OVERVIEW

We are a biotechnology company committed to developing innovative human vaccines and therapeutic biologics to prevent and control infectious diseases and treat cancer and autoimmune diseases. Since our inception in 2001, we have focused on human medicine and established technology platforms with our understanding of immunology and protein engineering.

After two decades of research and development and introduction of technologies, we have established an innovative precision protein engineering platform empowering the full cycle of drug development, which provides a solid foundation for the development of our human vaccines candidates, monoclonal antibody product candidates and bispecific antibody product candidates.

Our innovative antigen presentation technology for vaccine development starts from the concept of enhancing the immunogenicity of a target antigen, then streamlines the design of a recombinant virus vaccine antigen while retaining the primary structure of the natural antigen to enhance immunogenicity, improve safety and patient vaccination experience. Our internally developed next-generation bispecific antibody development platform, Fabite®, of which we own intellectual property rights, has competitive advantages in the development of bispecific antibody products for the treatment of relapsed/refractory hematological malignancies. Fabite® has a fully controllable mechanism of action and mode of administration to ensure the safety of patients. It can be used in a variety of immunotherapies based on the activation of T cells to kill cancer cells. Fabite® optimizes the purification process of bispecific antibodies, achieving high purity of monomers. At the same time, we have developed several types of liquid formulations to address stability issues, resulting in bispecific antibody solutions that can be stable for more than three years in storage conditions of 2-8°C.

By employing our Fabite® technology platform and mammalian expression technology platform and leveraging our in-house biologics manufacturing infrastructure and capabilities, we established a diversified and advanced product pipeline covering human vaccine candidates, monoclonal antibody product candidates and bispecific antibody product candidates.

- **LZ901**, our independently developed recombinant herpes zoster vaccine candidate and Core Product, has a tetrameric molecular structure to prevent shingles caused by varicella-zoster virus ("**VZV**") for adults aged 50 years and older. Its molecular structure has double the Fc regions for antigen presenting cells ("**APCs**") to bind to compared to naturally occurring VZV antigen. LZ901 actively presents VZV antigens to immune cells to trigger an immune response. In addition, LZ901 has demonstrated high immunogenicity, efficacy and safety profile in pre-clinical studies, while inducing specific humoral and cellular immunity. We have initiated a Phase I clinical trial in January 2022 and completed the Phase I clinical trial and initiated a Phase II clinical trial for LZ901 in China in April 2022. We expect to complete the Phase II clinical trial for LZ901 in China in the second quarter of 2023, initiate a multi-center, randomized, double-blind, placebo-controlled Phase III clinical trial comparing LZ901 against Shingrix® in the second quarter of 2023, and file Biologics License Application ("**BLA**") in the third quarter of 2024 for LZ901 to the NMPA. In addition, we have received IND approval from the United States Food and Drug Administration ("**FDA**") in July 2022 for LZ901 and initiated a Phase I clinical trial in the U.S. in February 2023. We plan to complete the Phase I clinical trial and initiate a Phase II clinical trial in the first quarter of 2024. Furthermore, we expect to complete the Phase II clinical trial in the second quarter of 2025, initiate a Phase III clinical trial in the fourth quarter of 2025, and complete the Phase III clinical trial in the second quarter of 2027.

- **K3**, our independently developed recombinant human anti-tumor necrosis factor ("**TNF**")-α monoclonal antibody injection product candidate, is a biosimilar of Humira® (adalimumab) and mainly used for the treatment of various autoimmune diseases, such as rheumatoid arthritis, ankylosing spondylitis and psoriasis. We initiated our Phase I clinical trial in China in September 2018, in which K3 displayed pharmacokinetics consistent with adalimumab, and completed the Phase I clinical trial in December 2019. We plan to initiate a Phase III clinical trial for K3 in China in the second quarter of 2023, complete the Phase III clinical trial in the second quarter of 2024 and submit a BLA to the NMPA in the fourth quarter of 2024. We expect K3 to receive BLA approval from the NMPA in 2025. We expect K3 to expand the market in China for adalimumab biosimilars.

- **K193**, our independently developed bispecific antibody injection (B-lymphocyte antigen CD19 ("**CD19**")-cluster of differentiation 3 ("**CD3**")) product candidate for the treatment of B cell leukemia and lymphoma, is the world's first bispecific antibody against CD19/CD3 with an asymmetric structure. K193 has an innovative molecular structure that was developed based on our internally developed bispecific antibody development platform, Fabite®, and our mammalian expression technology platform, which makes it less prone to polymerization and decreased activity compared to other similar products in the market. In our pre-clinical studies, K193 displayed high *in vivo* and *in vitro* anti-tumor activity, and its optimized formulation is stable and convenient to use. K193's unique mechanism of action endows it with a strong ability to treat various types of B cell leukemia and lymphoma. The safe and controllable administration of K193 also reduces the impact of patient stress caused by medication administration. In December 2019, we initiated a Phase I clinical trial of K193 in China and expect to complete the Phase I clinical trial in the second quarter of 2023. We plan to initiate a Phase II clinical trial for K193 in the first quarter of 2024 and complete the Phase II clinical trial of K193 in China in the fourth quarter of 2027.

- In addition, our diversified and advanced pipeline includes recombinant varicella vaccine, recombinant rabies vaccine, K333 bispecific antibody for the treatment of myeloid leukemia and K1932 bispecific antibody for the treatment of lymphoma.

The following diagram summarizes the status of our product pipeline as of the Latest Practicable Date:

PRODUCT TYPE	PRODUCT PIPELINE	MECHANISM/ TARGET	INDICATIONS	PRE-CLINICAL	CLINICAL TRIALS Phase I	Phase II	Phase III	Expected Timetable
Recombinant Vaccine	LZ901[1]	VZV gE	Herpes zoster			China		Complete Phase II in Q2 2023 and expected to initiate Phase III in Q2 2023
			Herpes zoster		US			Complete Phase I in Q1 2024 and expected to initiate Phase II in Q1 2024
Monoclonal Antibody	K3[2]	TNF-α	Rheumatoid arthritis, ankylosing spondylitis, plaque psoriasis			China		Initiate Phase III in Q2 2023 and expected to submit a BLA in Q4 2024
Bispecific Antibody	K193	CD3/CD19	Relapsed/Refractory B-cell lymphoma/leukemia		China			Complete Phase I in Q2 2023 and expected to initiate Phase II in Q1 2024
Recombinant Vaccine	Recombinant Varicella Vaccine	VZV gE	Varicella	China				Initiate Phase I in Q3 2023 and expected to initiate Phase II in Q3 2024
Recombinant Vaccine	Recombinant Rabies Vaccine	RABV-G	Rabies	China				Request pre-IND meeting with the NMPA in Q4 2023
Bispecific Antibody	K333	CD33/CD3	Myeloid leukemia	China				Request pre-IND meeting with the NMPA in the second half of 2024
Bispecific Antibody	K1932	CD19/CD3	Relapsed/Refractory B-cell lymphoma	China				Request pre-IND meeting with the NMPA in the second half of 2024

Notes:

(1) Core Product.

(2) K3 is a biosimilar of adalimumab and therefore, is not required to conduct a Phase II clinical trial. For more details, please see "— Our Products and Product Candidates — Our Core Product and Clinical-Stage Product Candidates — 2. K3" in this section.

Our full industrialization capabilities encompass the entire lifecycle of protein drugs from drug discovery to clinical research and production. Our production is excellent in terms of protein expression, purification and stability as we have established a mature process development, amplification and quality control system. Our R&D and pilot manufacturing facility located in Beijing, China, supplies materials for our pre-clinical studies and early-stage clinical trials, and occupies approximately 27 acres of land with a total GFA of approximately 3,757 sq.m. in the R&D and production area.

We plan to commence construction of a new R&D and manufacturing facility in Beijing in the second quarter of 2023 and expect to complete construction of the new Beijing R&D and manufacturing facility in the first quarter of 2025. The new Beijing R&D and manufacturing facility is expected to have a total production capacity of eight million doses of Recombinant Varicella Vaccine a year and four million doses of Recombinant Rabies Vaccine a year.

In addition, we are building our manufacturing facilities in Zhuhai in two-phases to expand our production in preparation for the commercialization of our pipeline candidates. We commenced operations at our first-phase Zhuhai manufacturing facility and commenced construction of our second-phase Zhuhai manufacturing facility, which is expected to commence operations by the second quarter of 2023. Our second-phase Zhuhai manufacturing facilities, as planned and approved by Zhuhai Municipal Bureau of Natural Resources, occupy approximately 69,366 sq.m. of land with a total gross floor area ("**GFA**") of approximately 120,000 sq.m. in the production area.

We assembled an experienced management team that manages our research and development, manufacturing and commercialization. Our experienced management team is led by a team of scientists who are deeply involved in the industry with a proven track record of obtaining strong endorsement from industry companies and financial institutions to accelerate our product development. Our founders have medical backgrounds, extensive experience in vaccine and antibody drug development and successfully developed the world's first liquid formulation Meningococcal Group A and C Polysaccharide Conjugate Vaccine, the world's first Meningococcal Group A and C and Haemophilus Influenzae Type b Conjugate Vaccine, China's first Haemophilus Influenzae Type b Conjugate Vaccine with aluminum phosphate adjuvant, and China's first Group $ACYW_{135}$ Meningococcal Polysaccharide Vaccine and a number of other blockbuster vaccines. In addition, our product development, clinical research, manufacturing, business development and capital operations are led by our experienced management team.

During the Track Record Period and up to the Latest Practicable Date, we did not generate any revenue as we had out-licensed most of our historically developed candidates before the Track Record Period, and by the Latest Practicable Date, we had not commercialized any of our product candidates. Since our inception in 2001 and prior to the Series A Financing in 2019, we primarily relied on (i) capital injections from our shareholders, primarily due to which our registered capital increased from RMB0.5 million in 2001 to RMB78.6 million in 2019, (ii) one-off or milestone payments of RMB34.8 million in total received from our historically developed products that had been transferred or out-licensed to third-parties prior to the Track Record Period, and (iii) revenue generated from the sales of the Immunoreagent Testing Kits to support our business operations, which amounted to RMB9.1 million from 2004 to 2018. For details of the revenue generated from the sales of the Immunoreagent Testing Kits, please see "Summary — Our Products and Product Candidates — Our Other Historically Developed Products" in this document. Our shareholders include well-known leading industry companies and financial institutions, such as Hangzhou Tigermed Consulting Co., Ltd., Livzon Pharmaceutical Group Inc., Beijing Science Sun, CCB Capital and CITIC Group, who provide us with financial support for clinical advancement and commercialization of our products. For details of the our registered capital and subsequent capital injections by our shareholders since our inception and prior to the Series A Financing, please see the section headed "History, Development and Corporate Structure" in this document.

OUR COMPETITIVE STRENGTHS

We believe the following strengths have contributed to our success and differentiate us from our competitors.

Innovative precision protein engineering platform, which empowers us to develop our recombinant vaccine and antibody product candidates with favorable efficiency, high purity and improved stability.

Our founders have conducted more than 30 years of research in the field of human vaccines and immunology and are able to design improved human vaccines through the identification of protective antigens of pathogens. Our recombinant virus vaccines are developed based on our innovative antigen presentation technology and the concept of enhancing the immunogenicity of a target antigen, and designed to enhance immunogenicity while retaining the primary structure of the natural antigen. By using our innovative technology platforms, we are empowered to improve the efficiency, purity and stability of our recombinant vaccine and antibody product candidates. Leveraging the experience and technical know-how of our founders, we have internally developed five technology platforms:

- *Fabite® technology platform*. Fabite®, our next-generation bispecific antibody development technology platform of which we own intellectual property rights, has competitive advantages in the development of bispecific antibody products for the treatment of hematological malignancies. It can be used in a variety of immunotherapies based on the activation of T cells to kill cancer cells. Fabite® optimizes the purification process of bispecific antibodies, achieving high purity of monomers. At the same time, we have developed several types of liquid formulations for bispecific antibody solutions that can be stable for more than three years in storage conditions of 2-8°C.

  We have developed three bispecific antibody injection product candidates, namely K193, K333 and K1932, using our Fabite® technology platform, the production process of which achieves consistent quality and high bispecific antibody yield and purity, featuring favorable safety profile and fewer side effects. In our research and development of K193, K333 and K1932, our Fabite® technology platform empowers us to develop bispecific antibodies with favorable efficiency, higher purity and strong affinity by recombinantly fusing a scFv molecule with a comparatively weak binding ability with a Fab fragment of a different specificity with strong binding ability, which ensures the tumor target protein is bound and then activates T cells to kill the malignant tumor cell.

- *Targeted recombinant antigen presentation technology platform*. Our targeted recombinant antigen presentation technology platform forms antigen expressing recombinant immune complexes ("**RICs**"), and directly presents viral membrane antigens to APCs. This technology platform technology greatly enhances the utilization efficiency of antigens and can induce high-titer specific antibodies and cellular immunity. Furthermore, the antigens expressed by our targeted recombinant antigen presentation technology platform contain multiple fragment crystallizable ("**Fc**") regions, which is an improvement upon traditional fusion protein technology that only expresses antigens with a single Fc region.

We have developed three recombinant protein vaccine candidates, namely LZ901, Recombinant Varicella Vaccine and Recombinant Rabies Vaccines, using our targeted recombinant antigen presentation technology platform. In our research and development of these three recombinant protein vaccine candidates, our targeted recombinant antigen presentation technology platform empowers us to improve the utilization efficiency of antigens and induce high-titer specific antibodies and cellular immunity, by using a molecular design that includes a genetically engineered target viral membrane antigen containing multiple Fc regions that cross-link to Fc receptors connected to the cell surface of APCs.

- *Polysaccharide-protein conjugation technology platform*. Our polysaccharide-protein conjugation technology platform links bacteria polysaccharides to carrier proteins. This technology platform can be used to develop conjugate vaccines and antibody-drug conjugates. We utilized our polysaccharide-protein conjugation technology platform to develop three bacterial polysaccharide-protein conjugate vaccines, which have enhanced immunogenicity and stability, and are in easy to administer liquid dosage forms.

  We have historically developed three commercialized vaccine products, namely (i) Haemophilus Influenzae Type b Conjugate Vaccine, (ii) Meningococcal Groups A and C and Haemophilus Influenzae Type b Conjugate Vaccine and (iii) Meningococcal Group A and C Polysaccharide Conjugate Vaccine, using our polysaccharide-protein conjugation technology platform. Our polysaccharide-protein conjugation technology platform empowered us to successfully develop three commercialized vaccine products with better solubility, stability, and targeting ability, through chemical conjugation of polysaccharide antigens to proteins.

- *Protein purification technology platform*. We have developed technology to purify complex recombinant proteins, such as humanized monoclonal antibodies and complex glycosylated proteins. We use a high-speed centrifugation or deep filtration workflow to isolate proteins in cell culture media, which is highly effective in removing cells and cellular debris from the soluble protein. In addition, we employ a series of chromatographic techniques during the protein purification process. First, we attach affinity protein tags to proteins of interest during the construct design and conduct affinity chromatography to purify and improve the solubility of the proteins of interest. Second, we perform an additional chromatographic step such as ion exchange chromatography or hydrophobic interaction chromatography to further increase purity. As a final polishing step, we perform size exclusion chromatography which results in high purity proteins of interest.

  As proteins are highly heterogeneous and different techniques are used to purify different types of proteins, we have utilized our protein purification technology platform to increase the purity of LZ901, K3, K193 and K11 using various techniques. By using diverse techniques to purify different kinds of proteins, our protein purification technology platform empowers us to characterize the function, structure and interactions of recombinant proteins in our development of LZ901, K3, K193 and K11.

- *Protein stability technology platform*. We have developed a variety of highly stable liquid formulations for human monoclonal antibodies, bispecific antibodies and recombinant protein vaccines. Our in-solution protein-stabilizers offer longer stability by extending the shelf life of antibodies, antigens and other recombinant proteins at working strength concentrations. In addition, they offer retained activity of most monoclonal antibodies or bispecific antibodies in solution for up to five years. Our liquid protein stabilizers also offer a variety of options for immune-assay development. We offer multiple formulations with different stabilizing mechanisms to satisfy different antibody or antigen requirements. Our formulations are protein-free that are able to satisfy the background requirements for human drugs or specific assay systems and stabilize enzymes and control materials in immunoassays.

  Our protein stability technology platform empowers us to improve the efficacy and stability of our human vaccine candidates, monoclonal antibody product candidates and bispecific antibody product candidates in various environmental conditions though in-solution protein-stabilizers developed by ourselves. All of our human vaccines candidates, monoclonal antibody product candidates and bispecific antibody product candidates utilize protein-stabilizers developed using our protein stability technology platform to enhance stability.

- *Mammalian expression technology platform*. We introduced the GS Xceed™ expression system from Lonza in 2012. The system covers a wide range of technologies and processes such as host cells, expression vectors, and optimized culture media, and provides high-quality, high-efficiency and high-capacity production services for a variety of biopharmaceuticals.

  Our mammalian expression technology platform empowers us to optimize the protein expression in our development of bispecific antibody product candidates and recombinant vaccine product candidates by rapidly and reliably generating high-producing cell lines. We have increased the purity and expression levels of LZ901 and K193 using our mammalian expression technology platform.

LZ901, our Core Product, is a herpes zoster vaccine in China seeking global filing with improved immunogenicity, and high safety and stability due to its specific structure

We are developing our recombinant herpes zoster vaccine candidate, LZ901, featuring a specific molecular structure and mechanism, improved immunogenicity, and high safety and stability profile. LZ901 has a tetrameric molecular structure to prevent shingles caused by VZV for adults aged 50 years and older. Its molecular structure has double the Fc regions for APCs to bind to compared to naturally occurring VZV antigen. LZ901 exhibits improved immunogenicity as demonstrated by the higher geometric mean titer ("**GMT**") level of antibodies compared against naturally occurring VZV antigen in pre-clinical studies, while inducing strong specific humoral and cellular immunity.

In a BALB/c mice study, LZ901 induced a stronger cellular immune response with higher expression of multiple types of immune cell activating biomarkers compared to Shingrix®, and the level of humoral immune response of LZ901 was non-inferior to that of Shingrix®. Compared to Shingrix®, mice immunized with LZ901 were observed to have significantly higher magnitude of expression of activation biomarkers and higher proportion of helper (CD4+) T cells and cytotoxic (CD8+) T cells expressing multiple biomarkers, which indicate LZ901 provides strong protection against shingles.

In the Phase I clinical trial for LZ901 in China, LZ901 was able to stimulate the rapid production of higher levels of anti-VZV antibodies after the first vaccination and no significant difference in the levels of anti-VZV antibodies after the full course of vaccination compared to Shingrix® based on humoral response data. In addition, LZ901 was able to stimulate helper (CD4+) T cells to express significantly higher levels of multiple types of immune cell activating biomarkers and cytotoxic (CD8+) T cells to express slightly higher levels of multiple types of immune cell activating biomarkers compared to Shingrix® based on cellular immune response data, indicating that the immunogenicity of LZ901 is not weaker than Shingrix® and LZ901 provides strong protection against shingles.

In addition, we developed a liquid formulation with improved stability to reduce the rate of degradation caused by storage in elevated temperatures. Our recombinant herpes zoster vaccine candidate, LZ901, adopts a highly stable liquid formulation, which allows for easy storage and transportation. It is stable for two weeks at 37°C, 12 weeks at 25°C and 24 months at 2-8°C. Furthermore, the side effects from the administration of LZ901 are minimal as the liquid formulation only contains an aluminum hydroxide adjuvant and is free of immune stimulants, which reduce the likelihood of serious adverse reactions at the injection site.

LZ901 is a herpes zoster vaccine in China seeking global filing, which demonstrates our outstanding R&D and product development capabilities. We have initiated a Phase I clinical trial in January 2022 and completed the Phase I clinical trial and initiated a Phase II clinical trial for LZ901 in China in April 2022. We expect to complete the Phase II clinical trial for LZ901 in China in the second quarter of 2023, initiate a multi-center, randomized, double-blind, placebo-controlled Phase III clinical trial comparing LZ901 against Shingrix® in the second quarter of 2023, and file the BLA in the third quarter of 2024 for LZ901 to the NMPA. In addition, we have received IND approval from the FDA in July 2022 for LZ901 and initiated a Phase I clinical trial in the U.S. in February 2023. We plan to complete the Phase I clinical trial and initiate a Phase II clinical trial in the first quarter of 2024. Furthermore, we expect to complete the Phase II clinical trial in the second quarter of 2025, initiate a Phase III clinical trial in the fourth quarter of 2025, and complete the Phase III clinical trial in the second quarter of 2027.

Strong pipeline of vaccine, autoimmune disease and hematological malignancy product candidates

We have a strong pipeline of vaccine, autoimmune disease and hematological malignancy product candidates developed based on our Fabite® bispecific antibody development, targeted recombinant antigen presentation, polysaccharide-protein conjugation, protein purification, protein stability and mammalian expression technology platforms. As of the Latest Practicable Date, in addition to LZ901, we had another two product candidates under clinical development stage in China, including K3 and K193, and four pre-clinical stage product candidates, including Recombinant Varicella Vaccine, Recombinant Rabies Vaccine, K333 and K1932.

K3, our independently developed recombinant human anti-TNF-α monoclonal antibody injection product candidate, is a biosimilar of adalimumab and mainly used for the treatment of various autoimmune diseases, such as rheumatoid arthritis, ankylosing spondylitis and plaque psoriasis. The molecular design of K3 maximizes the safety of the antibody when used in the human body.

K193, our independently developed bispecific antibody injection (CD19-CD3) product candidate for the treatment of B cell leukemia and lymphoma, is a bispecific antibody that binds to human CD19 and CD3. K193 is a bispecific antibody against CD19/CD3 with an asymmetric structure. K193's

molecular structure has good thermal stability and is less susceptible to polymerization, which ensures the stability and binding ability of K193. In addition, K193 displayed high *in vivo* and *in vitro* anti-tumor activity in pre-clinical studies. The liquid preparation formulation and stable molecular structure of K193 provide a guarantee for convenient and safe clinical administration. K193 is indicated for the treatment of B cell leukemia and lymphoma.

Recombinant Varicella Vaccine, our independently developed recombinant varicella vaccine candidate, is an adjusted dosage of LZ901 for the prevention of chickenpox caused by VZV. Recombinant Varicella Vaccine prevents childhood chickenpox and has a wide range of applications. It is expected to partially replace live attenuated vaccines of the OKA strain of VZV as an alternative vaccination method, reduce the chance of children suffering from VZV infection, and reduce the risk of developing shingles in adults. Unlike other marketed live-attenuated vaccines that contain weakened forms of VZV which may lay dormant in the patient and reactivate causing shingles, Recombinant Varicella Vaccine does not contain VZV and does not carry the risk of developing into shingles.

Recombinant Rabies Vaccine, our proprietary recombinant rabies glycoprotein G ("**RVG**") subunit vaccine candidate for the prevention of rabies in humans, is a prophylactic that provides protection against rabies prior to exposure and simplifies post-exposure treatment for rabies. In addition, Recombinant Rabies Vaccine has high purity and is suitable for immunizing both children and adults.

K333, our proprietary bispecific antibody injection (CD33-CD3) product candidate for the treatment of myeloid leukemia, is a bispecific antibody that binds to human CD33 and CD3.

K1932, our proprietary bispecific antibody injection (CD19-CD3) product candidate for the treatment of B cell lymphoma, is based on the molecular structure of K193. Compared with K193, K1932 has a much longer half-life in the human body. Patients administered K1932 following the first stage administration of K193 have lower risk of experiencing a cytokine storm, which allows for dose escalation. After the induction period of K193, K1932 can be administered on a weekly basis, which greatly improves the medication experience of B cell lymphoma patients.

Vaccine and antibody production facilities with commercial-scale manufacturing capacity and professional quality management system

We have assembled a manufacturing team with extensive industry experience and initiated a two-phase construction plan to further expand our production capacity. We commenced operations at our first-phase manufacturing facility in Zhuhai. Currently, our existing Zhuhai manufacturing facility occupies a total GFA of approximately 8,000 sq.m. and is equipped with several 500L stainless steel bioreactors, purification equipment and a high-speed vial filling linkage line.

We commenced construction of the second-phase manufacturing facility in Zhuhai, which is expected to be completed and commence operations by the second quarter of 2023. Our second-phase Zhuhai manufacturing facility will occupy approximately 69,366 sq.m. of land with a total GFA of approximately 120,000 sq.m. in the production area and will be equipped with multiple 2.5-ton stainless steel bioreactors and two antibody biopharmaceutical production workshops. Our first-phase Zhuhai manufacturing facility and the second-phase Zhuhai facility will have in total, an annual capacity to manufacture 20 million doses of LZ901, three million doses of K193 and two million doses of K3. For details of the manufacturing capacity of each existing and planned manufacturing facility, please see "— Manufacturing" in this section.

The construction standards of the above-mentioned manufacturing facilities in Zhuhai are designed according to international standards and are expected to meet the GMP requirements of the NMPA, the EMA, the FDA and related ICH guidelines.

In addition, we have an experienced quality management team with professional quality management system. Ms. ZHANG Yanping, our co-founder and deputy general manager, has over 36 years of experience in the biopharmaceutical industry with extensive experience in quality control, quality assurance, and preclinical safety studies of biological products. All of our Zhuhai quality management team members have received professional trainings in regulations, GMP standards and quality control analysis methods. We have implemented quality management systems that conform to national regulations and industry guidelines, and adopted standard operating procedures.

Experienced scientific and management team backed by strong investor support

We are led by an experienced scientific and management team with diverse backgrounds and skillsets.

Mr. KONG Jian, our co-founder, executive Director, general manager and chief scientist, has over 33 years of biopharmaceutical experience. Prior to starting our company and since 1988, he worked at National Vaccine and Serum Institute of the Ministry of Health. He worked as the deputy director of the Science and Technology Development Division (科技開發處副處長), and was later promoted as the director of the Science and Technology Development Division (科技開發處處長) and manager of the immunodiagnostic laboratory (免疫診斷研究室主任) of the National Vaccine and Serum Institute of the Ministry of Health in October 2000, and was primarily responsible for scientific research of biological products. Mr. KONG and his colleagues have developed five vaccines, including three types of bacterial polysaccharide conjugate vaccines and two multi-valent meningococcal polysaccharide vaccines. In addition, Mr. KONG has developed vaccines and monoclonal antibodies under clinical investigation, including a recombinant herpes zoster vaccine, two monoclonal antibodies, a bispecific antibody and an inactivated enterovirus 71 vaccine.

Ms. JIANG Xianmin, our co-founder, Chief Medical Officer and deputy general manager, has over 36 years of experience in biopharmaceutical research and development. Prior to starting our company and since 1984, she worked at National Vaccine and Serum Institute of the Ministry of Health. Ms. JIANG leads the development of our Meningococcal Group A and C Polysaccharide Conjugate Vaccine, Meningococcal Group A and C and Haemophilus Influenzae Type b Conjugate Vaccine, Group $ACYW_{135}$ Meningococcal Polysaccharide Vaccine, typhoid polysaccharide vaccine and tetanus toxoid vaccine.

Ms. ZHANG Yanping, our co-founder and deputy general manager, has over 36 years of experience in the biopharmaceutical industry. Prior to starting our company and since 1985, she previously worked at National Vaccine and Serum Institute. Ms. ZHANG has extensive experience in quality control, quality assurance, and preclinical safety studies of biological products. Ms. ZHANG led the team to obtain GMP certification for Meningococcal Group A and C Polysaccharide Conjugate Vaccine, and Group $ACYW_{135}$ Meningococcal Polysaccharide Vaccine.

Mr. ZHANG Hui, our Chief Financial Officer and head of global capital markets, has over 20 years of financial and investment experience, including at DBS Bank Ltd., BNP Paribas Capital (Asia Pacific) Limited, Lehman Brothers Securities Asia Limited, Deutsche Bank, Samsung Securities (Asia) Limited and Guosen Securities (HK) Capital Company Limited.

We have strong support from prominent shareholders, consisting of well-known industry companies and financial institutions, such as Hangzhou Tigermed Consulting Co., Ltd., Livzon Pharmaceutical Group Inc., Beijing Science Sun, CCB Capital and CITIC Group, endowing us with industry expertise and crucial connections to the biopharmaceutical industry.

OUR STRATEGIES

Our goal is to utilize state-of-the-art technologies to develop and produce various biological products that meet clinical needs, and focus on the research and development of vaccines and therapeutic bispecific antibodies for human disease prevention, control and treatment. We plan to implement the following strategies to achieve this goal:

Actively promote the clinical development of our pipeline candidates

We intend to actively promote the clinical development of our pipeline candidates, namely LZ901, K3 and K193.

LZ901

With the safety and efficacy results observed in pre-clinical studies to date of LZ901 for the prevention of herpes zoster, we intend to expedite clinical development of LZ901 in China and globally. We have initiated a Phase I clinical trial in January 2022 and completed the Phase I clinical trial and initiated a Phase II clinical trial for LZ901 in China in April 2022. We expect to complete the Phase II clinical trial for LZ901 in China in the second quarter of 2023, initiate a multi-center, randomized, double-blind, placebo-controlled Phase III clinical trial comparing LZ901 against Shingrix® in the second quarter of 2023, and file the BLA in the third quarter of 2024 for LZ901 to the NMPA. In addition, we have received IND approval from the FDA in July 2022 for LZ901 and initiated a Phase I clinical trial in the U.S. in February 2023. We plan to complete the Phase I clinical trial and initiate a Phase II clinical trial in the first quarter of 2024. Furthermore, we expect to complete the Phase II clinical trial in the second quarter of 2025, initiate a Phase III clinical trial in the fourth quarter of 2025, and complete the Phase III clinical trial in the second quarter of 2027.

K3

We initiated our Phase I clinical trial in September 2018, and have completed our Phase I clinical trial in China for K3 in December 2019, a biosimilar of adalimumab, for the treatment of various autoimmune diseases, such as rheumatoid arthritis, ankylosing spondylitis and plaque psoriasis, which displayed pharmacokinetics consistent with adalimumab. We plan to initiate a Phase III clinical trial for K3 in China in the second quarter of 2023, complete the Phase III clinical trial in the second quarter of 2024 and submit a BLA to the NMPA in the fourth quarter of 2024. We expect K3 to receive BLA approval from the NMPA in 2025.

We are currently constructing and plan to complete setting up our production line for K3 in the second quarter of 2023, which will be used to produce K3 required for our Phase III clinical trial.

K193

Our bispecific antibody injection (CD19-CD3) for the treatment of B cell leukemia and lymphoma, K193, displayed high *in vivo* and *in vitro* anti-tumor activity in pre-clinical studies. In December 2019, we initiated a Phase I clinical trial of K193 in China and expect to complete the Phase I clinical trial in the second quarter of 2023. We plan to initiate a Phase II clinical trial for K193 in the first quarter of 2024 and complete a Phase II clinical trial of K193 in China in the fourth quarter of 2027 due to difficulty finding suitable subjects, as K193 is a later-line therapy which requires enrolling patients who have failed other therapies, and difficulty enrolling subjects willing to commit to 28 consecutive days of hospitalization and treatment of K193. We plan to apply for a conditional BLA approval from the NMPA in 2027.

Rapidly advance the development of our other pre-clinical product candidates

We intend to rapidly advance the development of our other pipeline candidates in the pre-clinical stage, namely Recombinant Varicella Vaccine, Recombinant Rabies Vaccine, K333 and K1932.

Currently, we have completed pre-clinical studies for Recombinant Varicella Vaccine, and submitted an IND application for Recombinant Varicella Vaccine to the NMPA in June 2022. For Recombinant Varicella Vaccine, we plan to initiate a Phase I clinical trial in the third quarter of 2023, and complete a Phase I clinical trial in the second quarter of 2024. We plan to initiate a Phase II clinical trial in the third quarter of 2024, complete the Phase II clinical trial in the third quarter of 2025, initiate a Phase III clinical trial in the fourth quarter of 2025 in China, and complete the Phase III clinical trial in the second quarter of 2027.

Recombinant Rabies Vaccine is also in the pre-clinical stage, and we expect to request a pre-IND meeting with the NMPA as early as in the fourth quarter of 2023. We initiated pre-clinical studies for Recombinant Rabies Vaccine in the second quarter of 2020, and we expect to complete the pre-clinical studies in the fourth quarter of 2023. For Recombinant Rabies Vaccine, we plan to initiate a Phase I clinical trial in the second quarter of 2024 and expect to complete the Phase I clinical trial in the third quarter of 2024 in China. We plan to initiate a Phase II clinical trial for Recombinant Rabies Vaccine in the third quarter of 2024, and complete the Phase II clinical trial in the first quarter of 2025. Furthermore, we expect to initiate the Phase III clinical trial in the first quarter of 2025 and complete the Phase III clinical trial in the second quarter of 2026 in China.

For each of K333 and K1932, we expect to request a pre-IND meeting with the NMPA in the second half of 2024.

Expand production capacity to meet growing market demand

We plan to continue to advance our existing product development and production scale-up processes. In particular, we are continually optimizing our bioreactor production process to ensure robust manufacturing. In addition, we are exploring CMC development for different liquid formulations to improve patient experience and convenience when administering our drugs. We also plan to develop our culture expansion processes as we prepare to transfer and scale-up manufacturing at our new Zhuhai manufacturing facilities.

We plan to continue to promote the construction of our second-phase Zhuhai manufacturing facility to expand our production in preparation for the commercialization of our pipeline candidates. We commenced operations at our first-phase Zhuhai manufacturing facility and commenced construction of our second-phase manufacturing facility, which is expected to commence operations by the second quarter of 2023. Our second-phase Zhuhai manufacturing facilities, as planned and approved by the local government agency, occupy approximately 69,366 sq.m. of land with a total GFA of approximately 120,000 sq.m. in the production area.

Lay out strategic plans to promote commercialization at home and abroad

We formulate targeted commercialization strategies for each of our product candidates in China. We will assemble an in-house sales team for the commercialization of K193 and collaborate with contract sales organizations ("**CSOs**") for the commercialization of our other product candidates. In China, we plan to adopt a two-pronged approach for sales and marketing activities. Our commercialization team will cover Beijing, Chengdu, Guangzhou, Shanghai, Tianjin, Wuhan, Xi'an, Zhengzhou and other provincial capitals in China. We plan to engage CSOs to cover major provinces and municipalities in China, including the same cities as our commercialization team and neighboring second- and third-tier cities. We will select CSOs based on their industry experience and expertise, product sales experience, business channels, cold-chain transportation capabilities, financial condition, record of compliance with regulatory agencies and management capabilities. In addition, we will adopt commercialization strategies for LZ901 and K3, including favorable and competitive pricing in the short- to medium-term. LZ901 is expected to be priced at a retail price of approximately RMB500 to RMB800 an injection, with a total of two injections per treatment and does not require a third booster shot, which is more affordable compared to the retail price of the other commercially available herpes zoster vaccines in China, with Shingrix® priced at RMB1,600 an injection with a total of two injections per treatment. According to Frost & Sullivan, there is no booster shot requirement for other peer products of herpes zoster vaccine. K3 is expected to be priced at a retail price of approximately RMB400 to RMB500 a dose, which is more affordable compared to the retail price of the other commercially available biosimilars of adalimumab in China, which are priced at approximately RMB700 to RMB1,200 a dose.

For overseas markets, we will formulate international commercialization strategies according to market conditions to quickly promote our products to benefit patients worldwide. In particular, we plan to seek collaboration opportunities with global partners to leverage their established sales expertise. We will also focus on our layout strategy of the countries under China's Belt and Road Initiative, with a focus on Southeast Asian countries including Singapore and Indonesia, and accelerate our products' entry into relevant countries through seeking collaborations with local partners, which should have in-depth market expertise and are familiar with regulatory requirements of the relevant jurisdiction, after the successful commercialization of LZ901 in China and realize commercial opportunities with the support of government policies.

In order to increase adoption and acceptance of our product candidates by healthcare professionals and ensure end-patient compliance, we plan to promote awareness of our product candidates among patients, physicians, hospitals, CDCs and KOLs through academic promotion, including on-site trainings, academic conferences and events, and regular communications, visits and follow-ups on the safety and effectiveness of our product candidates.

Expand our product pipeline with collaboration

We will actively explore collaboration opportunities in the development, manufacturing and sales of our products. Through the active deployment of our overseas business development capabilities, we plan to introduce a diversified and advanced product pipeline to meet major unmet medical needs. We will seek collaboration opportunities domestically and worldwide and selectively enter into strategic partnerships or licensing transactions to combine our deep research and development experience with global resources to advance our product development and facilitate the commercialization of our product candidates. We will select collaboration partners based on their research and development capability, vaccine and therapeutic biologics development experience, management and research team, business scale and reputation. We believe building a global collaboration network provides us with global endorsement and enhances our brand recognition. Our collaborations will also lead to better access to leading drugs and candidates and potentially offer an extra funding source to advance our product development and facilitate the commercialization of our product candidates.

OUR PRODUCTS AND PRODUCT CANDIDATES

Overview

We are a biotechnology company committed to developing innovative human vaccines and therapeutic biologics for the prevention and control of infectious diseases and addressing the medical needs in the treatment of cancer and autoimmune diseases. We have built our product pipeline by employing our Fabite® technology platform, our mammalian expression technology platform and leveraging our in-house biologics manufacturing infrastructure and capabilities. As of the Latest Practicable Date, our product pipeline consisted of three clinical-stage product candidates, including our Core Product, LZ901, and four pre-clinical-stage product candidates.

The following table summarizes our product portfolio:

PRODUCT TYPE	PRODUCT PIPELINE	MECHANISM/ TARGET	INDICATIONS	CLINICAL TRIALS				Expected Timetable
				PRE-CLINICAL	Phase I	Phase II	Phase III	
Recombinant Vaccine	LZ901[1]	VZV gE	Herpes zoster			China		Complete Phase II in Q2 2023 and expected to initiate Phase III in Q2 2023
			Herpes zoster		US			Complete Phase I in Q1 2024 and expected to initiate Phase II in Q1 2024
Monoclonal Antibody	K3[2]	TNF-α	Rheumatoid arthritis, ankylosing spondylitis, plaque psoriasis			China		Initiate Phase III in Q2 2023 and expected to submit a BLA in Q4 2024
Bispecific Antibody	K193	CD3/CD19	Relapsed/Refractory B-cell lymphoma/leukemia		China			Complete Phase I in Q2 2023 and expected to initiate Phase II in Q1 2024
Recombinant Vaccine	Recombinant Varicella Vaccine	VZV gE	Varicella	China				Initiate Phase I in Q3 2023 and expected to initiate Phase II in Q3 2024
Recombinant Vaccine	Recombinant Rabies Vaccine	RABV-G	Rabies	China				Request pre-IND meeting with the NMPA in Q4 2023
Bispecific Antibody	K333	CD33/CD3	Myeloid leukemia	China				Request pre-IND meeting with the NMPA in the second half of 2024
Bispecific Antibody	K1932	CD19/CD3	Relapsed/Refractory B-cell lymphoma	China				Request pre-IND meeting with the NMPA in the second half of 2024

Notes:

(1) Core Product.

(2) K3 is a biosimilar of adalimumab and therefore, is not required to conduct a Phase II clinical trial. For more details, please see "Our Products and Product Candidates — Our Core Product and Clinical-Stage Product Candidates — 2. K3" in this section.

Our Core Product and Clinical-Stage Product Candidates

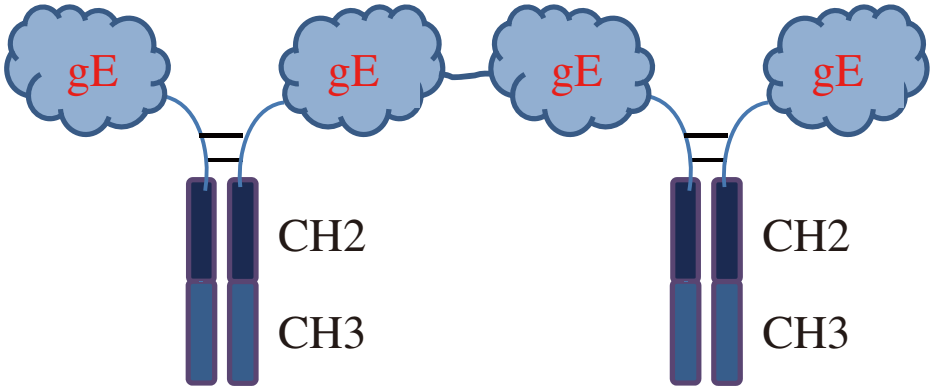
Our clinical-stage product candidates comprise one vaccine candidate, LZ901, our Core Product, and two antibody injection product candidates, including K3 and K193.

1. LZ901

Overview

LZ901, our Core Product and independently developed recombinant herpes zoster vaccine candidate, has a tetrameric molecular structure to prevent shingles caused by VZV for adults aged 50 years and older. LZ901 prevents the occurrence of herpes zoster and related complications caused by herpes zoster, including PHN. LZ901 is designed on the basis of making full use of the mechanism of the human immune system for processing foreign antigens. Employing the mammalian expression technology platform, we developed LZ901 based on the VZV glycoprotein E ("**gE**")-fragment crystallizable ("**Fc**") region. VZV gE is an antigen that is abundantly expressed on the surface of VZV, and the Fc region is the tail region of immunoglobulin G ("**IgG**"), a human antibody, that interacts with cell surface receptors. LZ901 is a recombinant tetramer fusion protein consisting of VZV gEs expressed on CHO cells bound to two Fc fragment of IgG. The carboxyl end of the VZV gE extracellular domain is connected to the Fc fragment of IgG1, and based on the characteristic of VZV gE to form covalent dimers, a multi-step liquid chromatography process is used to obtain high-purity recombinant VZV gE tetramer-Fc fusion proteins containing two Fcs by purification from protein solutions with complex compositions.

The tetrameric molecular structure of LZ901 is illustrated below:



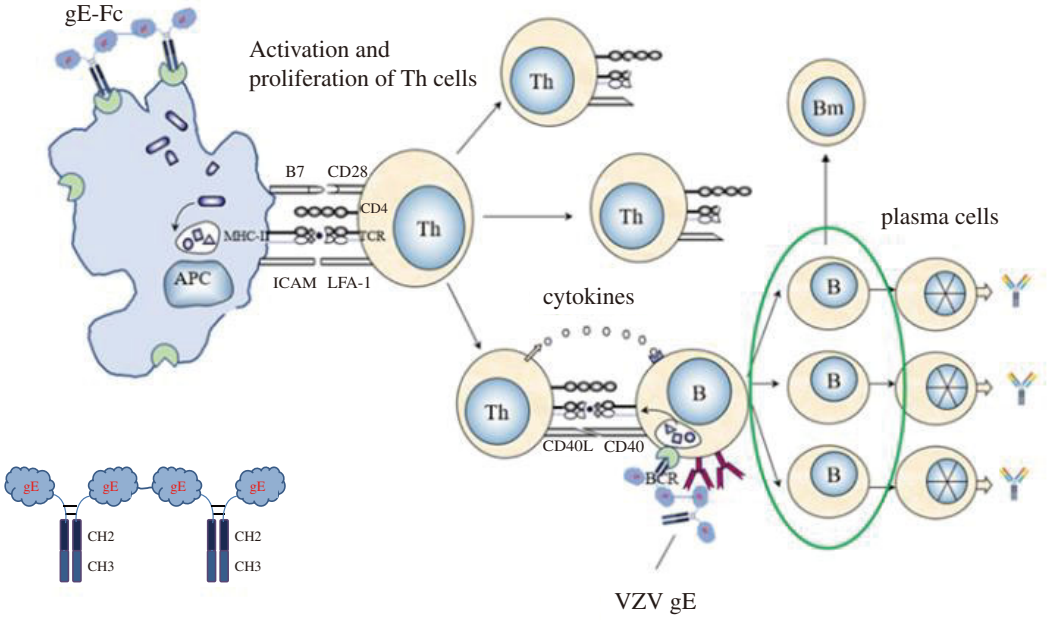
We commenced the development of LZ901 in March 2018. LZ901 has demonstrated high immunogenicity, efficacy and safety profile in pre-clinical studies, while inducing specific humoral and cellular immunity. An *in vitro* VZV plaque reduction neutralization test demonstrated the ability of the Oka strain to infect MRC-5 cells could be neutralized by the serum of mice, rats and cynomolgus monkeys immunized with the LZ901 aluminum adjuvant vaccine, which indicates that LZ901 can also stimulate the body's immune system to produce neutralizing antibodies. Mouse anti-VZV gE monoclonal antibody 2G9 also fully demonstrated the ability to block the Oka strain virus from infecting MRC-5 cells. The result of 2G9 monoclonal antibody neutralizing the Oka strain virus indicates 2G9 monoclonal antibody alone could completely neutralize the ability of the Oka strain to infect MRC-5, and this blocking did not require the participation of complements. By using 2G9 monoclonal antibody and WHO standard serum (W1044, varicella-zoster immunoglobulin), the detection of neutralizing antibody levels in the serum of mice, rats and cynomolgus monkeys after immunization with LZ901 by ELISA showed high contents/titers of neutralizing antibodies of in the serum of immunized animals, demonstrating that LZ901 can stimulate the body's immune system to produce anti-VZV neutralizing antibodies, and LZ901 can be used to prevent the onset of herpes zoster. We plan to observe whether LZ901 will prevent PHN in future clinical research.

We have initiated a Phase I clinical trial in January 2022 and completed the Phase I clinical trial and initiated a Phase II clinical trial for LZ901 in China in April 2022. We expect to complete the Phase II clinical trial for LZ901 in China in the second quarter of 2023, initiate a multi-center, randomized, double-blind, placebo-controlled Phase III clinical trial comparing LZ901 against Shingrix® in the second quarter of 2023, and file the BLA in the third quarter of 2024 for LZ901 to the NMPA. In addition, we have received IND approval from the FDA in July 2022 for LZ901 and initiated a Phase I clinical trial in the U.S. in February 2023. We plan to complete the Phase I clinical trial and initiate a Phase II clinical trial in the first quarter of 2024. Furthermore, we expect to complete the Phase II clinical trial in the second quarter of 2025, initiate a Phase III clinical trial in the fourth quarter of 2025, and complete the Phase III clinical trial in the second quarter of 2027.

Mechanism of Action

LZ901 is designed on the basis of making full use of the mechanism of using the human immune system to process foreign antigens. LZ901 is a recombinant tetramer fusion protein consisting of VZV gEs bound to two Fc to mimic the immune complex formed from the binding of VZV antigens to antibodies when VZV invades the body. Fc receptors on the surface of APCs bind to the two Fc regions of the LZ901 antigen, which is then internalized via either phagocytosis by macrophages and dendritic cells or receptor-mediated endocytosis by B cells, and degraded into peptide fragments. The APCs then display these peptide fragments co-presented with a class II major histocompatibility complex ("**MHC**") molecule or cross-presented with a class I MHC molecule on the surface of their cell membranes. Helper (CD4+) T cells recognize and interact with the LZ901 antigen-class II MHC molecule complex or LZ901 antigen-class I MHC molecule complex on the membrane of the APC. Such interaction induces a Th2-based humoral immune response and activates cytotoxic (CD8+) T cells to kill cells infected with VZV through apoptosis. In addition to presenting LZ901 antigens to helper (CD4+) T cells, B cells also produce neutralizing antibodies to neutralize VZV and form memory responses to provide long-term protection against VZV.

The following diagram illustrates the mechanism of action of LZ901:



Although both LZ901 and Shingrix® utilize recombinant protein technologies, the mechanics of LZ901 is different compared to Shingrix® and both have different subdivision technology routes and methods of presenting antigens. Shingrix® uses an innovative adjuvantant technology, while LZ901 has an innovative tetrameric molecular structure. Shingrix® has the same molecular structure as VZV gE which relies on the addition of adjuvants such as immune stimulant QS21 to enhance the immunogenicity of gE protein because the extracellular region of the gE protein relies on the addition of an adjuvant with a strong immune stimulant to stimulate the gE protein to produce stronger immunogenicity. LZ901 has a tetrameric molecular structure consisting of VZV gEs bound to two Fc to mimic the immune complex formed from the binding of VZV antigens to antibodies when VZV invades the body. As LZ901 exhibited improved immunogenicity compared to naturally occurring VZV gE in pre-clinical studies, LZ901 uses a safer liquid formulation that only contains an aluminum hydroxide adjuvant and is free of immune stimulants, which reduces the likelihood of serious adverse reactions at the injection site.

Market Opportunities and Competition

Shingles is becoming more prevalent in China due to a growing aging population that is more susceptible to shingles. According to Frost & Sullivan, the number of new cases of herpes zoster in people aged 50 years old and above in China increased from 2.5 million in 2015 to 3.9 million in 2021 at a CAGR of 7.8%. It is expected to increase to 4.9 million in 2025 at a CAGR of 6.0% from 2021 to 2025, and further increase to 6.0 million in 2030 at a CAGR of 4.2% from 2025 to 2030. As the public awareness of herpes zoster continues to grow and the number of available herpes zoster vaccines increases, the herpes zoster vaccine market in China is expected to grow significantly. Among global markets, the herpes zoster vaccination rate in the U.S. is the highest due to the earlier availability of the vaccine in the U.S., favorable reimbursement policies, high awareness of herpes zoster. The herpes zoster vaccination rate in China is relatively low compared

to the rate of U.S. Given the large patient population in China, there is great potential for the herpes zoster vaccine market to grow in the future. The number of new cases of herpes zoster in people aged 50 years old and above in China increased from 2.5 million in 2015 to 3.9 million in 2021 at a CAGR of 7.8%. It is expected to increase to 4.9 million in 2025 at a CAGR of 6.0% from 2021 to 2025, and further increase to 6.0 million in 2030 at a CAGR of 4.2% from 2025 to 2030. The vaccination rate of herpes zoster vaccine among people aged 50 years and older is expected to reach 1.9% in 2025 and 12.6% in 2030 in China. For details of the key assumptions driving the forecasted growth in herpes zoster vaccination rate in China, please see "Industry Overview — Herpes Zoster Vaccine Market — Overview" in this document. In comparison, the number of new cases of herpes zoster in people aged 50 years old and above in the U.S. is expected to grow at a slower rate compared to China. The number of new cases of herpes zoster in the U.S. increased from 1.0 million in 2015 to 1.1 million in 2021 at a CAGR of 2.4%, and is expected to increase to 1.2 million in 2025 at a CAGR of 1.8% from 2021 to 2025, and further increase to 1.3 million in 2030 at a CAGR of 1.5% from 2025 to 2030.

According to Frost & Sullivan, the recurrence rate of shingles for unvaccinated patients is approximately 4% to 6%, with the recurrence rate of shingles increasing with age. After receiving herpes zoster vaccination, the risk of recurrence of shingles is reduced by approximately 50% in vaccinated patients. For Shingrix®, two doses are recommend, and for Zostavax®, one dose is recommended. Currently, no booster is recommended for either Shingrix® or Zostavax® by the CDC, other clinical guidelines or medical organizations. Due to the low effectiveness of Zostavax® as a herpes zoster prophylaxis and its weakened market competitiveness, it has discontinued production in the U.S. LZ901 does not face the same risks of discontinued commercialization as Zostavax® because LZ901 is a recombinant vaccine while Zostavax® is a live attenuated vaccine and the cellular immune response and humoral response data from the Phase I clinical trial of LZ901 indicate the immunogenicity of LZ901 is not weaker than Shingrix®.

In 2021, the vaccination rate of herpes zoster, among those aged 50 years and older, was 0.1% in China, 5.2% in the EU and 26.8% in the U.S., according to Frost & Sullivan. According to 2022 China Herpes Zoster Vaccine Expert Consensus (帶狀皰疹疫苗預防接種專家共識), herpes zoster vaccine is recommended in order to prevent herpes zoster.(1) PRC government guidelines on herpes zoster vaccination recommend that individuals aged 50 years and older (regardless of whether the individual has a history of varicella infection or varicella vaccination) receive herpes zoster vaccine. The complete immunization program consists of two doses, and the second dose is administered two to six months after the first dose of herpes zoster vaccination. Individuals who are or may have immunodeficiency or immunosuppression due to disease or treatment are recommended to receive the second dose within one to two months after the first dose.

The U.S. CDC recommends that adults aged 50 years and older receive herpes zoster vaccine as a prevention regimen for shingles. The U.S. CDC recommends Shingrix® as the primary vaccine for shingles, and immunocompetent adults aged 50 years and older should obtain two doses of

Note:

(1) "2022 China Herpes Zoster Vaccine Expert Consensus": Dermatology Branch of China Medical Care International Exchange Promotion Association, Senile Dermatology Research Center of Chinese Medical Association Dermatology Branch. Herpes Zoster Vaccine Expert Consensus. Medical Journal, 2022, 102(8): 538-543. DOI: 10.3760/cma.j.cn112137-20210828-01958.

Shingrix® two to six months apart. In the EU, Shingrix® is indicated for both shingles and PHN, a common complication of shingles. However, having PHN listed as an indication does not imply that Shingrix® has any advantages over peer products that do not list PHN as a separate indication, because any vaccine that prevents herpes zoster will by nature prevent PHN, regardless of whether PHN is listed as a separate indication or not. The Background Paper on Herpes Zoster Vaccine authored by SAGE Working Group of WHO mentions recommendations for herpes zoster vaccine administration in Europe and Asia, including Austria and Sweden for individuals aged 50 years and older, the U.S., Canada, Greece, Korea and Thailand for individuals aged 60 years and older, Australia for individuals aged between 60 to 79 years old and the U.K. for individuals aged between 70 to 79 years old.

The vaccination rate in people age 50 or above in China increased from 0.04% in 2020 to approximately 0.13% in 2022 according to Frost & Sullivan. According to Frost & Sullivan, in terms of sales revenue, the herpes zoster vaccine market in China increased from nil in 2015 to RMB0.6 billion in 2021, and is expected to grow to RMB10.8 billion in 2025 at a CAGR of 103.8% from 2021 to 2025, and further grow to RMB28.1 billion in 2030 at a CAGR of 21.1% from 2025 to 2030. In the U.S., the vaccination rate of herpes zoster vaccine of people aged 50 or above in 2021. was approximately 26.8%, compared to approximately 0.1% in China. By 2030, the cumulative vaccination rate of people aged 50 or above in the U.S. is expected to be approximately 70%. In terms of sales revenue, the herpes zoster vaccine market in the U.S. increased from US$0.5 billion in 2016 to US$1.7 billion in 2021 at a CAGR of 27.2% from 2016 to 2021, and is expected to remain stable at US$1.7 billion in 2025 at a CAGR of 0.2% from 2021 to 2025, and decrease to US$1.6 billion in 2030 at a CAGR of -1.4% from 2025 to 2030. From 2023 to 2030, the herpes zoster vaccine market in the U.S. is expected to remain stable due to (i) the U.S. is a relatively mature market for herpes zoster vaccine, the vaccination rate of herpes zoster vaccine among people aged 50 years and older in the U.S. was 26.8% in 2021; and (ii) the number of people aged 50 years and older in the U.S. was 119 million in 2021 and is expected to reach 130 million in 2030, and the population of people aged 50 years old and above in the U.S. is expected to grow at a slower pace with an average year-over-year growth rate between 0.8% to 1.0%. Currently, Shingrix® is the only commercialized herpes zoster vaccine in the U.S. In terms of medical coverage, Shingrix® is covered by Medicare Part D in the U.S., which greatly reduce the financial burden of patient to be vaccinated, and Medicaid covers Shingrix® for people aged 50 and older in approximately two-thirds of the states in the U.S. The price of Shingrix® has remained stable in the U.S. at approximately US$120 per dose. The price of herpes zoster vaccines is expected to increase in the future as more herpes zoster vaccines featuring more advanced technology are approved and sold in the U.S.

In Southeast Asia, the number of people aged 50 and over grew from 134.7 million in 2016 to 144.5 million in 2021, with a CAGR of 1.4%. It is expected to continue to grow in the future, reaching 156.2 million in 2026, with a CAGR of 1.6% from 2021 to 2026. The number of new cases of herpes zoster in Southeast Asia increased from 1.57 million in 2016 to 1.79 million in 2021, with a CAGR of 2.7% over this period. With the increase in the population over 50 years old, the number of new cases in Southeast Asia will reach 1.99 million in 2026, with a CAGR of 2.2% from 2021 to 2026. The growing population of people aged over 50 coupled with increasing new cases of herpes zoster in Southeast Asia implies that there is a large potential market for shingles vaccine in Southeast Asia. Southeast Asia consists of 11 countries including Singapore, the Philippines, Malaysia, Indonesia, etc, and each country currently has different national medical insurance coverages. The herpes zoster vaccines have been marketed in some Southeast Asian countries such

as Singapore, Malaysia, and the Philippines, while the vaccines are not available in other Southeast Asian countries, such as Indonesia. The pricing of herpes zoster vaccines in different Southeast Asian countries vary which depends on the level of local medical development and the affordability of local people. For example, the price of Shingrix per dose is SGD430 in Singapore. In terms of medical insurance coverage, herpes zoster vaccines are generally not covered in the local vaccination schedule of Southeast Asian countries such as Singapore, Malaysia, and the Philippines. People have to pay it out-of-pocket when they want to get vaccinated. In addition, favorable government policies have promoted herpes zoster vaccines in Southeast Asia. For example, the Society of Infectious Disease (Singapore) Handbook (2020 edition) recommends herpes zoster vaccine for the prevention of shingles.

We also intend to conduct marketing activities raising the public awareness of shingles of the benefits and costs of receiving herpes zoster vaccines to further capitalize on the increased public awareness. According to Frost & Sullivan, LZ901, once approved, is not likely to be included in the National Immunization Program as it is mainly for adults aged 50 years or older and herpes zoster vaccines were not included in the NRDL as of the Latest Practicable Date. Accordingly, the public needs to purchase LZ901 at their own expense. Not being included under the National Immunization Program or the NRDL would not affect the pricing of LZ901 as we would price our product candidates at market price. However, if peer products are included under the NRDL, our peer products will gain market competitive advantage in market penetration, which would cause market pressure on our product candidates. As also confirmed by Frost & Sullivan, there are five antiviral drugs, including aciclovir, valaciclovir, famciclovir, brivudine and foscarnet for treatment of herpes zoster. Aciclovir is listed in Category A or Category B, depending on the dosage form, and valaciclovir, famciclovir, and foscarnet are listed in Category B of the NRDL. They are also four first-line treatment drugs for PHN, including pregabalin, gabapentin, amitriptyline and 5% lidocaine patch, all of which are listed in the Category B of the NRDL. According to the Interim Measures for the Administration of Use of Drugs Covered by the Basic Medical Insurance (《基本醫療保險用藥管理暫行辦法》), western drugs and Chinese drugs in the national Drug Catalog are divided into "drugs of Category A" and "drugs of Category B". The expenses for "drugs of Category A" used by the insured shall be paid according to the payment standards and sharing measures stipulated for basic medical insurance, while those for "drugs of Category B" shall be first paid by the insured in a certain percentage, and then paid according to the sharing measures stipulated for basic medical insurance. The percentage of expenses paid by individuals for "drugs of Category B" is determined by the provincial or pooling region's healthcare security administrative department. For details, please see "Regulatory Overview — Regulatory Provisions — Biosimilars Application and Approval — Drug Operation" in this document.

As of the Latest Practicable Date, there were two herpes zoster vaccines approved in China, namely GlaxoSmithKline plc's Shingrix® which also captured almost 100% of the global market share in terms of sales revenue in 2021, and BCHT Biotechnology's Gan Wei (感維), which was

recently approved in January 2023 and will commence to be sold in June 2023. The following table sets forth details of Shingrix® and BCHT Biotechnology's Gan Wei (感維):

Company Name	GlaxoSmithKline	BCHT Biotechnology
Product name	Shingrix®	Gan Wei (感維)
Indications	Herpes zoster and PHN(1)	Herpes zoster
Type of technology	Recombinant	Live attenuated
Targeted age/ gender group	Immunocompetent male and female adults aged 50 years and older and immunodeficient male and female adults aged ≥ 19 years old	Males and females aged 40 years and older
Effectiveness reducing herpes zoster	50-59 years old: 96.6% 60-69 years old: 97.4% 70+: 91.3%	≥40 years old: 57.6% 40-49 years old: 37.4% 50-59 years old: 62.7% 60-69 years old: 64.4% ≥70 years old: 18.6%
Effectiveness reducing post-herpetic neuralgia	≥50 years old: 91.2% ≥70 years old: 88.8%	≥45 years old: 62.8% ≥65 years old: 62.9%
Long-term vaccine effectiveness against herpes zoster	50 years and older: 81.6% (the first 6-10 years following vaccination)	N/A
Date of approval	U.S.: October 20, 2017 Europe: March 28, 2018 China: May 22, 2019(2)	China: January 29, 2023 (expected commencement of sales in June 2023)
Price	RMB1,600/dose in China, approximately US$120/dose overseas	RMB1,369/dose
Vaccine administration procedure	Two doses, second dose administered 2-6 months after first dose	One dose

Notes:

(1) Though indications of Shingrix® include PHN in EU, it doesn't mean that Shingrix® has any advantages over peer products that do not list PHN as a separate indication, because any vaccine that prevents herpes zoster will by nature prevent PHN, regardless of whether PHN is listed as a separate indication or not.

(2) GlaxoSmithKline plc did not conduct clinical trials for Shingrix® in mainland China but used overseas data to support the conditional approval for Shingrix® in China. After receiving conditional approval, GlaxoSmithKline plc had initiated a follow-up Phase III clinical trial for Shingrix® in mainland China in 2021, which is expected to be completed in 2023.

Source: Frost & Sullivan Analysis

As of the Latest Practicable Date, there was only one marketed herpes zoster vaccine, namely Shingrix®, and four herpes zoster vaccines under development in the U.S. In November 2020, Zostavax® was no longer available for use in the U.S., as it has discontinued production in the U.S. due to its low effectiveness of as a herpes zoster prophylaxis and its weakened market competitiveness. In 2021, sales of Shingrix® in the U.S. was US$1,727.2 million. As of the Latest Practicable Date, there were no marketed herpes zoster vaccines and no clinical research information of herpes zoster vaccines under development in Indonesia. As of the Latest Practicable Date, there were two marketed herpes zoster vaccines, namely Shingrix® and Zostavax®, and no herpes zoster vaccines under development in Singapore. Vaccines approved in the U.S. require additional clinical trials and approval procedures in Southeast Asia. Each Southeast Asian country has different regulations on vaccine products. However, once a vaccine is approved by FDA, it will be highly recognized in Southeast Asia and the time required to conduct local clinical trials and approval procedures will be greatly reduced.

Besides our LZ901, there were three other herpes zoster vaccines under development in China, including one live attenuated herpes zoster vaccine and two recombinant herpes zoster vaccines, and six other herpes zoster vaccine candidates at the clinical stage in Australia, the Philippines and the U.S., according to Frost & Sullivan. Wantai Biopharma strategically abandoned development of its live attenuated shingles vaccine as the Phase II clinical trial results demonstrated that its protective efficacy was inferior to Shingrix®. LZ901 does not face the same risks of discontinued research and development as Wantai Biopharma's shingles vaccine because LZ901 is a recombinant vaccine while Wantai Biopharma's shingles vaccine is a live attenuated vaccine and the cellular immune response and humoral response data from the Phase I clinical trial of LZ901 indicate the immunogenicity of LZ901 is not weaker than Shingrix®. Live attenuated herpes zoster vaccines usually are manufactured at a lower cost and cause fewer side effects, but they could retain residual virulence and are not applicable for people with weakened immune systems. Recombinant herpes zoster vaccines, on the other hand, have the advantage of inducing a immune response while avoiding other components of the pathogen that cause adverse health effects, and are safe for people with weak immune systems. The following chart sets forth details of the herpes zoster vaccines under development in Australia, China, the Philippines and the U.S.:

Vaccine Name	Technology	Company	R&D Progress	Clinical Application Country	Date of IND Approval	Date of Phase I Clinical Trial[1]	Formulation	Ages/Gender Eligible for Clinical Trial
Live attenuated herpes zoster vaccine	Live attenuated	Shanghai Institute of Biological Products (上海生物製品研究所)	Phase II (completed)	China	August 21, 2017	November 20, 2018	Powder for concentrate for solution for infusion	Males and females aged 40 years and older
Recombinant Herpes Zoster Vaccine (CHO)	Recombinant	Luzhu Biotech (綠竹生物)	Phase II	China	August 4, 2021	January 15, 2022	Liquid	Males and females aged 50 years and older
			Phase I	U.S.	July 13, 2022	February 2023		
Recombinant Herpes Zoster Vaccine (CHO)	Recombinant	Curevo Inc.	Phase II	U.S.	N/A	January 2019	N/A	Males and females aged 50 years and older
Recombinant Herpes Zoster Vaccine (CHO)	Recombinant	Eyegene Inc.	Phase I (completed)	Australia	N/A	January 2020	N/A	Males and females aged 50 years to 70 years
Recombinant Herpes Zoster Vaccine (CHO)	Recombinant	Dynavax Technologies Corporation	Phase I	Australia	N/A	January 2022	N/A	Males and females aged 50 years to 69 years
Recombinant Herpes Zoster Vaccine (CHO)	Recombinant	Ab&B Bio-Tech (中慧元通)/ Easyway (上海怡道)	Phase I/II	China	May 6, 2020	December 13, 2021	Liquid	Males and females aged 40 years and older
Recombinant Herpes Zoster Vaccine (CHO)	Recombinant	MAXVAX Biotechnology (邁科康生物)	Phase I	China	January 4, 2022	October 21, 2022	N/A	Males and females aged 18 years and older
Recombinant Shingles Vaccine	Recombinant	Jiangsu Recbio Technology Co., Ltd. (瑞科生物)	Phase I	Philippines	December 19, 2022	N/A	N/A	N/A
RNA Herpes Zoster Vaccine JCXH-105	srRNA	Immorna (Hangzhou) Biotechnology Co., Ltd. (嘉晨西海)	FDA approved to initiate Phase I	U.S.	December 19, 2022	N/A	N/A	N/A
VZV modRNA	mRNA	Pfizer Inc. & BioNTech SE	Phase I/II	U.S.	N/A	January 25, 2023	Frozen or freeze dry powder	Males and females aged 50 years to 69 years

Source: *Frost & Sullivan Analysis*

Notes:

(1) Date when the phase of clinical trial was first published.

(2) The recombinant herpes zoster vaccine developed by MAXVAX Biotechnology has adopted cytosine phosphoguanosine oligodeoxynucleotide ("**CpG ODN**") as an adjuvant, the safety of which is yet to be demonstrated. On the other hand, LZ901 has adopted aluminum adjuvant, which is widely used and safe for vaccine development, according to Frost & Sullivan.

Source: *Center for Drug Evaluation of the NMPA (the "**CDE**"), public disclosure of listed companies, Frost & Sullivan Analysis*

Curevo Inc. and Eyegene Inc. are unlikely to seek market approval for commercialization in China for their herpes zoster vaccines because Curevo Inc. and Eyegene Inc. are both South Korean companies and South Korean biopharmaceutical companies often expand their market by selling vaccines in Southeast Asia, but rarely in China. In addition, neither Curevo Inc. nor Eyegene Inc. has applied for CTA approval for their herpes zoster vaccines in China. As of the Latest Practicable Date, there were no approved vaccine in China manufactured by a South Korean company. Dynavax Technologies Corporation is also unlikely to seek market approval for commercialization in China for its Recombinant Herpes Zoster Vaccine (CHO). As of the Latest Practicable Date, Dynavax had no product sales in China and had not planned to initiate clinical trials in China. Jiangsu Recbio Technology Co., Ltd. and Immorna (Hangzhou) Biotechnology Co., Ltd. are Chinese companies and may be more motivated than international companies to seek to commercialize their respective product candidates in their own country in the future. However, even if they have such plans, their respective product candidates are unlikely to enter the Chinese market in a short term, because in order to commercialize the relevant product candidates in China, they are required to complete new clinical trials in China, while as of the Latest Practicable Date, none of them had registered for any clinical trials in China for the relevant product candidates.

To support our sales and marketing efforts for LZ901 in China, we plan to build our commercialization team for LZ901 in or around the third quarter of 2024 upon submitting the BLA for LZ901 to the NMPA. In addition, we plan to collaborate with CSOs according to the administrative regions to expand the sales volume and increase market penetration of LZ901. To improve the competitiveness of LZ901 in overseas markets, we will formulate corresponding sales strategies according to the market conditions. We may develop out-licensing or collaboration strategies. We plan to commercialize LZ901 in-house in China and collaborate with multinational pharmaceutical companies who have a robust sales and marketing network to rapidly commercialize LZ901 globally in overseas markets, including in the U.S. and Southeast Asian countries. Upon entering into collaborations with such multinational pharmaceutical companies, we plan to authorize such multinational pharmaceutical companies to produce and sell LZ901 in the markets and countries that are agreed upon. As of the Latest Practicable Date, we had explored collaboration opportunities with third parties to out-license LZ901 in markets outside of China but had not identified any collaboration partners, and may pursue such out-licensing opportunities after we complete the Phase II clinical trial for LZ901 in the U.S. in the second quarter of 2025. We may also build overseas production workshops and establish our own overseas sales team. For details, please see "Business — Commercialization" in this document. LZ901 may fail to achieve high market acceptance as Shingrix® has first-mover advantages and captured almost 100% of the global and Chinese market share in terms of sales revenue. For details, please see "Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to Sales and Distribution of Our Product Candidates — We operate in a competitive environment, and we may not be able to compete effectively against current and future competitors." and "Industry Overview — Herpes Zoster Vaccine Market — Competitive Landscape" in this document.

However, Shingrix® has a incidence rate of 23.3% of Grade III AEs, while LZ901 has a different antigen structure and a formulation that uses a different adjuvant compared to Shingrix®, which demonstrates a much lower incidence rate as no Grade III AEs were observed in subjects dosed with LZ901 based on the results of the Phase I clinical trial of LZ901. Besides, LZ901 is expected to be priced at a retail price of approximately RMB500 to RMB800 an injection, with a total of two injections per treatment and does not require a third booster shot, which is more affordable compared to the retail price of the other commercially available herpes zoster vaccines in China, with Shingrix® priced at RMB1,600 an injection with a total of two injections per treatment. As LZ901 is highly stable, easy to store and transport, and convenient to use, with low price, mild side effects and favorable safety profile, molecular structure advantages and strong protection, we expect that LZ901 will capture a large market share in the future. For more details of the competitive advantages of LZ901, please see "— Our Products and Product Candidates — Our Core Product and Clinical-Stage Product Candidates — 1. LZ901 — Competitive Advantages" in this section.

We believe there is significant market potential for our LZ901, considering the following factors.

- ***Favorable government policies for domestic vaccine manufacturers in China***. In 2017, Opinions of the General Office of the State Council on Further Strengthening the Management of Vaccine Circulation and Vaccination (國務院辦公廳關於進一步加強疫苗流通和預防接種管理工作的意見) set out principles to promote domestic vaccine manufacturers to scale up production of vaccines, independent R&D and to improve the quality of vaccines to support R&D and industrialization of new vaccines. Therefore, we believe we will benefit from such favorable government policies and LZ901 will capture a large market share in the future.

- ***Government support and new initiatives to encourage developments for vaccination***. According to China's 14th Five-Year Plan, it proposes improving the health of the elderly as a key task during this period. In addition, the NHC recommends people aged 50 years and older to obtain herpes zoster vaccination to prevent shingles. According to 2022 China Herpes Zoster Vaccine Expert Consensus (帶狀皰疹疫苗預防接種專家共識), herpes zoster vaccine is recommended in order to prevent herpes zoster, and individuals aged 50 years and older (regardless of whether the individual has a history of varicella infection or varicella vaccination) are recommended to receive herpes zoster vaccine.

- ***Cost effectiveness of vaccination***. Shingles is a viral infection that causes a painful rash that can negatively impact quality of life. Shingles can also reoccur, with the recurrence rate of shingles increasing with age. The recurrence rate of shingles for unvaccinated patients is approximately 4% to 6%. After receiving herpes zoster vaccination, the risk of recurrence of shingles is reduced by approximately 50% in vaccinated patients. Based on a research study, the average cost of treatment for shingles (including both patients that develop and do not develop complications) is approximately RMB840 per patient and the average cost of treatment for shingles for patients that develop complications is approximately RMB1,221 per patient in people aged 50 years old and above in China according to Disease Burden Due to Herpes Zoster among Population Aged ≥50 Years Old in China: A Community Based Retrospective Survey*, while LZ901 is expected to be priced at a retail price of approximately RMB500 to RMB800 an injection, with a total of two injections per treatment and does not require a third booster shot.[(1)] The treatment for shingles mainly includes outpatient service, hospitalization and medical treatment, and the average cost of

treatment for shingles was calculated based on (i) outpatient expenses, (ii) hospitalization expenses, and (iii) other expenses which include the cost of over-the-counter medication, transportation costs from seeking medical service, productivity loss for caring for the patient, and other costs considered to be associated with shingles. According to Frost & Sullivan, taking into consideration the pain and negative impact to quality life caused by shingles, higher recurrence rate of shingles for unvaccinated patients which could lead to increasing costs to treat shingles and its complications, and the cost of LZ901 is fixed at two injections of RMB500 to RMB800 an injection, it is the most advisable choice to receive LZ901 vaccination for shingles.

- ***Non-inferior safety and indicative efficacy of LZ901 compared to Shingrix®***. As demonstrated in the Phase I clinical trial for LZ901 in China, the overall number and incidence rate of Grade I AEs and Grade II AEs of subjects dosed with LZ901 were lower compared to subjects dosed with Shingrix®, and no Grade III AEs were observed in subjects dosed with LZ901 while one Grade III AE was observed in subjects dosed with Shingrix®, demonstrating the mild side effects and favorable safety profile of LZ901. In addition, both the low-dosed and high-dosed LZ901 groups reported an incidence rate of AEs of 55%, which is lower compared to the Shingrix® positive control group that reported an incidence rate of AEs of 100% and similar to the placebo group that reported an incidence rate of AEs of 50%.

  LZ901 induces a cellular immune response that confers strong protection against shingles. Compared to Shingrix® in BALB/c mice, LZ901 induces a stronger cellular immune response with higher expression of multiple types of immune cell activating biomarkers. In addition, based on immunogenicity data collected from the Phase I clinical trial for LZ901 in China, it has been demonstrated that there is no significant difference in the levels of anti-VZV antibodies after the full course of vaccination compared of LZ901 to Shingrix®, indicating that the immunogenicity of LZ901 is not inferior to that of Shingrix®.

Note:

* Li Y, An Z, Yin D, Liu Y, Huang Z, Xu J, Ma Y, Tu Q, Li Q, Wang H. Disease Burden Due to Herpes Zoster among Population Aged ≥50 Years Old in China: A Community Based Retrospective Survey. PLoS One. 2016 Apr 7; 11(4):e0152660.

Competitive Advantages

We believe LZ901 has the following advantages, low price and mild side effects in particular, when compared to the currently marketed herpes zoster vaccine in China:

Low Price

LZ901 is expected to be priced at a retail price of approximately RMB500 to RMB800 an injection, with a total of two injections per treatment and does not require a third booster shot, which is more affordable compared to the retail price of the other commercially available herpes zoster vaccines in China, with Shingrix® priced at RMB1,600 an injection with a total of two injections per treatment. As LZ901 is indicated for middle-aged and elderly adults aged 50 years and older, who are price sensitive and will likely choose a lower priced herpes zoster vaccine, we priced LZ901 at approximately RMB500 to RMB800 an injection. We believe that we are able to maintain a healthy profit margin and to increase acceptance of herpes zoster vaccines in the target population while gaining market share for LZ901 taking into consideration (i) the current competitive landscape of herpes zoster vaccines; (ii) the expected pricing of LZ901 and the pricing of other herpes zoster vaccines with Shingrix® priced at approximately RMB1,600/dose with a total of two doses per treatment and Gan Wei (感維) to be priced at approximately RMB1,369/dose with a total of one dose per treatment once it commences sales in June 2023; and (iii) our manufacturing capacity, which will enable us to lower production cost and improve the profitability for LZ901.

Mild Side Effects and Favorable Safety Profile

The side effects from the administration of LZ901 are minimal as its liquid formulation only contains an aluminum hydroxide adjuvant and is free of immune stimulants, which reduces the likelihood of serious adverse reactions at the injection site. As demonstrated in the Phase I clinical trial for LZ901 in China, the overall number and incidence rate of Grade I AEs and Grade II AEs of subjects dosed with LZ901 were lower compared to subjects dosed with Shingrix®, and no Grade III AEs were observed in subjects dosed with LZ901 while one Grade III AE was observed in subjects dosed with Shingrix®, demonstrating the mild side effects and favorable safety profile of LZ901. In addition, both the low-dosed and high-dosed LZ901 groups reported an incidence rate of AEs of 55%, which is lower compared to the Shingrix® positive control group that reported an incidence rate of AEs of 100% and similar to the placebo group that reported an incidence rate of AEs of 50%.

LZ901 is a recombinant herpes zoster virus vaccine. Unlike live attenuated virus vaccines, LZ901 induces an immune response while avoiding risks of residual virulence from vaccinating with weakened herpes zoster virus.

Molecular Structure Advantages

LZ901 has a tetrameric molecular structure containing two Fc regions that actively present VZV gE to cell membrane surface Fc receptors of APCs to trigger an immune response. The carboxyl end of the VZV gE extracellular domain is connected to the Fc fragment of IgG1, and based on the characteristic of VZV gE to form covalent dimers, a multi-step liquid chromatography process is used to obtain high-purity recombinant VZV gE tetramer-Fc fusion proteins containing two Fcs by purification from protein solutions with complex compositions. In pre-clinical studies, compared to the naturally occurring VZV gE, LZ901 exhibits improved immunogenicity and induces a higher level of neutralizing antibody titers.

Highly Stable, Easy to Store and Transport, and Convenient to Use

LZ901 adopts a liquid formulation with high stability, which allows for easy storage and transportation. It is stable for two weeks at 37°C, 12 weeks at 25°C and 24 months at 2-8°C.

Strong Protection

LZ901 induces a cellular immune response that confers strong protection against shingles. Compared to Shingrix® in BALB/c mice, our LZ901 induces a stronger cellular immune response with higher expression of multiple types of immune cell activating biomarkers. In addition, based on immunogenicity data collected from the Phase I clinical trial for LZ901 in China, it has been demonstrated that there is no significant difference in the levels of anti-VZV antibodies after the full course of vaccination compared of LZ901 to Shingrix®, indicating that the immunogenicity of LZ901 is not inferior to that of Shingrix®.

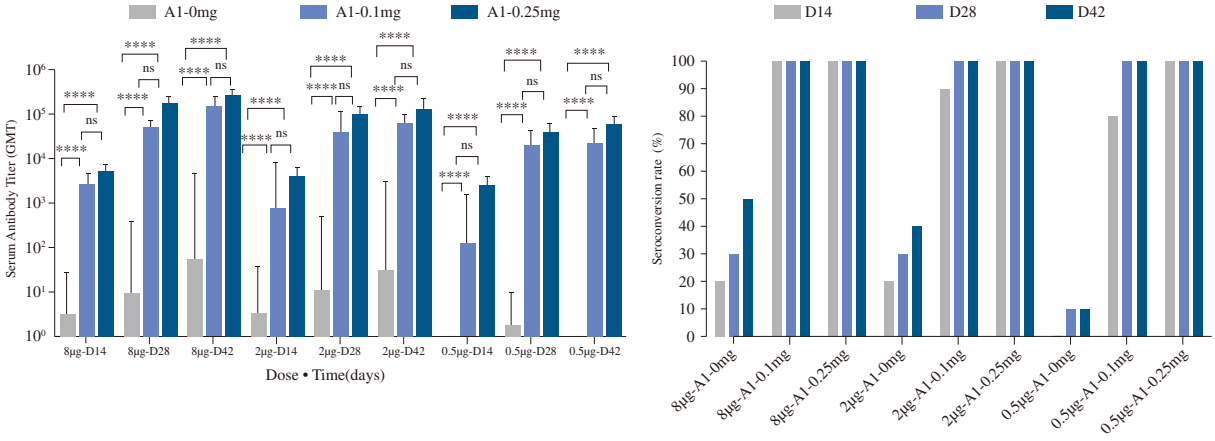
Summary of Preclinical Studies

We conducted a range of *in vitro*, *in vivo* and animal preclinical studies to characterize the immunogenicity, efficacy and safety of LZ901.

Immunogenicity Study of LZ901 With Aluminum Hydroxide Adjuvant Formulations

The addition of aluminum hydroxide adjuvant to the liquid formulation of LZ901 was confirmed to improve the immunogenicity of LZ901 as demonstrated in mice dosed with LZ901 with varying levels of aluminum hydroxide adjuvant. As shown in the graphs below, increasing the addition of aluminum hydroxide adjuvant from 0.1mg to 0.25mg significantly improved the immunogenicity of LZ901.

Geometric Mean Titer (GMT) of Serum VZV gE Antibody after Immunization of Mice With Three Doses of LZ901 Vaccine With Different Aluminum Content



Source: *Company Data*

Stability Study of LZ901 in Various Storage Conditions

LZ901 has been confirmed to be stable for two weeks at 37°C, 12 weeks at 25°C and 24 months at 2-8°C. The pH value, protein content, and adsorption rate of LZ901 were examined under 2-8°C conditions after 24 months, and the relative *in vitro* efficacy of LZ901 was determined by double-antibody sandwich ELISA to investigate the biological activity. The verification test results meet the requirements of the specifications, and the 2-8°C stability testing is still in progress.

In addition, LZ901 stored at 37°C for two weeks was subjected to positive conversion analysis to investigate the *in vivo* efficacy. The stability test results of LZ901 stored at 37°C for two weeks and 25°C for 12 weeks meet the requirements of the specifications, indicating LZ901 is stable at storage conditions of both 37°C for two weeks and 25°C for 12 weeks.

Head-to-Head Immunogenicity Study Comparing LZ901 and Shingrix®

In a BALB/c mice study, our LZ901 induced a stronger cellular immune response with higher expression of multiple types of immune cell activating biomarkers compared to Shingrix®. We conducted a BALB/c mouse study to evaluate the effect of LZ901 and Shingrix® to activate helper (CD4+) T cells and cytotoxic (CD8+) T cells by detecting the expression of activation biomarkers, comprising interferon-γ ("**IFN-γ**"), interleukin 2 ("**IL-2**"), interleukin 4 ("**IL-4**") and cluster of differentiation marker 40 ligand ("**CD40L**"). The purpose of this experiment was to compare BALB/c mice subcutaneously injected with LZ901 and Shingrix® twice, and to investigate the serum specific antibody titer of mice at different time points and the immunogenicity of cellular immune response two weeks after the last immunization.

gE-Specific Humoral Immune Response

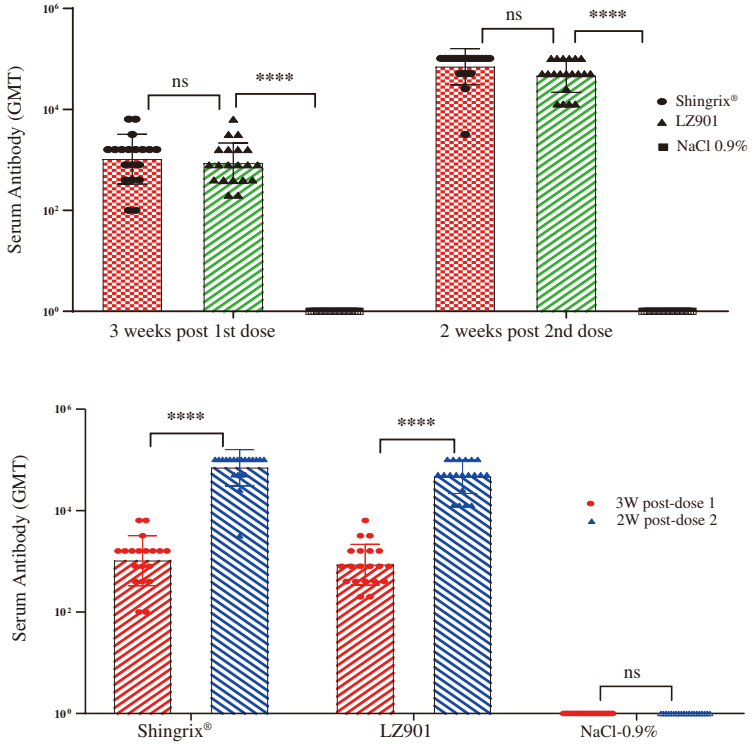
The titers of VZV gE-specific antibodies in the serum of mice immunized with LZ901 and Shingrix® were measured to evaluate the humoral immune response of LZ901 and Shingrix®. There was no significant difference in the titers between mice immunized with Shingrix® and mice immunized with LZ901, which indicates the level of humoral immune response of LZ901 is non-inferior to that of Shingrix®. The following table summarize the VZV gE-specific antibody titers of serum of mice immunized with LZ901, mice immunized with Shingrix® and the mice control group three weeks after the first dose and two weeks after the second dose.

Mouse Serum Titers and Antibody Positive Conversion Rates in Different Dose Groups

		Three weeks post 1st dose		Two weeks post 2nd dose		GMT Ratio
Group	**Number of mice**	**GMT**	**Positive rate**	**GMT**	**Positive rate**	**(Two doses/ One dose)**
			(%)		*(%)*	
Shingrix®	20	1,033	95	69,941	100	67.7
LZ901	20	857	100	46,144	100	53.8
NaCl-0.9%	20	1	0	1	0	1

Source: Company Data

Serum Antibody Titers of BALB/c Mice in Different Dose Groups



Note: No significant difference ("**ns**") p≥0.05, **** p<0.0001

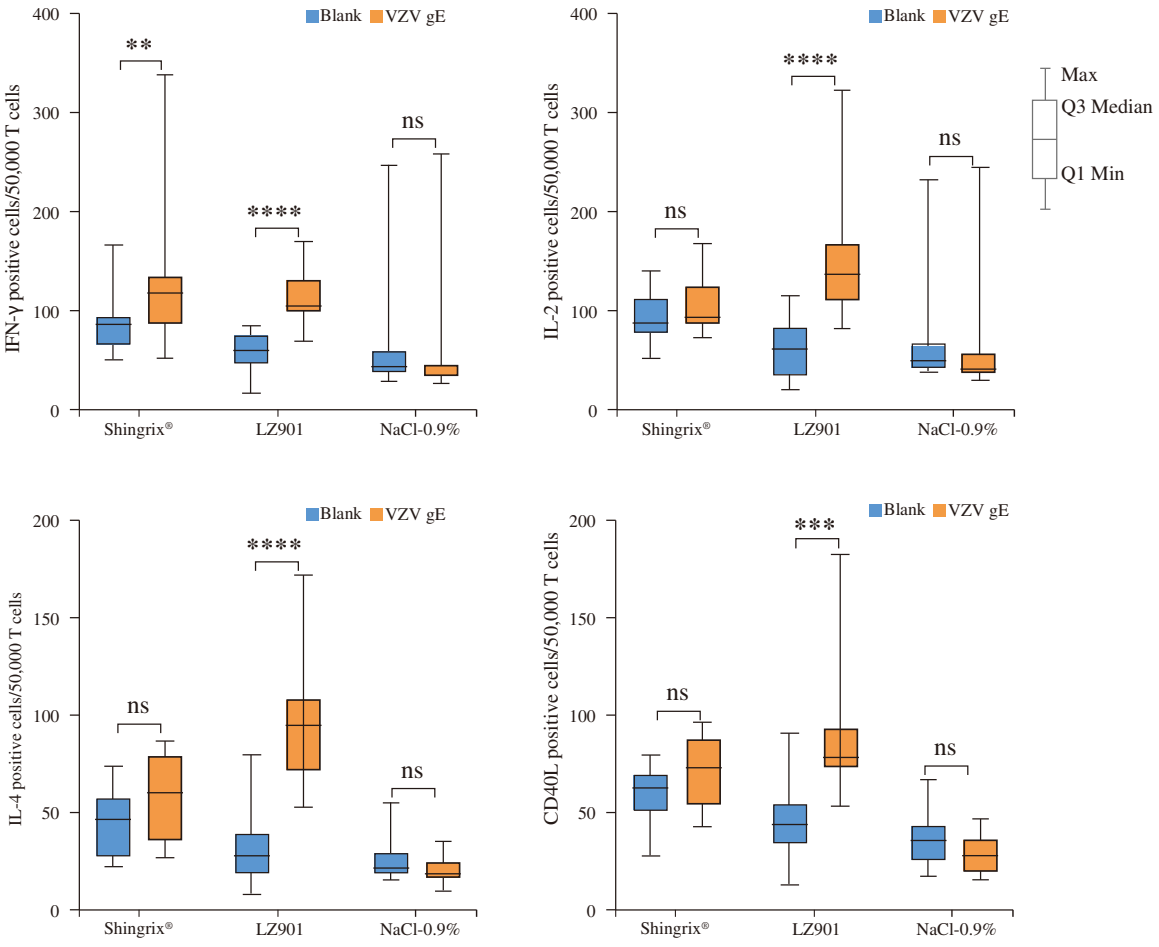
Source: *Company Data*

gE-Specific Cellular Immune Response

Shingrix® was used as a positive control to evaluate gE-specific cellular immune responses of LZ901 in the study. In order to evaluate the cellular immune response induced by LZ901, the spleen cells of BALB/c mice following the second inoculation were investigated to determine the number of helper (CD4+) T cells and cytotoxic (CD8+) T cells, and at least one of the detected markers (IFN-γ, IL-2, IL-4 and CD40L) in 50,000 T cells using intracellular cytokine staining.

After the administration of the second dose of LZ901, the number of helper (CD4+) T cells expressing VZV gE-specific IFN-γ, IL-2, IL-4, and CD40L in VZV gE stimulated mice increased significantly compared to baseline unstimulated mice. However, after the administration of the second dose of Shingrix®, only the number of helper (CD4+) T cells expressing VZV gE-specific IFN-γ in VZV gE stimulated mice increased significantly compared to baseline unstimulated mice. Compared to Shingrix®, mice immunized with LZ901 were observed to have significantly higher magnitude of expression of activation biomarkers and higher proportion of helper (CD4+) T cells and cytotoxic (CD8+) T cells expressing multiple biomarkers, which indicate LZ901 provides strong protection against shingles.

LZ901 and Shingrix® Activation of Helper (CD4+) T Cell Biomarker Expression

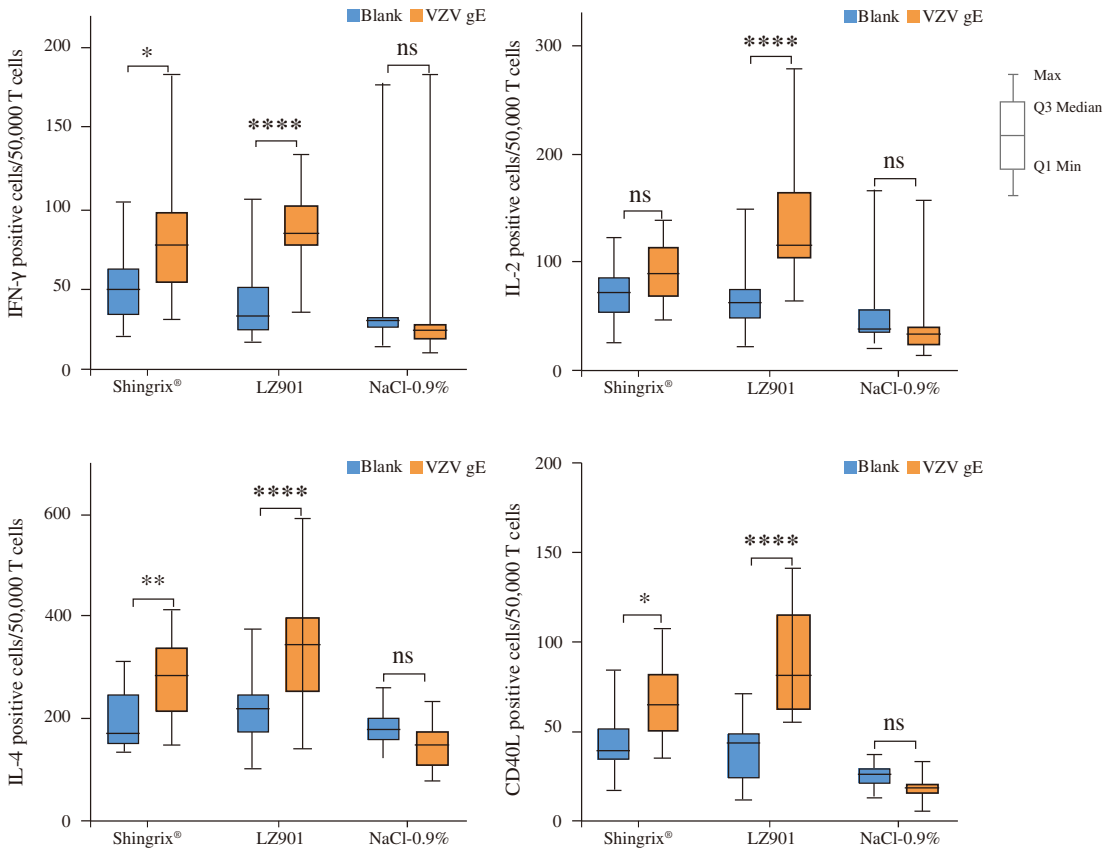


Note: ns p≥0.05, ** p<0.01, *** p<0.001, **** p<0.0001, error bars depict minimum and maximum values

Source: *Company Data*

10 to 14 days after the administration of the second dose of LZ901, the number of cytotoxic (CD8+) T cells expressing VZV gE-specific IFN-γ, IL-2, IL-4, and CD40L in VZV gE stimulated mice increased significantly compared to unstimulated mice. However, 10 to 14 days after the administration of the second dose of Shingrix®, only the number of cytotoxic (CD8+) T cells expressing VZV gE-specific IFN-γ, IL-4, and CD40L in VZV gE stimulated mice increased significantly compared to baseline unstimulated mice, but the level and magnitude of the increase were not as high as LZ901.

LZ901 and Shingrix® Activation of Cytotoxic (CD8+) T Cell Biomarker Expression



Note: ns p≥0.05, ** p<0.01, *** p<0.001, **** p<0.0001, error bars depict minimum and maximum values

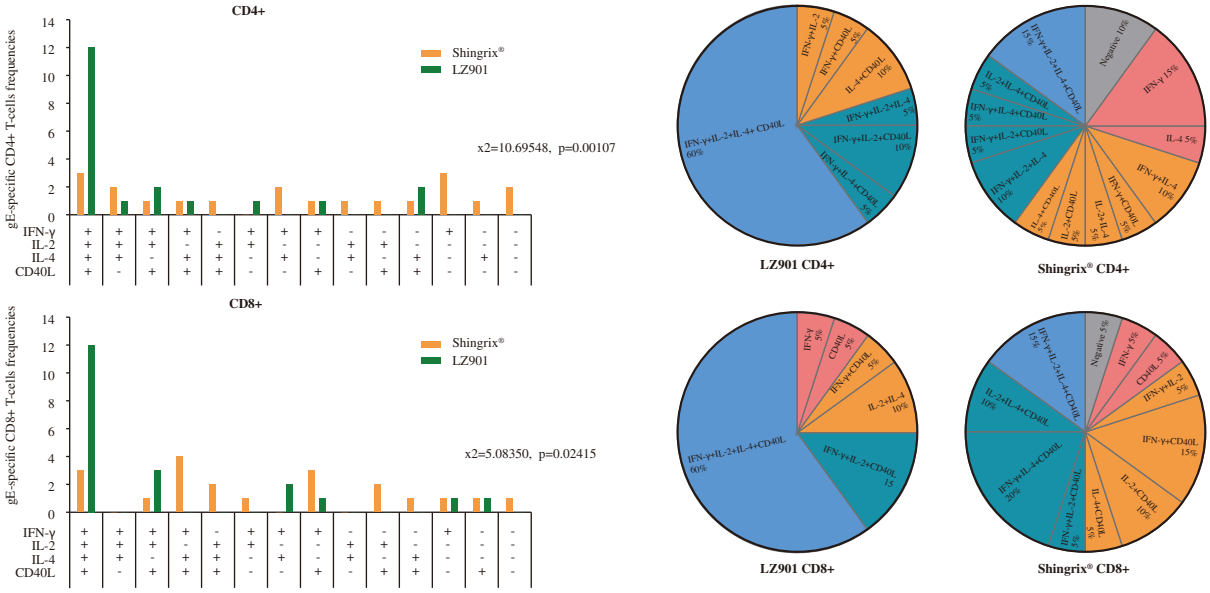
Source: *Company Data*

The proportion of helper (CD4+) T cells in LZ901 dosed mice expressing a combination of two, three or four activation biomarkers were significantly higher than that of helper (CD4+) T cells in Shingrix® dosed mice. The proportion of cytotoxic (CD8+) T cells in LZ901 dosed mice expressing a combination of two, three or four activation biomarkers were significantly higher than that of cytotoxic (CD8+) T cells in Shingrix® dosed mice.

For the group immunized with LZ901, the proportion of mouse gE-specific helper (CD4+) T cells expressing at least two activation biomarkers was 100%, at least three activation biomarkers was 80% and four activation biomarkers was 60%. In addition, the proportion of mouse gE-specific cytotoxic (CD8+) T cells expressing at least two activation biomarkers was 90%, at least three activation biomarkers was 75% and four activation biomarkers was 60%. 90% of mouse gE-specific helper (CD4+) T cells expressed IFN-γ and 85% of mouse gE-specific cytotoxic (CD8+) T cells expressed CD40L.

For the group immunized with Shingrix®, the proportion of mouse gE-specific helper (CD4+) T cells expressing at least two activation biomarkers was 70%, at least three activation biomarkers was 40% and four activation biomarkers was 15%. In addition, the proportion of mouse gE-specific cytotoxic (CD8+) T cells expressing at least two activation biomarkers was 85%, at least three activation biomarkers was 50% and four activation biomarkers was 15%. 65% of mouse gE-specific CD4+ T cells expressed IFN-γ and 85% of mouse gE-specific CD8+ T cells expressed CD40L.

LZ901 and Shingrix® Activation of Helper (CD4+) T Cell and Cytotoxic (CD8+) T Cell Expression of Multiple VZV gE Specific Biomarkers



Source: Company Data

Summary of Phase I Clinical Trial Results

Trial design. We conducted a randomized, blinded and active-controlled Phase I clinical trial to evaluate the safety and tolerability, and preliminarily explore the immunogenicity of LZ901 in healthy people aged between 50 to 70 years old. A total of 80 subjects were enrolled in the Phase I clinical trial for LZ901. The subjects were divided into four groups, including (i) low-dose group with 20 subjects receiving 50μg/0.5mL/vial of LZ901, (ii) high-dose group with 20 subjects receiving 100μg/0.5mL/vial of LZ901, (iii) 20 subjects receiving a 0.5mL/vial placebo control and (iv) 20 subjects receiving 50μg/0.5mL/vial of GlaxoSmithKline Biologicals SA's Shingrix® positive control vaccine. Details of the trial groups are set out in the following table:

	Number of Subjects		
Group	**LZ901**	**Adjuvant**	**Shingrix®**
Low-Dose	20	–	–
High-Dose	20	–	–
Placebo Control	–	20	–
Positive Control	–	–	20

The subjects in the low-dose LZ901 group, high-dose LZ901 group and placebo control group received an intramuscular injection on day 0 and one month, and the subjects in the Shingrix® positive control group received an intramuscular injection on day 0 and two months. Before each vaccine dose and the third day after vaccination, blood biochemistry, blood routine and urine routine tests were performed on all subjects, and abnormal laboratory indicators were observed. All 80 subjects completed the Phase I clinical trial.

The safety and tolerability primary endpoints were the occurrence of (i) adverse reaction ("**AEs**") within 30 minutes, seven days (including solicited local AEs and systemic AEs) and 30 days (non-solicited AEs) after injection of the vaccination, and incidence of vaccine-related and unrelated AEs of varying severity; (ii) severe adverse events ("**SAEs**") during the trial; and (iii) abnormal laboratory test indicators on the third day after each vaccination. The immunogenicity exploratory endpoints were (i) the content of anti-gE antibody and the GMT of anti-VZV antibody and positive conversion rate; (ii) cellular immune response 30 days after vaccination; and (iii) changes in anti-Fc antibody and anti-nuclear antibody levels 30 days after vaccination. The study to preliminarily explore the immunogenicity of LZ901 is voluntary, and the Phase II clinical trial has been be initiated after completing the safety and tolerability primary endpoints.

Trial status. The Phase I clinical trial was initiated in January 2022. As confirmed by the competent regulatory authority, the Phase I clinical trial was completed. For details, see "— Material Communications with Competent Authorities" in this section.

Safety and tolerability. The results indicate that LZ901 is safe and well tolerated in healthy people aged between 50 to 70 years old. The frequency and severity of AEs observed in the low-dose and high-dose LZ901 groups were much lower compared to the Shingrix® positive control group. The overall number and incidence rate of AEs for the low-dose and high-dose LZ901 groups were much lower than the Shingrix® positive control group. The AEs observed in each group were mainly Grade I AEs, followed by Grade II AEs. The overall number and incidence rate of Grade I and Grade II AEs for the low-dose and high-dose LZ901 groups were much lower than the Shingrix® positive control group. One Grade III AE was observed in the Shingrix® positive control group. None of the subjects in the low-dose LZ901 group and high-dose LZ901 group experienced any Grade III AEs or any SAEs and none of the subjects withdrew from trial, indicating LZ901 is well tolerated. The incidence rate of AEs in the low-dose LZ901 group and high-dose LZ901 group were similar, and lower than the Shingrix® positive control group.

In the low-dose LZ901 group, 26 AEs occurred in 11 of the 20 subjects, with an incidence rate of 55.0%. The incidence rate of Grade I, Grade II and Grade III AEs in the low-dose LZ901 group was 35.0%, 10.0% and 0%, respectively. AEs observed in the low-dose group were pain at the vaccination site, swelling at the vaccination site, itching at the vaccination site, fatigue, headache, stomachache, hemorrhoid, muscle ache, pharyngitis, fungal infection and increased tearing.

In the high-dose LZ901 group, 29 AEs occurred in 11 of the 20 subjects, with an incidence rate of 55.0%. The incidence rate of Grade I, Grade II and Grade III AEs in the high-dose LZ901 group was 50.0%, 5.0% and 0%, respectively. AEs observed in the high-dose group were pain at the vaccination site, swelling at the vaccination site, itching at the vaccination site, spotted erythema at the vaccination site, fatigue, chills, headache, neuralgia, toothache, stomachache, tonsilitis, bronchitis, oropharyngeal discomfort, allergic rhinitis, ligament sprain, itchiness and Meniere's disease.

In the placebo control group, 17 AEs occurred in 10 of the 20 subjects, with an incidence rate of 50.0%. The incidence rate of Grade I, Grade II and Grade III AEs in the placebo group was 25.0%, 5.0% and 0%, respectively. AEs observed in the placebo control group were pain at the vaccination site, discomfort at the vaccination site, fatigue, headache, abnormal sensation, constipation, blood in stool, diarrhea, muscle ache, osteoarthritis and dry eye.

In the Shingrix® positive control group, 107 AEs occurred in 20 of the 20 subjects, with an incidence rate of 100%. The incidence rate of Grade I, Grade II and Grade III AEs in the Shingrix® positive control group was 95.0%, 45.0% and 10%, respectively. AEs observed in the Shingrix® positive control group were pain at the vaccination site, swelling at the vaccination site, itching at the vaccination site, spotted erythema at the vaccination site, vaccination site induration, fever, fatigue, dizziness, muscle ache and urinary tract infection.

Mainly Grade I AEs and Grade II AEs were observed. One Grade III AE (swelling at the vaccination site) was observed in the Shingrix® positive control group. Grade III AEs are severe or medically significant but not immediately life-threatening, hospitalization or prolongation of hospitalization indicated, disabling, and limiting self-care activities of daily living.

The following table sets forth the AEs observed during the clinical trial.

	LZ901 High-Dose Group (N=20 subjects)			LZ901 Low-Dose Group (N=20 subjects)			Placebo Control Group (N=20 subjects)			Shingrix® Positive Control Group (N=20 subjects)		
	Number of AEs	Number of Subjects with AEs	Incidence (%)	Number of AEs	Number of Subjects with AEs	Incidence (%)	Number of AEs	Number of Subjects with AEs	Incidence (%)	Number of AEs	Number of Subjects with AEs	Incidence (%)
Adverse Events (AEs)	29	11	55	26	11	55	17	10	50	107	20	100
AEs associated with investigational vaccine	19	7	35	21	10	50	9	6	30	104	20	100
Grade I AEs	15	7	35	20	10	50	8	5	25	70	19	95
Grade II AEs	4	2	10	1	1	5	1	1	5	33	9	45
Grade III AEs	0	0	0	0	0	0	0	0	0	1	1	5
Solicited AEs	15	6	30	21	10	50	7	4	20	100	20	100
Local AEs	10	5	25	13	9	45	3	2	10	58	20	100
Systemic AEs	5	3	15	8	4	20	4	3	15	42	14	70
Unsolicited AEs	4	2	10	0	0	0	2	2	10	4	3	15
AEs not associated with investigational vaccine	10	7	35	5	3	15	8	6	30	3	2	10
AEs leading to shedding	0	0	0	0	0	0	0	0	0	0	0	0

Immunogenicity. Humoral immune response, cellular immune response, and anti-Fc antibody and anti-nuclear antibody data was obtained to preliminarily explore the immunogenicity of LZ901. LZ901 is able to stimulate the rapid production of higher levels of anti-VZV antibodies compared to Shingrix® 30 days after the first vaccination and there was no significant difference in the levels of anti-VZV antibodies of subjects dosed with LZ901 compared with subjects dosed with Shingrix® 30 days after the full course of vaccination based on humoral response data, and induce higher expression of multiple types of immune cell activating biomarkers compared to Shingrix® based on cellular immune response data, indicating that the immunogenicity of LZ901 is not weaker than Shingrix®.

Humoral immune response in terms of the GMT of anti-VZV antibody and positive conversion rate. 30 days after the first vaccination, the GMT of anti-VZV antibody of the high-dose LZ901 group was higher than the low-dose LZ901 group and the Shingrix® positive control group, but the difference was not statistically significant. 30 days after the first vaccination, the GMT of anti-VZV antibody for the low-dose LZ901, high-dose LZ901, placebo and Shingrix® positive control groups were 97.01 (95% CI: 46.64, 201.74), 207.94 (95% CI: 83.52, 517.67), 27.86 (95% CI: 17.28, 44.92) and 107.63 (95% CI: 45.51, 254.54), respectively, representing a 7.0 fold increase, 14.9 fold increase, 2.1 fold increase and 11.3 fold increase, respectively, compared to the GMT of anti-VZV antibody prior to the first vaccination. The positive conversion rate of anti-VZV antibody in the low-dose LZ901, high-dose LZ901, placebo and Shingrix® positive control groups 30 days after the first vaccination were 80.0%, 85.0%, 30.0% and 75.0%, respectively.

30 days after the full course of vaccination, the GMT of anti-VZV antibody of the high-dose LZ901 group was higher than the low-dose LZ901 group and the difference was statistically significant ($p < 0.05$), and similar to the Shingrix® positive control group and the difference was not statistically significant ($p=0.59$). There was no significant difference between the GMT of anti-VZV antibody of the high-dose LZ901 group and the Shingrix® positive control group (assuming the probability of occurrence of a class 1 error of $\alpha=0.05$ referring to the probability of an error in this conclusion being less than 5% and the statistical probability that the two results would be consistent was not less than 95% and the degree of certainty of $\beta=0.8$), indicating that the GMT values are consistent statistically and the immunogenicity of LZ901 is not weaker than that of Shingrix®. 30 days after the full course of vaccination, the GMT of anti-VZV antibody for the low-dose LZ901, high-dose LZ901, placebo and Shingrix® positive control groups were 194.01 (95% CI: 85.05, 442.59), 512.00 (95% CI: 290.48, 902.45), 36.76 (95% CI: 19.11, 70.69) and 652.58 (95% CI: 309.40, 1,376.36), respectively, representing a 13.9 fold increase, 36.8 fold increase, 2.7 fold increase and 68.6 fold increase, respectively, compared to the GMT of anti-VZV antibody prior to the first vaccination. The positive conversion rate of anti-VZV antibody in the low-dose LZ901, high-dose LZ901, placebo and Shingrix® positive control groups 30 days after the full course of vaccination were 90.0%, 100.0%, 55.0% and 95.0%, respectively.

Humoral immune response in terms of content of anti-gE antibody and positive conversion rate. Anti-gE antibodies are antibodies that are able to bind to recombinant gE protein, which include both functional and non-functional antibodies. Functional antibodies are neutralizing antibodies, while non-functional antibodies are non-neutralizing antibodies that have no virus killing effect. Therefore, the GMC values of anti-gE antibody do not determine the exact proportion of neutralizing antibodies compared to non-neutralizing antibodies, and cannot directly demonstrate immunogenicity. The geometric mean concentration ("**GMC**") of anti-gE antibody increased significantly in subjects in the low-dose LZ901, high-dose LZ901 and Shingrix® positive control groups 30 days after the first vaccination. 30 days after the first vaccination, the GMC of anti-gE antibody for the low-dose LZ901, high-dose LZ901, placebo and Shingrix® positive control groups were 14.81 IU/ml (95% CI: 7.91, 27.74), 18.95 IU/ml (95% CI: 10.83, 33.14), 1.26 IU/ml (95% CI: 0.81, 1.96) and 11.46 IU/ml (95% CI: 7.02, 18.69), respectively, representing a 20.3 fold increase, 13.5 fold increase, 1.1 fold increase and 19.1 fold increase, respectively, compared to the GMC of anti-gE antibody prior to the first vaccination. The positive conversion rate of anti-gE antibody in the low-dose LZ901, high-dose LZ901, placebo and Shingrix® positive control groups were 100.0%, 95.0%, 0.0% and 100.0%, respectively.

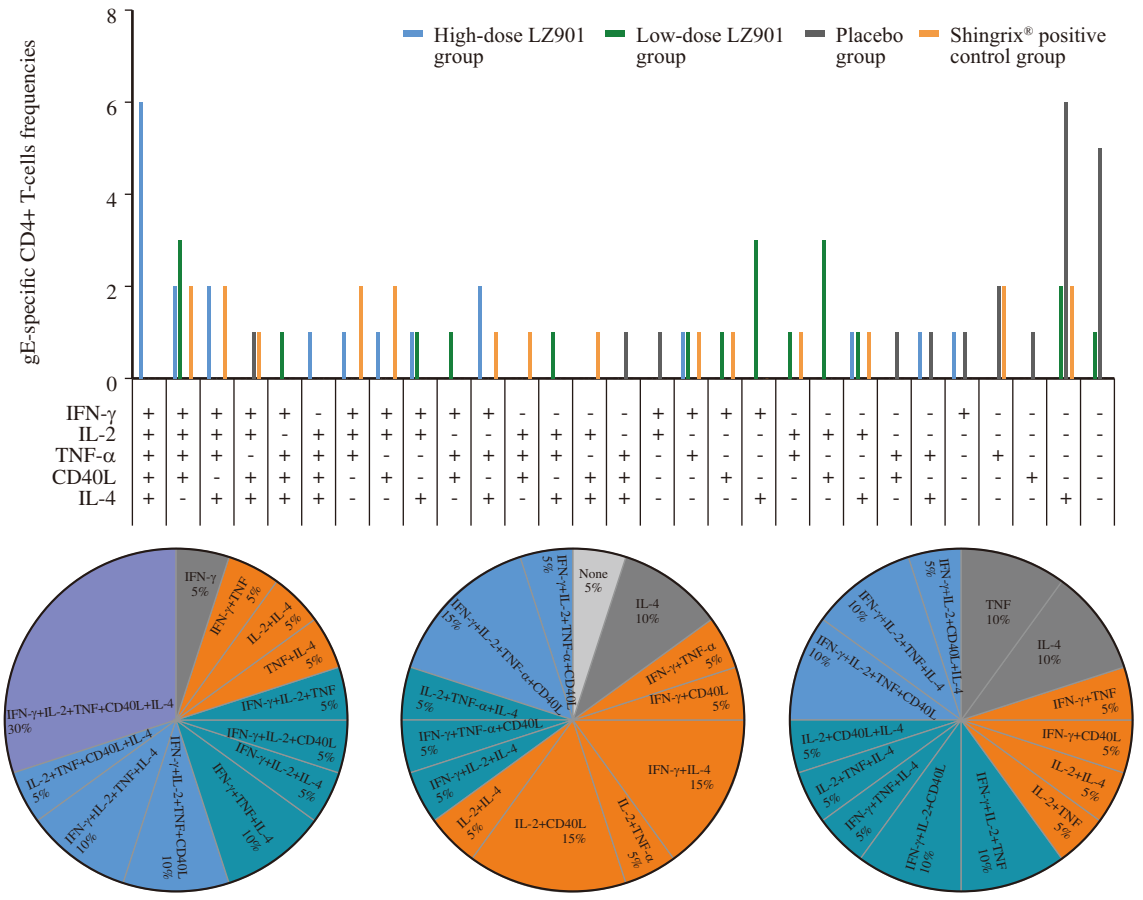
30 days after the full course of vaccination, the GMC of anti-gE antibody of the high-dose LZ901 group was slightly lower than the low-dose LZ901 group and the difference was not statistically significant (p=0.8637), and the GMC of anti-gE antibody of the high-dose LZ901 group and the low-dose LZ901 group were both lower than the Shingrix® positive control group and the differences were statistically significant (both p-values were less than 0.0001). The GMC of anti-gE antibody increased significantly in subjects in the low-dose LZ901, high-dose LZ901 and Shingrix® positive control groups 30 days after the full course of vaccination. 30 days after the full course of vaccination, the GMC of anti-gE antibody for the low-dose LZ901, high-dose LZ901, placebo and Shingrix® positive control groups were 24.84 IU/ml (95% CI: 17.39, 35.49), 23.73 IU/ml (95% CI: 15.52, 36.29), 1.22 IU/ml (95% CI: 0.85, 1.75) and 71.86 IU/ml (95% CI: 54.28, 95.13), respectively, representing a 34.0 fold increase, 16.9 fold increase, 1.1 fold increase and 119.0 fold increase, respectively, compared to the GMC of anti-gE antibody prior to the first vaccination. The positive conversion rate of anti-gE antibody in the low-dose LZ901, high-dose LZ901, placebo and Shingrix® positive control groups were 100.0%, 100.0%, 0.0% and 100.0%, respectively.

With respect to the GMC of anti-gE antibody, antibodies that are able to bind to recombinant gE protein are measured, which include both functional and non-functional antibodies (neutralizing antibodies and non-neutralizing antibodies that have no virus killing effect). Therefore, the GMC values do not determine the exact proportion of neutralizing antibodies compared to non-neutralizing antibodies, and cannot directly demonstrate immunogenicity. Since anti-VZV antibody is the neutralizing antibody, the FAMA test that detects anti-VZV antibody is the gold standard and approved by the CDE. Therefore, as discussed above, as the GMT of anti-VZV antibody of the high-dose LZ901 group (GMT of 512.00) and Shingrix® positive control group (GMT of 652.58) 30 days after the full course vaccination have been demonstrated to be consistent statistically, it is indicated that the immunogenicity of LZ901 is not weaker than that of Shingrix®.

Cellular immune response in terms of activation of helper (CD4+) T cell expression of gE-specific biomarkers (IFN-γ, TNF-α, IL-2, IL-4 and CD40L). For the low-dose LZ901 group, the number of subjects with helper (CD4+) T cells expressing at least two, at least three, at least four and five gE-specific activation biomarkers 30 days after the full course of vaccination was 17, seven, four and nil subjects, respectively, representing 85%, 35%, 20% and 0% of the subjects in the low-dose LZ901 group, respectively. For the high-dose LZ901 group, the number of subjects with helper (CD4+) T cells expressing at least two, at least three, at least four and five gE-specific activation biomarkers 30 days after the full course of vaccination was 19, 16, 11 and six subjects, respectively, representing 95%, 80%, 55% and 30% of the subjects in the high-dose LZ901 group, respectively. For the placebo group, the number of subjects with helper (CD4+) T cells expressing at least two, at least three, at least four and five gE-specific activation biomarkers 30 days after the full course of vaccination was five, two, one and nil subjects, respectively, representing 25%, 10%, 5% and 0% of the subjects in the placebo group, respectively. For the Shingrix® positive control group, the number of subjects with helper (CD4+) T cells expressing at least two, at least three, at least four and five gE-specific activation biomarkers 30 days after the full course of vaccination was 16, 12, five and nil subjects, respectively, representing 80%, 60%, 25% and 0% of the subjects in the Shingrix® positive control group, respectively.

The chi-square test for trend demonstrated that the ability of the high-dose LZ901 group to activate helper (CD4+) T cells to express gE-specific activation biomarkers 30 days after the full course of vaccination was significantly higher than that of the low-dose LZ901 group ($p_{\text{high-dose LZ901 group vs. low-dose LZ901 group}} = 0.0026$) and the Shingrix® positive control group ($p_{\text{high-dose LZ901 group vs. Shingrix® positive control group}} = 0.0158$). Compared to the Shingrix® positive control group, the low-dose LZ901 group had a similar ability to activate helper (CD4+) T cells to express gE-specific activation biomarkers 30 days after the full course of vaccination. There was no significant difference between the high-dose LZ901 group, low-dose LZ901 group and Shingrix® positive control group to activate helper (CD4+) T cells to express two or more gE-specific activation biomarkers 30 days after the full course of vaccination ($p_{\text{high-dose LZ901 group vs. low-dose LZ901 group}} = 0.6050$; $p_{\text{high-dose LZ901 group vs. Shingrix® positive control group}} = 0.3416$; $p_{\text{low-dose LZ901 group vs. Shingrix® positive control group}} = 1.000$).

LZ901 and Shingrix® Activation of Helper (CD4+) T Cell Expression of Multiple VZV gE-Specific Biomarkers 30 Days After the Full Course of Vaccination



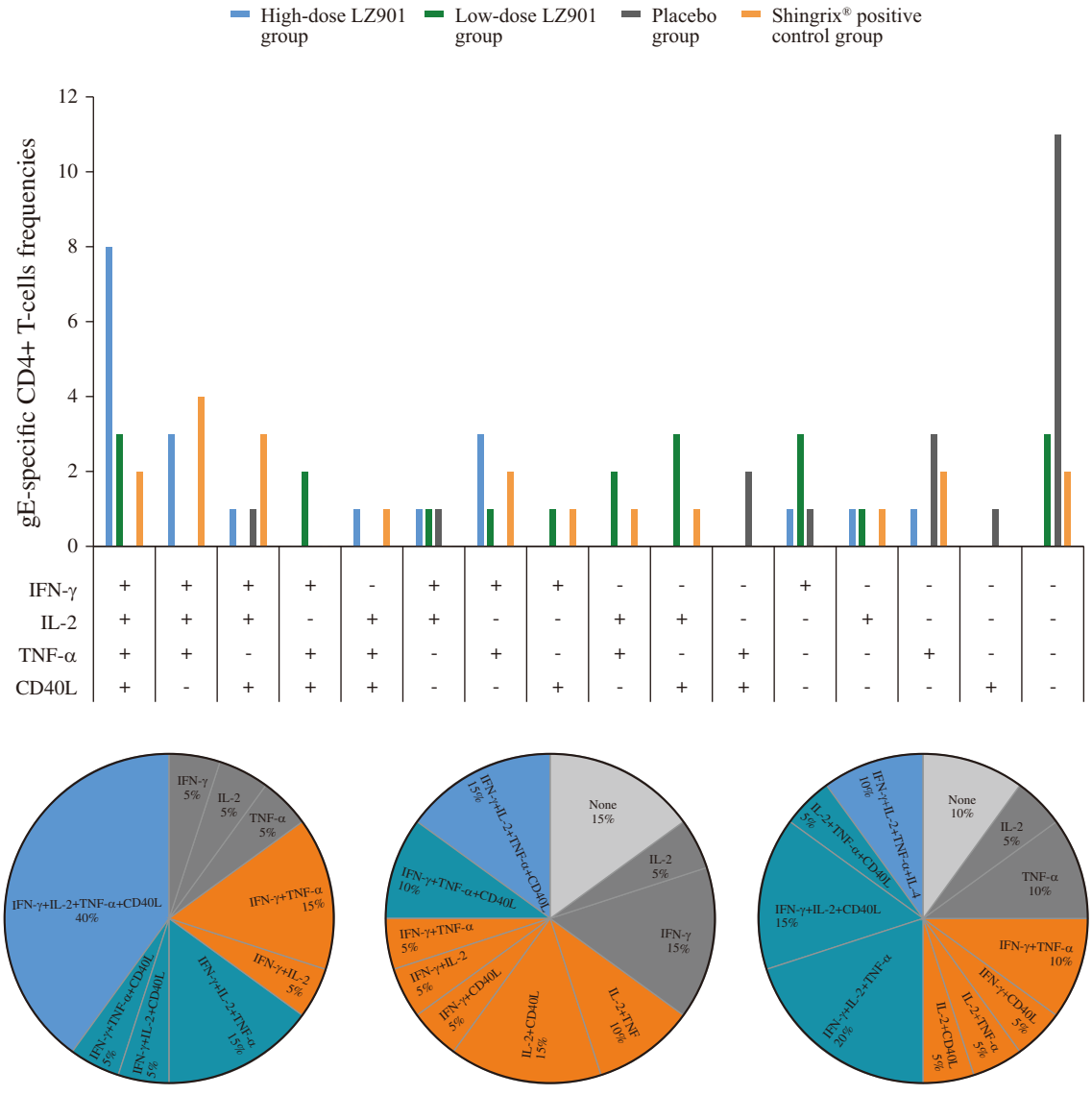
High-dose LZ901 group Low-dose LZ901 group Shingrix® positive control group

Source: Company Data

Cellular immune response in terms of activation of helper (CD4+) T cell expression of gE-specific biomarkers (IFN-γ, TNF-α, IL-2 and CD40L). For the low-dose LZ901 group, the number of subjects with helper (CD4+) T cells expressing at least two, at least three and four gE-specific activation biomarkers 30 days after the full course of vaccination was 13, five and three subjects, respectively, representing 65%, 25% and 15% of the subjects in the low-dose LZ901 group, respectively. For the high-dose LZ901 group, the number of subjects with helper (CD4+) T cells expressing at least two, at least three and four gE-specific activation biomarkers 30 days after the full course of vaccination was 17, 13 and eight subjects, respectively, representing 85%, 65% and 40% of the subjects in the high-dose LZ901 group, respectively. For the placebo group, the number of subjects with helper (CD4+) T cells expressing at least two, at least three and four gE-specific activation biomarkers 30 days after the full course of vaccination was four, one and nil subjects, respectively, representing 20%, 5% and 0% of the subjects in the placebo group, respectively. For the Shingrix® positive control group, the number of subjects with helper (CD4+) T cells expressing at least two, at least three and four gE-specific activation biomarkers 30 days after the full course of vaccination was 15, 10 and two subjects, respectively, representing 75%, 50% and 10% of the subjects in the Shingrix® positive control group, respectively.

The chi-square test for trend demonstrated the ability of the high-dose LZ901 group to activate helper (CD4+) T cells to express four gE-specific activation biomarkers 30 days after the full course of vaccination was significantly higher than that of the low-dose LZ901 group ($p_{\text{high-dose LZ901 group vs. low-dose LZ901 group}} = 0.0133$) and the Shingrix® positive control group ($p_{\text{high-dose LZ901 group vs. Shingrix® positive control group}} = 0.0800$). Compared to the Shingrix® positive control group, the low-dose LZ901 group and the high-dose LZ901 group had a similar ability to activate helper (CD4+) T cells to express gE-specific activation biomarkers 30 days after the full course of vaccination ($p_{\text{low-dose LZ901 group vs. Shingrix® positive control group}} = 0.3589$; $p_{\text{high-dose LZ901 group vs. Shingrix® positive control group}} = 0.0800$). There was no significant difference between the high-dose LZ901 group, low-dose LZ901 group and Shingrix® positive control group to activate helper (CD4+) T cells to express two or more gE-specific activation biomarkers 30 days after the full course of vaccination ($p_{\text{high-dose LZ901 group vs. low-dose LZ901 group}} = 0.1441$; $p_{\text{high-dose LZ901 group vs. Shingrix® positive control group}} = 0.6948$; $p_{\text{low-dose LZ901 group vs. Shingrix® positive control group}} = 0.4902$).

LZ901 and Shingrix® Activation of Helper (CD4+) T Cell Expression of Multiple VZV gE-Specific Biomarkers 30 Days After the Full Course of Vaccination



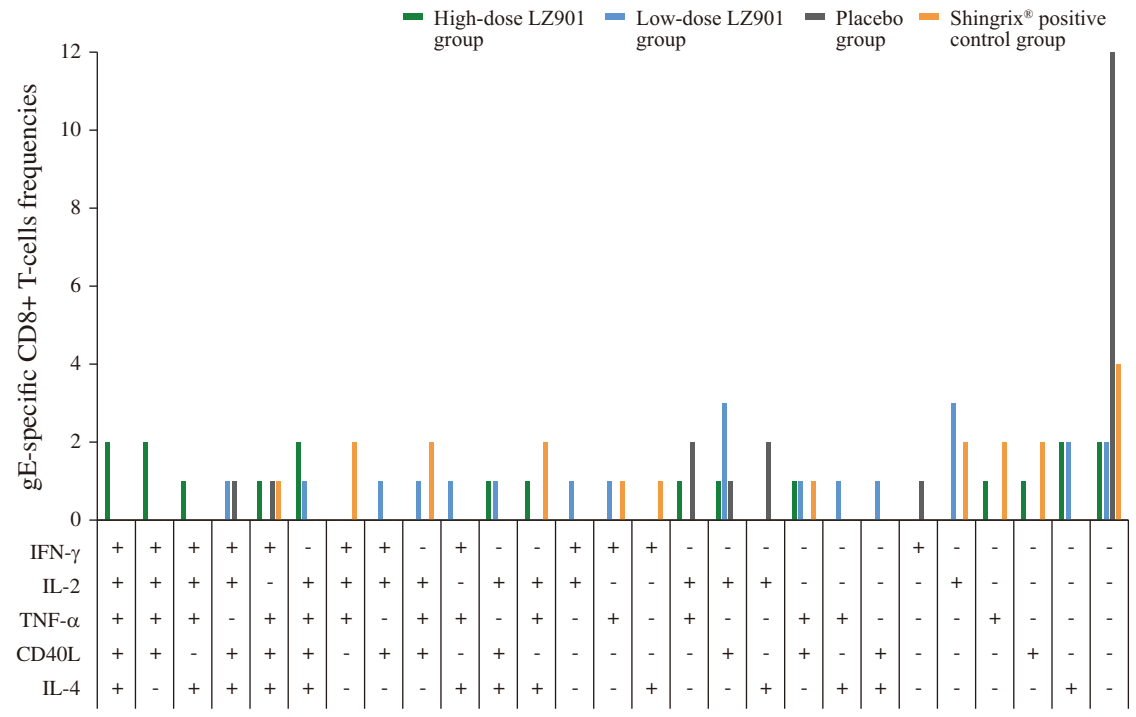
High-dose LZ901 group | Low-dose LZ901 group | Shingrix® positive control group

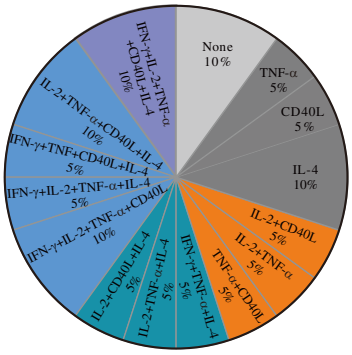
Source: Company Data

Cellular immune response in terms of activation of cytotoxic (CD8+) T cell expression of gE-specific biomarkers (IFN-γ, TNF-α, IL-2, IL-4 and CD40L). For the low-dose LZ901 group, the number of subjects with cytotoxic (CD8+) T cells expressing at least two, at least three, at least four and five gE-specific activation biomarkers 30 days after the full course of vaccination was 13, five, two and nil subjects, respectively, representing 65%, 25%, 10% and 0%, respectively. For the high-dose LZ901 group, the number of subjects with cytotoxic (CD8+) T cells expressing at least two, at least three, at least four and five gE-specific activation biomarkers 30 days after the full course of vaccination was 14, 11, eight and two subjects, respectively, representing 70%, 55%, 40% and 10% of the subjects in the high-dose LZ901 group, respectively. For the placebo group, the number of subjects with cytotoxic (CD8+) T cells expressing at least two, at least three, at least four and five gE-specific activation biomarkers 30 days after the full course of vaccination was seven, two, two and nil subjects, respectively, representing 35%, 10%, 10% and 0% of the subjects in the placebo group, respectively. For the Shingrix® positive control group, the number of subjects with cytotoxic (CD8+) T cells expressing at least two, at least three, at least four and five gE-specific activation biomarkers 30 days after the full course of vaccination was 10, seven, one and nil subjects, respectively, representing 50%, 35%, 5% and 0% of the subjects in the Shingrix® positive control group, respectively.

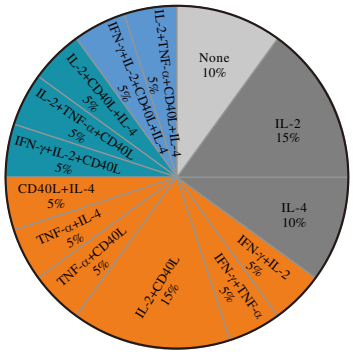
The chi-square test for trend demonstrated the ability of the high-dose LZ901 group to activate cytotoxic (CD8+) T cells to express gE-specific activation biomarkers was significantly higher than that of the Shingrix® positive control group ($p_{\text{high-dose LZ901 group vs. Shingrix® positive control group}} = 0.0452$), and the ability of the low-dose LZ901 group to activate cytotoxic (CD8+) T cells to express gE-specific activation biomarkers was not significantly different from the high-dose LZ901 group ($p_{\text{high-dose LZ901 group vs. low-dose LZ901 group}} = 0.0935$) and the Shingrix® positive control group ($p_{\text{low-dose LZ901 group vs. Shingrix® positive control group}} = 0.5923$). There was no significant difference between the high-dose LZ901 group, low-dose LZ901 group and Shingrix® positive control group to activate cytotoxic (CD8+) T cells to express two or more gE-specific activation biomarkers 30 days after the full course of vaccination ($p_{\text{high-dose LZ901 group vs. low-dose LZ901 group}} = 0.7537$; $p_{\text{high-dose LZ901 group vs. Shingrix® positive control group}} = 0.1967$; $p_{\text{low-dose LZ901 group vs. Shingrix® positive control group}} = 0.3373$).

LZ901 and Shingrix® Activation of Cytotoxic (CD8+) T Cell Expression of Multiple VZV gE-Specific Biomarkers 30 Days After the Full Course of Vaccination

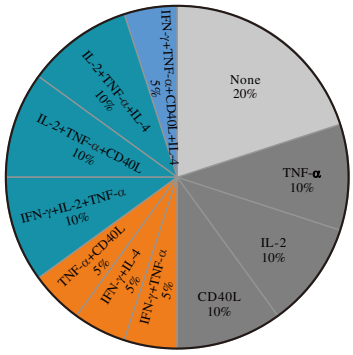




High-dose LZ901 group



Low-dose LZ901 group



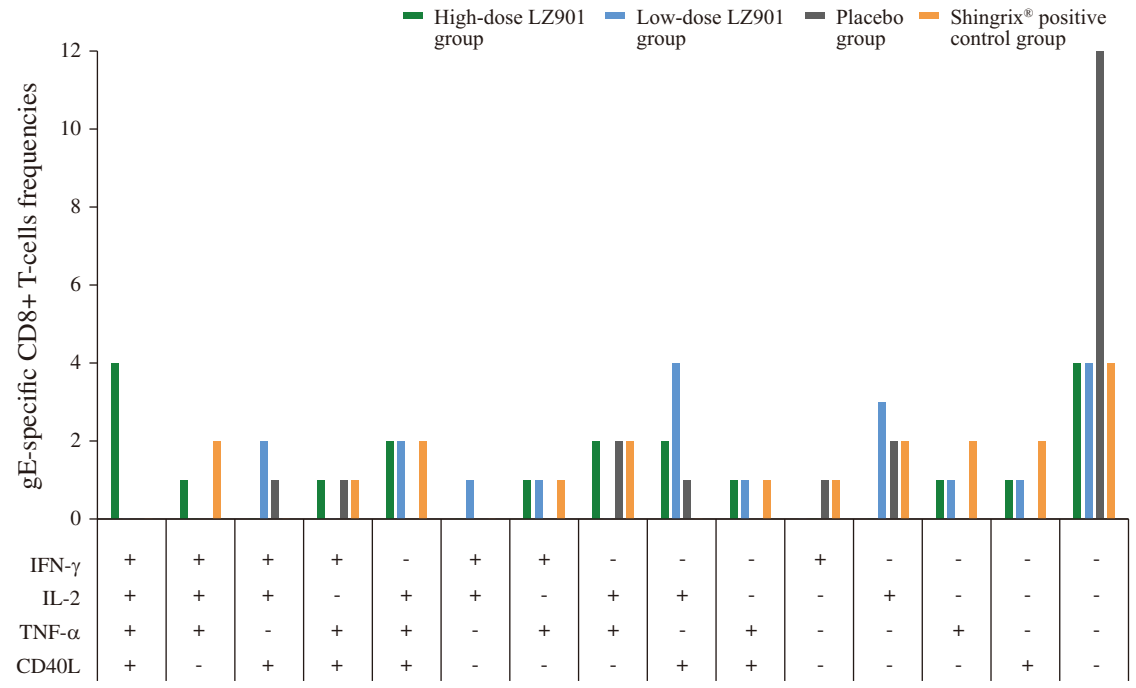
Shingrix® positive control group

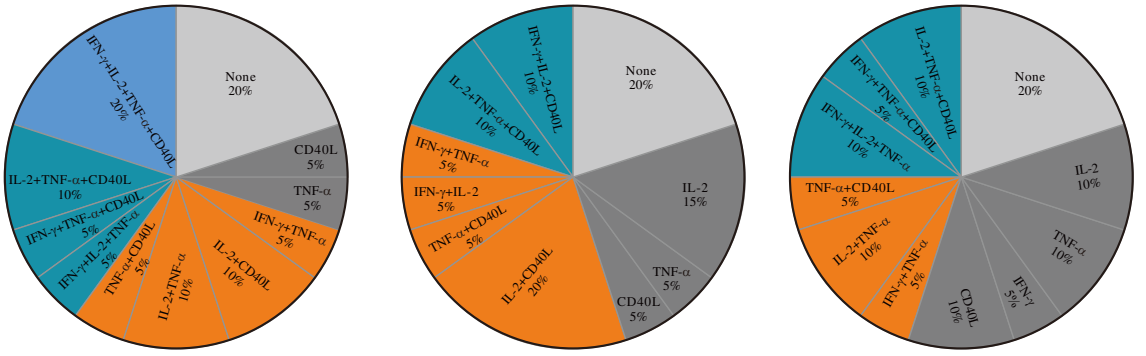
Source: Company Data

Cellular immune response in terms of activation of cytotoxic (CD8+) T cell expression of gE-specific biomarkers (IFN-γ, TNF-α, IL-2 and CD40L). For the low-dose LZ901 group, the number of subjects with cytotoxic (CD8+) T cells expressing at least two, at least three and four gE-specific activation biomarkers 30 days after the full course of vaccination was 11, four and nil subjects, respectively, representing 55%, 20% and 0%, respectively. For the high-dose LZ901 group, the number of subjects with cytotoxic (CD8+) T cells expressing at least two, at least three and four gE-specific activation biomarkers 30 days after the full course of vaccination was 14, eight and four subjects, respectively, representing 70%, 40% and 20% of the subjects in the high-dose LZ901 group, respectively. For the placebo group, the number of subjects with cytotoxic (CD8+) T cells expressing at least two, at least three and four gE-specific activation biomarkers 30 days after the full course of vaccination was five, two and nil subjects, respectively, representing 25%, 10% and 0% of the subjects in the placebo group, respectively. For the Shingrix® positive control group, the number of subjects with cytotoxic (CD8+) T cells expressing at least two, at least three and four gE-specific activation biomarkers 30 days after the full course of vaccination was nine, five and nil subjects, respectively, representing 45%, 25% and 0% of the subjects in the Shingrix® positive control group, respectively.

The chi-square test for trend demonstrated there was no significant difference between the ability of the high-dose LZ901 group, low-dose LZ901 group and Shingrix® positive control group to express four gE-specific activation biomarkers ($p_{\text{high-dose LZ901 group vs. low-dose LZ901 group}} = 0.1670$; $p_{\text{high-dose LZ901 group vs. Shingrix® positive control group}} = 0.1398$; $p_{\text{low-dose LZ901 group vs. Shingrix® positive control group}} = 0.8816$). There was no significant difference between the high-dose LZ901 group, low-dose LZ901 group and Shingrix® positive control group to activate cytotoxic (CD8+) T cells to express two or more gE-specific activation biomarkers 30 days after the full course of vaccination ($p_{\text{high-dose LZ901 group vs. low-dose LZ901 group}} = 0.3272$; $p_{\text{high-dose LZ901 group vs. Shingrix® positive control group}} = 0.1098$; $p_{\text{low-dose LZ901 group vs. Shingrix® positive control group}} = 0.5271$).

LZ901 and Shingrix® Activation of Cytotoxic (CD8+) T Cell Expression of Multiple VZV gE-Specific Biomarkers 30 Days After the Full Course of Vaccination





High-dose LZ901 group | Low-dose LZ901 group | Shingrix® positive control group

Source: Company Data

IL-4 is a gE-specific biomarker that induces an immune response by Th2 cells, while IFN-γ, TNF-α, IL-2 and CD40L are gE-specific biomarkers that induce an immune response by Th1 cells. Th2 cells are helper (CD4+) T cells that transmit immune signals to B cells, stimulating B cells to differentiate into plasma cells to create antibodies to produce humoral immunity. Th1 cells are helper (CD4+) T cells that transmit processed immune signals to other effector cells, including cytotoxic (CD8+) T cells, activating effector cells to kill invading microorganisms. The immune response in terms of T cell expression of gE-specific biomarkers with IL-4 assesses Th1 and Th2 cell immune responses and without IL-4 assesses only Th1 cell immune responses. With the detection of more gE-specific biomarkers, the process of immune responses can be understood more objectively.

Anti-Fc antibody and anti-nuclear antibody levels. The anti-Fc antibody and anti-nuclear antibody levels of subjects in the low-dose LZ901, high-dose LZ901, placebo and Shingrix® positive control groups remained relatively unchanged 30 days after vaccination.

Ongoing Phase II Clinical Trial

Trial design and status. We commenced a randomized, double-blinded and placebo-controlled Phase II clinical trial for LZ901 in Hubei province in April 2022. The primary objectives of this clinical trial are to evaluate the immunogenicity and safety of different doses of LZ901 in healthy people aged between 50 to 70 years old. The secondary objective of this clinical trial is to evaluate the immune persistence of different doses of LZ901 in healthy people aged between 50 to 70 years old. According to requirements of the approval notice of the NMPA for drug clinical trials of prophylactic biological products, only early studies with a positive control are required for prophylactic biological products. As LZ901 is classified as a prophylactic biological product, the active-controlled Phase I clinical trial for LZ901 satisfies this requirement and there is no further requirement to conduct a similar head-to-head study with Shingrix® for the Phase II clinical trial for LZ901, which we believe will not affect the future commercialization of LZ901.

A total of 450 subjects aged between 50 to 70 years old were enrolled in the Phase II clinical trial for LZ901. The subjects were divided into three groups, including (i) low-dose group with 150 subjects receiving 50μg/0.5mL/vial of LZ901, (ii) high-dose group with 150 subjects receiving 100μg/0.5mL/vial of LZ901 and (iii) placebo group with 150 subjects receiving a 0.5mL/vial placebo. Details of the trial groups are set out in the following table:

Group	Sample Size	Vaccination Program
Low-Dose	150 subjects	Day 0 and one month inoculate one dose in the deltoid muscle of the upper arm (injection in the deltoid muscle of the upper arm on the left and right sides in turn)
High-Dose	150 subjects	
Placebo	150 subjects	

The subjects in the low-dose LZ901 group, high-dose LZ901 group and placebo group received an intramuscular injection on day 0 and one month. During the treatment period, immunogenicity, safety and immune persistence will be evaluated. In order to evaluate the immunogenicity of LZ901, we conducted follow-up evaluations at 30 days following the administration of the second dose by collecting blood samples of subjects to test for the serum concentration of anti-gE antibody by ELISA and anti-VZV antibody titer by fluorescent antibody to membrane antigen ("**FAMA**"). In order to evaluate the safety of LZ901, we will conduct follow-up evaluations at six months following the administration of the second dose by recording the occurrence of AEs in subjects. In addition, we will conduct follow-up evaluations at six months, 12 months, 24 months and 36 months following the administration of the second dose to evaluate the long-term immune persistence of LZ901 by collecting blood samples of subjects to test for the serum concentration of anti-gE antibody by ELISA and anti-VZV antibody titer by FAMA.

The immunogenicity primary endpoints were (i) the GMC of anti-gE antibody and the GMT of anti-VZV antibody at 30 days following the administration of the second dose; and (ii) positive conversion rate of anti-gE antibody and anti-VZV antibody at 30 days following the administration of the second dose. The safety primary endpoints were the occurrence of (i) AEs within 30 minutes, seven days (including solicited AEs) and 30 days (non-solicited AEs) after administration of each

dose, and incidence of vaccine-related and unrelated AEs of varying severity; and (ii) SAEs after injection of the first dose to six months after administration of the second dose. The immune persistence secondary endpoint was the GMC and positive conversion rate of anti-gE antibody, and GMT and positive conversion rate of anti-VZV antibody at six months, 12 months, 24 months and 36 months following the administration of the second dose.

As of the Latest Practicable Date, we had (i) completed subject enrollment of all 450 trial subjects from April 2022 to May 2022, (ii) administered the first and second doses from May 2022 to July 2022, (iii) collected blood samples before the first dose, at 30 days following the administration of the first dose and 30 days following the administration of the second dose, and the number of samples has satisfied the criteria required for a valid study, and (iv) delivered such samples to the NIFDC for serum testing to evaluate the immunogenicity of LZ901 in August 2022, pending immunogenicity, safety or immune persistence data. In addition, we had completed six-month follow-ups with trial subjects following the administration of the second dose and collected blood samples from such trial subjects to evaluate the long-term immune persistence of LZ901. As of the Latest Practicable Date, the completion rate for the six-month follow-ups and blood sample collections reached 96.1%, which has already satisfied the criteria required for a valid study under the Phase II clinical trial study protocol for LZ901. We expect to complete the Phase II clinical trial in the second quarter of 2023. The incompletion of follow-up evaluations at six months to 36 months following the administration of the second dose to evaluate the long-term immune persistence of LZ901 will not affect the further clinical development of LZ901, including the commencement of the Phase III clinical, primarily because (i) according to the clinical trial protocol of the Phase II clinical trial for LZ901, such follow-up evaluations are secondary (exploratory) endpoints to evaluate the long-term immune persistence of LZ901, while the primary immunogenicity endpoint only requires a 30-day follow-up and safety endpoint only requires a six-month follow-up as stated above, which the on-site work had been completed and only sample testing was pending as of the Latest Practicable Date; and (ii) based on the umbrella CTA approval we obtained for LZ901, we do not need to apply for additional CTAs before commencing the Phase III clinical trial, and according to Frost & Sullivan, the CDE generally would not have any objection for a vaccine developer that had obtained the umbrella CTA approval to proceed with the next-stage clinical trial. The BLA approval and future commercialization of LZ901 is subject to various factors such as the demonstration of LZ901's safety and immunogenicity by clinical trial results and NMPA's confirmation that the relevant requirements on production (including determination of quality standards, completion of the validation of commercial-scale production processes, etc.) are completely satisfied. Some of such factors are beyond our control. Although we believe that the incompletion of the 36 months follow-ups would not materially affect the clinical development, BLA approval and future commercialization of LZ901, we could not assure your that there is no associated risk, given that the clinical development of LZ901, like any other drugs, is inherently unpredictable. Potential adverse events may occur and the clinical results may not be what we expect, which could halt our planned clinical plans and our commercialization efforts. For details, please see "Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to the Research and Development of Our Product Candidates" in the document.

Phase III Clinical Trial Design

The Phase III clinical trial protocol for LZ901 has not been finalized, however, we will hold a meeting with the CDE to communicate the results of the Phase II clinical trial for LZ901 and to determine whether any adjustments are required to finalize the Phase III clinical trial protocol

prior to initiating the Phase III clinical trial for LZ901. We plan to initiate a multi-center, randomized, double-blind, placebo-controlled Phase III clinical trial comparing LZ901 against Shingrix® for LZ901 in China in the second quarter of 2023.

The Phase III clinical trial for LZ901 will be divided into two studies, comprising the protective efficacy study, which we plan to enroll approximately 30,000 healthy subjects aged 40 years old and above and will divide the subjects in a 1:1 ratio into a LZ901 group and placebo group, to compare the protective efficacy, immunogenicity and immune persistence of LZ901 against placebo and the comparative study, which we plan to enroll approximately 300 healthy subjects aged 50 to 70 years old and will divide the subjects in a 1:1 ratio into a LZ901 group and Shingrix® group, to compare the immunogenicity of LZ901 against Shingrix®.

The primary objective of this clinical trial is to evaluate the protective efficacy of LZ901 compared to placebo in preventing herpes zoster in subjects aged 40 years old and above. The secondary objectives of this clinical trial are to evaluate (i) the immunogenicity and immune persistence of LZ901 compared to placebo in subjects aged 40 years old and above.

For the protective efficacy study, after the administration of all doses of LZ901 and the placebo have been completed and the number of herpes zoster cases required by the clinical trial protocol are accumulated, we plan to conduct a protective efficacy analysis and along with follow-up evaluations at 90 days after the cut-off date of the cases of herpes zoster are accumulated.

In order to evaluate the immunogenicity of LZ901, we plan to conduct follow-up evaluations at 30 days following the administration the final dose by collecting blood samples of subjects to test for the serum concentration of anti-gE antibody by ELISA.

In order to evaluate the long-term immune persistence of LZ901, we plan to conduct follow-up evaluations at 12 months, 24 months and 36 months following the administration of the final dose by collecting blood samples of subjects to test for the serum concentration of anti-gE antibody by ELISA.

For the comparative study against Shingrix®, we plan to collect cellular immune response, humoral response, and safety data to compare the immunogenicity and safety of LZ901 against Shingrix®.

After unblinding of the protective efficacy, immunogenicity and safety data, we plan to file the BLA to the NMPA in the third quarter of 2024, while continuing to observe and collect immune persistence data. All clinical trial data, excluding the immune persistence secondary endpoint data, will be used to file the BLA.

Ongoing Phase I Clinical Trial in the U.S.

Trail design and status. We commenced a randomized, double-blinded and placebo-controlled Phase I clinical trial for LZ901 in New Jersey, U.S. in February 2023. The primary objectives of this clinical trial are to evaluate the safety and tolerability of different doses of LZ901 in subjects aged between 50 to 70 years old. The exploratory objectives of this clinical trial are to preliminarily explore the immunogenicity of LZ901 in subjects aged between 50 to 70 years old and explore the safety of LZ901 by assessing the change of anti-Fc antibody in subjects aged 50 to 70 years old.

A total of approximately 66 subjects aged between 50 to 70 years old are expected to be enrolled in the Phase I clinical trial for LZ901 in the U.S. The subjects will be divided into five groups, including (i) low-dose sentinel group with three subjects receiving 50μg/0.5mL/vial of LZ901, (ii) high-dose sentinel group with three subjects receiving 100μg/0.5mL/vial of LZ901, (iii) low-dose main group with 20 subjects receiving 50μg/0.5mL/vial of LZ901, (iv) high-dose main group with 20 subjects receiving 100μg/0.5mL/vial of LZ901 and (v) placebo group with 20 subjects receiving a 0.5mL/vial placebo. Details of the trial groups are set out in the following table:

	LZ901		
Group	**50μg/0.5mL**	**100μg/0.5mL**	**Adjuvant**
Low-Dose Sentinel Group	3 subjects	–	–
High-Dose Sentinel Group	–	3 subjects	–
Low-Dose Main Group	20 subjects	–	–
High-Dose Main Group	–	20 subjects	–
Placebo Group			20 subjects (10 subjects enrolled with each low-dose main LZ901 group and high-dose main LZ901 group)

The subjects in the low-dose sentinel group, high-dose sentinel group, low-dose main group, high-dose main group and placebo group will receive an intramuscular injection on day 0 and day 30. During the treatment period, safety, tolerability and immunogenicity will be evaluated. In order to evaluate the early safety signals of LZ901, two sentinel groups will be sequentially enrolled from low-dose (low-dose sentinel group) to high dose-dose (high-dose sentinel group) in open-label, prior to initiation of dosing in each dose level main group (low-dose main group and high-dose main group). Three subjects will be first enrolled in the low-dose sentinel group and administered two doses of LZ901 on Day 0 and Day 30, respectively. After reviewing the safety through seven days after the first dose of LZ901, if no safety signals occur, another three subjects will be enrolled into the high-dose sentinel group. Then if also no safety signals occur through seven days after the first dose of LZ901 in the high-dose sentinel group, 30 subjects will be randomized in a 2:1 ratio to receive two doses of LZ901 in the low-dose main group or placebo in the placebo group in a double-blind fashion. Subjects will be enrolled in the high-dose main group and placebo group also after the safety review through seven days after the first dose of LZ901 in the low-dose main group or placebo in the placebo group.

The safety and tolerability primary endpoints are (i) the incidence and severity of vaccine-related and unrelated AEs, including AEs occurred within 30 minutes after each study intervention, solicited local and systemic AEs from Day 0 through Day 6, unsolicited AEs from Day 0 through Day 29 after each study intervention, (ii) the incidence of AEs leading to withdrawal, (iii) the incidence of all SAEs and medically attended adverse events ("**MAAEs**") from Day 0 through 6 months after the full course vaccination, and (iv) the incidence of abnormal laboratory tests results on Day 3 (+ 1 day) after each study intervention. The exploratory endpoint to preliminarily explore the immunogenicity of LZ901 are (i) the seropositivity rate (percentage of seropositive subjects) of anti-gE antibody and anti-VZV antibody on Day 30 after each study

intervention, (ii) GMC of anti-gE antibody and GMT of anti-VZV antibody on Day 30 after each study intervention, and (iii) the seroconversion rate (percentage of seroconversion subjects) of anti-gE antibody and anti-VZV antibody on Day 30 after each study intervention. The exploratory endpoint to explore the safety of LZ901 by assessing the change of anti-Fc antibody is the change of anti-Fc antibody on Day 30 after each study intervention compared with pre-immunization.

As of the Latest Practicable Date, we had initiated subject enrollment and plan to complete subject enrollment in the second quarter of 2023. We plan to complete the Phase I clinical trial for LZ901 in the U.S. in the first quarter of 2024.

Licenses, Rights and Obligations

We have the global rights to develop and commercialize LZ901.

Material Communications with Competent Authorities

We received an umbrella CTA approval for LZ901 from the NMPA in August 2021 and completed a Phase I clinical trial in China. Based on the umbrella CTA approval we obtained for LZ901 and the existing PRC laws and regulations, the umbrella CTA approval for LZ901 shall also apply to the Phase II and Phase III clinical trials and we do not need to apply for additional CTAs. For details of the PRC laws and regulations for umbrella approval, please see "Regulatory Overview — Regulatory Provisions — Laws and Regulations Related to Drugs — Clinical Trials Approval" in this document. Based on the interview with the CDE of the NMPA in June 2022, it confirmed that our Phase I clinical trial in China was completed and it has no objection for us to proceed to Phase II clinical trial in China. Our PRC Legal Adviser is of the view that the CDE is the competent authority to give the above confirmations.

We are currently conducting a Phase II clinical trial and expect to complete the Phase II clinical trial in the second quarter of 2023 in China as all on-site work and follow-up sampling for the Phase II clinical trial was completed in January 2023. We expect to complete serum testing, statistical analysis of data, and generation of the clinical trial report in the second quarter of 2023. The Phase III clinical trial protocol has not been finalized, however, we will hold a meeting with the CDE to communicate the results of the Phase II clinical trial for LZ901 and to determine whether any adjustments are required to finalize the Phase III clinical trial protocol prior to initiating the Phase III clinical trial. Currently, we have completed the production and verification of LZ901 clinical trial samples at our Zhuhai manufacturing facility, and the Phase III clinical trial can be initiated in the second quarter of 2023. We plan to initiate a multi-center, randomized, double-blind, placebo-controlled Phase III clinical trial comparing LZ901 against Shingrix® for LZ901 in China in the second quarter of 2023. Subject enrollment to unblinding of the clinical trial data is expected to be completed within approximately 10 months, which we expect to complete in the second quarter quarter of 2024, while continuing to conduct follow-up evaluations to observe and collect immune persistence secondary endpoint data. After completing the primary endpoint and secondary endpoints, excluding the immune persistence secondary endpoint, of the Phase III clinical trial, we plan to complete production and testing of three batches of LZ901 for commercialization by the third quarter of 2024 and file the BLA in the third quarter of 2024 to the NMPA. In addition, we have received IND approval from the FDA in July 2022 for LZ901 and initiated a Phase I clinical trial in the U.S. in February 2023.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET LZ901 SUCCESSFULLY.

2. K3

Overview

K3, our independently developed recombinant human anti-TNF-α monoclonal antibody injection product candidate, is a biosimilar of adalimumab and mainly used for the treatment of various autoimmune diseases, such as rheumatoid arthritis, ankylosing spondylitis and plaque psoriasis. We developed K3 based on the antibody structure of adalimumab. Adalimumab is a blockbuster TNF-α inhibitor marketed by AbbVie Inc. under the brand name Humira®, with global sales of US$20.7 billion in 2021. Since the initial FDA approval in December 2002, adalimumab has been approved for various indications worldwide, including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, plaque psoriasis, hidradenitis suppurativa, juvenile idiopathic arthritis and non-infectious uveitis. K3 is expected to primarily compete with the Qletli® (格樂立), Sulinno® (蘇立信), Anjianning (安建寧), Handayuan (漢達遠), Taibowei (泰博維), Junmaikang (君邁康) and other adalimumab biosimilars that have been launched or currently under development in China.

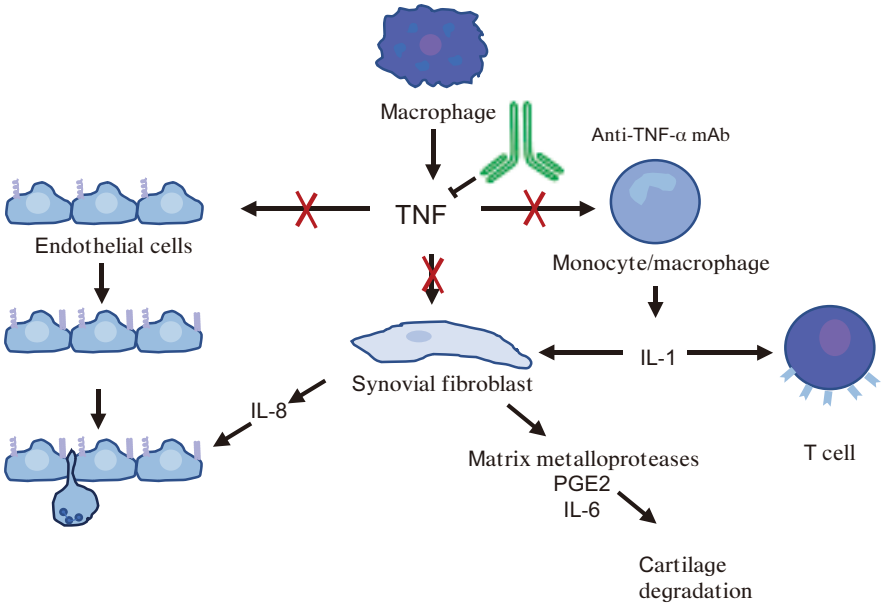
The molecular design of K3 maximizes the safety of the antibody when used in the human body. We expect K3 to expand the market in China for adalimumab biosimilars.

We commenced the development of K3 in 2010. Development of K3 is led by Mr. KONG Jian, our co-founder, executive Director, general manager and chief scientist, who has over 33 years of biopharmaceutical experience. Mr. KONG initiated the development of K3 in 2010 and led the development of K3 in gene synthesis, clone screening, establishing cell banks, production scale-up, purification method development and quality control testing. Mr. KONG contributed as the general director for the filing of the CTA application for K3 to the NMPA. In 2021, Mr. KONG guided the first-stage technology transfer at our Zhuhai manufacturing facilities to produce K3. Going forward, Mr. KONG will continue to guide the technology transfer to complete the large-scale commercial production of K3 at our first- and second-phase Zhuhai manufacturing facilities. We synthesized the genes that code for K3, developed the recombinant plasmid containing the K3 gene, transfected CHO K1 cells with the recombinant plasmid, cloned cell lines, screened clones for high-expression of K3 and established K3 cell banks. From 2010 to 2011, we developed the K3 cell bioreactor culture and antibody purification process parameters, and the K3 monoclonal antibody injection. In 2013, we engaged a CRO to conduct the preclinical safety research of K3. We produced the first pilot batch of K3 in 2016 and received an umbrella CTA approval for K3 from the NMPA in November 2017. In September 2018, we initiated a Phase I clinical trial for K3 in China for the treatment of various autoimmune diseases, and completed the Phase I clinical trial in December 2019. Since March 2021, we have optimized bioreactor culture conditions to improve our production capabilities, and monitored and improved K3 product stabilities. From the beginning of 2022 to October 2022, we increased the production yield of K3 by approximately 300%. In order to produce sufficient K3 antibodies to support our Phase III clinical trial for K3, we plan to conduct production testing for K3 on a large-scale bioreactor after we complete setting up our production line for K3. We plan to initiate a Phase III clinical trial for K3 in China in the second quarter of 2023, complete the Phase III clinical trial in the second quarter of 2024 and submit a BLA to the NMPA in the fourth quarter of 2024. We expect K3 to receive BLA approval from the NMPA in 2025.

Mechanism of Action

TNF-α is a key regulator of innate immunity and plays an important role in the regulation of Th1 immune responses against intracellular bacteria and certain viral infections. However, the natural occurring cytokines that TNF contribute to cause numerous pathological related inflammatory and immune responses and immune-mediated inflammatory diseases ("**IMIDs**"), including rheumatoid arthritis, Crohn's disease, psoriatic arthritis, ankylosing spondylitis, ulcerative colitis and severe chronic plaque psoriasis.

Anti-TNF-α monoclonal antibody ("**mAb**") is a next generation therapy for treating IMIDs with high effectiveness, safety and convenient administration methods. K3, our recombinant human anti-TNF-α monoclonal antibody injection product candidate, binds specifically to TNF-α to inactivate TNF-α and promote the production of regulatory T cells, which reduces pain and swelling due to inflammation. TNF-α is a proinflammatory cytokine mainly produced by activated macrophages, natural killer cells and T cells, which is involved in inflammatory and immune responses. Anti-TNF-α mAb can restrict TNF-α's ability to activate T cells, effectively neutralizing TNF-α bioactivity and inducing the apoptosis of TNF-expressing cells. Anti-TNF-α mAb can bind to human TNF-α monomer or trimer, block TNF-α binding to the cellular surface receptor, p55 and p75, and neutralize the cytotoxic effect of TNF-α, thereby inhibiting the release of TNF-α mediated inflammatory factors and cytokines, the adhesion and infiltration of inflammatory cells, the proliferation of fibroblasts and the activation of osteoclasts.



Source: *Frost & Sullivan Analysis*

Note: Mechanism of action is applicable to chimeric, humanized and fully human anti-TNF-α monoclonal antibodies.

Market Opportunities and Competition

Adalimumab is a blockbuster TNF-α inhibitor marketed by AbbVie Inc. under the brand name Humira®. Humira® was approved by the NMPA in 2010 and included in the Category B of the National Reimbursement Drug List ("**NRDL**"). Patients purchasing medicines included in Category B of the NRDL are required to pay a certain percentage of the purchase price, generally ranging from 10% to 40%, depending on the policies of local government, and the remainder of the purchase price shall be reimbursed in accordance with the regulations in respect of basic medical insurance. Accordingly, K3, once approved, is also likely to be included in the NRDL and will enjoy similar reimbursement as well. Its average selling price was originally RMB7,729 per unit in 2015, and decreased from RMB5,572 in 2019 to RMB1,258 in 2020, directly contributing to a 440% increase in sales in 2020 compared to 2019.

Due to the wide range of indications for adalimumab, large market demand and continuous availability of new biosimilar products, the adalimumab market size is growing rapidly in China. In terms of sales revenue, the adalimumab market in China increased from RMB0.2 billion in 2015

to RMB1.6 billion in 2021 at a CAGR of 41.3%, and is expected to grow to RMB6.8 billion in 2025 at a CAGR of 42.7% from 2021 to 2025, and further grow to RMB11.7 billion in 2030 at a CAGR of 11.3% from 2025 to 2030.

In China, K3 is expected to primarily compete with biosimilars of adalimumab that have been launched or currently under development. Although K3 faces fierce competition from adalimumab and its biosimilars, the market demand and the number of eligible patients for adalimumab and its biosimilars are large. K3 is indicated for the treatment of various autoimmune diseases, such as rheumatoid arthritis, ankylosing spondylitis and plaque psoriasis, of which the total combined prevalence of these three types of indications in China exceeded 16 million in 2021 according to Frost & Sullivan. Rheumatoid arthritis, ankylosing spondylitis and plaque psoriasis are chronic diseases that require long-term medication of two doses of adalimumab a month with a total of 24 doses of adalimumab a year. Although adalimumab is included in Category B of the NRDL, patients are still required to pay in the range of the 10% to 40% of the purchase price of adalimumab and its biosimilars, which can range from RMB100 to RMB400 per dose and RMB2,400 to RMB9,600 per year based on a price of approximately RMB1,000 per dose of adalimumab and its biosimilars. Due to the high cost of adalimumab and its biosimilars, we plan to price K3 at a retail price of approximately RMB400 to RMB500 a dose, which will significantly reduce the out-of-pocket expense of patients and provide a competitive pricing advantage for K3 as K3 faces fierce competition from adalimumab and its biosimilars. In addition, the second-phase Zhuhai manufacturing facility will be able to produce two million doses of K3 a year, which will support the required yearly doses of K3 for approximately 83,000 patients. As of the Latest Practicable Date, there were six biosimilars of adalimumab approved in China, namely Qletli® (格樂立), Sulinno® (蘇立信), Anjianning (安建寧), Handayuan (漢達遠), Taibowei (泰博維) and Junmaikang (君邁康), and 10 biosimilars of adalimumab in development in China, according to Frost & Sullivan. The following tables set forth details of approved drugs and product candidates that may compete with K3 in China:

Approved Products in China

Company Name	Product	NMPA Approval Date	Indications	Price
Bio-Thera Solutions, Ltd. (百奧泰)	QLETLI®／格樂立	November 6, 2019	Rheumatoid arthritis, ankylosing spondylitis, psoriasis, Crohn's disease, uveitis, childhood plaque psoriasis, polyarticular juvenile idiopathic arthritis, Crohn's disease in children	RMB1,080/40mg RMB676/20mg
Hisun Pharmaceutical (海正藥業)	安建寧	December 6, 2019	Rheumatoid arthritis, ankylosing spondylitis, psoriasis, Crohn's disease, non-infectious uveitis, polyarticular juvenile idiopathic arthritis, childhood plaque psoriasis	RMB1,090/40mg
Innovent Bio (信達生物)	SULINNO®／蘇立信	September 2, 2020	Rheumatoid arthritis, ankylosing spondylitis, psoriasis, polyarticular juvenile idiopathic arthritis, childhood plaque psoriasis, non-infectious uveitis	RMB1,088/40mg
Henlius Biotech (復宏漢霖)	漢達遠	December 2, 2020	Rheumatoid arthritis, ankylosing spondylitis, psoriasis, uveitis	RMB899/40mg
Chia Tai Tianqing (正大天晴)	泰博維	January 18, 2022	Rheumatoid arthritis, ankylosing spondylitis, psoriasis	RMB799/40mg
Junshi Biosciences (君實生物)/ Mabwell (邁威生物)	君邁康	March 1, 2022	Rheumatoid arthritis, ankylosing spondylitis, psoriasis	RMB998/40mg

Source: CDE, public disclosure of listed companies, Frost & Sullivan Analysis

Products Under Development in China

Company Name	Products	R&D Progress	Indication	Date of Phase I Clinical Trial*
SinoCellTech (神州細胞)	SCT630	Phase III completed, pending approval	Moderate-to-severe plaque psoriasis	January 29, 2019
Wuhan Institute of Biological Products (武漢生物製品研究所)	Recombinant fully human anti-human TNF-α monoclonal antibody injection	Phase III	Moderate-to-severe plaque psoriasis	May 24, 2019
Shandong Danhong Pharmaceutical Co., Ltd (山東丹紅)	BC002	Phase III	Ankylosing spondylitis	April 25, 2019
Huaota Biopharm (華奧泰生物)	HOT-3010	Phase III	Moderate-to-severe plaque psoriasis	September 21, 2018
Hualan Bio (華蘭生物)	HL01	Phase III	Rheumatoid arthritis, ankylosing spondylitis, psoriasis	May 21, 2018
Tonghua Dongbao Pharmaceutical (通化東寶)	DB101	Phase III	Moderate-to-severe plaque psoriasis	August 18, 2017
Luzhu Biotech (綠竹生物)	K3	Phase I (completed)	Rheumatoid arthritis, ankylosing spondylitis, psoriasis	November 13, 2018
Eastern Biotech (北京東方百泰生物／北京精益泰翔)	JY026	Phase I (completed)	Rheumatoid arthritis, ankylosing spondylitis	October 29, 2019
Anhui Weiming Damu Biomedicine Co., Ltd. (安徽未名達木生物醫藥有限公司)	Recombinant anti-TNF-α fully human monoclonal antibody injection	Phase I	Rheumatoid arthritis, ankylosing spondylitis	July 5, 2021
North China Pharmaceutical Company Ltd. (華北製藥)	Recombinant human antihuman tumour necrosis factor (TNF-a) monoclonal antibody injection	Phase I	Rheumatoid arthritis, ankylosing spondylitis, psoriasis	January 15, 2020

Note:

* Date when the Phase I clinical trial was first published by the CDE.

Source: CDE, public disclosure of listed companies, Frost & Sullivan Analysis

There may be further price adjustment for K3 in the next round of National Drug Price Negotiation (國家醫藥談判). The price control along with the fierce competition in the market may significantly impact the profitability of K3. For details, please see "Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to Sales and Distribution of Our Product Candidates — Because some of our vaccine candidates are intended to prevent diseases of major public health concerns, we are at risk of governmental actions detrimental to our business, such as price controls or waivers on vaccine patent." and "Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to Sales and Distribution of Our Product Candidates — We operate in a competitive environment, and we may not be able to compete effectively against current and future competitors" in this document.

Competitive Advantages

The molecular design of K3 maximizes the safety of the antibody when used in the human body. The pharmacokinetic, safety and immunogenicity evaluations of K3 have shown that it is

highly similar to adalimumab, with no clinically meaningful difference between K3 and adalimumab, indicating K3's potential to treat autoimmune diseases, such as rheumatoid arthritis, ankylosing spondylitis and plaque psoriasis. Our second-phase Zhuhai manufacturing facility will be able to produce two million doses of K3 a year, which will enable us to lower production cost and improve the profitability and competitive strength of K3. K3 is expected to be priced at a retail price of approximately RMB400 to RMB500 a dose, which will be a major competitive strength of K3. Taking into consideration the strong manufacturing capabilities of our second-phase Zhuhai manufacturing facility and our competitive pricing strategies for K3, we expect K3 to capture and further expand the market in China for adalimumab biosimilars. Please see "— Commercialization" in this section for more details about our commercialization plans for K3.

Non-human Primates Study (Cynomolgus Monkeys)

Study design. In the development of K3, we conducted animal studies in cynomolgus monkeys to evaluate the immunogenicity, pharmacokinetics and safety of K3 compared to adalimumab. 50 cynomolgus monkeys were randomly assigned to five groups, including one 2mg/kg dose group, one 10mg/kg dose group and one 50mg/kg dose group of K3, and one 10mg/kg dose control group of adalimumab and one negative control group, with 10 monkeys in each group. Each group of monkeys were injected subcutaneously with their respective dose and one dose a week for a period of four weeks, with a total of five doses.

Immunogenicity. The neutralizing antibody titers observed in monkeys in the 10mg/kg dose groups of K3 and adalimumab were similar. 28 days after the initial injection, neutralizing antibodies were detected in five of the ten monkeys in the 10mg/kg dose group of K3 with the highest antibody titer of 1:6,400, and four of the ten monkeys in the 10mg/kg dose group of adalimumab with the highest antibody titer of 1:1,600. In addition, the absolute and differential counts of white blood cells, the levels of immunoglobulins and albumin/globulin ("**A/G**") ratios, the distribution of lymphocyte subsets, cytokines and gross anatomical observations of lymphoid organs and tissues, and weight/coefficient of the thymus and spleen in the 10mg/kg dose groups of K3 and adalimumab were similar. The above results of the 10mg/kg dose groups of K3 and adalimumab indicate K3 indicate the immunogenicity of K3 and adalimumab are similar in monkeys.

Pharmacokinetics profile. The bioequivalence statistics for monkeys in the 10mg/kg dose groups of K3 and adalimumab for T_{max}, C_{max}, AUC_{last} and AUC_{∞} indicate the pharmacokinetics of K3 and adalimumab are similar. The following table sets forth the bioequivalence analysis of pharmacokinetic parameters of K3 and adalimumab we observed during the preclinical study.

Day	Group	T_{max} h (hours)	C_{max} μg/mL	AUC_{last} h•mg/mL	AUC_{∞} h•mg/mL
Day 1 to Day 8	10 mg/kg dose K3	38±25.16	145.78±20.63	19.46±2.61	49.77±12.32
	10 mg/kg dose adalimumab	52.80±10.12	130.19±19.73	17.53±2.57	54.40±29.45
Day 22 to Day 29	10 mg/kg dose K3	52.80±24.79	188.04±143.26	21.99±20.07	37.00±49.83
	10 mg/kg dose adalimumab	26.40±7.59	194.18±130.07	22.65±19.07	56.31±73.88

Safety. No noticeable toxic reactions were observed, indicating no acute toxicity in monkey subjects. The no observable effect level dose of K3 in monkeys was 50mg/kg, which is approximately 75 times higher than the designed clinical dose for humans of 0.67mg/kg.

Conclusion. Our preclinical study of K3 demonstrated the immunogenicity and pharmacokinetics of K3 are similar to adalimumab, and K3 is safe in cynomolgus monkeys.

Summary of Phase I Clinical Trial Results

Trial design. We conducted a single-center, randomized, blind, single dose, parallel-controlled Phase I clinical trial to study the pharmacokinetics, safety and immunogenicity of our K3 in relation to Vetter Pharma-Fertigung GmbH & Co KG's Humira® (adalimumab). During the trial, 647 subjects were screened and a total of 160 healthy Chinese male subjects aged between 18 to 45 years old were enrolled in the Phase I clinical trial for K3. Only male subjects were recruited due to uncertainty in the research of the effects of adalimumab on women, as there is currently no preclinical data on the postnatal toxicity of adalimumab and no clinical data on the effects of adalimumab on pregnant or lactating women. In addition, in a blinded study, it is necessary to ensure the uniformity of body weight and gender to a certain extent. If both male and female subjects were recruited, it cannot be guaranteed that the gender of the subjects will be maintained at a one-to-one ratio as men overall have higher body mass index figures and lower body fat compared to women. The Chinese male subjects were divided into two cohorts, 80 subjects per cohort: a K3 test group (K3, 40 mg) and a Humira® positive control group (adalimumab, 40 mg). Each subject in the K3 test cohort received a single dose of K3, and each subject in the Humira® positive control group received a single dose of Humira®. After subcutaneous administration, blood samples were collected at preset time points, and serum concentrations were tested by enzyme-linked immunosorbent assay ("**ELISA**") for immunogenicity testing. The pharmacokinetics and immunogenicity of the K3 test group and the Humira® positive control group were observed after 71 days of administration. Except for one subject in the K3 test group who requested to withdraw from the trial, all the remaining subjects completed the trial. The subject voluntarily withdrew from the trial because he had an accident that resulted in a bone fracture and was unable to return to the clinical trial site.

Trial status. The Phase I clinical trial was initiated in September 2018 and was completed in December 2019.

Pharmacokinetic profile. A total of 155 subjects who completed the collection of pharmacokinetic samples were included in the calculation of pharmacokinetic parameters. The bioequivalence statistics for C_{max}, AUC_{0-t} and $AUC_{0-\infty}$ of K3 and Humira® indicate the pharmacokinetics of K3 and Humira® are similar, as all results were within the bioequivalence margins of 80.00%-125.00%. The geometric mean ratios of C_{max}, AUC_{0-t} and $AUC_{0-\infty}$ between K3 and Humira® were 115.14% (90% confidence interval ("**CI**"), 106.87-124.05), 96.97% (90% CI, 87.88-107.00) and 97.16% (90% CI, 87.71-107.64), which fall within the acceptance range of 80.00%-125.00%. The following table sets forth the bioequivalence analysis of pharmacokinetic parameters of our K3 we observed during the clinical trial.

		Geometric Mean and Ratio				
Pharmacokinetic Parameters	**N**	**Test (K3)**	**Reference (Humira®)**	**Test/ Reference Ratio**	**90% Confidence Interval**	**Degree of Certainty**
(Unit)				*(%)*		*(%)*
C_{max} (ng/mL)	155	3,675.2	3,191.9	115.14	106.87-124.05	56.8
AUC_{0-t} (h*ng/mL)	155	2,032,726.1	2,096,237.4	96.97	87.88-107.00	93.8
$AUC_{0-\infty}$ (h*ng/mL)	154	2,156,640.6	2,219,567.7	97.16	87.71-107.64	92.3

Furthermore, in the pharmacokinetic per protocol set ("**PK-PPS**") analysis, the pharmacokinetic parameters for the K3 test group and the Humira® positive control group were highly similar. The following table sets forth the PK-PPS analysis of the pharmacokinetic parameters for the K3 test group and the Humira® positive control group.

	Mean ± SD	
Pharmacokinetic Parameters (Unit)	**K3 Test Group (N=76 subjects)**	**Humira® Positive Control Group (N=79 subjects)**
T_{max} (h), median (minimum, maximum)	168.0 (72, 336)	168.0 (72, 336)
C_{max} (ng/mL)	3,861.2 ± 1,236.80	3,281.0 ± 776.18
AUC_{0-t} (h*ng/mL)	2,191,973.639 ± 782,397.7956	2,200,422.897 ± 679418.1397
$AUC_{0-\infty}$ (h*ng/mL)	2,330,328.379 ± 862,469.6772	2,353,257.742 ± 814,920.8609
$t_{1/2}$ (h)	269.929 ± 134.5155	310.459 ± 149.1313
λ_z (1/h)	0.004 ± 0.0054	0.003 ± 0.0016
$\%AUC_{ex}$	4.359 ± 3.3283	5.454 ± 4.3464
CL (mL/h)	20.476 ± 11.0975	19.121 ± 6.7677
V_z (mL)	6,724.191 ± 2,191.5720	7,519.906 ± 2,333.0958

Note: T_{max} = time to maximum observed concentration; C_{max} = maximum observed concentration; $AUC_{0-\infty}$ = area under the concentration curve from time zero to infinity; AUC_{0-t} = area under the concentration curve from time zero to the last quantifiable concentration; $t_{1/2}$ = elimination half-life; λ_z = terminal phase elimination constant; $\%AUC_{ex}$ = percentage of area under the concentration curve extrapolated from time 0 to infinity; CL = clearance; V_z = apparent volume of distribution.

Safety data. The results indicate that K3 is safe and well tolerated. There were no statistical differences in terms of AEs between the K3 test group and the Humira® positive control group. During the Phase I clinical trial, 45 subjects in the K3 test group experienced 87 AEs with an incidence rate of 56.25%, and 49 subjects in the Humira® positive control group experienced 93 AEs with an incidence rate of 61.25%. The incidence of AEs for K3 and Humira® were similar, with 56.25% for K3 and 61.25% for Humira®. The most frequent AEs in the K3 test group were bacterial infection, and elevated triglyceride, uric acid and glucose levels in blood, and the most frequent AEs in the Humira® positive control group were bacterial infection, elevated bilirubin, triglyceride, and aminotransferase levels in blood, and presence of red blood cells in urine. For drug-related AEs, 34 subjects in the K3 test group experienced 64 AEs with an incidence rate of 42.50%, and 44 subjects in the Humira® positive control group experienced 77 AEs with an incidence rate of 55.00%. One SAE was observed in a subject in the Humira® positive control group, which resulted in right axillary lymph node enlargement and right axillary abscess. In addition, two incidences of AEs were moderate, which resulted in right foot swelling and elevated triacylglycerol level. All other observed incidences of AEs for K3 and Humira® were mild, and no AEs led to subject withdrawal from the Phase I clinical trial.

The following table sets forth the AEs observed during the clinical trial.

	K3 Test Group (N=80 subjects)		Humira® Positive Control Group (N=80 subjects)	
	Number of AEs	Vaccine-related or unrelated	Number of AEs	Vaccine-related or unrelated
Adverse Events (AEs)				
Low white blood cell count	1	Very likely related	–	–
High white blood cell count	1	Very likely related	–	–
Increased white blood cell count	1	Very likely related	3	2 May be related; 1 Very likely related
Decreased white blood cell count	1	Very likely related	4	2 Very likely related; 2 May be related
Inflammation of the tonsils	–	–	1	May be related
Constipation	4	May be related	2	May be related
Elevated alanine aminotransferase	3	2 Very likely related; 1 May be related	4	3 Very likely related; 1 May be related
Elevated bacteria count	–	–	1	May not be related
Blood in stool	1	May be related	–	–
Protein positive	–	–	1	May be related
Nausea	–	–	1	May be related
Abdominal pain	2	May be related	–	–
Bloating	–	–	1	May not be related
Cold	1	May be related	1	May be related
Cough	–	–	1	May be related
High creatine kinase	1	Very likely related	–	–
Elevated creatine kinase	1	May be related	1	Very likely related
Elevated urine leukocyte count	–	–	1	May be related
High urine white leukocyte count	–	–	1	May be related
Elevated urine bacteria count	3	May not be related	6	May be not related
Urine protein l+	–	–	1	May be related
Urine protein positive	–	–	1	May be related
High urine red blood cell count	–	–	1	May be related
Elevated urinary red blood cell count	–	–	3	May be related
Urine abnormalities: positive for ketone bodies	1	May not be related	–	–
Urinary red blood cells	1	May be related	–	–
Elevated urinary erythrocytes	–	–	1	May be related
Urine glucose positive	1	May be related	1	May be related
High uric acid	3	May be related	1	May be related
High urine pH	1	May not be related	–	–
Elevated uric acid	2	May be related	–	–
High urine bacteria	1	May not be related	3	May not be related

	K3 Test Group (N=80 subjects)		Humira® Positive Control Group (N=80 subjects)	
	Number of AEs	Vaccine-related or unrelated	Number of AEs	Vaccine-related or unrelated
Elevated urine bacteria	12	12 May not be related	3	May not be related
Urine bacterial abnormalities	1	May be not related	–	–
Urine occult blood 2+	–	–	1	May be related
Elevated urine occult blood	1	May be related	–	–
Positive urine occult blood test	–	–	1	May be related
Positive urine occult blood test	–	–	1	May be related
Skin rash	3	May be related	2	May be related
Anemia	–	–	1	May be related
Parotid gland pain	–	–	1	May be related
Parotid gland enlargement	–	–	1	May be related
High triglycerides	3	May be related	2	May be related
High triacylglycerol	–	–	1	May be related
Elevated triacylglycerol	3	May be related	2	May be related
Upper respiratory tract infection	–	–	1	May be related
Upper respiratory infection	–	–	1	May be related
Rash on both lower extremities	1	May be related	–	–
Elevated aspartate aminotransferase	–	–	1	Very likely related
Headache	2	May be related	–	–
Leg pain	1	May be related	–	–
Abnormal ECG (first degree atrioventricular block)	–	–	1	May be related
Abnormal ECG (sinus bradycardia)	–	–	1	May be related
Abnormal ECG (abnormal Q wave II, III, aVF)	–	–	1	May be related
Blood: Increased absolute number of neutrophils	–	–	1	May be related
Reduced hemoglobin	1	May be related	–	–
Increased blood creatine kinase	–	–	1	May be related
High blood potassium	1	May not be related	–	–
Elevated blood glucose	1	May be related	–	–
Low blood sugar	1	May be related	–	–
High blood sugar	1	May be related	1	May be related
Hyperglycemia	1	May be related	–	–
Elevated blood sugar	2	May be related	–	–
Elevated platelet count	2	May not be related	–	–
Direct blood bilirubin elevation	1	May be related	–	–
Elevated total bilirubin in blood	1	May be related	–	–
Toothache	1	May be related	–	–
Sore throat	1	May be related	–	–

	K3 Test Group (N=80 subjects)		Humira® Positive Control Group (N=80 subjects)	
	Number of AEs	Vaccine-related or unrelated	Number of AEs	Vaccine-related or unrelated
Occult blood positive	–	–	1	May be related
Swollen inside right nose	–	–	1	May be related
Inner right knee pain	–	–	1	May not be related
Right foot pain	2	May be related	–	–
Red and swollen right eye corner	3	May be related	–	–
Swollen right eye corner	1	May be related	–	–
Lump in the right armpit	–	–	1	May be related
Direct bilirubin elevation	–	–	3	2 Very likely related; 1 May be related
Low absolute number of neutrophils	1	Very likely related	–	–
Decreased absolute number of neutrophils	1	May be related	4	3 Very likely related; 1 May be related
Increased absolute number of neutrophils	2	Very likely related	2	May be related
Absolute number of neutrophils decreased	1	Very likely related	–	–
Swelling at the injection site	–	–	1	Very likely related
Itchy skin at the injection site	1	Very likely related	–	–
Consciously fever	1	May not be related	–	–
High total bilirubin	1	Very likely related	2	Very likely related
Increased total bilirubin	2	Very likely related	6	2 Very likely related; 4 May be related
Right axillary lymph node enlargement, right axillary abscess	–	–	1	May be related
Left earache	–	–	1	May not be related
Left cheek infection	–	–	1	May be related
ALT high	–	–	1	May be related
AST increased	–	–	1	May be related
Total	**87**		**93**	

Immunogenicity data. A total of 159 subjects were included in the calculation and statistical analysis of immunogenicity data. K3 was observed to have similar positive rate of anti-drug antibody ("**ADA**") and neutralizing anti-drug antibody ("**NADA**"), and antibody titer to Humira®. At day 22, the positive rate of ADA in the K3 test group and Humira® positive control group was 32.89% and 35.06%, respectively. At day 71, the positive rate of ADA in the K3 test group and Humira® positive control group was 58.44% and 61.04%, respectively. At day 22, the positive rate of NADA in the K3 test group and Humira® positive control group was 2.60% and 3.75%, respectively. At day 71, the positive rate of NADA in the K3 test group and Humira® positive

control group was 56.41% and 58.75%, respectively. At day 22, the K3 test group and Humira® positive control group had an average antibody titer of 18.36±24.01 and 16.00±14.35, respectively. At day 71, the K3 test group and Humira® positive control group had an average antibody titer of 20.27±20.69 and 25.43±32.81, respectively. The following table sets forth the positive rate of ADA and NADA of K3 and Humira® we observed during the clinical trial.

		K3 Test Group			Humira® Positive Control Group		
	Day	Number of Subjects	Number of Subjects Were Negative Before Receiving Dose	Number of Subjects Who Turned Positive After Receiving Dose (%)	Number of Subjects	Number of Subjects Who Were Negative Before Receiving Dose	Number of Subjects Who Turned Positive After Receiving Dose (%)
Anti-drug antibody (ADA)	22	77	76	25 (32.89%)	80	77	27 (35.06%)
	71	78	77	45 (58.44%)	80	77	47 (61.04%)
Neutralizing anti-drug antibody (NADA)	22	77	77	2 (2.60%)	80	80	3 (3.75%)
	71	78	78	44 (56.41%)	80	80	47 (58.75%)

Conclusion. The pharmacokinetic profile, safety data and immunogenicity data of K3 is highly similar to Humira®.

Clinical Development Plan

We plan to initiate a Phase III clinical trial for K3 in China in the second quarter of 2023 as we are currently constructing our second-phase Zhuhai manufacturing facilities in order to meet the production capacity requirement to produce K3 used for conducting the Phase III clinical trial. After the completion of our first- and second-phase Zhuhai manufacturing facilities, our Zhuhai manufacturing facilities will support the clinical trial needs of K3 and early commercialization needs after product launch. The clinical development of K3, like any other drugs, is inherently unpredictable. Potential adverse events may occur and the clinical results may not be what we expect, which could halt our planned clinical plans and our commercialization efforts. For details, please see "Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to the Research and Development of Our Product Candidates" in the document.

Licenses, Rights and Obligations

In July 2019, we entered into a technology transfer agreement with Beijing Science Sun, a Shenzhen Stock Exchange-listed biopharmaceutical company focused on research, manufacture and sales of injectable products, (the "**Beijing Science Sun License Agreement**"), with respect to the assets and intellectual property rights in and to K3 and K11 in China. Pursuant to the Beijing Science Sun License Agreement, we originally agreed to assign Beijing Science Sun the intellectual property rights in and to our K3 and K11 product candidates and transfer all test results and research data in relation to pre-clinical studies of K3 and K11, testing and proprietary technology related to K3 and K11, as well as pilot-scale manufacturing and testing, related testing technologies, clinical research approval documents and Phase I clinical research results and materials of K3 to Beijing Science Sun. In exchange Beijing Science Sun agreed to pay us (i) a one-time payment of RMB8.35 million to compensate us for the related expenses paid and to be paid for the completion of the Phase I clinical study of K3 and (ii) a certain percentage of net sales or net profits of selling K3 and K11 as royalty payments for ten years after the commercial launch of K3 or K11. Prior to signing the Beijing Science Sun License Agreement, we had entered into a contract with a CRO to provide services for the Phase I clinical trial for K3. At the time when the Beijing Science Sun License Agreement was signed, the CRO had already begun providing services. Therefore, we had to pay a final payment of RMB8.35 million to the CRO after the completion of the Phase I clinical trial for K3. The purpose of the one-time payment of RMB8.35 million by Beijing Science Sun was to compensate us for the final payment of RMB8.35 million owed to the CRO subsequent to the transfer of K3 to Beijing Science Sun. As we did not have any similar payment arrangement with third parties in relation to the development of K11, there was nil upfront payment for K11. According to Frost & Sullivan, it is industry norm for the amount of upfront payments and proportion of royalty fee to be decided by the contracting parties through negotiation, and the nil upfront payment for K11 but a one-time payment of RMB8.35 million to compensate the expenses for the Phase I clinical trial for K3 under the Beijing Science Sun License Agreement is commercially rational. We did not receive any payment pursuant to the Beijing Science Sun License Agreement during the Track Record Period. The follow-up improvement of the technical secrets in relation to K3 and K11 transferred to Beijing Science Sun shall be jointly completed by Beijing Science Sun and us, and the follow-up improvement results belong to Beijing Science Sun. Unless Beijing Science Sun obtains written permission from us in advance, Beijing Science Sun may only use the follow-up improvement technology for the development K3 and K11. The confidentiality period of the trade secrets in relation to K3 and K11 to be transferred to Beijing Science Sun is a period of 10 years from the signing date of the Beijing Science Sun License Agreement.

At the time of entering into the Beijing Science Sun License Agreement, our Beijing R&D and pilot manufacturing facility only had limited production capacity to support pre-clinical studies and early-stage clinical trials, and we did not have a manufacturing facility with high-quality mass production capacity to produce the required doses of K3 to conduct the Phase III clinical trial and support early commercialization needs after product launch. In order to produce at least two million doses of K3 a year at a commercially reasonable price point (at a production cost per dose of K3 that is more favorable to the production cost of approximately RMB80 per dose of other marketed adalimumab biosimilars in China according to Frost & Sullivan) to support a Phase III clinical trial and commercialization, the manufacturing facility would need to meet various requirements, including (i) production area of approximately 1,500 sq.m. to 2,500 sq.m. to be designated exclusively for K3 to place two to four 2,000L to 3,500L stainless steel bioreactors

of at least two tons, and supporting facilities area of approximately 500 sq.m. to 800 sq.m. for HVAC, systems for clean air, compressed air systems, pharmaceutical grade water purification systems, etc., (ii) inner factory height of approximately 6 meters, and (iii) load bearing of more than 700 kg/m^2, which our Beijing R&D and pilot manufacturing facility could not support. Therefore, we had to either build new manufacturing facilities or cooperate with business partners to further develop K3. We did not engage a CDMO to produce K3 to support the Phase III clinical trial for K3 because it would be commercially advisable to use the same CDMO for the commercial production of K3 as using different facilities would incur substantial additional cost for technology transfer, and we did not want to rely on a CDMO for production of K3, which would subject us to the risk of a CDMO controlling the cost of production of K3. When we were considering the further plans of K3, Beijing Science Sun approached us and proposed a collaboration opportunity with respect to K3. When considering the collaboration opportunity with Beijing Science Sun to further develop K3, we believed that Beijing Science Sun had the capability to further advance the development of K3 because Beijing Science Sun had (i) extensive experience in the research, manufacturing and sales of biological and biochemical pharmaceuticals, (ii) an existing manufacturing facility in Beijing, (iii) extensive commercialization capabilities and (iv) strong capital resources as a listed company. Although Beijing Science Sun had an existing manufacturing facility in Beijing, the existing manufacturing facility was not designed to manufacture K3 and Beijing Science Sun had to upgrade its existing manufacturing facility to carry out a Phase III clinical trial for K3, which we reasonably believed Beijing Science Sun would be able to accomplish due to its strong capital resources as a listed company.

After signing the Beijing Science Sun License Agreement, however, as (i) Beijing Science Sun considered K11 to be more in line with its pipeline development strategy compared to K3 as several of its product candidates were developed for the treatment of cancers, (ii) Beijing Science Sun did not establish necessary facilities to manufacture K3 antibodies or identify a suitable CDMO in China with high-quality mass-production capacity to meet the production capacity requirement for conducting the Phase III clinical trial for K3 and producing K3 at a commercially reasonable price point due to intense competition from other commercialized biosimilars of adalimumab in China and (iii) Beijing Science Sun, being one of our [**REDACTED**] Investors, had the knowledge that we were constructing our Zhuhai manufacturing facilities which would expand our production capacity, reduce production costs and increase the profit margin for K3, the transaction was not consummated as a result.

As K3 is expected to primarily compete with biosimilars of adalimumab that have been launched or currently under development in China, it is important to have sufficient production capacity to lower production cost and improve the profitability and competitive strength of K3. According to Frost & Sullivan, as of the Latest Practicable Date, there were six biosimilars of adalimumab approved in China and 10 biosimilars of adalimumab in development in China, and the average selling price of Humira® (under which the brand name adalimumab is marketed by AbbVie Inc) per unit in China decreased from RMB5,572 in 2019 to RMB1,258 in 2020 after being included in NRDL, and further decreased to RMB1,241 in 2021. The average selling price per unit of biosimilars of adalimumab in China ranged from RMB799 to RMB1,150 in 2020 to 2021. Considering the intense competition from other commercialized biosimilars of adalimumab in China which requires mass production capacity to produce K3 at a commercially reasonable price point, after signing the Beijing Science Sun License Agreement, Beijing Science Sun did not perform substantive research and development for K3 because (i) Beijing Science Sun did not establish the necessary manufacturing facilities with sufficient production capacity, which would

require substantial investment to build, or identify a suitable CDMO in China with high-quality mass-production capacity, and (ii) Beijing Science Sun had been informed in January 2021 that we were constructing our Zhuhai manufacturing facilities which would expand our production capacity, reduce production costs and increase the profit margin for K3. As advised by Beijing Science Sun, Beijing Science Sun did not incur research and development expenses for K3 after signing the Beijing Science Sun License Agreement. After signing the Beijing Science Sun License Agreement, we continued to supervise CROs and SMOs to complete the data analysis of the Phase I clinical trial of K3 and close out their engagements, and completed the Phase I clinical trial in December 2019. Given we have not transferred any K3 products after signing the Beijing Science Sun License Agreement due to Beijing Science Sun lacking the necessary manufacturing facilities to produce K3, we continued to monitor and improve the product stabilities, which is a part of our R&D efforts.

In January 2021, Beijing Science Sun and us had begun to discuss to rescind the Beijing Science Sun Licensing Agreement, shortly after we won the bid for purchasing manufacturing land in Zhuhai on December 29, 2020 and obtained a construction permit to build our Zhuhai manufacturing facilities on January 18, 2021. In April 2021, we obtained the state-owned land use right certificate to build the Zhuhai manufacturing facilities. Furthermore, in November 2021, we reached a consensus with Beijing Science Sun that we would be better positioned to accelerate the development and commercialization of K3 and lower the cost of manufacturing K3 to strengthen market competitiveness because of our increased R&D efficiency and expanded production capacity due to the construction of our first- and second-phase Zhuhai manufacturing facilities, and accordingly we and Beijing Science Sun entered into a supplemental technology transfer agreement (the "**Supplemental Beijing Science Sun License Agreement**"), which rescinded the previous technology transfer in respect to K3. After signing the Supplemental Beijing Science Sun License Agreement and as of the Latest Practicable Date, we had continued to optimize bioreactor culture conditions to improve our production capabilities for mass production of K3 antibodies required to support our Phase III clinical trial for K3. From August 2022 to October 2022, we increased the production yield of K3 by approximately 300%. Our R&D efforts for K3 include (i) conducting bridging experiments and production process tests for the Zhuhai manufacturing facilities, (ii) verifying the adaptability of small-scale production process systems and standardizing production process operations through small-scale multi-batch experiments to simulate pilot-scale and scale-up production processes for cell culture and purification of K3, (iii) investigating and evaluating the influence of cell culture media of other manufacturers on the cell culture process for K3, and (iv) preparing for the K3 technology transfer to the Zhuhai manufacturing facilities and process validation by training employees to become familiar with key process parameters and production processes of cell culture and fermentation of K3.

The Supplemental Beijing Science Sun License Agreement did not involve the re-assignment to us of any intellectual property rights related to our K3 product candidate. In addition, we agreed to repay and have paid Beijing Science Sun the one-time payment of RMB8.35 million Beijing Science Sun paid us under the Beijing Science Sun License Agreement.

We have entered into non-disclosure and confidentiality agreements with parties who have access to confidential aspects of our research and development output of K3, such as our employees, corporate collaborators, and other third parties. For details, please see "Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to Our Intellectual Property Rights — If we are unable to obtain and maintain adequate patent and other intellectual property

protection for our product candidates throughout the world, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties could compete directly against us and our ability to successfully develop and commercialize any of our product candidates would be materially and adversely affected" in this document. In November 2021, we entered into a perpetual non-disclosure agreement with Beijing Science Sun to keep confidential all test results and research data in relation to pre-clinical studies of K3, testing and proprietary technology related to K3, as well as pilot-scale manufacturing and testing, related testing technologies, clinical research approval documents and Phase I clinical research results and materials of K3 that were transferred to Beijing Science Sun after the signing of the Beijing Science Sun License Agreement and returned back to us after the signing of the Supplemental Beijing Science Sun License Agreement.

As advised by Hiways Law Firm, our legal adviser as to intellectual property law (the "**IP Legal Adviser**"), from the beginning of the research and development of K3, we took appropriate and reasonable confidentiality measures, including but not limited to (i) signing confidentiality agreements with research and development participants, (ii) establishing confidentiality regulations within the company and providing trainings to employees, (iii) grading management of technical secrets, (iv) setting the guard, installing access control, and installing camera, among others, to restrict the activity areas of employees and visitors, and (v) employees who participate in K3 research and development, including but not limited to preparation processes, purification processes and quality verification processes, can only participate in their responsible part and only have access to the technical information of their responsible part. In addition, we entered into a non-disclosure agreement with Beijing Science Sun, pursuant to which the confidentiality obligation of Beijing Science Sun in relation to K3 related technical information shall maintain for an indefinite term. According to the non-disclosure agreement, if Beijing Science Sun breaches the confidentiality obligation, we have the right to hold it liable for breach of contract and compensating the economic loss. The preparation, purification and identification processes of K3 meet the constitutive requirements of trade secrets. Meanwhile, we filed a patent application for the preparation process relating to the low mannose level of K3 antibody. Our IP Legal Adviser has conducted freedom-to-operate searches and analyses for K3, the result of which indicates that there is no material infringement risk for us following the scheduled development and commercialization process of K3. Accordingly, the IP Legal Adviser is of the view that the intellectual property rights of K3 are well protected through the combination of patent, trade secret and know-how and there is no material risk that future development and commercialization of K3 will be interfered or challenged by any relevant third parties known to the Company. Based on the view of our IP Legal Adviser, our Directors are of the view that all the intellectual property rights (including patents, trade secrets and know-hows) in relation to K3 are well protected against infringement by Beijing Science Sun and/or other relevant third parties, and there is no material risk that future development and commercialization of K3 will be interfered or challenged by any relevant third parties. Having taken into account the factors above, the independent due diligence work conducted by the Sole Sponsor and the view of the IP Legal Adviser, the Sole Sponsor concurs with the Directors' view above.

We have primarily engaged in and are responsible for the R&D of K3, including the Phase I clinical trial, and we have the global rights to develop and commercialize K3. Based on our unaudited management accounts, prior to signing the Beijing Science Sun License Agreement, our research and development expenses for K3 amounted to RMB48.2 million, which primarily consisted of staff costs, third-party contracting costs, costs of raw materials and depreciation and amortization, mainly in relation to pre-clinical studies and the Phase I clinical study of K3. Our research and development expenses for K3 after signing the Beijing Science Sun License Agreement and up to December 31, 2019, and in 2020 amounted to RMB2.2 million and RMB2.9 million respectively, which primarily consisted of staff costs, third-party contracting costs and costs of raw materials, mainly in relation to the Phase I clinical study and stability tests of K3. In 2021, our research and development expenses for K3 amounted to RMB4.1 million, which primarily consisted of staff costs, costs of raw materials and depreciation and amortization, mainly in relation to stability tests and the first-stage technology transfer at our Zhuhai manufacturing facilities to produce K3. In 2022 and from January 1, 2023 and up to the Latest Practicable Date, our research and development expenses for K3 amounted to RMB3.4 million and RMB0.3 million, respectively, which primarily consisted of staff costs, costs of raw materials and depreciation and amortization, mainly in relation to optimization of bioreactor culture conditions and improvement of the antibody purification.

As of the Latest Practicable Date, we did not have any disputes with Beijing Science Sun in association with the Beijing Science Sun Licensing Agreement and/or the Supplemental Beijing Science Sun License Agreement, and we expect to maintain a close and stable relationship with Beijing Science Sun.

Material Communications with Competent Authorities

We received an umbrella CTA approval for K3 from the NMPA in November 2017. We initiated and sponsored our Phase I clinical trial in September 2018, and completed our Phase I clinical trial for K3 in China in December 2019 for the treatment of various autoimmune diseases, such as rheumatoid arthritis, ankylosing spondylitis and plaque psoriasis, which displayed pharmacokinetics consistent with adalimumab. Based on the interview with the CDE of the NMPA in June 2022, it confirmed that our Phase I clinical trial in China was completed in December 2019 and it has no objection for us to proceed to Phase III clinical trial in China directly. Our PRC Legal Adviser is of the view that the CDE is the competent authority to give the above confirmations. Accordingly, we did not conduct any Phase II clinical trials for K3 in China. For details, please see "Regulatory Overview — Regulatory Provisions — Biosimilars Application and Approval" in this document. We submitted the Phase I clinical trial report to the CDE in March 2021 and plan to initiate communication with the CDE in April 2023 with respect to the clinical trial design of the Phase III clinical trial for K3 prior to initiating the Phase III clinical trial. We plan to initiate a Phase III clinical trial for K3 in China in the second quarter of 2023, complete the Phase III clinical trial in the second quarter of 2024 and submit a BLA to the NMPA in the fourth quarter of 2024. We expect K3 to receive BLA approval from the NMPA in 2025. Upon obtaining BLA approval for K3, we are expected to be the market authorization holder ("**MAH**") of K3.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET K3 SUCCESSFULLY.

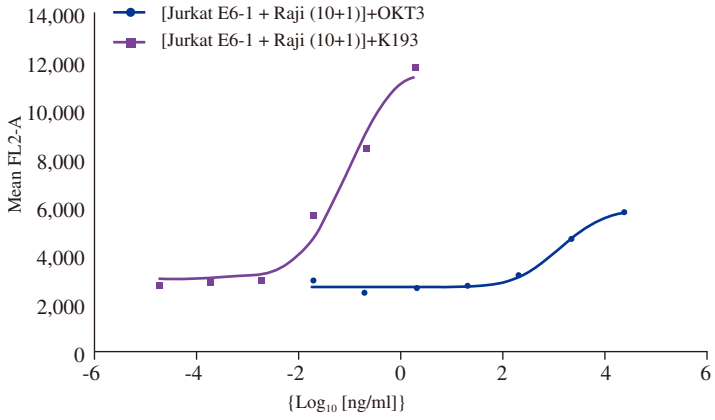
3. K193

Overview

K193, our independently developed bispecific antibody injection (CD19-CD3) product candidate for the treatment of B cell leukemia and lymphoma, is a bispecific antibody against CD19/CD3 with an asymmetric structure. Employing our proprietary Fabite® technology platform and our mammalian expression technology platform, we developed K193 with a fragment antigen-binding ("**Fab**")-single-chain variable fragment ("**scFv**") molecular structure, where the Fab region of humanized anti-CD19 monoclonal antibody that binds to antigens is linked to anti-CD3 epsilon ("**CD3ε**") scFv, a fusion protein of the variable regions of heavy and light chain immunoglobulins. K193 binds to CD19 on the surface of human B cells and CD3ε on the surface of T cells, which activates the T cells to kill B cells and tumor cells derived from B cells associated with leukemia and lymphoma. K193 has a short half-life and is expected to be a lastline treatment option for patients with rapidly progressing relapsed or refractory B cell leukemia and lymphoma. K193 is recommended for patients with relapsed or refractory B cell leukemia and lymphoma, who have received at least two failed chemotherapy and/or at least one failed combination therapy with CD20 monoclonal antibody, or for patients who are ready to receive CAR-T treatment, which may significantly limit the market potential of K193.

K193 displayed high *in vivo* and *in vitro* anti-tumor activity in pre-clinical studies. As shown below, K193's ability to activate T cells to kill B cells and tumor cells derived from B cells associated with leukemia and lymphoma is 10,000 times higher than OKT3 monoclonal antibody commonly used in CAR-T therapy.

Dose Response Curve of Comparison of K193 and OKT3 Activated T Cells

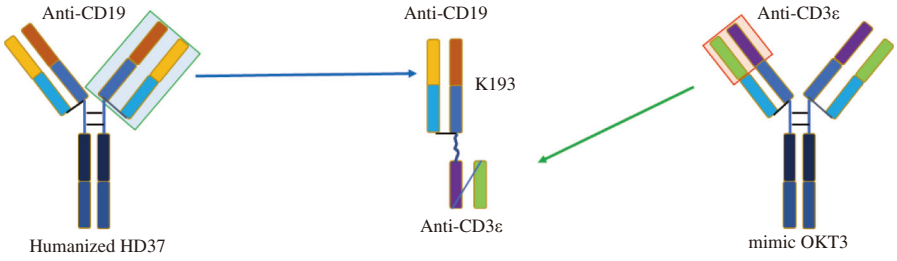


Source: Company Data

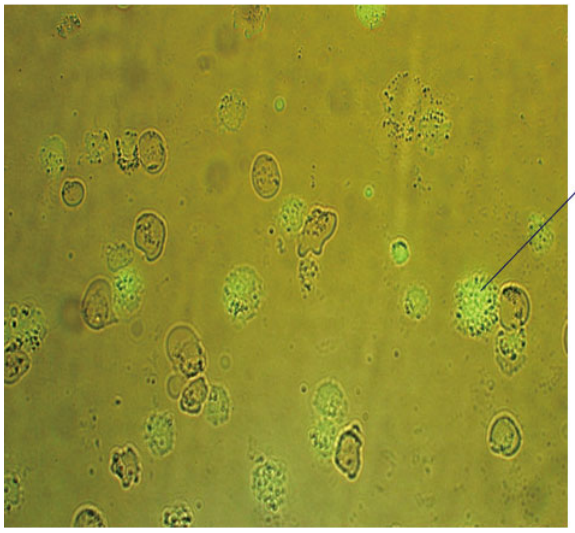
We initiated a Phase I clinical trial for K193 in China in December 2019 and we expect to complete the Phase I clinical trial in the second quarter of 2023. We plan to initiate a Phase II clinical trial for K193 in the first quarter of 2024 and complete the Phase II clinical trial of K193 in China in the fourth quarter of 2027. After receiving conditional approval, we plan to launch K193 in the second half of 2028.

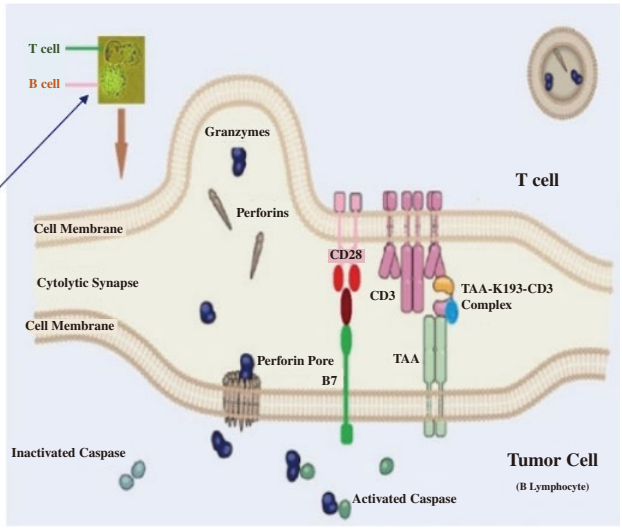
Mechanism of Action

K193 is a bispecific antibody with an asymmetric structure consisting of Fab linked to scFv developed by employing our Fabite® technology platform and our mammalian expression technology platform. A bispecific antibody is developed by utilizing protein engineering techniques to link two antigen binding domains (such as Fab or scFv), allowing a single antibody to simultaneously bind two different antigens. Thus, bispecific antibodies may be engineered to exhibit novel functions, which do not exist in mixtures of the two parental antibodies. The following diagram illustrates the structure of K193:



K193 has two specific binding sites, where the Fab region binds to CD19, which is an antigen on the surface of human B cells, and the scFv structure weakly binds to CD3, which is a protein complex and T cell co-receptor that is involved in activating both helper (CD4+) T cells and cytotoxic (CD8+) T cells. As K193 has a higher affinity to CD19-positive B cells compared to CD3-positive T cells, this allow K193 to preferentially bind to B cells and then to T cells. Only after K193 binds to CD3-positive T cells, K193 activates the T cell signaling pathway to initiate the process of killing CD19-positive B cells and tumor cells derived from B cells associated with leukemia and lymphoma. The following diagram illustrates the mechanism of action of K193:





400-fold fluorescence microscopy: K193 links to T cells and B cells and causes B cell death. The green fluorescence is observed in dead B lymphoma cells and the B cell membranes have been destroyed. The smaller unstained cells are T cells.

- K193 binds to CD19 first and then to CD3, which is conducive to synaptic interaction on the cell surface between T cells and B cells.
- B7:CD28 costimulatory molecules bind to each other to activate T cells.
- T cells activate, release perforins and granzymes, break the anchored B cell membrane and cause B cells to dissolve.

Market Opportunities and Competition

As of the Latest Practicable Date, there was only one bispecific antibody injection (CD19-CD3) approved in China, namely Amgen Inc.'s Blincyto®. Besides our K193, there were four other bispecific antibody injections (CD19-CD3), namely iExcyte's YK012, Generon Biomed's A-319, Curon Biopharma's CN201 and Shandong Xinshidai Pharmaceutical Co., Ltd's LNF1904, and one trispecific antibody injection (CD19-CD20-CD3), namely CMG1A46 of BioRay Pharmaceutical and Chimagen Biosciences, under clinical development registered with the CDE in China, according to Frost & Sullivan. Although the patient number is not large, the treatment cost is relatively high, and there remain great unmet medical needs from patients.

Name of Drug	Company Name	Indication	Target	Clinical Progress	Date of Clinical Publication[1]
Blincyto®[2]	Amgen	**Relapsed or refractory diffuse large B cell lymphoma**	**CD19×CD3**	**Listed**	**2014 FDA 2020 NMPA**
A-319	Generon Biomed[3]	Refractory or relapsed B cell lymphoma	CD19×CD3	Phase I	April 8, 2019
K193	Luzhu Biotech	Refractory/relapsed B cell non-Hodgkin's lymphoma	CD19×CD3	Phase I	November 18, 2019
CN201	Curon Biopharma	rr-B-NHL	CD19×CD3	Phase I	January 11, 2021
LNF1904	Shandong Xinshidai Pharmaceutical Co., Ltd	Refractory/relapsed B cell malignant tumor	CD19 × CD3	Phase I	September 15, 2022
CMG1A46	BioRay Pharmaceutical Chimagen Biosciences	B cell NHL	CD19 × CD20 × CD3	Phase I	April 27, 2022
YK012	iEcyte	r/r-B-NHL	CD19 × CD3	Phase I	February 1, 2023

Notes:

(1) Date of clinical publication is defined as the date of first publication of information based on clinical progress.

(2) Blincyto® is a non-IgG-type antibody and has adopted the form of powder for concentration for solution for infusion.

(3) Generon Biomed has changed its name to Evive Biotech.

Source: CDE, Frost & Sullivan Analysis

K193 is a bispecific antibody injection for the treatment of B cell leukemia and lymphoma, and according to Frost & Sullivan, its main competitors, such as Blincyto®, Yescarta® and Carteyva®, were not included in the latest NRDL as of the Latest Practicable Date. For the treatment of NHL/ALL, fludarabine, rituximab and imatinib were included in the Category B of the NRDL as of the Latest Practicable Date according to Frost & Sullivan, and patients generally pay 10% to 40% of the purchase price, depending on the policies of local government. Broad-spectrum anti-tumor drugs including cisplatin, carboplatin and doxorubicin were included in the Category A of the NRDL and were fully reimbursed as of the Latest Practicable Date according to Frost & Sullivan. Not being included under the National Immunization Program or the NRDL would not affect the pricing of K193 as we would price our product candidates at market price. However, if peer products are included under the NRDL, our peer products will gain market competitive advantage in mark penetration, which would cause market pressure on our product candidates.

Competitive Advantages

We believe K193 has the following advantages when compared to currently marketed antibody injections for the treatment of B cell leukemia and lymphoma globally:

Low Price

K193 is expected to be priced at a retail price of approximately RMB200,000 for the first two treatments, RMB200,000 for the third treatment, and no cost for unlimited treatments after the third treatment, for a maximum total cost of RMB400,000 per patient, which is more affordable compared to the retail price of approximately RMB360,000 for a treatment of Blincyto® and approximately RMB1.5 million a year per patient for treatment of Blincyto®. We provide K193 at no cost after the third treatment in order to reduce the financial burden of patients. In addition, the production cost per treatment of K193 is low compared to the treatment cost and providing K193 at no cost for unlimited treatments after the third treatment will not have a large impact on our financial performance. As confirmed by Frost & Sullivan, patients usually have three to four rounds of treatment for B cell leukemia and lymphoma. If a patient does not respond to treatment, the patient will consider other treatment modalities, including hematopoietic stem cell transplantation. Therefore, patients will likely only elect to receive three to four rounds of K193 treatment before considering other treatment options if there is no response to K193.

Liquid Formulation is Convenient and Easy to Administer

K193 has an optimized liquid formulation which remains stable for more than 36 months when stored in 2-8°C conditions. The liquid formulation also makes it convenient to administer compared with counterparts in the dosage form of powder for concentrate for solution for infusion. K193 can be readily administered without preparation steps, while the dosage form of powder for concentrate for solution for infusion requires preparation steps such as reconstitution with diluent before administration.

Strong Affinity to B Cells and Ability to Kill B Cells

K193 has strong binding affinity to CD19 on the surface of B cells, with a KD value of $2.6x10^{-9}$ mole/L. It adopts a humanized Fab antibody, which has a stronger affinity to CD19 than murine ScFv antibody. In comparison, its binding affinity to CD3 on the surface of T cells is weaker by the order of two magnitudes by adopting a ScFv structure with a KD value of $1.0x10^{-7}$ mole/L. The strong affinity to B cells facilitates K193 to first bind to B cells, then to T cells afterwards. The effect of K193's order of binding is strongly amplified by the participation of B7 molecules present on the surface of B cells, which interacts with cluster of differentiation 28 ("**CD28**") co-stimulatory molecules on the surface of T cells to release perforin and Granzyme B to efficiently and accurately kill B cells and tumor cells derived from B cells associated with leukemia and lymphoma.

Easy to Control Side Effects

The side effects of K193 are controllable with a low incidence. K193 is administered slowly at a constant rate. Administration of K193 can be stopped at any time to promptly avoid any adverse side effects. In addition, K193 can be metabolized with a short half-life after being injected and eliciting an immune response in the body to kill B cells and tumor cells derived from B cells associated with leukemia and lymphoma. Compared to competing CAR-T therapies, K193 does not have any risks of retroviral infection.

Ongoing Phase I Clinical Trial

Trial design and status. We commenced a Phase I, multicenter, open-label, single-arm, dose-escalating clinical trial ("3+3" design) for K193 in December 2019. The primary objectives of this clinical trial are to evaluate the safety and tolerability of our K193 for the treatment of relapsed/refractory B cell non-Hodgkin's lymphoma. The secondary objectives of this clinical trial are to assess the pharmacokinetics of K193, explore the recommended Phase II dose of K193, assess the cytokine levels of K193 for the treatment of relapsed/refractory B cell non-Hodgkin's lymphoma, assess the immunogenicity of K193 and preliminarily explore the anti-tumor efficacy of K193.

The clinical trial plans to enroll 26 to 33 subjects aged between 18 to 75 years old. The clinical trial comprises six dose cohorts, namely 0.2, 0.4, 0.6, 0.8, 1.4 and 2.0 μg/kg/d. Each dose cohort is administered a 0.05 μg/kg dose of K193 once daily over the first four consecutive days (Day 1-4), followed by a 0.1 μg/kg dose of K193 once daily over seven consecutive days (Day 5-11), and further followed by the cohort's respective 0.2, 0.4, 0.6, 0.8, 1.4 or 2.0 μg/kg dose of K193 once daily over 17 days (Day 12-28). The outbreak of COVID-19 reduced the number and availability of patients with relapsed/refractory B cell non-Hodkin's lymphoma who could commit to the 28 consecutive days of hospitalization and treatment of K193 for the Phase I clinical trial, which caused a temporary delay in subject enrollment. In addition, subject enrollment was further delayed due to difficulty finding suitable subjects, as K193 is a later-line therapy which requires enrolling patients who have failed other therapies. As of the Latest Practicable Date, we had enrolled 17 subjects and were in the dose escalation stage for this trial, but no safety or tolerability data is currently available. We expect to complete the Phase I clinical trial in the second quarter of 2023.

Clinical Development Plan

We plan to initiate a multi-center Phase II clinical trial to evaluate the safety and efficacy of K193 for the treatment of relapsed or refractory acute lymphoblastic leukemia ("**ALL**") in the first quarter of 2024, and have produced a bulk solution of sufficient K193 antibodies in November 2022 to support the Phase II clinical trial for K193. In the first half of 2024, we plan to commence enrollment of 150 subjects with ALL, who will receive two to five treatments cycles of K193 after enrollment. We expect to complete subject enrollment in 2025, complete treatment procedures for all subjects in the second half of 2026 and complete the Phase II clinical trial of K193 in China in the fourth quarter of 2027. In the fourth quarter of 2027, the Phase II clinical trial report is expected to be ready, based on which we plan to apply for conditional BLA approval from the NMPA. After receiving conditional approval, we plan to launch K193 in the second half of 2028.

Licenses, Rights and Obligations

We have the global rights to develop and commercialize K193.

Material Communications with Competent Authorities

Our bispecific antibody injection (CD19-CD3) for the treatment of B cell leukemia and lymphoma, K193, displayed high *in vivo* and *in vitro* anti-tumor activity in pre-clinical studies. We received CTA approval for K193 from the NMPA in April 2019. In December 2019, we initiated a Phase I clinical trial of K193 in China and expect to complete the Phase I clinical trial in the second quarter of 2023. We plan to initiate a Phase II clinical trial for K193 in the first quarter of 2024 and complete the Phase II clinical trial of K193 in China in the fourth quarter of 2027. We plan to apply for a conditional BLA approval from the NMPA prior to conducting a Phase III clinical trial for K193. For details, please see "Regulatory Overview — Regulatory Provisions — Laws and Regulations Related to Drugs — New Drug Application and Approval" in this document. Upon obtaining conditional BLA approval, the NMPA may require us to conduct Phase III clinical trials or confirmatory studies to verify the predicted clinical benefit and additional safety studies for K193.

In accordance with Drug Registration Regulation, conditional BLA approval can only be obtained for (i) biologics used for treatment of diseases that seriously endanger life and have no effective measure of treatment, and the data of clinical trials can prove the efficacy and forecast the clinical value of the biologic; (ii) biologics urgently needed for public health, and the data of clinical trials can prove the efficacy and forecast the clinical value of the biologics; or (iii) vaccines urgently needed to deal with major public health emergencies or other vaccines which the NHC deems to be urgently needed, and it is assessed that the benefits thereof outweigh the risks therein. BLA approval is usually obtained after the completion of a Phase III clinical trial, while conditional BLA can be obtained prior to completion of a Phase III clinical trial. For details of conditional BLA approval in China, see "Regulatory Overview — Regulatory Provisions — Laws and Regulations Related to Drugs — New Drug Application and Approval" in this document.

As K193 is indicated for the treatment of B cell leukemia and lymphoma, which are serious life-threatening diseases for which there are no effective treatment, our PRC Legal Adviser is of the view that there is a high possibility that K193 may obtain conditional approval and then conduct the Phase III clinical trial afterwards, which would accelerate the development and

commercialization of K193, so long as the data from the Phase I and Phase II clinical trials can prove the efficacy and forecast the clinical value of K193, and the NMPA confirms that the requirements for conditional approval of K193 are completely satisfied.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET K193 SUCCESSFULLY.

Our Pre-clinical-Stage Product Candidates

Our pre-clinical-stage product candidates comprise two vaccine candidates, including Recombinant Varicella Vaccine and Recombinant Rabies Vaccine, and two antibody injection product candidates, including K333 and K1932.

1. Recombinant Varicella Vaccine

Overview

Recombinant Varicella Vaccine, our independently developed recombinant varicella vaccine candidate, is an adjusted dosage of LZ901 for the prevention of chickenpox caused by VZV. We developed Recombinant Varicella Vaccine based on LZ901. Recombinant Varicella Vaccine is expected to partially replace live attenuated vaccines of the OKA strain of VZV as an alternative vaccination method, reduce the chance of children suffering from VZV infection, and reduce the risk of developing shingles in adults. Unlike other marketed live-attenuated vaccines that contain weakened forms of VZV which may lay dormant in the patient and reactivate causing shingles, Recombinant Varicella Vaccine does not contain VZV and does not carry the risk of developing into shingles. We submitted an IND application for Recombinant Varicella Vaccine to the NMPA in June 2022. We expect to initiate a Phase I clinical trial for Recombinant Varicella Vaccine in the third quarter of 2023, and complete the Phase I clinical trial in the second quarter of 2024. We plan to initiate a Phase II clinical trial in the third quarter of 2024, complete the Phase II clinical trial in the third quarter of 2025, and initiate a Phase III clinical trial in the fourth quarter of 2025 in China, and complete the Phase III clinical trial in the second quarter of 2027.

Mechanism of Action

Recombinant Varicella Vaccine is designed on the basis of making full use of the mechanism of the human immune system for processing foreign antigens. The carboxyl end of the VZV gE extracellular domain is connected to the Fc fragment of human IgG1,and based on the characteristic of VZV gE to form covalent dimers. A multi-step liquid chromatography process is used to obtain high-purity recombinant VZV gE tetramer-Fc fusion proteins containing two Fcs by purification from protein solutions with complex compositions. The VZV gE recombinant protein containing two Fcs mimics the mechanism of action of the VZV-antibody complex in the human body. The two Fc fragments bind to Fc-gamma receptors ("**FcγRs**") that are extensively present on the surface of APCs, including dendritic cells, macrophages and monocytes. As a result, VZV gE is actively engulfed into the cell by FcγR-mediated endocytosis, then degraded into polypeptides by

intracellular proteases, and eventually presented on the surface of the cell membrane together with MHC-II molecules or presented on the surface of the cell membrane together with MHC-I molecules through antigen cross-presentation. Then the processed antigen is presented to CD4+ or CD8+ T cells to induce an immune response dominated by Th1 and Th2, and the activated T cells and B cells will produce cytokines and specific antibodies including neutralizing antibodies.

Market Opportunities and Competition

As of the Latest Practicable Date, there were five commercialized varicella vaccines marketed in China. According to Frost & Sullivan, although several economically developed cities in China, such as Beijing, Tianjin and Shanghai, have implemented policies to provide free varicella vaccination for children, varicella vaccine is less likely to be included in the National Immunization Program in the next three to five years since the costs will be very high to provide free varicella vaccination and varicella vaccines were not included in the latest NRDL as of the Latest Practicable Date. As also confirmed by Frost & Sullivan, oral antiviral drugs, including acyclovir, valaciclovir and famciclovir can be used to treat varicella. Acyclovir was listed in Category A or Category B, depending on the dosage form, valaciclovir and famciclovir were listed in Category B of the latest NRDL as of the Latest Practicable Date. Not being included under the National Immunization Program or the NRDL would not affect the pricing of Recombinant Varicella Vaccine as we would price our product candidates at market price. However, if peer products are included under the NRDL, our peer products will gain market competitive advantage in market penetration, which would cause market pressure on our product candidates. The following tables set forth details of the approved varicella vaccines in China:

Commercialized Varicella Vaccines in China

Company	Technology	Vaccine Administration Procedure	Approval Date	Price, per Dose, 2021	Sales Revenue, 2021 (RMB million)	Market Share, 2021
Changchun Keygen Biological Products	Live attenuated	One dose administered for 12 month and older	March 30, 2007	RMB145.5-160.5	1,078.2	33.2%
BCHT Biotechnology	Live attenuated	One dose administered for 1-12 years of age; 2 dose administered for 13 years and older	February 4, 2008	RMB90-160.5	1,020.3	31.4%
Shanghai Institute Of Biological Products	Live attenuated	One dose administered for 12 month – 12 years old	November 7, 2006	RMB90-160.5	674.7	20.8%
RongSheng Biotech	Live attenuated	One dose administered for 12 months – 12 years old	October 25, 2016	RMB136-157	270.6	8.3%
Sinovac	Live attenuated	12 months – 12 years of age: One dose One booster dose can be administered when deemed necessary	December 18, 2019	RMB90	202.0	6.3%

Source: Public disclosure of listed companies, NMPA, Frost & Sullivan Analysis

Competitive Advantages

Recombinant Varicella Vaccine prevents childhood chickenpox and has a wide range of applications. It is expected to partially replace live attenuated vaccines of the OKA strain of VZV as an alternative vaccination method, reduce the chance of children suffering from VZV infection, and reduce the risk of developing shingles in adults.

The currently marketed varicella vaccines in China are live-attenuated vaccines of the OKA strain. Unlike other marketed live-attenuated vaccines that contain weakened forms of VZV which may lay dormant in the patient and reactivate causing shingles, Recombinant Varicella Vaccine does not contain VZV and does not carry the risk of developing into shingles. Live-attenuated vaccines of the OKA strain of VZV have been administered for more than 30 years. After inoculation with a live-attenuated vaccine, VZV will lurk in the ganglia of the human body. After the age of 40, the immune system diminishes in competence and latent viruses are activated to produce herpes zoster. Recombinant varicella vaccine is a high-purity protein vaccine manufactured by genetic engineering technology. It does not have the ability to reproduce and replicate, but it can make the vaccinated person produce specific antibodies and cellular immunity against VZV.

Licenses, Rights and Obligations

We have the global rights to develop and commercialize Recombinant Varicella Vaccine.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET RECOMBINANT VARICELLA VACCINE SUCCESSFULLY.

2. Recombinant Rabies Vaccine

Overview

We are currently developing Recombinant Rabies Vaccine, our recombinant RVG subunit vaccine candidate, for the prevention of rabies in humans. We developed Recombinant Rabies Vaccine based on the genetically engineered expression of rabies virus glycoprotein G in CHO cells.

Recombinant Rabies Vaccine is currently undergoing pre-clinical studies. We plan to request a pre-IND meeting for Recombinant Rabies Vaccine with the NMPA as early as the fourth quarter of 2023. We initiated pre-clinical studies for Recombinant Rabies Vaccine in the second quarter of 2020, and we expect to complete the pre-clinical studies in the fourth quarter of 2023. In September 2022, we screened CHO cell for high-yield clones to increase the expression level of Recombinant Rabies Vaccine and identified clones with a production yield of Recombinant Rabies Vaccine of more than 100 times higher compared to traditional tissue culture methods. We expect to initiate a Phase I clinical trial for Recombinant Rabies Vaccine in the second quarter of 2024 and complete the Phase I clinical trial in the third quarter of 2024 in China. We expect to initiate a Phase II clinical trial for Recombinant Rabies Vaccine in the third quarter of 2024, and complete the Phase II clinical trial in the first quarter of 2025. Furthermore, we expect to initiate the Phase III clinical trial in the first quarter of 2025 and complete the Phase III clinical trial in the second quarter of 2026 in China.

Mechanism of Action

The major immune effector against rabies is the production of virus neutralizing antibodies ("**VNA**") elicited by RVG protein. The capacity to trigger the production of VNA depends largely on the integrity of RVG protein "spikes" on the encapsulating viral envelope, which are comprised of trimers of RVG. RVG protein is the major viral antigen responsible for the induction of VNA and protective immunity against rabies. The RVG protein is responsible for cell attachment and membrane fusion in rabies virus and additionally is the main target for the host immune system.

Market Opportunities and Competition

Rabies is a vaccine-preventable viral disease often transmitted through the bite of a rabidly infected animal. Rabies is caused by the *Rabies lyssavirus*, which includes the rabies virus and the Australian bat rabies virus. The rabies virus infects the central nervous system of mammals, eventually leading to brain disease and death. Rabies is a contagious disease with a very high mortality rate, which is why countries around the world are dedicated to eliminating rabies. The disease, which is nearly always fatal, is preventable by vaccines given either before and/or after exposure to a rabid animal. Numerous factors including the high cost of vaccines, the relative complexity of post-exposure vaccination protocols requiring multiple doses of vaccine, and insufficient surveillance contribute to the estimated 59,000 human deaths caused by rabies each year, according to the World Health Organization ("**WHO**"). According to the Center for Disease Control and Prevention ("**CDC**") in China, the number of new human rabies cases in China was 2,048 cases in 2010 and decreased to 157 cases in 2021. A high post-exposure vaccination rate has led to the rapid decline in the number of cases in China.

Approved rabies vaccines for human use are based on inactivated purified rabies virus grown either in tissue culture or in embryonated duck or chicken eggs. A vaccine for post-exposure prophylaxis ("**PEP**") needs to induce virus neutralizing antibodies ("**VNAs**") as fast as possible to prevent rabies virus from spreading into the central nervous system. A pre-exposure prophylaxis ("**PrEP**") vaccine on the other hand should induce sustained VNA titers and robust memory B and CD4+ T helper cell responses that allow for rapid VNAs recall after a boost.

Currently, most human rabies vaccines marketed in China are for PEP. Although this type of vaccine can also be given prior to exposure, most people still receive rabies vaccines after being bitten or scratched by animals such as cats and dogs. In addition, human rabies vaccination is used for PrEP for populations at high risk of rabies virus exposure, including sub-populations in highly endemic settings with limited access to timely and adequate PEP, individuals at occupational risk, and travelers who may be at risk of exposure. People who are at an occupational risk of rabies virus exposure account for a small portion of the total vaccine recipients, including Centers for Disease Control and Prevention staff, veterinary clinic staff and dog trainers. In the future, the market for human rabies vaccines as a PrEP can be expanded to other groups of people with a potential risk of rabies virus exposure, including courier and food delivery staff and other potential target groups.

The pre-exposure human rabies vaccine market in China increased from RMB4.2 million in 2015 to RMB10.7 million in 2021 at a CAGR of 16.8% from 2015 to 2021, and is expected to increase to RMB2,960.2 million in 2035 at a CAGR of 49.4% from 2021 to 2035.

As of the Latest Practicable Date, there were 13 commercialized human rabies vaccines marketed in China, which can be injected in both adults and children. According to Frost & Sullivan, human rabies vaccines aim to help protect people at risk of being exposed to rabies, regardless of their age, and therefore, it is unlikely that human rabies vaccines will be included in the National Immunization Program in China, which aims to protect children. However, human rabies vaccines were included in the Category B of the NRDL for work-injury insurance as of the Latest Practicable Date according to Frost & Sullivan. Not being included under the National Immunization Program or the NRDL would not affect the pricing of Recombinant Rabies Vaccine as we would price our product candidates at market price. However, if peer products are included under the NRDL, our peer products will gain market competitive advantage in market penetration, which would cause market pressure on our product candidates. The following table sets forth details of the commercialized human rabies vaccines in China:

Commercialized Human Rabies Vaccines in China

Manufacturer	Cell Line	Administration	Approval Date	Price, 2021
Hualan Bio	PVCV	Pre-exposure: Three doses Post-exposure: Four doses (2-1-1) or five doses	January 29, 2023	/
Shandong Yidu Biotechnology		Pre-exposure: Three doses Post-exposure: Four doses (2-1-1) or five doses	July 12, 2021	/
Changchun Institute of Biological Products		Four-dose or five dose	April 30, 2021	/
Changchun Zhuoyi Biological		Pre-exposure: Three doses Post-exposure: Five doses	November 23, 2016	RMB65-93
Dalian Aleph Biomedical		Pre-exposure: Three doses Post-exposure: Five doses	September 28, 2016	RMB58.5-91.0
Liaoning Chengda	PVCV	Pre-exposure: Three doses Post-exposure: Four doses (2-1-1) or five doses	March 6, 2007	Frozen-dried: RMB60-258.5 Non-frozen-dried: RMB42.09-104
Rongan Biological		Pre-exposure: Three doses Post-exposure: Five doses	September 30, 2007	RMB53.85-87
Promise Biological		Pre-exposure: Three doses Post-exposure: Five doses	May 8, 2008	RMB53
Jilin Maifeng Biopharmaceutical		Pre-exposure: Three doses Post-exposure: Five doses	January 9, 2008	/
Liaoning Yisheng Biopharma		Pre-exposure: Three doses Post-exposure: Five doses	November 6, 2006	RMB68.5-243.5
Henan Grand Biopharmaceutical	Hamster Kidney Cell	Pre-exposure: Three doses Post-exposure: Five doses	June 12, 2007	RMB46.2-89.5
Zhongke Biopharm		Pre-exposure: Three doses Post-exposure: Five doses	May 28, 2007	RMB58.8-95
Chengdu Kanghua Biological Products	HDCV	Pre-exposure: Three doses Post-exposure: Five doses	April 28, 2012	RMB275-320

Note:

* *Excluding human rabies vaccines in China that did not have any batches issued by the NMPA in the last five years.*

Source: Public disclosure of listed companies, DataYes Inc., NMPA, Frost & Sullivan Analysis

Competitive Advantages

Recombinant Rabies Vaccine is a prophylactic that provides protection against rabies prior to exposure and simplifies post-exposure treatment for rabies. In addition, Recombinant Rabies Vaccine has high purity and is suitable for immunizing both children and adults.

Licenses, Rights and Obligations

We have the global rights to develop and commercialize Recombinant Rabies Vaccine.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET RECOMBINANT RABIES VACCINE SUCCESSFULLY.

3. K333

Overview

We are currently developing K333, our bispecific antibody injection (CD33-CD3) product candidate, for the treatment of myeloid leukemia. K333 is a bispecific antibody that binds to human CD33 and CD3. We developed K333 with a IgG molecular structure from an anti-CD33 monoclonal antibody (mAb) and an anti-CD3ε scFv. K333 has a molecular structure that contains two Fabs that bind to CD33 on the surface of human myeloid cells and two Fabs that bind to CD3ε on the surface of T cells linked to the C-terminus of the consistent region of kappa chain through a hydrophilic peptide-linker, which activates the T cells to kill myeloid cells and tumor cells derived from myeloid cells associated with leukemia. Currently, drugs for treatment of myeloid leukemia, such as azacitidine, imatinib, and dasatinib, are included in the Category B of the NRDL, and patients generally need to self-finance 10% to 40% of the purchase prices, depending on the policies of local government, according to Frost & Sullivan.

K333 is currently undergoing pre-clinical studies. K333 exhibited statistically significant antitumor activity *in vivo* in established disseminated and subcutaneous mouse models of human acute myeloid leukemia ("**AML**"). From February 2022 to October 2022, we optimized cell culture media and bioreactor culture conditions to improve our production capabilities, increasing the yield of K333 by approximately 400%. We plan to request a pre-IND meeting for K333 with the NMPA in the second half of 2024.

Mechanism of Action

AML is a genetically heterogeneous disease characterized by clonal expansion of leukemic cells. Despite an increased understanding of the underlying disease biology in AML, the standard treatment with cytotoxic chemotherapy has remained largely unchanged over the last decades, and the overall five-year survival remains poor at under 30%. Thus, there is a pressing need for novel therapies with increased efficacy and decreased toxicity.

CD33 is a 67 kD single-pass transmembrane glycoprotein and is a member of the sialic acid-binding immunoglobulin-like lectins family. Expression of CD33 is restricted to the hematopoietic lineage with low levels present in myeloid progenitors, neutrophils, and macrophages and high levels detected in circulating monocytes and dendritic cells. Importantly, CD33 is absent on normal hematopoietic stem cells but is expressed on blasts and leukemic stem cells of 85% to 90% of patients presenting with AML. These findings suggest that CD33 is a suitable target for an antibody-based therapy in AML.

K333 is capable of binding to CD33 and to CD3, and induces T cell recruitment and tumor cell cytotoxicity. K333 is composed of a human IgG which specifically recognizes a cell membrane antigen CD33 and a single-chain antibody which recognizes a CD3 molecule linked to the C-terminus of the consistent region of kappa chain through a hydrophilic linker peptide-linker. K333 specifically binds to CD33-expressing target cells and induces cytotoxicity of CD33+ AML cell lines *in vitro* along with T cell activation.

Licenses, Rights and Obligations

We have the global rights to develop and commercialize K333.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET K333 SUCCESSFULLY.

4. K1932

Overview

We are currently developing K1932, our bispecific antibody injection (CD19-CD3) product candidate, for the treatment of B cell lymphoma. K1932 is a bispecific antibody that binds to human CD19 and CD3. K1932 is recommended for patients with relapsed or refractory B cell leukemia and lymphoma, who have received at least two failed chemotherapy and/or at least one failed combination therapy with CD20 monoclonal antibody, or for patients who are ready to receive CAR-T treatment, which may significantly limit the market potential of K1932. We developed K1932 based on the molecular structure of K193, with the same binding sites for CD19 and CD3ε to K193. The bispecific antibody is composed of a human IgG which specifically recognizes a cell membrane antigen CD19 and a single-chain antibody which recognizes a CD3 molecule linked to the C-terminus of the consistent region of kappa chain through a hydrophilic peptide-linker.

K1932 is expected to be administered in combination with K193 for the treatment of relapsed or refractory B cell lymphoma, and is not expected to compete with K193 for the treatment of B cell leukemia as K1932 is not indicated for leukemia. Lymphoma patients administered K1932 following the first stage administration of K193 have lower risk of experiencing a cytokine storm, which allows for dose escalation. In addition, K1932 has a longer half-life in the human body compared to K193. Due to K193's short half-life, the continuous use of syringe pump infusion is required for the treatment of K193, which requires patients to be hospitalized. K1932 improves the medication experience of patients as it is administered via injection on a weekly basis and does not require hospitalization. Patients will only need to return to the hospital on a weekly basis to receive K1932 injections. Patients with relapsed or refractory B cell lymphoma have the option to choose whether to receive K193 treatment only, which requires hospitalization throughout the treatment process, or treatment of K193 for a period of seven to 10 days followed by weekly injections of K1932, which allows patients to have more freedom to leave the hospital after the seven to 10 day induction period of K193.

For a patient with relapsed or refractory B cell lymphoma who chooses to receive a combination treatment of K193 and K1932, the patient is administered K193 for a period of seven to 10 days and is hospitalized during the K193 treatment process due to the required continuous use of syringe pump infusion. Following the induction period of K193, the patient is administered K1932 on a weekly basis and allowed to leave the hospital. However, K1932 cannot be administered prior to K193, which can be potentially harmful to the patient due to the long half-life

of K1932. During the induction period, K193 slowly kills the B cells associated with lymphoma in the human blood circulatory system. At the end of the induction period, there are essentially no B cells in the blood circulatory system and K1932 can be administered on a weekly basis. Therefore, large doses of K1932 with long half-life will not cause massive lysis of B cells, and cytokine storms are less likely to occur, which greatly improves the medication experience of B cell lymphoma patients.

K1932 is currently undergoing pre-clinical studies. From March 2022 to October 2022, we optimized cell culture media and bioreactor culture conditions to improve our production capabilities, increasing the yield of K1932 by approximately 600%. We plan to request a pre-IND meeting for K1932 with the NMPA in the second half of 2024.

Competitive Advantages

The half-life of K1932 is expected to be longer than that of K193. Patients administered K1932 following the first stage administration of K193 have lower risk of experiencing a cytokine storm, which allows for dose escalation. Large doses of K1932 with long half-life will not cause massive lysis of B cells, and cytokine storms are less likely to occur, which greatly improves the medication experience of B cell lymphoma patients. In addition, K1932 is administered via injection and does not require hospitalization. As K1932 is complementary to K193 and the combination of K193 and K1932 provide patients with more treatment options, once K1932 is successfully developed and commercialized, K1932 is expected to mutually benefit K193 and not cannabalize the sales of K193.

Licenses, Rights and Obligations

We have the global rights to develop and commercialize K1932.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET K1932 SUCCESSFULLY.

Our Other Historically Developed Products

1. Inactivated Enterovirus 71 ("EV71") Vaccine

Inactivated EV71 Vaccine, a vaccine candidate we independently developed, is an inactivated Vero cell-based vaccine for the prevention of hand-foot-and-mouth disease. Inactivated EV71 Vaccine is produced by inoculating EV71 H9 strain into Vero cells. After culturing the EV71 H9 in media, the virus is harvested, inactivated and purified. Aluminum hydroxide adjuvant is added to enhance immunogenicity.

We commenced the development of Inactivated EV71 Vaccine in July 2007 and isolated EV71 H9 strain. From March to May in 2008, we established an Inactivated EV71 Vaccine seed bank. After three years of development, we finalized the production process for Inactivated EV71 Vaccine in August 2010. We continued to improve the purification process and produced an Inactivated EV71 Vaccine stock solution with high specific activity in September 2010. In February 2011, we prepared a batch of Inactivated EV71 Vaccine and conducted animal studies, including acute toxicity tests of BALB/c mice, repeated dose toxicity tests of cynomolgus monkeys, systemic active allergy tests of guinea pigs and injection irritation tests of rabbits. No abnormal adverse events were reported in the animals studies. In July 2011, we produced three batches of Inactivated EV71 Vaccines to perform further animals studies. We performed accelerated stability tests which indicated the three batches to be of good stability and stable quality.

In July 2011, we entered into a technology transfer agreement with Beijing Zhifei Luzhu Biopharmaceutical Co., Ltd. ("**Zhifei Biopharma**"), a wholly owned subsidiary of Chongqing Zhifei Biological Products Co., Ltd., a Shenzhen Stock Exchange-listed biotech company focused on researching, manufacturing, and selling vaccines and biological products ("**2011 Zhifei License Agreement**") with respect to the assets and intellectual property rights in and to Inactivated EV71 Vaccine in China. We entered into the 2011 Zhifei License Agreement in order to leverage Zhifei Biopharma's production and strong sales capacity to ensure the successful commercialization of Inactivated EV71 Vaccine. When we entered into the 2011 Zhifei License Agreement, Inactivated EV71 Vaccine was in the preclinical stage. Pursuant to the 2011 Zhifei License Agreement, we agreed to transfer Zhifei Biopharma all test results in relation to pre-clinical studies of Inactivated EV71 Vaccine, proprietary technology related to Inactivated EV71 Vaccine pilot-scale manufacturing and testing and relevant testing technologies that are not disclosed in the invention patent of Inactivated EV71 Vaccine to Zhifei Biopharma. We co-own with Zhifei Biopharma the invention patent of Inactivated EV71 Vaccine. Zhifei Biopharma solely owns all rights, titles, and interests in and to all innovations or improvement for Inactivated EV71 Vaccine by Zhifei Biopharma or us regardless of inventorship, authorship, or other origination. We agreed to provide guidance to the personnel of Zhifei Biopharma to fully master the technologies in relation to Inactivated EV71 Vaccine upon request by Zhifei Biopharma. The follow-up improvement of the technical secrets in relation to Inactivated EV71 Vaccine transferred to Zhifei Biopharma shall be jointly completed by Zhifei Biopharma and us, and the follow-up improvement results belong to Zhifei Biopharma. Unless Zhifei Biopharma obtains written permission from us in advance, Zhifei Biopharma may only use the follow-up improvement technology for the development Inactivated EV71 Vaccine. In addition, we agreed not to disclose the technologies in relation to Inactivated EV71 Vaccine to any third parties. The confidentiality period of the trade secrets in relation to Inactivated EV71 Vaccine to be transferred to Zhifei Biopharma is a period of 10 years from the signing date of the 2011 Zhifei License Agreement. Zhifei Biopharma agreed to pay us RMB19.0 million in milestone payments, comprising RMB5.0 million in October 2011, RMB5.0 million within 30 days of the acceptance of CTA, RMB5.0 million within 30 days of receiving CTA approval and RMB4.0 million within 30 days of receiving approval to commercialize Inactivated EV71 Vaccine, and royalty payments of 3% sales commission from sales of Inactivated EV71 Vaccine for a period of five years after receiving approval to commercialize Inactivated EV71 Vaccine. Zhifei Biopharma is an independent third party.

We transferred all assets of Inactivated EV71 Vaccine to Zhifei Biopharma, and co-own all intellectual property rights in and to Inactivated EV71 Vaccine with Zhifei Biopharma. After entering into the 2011 Zhifei License Agreement, we did not incur any expenses in relation to Inactivated EV71 Vaccine nor are we obligated to pay for any expenses in relation to Inactivated EV71 Vaccine after it was transferred to Zhifei Biopharma. As of the Latest Practicable Date, Zhifei Biopharma had paid us a total of RMB15.0 million under the 2011 Zhifei License Agreement. Zhifei Biopharma will further pay us a milestone payment of RMB4.0 million within 30 days after receiving approval to commercialize Inactivated EV71 Vaccine and royalty payments of low single-digit percentage of sales for a period of five years after the commercialization of Inactivated EV71 Vaccine according to the 2011 Zhifei License Agreement. We did not receive any payment pursuant to the 2011 Zhifei License Agreement during the Track Record Period. Except for China, we have the global rights to develop and commercialize Inactivated EV71 Vaccine. We currently have no global commercialization plan for Inactivated EV71 Vaccine because we do not own any patents in other countries in relation to Inactivated EV71 Vaccine.

In December 2018, CTA approval was granted for Inactivated EV71 Vaccine from the NMPA. Zhifei Biopharma initiated a single-center, randomized, double-blind, different-dosed and placebo-controlled Phase I clinical trial for Inactivated EV71 Vaccine in China in September 2020 and

received a clinical trial statistics report for the Phase I clinical trial for Inactivated EV71 Vaccine in October 2021. In October 2021, Zhifei Biopharma initiated a single-center, randomized, blinded, different-dosed and positive-controlled Phase II clinical trial for Inactivated EV71 Vaccine in China, which is currently ongoing. We and Zhifei Biopharma co-sponsored the Phase I clinical trial and Phase II clinical trial for Inactivated EV71 Vaccine in China. Upon obtaining NDA approval for Inactivated EV71 Vaccine, Zhifei Biopharma is expected to be the MAH of Inactivated EV71 Vaccine.

2. K11

K11, a humanized anti-VEGF monoclonal antibody injection product candidate we independently developed, is a biosimilar of bevacizumab and mainly used for the treatment of colorectal cancer, lung cancer and other cancers. K11 is expressed by Chinese hamster ovary ("**CHO**")-K1 cells grown in chemically-defined cell culture media containing no animal or plant-derived proteins. K11 binds to human vascular endothelial growth factor ("**VEGF**") to prevent VEGF from binding to two VEGF receptors (FMS-like receptor tyrosine kinase 1 ("**FLT-1**") and kinase insert domain receptor ("**KDR**")) on the surface of endothelial cells. This prevents the formation and growth of new blood vessels, hinders the blood supply in tumor tissue, and leads to unsustainable tumor growth. Combined with cytotoxic synthetic drugs, K11 can significantly inhibit the growth of tumors and inhibit the volume of existing malignant tumors.

Mr. KONG initiated the development of K11 in June 2012 and led the development of K11 in gene synthesis, clone screening, establishing cell banks, production scale-up, purification method development and quality control testing. Mr. KONG contributed as the general director for the filing of the CTA application for K11 to the NMPA and obtained CTA approval from the NMPA in April 2017. We commenced the development of K11 based on the antibody structure of bevacizumab in June 2012. In 2013, we created cell banks, performed purification method development and explored product formulas for K11. We also produced three batches of K11 in 2013. We stored the three batches of K11 in 2-8°C and -20°C conditions for 18 months and conducted stability tests with results that indicated the three batches of K11 were highly consistent with bevacizumab. In 2014, we produced an additional three batches of K11 and conducted preclinical evaluations of K11, including animal safety evaluations and pharmacodynamic research. We stored the three additional batches of K11 in 2-8°C conditions for 14 months and conducted stability tests with results that indicated the three additional batches of K11 were stable. In 2015, we began clinical sample production of K11 and completed preclinical studies in September 2015. In order to leverage Beijing Science Sun's R&D capabilities in developing anti-cancer drugs and its commercialization team that is mainly engaged in the sales of anti-cancer drugs to accelerate the R&D and commercialization of K11, we entered into the Beijing Science Sun Licensing Agreement in July 2019 and transferred all assets and intellectual property rights in and to K11 to Beijing Science Sun. Beijing Science Sun solely owns all rights, titles, and interests in and to all innovations or improvement for K11 by Beijing Science Sun or us regardless of inventorship, authorship, or other origination. Beijing Science Sun agreed to pay us royalty payments of 8% of net profits from sales of K11, or 50% of net profits from sales of K11 if the net profit margin is less than 15% for a period of ten years after receiving approval to commercialize K11. As we did not have other payment arrangements with third-parties in relation to the development of K11, there was nil upfront payment for K11 before and during the Track Record Period. As advised by Frost & Sullivan, it is industry norm for the amount of upfront payments and proportion of royalty fee to be decided by the contracting parties through negotiation, and the nil upfront payment for K11 under the Beijing Science License Agreement is commercially rational. When we entered into the Beijing Science Sun License Agreement, K11 was in the clinical stage. After entering into the Beijing Science Sun Licensing Agreement, we did not incur any expenses in relation to K11 nor are we obligated to pay for any expenses in relation to K11 after it was

transferred to Beijing Science Sun. Except for China, we have the global rights to develop and commercialize K11. We currently have no global commercialization plan for K11 because we do not own any patents in other countries in relation to K11. For further details regarding the terms of the Beijing Science Sun License Agreement with Beijing Science Sun, please see "— Our Products and Product Candidates — Our Core Product and Clinical-Stage Product Candidates — 2. K3 — Licenses, Rights and Obligations" in this section.

We received an CTA approval for K11 from the NMPA in April 2017. After receiving CTA approval, we engaged a CRO to commence a single-center, randomized, double-blinded, single dose, parallel-controlled Phase I clinical trial to study the pharmacokinetics, safety and immunogenicity of our K11 in relation to F. Hoffmann-La Roche AG's Avastin® (bevacizumab) in healthy males aged 18 to 45 years old in China at Tianjin Cancer Hospital, and initiated subject enrollment in January 2018. We sponsored the Phase I clinical trial for K11 in China. However, the Phase I clinical trial for K11 was suspended because we were only able to recruit 58 subjects and unable to complete enrollment of the planned number of 96 subjects, which is not within our control and is not related to the product quality of K11. According to Frost & Sullivan, subject enrollment criteria for clinical trials of oncology drugs in China often have high barriers of entry for subjects according to industry practice and patients may be unwilling to enroll due to their own personal reasons or other objective reasons unrelated to the quality of the drug, which may lead to low subject enrollment and suspension of the clinical trial due to failure in subject recruitment. In July 2019, we transferred all assets and intellectual property rights in and to K11 to Beijing Science Sun. From January 2020 to June 2020, Beijing Science Sun screened for CROs and prepared for a Phase I clinical trial for K11. Beijing Science Sun obtained approval for the clinical trial protocol from the ethics committee of a clinical trial institution in April 2020. In September 2021, Beijing Science Sun engaged a CDMO to produce K11. Beijing Science Sun plans to resume the Phase I clinical trial of K11 in China. Beijing Science Sun plans to initiate and sponsor a Phase III clinical trial of K11 in China, to complete the Phase III clinical trial in the fourth quarter of 2024 and file the BLA to the NMPA in the first quarter of 2026. Upon obtaining BLA approval for K11, Beijing Science Sun is expected to be the MAH of K11.

3. Immunoreagent Testing Kits

We have independently developed five immunoreagent testing kits (for research purposes only), including: Group A Meningococcal Polysaccharide IgG Antibody Detection Kit, Group C Meningococcal Polysaccharide IgG Antibody Detection Kit, Group Y Meningococcal Polysaccharide IgG Antibody Detection Kit, Group W_{135} Meningococcal Polysaccharide IgG Antibody Detection Kit and Haemophilus Influenzae Type b Polysaccharide IgG Antibody Detection Kit ("**Immunoreagent Testing Kits**"). Our Immunoreagent Kits are immunoreagent enzyme-linked kits and indirect enzyme-linked immunoassays used to detect the amount of Group A Meningococcal Polysaccharide Antibody (IgG), Group C Meningococcal Polysaccharide Antibody (IgG), Group Y Meningococcal Polysaccharide Antibody (IgG), Group W_{135} Meningococcal Polysaccharide Antibody (IgG) and Hib Polysaccharide Antibody (IgG) in human serum or plasma. We commenced the development of our Immunoreagent Testing Kits in 2003. During the development of Meningococcal Group A and C Polysaccharide Conjugate Vaccine, we first developed Group C Meningococcal Polysaccharide IgG Antibody Detection Kit to test serum samples. In 2004, we purchased meningococcal polysaccharide antibody reference standard from The National Institute for Biological Standards and Control, the reference standard provider of the World Health Organization, to develop a reference substance based on the meningococcal polysaccharide antibody reference standard for our Immunoreagent Testing Kits. In addition, we also began to provide our Immunoreagent Testing Kits to CDCs in China to determine the prevalence of meningococcal meningitis in different regions of China in 2004. Our Group A Meningococcal Polysaccharide IgG Antibody

Detection Kit, Group C Meningococcal Polysaccharide IgG Antibody Detection Kit, Group Y Meningococcal Polysaccharide IgG Antibody Detection Kit, Group W_{135} Meningococcal Polysaccharide IgG Antibody Detection Kit are the first domestically produced kits for the quantitative detection of meningococcal polysaccharide antibodies.

We had generated income of RMB4.7 million from sales of our immunoreagent testing kits (for research purposes only) to pharmaceutical companies during the Track Record Period.

Our Commercialized Vaccine Products

We have historically developed five commercialized vaccine products, namely (i) Haemophilus Influenzae Type b Conjugate Vaccine, (ii) Group $ACYW_{135}$ Meningococcal Polysaccharide Vaccine, (iii) Meningococcal Groups A and C and Haemophilus Influenzae Type b Conjugate Vaccine, (iv) Group A and C Meningococcal Polysaccharide Vaccine and (v) Meningococcal Group A and C Polysaccharide Conjugate Vaccine (the "**Bacteria Vaccines**").

Haemophilus Influenzae Type b Conjugate Vaccine. Zhifei Biopharma and we commenced the co-development of Haemophilus Influenzae Type b Conjugate Vaccine for the prevention of *Haemophilus influenzae* type b ("**Hib**") disease in infants and young children in January 2002 and completed preclinical studies in December 2006. Zhifei Biopharma and we received CTA approval for Haemophilus Influenzae Type b Conjugate Vaccine in July 2008. Zhifei Biopharma completed a Phase I clinical trial in November 2008 and a Phase III clinical trial in August 2009. Zhifei Biopharma sponsored the Phase I clinical trial and Phase III clinical trial for Haemophilus Influenzae Type b Conjugate Vaccine in China.

Group $ACYW_{135}$ Meningococcal Polysaccharide Vaccine. Zhifei Biopharma and we commenced the co-development of Group $ACYW_{135}$ Meningococcal Polysaccharide Vaccine for the prevention of Groups A, C, Y and W_{135} meningococcal disease in people over two years of age in March 2002 and completed preclinical studies in May 2004. Zhifei Biopharma and we received CTA approval for Group $ACYW_{135}$ Meningococcal Polysaccharide Vaccine in March 2005, and completed a Phase I clinical trial in May 2005 and a Phase III clinical trial in December 2005. We and Zhifei Biopharma co-sponsored the Phase I clinical trial and Phase III clinical trial for Group $ACYW_{135}$ Meningococcal Polysaccharide Vaccine in China. We received NDA approval for Group $ACYW_{135}$ Meningococcal Polysaccharide Vaccine from the NMPA in November 2007.

Meningococcal Groups A and C and Haemophilus Influenzae Type b Conjugate Vaccine. Zhifei Biopharma and we commenced the co-development of Meningococcal Groups A and C and Haemophilus Influenzae Type b Conjugate Vaccine for the prevention of Groups A and C meningococcal disease and Hib disease in infants in January 2002 and completed preclinical studies in December 2005. Zhifei Biopharma and we received CTA approval for Meningococcal Groups A and C and Haemophilus Influenzae Type b Conjugate Vaccine in February 2007, and completed a Phase I clinical trial in April 2007 and a Phase II clinical trial in January 2008. Zhifei Biopharma completed a Phase III clinical trial in April 2011. We and Zhifei Biopharma co-sponsored the Phase I clinical trial and Phase II clinical trial, and Zhifei Biopharma sponsored the Phase III clinical trial for Meningococcal Groups A and C and Haemophilus Influenzae Type b Conjugate Vaccine in China.

Group A and C Meningococcal Polysaccharide Vaccine. Zhifei Biopharma and we commenced the co-development of Group A and C Meningococcal Polysaccharide Vaccine for the prevention of Groups A and C meningococcal disease in people over two years of age in January 2002 and completed preclinical studies in February 2006. Zhifei Biopharma and we received CTA approval for Group A and C Meningococcal Polysaccharide Vaccine in July 2007, completed a Phase I clinical trial in September 2007 and completed a Phase III clinical trial in April 2008. We and Zhifei Biopharma co-sponsored the Phase I clinical trial and Phase III clinical trial for Group A and C Meningococcal Polysaccharide Vaccine in China.

Meningococcal Group A and C Polysaccharide Conjugate Vaccine. We commenced the independent development of Meningococcal Group A and C Polysaccharide Conjugate Vaccine for the prevention of Groups A and C meningococcal disease in infants and young children in March 2002 and completed preclinical studies in February 2003. We received CTA approval for Meningococcal Group A and C Polysaccharide Conjugate Vaccine in November 2003, completed a Phase I clinical trial in December 2003 and completed a Phase III clinical trial in September 2004. We sponsored the Phase I clinical trial and Phase III clinical trial for Meningococcal Group A and C Polysaccharide Conjugate Vaccine in China. We received NDA approval for Meningococcal Group A and C Polysaccharide Conjugate Vaccine from the NMPA in May 2006.

In October 2008, we entered into a technology transfer agreement with Zhifei Biopharma ("**2008 Zhifei License Agreement**") in order to leverage Zhifei Biopharma's production capacity to accelerate the commercialization of the Bacteria Vaccines. Pursuant to the 2008 Zhifei License Agreement, we assigned Zhifei Biopharma the intellectual property rights in and to the Bacteria Vaccines and transferred technical data and materials to produce the Bacteria Vaccines to Zhifei Biopharma for a total of RMB19.8 million, which was a one-off payment. We did not receive any payment pursuant to the 2008 Zhifei License Agreement during the Track Record Period and we do not expect to receive any further payments pursuant to the 2008 Zhifei License Agreement in the future. We agreed to provide guidance to the personnel of Zhifei Biopharma to carry out production operations according to the transferred technical data in relation to the Bacteria Vaccines. Zhifei Biopharma solely owns all rights, titles, and interests in and to all innovations or improvement for the Bacteria Vaccines by Zhifei Biopharma or us regardless of inventorship, authorship, or other origination. The confidentiality period of the trade secrets in relation to the Bacteria Vaccines that were transferred to Zhifei Biopharma was a period of 10 years from the signing date of the 2008 Zhifei License Agreement. When we entered into the 2008 Zhifei License Agreement, Haemophilus Influenzae Type b Conjugate Vaccine, Meningococcal Groups A and C and Haemophilus Influenzae Type b Conjugate Vaccine and Group A and C Meningococcal Polysaccharide Vaccine were in the clinical stage, and Group $ACYW_{135}$ Meningococcal Polysaccharide Vaccine and Meningococcal Group A and C Polysaccharide Conjugate Vaccine were already commercialized. Currently, all of the Bacteria Vaccines have been commercialized. After entering into the 2008 Zhifei License Agreement, we did not incur any expenses in relation to the Bacteria Vaccines nor are we obligated to pay for any expenses in relation to the Bacteria Vaccines after they were transferred to Zhifei Biopharma. Zhifei Biopharma is the MAH of the Bacteria Vaccines. Except for China, we have the global rights to develop and commercialize the Bacteria Vaccines. We currently have no global commercialization plan for the Bacteria Vaccines because we do not own any patents in other countries in relation to the Bacteria Vaccines. Furthermore, the global market for the Bacteria Vaccines is highly saturated with many similar products, and therefore, we have no plan to pursue global commercialization for the Bacteria Vaccines. Zhifei Biopharma is an independent third party.

RELATIONSHIP WITH ZHIFEI BIOPHARMA

Zhifei Biopharma, formerly known as Beijing Luzhu Biopharmaceutical Co., Ltd., is a biotech company based in Beijing that is focused on researching, manufacturing, and selling vaccines and biological products, and a wholly owned subsidiary of Chongqing Zhifei Biological Products Co., Ltd., a Shenzhen Stock Exchange-listed biotech company. As of the Latest Practicable Date, Zhifei Biopharma and Chongqing Zhifei Biological Products Co., Ltd. were Independent Third Parties.

During the first few years of operation since 2001, we focused on R&D instead of commercialization and did not establish our own commercial manufacturing facilities. We built the Beijing R&D and Pilot Manufacturing Facility, which only has limited production capacity because the industrial steam supplied to the Beijing R&D and Pilot Manufacturing Facility does not support the commercial production of vaccine products. In order to accelerate the commercialization of the Bacterial Vaccines of the Company, in October 2003, we, Mr. KONG Jian, and one other Independent Third Party jointly established Zhifei Biopharma to engage in the manufacturing of Meningococcal Group A and C Polysaccharide Conjugate Vaccine, Group $ACYW_{135}$ Meningococcal Polysaccharide Vaccine, and other vaccines, with an initial registered capital of RMB2.0 million. As of the date of establishment, Zhifei Biopharma was a subsidiary of us and was owned as to 80.0% by us, 5.0% by Mr. KONG and 15.0% by the other Independent Third Party, respectively. Zhifei Biopharma completed the construction of manufacturing facilities in 2005. Zhifei Biopharma obtained a series of capital increases from Chongqing Zhifei Biological Products Co., Ltd. to build the manufacturing facilities and Chongqing Zhifei Biological Products Co., Ltd. thereby became a shareholder of Zhifei Biopharma.

As our co-founders decided to pursue an R&D focused business strategy, and Chongqing Zhifei Biological Products Co., Ltd. decided to pursue a manufacturing and commercialization focused business strategy, in August 2008, shareholders of Zhifei Biopharma reached an agreement that Chongqing Zhifei Biological Products Co., Ltd. would purchase all other shares of Zhifei Biopharma from us, Mr. KONG, Ms. ZHANG Yanping, and Ms. JIANG Xianmin, who are our co-founders and Zhifei Biopharma's shareholders at the time of the proposal, in order to facilitate the development of the manufacturing and commercialization capabilities of Zhifei Biopharma and Chongqing Zhifei Biological Products Co., Ltd., and provide us with capital to support the R&D of our product candidates. In September 2008, Chongqing Zhifei Biological Products Co., Ltd. acquired Zhifei Biopharma and Zhifei Biopharma became a wholly-owned subsidiary of Chongqing Zhifei Biological Products Co., Ltd. After Chongqing Zhifei Biological Products Co., Ltd. acquired Zhifei Biopharma and up to the Latest Practicable Date, we, the Directors, Mr. KONG, Ms. ZHANG, and Ms. JIANG no longer held any shares in Zhifei Biopharma. In October 2008, we entered into the 2008 Zhifei License Agreement in order to leverage Zhifei Biopharma's production capacity to accelerate the commercialization of the Bacteria Vaccines. In July 2011, we entered into the 2011 Zhifei License Agreement in order to leverage Zhifei Biopharma's production and strong sales capacity to ensure the successful commercialization of Inactivated EV71 Vaccine. In 2013, Zhifei Biopharma was renamed as Beijing Zhifei Luzhu Biopharmaceutical Co., Ltd.

RESEARCH AND DEVELOPMENT

In-house Research and Development

Our in-house R&D team is involved in all stages of novel vaccine and biologic therapeutic candidates development, from pre-clinical studies, laboratory research, to clinical trials, regulatory filings and manufacturing process development. We have established a full range of in-house product discovery capabilities, including recombinant protein design and optimization, amplification, cultivation and harvesting. Leveraging our Fabite® technology platform, our mammalian expression technology platform and our deep understanding of recombinant protein engineering, we are focused on building out a diversified and advanced discovery pipeline of novel vaccines and biologic therapies targeting a broad spectrum of infectious diseases, cancer, autoimmune diseases and biologic targets. See also "— Our Research and Development Platforms" in this section for more information.

Led by our management team and supported by our in-house R&D team, we have adopted an efficient approach to identify proven targets, such as antigens, that have produced effects during treatment to optimize, transform and develop into product candidates that enhance our portfolio for the treatment of cancer and autoimmune diseases. Furthermore, we take into consideration unmet medical needs, scientific rationale, commercial potential, synergies with our existing product portfolio, competition, manufacturing capacity, commercialization capability, timelines and costs to evaluate whether to move forward with development. For each product candidate, we carefully design a detailed development plan in order to utilize our resources effectively and to efficiently complete the development process. During the preclinical stage, we conduct extensive early-stage investigation in relation to efficacy and safety of our product candidates. Prior to beginning clinical development, we evaluate the preclinical data of our product candidates to assess whether regulatory requirements are met and the likelihood of regulatory approval, and conduct a market evaluation weighing factors including competition, research results and market forecast through a risk-benefit assessment to avoid unnecessary costs, efforts, delays and market failures.

We are committed to developing innovative human vaccines and therapeutic biologics and have demonstrated strong R&D capabilities with a robust product pipeline of innovative vaccines and therapeutic biologics as well as extensive R&D experience and an innovative precision protein engineering platform.

We have established a diversified and advanced product pipeline of innovative human vaccines and therapeutic biologics. We have independently developed our Core Product, LZ901, an innovative human vaccine and recombinant vaccine product candidate featuring a specific molecular structure and mechanism, improved immunogenicity, and high safety and stability profile. LZ901 has a tetrameric molecular structure to prevent shingles caused by VZV for adults aged 50 years and older. We successfully completed pre-clinical studies and a Phase I clinical trial for LZ901, and expect to file the BLA for LZ901 to the NMPA in the third quarter of 2024. In addition, we are seeking global filing for LZ901 and received IND approval from the FDA in July 2022 for LZ901, which demonstrates our outstanding R&D and product development capabilities as one of the few vaccine companies in China to receive an IND approval from the FDA, as confirmed by Frost & Sullivan.

Our other innovative human vaccines in our product pipeline include two independently developed recombinant vaccine product candidates in the pre-clinical stage, namely Recombinant Varicella Vaccine and Recombinant Rabies Vaccine. Currently, there are no clinical stage or commercialized varicella vaccines or rabies vaccines in China based on recombinant protein technology. Recombinant vaccines induce a human immune response while avoiding other components of pathogens that cause adverse effects on the human body, and are safe for people with weak immune systems, which make recombinant vaccines suitable for immunizing both children and adults. Recombinant Varicella Vaccine is an adjusted dosage of LZ901 for the prevention of chickenpox caused by VZV and is expected to partially replace live attenuated vaccines of the OKA strain of VZV as an alternative vaccination method, reduce the chance of children suffering from VZV infection, and reduce the risk of developing shingles in adults. Unlike other marketed live-attenuated vaccines that contain weakened forms of VZV which may lay dormant in the patient and reactivate causing shingles, Recombinant Varicella Vaccine does not contain VZV and does not carry the risk of developing into shingles. Recombinant Rabies Vaccine is a recombinant rabies glycoprotein G subunit vaccine for the prevention of rabies in humans and is a prophylactic that provides protection against rabies prior to exposure and simplifies post-exposure treatment for rabies. Recombinant Rabies Vaccine has high purity and is suitable for immunizing both children and adults.

Our innovative therapeutic biologics in our product pipeline include one independently developed bispecific antibody product candidate in the clinical stage, namely K193, and two independently developed bispecific antibody product candidates in the pre-clinical stage, namely K333 and K1932. Bispecific antibodies recognize and specifically bind to two antigens or epitopes and simultaneously block the biological functions mediated by both antigens/epitopes or draws the cells of both antigens closer together and enhances the interaction. K193 is a bispecific antibody that binds to human CD19 and CD3 and is indicated for the treatment of B cell leukemia and lymphoma. K193's molecular structure has good thermal stability and is less susceptible to polymerization, which ensures the stability and binding ability of K193. K333 is a bispecific antibody that binds to human CD33 and CD3 and is indicated for the treatment of myeloid leukemia. K1932 is a bispecific antibody that binds to human CD19 and CD3 and is indicated for the treatment of B cell lymphoma. Compared with K193, K1932 has a much longer half-life in the human body. Patients administered K1932 following the first stage administration of K193 have lower risk of experiencing a cytokine storm, which allows for dose escalation. After the induction period of K193, K1932 can be administered on a weekly basis, which greatly improves the medication experience of B cell lymphoma patients.

With respect to our R&D experience, we have historically developed a broad range of human vaccines and therapeutic biologics, including bacteria vaccines, inactivated vaccines and monoclonal antibodies. We have made various breakthroughs in the R&D of bacteria vaccines, including completing pre-clinical studies and clinical trials and obtaining NDA approvals. Our leading R&D personnel, who have extensive biopharmaceutical experience, developed the world's first liquid formulation Meningococcal Group A and C Polysaccharide Conjugate Vaccine, the world's first Meningococcal Group A and C and Haemophilus Influenzae Type b Conjugate Vaccine, China's first Haemophilus Influenzae Type b Conjugate Vaccine with aluminum phosphate adjuvant, and China's first Group $ACYW_{135}$ Meningococcal Polysaccharide Vaccine. We independently developed the Bacteria Vaccines, and when we transferred the Bacteria Vaccines to Zhifei Biopharma in October 2008, the Bacteria Vaccines were mostly in the late clinical stage or commercialized. In addition, we independently developed K11, a humanized anti-VEGF monoclonal antibody injection product candidate and a biosimilar of bevacizumab. K11 is mainly used for the treatment of colorectal cancer, lung cancer and other cancers. We initiated the development of K11 in June 2012, completed pre-clinical studies for K11 in September 2015 and received CTA approval for K11 from the NMPA in April 2017 before transferring K11 to Beijing Science Sun in July 2019.

The R&D of technology platforms is time- and resource-consuming and requires strong R&D capabilities. We internally developed an innovative precision protein engineering platform comprising five technology platforms (including Fabite® technology platform, targeted recombinant antigen presentation technology platform, polysaccharide-protein conjugation technology platform, protein purification technology platform and protein stability technology platform). These technology platforms empower the full cycle of drug development to improve product efficiency, purity and stability, which provide a solid foundation for the development of human vaccine, monoclonal antibody, and bispecific antibody product candidates. From 2001 to 2008, we had established and refined our polysaccharide-protein conjugation technology platform to develop the Bacteria Vaccines. From 2009 to the Latest Practicable Date, we had established and refined our Fabite® technology platform, targeted recombinant antigen presentation technology platform, polysaccharide-protein conjugation technology platform, protein purification technology platform and protein stability technology platform to develop seven product candidates, including three product candidates in the clinical stage and four product candidates in the pre-clinical stage.

As of the Latest Practicable Date, our research and development team consisted of 71 personnel in China, most of whom hold bachelor's or higher degrees, mainly majoring in bioengineering, biology, organic chemistry, pharmaceutical engineering and pharmaceutical sciences. Nearly a third of our researchers have more than ten years of industry experience, and almost half of our researchers have at least five years of industry experience. The team is led by Mr. KONG Jian, our co-founder, executive Director, general manager and chief scientist, who has over 33 years of biopharmaceutical experience. For details of the background of Mr. KONG, please see "Directors, Supervisors and Senior Management" in this document. We plan to expand our research and development team to approximately 80 to 120 personnel in the next one to two years based on development and launch plans of our product candidates. As of the Latest Practicable Date, we do not have research and development personnel in the U.S., but we currently have one administrative personnel in the U.S., who is mainly responsible for our business development overseas and will supervise the Phase I clinical trial of LZ901 in the U.S. In addition, we have engaged a CRO to support the research and development of LZ901 in the U.S. since November 2022.

Our research and development expenses primarily consisted of staff costs, including salaries, welfare and share-based payment to our research and development personnel, third-party contracting costs, costs of raw materials and depreciation and amortization. Our research and development expenses increased from RMB43.0 million in 2021 to RMB91.4 million in 2022, largely due to (i) an increase of share-based payments of RMB15.7 million primarily arising from the share options and awards we granted to our research and development personnel and (ii) an increase of sub-contracting costs of RMB12.5 million mainly arising from our Phase I clinical trial and Phase II clinical trial for LZ901. The research and development expenses incurred for our Core Product, excluding share-based payments, amounted to RMB6.2 million and RMB38.2 million in 2021 and 2022, respectively. As our research and development expenses incurred for our Core Product (excluding share-based payments) increased by RMB32.0 million from 2021 to 2022, primarily relating to our initiations of the Phase I clinical trial and the Phase II clinical trial for LZ901 in China in 2022, the proportion of the research and development expenses incurred for our Core Product (excluding share-based payments) in our total research and development expenses (excluding share-based payments) increased from 38.3% in 2021 to 78.1% in 2022, and the proportion of our total research and development expenses in our total operating expenses* increased from 41.7% in 2021 to 51.6% in 2022. The proportion of our total research and development costs (excluding share-based payments) in our total cash operating costs increased from 80.0% in 2021 to 82.6% in 2022.

Note:

* Operating expenses consist of research and development expenses and administrative expenses.

Our Research and Development Platforms

Fabite® Technology Platform

Our internally developed next-generation Fab-scFv bispecific antibody development platform, Fabite®, of which we own intellectual property rights, has competitive advantages in the development of bispecific antibody products for the treatment of relapsed/refractory hematological malignancies. It uses humanized Fab fragments to bind to target antigens on the surface of malignant tumor cell membranes and scFv to bind to T cells, which activates the T cells to kill the malignant tumor cells. The humanized Fab fragments strongly bind to the tumor target protein, while the scFvs weakly bind to T cells, which ensures that the tumor target protein is bound. The bispecific antibodies developed by our Fabite® technology platform are capable of binding to two targets and have a molecular design that not only ensures the targeting of the bispecific antibodies but also does not over activate T cells. Our Fabite® technology platform has a fully controllable mechanism of action and mode of administration to ensure the safety of patients. It can be used in a variety of immunotherapies based on the activation of T cells to kill malignant tumor cells. Our Fabite® technology platform optimizes the purification process of bispecific antibodies, achieving high purity of monomers.

We have developed three bispecific antibody injection product candidates, namely K193, K333 and K1932, using our Fabite® technology platform, the production process of which achieves consistent quality and high bispecific antibody yield and purity, featuring favorable safety profile and fewer side effects.

Targeted Recombinant Antigen Presentation Technology Platform

Our targeted recombinant antigen presentation technology platform forms antigen expressing RICs, and directly presents viral membrane antigens to APCs, which simulates the natural human immune system response to invading microorganisms. The recombinant protein vaccine candidates developed by our targeted recombinant antigen presentation technology platform have a molecular design that include a genetically engineered target viral membrane antigen containing multiple Fc regions that bind to APCs. Once bound to the APC, the APC engulf the antigen and then presents the antigen to other immune cells, which elicits an immune response to target viruses. Our targeted recombinant antigen presentation technology platform greatly enhances the utilization efficiency of antigens and can induce high-titer specific antibodies and cellular immunity. Furthermore, the antigens expressed by our targeted recombinant antigen presentation technology platform contain multiple Fc regions, which is an improvement upon traditional fusion protein technology that only expresses antigens with a single Fc region.

We have developed three recombinant protein vaccine candidates, namely LZ901, Recombinant Varicella Vaccine and Recombinant Rabies Vaccines, using our targeted recombinant antigen presentation technology platform.

Polysaccharide-Protein Conjugation Technology Platform

Our polysaccharide-protein conjugation technology platform links bacteria polysaccharides to carrier proteins. This technology platform can be used to develop conjugate vaccines and antibody-drug conjugates. We utilized our polysaccharide-protein conjugation technology platform to develop three bacterial polysaccharide-protein conjugate vaccines, which have enhanced immunogenicity and stability, and are in easy to administer liquid dosage forms.

We have historically developed three commercialized vaccine products, namely (i) Haemophilus Influenzae Type b Conjugate Vaccine, (ii) Meningococcal Groups A and C and Haemophilus Influenzae Type b Conjugate Vaccine and (iii) Meningococcal Group A and C Polysaccharide Conjugate Vaccine, using our polysaccharide-protein conjugation technology platform.

Protein Purification Technology Platform

We have developed technology to purify complex recombinant proteins, such as humanized monoclonal antibodies and complex glycosylated proteins. We use a high-speed centrifugation or deep filtration workflow to isolate proteins in cell culture media, which is highly effective in removing cells and cellular debris from the soluble protein. In addition, we employ a series of chromatographic techniques during the protein purification process. First, we attach affinity protein tags to proteins of interest during the construct design and conduct affinity chromatography to purify and improve the solubility of the proteins of interest. Second, we perform an additional chromatographic step such as ion exchange chromatography or hydrophobic interaction chromatography to further increase purity. As a final polishing step, we perform size exclusion chromatography which results in high purity proteins of interest.

As proteins are highly heterogeneous and different techniques are used to purify different types of proteins, we have utilized our protein purification technology platform to increase the purity of LZ901, K3, K193 and K11 using various techniques.

Protein Stability Technology Platform

We have developed a variety of highly stable liquid formulations for human monoclonal antibodies, bispecific antibodies and recombinant protein vaccines. Our in-solution protein-stabilizers offer longer stability by extending the shelf life of antibodies, antigens and other recombinant proteins at working strength concentrations. In addition, they offer retained activity of most monoclonal antibodies or bispecific antibodies in solution for up to five years. Our liquid protein stabilizers also offer a variety of options for immune-assay development. We offer multiple formulations with different stabilizing mechanisms to satisfy different antibody or antigen requirements. Our formulations are protein-free that are able to satisfy the background requirements for human drugs or specific assay systems and stabilize enzymes and control materials in immunoassays.

All of our human vaccines candidates, monoclonal antibody product candidates and bispecific antibody product candidates utilize protein-stabilizers developed using our protein stability technology platform to enhance stability.

Mammalian Expression Technology Platform

We have used the GS Xceed^{TM} expression system from Lonza in combination with our internally developed recombinant protein purification process to increase the purity of protein expression to a leading level. The system covers a wide range of technologies and processes such as host cell lines, a range of vectors, and access to optimize culture media and feeds and detailed system know-how, and provides high-quality, high-efficiency and high-capacity production services for a variety of biopharmaceuticals.

We have increased the purity and expression levels of LZ901 and K193 using our mammalian expression technology platform.

Clinical Development Team

As of the Latest Practicable Date, our medical affairs and clinical operations team consisted of ten members. Our medical affairs and clinical operations team is led by our co-founder, Chief Medical Officer and deputy general manager, Ms. JIANG Xianmin, who has over 37 years of experience in biopharmaceutical research and development.

The clinical development team manages all stages of clinical trials, including clinical trial design, implementation, drug supply, and the collection and analysis of trial data. Each of our clinical development programs is led by a program leader who (i) formulates a clinical development plan, (ii) designs the trial protocol and (iii) oversees the trial execution, all with support from relevant team members. We employ an adaptive clinical trial design strategy to achieve efficiency in product development processes and potentially accelerate approvals for our product candidates. Our clinical development unit is also responsible for the selection of trial sites. To maximize trial efficiency, we strategically select trial sites based on their location in proximity to major metropolitan cities, number of addressable patients, and principal investigators in order to optimize trial speed, cost effectiveness, and cultural compatibility. We plan to enter into agreements with hospitals and principal investigators located worldwide that can support our various stages of clinical trials and indications.

Relationships with Third Parties in Research and Development

In line with industry norms, we outsource certain pre-clinical studies and clinical trial-related activities to CROs and SMOs that are independent from our Group. We select CROs and SMOs based on various factors, including their quality, reputation and research experience in the vaccine field. The services provided by CROs include helping us select and work with clinical trial institutions, to implement the trial protocols and execute the clinical trials, and to prepare materials for NDA filings. We closely monitor and manage the activities of these CROs to ensure their progress and quality, including (i) requiring CROs to conduct clinical trials in accordance with the agreed-upon protocols and GCP requirements; (ii) conducting periodic review of progress of clinical trials; and (iii) requiring CROs to offer assistance to audit clinical trials. We also outsource certain pre-clinical studies activities to CROs. Such activities primarily include safety and immunogenicity evaluation. Key terms of these agreements with CROs are summarized as follows:

- *Services*. With respect to pre-clinical studies, the CROs mainly help us conduct safety and immunogenicity evaluation by conducting tests on animals. With respect to clinical trials, the CROs are responsible for assisting in preparing clinical trial protocols and trial plans, clinical monitoring and inspection, clinical research coordination, data management, and medical monitoring.

- *Term*. For pre-clinical studies, contract term is typically one year or the duration of the study. The agreements for clinical trials typically do not have a fixed term, and agreements generally expire after the completion of the relevant clinical trials and passing of NMPA inspection.

- *Payments*. We are typically required to make payments to CROs by installments according to milestones of respective services during the trials and clinical studies.

- *Intellectual property rights*. All intellectual property rights arising from the pre-clinical studies and clinical trials conducted by CROs are owned by us.

During the Track Record Period, we also engaged an SMO to assist researchers to complete certain supporting duties in relation to our ongoing Phase I clinical trial of K193, including collecting source data and providing progress reports, among others.

In 2021 and 2022, we engaged 18 CROs and one SMO to manage, conduct and support our clinical trials and pre-clinical studies, and the aggregate service fees paid by us to such CROs and SMO were RMB2.0 million and RMB8.9 million, respectively. We determine the service fee for such CROs and SMO based on the expected or actual work performed by the CRO or SMO as well as the estimated or actual cost incurred on an hourly, monthly or by project basis. The following table sets forth the detailed information of the key CROs and SMO engaged by us during the Track Record Period:

Identity	Background	Primary Involvement	Service fees paid by us during the Track Record Period
			RMB'000
CRO A	A company that provides CRO services, including large sample, multi-center clinical trial operations, data management and statistical analysis	Provision of project management, clinical supervision and medical affairs services for the Phase I clinical trial for LZ901	4,050.1
CRO B	A company that provides CRO services, including clinical trial operations, medical writing and translation, medical registration services, statistical analysis, independent audits and pharmacovigilance	Provision of pre-clinical pharmacology research, pre-clinical safety evaluation and subject sample detection in Phase I clinical trials for LZ901 and K193	2,274.7
Hangzhou Tigermed Consulting Co., Ltd.*	A company that provides services for new drug research and development and other supporting services to global and Chinese pharmaceutical and biotechnology companies	Provision of U.S. filing clinical registration services for the development of LZ901	1,696.2
CRO C	A company that provides CRO services, including clinical trial data management and statistical analysis	Provision of data management and statistical analysis services for the Phase I clinical trial for LZ901	794.0
CRO D/SMO A	A company that provides CRO and SMO services including project evaluation, research and development, registration management, clinical trials and post-marketing studies, and clinical trial site management	Provision of clinical trial project management, inspection and verification services, and clinical trial site management services in the development of K193	75.8

Note:

* Provided CRO services during the Track Record Period.

During the Track Record Period, none of our CROs and SMO, other than Hangzhou Tigermed Consulting Co., Ltd., (being one of our [**REDACTED**] Investors) including their directors, shareholders and senior management, had any past or present relationship with us or our subsidiaries, shareholders, directors or senior management, or any of their respective associates. For further details of Hangzhou Tigermed Consulting Co., Ltd., see "History, Development and Corporate Structure — [**REDACTED**] Investments — Background of the [**REDACTED**] Investors — 5. Hangzhou Taikun" in this document.

MANUFACTURING

Manufacturing Team

Our manufacturing team is led by our deputy general manager and head of manufacturing and engineering, Mr. HAN Chaowei, who has 21 years of experience in the biopharmaceutical industry. As of the Latest Practicable Date, we had 29 manufacturing personnel. We will provide training to our manufacturing personnel to ensure that they possess the skill sets and techniques required in the relevant production process, and comply with our quality control requirements, as well as applicable laws and regulations.

Beijing R&D and Pilot Manufacturing Facility

We have a self-owned R&D and pilot manufacturing facility located in Beijing, China to supply materials for our pre-clinical studies and early-stage clinical trials of every product candidate, which occupies approximately 27 acres of land with a total GFA of approximately 3,757 sq.m. in the R&D and production area. The material refers to the bulk solution that can be used to prepare samples for pre-clinical and clinical research of our product candidates after fermentation and culture in a bioreactor and a series of chromatographic purification. Our Beijing R&D and pilot manufacturing facility has 5L, 10L, 15L, 40L, 50L, 75L and 500L stainless steel bioreactor capacity as well as a pilot-scale drug product (DP) filling line. Utilizing our Beijing R&D and pilot manufacturing facility, we have supplied materials for pre-clinical studies and early-stage clinical trials for our product candidates, including LZ901, K3, K193, Recombinant Varicella Vaccine, Recombinant Rabies Vaccine, K333 and K1932. As of the Latest Practicable Date, we owned all the equipment and machinery used in our manufacturing process. During the Track Record Period, we did not outsource any manufacturing activities of our product candidates to CDMOs.

The following table sets forth our manufacturing capacity, manufacturing volume and utilization rate of our Beijing R&D and Pilot Manufacturing Facility for the periods indicated.

	For the year ended December 31.	
	2021	**2022**
Manufacturing capacity *(batch)*[(1)]	40	40
Actual manufacturing volume *(batch)*	24	30
Utilization rate *(%)*[(2)]	60.0	75.0

Note:

(1) The production of one batch means one fermentation in the selected bioreactors. Our Beijing R&D and pilot manufacturing facility is only used to support pre-clinical studies and early-stage clinical trials and phase I and phase II clinical research. It has a small volume of production capacity with 5L, 10L, 15L, 40L, 50L, 75L and 500L stainless steel bioreactors. During the pilot production, we select the bioreactors with appropriate scale according to the development stage of our product candidate for pilot production.

(2) Utilization rate is calculated based on the actual manufacturing volume of the relevant period divided by the manufacturing capacity for the relevant period, multiplied by 100%.

Beijing R&D and Commercial Manufacturing Facility

We plan to commence construction of a new R&D and manufacturing facility in Beijing in the second quarter of 2023 and expect to complete construction of the new Beijing R&D and manufacturing facility in the first quarter of 2025. The new Beijing R&D and manufacturing facility is expected to have a total production capacity of eight million doses of Recombinant Varicella Vaccine a year and four million doses of Recombinant Rabies Vaccine a year. The utilization rate of the new Beijing R&D and manufacturing facility is expected to increase form less than 5% from 2024 to 2026, to 60%-90% after 2027 given the commercialization of Recombinant Varicella Vaccine and Recombinant Rabies Vaccine. We will adjust our actual capacity based on our marketing plan and the market conditions.

Zhuhai Commercial Manufacturing Facilities

In January 2018, we began to explore various sites in China for constructing a manufacturing facility, but did not locate a suitable plot of land to build our manufacturing facility until December 2020, when the plot of land to build our first- and second-phase Zhuhai manufacturing facilities became available. After we bought the land in April 2021, we began construction of our first- and second-phase Zhuhai manufacturing facilities. We commenced operations at our first-phase Zhuhai manufacturing facility and are constructing our second-phase Zhuhai manufacturing facility to expand our production in preparation for commercialization of our pipeline candidates. Currently, our existing Zhuhai manufacturing facility occupies a total GFA of approximately 8,000 sq.m. and is equipped with several 500L stainless steel bioreactors, purification equipment and a high-speed vial filling linkage line.

We commenced construction of our second-phase manufacturing facility in April 2022, and expect to complete the construction of the second-phase Zhuhai manufacturing facility in the second quarter of 2023, which is expected to commence operations by the second quarter of 2023. Our first- and second-phase Zhuhai manufacturing facilities, as planned and approved by the local government agency, occupy approximately 69,366 sq.m. of land with a total GFA of approximately 120,000 sq.m. in the production area. The second-phase Zhuhai manufacturing facility will be equipped with multiple 2.5-ton stainless steel bioreactors and two antibody biopharmaceutical production workshops. In total, the first-phase Zhuhai manufacturing facility and the second-phase Zhuhai facility will have an annual capacity to manufacture 20 million doses of LZ901, three million doses of K193 and two million doses of K3.

The construction standards of the above-mentioned manufacturing facilities in Zhuhai are designed according to international standards and are expected to meet the GMP requirements of the NMPA, the EMA, the FDA and related ICH guidelines. We will equip our workshops with appropriate facilities, equipment and instruments to enhance the quality management systems in chemistry, manufacturing and controls of large-scale production.

The following table sets forth the timeframe of the commencement and completion of the construction and (expected) manufacturing capacity and utilization rate of each existing and planned manufacturing facility by each product type. For the development status and commercialization plans of relevant product candidates, please see "— Our Products and Product Candidates — Our Core Product and Clinical-Stage Product Candidates" and "— Commercialization" in this section.

Manufacturing Facility		Commencement of the Construction	Completion of the Construction	Capacity[1]	Expected Average Utilization Rate[5]	
					2025-2027	2028-2030
Zhuhai manufacturing Facility	First-phase	July 2021	April 2022	LZ901: 20 million doses a year[2]	~42%-47%	~89%
	Second-phase	April 2022	2023Q2	K193: 3 million doses a year[3] K3: 2 million doses a year[4]		

Notes:

(1) The capacity represents the total capacity to produce end products of the firs-phase Zhuhai manufacturing facility and second-phase Zhuhai facility. The production capacities of our product candidates were estimated based on (i) the number of working hours needed for a production worker to manufacture or package and storage one unit of stock solution of our product candidates; (ii) the number of production workers designated by us for the manufacturing of our product candidates during the respective year; (iii) each of our production workers works eight hours per day and 250 days per year; and (iv) our production lines operated on a one-shift per day basis.

(2) The production process of LZ901 includes the production of stock solution, sub-packaging, packaging and storage. In relation to the manufacturing capacity of LZ901, the first-phase Zhuhai manufacturing facility only has a capacity of stock solution manufacturing of 14 million doses for LZ901 a year, to support the Phase III clinical trial and the initial stage of commercialization of LZ901 as the first-phase Zhuhai facility has limited production area and equipment. The second-phase Zhuhai manufacturing facility has the capacity of sub-packaging, packaging and storage of 20 million doses for LZ901 a year. The second-phase Zhuhai manufacturing facility will reserve a production line for stock solution manufacturing with capacity of 6 million doses a year, to support the further commercialization in domestic and overseas markets of LZ901.

(3) In relation to the manufacturing capacity of K193, the first-stage Zhuhai manufacturing facility has a capacity to produce 1 million doses end products of K193 a year, to support clinical trials of K193. The second-phase Zhuhai manufacturing facility has a capacity to produce 2 million doses end products of K193 a year to support the BLA submission and commercialization of K193.

(4) The second-phase Zhuhai manufacturing facility has a capacity to produce 2 million doses end products of K3 a year to support clinical trials and commercialization of K3.

(5) Utilization rate is calculated based on the average manufacturing volume divided by the manufacturing capacity for the relevant period, multiplied by 100%.

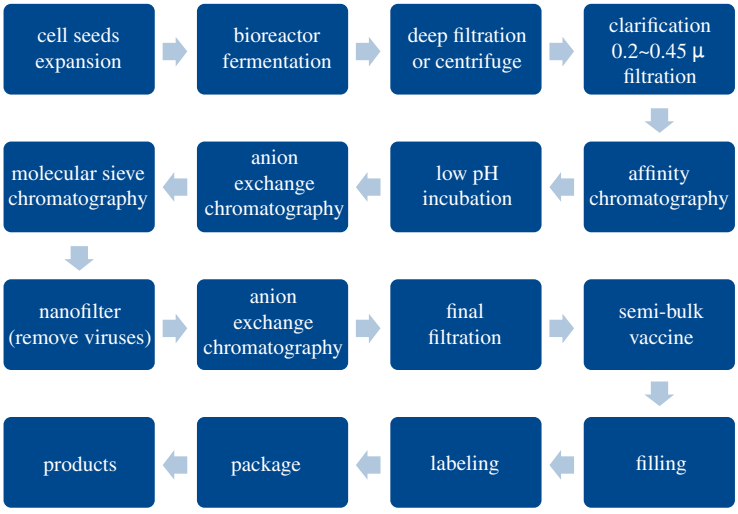
(6) The abovementioned manufacturing volume and utilization rate is based on our marketing plan and the market conditions, and may be different from actual circumstances in the relevant period.

Manufacturing Process

Our ability to manufacture different vaccines in large scale is demonstrated by the unique production processes and techniques used for each of our vaccine products. Below are the manufacturing process charts that highlight the key steps in producing our vaccine and therapeutic biologics product candidates.

Vaccine Manufacturing Process:

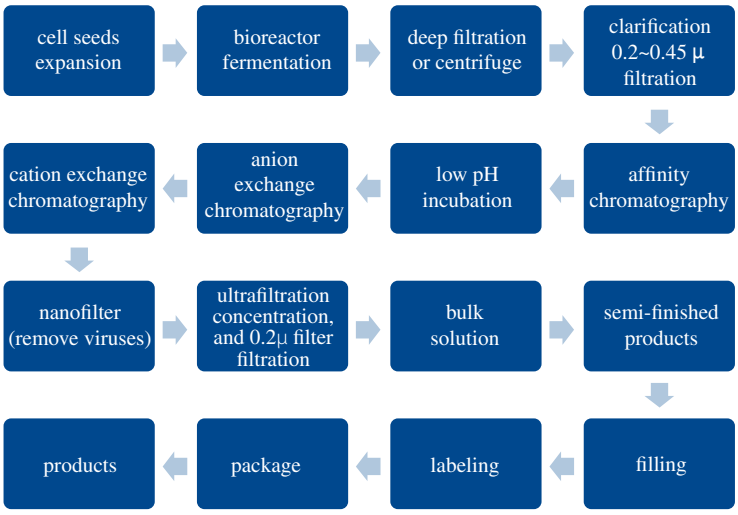
Our vaccine manufacturing process includes the following steps: cell seed expansion, fermentation culture, depth filtration, clarification and harvest, affinity chromatography, inactivation, anion exchange chromatography, molecular sieve chromatography, virus removal by nanofiltration, diethylaminoethyl ("**DEAE**") anion exchange chromatography (or ultrafiltration) exchange buffer, sterilization and virus removal filtration, stock solution storage, adjuvant preparation, semi-finished products preparation, formulation filling, packaging and labeling, boxing and palletizing, finished product storage. Below is the manufacturing process chart that highlights the key steps in producing our vaccine product candidates.



Antibody Manufacturing Process:

Our antibody drug manufacturing process includes the following steps: cell seed expansion, fermentation culture, deep filtration (or high speed centrifugation), clarification, affinity layer analysis, low pH incubation and pH adjustment, anion exchange chromatography, cation exchange chromatography, virus removal by nanofiltration, ultrafiltration concentration shrinkage, adding antibody protection solution, stock solution storage, semi-finished product preparation, preparation

filling, boxing and testing, finished product storage. Below is the manufacturing process chart that highlights the key steps in producing our antibody drug product candidates.



QUALITY CONTROL AND ASSURANCE

The quality and safety of our vaccine and therapeutic biologics products are crucial to our continued success. We endeavor to ensure the quality of our operations through a comprehensive quality management system. Our quality management system was designed to adhere to applicable national standards, including the GMP standards, covering substantially every aspect of our operations including product design, raw materials and manufacturing, among others.

Our Quality Control System

We have an experienced quality management team, consisting of 27 personnel as of the Latest Practicable Date. All of our Zhuhai quality management team members have received professional training in regulations, GMP standards and quality control analysis methods. After the commercialization of K3, we plans to employ 10 more personnel to enlarge the quality management team and further enhance the quality management systems. We have implemented quality management systems that conform to national regulations and industry guidelines and adopted standard operating procedures. All of our manufacturing facilities are designed and maintained, and we implement quality standards, in conformity with GMP standards adopted by NMPA, the EMA, the FDA and related ICH guidelines. GMP is the basic principle of pharmaceutical manufacturing and quality management for ensuring that products are consistently produced while achieving the required quality.

Quality Control of Raw Materials

We have established detailed internal rules governing the selection of raw material suppliers and raw material quality control. We purchase raw materials only from suppliers of which we have verified business qualifications and product quality. We select suppliers based on a variety of factors including qualifications, business reputation, production scale, technological strengths, quality management capabilities, after-sales services and price. After initial screening by our procurement department, we typically request product samples from a supplier, which is examined by our quality management team. The examination result provides an important basis for our supplier selection decisions. In addition, we

would conduct on-site quality audit at the supplier's manufacturing facilities, and we require the supplier to execute a quality guarantee agreement with us. Our purchased supplies are inspected, and for supplies that do not pass our inspection, they will be transferred to our warehouse, categorized as unqualified supplies, pursuant to our protocols regarding non-conforming products.

Quality Control of Manufacturing

Our quality management team is responsible for ensuring that our manufacturing processes consistently conform to applicable standards through regular on-site inspections. We perform cleaning and maintenance procedures in accordance with the regulations. Each batch of our products is subject to internal inspection before lot release to ensure the product has met the quality requirements. We conduct sample testing on certain work in progress at particular stages of production. Our quality assurance department also inspects the documentation relating to product quality, including the laboratory control records and production process records. Products that do not meet our quality standards will be destroyed or otherwise disposed of in accordance with the relevant disposal requirements.

COMMERCIALIZATION

According to Frost & Sullivan, our vaccine candidates, once approved, are not likely to be included in the National Immunization Program, which primarily aims to protect children in China. When determining the types of vaccines to be included in the National Immunization Program, the government would consider various factors, such as the prevalence of infectious diseases, disease burden, effectiveness and safety of the vaccine, the supply capacity of vaccine manufacturers, adequate government funds and social benefits. LZ901 is mainly for adults aged 50 years and older, therefore, it is unlikely to be included in the National Immunization Program in China or similar programs in the U.S. in the foreseeable future. Human rabies vaccine aims to help protect people at risk of being exposed to rabies, regardless of their age, and therefore, it is unlikely that recombinant human rabies vaccine will be included in the National Immunization Program in China. For varicella vaccine, although several economically developed cities in China, such as Beijing, Tianjin and Shanghai, have implemented policies to provide free varicella vaccination for children, it is less likely to be included in the National Immunization Program in the next three to five years since the costs will be very high for the nation to provide free varicella vaccination. The U.S. CDC recommends that adults aged 50 years and older to get two doses of Shingrix® to prevent shingles and the complications from the disease. In the 2018 Chinese Expert Consensus on Herpes Zoster*, it was mentioned that herpes zoster vaccine can significantly reduce the disease burden of herpes zoster. K3, a biosimilar of adalimumab, is likely to be included in the NRDL as adalimumab under the brand name Humira® has been included in the NRDL. However, herpes zoster vaccine, varicella and rabies vaccines are prophylactic vaccines which are not included in the NRDL. K193, K333, K1932 are Class A innovative biological products. There are no similar products in

Note:

* The 2018 Chinese Expert Consensus on Herpes Zoster is written by Chinese Dermatologist Association (CDA) under CMDA, which is registered and approved by the State Ministry of Health and the Ministry of Civil Affairs; and CDA is a national, professional, non-profit academic group voluntarily formed by practicing physicians. Experts evaluated and analyzed literature published domestically and internationally to conduct a comprehensive analysis for the expert teams to discuss and revise repeatedly to reach a consensus that will guide the clinical standardized diagnosis and treatment of herpes zoster, and provide patients with an economic and efficient diagnosis and treatment plan. Therefore, the authority and relevance of this consensus is well-recognized. There is no mandated frequency to update this consensus. Referring to expert guidance, which is another similar format for diagnosis and treatment of diseases, the recommended frequency is two to five years.

this category covered by NRDL. Therefore, our vaccine product candidates, K193, K333 and K1932 are unlikely to be included in the NRDL. Not being included under the National Immunization Program, regional equivalent immunization programs or NRDL would not affect the pricing of our product candidates as we would price our product candidates at market price. However, if peer products are included under the National Immunization Program or regional equivalent immunization programs, our peer products will gain market competitive advantage in market penetration, which would cause market pressure on our product candidates. For details, please see "Risk Factors", "Regulatory Overview" and "Industry Overview" in this document. As some of our product candidates are unlikely to be included in the NRDL, we plan to seek opportunities to collaborate with insurance companies to include such product candidates into their coverage. According to Frost & Sullivan, some of private insurance companies in China are able to provide insurance coverage for vaccines that are not covered in the NRDL. For example, certain high-end medical insurances of Taikang Insurance Group Inc. and Axa Tianping Property & Casualty Insurance Co., Ltd. provide insurance coverage for vaccines. We expect that some of the private insurance companies in China will be able to include LZ901 into their coverage in the future. Furthermore, Shingrix® is covered by commercial insurance in the United States, and thus, we expect that we will be able to collaborate with insurance companies to include LZ901 into their coverage in the U.S. as well.

As of the Latest Practicable Date, we did not have a commercialization team. Our director of overseas business development has over 17 years of experience in the biopharmaceutical industry. We are in the process of executing our launch readiness plan and formulating our sales and marketing plans in anticipation of multiple potential product launches within the next few years. The focus will be on product readiness, market readiness, and organizational readiness. As we expect our major customers to be local CDCs, hospitals and/or other medical institutions, we will focus on improving the recognition of our vaccine products among local CDCs, hospitals and physicians. In addition, since whether local CDCs, hospitals and/or other medical institutions will purchase our products ultimately depends on the vaccination willingness of individuals, we will also conduct marketing activities raising the public awareness of the relevant diseases, and the benefits and costs of receiving our vaccine products.

We plan to begin building our commercialization team ahead of the launch of our product candidates. We intend to build our commercialization capabilities through a combination of efficient and specialized internal sales and marketing teams and external marketing and distribution partnerships with CSOs, with the goal of achieving broad product access across the globe to benefit patients worldwide. We plan to set up our commercialization team in China after the filing of the BLA of LZ901. We expect to build a commercialization team with about 300 people, consisting of four departments, including sales department, marketing department, medical department, storage and transportation department.

In China, we plan to adopt a two-pronged approach for sales and marketing activities. Our commercialization team will cover Beijing, Chengdu, Guangzhou, Shanghai, Tianjin, Wuhan, Xi'an, Zhengzhou and other provincial capitals in China. We plan to engage CSOs to cover major provinces and municipalities in China, including the same cities as our commercialization team and neighboring second- and third-tier cities. We will select CSOs based on their industry experience and expertise, product sales experience, business channels, local promotion capabilities, logistics and distribution capabilities, cold-chain transportation capabilities, financial condition, record of compliance with regulatory agencies and management capabilities and other important indicators, to further improve clients' experience.

Our commercialization team will formulate the criteria for screening CSOs, determine the cooperation conditions, select CSOs, assess the performance of CSOs, participate in the discussion of CSO sales strategies, and carry out national promotion of our product candidates, while do not participate in terminal sales. CSOs will mainly be responsible for regional promotion of our product candidates, establishment of sales channels and provision of logistics services, and will regularly report market demands and other feedbacks to our commercialization team. We do not have any plan to out-license our Core Product and product candidates in China.

We intend to formulate targeted commercialization strategies for each of our product candidates in China.

- *LZ901*. To support our sales and marketing efforts for LZ901, we plan to build our commercialization team for LZ901 in or around the third quarter of 2024 upon submitting the BLA for LZ901 to the NMPA. In addition, we plan to collaborate with CSOs to increase market penetration of LZ901. Our sales and marketing strategy to jointly promote LZ901 includes selecting various CSOs, along with our commercialization team for LZ901, to cover four regions, namely Northern China, Yangtze River Delta, Greater Bay Area and Midwestern China, and providing sales goals for such CSOs based on population density, consumption level, morbidity associated with shingles, and other factors of the regions covered. Such CSOs will be responsible for sales of LZ901 in the cities and provinces of the regions that they are selected to cover. Our sales department and CSOs will look into the needs of doctors in community hospitals or grass-roots hospitals, discover the cognitive weaknesses of relevant doctors on the applicable groups of herpes zoster vaccine, the advantages and disadvantages of different herpes zoster vaccines and other key information, summarize the doctors' preference for cases, literature or other vaccine promotion methods, and provide feedback to our marketing department. We plan to adopt favorable and competitive pricing for our LZ901. LZ901 is expected to be priced at a retail price of approximately RMB500 to RMB800 an injection, with a total of two injections per treatment and does not require a third booster shot, which is more affordable compared to the retail price of the other commercially available herpes zoster vaccine in China, with Shingrix® priced at RMB1,600 an injection with a total of two injections per treatment. In addition, we also plan to provide incentives for our CSOs to further motivate our CSOs to increase sales.

  Furthermore, we plan to continuously educate and guide the market by conducting academic promotion and publishing scientific papers to introduce the advantages of LZ901. We will highlight the advantages of LZ901 compared with Shingrix®. Our commercialization team will be responsible for national promotion of LZ901, including educating the market of the advantages of LZ901 and promoting LZ901 through national media advertisements, and will collaborate with our CSOs to promote and increase market awareness of LZ901 in their respective regions, including holding academic conferences and events. Our marketing department will cooperate with not-for-profit organizations and local CDCs to organize seminars and participate in industry conferences to introduce the importance of vaccination of the herpes zoster vaccine and the competitiveness of LZ901 both to relevant doctors and the public. We will customize the forms of doctor education, including but not limited to academic lectures and seminars, to deepen doctors' understanding of the various advantages of LZ901. At the same time, our marketing department will carry out targeted marketing for the middle-aged and elderly groups and their children respectively, and create a brand image

with high quality, low price and good vaccination experience through professional education regarding the importance of vaccination of the herpes zoster vaccine and the advantages of LZ901.

Our medical department will be responsible for the collection of adverse reaction information and the treatment of adverse reactions. In order to protect the privacy of patients, we are not responsible for and the associated costs of gathering, maintaining and storing vaccination information for patients who will be administered LZ901, which is the responsibility of local CDCs and hospitals. Our storage and transportation department is responsible for the storage of LZ901 and cold chain transportation management.

- *K3*. To support our sales and marketing efforts for K3, we plan to build our commercialization team for K3 in or around the fourth quarter of 2024 upon submitting the BLA for K3 to the NMPA. Our sales and marketing strategy to jointly promote K3 includes our commercialization team for K3 and CSOs both covering four regions, namely Northern China, Yangtze River Delta, Greater Bay Area and Midwestern China. Such CSOs will be responsible for sales of K3 in the cities and provinces of the regions that they are selected to cover. Our commercialization team will be responsible for national promotion of K3, including educating the market of the advantages of K3 and promoting K3 through national media advertisements, and will collaborate with our CSOs to promote and increase market awareness of K3 in their respective regions, including holding academic conferences and events. We plan to adopt favorable and competitive pricing for our K3. K3 is expected to be priced at a retail price of approximately RMB400 to RMB500 a dose, which is more affordable compared to the retail price of the other commercially available biosimilars of adalimumab in China, which are priced at approximately RMB700 to RMB1,200 a dose.

- *K193*. To support our sales and marketing efforts for K3, we plan to build our commercialization team for K193 in 2027 after completing the Phase II clinical trial for K193.

For overseas markets, we plan to formulate international commercialization strategies according to market conditions to promote our products. In particular, we plan to seek collaboration opportunities with global partners to leverage their established sales expertise. We currently have one administrative personnel in the U.S., who is mainly responsible for our business development overseas, and we have no plan to expand commercialization team for the overseas market for the next three years. For LZ901, we plan to collaborate with multinational pharmaceutical companies who have a robust sales and marketing network to rapidly commercialize LZ901 globally, including in the U.S. and Southeast Asian countries. Upon entering into collaborations with such multinational pharmaceutical companies, we plan to authorize such multinational pharmaceutical companies to produce and sell LZ901 in the markets and countries that are agreed upon. We may develop corresponding out-licensing or collaboration strategies. Our domestic commercialization team will be responsible for the out-licensing of LZ901. As of the Latest Practicable Date, we had explored collaboration opportunities with third parties to out-license LZ901 in markets outside of China but had not identified any collaboration partners, and may pursue such out-licensing opportunities after we complete the Phase II clinical trial for LZ901 in the U.S. in the second quarter of 2025. Before deciding whether to out-license a product candidate, we identify collaboration partners who may be better positioned to accelerate or further research and development or successful commercialization of the product candidate. We evaluate and select collaboration partners based on their research and development and commercialization capabilities and experience, management and research team, business scale and reputation. For each collaboration partner, we will enter into an agreement setting out the transfer of right to intellectual property, technology and assets to

develop or market within a particular geographical area, license fees, milestones and duration of the license. For other products, we do not have plans or intention for out-licensing. We may also build overseas production workshops and establish our own overseas sales team. In addition, we will focus on our layout strategy of the countries under China's Belt and Road Initiative, with a focus on Southeast Asian countries including Singapore and Indonesia, and accelerate our products' entry into relevant countries through seeking collaborations with local partners, which should have in-depth market expertise and are familiar with regulatory requirements of the relevant jurisdiction, after the successful commercialization of LZ901 in China and realize commercial opportunities with the support of government policies. According to Frost & Sullivan, herpes zoster vaccine is not included in the reimbursement coverage of Southeast Asian countries including Singapore and Indonesia, and we or our local partner may seek opportunities to collaborate with insurance companies to include LZ901 into their coverage in the future. We will authorize local partners to complete the commercialization of LZ901 in the countries under China's Belt and Road Initiative, and we will only obtain milestone payments and royalty payments. The pricing of LZ901 in the relevant countries will be determined jointly by the local partners and us after discussion or by the local partners themselves. We and our local partner will obtain relevant licenses and comply with relevant requirements during the process of commercialization of LZ901 in the future. We currently do not have concrete overseas commercialization plans for our other product candidates. With the advancement of the research and development and commercialization of other product candidates, we will make relevant commercialization strategies for them accordingly.

In order to increase adoption and acceptance of our product candidates by healthcare professionals and ensure end-patient compliance, we plan to promote awareness of our product candidates among patients, physicians, hospitals, CDCs and KOLs through academic promotion, including on-site trainings, academic conferences and events, and regular communications, visits and follow-ups on the safety and effectiveness of our product candidates.

SUPPLIERS

During the Track Record Period, our major suppliers primarily consisted of (i) suppliers of raw materials and consumables for our vaccine and therapeutic biologics development, (ii) construction service providers, (iii) property leasing providers and (iv) CROs, who provide third-party contracting services for research and development.

We procure raw materials from numerous suppliers around the world according to our product development plans. Our raw materials for our product candidates primarily include biological and chemical materials. Most of our raw materials are widely available. We have established stable collaboration relationships with qualified suppliers for raw materials, which we believe have sufficient capacity to meet our demands. Nevertheless, we believe that adequate alternative sources for such supplies exist. Based on our management account and as measure by purchase price, in 2021 and 2022, the raw materials from overseas suppliers accounted for approximately 50.6% and 42.1% of our total raw materials, respectively. The price of raw material sourced from overseas and their delivery time increased due to the outbreak of COVID-19. However, we have not experienced any shortage or delays in the supply of raw materials during the Track Record Period, and the increasing price of raw materials sourced from overseas has little impact on our costs as (i) the amount of raw materials used in the research and development stage is small, and (ii) our overseas suppliers, most of which are domestic agents, have cooperated with us for many years, with stable supply of goods and reasonable prices, and (iii) there are more alternative raw materials with the same quality available in China, which reduces the proportion of raw materials sourced from overseas to a certain extent. We currently do not expect our supply chain to be materially and negatively impacted by the COVID-19. Our major domestic suppliers maintained normal operations during the Track Record Period and up to the Latest Practicable Date. We have not experienced any material difficulties in procuring our major raw materials and have not experienced significant fluctuations in the prices of our supplies. We expect the situation to continue to be improved with the

sustained implementation of containment policies in response to the COVID-19 outbreak, and we may adjust our current clinical development plan covering multiple jurisdictions to the extent necessary depending on the status of the COVID-19 outbreak worldwide. Currently, we do not expect the COVID-19 outbreak to have any material long-term impact on data quality of our clinical trials or our overall clinical development plans.

We select our suppliers by considering their qualifications, compliance with relevant regulations and industry standards, manufacturing facilities, production quality, prices, business scale, market share, reputation, and after-sales service quality. During the Track Record Period, we did not experience any material disputes with suppliers, difficulties during the procurement of raw materials, interruptions in our operations due to a shortage or delay of raw materials, or significant fluctuations in raw material prices.

Our purchases from our five largest suppliers in each year during the Track Record Period amounted to RMB86.7 million and RMB152.2 million, respectively, representing 66.3% and 80.3% of our total purchases for the same periods, respectively. Our purchases from our largest supplier in each year during the Track Record Period amounted to RMB26.4 million and RMB127.1 million, respectively, representing 20.2% and 67.1% of our total purchases for the same periods, respectively.

We generally settle with our suppliers by wire transfer. Credit terms granted to us are determined on a case-by-case basis based on milestone payments contemplated under the supply agreements. The following table sets forth details of our five largest suppliers during the Track Record Period.

Five Largest Suppliers for the year ended December 31, 2021	Supplier Background	Products/ Services Purchased	Length of Business Relationship	Credit Term Granted and Settlement Information	Purchase Amount	Percentage of Total Purchase
					RMB'000	*%*
Supplier A	Local land bureau in Guangdong province	Land use rights	Since 2021	Net 30 days by wire transfer	26,364	20.2
Supplier B	Property management company based in Guangdong province	Property leasing	Since 2020	Net 30 days by wire transfer	23,546	18.0
Supplier C	Construction service provider based in Hebei province	Construction services	Since 2021	Net 30 days by wire transfer	16,789	12.8
Supplier D	Bioengineering product and service provider based in Shanghai	Bioreactors and manufacturing equipment	Since 2021	Net 10 days by wire transfer	13,404	10.3
Supplier E	Construction service provider based in Guangdong province	Construction services	Since 2021	Net 30 days by wire transfer	6,556	5.0
Total					**86,659**	**66.3**

Five Largest Suppliers for the year ended December 31, 2022	Supplier Background	Products/ Services Purchased	Length of Business Relationship	Credit Term Granted and Settlement Information	Purchase Amount	Percentage of Total Purchase
					RMB'000	*%*
Supplier F	Construction service provider based in Wuhan	Construction services	Since 2022	Net 30 days by wire transfer	127,125	67.1
Supplier D	Bioengineering product and service provider based in Shanghai	Bioreactors and manufacturing equipment	Since 2021	Net 10 days by wire transfer	8,614	4.5
Supplier G	Local public health department in Hubei province	Clinical trial services	Since 2021	Net 10 days by wire transfer	7,705	4.1
Supplier H	Purification products and equipment provider based in Shanghai	Chromatography columns	Since 2021	Net 7 days by wire transfer	5,142	2.7
Supplier I	Biopharmaceutical integrated solutions provider based in Switzerland	Patented expression technology	Since 2012	Net 360 days by wire transfer	3,653	1.9
Total					**152,239**	**80.3**

During the Track Record Period, we engaged 18 CROs and one SMO based on the needs of our pre-clinical and clinical studies. Our procurement of CRO and SMO services will continue to depend on the cadence of our clinical and pre-clinical studies. We also had suppliers of equipment and construction of production lines as we built our Zhuhai manufacturing facilities and equipped our R&D facilities.

During the Track Record Period, all of our five largest suppliers were Independent Third Parties. None of our Directors, Supervisors, their respective associates nor 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 to decrease our reliance on existing suppliers. We will establish necessary relationships with alternative sources based on our assessment on the risk of supply continuity.

INVENTORY

Our inventory primarily consists of raw materials and consumables used for vaccine and therapeutic biologics development and immunoreagent testing kits. We regularly monitor our inventories and endeavor to keep an optimal inventory level in line with the expected usages in the near term. We have established an inventory management system to monitor each stage of the warehousing process. Warehouse personnel are responsible for the inspection, storage and distribution of raw materials. Raw materials are separately stored in different areas of the warehouse according to their storage condition requirement, usage and batch number.

COMPETITION

We face competition in several different forms. Product candidates engineered using our Fabite® technology platform and our other protein engineering platforms face actual or potential competition from various companies. Our Fabite® technology platform and our other protein engineering platforms also face actual or potential competition from other technology platforms.

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, competition, and a strong emphasis on proprietary products. While our Fabite® technology platform, our other protein engineering platforms, well-established management team, and robust pipeline of clinical and pre-clinical stage product candidates will provide us with competitive advantages, we face actual or potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing products and new products that may become available in the future.

We operate in the segments of the pharmaceutical, biotechnology, and other related markets that develop vaccines, oncology, or autoimmune disorders. There are other companies working to develop similar vaccines or therapies in these fields. These companies include divisions of large pharmaceutical companies and biotechnology companies of various sizes. Many of these companies and institutions, either alone or together with their partners, have substantially greater financial resources and larger research and development divisions than we have. In addition, many of these competitors, either alone or together with their partners, have substantially greater experience than us in developing pharmaceutical products, undertaking pre-clinical testing and clinical trials, obtaining the relevant regulatory approvals of such products and the manufacturing and commercialization of such products. Accordingly, our competitors may succeed in obtaining patent protection, relevant marketing approval, and commercializing products more rapidly than us.

We face competition from companies developing or testing product candidates for the same or similar targets we are pursuing with our own pipeline. Please see "— Our Products and Product Candidates" and "Industry Overview" for further details of our major competitors. In addition, there may be additional competitors working on the targets of our critical programs of whom we are currently unaware.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are more potent and effective, are safer and have fewer side effects, are more convenient, or are less expensive than any drugs that we may develop. Our competitors also may obtain the relevant regulatory approvals for their drugs or vaccines earlier than we obtain approval for ours, which could result in our competitors establishing a strong market position before we or our collaborators are able to enter the market. The key competitive factors affecting the success of our product candidates, if approved, are likely to be their efficacy, safety, convenience and price, the effectiveness of companion diagnostics in guiding the use of related therapeutics, the level of generic competition, and the availability of reimbursement from government and other third-party payers.

INTELLECTUAL PROPERTY RIGHTS

Our continued success depends on our ability to obtain and maintain proprietary or intellectual property protection for our vaccine products, vaccine and therapeutic biologics candidates and our core technologies and other know-how. We also have internal protocols in place to ensure that we operate without infringing, misappropriating or otherwise violating the proprietary rights of others, and to prevent others from infringing, misappropriating or otherwise violating our proprietary or intellectual property rights. We protect our proprietary and intellectual property position by, among other methods, licensing or filing patent applications related to our proprietary technology, inventions and improvements. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position, which we generally seek to protect through contractual obligations with third parties.

According to Hiways Law Firm, our legal advisor as to intellectual property law ("**IP Legal Adviser**"), who has taken a thorough review of the specifications and claims of our filed patent applications, the technical subject matters of the patents for our Core Product, LZ901, cover the expression gene of biomacromolecule, and vaccine formulation containing the biomacromolecule. Meanwhile, the technical characteristics of independent and dependent claims of the patent cover the key characteristics of LZ901 hierarchically and therefore, LZ901 has been well protected hierarchically from different aspects through the patents. Furthermore, our IP Legal Adviser conducted the FTO analysis on LZ901 from three technical subject matters, including biomacromolecule itself, the pharmaceutical formulation thereof, and the pharmaceutical use of the biomacromolecule. Regarding the patent protection, the above three technical subjects cover the routine and main aspects of a biomacromolecule medicine, and therefore, the risk of our Core Product infringing on the intellectual property rights of third parties is low.

As of the Latest Practicable Date, we had three invention patents granted and eight registered trademarks in the PRC, one invention patent granted in Russia and one registered trademark in Hong Kong. As of the same date, we had filed eight patent applications worldwide. The following table sets forth the material patents and patent applications we owned as of the Latest Practicable Date.

Number	Patent Number	Patent Name	Product	Jurisdiction	Patent Type	Patent Filing Date	Patent Status	Patent Expiration	Protection
1.	ZL201010127032.X*	A hand-foot-and-mouth disease virus vaccine (一種手足口病病毒疫苗)	Inactivated EV71 Vaccine	PRC	Invention	March 18, 2010 (Filing Date) July 25, 2012 (Grant Date)	Effective	March 18, 2030	Protecting the vaccine used in the Company's product of EV71, the use of the vaccine in the preparation of EV71, and the virus strain for preparing the vaccine in EV71
2.	ZL201711131955.0	A bispecific antibody binding to human CD19 and CD3 (一種結合人CD19和CD3的雙特異性抗體)	K193	PRC	Invention	November 15, 2017 (Filing Date) January 29, 2021 (Grant Date)	Effective	November 15, 2037	Protecting the bispecific antibody used in the Company's product of K193, the preparation method of the bispecific antibody used in K193, the use of the bispecific antibody in K193 and the pharmaceutical composition of K193
3.	CN112870344B	A recombinant varicella-zoster virus vaccine (一種重組水痘帶狀疱疹病毒疫苗)	LZ901	PRC	Invention	November 29, 2019 (Filing Date) July 19, 2022 (Grant Date)	Effective	November 29, 2039	Protecting the vaccine formulation of LZ901 and the recombinant gene for the fusion protein used in LZ901

Number	Patent Number	Patent Name	Product	Jurisdiction	Patent Type	Patent Filing Date	Patent Status	Patent Expiration	Protection
4.	2021120973	A recombinant varicella-zoster virus vaccine (一種重組水痘帶狀疱疹病毒疫苗)	LZ901	Russia	Invention	May 14, 2020 (Filing Date) May 26, 2022 (Grant Date)	Effective	May 14, 2040	
5.	17422835	A recombinant varicella-zoster virus vaccine (一種重組水痘帶狀疱疹病毒疫苗)	LZ901	US	Invention	May 14, 2020	Pending	–	Protecting the vaccine formulation of LZ901 and the recombinant gene for the fusion protein used in LZ901
6.	3,125,908	A recombinant varicella-zoster virus vaccine (一種重組水痘帶狀疱疹病毒疫苗)	LZ901	Canada	Invention	May 14, 2020	Pending	–	
7.	20891532.2	A recombinant varicella-zoster virus vaccine (一種重組水痘帶狀疱疹病毒疫苗)	LZ901	EU	Invention	May 14, 2020	Pending	–	Protecting the vaccine formulation of LZ901 and the recombinant gene for the fusion protein used in LZ901
8.	2108457.9	A recombinant varicella-zoster virus vaccine (一種重組水痘帶狀疱疹病毒疫苗)	LZ901	UK	Invention	May 14, 2020	Pending	–	
9.	2020391074	A recombinant varicella-zoster virus vaccine (一種重組水痘帶狀疱疹病毒疫苗)	LZ901	Australia	Invention	May 14, 2020	Pending	–	
10.	10-2021-7021384	A recombinant varicella-zoster virus vaccine (一種重組水痘帶狀疱疹病毒疫苗)	LZ901	Korea	Invention	May 14, 2020	Pending	–	
11.	2021537120	A recombinant varicella-zoster virus vaccine (一種重組水痘帶狀疱疹病毒疫苗)	LZ901	Japan	Invention	May 14, 2020	Pending	–	
12.	202210919694.3	A low mannose human anti-tumor necrosis factor-α monoclonal antibody and use thereof (一種低甘露糖型抗人腫瘤壞死因子-α單抗及其用途)	K3	PRC	Invention	August 2, 2022	Pending	–	Protecting the low mannose type antibody used in K3 and the preparation method thereof

Note:

* Patent co-owned with Zhifei Biopharma.

For details of our other intellectual property rights, see Appendix VII to this document.

According to our IP Legal Adviser, there is no substantive legal impediment for each of our filed patent applications in relation to LZ901 and K193 of being granted, because each has a high possibility to satisfy the patentability requirements for novelty and inventive step of their respective jurisdictions and to be granted after substantive examination. Furthermore, there is no substantive legal impediment for our filed patent application in relation to K3 of being granted, because it possesses the essential content that may be authorized, and it is possible to obtain authorization as long as the protection scope of the claims are determined to be appropriate in the examination procedure.

In the event that these pending patent applications are ultimately rejected, this would simply mean that the technology intended to be covered by such patent applications is not protected by patent rights. For more details, please see "Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to Our Intellectual Property Rights — If we are unable to obtain and maintain adequate patent

and other intellectual property protection for our product candidates throughout the world, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties could compete directly against us and our ability to successfully develop and commercialize any of our product candidates would be materially and adversely affected" in this document. Practically, however, the loss of patent protection will not hinder us from developing and commercializing our product candidates by using such technology. In the absence of patent protection, we may also have extensive know-how in developing product candidates which enable us to maintain a competitive advantage in the market.

The term of an individual patent may vary based on the countries/regions in which it is granted. The actual protection afforded by a patent varies on a claim-by-claim and country-by-country basis and depends upon many factors, including the type of patent, the scope of its coverage, the availability of any patent term extension or adjustment, the availability of legal remedies in a particular country/region 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, licensed or issued patents or any such patents that may be issued in the future will be commercially useful in protecting our product candidates and methods of manufacturing the same.

In February 2023, our IP Legal Adviser conducted freedom-to-operate ("**FTO**") searches and analyses in target country(s) and/or region(s) in relation to our Core Product, namely LZ901, as well as K3 and K193, and did not identify any substantial risk of infringement by all of the current key technologies and features of our Core Product, K3 and K193 against active patents in such country(s) and/or region(s).

We rely, in some circumstances, on trade secrets and/or confidential information to protect aspects of our technology. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality arrangements with our core research and development team members and CROs. We have entered into confidentiality and non-compete agreements with our key employees and employees involved in research and development, pursuant to which intellectual property conceived and developed during their employment belongs to us and they waive all relevant rights or claims to such intellectual property. We also have established an internal policy governing the confidentiality of all company information. Despite the measures we have taken to protect our intellectual property, our proprietary information may be obtained by unauthorized parties. For details, see "Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to Our Intellectual Property Rights — We may fail to protect the confidentiality of our trade secrets, as we may be subject to claims that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their former employers, or that asserting ownership of what we regard as our own intellectual property" in this document.

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

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

We also own a number of registered trademarks and pending trademark applications. As of the Latest Practicable Date, we had registered eight trademarks in China and one trademark in Hong Kong for our Company, and are seeking trademark protection for our Company and our corporate logo.

As of the Latest Practicable Date, we were not involved in any material proceedings in respect of, and we had not received written notice of any material claims of infringement of any intellectual property rights, in which we may be a claimant or a respondent. However, there are risks if we fail to protect our intellectual property rights in the future. For details, see "Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to Our Intellectual Property Rights" in this document for a description of risks related to our intellectual property.

HEALTH, SAFETY, SOCIAL AND ENVIRONMENTAL MATTERS

We strive to operate our facilities in a manner that protects the environment and the health and safety of our employees, patients, and communities. We have implemented company-wide environmental, health and safety ("**EHS**") manuals, policies, and standard operating procedures in relation to wastewater treatment, biological solid waste management, and emergency response and practices. We periodically provide EHS trainings to our employees.

Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. To further ensure our compliance with applicable environmental protection and health and safety laws and regulations, we (i) have established various guidelines governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes to ensure such guidelines are strictly enforced for the disposal of laboratory materials and wastes; (ii) inspect our equipment and facilities regularly to identify and eliminate safety hazards; (iii) provide regular safety awareness training to our employees; (iv) keep health records for all employees and conduct health examinations before, during and after their time at the Company, especially for employees engaged in work involving occupational hazards; and (v) conduct regular fire safety inspections, maintenance of fire-fighting equipment and regular emergency drills.

Our EHS coordinator is responsible for implementing and enforcing the compliance of our operations with environment, health and safety laws and regulations. This responsibility is executed through supervision and inspection of environmental protection work and participate in incident investigation. We have not had any significant workplace accidents in the history of our Company.

We believe we have maintained good relationships with the communities surrounding our manufacturing facilities. During the Track Record Period and up to the Latest Practicable Date, we complied with the relevant environmental and occupational health and safety laws and regulations in all material aspects, and we did not have any incidents or complaints which had a material and adverse effect on our business, financial condition or impact on the operations of our business during the period. For the years ended December 31, 2021 and 2022, our expenses in relation to environmental protection amounted to approximately RMB3,000 and RMB13,000, respectively. We expect our costs of complying with current and future environmental protection laws to increase in the future, as we further our research and development efforts and commence commercial manufacturing of our products after regulatory approval.

Governance of Environmental and Social Matters

We incorporate a sustainable development approach in our daily business operation decisions. Our EHS department is responsible for establishing, adopting and reviewing our environmental, social, and governance ("**ESG**") policies, vision and goals to evaluate, determine and address our ESG-related risks once a year.

We are subject to environmental-related and social related risks. See "Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to Our General Operations — If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could materially and adversely affect the success of our business" in this document. We may adopt more ESG policies relating to social responsibility and internal governance as our EHS department deems fit. Our EHS department takes full responsibility to our ESG strategy and reporting. Our EHS department may assess or engage independent third-party advisory companies to evaluate the ESG risks and review our existing strategy, target and internal controls. Necessary improvements will then be implemented to mitigate the risks. At the same time, we are committed to the sustainable growth and long-term development of the Company.

Environmental Matters

We are concerned about the impact of our business on climate and environment. We strive to take measures to protect the ecological environment during our business operation, so as to minimize adverse environmental impact. The projects under our management are subject to PRC environmental laws and regulations as well as environmental regulations promulgated by local governments including, but not limited to the PRC Environmental Protection Law (《中華人民共和國環境保護法》), the PRC Environmental Impact Appraisal Law (《中華人民共和國環境影響評價法》), the Administration Rules on Environmental Protection of Construction Projects (《建設項目環境保護管理條例》), and the Regulation on Pollutant Discharge Permit Administration (《排污許可管理條例》).

Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. We have implemented company-wide EHS manuals, policies and standard operation procedures and periodically provide EHS trainings to our employees to ensure the compliance with applicable environmental protection and health and safety laws and regulations. See "— Health, Safety, Social and Environmental Matters" in this section. Specifically, in January 2022, we established a hazardous waste management system, under which we set up a leading group to supervise and coordinate our environmental protection work. This leading group is headed by Mr. KONG and consists of seven members. We have also engaged third-party waste management company to assist in the preparation of hazardous waste management plan and provide consulting services on the problems arising from the process of hazardous waste treatment since January 2022. During the Track Record Period, we actively monitored our resource consumption for our manufacturing function. For the years ended December 31, 2021 and 2022, our consumption of water amounted to approximately 5,096 tons and 18,843 tons, respectively, and electricity amounted to 462.3 thousand kWh and 1,485.0 thousand kWh, respectively. In addition, the gas generated from our operations and discharged into the air is mainly oxygen and a small amount of nitrogen, which will not cause pollution of the air, and we are not subject to any climate-related issues.

While there is no virus used in the manufacturing process of our vaccine-related products, the manufacturing process of our potential commercialized products may involve the use of non-biodegradable raw materials, mainly include mixing plastic bag, and may produce hazardous waste products. Under our ESG policies, we have established stringent guidelines in relation to the manufacturing procedures and the handling, use, storage, treatment and disposal of hazardous materials. We provide periodic training on these guidelines and procedures to our employees as part of our employee-training program to ensure such procedures are strictly enforced. In addition, we monitor the implementation of our ESG policies through our EHS department for each stage of the manufacturing process. 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 ESG policies after the [**REDACTED**]. We will continue to use quantitative metrics to evaluate, assess and manage our pollutants emission and resource consumption after the commercialization of our product candidates. We may engage an external consultant or establish an internal committee to further assess the Company's ESG approach after the [**REDACTED**].

We pay close attention to the global trend and China's national strategy of addressing climate change and ecological environment protection, and will actively enhance our ability to address climate change and cope with China's initiatives and action plans regarding future carbon dioxide emission. In terms of major climate change-related initiatives or action plans that may affect us, we plan to formulate policies after the [**REDACTED**] to systematically identify, assess and manage climate change-related risks, and formulate relevant response strategies.

Social Matters

We endeavor to provide safe products to the society through a comprehensive quality management system. We have an experienced quality management team, consisting of 27 personnel as of the Latest Practicable Date. Ms. ZHANG Yanping, our co-founder and deputy general manager, has extensive experience in quality control, quality assurance, and preclinical safety studies of biological products. All of our Zhuhai quality management team members have received professional training in regulations, GMP standards and quality control analysis methods. All of our manufacturing facilities are designed and maintained, and we implement quality standards, in conformity with GMP standards adopted by NMPA, the EMA, the FDA and related ICH guidelines.

In addition, we also have an effective supply chain management as we have established detailed internal rules governing the selection of raw material suppliers and raw material quality control. We purchase raw materials only from suppliers of which we have verified business qualifications and product quality. We select suppliers based on a variety of factors including qualifications, business reputation, production scale, technological strengths, quality management capabilities, after-sales services and price. After initial screening by our procurement department, we typically request product samples from a supplier, which is examined by our quality management team. The examination result provides an important basis for our supplier selection decisions. In addition, we would conduct on-site quality audit at the supplier's manufacturing facilities, and we require the supplier to execute a quality guarantee agreement with us. Our purchased supplies are inspected, and for supplies that do not pass our inspection, they will be transferred to our warehouse, categorized as unqualified supplies, pursuant to our protocols regarding non-conforming products. Therefore, we believe that we have the ability to ensure that our product candidates are consistently produced while achieving the required quality and safety.

We plan to increase the public accessibility and improve the affordability of herpes zoster vaccines and treatment for autoimmune diseases through adopting commercialization strategies, including

favorable and competitive pricing in the short- to medium-term for LZ901 and K3. Our pricing policy aims to provide affordable products for the public. LZ901 is expected to be priced at a retail price of approximately RMB500 to RMB800 an injection, with a total of two injections per treatment and does not require a third booster shot, which is more affordable compared to the retail price of the other commercially available herpes zoster vaccines in China. K3 is expected to be priced at a retail price of approximately RMB400 to RMB500 a dose, which is more affordable compared to the retail price of the other commercially available biosimilars of adalimumab in China, which are priced at approximately RMB700 to RMB1,200 a dose. We also plan to seek opportunities to collaborate with insurance companies to include the product candidates which are not included in the NRDL into their coverage, which will make treatments of relevant diseases more accessible to the public. Furthermore, we endeavor to achieve broad product access to benefit patients and improve their access to healthcare through building our commercialization capabilities. For examples, our marketing department of our commercialization team will cooperate with not-for-profit organizations and local CDCs to organize seminars and participate in industry conferences to introduce the importance of vaccination of the herpes zoster vaccine and the competitiveness of LZ901 both to relevant doctors and the public, which will improve the public awareness of herpes zoster. For details, please see "— Commercialization" in this section.

Regarding the data security and privacy protection, we have taken measures to maintain the confidentiality of the medical records and personal data of subjects enrolled in our clinical trials we collected, including setting internal rules requiring our employees and business partners to maintain the confidentiality of our subjects' medical record. In addition, the CROs and SMOs that we select have professional data management with complete privacy protection policies. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and electronic security of our information technology systems. Therefore, we believe we have implemented effective measures for data security and privacy protection. We also have relevant procedures and controls to monitor compliance with applicable anti-corruption laws during the collaboration with CROs and SMOs and we require all of our employees, especially those involved in business development activities, to abide by our anti-bribery and anti-corruption compliance requirements and applicable laws and regulations to eliminate bribery and corruption risks.

We have policies on compensation and dismissal, equal opportunities and anti-discrimination. If our employees encounter any unequal discrimination, they should seek immediate assistance from either their department head, human resources department or our management team. We will immediately follow up, investigate, and, if necessary, report to the law enforcement authorities. Our Directors confirmed that during the Track Record Period and up to the Latest Practicable Date, there had been no violation of any applicable social laws, rules and regulations and no claim or penalty imposed upon us as a result of such laws, rules and regulations.

We have adopted and maintained a series of rules, standard operating procedures and measures to maintain a healthy and safe environment for our employees. We ensure safe storage and handling of flammable and corrosive materials used in our manufacturing process. We also have safety equipment and instruments in place, and we periodically inspect our utility equipment and fire services to ensure the safety of our employees. Additionally, we have established an EHS department in charge of safety and emergency issues consisting of four employees mainly responsible for identifying and mitigating safety risks, improving the safety production policies and procedures, supervising the implementation of such policies and procedures, making emergency plans and providing trainings in respect of production safety to our employees. In addition, we provide our employees with training in various areas to improve their knowledge and skills.

EMPLOYEES

As of the Latest Practicable Date, we employed 131 full-time employees. The following table sets forth the number of our full-time employees by function as of the Latest Practicable Date.

Function	Number of full-time employees	Percentage
Management and General Administrative (including Financial Department)	39	29.8%
Research and Development (including Manufacturing Department and Quality Management Department)	71	54.2%
Medical Affairs and Clinical Operations	10	7.6%
Engineering	11	8.4%
Total	**131**	**100.0%**

The total staff costs of our Group, which consist of (i) salaries and other allowances, (ii) retirement benefits and (iii) equity-settled share-based payment expenses, for the years ended December 31, 2021 and 2022 were approximately RMB87.9 million and RMB134.1 million, respectively.

We recruit our employees based on a number of factors, including work experience, educational background and the requirements of a relevant vacancy. We invest in continuing education and training programs for our management staff and other employees to upgrade their skills and knowledge continuously. We also provide training and development programs to our employees from time to time to ensure their awareness and compliance with our various policies and procedures. We provide our employees with regular feedback as well as internal and external training in various areas, such as product knowledge, project development and team building. We also assess our employees based on their performance to determine their salary, promotion and career development.

We require all of our employees, especially those involved in business development activities, to abide by our anti-bribery and anti-corruption compliance requirements and applicable laws and regulations to eliminate bribery and corruption risks. We closely monitor our employees' compliance with anti-bribery and anti-corruption policies.

In compliance with the relevant PRC labor laws, we enter into individual employment contracts with our employees covering matters such as terms, wages, bonuses, confidentiality obligations and grounds for termination. In addition, we are required under PRC law to make contributions to statutory employee benefit plans (including pension plans, medical insurance, work-related injury insurance, unemployment insurance, maternity insurance and housing funds) at a certain percentage of our employees' salaries, including bonus and allowances, up to a maximum amount specified by the local government. As of the Latest Practicable Date, we did not have any non-compliance with statutory social security insurance fund and housing fund obligations applicable to us under applicable laws in all material respects.

We are also subject to safety laws and regulations of the PRC. We have implemented various internal occupational health and safety procedures to maintain a safe work environment, including adopting protective measures at our testing and manufacturing facilities, inspecting our equipment and facilities regularly to identify and address safety hazards, and providing regular training to our employees on safety awareness.

As of the Latest Practicable Date, one of our employees was represented by a labor union. All labor disputes are handled in accordance with all applicable laws, rules and regulations. We believe that we have maintained good working relationships with our employees. During the Track Record Period and up to the Latest Practicable Date, we were not subject to any material claims, lawsuits, penalties or administrative actions relating to non-compliance with occupational health and safety laws or regulations, and had not experienced any strikes, labor disputes or industrial actions which have had a material effect on our business.

PROPERTIES

We are headquartered in Beijing, China, where we conduct our R&D and manufacturing operations. As of the Latest Practicable Date, we owned three properties in Beijing and Zhuhai with a total site area of approximately 107,973 sq.m. We have obtained the land use right certificates for all three parcels of land. As of the Latest Practicable Date, we had also obtained the building ownership right certificate for one building in Beijing, with a total GFA of approximately 3,757 sq.m. We use this building primarily for the R&D of our products. The following table sets forth a summary of our owned properties.

No.	Address	Usage	Owned Area
			(Approximate sq.m.)
1.	Xiangtian Road East, Anwan Road South, Sanzao Town, Jinwan District, Zhuhai City, Guangdong Province	Manufacturing	69,366
2.	No. 3, Guangtong Street, Tongzhou Industrial Development Zone, Tongzhou District, Beijing	Offices, Laboratories and Pilot Manufacturing Facility	17,422
3.	Block X29F2, No. X29, Beijing Economic-Technological Development Area, Beijing	Offices, Laboratories and Manufacturing Facility	21,185

As of the Latest Practicable Date, we also leased properties in Zhuhai and Beijing mainly for offices, manufacturing and/or research and development. The following table sets forth a summary of leased properties.

No	Address	Usage	Leased Area	Term
			(Approximate sq.m.)	
1	Floor 1-3, Building 8, Zhuhai International Health Port, No. 628 Airport West Road, Sanzao Town, Jinwan District, Zhuhai City, Guangdong Province	Manufacturing, Research and Development, Testing, Laboratories and Offices	8,061	10 years
2	Room 302-303, Building A, Zhuhai International Health Port, No. 628 Airport West Road, Sanzao Town, Jinwan District, Zhuhai City, Guangdong Province	Testing, Laboratories and Offices	499	3 years

No	Address	Usage	Leased Area	Term
			(Approximate sq.m.)	
3	Room C535, 5th floor, Building C, No. 18 Xihuan South Road, Beijing Economic Technological Development Area, Daxing District, Beijing	Offices	31	1 year

According to Chapter 5 of the Listing Rules and section 6(2) of the Companies (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice (Chapter 32L of the Laws of Hong Kong), we need to comply with the requirements of section 38(1) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance in relation to paragraph 34(2) of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance which requires a valuation report with respect to all of our Group's interests in land or buildings, as we have property interest with a carrying amount of 15% or more of our consolidated total assets. Accordingly, we have prepared a property valuation report with respect to our Group's owned properties pursuant to Chapter 5 of the Listing Rules. For more details, please see "Appendix III — Property Valuation Report" to this document.

INSURANCE

We maintain property insurance covering our manufacturing facilities and equipment that we believe are sufficient in accordance with customary industry practice, as well as social welfare insurance in accordance with the relevant laws and regulations in China. In line with industry practice in the PRC, we have elected not to maintain certain types of insurances, such as business interruption insurance or product liability insurance. We are responsible for any adverse events or deaths caused by the vaccination of LZ901 due to product defects. We maintain clinical trial insurance and plan to obtain liability insurance for LZ901 to cover product liability claims in accordance with the relevant laws and regulations after we obtain approval for LZ901 in China and overseas. See "Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to Our General Operations — We have limited insurance coverage, and any claims beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources", "Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to the Research and Development of Our Product Candidates — Our product candidates may cause AEs or undesirable side effects, which could interrupt, delay or halt clinical trials, delay or prevent regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following any regulatory approval" and "Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to the Research and Development of Our Product Candidates — In conducting research and development, we face potential liabilities, in particular, product liability claims or lawsuits that could cause us to incur substantial liabilities" in this document for further details of risks relating to our current insurance coverage. Our Directors are of the view that our current insurance coverage is in line with industry practice and is adequate for our operations.

LICENSES, PERMITS AND APPROVALS

As we are primarily engaged in the R&D of vaccine and therapeutic biologics products in China, we are required to obtain necessary licenses, permits and certificates for our business. Our PRC Legal Adviser has advised us that, as of the Latest Practicable Date, we had obtained all requisite and material licenses, approvals and permits required by PRC laws and regulations for our operations. The table below sets forth the relevant details of the material licenses we hold for our operations.

Entity	Name of the License, Approval or Permit	Expiry Date	Description of the License
Guangdong MPA (廣東省藥品監督管理局)	Drug Production License (藥品生產許可證)	January 12, 2028	Production of therapeutic biologics (LZ901)
Tongzhou Branch of Beijing Public Security Bureau (北京市公安局通州區分局)	The record certificate of the business unit of explosive hazardous chemicals (易製爆危險化學品從業單位備案證明)	December 25, 2023	Use of hazardous chemicals, including potassium permanganate, hexamethylenetetramine, silver nitrate, lead nitrate, nitric acid, potassium dichromate, hydrogen peroxide solution (>8%)
Beijing Tongzhou District Emergency Management Bureau (北京市通州區應急管理局)	Safety Production Standardization Certificate (Beijing AQBHQ) (安全生產標準化證書（京AQBHQ）)	November 30, 2023	Safety production standardization three-level enterprise
Beijing Tongzhou District Water Affairs Bureau (北京市通州區水務局)	Urban sewage discharge into the drainage network permit (城鎮污水排入排水管網許可證)	April 7, 2024	Sewage discharge permit
Zhongguancun High-Tech Certificate (中關村高新技術證書)	Zhongguancun Science and Technology Park Management Committee (中關村科技園區管理委員會)	August 16, 2023	High-tech certificate
Certificate of Beijing-level Enterprise Science and Technology Research and Development Organization (北京市級企業科技研究開發機構證書)	Beijing Municipal Commission of Science and Technology (北京市科學技術委員會)	–	Science and technology research and development certificate

AWARDS AND RECOGNITION

We received various awards, honors, and recognitions, including:

Prize	Year	Awarding Organization
Top 50 Innovative Biotechnology Companies in Guangdong-Hong Kong-Macao Greater Bay Area Award 2022	2022	ZDVC Research; Guangdong Medical Valley
Beijing's "specialized and new" small and medium-sized enterprises	2022	Beijing Municipal Bureau of Economy and Information Technology
Second Prize — Beijing Science and Technology Award	2017	The People's Government of Beijing Municipality
Patent Pilot Certificate	2014	Beijing Municipal Intellectual Property Office

LEGAL PROCEEDINGS AND REGULATORY COMPLIANCE

As of the Latest Practicable Date, we had not been a party to any actual or threatened material legal or administrative proceedings, and our Directors had not been involved in any such proceedings. 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.

RISK MANAGEMENT AND INTERNAL CONTROL

Risk Management

We recognize that risk management is critical to our long-term development and success. Key operational risks faced by us include changes in the general market conditions and the regulatory environment of the PRC and global biopharmaceutical markets, our ability to develop, manufacture and commercialize our drug and vaccine candidates, and our ability to compete with other vaccines, immuno-oncology and biotechnology companies. See "Risk Factors" in this document for a more detailed discussion on various risks we may subject to.

We have adopted a consolidated set of risk management policies which set out a risk management framework to identify, assess, evaluate, and monitor key risks associated with our strategic objectives on an ongoing basis. Our senior management, and ultimately our Directors, supervise the implementation of our risk management policies. 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.

The following key principles outline our Group's approach to risk management and internal control we plan to implement:

- Our senior management oversees and manages 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) monitoring the most significant risks associated with our business operations and our management's handling of such risks; and (iii) ensuring the appropriate application of our risk management framework across our Group;

- Our executive Director, general manager and chief scientist, Mr. KONG Jian, is responsible for (i) formulating and updating our risk management policy; (ii) reviewing and approving major risk management issues of our company; (iii) promulgating risk management measures; (iv) providing guidance on our risk management approach to the relevant departments in our company; (v) reviewing the relevant departments' reporting on key risks and providing feedback; (vi) supervising the implementation of our risk management measures by the relevant departments; (vii) ensuring that the appropriate structure, processes and competencies are in place across our company; and (viii) reporting to our audit committee on our material risks;

- The relevant departments in our Company, including but not limited to the finance department, the general manager office, 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. 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, environmental protection and occupational health and safety. For more information, see "— Health, Safety, Social and Environmental Matters" in this section. We have also adopted various measures and procedures regarding our business operation, for example. Our internal audit department conducts audit field work to monitor the implementation of our internal control policies, reports any weaknesses identified to our management and audit committee, and follows up on the rectification actions.

- We provide various training programs to keep our employees updated on relevant laws, regulations, and policies. Our new employees are required to attend compliance training programs soon after on-boarding and must pass tests which examine their understanding of the compliance issues addressed by the training programs. Our employees are also required to regularly attend on-site and online training sessions to keep them informed of recent updates in the relevant laws and regulations.

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

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

- We have engaged Fosun International Capital Limited as our compliance adviser to provide advice to our Directors and management team until the end of the first fiscal year after the [**REDACTED**] regarding matters relating to the Listing Rules. Our compliance adviser is expected to ensure our use of funding complies with the section entitled "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 have engaged a PRC law firm to advise us on and keep us informed on PRC laws and regulations after the [**REDACTED**]. We will continue to arrange various trainings to be provided by external legal advisers from time to time when necessary and/or any appropriate accredited institution to update our Directors, senior management, and relevant employees on the latest PRC laws and regulations.

- We maintain strict anti-corruption policies 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 biopharmaceutical industry.

In addition, as part of our risk management measures, we have implemented specific measures against corruption and bribery, including providing anti-corruption and anti-bribery compliance training for our Directors, supervisors and senior management to enhance their knowledge and compliance of applicable laws and regulations. We require our employees, especially those involved in procurement and other business functions which are more susceptible to bribery and corruptions, to abide by our compliance requirements, and make necessary representations and warranties to the Company. We also have established a system of supervision that allows complaints and reports to be submitted to management regarding non-compliant behavior of our internal employees.

During the Track Record Period, we have regularly reviewed and enhanced our internal control system. 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.