory	6,351.1	April 30, 2025
3DMed Xuzhou	Xuzhou	Employee dormitory	154	December 19, 2022
3DMed Xuzhou	Xuzhou	Employee dormitory	310.56	January 9, 2023
3DMed Xuzhou	Xuzhou	Employee dormitory	331	December 31, 2022

Six of our leases are expiring in 2022. With respect to these leases, we are currently in the process of negotiating actively with the relevant lessors to renew such leases. Considering our stable cooperation relationship with the lessors, our Directors believe that we will be able to successfully renew the leases before the end term. Given our commercial interest, we may not renew all the expiring leases. However, given the nature of the usage under such leases (office), our Directors are of the view that there would not be any material impact on our operations.

We do not have any property interest with a carrying amount of 15% or more of our consolidated total assets as of May 31, 2022. Therefore, according to Chapter 5 of the Listing Rules and section 6(2) of the Companies (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice (Chapter 32L of the Laws of Hong Kong), this Document is exempted from compliance with the requirements of section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance in relation to paragraph 34(2) of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance which requires a valuation report with respect to all of our interests in land or buildings.

ENVIRONMENTAL MATTERS AND WORKPLACE SAFETY

We are committed to operate our business in a manner that protects environment and provides a safety workplace for our employees. We have implemented company-wide environmental, health and safety (EHS) manuals, policies and standard operating procedures. In particular, our environmental, health and safety protection measures include (i) strict compliance with the GMP qualification requirements and relevant pollutant emissions standards and pollutants management policies during our production process to reduce pollutant emissions of exhaust gas, sewage and hazardous solid waste; (ii) implementation of 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; (iii) storage of hazardous substances in special warehouse and contract with qualified third parties for the disposal of hazardous materials and waste on a quarterly basis; (iv) conducting periodic environmental evaluations on exhaust gas detection and emissions, hazardous waste disposals, noise emissions, and waste water detection and emissions to make sure all operations are in compliance with the applicable laws and regulations, and (v) resource conservation policies to reduce the levels of resource consumption. The cost of compliance with relevant environmental protection laws and regulations incurred by us in 2020, 2021 and for the five months ended May 31, 2022, was approximately RMB37,500, RMB298,200 and RMB56,009, respectively.

We closely monitor the below metrics in relation to the formulation and implementation of our pollutants management and resource conservation policies as appropriate:

Pollutants emission

- *Exhaust gas discharge*. During the Track Record Period, based on our best estimates, exhaust gas discharge levels were approximately 6 kilograms and 8.45 kilograms in aggregate in 2021 and for the five months ended May 31, 2022, respectively.

- *Sewage discharge*. During the Track Record Period, based on our best estimates, sewage discharge levels were approximately 10 tons and 42 tons in aggregate in 2021 and for the five months ended May 31, 2022, respectively.

- *Hazardous solid waste discharge*. During the Track Record Period, based on our best estimates, hazardous solid waste discharge levels were approximately 1.5 tons and 0.3 ton in aggregate in 2021 and for the five months ended May 31, 2022, respectively.

- *Hazardous liquid waste discharge*. During the Track Record Period, based on our best estimate, hazardous liquid waste discharge levels were 0.2 ton and 0.5 ton in aggregate in 2021 and for the five months ended May 31, 2022, respectively.

Resource consumption

- *Electricity consumption*. In 2020, 2021 and for the five months ended May 31, 2022, electricity consumption levels were approximately 95.30 thousand kWh, approximately 615.62 thousand kWh and approximately 431.68 thousand kWh in aggregate, respectively.

- *Water consumption*. In 2020, 2021 and for the five months ended May 31, 2022, water consumption levels were approximately 490 tons, 3,141 tons and 4,527.6 tons in aggregate, respectively.

We will continue to monitor our pollutants emission and resource consumption levels, and will strive to operate in an environmentally friendly way. We have also adopted greenhouse gases reduction measures (including using cleaner energy source and formulating policies to conserve electricity and reuse paper), to gradually reduce our resource consumption and greenhouse gases emissions in the future.

During the Track Record Period and up to the Latest Practicable Date, we complied with the relevant environmental and occupational health and safety 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 during the period.

INSURANCE

We maintain insurance policies that we consider to be in line with market practice and adequate for our business. Our principal insurance policies cover property loss due to accidents or natural disasters, employee benefits liability and personal injury. We currently maintain insurance for adverse events in clinical trials. We currently do not maintain insurance for environmental liability. Please refer to the section headed "Risk Factors – Risks Relating to our Operations – We have limited insurance coverage, and any claims beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources" in this document.

We consider that the coverage from the insurance policies maintained by us is adequate for our present operations and is in line with the industry norm. During the Track Record Period, we had not made, or been the subject of, any material insurance claims.

LEGAL PROCEEDINGS AND COMPLIANCE

During the Track Record Period and up to the Latest Practicable Date, we were not a party to any actual or threatened legal or administrative proceedings which would have a material and adverse impact on our business, financial condition or results of operations. We are committed to maintaining the highest standards of compliance with the laws and regulations applicable to our business. However, we may from time to time be subject to various legal or administrative claims and proceedings arising in the ordinary course of business. Please refer to the paragraphs headed "Risk Factors – Risks Relating to Our Operations" in this document for a description of risks related to legal or administrative claims and proceedings arising in the ordinary course of business.

Our PRC Legal Advisers confirmed that during the Track Record Period and up to the Latest Practicable Date, we had complied with applicable PRC laws and regulations in all material aspects. Our Directors confirmed that we were not involved in any material or systematic non-compliance incidents.