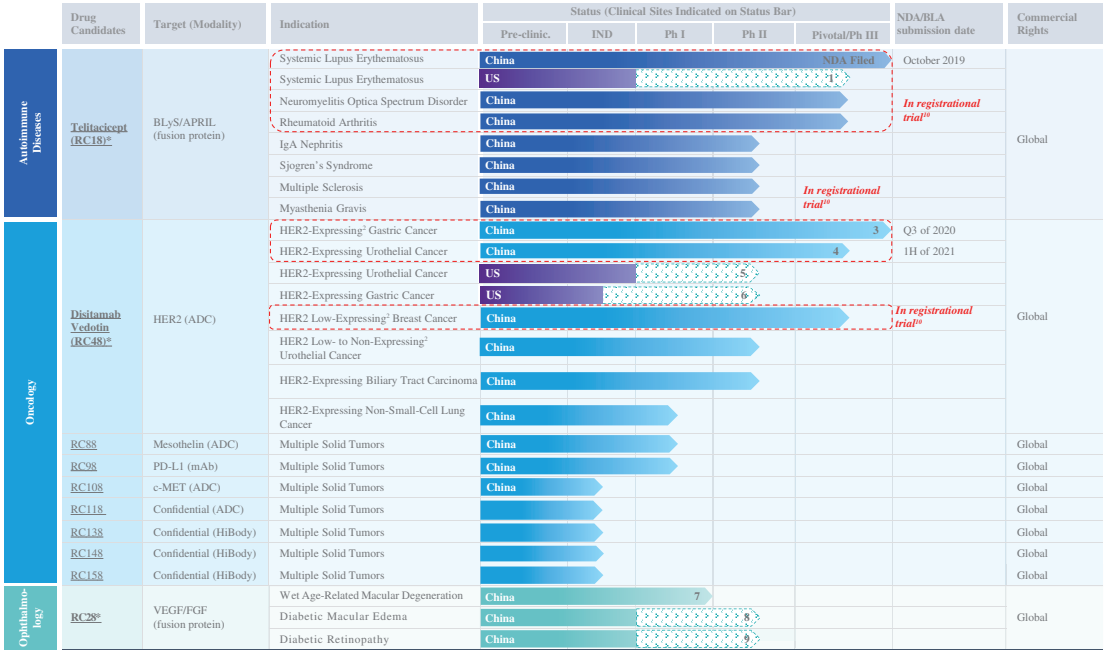
OVERVIEW

We are a commercial-ready biopharmaceutical company committed to the discovery, development and commercialization of first-in-class and best-in-class biologics for the treatment of autoimmune, oncology and ophthalmic diseases with unmet medical needs in China and globally. Our vision is to become a leading player in the global biopharmaceutical industry.

Since our inception in 2008, we have been dedicated to the research and development of biologics with novel targets, innovative design and breakthrough potential to address global unmet clinical needs. Through more than ten years of meticulous efforts, we have built a fully-integrated, end-to-end therapeutics platform encompassing all the key biologic drug development functionalities, including discovery, pre-clinical pharmacology, process and quality development, clinical development, and GMP manufacturing. Leveraging our strong R&D platforms, we have discovered and developed a robust pipeline of more than ten drug candidates. Among our drug candidates, five are in clinical development stage targeting 17 indications and more than five are in IND-enabling stage. Two of our clinical-stage candidates, telitacicept (RC18) and disitamab vedotin (RC48), are in registrational trials targeting six indications in China and the U.S. Our new drug application (NDA) for telitacicept in China for SLE was accepted by the NMPA in November 2019 and was granted priority review the following month. We expect to receive approval from the NMPA to market telitacicept in China for SLE in the fourth quarter of 2020.

The following chart illustrates our pipeline and summarizes the development status of our clinical-stage drug candidates and selected IND-enabling stage candidates as of the Latest Practicable Date:



* Denotes our core drug candidates.

Abbreviations: 1H = first half; ADC = antibody drug conjugate; HiBody = a novel bifunctional antibody; mAb = monoclonal antibody; Q3 = third quarter

Notes:

(1) The FDA has provided clearance for us to proceed with the Phase III clinical trial of telitacicept for SLE in the U.S in January 2020 and granted telitacicept Fast Track designation in April 2020.

(2) HER2-expressing refers to a HER2 status of tumor cells identified with a test score of IHC 1+ or above. HER2 low-expressing refers to a HER2 status of tumor cells identified with a test score of IHC 1+ or IHC 2+/FISH-. HER2 non-expressing refers to HER2 status of tumor cells identified with a test score of IHC 0.

(3) In China, we are (i) finalizing a Phase II registrational trial to evaluate disitamab vedotin as monotherapy for the treatment of HER2 over-expressing (IHC 2+ or IHC 3+) gastric cancer (GC), and (ii) conducting a Phase I clinical trial to evaluate distamab vedotin in combination with PD-1 inhibitor for the treatment of HER2 over-expressing GC.

(4) In China, we are conducting (i) a Phase II registrational trial to evaluate disitamab vedotin as monotherapy for the treatment of HER2 over-expressing (IHC 2+ or IHC 3+) urothelial cancer (UC), and (ii) a Phase Ib/II trial to evaluate disitamab vedotin in combination with PD-1 inhibitor for the treatment of UC.

(5) The FDA has provided clearance for us to proceed with the Phase II clinical trial of disitamab vedotin in the U.S in April 2020.

(6) We have initiated pre-IND discussion with the FDA to obtain their consents for disitamab vedotin's Phase II clinical trial in GC in the U.S.

(7) We have completed a Phase I trial of RC28 in wet age-related macular degeneration (wet AMD) in August 2019 in China, of which the primary endpoint of safety was met. In July 2018, we obtained the NMPA's approval for us to conduct Phase I, II and III trials of RC28 according to our clinical development plan and progress, and the NMPA has not raised any objections towards our clinical trials of RC28 since then. We are currently conducting a Phase Ib trial of RC28 to further evaluate its efficacy and safety for the treatment of wet AMD.

(8) We plan to initiate a Phase II trial for RC28 in diabetic macular edema in the second half of 2020 in China.

(9) We plan to initiate a Phase II trial for RC28 in diabetic retinopathy in the second half of 2020 in China.

(10) Registrational trial, or pivotal trial, means the clinical trial or study to demonstrate clinical efficacy and safety evidence required before submission for drug marketing approval.

Our pipeline features three highly-differentiated core drug candidates, and we are developing them for autoimmune, oncology and ophthalmic diseases, respectively:

- **Telitacicept (RC18)** is a first-in-class NDA-filed late-stage innovative TACI-Fc fusion protein targeting two important cell-signaling molecules, BLyS and APRIL, implicated in B cell-mediated autoimmune diseases. We are carrying out a broad clinical development program for this drug candidate targeting a variety of B cell-mediated autoimmune diseases with unmet or underserved medical needs.

  Systemic lupus erythematosus (SLE) is the lead indication of telitacicept. In SLE, we have completed a Phase IIb registrational study in China, where telitacicept showed robust efficacy and a favorable safety profile, and has supported best-in-class potential in treating SLE. Based on the results of this trial, the NMPA accepted our NDA for conditional approval of telitacicept for SLE in November 2019 and granted it priority review based on the significant unmet medical need in December 2019. The approval will be conditional on a commitment to complete a confirmatory Phase III trial in SLE post the commercial launch, and we are currently in the process of enrolling patients in this Phase III trial. We expect to receive marketing approval in China and commence commercialization activities in the fourth quarter of 2020. In addition to SLE, we are actively developing telitacicept for six other B cell-mediated autoimmune diseases in late-stage clinical trials in China, including (i) two registrational studies in neuromyelitis optica spectrum disorder (NMOSD) and in rheumatoid arthritis (RA), (ii) two Phase II studies in indications with large patient populations but few efficacious treatments available, including IgA nephropathy (IgAN) and Sjögren's syndrome (SS), and (iii) two additional Phase II studies in hard-to-treat rare diseases, including multiple sclerosis (MS) and myasthenia gravis (MG).

Based on the encouraging clinical trial results in China and our clearly defined U.S. clinical development strategy, telitacicept has the potential to become the first created-in-China first-in-class biologic drug to be approved for marketing in the U.S. Among other efforts, we obtained the FDA's consent for entry into a registrational trial for the treatment of SLE in the U.S. in January 2020, and the FDA granted telitacicept Fast Track designation in April 2020. We expect to initiate the global Phase III clinical trials covering multiple jurisdictions, including the U.S., Europe and other countries, in the first half of 2021. For further details, please refer to "Summary—Impact of the COVID-19 Outbreak."

- **Disitamab vedotin (RC48)** is a late-stage anti-HER2 antibody-drug conjugate (ADC) targeting prevalent cancers with significant unmet medical needs, and it is the first domestically-developed ADC in China to have entered clinical development. We are implementing a differentiated development and commercial strategy for disitamab vedotin, targeting prevalent HER2-expressing indications that are currently underserved, including both (i) HER2-expressing cancer (IHC 1+ or above) indications beyond BC, such as gastric cancer (GC) and urothelial carcinoma (UC) (both currently in registrational trials in China), and (ii) HER2 low-expressing cancer (IHC 2+/FISH- or IHC 1+) indications, such as HER2 low-expressing BC (currently in a registrational trial in China). These therapeutic areas represent a less crowded but underserved field for HER2-targeted therapies, and a broad addressable patient population for disitamab vedotin.

  Based on its design advantages, disitamab vedotin has demonstrated superior anti-tumor activity and good tolerability in a registrational study in GC and a Phase II study in UC. We plan to file NDAs with the NMPA for disitamab vedotin in the third quarter 2020 for GC and in the first half of 2021 for UC.

  Leveraging the promising efficacy and safety data observed in our clinical trials in China so far, we are actively exploring overseas trial opportunities for disitamab vedotin. In the U.S., disitamab vedotin has received orphan drug designation from the FDA for GC, and the FDA has cleared its IND application for a Phase II study in the U.S. for UC. We plan to initiate U.S. studies of disitamab vedotin in UC and GC patients in 2021.

- **RC28** is a potential first-in-class VEGF/FGF dual-targeting fusion protein for the treatment of eye diseases. Compared to single-target VEGF inhibitors, RC28 has the potential to more effectively inhibit the abnormal blood vessel growth implicated in various eye diseases through both VEGF and FGF pathways, and potentially allows for a better dosing profile. RC28 has demonstrated good safety in a Phase I dose escalation study in patients with wet age-related macular degeneration (wet AMD) in China. We have initiated a Phase Ib study in wet AMD and plan to initiate Phase II clinical studies in diabetic macular edema (DME) and diabetic retinopathy (DR) in the second half of 2020 in China.

Our fully-integrated platform is driven by a proprietary R&D engine, which consists of three specialized platforms, including (i) an antibody and fusion protein platform, based on which we are internally developing telitacicept, RC28 and RC98 (a clinical-stage PD-L1 antibody); (ii) an ADC platform, based on which we are internally developing disitamab vedotin, RC88 (a clinical-stage anti-mesothelin ADC) and two IND-enabling stage ADCs

(RC108 and RC118); and (iii) a bifunctional antibody (HiBody) platform, based on which we are internally developing three IND-enabling stage HiBody compounds (RC138, RC148 and RC158).

Our Co-Founder, CEO and CSO, Dr. Jianmin Fang, is one of the few founders in China's biopharmaceutical industry with a successful track record of progressing novel biological drugs from discovery though development and commercialization. A Harvard-trained scientist, Dr. Fang is a visionary leader in translating biomedical discovery into therapeutics. He invented many molecules in our pipeline and is the key driving force for our continual innovation. Furthermore, we have assembled an experienced senior management team with an average of more than 20 years of industry experience (mostly in the U.S.) and proven track records of innovative drug R&D, clinical development and commercialization.

Another key driver of our success has been our strong clinical development capability and insights in regulatory affairs. Led by our Chief Medical Officer, Dr. Ruyi He, our clinical development function has approximately 200 employees and carries out our global clinical development plan through both rigorous trial design and trial operational excellence. More importantly, our clinical development team discovers and explores often unanticipated clinical opportunities, which has organically stimulated the growth and expansion of our clinical development programs. Leveraging Dr. He's nearly 20 years of unique policy-making and managerial experience at the FDA in the U.S. and the NMPA in China, we have accumulated substantial expertise in and familiarity with regulatory review requirements and approval processes in China, the U.S. and beyond. Since our inception, we have submitted ten IND applications for five drug candidates and have obtained approvals for all applications, including two applications which received clearance from the FDA in the U.S. for telitacicept and disitamab vedotin. In addition, we have submitted an NDA in China for our telitacicept and have obtained priority review status.

Our global GMP-compliant manufacturing facilities houses six 2,000L disposable bag bioreactors for a total capacity of 12,000L. With these capabilities and experiences, we have established a successful track record of manufacturing five drug candidates in-house. We are building new manufacturing facilities and plan to expand our total production capacity to 36,000L by the end of 2021. To support our near-term launch of telitacicept, we have assembled the sales leadership team and expect to build a strong sales and marketing team of around 100 members with rich sales experience in the autoimmune areas, which is expected to further expand to 200 members in the second 12-month period after the commercial launch.

We build and operate our fully-integrated platform with a global vision. In addition to designing and implementing our global clinical development programs for our innovative drug candidates, our regulatory affairs and commercialization teams have invested significant resources in seeking regulatory filings, marketing approvals and eventually successful commercial launches for these products in major markets both in and outside China. We also have been actively seeking strategic partnership opportunities with global leading pharmaceutical companies to maximize the clinical and commercial value of these potential first-in-class and/or best-in-class drug products.

OUR STRENGTHS

First-in-class registrational-stage fusion protein telitacicept (RC18) with impressive therapeutic efficacy in B cell-mediated autoimmune diseases

Telitacicept is a first-in-class late-stage innovative recombinant TACI-Fc fusion protein we have internally developed for the treatment of B cell-mediated autoimmune diseases. Telitacicept targets and neutralizes two important cell-signaling molecules implicated in B cell-mediated autoimmune diseases, and has shown a robust efficacy with a favorable safety profile. Its demonstrated advantages have enabled us to carry out a broad clinical development program for this product targeting a variety of B cell-mediated autoimmune diseases with unmet or underserved medical needs, and have allowed us to continue to explore and expand the range of its treatment indications.

SLE, currently the lead trial indication for telitacicept, is a hard-to-treat systemic autoimmune disorder that causes widespread immune attack in the human body, which inflicts tissue damage in multiple organs, and has one of the highest mortality and disability rates among autoimmune diseases. Most prevalent among females between the ages of 15 and 44, SLE patients can lose part of their physical and mental capabilities, causing a significant socioeconomic burden on patients' social functions and quality of life.

To this day, there is no effective cure for SLE, while the currently available treatments to control the disease are either limited in efficacy or can cause severe side effects. As SLE often occurs in young patients who usually require lifelong treatment to control the chronic disease conditions, the medical needs for effective SLE therapeutics are huge, which has been underserved in the long history of SLE drug development.

We believe that telitacicept has the potential to become the best-in-class therapy in this growing and yet largely untapped global SLE market. Telitacicept's fundamental design-based advantages and differentiation in comparison with competing drugs (especially biologics) lie in: (i) its dual-targeting mechanism and bioinformatics-optimized structure design, which enhance its biological activity, promote molecular stability, and facilitate our production; and (ii) its full human amino acid sequence, which minimizes undesired potential immunogenicity.

Results from our recently completed Phase IIb registrational trial of telitacicept in China have demonstrated a superior clinical efficacy and good safety profile supporting a best-in-class potential in SLE. The primary endpoint of this trial was the proportion of patients achieving SRI-4 response at week 48. Telitacicept treatment groups at multiple doses in this trial had statistically significantly higher SRI-4 response rates (70% to 79%) than the placebo group (32%), which indicates significant reduction in SLE disease activity in the telitacicept treatment groups. In general, telitacicept was well tolerated by patients in this trial, with a serious adverse event (SAE) rate ranging from 13% to 16% across the treatment groups for dose levels ranging from 80mg to 240mg, comparing to the placebo group which had an SAE rate of 16%.

For SLE alone, we are implementing a comprehensive clinical development plan for telitacicept both in and outside China. In China, we submitted our NDA for conditional approval of telitacicept for the treatment of SLE in October 2019. The NMPA accepted our NDA in November 2019 and granted us priority review in December 2019. The approval will be conditional on a commitment to complete a confirmatory Phase III trial in SLE post the commercial launch, and we are currently in the process of enrolling patients in this Phase III trial. We expect to receive marketing approval in China and commence commercialization activities in the fourth quarter of 2020. In the U.S., we completed an end-of-Phase II meeting with the FDA in January 2020, and received the FDA's consent for entry into a registrational trial in the U.S. for the treatment of SLE. In April 2020, the FDA granted telitacicept Fast Track designation, which could expedite the FDA's review and potential approval process. We expect to initiate global Phase III clinical trials covering multiple jurisdictions, including the U.S., Europe and other countries, in the first half of 2021, which is expected to commence under the supervision of Dr. Joan Merrill, our clinical program coordinator and a world-renowned rheumatologist. We plan to make a BLA filing for telitacicept in the U.S. for SLE treatment if the registrational trial meets the primary endpoints.

In order to facilitate the successful global registrations and commercial launches of telitacicept, to which we own worldwide development and commercialization rights, we plan to collaborate with global leading biopharmaceutical companies for the potential co-development or out-license of telitacicept and its commercialization outside China.

Telitacicept's promising efficacy in treating SLE has lent support to our belief that it will also be effective in treating other B-cell mediated autoimmune diseases. We are managing a broad clinical development program for telitacicept in six other autoimmune diseases besides SLE, and we expect to further expand its range of indications as we continue to advance our clinical research. Among other indications, we are currently conducting registrational studies of telitacicept in neuromyelitis optica spectrum disorder (NMOSD) and rheumatoid arthritis (RA). We are also conducting Phase II studies in indications with large patient populations but few efficacious treatments, including IgA neurophathy (IgAN) and Sjögren's syndrome (SS), as well as hard-to-treat rare diseases, including multiple sclerosis (MS) and myasthenia gravis (MG). Given its potential clinical value in these and additional indications, we see a tremendous overall addressable market of telitacicept and significant commercial potential.

Late-stage anti-HER2 antibody-drug conjugate disitamab vedotin (RC48) targeting prevalent cancers with significant unmet medical needs

Antibody-drug conjugates (ADCs) are one of the classes of oncology therapeutics attracting significant attention and investment of its therapeutic potential. ADCs, which consist of a monoclonal antibody linked to a cytotoxic drug, can selectively deliver a highly potent anti-cancer drug into tumor cells while sparing healthy cells, thus generating a wide therapeutic window. Our disitamab vedotin, a novel anti-HER2 ADC, is the first domestically-developed ADC drug to have entered clinical studies in China. With global development and commercialization rights to the candidate, we are evaluating disitamab vedotin in clinical trials for various HER2-expressing (including HER2 low-expressing) solid tumors, including three registrational studies for the treatment of gastric cancer (GC), urothelial carcinoma (UC) and HER2 low-expressing breast cancer (BC). In these cancer types, disitamab vedotin has the potential to become the first-to-market ADC in China and is well-positioned to capture the largely unmet market needs.

HER2 is an important biomarker commonly expressed in many different tissues, and its overexpression has been recognized as a genetic driver of multiple cancer types. While HER2 has emerged as one of the main targets for the ADCs developed by global pharmaceutical companies in recent years, HER2-positive/high-expressing BC (IHC 2+/FISH+ or IHC 3+) continues to be the most heavily investigated, and the only approved, cancer type for the use of anti-HER2 ADC. However, HER2-expression at various levels (including low expression levels) is also observed in a number of other cancer types, such as GC, UC, biliary tract cancer (BTC) and non-small cell lung cancer (NSCLC), and low-level HER2 expression (IHC 2+/FISH- or IHC 1+) is observed in around 50% of BC cases, indicating a large therapeutic potential and opportunity for anti-HER2 ADCs beyond HER2 high-expressing BC.

We are strategically developing disitamab vedotin to meet these needs of an underserved market, and we are currently conducting its lead trials in GC, UC and HER2 low-expressing BC in China. These therapeutic areas represent a less crowded but underserved field for HER2-targeted therapies, and a large addressable patient population for disitamab vedotin.

Disitamab vedotin's fundamental advantages and differentiation in comparison with competing drugs and drug candidates lie in its "quality by design" molecular structure. In particular, disitamab vedotin features a novel humanized antibody (disitamab) with high HER2 affinity, which enables a strong anti-tumor effect on HER2 low-expressing cancers. It features a potent and highly membrane-permeable cytotoxic drug that allows for a strong bystander-killing effect on surrounding tumor cells (regardless of their HER2 expression levels). It also features a cleavable linker with no lysosomal resistance and enables release of the cytotoxic payload in lysosomes after the internalization of disitamab vedotin by the targeted HER2-expressing tumor cells.

Indeed, disitamab vedotin has demonstrated strong anti-tumor activity in clinical trials for GC and UC patients. In our Phase II registrational trial for GC, disitamab vedotin delivered an independent review committee (IRC)-assessed confirmed objective response rate (ORR) of 24.4%, median progression-free survival (PFS) of 4.1 months and median overall survival (OS) of 7.6 months in 127 patients with HER2 over-expressing (IHC 2+ or IHC 3+) GC or GEJ cancer post to second lines of prior chemotherapy treatment as of June 22, 2020. In June 2019, we presented positive clinical data from our initial Phase II study of disitamab vedotin in second-line UC at ASCO 2019 held in Chicago, Illinois. In this study with 43 HER2 over-expressing (IHC 2+ or IHC 3+) second line UC patients, disitamab vedotin generated best ORR of 60.5% (26/43), confirmed ORR of 51.2%, and median PFS of 6.9 months. In comparison, in reported studies, the second line UC patients on PD-1/PD-L1 therapy had ORR of 20-30% and median PFS of two to three months. Although these were not head-to-head studies, we believe that valuable insight can nonetheless be drawn from the comparison. These results revealed a clinically meaningful response to our disitamab vedotin among GC and UC patients whose previous treatment failed, which is a population with high unmet medical needs. In addition, disitamab vedotin has also demonstrated favorable safety profile in these trials.

We are executing a comprehensive set of clinical development programs for disitamab vedotin targeting a variety of HER2-expressing cancer types. In China, we are currently evaluating disitamab vedotin in registrational studies in both GC and UC. We plan to file NDAs with the NMPA for disitamab vedotin in the third quarter of 2020 for GC and in the first half of 2021 for UC. In addition, we have the NMPA's approval for conducting a Phase III trial of disitamab vedotin in HER2 low-expressing BC and are currently in the process of enrolling patients in this trial.

Leveraging the robust efficacy and favorable safety data observed in our trials in China so far, we are actively exploring overseas trial opportunities for disitamab vedotin. In the U.S., the FDA has already provided clearance for us to proceed with a Phase II trial of disitamab vedotin in UC in the U.S. and we plan to initiate this Phase II trial in the first quarter of 2021. Disitamab vedotin has also received orphan drug designation from the FDA for GC. In the meantime, we plan to initiate a bridging trial in GC patients in the first half of 2021 in the U.S. to seek expedited approval.

Late-stage HER2-targeted ADC drugs, especially the few (including our disitamab vedotin) that target a broad range of solid tumors at varied HER2 expression levels, represent substantial commercial value, in light of AstraZeneca's commitment in March 2019 to pay up to US$6.9 billion to its Japanese partner Daiichi-Sankyo for the right to co-develop and co-commercialize trastuzumab-deruxtecan (DS-8201), which is a HER2-targeting ADC and received FDA approval for HER2-positive/high-expressing BC in December 2019. To support our global strategy for the development and commercialization of disitamab vedotin, and given its large addressable patient population globally, we may consider pursuing international partnership opportunities in regions outside China.

Potential first-in-class VEGF/FGF dual-targeting fusion protein (RC28) targeting ophthalmic diseases with huge market potential

RC28 is a potential first-in-class fusion protein targeting both vascular endothelial growth factor (VEGF) and fibroblast growth factor (FGF). We are developing RC28 for the treatment of hard-to-treat ocular diseases, including wet age-related macular degeneration (wet AMD), diabetic macular edema (DME) and diabetic retinophathy (DR). As the current standard of care treatments for wet AMD and DME are all VEGF single-targeted agents, we believe that RC28 has the potential to be a best-in-class biologics for these diseases by inhibiting VEGF and FGF pathways simultaneously.

AMD is a medical condition characterized by the abnormal growth of blood vessels in the retina. Wet AMD is the most serious form of AMD and is a leading cause of blindness among senior patients globally. According to Frost & Sullivan, the number of wet AMD patients in China and the U.S. reached 3.6 million and 1.8 million in 2019, respectively, and the number is estimated to grow to 4.9 million and 2.1 million by 2030, respectively. With the global aging population, this therapeutic area represents a sizable market with significant growth potential. The current biological treatment approved for wet AMD in China and the U.S. include ranibizumab, aflibercept, conbercept and brolucizumab, all of which are VEGF single-targeted biologics.

Our Co-Founder, CEO and CSO, Dr. Jianmin Fang, is the inventor of conbercept, an anti-VEGF fusion protein and the first domestically-developed biologic drug approved for wet AMD in China. Conbercept achieved RMB1.2 billion in sales in 2019, according to Frost & Sullivan. Leveraging Dr. Fang's successful experience in developing conbercept, we have designed and differentiated RC28 and have gained its competitive advantages through:

(i) dual-targeting mechanism that overcomes the major challenge faced by single-target VEGF antagonists, which is the upregulated expression of other pro-angiogenic factors when the VEGF pathway alone is inhibited; and

(ii) potentially less frequent dosing schedule due to a long half-time pharmacokinetic profile that could translate to reduction in treatment costs and improved compliance.

In a Phase I study in China, RC28 has demonstrated its good safety in wet AMD patients up to single dose of 2 mg. Based on the encouraging results from this Phase I study, we have initiated a Phase Ib trial in wet AMD patients and plan to further evaluate RC28 for the treatment of other prevalent ocular indications, such as DME and DR, to address the medical needs of larger population.

A proprietary R&D engine pursuing breakthrough science to generate innovative and best-/first-in-class therapeutics

We have built a world-class innovative proprietary R&D engine that spans biology discovery, target selection and validation, drug discovery, research and development. Our R&D engine consists of three specialized platforms enabling a variety of novel biological therapeutics. These include:

(1) an antibody and fusion protein platform, featuring generation of novel monoclonal antibodies and fusion proteins through our internal studies. We can generate high affinity monoclonal antibodies in house using various technologies, including murine hybridoma, human B cell cDNA phage-display library and llama nanobody phage-display library. We have extensive capabilities in bioinformatics-aided protein design and engineering for Fc fusion proteins. We humanize antibody sequences to generate murine antibodies by hybridoma technology. We have generated a number of monoclonal antibody molecules using these technologies, some of which have been advanced to preclinical development stage as our drug candidates or for the use in companion diagnostic kits;

(2) an ADC platform, featuring fully-integrated in-house capabilities covering the whole process of ADC development and manufacturing, including the syntheses of antibody, linker and chemotherapy payload. For each ADC drug candidate, we screen a large panel of combinations of conjugation methods, linkers and payloads to optimize molecular composition. We developed a proprietary Thiel-bridge conjugation technology to yield more homogeneous ADC products that can improve pharmacodynamics and increase therapeutic window. We also have global GMP-compliant manufacturing facility for entire ADC manufacturing process, including antibody production, syntheses of payloads, linkers, and payload-linkers, ADC conjugation, and fill/finish; and

(3) a bifunctional antibody (HiBody) platform, featuring cutting-edge design and engineering capabilities for next-generation bifunctional antibodies with significant potential for future exploration. This bifunctional antibody (HiBody) technology is based on novel molecular format and is versatile in generating various bispecific antibodies. Using this novel molecular format, we have constructed a number of bifunctional antibodies and have three IND-enabling drug candidates in pipeline (RC138, RC148, and RC158). For many bispecific platforms, manufacturability is a key issue that often results in project failure. Our HiBody products have shown high expression level in our system and have constantly had product yield similar to conventional antibodies. The products from this HiBody platform is homogeneous and easy to adapt to our manufacturing process. We have filed an invention patent application for the molecular format of HiBody with broad claims.

Leveraging our proprietary R&D platforms, our team is strategically focused on the research and development of novel biologic drugs with first-in-class and/or best-in-class potential. We have established a new R&D center in Shanghai, a main hub for new drug research and development in China, which helps us to tap and leverage China's best R&D talent pool. We also plan to establish an early-stage drug R&D center in California of the United States, which will help us to scout for and develop the most cutting-edge early-stage programs. These R&D centers will work and interact closely with our headquarters and R&D center in Yantai, and will allow us to strengthen and flex our innovative drug development prowess on a global scale. Led by Dr. Fang with his successful track record of innovative biologic drug development at renowned research institutions and biopharmaceutical companies, our R&D team consists of over 280 members, spanning all the key biologic drug development functionalities as of the Latest Practicable Date. As of the Latest Practicable Date, 55% of our R&D team members hold masters or doctorate degrees in life science related majors.

Utilizing our proprietary platforms, our R&D team has developed a robust pipeline of more than ten novel biologic drug candidates targeting hard-to-treat therapeutic areas of autoimmune diseases, oncology and ophthalmology with significant unmet medical needs both in China and globally. Among these candidates, we have developed five clinical-stage assets, and they are in different stages of clinical development stages that ensure a steady stream of market launches in the coming years. These five drug candidates had been or are currently in over 30 clinical trials spanning 17 indications. In addition to our three core drug candidates (telitacept, disitamab vedotin and RC28), we are also conducting early clinical studies to evaluate RC88 (an anti-mesothelin ADC) and RC98 (an innovative PD-L1 monoclonal antibody), both targeting solid tumors with the potential for combination therapies.

Our R&D engine has enabled us to develop pre-clinical drug candidates that feature both target and design novelty and offer us foreseeable upside potential going forward. Three of our pre-clinical assets are innovative bifunctional antibodies discovered and developed on our proprietary HiBody platform. The most advanced asset among them, RC138, is a next-generation bifunctional fusion protein composed of a monoclonal antibody and a decoy receptor, and it is being developed for the treatment of a variety of solid tumors. We expect to file an IND application for RC138 in China in 2021.

Furthermore, we actively seek and leverage partnership opportunities with preeminent academic researchers and institutions as we pursue and transfer cutting-edge biological and medical sciences. Since January 2011, we have established academic partnerships and entered into a joint development agreement with Tongji University, a top research institution in China, for the research and development of our RC28. Through this collaboration, we developed and optimized the VEGF/FGF dual-targeting fusion protein and solved many challenges during development. RC28 is now being studied in a Phase Ib clinical trial in wet AMD in China.

Integrated in-house capabilities that well position us for biomedical innovation from bench to bedside

We have built a fully-integrated, end-to-end biological therapeutics platform that encompasses all the key biologic drug development functionalities, including not only early-stage drug discovery and development, but also clinical development, regulatory affairs, manufacturing and commercialization. The full integration of these functionalities allows us to bring our drug candidates efficiently from bench to bedside, and it also enables us to identify and address potential clinical, manufacturing and commercial opportunities as well as issues early in the development process, so we can direct our efforts towards molecules with the best potential to become clinically active, cost-effective and commercially viable drugs. Our platform also allows us to carry out process validation and product manufacturing, maintain consistent quality control, and redeploy resources quickly to prioritize our more promising assets and development programs.

Our success has in a large part been driven by our strong clinical development capability and outstanding clinical results of our innovative drugs. We have achieved these through both rigorous trial design and trial operational excellence. Led by our Chief Medical Officer, Dr. Ruyi He, the clinical development function of our fully-integrated platform consists of approximately 200 employees as of the Latest Practicable Date. The team manages our clinical trials and carries out a comprehensive suite of clinical development activities, including clinical trial design, implementation, and the collection and analysis of trial data. We maintain control and oversight over these key functions of clinical trials while partnering with globally reputable CROs for trial execution. We also employ in-house translational medicine research to discover and validate biomarkers, direct patient selection, monitor treatment responses in clinical trials, and analyze clinical data to guide the design and execution of preclinical studies. More importantly, our clinical development team discovers and explores often unanticipated clinical opportunities. For instance, telitacicept's application in NMOSD and disitamab vedotin's application in UC (among other HER2-expressing indications) were discovered and explored during the products' respective early-stage clinical development and now indicates substantial potential to address unmet medical needs.

To support the global clinical development strategy for our rich product pipeline, we have built a seasoned team of regulatory affairs specialists with rich experience in communicating and cooperating with global drug regulatory agencies. Leveraging Dr. He's unique experience working for nearly 20 years in leadership positions with the FDA in the U.S. and the NMPA in China, we have accumulated substantial expertise at and familiarity with regulatory review

requirements and processes both in China and abroad, including the approval and conduct of registrational trials in the U.S. and Europe. Since our inception, we have submitted ten IND applications for five drug candidates and have obtained approvals for all applications, including two IND applications which received clearance from the FDA in the U.S. for telitacept and disitamab vedotin. With efficient communication with the FDA, we were able to convince the FDA to skip early phase studies for telitacept and disitamab vedotin in the U.S. and clear our IND application for a Phase III trial for telitacept and potential registrational trial for disitamab vedotin. In addition, the NMPA has accepted our NDA in China for our telitacicept in November 2019 and granted it priority review in the following month.

Our industry-leading manufacturing capabilities boast global GMP-compliant and world-class manufacturing facilities with six 2,000L disposable bag bioreactors for a total capacity of 12,000L for large-scale recombinant protein production. Our existing GMP facility for commercial manufacturing is capable of an annual output of up to 2.3 million vials of antibodies and up to 1.5 million vials of ADCs. With these capabilities and experiences, we have established a successful track record of manufacturing five drug candidates in-house.

To prepare for the anticipated commercialization of telitacicept, we are building a strong sales and marketing team that is expected to consist of around 100 members with rich sales experience in the autoimmune areas. The team is expected to further expand to 200 members in the second 12-month period after we commence market launch of telitacicept. We will also build a separate team for oncology and we expect the team to be well positioned to target the right markets with high operational efficiency. In addition, we benefit significantly from our management team's successful experience with founding and operating RC Pharma, our strategic partner and a leading pharmaceutical company in China. Among other invaluable assets, our management team brings us nearly three decades of substantial operational, managerial and commercialization experience, resources and expertise, especially market access and distribution resources that are often valuable and can be leveraged to accelerate the build-out of our own commercialization infrastructure.

We have built our fully-integrated platform with a global vision for our business operations and drug products. Encouraged by the promising clinical results and substantial addressable markets for our lead products including telitacicept and disitamab vedotin, our clinical development team is currently implementing global clinical development programs for them. In the meantime, our regulatory affairs and commercialization teams have invested significant resources in seeking regulatory filings, marketing approvals and eventually successful commercial launches for these products in major markets both in and outside of China. Finally, our management team has been actively seeking strategic partnership opportunities with global leading pharmaceutical companies to maximize the clinical and commercial value of these potential first-in-class and/or best-in-class drug products.

A visionary management team with rich industry experience and scientific expertise and backed by leading healthcare investors

We are led by our visionary management team with an average of more than 20 years of industry experience and proven track records of innovative drug R&D, clinical development and commercialization.

Dr. Jianmin Fang, our Co-Founder, CEO and CSO, has over 20 years of fruitful experience in biopharma R&D and over 40 drug invention patents. Dr. Fang obtained a Ph.D. in biology from Dalhousie University, Canada, and received post-doctoral training in Harvard Medical School. Among his many roles, he is a member of scientific expert committee of the National Scientific and Technological Major Project for "Major Drug Innovation" ("重大新藥創制"國家科技重大專項) of China. He is the inventor for our core products including telitacicept, disitamab vedotin and RC28, as well as conbercept, which was the first domestically-developed wet AMD biologic drug in China. Having received approvals for wet AMD in 2013 and pathological myopia choroidal neovascularization (pmCNV) in 2017, conbercept has an over 40% market share of anti-VEGF therapeutics in China in 2019. Dr. Fang is one of the few founders in China's biopharmaceutical industry with successful track record of progressing novel drug from discovery through commercialization.

Mr. Weidong Wang, our Co-Founder and Chairman, brings us 25 years of entrepreneurial, operational and managerial experience in the pharmaceutical sector. Mr. Wang founded and managed RC Pharma, a top Chinese pharmaceutical company for the development, production, marketing and sales of traditional Chinese medicine. Mr. Wang has been dedicated to the Company's entry into innovative biologics development since 1997. Mr. Wang was recognized as the Entrepreneurs with Outstanding Contribution in Shandong Province, China, and he was elected a Representative of China's 13th National People's Congress.

Dr. Daotian Fu, our President, was previously the vice president and executive director of Livzon Pharmaceutical Group and also the general manager of Livzon MABPharm, Inc., a biologics development company. At Livzon, he led the biologics development efforts with one successful NDA submission and multiple programs in clinical development. Dr. Fu returned to China after spending 28 years working in the biopharmaceutical industry in the U.S. Between 1998 and 2012, he served as the vice president of R&D at Genzyme Corp., one of the top five global biotech companies (later acquired by Sanofi). During this period, Dr. Fu was responsible for CMC development of clinical stage programs, and was directly involved in global launching of five major biologics and clinical development of multiple R&D programs. Dr. Fu received his B.S. from Shandong University in China, and his Ph.D. from Iowa State University.

Dr. Ruyi He, our Chief Medical Officer, is one of the most authoritative experts in China in the areas of clinical development and global regulatory regimes for medical products. He brings us nearly 20 years of experience working at the FDA in the U.S. and the NMPA in China. In the more than 17 years with the FDA, he held a number of strategic leadership positions and chaired several working groups that were tasked with drafting and finalizing guidelines for the pharmaceutical industry. He was also involved in FDA guidance development in multiple therapeutic areas. In China, Dr. He was Chief Scientist at the Center for Drug Evaluation (CDE) of the NMPA where he led multiple important policy initiatives. In addition to his policy-making roles with both the FDA and the NMPA, Dr. He also gained first-hand experience reviewing and approving numerous applications for INDs and NDAs in both the U.S. and China. A prolific author, Dr. He has also published more than 20 research papers and abstracts in the fields of drug regulatory science and internal medicine. Dr. He received his medical degree from China Medical University. He completed his intern and residency training in Internal Medicine at Howard University Hospital in Washington, D.C. He received his clinical research training at the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) at the National Institutes of Health (NIH) in Bethesda, Maryland. Dr. He is a licensed, board-certified physician in internal medicine in the U.S.

We have also established our Scientific Advisory Board which currently comprises five renowned professors and key opinion leaders in the areas of our research and development, including Dr. Gang Pei, Dr. Jianmin Fang, Dr. Ruyi He, Dr. Marsha A. Moses and Dr. Lorne Babiuk. Members of our Scientific Advisory Board routinely meet or communicate with us and provide us with advisory services including advice in respect of our business strategies and objectives, academic updates and technical insights relevant to our research and development plans, recommendations relating to innovative drug targets, mechanisms and modalities, and advice on new drug discovery projects, as well as biopharmaceutical market data and intelligence.

Dr. Pei, a world-leading expert in the area of GPCR research, is an academician of the Chinese Academy of Sciences, and the former president of Tongji University and Shanghai Institute of Biological Sciences of Chinese Academy of Sciences. With more than 150 research publications on international academic research journals, Dr. Pei serves for many professional societies in China and around the world, such as Chinese Society of Cell Biology, the World Academy of Sciences, the Consortium for Globalization of Chinese Medicine, and the Editor-in-Chief of the renowned scientific journal "*Cell Research*."

Dr. Moses is the Julia Dyckman Andrus Professor at Harvard Medical School and the Director of the Vascular Biology Program at Boston Children's Hospital. Dr. Moses has published work in Science, The New England Journal of Medicine, Cell, PNAS and Nature Communications, among other journals, and has made significant contributions to our understanding of the biochemical and molecular mechanisms that underlie the regulation of tumor development and progression. Dr. Moses has been named a pioneer in the field of Biomarker Medicine by the Journal of the National Cancer Institute and has been elected to the Institute of Medicine (National Academy of Medicine) of the National Academies of the United States.

Dr. Babiuk is a Canadian scientist and a global authority in immunology, pathogenesis, virology, molecular virology, and vaccinology. He was the former Vice-President of Research at the University of Alberta and the former Director of the Vaccine and Infectious Disease Organization at the University of Saskatchewan. Dr. Babiuk has published over 500 manuscripts and has trained over 100 Ph.D.s and post-doctoral fellows. Dr. Babiuk has been awarded or made a Fellow of the Royal Society of Canada, the Saskatchewan Order of Merit, an Officer of the Order of Canada, and the Gairdner Foundation Wightman Award, among many other honors and awards.

Our shareholders consist of leading healthcare investors, including renowned global institutional investors, such as Lilly Asia Ventures and Lake Bleu Capital, and reputable domestic investors, providing us with industry expertise and vital connections to the pharmaceutical sector in China and worldwide.

OUR STRATEGY

Our mission is to discover, develop, manufacture and commercialize innovative biologic drugs to address unmet medical needs in the major therapeutic areas of autoimmune diseases, oncology and ophthalmology for patients worldwide. Our vision is to become a leading player in the global biopharmaceutical industry. To achieve our mission and vision, we intend to execute the following strategies.

Rapidly advance the development and commercialization of our existing pipeline products, primarily focusing on obtaining marketing approvals and launching commercial sales of our core products

Obtain marketing approval and launch telitacicept (RC18) for the treatment of SLE in China in fourth quarter of 2020.

Telitacicept is a first-in-class and potential best-in-class drug candidate targeting various B cell-mediated autoimmune diseases. Our NDA for telitacicept for the treatment of SLE was accepted by the CDE of the NMPA in November 2019 and was granted priority review the following month. We expect to obtain conditional marketing approval and commence commercial sales of telitacicept in the fourth quarter of 2020. We have started preparing for the commercial launch of this product. We have assembled our sales and marketing leadership team, and expect to build a sales and marketing team consisting of around 100 members with extensive expertise in the field of autoimmune diseases by 2020.

In the meantime, we will continue to advance telitacicept in clinical trials for other indications, including NMOSD (a rare disease), RA, IgAN, SS, MG (a rare disease) and MS (a rare disease). We strive to obtain marketing approvals for these indications as early as possible, which will allow us to establish comprehensive competitive advantages in China's autoimmune disease market.

Advance the clinical development of disitamab vedotin (RC48) towards commercialization across a variety of solid tumor types.

Disitamab vedotin is a potential best-in-class HER2 ADC. We are finalizing a registrational clinical study for GC in China and plan to submit an NDA to the CDE of the NMPA for conditional approval in the third quarter of 2020. With respect to the registrational clinical study in UC, we expect to complete patient enrollment in the second half of 2020 and plan to submit an NDA in the first half of 2021. Furthermore, we will also advance the Phase III clinical studies for HER2 low-expressing BC and clinical trials for other solid tumors as planned. We are currently building a specialized oncology marketing team based on the progress of clinical trials and regulatory reviews.

Advance clinical development of RC28 in various ophthalmic diseases.

RC28 is a next-generation dual inhibitor of VEGF and FGF designed by our Co-Founder, CEO and CSO and conbercept's original inventor, Dr. Jianmin Fang. It is developed for the treatment of wet AMD, DME, DR and other potential indications. The product is the first VEGF/FGF dual-targeting drug candidate worldwide to be in clinical trials and has the potential to become best-in-class. We are currently conducting a Phase Ib clinical trial for wet AMD and plan to initiate Phase II clinical trials for DME and DR in the second half of 2020 and 2021, respectively, in China.

Continuously advance clinical trials of other products by leveraging our outstanding in-house clinical research and development capabilities.

We have a clinical development team of approximately 200 members with rich experience and abundant resources as of the Latest Practicable Date. In addition to developing our core products, we are also carrying out clinical trials to evaluate RC88 (an innovative anti-mesothelin ADC) and RC98 (an innovative PD-L1 monoclonal antibody) and may conduct clinical trial to evaluate their combination therapies, in order to realize their substantial clinical value and potential.

Leveraging our advanced and reliable proprietary technology platforms, we have been able to continuously enrich our drug pipeline. Over the years, we established technology platforms for antibody and fusion protein, ADC and bifunctional antibody (HiBody), and have developed the above-mentioned core products and other products in the pipeline. We will continue to leverage these technology platforms to design and create new molecules with innovative mechanisms and novel targets. That would allow us to enrich our product pipeline, and we expect to submit IND applications for one to two drug candidates each year to ensure our sustained growth.

Execute our well-planned and organized global strategy

It is our vision to become a leading player in the global biopharmaceutical industry. In order to achieve this strategic goal, we are committed to accomplishing the following.

Actively carry out global multi-center clinical trials for our core products.

With the global planning for our products and an overall global strategy, we are determined to initiate global multi-center clinical trials for our products.

- **Telitacicept:** In January 2020, the FDA held a meeting with us, where we were allowed to conduct the global Phase III clinical trial of SLE in the U.S. based on the clinical trial data used in our NDA for SLE in China. On April 15, 2020, the FDA granted Fast Track designation for telitacicept. We have also communicated with the EMA and submitted our application for a Phase III clinical trial in SLE in Europe. We expect to initiate global multi-center Phase III clinical trials in multiple

jurisdictions including the U.S., Europe and other countries in the first half of 2021. Meanwhile, we will also conduct global multi-center Phase II/III clinical trials for other indications as we have planned, and we seek to obtain marketing approvals as soon as possible.

- **Disitamab vedotin**: This product has been granted orphan drug designation for GC by the FDA in July 2018. For UC, we held a pre-IND meeting with the FDA in December 2019 and obtained the FDA's clearance to proceed with a Phase II clinical trial in April 2020. Therefore, we expect to initiate the global clinical trial for HER2-expressing UC in the first quarter of 2021. In the meantime, we plan to initiate a bridging study for disitamab vedotin for GC in the U.S. in 2021 to seek expedited approval. In addition, we are also considering and planning global multi-center clinical trials of HER2 low-expressing BC and other indications.

- For our RC28 and other innovative drug candidates in our pipeline, we are also designing their clinical trial development plans with the considerations with going global in the near future. Depending on the development status of our candidates in the future, we also plan to submit IND applications for our drug candidates at appropriate times for global multi-center clinical trials to explore their clinical value and implement our global strategy.

- We are building out a strong clinical operation team that is led by our Chief Medical Officer (CMO), Dr. Ruyi He, and possesses rich experience in carrying out global multi-center clinical trials. This team will be responsible for planning and high-quality execution of clinical trials by closely working with multinational collaboration partners, CRO companies and principal investigators.

Implement a global registration strategy to achieve commercialization of our products globally.

Advancing the global registration plan for our pipeline products is a critical aspect in the implementation of our global strategy. Therefore, we are building a regulatory affairs team led by Dr. Ruyi He to cover China and overseas markets. This team will formulate a global registration strategy and detailed working plan for all the products in our pipeline according to their different stages of development. This team will also coordinate and systematically push forward the regulatory review processes in and outside of China, and will oversee the submission of IND applications and NDAs/BLAs in a timely manner to facilitate our drug candidates' accelerated entry into clinical trials and ensure a smooth path to commercialization. Meanwhile, we intend to also strengthen the protection of our intellectual property rights by prosecuting patent applications and enhancing patent protection for our pipeline assets in major overseas markets as planned.

Actively seek commercial partnerships with global pharmaceutical companies to maximize the clinical and commercial value of our pipeline products.

Two of our core products, telitacicept and disitamab vedotin, are both potential first-in-class/best-in-class drug candidates with great clinical value and commercial potential. We are actively communicating with the world's leading multinational pharmaceutical companies that could bring significant strategic synergy with us in the pursuit of potential opportunities for strategic collaboration, in order to gain reasonable commercial returns and expedite the clinical use of our products globally. We are assembling a seasoned international commercialization team with extensive industry experience. In addition to our ongoing business discussions with respect to the two core products, we will also introduce other assets in our pipeline to the global market, explore licensing or acquisition of valuable assets in our interested fields and carry out collaborations with domestic players.

Expand our global footprint and enhance our all-around drug discovery and development capabilities.

Our core competencies lie in our capabilities to design and discover new molecules with novel targets and novel mechanisms of action and develop them into drugs, and we have made remarkable achievements so far. In the future, we will continue to strengthen these capabilities. We plan to establish an R&D center in California, the U.S. in order to take advantages of the abundant resources of talents, technology, information and supply chain in the U.S. This R&D center will focus on drug discovery activities to help feed and sustain the continued growth of our drug pipeline and will be tasked with developing blockbuster drugs with competitive advantages at the global level. At the same time, we aim to enhance the synergy among our Yantai headquarters, Shanghai R&D center and the U.S. R&D center. We will design an R&D roadmap and reasonably allocate the resources among our R&D centers to achieve efficiency and significantly enhance our drug discovery capabilities.

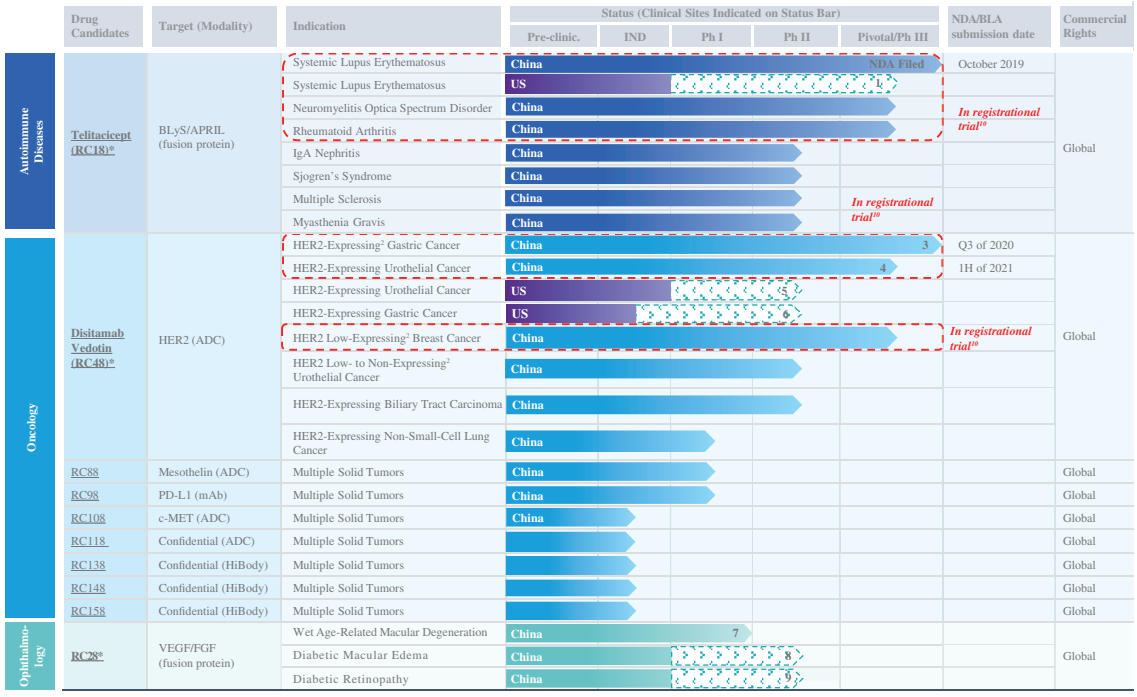
Scale up manufacturing capacity to meet the needs of global clinical studies and commercial sales

With the support of the local government to the biopharmaceutical industry, an investment-friendly environment, and sufficient and cost-effective supply of land and manpower in Yantai, Shandong, we believe that we are in an ideal location for the production of large molecule biologics. We plan to establish our global GMP-compliant manufacturing and supply base for the domestic market and global trials in our headquarters in Yantai. We intended to increase our antibody manufacturing capacity to 36,000L by 2021 and to 80,000L by 2025. In the first quarter 2020, we purchased the use right to land with an aggregate area of 81,038 m^2, and we have started construction of new manufacturing facilities. According to the schedule of our construction project, we plan to complete the construction of the first stage of new manufacturing facilities by 2022 and use those new facilities to manufacture drug products for telitacicept's global multi-center clinical trial, and we expect to complete the entire construction project by 2025. Upon the completion of new facilities together with our existing manufacturing facilities, we plan to increase our total antibody manufacturing capacity to an annual output of up to 9.3 million vials for antibodies and an annual output of up to 7.5 million vials for ADCs. We will reasonably manage the schedule of these new construction projects according to the development status and commercialization plan of our pipeline products.

OUR DRUG CANDIDATES

We strategically focus on the discovery, research and development (R&D) and commercialization of innovative biologics mainly in the therapeutic areas of autoimmune diseases, oncology and ophthalmology. Leveraging our strong capabilities in drug discovery, research and development, we have built a robust pipeline of more than 10 drug candidates. Among our drug candidates, five have entered into clinical trials targeting 17 indications. Two of our five clinical-stage drug candidates, telitacicept, a novel TACI-Fc fusion protein, and disitamab vedotin, a novel anti-HER2 antibody-drug conjugate (ADC), are currently being evaluated in a total of six registrational clinical trials for various indications, and both drug candidates have demonstrated the potential to become first-in-class and/or best-in-class therapies. For telitacicept, we have submitted an NDA in China for the first indication (SLE), and the NMPA has accepted the NDA in November 2019 and granted us priority review in the following month.

With technologies and industry know-how accumulated over ten years, we have established a world-class biopharmaceutical discovery and R&D platform which serves as the foundation of our continuous innovations. Our discovery and R&D platform consists of three proprietary specialized platforms, including an antibody and fusion protein platform, an ADC platform and a bifunctional antibody (HiBody) platform. Leveraging these platforms, we have developed a robust pipeline of drug candidates. The following chart illustrates our pipeline and summarizes the development status of clinical-stage drug candidates and selected IND-enabling stage candidates as of the Latest Practicable Date:



* Denotes our core drug candidates.

Abbreviations: 1H = first half; ADC = antibody drug conjugate; HiBody = a novel bifunctional antibody; mAb = monoclonal antibody; Q3 = third quarter

Notes:

(1) The FDA has provided clearance for us to proceed with the Phase III clinical trial of telitacicept for SLE in the U.S in January 2020 and granted telitacicept Fast Track designation in April 2020.

(2) HER2-expressing refers to a HER2 status of tumor cells identified with a test score of IHC 1+ or above. HER2 low-expressing refers to a HER2 status of tumor cells identified with a test score of IHC 1+ or IHC 2+/FISH-. HER2 non-expressing refers to HER2 status of tumor cells identified with a test score of IHC 0.

(3) In China, we are (i) finalizing a Phase II registrational trial to evaluate disitamab vedotin as monotherapy for the treatment of HER2 over-expressing (IHC 2+ or IHC 3+) gastric cancer (GC), and (ii) conducting a Phase I clinical trial to evaluate distamab vedotin in combination with PD-1 inhibitor for the treatment of HER2 over-expressing GC.

(4) In China, we are conducting (i) a Phase II registrational trial to evaluate disitamab vedotin as monotherapy for the treatment of HER2 over-expressing (IHC 2+ or IHC 3+) urothelial cancer (UC), and (ii) a Phase Ib/II trial to evaluate disitamab vedotin in combination with PD-1 inhibitor for the treatment of UC.

(5) The FDA has provided clearance for us to proceed with the Phase II clinical trial of disitamab vedotin in the U.S in April 2020.

(6) We have initiated pre-IND discussion with the FDA to obtain their consents for disitamab vedotin's Phase II clinical trial in GC in the U.S.

(7) We have completed a Phase I trial of RC28 in wet age-related macular degeneration (wet AMD) in August 2019 in China, of which the primary endpoint of safety was met. In July 2018, we obtained the NMPA's approval for us to conduct Phase I, II and III trials of RC28 according to our clinical development plan and progress, and the NMPA has not raised any objections towards our clinical trials of RC28 since then. We are currently conducting a Phase Ib trial of RC28 to further evaluate its efficacy and safety for the treatment of wet AMD.

(8) We plan to initiate a Phase II trial for RC28 in diabetic macular edema in the second half of 2020 in China.

(9) We plan to initiate a Phase II trial for RC28 in diabetic retinopathy in the second half of 2020 in China.

(10) Registrational trial, or pivotal trial, means the clinical trial or study to demonstrate clinical efficacy and safety evidence required before submission for drug marketing approval.

Our Core Drug Candidates

Telitacicept (RC18)

Telitacicept is a proprietary novel fusion protein of us to treat autoimmune diseases. It is constructed with the extracellular domain of the human transmembrane activator and calcium modulator and cyclophilin ligand interactor (TACI) receptor and the fragment crystallizable (Fc) domain of human immunoglobulin G (IgG). Telitacicept targets two cell-signaling molecules critical for B-lymphocyte development: B-cell lymphocyte stimulator (BLyS) and a proliferation inducing ligand (APRIL), which allows it to effectively reduce B-cell mediated autoimmune responses that are implicated in several autoimmune diseases.

We are currently evaluating telitacicept in late-stage clinical trials in order to explore its potential to address seven autoimmune diseases, in an attempt to address the significant unmet or underserved medical needs in this therapeutic area. The chart below shows the indications for which we are currently evaluating telitacicept in clinical trials:

	Status					
		Phase I				
Indication[1]	IND (Accepted)	Ia	Ib	Phase II	Pivotal/ Phase III	NDA/BLA (Filed)
China						
SLE[2]	●	●		● (pivotal) ◑ (post-launch confirmatory)		●
NMOSD	●				◑	
RA[2]	●	●	●	●	◑	
SS	●			◑		
IgAN	●			◑		
MS	●			◑		
MG	●			◑		
U.S.						
SLE	●				◔	

Abbreviations: IgAN = IgA nephropathy; MG = myasthenia gravis; MS = multiple sclerosis; MTX = methotrexate; NMOSD = neuromyelitis optica spectrum disorder; RA = rheumatoid arthritis; SLE = systemic lupus erythematosus; SS = Sjögren's syndrome.

Symbols: ● = complete; ◑ = in progress (a clinical trial is deemed to have been initiated when we submit trial design and protocol to apply for ethical approval); ◔ = to be initiated

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. Based on the encouraging safety data from our clinical trials in SLE and RA, we advanced the clinical studies of telitacicept for SS, IgAN, MS and MG to Phase II stage. In addition, as NMOSD is a rare disease with highly unmet medical needs and based on our communication with the NMPA, we skipped the early clinical studies and initiated a Phase III trials in NMOSD.

(2) These trials evaluate telitacicept in patients with moderate to severe SLE who have an inadequate response to standard of care (SOC), and patients receive telitacicept plus SOC in the experimental group of these trials.

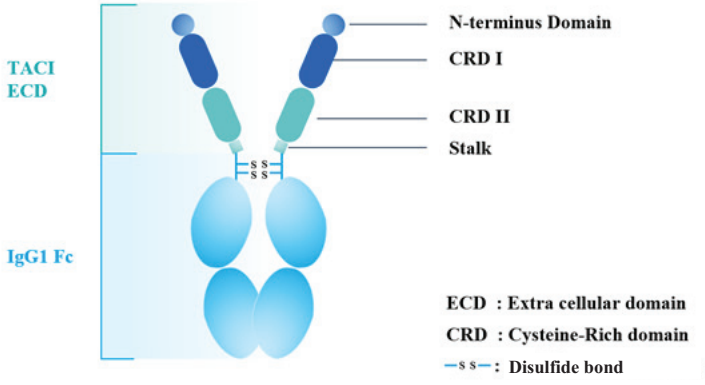
(3) These trials evaluate telitacicept in patients with moderate to severe RA who have an inadequate response to methotrexate (MTX) therapy, and patients receive telitacicept plus MTX in the experimental group of these trials.

Telitacicept demonstrated encouraging efficacy and safety results in SLE patients from our recently completed Phase IIb registrational trial in China. The NMPA accepted our NDA for telitacicept for the treatment of SLE in November 2019 and granted us priority review in December 2019 and we expect to receive conditional approval to market telitacicept for the treatment of SLE in the fourth quarter of 2020. The approval will be conditional on a commitment to complete a confirmatory Phase III trial in SLE post the commercial launch, and we are currently in the process of enrolling patients in this Phase III trial.

In parallel with the clinical development and regulatory process in China, we plan to also carry out a global clinical development plan for telitacicept in order to maximize its therapeutic and commercial value. We expect to initiate global Phase III clinical trials in the first half of 2021 to cover multiple jurisdictions, including the United States, Europe and other countries. On April 15, 2020, the FDA granted Fast Track designation to telitacicept, which could expedite the review and potential approval process with the FDA. With Fast Track designation, the frequency of communication assures that questions and issues are resolved quickly, often leading to earlier drug approval and access by patients.

Mechanism of Action

As illustrated by the diagram below, telitacicept is a novel recombinant fusion protein designed to simultaneously target two important cell-signaling molecules, B-cell lymphocyte stimulator (BLyS) and a proliferation inducing ligand (APRIL).



Source: Company data

BLyS (also known as B-cell activating factor, or BAFF) and APRIL are both involved in the development of B cells from pre-B lymphocytes to mature B cells, and ultimately to plasma cells, the professional cells producing antibodies, as well as in the co-stimulation of T-cell proliferation under certain conditions. Aberrant B cell activities and antibody production are known to be implicated in a number of autoimmune diseases. BLyS and APRIL function through the following mechanisms:

- BLyS binds to three types of membrane receptors expressed on B-cells, i.e., (1) TACI, (2) B-cell maturation antigen (BCMA) and (3) B-cell activating factor receptor (BAFF-R), to inhibit cell death and stimulate differentiation of B cells into antibody-producing plasma cells. The interaction between BLyS and TACI induces a T-cell independent B-cell activation, immunoglobulin class-switching and B-cell homeostasis, while BLyS' interaction with BCMA is important for the differentiation and survival of plasma cells.

- Unlike BLyS, APRIL only binds to TACI and BCMA (but not BAFF-R) to modulate the function and survival of B cells and promotes their differentiation into plasma cells.

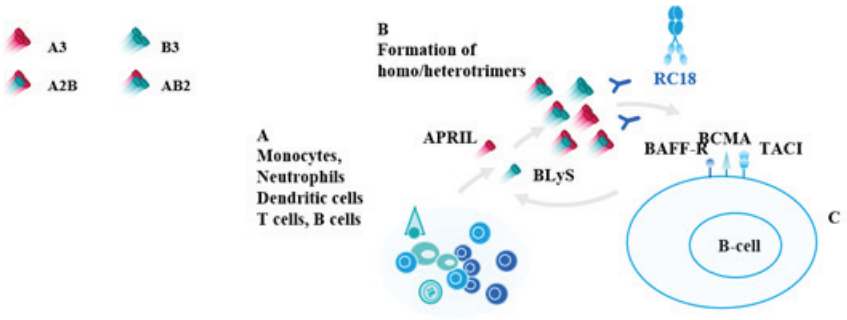
- In sum, whereas BCMA binds to BLyS weakly and BAFF-R does not bind to APRIL, TACI binds to BLyS and APRIL with equal affinity and can also bind to heteromeric forms of BLyS and APRIL.

- BLyS and APRIL also play a role in the co-stimulation of T cells as B cells and T cells cross-talk. For instance, since BAFF-R is a potent T cell co-stimulator, the signalling of BLyS to BAFF-R could promote aberrant T cell maturation, which is known to be implicated in certain autoimmune diseases.

Consistent with their known functionalities, increased BLyS and APRIL expression has been observed in various B cell-mediated autoimmune diseases, such as SLE, NMOSD and RA. Studies have shown that direct inhibition of BLyS and APRIL has the potential to prevent the engagement of their receptors, BAFF-R, TACI and BCMA, and thus to prevent the subsequent activation of B cell-driven mechanisms, such as autoantibody production that contributes to the pathology of autoimmune diseases. BLyS and APRIL have therefore emerged as important targets for autoimmune therapeutics, although most of the clinical-stage drug candidates targeting this signaling pathway have been designed to neutralize either BLyS or APRIL, but not both.

As illustrated in the diagram below, telitacicept blocks BLyS and APRIL from binding to BAFF-R, BCMA and TACI receptors expressed on B-cell surface, suppressing the BLyS and APRIL signaling, and inhibiting the development and survival of mature B cells and plasma cells.

Mechanism of Action for Telitacicept



	B-Cell surface binding sites		
	BAFF-R	BCMA	TACI
BLyS	++	++	+++
APRIL	–	++	++

Abbreviation: A3 = APRIL homotrimers; B3 = BLyS homotrimers; A2B = heterotrimers of two APRIL and one BLyS molecules; AB2 = heterotrimers of one APRIL and two BLyS molecules

Source: Company data

Market Opportunities and Competition

- SLE

We have completed Phase IIb registrational trial of telitacicept for the treatment of moderate to severe systemic lupus erythematosus (SLE). SLE is an autoimmune disease in which the body's immune system mistakenly attacks healthy body tissues, often leading to long-term damage to patient health. Clinical manifestations of SLE range from joint pains and skin rashes to severe organ damage and complications at later stages, such as kidney failure, heart and lung inflammation and central nervous system abnormalities. The disease places a substantial economic burden on the patients due to high healthcare costs and loss of ability to work, and it also imposes considerable negative impact on patients' social functions and quality of life. SLE has one of the highest mortality and disability rates among autoimmune rheumatic diseases.

According to Frost & Sullivan, the global SLE prevalence was approximately 7.7 million in 2019, and it is estimated to reach 8.6 million by 2030. In China, there were approximately 1.0 million SLE patients in 2019, which is estimated to grow to approximately 1.1 million by 2030. Studies also show a tenfold higher prevalence of SLE in women compared to men – predominantly young and middle-aged women (typically within the age band of 15 to 45). According to the Frost & Sullivan, the market size of global SLE biological therapeutics is estimated to grow at a CAGR of 26.8% from US$0.8 billion in 2019 to US$10.8 billion by 2030.

While a large population of SLE patients in China and the world have an urgent need for effective medical treatment, there is no effective cure for SLE and currently available treatments are either limited in efficacy or poorly tolerated in a sizeable group of patients. The medications most commonly used to control SLE symptoms include corticosteroids, anti-malarial agents, non-steroidal anti-inflammatory drugs, immunosuppressants and biologics. Among these medications, although high doses of corticosteroids and immunosuppressants can be helpful in severe cases of SLE, the patients tend to progress and relapse over time and face a high risk of serious side effects, including weight gain, easy bruising, thinning bones (osteoporosis), high blood pressure, diabetes and increased risk of infections. In addition, treatment with immunosuppressants may result in an increased risk of serious infections and certain types of cancer.

As of the Latest Practicable Date, GlaxoSmithKline's Benlysta (belimumab), a BLyS single-targeted therapy and immunosuppressant biologic, is the only FDA-approved biologic therapy for SLE, and the only FDA-approved novel drug for SLE in the last nearly 60 years. GlaxoSmithKline acquired Benlysta along with its developer Human Genome Sciences in 2012 for approximately US$3.6 billion, and reported US$782.8 million in worldwide sales of Benlysta in 2019, including US$683.2 million in the U.S. Benlysta was approved in Europe also in 2011, but has not yet been covered by mainstream medical insurance in Europe. In July 2019, Benlysta was approved by the NMPA to treat SLE in China, and its estimated annual treatment cost in China was around RMB79,040 in 2019 under patient assistance program.

There remains significant unmet needs for new therapeutics for SLE that effectively control disease activity, have a favorable safety profile and improve the patients' quality of life. Despite substantial investments by biopharmaceutical companies in the development of SLE therapies over the years, many drug candidates have failed to show clinical efficacy (especially the late-stage clinical trial results). The table below summarizes the development status of telitacicept and its major global competitors for SLE that are marketed or in Phase III clinical trials as of the Latest Practicable Date.

Molecule	Target	Company	Indication	Status	Initiation Date[1]
		China			
belimumab	BLyS	GlaxoSmithKline	SLE	Marketed	N.A.
telitacicept	BLyS/APRIL	RemeGen	SLE	NDA	N.A.
		Global (Outside of China)			
belimumab	BLyS	GlaxoSmithKline	SLE	Marketed	/
anifrolumab	IFNAR1	AstraZeneca	SLE	Phase III	2015-05
dapirolizumab pegol	CD40L	UCB	SLE	Phase III	2020-03

Note:

1. denotes the first public announcement date of the trial.

Source: Frost & Sullivan Report

- NMOSD:

We are also evaluating telitacicept in a Phase III clinical trial in China for the treatment of neuromyelitis optica spectrum disorder (NMOSD). NMOSD is a central nervous system disorder that occurs when the body's immune system mistakenly attacks against its own cells in the central nervous system, mainly in the optic nerves and spinal cord, but sometimes in the brain as well. These attacks often lead to severe visual loss, and cause limb weakness, sensory loss, and bladder dysfunction. Most NMOSD patients experience relapses in one to three years. With each relapse, the disability can be worsen.

According to Frost & Sullivan, the global prevalence of NMOSD reached 169,300 in 2019 and is estimated to reach 187,600 by 2030, while in China there were 48,300 NMOSD patients in 2019 and that figure is estimated to increase to 52,600 by 2030.

The current standard of care for NMOSD includes corticosteroids. High-dose or long-term use of corticosteroids carries a significant risk of side effects. As of the Latest Practicable Date, Alexion's Soliris (eculizumab) and Viela's Uplizna (inedilizumab) are the two biologic therapies that have been approved by the FDA for the treatment of NMOSD. So far, no biologic therapy has received marketing approval for NMOSD in China.

The table below summarizes the development status of telitacicept and its major global competitors for NMOSD that are marketed or in late-stage clinical trials as of the Latest Practicable Date.

Molecule	Target	Company	Indication	Status	Initiation Date[1]
		China			
telitacicept	BLyS/APRIL	RemeGen	NMOSD	Phase III	2017-10
		Global (Outside of China)			
Soliris (eculizumab)	C5	Alexion	NMOSD	Marketed	N.A.
inebilizumab	CD19	Viela	NMOSD	Marketed	N.A.
satralizumab	IL-6	Roche	NMOSD	BLA	N.A.
ravulizumab	C5	Alexion	NMOSD	Phase III	2019-12

Note:

1. denotes the first public announcement date of the trial.

Source: Frost & Sullivan Report

- RA:

We are evaluating telitacicept for the treatment of moderate to severe rheumatoid arthritis (RA) in a Phase III clinical trial in China. Similar to SLE, RA is an autoimmune disorder that occurs when the body's immune system mistakenly attacks its healthy tissues, affecting twice as many women as men with a mean age of 40-60 years. As a chronic inflammatory disorder, RA can affect the joints and, in some cases, damage a wide range of human body organs, including the skin, eyes, lungs, heart and blood vessels.

RA is the third largest therapeutic area globally in terms of market size, following oncology and diabetes. According to Frost & Sullivan, there were 39.3 million RA patients globally in 2019 and this figure is estimated to increase to 45.0 million by 2030, while RA prevalence in China reached 5.9 million in 2019 and is estimated to reach 6.4 million by 2030.

The current standard of care for RA includes non-steroidal anti-inflammatory drugs, corticosteroids, disease-modifying anti-rheumatic drugs, and subcutaneous biologics. Except for a few targeted therapeutics, the existing medications either lack effectiveness in controlling the diseases or are associated with high risks of serious side effects. The most commonly used biologic therapy in RA patients is AbbVie's Humira (adalimumab), a TNF-α inhibitor, whose efficacy and safety both can be further improved. In 2018, Humira (adalimumab) recorded global sales of US$20.5 billion. Currently, the penetration rate of biologic therapies in China's RA market is extremely low, indicating a significantly unmet medical need and the commercial potential for new RA biologic therapies in China.

As of the Latest Practicable Date, there were ten innovator biologics approved for RA in the U.S. and seven in China. Our telitacicept has entered Phase III clinical trials. For further details, please refer to the paragraph headed "Industry Overview—2. Autoimmune Disease Drug Market—2.4 Rheumatoid Arthritis—2.4.3 Competitive Landscape of Biologics Treatment of RA in the U.S. and in China".

- Sjögren's syndrome:

We are evaluating telitacicept for the treatment of Sjögren's syndrome (SS) in a Phase II clinical trial in China. SS is a female-dominated, autoimmune disorder characterized by autoimmune destruction of moisture-producing glands. It is identified by two most common symptoms, i.e., dry eyes and dry mouth. The condition of SS often accompanies other immune system disorders, such as RA and lupus. The condition is much more common in women, who are affected at a 9:1 ratio in comparison to men, and most patients are older than 40 at the time of diagnosis.

According to the Frost & Sullivan, the prevalence of SS in China was 628,600 in 2019 and is expected to reach 644,900 in 2030, while the prevalence of SS in the U.S. was 198,800 in 2019 and is expected to reach 215,600 in 2030. Though there is no cure for SS, medical treatments, from over-the-counter eyedrops, sipping water, prescription drugs to minor surgical procedures, can help manage the symptoms depending on the parts of body affected.

Currently, no biologics anywhere in the world have been approved for the treatment of SS. As of the Latest Practicable Date, our telitacicept is the only biologic to have entered clinical trials in China in SS. For further details, please refer to the paragraph headed "Industry Overview—2. Autoimmune Disease Drug Market—2.5 Sjögren's Syndrome—2.5.3 Competitive Landscape of Biologics Treatment of SS in the U.S. and in China".

- IgA Nephropathy:

We are evaluating telitacicept for the treatment of IgA nephropathy (IgAN) in a Phase II clinical trial in China. IgAN is an autoimmune disease affecting kidney that occurs when an antibody called immunoglobulin A (IgA) builds up in the kidneys, resulting in local inflammation and damage that, over time, results in a decline in the kidneys' function and ability to filter waste from the blood. IgAN usually progresses slowly over years, but the course of the disease varies from person to person. In some patients, IgAN can eventually lead to end-stage kidney failure.

China has a high prevalence of IgAN, with 2.2 million patients in 2019, and this patient population is estimated to reach 2.4 million by 2030, according to the Frost & Sullivan. There is currently no cure for IgAN, but certain medications can slow its course and control its symptoms, such as blood pressure medicines, corticosteroids, prescription strength fish oil and cholesterol-lowering medicines. This disease most frequently occurs in teenagers and young adults. For these young patients, treatment with corticosteroids generally creates a higher risk of adverse events and negative psychological effects.

Currently, no biologics anywhere in the world have been approved for the treatment of IgAN. As of the Latest Practicable Date, our telitacicept is the only one biologics to have entered clinical trials in China for IgAN. For further details, please refer to the paragraph headed "Industry Overview—2. Autoimmune Disease Drug Market—2.6 Immunoglobulin A Nephropathy—2.6.3 Competitive Landscape of Biologics Treatment of IgAN in the U.S. and in China".

In addition to the above, we are also developing telitacicept for other B-cell mediated autoimmune diseases for which there is a significantly unmet medical need, including multiple sclerosis (MS) and myasthenia gravis (MG). For further details of market opportunities and competition for MS and MG, please refer to the paragraph headed "Industry Overview—2. Autoimmune Disease Drug Market—2.7 Myasthenia Gravis" and "Industry Overview—2. Autoimmune Disease Drug Market—2.8 Multiple Sclerosis" in this document.

Competitive Advantages of Telitacicept

With its significant efficacy and favorable safety profile observed in SLE patients in the China trials, telitacicept has demonstrated the potential to become a global first-in-class and best-in-class biological therapy for SLE. We believe that telitacicept has the following major competitive advantages:

Optimized structure design leads to improved biological activities and productivity

Benefiting from our expertise in structural biology and advanced protein engineering capabilities, telitacicept incorporates almost the full extracellular BLyS/APRIL-binding domain of human TACI. The structural design allows telitacicept to target and neutralize activities of two important B cell-signaling molecules, i.e., BLyS and APRIL. As both BLyS and APRIL are over-expressed in patients suffering from SLE as well as certain other B cell-mediated autoimmune diseases, dual blockade of BLyS/APRIL pathway can be more potent in the treatment of SLE and other B cell-mediated autoimmune diseases than blocking either BLyS or APRIL alone and can have the benefit of inhibiting B cell maturation as well as T cell maturation.

Moreover, employing neural network-based bioinformatics, we have constructed telitacicept in a way that allows it to retain most of the N-terminal and C-terminal domains of the TACI molecule. The bioinformatics-optimized TACI fragment retains human TACI's high binding affinity for BLyS, APRIL and BLyS/APRIL homo/heterotrimers and to preserve its *in vivo* biological functions.

In animal models of SLE, telitacicept's innovative dual-targeting mechanism appears to have generated more pronounced pharmacodynamics effects than a BLyS single-targeting mechanism, suggesting a stronger efficacy profile. In one of our studies, telitacicept led to meaningful reduction in IgM and IgG levels in cynomolgus monkeys, while according to published data, belimumab, a BLyS single-targeting monoclonal antibody, demonstrated less reduction on the same measurements in the monkeys. Our study also found that treatment with telitacicept resulted in a linear, dose-dependent reduction in both IgG and IgM across a dosing range from 6mg/kg up to 60mg/kg, suggesting a wide dosing range that would be available for controllable modulation of B-cell immune activity. Although these were not head-to-head studies, we believe that valuable insight can nonetheless be drawn from the comparisons.

In addition, leveraging our antibody and fusion protein engineering platform, we have combined the TACI fragment of telitacicept with the Fc region of human IgG. Human immunoglobulins of the IgG isotypes are known to have remarkable serum stability and long half-lives, and also to help increase the stability and half-lives of fusion proteins when they are integrated as a component. These optimized structural features of telitacicept promote its molecular stability and facilitate our remarkable productivity of the fusion protein.

Full human amino acid sequence to minimize potential immunogenicity

Therapeutic proteins may be seen as foreign antigens by the immune system of human bodies and as a result elicit unwanted immune responses against themselves called immunogenicity, thereby limiting therapeutic effects and even causing life-threatening complications. In order to minimize the immunological risks, telitacicept is designed and genetically engineered to be composed of TACI and Fc portions derived from human TACI receptor and human IgG, respectively.

Leveraging our advanced fusion protein engineering technology, we successfully produced the fusion protein with TACI fragment preserving almost the full amino acid sequence of human TACI to the maximum extent. The optimal truncation sites of human TACI domain were determined through our analysis using neural network bioinformatics. As a result, the structure of telitacicept incorporates most of the N-terminal and C-terminal of human TACI molecule in order to preserve the biological functions while reducing immunogenicity. Furthermore, we have the TACI fragment fused to the Fc portion of human IgG. Immunoglobulins, especially IgG subclasses, are known to be tolerogenic, or capable of producing immunological tolerance. Therefore, we engineered TACI fragment in frame with an IgG heavy chain to improve immunological tolerance and, with the design-based advantages, we have not observed signs of immunogenicity in our clinical trials of telitacicept.

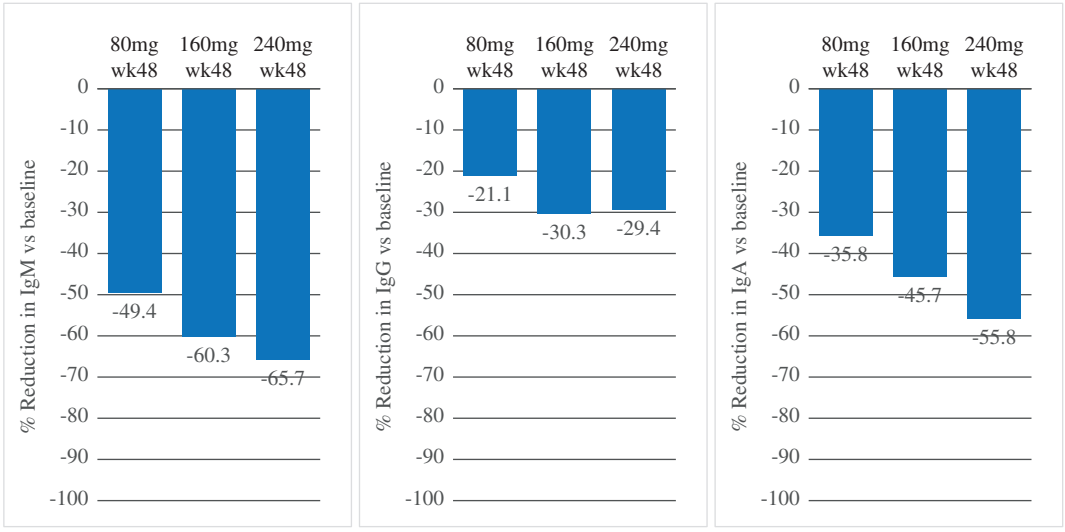
Superior clinical efficacy profile

Our telitacicept's innovative BLyS/APRIL dual-targeting mechanism and bioinformatics-optimized molecular structure and biochemical properties, including its enhanced binding affinity for the targeted signaling factors, have enabled it to demonstrate more robust clinical benefit than its competitors.

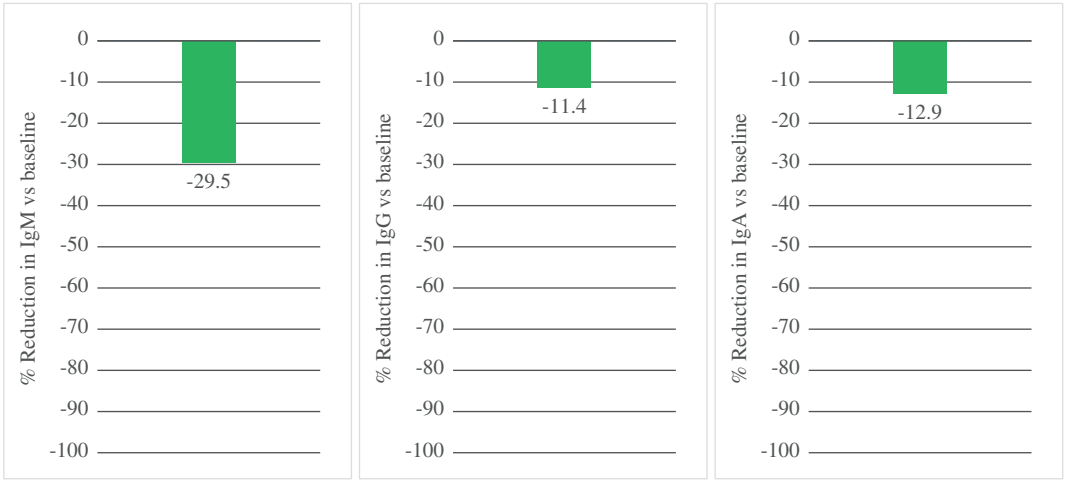
While there is no head-to-head clinical trial comparison, our telitacicept and GlaxoSmithKline's Benlysta (belimumab) have both completed registrational trials in SLE patients, and telitacicept has demonstrated potential superior clinical efficacy to that of belimumab in SLE patient population based on the published data. In the clinical trials, our telitacicept demonstrated a dose-dependent modulation of B-cell immune response in SLE patients and resulted in large reductions in IgM, IgG and IgA levels. As shown in the figures below, telitacicept generally achieved a dose-dependent linear and robust effect on IgM, IgG and IgA reduction within a wide dosing range from 80 mg to 240 mg, while subcutaneous administration of 200 mg belimumab resulted in modest reduction in IgM, IgG and IgA compared to baseline.

Comparison of Median Percentage Reduction in IgM, IgG and IgA from Baseline in SLE Patients

Telitacicept (QW x 48 SC, 80-240 mg)



Belimumab (QW x 52 SC, 200 mg)

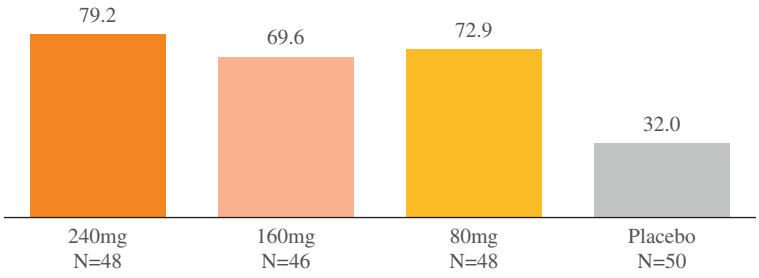


Source: (1) Belimumab: European Medicines Agency: EMA/CHMP/346577/2017, 2017; (2) Telitacicept: Company data

In November 2019, we orally presented the results of our Phase IIb registrational trial of telitacicept for the treatment of SLE in China at the 2019 American College of Rheumatology (ACR)/Association of Rheumatology Professionals (ARP) Annual Meeting held in Atlanta, Georgia, United States. As observed in this Phase IIb trial, telitacicept showed a superior clinical efficacy and good safety profile that suggests best-in-class potential in SLE. The primary endpoint of this trial was the proportion of patients achieving SLE responder index-4 (SRI-4) response at week 48, which is a composite measurement for disease activity and response in SLE. In each of three treatment arms receiving subcutaneous telitacicept at multiple dose levels throughout the

duration of the trial, a significant larger portion of patients achieved SRI-4 response than the patients in the placebo arm, which indicates significant reduction in SLE disease activity in the telitacicept treatment arms. The high-dose arm (240 mg) in this trial achieved SRI-4 response rate as high as 79%, as compared to 32% in the placebo arm, in per protocol set (PPS) analysis with 192 randomised patients. The chart below shows the SRI-4 response rates of telitacicept at different dose levels in the PPS analysis. Additionally, given good efficacy was seen in all groups of different doses, lower doses are planned to be investigated in future studies to potentially further enhance the safety profile of telitacicept.

Telitacicept: SRI-4 Response Rate (PPS)



Source: Company data

Favorable safety profile

As of the Latest Practicable Date, telitacicept demonstrated a good safety profile and tolerability in eight clinical trials that we have completed to evaluate telitacicept in various autoimmune diseases. Although patients treated with telitacicept were slightly more prone to experience adverse events (AEs) as compared to placebo-treated patients, most of the AEs were rated mild or moderate on the mild-moderate-severe scale and were resolved without leading to withdrawal from the studies.

The table below summarizes the safety results of telitacicept in our Phase IIb registrational trial in SLE in China per full analysis (FAS) with 249 patients.

	240mg (N=62), n (%)	**160mg (N=63), n (%)**	**80mg (N=62), n (%)**	**Placebo (N=62), n (%)**
AEs	58(93.5)	58(92.1)	56(90.3)	51(82.3)
SAEs	8(12.9)	10(15.9)	8(12.9)	10(16.1)
SARs	3(4.8)	2(3.2)	3(4.8)	2(3.2)
AEs leading to permanent discontinuation	7(11.3)	8(12.7)	7(11.3)	8(12.9)
ARs leading to permanent discontinuation	2(3.2)	3(4.8)	2(3.2)	6(9.7)

Abbreviation: AE=adverse event; AR=adverse reaction; SAE=serious adverse event; SAR=serious adverse reaction

In general, telitacicept was well tolerated by patients in the Phase IIb registrational study. The SAE rate was 13% – 16% in the treatment groups for dose levels ranging from 80mg to 240mg, which was lower or in line with the placebo group which had an SAE rate of 16%. The overall incidence of adverse events (AEs) was 92.0% across the treatment arms, compared to 82.3% in the placebo arm. There was no statistically significant difference in the incidence of AEs between treatment and placebo arms. The most frequent AEs noted in this study were infections and infestations (72.7%). The majority of AEs with telitacicept were mild or moderate. The percentage of patients who discontinued the treatment due to AEs or ARs in the treatment groups was lower or in line with that in the placebo group. The one and only fatality reported in the telitacicept 240 mg treatment arm was considered not to be drug-related.

Summary of Clinical Trial Results

As of the Latest Practicable Date, we had evaluated the safety and efficacy profiles of telitacicept in eight completed clinical trials and seven ongoing clinical trials covering a wide variety of indications, including SLE, NMOSD, RA, SS, IgAN, multiple sclerosis and myasthenia gravis. We have completed the Phase IIb registrational trial of telitacicept in SLE patients in China, and we have two other registrational trials of telitacicept respectively in RA and NMOSD patients ongoing.

Clinical Trials in SLE

We have completed Phase I, IIa and IIb trials in China to assess the safety, efficacy, pharmacokinetics (PK) and pharmacodynamics (PD) of telitacicept either as a monotherapy or in combination with standard therapy in SLE patients.

We completed two Phase I trials of telitacicept to evaluate the safety and PK/PD profile of telitacicept in October 2012 and December 2019, respectively. In the first Phase I trial, 12 patients were randomized into two groups at the ratio of 3:1, and received telitacicept at 180 mg or placebo, in each case plus standard of care. In the second Phase I trial, 36 healthy volunteers were randomized into three groups at the ratio of 1:1:1, and received telitacicept at the dosage of 80 mg, 160 mg and 240 mg, respectively. In these two trials, telitacicept demonstrated that it was well tolerated in SLE patients and had a linear PK profile, and in the first Phase I trial, we also obtained preliminary evidence of its promising efficacy in SLE. We also conducted Phase Ia and Ib trials in RA patients to assess the safety, PK and PD of telitacicept prior to initiation of our Phase II trials in SLE patients. In January 2016, we completed a multi-center, randomized, double-blinded and placebo-controlled Phase IIa trial to explore recommended dose and dosing frequency for late-stage clinical trials. 138 patients with moderate to severe SLE were randomized at the ratio of 1:1:1:1 to receive telitacicept at low-dosages (40 mg, 80 mg or 120 mg) or placebo, in each case plus standard of care, for a total of 14 doses across 48 weeks (once every two weeks for the first three doses and once every four weeks thereafter). In this trial, no significant difference in the incidence of AEs, ARs or SAEs were observed

between treatment and placebo groups, which showed a favorable safety profile of telitacicept. However, the treatment groups did not show statistically significant improvement on disease conditions, comparing to the placebo group, at these dose levels. Considering the results of this study, we determined that the dosing level and schedule used in this study was insufficient to achieve sustained therapeutic benefits of telitacicept, and then largely increased the dose and frequency in designing the subsequent Phase IIb registrational trial in which the patients received 80, 160 or 240 mg telitacicept once every week. In the completed Phase IIb registrational trial, telitacicept demonstrated its high efficacy and excellent safety for SLE patients at all doses. Based on the data from this clinical trial, we submitted our NDA for conditional approval of telitacicept for the treatment of SLE, which was accepted and granted with priority review status by the NMPA. We are currently enrolling patients in a confirmatory Phase III trial in China to evaluate telitacicept in combination with standard therapy in SLE patients.

Registrational Phase IIb trial in patients with moderate to severe SLE in China

Trial Design: This is a multi-center, randomized, double-blind and placebo-controlled Phase IIb clinical trial conducted in China. A total of 249 patients with moderate or severe SLE were enrolled in this trial. The duration of this trial was 48 weeks. Patients were equally divided into four groups to receive subcutaneous telitacicept (at dose levels of 80 mg, 160 mg or 240 mg) or placebo once a week, in each case in combination with standard of care. For purposes of this trial, standard therapy comprises any of the following (alone or in combination): corticosteroids, antimalarials, non-steroidal anti-inflammatory drugs (NSAIDs), and immunosuppressive and immunomodulator therapy (i.e., azathioprine, mycophenolate, cyclophosphamide, methotrexate, tacrolimus or ciclosporin).

The primary endpoint of the trial is the proportion of patients achieving the SLE Responder Index 4 (SRI-4) response at week 48. SRI-4 response is a composite endpoint used in SLE clinical trials that assesses disease activity and response to treatment. Clinically meaningful disease activity improvement is achieved if a greater than four point reduction in SRI occurred. SRI-4 includes criteria from three internationally validated indices, including SELENA-SLE Disease Activity Index (SELENA-SLEDAI), British Isles Lupus Assessment Group (BILAG) and Physician's Global Assessment (PGA).

The secondary endpoints are (i) proportion of patients with a four points or more decrease in SELENA-SLEDAI scores after treatment, (ii) change in the overall evaluation by physicians versus baseline, (iii) proportion of patients with prednisone doses of $\leq$ 7.5 mg/d or $\geq$ 25% reduction from baseline after 44 to 48 weeks of treatment, and (iv) changes from the baseline values in serological tests of IgG, IgA, IgM, B-cell ($CD19^+$), anti-ds-DNA antibodies, antinuclear antibodies (ANA) and complement (C3 and C4).

Trial Status: This trial was completed in June 2019 and we finalized the analysis in October 2019.

Efficacy Data: Telitacicept achieved statistically significant results and reached both the primary and secondary endpoints of this trial.

In all three groups receiving telitacicept (80 mg, 160 mg and 240 mg) in this trial, the proportion of patients achieving clinically meaningful disease activity improvement were significantly higher than that of the placebo group in both the full analysis set (FAS) which includes all 249 patients randomly assigned to a treatment group having at least one efficacy assessment after randomization and the per protocol set (PPS) which includes 192 randomised patients who had received at least 12 doses of telitacicept and completed the SRI-4 assessment. In the FAS analysis, disease activity was significantly reduced among 75.8% patients treated with telitacicept at 240 mg, as compared to a 33.9% in the placebo group. Significant reduction of disease activity was also observed in a large proportion of patients treated at lower doses: 68.3% at 160 mg and 71.0% at 80 mg in the FAS analysis. The following figures show the SRI-4 response rates of telitacicept in both FAS and PPS analyses.

Telitacicept (RC18): SRI-4 Response Rate (FAS)

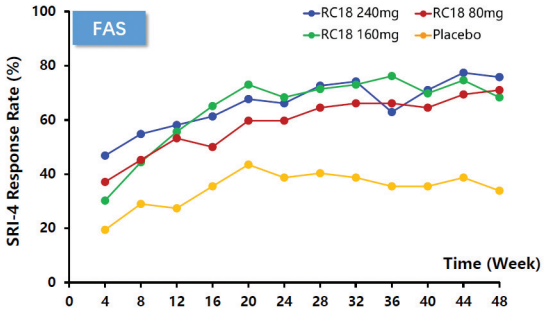


Figure 1. Diachronic changes of the SRI-4 Response Rate from Week 0 to Week 48 (FAS)

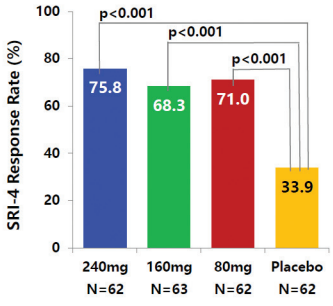


Figure 2. The SRI-4 Response Rate at Week 48 (FAS)

Telitacicept: SRI-4 Response (PPS)

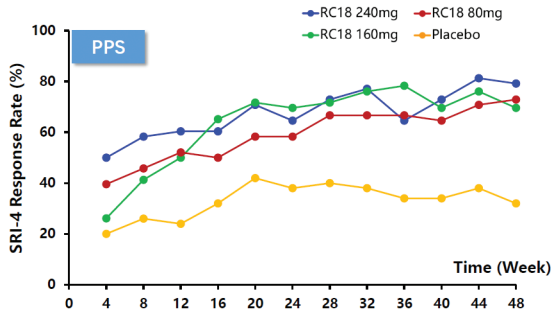


Figure 3. Diachronic changes of the SRI-4 Response Rate from Week 0 to Week 48 (PPS)

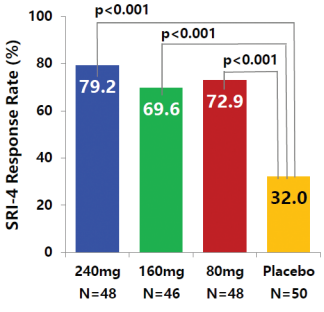


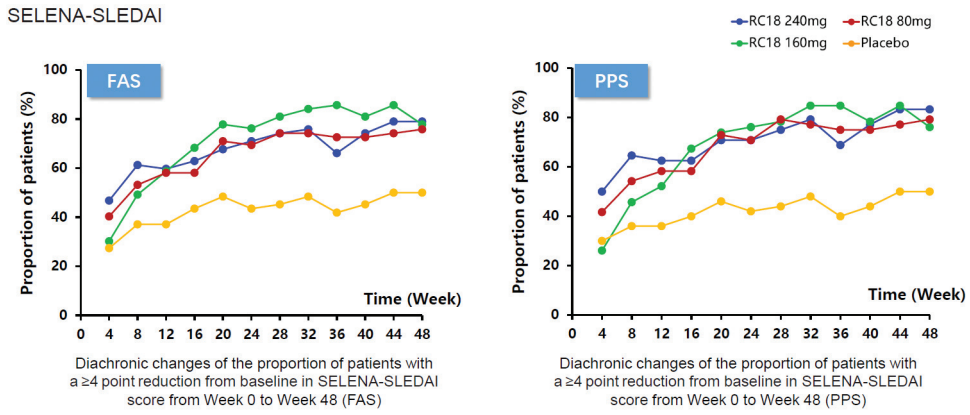
Figure 4. The SRI-4 Response Rate at Week 48 (PPS)

Source: Company data

The proportion of patients with a four points or more decrease in SELENA-SLEDAI scores also increased significantly after four weeks of treatment with telitacicept and continued to grow in the remainder of the 48-week treatment period. At Week 48, this proportion in the treatment groups reached around 79.0% at 240

mg, 77.8% at 160 mg and 75.8% at 80 mg in the FAS analysis, as compared to 50.0% in the placebo group, whereas this proportion in the treatment groups reached around 83.3% at 240 mg, 76.1% at 160 mg and 79.2% at 80 mg in the PPS analysis, as compared to 50.0% in the placebo group. The following figures show the proportion of patients with a four points or more decrease in SELENA-SLEDAI scores in both FAS and PPS analyses.

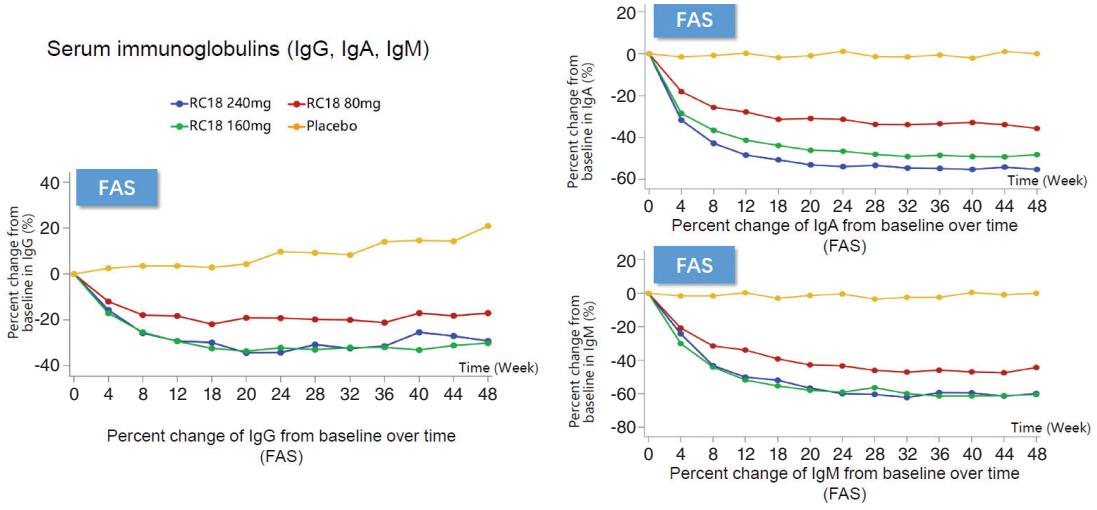
Telitacicept: SELENA-SLEDAI Results



Source: Company data

As compared to the placebo group, significant reductions of serum immunoglobulins (IgG, IgA, IgM) in the three treatment groups receiving telitacicept were observed at Week 4 and were sustained throughout the remainder of the 48-week treatment period. The following figures show the percentage changes from the baseline values in serological tests of IgG, IgA and IgM.

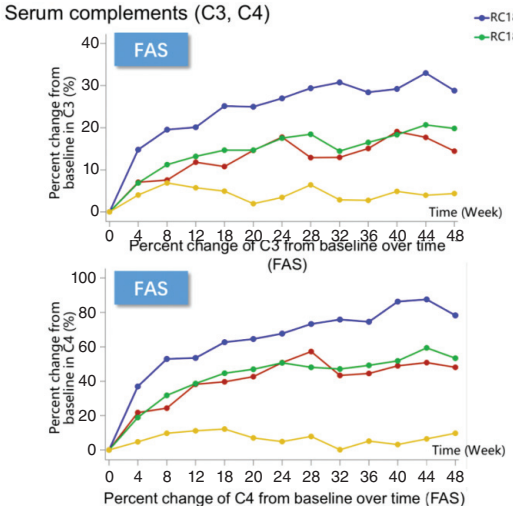
Telitacicept: Percentage Changes of Serum Immunoglobulins



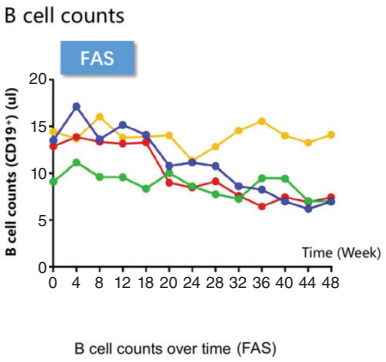
Source: Company data

In addition, significant increases in serum complements (C3 and C4) and decreases in B cell counts were observed in telitacicept treatment groups compared to the placebo group over the treatment period. The following figures show the percentage changes of C3 and C4 from the baseline and the changes in B cell counts.

Telitacicept: Percentage Change of Serum Complements



Telitacicept: B Cell Counts



Source: Company data

Safety Data: In this trial, telitacicept demonstrated a favorable safety profile and tolerability in SLE patients. Serious adverse events (SAEs) were observed with 8 patients (12.9%), 10 patients (15.9%) and 8 patients (12.9%) in treatment groups with telitacicept of 240 mg, 160 mg and 80 mg, respectively, as compared to 10 patients (16.1%) experiencing SAEs in the placebo group. The adverse events observed in this trial are summarized in the table below.

	240mg (N=62), n (%)	160mg (N=63), n (%)	80mg (N=62), n (%)	Placebo (N=62), n (%)
AEs	58(93.5)	58(92.1)	56(90.3)	51(82.3)
SAEs	8(12.9)	10(15.9)	8(12.9)	10(16.1)
SARs	3(4.8)	2(3.2)	3(4.8)	2(3.2)
AEs leading to dose reduction or suspension of treatment	39(62.9)	24(38.1)	25(40.3)	27(43.5)
ARs leading to dose reduction or suspension of treatment	30(48.4)	21(33.3)	20(32.3)	22(35.5)
AEs leading to permanent discontinuation	7(11.3)	8(12.7)	7(11.3)	8(12.9)
ARs leading to permanent discontinuation	2(3.2)	3(4.8)	2(3.2)	6(9.7)
AEs leading to death	1(1.6)	0(0)	0(0)	0(0)
ARs leading to death	0(0)	0(0)	0(0)	0(0)
AEs at injection site	6(9.7)	12(19.0)	7(11.3)	4(6.5)
ARs at injection site	6(9.7)	11(17.5)	7(11.3)	4(6.5)

In general, telitacicept has been well tolerated by patients in the study, although more mild to moderate infections were reported in patients receiving telitacicept than patients receiving placebo. Among all patients, the most common (≥ 10%) treatment-related AEs were upper respiratory tract infection (telitacicept vs. placebo: 35.5%-43.5% vs. 46.8%), urinary tract infection (telitacicept vs. placebo: 8.1%-12.9% vs. 4.8%) and injection site reaction (telitacicept vs. placebo: 8.1%-12.7% vs. 4.8%). The percentage of patients who discontinued the treatment due to AEs or ARs in the treatment groups was lower or in line with that in the placebo group. One death was reported in the telitacicept 240 mg group but it was considered not to be drug-related.

SLE predominantly occurs in young women at childbearing ages. Pregnancy in a woman with SLE carries a higher risk of maternal and fetal mortality and morbidity as compared to pregnancy in healthy women. In this Phase IIb trial, 11 patients' health conditions were so improved under the treatment with telitacicept that they were able to get pregnant during the trial and withdrew from the trial according to the protocol. Among these pregnant patients, one patient gave birth to a fetus while ten others chose active termination of pregnancy. The status of pregnant patients in this trial are summarized in the table below.

		240mg (N=62)	**160mg (N=63)**	**80mg (N=62)**	**Placebo (N=62)**
Number of Pregnant Recipients		4	3	4	0
Pregnancies					
Active termination of pregnancy	n(%)	4(100.0)	3(100.0)	3(75.0)	0
Birth of Fetus	n(%)	0(0)	0(0)	1(25.0)	0

Conclusion: Based on the data from this clinical trial, telitacicept in combination with standard therapy has demonstrated a strong profile in terms of both efficacy and safety in patients with moderate to severe SLE. Based on the trial results, our NDA for conditional approval of telitacicept for the treatment of SLE was accepted by the NMPA in November 2019, which was granted priority review in December 2019. Based on our communication with the NMPA, we have also initiated a Phase III confirmatory clinical trial in China in 2019.

Clinical Trials in RA

We have completed Phase Ia, Ib, IIa and IIb trials in China to assess safety, efficacy, PK and PD of telitacicept in RA patients. In these trials, telitacicept was well tolerated over a wide dose range.

In the Phase Ia study and the Phase Ib study, telitacicept demonstrated that it was safe and well tolerated in RA patients at dose levels of up to 360 mg once a week for 5 weeks. We also obtained preliminary evidence of its promising efficacy in RA. We

completed the Phase Ia study in February 2012 in a total of 28 RA patients. No serious adverse events occurred in RA patients receiving a single subcutaneous injection of telitacicept at doses levels of 1.2mg to 540mg. In the Phase Ib study completed in October 2012, a total of 21 RA patients were enrolled and treated with subcutaneous injections of 180mg once a week (QW) for 3 weeks, 180mg twice weekly (BIW) for 4 weeks or 360mg once a week (QW) for 5 weeks. 16 patients showed clinically meaningful disease activity improvement. For purposes of this trial, clinically meaningful disease activity improvement is achieved if a greater than 3.2 point disease activity score-28 (DAS28) score above baseline is recorded. The DAS28 is a measure of disease activity in RA and examines 28 joints in the assessment. No serious adverse events occurred in the patients in this trial. Compared with the placebo arm, the treatment arm was more likely to have various mild to moderate infections and skin reactions at the injection site.

In the multi-center, randomized, double-blinded and placebo-controlled Phase IIa trial, a total of 74 patients were enrolled and randomized into a treatment arm and a placebo arm. We have completed the Phase IIa trial in September 2014. The patients received 160mg telitacicept or placebo, as applicable, in each case in combination with methotrexate once a week (QW) for the first four weeks and every two weeks (Q2W) for the next 20 weeks. In the FAS analysis, 58.3% of 36 patients treated with telitacicept achieved ACR20 responses at Week 24, as compared to 39.5% of 38 patients in the placebo arm. 43.8% of 32 patients treated with telitacicept achieved ACR50 responses at Week 24, as compared to 14.3% of 28 patients in the placebo arm. ACR20 and ACR50 are measurements of disease activity improvement for RA. The incidence rate of adverse events was 47.2% in the treatment arm, compared to 39.5% in the placebo arm. There were no SAEs or premature study discontinuations due to AEs in this trial.

In the multi-center, randomized, double-blinded and placebo-controlled Phase IIb trial, 182 patients were enrolled and randomized to three groups receiving 160 mg and 240 mg of telitacicept and placebo, respectively, in each case in combination with methotrexate. We have completed the Phase IIb trial in April 2016. The patients received telitacicept or placebo, as applicable, QW for the first 13 weeks and every two weeks (Q2W) for the next 12 weeks. In the per protocol set (PPS), 69.8% of 43 patients in the 240mg dosage-level treatment arm and 68.3% of the 41 patients in 160 mg dosage-level treatment arm respectively achieved ACR20 responses at Week 24, as compared to 45.0% of 40 patients in the placebo group. We also measured other markers including the erythrocyte sedimentation rate, rheumatoid factor, total number of B cells, IgM, IgA, and IgG levels of patients in treatment and placebo arms. In the telitacicept treatment arms, these markers of patients gradually decreased and remained relatively low, as compared with those in the placebo arm. The incidence rate of adverse events was 52.5% and 63.3% in the 160 mg and 240 mg treatment arms, respectively, compared to 41.0% in the placebo arm. The incidence rate of SAE was 1.6% and 3.3% in the 160 mg and 240 mg treatment arms, respectively, compared to 1.6% in the placebo arm. The safety results further confirmed that telitacicept was safe and well tolerated in RA patients at dose levels of up to 160 mg QW.

In April 2017, we enrolled the first patient in a randomized, double-blind and placebo-controlled Phase III clinical trial to evaluate the efficacy and safety of telitacicept at varied dosage levels in combination with methotrexate for the treatment of RA in China. We plan to enroll a total of 480 patients. The primary endpoint of this trial is the proportion of patients achieving the ACR20 response at week 24. As of June 22, 2020, a total of 233 RA patients were enrolled.

Clinical Development Plan

We are implementing an advanced and comprehensive strategy for the research and development of telitacicept globally. We have been building a foundation for the strategy by developing telitacicept in China for the treatment of patients with a variety of B-cell mediated autoimmune diseases, with our leading indications in SLE, NMOSD and RA. We have generated abundant and encouraging efficacy and safety data of telitacicept in SLE patients from clinical trials in China. We believe that these SLE data and the additional data from our China trials for other indications will allow us to pursue and achieve global registration and commercialization of telitacicept. Among all indications for which we are currently developing telitacicept, SLE is our highest priority on the product's global development agenda, and it is closely followed by other autoimmune diseases.

The table below sets forth the details of our global clinical development plan for telitacicept:

Indication	Clinical trial stage	(Expected) first patient in date	(Expected) NDA submission date	Location and competent authority
SLE	Phase III (confirmatory)	October 2019	October 2019[(1)]	China/NMPA
	Phase III	1H 2021	–	U.S./FDA
NMOSD	Phase III	January 2018	–	China/NMPA
RA	Phase III	April 2017	–	China/NMPA
SS	Phase II	November 2019	–	China/NMPA
IgAN	Phase II	May 2020	–	China/NMPA
MS	Phase II	Q3 2020	–	China/NMPA
MG	Phase II	Q3 2020	–	China/NMPA

Note:

(1) The NDA submission for conditional approval was based on the data from our Phase IIb registrational trial.

- SLE:

We have completed a Phase IIb registrational trial in China for SLE, in which telitacicept met the primary endpoint with statistically significant difference between treatment and placebo groups. In October 2019, we submitted our first NDA to the NMPA for the conditional approval of telitacicept in China for the treatment of SLE. The NMPA accepted our NDA in November 2019, and granted us priority review in December 2019, based on the urgent unmet medical needs in the treatment of SLE. Based on our communication with the NMPA, we initiated a Phase III confirmatory clinical trial in China in July 2019 and patient enrollment started in October 2019. We have enrolled 158 patients in this trial as of June 22, 2020 and plan to enroll a total of 318 patients in this trial. The primary endpoint of this trial is the proportion of patients achieving SLE responder index-4 (SRI-4) at Week 52. We expect to complete patient enrollment in the first half of 2021.

We plan to conduct global Phase III clinical trials of telitacicept for SLE covering multiple jurisdictions and regions, including the U.S., Europe, South America and Asia. If the global trials meet their primary endpoints, we will use the data to apply for marketing approvals of telitacicept in the U.S. and Europe, and at a later stage in other jurisdictions included in this study.

The FDA has cleared our Phase II IND application for telitacicept in August 2019. We held an end-of-Phase II meeting with the FDA in January 2020 when the FDA reviewed the drug candidate's positive data from our trials in China and discussed the design for the Phase III clinical trials. Based on this meeting, the FDA allowed us to conduct the Phase III studies of telitacicept for the treatment of SLE in the U.S. On April 15, 2020, the FDA granted Fast Track designation to telitacicept, which could expedite the review and potential approval process with the FDA. We expect to initiate this global study with patient cohorts in the U.S. in the first half of 2021.

In addition to the U.S., we plan to initiate Phase III trials with extension cohorts in Europe and Asia in the first half of 2021, as part of the global Phase III trials. We have communicated with the EMA for the global Phase III clinical trials for SLE.

Dr. Joan Merrill is the coordinating investigator for the upcoming global study of telitacicept in SLE and has been advising on the development of our protocol for this global study since 2018. Dr. Merrill is a member of the Oklahoma Medical Research Foundation (OMRF) and OMRF Professor of Medicine at the University of Oklahoma Health Sciences Center. She is also an Adjunct Professor of Medicine at New York University and Chief Advisor for Clinical Development for the Lupus Foundation of America. Dr. Merrill is the director of the Oklahoma Lupus Cohort which includes more than 650 lupus patient volunteers, and has been involved in the design and execution of many clinical trials of immune modulating treatments for SLE for over 20 years. She has helped to pioneer innovative protocols aimed at ensuring interpretable outcomes in SLE trials by combining novel approaches for safely reducing polypharmacy with biomarker-based adaptive designs. She received the 2016 Research & Hope Award for Excellence in Academic/Government Research from the Pharmaceutical Research and Manufacturers of America (PhRMA).

To ensure the success of global registration and commercial launch of telitacicept, we are also actively pursuing potential partnership opportunities with global leading pharmaceutical companies.

- NMOSD:

As NMOSD is a rare disease with highly unmet medical needs, we have consulted with the NMPA and, after reviewing the clinical data of telitacicept in SLE and RA and the overall design of the Phase III trial, CDE confirmed that it has no objection to the entry into a Phase III trial of telitacicept for the treatment of NMOSD.

We are conducting a randomized, double-blind and placebo-controlled Phase III clinical trial to evaluate the efficacy and safety of telitacicept for the treatment of NMOSD in China. We initiated the Phase III clinical trials in September 2017 and enrolled the first patient in January 2018. We have enrolled 107 patients in this trial as of June 22, 2020 and plan to enroll a total of 118 patients in this trial. The primary endpoint of this trial is the time to first relapse after randomization.

- RA:

We are conducting a multi-center, double-blinded and placebo-controlled Phase III trial in China to evaluate the efficacy and safety of telitacicept in patients with moderate to severe RA who have an inadequate response to methotrexate (MTX), an antimetabolite and antifolate drug and the standard of care for RA. We have enrolled 233 patients in this trial as of June 22, 2020 and plan to enroll a total of 480 patients in this trial. Patients in the treatment group receive telitacicept at 160mg dose level plus MTX through weekly subcutaneous administration for 24 weeks. Patients in the control group receive standard of care plus MTX weekly for 24 weeks.

The primary endpoint of this trial is the proportion of patients in each group achieving an ACR20 response at Week 24. An ACR20 response is defined as at least 20% improvement in both the tender joint count and the swollen joint count and at least 20% improvement in three of five other core set measures, including patient global assessment, physician global assessment, Health Assessment Questionnaire (HAQ), visual analog pain scale (VAS), and acute phase reactants (erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP)).

- SS:

We are conducting a randomized, double-blind and placebo-controlled Phase II clinical trial to evaluate the efficacy and safety of telitacicept for the treatment of SS in China. We have enrolled 17 patients in this trial as of June 22, 2020 and plan to enroll a total of 30 patients in this trial. The primary endpoint of this trial is the change in ESSDAI scores from baseline at Week 24.

- IgAN:

We are conducting a randomized, double-blind and placebo-controlled Phase II clinical trial in China to evaluate the efficacy and safety of telitacicept in IgAN patients. We have enrolled four patients in this trial as of June 22, 2020 and plan to enroll a total of 30 patients in this trial. The primary endpoint of this trial is the change in urinary protein within 24 hours from the baseline at Week 24.

- Other indications:

In addition to the indications described above, we are also evaluating telitacicept for two other hard-to-treat autoimmune diseases, namely MS and MG. For MS, we have initiated an open-label, randomized Phase II clinical trial in China. We plan to enroll a total of 18 patients and expect to enroll the first patient in the third quarter of 2020. The primary endpoint of this trial is the number of gadolinium-enhanced T1 lesions in brain at Weeks 12, 24, 36 and 48 compared to baseline. For MG, we have initiated an open-label, randomized Phase II clinical trial in China. We plan to enroll a total of 20 patients and expect to enroll the first patient in the third quarter of 2020. The primary endpoint of this trial is the weekly average change in QMG score from the baseline at Week 24.

Leveraging our experience in developing telitacicept for SLE globally, we will continue to explore the global path of approval and commercialization for the treatment of other autoimmune diseases. We intend to prioritize indications with high unmet medical need and a sizeable addressable patient population in the global market, such as IgAN and primary Sjögren's syndrome, or indications for which telitacicept has the potential to be the first biologic therapy, such as NMOSD.

Licenses, Rights and Obligations

We maintain the global rights to develop and commercialize this drug candidate.

Material Communications

We have not received any relevant regulatory agency's concerns or objections to our clinical development plans as of the Latest Practicable Date. As of the Latest Practicable Date, no material unexpected or adverse changes have occurred since the date of issue of relevant regulatory for telitacicept.

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 TELITACICEPT SUCCESSFULLY.

Disitamab vedotin (RC48)

Antibody-drug conjugate (ADC) has been one of the focuses of our research and development efforts since our inception. Over the past eight years, we have established an end-to-end ADC platform with industry-leading technologies covering the discovery/optimization, process/analytical development and production of novel ADC therapeutics. Leveraging this platform, we are developing four ADC drug candidates, including two in clinical development (disitamab vedotin and RC88) and two in IND filing preparations (RC108 and RC118).

Disitamab vedotin is our leading ADC product candidate and is the first ADC in China to have received IND approval for clinical trials. Disitamab vedotin is a novel ADC independently developed by us to treat human epidermal growth factor receptor 2 (HER2) expressing (including low-expressing) solid tumors. Disitamab vedotin is currently being studied in multiple late-stage clinical trials in China across a variety of solid tumor types. In two Phase II clinical trials in China, disitamab vedotin has demonstrated promising efficacy in patients with HER2-expressing advanced or metastatic gastric cancer (GC) and urothelial cancer (UC), and has also proved its potential as treatment for HER2-expressing (including low-expressing) breast cancer (BC) in a Phase Ib clinical trial.

In the U.S., the FDA provided clearance for us to proceed with a Phase II study for disitamab vedotin in UC in April 2020. We plan to initiate trials of disitamab vedotin for the treatment of HER2-expressing locally advanced or metastatic UC in the U.S. in the first quarter of 2021. In addition, the FDA has also granted orphan drug designation to disitamab vedotin for GC in July 2018. With orphan drug designation, we are entitled to a seven-year exclusive marketing period in the U.S. for disitamab vedotin for this indication, and among the other benefits of orphan drug designation, we may enjoy tax credits for certain research and a waiver of the BLA application user fee.

The chart below shows the indications for which we are currently evaluating disitamab vedotin in clinical trials and indicates the status for each of these clinical trials:

Indication	HER2 Status[3]	Mono-/Combo-Therapy	Status[4]					
			IND (Accepted)	Phase I		Phase II	Pivotal/ Phase III	NDA/BLA (Filed)
				Ia	Ib			
China								
HER2-expressing GC:								
HER2 over-expressing locally advanced or metastatic GC	IHC 2+ or IHC 3+	Mono	●			◑ (pivotal Phase II)		◔ (Q3 2020)
HER2-expressing advanced solid tumors[5]	IHC 1+, IHC 2+, or IHC 3+	Combo (PD-1)	●	◑				
HER2-expressing UC:								
HER2 over-expressing advanced or metastatic UC	IHC 2+ or IHC 3+	Mono	●			● (initial Phase II) ◑ (pivotal Phase II)		◔ (1H 2021)
HER2 low- to non-expressing locally advanced UC	IHC 1+ or IHC 0	Mono	●			◑		
Locally advanced or metastatic UC	All	Combo (PD-1)	●			◑ (Ib/II)		
HER2 low-expressing advanced BC	IHC 2+ and FISH-	Mono	●				◑	
HER2 over-expressing or HER2 mutated advanced NSCLC	IHC 2+ or IHC 3+ or HER2 mutated	Mono	●		◑			
HER2 over-expressing metastatic BTC	IHC 2+ or IHC 3+	Mono	●			◑		
U.S.								
HER2-expressing locally advanced or metastatic UC	IHC 2+ or IHC 3+	Mono	●			◑		
HER2-expressing locally advanced or metastatic GC	IHC 2+ or IHC 3+	Mono	◑			◔		

Notes:

1. Abbreviations: 1L = first-line; BC= breast cancer; BTC=biliary tract carcinoma; FISH= fluorescence in situ hybridization; GC= gastric cancer; IHC = immunohistochemistry; UC=urothelial cancer; NSCLC= non-small-cell lung cancer.
2. Symbols: ● = complete; ◑ = in progress (a clinical trial is deemed to have been initiated when we submit trial design and protocol to apply for ethical approval); ◔ = to be initiated
3. denotes the HER2 status in patients criteria of the most advanced clinical trial of an indication.
4. Some indications may not require every phase of the clinical trials indicated in this chart to be completed prior to the filing of an NDA. We conducted a Phase I trial in multiple advanced solid tumors to evaluate the safety of disitamab vedotin. Based on the safety data from this trial, we initiated the Phase II trials of various specific cancer indications. For BC, we have initiated a Phase I trial in advanced solid tumors (which enrolled BC patients only) and Phase Ib and II trials in HER2-expressing BC. Based on the data from these trials and our communication with CDE, we have initiated a Phase III clinical trial in HER2 low-expressing BC.
5. This trial is designed to include a cohort of 20-50 GC patients to evaluate this combo therapy for the treatment of HER2-expressing GC.

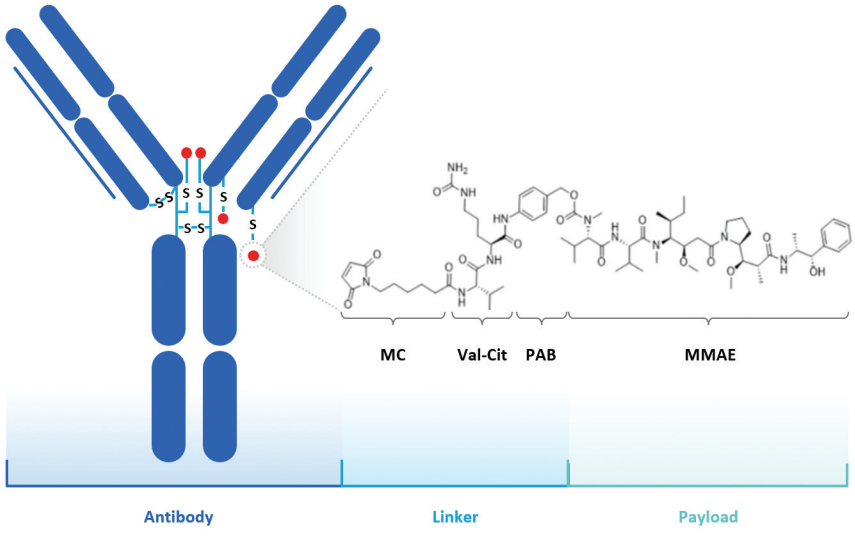
Mechanism of Action

ADCs are a type of cancer treatment designed to specifically and directly deliver chemotherapies to tumor cells while sparing healthy cells. The concept of ADCs is based on exploiting the high specificity of a monoclonal antibody toward a selected tumor

cell-surface antigen and enhancing the cell-killing capacity of the antibody by attaching a highly cytotoxic agent. Typically, several molecules of a highly potent cytotoxic compound are linked to each antibody molecule to enhance its activity, while retaining the favorable pharmacokinetic and pharmacodynamic properties of the antibody. The key to this type of therapy is getting three distinct molecules—antibody, active drug and linker—to work together.

Unlike traditional chemotherapy that indiscriminately damages healthy cells as well as tumor cells, ADC utilizes monoclonal antibody to bind to tumor-specific antigen targets and then delivers the chemotherapy, a highly potent cytotoxic agent, to kill tumor cells. In this way, ADCs may significantly benefit cancer patients by causing less adverse effects (AEs) or severe adverse effects (SAEs).

Structure of Disitamab Vedotin



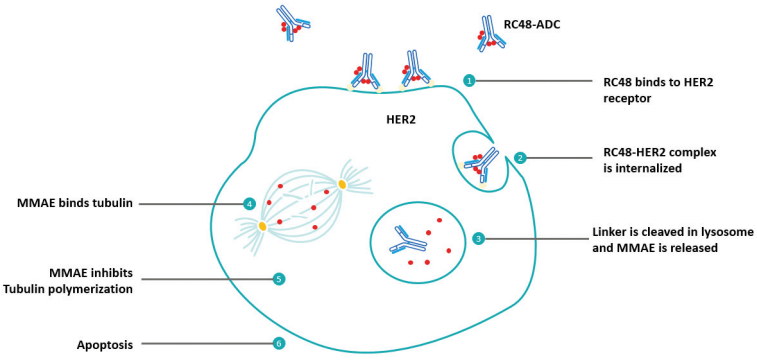
Abbreviation: MC = maleimidocaproyl; MMAE = monomethyl auristatin E; PAB = p-aminobenzyl.
Note: MC-Val-Cit-PAB is a cathepsin cleavable ADC linker.
Source: Company data

As illustrated in the diagram above, in disitamab vedotin, a novel humanized HER2 antibody and monomethyl auristatin E (MMAE), a potent tubulin binder with a half maximal inhibitory concentration (IC_{50}) in the subnanomolar range, as the cytotoxic payload, are conjugated to each other through a cathepsin cleavable linker, with optimized drug-antibody ratio. The anti-HER2 antibody allows disitamab vedotin to selectively deliver the anti-cancer agent MMAE to HER2-expressing tumor cells.

HER2 is a member of the epidermal growth factor receptor (EGFR) family. It is expressed in many tissues, including the breast, gastrointestinal tract, kidney and heart. Its major role in these tissues is to promote cell proliferation and suppress apoptosis. Amplification of the HER2 gene and overexpression of its product may drive excessive or uncontrolled cell growth and tumorigenesis. Our clinical data support the scientific view that the HER2 pathway may play a key role in the treatment of many cancer types with tumors that express HER2 antigen, such as breast, gastric, lung and urothelial cancers.

Compared with Roche/Genentech's ado-trastruzuman emtansine (T-DM1) which uses monoclonal antibody trastuzumab, disitamab vedotin comprises a novel HER2 monoclonal antibody that targets a different epitope of, and also shows a higher binding affinity for, HER2 receptors on the tumor cell. Once disitamab vedotin binds to its target (HER2) which is expressed on tumor cell surface, through its antibody component (disitamab), the ADC-HER2 complex is internalized by the tumor cell via endocytosis. The linker connecting antibody and cytotoxic payload is then cleaved in the presence of lysosomal protease. Once the payload, MMAE, is released into cytosol, it binds tubulin and inhibits its polymerization, which triggers apoptosis or the programmed cell death of the HER2-expressing tumor cell. MMAE, once released, also has the capacity to kill neighboring tumor cells (whether HER2-expressing or not), which is known as the bystander-killing effect. Studies have found that ADCs with highly membrane-permeable payloads, such as MMAE, have a more potent bystander killing effect than those ADCs such as ado-trastuzumab emtansine (T-DM1) that have low membrane-permeable payloads, indicating a higher anti-tumor potential for our disitamab vedotin.

Mechanism of Action



Source: Company data

Market Opportunities and Competition

The commercial value of ADC therapy for HER2-expressing cancers is well-recognized by the market. Disitamab vedotin has great potential to address this sizable and growing market.

- Gastric Cancer:

According to the National Cancer Registry and National Bureau of Statistics, gastric cancer (GC) is the second most common cancer type in China in terms of both incidence rate and mortality rate. There were 455,800 and 27,500 new incidences of GC in China and the U.S. in 2019 respectively, which is expected to increase to 613,800 and 34,800 in 2030 respectively, according to Frost & Sullivan. Approximately 22% of GC patients are HER2 positive/high-expressing. In addition to the patients with HER2-positive as defined by IHC 3+ or IHC 2+/FISH+, there are certain percentage of patients who have low level HER2 expression, which is either IHC 1+ or IHC 2+/FISH-.

As GC is often diagnosed at an advanced stage, systemic chemotherapy is the mainstay of treatment for these patients. The five-year survival rate of GC patients is around 35.1% in China.

In recent years, targeted cancer therapies are widely tested in clinical studies and have been approved to treat various specific types of cancer. Yet, a large unmet medical need continues to exist. Trastuzumab, in combination with chemotherapy, was the first targeted drug to be approved as a new first-line standard of care for patients with HER2-positive/high-expressing advanced GC. However, only approximately 20% of patients with metastatic GC can benefit from the addition of trastuzumab to chemotherapy. Patients beyond progression on second-line therapy continue to lack effective treatment options. In China, for instance, standard third-line therapies for GC patients include apatinib, mono-chemotherapy and PD-1 monoclonal antibody, none of which has demonstrated strong efficacy in terms of survival benefits measured by progress-free survival (PFS) or overall survival (OS) for HER2-expressing GC. The annual treatment cost of apatinib is around RMB126,020, while the annual treatment cost of nivolumab (PD-1 antibody) reaches RMB222,240 under patient assistance programs.

In addition to our disitamab vedotin, several other ADCs are under clinical investigation for GC. For example, Roche's Kadcyla (T-DM1/ado-trastuzumab emtansine) was studied in Phase III clinical study in previously treated gastric and gastroesophageal junction (GEJ) patients but did not show a better efficacy than control taxane group. DS-8201 ([fam-] trastuzumab deruxtecan) developed by Daiichi-Sankyo is in development for the treatment of multiple HER2-expressing cancer types, including breast cancer and GC. Daiichi-Sankyo out-licensed the global rights to jointly develop and commercialize DS-8201 (except for Japan) to AstraZeneca for a total of US$6.9 billion, including US$1.35 billion in upfront payment.

The table below summarizes the development status of ADC targeting HER2-expressing GC in clinical trials or later as of the Latest Practicable Date.

Molecule	Cytotoxic Payload	Company	Indication	Clinical Phase
		China		
disitamab vedotin	MMAE	RemeGen	HER2 over-expressing GC	II (pivotal)
ARX788	AS269	Zhejiang Medicine/ Ambrx	HER2 over-expressing GC	II
DX126-262 (DAC-001)	Tubulysin B analogues	Hangzhou DAC Biotech	HER2 over-expressing GC	I
		Global (Outside of China)		
[fam-] trastuzumab deruxtecan (DS-8201)	deruxtecan	Daiichi-Sankyo/ AstraZeneca	HER2 over-expressing GC	II

Source: Frost & Sullivan Report

- Urothelial Carcinoma:

Urothelial carcinoma (UC) is the most common type of bladder cancer (90% of cases). UC is the 13th most common cancer worldwide, and the fourth most common cancer in men in the United States. According to Frost & Sullivan, around 508,200 new cases were diagnosed with UC globally in 2019 and it is estimated that there will be 694,400 new cases in 2030. While UC is historically more common in the U.S. and western Europe, the incidence has increased gradually in China in the past few years. There were 76,400 new cases occurred in 2019 in China, and this figure is expected to reach 106,600 in 2030, according to the Frost & Sullivan.

Metastatic or unresectable disease is identified in approximately 20% of patients presenting with invasive UC. In addition, up to 50% of patients will develop metastases following radical cystectomy for clinically localized disease. Unfortunately, limited breakthrough treatments for metastatic UC have emerged in over two decades. The first-line therapy for UC in China is chemotherapy, and the treatment paradigm for UC in China also include systemic immunotherapy, radiotherapy, palliative cystectomy and supportive treatment. Traditional therapeutic options, such as cisplatin-based combination chemotherapy, have subpar efficacy, as reflected in high rates of recurrence and mortality.

In the past five years, five PD-(L)1 inhibitors have been approved by the FDA for the treatment of UC, among which two agents, pembrolizumab and atezolizumab, have also been approved as first-line therapy for a subset of UC patients. None of the PD-(L)1 inhibitors has been approved for first-line treatment of UC in China. Despite durable activity observed in many patients, the majority of UC patients unfortunately do not respond to PD-(L)1 inhibitors and their overall improvements to the survival and quality of life of UC patients are modest. Therefore, the development of new safe and effective therapeutics are urgently needed to address the highly unmet medical needs.

Astellas/Seattle Genetics's Padcev (enfortumab vedotin), a nectin-4-targeting ADC, was approved by the FDA for the treatment of locally advanced or metastatic UC in December 2019, and became the first and only ADC approved for this indication. To this date, disitamab vedotin is the most advanced ADC in clinical stage targeting HER2-expressing UC.

The table below summarizes the development status of all ADCs targeting UC in clinical trials as of the Latest Practicable Date.

Molecule	Antibody (Target)	Cytotoxic Payload	Company	Indication	Status
			China		
disitamab vedotin	disitamab (HER2)	MMAE	RemeGen	HER2 over-expressing UC	Phase II (pivotal)
				HER2 low- to non-expressing UC	Phase II
			Global (Outside of China)		
Padcev (enfortumab vedotin)	enfortumab (Nectin-4)	vedotin	Astellas Pharma (安斯泰來製藥)/ Seattle Genetics	Locally advanced or metastatic UC	Marketed

Source: Frost & Sullivan Report

- Breast Cancer:

According to the National Cancer Registry and National Bureau of Statistics, breast cancer (BC) is the most common cancer type among women in China, as the fifth largest cancer in the country in terms of the incidence. There were 326,200 new incidences of BC in China in 2019 and over 2.1 million new incidences globally in 2019. Globally, approximately 20-30% of all BC cases belong to the HER2-positive/high-expressing subtype, which is defined by HER2 protein overexpression and/or HER2 gene amplification. In about 50% of BC, a low-level expression of HER2 without HER2 amplification can be observed. Overexpression or amplification of HER2 in BC is associated with very poor prognosis and increased risk of local growth and distant metastasis, compared with HER2-negative BC.

As of May 2020, six biologics drugs have been approved by the FDA to treat BC, of which most are HER2-targeted therapies and Roche's Herceptin (tratuzumab) has the largest market share. In 2019, the global sales of Herceptin reached US$6.1 billion (including sales for other indications). As of May 2020, biologics approved for HER2-positive/high-expressing BC in China included Herceptin (trastuzumab), Perjeta (pertuzumab) and Kadcyla (ado-trastuzumab emtansine).

Roche's Kadcyla (T-DM1/ado-trastuzumab emtansine) and Daiichi Sankyo/Astrazeneca's Enhertu ([fam-] trastuzumab deruxtecan/DS-8201) are currently the only two FDA-approved ADC drugs for the treatment of advanced HER2-positive/high-expressing BC. Kadcyla and Enhertu were initially approved by the FDA in February 2013 and December 2019, respectively. In 2019, Kadcyla recorded global sales of US$1.4 billion. In China, ado-trastuzumab emtansine (T-DM1) has been approved for the treatment of BC. The annual treatment costs of ado-trastuzumab emtansine (T-DM1) reaches RMB469,150 under patient assistance programs. Although effective in treating advanced breast cancer, all patients eventually develop T-DM1 resistance.

Despite the availability of a number of targeted therapies for HER2-positive/high-expressing BC, there is currently no anti-HER2 therapies approved for breast cancer with a low-level HER2 expression. As a result, these patients are generally treated as HER2-negative BC patients in current clinical practice and eventually progress on current treatments to a point where limited options are available. Clinical evidence suggests a lower activity of T-DM1 against cancers with low-HER2 expression, while DS-8201 is being investigated in clinical trials to evaluate its efficacy in HER2 low-expressing BC.

As of the Latest Practicable Date, there are three HER2-targeted ADC candidates in Phase III clinical trials for BC in China and three in the U.S., among which disitamab vedotin is one of them. For further details, please refer to the paragraph "Industry Overview—3. Oncology Drug Market—3.5 Breast Cancer—3.5.4 Competitive Landscape of Biologics Treatment of Breast Cancer in the U.S. and in China."

Competitive Advantages of Disitamab Vedotin

Innovative molecular design leads to improved efficacy and reduced resistance with therapeutic potential in HER2-expressing cancer indications

HER2 is a naturally occurring receptor that is expressed in many types of cancer, including UC, GC, BC, ovarian cancer, non-small cell lung cancer and others. In recent years, clinical evidence and research suggest promising therapeutic prospects of HER2-targeting ADC drugs in treating HER2-positive cancer as they provide a much more effective solution of targeted drug delivery than standard chemotherapy. The commercial value of HER2-targeting ADCs is also well recognized in the market, by the impressive sales revenue of Kadcyla (ado-trastuzumab emtansine/T-DM1) and the purchase consideration of DS-8201 ([fam-] trastuzumab deruxtecan) in a recent transaction.

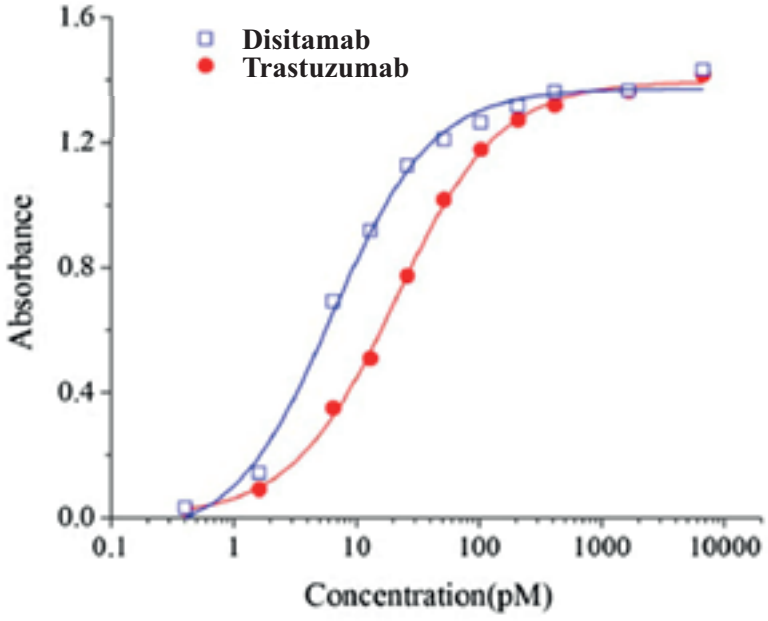
Disitamab vedotin is an innovative HER2-targeting ADC comprising a novel humanized HER2 antibody, a potent cytotoxic payload (MMAE) and a cleavable peptide-linker. Each component of disitamab vedotin has differentiated biological properties as compared with its major competitors, allowing for potentially better targeting, improved efficacy and reduced resistance.

- Novel antibody with higher affinity for HER2 compared to standard of care

Disitamab vedotin contains a novel antibody that targets a HER2 epitope different from that for trastuzumab, and that is highly selective for HER2. The novel HER2-targeting monoclonal antibody can effectively inhibit HER2 signaling to pathways like PI3K or AKT and thus restrict the growth of HER2-expressing tumor cells. Taking advantage of this specific targeting, disitamab vedotin is able to selectively deliver potent cytotoxic drug to tumor cells expressing HER2 without affecting normal cells with little or no HER2 expression, leading to significant improvement of drug efficacy while reducing the side effects.

As illustrated in the figure below, an *in vitro* assay found that disitamab has a higher affinity for HER2 as compared with trastuzumab as the EC_{50} value of disitamab was 6.4 pM compared to EC_{50} value of trastuzumab of 20.1 pM.

HER2 Binding Affinity Profiles of Disitamab and Trastuzumab



Source: Yao et al., BCRT (2015), company data

Further studies have found that the binding ability of disitamab is largely unaffected after conjugating with MMAE. Attributable to the high affinity of the innovative antibody, disitamab vedotin has the potential to respond to significant unmet medical needs of patients with HER2 low-expressing cancer or for whom current HER2-targeting therapies are ineffective.

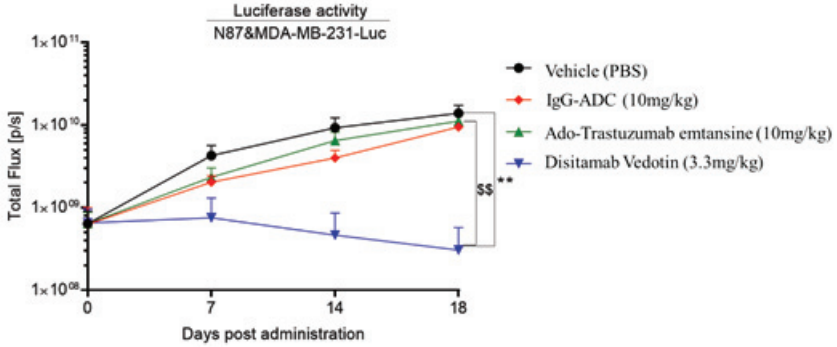
While exhibiting strong activities against the HER2-expressing cells, disitamab vedotin had none or limited effects on HER2-negative cells in our in vitro assay, suggesting the high selectivity of the molecules for HER2-expressing cells and the potential to reduce systemic toxicity of MMAE.

- Potent cytotoxic payload with bystander-killing effects

MMAE is a highly toxic drug that functions as an agent to block polymerisation of tubulin and eventually lead to cell death. MMAE, as the payload of disitamab vedotin, is attached to the antibody component through a cleavable linker, and is only released in the intracellular environment after the molecule is internalized by HER2-expressing tumor cells. Notably, disitamab vedotin showed a more potent bystander-killing effect than T-DM1, which means disitamab vedotin kills both HER2-expressing and HER2-negative cells under coculture conditions.

In vivo study results suggest that MMAE has higher membrane permeability than emtansine (DM1) and, therefore, after disitamab vedotin is internalized into HER2-expressing cells and releases MMAE into the cytoplasm, MMAE could penetrate into adjacent cells to have a bystander-killing effect, whereas it would be difficult for agent with lower membrane permeability to penetrate adjacent cells. In this study, Balb/c nude mice were inoculated with combination of HER2-expressing N87 cancer cells and HER2-negative MDA-MB-231-Luc cancer cells. Luciferase activity of MDA-MB-231 cancer cells reflected HER2-negative tumor burden, and the decrease of luciferase signal suggested the bystander killing of tested ADC drugs. As illustrated by the figure below, 3.3mg/kg disitamab vedotin showed significant stronger bystander killing against MDA-MB-231 cells than 10mg/kg ado-trastuzumab emtansine (T-DM1).

Bystander Killing Effect of Disitamab Vedotin and T-DM1



Source: Company data

- Cleavable linker with no lysosomal resistance

Disitamab vedotin's HER2 antibody and cytotoxic agent are bound together by an enzymatically cleavable peptide-linker. Our newly developed drug-linker system has superior stability in plasma and release mechanism in tumor sites. The scission of peptidic bonds of the linker relies on lysosomal proteolytic enzymes, which have very low activities in blood. Therefore, this linker can maintain the stability of disitamab vedotin in plasma during the systemic circulation to ensure that disitamab vedotin reaches and is internalized by the tumor cells in the original formation. After internalization by a tumor cell, the linker can be cleaved by lysosomes in the intracellular environment to trigger the release of the cytotoxic drug at tumor sites.

As compared to non-cleavable linkers, such as the linker used in ado-trastuzumab emtansine (T-DM1), the enzymatically cleavable linker is less dependent on the internalization by tumor cells and thus benefits the bystander-killing effect of the ADC. The non-cleavable linker of T-DM1 is stable in both the circulation and the tumor microenvironment, and therefore the release of active emtansine (DM1) requires lysosome degradation in a highly acidic microenvironment in cells. A published study has found that aberrant activity of V-ATPase in lysosomes of gastric cancer cells resulted in a decrease of the T-DM1 metabolite, leading to T-DM1 resistance in these cancer cells. And the study has also shown that HER2-targeted ADCs with cleavable linkers such as disitamab vedotin may be used to overcome this type of T-DM1 resistance because the cleavable linkers may have eliminated disitamab vedotin's reliance on tumor lysosome V-ATPase activity for payload release.

(2) Strong anti-tumor activity

Disitamab vedotin has demonstrated encouraging efficacy as compared to standard second line therapy in clinical trials of HER2-expressing GC and UC and also shown a potential in treating HER2 low-expressing cancer.

In addition to the *in vitro* assays discussed above, disitamab vedotin also showed stronger antitumor effects compared to other marketed HER2 targeted therapies, including trastuzumab, lapatinib and T-DM1, in *in vivo* studies. Figure 1 below shows the antitumor activity of disitamab vedotin against subcutaneous xenografts of HER2-positive human BC cell line (BT-474) in nude mice. In this study, disitamab vedotin resulted in a much higher tumor inhibition rate (170%) at a dose of 5mg/kg, than that of trastuzumab at 10 mg/kg (81%) and lapatinib at 200 mg/kg (97%). All tested molecules were well tolerated by the tumor-bearing mice. Figure 2 below shows the antitumor activity of disitamab vedotin against subcutaneous xenografts of HER2-positive, trastuzumab-resistant human BC cell line (BT-474/T721) in nude mice. At the dose of 5 mg/kg, disitamab vedotin and T-DM1 achieved a tumor inhibition rate of 108% and 93%, respectively, both of which are better than that of trastuzumab at 10 mg/kg. Figure 3 below shows the antitumor activity of disitamab vedotin against subcutaneous xenografts

of HER2-positive, trastuzumab-and lapatinib-resistant human BC cell line (BT-474/L 1.9) in nude mice. At the dose of 5 mg/kg, disitamab vedotin had a tumor inhibition rate of 91%, as compared to that of T-DM1 at 58%, suggesting BT-474/L 1.9 is also T-DM1-resistant. The results suggest that disitamab vedotin has an appreciably higher efficacy against trastuzumab- and lapatinib-resistant BT-474/L 1.9 xenografts than T-DM1 at the same dose. All tested molecules were well tolerated by the tumor-bearing mice in these studies.

Figure 1:

Antitumor Activity in HER2-Positive Cells

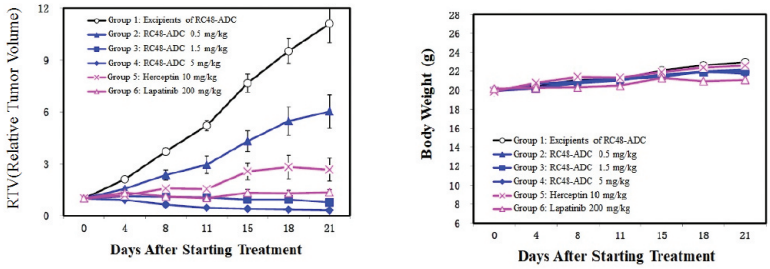


Figure 2:

Antitumor Activity in HER2-Positive, Trastuzumab-Resistant Cells

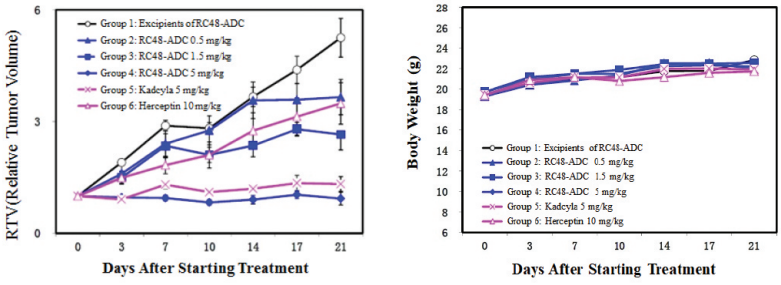
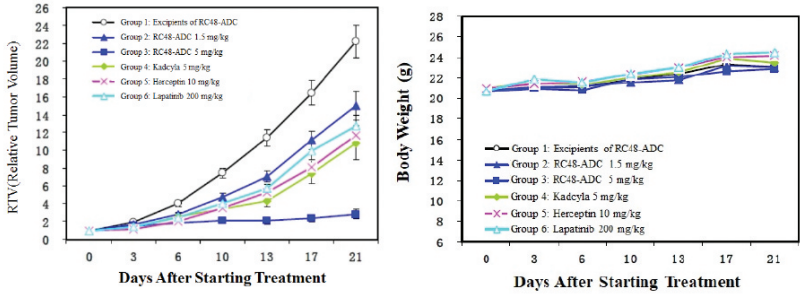


Figure 3:

Antitumor Activity in HER2-Positive, Trastuzumab- and Lapatinib-Resistant Cells

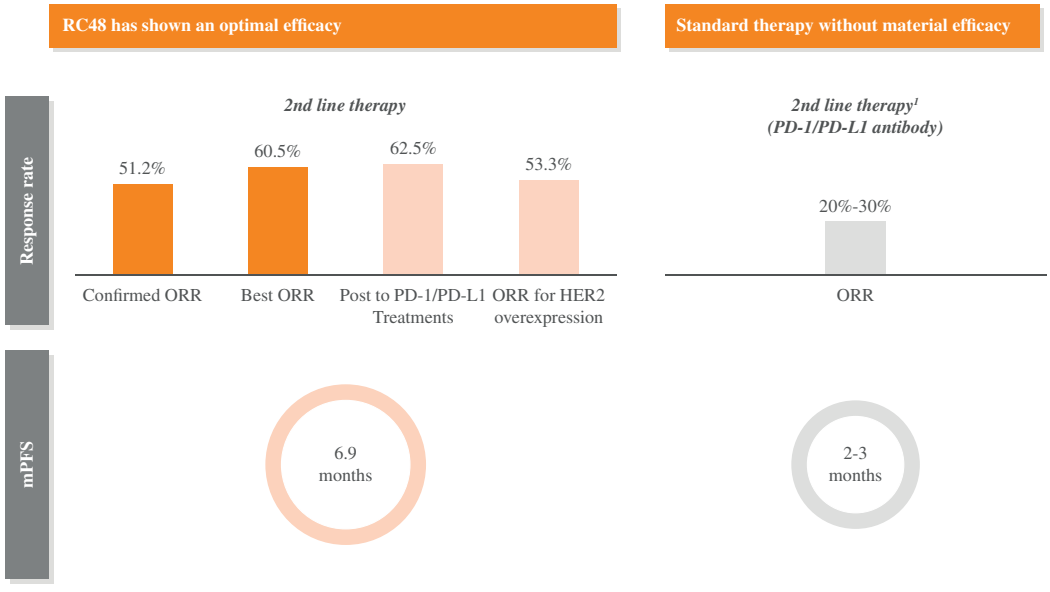


Source: Company data

Strong efficacy of disitamab vedotin in HER2-expressing cancer patients was further demonstrated in our clinical trials.

In a Phase II registrational trial in HER2 over-expressing (IHC 2+ or IHC 3+) locally advanced or metastatic GC or gastro-esophageal junction (GEJ) cancer, disitamab vedotin achieved an independent review committee (IRC)-assessed confirmed ORR (cORR) of 24.4%, median progression-free survival (PFS) of 4.1 months and overall survival (OS) of 7.6 months as of June 22, 2020. The patients enrolled in this trial had failed at least two lines of chemotherapy treatment for GC. Under the current treatment regime, these heavily pre-treated patients lack effective treatment options and therefore have particularly urgent medical needs. With the promising efficacy and survival benefits observed in this trial, disitamab vedotin demonstrated its potential to become a best-in-class post second-line therapy for patients with both HER2 high-expressing and low-expressing GC who have a large population in China. Based on the data of this trial, we expect to submit an NDA for conditional approval of disitamab vedotin for the treatment of GC in the third quarter of 2020.

In a Phase II trial in patients with HER2 over-expressing (IHC 2+ or IHC 3+) metastatic or unresectable UC, disitamab vedotin brought in best overall response (BOR) of 60.5%, cORR of 51.2% and median PFS of 6.9 months. In comparison with the newly emerging disitamab vedotin, PD-1/PD-L1 inhibitors only had cORR of 20% to 30% and median PFS of 2-3 months in the patients with 2L+ UC in the published clinical trials. Although these are not head-to-head studies, we believe that valuable insight can nonetheless be drawn from the comparisons. The encouraging efficacy observed in this trial indicates disitamab vedotin's significant potential to satisfy the hugely unmet medical needs of HER2-positive UC patients who failed the first-line treatment.



Note: PD-1/PD-L1 inhibitors approved to use as a second line therapy include pembrolizumab, atezolizumab, nivolumab, durvalumab and avelumab.

Source: Company data, other companies' press releases

Notably, patients with HER2 low-expressing cancer also showed encouraging responses to disitamab vedotin in our clinical trials. In a Phase II study in patients with HER2 over-expressing UC, patients with low-level HER2 expression (IHC 2+/FISH-) achieved overall response rate (ORR) of 45.8%. Based on the clinical potential of disitamab vedotin in treating HER2 low-expressing cancer as observed in our clinical trials, we have initiated a Phase III trial and a Phase II trial to evaluate the efficacy and safety of disitamab vedotin for the treatment of HER2 low-expressing (IHC2+/FISH-) BC and HER2 low- to non-expressing (IHC 1+ or IHC 0) UC, respectively.

Favorable safety profile

Disitamab vedotin has demonstrated favorable safety and tolerability in cancer patients in various clinical trials. In a Phase I study in patients with advanced solid tumors, 28 patients (49.1%) experienced Grade 3/4 treatment-related adverse events (TRAEs). In a Phase II study in patients with HER2 over-expressing GC or GEJ cancer, the most commonly reported Grade 3/4 TRAEs were neutrophil count decreased (14.2%), leukopenia (11.8%) and anemia (6.3%). In a Phase II trial in patients with HER2 over-expressing UC, the most commonly reported Grade 3/4 TRAEs were hypoesthesia in 7 patients (16.3%) and neutrophil count decreased in 6 patients (14.0%), and serious adverse event was reported in 14 patients (32.6%). The adverse events reported in this trial were manageable. In a Phase I trial and Phase Ib trial in patients with HER2 high-expressing BC, only 4 patients (5.7%) experienced treatment-related serious adverse events.

Summary of Clinical Trial Results

Disitamab vedotin is the first ADC drug approved for human clinical trials in China. It is currently being studied in multiple late-stage clinical trials across solid tumor types, including a Phase II registrational trial for GC, a Phase II registrational trial for UC and a Phase III trial for HER2 low-expressing BC.

Clinical Trials in Advanced Solid Tumors

Phase I trial in patients with HER2 over-expressing (IHC 2+ or IHC 3+) advanced solid tumors

Trial Design: This trial was an open-label, dose-escalation and expansion study in patients with HER2 over-expressing (IHC 2+ or IHC 3+) advanced solid tumors. The dose escalation phase was initiated by accelerated titration (0.1 and 0.5 mg/kg) and then switched to 3+3 scheme (1.0, 2.0, 2.5 and 3.0 mg/kg). In the dose expansion phase, patients were given disitamab vedotin at 2.0mg/kg Q2W. As of August 20, 2019, 57 patients (including 47 with GC and four with UC) were treated with disitamab vedotin at 0.1 (1 patient), 0.5 (1 patient), 1.0 (3 patients), 2.0 (6 patients in dose escalation and 32 patients in dose expansion), 2.5 (11 patients), and 3.0 mg/kg (3 patients), respectively, and were available for analysis. Most of the patients were at Stage IV (91.2%) or with metastasis (96.5%).

The primary endpoint is to determine maximum tolerated dose (MTD) of disitamab vedotin. It is also designed to evaluate the safety of disitamab vedotin.

Trial Status: This trial was completed in June 2019. The data cut off at August 20, 2019 was used for the below analyses.

Safety Data: In this trial, dose-limiting toxicity (DLT) was observed in 1, 2, and 1 patient at the dose of 2.0, 2.5, and 3.0 mg/kg, respectively. The MTD was 2.5 mg/kg. Most commonly reported treatment-related AEs (TRAEs) in 57 patients were white blood cell count decreased (66.7%), fatigue (56.1%), neutrophil count decreased (54.4%) and hemoglobin decreased (52.6%). Grade 3/4 TRAEs were reported in 28 patients (49.1%).

Efficacy Data: Confirmed objective response rate (ORR) was 21.1% (8/38) at the dose of 2.0 mg/kg and of 17.5% (10/57) of all patients. Disease control rate (DCR) was 52.6% and 49.1%, respectively. The subgroup ORR was 20.7% (6/29) at 2.0 mg/kg and 18.2% (2/11) at 2.5 mg/kg in the patients with GC, and 50% (2/4) in the patients with UC.

Conclusion: Disitamab vedotin has demonstrated a good safety profile and promising antitumor activity in patients with late-stage solid tumors. Notably, patients with GC and UC showed clinical meaningful responses and PFS improvement at the dose of 2.0 and 2.5 mg/kg. Based on the results of this trial, we initiated the Phase II studies of disitamab vedotin in patients with GC and UC.

Clinical Trial in GC

We have conducted a Phase II registrational trial in China to assess the safety and efficacy of disitamab vedotin for HER2 over-expressing (IHC 2+ or IHC 3+) advanced or metastatic GC. In this trial, disitamab vedotin demonstrated clinically meaningful response and survival benefit in patients with HER2 over-expressing gastric or gastro-esophageal junction (GEJ) cancer who failed at least two lines of prior treatment. Based on the data of this trial, we plan to submit an NDA for conditional approval of disitamab vedotin for the treatment of GC in China in the third quarter of 2020.

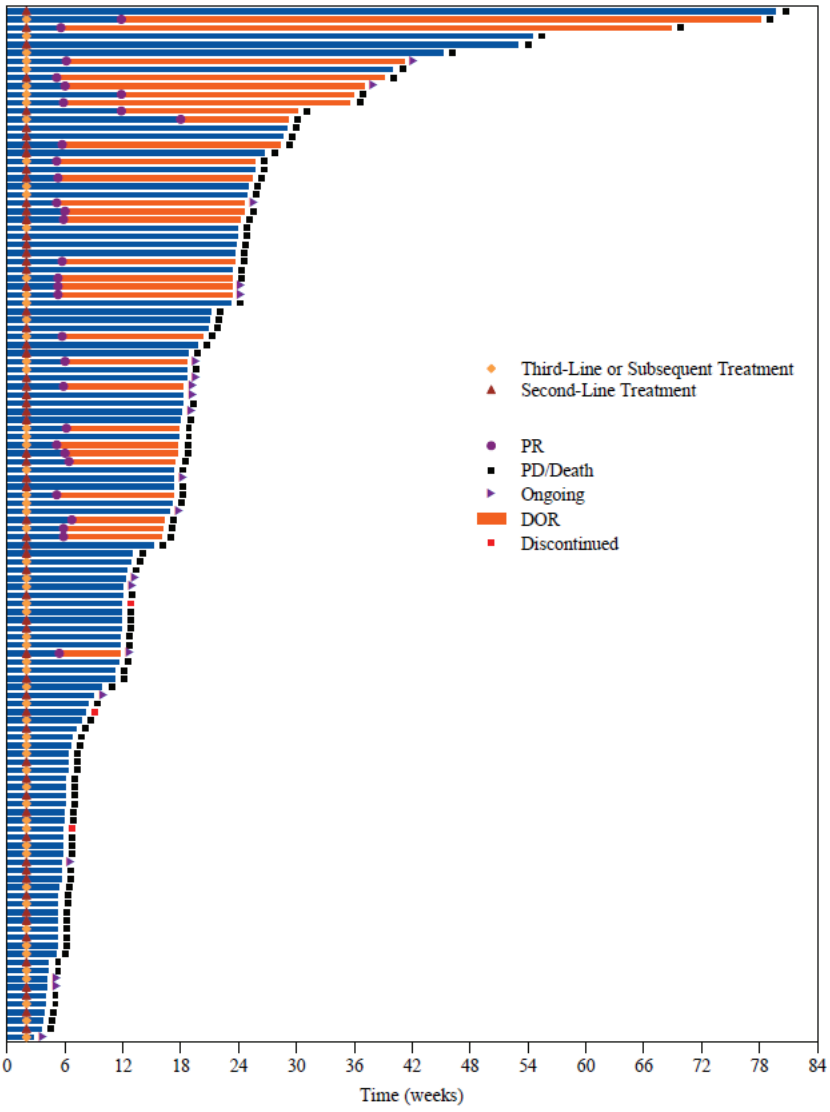
Phase II registrational trial in patients with HER2 over-expressing (IHC 2+ or IHC 3+) locally advanced or metastatic GC or GEJ cancer in China

Trial Design: This trial was an open-label, multi-center, single-arm Phase II study. As of June 22, 2020, 127 patients with HER2 over-expressing (IHC 2+ or 3+) GC or GEJ cancer who had previously received at least two lines of chemotherapy treatment were enrolled in this trial, with a median age of 58. 59 patients (46.5%) had received at least three lines of prior treatment. These patients received disitamab vedotin treatment at 2.5 mg/kg once every two weeks for six weeks. The primary endpoint of this trial is ORR. Other endpoints, including progression-free survival (PFS), overall survival (OS) and safety, were also assessed.

Trial Status: Patient enrollment of this trial was completed in November 2019. The data cut off at June 22, 2020 and December 17, 2019 were used for the below efficacy and safety analyses, respectively.

Efficacy Data: As of June 22, 2020, for all 127 patients, the independent review committee (IRC)-assessed cORR was 24.4% (95% CI: 17.2%, 32.8%), median PFS was 4.1 months (95% CI: 3.5, 4.8) and median OS was 7.6 months (95% CI: 6.6, 9.0). The figure below shows the best overall response for each patient.

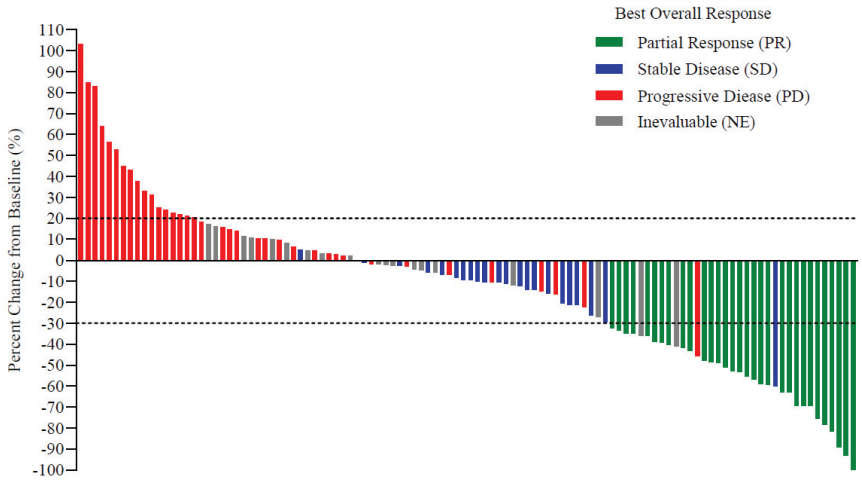
Best Overall Response of Disitimab Vedotin in GC or GEJ Cancer Patients



Source: Company data

The below waterfall plot shows the best percent change from baseline in target lesions for each patient.

Best Change of Target Lesion from Baseline of Disitamab Vedotin in GC and GEJ Cancer Patients



Source: Company data

Safety Data: Among 127 patients, the most commonly reported TRAEs were leukopenia (52.0%), alopecia (51.2%), neutropenia (48.0%), and fatigue (42.5%).

Conclusion: Disitamab vedotin has demonstrated a clinically meaningful response and survival benefit in patients with HER2 over-expressing GC or GEJ cancers. The safety profile was in line with the previously reported data of disitamab vedotin. Disitamab vedotin showed positive benefit/risk ratio for the target population. Based on these trial results, we expect to submit an NDA for conditional approval of disitamab vedotin for the treatment of GC in China in the third quarter of 2020.

Clinical Trials in UC

We have completed a Phase II trial in China to assess the safety and efficacy of disitamab vedotin for HER2 over-expressing (IHC 2+ or IHC 3+) metastatic or unresectable UC. We have two Phase II trials in UC. The data below are all from the first/initial Phase II (non-registrational) trial. Based on these data, and at CDE's request, we are initiating a second (registrational) Phase II trial in UC and we are in the process of enrolling patients. Our U.S. IND applications are also based on the data presented below from the initial Phase II (non-registrational) trial in UC.

In June 2019, we were invited to present results of our first Phase II study of disitamab vedotin in UC patients at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting held in Chicago, Illinois. We presented positive top line results at this influential meeting, including a 51% confirmed objective response rate (cORR) per independent committee review, which demonstrated clinically meaningful response to our disitamab vedotin in UC patients whose previous treatment failed, a population with highly unmet medical needs. The most common treatment-related adverse events in this trial included hypoesthesia, alopecia and hemotoxicity.

The FDA cleared our IND application in April 2020 based on these results, which would allow us to conduct a Phase II clinical trial of disitamab vedotin in UC in the U.S.

First Phase II trial in patients with HER2 over-expressing metastatic or unresectable UC (IHC 2+ or IHC 3+) in China

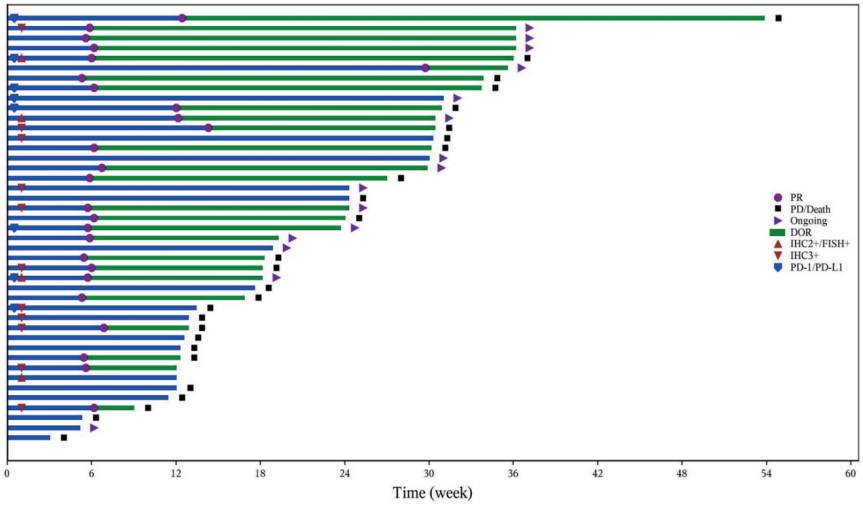
Trial Design: This trial was an open-label, multi-center, single-arm Phase II study. 43 patients with HER2 over-expressing metastatic or unresectable UC who had received previous treatment with systemic chemotherapies were enrolled in this trial, with a median age of 64. Among these patients, 86% had visceral metastases and 28% had two prior lines of chemotherapy treatment. 19% of patients had prior immune checkpoint inhibitor therapy. All patients were HER2 over-expressors as defined by IHC 2+ or 3+. These patients received disitamab vedotin treatment alone (2 mg/kg IV infusion) once every two weeks for six weeks.

The primary outcome measure of this trial is ORR. Other endpoints, including PFS, DOR, overall survival (OS) and safety, were also assessed.

Trial Status: Patient enrollment of this trial was completed in October 2018. The data cut off at April 30, 2019 was used for the below analyses.

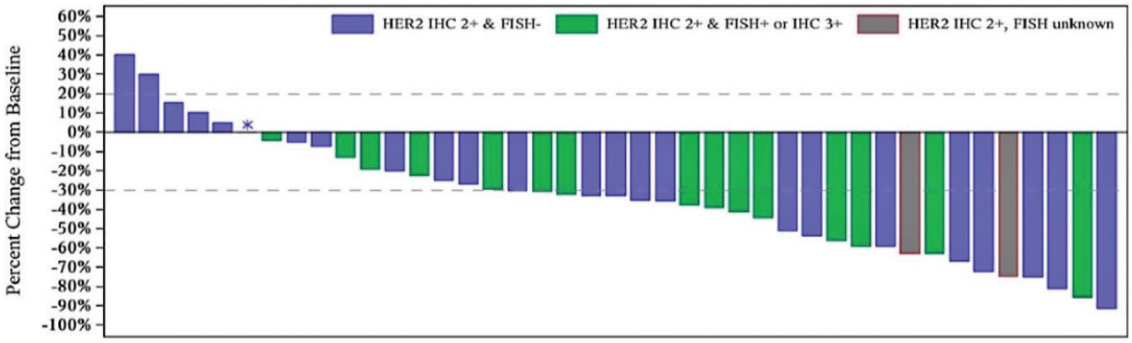
Efficacy Data: Overall, the study results demonstrated a 51.2% cORR (22/43). The best overall response (BOR) was PR in 26 patients and stable disease (SD) in 13 patients, bringing to a best overall response rate of 60.5% (26/43) and disease control rate (DCR) of 90.7% (39/43). For patients with liver metastases, the ORR was 60% (12/20). The median PFS was 6.9 months. As shown in the graph below, there are several patients with ongoing responses past 30 weeks.

Best Overall Response of Disitamab Vedotin in UC Patients



Source: Company data

Best Change of Target Lesion from Baseline of Disitamab Vedotin in UC Patients



Note: * means percentage change from baseline of target lesion is 0%.

Source: Company data

As can be seen in the table below, subgroup analysis for confirmed ORR showed consistently robust antitumor effects of disitamab vedotin among different types of metastatic or unresectable UC:

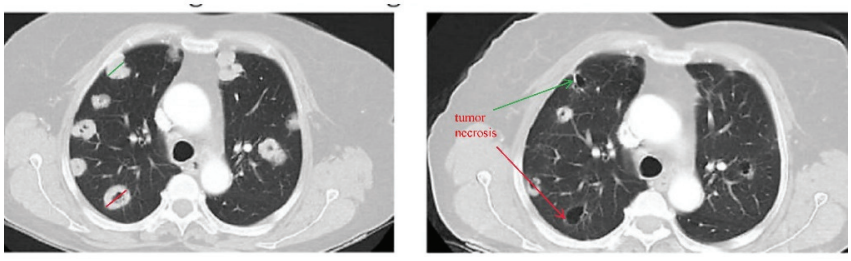
Subgroup Analysis for cORR

Subgroups	cORR (%, 95% CI)
IHC2+FISH+or IHC3+(n=15)	53.3% (26.6%, 78.7%)
IHC2+FISH-(n=24)	45.8% (25.6%, 67.2%)
Visceral Metastasis (n=37)	56.8% (39.5%, 72.9%)
Metastasis to Liver (n=20)	60.0% (36.1%, 80.9%)
Post to PD1/PDL1 Treatments (n=8)	62.5% (24.5%, 91.5%)
Post to 1 line of Chemotherapy (n=31)	54.8% (36.0%, 72.7%)
Post to ≥2 Lines of Chemotherapy (n=12)	41.7% (15.2%, 72.3%)

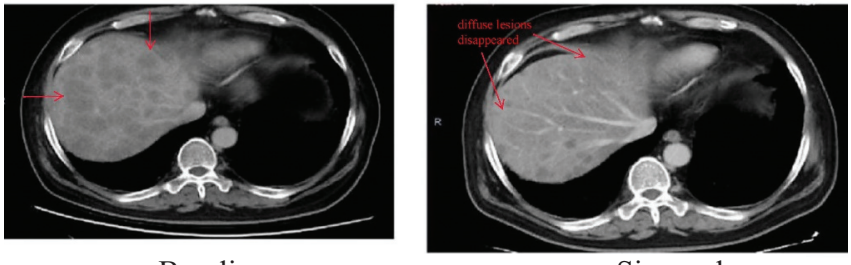
Source: Company data

There were impressive radiographic examples of response as shown below. As shown in the two CT images on the left side, two patients' tumors spread to lung and liver, respectively. After being treated with disitamab vedotin for a certain period, encouraging tumor shrinkage in lung and liver were observed in the two CT images on the right side below.

CT Images of Two Patients Treated with Disitamab Vedotin



Baseline Six months



Baseline Six weeks

Source: Company data

Safety Data: The most common treatment-related adverse events (TRAEs) were hypoesthesia (55.8%), alopecia (55.8%), white blood cell count decreased (55.8%) and neutrophil count decreased (41.9%). The most commonly reported Grade 3/4 TRAEs were hypoesthesia in 7 patients (16.3%) and neutrophil count decreased in 6 patients (14.0%). SAE was reported in 14 patients (32.6%). Most commonly reported SAEs were intestinal obstruction (4.7%) and incomplete intestinal obstruction (4.7%). The adverse events were manageable.

Conclusion: Disitamab vedotin has demonstrated encouraging anti-tumor effects on metastatic or unresectable UC. This study also showed disitamab vedotin was well tolerated in UC patients.

Clinical Trials in Breast Cancer

We have completed patient enrollment in a Phase I trial in advanced solid tumors, of which all patients enrolled are BC patients. We are also conducting Phase Ib and II trials in BC in China. Based on the pooled analysis of the data from the Phase I dose-escalation trial and part of the data from the Phase Ib trial as below, disitamab vedotin has demonstrated good tolerability and promising efficacy at multiple dose levels in BC patients.

In an additional cohort of the Phase Ib trial, we are specifically exploring the efficacy of disitamab vedotin in HER2 low-expressing BC and have observed promising preliminary outcome. Based on the results of our previous clinical studies and communication with NMPA, we have initiated a Phase III trial to evaluate disitamab vedotin for patients with HER2 low-expressing BC.

Phase I and Ib trials in patients with metastatic BC in China

Trial Design: The Phase I trial was an open-label, dose escalation study (0.5, 1.0, 1.5, 2.0 and 2.5 mg/kg) aiming to evaluate the maximum tolerated dose (MTD) of disitamab vedotin.

The Phase Ib trial was an open-label study with three dose cohorts (1.5, 2.0 and 2.5 mg/kg, Q2W) of patients with HER2-positive/high-expressing (IHC 3+ or IHC 2+/FISH+) BC and one cohort (2.0 mg/kg Q2W) of patients with HER2 low-expressing (IHC 3+ or IHC 2+/FISH-) BC. The data used in the pooled analysis below only include the data from cohorts of HER2 high-expressing BC. This trial was primarily designed to determine Phase II recommended dose.

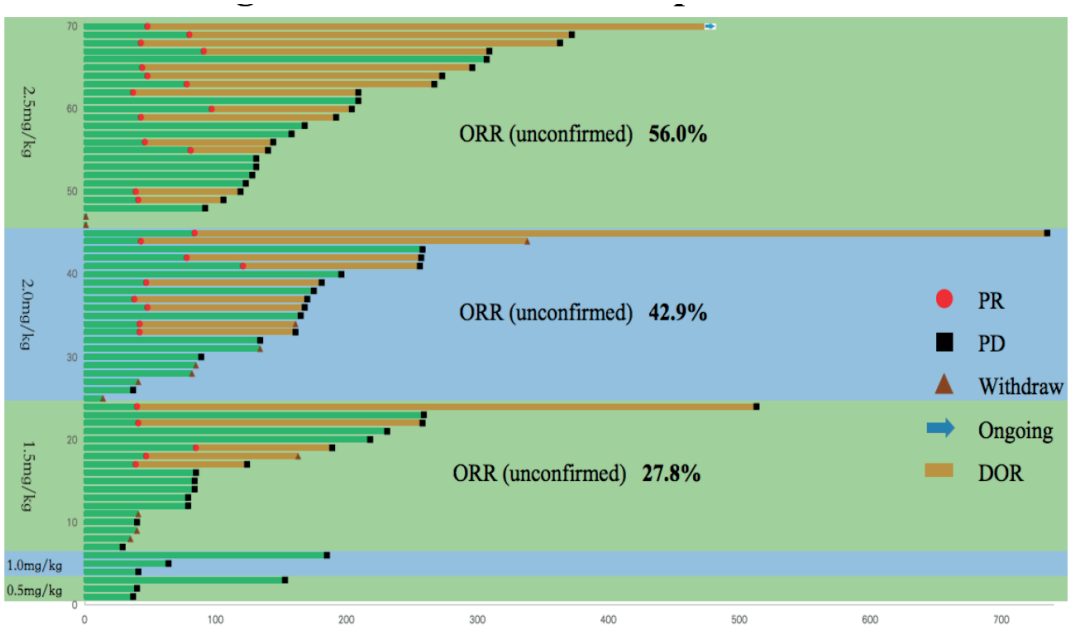
As of July 3, 2019, a total of 70 patients with HER2 high-expressing BC were enrolled and treated in the above two trials. Most of the patients had visceral metastasis (87.1%) and at least two lines of chemotherapy (78.6%) for metastatic BC. 47 patients (67.1%) had previously received trastuzumab for (neo) adjuvant or metastatic BC treatment. About half of the patients (42.9%) had previously received anti-HER2 tyrosine kinase inhibitor therapy and 24 patients (34.3%) had received at least two lines of anti-HER2 therapy.

Trial Status: Patient enrollment of the Phase I trial was completed in February 2018. Patient enrollment of the Phase Ib trial was still ongoing. The data cut off at July 3, 2019 was used for the below analyses, and with respect to the Phase Ib trial, the below analysis only included the data of HER2 high-expressing BC cohorts.

Safety Data: For all 70 patients, the most commonly reported TRAEs were AST increased (62.9%), ALT increased (61.4%), leukopenia (51.4%), hypoesthesia (51.4%) and neutropenia (51.4%). The most commonly reported Grade 3/4 TRAEs were neutropenia (21.4%) and asthenia (15.7%). Treatment-related serious adverse events (SAEs) occurred in 4 patients (5.7%). Gastrointestinal obstruction was the most commonly reported treatment-related SAE (2.9%). In the Phase I trial, MTD was not reached up to 2.5 mg/kg.

Efficacy Data: For all 70 patients, the cORR was 31.4% (22/70), the clinical benefit rate (CBR) was 38.6% (27/70), median PFS was 5.8 months and six-month PFS rate was 47.5%. For the 64 patients who received disitamab vedotin at the dose levels ≥ 1.5 mg/kg, the cORR was 34.4% (22/64), and the median PFS was 6.2 months. For patients received disitamab vedotin at the dose levels of 1.5mg/kg, 2.0mg/kg and 2.5mg/kg, the cORR was 22.2%, 42.9% and 36.0%, respectively, and the median PFS was 6.2 months,6.0 months, and 6.3 months, respectively. The graph below shows the best overall response of the patients at all dose levels.

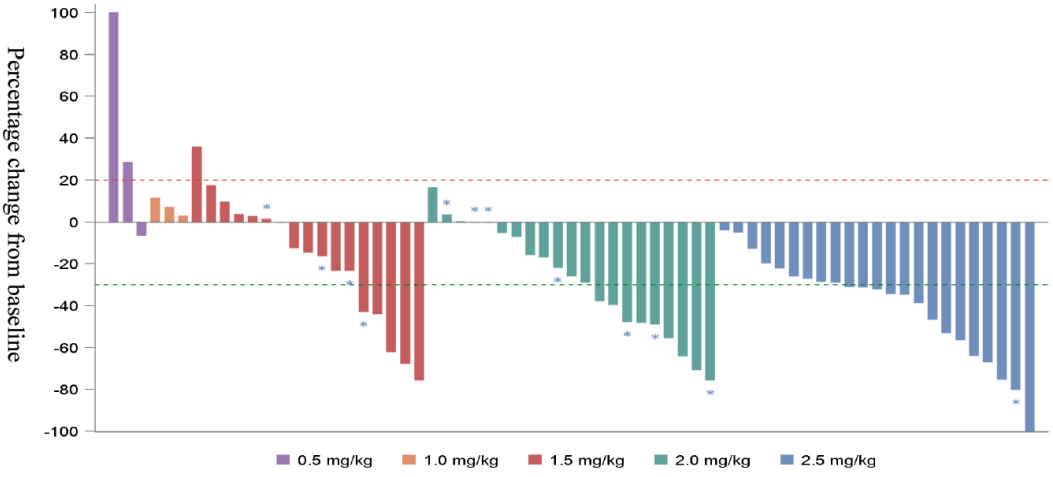
Best Overall Response of Disitamab Vedotin in BC Patients



Source: Company data

The waterfall plot below shows the best percent change from baseline in target lesions for BC patients at all dose levels.

Best Change of Target Lesion from Baseline of Disitamab Vedotin in BC Patients



Source: Company data

Conclusion: Disitamab vedotin demonstrated good tolerability and promising efficacy when administrated at 1.5 mg/kg, 2.0 mg/kg, and 2.5 mg/kg Q2W in the patients with HER2 high-expressing metastatic BC. Comparing with the other dose levels, 2.0 mg/kg Q2W was proved to be more favorable in terms of benefit and risk balance. Furthermore, we are exploring preliminary efficacy of disitamab vedotin at the dose level of 2.0 mg/kg Q2W in an additional cohort of low HER2-expressing metastatic BC in the Phase Ib trial.

Clinical Development Plan

We have been developing disitamab vedotin for a variety of HER2-expressing cancer types. Currently, we are strategically focused on clinical investigation of disitamab vedotin as a second-line or third-line therapy for GC, UC and BC, which suggest particularly significant unmet medical needs. We are also exploring the efficacy of disitamab vedotin in other prevalent cancer types with HER2 expression, such as NSCLC and BTC.

Leveraging the promising efficacy and safety data observed so far, we also intend to pursue global clinical development of disitamab vedotin in 2020. We have received FDA approval for a Phase II clinical trial for UC in the U.S. We have initiated communication with the FDA for a phase II clinical trial for GC in the U.S. The FDA already granted an orphan drug designation for disitamab vedotin in GC in 2018.

The table below sets forth details of our clinical development plan for disitamab vedotin.

Indication	Clinical trial stage	HER2 status	Type of therapy	(Expected) first patient in date	Expected NDA submission date	Location and competent authority
HER2 over-expressing locally advanced or metastatic GC	II (pivotal)	IHC 2+ or IHC 3+	Mono	May 2018	Q3 2020	China/NMPA
HER2 over-expressing locally advanced or metastatic GC	II	IHC 2+ or IHC 3+	Mono	1H 2021	–	U.S./FDA
HER2 over-expressing locally advanced or metastatic GC(1)	I	IHC 2+ or IHC 3+	Combo (PD-1)	Q3 2020	–	China/NMPA
HER2 over-expressing advanced or metastatic UC	II (pivotal)	IHC 2+ or IHC 3+	Mono	December 2018	1H 2021	China/NMPA
HER2 over-expressing advanced or metastatic UC	II	IHC 2+ or IHC 3+	Mono	Q1 2021	–	U.S./FDA
HER2 low- to non-expressing locally advanced UC	II	IHC 1+ or IHC 0	Mono	August 2019	–	China/NMPA
Locally advanced or metastatic UC	Ib/II	All	Combo (PD-1)	Q3 2020	–	China/NMPA
HER2 low-expressing advanced BC	III	IHC 2+/ FISH-	Mono	Q3 2020	–	China/NMPA
HER2 over-expressing or HER2 mutated advanced NSCLC	Ib	IHC 2+ or IHC 3+ or HER2 mutated	Mono	September 2018	–	China/NMPA
HER2 over-expressing metastatic BTC	II	IHC 2+ or IHC 3+	Mono	Q3 2020	–	China/NMPA

Note:

(1) We have initiated a Phase I clinical trial in patients with various HER2 over-expressing solid tumors, which is expected to include a cohort of 20-50 patients with HER2 over-expressing GC to explore the efficacy and safety of the combo therapy of disitimab vedotin and PD-1 inhibitor for th treatment of HER2 over-expressing GC.

- GC:

We have completed the patient enrollment in our Phase II registrational trial of disitamab vedotin as monotherapy for the treatment of HER2 over-expressing (IHC 2+ or IHC 3+) GC in China in November 2019 and are in the process of collecting and analysing trial data. We plan to submit an NDA of disitamab vedotin for HER2 over-expressing GC to the NMPA in the third quarter of 2020.

We are also exploring the clinical potential of disitamab vedotin in combination of PD-1 antibody for the treatment of HER2 over-expressing GC. We have initiated a Phase I trial in China to evaluate the efficacy and safety of this combination therapy in patients with various HER2 over-expressing solid tumors. In this trial, we plan to enroll a total of 29-68 patients, including 25-50 patients with HER2 over-expressing GC, and we expect to enroll the first patient with GC in the third quarter of 2020 for this trial.

In the U.S., the FDA has also granted orphan drug designation to disitamab vedotin for GC in July 2018. With the orphan drug designation, we are entitled to a seven-year exclusive marketing period of disitamab vedotin for this indication upon marketing approval. In addition, we plan to initiate a bridging study in the U.S. in 2021 to seek expedited approval. We also aim for the European market, and we anticipate to complete clinical trial application (CTA) filing with the EMA in GC in 2020.

- UC:

We have completed a Phase II trial of disitamab vedotin in the patients with HER2 over-expressing (IHC 2+ or IHC 3+) UC in China. Based on the positive clinical results of this Phase II trial and after communicating with the NMPA, we initiated a multi-center, single-arm and open-label Phase II registrational trial to evaluate disitamab vedotin as monotherapy for the treatment of HER2 over-expressing UC in China. We plan to submit an NDA for this indication to the NMPA in the first half of 2021. We have completed the enrollment of a total of 60 patients in this trial in June 2020. The patient enrollment is expected to be completed in July 2020. The primary endpoint of this trial is the ORR. In addition, we may need to conduct a post-launch Phase III confirmatory trial of disitamab vedotin as treatment for UC subject to discussion with the NMPA.

As promising efficacy of disitamab vedotin was observed in patients with lower-level expression of HER2, we are conducting a single-center, single-arm and open-label Phase II trial to evaluate disitamab vedotin as monotherapy for HER2 low- to non-expressing (IHC 1+ or IHC 0) UC. We have enrolled 9 patients as of June 22, 2020 and plan to enroll a total of 18 patients for this trial. The primary endpoint of this trial is the ORR.

In addition, a Phase Ib/II trial has been initiated to evaluate the combination of disitamab vedotin and PD-1 antibody in UC patients without detecting HER2 status. We plan to enroll a total of 12-36 patients and expect to enroll the first patient in the third quarter of 2020 for this trial.

In the U.S., we have obtained FDA's approval for the IND application for a Phase II trial in UC in April 2020. We plan to initiate the Phase II trial in UC in the U.S. in the first quarter of 2021.

- BC

As we have observed preliminary efficacy of disitamab vedotin in patients with low-level HER2 expression, we have communicated with the CDE and obtained their consent for us to initiate a Phase III trial of disitamab vedotin in patients with HER2 low-expressing (IHC 2+ and FISH–) BC. The primary endpoint of this trial is the PFS. We plan to enroll a total of 366 patients for this trial and expect to enroll the first patient in the third quarter of 2020. We expect to complete patient enrollment in the fourth quarter of 2021 and potentially file an NDA to the NMPA in 2022.

- NSCLC

We are conducting an open-label Phase Ib trial to evaluate disitamab vedotin as monotherapy for the treatment of HER2 over-expressing (IHC 2+ or IHC 3+) or HER2-mutant NSCLC in China. We have enrolled 27 patients as of June 22, 2020 and plan to enroll a total of 26-38 patients in this trial. The primary endpoint of this trial is the ORR.

- BTC

We are conducting a multi-center, single-arm and open-label Phase II trial to evaluate disitamab vedotin as monotherapy in the patients with HER2 over-expressing (IHC 2+ or IHC 3+) BTC post to the failure of 1L chemotherapy in China. We expect to enroll the first patient in the third quarter of 2020 and plan to enroll a total of 57 patients in this trial. The primary endpoint of this trial is the ORR.

Licenses, Rights and Obligations

We maintain the global rights to develop and commercialize disitamab vedotin. In March 2015, we entered into an agreement with a pre-clinical CRO for their technical support to assist us in the establishment of our ADC platform and the development of an ADC drug candidate based on our platform. Under this agreement, this supplier shall be eligible to receive milestone payments from us upon the achievement of certain development milestones, and to receive royalties from us in the amount of a low single-digit percentage based on the sales of this ADC. With the supporting services provided by this supplier, we developed disitamab vedotin and exclusively own its intellectual property rights and global commercial rights.

Material Communications

We have not received any relevant regulatory agency's concerns or objections to our clinical development plans as of the Latest Practicable Date. As of the Latest Practicable Date, no material unexpected or adverse changes have occurred since the date of issue of relevant regulatory for disitamab vedotin.

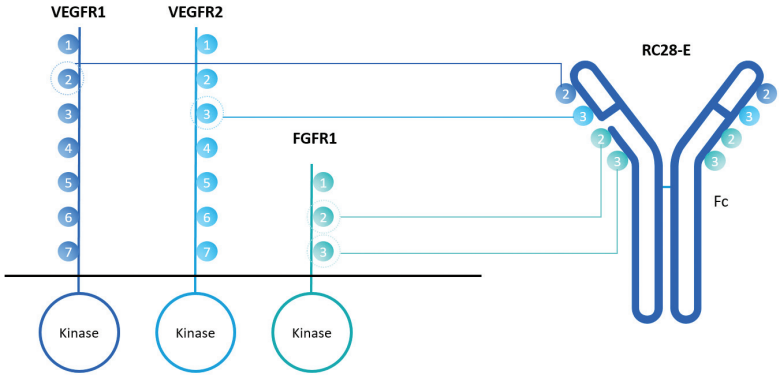
Cautionary Statement required by Rule 18A.05 of the Listing Rules of the Hong Kong Stock Exchange: WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET DISITAMAB VEDOTIN SUCCESSFULLY.

RC28

RC28 is an innovative fusion protein targeting both vascular endothelial growth factor (VEGF) and fibroblast growth factor (FGF). We are evaluating, and plan to evaluate, RC28 in clinical studies for several ophthalmic diseases, including wet age-related macular degeneration (wet AMD), diabetic macular edema (DME) and diabetic retinopathy (DR). In the Phase I clinical trial, no safety concerns were detected for up to 2.0 mg injection of RC28 in wet AMD patients.

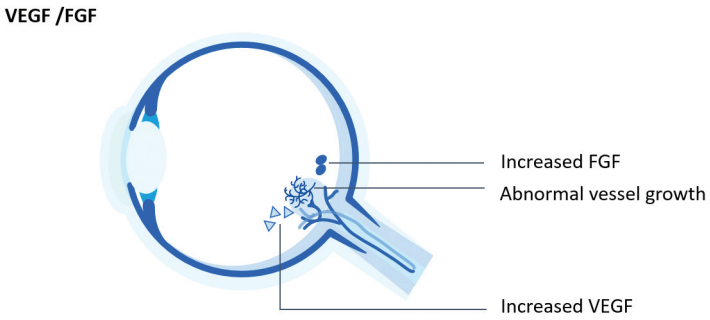
Mechanism of Action

As illustrated in the diagram below, RC28 is a recombinant dual decoy receptor IgG1 Fc-fusion protein, targeting both VEGF and FGF families simultaneously. These two growth factors, VEGF and FGF, are key pathway regulators in the formation of new blood vessels (angiogenesis), and are found in higher levels in patients with diabetes.



Source: Company data

Certain ophthalmic diseases, such as wet AMD, DME and DR, develop when blood vessels grow into the macula, causing fluid leaked from blood vessels into the eyes. These leak blood or fluid may lead to progressive vision loss and blindness. By binding to both of VEGF and FGF, RC28 can block angiogenesis factors in both VEGF and FGF families, thereby effectively slowing down the growth of new blood vessels and ultimately slowing the disease progression.



Source: Company data

Market Opportunities and Competition

Ophthalmic diseases present a sizeable market with massive potential driven by global aging population and rising awareness. RC28 targets hard-to-treat ophthalmic diseases including wet AMD and DME, which has a sizable and growing addressable market:

- Wet AMD:

Wet AMD, also known as neovascular exudative AMD, is a chronic eye disorder characterized by the abnormal growth of blood vessels and leakage of fluid and blood into the macula, which is responsible for central vision. Wet AMD is one of two types of age-related macular degeneration. While the other type—dry AMD—leads to a gradual loss of vision, wet AMD, accounting for 10% of total AMD cases, leads to sudden and severe vision loss and is the most advanced form of the disease. In addition, a fraction of dry AMD patients eventually evolve into wet AMD. The most severe form of wet AMD is the leading cause of blindness among older Chinese and Americans. There are more than 3.6 million and 1.8 million wet AMD patients in China and the U.S. in 2019, respectively. On average, around 90% of wet-AMD patients progressed to severe cases of vision loss.

- DME:

Diabetic macular edema (DME) is a complication of diabetes caused by fluid accumulation in the macula, or central portion of the eye, that leads the macula to swell. In people with diabetes, high blood sugar concentration can damage the tiny blood vessels at the back inner wall of the eye (retina) or block them completely. This condition is diabetic retinopathy. Sometimes, tiny bulges (microaneurysms) protrude from the vessel walls, leaking or oozing fluid and blood into the retina. This fluid can cause swelling in the macula, causing vision problems or even blindness. While diabetes is becoming increasingly common globally, its prevalence has been growing faster in China than the rest of the world in recent years and especially in the younger generation. According to the World Health Organization,

about 10% of Chinese adults live with diabetes, and nearly half of all adults are prediabetic, a condition in which blood glucose levels are higher than normal. There were around 129 million diabetes patients and 6.7 million with DME in China in 2019. Diabetes is also a key and growing health concern in the U.S. In 2019, about 34 million people in the U.S. had diabetes, among which 1.3 million patients had DME.

The emergence of anti-VEGF therapy has revolutionized the treatment of wet AMD and DME by allowing a more direct approach to inhibit choroidal neovascularization. There are several anti-VEGF drugs available that are currently used to treat these diseases, in which four are most commonly used for the condition. Three of these, Bayer's Eylea (aflibercept), Novartis's Beovu (brolucizumab) and Lucentis (ranibizumab), marketed by Roche in the U.S. and by Novartis outside the U.S., were designed specifically for the treatment of ophthalmic diseases such as wet AMD and DME. The fourth commonly used drug, Roche's Avastin (bevacizumab), was originally developed to treat various types of cancer, but is commonly used "off-label" in patients with wet AMD and DME as a less expensive alternative for the other three drugs. In China, Chengdu Kang Hong's Lumitin (conbercept) was another drug approved for the treatment of wet AMD and DME. Ranibizumab, brolucizumab, and bevacizumab are single-target VEGF monoclonal antibodies, and aflibercept and conbercept are both VEGF-targeting fusion proteins. As of the Latest Practicable Date, there has not been any VEGF/FGF dual-targeted antibody targeting wet AMD or DME that is approved by FDA or NMPA.

Eylea and Lucentis are considered by the American Academy of Ophthalmology (AAO) as clinically indifferent and of minimal differences in risk, while Eylea requires only half of doses of Lucentis per annum (i.e. 6 doses vs. 12 doses p.a.). Since 2015, the global sales of Eylea surpassed Lucentis, acting as a substitute, primarily attributable to its reduced dosing frequency. In 2019, the global sales of Eylea and Lucentis reached US$7.5 billion and US$3.9 billion, respectively.

Beovu (brolucizumab) from Novartis obtained approvals from the FDA and the European Commission in October 2019 and February 2020, respectively, for the treatment of wet AMD. Beovu allows for a less frequent dosing than Eylea and Lucentis, i.e. three-month dosing intervals after a three-month loading phase. It is currently the only anti-VEGF treatment approved in Europe for wet AMD.

Competitive Advantages of RC28

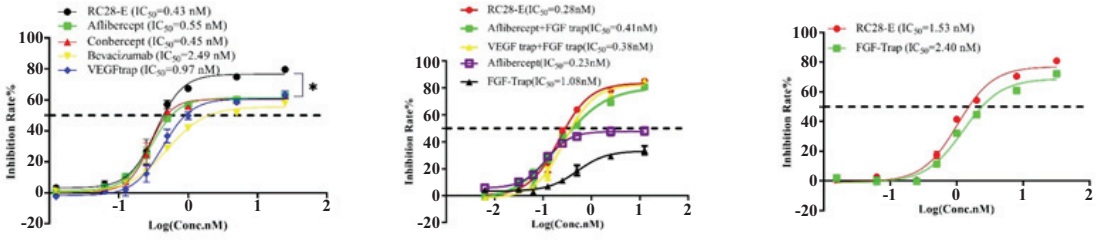
Dual-targeting mechanism leads to effective inhibition of blood vessel growth

A major challenge faced by single-target anti-VEGF therapies is the upregulated expression of other pro-angiogenic factors, such as FGF-2, when the activation of VEGF is inhibited. With the dual-targeting mechanism, RC28 can block angiogenesis factors at both VEGF and FGF families simultaneously and therefore can inhibit the abnormal vessel growth more effectively.

We conducted *in vitro* and *in vivo* studies to investigate the anti-angiogenesis effects of RC28 and to compare the biological activities of RC28 with other VEGF and FGF antagonists. By blocking both VEGF and FGF-2 pathways, RC28 inhibits the proliferation and migration of endothelial cells during the growth of new blood vessels.

In an *in vitro* study, we assessed the potency of RC28 and other antagonists in the inhibition of proliferation, migration and tube formation of human umbilical vein endothelial cells (HUVEC) induced by VEGF, FGF-2 or VEGF combined with FGF-2. As shown in the figure below, RC28 is able to inhibit proliferation of HUVEC induced by either or both of VEGF and FGF-2 in a concentration-dependent manner. While the anti-proliferative effect of RC28 induced by single factor binding was similar to that of VEGF or FGF antagonists as measured by IC50, the maximum relative inhibition rate of RC28 was higher than other antagonists as shown in all three panels in the figure below. In particular, RC28's ability to block double factors (VEGF+FGF-2)-induced HUVEC proliferation was significantly stronger than the other antagonists, as shown in the right panel of the figure below.

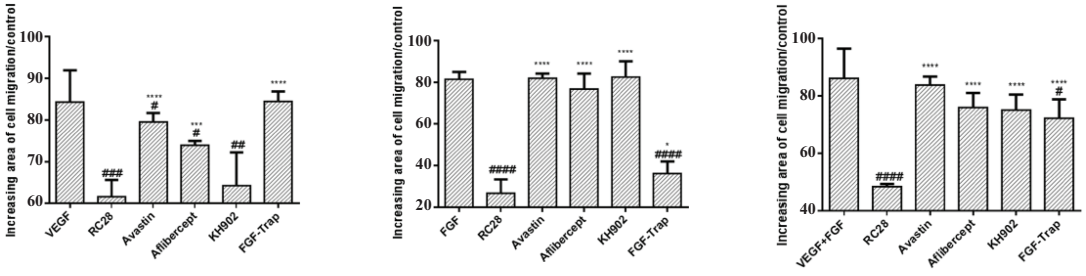
VEGF-induced HUVEC | **FGF-2-induced HUVEC** | **VEGF+FGF-2-induced HUVEC**



Source: Jiang et al., Eur. J. Pharm. Sci., 121 (2018)

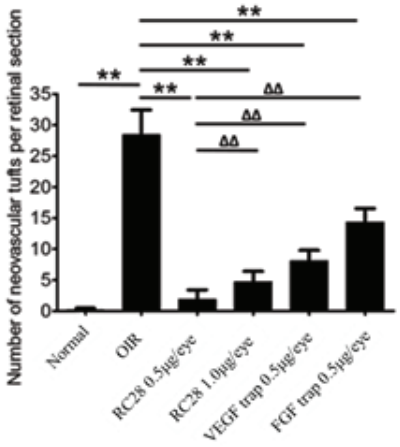
As shown in the figures below, RC28 also exhibited stronger inhibition effects on VEGF-induced migration, as compared to Avastin (bevacizumab) (P<0.001) and aflibercept (P<0.005) at the same concentration (1nM), and on FGF-2-induced migration, as compared to FGF-Trap (P<0.05). Notably, as shown in the right panel below, RC28 resulted in significant inhibition effects on VEGF+FGF-2-induced migration at the half concentration (1nM) among all the tested antagonists (2nM) (P<0.001).

VEGF-induced Migration **FGF-2-induced Migration** **VEGF+FGF-2-induced Migration**



Source: Jiang et al., Eur. J. Pharm. Sci., 121 (2018)

We also evaluated efficacy of RC28 in oxygen induced retinopathy (OIR) mouse models. High oxygen stress induced neo-vascular nucleus number increase in retina, while normal oxygen stress had no such effect. RC28, VEGF trap (aflibercept) and FGF trap significantly decreased neo-vascular nucleus number in these OIR mice. In addition, the dual-targeting RC28 (0.5μg/eye) showed significant stronger inhibitory effect than equivalent dose of VEGF-trap or FGF-trap.



Note: Nucleus number of neo-vascular in mouse retina by H&E staining.

** P <0.01 vs OIR group; ΔΔP<0.01 vs RC28 0.5 μg/eye group>

Source: Company data

Potentially better dosing profile translates to reduction in treatment costs

RC28 is constructed as the extracellular domains of VEGFR1, VEGFR2, and FGFR1 are fused with human IgG1 to achieve dual-blockade of VEGF and FGF, and to extend the half-life of the drug in serum. As observed in the mouse model discussed above, RC28 largely reduced neo-vascular nucleus number at the dosage of 0.5μg/eye as compared to other VEGF antagonists at the same dosage. Furthermore, as observed in a monkey choroidal neovascularization (CNV) model, traces of RC28 were detected as dispersing from eyeballs to the liver after 20 days, and a prolonged half-time pharmacokinetic profile was exhibited in this *in vivo* assay. Given the strong efficacy at low dose-level and an extended half-life of the drug, RC28 can potentially allow for a less frequent dosing profile and therefore reduce discomfort of the patients which is important as the drug is directly injected into the eyes.

Summary of Clinical Trial Results

We have completed a Phase I dose-escalation trial of RC28 in wet AMD patients in August 2019. Four dose levels of RC28 (0.25, 0.5, 1.0, and 2.0 mg) were investigated in a dose-escalation paradigm in which three patients were enrolled in each dose cohort. No safety concerns were detected after a single, intravitreal injection of RC28 up to 2.0 mg in this trial. 12 patients completed the study with no dose-limiting toxicity (DLT) and no serious or drug-related adverse events occurred. Moreover, no serum anti-RC28 antibodies were detected. This trial shows that RC28 was well tolerated in wet AMD patients with a single dose of up to 2.0 mg.

Clinical Development Plan

Currently, we are conducting an open-label, single-arm Phase Ib dose-expansion trial to evaluate the efficacy and safety of RC28 in the patients with wet AMD. We have enrolled 20 patients as of June 22, 2020 and plan to enroll a total of 36 patients for this trial. The primary endpoints of this trial are the average change of BCVA from the baseline at Week 12 and 48 and the incidence rate and severity of ocular and non-ocular adverse events.

We plan to initiate Phase II clinical trials for DME and DR in China in the second half of 2020.

Licenses, Rights and Obligations

We maintain the global rights to develop and commercialize RC28. We collaborated with Tongji University in the discovery and development of RC28 pursuant to our collaboration agreement with Tongji University. For details, please refer to the paragraph headed "—Collaboration Agreements—Collaboration with Tongji University."

Material Communications

We have not received any relevant regulatory agency's concerns or objections to our clinical development plans as of the Latest Practicable Date. As of the Latest Practicable Date, no material unexpected or adverse changes have occurred since the date of issue of relevant regulatory for RC28.

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 RC28 SUCCESSFULLY.

Our Other Clinical-Stage Drug Candidates (RC88 and RC98)

RC88

RC88 is a novel mesothelin-targeting ADC we developed for the treatment of solid tumors. It is currently in a Phase I clinical trial in patients with multiple advanced solid tumors, with a particular focus on pancreatic cancer, mesothelioma, ovarian carcinoma, gastric cancer, triple-negative breast cancer and lung adenocarcinoma. Although still in early clinical development, promising efficacy and safety results have been observed in its clinical trial.

Mechanism of Action

Mesothelin (MSLN) is a tumor-associated antigen with limited expression in normal tissues. It is frequently over-expressed on the cell membrane of a number of epithelial malignancies (e.g., mesothelioma, pancreatic, ovarian, lung, triple negative breast and gastric cancers).

Differential over-expression of MSLN in tumors and its role in cell adhesion and tumor metastasis make MSLN a suitable target for cancer therapy.

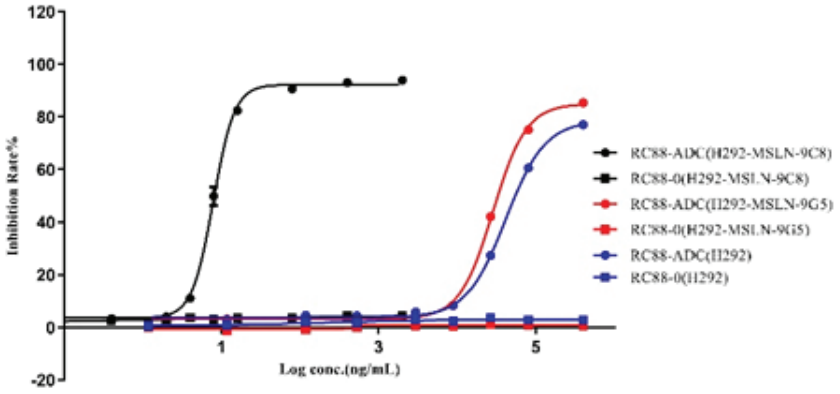
RC88 is composed of an MSLN-targeted antibody and MMAE connected by a cleavable linker. As described under "—Our Core Drug Candidates—Disitamab vedotin (RC48)—Mechanism of Action," ADC therapeutics can effectively deliver cytotoxic payload into cancer cells through the internalization of the antibody upon target binding.

Competitive Advantages of RC88

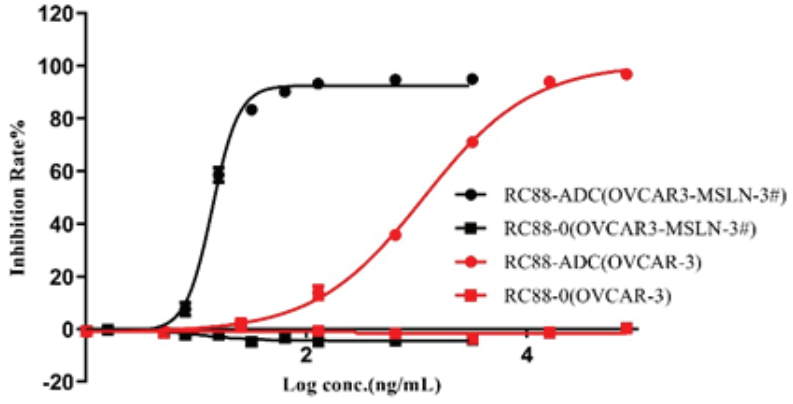
Based on our pre-clinical data, we believe that RC88 has two potential competitive advantages as compared to standard of care: (1) more target-specific inhibition on tumor growth and (2) stronger efficacy against MSLN-expressing cancer.

We assessed the anti-tumor activity of RC88 and compared it to that of the antibody component of RC88 (i.e., naked RC88) *in vitro*. In this study, RC88 was shown to be both potent and highly selective in killing MSLN-expressing tumor cells compared with MSLN-negative cells. As indicated in the charts below, RC88 showed a MSLN-dependent cellular cytotoxicity as the IC50 and maximum killing rates of RC88 corresponds to MSLN expression level of different cell lines. By contrast, naked RC88 antibody (RC88-0) showed none or limited tumor-killing effects to either mesothelin-positive or-negative cells.

Cytotoxic Effect in MSLN+/- H292 Cells



Cytotoxic Effect in MSLN+/- OVCAR-3 Cells



Abbreviations: RC88-0 = naked RC88 antibody

Notes: The MSLN expression level of cell lines used in this study is follows (highest to lowest): H292-MSLN-9C8>OVCAR-3-MSLN-3#>H292-MSLN-9G5>OVCAR-3>H292. RC88-0 had no inhibition effects on cancer cells in this study.

Source: Company data

Clinical Development Plan

We obtained IND approval from the NMPA in November 2018 and have initiated a single-arm, open-label Phase I trial to evaluate the safety, PK, PD, immunogenicity and efficacy of RC88 in patients with advanced solid tumors in China. This trial comprises of a Phase Ia-stage dose-escalation study and a Phase Ib-stage basket study. Patients will be randomized into six treatment groups to receive intravenous drip of RC88 every three weeks (Q3W) at dose levels of 0.1 mg/kg, 0.5 mg/kg, 1.0 mg/kg, 1.5 mg/kg, 2.0 mg/kg and 2.5 mg/kg. We plan to enroll a total of up to 31 patients for the Ia stage of this trial, and enrolled the first patient in May 2020. The primary endpoints are AEs and MTD.

Licenses, Rights and Obligations

We maintain the global rights to develop and commercialize RC88.

Material Communications

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 RC88 SUCCESSFULLY.

RC98

RC98 is an innovative PD-L1 monoclonal antibody we developed for the treatment of solid tumors. We obtained the IND approval for RC98 from the NMPA in July 2019 and we have initiated a Phase I clinical trial in patients with multiple advanced solid tumors and we expect to enroll the first patient in the third quarter of 2020.

Mechanism of Action

Under normal conditions, T cells will be activated by the immune system in response to antigens. 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, T cells express immune checkpoint receptors, such as PD-1, on its 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 tumor cells can overexpress PD-L1 to protect themselves from being detected and killed by T cells. As a PD-L1 antibody, RC98 is designed to specifically bind to PD-L1 in order to block the PD-1/PD-L1 inhibitory pathway and enable T cells to recover anti-tumor immune response.

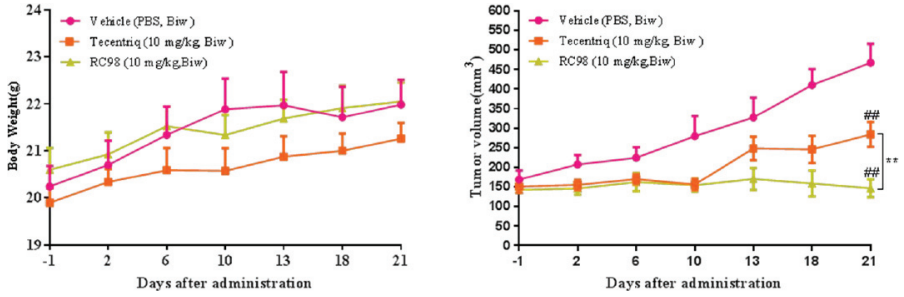
Competitive Advantages of RC98

Our pre-clinical research showed that RC98 has two potential competitive advantages as compared to other PD-L1 antibodies: (1) comparable or even better affinity for targets and anti-tumor effects, and (2) significant combination potential with other drug candidates in our pipeline, such as disitamab vedotin and RC88.

In vitro pharmacology studies showed that RC98 has high affinity for PD-L1 and can effectively block the association of PD-L1 with PD-1 by binding to PD-L1 protein expressed on cell surface. RC98 was also shown to induce the proliferation of $CD4^+$ T lymphocytes and the production of interleukin-2 (IL-2) and interferon-γ (IFN-γ) to promote immune responses in the *in vitro* studies.

In vivo studies demonstrated the strong anti-tumor activity of RC98 which is comparable or better than atezulizumab. Atezulizumab (brand name: Tecentriq) is a PD-L1 antibody approved for various cancer types by FDA and NMPA. As shown in the figure on the right below, RC98 showed stronger tumor inhibition effects on clonal tumor cells expressing human PD-L1 than atezulizumab (P<0.01) at the same dose in a mice model, while the figure on the left below suggested that the two molecules met with equivalent tolerability over time.

***In Vivo* Antitumor Activity of RC98 and Atezulizumab**

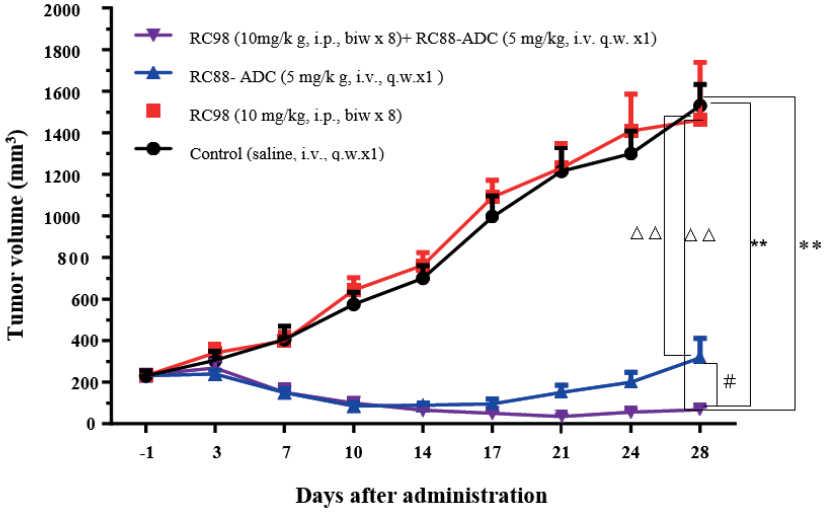


Note: ##P<0.01 vs Vehicle, **P<0.05 vs Tecentriq (atezulizumab).

Source: Company data

Furthermore, the combination of RC98 and our other oncology drug candidates have shown encouraging synergistic anti-tumor effects in our *in vitro* pharmacology studies. In mice models, we assessed the anti-tumor activities of the combination of RC98 with RC88 (MSLN ADC). As illustrated in figure below, the combination of RC98 and RC88 showed better antitumor effects than either of RC98 and RC88 against pancreatic adenocarcinoma epithelial cell. These results suggested the potent and synergistic tumor inhibitory effects of potential combination therapies using RC98.

***In Vitro* Antitumor Activity of RC98 + RC88**



Note: **P<0.01 vs Control, ΔΔP<0.01 vs RC98, #P<0.05 vs RC48-ADC.

Source: Company data

Clinical Development Plan

We have initiated a single-arm, open-label Phase I trial to evaluate the safety, PK, immunogenicity and efficacy of RC98 in patients with advanced solid tumors in China. We plan to enroll a total of 25 patients for this trial, and expect to enroll the first patient in the third quarter of 2020. The primary endpoints are MTD and the number and rate of AEs. Following this Phase I trial, we plan to further explore the clinical potential of RC98 in combination with our other pipeline assets, such as disitamab vedotin and RC88, for the treatment of advanced solid tumors.

Licenses, Rights and Obligations

We maintain the global rights to develop and commercialize RC98.

Material Communications

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 RC98 SUCCESSFULLY.

Our IND-Enabling Drug Candidates (RC108, RC118, RC138, RC148 and RC158)

In addition to our clinical-stage drug candidates, we are also developing a number of IND-enabling drug candidates in our rich pipeline. As of the Latest Practicable Date, we are evaluating five of our innovative IND-enabling candidates' pharmacokinetic and toxicokinetic in a variety of pre-clinical studies using in vitro and in vivo laboratory animal testing techniques, and these candidates have shown encouraging preliminary results in our preclinical studies. We are in the process of generating and collecting necessary data in preparation for filing INDs in order to explore their clinical development opportunities both in China and beyond. These five drug candidates include:

RC108: RC108 is a proprietary innovative c-MET-targeted ADC of us. c-MET is a receptor tyrosine kinase that, after binding with its ligand, hepatocyte growth factor, activates a wide range of different cellular signaling pathways, including those involved in proliferation, motility, migration and invasion. It is a well-characterized oncogene that is associated with poor prognosis in many solid tumor types. We are developing RC108 as a monotherapy for the treatment of advanced solid tumors. It is currently being evaluated in multiple pre-clinical studies, and we aim to file the IND application for RC108 in the third quarter of 2020. We maintain the global rights to develop and commercialize RC108.

RC118: RC118 is a proprietary innovative ADC of us. We are developing RC118 as a monotherapy for the treatment of advanced solid tumors. It is currently being evaluated in multiple pre-clinical studies, and we aim to file the IND application for RC118 in the second quarter of 2021. We maintain the global rights to develop and commercialize RC118.

RC138: RC138 is a proprietary innovative HiBody of us. We are developing RC138 as a monotherapy for the treatment of advanced solid tumors. It is currently being evaluated in multiple pre-clinical studies. We maintain the global rights to develop and commercialize RC138.

RC148: RC148 is a proprietary innovative HiBody of us. We are developing RC148 as a monotherapy for the treatment of advanced solid tumors. It is currently being evaluated in multiple pre-clinical studies, and we aim to file the IND application for RC148 in the second half of 2021. We maintain the global rights to develop and commercialize RC148.

RC158: RC158 is a proprietary innovative HiBody of us. We are developing RC158 as a monotherapy for the treatment of advanced solid tumors. It is currently being evaluated in multiple pre-clinical studies, and we aim to file the IND application for RC158 in the second half of 2021. We maintain the global rights to develop and commercialize RC158.

OUR PLATFORM

We have built a fully-integrated platform to enable our strategic focus on the research, development and commercialization of innovative biologics in the therapeutic areas of autoimmune diseases, oncology and ophthalmology. Our platform encompasses all the key biologic drug development functionalities and capabilities, which are housed in four main functional divisions: research and development (drug discovery and pre-clinical development), clinical development, manufacturing, and commercialization. These functional divisions have been individually optimized and collectively synergized to produce cross-function integration at various key points in the lifecycle of a drug candidate. We have also built and employ an efficient operating system for all these individual functional divisions, laying a solid foundation for bringing our strong pipeline of innovative drugs from inception through manufacturing and commercialization.

Research and Development Platforms

Led by Dr. Fang, our Co-Founder, CEO and CSO, our in-house research and development function has over 280 members with of drug discovery and development experience in multinational pharmaceutical companies and world-renowned laboratories as of the Latest Practicable Date. Around 55% of our research and development team members have masters or doctorate degrees in biology-related majors. Leveraging our strong research and development capabilities, we have developed a robust pipeline of over ten innovative drug candidates with 17 indications, including five in clinical development stage.

Our world-class biopharmaceutical research and development function consists of three specialized platforms targeting a variety of biological therapeutics. These include an antibody and fusion protein platform, an ADC platform and a bifunctional antibody (HiBody) platform. Our platforms are capable of discovering, screening and engineering novel molecules, developing proprietary technologies, and optimizing processes to produce biologics in an efficient and effective manner, which ensure an end-to-end integration from R&D to commercialization of our pipeline assets.

Antibody and fusion protein platform

Our antibody and fusion protein discovery and development capabilities are driven by innovative technologies and our expertise in bioinformatics-aided protein design and engineering. Our antibody and fusion protein platform is well-established and includes the following main functionalities: (i) antibody/fusion protein screening and engineering; (ii) cell line/process development; and (iii) drug substance (DS)/drug product (DP) GMP manufacturing.

Led by Dr. Fang, our Co-Founder, CEO and CSO, our R&D team brings us extensive expertise in the engineering and optimization of antibodies and fusion proteins. Dr. Fang has over 20 years of rich experience in biopharmaceutical R&D and manufacturing. He is the inventor for conbercept, a recombinant fusion protein which was approved in China for the treatment of wet AMD in 2013 and for the treatment of pathological myopia choroidal neovascularization (pmCNV) in 2017. Conbercept is also the first biologic wet AMD drug developed in China with over 40% market share of anti-VEGF therapeutics in China in 2019.

Our antibody and fusion protein platform features generation of novel monoclonal antibodies and fusion proteins through our internal studies. We can generate high affinity monoclonal antibodies in house using various technologies, including murine hybridoma, human B cell cDNA phage-display library and llama nanobody phage-display library. We have extensive knowledge in bioinformatics-aided protein design and engineering for Fc fusion proteins. We humanize antibody sequences to generate murine antibodies by hybridoma technology. We have generated a number of monoclonal antibody molecules using these technologies, some of which have been advanced to preclinical development stage as our drug candidates or for the use in companion diagnostic kits.

Indeed, synthetic fusion proteins such as our recombinant TACI-Fc fusion protein (telitacicept) could be designed to achieve improved efficacy or new functionalities by synergistically incorporating multiple protein fragments. Among other hypothetical benefits, the fusion of two or more protein domains could enhance bioactivities or generate novel functional combinations with a wide range of biotechnological and biopharmaceutical applications. In the case of telitacicept, for instance, the TACI-Fc fusion protein is bioinformatics-optimized and incorporates the extracellular BLyS/APRIL-binding domain of human TACI to the maximum extent. The structural design allows for telitacicept's enhanced dual-target binding affinity and better biological activity. The structure-based advantages of telitacicept are demonstrated by encouraging efficacy and favorable safety profile observed in its clinical trials for a variety of autoimmune diseases. Based on its clinical trial results for the treatment of SLE, the NMPA accepted our NDA of telitacicept for SLE in November 2019, which has been granted priority review in December 2019.

RC28 is another example that showcases the R&D capabilities of our platform. Our RC28 is an innovative fusion protein targeting both vascular endothelial growth factor (VEGF) and fibroblast growth factor (FGF). We are evaluating RC28 in clinical studies for several ophthalmic diseases, including wet age-related macular degeneration (wet AMD), diabetic macular edema (DME) and diabetic retinopathy (DR).

In addition to R&D capabilities, this platform also has the capacity to manufacture complex fusion proteins of high quality in large scale, which is proven by our successful track record of producing our fusion protein products, including telitacicept and RC28, for clinical trials.

ADC platform

Our ADC platform allows us to discover and develop ADCs which are designed to deliver chemotherapies specifically and directly to tumor cells while sparing healthy cells that could otherwise be subject to other treatments' undifferentiated attacks.

We are one of only a few biopharmaceutical companies that have a fully-integrated ADC platform with in-house capabilities covering the whole process of ADC development and manufacturing. Our ADC platform includes the following main functionalities: (i) screening platform for ADC linker and payload optimization; (ii) proprietary Thiel-bridge conjugation technology; (iii) process development for linker, payload and conjugation; (iv) GMP syntheses of linker, payload, and link-payload; and (v) GMP manufacturing of ADC DS and DP.

Leveraging this platform, we have discovered and are developing more than 5 ADC drug candidates, among which two have been advanced to clinical stage. Our leading ADC product, disitamab vedotin, is a novel ADC which we have independently developed to treat HER2-expressing solid tumors. Disitamab vedotin is the first ADC drug approved for human clinical trials in China and has demonstrated an excellent safety profile in clinical trials.

The key to ADC discovery and development is to get three distinct components to work together: (i) a monoclonal antibody that binds to a protein or antigen overexpressed on the surface of tumor cells, (ii) an active cytotoxic drug molecule (chemotherapy) that is designed to kill a tumor cell once it is internalized, and (iii) a stable molecular linker between the foregoing antibody and active cytotoxic drug, which is cleavable once internalized. Given the complicated structure of ADCs, the process development and manufacturing of ADC involve additional technical difficulties and complexities that are not presented in conventional manufacturing of monoclonal antibody, such as the antibody-drug conjugation reaction and subsequent drug substance purification.

Through around eight years of ADC research, we accumulated extensive expertise on choice of conjugation chemistry and linker and optimization of the conjugation reaction parameters. For each ADC drug candidate, we screen a large panel of combinations of conjugation methods, linkers and payloads to optimize molecular composition. For example, we used a cleavable linker in disitamab vedotin to bridge the HER2 antibody and the cytotoxic payload. The cleavability of this linker enables the payload to be released efficiently which enhances the therapeutic effects of the ADC. We developed a proprietary Thiel-bridge conjugation technology to yield more homogeneous ADC products that can improve pharmacodynamics and increase therapeutic window.

We also have global GMP-compliant manufacturing facility for entire ADC manufacturing process, including antibody production, syntheses of payloads, linkers, and payload-linkers, ADC conjugation, and fill/finish. The establishment and operation of such manufacturing facilities are capital intensive and require well-trained and specialized personnel.

Bifunctional antibody (HiBody) platform

Our bifunctional antibody platform focuses on the research and development of next-generation bifunctional antibodies that help us implement an emerging new therapeutic strategy. This bifunctional antibody (HiBody) technology is based on novel molecular format and is versatile in generating various bispecific antibodies, which have the potential to increase the efficacy and specificity of the antibody-based therapy.

Our HiBody platform includes the following main functionalities: (i) R&D on proprietary bifunctional antibody (HiBody) format for multiple products; (ii) R&D on next generation immune oncology therapeutics; and (iii) high manufacturability and product quality.

Using this novel molecular format, we have constructed a number of bifunctional antibody molecules and have three drug candidate in pipeline (RC138, RC148, and RC158). Our RC138 is the most advanced one among these product candidates. RC138 is a novel bifunctional antibody composed of a monoclonal antibody and a decoy receptor, which are implicated in two key pathways with independent and complementary immunosuppressive functions. RC138 has shown promising biological activities in pre-clinical studies and is expected to be further evaluated in clinical trials for the treatment of cancer in the future.

For many bispecific platforms, manufacturability is a key issue that often results in project failure. Our HiBody drug candidates have shown high expression level in our system and have constantly had product yield similar to conventional antibodies. The products from this HiBody platform are homogeneous and easy to be adapted to our manufacturing process. This platform was invented by Dr. Fang, our Co-Founder, CEO and CSO, and we have filed an invention patent for the molecular format of HiBody with broad claims.

Clinical Development Team

The clinical development function of our fully integrated platform manages clinical trials and in-house carries out a comprehensive suite of clinical development activities, including clinical trial design, implementation, and the collection and analysis of trial data.

Our clinical development efforts are led by our Chief Medical Officer, Dr. Ruyi He, and builds on Dr. He's expertise in and familiarity with regulatory review processes both in China and beyond, including the approval and conduct of registrational trials around the world. Dr. He has worked for the NMPA in China and the FDA in the U.S. for nearly 20 years, where he held a number of strategic leadership positions and chaired several working groups that were tasked with drafting and finalizing guidelines for the industry. He was also responsible for approving numerous applications for INDs and NDAs/BLAs in the regulatory authorities. He has published more than 20 research papers and abstracts in the field of internal medicine and drug regulatory science. As of the Latest Practicable Date, our clinical team consists of 200 employees.

As of the Latest Practicable Date, we have designed and implemented more than 30 clinical studies, including seven Phase II/III registrational trials. We rely on our strong medical team to manage substantially all stages of our clinical trials in-house, including trial protocol design, selection of investigators and sites, and implementation of clinical trial programs. Leveraging extensive knowledge and experience in clinical trials, our clinical development experts are particularly good at identifying unique therapeutic opportunities for our drug candidates based on the differentiating properties observed in the trials and improving their clinical plans accordingly.

Our clinical development team also possesses expertise in bioinformatics research and omics data analytics. We utilize proprietary algorithms to process and analyze a vast amount of genetic and molecular data in order to facilitate drug discovery and clinical studies. We also conduct translational research and use data to assess the effectiveness of treatment, evaluate different ways to customize therapies, and improve personalized medicine guidelines. These insights help further guide us toward new directions in novel drug and biomarker discovery.

Our clinical function has established long-term partnerships with numerous hospitals and principal investigators in various therapeutic areas and from different regions of China and the U.S. that offer us readily available clinical trial facilities and services. We believe that the size and geographic diversity of these facilities provide us a significant advantage in implementing large-scale global clinical trials and also enable us to conduct multiple clinical trials concurrently. We also work with highly reputable contract research organizations (CROs) to support our pre-clinical and clinical studies and provide regulatory and technical advises. Please refer to the paragraph headed "—Raw Materials and Suppliers" for details.

Manufacturing

As our lead products near the commercialization stage, we are preparing for commercial-scale manufacturing capabilities to ensure large scale delivery of high quality biologics. We have built manufacturing facilities with world-class production capacity of 6 x 2,000L disposable bag bioreactors in Yantai, China, which we plan to increase to 36,000L by 2021 and to 80,000L by 2025. Our manufacturing team in Yantai consists of approximately 319 employees as of the Latest Practicable Date.

We have in-house capabilities to manufacture our drug candidates, and we employ advanced technology to synthesize complicated drug compounds, such as ADCs, fusion proteins, and HiBodies. Our manufacturing facilities in Yantai recently passed the GMP inspection of an auditor from the European Union. We expect our manufacturing facilities in Yantai will have sufficient capacity to meet our commercial manufacturing needs in the foreseeable future.

Our existing and new manufacturing facilities are designed in compliance with global GMP standards. Our existing manufacturing facilities have a total floor area of approximately 31,862 m^2 and consist of (i) antibody manufacturing suites with production capacity of 2.3 million vials per year and (ii) ADC drug substances (DS) and drug products (DP) manufacturing suites with an annual output of 1.5 million vials. In anticipation of large needs of our drugs upon the commercialization, we purchased the use right to two additional pieces of land with an aggregate area of 81,038.47 m^2 and have started construction of new manufacturing facilities. The new construction project features an anticipated annual production capacity of seven million vials for antibody and six million vials for ADC. We expect to complete building the facilities and commence operation by 2025. In order to meet our near-term needs for telitacicept's global multi-center clinical trial, we plan to complete the first stage of the new construction project and commence operations by 2022, which is expected to have an anticipated annual production capacity of two million vials.

Our manufacturing facilities are equipped with system and equipment from industry-leading, highly reputable manufacturers and suppliers around the world. The up-stream manufacturing system uses disposable bag bioreactors of Sartorius and the down-stream manufacturing system is equipped with AKTA's device. We use purification equipment produced by General Electric. Our quality control system has been validated/audited by regulators for multiple times and meets rigorous and comprehensive requirements under Chinese and international standards. We obtained the drug manufacturing license issued by Shandong Provincial Medical Products Administration with the valid term until August 13, 2021 and were certified as Level-3 Standardized Safe Production Enterprise.

Our manufacturing team also performs the quality assurance (QA) and quality control (QC) function to oversee the quality of our facilities and our products, as well as the quality systems in research and development, manufacturing and commercialization of drug candidates and potential future commercial products. The tasks for QA and QC include (i) ensuring quality control throughout the manufacturing process, including specification of the drug substance and the drug product, testing of raw materials, and product quality assessments; (ii) establishing a quality assurance system across the entire business, including employee training programs, audits of various business segments and product manufacturing; and (iii) validation of facilities and equipment, which includes laboratory tests to verify that a particular process, method, program, equipment or material works properly.

Commercialization

We have established our sales and marketing department dedicated to the commercialization of our pipeline products. By the time we receive marketing approval of telitacicept in the fourth quarter of 2020, we expect our sales and marketing department to initially have around 100 members with rich experience in the commercialization of autoimmune therapeutics in the second half of 2020. As of the Latest Practicable Date, the leadership team of sales and marketing department is in place with department head, and a majority of director-level personnel and regional sales directors on board. Along with the increasing market penetration of telitacicept down the road, we expect to double the size of this department to 200 members in the second 12-month period of its commercial launch.

Our sales and marketing department will consist of a marketing team and a sales team:

- Our marketing team will initially have around ten members led by two department directors, and is mainly responsible for product positioning, market strategy, promotional activity planning and patient assistance.

- Our sales team will consist of a total of 90 members, including five to six regional sales directors, 12-16 sub-regional sales managers, and approximately 70 sales representatives. The sales team is mainly responsible for the formulation of detailed sales plan, the implementation of marketing and promotional activities, and the communication with, and training for, medical experts. This team will be split into several forces to cover different sales regions in order to ensure adequate market coverage in most of the provinces and municipalities in China and increase market penetration.

The leadership team of our sales and marketing department has significant expertise in commercialization of rheumatic, autoimmune and other biologic therapeutics. The head of our sales and marketing department, Mr. Jingping Wu, was previously general manager of Sunshine Guojian Pharmaceutical (Shanghai) Co., Ltd. ("三生國健藥業(上海)股份有限公司"), in charge of the overall sales and marketing work of Yisaipu ("益賽普") and other biologics products of the business unit. Mr. Wu is supported by key commercial leadership members who have an average of ten years of commercial experience in leading multinational and domestic pharmaceutical companies and have strong relationship with hospital administrators, physicians and leading experts, particularly in the field of rheumatology. We also intend to build a separate sales team for our immuno-oncology therapies when disitamab vedotin and other oncology drug candidates comes to the market.

Leveraging the expertise and industry connections of our team, we will market the 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 are expected to commence several months before the expected approval for the commercialization of a drug candidate. In preparation for the sales of telitacicept, we have

identified a number of hospitals, clinics and physicians specialized in the treatment of SLE, classified them into several levels based on the patient bases and academic influence, and have started to visit the sites and physicians in person for pre-launch training and liaison.

As telitacicept is a fully domestically-developed innovative biologics and has the potential to be a first-in-class and best-in-class therapy for SLE, we are, and will continue, sponsoring numerous investigator-led clinical trials to generate local clinical data and accumulate relevant clinical experience. We believe that these academic-oriented marketing efforts will be beneficial for improving alignment of expert opinions on, and promoting clinical use of, telitacicept after it becomes available for sale. 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. Moreover, we will actively organize academic conferences and seminars to publicize the clinical data and research results in relation of our drug candidates in order to raise our brand awareness and recognition.

In addition, we benefit significantly from our management team's successful experience with founding and operating RC Pharma, our strategic partner and a leading pharmaceutical company in China. Among other invaluable assets, our management team brings us nearly three decades of substantial operational, managerial and commercialization experience, resources and expertise, especially market access and distribution resources that are often coveted but cannot be easily replicated.

We are also pursuing co-development and licensing relationship with global pharmaceutical companies to promote and market our products worldwide. To implement our global marketing strategy, we have applied for patents regarding molecules of our core products in major regions and countries across the world. As of the Latest Practicable Date, we have 19 patents issued in China, five in the U.S., and 58 in a number of other major target markets, including South Korea, Russia, Australia, Canada, Japan and Hong Kong of China. We also have 21 pending patent applications in China, four pending patent applications in the U.S., nine pending patent applications under the Patent Cooperation Treaty and 33 pending patent applications under review in various other major target markets.

COLLABORATION AGREEMENT

Collaboration with Tongji University

In January 2011, we entered into a co-development agreement with Tongji University whereby we agreed to collaborate on a program to discover and conduct pre-clinical research of a VEGF/FGF dual inhibitor. Tongji University is one of most selective and most prestigious comprehensive universities in China. We co-discovered RC28 with Tongji University through this collaboration. Both parties agreed to make joint efforts in the discovery and pre-clinical development of the molecule and to jointly evaluate the development status of the program every year. Tongji University will not participate in the development of RC28 in the clinical stage.

Pursuant to the agreement, we and Tongji University agreed to co-file the patent applications covering such product, and Tongji University assigned its rights to the patent application to us such that we will be the sole owner of any and all patents granted to such product. Upon our consent, Tongji University can use the research results relating to this product in the application for other research program grants. Each party has the right to make improvements to the inventions and enjoy the title to such improvements, while the other party should be notified of, and have a first right of refusal to acquire, such improvements. Any improvements to the inventions co-developed by both parties will be jointly owned.

We are responsible for all the costs associated with the development activities subject to the term of the agreement, which are not refundable even if the program is terminated. According to this agreement, we will pay a total amount of up to RMB8 million as reimbursement for research and development expenses incurred by Tongji University and in consideration for Tongji University's assignment of its patent application rights to us in relation to RC28. As of the Latest Practicable Date, we had paid a total of RMB8 million to Tongji University under this agreement. The parties will equally share any government grants relating to preclinical development of such product if the parties jointly applied for and obtained any such grants, while the party who individually applies for and obtains any grant is entitled to receive such grant in its entirety.

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 drug candidates, novel discoveries, product development technologies, inventions, improvements 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 other confidential or proprietary information, and operate without infringing, misappropriating, or otherwise violating the valid and enforceable patents and intellectual property rights of other parties.

We have a global portfolio of patents to protect our drug candidates and technologies. As of the Latest Practicable Date, we owned (i) 19 issued patents in China, (ii) five issued patent in the U.S., (iii) 58 issued patents in other jurisdictions, and (iv) 67 pending patent applications, including 21 Chinese patent applications, four U.S. patent applications, nine patent applications under the Patent Cooperation Treaty and 33 patent applications in other jurisdictions.

As of the Latest Practicable Date, with respect to our three core drug candidates, telitacicept, disitamab vedotin and RC28, we own three issued Chinese patents, six pending Chinese patent applications, two issued U.S. patents, one pending U.S. patent applications, four pending PCT applications, 36 issued patents and 15 patent applications in other jurisdictions. In particular:

- Telitacicept: As of the Latest Practicable Date, we owned 11 issued patents, including one in China, one in the U.S. and nine in other jurisdictions, one patent application in other jurisdiction and one pending PCT application directed to telitacicept, our novel recombinant TACI-Fc fusion protein. The expected expiration for the issued patents and any patents that may issue from the currently pending PCT patent application ranges from 2027 to 2039, without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity and other government fees.

- Disitamab vedotin: As of the Latest Practicable Date, we owned 20 issued patents, including one in China, one in the U.S. and 18 in other jurisdictions, three pending Chinese patent applications and 14 patent applications in other jurisdictions, and two pending PCT applications directed to disitamab vedotin, our novel anti-HER2 monoclonal antibody-drug conjugate. The expected expiration for the issued patents and any patents that may issue from the currently pending patent applications ranges from 2034 to 2040, without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity and other government fees.

- RC28: As of the Latest Practicable Date, we owned ten issued patents, including one in China and nine in other jurisdictions, three pending Chinese patent applications, and one patent application in other jurisdiction and one pending PCT application, directed to RC28, our novel VEGF/FGF dual-targeted fusion protein. The expected expiration for the issued patents and any patents that may issue from the currently pending patent applications ranges from 2031 to 2039, without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity and other government fees.

The following table summarizes the details of the material granted patents and filed patent applications by our Company in connection with our clinical drug candidates.

Product	Title of Patent/ Patent Application	Jurisdiction	Status	Applicant	Patent Expiration[1]	Our Commercial Rights
Telitacicept	Optimized TACI-Fc Fusion Proteins	China	Granted	Company	June 15, 2027	All rights
	Optimized TACI-Fc Fusion Proteins	U.S., EPO (Germany, France, England, Switzerland, Italy), Japan, Republic of Korea, Russia, India	Granted	Company	June 16, 2028	All rights
	Optimized TACI-Fc Fusion Proteins	Brazil	Pending	Company	June 16, 2028	All rights
	TACI-Fc Fusion Protein and Use thereof	PCT	Pending	Company	December 24, 2039	All rights
Disitamab vedotin	Anti-HER2 Antibody and Conjugate thereof	China, U.S., EPO (Germany, France, Great Britain, Switzerland, Italy, Holland, Denmark, Sweden, Ireland, Belgium), Japan, Republic of Korea, Russia, Australia, Canada, Hong Kong	Granted	Company	November 18, 2034	All rights
	Anti-HER2 Antibody and Conjugate thereof	China, EPO, Japan, Brazil, India	Pending	Company	November 18, 2034	All rights
	Formulation of anti HER2 Antibody Drug Conjugate	Taiwan (China)	Pending	Company	March 26, 2040	All rights

Product	Title of Patent/ Patent Application	Jurisdiction	Status	Applicant	Patent Expiration[1]	Our Commercial Rights
	Formulation of anti HER2 Antibody Drug Conjugate	PCT	Pending	Company	March 25, 2040	All rights
	Use of Anti-HER2 Antibody-Drug Conjugate in Treating Urothelial Carcinoma	PCT, China, U.S., EPO, Japan, Australia, Russia, Canada, India, Brazil	Pending	Company	August 19, 2039	All rights
	Use of Anti-HER2 Antibody-Drug Conjugate in Treating Urothelial Carcinoma	Taiwan (China)	Pending	Company	August 28, 2039	All rights
RC28	Fusion Protein for Antagonizing Angiogenesis Inducible Factors and Uses thereof	China	Granted	Company	May 20, 2031	All rights
	Fusion Protein for Antagonizing Angiogenesis Inducible Factors and Uses thereof	EPO (Germany, France, Great Britain, Switzerland, Italy), Russia, Australia, Canada, Hong Kong	Granted	Company	May 18, 2032	All rights
	Fusion Protein for Antagonizing Angiogenesis Inducible Factors and Uses thereof	China	Pending	Company	February 11, 2035	All rights
	Use of Dual Targeting Vascular Inhibitor in the Manufacture of a Medicament for Preventing or Treating Fibrosis	China	Pending	Company and Binzhou Medical College	July 11, 2039	All rights

Product	Title of Patent/ Patent Application	Jurisdiction	Status	Applicant	Patent Expiration[1]	Our Commercial Rights
	Bifunctional Vascular Inhibitor and Use thereof	PCT, China	Pending	Company	December 4, 2039	All rights
	Bifunctional Vascular Inhibitor and Use thereof	Taiwan (China)	Pending	Company	December 6, 2039	All rights
RC88	Process for Preparing Intermediate of Antibody Drug Conjugate	PCT, China, U.S., EPO, Japan, Australia, Russia, Canada, India, Brazil	Pending	Company	May 20, 2039	All rights
	Anti-Mesothelin Antibody and Antibody – Drug Conjugate Thereof	PCT, China, U.S., EPO, Australia, Russia, India, Canada	Pending	Company	May 15, 2039	All rights
	Anti-Mesothelin Antibody and Antibody – Drug Conjugate Thereof	Taiwan (China)	Pending	Company	May 21, 2039	All rights

Abbreviation: PCT = Patent Cooperation Treaty.

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.

To protect proprietary technology of our specialized platforms, we have also filed three patent applications, including two patent applications in China and Taiwan (China) respectively and one PCT application, in relation to the Thiel-bridge conjugation technology of our ADC platform in 2019, and one patent application in China in relation to the molecular format of HiBody in 2020. These patent applications are currently pending.

As of the Latest Practicable Date, we owned 13 issued Chinese utility model patents and 4 Chinese utility model patent applications for our various innovative technologies that are utilized throughout our drug development and manufacturing process, including without limitation those related to mesothelin test, tunnel oven, unpacking tool and cooling equipment. These utility model patents have a term of ten years from the date of filing and are expected to expire in and after 2028.

The term of individual patents may vary based on the jurisdictions in which they are obtained. In most jurisdictions in which we file patent applications, including China and the United States, the term of an issued patent is generally 20 years from the filing date of the earliest non-provisional patent application to which the patent claims priority. In the United States, a patent's term may be extended or adjusted to account for administrative delays during prosecution by the 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 United States 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 United States, 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 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.

In the future, if and when our product candidates receive approval from the FDA in the United States or similar governmental authorities in other jurisdictions, we expect to apply for patent term adjustments and extensions on issued patents covering those product candidates in jurisdictions where such adjustments and extensions are available; however, there is no guarantee that the applicable authorities, including the USPTO and FDA, will agree with our assessment of whether such adjustments and extensions should be granted, and even if granted, the length of such adjustments and extensions.

The actual protection afforded by a patent varies on a claim-by-claim and jurisdiction-by-jurisdiction 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 jurisdiction and the validity and enforceability of the patent. We cannot provide any assurance that patents will issue with respect to any of our owned or licensed pending patent applications or any such patent applications that may be filed in the future, nor can we provide any assurance that any of our owned or licensed issued patents or any such patents that may be issued in the future will be commercially useful in protecting our drug candidates and methods of manufacturing the same. We are aware of numerous issued patents and pending patent applications belonging to third parties that exist in fields in which we are developing our drug candidates. For example, we are aware of a third-party issued patent in the U.S. that may be alleged to cover the use of our telitacicept in treating autoimmune disease which will expire in 2021, and a third-party issued patent in Europe that

may be alleged to cover the use of our telitacicept in treating mild-to-moderate SLE, although we do not expect to commercially launch telitacicept in the U.S. before the expiration of the third-party patent in the U.S. and telitacicept targets to treat moderate-to-severe SLE. Moreover, we are aware of third-party issued patents in the U.S. and Europe that may be alleged to cover our disitamab vedotin, and pending third-party patent applications in the U.S., Europe and mainland China that may be alleged to cover our disitamab vedotin's potential combination with immune checkpoint therapies. In addition, we are aware of a third-party issued patent in the U.S. that may be alleged to cover our RC88 which will expire in 2022, although we do not expect to commercially launch RC88 in the U.S. before the expiration of this third-party patent. We may need to obtain the license for using the patented technology from the third parties before the commercialization of our products in relevant jurisdictions and to pay license fees; otherwise, third parties may assert that we are using technology in violation of their patent or other proprietary rights. There can be no assurance that we would be able to obtain the license from third parties at a reasonable fee rate, or at all. For further details, please refer to the paragraph headed "Risk Factors – Risks Relating to Our Business – Risk Relating to Our Intellectual Property – Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain, and we may be subject to substantial costs and liability, or be prevented from using technologies incorporated in our drug candidates or future drugs, as a result of such litigation or other proceedings relating to patent or other intellectual property rights."

We may also rely, in some circumstances, on trade secrets, confidential information, know-how, unpatented technology and other proprietary information to protect aspects of our technology. We seek to protect our trade secrets and other proprietary or confidential technology and processes, in part, by entering into confidentiality agreements with consultants, scientific advisors and contractors, and invention assignment agreements with our employees. We have entered into confidentiality agreements and non-competition agreements with our senior management and key members of our R&D team and other employees who have access to our trade secrets and other proprietary or confidential information relating to our business. Our standard employment contract is executed with each of our employees, contains an invention assignment clause, under which we own the rights to all inventions, technology, know-how and trade secrets resulting from work performed for us or relating to our business and conceived or completed during the course of such employee's work.

These agreements may not provide sufficient protection of our trade secrets and other proprietary or confidential information. These agreements may also be breached, resulting in the misappropriation of our trade secrets and other proprietary or confidential information, and we may not have an adequate remedy for any such breach. In addition, our trade secrets and other proprietary or confidential information may become known or be independently developed by a third party, or misused by any collaborator or other third party to whom we disclose such information. Despite any measures taken to protect our trade secrets, confidential or proprietary information and other 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 paragraph headed "Risk Factors – Risks Relating to Our Business – Risk Relating to Our Intellectual Property" for a description of risks related to our intellectual property.

We conduct our business under the brand name of "RemeGen" ("榮昌生物"). As of the Latest Practicable Date, we had registered 15 trademarks in China and filed 13 trademark applications in China and other jurisdictions. We are also the registered owner of seven domain names and have irrevocable licenses for seven domain names.

We enter into collaboration agreements and other relationships with pharmaceutical companies and other industry participants to leverage our intellectual property and gain access to the intellectual property of others. For more information, please see the paragraph headed "– Collaboration Agreements."

As of 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, misappropriation or other violations of third-party intellectual property and we are not involved in any proceedings in respect of any intellectual property rights that may be threatened or pending and that may have an influence on its research and development for any Core Product in which we may be a claimant or a respondent.

Please refer to the paragraph headed "Statutory and General Information – B. Further Information about the Business of our Company – 2. Intellectual Property Rights" in Appendix VII to this document for further information.

CUSTOMERS

During the Track Record Period, all of our revenue was generated from the provision of contract research and pre-clinical development services to Rongchang Zibo, our related party, in 2018. Rongchang Zibo engaged us to provide research and pre-clinical development services for the development of certain biologics in 2018. For further details, please refer to the paragraph headed "Financial Information – Description of Selected Components of Statements of Profit or Loss and Other Comprehensive Income Items – Revenue".

RAW MATERIALS AND SUPPLIERS

We procure raw materials and equipment for the development and manufacture of our drug candidates from industry-leading and highly reputable manufacturers and suppliers around the world. We also engage a limited number of reputable CROs to support our internal team in managing and conducting pre-clinical and clinical studies of our pipeline candidates in China. For further details, please refer to the paragraph headed "– Our Platform."

For the years ended December 31, 2018 and 2019 and the three months ended March 31, 2020, our purchases from our five largest suppliers in the aggregate accounted for 28.1%, 17.3% and 20.3% of our total purchases (including value added tax), respectively. Our purchases mainly include raw materials, third-party contracting services for research and development purposes, machines and equipment, clinical trials, project construction and administrative services. To the best of our knowledge, all of our five largest suppliers during the Track Record Period are independent third parties. None of our Directors, their respective associates or any shareholder who, to the knowledge of our Directors, owned more than 5% of our issued share capital as of the Latest Practicable Date, has any interest in any of our five largest suppliers during the Track Record Period.

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

GOVERNMENT GRANTS, AWARDS AND RECOGNITIONS

We have received numerous national, provincial and local level government research grants and a wealth of awards and recognitions for our innovative drug development achievements. Some of national-level government research grants as well as significant awards and recognition that we have received are set forth in the tables below:

National-level Government Research Grants

Drug Candidate	Grant Type	Project Name	Grant Period
Telitacicept	National Scientific and Technological Major Project for "Major Drug Innovation" – First Batch of Drug Candidates of the "Eleventh Five-Year" Plan	Research and development of TACI-Fc fusion protein (telitacicept) as Category I innovative drug for the treatment of autoimmune diseases	Jan 2009 – Dec 2010
Telitacicept	National "Major Drug Innovation"	Clinical study of TACI-Fc antibody fusion protein for the treatment of neuromyelitis optica spectrum disorder	2019
Telitacicept	National "Major Drug Innovation"	Phase II and III clinical study of RC18	2018
Disitamab vedotin	National Scientific and Technological Major Project for "Major Drug Innovation"	Research on significant novel antibody-drug conjugate (ADC) and related technologies for the treatment of malignant tumors	Jan 2014 – Dec 2016
Disitamab vedotin	National Scientific and Technological Major Project for "Major Drug Innovation"	Research on significant novel antibody-drug conjugate (ADC) and related technologies for the treatment of malignant tumors – Phase I clinical trial of "novel anti-Her 2 ADC drug"	Jan 2014 – Dec 2016
Disitamab vedotin	National "Major Drug Innovation"	Research on diagnostic test of molecular phenotype in companion with HER2 ADC drug for the treatment of malignant tumors	2019

Drug Candidate	Grant Type	Project Name	Grant Period
Disitamab vedotin	National "Major Drug Innovation"	Clinical study of recombinant humanized HER2 antibody-MMAE conjugate (RC48) for injection	2020
RC28	Research and Development Program of Drug Types and Key Technology related to Key Tasks of National Scientific and Technological Major Project for "Major Drug Innovation" (Triple-Key Program)	Innovative dual-targeting anti-tumor receptor-IgG fusion protein drug (VF-28)	Jan 2013 – Dec 2015
RC28	National "Major Drug Innovation"	Clinical study of a dual-targeting antibody fusion protein drug (RC28-E) for the treatment of diabetic macular edema	2019
/	National Scientific and Technological Major Project for "Major Drug Innovation"	Protein-engineering platform and incubation center for research and development of innovative drugs	Jan 2013 – Dec 2015
/	National "Major Drug Innovation"	Innovative antibody-drug conjugate (ADC) drug and key technologies	2019

Key Awards and Recognitions

Award/Recognition Name	Recipient	Year	Certification Level
National Large-scale Integrated New Drug Research and Development Technology Platform – (Shandong) Model Enterprise of Industrialization	RemeGen, Ltd.	2010	National
National (Shandong) Innovative Drug Incubation Base	RemeGen, Ltd.	2010	National
Post-doctoral Scientific Research Center	RemeGen, Ltd.	2013	National
Academician's Research Center	RemeGen, Ltd.	2018	Shandong Province
Shandong Province Model Engineering Technology Research Center	RemeGen, Ltd.	2014	Shandong Province
Provincial-level Key Laboratory of Shandong Province	RemeGen, Ltd.	2015	Shandong Province

COMPETITION

The pharmaceutical and biopharmaceutical industries are highly competitive and subject to rapid and significant change. While we believe that our robust pipeline of innovative drug candidates in clinical and pre-clinical trials, strong research and development capability, fully-integrated platform and world-class 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 drug candidates, in particular in the fields of autoimmune diseases, oncology and ophthalmology. These include major pharmaceutical companies, such as GlaxoSmithKline, Novartis, Daiichi-Sankyo, Roche and Sichuan Kanghong, specialty pharmaceutical and biotechnology companies of various sizes, such as BeiGene, Junshi, Innovent and Akeso, academic institutions, government agencies and research institutions. Any drug candidates that we successfully develop and commercialize will compete both with existing drugs and with any new drugs that may become available in the future. For more information on the competitive landscape of our drug candidates, please refer the paragraph headed "—Our Drug Candidates."

EMPLOYEES

As of the Latest Practicable Date, we had 998 employees in total. The following table sets forth the number of our employees categorized by function as of the Latest Practicable Date.

Function	Number	% of Total
Research and development	285	28.6%
Clinical development	197	19.7%
Manufacturing and quality	319	32.0%
Commercial, general and administrative	197	19.7%
Total	998	100%

Among the 998 employees, 794 of our employees are stationed in Yantai, Shandong Province, and 204 of our employees are based in 34 other cities including Beijing, Shanghai and Hefei in China and Fremont, California and Washington, D.C. in the U.S.

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 also enter into separate confidentiality and non-competition 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.

We provide various incentives and benefits to our employees. We offer competitive salaries, bonuses and share-based compensation to our employees, especially key employees. In China, during the Track Record Period and up to the Latest Practicable Date, we have made contributions to social security insurance funds (including pension plans, medical insurance, work-related injury insurance, unemployment insurance and maternity insurance) and housing funds for our employees in accordance with applicable Chinese laws. As of the Latest Practicable Date and up to the Latest Practicable Date we had complied with all statutory social security insurance fund and housing fund obligations applicable to us under Chinese laws in all material aspects.

We consider our relations with our employees to be good. Our employees are represented by a labor union. 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

We own our main campus on 107,702 m^2 of land in Yantai, Shandong province, China, in which we built manufacturing, R&D, administrative and ancillary buildings with a total of 36,999 m^2 of floor space. Our existing manufacturing facilities occupy 31,862 m^2 of floor space, which houses 12,000 L of bioreactors. 68,000 L biologics manufacturing facilities are currently being constructed on two pieces of land with an aggregate area of 81,038 m^2, some of which will be reserved for future expansion. Our main campus also includes laboratories, offices, water treatment facilities, warehouses for storing drugs and chemicals, and other facilities for employees.

As of the Latest Practicable Date, we also rent a total of 5,297 m^2 of office space in Yantai, Beijing and Shanghai for laboratory use and for administrative functions. The relevant rental agreements provide lease expiration date ranging from September 2020 to May 2024.

The property valuation report from JLL, set out in Appendix III to this document, sets forth details of our property interest at our main campus in Yantai, Shandong province as of March 31, 2020. JLL valued such property interest at an amount of RMB200.4 million as of March 31, 2020, which does not include the value of a piece of land of 69,727 m^2 we acquired after March 31, 2020. For further details, please refer to Appendix III to this document. Save for the above-mentioned property interest, no single property interest that forms part of our non-property activities had a carrying amount representing 15% or more of our total assets as of March 31, 2020.

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. Our operations involve the use of hazardous chemicals. We implemented safety guidelines setting out information about potential safety hazards and procedures for operating in the manufacturing facilities, and we installed video surveillance systems inside the manufacturing facilities to monitor the operation process.

Our operations also produce waste water and chemical waste. We treat the waste water existing our bioreactors in our biological waste disposal facilities, and store hazardous wastes in special warehouse. We also contract with third parties for the disposal of hazardous materials and wastes. During the Track Record Period and up to the Latest Practicable Date, we did not incur material cost of compliance with relevant environment protection laws and regulations.

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 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.

PERMITS, LICENSES AND OTHER APPROVALS

As of the Latest Practicable Date, we had obtained all requisite licenses, approvals and permits from relevant authorities that are material to our operations. 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	RemeGen, Ltd.	Shandong Provincial Medical Products Administration	August 14, 2016	August 13, 2021
Certificate of Filing for Pathogenic Microorganism Laboratory and Science Experiments in Shandong Province (Microorganism Laboratory)	RemeGen, Ltd.	Yantai Municipal Health and Family Planning Committee	August 14, 2017	August 13, 2022
Certificate of Filing for Pathogenic Microorganism Laboratory and Science Experiments in Shandong Province (Molecular Biology Laboratory)	RemeGen, Ltd.	Yantai Municipal Health and Family Planning Committee	June 27, 2017	/

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 do not maintain insurance for adverse events in clinical trials as we estimate the risk exposure to be minimal. We currently do not maintain product liability insurance or key person insurance.

LEGAL PROCEEDINGS AND COMPLIANCE

As of 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.

Compliance

Substantially all of our operations are in the PRC. During the Track Record Period and as of the Latest Practicable Date, we did not experience any non-compliance that, in the opinion of our Directors, is likely to have a material adverse effect on our business, financial condition or results of operations. As advised by our PRC Legal Advisor, during the Track Record Period and up to the Latest Practicable Date, we have been in compliance with related laws and regulations in all material respects, and have obtained all necessary licenses, permits and certificates that are material in respect of our business in the PRC.

Set forth below is a summary of our systemic non-compliance matters under Guidance Letter HKEX-GL63-13 issued in July 2013 and last updated in March 2019 by the Stock Exchange during the Track Record Period and up to the Latest Practicable Date.

Deviation from intended use of loan proceeds

Background

For the year ended December 31, 2019, our Company has obtained a credit line of RMB52 million from Bank A and a credit line of RMB70 million from Bank B (together with Bank A, the "Lending Banks"), which were secured by pledging our Company's assets. For the three months ended March 31, 2020, our Company has increased the credit line from Bank B from RMB70 million to RMB143 million, secured by pledging our Company's assets.

Under these approved credit lines, our Company made drawdowns by entering into four loan contracts to draw down an aggregate amount of RMB146 million for the year ended December 31, 2019 and three loan contracts to draw down an aggregate amount of RMB60 million for the three months ended March 31, 2020 with the Lending Banks (the "Loan

Contracts") (the "Loans"). The Loans were revolving in nature and the maximum outstandingbalance of the Loans at any time was RMB86 million during the year ended December 31, 2019 and RMB90 million during the three months ended March 31, 2020. We have fully repaid these Loans before March 31, 2020. Details of the Loan Contracts are as follows:

	Lending banks	Loan amount	Interest rate	Loan drawdown date	Loan repayment date
		(RMB million)			
1	Bank A	26	5.50%	June 25, 2019	December 25, 2019
2	Bank B	40	6.31%	September 10, 2019	December 27, 2019
3	Bank B	20	6.31%	September 20, 2019	December 27, 2019
4	Bank B	60	6.31%	December 30, 2019	March 13, 2020[(1)]
5	Bank B	30	6.31%	January 13, 2020	March 13, 2020
6	Bank B	25	6.31%	February 12, 2020	March 13, 2020
7	Bank B	5	6.31%	February 26, 2020	March 13, 2020

Note:

(1) RMB30 million was repaid on January 7, 2020 and the remaining RMB30 million was repaid on March 13, 2020.

To expedite the drawdown procedure, the Company submitted contracts with MabPlex and CelluPro (the "Connected Suppliers") as supporting documents for each drawdown application (the "Supplier Contracts"). The transaction amounts stated in such Supplier Contracts were greater than the aggregate actual transaction amounts for the same period between our Company and the Connected Suppliers for the purchase of reagents and culture medium in the ordinary and usual course of business. Our Company, MabPlex and CelluPro were fellow subsidiaries of RC Pharma prior to the completion of the Reorganization in December 2019. Each of MabPlex, CelluPro and RC Pharma will be our connected persons upon [**REDACTED**].

The Loan Contracts provided that the loan proceeds should be used to make payment to the Connected Suppliers under the Supplier Contracts. Instead, the Connected Suppliers transferred the total Loan proceeds to our Company upon receiving the same from the Lending Banks (the "Bank Loan Transfer Arrangements"), we then used them for different purposes including settlements with MabPlex, settlement of related party loans and payables owed to RC Pharma and other general working capital uses.

Since the Lending Banks required a separate supplier's contract to support each drawdown application and given that the average transaction amount of our supplier contracts was generally lower than the amount of the Loans applied for, the Lending Banks had indicated their preference for us to submit contracts with the Connected Suppliers (with aggregated amounts of our actual financial needs) as supporting documents in order to avoid the administrative burden of having to approve a large number of drawdown applications and for administrative convenience purpose. As such, it was mutually agreed between the Lending Banks and our Company that we would submit contracts with the Connected Suppliers to apply for the drawdowns, whilst the transaction amounts of such contracts would be increased to

include our other financial needs. As confirmed by the Lending Banks, they were aware of the financial needs of our Company through their due diligence process before approving the credit lines and were aware of the abovementioned actual uses.

Our Directors confirmed that we obtained financing via the Bank Loan Transfer Arrangements because: (i) the Bank Loan Transfer Arrangements were administratively convenient for both the Lending Banks and our Company given the large number of drawdown applications which would otherwise be required; (ii) the Lending Banks were aware of the deviation from the stated use of loan proceeds; (iii) the Lending Banks did not take the view that the Bank Loan Transfer Arrangements were non-compliant; (iv) the responsible personnel of the Company were not aware of the non-compliant nature of this arrangement due to lack of proper legal advice; and (v) it was a practicable and expedient way to meet our financing needs.

Legal Impact

In preparing for the [**REDACTED**], we were advised by our PRC Legal Advisor that the Bank Loan Transfer Arrangements were not in strict compliance with the relevant PRC regulations. Upon becoming aware of such non-compliance, our Company ceased the Bank Loan Transfer Arrangements and repaid all outstanding principal amounts and interests of the Loans by March 2020, and no penalty has been imposed on us during the Track Record Period and up to the Latest Practicable Date.

As advised by our PRC Legal Advisor, the Bank Loan Transfer Arrangements were not in strict compliance with Article 19(iii) of the General Rules of Loans (中華人民共和國貸款通則) issued by the People's Bank of China ("PBOC") (the "General Rules") which states that "obligations of a borrower are to: … use a loan for the purposes as agreed in the loan contract". It is not explicitly provided in the General Rules that our Company would be subject to administrative penalties imposed by the relevant PRC competent government authorities for the violation of Article 19(iii). This was supported by the following confirmations obtained in May and June 2020 from governmental authorities which, as advised by the PRC Legal Advisor, are the relevant PRC competent government authorities in respect of the Bank Loan Transfer Arrangements:

i. The Yantai Office of China Banking and Insurance Regulatory Commission (中國銀行保險監督管理委員會煙台監管分局) (the "CBIRC"), the competent authority for the banking and insurance industries in Yantai, confirmed that, within its supervision scope, since 2017: (i) no activities of our Company for the purpose of illegally obtaining of bank loans have been found; (ii) our Company, our shareholders, directors and senior management have not been in violation of laws and regulations in respect of bank loan that will lead to administrative penalties; (iii) no record of administrative penalties has been found against them; and (iv) the Lending Banks, but not our Company, are subject to the regulations of the CBIRC and accordingly, no administrative penalties will be imposed on our Company in relation to the Bank Loan Transfer Arrangements or the Bill Transfer Arrangements (as defined below).

ii. The Yantai Central Branch of the People's Bank of China (中國人民銀行) (the "PBOC") confirmed that (i) no activities of the Company in respect of using of bills have been found to be in violation of the rules promulgated by PBOC; (ii) no administrative penalties have been found against our Company, our shareholders, directors and senior management; and (iii) the business of our Company is not within the PBOC's scope of authority for imposing penalties.

iii. The Financial Administration Bureau of Yantai Economic and Technological Development Area (煙台經濟技術開發區財政金融局) (the "Financial Bureau", together with the CBIRC and PBOC, the "PRC Governmental Authorities") confirmed that (i) use of the Bank Loan Transfer Arrangements was not for the purpose of obtaining bank loans illegally or fraudulently and the Bill Transfer Arrangements did not amount to finance fraud, bill fraud or illegal financing; (ii) our Company has repaid all bank loans when they were due on time since January 1, 2017; and (iii) the Bank Loan Transfer Arrangements and the Bill Transfer Arrangements do not constitute material non-compliance and the Financial Bureau will not impose any penalties against our Company, our shareholders, directors and senior management.

In addition, the Lending Banks confirmed that: (i) all principal amounts and interests under the Loans had been fully repaid; (ii) the Lending Banks did not take the view that the Bank Loan Transfer Arrangements were non-compliant; (iii) the Lending Banks would not hold our Company liable, or initiate any claims against our Company, for breach of the Loan Contracts or of PRC laws and regulations applicable to the Bank Loan Transfer Arrangements, including but not limited to claiming penalty; (iv) the Lending Banks would have extended the same principal amount to our Company with the same interest rates regardless of the specified use of proceeds; and (v) our Company's business relationship with the Lending Banks would not be adversely affected by the Bank Loan Transfer Arrangements.

Based on the above, our PRC Legal Advisor is of the opinion that:

- on the bases of (i) the confirmations from the Lending Banks; and (ii) the fact that our Company has fully repaid the Loans, the likelihood of claims by the Lending Banks against our Company for the Bank Loan Transfer Arrangements is remote;

- on the basis of the confirmation from our Company, the Bank Loan Transfer Arrangements did not involve any fraud or dishonesty or any intent to obtain loans from the Lending Banks illegally, and our Company did not obtain any illegal benefits from such arrangements;

- on the basis of the confirmations from the PRC Governmental Authorities, our Company is not involved in any illegal or non-compliant activities in obtaining the Loans,

accordingly, our PRC Legal Advisor has advised that the Bank Loan Transfer Arrangements do not amount to any material non-compliances or criminal activities, and that

our Company will not be subject to any administrative penalties by the PRC Governmental Authorities for the Bank Loan Transfer Arrangements. As such, the Bank Loan Transfer Arrangements are not expected to have any material adverse legal impact on our Company.

Financial impact

As a pre-revenue biotech Company, our financial needs have historically been funded by related party loans, bank borrowings, third party investments and government grants. Our Directors confirmed that, during the year ended December 31, 2019 and the three months ended March 31, 2020, our Group's operating activities did not rely on the Loans in any material respect and the funds obtained could have been sourced elsewhere. For the analysis of our financial independence, please refer to the paragraphs headed "Relationship with our Controlling Shareholders – Independence from our Controlling Shareholders – Financial Independence" in this document.

The maximum outstanding balance of the Loans at any time was RMB86 million during the year ended December 31, 2019, and RMB90 million during the three months ended March 31, 2020. This was approximately 6.86% and 6.99%, respectively, of the total financial resources available to the Company under the abovementioned fundraising channels during the year ended December 31, 2019 and the three months ended March 31, 2020.

Since the completion of the Reorganization in December 2019, our Company has relied on our own independent fundraising ability, raising RMB826 million in total as of the Latest Practicable Date from the 2019 Subscription and the 2020 Subscription. Further, as of March 31, 2020, we had cash and cash equivalent of RMB288 million and, as of the Latest Practicable Date, we had a total of unutilized credit facilities of RMB630 million which were granted by Yantai Bank upon its approval for drawdowns.

Our Directors confirmed that, because of the foregoing, our Group's financial position would not be adversely affected in any material respect without such Loans and therefore, we have not made any provision for the Bank Loan Transfer Arrangements.

Operational Impact

As a pre-revenue biotech company, our Company is primarily engaged in the research and development, application and commercialization of innovative biologics. As we would have sufficient financial resources available to carry out our principal business activities without the Loans, our Directors are of the view that the operations of our Company would not be affected without the Loans. Our Directors believe that the Bank Loan Transfer Arrangements have not had, and are not reasonably likely to have in the future, a material adverse impact on our business and operations.

Rectification measures and internal control

Upon becoming aware of the non-compliance and with the advice of our professional advisors, our Company ceased the Bank Loan Transfer Arrangements since March 1, 2020 and has fully repaid all of the Loans under the Bank Loan Transfer Arrangements by March 13, 2020.

We have also implemented the following internal control measures to prevent recurrence of the non-compliant financing arrangements:

(a) Engagement of Internal Controls Consultant: Since January 2020, we have engaged an independent internal control consultant (the "IC Consultant"). The IC Consultant has performed a thorough review of the Bank Loan Transfer Arrangements in the course of its engagement, including meetings, interviews and discussions with various departments and representatives of the Company. In March 2020, it provided recommendations on rectification measures, accordingly, we ceased the Bank Loan Transfer Arrangements and implemented the recommended policies (including the new loan management policy and fund management rules) to strengthen the monitoring of our Company's internal fund flow process. In April 2020, the IC Consultant completed its review of our Company's internal control systems and was of the view that the remedial measures have been properly implemented and no further deficiencies have been identified. For details of such remedial measures, please refer to the paragraph headed "(d) Adoption of Policies" below.

(b) Appointment of chief financial officer: In preparation of the [**REDACTED**], our Company has appointed Mr. Li Jia as our chief financial officer, responsible for overseeing the financial management of the Group. In particular, Mr. Li supervises matters relating to the approval, reporting and monitoring of loans and bill-related transactions to prevent the recurrence of the non-compliant incidents. Mr. Li will also become our Company's joint company secretary upon [**REDACTED**]. Given Mr. Li's experience, our Directors believe that he will guide our Company to comply with the relevant rules and regulations when performing his duties. For details of Mr. Li's biographical information, please refer to the section headed "Directors, Supervisors and Senior Management" in this document.

(c) Training: In February and May 2020, members of our management team received trainings which covered relevant laws and regulations relating to the Bank Loan Transfer Arrangements, the Bill Transfer Arrangements, new policies to be adopted, and disciplinary actions for breach of such policies. Our Company will continue to conduct regular internal trainings and engage external professionals, including our PRC Legal Advisor, to meet its ongoing compliance obligations.

(d) Adoption of Policies: Since April 2020, our Company has implemented the new loan management policy and fund management rules. Under the new policies, the approval process will distinguish between two types of loans:

(1) monthly and annual loan plans under our Company's annual budget will be submitted to the Board for approval annually; and

(2) for loans beyond the annual budget, our Company's finance department will be required to submit a loan application to the financial controller, who will review the requisite documentation and intended use of proceeds. In addition to Board authorization, the request will be subject to the approval of: (i) the chief financial officer, for loans below RMB10 million, (ii) a designated team, along with review by the internal audit department, for loans between RMB10 million and RMB30 million, and (iii) our Audit Committee, for loans over RMB30 million.

(e) Enhanced Corporate Governance Structure: In preparation for the [**REDACTED**], we have also enhanced our corporate governance structure to strengthen its reporting and review structure. Our Company has established an Audit Committee comprising three independent non-executive directors, in compliance with Rule 3.21 of the Listing Rules. Our Audit Committee is responsible for reviewing and supervising our internal controls in relation to financial management periodically. From a perspective of ensuring strict compliance with the new loan management policy, it will approve loans which are over RMB30 million and beyond our annual budget, In addition, together with our internal audit department, it will also review our loan transactions on a quarterly basis.

(f) External Review: We have engaged Rainbow Capital (HK) Limited as our compliance advisor in accordance with Rule 3A.19 of the Listing Rules upon the [**REDACTED**]. Our Company will also extend the engagement of the IC Consultant to continue to review our internal controls in relation to financial management on a quarterly basis until 24 months after the [**REDACTED**]. This would enable the IC Consultant to conduct further reviews on such internal control measures after the [**REDACTED**].

In light of the above, our Directors believe that the internal control measures adopted are sufficient and effective to prevent the recurrence of the non-compliant incidents in relation to the Bank Loan Transfer Arrangements, and nothing has come to the attention of the Joint Sponsors, as non-experts with respect to internal control, that would reasonably cause the Joint Sponsors to cast doubt on the Directors' views above.

Indemnity given by the Controlling Shareholders

Pursuant to the Deed of Indemnity dated [●], our Controlling Shareholders have undertaken to fully indemnify us against, amongst other things, any and all liabilities arising from the Bank Loan Transfer Arrangements.

Bill Transfer Arrangements

Background

As a pre-revenue biotech company, our financial needs have historically been met by related party loans, bank borrowings, third party investments and government grants. Given that we were a wholly-owned subsidiary of RC Pharma prior to the completion of the Reorganization in December 2019, related party loans provided by RC Pharma has been a major source of financing for our Company historically and such related party loans have been provided in the form of cash or transfer of bank acceptance bills (the "Bills"). Both cash loans and transfer of Bills are treated as related party loans from an accounting perspective and there is no difference between the interest rates on cash loans and the transfer of Bills (i.e. at prevailing market interest rate comparable to what third party commercial banks would charge). Same as the terms for the cash loans, the repayment of the Bills to RC Pharma were settled in the form of cash payment in the amount of the face value of the Bills transferred plus interest. The Bills transfer arrangements were conducted as part of the then intra-group financial management to facilitate allocation and use of funds amongst RC Pharma and its subsidiaries (including our Company). RC Pharma, as the then sole shareholder of our Company, determined in its sole discretion the form of related party loan to be extended to our Company. Our officers who authorized the Bill Transfer Arrangements confirmed that they were previously not aware that the intra-group financial management involving the Bill Transfer Arrangements would not strictly comply with PRC laws or regulations as they did not have the relevant legal knowledge.

In its ordinary and usual course of business, many customers of RC Pharma settle their trade payables with RC Pharma by transferring Bills to it. The Bills obtained by RC Pharma from its customers were supported by genuine underlying transactions between RC Pharma and its customers. As Bills were obtained from customers of RC Pharma and were readily available for its use and for our utilization, RC Pharma considered the transfer of Bills an expedient method of extending related party loans to our Company. For the years ended December 31, 2018 and 2019, RC Pharma transferred the Bills in the aggregate amount of RMB86.8 million and RMB25.6 million to our Company, respectively. Our Company has then used such Bills for settlement of the payables to some of its suppliers which, in each and every case, were all supported by genuine underlying transactions.

The interest rate RC Pharma charged us on the borrowings under the Bill Transfer Arrangements was 6.25% and 5.96% during the years ended December 31, 2018 and 2019, respectively, which are generally in line with the interest rates charged on the loans obtained by our Company directly from third party commercial banks. As confirmed by our Directors, no extra payment is charged or received by RC Pharma in connection with the Bill Transfer Arrangements. Neither our Directors, senior management nor any of their associates received any amount as a rebate in connection with the Bill Transfer Arrangements during the years ended December 31, 2018 and 2019.

Upon becoming aware of such non-compliance and the advice of our professional advisors, we ceased conducting such Bill Transfer Arrangements since March 31, 2019. The relevant Bills had been repaid and released by March 31, 2019. In addition, our Group has been operating in compliance with the PRC Negotiable Instruments Law (《中華人民共和國票據法》) since then.

Legal Impact

Article 10 of the PRC Negotiable Instruments Law states that bank acceptance bills must be transferred with and on the basis of the actual underlying transactions.

Although the Bills were supported by genuine underlying transactions between RC Pharma and its customers, such Bills were transferred to the Company as part of the then intra-group financial management without conducting actual transactions between RC Pharma and our Company (the "Bill Transfer Arrangements"). According to our PRC Legal Advisor, such arrangements were not in strict compliance with Article 10 of the PRC Negotiable Instruments Law and the Measures for Payment and Settlement (支付結算辦法) issued by the PBOC.

However, there are no provisions in the PRC Negotiable Instruments Law or any other relevant laws or administrative regulations that impose any administrative liability on Bill Transfer Arrangements, and during the Track Record Period and as of the Latest Practicable Date, no penalty has been so imposed. As such, our PRC Legal Advisor is of the view that the Bill Transfer Arrangements did not constitute any material non-compliance under PRC law.

According to the Review Report on the Draft PRC Negotiable Instruments Law (《中華人民共和國票據法(草案)》) by the Legal Committee of the National People's Congress in May 1995, the Legal Committee had expressed the review opinion that "a major issue which emerged during the usage of the bills is that some parties issue bills without underlying transactions and use such bills to conduct fraudulent activities, therefore, it is proposed that the PRC Negotiable Instrument Laws shall include provisions such that the issuance, acceptance and transfer of bills shall be based on the principle of good faith and shall be supported by genuine underlying transactions and contractual relations". Based on such review opinion by the Legal Committee of the National People's Congress, our PRC Legal Advisor is of the view that Article 10 of the PRC Negotiable Instruments Law is intended to prevent and regulate the fraudulent activities in connection with the issuance of bills without support by genuine

underlying transactions. Given that the Bills have been issued with support by genuine underlying transactions, the likelihood that the Bill Transfer Arrangements, as a subsequent transfer of legally issued bills, will be actually regulated or corrected by Article 10 of the PRC Negotiable Instruments Law is extremely low.

Further, pursuant to Article 3 of the PRC Criminal Law (中華人民共和國刑法), an act not expressly defined by criminal legislation shall not be convicted and sentenced. As the Bill Transfer Arrangements do not fall under any criminal legislation, our PRC Legal Advisor does not consider the Bill Transfer Arrangements to be a criminal act or constitute any criminal offence as a result.

The opinions above were supported by the confirmations obtained from the PRC Governmental Authorities as set out under the paragraph headed "Business – XIII. Legal Proceedings and Compliance – Compliant – Deviation from intended use of loan proceeds – Non-compliance with the General Rules of Loans and legal consequences" above. As advised by our PRC Legal Advisor, the PRC Governmental Authorities are the relevant PRC competent government authorities in respect of the Bill Transfer Arrangements.

Based on the above, our PRC Legal Advisor is further of the opinion that:

- on the bases that: (i) our Company ceased all Bill Transfer Arrangements since March 31, 2019; (ii) the confirmations obtained from the PRC Governmental Authorities that no administrative penalties from relevant governmental authorities have been imposed on our Company as of the date of this submission; and (iii) the fact that all the Bills involved in the Bill Transfer Arrangements had been repaid and released, the Bill Transfer Arrangements did not constitute material non-compliances and there are no provisions in the PRC Negotiable Instruments Law or any other relevant laws or administrative regulations that impose any administrative penalty on our Company from the relevant government authorities due to the Bill Transfer Arrangements;

- on the bases that: (i) the confirmation obtained from the PRC Governmental Authorities and confirmation from our Company that the Bill Transfer Arrangements did not involve any fraud or dishonesty; and/or (ii) pursuant to the PRC Criminal Law (中華人民共和國刑法), the Bill Transfer Arrangements are not considered to be a criminal act, and do not constitute any violation of criminal laws and regulations. Therefore, our Company would not be subject to any criminal liability; and

- on the bases that: (i) all the Bills involved in the Bill Transfer Arrangements had been repaid and released and there is no dispute or civil claim between RC Pharma, our Company, or any other third parties in connection with the Bill Transfer Arrangements as of the date of this submission; (ii) the confirmations obtained from the PRC Governmental Authorities confirming that no administrative penalties have been imposed on our Company, our shareholders, directors and senior management and that there were no fraudulent activities involved in the Bill Transfer Arrangements, our Company will not be subject to any administrative penalties by the PRC Governmental Authorities for the Bill Transfer Arrangements, and the likelihood that any interested party would initiate any civil proceedings on our Company is low.

Accordingly, our PRC Legal Advisor has advised that the Bill Transfer Arrangements do not give rise to any material adverse legal consequences to our Company.

Financial Impact

Our Directors are of the view that, since the transfer of Bills from RC Pharma was merely a form of related party loan provided by RC Pharma, if our Company had not used such Bill Transfer Arrangements, RC Pharma would have provided related party loans by way of cash or in other forms. Furthermore, our Company could also obtain working capital through other financial resources such as bank borrowings, third party investments and government grants. During the years ended December 31, 2018 and 2019, the monthly incurred amount of the loans under the Bill Transfer Arrangements was immaterial as compared to the financial resources available to our Company during the same periods.

After we ceased the Bill Transfer Arrangements since March 31, 2019, RC Pharma has continued to provide related party loans by way of cash bearing an average interest rate of 5.96%, which are similar to the interest rates on the loans under the Bill Transfer Arrangements. Further, during the years ended December 31, 2018 and 2019, the interest rates charged by banks on loans we obtained directly from them are either 5.50% or 6.31%. As such, our Group did not achieve material savings as to financing costs, nor any artificial enhancement of our financial performance using the loans under the Bill Transfer Arrangements.

Our Directors confirmed that, because of the foregoing, our Group's financial position would not be adversely affected in any material respect without the loans under Bill Transfer Arrangements and therefore we have not made any provision for the Bill Transfer Arrangements.

Operational Impact

As we did not rely on the Bill Transfer Arrangements to support our working capital or principal business activities in any material way, our Directors are of the view that our operating activities would not be affected even if the loans obtained under the Bill Transfer Arrangement was not available.

Enhanced Internal Control Procedures

Our Directors are of the view that the enhanced internal control measures as set out under the paragraphs headed "Compliance – Deviation from intended use of proceeds – rectification measures and internal control" in this section are also sufficient and effective to prevent the recurrence of the non-compliant incidents in relation to the Bill Transfer Arrangements.

Indemnity given by the Controlling Shareholders

Pursuant to the Deed of Indemnity dated [●], our Controlling Shareholders have undertaken to fully indemnify us against, amongst other things, any and all liabilities arising from the Bill Transfer Arrangements.

Directors' and Joint Sponsors' confirmation

Our Directors are of the view that the Bank Loan Transfer Arrangements and the Bill Transfer Arrangements (together, the "Arrangements") do not, individually or in aggregate, constitute material non-compliance under Guidance Letter HKEX-GL63-13 issued in July 2013 and last updated in March 2019 by the Stock Exchange, and do not have any material impact on the suitability of our Directors under Rules 3.08 and 3.09 of the Listing Rules and the suitability of our Company under Rule 8.04 of the Listing Rules because: (i) our Directors are of the view that the Arrangements did not have, and are reasonably unlikely to have in the future, a material financial or operational impact on our Company; (ii) the internal control measures adopted are sufficient and effective to prevent future non-compliances in relation to Arrangements; (iii) the Arrangements did not involve any fraud or dishonesty on the part of our Company or of our Directors, nor did our Company obtain any inappropriate benefits from the Arrangements; (iv) neither our Directors, senior management nor any of their associates received any rebate or other financial interest in connection with the Arrangements; (v) our Company did not benefit from any material savings in interest expenses by using the Loans or the Bills given that their interest rates were consistent with the prevailing market interest rate for ordinary commercial loans; (vi) our enhanced corporate governance structure (including the appointment of independent non-executive Directors and the setting up of the Audit Committee in accordance with the requirements of the Listing Rules) will be beneficial for us to prevent the reoccurrence of non-compliance related to the Arrangements; and (vii) as our Directors were mainly focused on the R&D activities of the Company, their inadvertent oversight to identify the technical non-compliant nature of the Arrangements at the time should be assessed holistically bearing the core business operation of the Company in mind. As far as our Directors are aware, save for the Arrangements, there has not been any material issues with our compliance record. Accordingly, our Directors are of the view that the systemic non-compliant incidents in relation to the Arrangements should not affect their suitability or competence to act as our Directors.

Based on: (i) the confirmations obtained by the Company from the PRC Governmental Authorities; (ii) the above opinions of the Company's PRC Legal Advisor; (iii) the rectification measures and internal control procedures adopted by the Company; and (iv) the independent due diligence conducted by the Joint Sponsors (including but not limited to independent interviews with the Company's management, suppliers and the Lending Banks, obtaining and reviewing relevant underlying transaction documents, and discussions with the IC Consultant on the progress and effectiveness of the Company's rectification measures and internal controls), nothing has come to the Joint Sponsors' attention in relation to the Arrangements, individually or in aggregate, that would lead them to cast doubt on the Directors' views above.

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 "Financial Information – Market Risk Disclosure" for a discussion of these market risks.

We have adopted a serious 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.

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, 2018 to December 31, 2019 of our Company and our major operating subsidiaries in certain aspects, including financial reporting and disclosure controls, corporate-level control, human resources and payroll management, general controls of IT system and other procedures of our operations. The Internal Control Consultant performed the Internal Control Review in January 2020 and follow-up reviews in May 2020. 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, protection of intellectual property, environmental protection and occupational health and safety.

For more information, please refer to the paragraph headed "– Intellectual Property" and "– Environmental Matters and Workplace Safety." We provide periodic training about these measures and procedures to our employees as part of our employee training program. Our internal audit department conducts 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 advisors, 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 Rainbow Capital (HK) Limited as our compliance advisor 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 advisor 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.