OVERVIEW

Founded in the PRC in 2015, we are a clinical-stage biotech company exclusively focused on biologic therapies for autoimmune and allergic diseases, with a self-developed drug pipeline and an established commercial-scale in-house manufacturing capability. To address significant unmet medical needs in the autoimmune and allergic disease drug market in China, which is forecast by Frost & Sullivan to surpass one hundred billion yuan by 2025, we have built a broad pipeline that covers the four major disease areas in the field, including skin, rheumatic, respiratory and digestive diseases. According to Frost & Sullivan, among Chinese domestic companies, we had one of the most numbers of IND-approved drug candidates in autoimmune and allergic diseases as of the Latest Practicable Date. As of such date, our pipeline encompassed two Core Products, QX002N and QX005N, and seven other drug candidates. In particular, our pipeline featured QX001S, an IL-12/IL-23p40 inhibitor for psoriasis (Ps), the first domestically developed ustekinumab biosimilar with BLA submitted in China and potentially one of the first ustekinumab biosimilars to be approved in China; QX002N, an IL-17A inhibitor in Phase III clinical trial for ankylosing spondylitis (AS) with promising efficacy; and QX005N, a monoclonal antibody (mAb) blocking IL-4Rα, a well-validated, broad-acting target for a wide range of indications. QX005N is one of the most advanced biologic drug candidates for atopic dermatitis (AD), and the first biologic drug candidate developed by a Chinese domestic company in clinical trial for prurigo nodularis (PN), in China. Our mission is to pursue scientific innovation and deliver affordable and quality therapeutics.

Autoimmune and allergic diseases represent the second-largest therapeutic area globally, only after oncology, and have witnessed a succession of blockbuster drugs. According to Frost & Sullivan, the market size of autoimmune and allergic disease drugs amounted to US$187.5 billion in 2022, which was 12.5% for all drugs combined. Among the 100 top-selling drugs in 2022, around one fifth were autoimmune or allergic drugs, including two—Humira (adalimumab) (No. 2; US$21.2 billion) and Stelara (ustekinumab) (No. 9; US$9.7 billion)—in the top 10. Humira, in particular, was the world's best-selling drug for eight years in the last ten (2013-2022). In contrast, market development in China has lagged significantly behind. According to Frost & Sullivan, the total patient population of autoimmune and allergic diseases in China exceeded 420 million as compared to 100 million in the United States in 2020. However, China's autoimmune and allergic drug market was only US$7.2 billion in 2020, approximately 7.5% of the U.S. market of US$95.6 billion. Specifically, biologic drugs dominate developed markets, but their penetration in China remains low. In 2020, biologic drugs made up over 60% of the autoimmune and allergic disease drug market in the United States, but only about 10% of the China market.

The underdevelopment of the China market has historical reasons. Due to an innovation gap, most of the innovative biologic drugs available in China have been expensive blockbuster drugs developed by multinational corporations, or MNCs, typically not covered by public medical insurance. This has had two effects. On the one hand, because autoimmune and allergic diseases are often not fatal, Chinese patients, when they have limited ability to pay and are price-sensitive, are less inclined to address them with significant economic resources as committedly as they might with fatal diseases such as cancer, leading to discontinued treatment, ineffective traditional treatment or no treatment at all. On the other hand, due to limited returns, the MNCs have not invested extensively in physician and patient education in China, which has perpetuated poor awareness. As a result, diagnosis and treatment rates for

many diseases in this field have been low. The *status quo* indicates a deep structural misalignment with the unmet medical need. Autoimmune and allergic diseases are serious diseases. They can severely affect patients' quality of life in various manifestations, including great pain, persistent itchiness, disfigurement, disability, severe psychological pressure and social exclusion. They impose profound disease burden on patients and society and require safe and effective treatment.

Despite the historical underdevelopment, China's autoimmune and allergic disease drug market has been changing in recent years, especially since 2021. Several important factors have driven the industry toward more alignment with global trends and more certainty in market prospect:

- *Approvals, NRDL admissions and accelerated sales ramp-up of blockbuster drugs.* A number of blockbuster drugs developed by MNCs were approved in China and admitted to the NRDL. While unit prices dropped, sales soared. For example, Cosentyx (secukinumab, an IL-17A inhibitor) was approved in China for moderate-to-severe plaque Ps in March 2019 and admitted to the NRDL in March 2021. While its unit price (150 mg) decreased from RMB2,998 in 2020 to RMB1,188 in 2022, its China sales increased from US$72.5 million in 2020 to US$279.0 million in 2021 and US$601.4 million in 2022. Dupixent (dupilumab, an IL-4Rα inhibitor) was approved for moderate-to-severe AD in June 2020 and admitted to the NRDL in January 2021. While its unit price (300 mg) decreased from RMB6,666 in 2020 to RMB3,160 in 2022, its China sales increased from US$13.7 million in 2020 to US$87.4 million in 2021 and US$248.1 million in 2022. Apart from the expansion in sales volume, there has also been an evident acceleration in such expansion. According to Frost & Sullivan, it took seven years for Humira (adalimumab) to achieve annual sales of US$100.0 million in China since its approval in the country in 2010, whereas it took Cosentyx only two years to reach the same milestone.

- *Evolution of treatment paradigm from traditional anti-inflammatory agents to biologics.* Traditional anti-inflammatory agents are commonly used treatment options for autoimmune diseases, particularly during the initial stages of the diseases. However, traditional anti-inflammatory agents are also noted with limited efficacy in patients with more severe symptoms and there remain concerns over the potential side effects from long-term use of some of these agents. Therefore, over the past decades, biologic drugs with superior efficacy and safety have been increasingly accepted by physicians and patients globally. The evolution of treatment paradigm from traditional anti-inflammatory agents to biologics is also accompanied by continuous upgrades in classes of biologic drugs. For example, compared to first-generation inhibitors targeting tumor necrosis factor alpha (TNF-α), which have relatively high risk of serious infections, certain biologics targeting interleukins (*e.g.*, IL-17 and IL-23) have demonstrated better efficacy and/or safety for certain indications and are under extensive investigation with more drugs potentially to be approved. The same trend is also found and followed in China, and drives an increasing demand for novel biologic drugs.

- *Rise of domestic developers.* Recognizing the great potential of the therapeutic area, a growing number of Chinese pharmaceutical companies have begun to conduct R&D on autoimmune and allergic disease drugs. Drugs developed by Chinese domestic companies are expected to have a price advantage. Domestic companies may also leverage their in-depth understanding and extensive coverage of local patients and hospitals to, together with MNCs, improve awareness of autoimmune and allergic diseases and biologic therapies through more precise and effective marketing activities and patient education.

Due to these favorable changes, the autoimmune and allergic disease drug market in China expanded from US$7.2 billion in 2020 to US$9.0 billion in 2022, representing a CAGR of 11.8%, with the proportion of biologic drugs increased to 20.4% in 2022. The market is expected to continue to develop. According to Frost & Sullivan, it is estimated to grow to US$41.5 billion in 2030, at a CAGR of 21.1% from 2022, and with the proportion of biologic drugs increased to about 60%. The market has significant further, long-term growth potential. On the demand side, although usually not fatal, autoimmune and allergic diseases are also usually incurable, and are classic chronic diseases that require long-term or even life-long care. Accordingly, patients have stable need for medication over long periods of time, resulting in high lifetime value (LTV). In addition, long-term medication causes drug resistance and adherence issues, creating a need for alternative therapies. Furthermore, the pathogenic mechanisms of many autoimmune and allergic diseases are not fully understood. One drug is often used for multiple indications, with varying response rates, indicating that the development of precision medicine and individualized treatment is still at a very early stage. On the supply side, compared with oncology, which is crowded with many international and domestic pharmaceutical companies, competition in the autoimmune and allergic drug market is relatively less intense. As indicated in the 2022 Drug Evaluation Report released by the NMPA, among 769 IND approvals granted in 2022, fewer than 140 were in the autoimmune and allergic field, compared with more than 430 in oncology.

We are well positioned to take advantage of this market opportunity. Since our establishment in 2015, we have exclusively focused on the autoimmune and allergic field and built a broad pipeline covering the four major disease areas in the field, namely, skin, rheumatic, respiratory and digestive diseases.

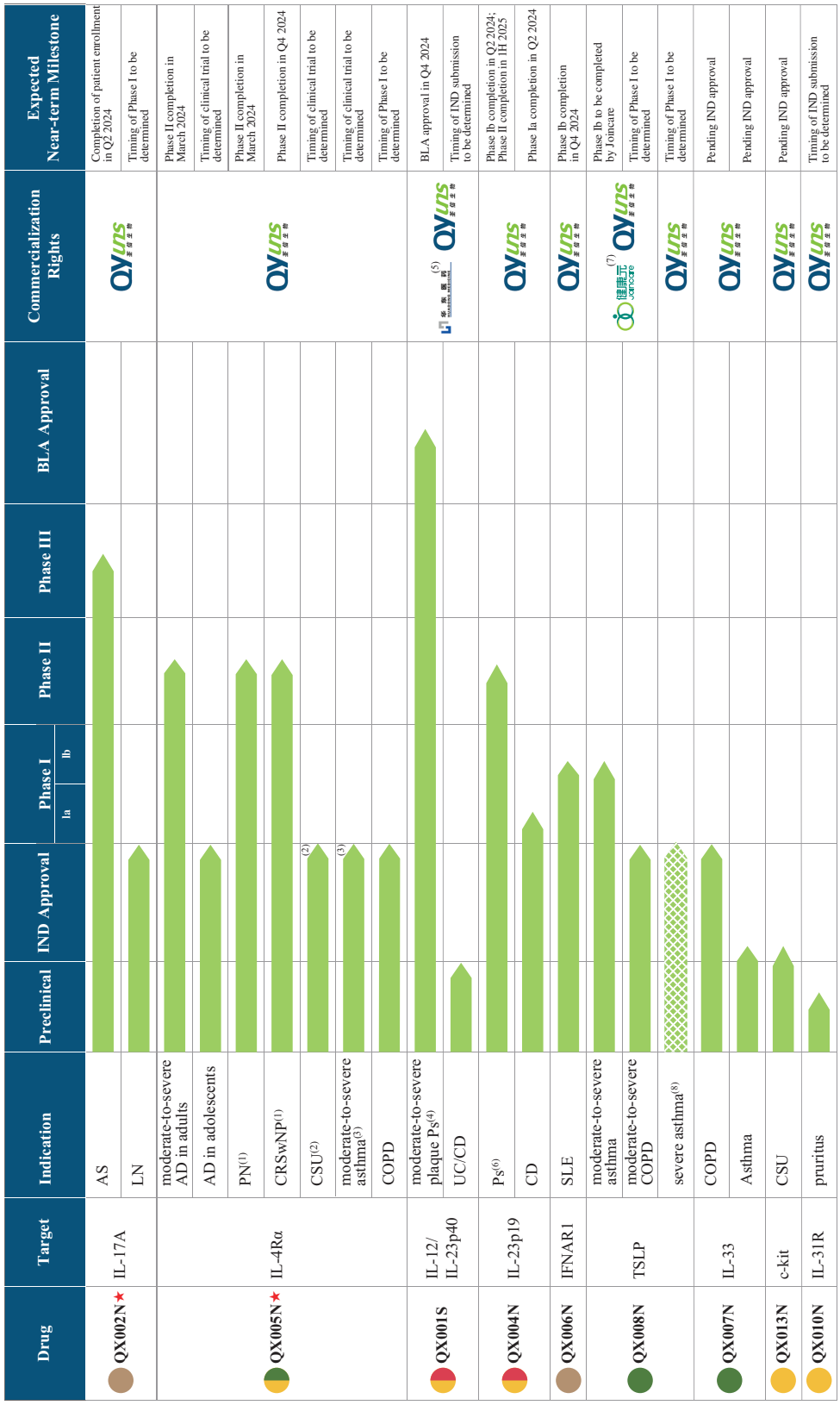
- *Skin diseases.* Inflammatory skin diseases have large patient populations in China. According to Frost & Sullivan, there are estimated to be 6.8 million Ps patients in China by 2030, 20% to 30% of whom having moderate-to-severe disease, indicating an estimated drug market of US$9.9 billion. In the same year, there are estimated to be 78.5 million AD patients, 30% of whom having moderate-to-severe disease, indicating an estimated drug market of US$7.1 billion, and 2.1 million PN patients, with no approved biologic therapies, indicating a market with substantial unmet medical needs. Our pipeline consists of five drug candidates for skin diseases, namely, QX001S, an IL-12/IL-23p40 inhibitor, for Ps; QX004N, an IL-23p19 inhibitor, for the same indication; QX005N, an IL-4Rα inhibitor, for AD, PN and chronic spontaneous urticaria (CSU); QX013N, a humanized IgG1 mAb targeting c-kit, for CSU; and QX010N, an IL-31R inhibitor, for pruritus.

- *Rheumatic diseases*. Inflammatory rheumatic diseases are multiple immune diseases, such as ankylosing spondylitis (AS), systemic lupus erythematosus (SLE) and lupus nephritis (LN). In addition to persistent and mysterious pain, rheumatic conditions can cause patients to develop deformities so severe that daily tasks like walking or getting dressed feel impossible. In 2030, there are estimated to be 4.0 million AS patients in China, with an estimated drug market of US$6.5 billion, and 1.1 million SLE patients, with an estimated drug market of US$3.4 billion. Our pipeline consists of two drug candidates for rheumatic diseases, namely, QX002N, targeting IL-17A, for AS and LN; and QX006N, targeting IFNAR1, for SLE.

- *Respiratory diseases.* Inflammatory respiratory diseases, such as asthma, chronic rhinosinusitis with nasal polyps (CRSwNP) and chronic obstructive pulmonary disease (COPD), have large patient populations in China. In 2030, there are estimated to be 78.1 million asthma patients in China, about 10% of whom having severe disease, indicating an estimated drug market of US$10.6 billion. In the same year, there are estimated to be 22.3 million CRSwNP patients, with an estimated drug market of US$0.6 billion, and 110.7 million COPD patients, with an estimated drug market of US$6.3 billion. Our pipeline consists of three drug candidates for respiratory diseases, namely, QX005N, targeting IL-4Rα, for CRSwNP, moderate-to-severe asthma and COPD; QX008N, targeting TSLP, for moderate-to-severe asthma and moderate-to-severe COPD; and QX007N, targeting IL-33, for COPD and asthma.

- *Digestive diseases*. Inflammatory digestive diseases, such as ulcerative colitis (UC) and Crohn's disease (CD), are conditions characterized by chronic inflammation of the gastrointestinal tract, which can be aggressive and significantly impact the patient's quality of life. In 2030, there are estimated to be 1.2 million UC and CD patients in China, with an estimated drug market of US$5.5 billion. Our pipeline consists of two drug candidates for digestive diseases, namely, QX001S for UC/CD and QX004N for CD.

The chart below sets forth key information about our pipeline as of February 20, 2024.



★ Core Product

AD: atopic dermatitis
AS: ankylosing spondylitis
CD: Crohn's disease
COPD: chronic obstructive pulmonary disease
CRSwNP: chronic rhinosinusitis with nasal polyps
CSU: chronic spontaneous urticaria
LN: lupus nephritis
PN: prurigo nodularis
Ps: psoriasis
SLE: systemic lupus erythematosus
UC: ulcerative colitis

IFNAR1: interferon-alpha/beta receptor subunit 1
IL-4Rα: interleukin-4 receptor subunit α
IL-12/IL-23p40: interleukin-12/interleukin-23 subunit p40
IL-17A: interleukin-17A
IL-23p19: interleukin-23 subunit p19
IL-31R: interleukin-31 receptor
IL-33: interleukin-33
TSLP: thymic stromal lymphopoietin

Notes:

(1) We directly commenced a Phase II clinical trial of QX005N for PN and a Phase II clinical trial of QX005N for CRSwNP by leveraging the Phase Ia clinical trial results of QX005N in healthy subjects and the Phase Ib clinical trial results of QX005N for moderate-to-severe AD in adults.

(2) We plan to consult with the NMPA about directly initiating a Phase III clinical trial of QX005N for CSU by leveraging the Phase I clinical trial results of QX005N for moderate-to-severe AD in adults as well as the Phase II clinical trial results of QX005N for moderate-to-severe AD in adults and/or PN.

(3) We plan to consult with the NMPA about directly initiating a Phase III clinical trial of QX005N for asthma by leveraging the Phase I clinical trial results of QX005N for moderate-to-severe AD in adults as well as the Phase II clinical trial results of QX005N for CRSwNP.

(4) Zhongmei Huadong and we directly commenced the Phase III clinical trial of QX001S for Ps after completion of the Phase I clinical trial as Phase II clinical trials are not required for biosimilars.

(5) In August 2020, we entered into a collaboration agreement with Zhongmei Huadong, a subsidiary of Huadong Medicine, with respect to the joint development and exclusive commercialization of QX001S in China. We retain the exclusive development and commercialization rights of QX001S outside China. For further details, please refer to "—Collaboration with Zhongmei Huadong."

(6) As of Feburary 20, 2024, we had completed subject enrollment for both the Phase Ib clinical trial and the Phase II clinical trial of QX004N for Ps. We expect to complete the Phase Ib clinical trial in the second quarter of 2024.

(7) In January 2024, we entered into a technology transfer agreement with Joincare Pharmaceutical Group Industry Co., Ltd. ("Joincare"), to grant Joincare an exclusive license to develop, manufacture and commercialize QX008N in mainland China, Hong Kong and Macau. Joincare will be responsible for the BLA application and will be the MAH of QX008N in the licensed territory, once approved. We retain the exclusive rights to develop, manufacture and commercialize QX008N outside the licensed territory. See "Business—Our Other Key Product Candidates—QX008N—Licenses, Rights and Obligations" for details.

(8) We obtained an IND approval of QX008N for the treatment of severe asthma from the FDA in September 2022 and intend to formulate a clinical development plan for QX008N in the United States depending on the data from our Phase Ia and Phase Ib clinical trials in China.

Our Core Products

QX002N

One of our Core Products, QX002N, is a high-affinity mAb targeting IL-17A, a key player in the pathological mechanism of various autoimmune diseases. IL-17A inhibitors are recommended by prevailing clinical guidelines as second-line standalone treatment (the same designation as TNF inhibitors) for AS patients with high disease activity after receiving first-line traditional treatments. Between the two classes of biologics, IL-17A inhibitors have shown clear clinical benefit in patients who are intolerant to or fail to achieve adequate disease control with TNF-α inhibitors. We have obtained IND approval for QX002N for both AS and LN and plan to prioritize the development of the former indication. QX002N demonstrated promising efficacy in our Phase Ib and Phase II clinical trials for AS. In our Phase Ib clinical trial, 62.5% and 37.5% of subjects receiving QX002N (160 mg) once every 2 weeks achieved ASAS20 and ASAS40 responses at week 16, respectively. In our Phase II clinical trial, the ASAS20 and ASAS40 response rates of subjects receiving QX002N (160 mg) once every 4 weeks reached 60.0% and 40.0% at week 16, respectively. We conducted a pre-Phase III consultation with the NMPA, which raised no material questions and confirmed that it had no objections to the commencement of such trial in its official response in July 2023. We commenced the Phase III clinical trial in September 2023 and expect to complete it in the second half of 2025.

QX005N

Our other Core Product, QX005N, is designed to inhibit IL-4Rα, a well-validated, broad-acting target for a wide range of indications. Because IL-4Rα controls the signaling of both IL-4 and IL-13, which is critical in the initiation of type 2 inflammation, it has emerged as a key target for new drug development in related indications. According to Frost & Sullivan, IL-4Rα inhibitors had been approved or were under development for 20 indications globally as of the Latest Practicable Date. Dupilumab, the first FDA-approved IL-4Rα inhibitor, is one of the best-selling biologic drugs globally for allergic diseases, with annual sales of US$8.7 billion in 2022. As of the Latest Practicable Date, we had obtained seven IND approvals for QX005N (namely, AD in adults, AD in adolescents, PN, CRSwNP, CSU, asthma and COPD), the most among IL-4Rα-targeting drug candidates in China. QX005N demonstrated favorable safety and efficacy results in our Phase Ia and Phase Ib clinical trials for AD. In the Phase Ib clinical trial in patients with moderate-to-severe AD, in each of the 300 mg and 600 mg groups, 75.0% of subjects achieved Eczema Area and Severity Index-75 (EASI-75) responses (defined as $\geq$ 75% improvement from baseline in the EASI score) and 50.0% of subjects reached Investigator's Global Assessment (IGA) scores (0 or 1) at week 12 without significantly increased safety risks. We have started a Phase II clinical trial for AD and completed patient enrollment in February 2023. In addition, we commenced a Phase II clinical trial for PN in February 2023. According to Frost & Sullivan, QX005N was the first biologic drug candidate developed by a Chinese domestic company to start a clinical trial for PN in China. In January 2024, the CDE granted QX005N the breakthrough therapy designation for the treatment of PN, signifying its superior clinical benefits compared to current treatment methods. The designation is designed to expedite the development and regulatory review of innovative drugs demonstrating substantial potential in addressing serious conditions. We also commenced a Phase II clinical trial of QX005N for CRSwNP in April 2023.

Our other key drug candidates

- QX001S: QX001S is our first expected commercial drug, the first domestically developed ustekinumab biosimilar with BLA submitted in China and potentially one of the first ustekinumab biosimilars to be approved in China. Initially approved by the FDA in 2009, ustekinumab was the first biologic treatment to selectively inhibit the IL-23 and IL-12 pathways and has been widely regarded as one of the major treatments for Ps worldwide. In 2022, it recorded sales of US$9.7 billion globally and ranked the ninth best-selling drug worldwide in the same year, according to Frost & Sullivan. In our Phase I clinical trial for Ps, QX001S demonstrated a safety and PK profile comparable to that of ustekinumab. In our Phase III clinical trial for Ps, QX001S demonstrated clinical equivalence to ustekinumab in terms of efficacy, safety, immunogenicity and PK profile. Zhongmei Huadong, a subsidiary of Huadong Medicine and our commercialization partner for QX001S, submitted a BLA in China in July 2023, which was accepted by the NMPA in August 2023 and under review as of the Latest Practicable Date. We and Zhongmei Huadong plan to begin commercializing QX001S upon expected BLA approval in the fourth quarter of 2024. We expect QX001S to be an affordable drug for a broad section of Ps patients. We also plan to develop QX001S for the treatment of UC and CD.

- QX004N: We are developing QX004N, an IL-23p19 inhibitor, for Ps and CD. IL-23p19 has emerged as a key target associated with superior efficacy for Ps patients with more severe symptoms or inadequate response to existing treatments. We completed a Phase Ia clinical trial of QX004N in healthy subjects for the Ps indication in China in September 2023 and QX004N showed a good safety profile. As of September 30, 2023, we had also commenced a Phase Ib clinical trial and a Phase II clinical trial in China to evaluate QX004N for this indication and expect to complete them in the second quarter of 2024 and the first half of 2025, respectively. We also commenced a Phase Ia clinical trial of QX004N for CD in China in February 2023.

- QX006N: We are developing QX006N, an IFNAR1-targeting mAb, for the treatment of SLE. SLE has been a difficult indication for new drug development. SAPHNELO (anifrolumab), a first-in-class IFNAR1 inhibitor, was approved by the FDA in 2021, making it the only new SLE treatment in more than 10 years. (The previous approved SLE drug, belimumab, was, at its time, the first approved SLE drug in 50 years.) Anifrolumab demonstrated clear clinical benefit in patients with moderate-to-severe SLE in a Phase III study (TULIP-2) and a Phase IIb study (MUSE). As of the Latest Practicable Date, there were no approved IFNAR1 inhibitors in China for the treatment of SLE, indicating a huge underserved market. As of the same date, our QX006N was one of the only two IFNAR1 inhibitors developed by Chinese domestic companies that had entered the clinical stage for SLE in China. We completed our Phase Ia clinical trial in healthy subjects (individuals in good general health and not having any mental or physical disorder requiring regular or frequent medication) in July 2023, where QX006N showed a good safety profile. We also initiated a Phase Ib clinical trial in SLE patients in March 2023.

- QX008N: QX008N is a humanized IgG1 mAb targeting TSLP, designed for the treatment of moderate-to-severe asthma and moderate-to-severe COPD. TSLP-targeting therapy is the only class of biologic drugs globally approved for asthma that can slow disease progression for asthma patients with low-level or no expression of type 2 biomarkers. QX008N demonstrated a potency superior to an internally prepared tezepelumab analog and exhibited a good safety profile in our Phase Ia clinical trial. We commenced a Phase Ib clinical trial in adult patients with moderate-to-severe asthma in August 2023, the remainder of which will be completed by Joincare Pharmaceutical Group Industry Co., Ltd. ("Joincare"), our licensing partner.

We are one of only a few Chinese biotech companies that are focused on autoimmune and allergic diseases and have an established commercial-scale in-house manufacturing capability, according to Frost & Sullivan. Our manufacturing facility, located at Taizhou, Jiangsu, was established according to the cGMP standards of China, the United States and the EU. Our drug substance manufacturing site has four 2,000L single-use bioreactors and one downstream purification/production line with an annual manufacturing capacity of approximately 300 kg therapeutic antibodies. Our drug product manufacturing site has one vial fill-finish and packaging production line and one prefilled syringe production line. We have successfully manufactured multiple batches of drug substance and drug products for various clinical trials, scale-up research and BLA-required process validation. We believe that our self-owned cGMP-standard manufacturing capability, coupled with our strong R&D capability, will allow us to achieve reliable cost control and ensure stable clinical and commercial drug supply to weather any supply chain disruptions.

In order to ensure the successful launch of our first expected commercial drug, QX001S, we formed a strategic collaboration with an established pharmaceutical company, Huadong Medicine, which is experienced in chronic disease management and has strong sales networks for autoimmune and allergic drugs. Huadong Medicine has established and comprehensive commercialization capabilities, with a sales team of more than 7,000 members experienced in the management of chronic diseases, such as diabetes and autoimmune diseases, an area it has focused on for over 30 years. According to Frost & Sullivan, Huadong Medicine has top-tier commercialization capabilities for autoimmune drugs in China, covering over 3,000, or more than 90% of all, Grade IIIA hospitals in China and over 15,500 hospitals of Grade II and below. A significant proportion of autoimmune and allergic disease patients (*e.g.*, Ps patients) in China initially receive treatment in local hospitals in vast, geographically dispersed areas, according to Frost & Sullivan. Therefore, an extensive sales network providing robust coverage of these areas is essential. We believe that the strategic cooperation with Huadong Medicine will help ensure effective and efficient commercialization of QX001S. Going forward, we also plan to leverage the strong physician resources and networks of established pharmaceutical companies to build connections with participants in the drug sales and distribution chain, to prepare us for future commercial launches of our other drug candidates. In the future, we plan to build a relatively small, indication-specialized in-house commercialization team, beginning with indications with relatively limited patient populations treated in a small number of key hospitals, leveraging our deep understanding of these indications and physician resources.

We are led by a seasoned management team with successful track records. Mr. Qiu Jiwan, our founder and CEO, has nearly 30 years of experience in the biotech industry, where he started as a research scientist, and extended his expertise to the management and operation of biopharmaceutical companies. As an early participant in China's nascent innovative biopharmaceutical industry, Mr. Qiu had founded Jiangsu T-mab BioPharma Co., Ltd., or Jiangsu T-mab, a venture before our Company which specialized in the R&D of genetically engineered therapeutic antibodies. During his tenure at Jiangsu T-mab, Mr. Qiu and his team developed four therapeutic biologic drugs, among which two had obtained IND approvals and two had submitted IND applications. Different from those scientist-founders who may have recently joined the industry with limited business experience, Mr. Qiu is a successful serial entrepreneur and industry veteran who has already launched and operated antibody-focused biotech companies. With in-depth insights into the market and strong resource integration capabilities, Mr. Qiu has since 2015 proactively focused on autoimmune and allergic diseases, and successfully driven the advancement of our six drug candidates to clinical stage within seven years. The rest of our management team members also have extensive and complementary experience in R&D, clinical operation, CMC and business development. Ms. Fang Min, our deputy general manager, previously worked in MNCs such as GSK plc, and has extensive experience in clinical management. Dr. Li Jianwei, the chief operating officer and deputy general manager of our Company and the general manager of Cellularforce, has over 14 years of experience in the R&D and manufacturing of recombinant protein drugs, and previously worked in a number of global biopharmaceutical companies such as Sorrento Therapeutics Inc., AbbVie Inc. and Syagen Technology Inc. Mr. Wu Shenglong, our chief business officer and deputy general manager, has extensive experience in business development, investment and financing, M&A and consultation in the pharmaceutical industry. Mr. Wu Yiliang, the executive deputy general manager of Cellularforce, has over 15 years of experience in the biotech industry, specialized in process development, quality control and commercial manufacturing of recombinant protein drugs.

We are proud to have a diverse pool of Shareholders. They include some of China's top investment funds with significant experience in the biotech sector, including Hongtai Aplus, Matrix Partners China, Triwise Capital and Efung Capital, which could provide us with complementary capabilities, strategic insights and development opportunities. Our Shareholders also include strategic investors, such as Huadong Medicine, which create strategic synergy with us in terms of drug development and commercialization.

OUR STRENGTHS

Exclusive focus on autoimmune and allergic diseases, covering four major disease areas and key therapeutic pathways

Different from our peers, we have been exclusively focused on autoimmune and allergic diseases since our inception. With an "all in" mindset, we aim to take advantage of the massive market opportunity in China through specialization and domain expertise.

There are significant unmet medical needs in autoimmune and allergic diseases in China. While autoimmune and allergic diseases represent the second-largest therapeutic area globally, only after oncology, market development in China has lagged significantly behind. According to Frost & Sullivan, China's autoimmune and allergic drug market was approximately 7.5% of that of the United States in 2020 and with biologic drugs accounting for just about 10% of the market as compared to more than 60% for the U.S. market. Despite the historical underdevelopment, the China autoimmune and allergic disease drug market has been changing in recent years. Several important factors, including approvals, NRDL admissions and accelerated sales ramp-up of blockbuster drugs, evolution of treatment paradigm from chemical drugs to biologics as well as the rise of domestic developers, have driven the industry toward more alignment with global trends and more certainty. As a result of these favorable factors, the autoimmune and allergic disease drug market in China expanded from US$7.2 billion in 2020 to US$9.0 billion in 2022, representing a CAGR of 11.8%, with the proportion of biologic drugs increased to about 20% in 2022. The market is expected to continue to unlock. According to Frost & Sullivan, it is estimated to grow to US$41.5 billion in 2030, at a CAGR of 21.1% from 2022, and with the proportion of biologic drugs increased to about 60%.

We have built a comprehensive drug pipeline that covers the four major disease areas in the field.

- *Skin diseases.* We believe that skin diseases represent one of the most desirable segments of the autoimmune and allergic disease drug market and our strategically designed skin disease drug pipeline presents a significant competitive advantage. Our pipeline comprises five drug candidates with great potential synergy, covering three indications in the area that we consider the most valuable: Ps, AD and PN. For Ps, we are developing QX001S, which is the first domestically developed biosimilar to ustekinumab, a global blockbuster biologic drug, with BLA submitted in China and potentially one of China's first approved ustekinumab biosimilars, for a broad section of Ps patients. At the same time, to achieve better coverage of Ps patients in China, we are also developing QX004N, an mAb targeting IL-23p19, which has emerged as a key target associated with superior efficacy for Ps patients with more severe symptoms or inadequate response to existing treatments. For AD, PN and CSU, we are developing QX005N, one of our Core Products, an mAb blocking IL-4Rα, a well-validated, broad-acting target for a wide range of indications. We are also developing QX013N for CSU and QX010N for pruritus. According to Frost & Sullivan, we ranked first in China in terms of the number of IND-approved biologic drug candidates and indications for skin diseases as of the Latest Practicable Date. We plan to rapidly commercialize QX001S by cooperating with Huadong Medicine. We anticipate that QX001S will benefit a large number of patients and prepare us for the future commercial launch of our other skin disease drug candidates.

- *Rheumatic diseases.* Our rheumatic disease pipeline consists of two drug candidates. We are developing QX002N, our other Core Product, for AS, a rheumatic disease with a large patient population in China. QX002N is a high-affinity recombinant humanized IgG1 mAb designed to bind specifically to IL-17A, a key player in the pathogenesis of various autoimmune diseases, including Ps and AS. We strategically chose AS as the indication for QX002N considering that we have already built a tiered and competitive Ps drug pipeline with QX001S and QX004N, and IL-17A inhibitors have demonstrated clear clinical benefit in AS patients who are intolerant to or fail to achieve effective disease control with traditional therapies. We have also obtained an IND approval for QX002N for LN. In addition, we are developing QX006N for SLE, an indication with substantial unmet medical needs in China.

- *Respiratory diseases.* Our respiratory disease pipeline consists of three drug candidates. We are developing QX005N for CRSwNP, moderate-to-severe asthma and COPD. We are also developing an innovative drug candidate QX008N for moderate-to-severe asthma and moderate-to-severe COPD. We entered into a technology transfer agreement in January 2024 to grant Joincare an exclusive license to develop, manufacture and commercialize QX008N in mainland China, Hong Kong and Macau. See "—Our Other Key Product Candidates—QX008N—Licenses, Rights and Obligations" for details. QX008N, as a TSLP inhibitor, has the potential to become an effective treatment for asthma and COPD patients with low-level or no expression of type 2 biomarkers. We are also developing QX007N, an anti-IL-33 antibody for COPD and asthma.

- *Digestive diseases*. Our digestive disease pipeline consists of two drug candidates. We are developing QX004N for CD. We also plan to develop QX001S for the treatment of UC and CD.

Our broad pipeline can create strong synergies in various of aspects, from early-stage R&D to clinical resource sharing, patient education and commercialization. In early-stage R&D, especially drug discovery and target selection, leveraging our knowledge and technical expertise in the field, we are well-versed in global scientific advancement and are able to optimize our pipeline with technological upgrade or expanded indication coverage. This way we can build a product franchise for each disease, serving the needs of patients of varying levels of conditions and paying abilities, and hence improving patient retention. With regard to clinical resources, we build and leverage our solid cooperative relationships with hospitals (as trial cites) and principal investigators (PIs, usually physicians at the hospitals responsible for the conduct of our clinical trials) and provide them with in-depth understanding of our products and pipeline, enabling us to repeatedly use these resources during our clinical trials and sales and marketing and in so doing accelerate the clinical development and commercialization of our drug candidates. For patient education and commercialization, we expect the synergies created by our pipeline to materialize as our drug candidates enter the commercial stage, especially between drug candidates with the same indication. For example, as we rapidly push forward the development and commercialization of QX001S in collaboration with Huadong Medicine, we believe QX004N could also benefit from the commercialization network and market acceptance that we expect to establish for QX001S, as both are indicated for Ps.

We are confident that our steadfast focus on the autoimmune and allergic field and our pipeline covering the four major disease areas will not only benefit patients with life-long protection and improved quality of life, but also enable us to establish ourselves as a leading Chinese innovative drug developer among physicians and patients and help us realize long-term growth.

Broad pipeline of biologics in autoimmune and allergic diseases, with Core Products in late-stage clinical development for the most advanced indications

We had built a pipeline of nine drug candidates as of the Latest Practicable Date, with six in the clinical stage. According to Frost & Sullivan, among Chinese domestic companies, we had one of the most numbers of IND-approved drug candidates in autoimmune and allergic diseases as of the Latest Practicable Date. Several of our key clinical trials have progressed or are progressing to the advanced stage according to our development plan.

- QX002N: One of our Core Products, QX002N, a high-affinity mAb targeting IL-17A, a key player in the pathological mechanism of various autoimmune diseases. IL-17A inhibitors are recommended by prevailing clinical guidelines as second-line standalone treatment (the same designation as TNF inhibitors) for AS patients with high disease activity after receiving first-line traditional treatments. Between the two classes of biologics, IL-17A inhibitors have shown clear clinical benefit in patients who are intolerant to or fail to achieve adequate disease control with TNF-α inhibitors. We have obtained IND approval for QX002N for both AS and LN and plan to prioritize the development of the former indication. QX002N has demonstrated promising efficacy in our Phase Ib and Phase II clinical trials for AS. In our Phase Ib clinical trial, 62.5% and 37.5% of subjects receiving QX002N (160 mg) once every 2 weeks achieved ASAS20 and ASAS40 responses at week 16, respectively. In our Phase II clinical trial, the ASAS20 and ASAS40 response rates of subjects receiving QX002N (160 mg) once every 4 weeks reached 60.0% and 40.0% at week 16, respectively. We conducted a pre-Phase III consultation with the NMPA, which raised no material questions and confirmed that it had no objections to the commencement of such trial in its official response in July 2023. We commenced the Phase III clinical trial in September 2023.

- QX005N: Our other Core Product, QX005N, is designed to inhibit IL-4Rα, a well-validated, broad-acting target for a wide range of indications. Because IL-4Rα controls the signaling of both IL-4 and IL-13, which is critical in the initiation of type 2 inflammation, it has emerged as a key target for new drug development in related indications. According to Frost & Sullivan, IL-4Rα inhibitors had been approved or were under development for 20 indications globally as of the Latest Practicable Date. Dupilumab, the first FDA-approved IL-4Rα inhibitor, is one of the best-selling biologic drugs globally for allergic diseases, with annual sales of US$8.7 billion in 2022. As of the Latest Practicable Date, we had obtained seven IND approvals for QX005N (namely, AD in adults, AD in adolescents, PN, CRSwNP, CSU, asthma and COPD), the most among IL-4Rα-targeting drug candidates in China. QX005N demonstrated favorable safety and efficacy results in

our Phase Ia and Phase Ib clinical trials for AD. In the Phase Ib clinical trial in patients with moderate-to-severe AD, in each of the 300 mg and 600 mg groups, 75.0% of subjects achieved EASI-75 responses and 50.0% of subjects reached IGA scores (0 or 1) at week 12 without significantly increased safety risks. We have started a Phase II clinical trial for AD and completed patient enrollment in February 2023. In addition, we commenced a Phase II clinical trial for PN in February 2023. According to Frost & Sullivan, QX005N was the first biologic drug candidate developed by a Chinese domestic company to start a clinical trial for PN in China. In January 2024, the CDE granted QX005N the breakthrough therapy designation for the treatment of PN, signifying its superior clinical benefits compared to current treatment methods. The designation is designed to expedite the development and regulatory review of innovative drugs demonstrating substantial potential in addressing serious conditions.

- QX001S: QX001S is our first expected commercial drug, the first domestically developed ustekinumab biosimilar with BLA submitted in China and potentially one of the first ustekinumab biosimilars to be approved in China. Initially approved by the FDA in 2009, ustekinumab was the first biologic treatment to selectively inhibit the IL-23 and IL-12 pathways and has been widely regarded as one of the major treatments for Ps worldwide. In 2022, it recorded sales of US$9.7 billion globally and ranked the ninth best-selling drug worldwide in the same year, according to Frost & Sullivan. In our Phase I clinical trial for Ps, our QX001S demonstrated a safety and PK profile comparable to that of ustekinumab. In our Phase III clinical trial for Ps, QX001S demonstrated clinical equivalence to ustekinumab in terms of efficacy, safety, immunogenicity and PK profile. We expect QX001S to be an affordable drug for a broad section of Ps patients. We also plan to develop QX001S for the treatment of UC and CD.

- QX004N: We are developing QX004N, an IL-23p19 inhibitor, for Ps and CD. IL-23p19 has emerged as a key target associated with superior efficacy for Ps patients with more severe symptoms or inadequate response to existing treatments. We completed a Phase Ia clinical trial of QX004N in healthy subjects for the Ps indication in China in September 2023 and QX004N showed a good safety profile. As of the Latest Practicable Date, we also commenced a Phase Ib and a Phase II clinical trial of QX004N for Ps in China. We also commenced a Phase Ia clinical trial of QX004N for CD in China in February 2023.

- QX006N: We are developing QX006N, an IFNAR1-targeting mAb, for the treatment of SLE. SLE has been a difficult indication for new drug development. SAPHNELO (anifrolumab), a first-in-class IFNAR1 inhibitor, was approved by the FDA in 2021, making it the only new SLE treatment in more than 10 years. (The previous approved SLE drug, belimumab, was, at its time, the first approved SLE drug in 50 years.) Anifrolumab demonstrated clear clinical benefit in patients with moderate-to-severe SLE in a Phase III study (TULIP-2) and a Phase IIb study (MUSE). As of the Latest Practicable Date, there were no approved IFNAR1 inhibitors in China for the treatment of SLE, indicating a huge underserved market. As of the same date, our

QX006N was one of the only two IFNAR1 inhibitors developed by Chinese domestic companies that had entered the clinical stage for SLE in China. We completed our Phase Ia clinical trial in healthy subjects (individuals in good general health and not having any mental or physical disorder requiring regular or frequent medication) in July 2023, where QX006N showed a good safety profile. We also initiated a Phase Ib clinical trial in SLE patients in March 2023.

- QX008N: QX008N is a humanized IgG1 mAb targeting TSLP, designed for the treatment of moderate-to-severe asthma and moderate-to-severe COPD. TSLP is a key upstream cytokine mediating multiple inflammatory pathways. TSLP-targeting therapy is the only class of biologic drugs globally approved for asthma that can slow disease progression for asthma patients with low-level or no expression of type 2 biomarkers. QX008N demonstrated a potency superior to an internally prepared tezepelumab analog and exhibited a good safety profile in our Phase Ia clinical trial. We commenced a Phase Ib clinical in adult patients with moderate-to-severe asthma in China in August 2023, the remainder of which will be completed by Joincare, our licensing partner.

Our pipeline also consists of QX007N for COPD and asthma, QX013N for CSU and QX010N for pruritus.

Commercial-scale in-house manufacturing capacity ensuring stable and cost-controllable supply of our products

We are one of only a few Chinese biotech companies that are focused on autoimmune and allergic diseases and have an established commercial-scale in-house manufacturing capability, according to Frost & Sullivan. Our manufacturing facility, located at Taizhou, Jiangsu, was established according to the cGMP standards of China, the United States and the EU, and has an annual manufacturing capacity of approximately 300 kg therapeutic antibodies. We believe that our self-owned cGMP-standard manufacturing capability, coupled with our strong R&D capability, will allow us to achieve reliable cost control and ensure stable clinical and commercial drug supply to weather any supply chain disruptions.

- *Manufacturing facility.* We have a CMC team of more than 150 members at our Taizhou manufacturing facility, covering the full-cycle development of monoclonal antibodies. Our drug substance manufacturing site has four 2,000L single-use bioreactors and one downstream purification/production line with an annual manufacturing capacity of approximately 300 kg therapeutic antibodies. Our drug product manufacturing site has one vial fill-finish and packaging production line, with a manufacturing capability of 18,000 vials/hour, and one prefilled syringe production line, with a manufacturing capability of 9,000 syringes/hour. We have manufactured more than 30 batches of drug substance of both 200L and 2,000L scales, more than 30 batches of drug products in vials (with 2,000 to 5,000 vials per batch) and more than 10 batches of drug products in prefilled syringes (with 3,000 to 30,000 syringes per batch), for various clinical trials, scale-up research and BLA-required process validation.

- *Cost control measures and supply chain security.* To achieve cost-controllable manufacturing and reduce risks associated with an international supply chain, we have begun to strategically seek domestic supply of cell culture media and downstream purification chromatography media since 2021, which we expect to reduce related one-off costs by, on average, approximately 40% and 30%-50%, respectively. Additionally, we have successfully developed a new drug substance upstream process, which starts a production run with high cell-density and large volume of working cell bank, and therefore could significantly shorten the production time required for each batch, improve capacity utilization and lower unit manufacturing costs. We believe our continuous cost control and efficiency improvement measures will enhance the accessibility of our drugs for both patients currently undergoing expensive biologic therapies and those who previously could not afford them. In the meantime, the strategic cooperation with domestic suppliers could also help us improve control and oversight of our supply chain to ensure stable supply of our products.

Practical commercialization model leveraging strategic partnership to secure early product launch

In order to ensure the successful launch of our first expected commercial drug, QX001S, we have formed a strategic collaboration with an established pharmaceutical company, Huadong Medicine, which is experienced with chronic disease management and has strong sales networks for autoimmune and allergic drugs. In August 2020, we entered into a strategic collaboration agreement with Zhongmei Huadong, a subsidiary of Huadong Medicine, with respect to the joint development and exclusive commercialization of QX001S in China. Huadong Medicine has established and comprehensive commercialization capabilities, with a sales team of more than 7,000 members experienced in the management of chronic diseases such as diabetes and autoimmune diseases, an area it has focused on for over 30 years. According to Frost & Sullivan, Huadong Medicine has top-tier commercialization capabilities for autoimmune drugs in China, covering over 3,000, or more than 90% of all, Grade IIIA hospitals in China and over 15,500 hospitals of Grade II and below. A significant proportion of autoimmune and allergic disease patients (*e.g.*, Ps patients) in China initially receive treatment in local hospitals in vast, geographically dispersed areas, according to Frost & Sullivan. Therefore, an extensive sales network providing robust coverage of these areas is essential. However, as we are at an early stage of preparation for future commercialization of our drug candidates, building a large commercialization team would be time-consuming and expensive, which would increase our commercial risk and distract us from our R&D efforts. To address this conundrum, we strategically choose to cooperate with established pharmaceutical companies to quickly and cost-effectively commercialize selected products. We believe that the strategic cooperation with Huadong Medicine will help ensure effective and efficient commercialization of QX001S. Going forward, we also plan to leverage the strong physician resources and networks of established pharmaceutical companies to build connections with participants in the drug sales and distribution chain, to prepare us for future commercial launches of our other drug candidates. In the future, we plan to build a relatively small, indication-specialized in-house commercialization team for some of our future drugs, beginning with indications with relatively limited patient populations treated in a small number of key hospitals, leveraging our deep understanding of these indications and physician resources.

Seasoned management team with extensive industry experience and successful entrepreneurial track records

Mr. Qiu Jiwan, our founder and CEO, has nearly 30 years of experience in the biotech industry, where he started as a research scientist, and extended his expertise to the management and operation of biopharmaceutical companies. As an early participant in China's nascent innovative biopharmaceutical industry, Mr. Qiu had founded Jiangsu T-mab, a venture before our Company which specialized in the R&D of genetically engineered therapeutic antibodies. During his tenure at Jiangsu T-mab, Mr. Qiu and his team developed four therapeutic biologic drugs, among which two had obtained IND approvals and two had submitted IND applications before the disposal of such company by Mr. Qiu. During his tenure in Hangzhou Jiuyuan Gene Engineering Co., Ltd., Mr. Qiu was primarily responsible for the R&D of innovative drug candidates and awarded for his work on the research of recombinant human interleukins (ILs). Mr. Qiu was primarily responsible for the establishment of the R&D and manufacturing platform during his time as a deputy general manager of Epitomics (Hangzhou) Biotechnology Co., Ltd., a biotech company focused on the R&D and manufacturing of antibodies. Different from those scientist-founders who may have recently joined the industry with limited business experience, Mr. Qiu is a successful serial entrepreneur and industry veteran who has already launched and operated antibody-focused biotech companies. With in-depth insights into the market and strong resource integration capabilities, Mr. Qiu has since 2015 proactively focused on autoimmune and allergic diseases, and successfully driven the advancement of our six drug candidates to clinical stage within seven years.

The rest of our management team members also have extensive and complementary experience in R&D, clinical operation, CMC and business development. Ms. Fang Min, our deputy general manager, has extensive experience in clinical management. Prior to joining us, Ms. Fang worked at various global pharmaceutical companies, including as a senior clinical research manager at GlaxoSmithKline (China) R&D Company Limited, a wholly owned subsidiary of GSK plc. Dr. Li Jianwei, the chief operating officer and deputy general manager of our Company and the general manager of Cellularforce, has over 14 years of experience in the R&D and manufacturing of recombinant protein drugs. Prior to joining us, Dr. Li worked in a number of global biopharmaceutical companies, including serving as a vice president at Sorrento Therapeutics Inc., where he was primarily responsible for process development and manufacturing of recombinant protein therapeutics, and the principal scientist at Allergan, Inc. (currently known as AbbVie Inc.), a global pharmaceutical company. Mr. Wu Shenglong, our chief business officer and deputy general manager, has extensive experience in business development, investment and financing, M&A and consultation in the pharmaceutical industry. Prior to joining us, Mr. Wu worked in a business development capacity at multiple pharmaceutical consultancy or investment companies, such as Pfizer Investment Co., Ltd. (輝瑞投資有限公司), a subsidiary of Pfizer Inc. Mr. Wu Yiliang, the executive deputy general manager of Cellularforce, has over 15 years of experience in the biotech industry, specialized in process development, quality control and commercial manufacturing of recombinant protein drugs. Prior to joining us, Mr. Wu successively served various positions at Jiangsu T-mab and was primarily responsible for process development and scale-up, among other things.

OUR STRATEGIES

Build leadership in dermatology, advance other drug candidates and strategically expand our pipeline

We plan to focus on advancing our broad pipeline in the near term, with a current priority on skin diseases. We aim to execute our multiple-asset, multiple-indication pipeline strategy for dermatology and rapidly build our leadership in this disease area. In the meantime, we also plan to advance our drug candidates for rheumatic, respiratory and digestive diseases.

- Skin diseases:
  - QX001S: We understand that Zhongmei Huadong, a subsidiary of Huadong Medicine and our commercialization partner for QX001S, plans to begin commercializing QX001S upon expected BLA approval in the fourth quarter of 2024.
  - QX005N: Among the seven indications for which we have obtained IND approvals, we plan to prioritize AD and PN in skin diseases and expect to complete the respective Phase II clinical trials for these two indications in March 2024.
  - QX004N: We also commenced a Phase Ib clinical trial and a Phase II clinical trial of QX004N for Ps in February 2023 and September 2023, respectively, and expect to complete these trials in the second quarter of 2024 and the first half of 2025, respectively.
- Rheumatic diseases:
  - QX002N: We will prioritize the development of QX002N for AS. We commenced the Phase III clinical trial in September 2023 and expect to complete it in the second half of 2025. We plan to continue the development of QX002N for LN after it obtains BLA approval for the treatment of AS.
  - QX006N: We completed our Phase Ia clinical trial in healthy subjects in July 2023. We initiated a Phase Ib clinical trial in SLE patients in March 2023 and expect to complete the trial in the fourth quarter of 2024.

- Respiratory diseases:
  - QX005N: We commenced a Phase II clinical trial for CRSwNP in April 2023 and plan to complete the trial in the fourth quarter of 2024.
  - QX008N: We commenced a Phase Ib clinical trial for moderate-to-severe asthma in August 2023, the remainder of which will be completed by Joincare, our licensing partner.
- Digestive diseases:
  - QX004N: We commenced a Phase Ia clinical trial for CD in February 2023 and expect to complete the trial in the second quarter of 2024.

In early-stage R&D, we will continue to focus on the four major disease areas in the autoimmune and allergic field. As we continue to accumulate more clinical data, we plan to conduct translational medical research to discover and validate novel biomarkers through targeted analysis of patients' response to biomarkers, which we believe will guide our preclinical evaluations and clinical studies. As we selectively expand our pipeline, we will consider our existing pipeline layout and market competition to strategically select indications for promising targets. We will also explore combination therapies based on our existing clinical data, thereby creating synergies and maximizing the value of our pipeline.

For certain indications (such as Ps, asthma and COPD), we are developing multiple drug candidates. We believe risk of competition among the drug candidates with the same indication would not cause material obstacles or market cannibalization in their commercialization because we position such drug candidates strategically as a "franchise" to serve the needs of patients of varying clinical characteristics or levels of conditions, and thereby improve patient coverage. Moreover, the drug candidates (including those with overlapping indications) have their own specific targets and achieve their therapeutic effect through different mechanisms of action. The chronic nature of autoimmune and allergic diseases dictates patients' need for long-term medication, which, in turn, leads to drug resistance and adherence issues and creates an ongoing need for therapies with alternative MOAs in the field. Having multiple candidates with diverse MOAs indicated for the same disease could help improve patient retention if they become resistant or non-responsive to a particular class of drugs.

Generally, we will continue to monitor the global scientific advances and medical needs for autoimmune and allergic diseases, and endeavor to ensure that our pipeline is in a leading position in China scientifically and we can continuously provide accessible medical solutions for patients.

Continue to optimize CMC quality management system and improve production efficiency and enhance manufacturing capacity utilization

We plan to continuously optimize our CMC quality system and improve production efficiency. In order to ensure the stability of the supply chain and further improve production efficiency, we will continue to procure quality raw materials from Chinese suppliers and develop high-density cell technology. We aim to further reduce the costs of production of biologic drugs and improve their accessibility.

While prioritizing internal R&D and commercialization demand, we plan to further enhance the utilization of our production capacity by retaining the manufacturing rights of drug candidates for which we may have established strategic collaborations. We will also continue to develop external CDMO services to diversify our source of revenue, which in turn can also support our R&D activities.

Cooperate with established pharmaceutical companies in commercialization

With respect to the commercialization of certain drug candidates, in particular, drug candidates indicated for diseases with patients located in vast, geographically dispersed areas, we plan to continue to strategically cooperate with established pharmaceutical companies that have extensive experience in chronic disease management and broad sales networks covering such areas. We believe that such strategic cooperation can improve the availability of our drugs in the fastest and most cost-effective manner. We also plan to utilize the abundant expert resources and networks of these established pharmaceutical companies to connect with participants in the drug sales and distribution chain, to set the stage for the commercialization of our forthcoming drugs. We also plan to continue working with business partners to address the insufficient awareness of chronic disease management and autoimmune and allergic diseases in China. Leveraging our business partners' academic and marketing channels, we and our business partners will jointly conduct marketing activities and academic education to physicians and patients, to improve their understanding of biologic drugs for autoimmune and allergic diseases and chronic disease management. Given the chronic nature of autoimmune and allergic diseases and the need for long-term or even life-long medication, we plan to, together with our business partners, provide continuous support to physicians and patients. We also aim to have our Core Products, QX001S and other pipeline products admitted into the NRDL after they are approved in China, thereby further increasing market access.

In terms of the status of our collaboration with Zhongmei Huadong for the commercialization of QX001S, we and Zhongmei Huadong further entered into a manufacturing agreement in September 2022, which provided that we will be solely responsible for the commercial production and quality control of QX001S. Zhongmei Huadong has completed the onsite assessment and verification of our manufacturing facility. In addition, we and Zhongmei Huadong will establish a joint commercialization committee, which is responsible for preparing the commercialization plan and manufacturing and marketing budget. Going forward, we do not expect to commit material financial resources to the collaboration with Huadong Medicine for QX001S as the cost of the Phase III clinical trial was borne by Zhongmei Huadong and the commercial production will be paid by Zhongmei Huadong at a unit supply price which will be determined by taking into account our actual costs expected to be incurred for manufacturing of QX001S and a cost-plus margin of 25% for such

manufacturing. Various departments of our team work with Zhongmei Huadong to implement the QX001S Agreements. In particular, our R&D and manufacturing teams of Cellularforce are responsible for process scale-up, process optimization, process verification, analytical method verification, stability study of drug substance or product, bio-similarity study and production of drug product for the clinical trials. We allocate relevant personnel depending on the progress of each project under the QX001S Agreements, which we do not expect to have a material impact on our R&D and manufacturing teams after the Track Record Period. Our Directors are of the view that the collaboration with Zhongmei Huadong for QX001S will unlikely affect our R&D progress of and manufacturing capacities for the Core Products, primarily because we have sufficient manufacturing capacities and the commercial production arrangement pursuant to the QX001S Agreements will be a small portion of our R&D and manufacturing activities, and we have built an efficient project management system to prioritize our R&D and manufacturing projects and we review/prioritize our annual R&D and manufacturing plans monthly. We believe the collaboration with Zhongmei Huadong will enable us to leverage Huadong Medicine's nationwide sales and marketing network to ensure successful commercialization of QX001S and such collaboration will provide valuable insights and experience for any future cooperation we might consider with respect to the development and/or commercialization of our other drug products. As of the Latest Practicable Date, we had not entered into any licensing arrangements for our drug candidates other than QX001S and QX008N (see "—Our Other Key Product Candidates—QX008N—Licenses, Rights and Obligations" for details with respect to our cooperation with Joincare).

With respect to our Core Products, QX002N and QX005N, which we anticipate will be approved and commence commercialization in China subsequent to QX001S, we aim to devise a commercialization strategy that focuses on competitive pricing and expeditious market entry, with a strategic emphasis on market cultivation. We believe that market cultivation is critical because our future competition with the incumbent MNCs and domestic biotech companies offering competing products will not be a zero-sum game. Given the low penetration rates of biologic drugs for autoimmune and allergic diseases in China, it will be of paramount importance, for us and our competitors alike, to make our best endeavors to grow the market, so that clinical and commercial value of the innovative biologic drugs could be maximized.

In terms of pricing, upon initial commercialization, we expect the estimated annual costs of QX002N and QX005N to be 20% to 30% lower than those of the same-target drugs developed by MNCs. We believe that such indicative pricing could be competitive, based on analysis of target patient population's unmet medical needs and affordability, evaluation of clinical trial data and cost analysis against competing products and comparable countries and regions. For example, our analysis includes a comparison of the annual costs of domestically developed innovative drugs with those of same-target MNC products in oncology, such as zanubrutinib and ibrutinib (comparable domestically and MNC-developed Bruton's tyrosine kinase (BTK) inhibitors indicated for various types of lymphoma), because oncology is a highly competitive landscape where there is greater availability of approved products and pricing information. We will continue to monitor the competitive landscape and strive to respond swiftly and strategically in terms of pricing to any changes that arise.

We attribute our cost advantages in part to our established in-house manufacturing capacities. Compared with most Chinese biotech companies in the autoimmune and allergic disease field, which rely on external CDMOs for product supply, our in-house manufacturing facilities enable us to better control our manufacturing costs through (i) efficient utilization of resources by effectively aligning manufacturing cycles with market feedback, maximizing utilization our existing capacity while ensuring prudent capacity planning; (ii) technological innovations and process improvements, such as the high cell-density and large-volume working cell bank that can shorten the manufacturing cycle for 2,000L drug substance batches by approximately 8-10 days and reduce unit manufacturing costs; (iii) standardization of raw materials and consumables across different projects, which promotes economies of scale and enhances our bargaining power in price negotiation with suppliers; and (iv) supply chain management, such as strategically seeking domestic supply of cell culture media and downstream purification chromatography media, which we expect to reduce related one-off costs by, on average, approximately 40% and 30%-50%, respectively.

In terms of market entry, we will adopt a multi-pronged, differentiated approach to different target market segments. We will actively seek admission for our Core Products into the NRDL upon approval, thereby attaining coverage of public hospitals in major cities and regional centers. We also aim to penetrate lower-tier markets, such as public hospitals in rural areas, through collaboration with local partners or resources to deliver our products as well as medical education on autoimmune and allergic diseases. For example, we plan to cooperate with professional academic organizations, such as the Dermatology Branch of the Chinese Medical Association, through online educational platforms as well as on-site training centers in hospitals to provide training programs for medical practitioners and relevant healthcare professionals to enhance their understanding of autoimmune and allergic diseases and the evolving treatment paradigms. We have closely cooperated with relevant hospitals and PIs through various clinical trials, especially in the dermatology area. With respect to out-of-pocket markets, we plan to achieve coverage of private hospitals, private clinics and direct-to-patient retail channels through collaborations with commercial insurance companies.

Explore international expansion opportunities

To maximize the commercial potential of our assets, we plan to explore opportunities for overseas commercialization for drug candidates that could have competitive advantages in the global market. To do so, we expect to cooperate with MNCs or pharmaceutical companies with established local sales networks to expedite the overseas clinical development, approval and commercialization efforts.

We have formulated specific development plans, including target regions and collaboration strategies, for several drug candidates. For example, for QX001S, we plan to explore collaborative opportunities in Europe, the United States and Southeast Asia and conduct trials in accordance with the local requirements, leveraging our Phase III trial results from China where possible. We obtained IND approval from the FDA for our self-developed innovative mAb QX008N for severe asthma in September 2022 and plan to explore collaboration opportunities for QX008N in the United States. In addition, considering the vast global market as evidenced by strong sales of blockbuster drugs developed by MNCs, we will also explore overseas collaboration opportunities for our drug candidates with potential competitive advantages. We intend to continue to promote our drug candidates to potential business partners globally.

Continue to recruit and develop talent

Talent is key to our development. We plan to continually recruit and develop talent.

- *R&D, clinical and registration teams*. With the advancement of our pipeline, especially with more candidates entering Phase III clinical trials, we plan to recruit more R&D, clinical and registration personnel, including professionals with working experience in MNCs or rich experience in clinical development in China or overseas. We expect these measures to enhance our R&D capabilities, advance the development, registration and globalization of our drug candidates, and enable us to identify more innovative therapeutic targets for autoimmune and allergic diseases with significant unmet medical needs, continue to expand the coverage and depth of our pipeline and enhance our market position.

- *Marketing and business development team.* While strategically cooperating with established pharmaceutical companies on the commercialization of our future drugs for diseases with patients located in vast, geographically dispersed areas, we also plan to establish a relatively small, indication-specialized in-house commercialization team, beginning with indications with relatively limited patient populations treated in a small number of key hospitals. We believe these measures will help us cover medical institutions and patient groups more precisely and comprehensively.

- *CMC and quality management team*. With a view to supporting our R&D activities and the upcoming commercialization of our drug candidates and building and maintaining a manufacturing and quality system in compliance of GMP standards, we plan to train more CMC and quality management personnel to enhance our CMC technology development capabilities and improve our quality control standards.

OUR DRUG CANDIDATES

Our Pipeline

Leveraging our integrated R&D and manufacturing platform, we had developed a pipeline of nine drug candidates as of the Latest Practicable Date, including eight innovative and one biosimilar monoclonal antibodies. The following chart summarizes our pipeline of drug candidates as of February 20, 2024.

Drug
Target
Indication
Preclinical
IND Approval
Phase I
Ia
Ib
Phase II
Phase III
BLA Approval
Commercialization Rights
Expected Near-term Milestone
QX002N
IL-17A
AS
LN
QX005N
IL-4Rα
moderate-to-severe AD in adults
AD in adolescents
PN(1)
CRSwNP(1)
CSU(2)
moderate-to-severe asthma(3)
COPD
QX001S
IL-12/ IL-23p40
moderate-to-severe plaque Ps(4)
UC/CD
QX004N
IL-23p19
Ps(6)
CD
QX006N
IFNAR1
SLE
QX008N
TSLP
moderate-to-severe asthma
moderate-to-severe COPD
severe asthma(8)
QX007N
IL-33
COPD
Asthma
QX013N
c-kit
CSU
QX010N
IL-31R
pruritus
QYuns
(5)
(7)
Completion of patient enrollment in Q2 2024
Timing of Phase I to be determined
Phase II completion in March 2024
Timing of clinical trial to be determined
Phase II completion in March 2024
Phase II completion in Q4 2024
Timing of clinical trial to be determined
Timing of clinical trial to be determined
Timing of Phase I to be determined
BLA approval in Q4 2024
Timing of IND submission to be determined
Phase Ib completion in Q2 2024; Phase II completion in 1H 2025
Phase Ia completion in Q2 2024
Phase Ib completion in Q4 2024
Phase Ib to be completed by Joincare
Timing of Phase I to be determined
Timing of Phase I to be determined
Pending IND approval
Pending IND approval
Pending IND approval
Timing of IND submission to be determined
Skin
Rheumatic
Respiratory
Digestive
China
United States

★ Core Product

AD: atopic dermatitis
AS: ankylosing spondylitis
CD: Crohn's disease
COPD: chronic obstructive pulmonary disease
CRSwNP: chronic rhinosinusitis with nasal polyps
CSU: chronic spontaneous urticaria
LN: lupus nephritis
PN: prurigo nodularis
Ps: psoriasis
SLE: systemic lupus erythematosus
UC: ulcerative colitis

IFNAR1: interferon-alpha/beta receptor subunit 1
IL-4Rα: interleukin-4 receptor subunit α
IL-12/IL-23p40: interleukin-12/interleukin-23 subunit p40
IL-17A: interleukin-17A
IL-23p19: interleukin-23 subunit p19
IL-31R: interleukin-31 receptor
IL-33: interleukin-33
TSLP: thymic stromal lymphopoietin

Notes:

(1) We directly commenced a Phase II clinical trial of QX005N for PN and a Phase II clinical trial of QX005N for CRSwNP by leveraging the Phase Ia clinical trial results of QX005N in healthy subjects and the Phase Ib clinical trial results of QX005N for moderate-to-severe AD in adults.

(2) We plan to consult with the NMPA about directly initiating a Phase III clinical trial of QX005N for CSU by leveraging the Phase I clinical trial results of QX005N for moderate-to-severe AD in adults as well as the Phase II clinical trial results of QX005N for moderate-to-severe AD in adults and/or PN.

(3) We plan to consult with the NMPA about directly initiating a Phase III clinical trial of QX005N for asthma by leveraging the Phase I clinical trial results of QX005N for moderate-to-severe AD in adults as well as the Phase II clinical trial results of QX005N for CRSwNP.

(4) Zhongmei Huadong and we directly commenced the Phase III clinical trial of QX001S for Ps after completion of the Phase I clinical trial as Phase II clinical trials are not required for biosimilars.

(5) In August 2020, we entered into a collaboration agreement with Zhongmei Huadong, a subsidiary of Huadong Medicine, with respect to the joint development and exclusive commercialization of QX001S in China. We retain the exclusive development and commercialization rights of QX001S outside China. For further details, please refer to "—Collaboration with Zhongmei Huadong."

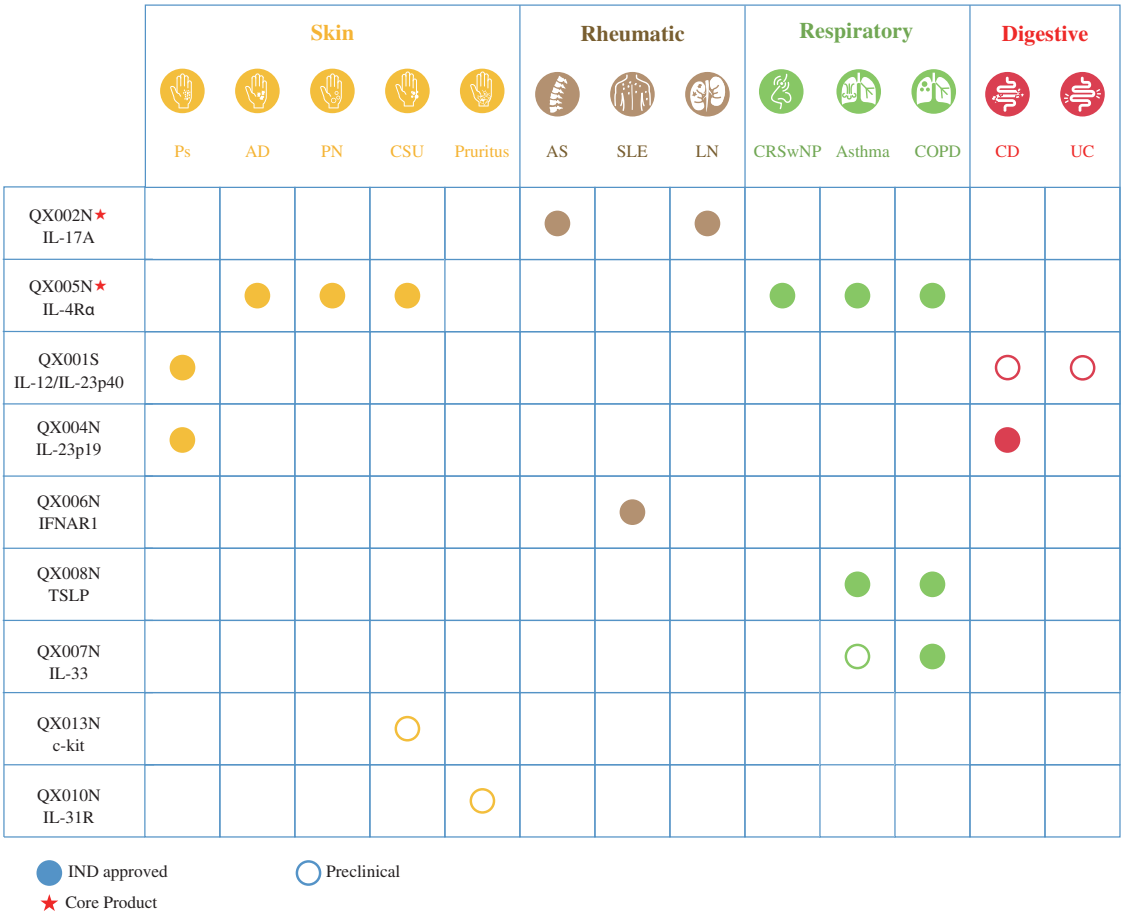
(6) As of February 20, 2024, we had completed subject enrollment for both the Phase Ib clinical trial and the Phase II clinical trial of QX004N for Ps. We expect to complete the Phase Ib clinical trial in the second quarter of 2024.

(7) In January 2024, we entered into a technology transfer agreement with Joincare Pharmaceutical Group Industry Co., Ltd. ("Joincare"), to grant Joincare an exclusive license to develop, manufacture and commercialize QX008N in mainland China, Hong Kong and Macau. Joincare will be responsible for the BLA application and will be the MAH of QX008N in the licensed territory, once approved. We retain the exclusive rights to develop, manufacture and commercialize QX008N outside the licensed territory. See "Business—Our Other Key Product Candidates—QX008N—Licenses, Rights and Obligations" for details.

(8) We obtained an IND approval of QX008N for the treatment of severe asthma from the FDA in September 2022 and intend to formulate a clinical development plan for QX008N in the United States depending on the data from our Phase Ia and Phase Ib clinical trials in China.

Our Disease Area Coverage and Product Matrix

Our broad pipeline covers the four major disease areas in the autoimmune and allergic disease field, namely, skin, rheumatic, respiratory and digestive diseases. In this field, there are often complex relationships between and among various targets and indications across disease areas. For a drug developer, product positioning is key to the potential clinical and commercial value of its pipeline. We illustrate in the chart below the positioning of our product matrix in context, and further set out our pipeline design for each of the major disease areas.



Our Skin Disease Drug Pipeline

Inflammatory skin diseases, such as psoriasis, atopic dermatitis and chronic urticaria, are characterized by the activation of immune responses via production of pro-inflammatory cytokines. Patients with these conditions often experience symptoms such as itch, dry skin, changes in skin appearance (including redness and flaky skin) and sometimes pain, to varying degrees of severity and bodily involvement. In addition, chronic inflammatory skin diseases significantly affect patients' quality of life, including their physical well-being, psychological health, social development and family relationships.

The pathogenesis of skin diseases is complex and many aspects are not fully understood. Recent research and investigation have increasingly focused on the delineation of the precise roles particular pro-inflammatory cytokines play in causing skin inflammation and the development of cytokine-directed therapeutics, including strategies targeting cytokine signaling pathways. We believe that skin diseases represent one of the most desirable segments of the autoimmune and allergic disease drug market and our strategically designed skin disease drug pipeline presents a significant competitive advantage.

Our skin disease pipeline comprises five drug candidates with great potential synergy, covering three indications in the area that we consider the most valuable: Ps, AD and PN. Specifically, we are developing (i) QX005N, one of our Core Products, for treating AD, PN and CSU; (ii) QX001S, an affordable ustekinumab biosimilar, to reach a broad section of Ps patients; (iii) QX004N, a promising alternative treatment choice for Ps, which, together with QX001S, is expected to achieve better coverage of Ps patients in China; (iv) QX013N, a promising biologic drug candidate for treating CSU; and (v) QX010N, an early-stage biologic drug candidate for treating pruritus. The following chart summarizes our inflammatory skin disease drug candidates as of February 20, 2024.

Skin disease drug candidates	QX005N				QX001S	QX004N	QX013N	QX010N
Target	IL-4Rα				IL-12/IL-23p40	IL-23p19	c-kit	IL-31R
Development stage	Phase II	Phase II	IND Approval	IND Approval	BLA Submission	Phase II	IND Submission	Preclinical
Indications	AD in adults	PN	CSU	AD in adolescents	Ps	Ps	CSU	Pruritus

Our Rheumatic Disease Drug Pipeline

Inflammatory rheumatic diseases encompass a wide variety of illnesses in which innate and adaptive immune responses lead to autoimmune-mediated inflammation and damage in the joints and connective tissues. The most common rheumatic diseases include rheumatoid arthritis (RA), spondyloarthropathies, such as ankylosing spondylitis (AS), psoriatic arthritis and reactive arthritis, and systemic lupus erythematosus (SLE). Patients with these conditions often experience symptoms such as swelling, stiffness and pain in the joints or affected area, fatigue and fever to varying degrees of severity and bodily involvement. Inflammatory rheumatic diseases could result in substantial morbidity, increased mortality and considerable financial burden for the patients in the long term.

The pathogenesis of these diseases is usually multifaceted and not fully understood. In recent decades, based on the growing knowledge of the regulatory roles certain pro-inflammatory cytokines play in the immune system, research and investigation have increasingly focused on the development of cytokine-targeting biologic therapeutics. As of the Latest Practicable Date, we had two drug candidates indicated for rheumatic diseases, namely, QX002N, one of our Core Products, and QX006N. Specifically, we are developing (i) QX002N as a promising AS and lupus nephritis (LN) drug candidate with potentially improved efficacy and safety profile for patients with inadequate response or intolerant to existing treatments, and (ii) QX006N, a humanized mAb targeting the receptor for type I interferons (IFNs), for the treatment of SLE, an indication with substantial unmet medical needs in China.

The following table summarizes our inflammatory rheumatic disease drug candidates as of February 20, 2024.

Rheumatic disease drug candidates	QX002N		QX006N
Target	IL-17A		IFNAR1
Development stage	Phase III	IND Approval	Phase I
Indications	AS	LN	SLE

Our Respiratory Disease Drug Pipeline

Inflammatory respiratory diseases are conditions characterized by chronic inflammation of the respiratory system, such as asthma, chronic obstructive pulmonary disease (COPD) and chronic rhinosinusitis. People with these conditions often experience breathing problems and other symptoms such as coughing, wheezing, chest pressure and fatigue to varying degrees of severity. These conditions are not only frustrating to live with. They can also be life-threatening, particularly asthma and COPD. While current treatment of such inflammatory respiratory diseases are dominated by inhaled corticosteroids, target-specific biologics are an emerging treatment option. In addition, based on the particular pathology of each subtype of inflammatory respiratory diseases, especially asthma and COPD, some targets have been discovered to be specifically suitable for certain subtypes of such diseases. As of the Latest Practicable Date, we had three drug candidates indicated for chronic rhinosinusitis with nasal polyps (CRSwNP), asthma and COPD. By developing drug candidates for various subtypes of such inflammatory respiratory diseases, we believe we have a strong and comprehensive product pipeline to cover this field. Specifically, our respiratory disease pipeline consists of (i) QX005N as a drug candidate to reach a large number of CRSwNP and asthma patients and for patients with eosinophilic COPD, (ii) QX008N as a drug candidate for asthma and COPD patients, including those with low-level or no expression of type 2 inflammation biomarkers, and (iii) QX007N as a drug candidate with particular promising efficacy for COPD patients with prior smoking history and an alternative drug candidate for asthma patients. The following chart summarizes our inflammatory respiratory disease drug candidates as of February 20, 2024.

Respiratory disease drug candidates	QX005N			QX008N		QX007N	
Target	IL-4Rα			TSLP		IL-33	
Development stage	Phase II	IND Approval	IND Approval	Phase Ib	IND Approval	IND Approval	IND submission
Indications	CRSwNP	Asthma	COPD	Asthma	COPD	COPD	Asthma

Our Digestive Disease Drug Pipeline

Inflammatory digestive diseases, particularly inflammatory bowel disease (IBD), are conditions characterized by chronic inflammation of the digestive system. The two most common types of IBD are ulcerative colitis (UC) and Crohn's disease (CD). Both conditions involve an abnormal response of the body's immune system and have a significant impact on the patient's quality of life. In many cases, both conditions can be aggressive and disabling. As of the Latest Practicable Date, we had two drug candidates indicated for inflammatory digestive diseases, including QX004N for CD and QX001S for UC/CD. Specifically, we are developing QX004N as a promising alternative drug candidate for CD with potentially improved efficacy for patients with more severe symptoms or inadequate response to existing treatments and plan to develop QX001S as an affordable drug to reach a large number of UC and CD patients. The following chart summarizes our digestive disease drug candidates as of February 20, 2024.

Digestive disease Drug candidates	QX004N	QX001S
Target	IL-23p19	IL-12/IL-23p40
Development stage	Phase Ia	Preclinical
Indications	CD	UC/CD

Our Core Products

QX002N

QX002N, discovered and developed by our Company, is one of the first domestically developed IL-17A antibodies to obtain an IND approval from the NMPA for the treatment of AS. IL-17A is a key pro-inflammatory cytokine involved in the regulation of inflammatory responses and bone metabolism. Research has shown that IL-17A plays an important role in the pathogenesis of AS and is also involved in autoantibody production and organ damage in SLE patients, which could lead to LN development. We believe that QX002N, as an anti-IL-17A therapy, can offer a much-needed effective treatment option with a different mechanism of action for AS and LN patients experiencing inadequate response, intolerance or unacceptable safety concerns with the currently available treatments.

As of the Latest Practicable Date, we were developing QX002N for two indications, AS and LN.

- AS: We obtained an IND approval for QX002N for the treatment of active AS in adults in April 2019. QX002N showed favorable safety and immunogenicity properties in our Phase Ia study in healthy subjects and promising efficacy in our Phase Ib and Phase II clinical trials in AS patients in China. We conducted a pre-Phase III consultation with the NMPA, which raised no material questions and confirmed that it had no objections to the commencement of such trial in its official response in July 2023. We commenced the Phase III clinical trial in September 2023.

- LN: We received IND approval of QX002N for LN in October 2021 and expect to continue the development of QX002N for the treatment of LN after it obtains the BLA approval for the treatment of AS. As of the Latest Practicable Date, we had not initiated any clinical trial of QX002N for LN.

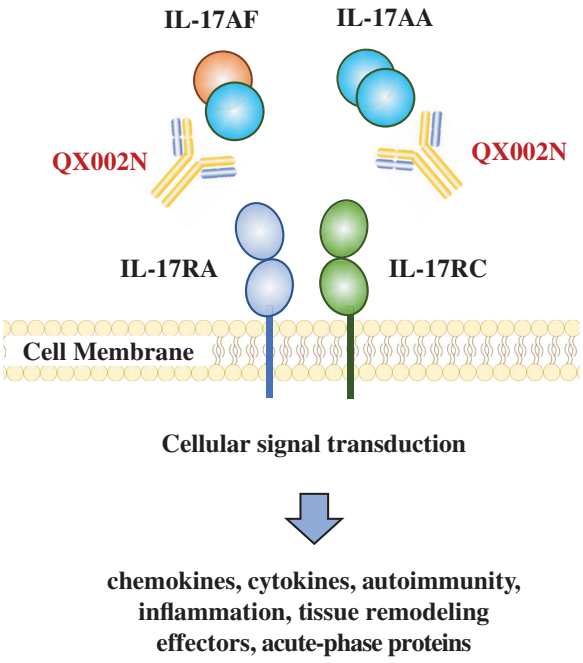
We hold the rights for the development and commercialization of QX002N globally and do not have any current plan to out-license QX002N in domestic or overseas markets.

Mechanism of Action

IL-17A is a member of the IL-17 superfamily of cytokines, which perform regulatory functions in the host immune system by inducing and working in synergy with various other pro-inflammatory cytokines, enhancing chronic inflammation. In addition, IL-17A is also involved in the regulatory mechanism of bone remodeling, by inducing the expression of receptor activator of nuclear factor-κB ligand (RANKL), which activates osteoclast, a type of bone cells responsible for bone erosion and remodeling. Elevated levels of IL-17A have been detected in the serum and synovial joint fluid of AS patients and identified as a major factor in AS pathogenesis and IL-17A inhibition has been shown to have significant clinical efficacy in treating AS. In addition, studies have shown that elevated expression of Th17-related cytokines (such as IL-17) in the urinary system is also associated with enhanced recruitment of immune cells to the kidney and thereby leading to LN development in SLE patients.

QX002N is a humanized IgG1 mAb that is designed to specifically bind to IL-17A, including IL-17AA and IL-17AF, thereby blocking their binding to the intended receptor complex, comprised of interleukin 17 receptor A (IL-17RA) and interleukin 17 receptor C (IL-17RC), and preventing the subsequent activation of several pro-inflammatory signaling pathways.

The following diagram illustrates the mechanism of action of QX002N.



Source: the Company

Ankylosing Spondylitis

Ankylosing spondylitis (AS) is a chronic progressive inflammatory disease that is primarily characterized by inflammation of the spinal joints, leading to reduced flexibility of the joints and stiffness in the spine over time. The pathology mainly affects the entheses, where ligaments, tendons and capsules attach to the bone. In severe cases of AS, the entheses are affected by inflammation, as well as bone erosion and formation of syndesmophytes, aberrant bony growths as a result of the calcification of or hardening inside ligaments, which could cause the adjacent bones in the spine to fuse (grow together) and form one cohesive unit. Those parts of the spine become stiff and inflexible. Fusion can also stiffen the rib cage, restricting lung capacity and function. AS may also cause inflammation in other parts of the body, including the eyes, shoulders and knees, as well as the aorta, the main artery of the body.

There is currently no cure for AS and available treatments aim to control inflammation, prevent joint damage and provide symptom relief. In recent decades, the pivotal role of cytokines (small signal proteins that regulate the growth and activity of other immune system cells) in the development of AS has been closely studied and biologics targeting pro-inflammatory cytokines, in particular, tumor necrosis factors (TNFs) and interleukins (ILs), have been recommended as second-line treatment for AS patients with high disease activity after receiving first-line traditional treatments. We are developing our Core Product, QX002N, a monoclonal antibody (mAb) targeting IL-17A, as a treatment option with a potentially favorable efficacy and safety profile for AS patients.

Market Opportunity and Competition

According to Frost & Sullivan, the AS patient population in China reached 3.9 million in 2022, and is expected to remain relatively stable over the next decade. A considerable proportion of AS patients first develop symptoms in their early adulthood or adolescence, and require long-term treatment to control disease progression.

Medications indicated for AS mainly include NSAIDs, which are widely accepted as the first-line medication for treating AS, traditional immunosuppressive disease-modifying anti-rheumatic drugs (DMARDs) and corticosteroids. However, NSAIDs are noted with limited efficacy in patients with more severe cases of AS and their effectiveness in suppressing bone erosion and remodeling associated with AS remains unclear. In addition, there are safety risks associated with long-term systemic use of such therapies, especially corticosteroids. Maintenance treatment with systemic use of corticosteroids can cause a series of severe adverse effects, such as osteoporosis, adrenal suppression and hyperglycemia (high blood sugar), and dose-dependent growth suppression in children and adolescents.

In the past decades, biologic drugs have emerged as effective innovative therapies for AS. According to Frost & Sullivan, the market for biologic drugs indicated for AS in China is estimated to increase from US$0.3 billion in 2022 to US$3.9 billion in 2030, at a CAGR of 37.8%. There are two classes of approved biologic drugs in China for the treatment of AS, namely, TNF inhibitors and IL-17 inhibitors. TNF, most prominently TNF-α, is a type of pro-inflammatory cytokine produced by certain types of white blood cells during acute inflammation and plays a role in the regulation of the immune system. Dysregulation of TNF may lead to excessive inflammation, which in turn may cause various autoimmune and immune-mediated disorders. TNF inhibitors block the binding of TNF to TNF receptors, thereby suppressing their biological effects. TNF inhibitors are currently one of the most commonly used biologic drugs for AS in China. However, studies have shown that up to 40% of patients with AS become intolerant to or fail to achieve adequate disease control with anti-TNF therapies, indicating significant heterogeneity in treatment response. Thus, there remains an unmet medical need for novel treatments with a different mechanism of action.

With recent scientific advancements demonstrating the role of IL-17A in AS pathogenesis, IL-17A antibodies have emerged as a new class of biologic drugs for AS and have been recommended by prevailing clinical guidelines as second-line standalone treatment (the same designation as TNF inhibitors) for AS patients with high disease activity after receiving first-line traditional treatments. We believe our QX002N will primarily compete with anti-IL-17 drugs and other biologic drugs, primarily TNF inhibitors, in China.

As of the Latest Practicable Date, there were 20 biologic drugs approved for AS treatment in China, comprising 18 TNF inhibitors (including adalimumab and 7 adalimumab biosimilars) and 2 IL-17A antibody drugs, namely, secukinumab and ixekizumab, both of which had also been approved by the FDA for the treatment of adults with AS. As of the same date, in addition to our QX002N, there were 21 biologic drug candidates indicated for AS in the clinical stage in China, comprising 11 TNF inhibitors (including 8 proposed adalimumab biosimilars) and 10 IL-17 inhibitors.

The following table sets forth details of QX002N and IL-17 antibody drugs or drug candidates in the clinical stage for AS in China as of the Latest Practicable Date.

Marketed IL-17A Inhibitors for AS in China

Target	Brand Name	INN	Company	NMPA Approval Time	Median Price[1]	NRDL Inclusion	Expected Patent Expiration[2]
IL-17A	Cosentyx	Secukinumab	Novartis	2020	1,188.0	Yes	2025
	Taltz	Ixekizumab	Eli Lilly	2022	1,218.0	Yes	2026

Clinical-Stage IL-17A Inhibitor Candidates for AS in China

Target	Drug Code	Company	Status	First Posted Date
IL-17A	GR1501	GenrixBio	BLA submission	2024-01-04
	SHR-1314	Hengrui	BLA submission	2024-02-08
	Netakimab	Biocad	Phase III	2022-09-30
	QX002N	**the Company**	**Phase III**	**2023-08-31**
	AK111	Akeso	Phase III	2023-10-08
	JS005	Junshi Bioscience	Phase II	2021-09-30
	HB0017	Huabo	Phase II	2023-04-12
	SSGJ-608	SunShine Guojian	Phase II	2024-01-29
	Secukinumab-CMAB015	MabPharm	Phase I	2023-01-18
IL-17A, IL-17F	Bimekizumab	UCB Pharma	BLA submission	2023-07-20
	LZM012	Livzon	Phase III	2023-07-28

Source: Frost & Sullivan Report (based on annual reports of relevant companies and information published by the NMPA)

Notes:

(1) Reflects the NRDL median price for minimum formulation unit in 2022 in RMB.

(2) Reflects the present anticipated expiration time of the relevant amino acid sequence patent in the PRC.

In addition to the traditional and biologic therapies, tofacitinib by Pfizer, a small molecule Janus kinase (JAK) inhibitor, has also been approved for AS treatment by the FDA and the NMPA. JAK is a family of signaling molecules involved in the intracellular transduction of immune signaling of various cytokine receptor cells. JAK inhibitors have shown clear clinical benefit in AS patients in terms of symptom relief and reduction of inflammation. However, tofacitinib is recommended by the FDA only for AS patients who are intolerant or non-responsive to one or more TNF inhibitors as there remain concerns over the safety profile of JAK inhibitors.

Our Advantages

Compared with other biologic drugs and drug candidates indicated for AS, QX002N has the following potential advantages:

- *Effective biologic drug for AS with a different mechanism of action.* In the updated guidelines published by ASAS and European Alliance of Associations for Rheumatology (EULAR) for the management of AS, IL-17A inhibitors are recommended as second-line standalone treatment (the same designation as TNF inhibitors) for AS patients with persistently high disease activity after receiving

first-line traditional treatments. Additionally, studies have shown that many patients with inflammatory rheumatic disease, particularly AS and psoriatic arthritis (PsA), who were intolerant or non-responsive to TNF inhibition therapies showed disease improvement when treated with anti-IL-17A drugs. A Phase III clinical study of ixekizumab (an IL-17A inhibitor) in AS patients showed that, at week 16, 69% and 52% of patients who had received 80 mg ixekizumab once every two weeks (Q2W) achieved ASAS20 and ASAS40 responses, respectively, as compared to 59% and 36% for patients who had received 40 mg adalimumab (one of the best-selling TNF inhibitors) Q2W, indicating a better trend of efficacy by ixekizumab. ASAS20 and ASAS40 are industry benchmarks for AS disease improvement, representing a 20% and 40% improvement, respectively, in key aspects of AS symptoms according to measurements selected by ASAS. Moreover, compared with TNF inhibitors, IL-17A inhibitors are more targeted and with generally fewer warnings and precautions. In particular, studies suggest that IL-17A inhibitors could be safer for patients with high risk for severe and opportunistic infections such as tuberculosis, which were the primary side effects of TNF inhibitors. As an IL-17A antibody drug candidate, QX002N has the potential to provide AS patients with an effective and well-tolerated biologic therapy.

- *Promising efficacy.* QX002N showed promising efficacy in AS patients in our Phase Ib and Phase II clinical trials. In our Phase Ib trial, 62.5% and 37.5% of subjects in the treatment group receiving QX002N (160 mg) Q2W achieved ASAS20 and ASAS40 responses, respectively, at week 16. In our Phase II clinical trial, the ASAS20 and ASAS40 response rates of subjects receiving QX002N (160 mg) once every four weeks (Q4W) reached 60.0% and 40.0% at week 16, respectively. For details, see "—Summary of Clinical Trials" below.

- *Good safety profile.* In comparison with approved and other clinical stage IL-17A inhibitors with reported clinical data, QX002N demonstrated a good safety profile in its clinical trials. No SAEs were reported in the Phase Ia and Phase Ib trials. In its Phase II clinical trial in 120 AS patients, only one SAE (unrelated to the drug) was reported, lower than those reported by secukinumab and ixekizumab in their respective registrational trials (5 SAEs among 249 patients in Measure 1 and 8 SAEs among 249 patients in Measure 2 for secukinumab, and 17 SAEs among 327 patients on Q4W regimen and 19 SAEs among 314 patients on Q2W regimen in Coast-V and Coast-W for ixekizumab). Additionally, in comparison with TNF inhibitors, QX002N, as an IL-17 inhibitor, could provide a more suitable treatment option for patients with high risk for tuberculosis infections, which were the primary side effects of TNF inhibitors.

- *Promising accessibility*. Historically, treatment regimens of anti-IL therapies for AS have been relatively costly, which in turn limited patients' access. For example, according to Frost & Sullivan, in 2022, the annual cost of ixekizumab for the treatment of AS in China was estimated to be approximately RMB15,000 to RMB17,000, with a treatment regimen of two doses of 80 mg for the first week and 80 mg Q4W thereafter. According to Frost & Sullivan, in 2022, the annual cost of secukinumab in China was estimated to be approximately RMB19,000 (with a loading dose regimen of 150 mg for five consecutive weeks and then Q4W thereafter) or RMB15,000 (with a dosing regimen of 150 mg Q4W without loading doses). Leveraging our integrated R&D and in-house manufacturing capabilities and cost control measures, we aim to make QX002N more accessible to AS patients in China. QX002N is designed to be administered with a dosing regimen of 160 mg Q4W. Its estimated annual cost would be lower than secukinumab and ixekizumab by approximately 20% to 30% upon commercialization, making it a more affordable option.

Summary of Clinical Trials

We commenced a Phase III clinical trial of QX002N for the treatment of AS in September 2023, which is expected to be completed in the second half of 2025.

Ongoing Phase III Clinical Trial

Trial design: Our phase III clinical trial in China is a multi-center, randomized, double-blind and placebo-controlled trial in adult patients with active AS. The primary endpoint is the efficacy and safety features of QX002N at week 16 in comparison to placebo. The secondary endpoints include QX002N's long-term efficacy and safety features at week 52, PK and PD characteristics and immunogenicity. The full treatment period is expected to be 52 weeks, consisting of a 16-week placebo-controlled treatment period and a 36-week extended treatment period. A total of 640 patients with active AS are expected to be enrolled and randomly assigned at the ratio of 1:1 to a QX002N group, which would receive 160 mg QX002N Q4W through out the placebo-controlled treatment period and the extended treatment period, and a control group, which would receive placebo Q4W for the placebo-controlled treatment period and then 160 mg QX002N Q4W after the evaluation of all relevant parameters at week 16 and throughout the extended treatment period.

Trial status: The Phase III clinical trial was initiated in September 2023. We had enrolled 337 patients as of the Latest Practicable Date and expect to complete patient enrollment in the second quarter of 2024.

Phase II Clinical Trial

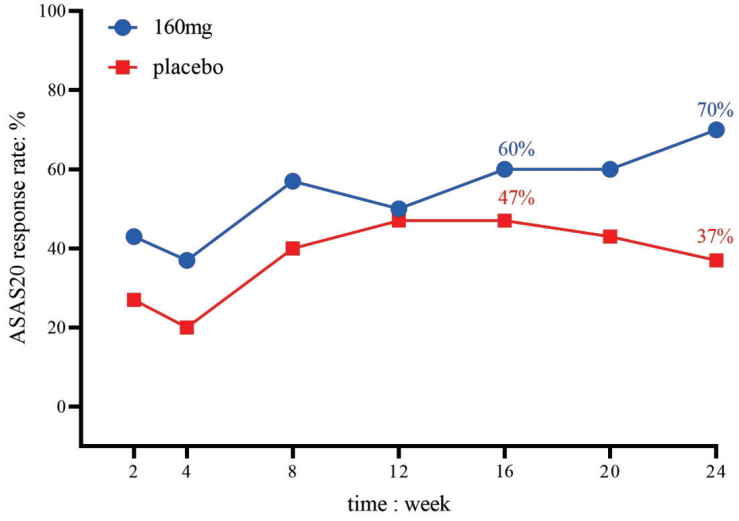
Trial design: Our phase II clinical trial in China was a multi-center, randomized, double-blind and placebo-controlled trial in patients with AS. The primary endpoint was the percentage of patients achieving ASAS20 response at week 16 and safety parameters. The secondary endpoints included, among others, efficacy parameters, such as ASAS20/ASAS40 at weeks 2, 4, 8, 12, 20 and 24 and improvements in quality of life, PK parameters and immunogenicity. A total of 120 patients with AS would be enrolled and randomly assigned to four groups at the ratio of 1:1:1:1 to receive 80 mg QX002N, 160 mg QX002N, 240 mg QX002N or placebo Q4W, respectively. The treatment period would be 16 weeks, followed by eight weeks of follow-up visits.

Trial status: The Phase II clinical trial was initiated in January 2022. We completed patient enrollment in September 2022, with a total of 120 patients enrolled. During the trial, we experienced delay in the completion of patient enrollment for approximately two months (from the expected completion in July 2022 to September 2022) and interruption in follow-up visits of some patients due to COVID-19-related lockdown measures in cities where our clinical trial sites/patients were located. We completed the trial in August 2023.

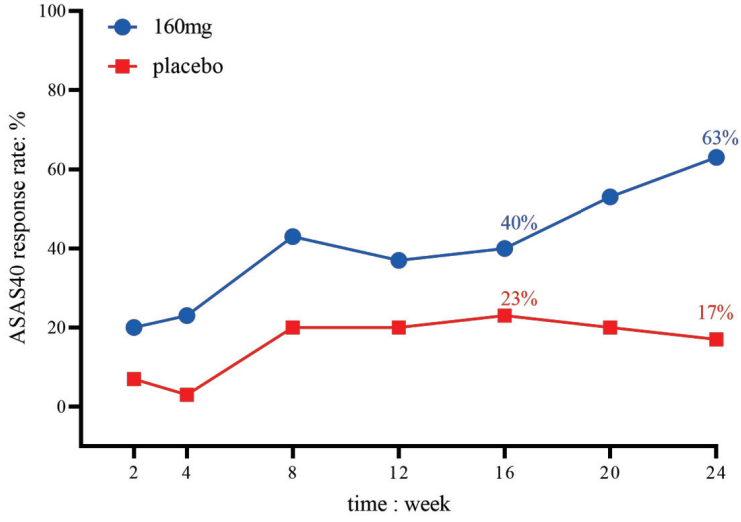
Safety results: QX002N showed a good safety profile among AS patients in all dose groups. The overall TEAE incidence rates of QX002N groups were slightly higher than that of the placebo group, but no significant difference was observed. Among the 119 patients who received at least one drug administration and were included in the safety analysis, 107 (89.9%) patients (28 in the 80 mg group, 28 in the 160 mg group, 26 in the 240 mg group and 25 in the placebo group) reported TEAEs, among which 61 (51.3%) patients (16 in the 80 mg group, 16 in the 160 mg group, 16 in the 240 mg group and 13 in the placebo group) reported TEAEs that were considered to be drug-related. Five patients (four in the 80 mg group and one in the 160 mg group) reported six TEAEs of grade 3 or above as defined in the CTCAE 5.0, consisting of one grade 4 AE of hypertriglyceridemia (HTG, indicating an excessive amount of fats in the blood, possibly resulting from the changes in fat metabolism induced by inflammatory responses of the immune system), one grade 3 AE of HTG, two grade 3 AEs of elevated blood triglycerides, one grade 3 AE of hematochezia (blood in the stool) and one grade 3 AE of AS. None of the grade 3 or grade 4 AEs were considered to be drug-related. In particular, one patient in the 160 mg group reported one grade 3 AE of AS worsening from day 135 to day 141 of the trial (after the treatment period) and was hospitalized for six days. This AE was determined to be unrelated to the drug and recorded as SAE due to hospitalization. The patient recovered after medical treatment before the end of trial. Two patients experienced TEAEs that resulted in the termination of the trial. In particular, one patient in the 160 mg QX002N group experienced a grade 2 TEAE of urticaria from day 14 to day 99 of the trial, which was considered to be possibly drug-related and resulted in the termination of the patient's participation in the trial and permanent discontinuation of the drug. The patient recovered from the TEAE after medical treatment. One patient in the 240 mg QX002N group experienced a grade 1 TEAE of rash at injection site from day 2 to day 16 of the trial, which was considered to be possibly drug-related and resulted in the termination of the patient's participation in the trial and permanent discontinuation of the drug. The patient recovered from the TEAE without medical treatment.

Efficacy results: The ASAS20 response rates of the 80 mg, 160 mg and 240 mg QX002N groups reached 70.0%, 60.0% and 55.2%, respectively, at week 16, compared to 46.7% of the placebo group at the same week. The ASAS20 response rates of all QX002N groups demonstrated clear clinically significant (albeit not statistically significant) difference compared to that of the placebo group at week 16. At week 20, the ASAS40 response rates of all QX002N groups showed statistically significant advantage compared to that of the placebo group at the same week. At week 24, the ASAS20 response rates and ASAS40 response rates of all QX002N groups showed statistically significant advantage compared to those of the placebo group at the same week. The charts below illustrate the percentages of patients achieving ASAS20 and ASAS40 responses in the 160 mg QX002N group in comparison with the placebo group from week 2 to week 24.

ASAS20 response rates



ASAS40 response rates



PK: During the treatment period, at the same follow-up visit point, the geometric means of drug plasma trough concentrations (C_{trough}, indicating the concentration reached by a drug immediately before the next dose) increased with dose escalation for patients receiving QX002N. Temporary steady-state was not achieved at week 8 after multiple administrations of QX002N, indicating a certain degree of accumulation with Q4W dosing. The geometric means of C_{trough} of QX002N groups prior to week 16 administration were similar to the simulation predictions based on the analysis of PK data from the Phase Ib trial of QX002N, indicating that QX002N reached the expected target concentration levels in this trial.

PD: The PD parameter measured the total concentration of IL-17A in serum, which consisted of the amount of free IL-17A and IL-17A complexed with QX002N. At all follow-up visit points after QX002N administration, the average total serum IL-17A concentrations of all QX002N groups significantly increased compared to that of the placebo group, which was similar to the trend observed for secukinumab, an FDA- and NMPA-approved IL-17A inhibitor and consistent with the hypothesis that the clearance of IL-17A as complexed with QX002N was slower than that of free IL-17A.

Immunogenicity: One patient (in the 240 mg group) reported a positive ADA response before week 12 administration, two patients (one in the 80 mg group and one in the 240 mg group) reported positive ADA responses before week 16 administration and five patients (two in the 80 mg group, one in the 160 mg group and two in the 240 mg group) reported positive ADA responses before week 24 administration. One patient with positive ADA response reported an AE of rash at the injection site and other ADA positives reported no injection site reactions or severe allergies.

Conclusion: In this trial, QX002N demonstrated a good safety profile in AS patients after multiple administrations, with no significant safety risk identified compared to the placebo group. The ASAS20 response rates of all QX002N groups demonstrated clear clinically significant (albeit not statistically significant) difference compared to that of the placebo group at week 16. The ASAS20 response rates of all QX002N groups at week 20 and the ASAS20 and ASAS40 response rates of all QX002N groups at week 24 showed statistically significant differences compared to those of the placebo group at the same weeks. Therefore, a Phase III clinical trial was recommended, with a dose regimen of 160 mg QX002N administered Q4W.

Phase Ib Clinical Trial

Trial design: Our Phase Ib clinical trial was a single-center, randomized, double-blind and placebo-controlled multiple-dose escalation trial in AS patients. The primary endpoints were safety, tolerability and PK parameters. The secondary endpoints included (i) efficacy parameters, including the percentage of patients achieving ASAS20 and ASAS40 responses, (ii) immunogenicity and (iii) recommending dosing regimen for a Phase II clinical trial. We planned to enroll 30 AS patients in this trial and randomly assign them into three groups to receive 40 mg, 80 mg and 160 mg QX002N or placebo, respectively, once every 2 weeks (Q2W). Within each dose group, eight patients would receive QX002N and two patients would receive placebo. The patients would receive a total of six doses of QX002N (or placebo) from week 0 to week 10, followed by 14 weeks of follow-up visits.

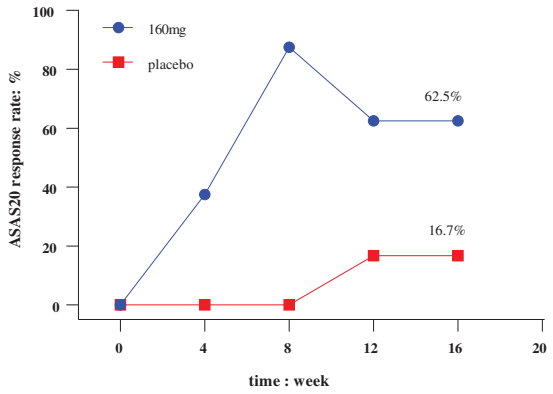
Trial status: The phase Ib clinical trial was initiated in September 2020 and completed in September 2022. A total of 30 patients were enrolled, among which 28 completed the trial.

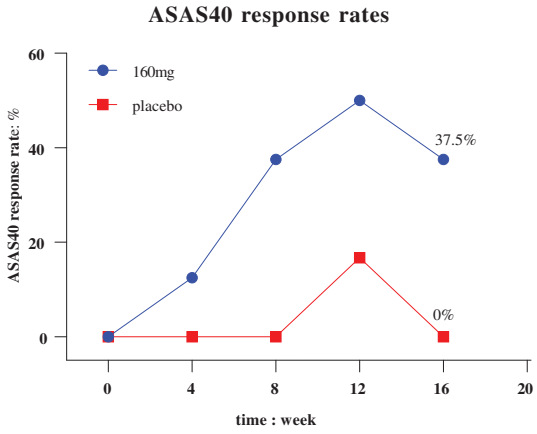
Safety results: QX002N was well-tolerated and showed a good safety profile in AS patients of all dose groups. No serious AEs (SAEs) were reported. No patients withdrew from the clinical trial due to AEs, and no patients were suspended or down-regulated due to AEs. 27 (90.0%) patients had 132 AEs, among which 85 AEs were considered to be drug-related. Four patients reported seven AEs of grade 3 or above (one of grade 4 and six of grade 3 as defined in the CTCAE 5.0), among which only one AE of grade 3 was considered to be drug-related. Specifically, one patient in the 40 mg group reported one grade 4 AE of HTG, which was determined to be possibly unrelated to the drug and the patient recovered from the AE without any medical treatment. One patient in the 40 mg group reported one grade 3 AE of high blood pressure that was possibly unrelated to the drug and recovered after medical treatment before the end of trial. One patient in the 80 mg group reported four grade 3 AEs of HTG, only one of which was determined to be possibly related to the drug and the patient received treatment for such AE and recovered before the end of the trial. One patient in 160 mg group reported one grade 3 AE of HTG that was possibly unrelated to the drug and recovered without any medical treatment.

PK: Over a dose range from 40 mg to 160 mg, systemic exposure of QX002N (C_{max}, AUC_{last} and AUC_{inf}) increased in a roughly proportional manner with increasing dose. The mean $T_{1/2}$ of QX002N ranged between 25.3 to 29.5 days in AS patients.

Efficacy results: The ASAS20 response rates in the 40 mg-160 mg dose groups reached 25.0%-62.5% at week 16, compared to 16.7% in the placebo group at the same week. The ASAS40 response rates in the 40 mg-160 mg dose groups reached 12.5%-37.5% at week 16, and no subject in the placebo group reached ASAS40 response at week 16. The charts below illustrate the percentages of patients achieving ASAS20 and ASAS40 responses in the 160 mg group in comparison with the placebo group from week 4 to week 16.

ASAS20 response rates





Immunogenicity: In this trial, the immunogenicity risk of QX002N was low, with only one patient (in the 160 mg group) showing a positive ADA response on day 99 and returning to negative on day 127 of the trial.

Conclusion: The trial met its primary and secondary endpoints. In this trial, QX002N was well-tolerated in AS subjects, and demonstrated a good safety profile and dose-proportional PK after multiple administration. Over the dose range of 40 mg, 80 mg and 160 mg, the efficacy of QX002N enhanced as the dose level increased. In addition, the immunogenicity risk of QX002N was extremely low. Based on the trial results, the recommended starting dose for the Phase II clinical trial was 80 mg.

Phase Ia Clinical Trial

Trial design: The phase Ia clinical trial in China was a single-center, randomized, double-blind and placebo-controlled dose-escalation trial in healthy subjects. The primary objective of this trial was to evaluate the safety and tolerability of single escalating dose of QX002N in healthy subjects. The secondary objectives were to evaluate the PK and immunogenicity of QX002N, and to determine the recommended dose for a Phase Ib clinical trial. A total of 65 subjects would be assigned to seven groups to receive a single subcutaneous injection of 10 mg, 20 mg, 40 mg, 80 mg, 160 mg, 240 mg and 320 mg QX002N or placebo, respectively, with five subjects assigned to the 10 mg group and ten subjects assigned to each of the remaining six dose groups. Within each dose group, the ratio of subjects receiving QX002N to those receiving placebo would be 4:1.

Trial status: The phase Ia clinical trial was initiated in June 2019 and was completed in September 2021. A total of 65 subjects were enrolled and completed the trial.

Safety results: QX002N was well-tolerated in healthy subjects in the dose range from 10 mg to 320 mg. No SAEs were reported. 31 (59.6%) subjects in QX002N groups and 6 (46.2%) subjects in the placebo group reported 91 AEs, among which only one subject in 10 mg QX002N group experienced one grade 3 AE (as defined in the CTCAE 5.0) of HTG that was possibly related to the drug and recovered without any medical treatment. All subjects fully recovered from the AEs at the end of the study.

PK: QX002N exhibited dose-proportional PK in healthy subjects over a dose range from 10 mg to 320 mg following single subcutaneous administration. The mean $T_{1/2}$ of QX002N ranged between 24.3 to 35.1 days, which is comparable to the previously published data of secukinumab (22 to 31 days in Ps patients) and better than the previously published data of ixekizumab (13 days in Ps patients).

Immunogenicity: In this trial, the immunogenicity risk of QX002N was low. One subject in the 20 mg group and one subject in the placebo group showed positive ADA responses.

Conclusion: The trial met its primary and secondary endpoints. In this trial, QX002N was well-tolerated in healthy subjects, and demonstrated a good safety profile and dose-proportional PK. In addition, the immunogenicity risk of QX002N was extremely low. Based on the trial results, the recommended starting dose for the Phase Ib clinical trial was 40 mg.

Summary of Preclinical Study Results

We conducted a series of preclinical studies in order to characterize the PD, PK and toxicology profile of QX002N. In our *in vitro* PD study, QX002N demonstrated high levels of affinity, and potency comparable to ixekizumab and better than secukinumab, both of which are FDA-approved IL-17A antibodies. In our preclinical PK study, QX002N exhibited dose-proportional PK in rhesus monkeys over a dose range from 1.5 mg/kg to 15 mg/kg following single subcutaneous or intravenous administration. In our preclinical toxicological studies, QX002N showed no obvious systemic toxicity.

Material Communications and Next Steps

We received IND approval of the Phase I, Phase II and Phase III clinical trials of QX002N for active AS in adults from the NMPA in April 2019. In compliance with the Administrative Measures for Drug Registration (《藥品註冊管理辦法》) issued by the NMPA, before the initiation of each of the Phase Ib and Phase II clinical trials, we had submitted requisite documents, including results from previous trial phase(s), to the NMPA and received no concerns or objections from the NMPA. Our PRC Legal Advisors are of the view that based on the results from the Phase Ia/Ib clinical trials, the NMPA had no objection to the commencement of each of the Phase Ib/II clinical trials of QX002N. We conducted a pre-Phase III consultation with the NMPA (as required by the IND approval of QX002N) and submitted, among others, key results from all prior trial phases and the Phase III trial design. We received the NMPA's official response in July 2023, which raised no material questions and confirmed that it had no objections to the commencement of the Phase III clinical trial. We commenced such trial in September 2023. As of the Latest Practicable Date, we had not received any relevant regulatory agency's concerns or objections to the commencement of any of our clinical trials or our clinical development plans. No material adverse changes had occurred since we obtained the IND approval and up to the Latest Practicable Date.

Lupus Nephritis

Lupus nephritis (LN) is the most common severe complication of SLE, involving inflammation of and possible organ damage to the kidneys, which can harm the overall function of the renal system. LN affects 30% to 60% of adults and up to 70% of children with SLE, leading to increased risks of hospitalization, end-stage renal disease and death. There is no cure for LN and currently available treatments merely aim to provide symptom relief. As of the Latest Practicable Date, belimumab was the only targeted biologic drug approved by the FDA or NMPA for the treatment of LN. We are exploring the therapeutic potential of our Core Product, QX002N, for the treatment of LN.

Leveraging the promising profile QX002N demonstrated in our preclinical studies and Phase Ia clinical trial in healthy subjects, we plan to further explore its potential as a novel therapy for the treatment of LN. We received IND approval of the Phase I, Phase II and Phase III clinical trials of QX002N for LN from the NMPA in October 2021, and expect to continue the development of QX002N for the treatment of LN after it obtains the BLA approval for the treatment of AS. As of the Latest Practicable Date, we had not initiated any clinical trial of QX002N for LN. Pursuant to the Administrative Measures for Drug Registration, LN will be considered an indication expansion of QX002N and treated as the same product in the subsequent regulatory registration process.

Market Opportunity and Competition

According to Frost & Sullivan, the LN patient population in China reached approximately 567,700 in 2022, and is expected to remain relatively stable over the next decade.

Similar to treatment options for SLE, the types of drugs that have been used to treat LN mainly include corticosteroids, traditional DMARDs (such as hydroxychloroquine) and biologic drugs, with corticosteroids and hydroxychloroquine recommended as initial treatment options and standard of care. As the investigation of biologic drugs for the treatment of LN is still at an early stage, there is no clear designation of line of treatment for biologic drugs for this indication. Compared to SLE, biologic drugs and drug candidates indicated for LN are even more limited.

As of the Latest Practicable Date, belimumab was the only targeted biologic drug approved by the FDA or NMPA for the treatment of LN. See "—Our Other Key Product Candidates—QX006N—Systemic Lupus Erythematosus—Market Opportunity and Competition" for more details on belimumab.

As of the same date, there were 11 biologic drug candidates for LN in the clinical stage in China, 3 of which were IL-17 inhibitors. Other targets under investigation include B cell membrane proteins, such as CD80/CD86 and CD20.

Our Advantages

In the last decade, LN therapy has remained largely unchanged, with limited probability of achieving complete or partial remission. Multiple immunological pathways are involved in inducing tissue damage in SLE and LN, therefore developing effective single-target biologic drugs has been challenging. Studies have shown that IL-17, alone or together with BLyS, may stimulate B cell survival and differentiation, indicating the ability of IL-17 to contribute to several pathological pathways of LN, such as the induction of vascular inflammation, recruitment of leukocytes, activation of B cells and autoantibody production, contributing to the persistence of inflammation and renal damage. Therefore, IL-17A inhibitors have the potential to become a novel therapeutic option for LN patients.

Summary of Clinical Trials and Preclinical Studies

See "—Ankylosing Spondylitis—Summary of Clinical Trials—Phase Ia Clinical Trial" and "—Ankylosing Spondylitis—Summary of Preclinical Study Results" for more details on our Phase Ia clinical study in healthy subjects and preclinical studies.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET QX002N SUCCESSFULLY.

QX005N

QX005N, our other Core Product and discovered and developed by our Company, is a recombinant humanized IgG4 monoclonal antibody directed against the interleukin-4 receptor subunit α (IL-4Rα). IL-4Rα is a well-validated, broad-acting target and controls the signaling of both IL-4 and IL-13, which is critical in the initiation of type 2 inflammation (a pattern of immune response that underpins the pathophysiology of several chronic allergic diseases). According to Frost & Sullivan, IL-4Rα inhibitors had been approved or were under development for 20 indications globally as of the Latest Practicable Date.

As of the Latest Practicable Date, we were developing QX005N for seven indications: moderate-to-severe AD in adults, AD in adolescents, PN, CRSwNP, CSU, moderate-to-severe asthma and COPD.

- AD: We received an IND approval for QX005N for moderate-to-severe AD in adults from the NMPA in June 2020. QX005N has demonstrated favorable safety and efficacy results in our Phase Ia (in healthy subjects) and Phase Ib (in patients with moderate-to-severe AD) clinical trials in China. In the Phase Ib clinical trial, similar response rates of QX005N were observed in the 300 mg and 600 mg groups, with 75.0% of subjects in each group reaching EASI-75 and 50.0% of subjects in each group reaching IGA score (0 or 1) at week 12 without significantly increased safety risks. It is currently being evaluated in a Phase II clinical trial in patients with moderate-to-severe AD in China. In addition, we obtained an IND approval of QX005N for the treatment of AD in adolescents aged between 12 and 17 years from the NMPA in October 2023.

- PN: We received an IND approval for QX005N for PN from the NMPA in March 2022. It is currently being evaluated in a Phase II clinical trial in PN patients in China.

- CRSwNP: We received an IND approval for QX005N for CRSwNP from the NMPA in November 2021. It is currently being evaluated in a Phase II clinical trial in CRSwNP patients in China.

- CSU: We received an IND approval for QX005N for CSU from the NMPA in January 2022.

- Moderate-to-severe asthma: We received an IND approval for QX005N for moderate-to-severe asthma from the NMPA in February 2022.

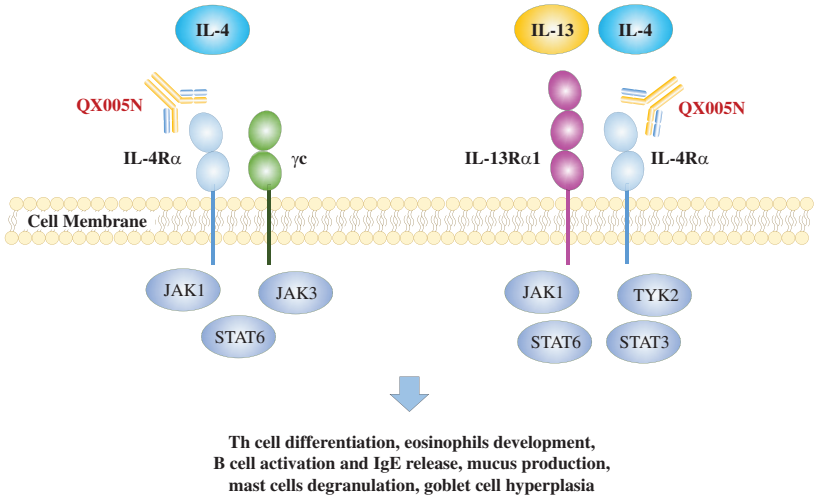
- COPD: We received an IND approval for QX005N for COPD from the NMPA in September 2023.

We do not have any current plan to out-license QX005N domestically or overseas.

Mechanism of Action

IL-4 and IL-13 are both key players in the inflammatory response triggered either by an invading parasite or allergen. IL-4 induces isotype switching to IgE in B cells (a type of white blood cells that produces antibodies) and causes an elevated IgE level. This leads to the degranulation of basophils and mast cells, which is a cellular process used by these cells involved in the immune system to release a mixture of compounds to destroy invading microorganisms, and release of pro-inflammatory mediators. IL-4 and IL-13 stimulate trafficking of eosinophils to the site of inflammation, leading to tissue eosinophilia. In addition, they are involved in causing other common pathophysiological effects, such as mucus overproduction, goblet cell hyperplasia (a feature of asthma and other respiratory diseases) and tissue remodeling. Furthermore, IL-4 drives $CD4^+$ T cell differentiation toward the Th2 subtype, which produces IL-4, IL-13 and IL-5, thus creating a cyclical effect.

IL-4 and IL-13 exert their signaling activities by interacting with specific receptors on the cell surface, *i.e.*, the type 1 IL-4Rα/gamma common (γc) and/or the type 2 IL-4Rα/IL-13Rα1 receptor complexes. The type 1 receptor complexes can only be activated by IL-4 while the type 2 receptor complexes can be activated by both IL-4 and IL-13. By binding to IL-4Rα, QX005N is designed to block the signaling pathways of both IL-4 and IL-13 that drive type 2 inflammatory response and presents a promising therapeutic solution to type 2-driven allergic diseases. The diagram below illustrates the mechanism of action of QX005N, which is designed to block the signaling pathways of both IL-4 and IL-13 by binding to IL-4Rα.



Source: the Company

Atopic Dermatitis

Atopic dermatitis (AD) is one of the most common skin disorders globally and in China. It is a skin immune-mediated inflammatory disease that causes dry, itchy and inflamed skin, and is commonly developed in young children but can occur at any age. AD is chronic with acute exacerbations, or flares, as an integral part of its course, which are generally defined as worsening condition and require escalation or intensification of treatment. Such irritation can negatively impact patients' quality of life and potentially cause psychological damage. Additionally, AD patients are at risk of developing co-morbidities such as food allergies and asthma. According to Frost & Sullivan, there are few effective and safe treatment options for AD, with dupilumab being the only biologic drug approved by the NMPA for AD in China as of the Latest Practicable Date, indicating significant unmet clinical needs and huge market potential. As of the Latest Practicable Date, we were developing QX005N for the treatment of moderate-to-severe AD in adult patients, which is one of the most advanced biologic drug candidates for AD in China. In October 2023, we also received an IND approval for QX005N for AD in adolescents aged between 12 and 17 years from the NMPA.

Market Opportunity and Competition

According to Frost & Sullivan, the prevalence of AD in China increased from 64.0 million in 2018 to 70.3 million in 2022 and is anticipated to reach 78.5 million in 2030. 20% of the patients have moderate-to-severe AD. The AD drug market in China increased from US$502.6 million in 2018 to US$966.8 million in 2022, at a CAGR of 17.8% and is estimated to grow rapidly to reach US$7,071.8 million in 2030, at a CAGR of 28.2% from 2022 to 2030. Biologic drugs accounted for 28.2% of the AD drug market in China in 2022, which is estimated to increase to 77.5% in 2030.

Treatment of AD usually involves a step-up approach, *i.e.*, depending on the severity and extent of a patient's symptoms, different medication and treatment options may be recommended. Mild cases of AD can be treated with moisturizing agents and topical treatments, such as corticosteroids and calcineurin inhibitors. However, overuse of these drugs may cause side effects, including thinning skin or impaired immune system. In moderate-to-severe cases, phototherapy and systemic conventional DMARDs, such as cyclosporine A (CsA), methotrexate and azathioprine, may be used. In recent years, biologic drugs with better safety and efficacy profiles have become an emerging treatment for moderate and severe AD. According to the Guideline for Diagnosis and Treatment of AD in China (2020), biologics, as a main treatment option for AD patients, are recommended to be combined with topical drugs and moisturizers for long-term use. In particular, as IL-4, IL-13, IL-5 and IL-10 are important cytokines involved in the pathogenesis of AD, they present potential targets suitable for biologics development. IL-4Rα is the mainstream target under investigation for AD treatment due to its role in controlling the signaling of both IL-4 and IL-13, and research on other targets, such as IL-31, IL-33 and OX40, is also ongoing. In addition, small-molecule treatments, including PDE-4 inhibitors and JAK inhibitors, have been explored as potential treatment options for AD patients. As of the Latest Practicable Date, two JAK inhibitors (sold under the brand names of RINVOQ and CIBINQO, respectively) and one PDE-4 inhibitor (sold under the brand name of Staquis) had been approved for AD in China, according to Frost & Sullivan, the JAK inhibitors had only recently been included in the latest Guideline for Diagnosis and Treatment of Moderate-to-severe AD (2023) in China with limited recommendation for certain patient populations, and the PDE-4 inhibitor is listed under other topical drugs in the Guideline for Basic Diagnosis and Treatment of AD in China (2022).

As of the Latest Practicable Date, dupilumab (an anti-IL-4Rα antibody) was the only biologic drug approved in China for AD, which had also been admitted to the NRDL. Since its launch in 2017, the global sales of dupilumab (under the brand name Dupixent) increased sharply from US$256.5 million in 2017 to US$8,681.2 million in 2022, at a CAGR of 102.3%. Since its approval in China in 2020, the sales of dupilumab in China (as disclosed by Sanofi) also experienced a sharp increase from US$13.7 million in 2020 to US$248.1 million in 2022, at a CAGR of 325.0%. As of the same date, in addition to QX005N, there were 20 biologic drug candidates for AD in the clinical stage in China, among which 9 were IL-4Rα inhibitors and other disclosed targets under investigation included IL-13, TSLP, IL-33, ST2, CD200R, OX40, IL-2R and IL-17RB. As IL-4Rα remains the mainstream target under investigation for AD treatment, we believe QX005N will primarily compete with other IL-4Rα inhibitors. The following table sets forth details of QX005N as well as approved biologic drugs and drug candidates in the clinical stage in China that target IL-4Rα as of the Latest Practicable Date.

Marketed Anti-IL-4Rα Biologics for AD in China

Target	Brand Name	INN	Company	NMPA Approval Time	Branded or Biosimilar	Availability of biosimilar	2022 NRDL covered	NRDL Median price in 2022[1] (RMB)
IL-4Rα	Dupixent	Dupilumab	Sanofi/Regeneron	2020	Branded	—	Yes	3,160.0

Clinical-Stage Anti-IL-4Rα Biologic Drug Candidates AD in China

Target	Drug Code	Company	Status	First Posted Date
IL-4Rα	CM310	Keymed Bioscience	BLA submission	2023-12-07
	CBP-201	Connect Biopharmaceuticals	Phase II	2020-11-20
	TQH2722	Chia Tai-tianqing	Phase II	2023-03-27
	QX005N	**the Company**	**Phase II**	**2022-07-14**
	MG-K10	Mabgeek	Phase III	2023-11-29
	SSGJ-611	Sunshine Guojian	Phase III	2023-12-18
	SHR-1819	Hengrui	Phase II	2022-09-27
	GR1802	Genrix Bio	Phase III	2023-12-14
	AK120	Akeso	Phase I / II	2021-08-20
	BA2101	Boan Bio	Phase I	2023-01-16

Source: NMPA, CDE, Frost & Sullivan Report

Note:

(1) Reflects the median price for a drug's minimum formulation unit as included in the NRDL.

Our Advantages

We believe QX005N has the following potential advantages in comparison with the approved drugs and drug candidates targeting AD:

- *Promising efficacy*. In our Phase Ib clinical trial of QX005N in adult patients with moderate-to-severe AD, similar response rates of QX005N were observed in the 300 mg and 600 mg groups, with 75.0% of subjects in each group reaching EASI-75 and 50.0% of subjects in each group reaching IGA score (0 or 1) at week 12 without significantly increased safety risks. Additionally, thymus and activation-regulated chemokine (TARC) and IgE are both PD biomarkers associated with type 2 immune responses. TARC is also a key PD biomarker in AD patients. In particular, TARC is expressed in AD patients and their TARC level in serum is significantly increased as compared to patients with other inflammatory skin diseases. Therefore, according to Frost & Sullivan, a reduction in TARC levels suggests that the AD symptom has been alleviated and indicates a favorable efficacy of the treatment. A reduction in IgE levels also suggests similar favorable outcomes, according to Frost & Sullivan, because the release of IgE from autoantigens and corresponding enhanced IgE levels are associated with repeated scratching, which is an important cause of aggravation and persistence of skin inflammation. In our Phase Ib clinical trial of QX005N for AD, the reduction of TARC and IgE levels from baseline in the active treatment groups were higher than those in the placebo group. We believe the reduction in TARC and IgE levels induced by QX005N may be indicative of its favorable efficacy profile.

- *Good safety profile*. In comparison with other IL-4Rα inhibitors under development and with reported clinical data, QX005N has demonstrated a good safety profile in its Phase Ia and Ib clinical trials. In our Phase Ib clinical trial of QX005N in adult patients with moderate-to-severe AD, no SAE was observed and none of the patients in the active treatment groups developed conjunctivitis, which is one of the most common AEs observed in patients using dupilumab, according to Frost & Sullivan. In our Phase Ia clinical trial, QX005N was also well-tolerated with a good safety profile in healthy subjects in the dose range from 75 mg to 800 mg. Additionally, in comparison with non-IL-4Rα inhibitors (such as JAK inhibitors) and conventional AD therapies such as corticosteroids, we believe QX005N is potentially superior in terms of its long-term safety profile.

- *Promising accessibility*. The high annual costs of AD drugs, such as dupilumab, the only NMPA-approved anti-IL-4Rα inhibitor for AD, may limit patient access. Dupilumab is designed to be administered with an initial injection of 600 mg (with two injections of 300 mg at different injection sites on the patient) and then with a treatment frequency of Q2W at 300 mg. According to Frost & Sullivan, since 2021, the annual cost for dupilumab as included in the NRDL has been RMB85,320 for 27 doses of 300 mg/2 mL in the first year and RMB82,160 for 26 doses of 300 mg/2 mL per year for subsequent treatment for AD patients. We aim to make QX005N more accessible to patients in China taking into account various factors such as our in-house manufacturing capacity and potential competitor pricing. QX005N is expected to be administered at the same dosage and frequency as dupilumab. Its estimated annual cost is expected to be lower than dupilumab by approximately 20% to 30% upon commercialization, making it a more affordable option in comparison to dupilumab.

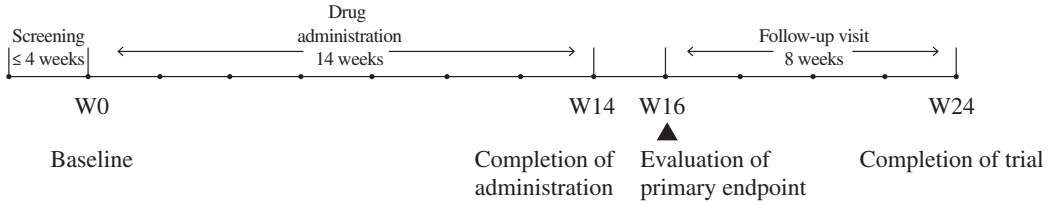
Summary of Clinical Trial Results

We completed a Phase Ia clinical trial of QX005N in healthy subjects in China in January 2023 and a Phase Ib clinical trial of QX005N in patients with moderate-to-severe AD in China in February 2023. We are currently evaluating the safety and efficacy of QX005N in a Phase II clinical trial in adult patients with moderate-to-severe AD in China, which we expect to complete in March 2024.

Ongoing Phase II Clinical Trial

The Phase II clinical trial in China is a multi-center, randomized, double-blind and placebo-controlled clinical study with multiple dosing to evaluate the efficacy, safety, PK and PD profile of QX005N in adult patients with moderate-to-severe AD.

Trial design: The primary endpoint is the percentage of reduction from baseline in EASI scores at week 16. The secondary endpoints include efficacy parameters, such as percentage of subjects responding to the treatment as measured by reduction in the Investigator's Global Assessment (IGA) score and EASI scores at week 16 as well as subjects' IGA and EASI scores from baseline to week 24; safety and tolerability of QX005N in subjects from baseline to week 24; PK and PD parameters from baseline to week 24; and percentage of ADA-positive subjects from baseline to week 24. We plan to enroll a total of 120 subjects, who will be randomly assigned to three groups (each consisting of 40 subjects) with two active treatment groups receiving QX005N and one control group receiving placebo. Each of the two active treatment groups will receive a dose of QX005N of 300 mg (600 mg for the first dose) every two weeks (Q2W) and 600 mg (Q2W), respectively. The control group will receive the placebo (Q2W). The treatment period is expected to be 16 weeks, followed by eight weeks of follow-up visit. The chart below summarizes the design of this trial.



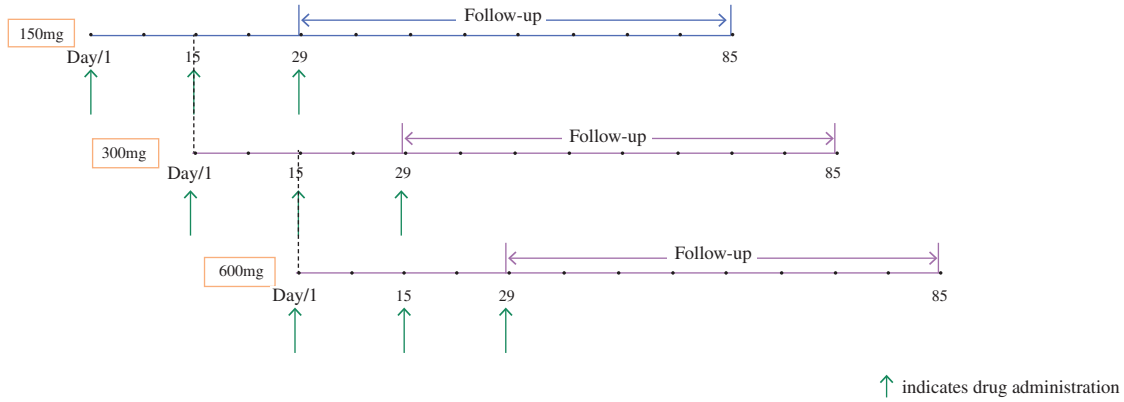
Trial status: Subject enrollment commenced in September 2022 and was completed in February 2023. A total of 120 subjects were enrolled, including 40 receiving QX005N in each of the 300 mg and 600 mg group and 40 receiving placebo in the control group. As of the Latest Practicable Date, we had completed data readout and this trial reached its primary endpoint as reviewed by the IDMC. We expect to complete this trial in March 2024.

Phase Ib Clinical Trial

The Phase Ib clinical trial in China was a multi-center, randomized, double-blind, placebo-controlled and multiple-ascending-dose clinical study to evaluate the efficacy, safety, PK and PD profile of QX005N in adult patients with moderate-to-severe AD.

Trial design: The primary endpoints were safety and tolerability of QX005N in moderate-to-severe AD patients at week 12. The secondary endpoints included PK parameters; efficacy parameters at week 12, such as percentage of patients responding to the treatment as measured by reduction in the Investigator's Global Assessment (IGA) score and the Eczema Area and Severity Index-50 (EASI-50) and EASI-75 response (defined as ≥50% and ≥75% improvement from baseline in the EASI score, respectively); and immunogenicity. The exploratory purpose was to evaluate the PD profile of QX005N in these patients. We planned to enroll a total of 30 patients, who would be assigned to three groups with ten patients in each group (eight receiving QX005N and two receiving placebo). Each group would receive three doses of either QX005N or placebo at their designated dose level (150 mg, 300 mg and 600 mg, respectively), to be administered on day 1, day 15 and day 29, followed by safety follow-up until day 85. The trial would proceed from one dose level to the next only if the evaluation of tolerability and safety on the previous dose level group on day 14 has been completed. In the

event where termination may be warranted, the sponsor and investigator would determine whether to terminate the trial or resume the trial with the median level of the previous and current dose levels. The maximum dose level is set at 600 mg, which may be adjusted based on the trial outcome at the dose level of 150 mg and 300 mg. The diagram below illustrates the design of this trial.

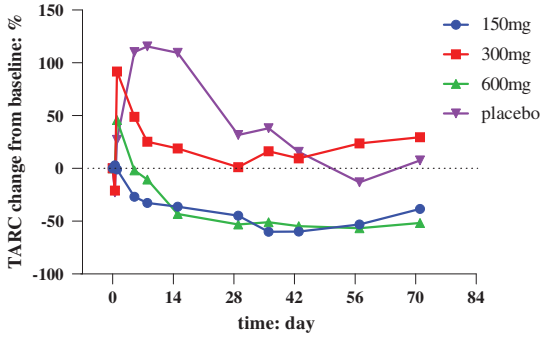


Trial status: This trial was initiated in November 2021 and completed in February 2023. A total of 30 subjects were enrolled with eight receiving QX005N and two receiving placebo in each of the 150 mg, 300 mg and 600 mg groups. Due to the COVID-19 pandemic, one subject in the 600 mg group was lost to follow-up, whose data were considered invalid.

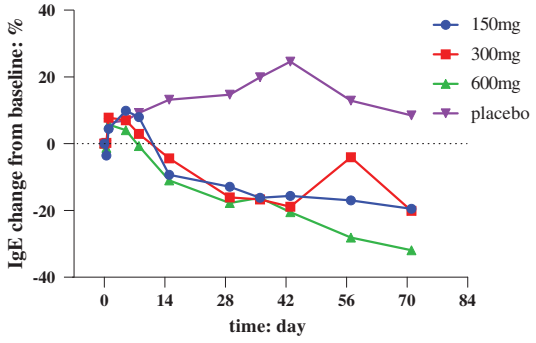
PK: In this trial, there was no obvious difference in T_{max} (the time it takes for a drug to reach C_{max} after administration) among the active treatment groups. Systemic exposure of QX005N (C_{max} and AUC_{0-t}) showed an increasing trend as the dose level increased.

PD: TARC and IgE are both PD biomarkers associated with type 2 immune responses. TARC is also a key PD biomarker in AD patients. In this trial, the reduction of TARC and IgE levels from baseline in the active treatment groups were higher than those in the placebo group, as shown in the charts below. We believe the reduction in TARC and IgE levels induced by QX005N may be indicative of its favorable efficacy profile.

Mean TARC change from baseline-time profile of QX005N



Mean IgE change from baseline-time profile of QX005N



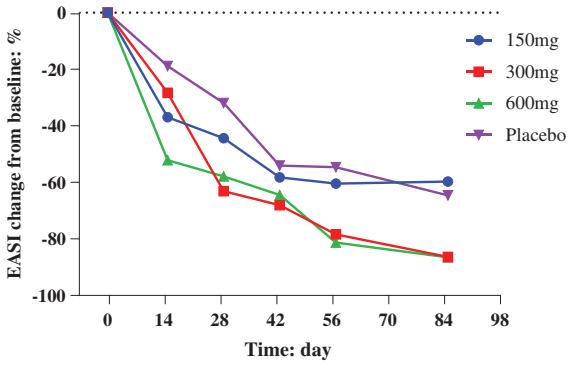
Immunogenicity: Immunogenicity of monoclonal antibody drugs occurs when anti-drug antibodies (ADAs) are elicited from drug administration, which is common and may cause decreased drug exposure and/or formation of highly immunogenic complexes, which, in turn, could cause decreased efficacy and/ or increased safety risks. However, according to Frost & Sullivan, observation of immunogenicity in a clinical trial does not necessarily impact the PK, PD and/or safety of a drug candidate, which are key factors the NMPA considers when determining whether the drug candidate may be approved for marketing. Therefore, if the occurrence of immunogenicity shows no impact on these parameters, it will not affect a drug candidate's registration approval. In this trial, immunogenicity was observed in 13 subjects receiving QX005N and 1 subject in the control group but no impact on QX005N's efficacy or safety was observed.

Safety results: In this trial, QX005N was well-tolerated and had a good safety profile in adult patients with moderate-to-severe AD. Among subjects receiving QX005N, 22 (91.7%) subjects reported a total of 95 TEAEs, with 2 AEs of Grade 3 (severe or medically significant but not immediately life-threatening) and above (1 of Grade 3 and 1 of Grade 4 (life-threatening consequences; urgent intervention indicated)) under the Common Terminology Criteria for Adverse Events (CTCAE version 5.0) observed in the 300 mg group. 6 (100%) subjects in the placebo group reported a total of 24 TEAEs, among which, 2 AEs of Grade 3 were reported. One subject with the AE of Grade 4 in the 300 mg group was found to have elevated creatine kinase (an enzyme that mainly exists in the heart and skeletal muscle) during the follow-up at day 29 before the third drug administration, which was determined to be Grade 4 and possibly related to the drug. One subject with the AE of Grade 3 in the 300 mg group was reported to have syncope (a loss of consciousness for a short period of time), and each of the two subjects with AEs of Grade 3 in the placebo group was reported to have elevated lipase (a family of enzymes that participates in fat digestion and metabolism) and elevated transaminases (a group of enzymes that is important in the synthesis of amino acids), respectively, which are not the same as the AEs of Grade 3 reported in the Phase Ia clinical trial of QX005N in healthy subjects. All subjects who experienced AEs of Grade 3 and above recovered in this trial. All other AEs observed in this trial were of Grade 1 (mild) or 2 (moderate) using CTCAE version 5.0. None of the patients in the trial developed conjunctivitis, which is one of the most common AEs observed in patients using dupilumab, according to Frost & Sullivan. No significant difference was observed in safety results between the QX005N active treatment groups and the placebo group. No SAE or death was observed and no patients discontinued treatment or withdrew from the study due to safety issues in this trial.

Efficacy results: The percentage of subjects in the 300 mg group responding to the treatment as measured by EASI-50, EASI-75 and IGA score (0 or 1) at week 12 was 100.0%, 75.0% and 50.0%, respectively. Such percentage in the 600 mg group was 87.5%, 75.0% and 50.0%, respectively. The mean EASI change from baseline exceeded 80% at week 12 in the 300 mg and 600 mg groups, which was better than that in the 150 mg group and placebo group, as shown in the chart below. According to Frost & Sullivan, the EASI and IGA scales are the most authoritative evaluation methods to determine the severity of an AD patient's symptoms. In this trial, the EASI-75 and IGA score (0 or 1) results of QX005N in the 300 mg and 600 mg groups

at week 12 are similar to that of dupilumab at week 16 (53.1% and 29.7%) in a Phase IIb clinical trial in moderate-to-severe AD patients, where dupilumab of 300 mg was administered Q2W, suggesting a good preliminary clinical efficacy of QX005N, according to Frost & Sullivan.

Mean EASI change from baseline-time profile of QX005N



Conclusion: In this trial, similar response rates of QX005N were observed in the 300 mg and 600 mg groups, with 75.0% of subjects in each group reaching EASI-75 and 50.0% of subjects in each group reaching IGA score (0 or 1) at week 12 without significantly increased safety risks.

Phase Ia Clinical Trial

The Phase Ia clinical trial in China was a single-center, randomized, double-blind, single-ascending-dose and placebo-controlled clinical study to evaluate the PK profile, safety, tolerability and immunogenicity of QX005N in healthy subjects.

Trial design: The primary endpoints included safety and tolerability of QX005N in healthy subjects. The secondary endpoints included PK parameters and immunogenicity. The exploratory purpose is to evaluate the PD profile of QX005N in these subjects. We planned to enroll a total of 48 subjects, who would be assigned to six groups with eight subjects in each group (six receiving QX005N and two receiving placebo). The trial would start with the first group receiving a single subcutaneous injection of 75 mg and the subsequent five groups each receiving an increased single dose of 150 mg, 300 mg, 450 mg, 600 mg and 800 mg, respectively. Each subject would receive only one corresponding dose of QX005N (or placebo). The trial would proceed from one dose level to the next only if safety of the previous dose level is confirmed after a two-week evaluation period upon drug administration. In the event where termination may be warranted, the sponsor and investigator would determine whether to terminate the trial or resume the trial with the median level of the previous and current dose levels.

Trial status: This trial was initiated in December 2020 and completed in January 2023. A total of 49 healthy volunteers were enrolled and 48 subjects completed dosing, including 36 receiving QX005N in the active treatment group and 12 receiving placebo in the control group.

PK: QX005N exhibited nonlinear PK in healthy subjects within the dose range from 75 mg to 800 mg following single subcutaneous administration. Systemic exposure of QX005N (C_{max}, AUC_{last} and AUC_{inf}) increased in a greater-than-proportional manner with increasing dose. In addition, the $T_{1/2}$ of QX005N showed an increasing trend as the dose level increased from 75 mg to 450 mg and remained stable within the range of 600 mg and 800 mg.

Immunogenicity: In this trial, immunogenicity was observed in 31 subjects receiving QX005N but no impact on QX005N's PK or safety was observed.

Safety results: In this trial, QX005N was well-tolerated and had a good safety profile in healthy subjects in the dose range from 75 mg to 800 mg. 34 (94.4%) subjects in the active treatment groups reported a total of 115 AEs and 11 (91.7%) subjects in the placebo group reported a total of 36 AEs, none of which led to a subject's withdrawal from the trial. In the active treatment groups, two AEs of Grade 3 under CTCAE version 5.0 were reported, including one in each of the 300 mg group and 600 mg group. Each of the two subjects with AEs of Grade 3 in the 300 mg group and 600 mg group was reported to have elevated blood triglycerides (a type of fat that circulates in the blood) and right adrenal ganglioneuroma (a benign tumor of the sympathetic nervous system), respectively. Both subjects experiencing such AEs of Grade 3 recovered in this trial. All other AEs observed in this trial were of Grade 1 or 2 using CTCAE version 5.0. One subject receiving QX005N in the 600mg group experienced one SAE of Grade 3, which was considered to have no relationship with the drug, and the subject recovered after treatment. No death was observed in this trial. No significant difference was observed in the incidence of AEs between the QX005N groups and the control group and there was no significant correlation between the incidence of AEs and drug exposure.

Conclusion: In this trial, QX005N was safe and well-tolerated in healthy subjects in the dose range from 75 mg to 800 mg. Based on the trial results, we have initiated the Phase Ib and Phase II clinical trials to further evaluate QX005N for the treatment of moderate-to-severe AD in China.

Material Communications and Next Steps

We received an IND approval of the Phase I, Phase II and Phase III clinical trials of QX005N for moderate-to-severe AD in adults from the NMPA in June 2020. In compliance with the Administrative Measures for Drug Registration (《藥品註冊管理辦法》) issued by the NMPA, before the initiation of the Phase Ib/Phase II clinical trial[1], we had submitted requisite documents, including results from the Phase Ia trial[2], to the NMPA and received no concerns or objections from the NMPA. In September 2023, we conducted a formal consultation with the CDE of the NMPA inquiring whether the NMPA had any objections to or additional requirements on our conduct of the Phase Ib/Phase II clinical trial, and the NMPA did not raise any objections or additional requirements. Our PRC Legal Advisors are of the view that based on the results from the Phase Ia clinical trial, the NMPA had no objection to the commencement of the Phase Ib/Phase II clinical trial of QX005N. We have completed the Phase Ia and Phase Ib clinical trials for this indication and are currently conducting the Phase II clinical trial, which we expect to complete in March 2024. We submitted an application to consult with the NMPA in December 2023 before initiating the Phase III clinical trial for this indication in accordance with the IND approval. As of the Latest Practicable Date, we had not received any relevant regulatory agency's concerns or objections to the commencement of our Phase II clinical trial or our clinical development plans and no material adverse changes had occurred since we obtained the IND approval.

In October 2023, we also received an IND approval of QX005N for the treatment of AD in adolescents aged between 12 and 17 years from the NMPA. As of the Latest Practicable Date, we had not received any relevant regulatory agency's concerns or objections to our clinical development plans and no material adverse changes had occurred since we obtained the IND approval and up to the Latest Practicable Date.

Notes:

1. The Phase Ib/Phase II trial was designed as a multiple-dose clinical study to evaluate the efficacy, safety, PK and PD profile of QX005N in adult patients with moderate-to-severe AD, consisting of two parts: a Phase Ib (30 subjects) and a Phase II (120 subjects). The trial design of Phase Ib and Phase II was submitted to the NMPA under the same title and with the same protocol number, with Phase Ib labeled as Part A of the trial and Phase II labeled as Part B of the trial.

2. For the avoidance of doubt, the emphasis on a Phase I trial is whether enough clinical safety data have been gathered and observed. While our Phase Ia trial was labeled as Ia, this trial was essentially a Phase I trial as it was conducted in healthy subjects and with safety and tolerability of the drug candidate as the primary endpoints, and equivalent to a conventional Phase I trial designed to evaluate similar drug candidates for similar indications, according to Frost & Sullivan. Additionally, the safety data generated from this trial allowed us to initiate the Phase Ib/II trial based on communication with the NMPA, which had the same effect as the completion of a Phase I trial.

Prurigo Nodularis

Prurigo Nodularis (PN) is a chronic skin disorder characterized by the presence of hard and extremely itchy bumps known as nodules, which tend to be found in easy-to-scratch areas, such as the arms, legs, the upper back and abdomen. It is commonly associated with other skin diseases or underlying medical conditions that affect multiple body systems. Severe and chronic PN is painful and leaves visible nodules on the patients' skin, which could significantly interfere with their quality of life, sleep and psychological well-being. However, the exact cause of PN is unknown, but symptoms of PN are believed to stem from dysregulation of the nerves and immune system in the skin, and its pathophysiology is increasingly attributed to nonhistaminergic mediators and type 2 inflammation. Compared to the healthy population, PN patients tend to have more immune cells in their skin producing inflammatory cytokines, including IL-4, IL-13 and IL-31. According to Frost & Sullivan, there has been significant unmet clinical needs from PN patients due to limited understanding of the pathogenesis of PN and a lack of effective PN treatments. As of the Latest Practicable Date, dupilumab was the only treatment approved for PN by the FDA and by the NMPA in China. As of the same date, we were developing QX005N for the treatment of PN, the first biologic drug candidate developed by a Chinese domestic company in clinical trial for PN in China. We believe QX005N has the potential to be an effective treatment of PN by targeting IL-4Rα, a key target in mediating type 2 inflammation, and inhibiting the signaling pathways of both IL-4 and IL-13. In January 2024, the CDE granted QX005N the breakthrough therapy designation for the treatment of PN, signifying its superior clinical benefits compared to current treatment methods. The designation is designed to expedite the development and regulatory review of innovative drugs demonstrating substantial potential in addressing serious conditions.

Market Opportunity and Competition

According to Frost & Sullivan, the prevalence of PN in China increased slightly from 1.9 million in 2018 to 2.0 million in 2022 and is anticipated to reach approximately 2.1 million in 2030. There has been a lack of effective treatments for PN and development of the PN drug market in China is still at an early stage. The typical PN treatments for itch relief involve topical creams, such as topical antihistamine, steroids and anesthetics, and systemic drugs, such as antihistamine, steroids and opioid receptor agonists or antagonists. However, some PN treatments such as topical steroids and topical anesthetics are recommended to be used only for a limited duration due to their side effects. Because of the discovery of new therapeutic targets in recent years, there has been increasing research on biologic drugs for treating PN as a potentially promising treatment option. Biologics have become a guideline treatment option but as a relatively new class of drugs, they have not yet been recommended as a main treatment option for PN.

As of the Latest Practicable Date, dupilumab was the only biologic drug approved for PN by the FDA and by the NMPA in China. As of the same date, there were only two biologic drug candidates for PN in the clinical stage in China, including QX005N, as set out below.

Marketed Targeted Biologics for PN in China

Brand Name	INN	Company	Target	NMPA Approval Time
Dupixent	Dupilumab	Sanofi	IL-4Rα	2023

Clinical-Stage Biologic Drug Candidates for PN in China

Target	Drug Code	Company	Status	First posted Date
IL-4Rα	**QX005N**	**the Company**	**Phase II**	**2022-12-16**
	BA2101	Boan Biotech	Phase I	2023-01-16

Source: NMPA, Frost & Sullivan Report

Our Advantages

PN is associated with many co-morbidities, resulting in a huge burden on patients, including impaired quality of life. High-potency topical steroids are commonly used but they are associated with safety risks if used long term. As of the Latest Practicable Date, dupilumab was the only treatment approved for PN by the FDA and by the NMPA in China. Our QX005N was the first biologic drug candidate for PN developed by a Chinese domestic company in the clinical stage in China as of the Latest Practicable Date, according to Frost & Sullivan.

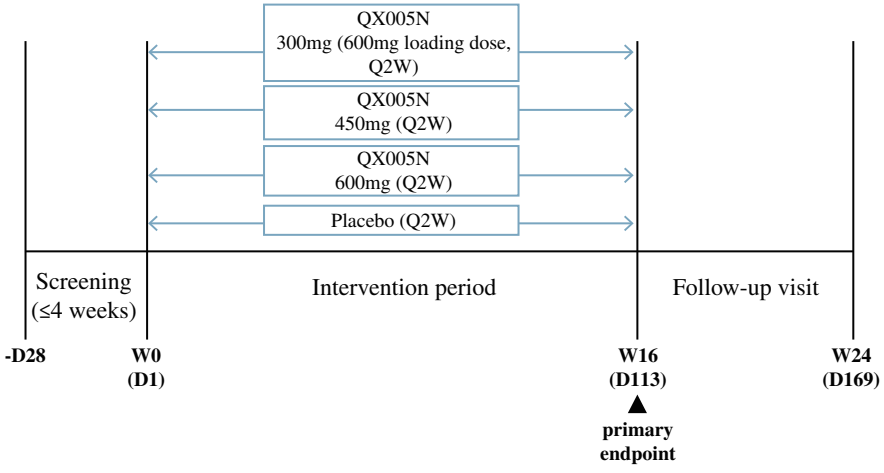
Additionally, IL-4Rα has been reported to be a promising target with good efficacy and safety profile in the treatment of diseases associated with type 2 inflammation by controlling the signaling of both IL-4 and IL-13 that drives type 2 inflammatory response. Dupilumab, an anti-IL-4Rα antibody, has shown potentially significant improvements for patients with PN in its Phase III clinical trials. For details of other potential advantages of QX005N, see "—Atopic Dermatitis—Our Advantages" above.

Summary of Ongoing Phase II Clinical Trial

We commenced a Phase II clinical trial of QX005N for the treatment of PN in February 2023, which was ongoing as of the Latest Practicable Date and is expected to be completed in March 2024. The Phase II clinical trial in China is a multi-center, randomized, double-blind and placebo-controlled clinical study to evaluate the efficacy, safety, PK and PD profile of QX005N in adult patients with PN.

Trial design: The primary endpoint is the percentage of subjects who experience a reduction from baseline in the weekly average of the Worst Itch Numeric Rating Scale (WI-NRS) score that is more than or equal to four points, from baseline to week 16. The secondary endpoints include safety and tolerability of QX005N in subjects from baseline to week 24; PK and PD parameters from baseline to week 24; percentage of ADA-positive subjects from baseline to week 24; and efficacy parameters from baseline to week 24, such as

(i) the time when subjects first respond to the treatment between baseline and week 16, as measured by comparing the percentage of subjects experiencing a reduction from baseline in the weekly average of WI-NRS score that is more than or equal to four points in each group, (ii) changes from baseline in the weekly average of WI-NRS score at week 2, 4, 8, 12, 16, 20 and 24, (iii) the percentage of subjects experiencing a reduction from baseline in the weekly average of WI-NRS score that is more than or equal to four points at week 20 and 24, (iv) the percentage of subjects with an IGA of PN-Stage (PN-S) score (an instrument used to assess the overall number and thickness of PN lesions at a given time point) of 0 or 1 at week 4, 8, 12, 16, 20 and 24, (v) changes from baseline in the IGA PN-S score at week 4, 8, 12, 16, 20 and 24, (vi) the percentage of subjects with an IGA of PN-Activity (PN-A) score (an instrument used to assess the overall activity of PN lesions at a given time point) of 0 or 1 at week 4, 8, 12, 16, 20 and 24, and (vii) changes from baseline in DLQI score at week 4, 8, 12, 16, 20 and 24. We plan to enroll a total of 120 PN patients, who will be randomly assigned to four groups (each consisting of 30 patients) with three active treatment groups receiving QX005N and one control group receiving placebo. The three active treatment groups will each receive a dose of QX005N of 300 mg (600 mg for the loading dose, Q2W), 450 mg (Q2W) and 600 mg (Q2W), respectively. The control group will receive the placebo (Q2W). Both QX005N and placebo will be administered through subcutaneous injection. The treatment period is expected to be 16 weeks, with drug/placebo administration starting from week 0 and completing in week 14, and followed by eight weeks of follow-up visit. The chart below summarizes the design of this trial.



Trial status: Subject enrollment commenced in February 2023 and was completed in May 2023. A total of 120 subjects were enrolled, including 30 receiving QX005N in each of the 300 mg, 450 mg and 600 mg groups and 30 receiving placebo in the control group. As of the Latest Practicable Date, we had completed data readout and this trial reached its primary endpoint as reviewed by the IDMC. We expect to complete this trial in March 2024.

Material Communications and Next Steps

We received an IND approval of the Phase I, Phase II and Phase III clinical trials of QX005N for PN from the NMPA in March 2022. In compliance with the Administrative Measures for Drug Registration (《藥品註冊管理辦法》) issued by the NMPA, before the initiation of the Phase II clinical trial, we had submitted requisite documents, including results from the Phase Ia clinical trial of QX005N in healthy subjects and the Phase Ib clinical trial of QX005N in AD patients, which we intended to leverage for this trial, to the NMPA and received no concerns or objections from the NMPA. Our PRC Legal Advisors are of the view that based on the results from such earlier trials, the NMPA had no objection to the commencement of the Phase II clinical trial of QX005N for PN. We commenced the Phase II clinical trial for this indication in February 2023, and expect to complete it in March 2024. We submitted an application to consult with the NMPA in December 2023 before initiating the Phase III clinical trial for this indication in accordance with the IND approval. In January 2024, the CDE granted QX005N the breakthrough therapy designation for the treatment of PN, signifying its superior clinical benefits compared to current treatment methods. The designation is designed to expedite the development and regulatory review of innovative drugs demonstrating substantial potential in addressing serious conditions. As of the Latest Practicable Date, we had not received any relevant regulatory agency's concerns or objections to the commencement of our Phase II clinical trial or our clinical development plans and no material adverse changes had occurred since we obtained the IND approval. Pursuant to the Administrative Measures for Drug Registration, PN is considered an indication expansion of QX005N and will be treated as the same product in the subsequent regulatory registration process.

Chronic Rhinosinusitis with Nasal Polyps

Chronic rhinosinusitis with nasal polyps (CRSwNP) is a subgroup of chronic rhinosinusitis characterized by the presence of fleshy swellings (nasal polyps) that develop in the lining of the nose and paranasal sinuses, which is believed to arise due to chronic inflammation. Although the mechanisms underlying the pathogenesis of CRSwNP remain poorly understood, CRSwNP is a common comorbidity in type 2 inflammation-driven diseases, indicating that type 2 inflammation plays an important role in its disease pathogenesis. Studies show that patients diagnosed with CRSwNP had a significantly higher premorbid prevalence of acute rhinosinusitis, chronic rhinitis, asthma, gastroesophageal reflux disease and sleep apnea. CRSwNP is a challenging condition to cure, and patients usually need appropriate long-term treatment plans to manage symptoms. Efficacy of traditional treatments, such as surgery, is limited, with high nasal polyps recurrence rate, and biologics have shown better efficacy in both clinical and animal studies.

As IL-4Rα is a promising therapeutic target for allergic diseases driven by the type 2 immune response we are developing QX005N, an anti-IL-4Rα antibody, to address the unmet medical needs for treatment options of CRSwNP. We directly commenced a Phase II clinical trial for treatment of CRSwNP in April 2023, by leveraging the Phase I clinical trial results of QX005N for AD.

Market Opportunity and Competition

According to Frost & Sullivan, the prevalence of CRSwNP in China increased from 19.1 million in 2018 to 20.4 million in 2022, and is estimated to reach 22.3 million in 2030. The CRSwNP drug market in China increased from US$90.0 million in 2018 to US$141.7 million in 2022, representing a CAGR of 12.0%, and is estimated to reach US$633.4 million in 2030, representing a CAGR of 20.6% from 2022 to 2030.

CRSwNP was traditionally treated with nasal saline irrigations and surgery. However, efficacy of nasal saline irrigation is limited, and there is a high nasal polyps recurrence rate of up to 60% post surgery. Corticosteroids, biologics and antibiotics have subsequently emerged as treatment options for CRSwNP patients. Antibiotics therapy after desensitization are primarily used for NSAID-exacerbated respiratory disease, a chronic eosinophilic, inflammatory disorder of the respiratory tract occurring in patients with asthma and/or CRSwNP. Corticosteroids for CRSwNP include intranasal corticosteroids, systemic corticosteroids and corticosteroid-eluting implants, which are primarily used following endoscopic sinus surgery. While intranasal and systemic corticosteroids are effective to some extent in the management of CRSwNP, their long-term benefits are limited. According to the Guidelines for the Diagnosis and Treatment of CRS in China (2018) (中國慢性鼻竇炎診斷和治療指南(2018)), it is difficult to maintain the clinical efficacy of systemic corticosteroids in the treatment of CRSwNP, which may lead to recurrence of nasal polyps. Moreover, systemic corticosteroids can only be administered cautiously given their association with serious systemic side effects. In contrast, biologics are proved to be more effective and safer in the treatment of CRSwNP in both clinical and animal studies. However, as a relatively new class of drugs, they have not been recommended as a main treatment option for CRSwNP in China by prevailing clinical guidelines.

Currently, biologic drugs have a limited track record globally for CRSwNP treatment. Only three biologics had been approved by the FDA for the treatment of CRSwNP as of the Latest Practicable Date and none had been approved in China as of the same date, leaving a large unmet market opportunity in China. Biologic drug candidates for CRSwNP in China primarily include IL-4Rα inhibitors, IL-5 inhibitors and TSLP inhibitors. IL-4Rα is a promising target for CRSwNP as IL-4Rα controls the signaling of both IL-4 and IL-13, the key Th2 cytokines. Since IL-5 is a key signaling factor for eosinophil activation by Th2 cells and is highly expressed in eosinophilic diseases, IL-5 inhibitors can be particularly effective for treatment of eosinophilic CRSwNP. However, the efficacy of IL-4Rα inhibitors and IL-5 inhibitors has shown to be correlated to the levels of certain type 2 biomarkers, such as blood eosinophil counts and IgE. In contrast, as TSLP is an upstream regulator of type 2 inflammation, TSLP inhibitors can be a treatment for patients with low-level or no expression of type 2 biomarkers. As of the Latest Practicable Date, there were 13 biologic drug candidates for CRSwNP in the clinical stage in China, including five IL-4Rα inhibitors, three IL-5 inhibitors, four TSLP inhibitors and one IL-5Rα inhibitor. The following table sets forth details of QX005N as well as biologic drug candidates in the clinical stage in China as of the Latest Practicable Date.

Clinical-Stage Biologic Drug Candidates for CRSwNP in China

Target	Drug Code	Company	Status	First posted Date
IL-4Rα	CM310	Keymed Bioscience	Phase III	2022-06-20
	Dupilumab	Sanofi	Phase III	2023-03-24
	GR1802	Genrix Bio	Phase II	2023-01-03
	QX005N	**the Company**	**Phase II**	**2023-01-06**
	SSGJ-611	Sunshine Guojian	Phase II	2023-04-27
IL-5	Mepolizumab	GSK	Phase III	2021-04-12
	Depemokimab	GSK	Phase III	2022-05-20
	Mepolizumab-BAT2606	Biothera	Phase I	2022-07-27
TSLP	Tezepelumab	Amgen/AstraZeneca	Phase III	2021-03-25
	SHR-1905	Hengrui	Phase II	2023-05-29
	TQC2731	Chia Tai Tianqing	Phase II	2023-08-01
	CM326	Keymed Bioscience	Phase I / II	2022-03-14
IL-5Rα	Benralizumab	AstraZeneca	Phase III	2020-06-02

Source: Frost & Sullivan Report (based on annual reports of relevant companies and information published by the NMPA)

Our Advantages

Treatments for patients with CRSwNP remain limited, which not only undermines quality of life but also causes a considerable socioeconomic burden. CRSwNP is considered difficult to treat, reflected by a high nasal polyps recurrence rate of up to 60% and frequent need of endoscopic sinus surgery. Biologic drugs are an emerging treatment option for patients with CRSwNP. As of the Latest Practicable Date, dupilumab was the only FDA-approved IL-4Rα inhibitor for CRSwNP. While dupilumab can cost over RMB82,000 a year, based on its pricing in China for the treatment of AD in 2022, according to Frost & Sullivan, we aim to make QX005N more accessible to patients in China. See "—Atopic Dermatitis—Our Advantages" above for more details.

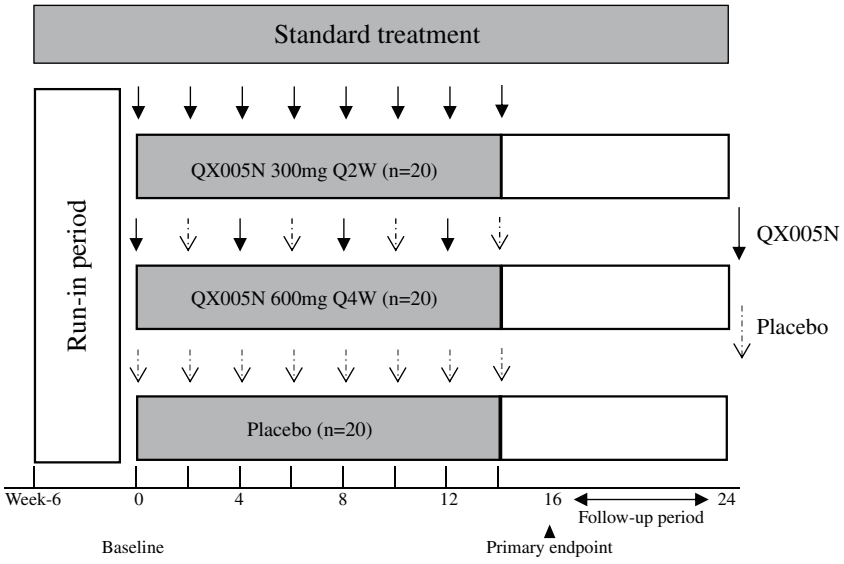
Summary of Clinical Trial

We commenced a Phase II clinical trial of QX005N in China for the treatment of CRSwNP in April 2023. We expect to complete such trial in the fourth quarter of 2024.

Ongoing Phase II Clinical Trial

Trial design: The Phase II clinical trial is a multi-center, randomized, double-blind, placebo-controlled clinical study evaluating the safety, efficacy, PK and PD of QX005N in adult patients with CRSwNP. The primary endpoint is the efficacy of repeated subcutaneous injection of QX005N in adult patients with CRSwNP, which is measured by the change in active treatment groups' nasal polyp scores at week 16 from baseline as compared to the control group. The secondary endpoints include efficacy at week 16 and safety, tolerability, PK and immunogenicity parameters of repeated subcutaneous injection of QX005N. The exploratory endpoints include PD parameters of QX005N in these subjects. We plan to enroll a total of 60 patients, who will be randomly assigned to three groups (each consisting of 20 patients) with two active treatment groups receiving QX005N and one control group receiving

placebo. The two active treatment groups will receive a dose of QX005N of 300 mg every two weeks (Q2W) and 600 mg every four weeks (Q4W), respectively. The control group will receive placebo (Q2W). The treatment period is expected to be 16 weeks, followed by eight weeks of follow-up. For subjects in the active treatment group of 600 mg of QX005N (Q4W), matching placebo will be administered at week 2, 6, 10 and 14 in order to ensure that all subjects will receive eight administrations during this trial. The chart below summarizes the design of this trial.



Trial status: As of the Latest Practicable Date, we had enrolled a total of 53 subjects. We expect to complete subject enrollment by the first quarter of 2024.

Phase Ia Clinical Trial

We completed a Phase Ia clinical trial of QX005N in healthy subjects in China in January 2023. In this trial, QX005N was safe and well-tolerated in healthy subjects in the dose range from 75 mg to 800 mg. See "—Atopic Dermatitis—Summary of Clinical Trial Results—Phase Ia Clinical Trial" for details.

Material Communications and Next Steps

We obtained an IND approval of the Phase I, Phase II and Phase III clinical trials of QX005N for treatment of CRSwNP from the NMPA in November 2021. In compliance with the Administrative Measures for Drug Registration (《藥品註冊管理辦法》) issued by the NMPA, before the initiation of the Phase II clinical trial, we had submitted requisite documents, including results from the Phase Ia clinical trial of QX005N in healthy subjects and the Phase Ib clinical trial of QX005N in AD patients, which we intended to leverage for this trial, to the NMPA and received no concerns or objections from the NMPA. Our PRC Legal Advisors are of the view that based on the results from such earlier trials, the NMPA had no objection to the commencement of the Phase II clinical trial of QX005N for CRSwNP. We commenced the

Phase II clinical trial in China in April 2023 and plan to complete such trial in the fourth quarter of 2024. As of the Latest Practicable Date, we had not received any relevant regulatory agency's concerns or objections to the commencement of our Phase II clinical trial or our clinical development plans. No material adverse changes had occurred since we obtained the IND approval and up to the Latest Practicable Date. Pursuant to the Administrative Measures for Drug Registration, CRSwNP is considered an indication expansion of QX005N and will be treated as the same product in the subsequent regulatory registration process.

Chronic Spontaneous Urticaria

Urticaria, or hives, is a common and heterogeneous inflammatory skin disorder characterized by itchy swelling on the skin surface and can be accompanied by angioedema, which is swelling of the subcutaneous tissues under the skin. Chronic spontaneous urticaria (CSU) is characterized by the occurrence of urticaria for six weeks or longer without identifiable specific triggers. CSU could cause significant impact on the patients' quality of life, ability to perform daily tasks and their mental health. Urticaria is considered a disease driven mainly by mast cell degranulation, followed by the release of various mediators, including inflammatory cytokines such as IL-4. Establishing the cause of CSU and finding the appropriate cause-specific management can be difficult, leading to further frustration on the patients. According to Frost & Sullivan, typical treatments for CSU include second-generation non-sedating antihistamines, while for patients who are intolerant or have shown inadequate response to antihistamines, omalizumab, an anti-IgE mAb and the only biologic drug approved by the NMPA for urticaria in China as of the Latest Practicable Date, remains the mainstream treatment option. Biologics (including IgE inhibitors) are recommended by prevailing clinical guidelines as third-line treatment for CSU patients. As a result, the development of new therapies with improved efficacy and safety is underway.

As of the Latest Practicable Date, we were developing QX005N for the treatment of CSU, which we believe has the potential to be an effective treatment of CSU by targeting IL-4Rα and inhibiting IL-4 signaling. We obtained an IND approval of the Phase I, Phase II and Phase III clinical trials of QX005N for CSU from the NMPA in January 2022. We plan to consult with the NMPA about directly initiating a Phase III clinical trial of QX005N for CSU by leveraging the Phase Ia clinical trial results of QX005N in healthy subjects, the Phase Ib clinical trial results of QX005N for AD as well as the Phase II clinical trial results of QX005N for AD and/or PN. As of the Latest Practicable Date, we had not initiated consultation with the NMPA about the proposed Phase III clinical trial. As of the same date, we had not received any relevant regulatory agency's concerns or objections to our clinical development plans and no material adverse changes had occurred since we obtained the IND approval. Pursuant to the Administrative Measures for Drug Registration, CSU is considered an indication expansion of QX005N and will be treated as the same product in the subsequent regulatory registration process.

Asthma

Asthma, a condition that affects the lungs and respiratory functions, is one of the world's most common diseases. It is caused by inflammation of the breathing tubes that carry air in and out of the lungs. Asthma affects both children and adults, and is the most common chronic disease among children. For a significant number of patients, asthma may be a major problem that interferes with daily activities and may potentially lead to life-threatening attacks. Asthma cannot be cured and is often under-diagnosed and under-treated, particularly in low- and middle-income countries. Approximately 50% to 70% of asthma patients have predominant type 2 inflammation. As IL-4Rα is a promising therapeutic target for type 2 inflammation-driven diseases, we are developing QX005N as a drug candidate aiming to reach such major portion of asthma patient population.

In addition to QX005N, to address the unmet medical needs for treatment options with efficacy over a broad range of asthma severities and subtypes, we have two other innovative drug candidates with different mechanism and clinical benefit from QX005N in our asthma pipeline, namely, (i) QX008N, an anti-TSLP antibody, as a drug candidate for asthma patients, including those with low-level or no expression of type 2 inflammation biomarkers and (ii) QX007N, an anti-IL-33 antibody, as an alternative drug candidate for asthma patients. See "—Our Other Key Product Candidates—QX008N—Asthma" and "—Our Other Product Candidates—QX007N—Asthma" for details.

Market Opportunity and Competition

The prevalence of asthma in China increased from 62.5 million in 2018 to 67.3 million in 2022, and is estimated to reach 78.1 million in 2030. The market for biologic drugs targeting asthma in China is estimated to increase from US$0.1 billion in 2022 to US$4.7 billion in 2030, at a CAGR of 61.8%. Biologic drugs accounted for 3.5% of the drug market for asthma in China in 2022, which is estimated to increase to 44.1% in 2030.

The long-term goals of asthma management are to control symptoms and reduce the risk of exacerbations, airway damage and side-effects of medication. Medications for asthma primarily include inhaled corticosteroids (ICSs) and bronchodilators. ICSs are widely used for long-term treatment of asthma in people of all ages who require daily management. Bronchodilators for the treatment of asthma include long-acting β2 receptor agonist (LABA), long-acting muscarinic antagonist (LAMA), short-acting β2 receptor agonist (SABA), and short-acting muscarinic antagonist (SAMA). However, for patients with moderate-to-severe asthma, treatment with ICS and bronchodilators alone may not be effective enough to control the disease due to a variety of factors including intolerance after long-term administrations and side effects. In addition, research has shown that SABA overuse and subsequent ICS underuse are responsible for safety concerns and poor outcomes, including hospitalization and possibly death. Therefore, the Global Initiative for Asthma ("GINA"), a medical organization that works with public health officials and healthcare professionals globally and publishes guidelines for the treatment of asthma, made a fundamental change to its recommendations for the pharmacological treatment of asthma in 2019, which no longer recommended regular use of SABAs for asthma patients who should all be prescribed ICSs, either regularly or as needed for respiratory symptoms. Moreover, the maintenance treatment of systemic corticosteroids can cause dose-dependent growth suppression and a series of severe adverse effects in children and adolescents, which leaves them with even more limited treatment options. In contrast, biologics that specifically target cytokine signaling pathways have shown to be a well-tolerated and effective option for patients with moderate-to-severe asthma. Therefore, for patients with

moderate-to-severe asthma, biologics have a more important role in disease management and can work as an add-on treatment with LABA, LAMA, SABA, SAMA and/or ICS. However, as a relatively new class of drugs, they have not yet been recommended as a main treatment option for asthma by prevailing clinical guidelines.

As of the Latest Practicable Date, three biologic drugs were approved for the treatment of asthma in China, including omalizumab, omalizumab alfa and dupilumab. As of the Latest Practicable Date, there were six IL-4Rα inhibitor candidates in the clinical stage in China. The following tables sets forth details of the approved biologic drugs and biologic drug candidates in clinical stage in China as of the Latest Practicable Date.

Marketed Targeted Biologics for Asthma in China

Target	Brand Name	INN	Company	Median Price[1]	NMPA Approval Time	NRDL Inclusion
IgE	Xolair	Omalizumab	Novartis/Genentech[2]	1,406	2017	Yes
	Aomaishu (奧邁舒)	Omalizumab alfa	Mabpharm	N/A	2023	No
IL-4Rα	Dupixent	Dupilumab	Sanofi	3,160	2023	Yes

Notes:

(1) Reflects the NRDL median price per minimum formulation unit in 2022 in RMB.

(2) Novartis and Genentech co-develop and co-promote omalizumab. Novartis markets omalizumab outside the United States.

Clinical-Stage Biologic Drug Candidates for Asthma in China

Target	Drug Code	Company	Status	First posted Date
TSLP	Tezepelumab	AstraZeneca	Phase III	2019-07-15
	TQC2731	Chia Tai Tianqing	Phase II	2022-06-21
	SHR-1905	Hengrui	Phase II	2022-09-29
	CM326	Keymed Bioscience	Phase II	2023-03-17
	QX008N	**the Company**	**Phase I**	**2022-07-08**
	HBM9378	Harbour Biomed; Kelun-Biotech	Phase I	2022-08-29
	LQ043	Novamab	Phase I	2023-01-13
	GR2002	Genrixbio	Phase I	2023-05-25
	STSA-1201	Staidson Biopharmaceuticals	Phase I	2023-08-01
	MG-ZG122	Mabgeek	Phase I	2022-12-12
IL-4Rα	CM310	Keymed Bioscience	Phase II/III	2023-03-08
	CBP-201	Connect Biopharmaceuticals	Phase II	2021-08-18
	GR1802	Genrix Bio	Phase II	2022-05-12
	MG-K10	Mabgeek	Phase I / II	2022-04-29
	SHR-1819	Hengrui	Phase I	2021-02-01
	LQ036	Novamab	Phase II	2024-02-04
IL-5	Mepolizumab	GSK	BLA submission	2023-03-14
	Depemokimab	GSK	Phase III	2021-09-18
	SSGJ-610	Sunshine Guojian	Phase II	2022-08-22
	SHR-1703	Hengrui	Phase II	2022-09-05
IL-4Rα, IL-5	RC1416	Regenecore	Phase I	2023-06-20
IL-5Rα	Benralizumab	AstraZeneca	Phase III	2017-07-26
IgE	Omalizumab-HS632	Hisun	Phase I	2020-04-29
	Omalizumab-SYN008	CSPC Baike	Phase I	2020-11-03
	Omalizumab-SYB507	Yuanda Shuyang	Phase I	2020-11-09
	JYB1904	Jiye Biotechnology	Phase I	2022-04-28
IL-25	XKH001	Kanova biopharma	Phase I	2022-03-07
ST2	9MW1911	Mabwell	Phase I	2021-10-13
	TQC2938	Chia Tai Tianqing	Phase I	2023-03-31
Undisclosed	Recombinant ε and γ Human Immunoglobulin Fc Fusion Protein	Kexin Biotech	Phase I	2018-11-16
	ZHB107-108	ZonHon Biopharma	Phase I	2023-11-17

Source: Frost & Sullivan Report (based on annual reports of relevant companies and information published by the NMPA)

Our Advantages

Asthma has a complex and heterogeneous nature which each patient needs targeted treatment. Therefore, the demand for targeted biologic treatment is increasing. As of the Latest Practicable Date, dupilumab was the only approved IL-4Rα inhibitor for asthma in China. While dupilumab can cost over RMB82,000 a year based on its pricing in China for the treatment of AD in 2022, according to Frost & Sullivan, we aim to make QX005N more accessible to patients in China. See "—Atopic Dermatitis—Our Advantages" for more details.

Material Communications and Next Steps

We obtained the IND approval of the Phase I, Phase II and Phase III clinical trials of QX005N for treatment of moderate-to-severe asthma from the NMPA in February 2022. As of the Latest Practicable Date, we had not received any relevant regulatory agency's concerns or objections to our clinical development plans. No material adverse changes had occurred since we obtained the IND approval and up to the Latest Practicable Date. Pursuant to the Administrative Measures for Drug Registration, asthma is considered an indication expansion of QX005N and will be treated as the same product in the subsequent regulatory registration process.

Chronic Obstructive Pulmonary Disease

Chronic obstructive pulmonary disease (COPD) is a chronic inflammatory lung disease which obstructs air flow from the lungs. It consists of three separate illnesses: emphysema (a lung condition that causes shortness of breath), chronic bronchitis (long-term inflammation of the breathing tubes), and chronic obstructive asthma. COPD causes the destruction of barriers between alveoli inside lungs, causing airways to be swollen and clogged with mucus. COPD can be caused by smoking, long-term exposure to irritating gases such as second-hand smoke, chemical fumes or toxic substances, genetic defect and untreated asthma. In most cases, COPD develops very slowly and people may not experience any symptom for years before being diagnosed. The major diagnosis method for COPD is the lung function test, and the diagnosis is confirmed when the FEV1/FVC ratio, a ratio commonly used for COPD diagnosis that represents the maximum amount of air that a person can forcibly expel during the first second following maximal inhalation (FEV1) to the full forced vital capacity (FVC), is less than 70% after using bronchodilator.

COPD is mainly treated with drugs to prevent and control chronic inflammation and reduce clinical symptoms. Meanwhile, COPD patients can also be treated by rehabilitation, oxygen therapy and surgery. Control drugs for long-term treatment of COPD primarily include corticosteroids, such as ICSs and systemic corticosteroids, long-acting bronchodilators (LABA and LAMA) and anti-inflammatory drugs such as PDE4 inhibitors. Other drug treatments such as mucolytic, antioxidant drugs and immunomodulator can also be used to control inflammation. In the initial treatment of COPD, patients are recommended to use one type of bronchodilator. For patients with higher moderate exacerbations and more severe dyspnea, combination therapy of LABA and LAMA are recommended. For patients with higher eosinophil count, combined therapy of ICS with LABA and LAMA are recommended to improve lung function and reduce exacerbations. However, approximately 40% of moderate-to-severe COPD patients on the triple therapy of ICS with LABA and LAMA still remain

uncontrolled and continue to experience exacerbations. Therefore, there are significant unmet clinical needs from COPD patients. According to Frost & Sullivan, approximately 20% to 40% of COPD patients have eosinophilic COPD, which is characterized by predominant type 2 inflammation. As IL-4Rα is a promising therapeutic target for type 2 inflammation-driven diseases, we are developing QX005N as a drug candidate for such patients with eosinophilic COPD.

In addition to QX005N, to address the unmet medical needs for treatment options with efficacy over a broad range of COPD severities and subtypes, we have two other innovative drug candidates with differentiated mechanisms and clinical benefits in our COPD pipeline, which we believe can potentially address a broad COPD patient population, namely: (i) QX008N, an anti-TSLP antibody, as a drug candidate for COPD patients, including those with low-level or no expression of type 2 inflammation biomarkers; and (ii) QX007N, an anti-IL-33 antibody, as a drug candidate with particular promising efficacy for patients with prior smoking history. See "—Our Other Key Product Candidates—QX008N—Chronic Obstructive Pulmonary Disease" and "—Our Other Product Candidates—QX007N—Chronic Obstructive Pulmonary Disease" for details.

Market Opportunity and Competition

According to Frost & Sullivan, the prevalence of COPD in China increased from 103.5 million in 2018 to 106.4 million in 2022, and is estimated to reach 110.7 million in 2030. While ICSs and long-acting bronchodilators are the primary drug treatments for COPD, no biologics had been approved for the treatment of COPD as of the Latest Practicable Date. According to Frost & Sullivan, the COPD drug market in China is estimated to increase from US$3.2 billion in 2022 to US$6.3 billion in 2030, at a CAGR of 8.8%. Biologic drug candidates for COPD in China primarily include IL-4Rα inhibitors, IL-5 inhibitors, ST2 inhibitors and IL-33 inhibitors. As asthma and COPD share common pathophysiological mechanisms, IL-4Rα and IL-5, two of the most commonly developed targets for treatment of asthma, are also being developed as targets for treatment of COPD. Since IL-33 can induce Th2 cytokine production and promote the pathogenesis of COPD, IL-33 and its receptor, ST2, can be promising targets for the treatment of COPD as well. However, as a relatively new class of drugs, biologics have not yet been recommended as a main treatment option for COPD by prevailing clinical guidelines. As of the Latest Practicable Date, there were seven biologic drug candidates for COPD in the clinical stage in China, including two candidates targeting IL-4Rα, namely, dupilumab and SSGJ-611. See "Industry Overview—Overview of the Allergic Disease Drug Market—Major Allergic Diseases—Chronic Obstructive Pulmonary Disease" for details.

Our Advantages

Approximately 20% to 40% of COPD patients have a predominant type 2 inflammation. IL-4Rα has been reported to be a promising target with good efficacy and safety profile in the treatment of diseases associated with type 2 inflammation by controlling the signaling of both IL-4 and IL-13 that drives type 2 inflammatory response. While dupilumab, one of the two anti-IL-4Rα drug candidates for COPD in China as the of Latest Practicable Date, can cost over RMB82,000 a year based on its pricing in China for the treatment of AD in 2022, according to Frost & Sullivan, we aim to make QX005N more accessible to patients in China. See "—Atopic Dermatitis—Our Advantages" for more details.

Material Communications and Next Steps

We obtained the IND approval of the Phase I, Phase II and Phase III clinical trials of QX005N for treatment of COPD from the NMPA in September 2023. As of the Latest Practicable Date, we had not received any relevant regulatory agency's concerns or objections to our clinical development plans. No material adverse changes had occurred since we obtained the IND approval and up to the Latest Practicable Date. Pursuant to the Administrative Measures for Drug Registration, COPD is considered an indication expansion of QX005N and will be treated as the same product in the subsequent regulatory registration process.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET QX005N SUCCESSFULLY.

Our Other Key Product Candidates

QX001S

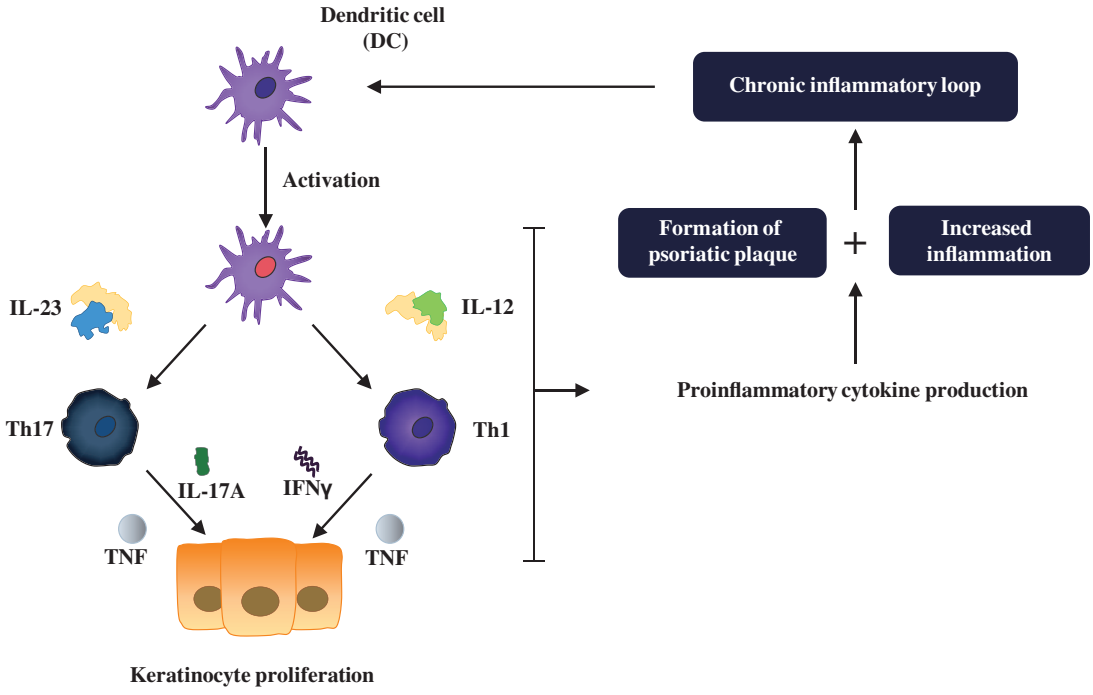
QX001S, our most advanced drug candidate, is the first domestically developed ustekinumab biosimilar with BLA submitted in China and potentially one of the first ustekinumab biosimilars to be approved in China. It is a humanized monoclonal antibody inhibiting the bioactivity of the cytokines IL-12 and IL-23 by targeting their common p40 subunit. IL-12 and IL-23 are involved in inflammatory and immune responses and have been implicated as important contributors to chronic inflammation, a hallmark of many autoimmune diseases such as Ps.

We received an IND approval of QX001S for the treatment of moderate-to-severe plaque Ps from the NMPA in January 2018. In our Phase I clinical trial, our QX001S demonstrated a safety and PK profile comparable to that of ustekinumab, indicating its potential to be an effective treatment for Ps suitable for long-term use. In our Phase III clinical trial for Ps, QX001S demonstrated clinical equivalence to ustekinumab in terms of efficacy, safety, immunogenicity and PK profile. In August 2020, we entered into a collaboration agreement with Zhongmei Huadong, a subsidiary of Huadong Medicine, with respect to the joint development and exclusive commercialization of QX001S in China. For details, see "—Collaboration with Zhongmei Huadong." Zhongmei Huadong submitted a BLA in China in July 2023, which was accepted by the NMPA in August 2023 and under review as of the Latest Practicable Date. Additionally, we, together with our commercialization partner Zhongmei Huadong, plan to develop QX001S for the treatment of UC/CD.

Mechanism of Action

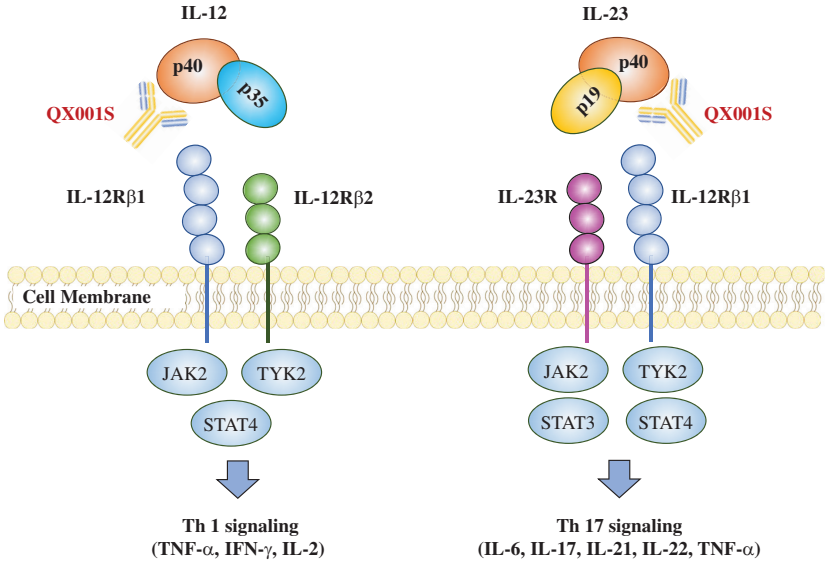
IL-12 and IL-23 are cytokines involved in inflammatory and immune responses. IL-12 and IL-23 are involved in the differentiation of T helper 1 (Th1) and Th17 cells (subsets of T helper cells), respectively, by binding to the receptor proteins expressed on the immune cell surface and activating the Janus kinase–signal transducer and activator of transcription (JAK-STAT) signaling pathway that allows signal transduction into the immune cells. Th1 cells and Th17 cells each release various cytokines, among which interferon-gamma (IFN-γ), tumor necrosis factor alpha (TNF-α) and IL-17 are considered key in the pathogenesis of chronic inflammatory diseases.

Structurally, IL-12 and IL-23 are both composed of two subunits. IL-12 comprises a p40 subunit linked to a p35 subunit, while IL-23 comprises the same p40 subunit linked to a unique p19 subunit. The common subunit, p40, is required for receptor binding of both IL-12 and IL-23, which is essential for their function. Similar to ustekinumab, QX001S is designed to bind to the p40 subunit of IL-12 and IL-23 and prevent it from binding to the cell surface IL-12Rβ1 receptor, which in turn blocks signal transduction through the JAK-STAT pathway and inhibits the differentiation of Th1 and Th17 cells. This way, QX001S reduces the production of those pro-inflammatory cytokines and alleviates inflammatory response. The diagram below illustrates the involvement of IL-12 and IL-23 in causing inflammatory and immune responses that lead to plaque Ps.



Source: Frost & Sullivan Report

The diagram below illustrates the mechanism of action of QX001S.



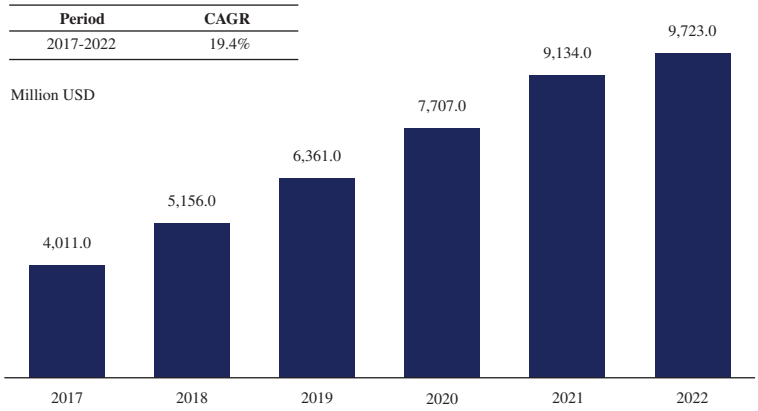
Source: the Company

Background of Reference Drug

According to the Guidelines for the R&D and Evaluation Techniques of Biosimilar Drugs (Trial) (《生物類似藥研發與評價技術指導原則(試行)》), all biosimilars must demonstrate a similar nature to the originator drug in terms of their safety and efficacy (including PK and PD parameters). This also applies to QX001S and other proposed biosimilars to ustekinumab, including their administration methods.

Ustekinumab is a humanized IgG1k monoclonal antibody that binds to the common p40 subunit of IL-12 and IL-23 in order to inhibit their bioactivity. It is developed by Johnson & Johnson and sold under the brand name Stelara. Initially approved by the FDA in 2009, ustekinumab was the first biologic treatment to selectively inhibit the IL-12 and IL-23 pathways and has been widely regarded as one of the major treatments for Ps worldwide. In 2022, it recorded sales of US$9.7 billion globally and ranked the ninth best-selling drug worldwide, according to Frost & Sullivan. The following chart sets forth the global sales of ustekinumab for the periods indicated.

Global Sales of Ustekinumab (Stelara), 2017-2022



Source: Frost & Sullivan Report (based on the annual report of relevant company)

Ustekinumab was first approved for the treatment of moderate-to-severe Ps in China in 2017. The China patent on the amino acid sequence of ustekinumab expired in August 2021, and U.S. and European patents will expire in September 2023 and January 2024, respectively.

Licenses, Rights and Obligations

In August 2020, we entered into a collaboration agreement with Zhongmei Huadong with respect to the joint development and exclusive commercialization of QX001S in China. We retain the exclusive development and commercialization rights of QX001S outside China. For further details, please refer to "—Collaboration with Zhongmei Huadong."

Psoriasis

Psoriasis (Ps) is a skin disease associated with dysregulation of the immune system that causes a rash with itchy and scaly patches, most commonly on the knees, elbows, trunk and scalp. It is a common chronic disease with no cure. It can sometime cause pain in patients and interfere with patients' daily life. Plaque Ps is the most common type of Ps, causing dry, itchy and raised skin patches (plaques) covered with scales. The plaques may appear anywhere on the skin and their visibility could have a detrimental impact on the patients' psychological health. Even worse, for many Ps patients, the skin may never be completely clear. As of the Latest Practicable Date, we were developing QX001S and QX004N indicated for Ps. We expect QX001S, which is the first domestically developed biosimilar to ustekinumab, a global blockbuster biologic drug, with BLA submitted in China and potentially one of China's first approved ustekinumab biosimilars, to be an affordable therapy for a broad section of Ps patients. In addition, due to its chronic and relapsing nature, there is an unmet medical need for new Ps drugs with a superior efficacy and safety profile suitable for long-term disease management. We believe that QX004N, as an IL-23p19 inhibitor, will be a promising alternative for Ps patients with more severe symptoms or inadequate response to existing treatments. In doing so, we hope to improve accessibility of QX001S and QX004N and establish a comprehensive coverage of Ps patients who experience different levels of disease severity and have different abilities to pay.

Market Opportunity and Competition

According to Frost & Sullivan, the prevalence of Ps in China has generally remained stable, which increased from 6.6 million in 2018 to 6.7 million in 2022, and is anticipated to reach 6.8 million in 2030. 20% to 30% of the patients have moderate-to-severe Ps. The Ps drug market in China grew rapidly from US$604.2 million in 2018 to US$1,435.8 million in 2022, at a CAGR of 24.2%, and is estimated to increase to US$9,943.6 million in 2030, at a CAGR of 27.4% from 2022 to 2030. Biologic drugs accounted for 43.4% of the drug market for Ps in China in 2022, which is estimated to increase to 56.8% in 2030.

Topical drugs, NSAIDs and conventional DMARDs are commonly used to control Ps but with limited efficacy as compared to biologic drugs with specific targeting, which has become a main treatment option for moderate-to-severe plaque Ps in China. In addition, small-molecule targeted drugs are a relatively new class of medications as a potentially promising treatment option for Ps patients. For example, JAK inhibitors have shown promising clinical results but may lead to more severe side effects and higher toxicity, causing the FDA to advise that they should be used with caution for patients with certain risk factors. PDE-4 inhibitors, another family of small-molecule drugs, have shown a good safety profile but limited efficacy. As a result, their use as a recommended long-term treatment option for a broad section of Ps patients remains under evaluation. Recently, TYK2 inhibitors, a newer family of small-molecule targeted drugs, have demonstrated in clinical studies promising efficacy profiles for treating Ps and improvements on traditional limitations of JAK-related toxicities.

Since the first biologic drug for Ps treatment, namely, an anti-IL-8 humanized mAb, was approved in China in 2003, there have been over ten biologic drugs approved for Ps in China in recent years. They belong to two main types, namely, TNF inhibitors and IL inhibitors, which are considered first-generation and second-generation drugs, according to Frost & Sullivan. Adalimumab, a TNF-α inhibitor and sold under the brand name Humira, was the world's best-selling drug for eight years in the last ten (2013-2022). As TNF inhibitors have significant limitations, including multiple adverse effects and a high rate of non-responsiveness, IL inhibitors, such as those targeting IL-17A and IL-23, present promising treatments for Ps. Among IL inhibitors, IL-23 is expected to be one of the mainstream targets for Ps treatment given its key role in the alleviation of inflammation and its superior efficacy and safety profile in comparison with IL-17A inhibitors in clinical studies. The chart below sets forth the global sales of marketed biologics targeting IL-23 and IL-17A in 2022.

Target	Drug	Global sales 2022 (million USD)	SUM – Global sales 2022 (million USD)
IL-23	Ustekinumab	9,723	17,556
	Guselkumab	2,668	
	Tildrakizumab-asmn	Undisclosed	
	Risankizumab-rzaa	5,165	
IL-17A	Secukinumab	4,788	7,270
	Ixekizumab	2,482	

Source: Frost & Sullivan Report (based on annual reports of relevant companies)

As of the Latest Practicable Date, there were 21 biologic drugs for Ps approved in China, including 13 TNF inhibitors (including adalimumab and 6 adalimumab biosimilars) and 8 IL inhibitors, among which ustekinumab was the only approved IL-12/IL-23 inhibitor while guselkumab and tildrakizumab were the only approved IL-23 inhibitors. As of the same date, besides QX001S and QX004N, there were 32 biologic drug candidates for Ps in the clinical stage in China, including 15 IL-17 inhibitors, 8 TNF-α inhibitors (including 7 proposed adalimumab biosimilars), 3 targeting IL-23, 3 targeting IL-12/IL-23 (including 2 proposed ustekinumab biosimilars) and 3 targeting IL-36R. Due to the aforementioned limitations of TNF inhibitors, we believe that QX001S and QX004N will primarily compete with other IL inhibitors. In particular, we expect QX001S to face intense competition upon its commercialization, see "Risk Factors—Our drug candidates will be subject to intense competition with biologics drugs and other drugs for autoimmune and allergic diseases after commercialization and may fail to compete effectively against competitors" for details. The following table sets forth details of QX001S and QX004N as well as approved biologic drugs and drug candidates in the clinical stage for Ps in China that are IL inhibitors as of the Latest Practicable Date.

Marketed IL Inhibitors for Psoriasis in China

Target	Brand Name	International Nonproprietary Name (INN)	Company	NMPA Approval Time	Branded or Biosimilar	Availability of biosimilar	2022 NRDL covered	NRDL Median price in 2022[1] (RMB)
IL-23	Tremfya	Guselkumab	Janssen (J&J)	2019	Branded	—	No	—
	益路取	Tildrakizumab-asmn	Sun Pharma; Kangzhe Biotech	2023	Branded	—	No	—
IL-12, IL-23	Stelara	Ustekinumab	Janssen (J&J)	2017	Branded	—	Yes	4,318.0
IL-17A	Cosentyx	Secukinumab	Novartis	2019	Branded	—	Yes	1,188.0
	TALTZ	Ixekizumab	Eli Lilly	2019	Branded	—	Yes	1,218.0
IL-17RA	LUMICEF	Brodalumab	Kyowa Kirin	2020	Branded	—	No	—
IL-8	Enboke (恩博克)	—	ASIA SPACE	2003	Branded	—	Yes	270.0
IL-36R	Spevigo	Spesolimab	Boehringer Ingelheim	2022	Branded	—	No	—

Clinical-Stage IL Inhibitor Candidates for Psoriasis in China

Target	Drug Code	Company	Status	First Posted Date
IL-23	IBI112	Innovent	Phase III	2022-12-26
	QX004N	**the Company**	**Phase II**	**2023-01-06**
	Risankizumab	Boehringer Ingelheim	Phase I	2019-07-18
	NBL-012	NovaRock	Phase I	2021-06-03
IL-12, IL-23	**Ustekinumab-QX001S**	**the Company**	**BLA submission**	**2023-08-12**
	Ustekinumab-BAT2206	Bio-Thera	Phase III	2021-06-25
	AK101	Akeso	BLA submission	2023-08-23
	Ustekinumab-SYSA1902	CSPC	Phase III	2023-01-29
IL-17A	GR1501	GenrixBio	BLA submission	2023-03-25
	SHR-1314	Henrui	BLA submission	2023-04-27
	JS005	Junshi Bioscience	Phase III	2023-07-12
	Secukinumab-BAT2306	Bio-Thera	Phase III	2022-07-25
	SSGJ-608	Sunshine Guojian	Phase III	2022-11-10
	AK111	Akeso	Phase III	2023-02-15
	HB0017	Huaota Biopharm; Huabo Bio	Phase II	2022-08-22
	SYS6012	CSPC	Phase I	2023-12-05
	BR201	BioRay	Phase I	2023-11-16
	Netakimab	BIOCAD	Phase I	2022-10-19
	Secukinumab-CMAB015	Mabpharm	Phase I	2023-01-18
	NVS451	National Vaccine & Serum Institute	Phase I	2023-05-08
	FTC001/CNTO6785	Shandong Fontacea	Phase I	2023-06-26
IL-17A, IL-17F	Bimekizumab	UCB Pharma	BLA submission	2023-07-20
	LZM012	LIVZON	Phase III	2023-06-27
IL-36R	Imsidolimab	AnaptysBio	Phase III	2023-03-09
	TQH2929	Chiatai Tianqing	Phase I	2023-11-02
	HB0034	Huaota Biopharm; Huabo Bio	Phase I	2022-09-05

Source: NMPA, CDE, Frost & Sullivan Report

Note:

(1) Reflects the median price for a drug's minimum formulation unit as included in the NRDL.

Our Advantages

We believe our QX001S has the following potential advantages in comparison with the approved drugs and drug candidates indicated for Ps:

- *Good efficacy and safety profile*. Ps is a chronic disease with no cure and typically requires long-term treatment plans to manage symptoms. However, a majority of patients discontinue treatment due to ineffectiveness. In comparison with other biologics currently approved for Ps in China, such as TNF-α and IL-17 inhibitors, ustekinumab, the reference drug of QX001S, has shown a promising safety and efficacy profile for long-term use. A head-to-head study in 903 patients with moderate-to-severe plaque Ps showed that at week 12, there was at least 75%

improvement in the Psoriasis Area and Severity Index (PASI) score (PASI75) in 67.5% and 73.8% of patients who received 45 mg and 90 mg of ustekinumab, respectively, as compared with 56.8% of those who received etanercept, a TNF-α inhibitor, demonstrating better efficacy of ustekinumab. Additionally, several gastrointestinal symptoms have been reported after IL-17 inhibitor treatment despite their high levels of efficacy, which have not been observed in therapy with ustekinumab. Furthermore, ustekinumab is reported to have higher drug survival, which is a measure of the time period until treatment discontinuation that is used to evaluate the effectiveness of a Ps drug, than TNF-α and IL-17 inhibitors. A study in 1,606 patients with moderate-to-severe plaque Ps treated with biologics showed that ustekinumab also had higher drug survival and lower rates of discontinuation as compared to IL-17 inhibitors, such as secukinumab, which has been reported to have less long-term efficacy in clinical studies. These findings suggest that ustekinumab may be more suitable to be used in a long-term treatment plan for Ps patients. In our Phase I clinical trial, our QX001S demonstrated comparable safety and PK profile to ustekinumab, indicating its potential to be an effective treatment for Ps suitable for long-term use. In our Phase III clinical trial for Ps, QX001S also demonstrated clinical equivalence to ustekinumab in terms of efficacy, safety, immunogenicity and PK profile.

- *Convenient treatment regimen*. Benefiting from its strong efficacy and safety profile, ustekinumab can be administered with a lower dose frequency (typically one dose every three months after the loading doses) than IL-17 inhibitors (usually one dose every month after the loading doses). Similarly, QX001S is designed to be administered four times a year after the loading doses, which presents a convenient treatment regimen with lower administration frequency. It could potentially improve patient compliance and in turn further improve efficacy.

- *Rapid commercialization strategy*. To commercialize QX001S in China, we have entered into a collaboration agreement with a subsidiary of Huadong Medicine, a leading PRC pharmaceutical company. We believe that the collaboration with Huadong Medicine will enable us to leverage its market access, nationwide sales and marketing network targeting the autoimmune and allergic disease field as well as its extensive experience in chronic disease management, which will be crucial to help achieve rapid commercialization of QX001S in China.

- *Promising accessibility*. While ustekinumab has been included in the NRDL with a price cut, it is still an expensive treatment. Ustekinumab is designed to be administered with one initial injection of 45 mg at week 0 and week 4, respectively, and then with a treatment frequency of Q12W at 45 mg. Since 2022, the annual cost of ustekinumab has been approximately RMB21,590 for five doses in the first year and approximately RMB17,272 for four doses per year for subsequent treatment for Ps patients in China, according to Frost & Sullivan. Therefore, there is still room for this treatment to reach more patients, with further price deductions. In collaboration with Huadong Medicine, we aim to make QX001S more accessible to patients in

China taking into account various factors such as our in-house manufacturing capacity, potential competitor pricing and regulatory requirements. QX001S is designed to be administered at the same dosage and frequency as ustekinumab. Its estimated annual cost is expected to be lower than ustekinumab by approximately 10% upon commercialization. By marketing QX001S as an affordable biosimilar to ustekinumab, we believe QX001S has the potential to benefit both patients currently undertaking ustekinumab therapy and those who previously could not afford it.

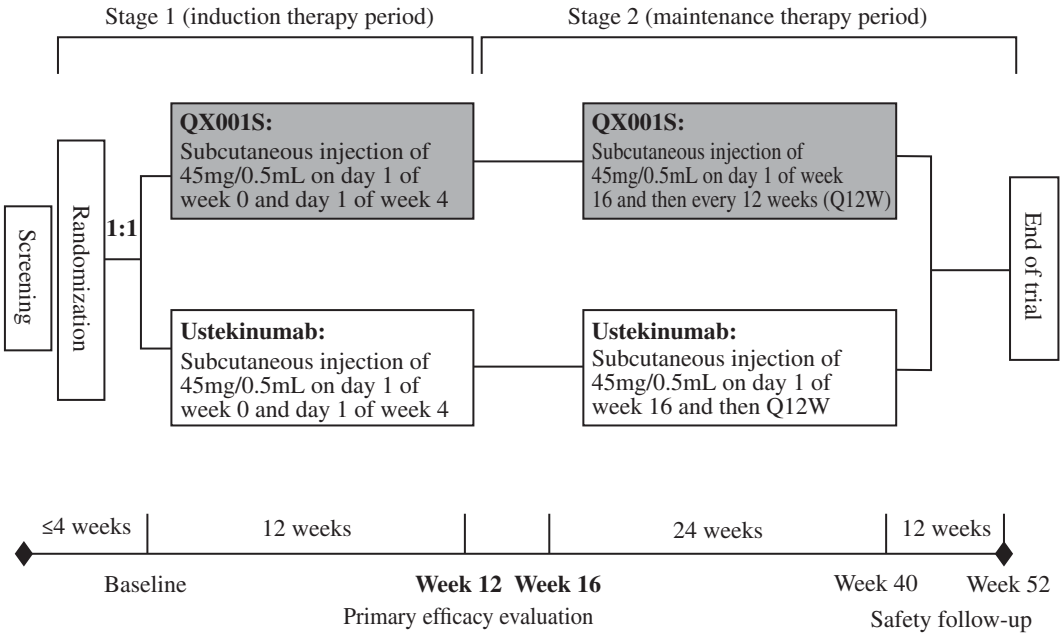
Summary of Clinical Trial Results

We completed a Phase I clinical trial of QX001S in healthy subjects (individuals in good general health and not having any mental or physical disorder requiring regular or frequent medication) in China in May 2020, and Zhongmei Huadong and we completed a Phase III clinical trial of QX001S in patients with moderate-to-severe plaque Ps in China in June 2023.

Phase III Clinical Trial

The Phase III clinical trial in China was a multi-center, randomized, double-blind and parallel-controlled head-to-head clinical study in patients with moderate-to-severe plaque Ps to evaluate the efficacy and safety of QX001S versus ustekinumab.

Trial design: The primary endpoint of this trial was the proportion of subjects who experience at least 75% improvement in the PASI score ("PASI-75"), the current benchmark of primary endpoints for most clinical trials for Ps treatments, at week 12. The secondary endpoints included safety parameters, PK, immunogenicity and efficacy parameters, such as (i) the percentage of improvement in PASI, (ii) the proportion of subjects who experience PASI-75 at weeks 4, 16, 20, 28, 40 and 52, (iii) the proportion of subjects who achieve clearance or near elimination of Ps symptoms ("IGA=0" or "IGA=1," respectively), and (iv) changes in the Dermatology Life Quality Index ("DLQI," which is a questionnaire designed to measure the health-related quality of life of adult patients suffering from a skin disease). There would be two stages in this trial, including an induction therapy period of 12 weeks (stage 1) and a maintenance therapy period of 36 weeks (stage 2). We planned to enroll a total of 508 subjects, who would be assigned to an active treatment group receiving QX001S (45 mg/0.5 mL) and a control group receiving ustekinumab (45 mg/0.5 mL) equally. The subjects would receive a dose of either QX001S or ustekinumab at 45 mg on the first day of trial (day 0) and another injection of the same dose at week 4. The PK, immunogenicity, efficacy and safety evaluation would be conducted at week 12, which would be reviewed by an IDMC. The trial would be terminated if the IDMC concludes that the trial results at week 12 cannot show clinical equivalence between QX001S and ustekinumab. If the trial proceeds to stage 2, the subjects would receive another dose of either QX001S or ustekinumab at 45 mg on the first day of week 16 and then a dose every 12 weeks (Q12W) until week 40, followed by the efficacy and safety evaluation at week 52. The diagram below illustrates the design of this trial.



Trial status: This trial was initiated in June 2021 and completed in June 2023. A total of 508 subjects were enrolled in the study, with 253 and 255 subjects in the QX001S and ustekinumab groups, respectively.

Efficacy results: In this trial, the primary endpoint, *i.e.*, the proportion of subjects responding to the treatment as measured by PASI-75 at week 12, was 70.4% and 64.3% in the QX001S and ustekinumab groups, respectively, indicating a similar efficacy of QX001S and ustekinumab. In addition, the QX001S and ustekinumab groups showed similar improvement trends and magnitudes in terms of secondary efficacy parameters. For example, both groups showed improvements in PASI and DLQI scores at week 4 in comparison with baseline, which were maintained during the subsequent treatment. The proportion of subjects achieving PASI-50, PASI-75, PASI-90 and PASI-100 in the QX001S and ustekinumab groups also increased and maintained as drug administration time prolonged. The proportion of subjects achieving IGA score (0 or 1) in both groups increased gradually after drug administration and stabilized at week 40, which then experienced a slight decrease after week 40.

Safety results: In this trial, QX001S was well-tolerated and overall its safety profile was good and comparable to ustekinumab. 216 of the 253 (85.4%) subjects in the QX001S group and 206 of the 255 (80.8%) subjects in the ustekinumab group reported TEAEs, including 16 (6.3%) incidents in the QX001S group and 30 (11.8%) incidents in the ustekinumab group being Grade 3 or higher under CTCAE. Additionally, 141 of the 253 (55.7%) subjects in the QX001S group and 111 of the 255 (43.5%) subjects in the ustekinumab group reported drug-related AEs, including 6 (2.4%) incidents in the QX001S group and 8 (3.1%) incidents in the ustekinumab group being Grade 3 or higher under CTCAE. Furthermore, 10 of the 253 (4.0%) subjects in the QX001S group and 13 of the 255 (5.1%) subjects in the ustekinumab group reported TESAEs. Only one TESAE, of abnormal liver function, in the QX001S group was considered related to the treatment. There were 2 (0.8%) subjects in the QX001S group and 3 (1.2%) subjects in the ustekinumab group that discontinued treatment and withdrew from the study due to TEAEs occurred in this trial. No death was observed in this trial.

Immunogenicity: In this trial, the proportion of ADA-positive subjects was overall not higher in the QX001S group than in the ustekinumab group, with 48 and 78 ADA-positive subjects observed in the QX001S and ustekinumab groups, respectively. Neutralizing antibody (NAb) was also tested in this trial, which is often a required indicator of a clinical trial if immunogenicity is observed in subjects, because ADAs have the potential to neutralize the effects of a drug. The QX001S and ustekinumab groups had a similar NAb-positive rate in this trial, with 25 NAb-positive subjects in each of the groups.

PK: In this trial, QX001S and ustekinumab showed comparable PK profile with similar trends and no significant difference in drug concentration. Additionally, drug concentration is considered to have stabilized at week 16 with no significant accumulation under a drug administration frequency of Q12W.

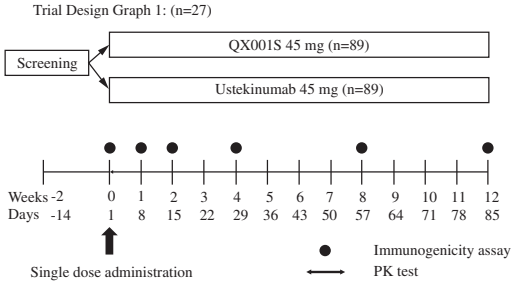
Conclusion: In this trial, QX001S demonstrated a clinical equivalence to ustekinumab as measured by the proportion of subjects achieving PASI-75 at week 12. Additionally, similar clinical efficacy, safety, immunogenicity and PK characteristics were observed in the QX001S and ustekinumab groups for long-term use, further supporting the clinical equivalence of QX001S and ustekinumab.

Phase I Clinical Trial

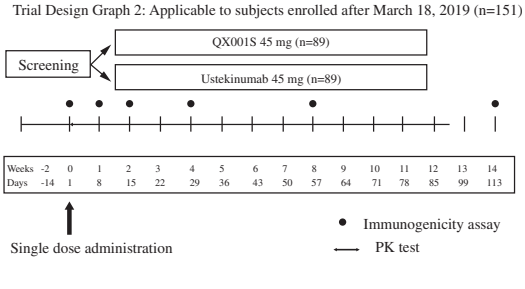
The Phase I clinical trial in China was a randomized, double-blind, single-dose, parallel and comparison clinical study in healthy male subjects to evaluate the PK profile of QX001S versus ustekinumab.

Trial design: The primary endpoints included PK parameters for evaluating the PK similarity of a single dose of QX001S (45 mg/0.5 mL) versus ustekinumab (45 mg/0.5 mL) in healthy male subjects. The secondary endpoints included safety parameters and immunogenicity. We planned to enroll a total of 178 subjects, who would be assigned to two groups with 89 subjects in each group. The active treatment group and control group would receive a single subcutaneous injection of QX001S (45 mg/0.5 mL) and ustekinumab (45 mg/0.5 mL), respectively, under fasting conditions. The trial would include a screening period of 14 days and an evaluation period of 85 days. The evaluation period was later amended to 113 days for subjects enrolled after March 18, 2019. The diagrams below illustrate the design of this trial.

Trial Design Graph 1: (n=27)



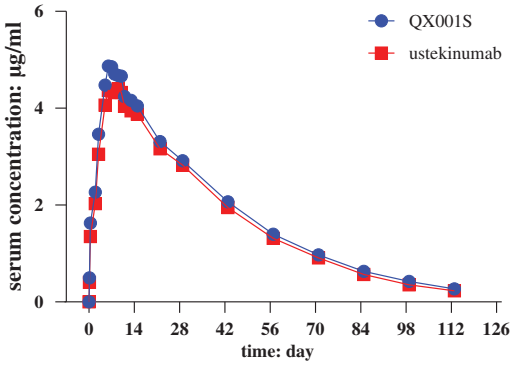
Trial Design Graph 2: Applicable to subjects enrolled after March 18, 2019 (n=151)



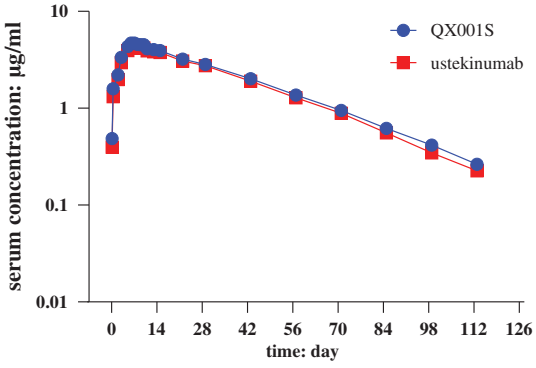
Trial status: This trial was initiated in November 2018 and completed in May 2020. A total of 178 subjects were enrolled in the study with 177 subjects included in the safety, PK and immunogenicity analysis sets as one subject withdrew from the study for personal reasons. 89 and 88 subjects were assigned to the QX001S and ustekinumab groups, respectively.

PK: In this trial, QX001S and ustekinumab showed comparable PK profile in healthy male subjects, as indicated by their ratios of the adjusted geometric means (90% confidence intervals) for the main PK parameters (C_{max}, AUC_{0-t} and AUC_{0-inf}), which were all within the range of 80% to 125% (the predefined bioequivalence limits). The mean serum concentration-time curves are shown below.

Serum drug concentration-time profile for QX001S and ustekinumab (linear)



Serum drug concentration-time profile for QX001S and ustekinumab (semi-log)



Immunogenicity: In this trial, the proportion of ADA-positive patients was overall lower in the QX001S group than in the ustekinumab group, as shown in the table below.

Time	**QX001S group (*n* = 89)**	**Ustekinumab group (*n* = 88)**	
hour (day)	**n (%)**	**n (%)**	***p***
Pre-dose	2 (2.2)	3 (3.4)	0.64
168 (8)	1 (1.1)	15 (17)	<0.05
336 (15)	3 (3.4)	14 (15.9)	<0.05
672 (29)	3 (3.4)	11 (12.5)	<0.05
1,344 (57)	11 (12.4)	15 (17)	0.37
2,688 (113)	11 (12.4)	21 (23.8)	<0.05

Safety results: In this trial, QX001S was well-tolerated and its safety profile was good and comparable to ustekinumab. 98 of the 177 (55.4%) subjects in the safety analysis set reported a total of 228 AEs, all of which were treatment-emergent adverse events (TEAEs). 143 of those AEs were adverse drug reactions (ADRs), reported by 75 (42.4%) subjects. Most TEAEs were of mild or moderate severity. There were no serious adverse events (SAEs) and no subjects discontinued treatment or withdrew from the study due to safety issues in this trial. The following table summarizes the AEs occurred in this trial.

	QX001S group (*n* = 89)		**Ustekinumab group (*n* = 88)**		**Total (*n* = 177)**		
	n (%)	**Number of reactions**	**n (%)**	**Number of reactions**	**n (%)**	**Number of reactions**	***p***
Total	38 (42.7)	88	37 (42.0)	55	75 (42.4)	143	0.93
Upper respiratory infection	9 (10.1)	9	6 (6.8)	6	15 (8.5)	15	0.43
Elevated triglyceride level	3 (3.4)	4	6 (6.8)	6	9 (5.1)	10	0.29
Elevated leukocyte count	5 (5.6)	6	3 (3.4)	3	8 (4.5)	9	0.47
Elevated alanine aminotransferase	12 (13.5)	14	4 (4.5)	4	16 (9.0)	18	0.04
Elevated aspartate aminotransferase	8 (9.0)	9	0 (0.0)	0	8 (4.5)	9	NA
Elevated neutrophil counts	5 (5.6)	6	3 (3.4)	3	8 (4.5)	9	0.47

Conclusion: In this trial, QX001S demonstrated a good PK and safety profile in healthy male subjects comparable to that of ustekinumab. In addition, the rate of ADA-positive subjects in the QX001S group was lower than that in the ustekinumab group. Based on the trial results, we have initiated a Phase III clinical trial in China to further evaluate QX001S for the treatment of moderate-to-severe plaque Ps.

Material Communications and Next Steps

We received an IND approval of QX001S for the treatment of moderate-to-severe plaque Ps from the NMPA in January 2018. Zhongmei Huadong, a subsidiary of Huadong Medicine and our commercialization partner for QX001S, and we completed the Phase III clinical trial for this indication in June 2023. Zhongmei Huadong submitted a BLA in China in July 2023, which was accepted by the NMPA in August 2023 and under review as of the Latest Practicable Date. According to Frost & Sullivan, QX001S was the first and only ustekinumab biosimilar candidate that had been submitted for a BLA in China as of the Latest Practicable Date. Zhongmei Huadong and we plan to initiate the commercial launch of QX001S in China for the treatment of Ps upon expected BLA approval in the fourth quarter of 2024. As of the Latest Practicable Date, we had not received any relevant regulatory agency's concerns or objections to our clinical development plans and no material adverse changes had occurred since we obtained the IND approval.

Inflammatory Bowel Disease

Ustekinumab, the reference drug of QX001S, was first approved by the FDA for the treatment of CD in 2016 and for the treatment of UC in 2019. We, together with our commercialization partner Zhongmei Huadong, plan to develop QX001S, an anti-IL-12/IL-23p40 antibody and an ustekinumab biosimilar, for the treatment of UC/CD. During our joint development with Zhongmei Huadong of QX001S in China for indications other than Ps, Zhongmei Huadong shall be responsible for any expenses related to the clinical trials and regulatory communication and registration for QX001S; we shall be responsible for expenses related to the sample production and process development and optimization prior to the commercialization of QX001S. See "—Collaboration with Zhongmei Huadong—QX001S Framework Agreement" for details of our collaboration with Zhongmei Huadong. See "—QX004N—Inflammatory Bowel Disease" below for details of UC and CD.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET QX001S SUCCESSFULLY.

QX004N

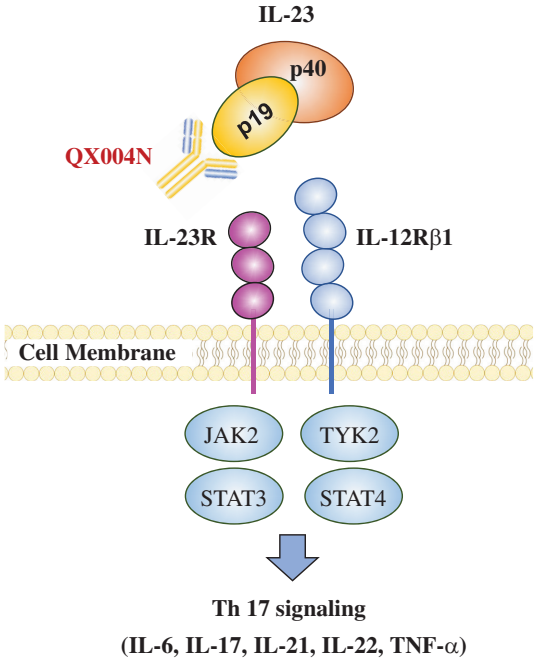
QX004N, a recombinant humanized IgG1 monoclonal antibody targeting the p19 subunit of IL-23, is an innovative drug candidate indicated for Ps and CD. IL-23p19 has emerged as a key target associated with superior efficacy for Ps patients with more severe symptoms or inadequate response to existing treatments and has a more dominant role than IL-12 in causing CD. Specifically, blocking the signaling of IL-23 may lead to better clinical benefits than blocking the signaling of both IL-23 and IL-12, primarily because the immune response and surveillance mediated by IL-12 are preserved. Additionally, it has been reported to be a target with favorable safety profile that is suitable for long-term use.

We obtained an IND approval for QX004N for the treatment of Ps and CD from the NMPA in August 2021 and November 2022, respectively. We completed a Phase Ia clinical trial of QX004N in healthy subjects for the Ps indication in China in September 2023 and QX004N showed a good safety profile. As of the Latest Practicable Date, we also commenced a Phase Ib clinical trial and a Phase II clinical trial in China to evaluate QX004N for this indication and expect to complete them in the second quarter of 2024 and the first half of 2025, respectively. As of the Latest Practicable Date, we also commenced a Phase Ia clinical trial in healthy subjects for the treatment of CD in China, which we expect to complete in the first quarter of 2024. In addition, we may investigate QX004N for further indication expansion to UC.

Mechanism of Action

IL-23 drives Th17 cell differentiation by binding and signaling through its receptor complex composed of two subunits, *i.e.*, IL-12Rβ1, which binds to the p40 subunit of IL-23, and IL-23R, which binds to the p19 subunit of IL-23. Th17 cells are characterized by the production of a group of cytokines, such as IL-6, IL-17A, IL-17F, IL-21 and IL-22. Particularly, IL-17A and IL-17F signal through the IL-17 receptor (IL-17R) complex to induce

the production of pro-inflammatory cytokines, which drives the inflammatory response in psoriasis lesions. This suggests that the IL-23/IL-17 pathway plays an important role in the pathogenesis of psoriasis. By binding to the p19 subunit of IL-23, QX004N blocks the binding between IL-23 and IL-23R and the corresponding signal transduction, which inhibits the development of Th17 cells and leads to reduced production of IL-17 cytokines. The diagram below illustrates the mechanism of action of QX004N, which is designed to bind to IL-23p19 and block the binding between IL-23 and IL-23R.



Source: the Company

Psoriasis

Due to the chronic and relapsing nature of Ps, there is an unmet medical need for new Ps drugs with a superior efficacy and safety profile suitable for long-term disease management. We believe QX004N will be a promising alternative for Ps patients as drugs targeting IL-23p19 are expected to show an improved efficacy profile with higher potency than those targeting IL-12/IL-23p40. Additionally, it has been reported to be a target with favorable safety profile that is suitable for long-term use. Together with QX001S, we hope to improve accessibility of the two drug candidates and establish a comprehensive coverage of Ps patients who experience different levels of disease severity and have different abilities to pay.

We completed a Phase Ia clinical trial of QX004N in healthy subjects for the Ps indication in China in September 2023 and QX004N showed a good safety profile. As of the Latest Practicable Date, we had commenced a Phase Ib clinical trial and a Phase II clinical trial in China to evaluate QX004N for this indication and expect to complete them in the second quarter of 2024 and the first half of 2025, respectively.

Market Opportunity and Competition

For details of the prevalence of Ps in China and its current treatments, as well as the competitive landscape of biologic drugs for Ps, see "Industry Overview—Overview of the Autoimmune Disease Drug Market—Major Autoimmune Diseases—Psoriasis" and "—QX001S—Market Opportunity and Competition" above.

Our Advantages

We believe QX004N has the following potential advantages in comparison with the approved drugs and drug candidates targeting Ps:

- *Potentially better efficacy profile*. The IL-12/IL-23 axis is one of the many proposed mechanistic pathways of Ps, with IL-23 reported to be the key player in the alleviation of inflammation. IL-23p19 inhibitors have shown favorable efficacy results in clinical studies. For example, in the PsO-1 and PsO-2 clinical trials in 406 and 392 adult patients with plaque Ps, respectively, subjects receiving risankizumab, an IL-23p19 inhibitor, achieved PASI 90 (75% and 75%, respectively) and static Physician's Global Assessment (sPGA, which is used to determine the overall severity of a patient's disease at a given point in time) level of 0 or 1 (88% and 84%, respectively) at week 16. Additionally, IL-23p19 inhibitors have been reported to maintain effective in long-term use. In the VOYAGE 1 and VOYAGE 2 clinical trials in 837 and 992 patients with moderate-to-severe Ps, respectively, response rates as measured by the proportions of subjects achieving PASI 75, PASI 100, IGA level of 0 or 1 and IGA level of 0 were maintained in subjects receiving guselkumab, another IL-23p19 inhibitor, from week 52 through week 204. QX004N showed a good safety profile based on preliminary results from our Phase Ia clinical trial. In addition, as IL-23 promotes differentiation of naïve T helper cells to Th17 cells, a subset of effector Th cells characterized by the production of multiple pro-inflammatory cytokines, including IL-17, IL-21, IL-22 and IL-26, selective blockade of the specific p19 subunit of IL-23 is able to act upstream in the IL-23/IL-17 cytokine pathway as compared to the more distant blockade of IL-17A or its receptor. For example, the ECLIPSE trial in 1,048 patients with moderate-to-severe plaque Ps showed that guselkumab had superior long-term efficacy in comparison with secukinumab, an IL-17A inhibitor, in terms of the proportion of patients with a PASI90 response at week 48.

- *Commercialization synergy between QX001S and QX004N*. We plan to rapidly develop and commercialize QX001S in collaboration with Huadong Medicine. In doing so, we expect to create development and commercialization synergy for QX004N as both are indicated for Ps. We believe that QX004N, as a promising drug candidate for Ps with a potentially improved efficacy and safety profile, could also benefit from the commercialization network and market acceptance that we will establish for QX001S.

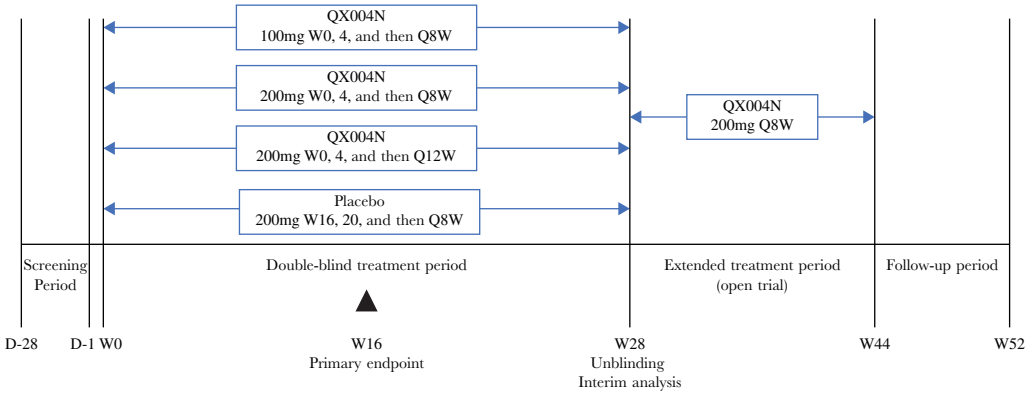
Summary of Clinical Trial Results

We commenced a Phase Ia clinical trial in healthy subjects, a Phase Ib clinical trial in adult patients with moderate-to-severe plaque Ps and a Phase II clinical trial in adult patients with moderate-to-severe plaque Ps to evaluate QX004N for the Ps indication in China in November 2021, February 2023 and September 2023, respectively. We completed the Phase Ia clinical trial in September 2023. The Phase Ib trial and Phase II trial were ongoing as of the Latest Practicable Date and we expect to complete them in the second quarter of 2024 and the first half of 2025, respectively.

Ongoing Phase II Clinical Trial

The Phase II clinical trial in China is a multi-center, randomized, double-blind and placebo-controlled clinical study in adult patients with moderate-to-severe plaque Ps to evaluate the efficacy, safety, PK and PD profile of QX004N.

Trial design: The primary endpoint of this trial is the proportion of subjects who experience PASI90 at week 16. The secondary endpoints include safety and tolerability, PK, immunogenicity, PD and efficacy parameters, including (i) the proportion of subjects who experience PASI75 at week 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48 and 52; (ii) the proportion of subjects who experience PASI90 at week 4, 8, 12, 20, 24, 28, 32, 36, 40, 44, 48 and 52; (iii) the proportion of subjects who experience PASI100 at week 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48 and 52; (iv) the proportion of subjects who achieve IGA level of 0 or 1 at week 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48 and 52; (v) the proportion of subjects who achieve IGA level of 0 at week 8, 16, 28, 40 and 52; (vi) improvement in BSA assessments at week 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48 and 52; and (vii) improvement in DLQI score at week 4, 8, 12, 16, 28, 40 and 52. We plan to enroll a total of 160 patients, who will be assigned to 4 groups (including 3 treatment groups and 1 control group) with 40 patients in each group. There will be two treatment periods in this trial, including the double-blind treatment period (from week 0 to week 28) and extended treatment period (from week 28 to week 44). During the double-blind treatment period, the first treatment group will receive QX004N at 100 mg at week 0 and 4 and then Q8W until week 28; the second treatment group will receive QX004N at 200 mg at week 0 and 4 and then Q8W until week 28; the third treatment group will receive QX004N at 200 mg at weeks 0 and 4 and then Q12W until week 28; and the control group will receive placebo at week 0, 4 and 12 and then receive QX004N at 200 mg at week 16, 20 and 28. During the extended treatment period, all four groups will receive QX004N at 200 mg Q8W until week 44. After week 44, there will be a follow-up period of eight weeks. The chart below summarizes the design of this trial.

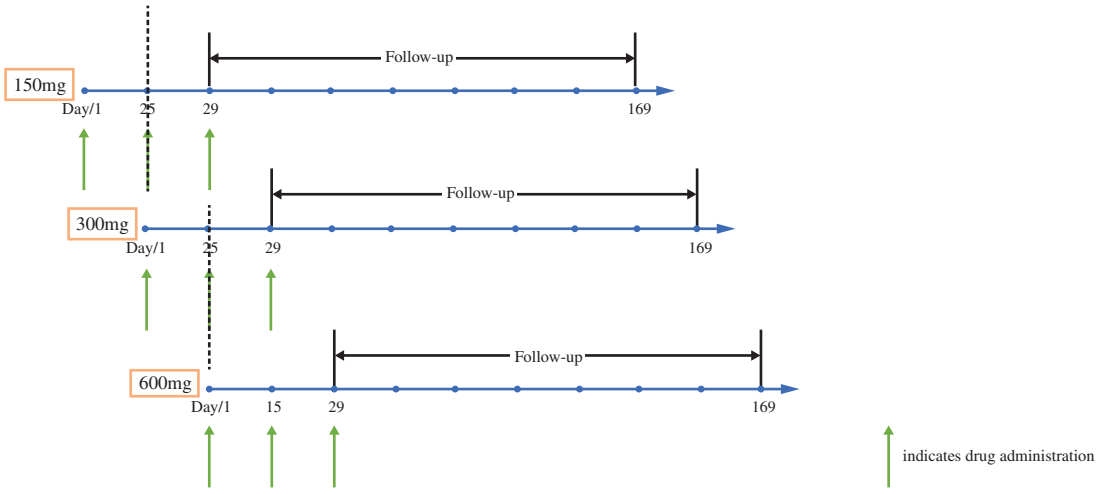


Trial status: Subject enrollment commenced in September 2023 and was completed in January 2024. A total of 160 subjects were enrolled, including 40 in each of the three treatment groups and the control group. We expect to complete this trial in the first half of 2025.

Ongoing Phase Ib Clinical Trial

The Phase Ib clinical trial in China is a multi-center, randomized, double-blind, multi-ascending-dose and placebo-controlled clinical study in adult patients with moderate-to-severe plaque Ps to evaluate the safety, tolerability, efficacy and PK profile of QX004N.

Trial design: The primary endpoints of this trial included safety and tolerability of QX004N in adult patients with moderate-to-severe plaque Ps. The secondary endpoints included PK parameters, immunogenicity and efficacy parameters, including (i) the proportion of subjects who experience PASI75 at week 12 as the primary efficacy measure, (ii) average improvement in PASI at week 2, 4, 8, 12, 16, 20 and 24, (iii) the proportion of subjects who experience PASI75, PASI50, PASI90 and PASI100 at week 2, 4, 8, 12, 16, 20 and 24, (iv) the proportion of subjects who achieve IGA level of 0 or 1 at week 2, 4, 8, 12, 16, 20 and 24, (v) improvement in BSA (body surface area affected by Ps) assessments at week 2, 4, 8, 12, 16, 20 and 24, and (vi) improvement in DLQI score at week 2, 4, 8, 12, 16, 20 and 24. We planned to enroll a total of 30 patients, who would be assigned to three groups with ten patients in each group (eight receiving QX004N and two receiving placebo). Each group would receive three doses of either QX004N or placebo at their designated dose level (150 mg, 300 mg and 600 mg, respectively), to be administered on day 1, day 15 and day 29, followed by safety follow-up until day 169. The trial would proceed from one dose level to the next only if the evaluation of tolerability and safety on the previous dose level group on day 15 has been completed. In the event where termination may be warranted, the sponsor and investigator would determine whether to terminate the trial or resume the trial with the median level of the previous and current dose levels. The chart below summarizes the design of this trial.



Trial status: Subject enrollment commenced in February 2023 and was completed in June 2023. We enrolled a total of 30 subjects, including 10 subjects (8 receiving QX004N and 2 receiving placebo) in each of the 150 mg, 300 mg and 600 mg groups. We expect to complete the Phase Ib clinical trial in the second quarter of 2024.

Phase Ia Clinical Trial

The Phase Ia clinical trial in China was a single-center, randomized, double-blind, single-ascending-dose and placebo-controlled clinical study in healthy subjects to evaluate the PK profile, safety, tolerability and immunogenicity of QX004N.

Trial design: The primary endpoints of this trial included safety and tolerability of QX004N in healthy subjects. The secondary endpoints included PK parameters and immunogenicity. We planned to enroll a total of 45 subjects, who would be assigned to five groups with five subjects in the first group (four receiving QX004N and one receiving placebo) and ten subjects in each of the other four groups (eight receiving QX004N and two receiving placebo). The trial would start with the first group receiving a single subcutaneous injection of 10 mg and the subsequent four groups each receiving an increased single dose of 50 mg, 100 mg, 300 mg and 600 mg, respectively. Each subject would receive only one corresponding dose of QX004N (or placebo). The trial would proceed from one dose level to the next only if safety of the previous dose level is confirmed after a two-week evaluation period upon drug administration. In the event where termination may be warranted, the sponsor and the investigator would determine whether to terminate the trial or resume the trial with the median level of the previous and current dose levels.

Trial status: This trial was initiated in November 2021 and completed in September 2023. We enrolled a total of 55 subjects. In the 10 mg group, we enrolled five subjects with four receiving QX004N and one receiving placebo. In each of the 50 mg, 100 mg and 600 mg group, we enrolled ten subjects with eight receiving QX004N and two receiving placebo. For the 300 mg group, we enrolled 20 subjects with 16 receiving QX004N and four receiving placebo, as the initial data collection of this dose level halted due to the COVID-19 pandemic and it was later reassessed to meet the requirements for this trial.

Safety results: In this trial, QX004N was well-tolerated and its safety profile was good. 43 (78.2%) subjects in the safety analysis set reported AEs, among which 34 (61.8%) subjects reported ADRs. One AE of CTCAE Grade 3 was reported in the 10 mg group that was possibly unrelated to the drug. The subject was reported to have elevated blood triglycerides and later recovered without treatment. All other AEs observed in this trial were of CTCAE Grade 1 or 2. There was one SAE reported in the 300 mg group that was possibly unrelated to the drug. The subject was reported to have a miscarriage and later physically recovered. No other SAEs or death were observed in this trial. No significant difference was observed in terms of safety between the QX004N groups and the control group and there was no significant correlation between the incidence of AEs and ascending dosage levels.

PK: The plasma exposure of QX004N in healthy subjects showed an increasing trend as the dose level increased from 10 mg to 600 mg following a single subcutaneous administration, suggesting a linear PK.

Immunogenicity: In this trial, seven (15.9%) subjects in the QX004N groups were reported ADA-positive after treatment. Subjects who were ADA-positive before treatment did not experience increases in antibody levels after treatment. No impact of immunogenicity on safety was found in this trial.

Conclusion: In this trial, QX004N was safe and well-tolerated in healthy subjects in the dose range from 10 mg to 600 mg. The plasma exposure of QX004N in healthy subjects also showed an increasing trend as the dose level increased, suggesting a linear PK.

Summary of Preclinical Study Results

As of the Latest Practicable Date, we had conducted a series of preclinical studies to characterize the PD, PK and toxicity of QX004N. Overall, QX004N has demonstrated high potency, comparable to risankizumab and better than guselkumab. Our *in vivo* studies in a Ps mouse model showed that QX004N (10 mg/kg, 3 mg/kg and 1 mg/kg) could effectively reduce ear thickness, ear weight and protein level of IL-17 and IL-22 in the mice. QX004N (10 mg/kg and 3 mg/kg) could also effectively decrease epidermal thickness, lymphocyte infiltration and the comprehensive pathological score. The effective dose of QX004N in this study was 1 mg/kg and there was a dose-dependent relationship within the dose range from 1 mg/kg to 10 mg/kg. At the same dose level (10 mg/kg), risankizumab and QX004N had comparable PD effects.

Material Communications and Next Steps

We obtained an IND approval for QX004N for the treatment of Ps from the NMPA in August 2021. We expect to complete the ongoing Phase Ib clinical trial and Phase II clinical trial in China in the second quarter of 2024 and the first half of 2025, respectively. As of the Latest Practicable Date, we had not received any relevant regulatory agency's concerns or objections to our clinical development plans and no material adverse changes had occurred since we obtained the IND approval.

Inflammatory Bowel Disease

Inflammatory bowel disease (IBD) is a broad term that describes conditions characterized by chronic inflammation of the gastrointestinal tract. The two most common types of IBD are UC and CD. UC is characterized by mucosal inflammation limited to the colon which involves the rectum in approximately 95% of cases and may extend to parts or all of the large intestine. In contrast, CD is characterized by full thickness inflammation that can occur anywhere in the digestive tract but most typically involves the terminal ileum and colon. Symptoms for UC and CD can vary, depending on the location and severity of inflammation, but some of the most common are diarrhea, abdominal cramps and rectal bleeding. IBD is a chronic inflammatory condition that requires lifelong treatment, which usually involves either drug therapy, including anti-inflammatory drugs, immunomodulators and biologics, or surgery.

Ulcerative Colitis

Aminosalicylic acids, also known as 5-ASA, are the standard of care for the first-line treatment of adult UC. Aminosalicylic acids, which control the inflammatory process and thus allow damaged tissue to heal, are largely effective for mild-to-moderate disease. Corticosteroids are often effective for patients with moderate-to-severe UC, but safety concerns preclude their long-term use. Moderate-to-severe UC patients in the United States are provided with more treatment options, including biologic therapies, compared to patients in China, where there remains significant unmet need. As of the Latest Practicable Date, vedolizumab, infliximab and infliximab biosimilars were the only biologic therapies that had been approved for treating UC in China.

Crohn's Disease

Choice of treatment for CD is based on the overall evaluation of the disease condition, such as infection status. For patients with mild disease, treatment options include aminosalicylic acids and budesonide. For patients with moderate disease, corticosteroids are the primary systemic treatment option, while immunosuppressants can be used for maintenance therapy. For severe disease, biologics are the primary treatment options.

We are developing QX004N for the treatment of moderate-to-severe CD. Similar to the case of psoriasis, IL-23 has a more dominant role than IL-12 in causing CD. Specifically, blocking the signaling of IL-23 may lead to better clinical benefits than blocking the signaling of both IL-23 and IL-12, primarily because the immune response and surveillance mediated by IL-12 are preserved. We commenced a Phase Ia clinical trial in February 2023.

In addition to QX004N, to address the vast and underserved market demand for more effective, safe and affordable drugs for moderate-to-severe UC/CD, we are also developing QX001S, an anti-IL-12/IL-23p40 antibody with different mechanism and benefit from QX004N, for the treatment of UC/CD. See "—QX001S—Inflammatory Bowel Disease" above for details.

Market Opportunity and Competition

The number of CD patients in China increased from 120,400 in 2018 to 173,500 in 2022 at a CAGR of 9.6%, and is estimated to reach 271,700 in 2030, at a CAGR of 5.8% from 2022 to 2030. The significantly overlapping UC/CD drugs market in China grew rapidly in recent years, from US$594.3 million in 2018 to US$1,051.2 million in 2022, representing a CAGR of 15.3%, and is estimated to reach US$5,490.1 million in 2030, representing a CAGR of 23.0% from 2022 to 2030. Biologic drugs accounted for 13.7% of the UC/CD drugs market in China in 2022, which is estimated to increase to 55.9% in 2030.

Medications indicated for moderate-to-severe CD mainly include corticosteroids, immunosuppressants and biologics. However, a large portion of the patients who initially respond to corticosteroid therapy develop a dependency on corticosteroids or have a relapse within 1 year. In addition, use of corticosteroids is often limited by a relatively high risk of serious adverse effects including bone loss, metabolic complications, increased intraocular pressure and glaucoma and potentially lethal infections. While both biologics and immunosuppressants are particularly useful when patients are not responsive to corticosteroid for induction or relapse prevention, biologics have been demonstrated in studies to achieve higher response rate with less flare up and side effect rates compared to immunosuppressants. As of the Latest Practicable Date, biologics have been recommended as a main treatment option for UC/CD by prevailing clinical guidelines.

There are three types of approved biologic drugs in China for the treatment of CD, namely, TNF-α inhibitors, integrin α4 (ITGA4)/integrin β7 (ITGB7) inhibitors and IL-12/IL-23 inhibitors. TNF-α inhibitors block the binding of TNF to TNF receptors, thereby suppressing their biological effects. Integrin α4/integrin β7 inhibitors bind to the surface of white blood cells so they cannot pass through tissue layers and exacerbate inflammation. However, use of certain integrin α4/integrin β7 inhibitors carries an increased risk of progressive multifocal leukoencephalopathy, a severe brain condition. In contrast, IL-23 inhibitors have exhibited strong safety profile while maintaining satisfactory efficacy. However, all such classes of biologics are likely to result in drug-resistance, forcing CD patients to switch between such types of biologics to prolong treatment.

As of the Latest Practicable Date, there were 12 biologic drugs for CD approved in China, including ten TNF-α inhibitors (including infliximab, adalimumab, three infliximab biosimilars and five adalimumab biosimilars), one integrin α4/integrin β7 inhibitor and one IL-12/IL-23 inhibitor, namely, ustekinumab. See "—QX001S—Background of Reference Drug" for details of ustekinumab. The TNF-α inhibitors, integrin α4/integrin β7 inhibitors and IL-12/IL-23 inhibitors are expected to continue to be mainstream biologic treatments for CD in the near future. As of the same date, there were eight biologic drug candidates for CD in the clinical stage in China, five of which are IL-12/IL-23 inhibitors or IL-23 inhibitors. The following tables sets forth details of QX004N as well as the approved biologic drugs and biologic drug candidates for CD in clinical stage in China as of the Latest Practicable Date.

Marketed Targeted Biologics for CD in China

Target	Brand Name	INN	Company	Median Price[1]	NMPA Approval Time	NRDL Inclusion
IL-12/IL-23	Stelara	Ustekinumab	Janssen (J&J)	4,318	2020	Yes
TNF-α	Remicade	Infliximab	Janssen (J&J)	2,007	2006	Yes
	QLETLI (格乐立)	Adalimumab-BAT1406	Bio-Thera	1,080	2019	Yes
	Anjianning (安健宁)	Adalimumab-HS016	Hisun	1,148	2019	Yes
	Humira	Adalimumab	AbbVie	1,290	2020	Yes
	SULINNO (苏立信)	Adalimumab-IBI303	Innovent	1,088	2020	Yes
	Leiting (类停)	Infliximab-CMAB008	MabPharm	1,268	2021	Yes
	Anbaite (安佰特)	Infliximab-HS626	Hisun	1,268	2021	Yes
	Jiayoujian (佳佑健)	Infliximab-GB242	Yuxi Genor Biotechnology	1,280	2022	Yes
	Junmaikang (君迈康)	Adalimumab-UBP1211	Junshi Bioscience	998	2022	Yes
	安佳润®	Adalimumab-SCT630	SinoCelltech	N/A	2023	No
Integrin α4/ Integrin β7	Entyvio	Vedolizumab	Takeda	4,980	2020	Yes

Note:

(1) Reflects the NRDL median price per minimum formulation unit in 2022 in RMB.

Clinical-Stage Biologic Drug Candidates for CD Treatment in China

Target	Drug Code	Company	Status	First Posted Date
IL-12, IL-23	Ustekinumab-BAT2206	Bio-Thera	Phase I	2020-05-06
IL-23	Risankizumab	AbbVie	BLA submission[1]	2023-07-06
	LY3074828	Eli Lilly	Phase III	2020-04-24
	Guselkumab	Janssen (J&J)	Phase III	2020-06-08
	QX004N	**the Company**	**Phase I**	**2022-12-28**
TNF-α	Adalimumab-TQZ2301	Chia Tai Tianqing	Phase I	2018-11-13
TNFSF15	PF-06480605	Pfizer	Phase I	2021-11-17
Undisclosed	HZBio2	Grand pharma	Phase I	2022-05-16

Source: Frost & Sullivan Report (based on annual reports of relevant companies and information published by the NMPA)

Note:

(1) AbbVie has not announced the specific indication for BLA submission of Risankizumab for UC/CD.

Our Advantages

CD is a chronic inflammatory condition that requires lifelong treatment. The demand for biologic drugs is increasing as a result of rising disease prevalence. With the first IL-12/IL-23 inhibitor approved for treating CD in China 2020, IL-12/IL-23 inhibitors have emerged as an important modality for treating CD, leveraging their important roles in the regulation of tissue inflammation. With its potentially better efficacy profile, we expect that our QX004N will become a favorable option for patients with moderate-to-severe CD. See "—Psoriasis—Our Advantages."

Summary of Clinical Trial

We commenced a Phase Ia clinical trial of QX004N for CD through intravenous injection in China in February 2023, which was ongoing as of the Latest Practicable Date and is expected to be completed in the second quarter of 2024.

Trial design: The Phase Ia clinical trial is a single-center, randomized, double-blinded, placebo-controlled and single ascending-dose clinical study to evaluate the PK, safety, tolerability and immunogenicity of intravenous injection of QX004N in healthy subjects. The primary endpoints of this trial include safety and tolerability of intravenous injection of QX004N in healthy subjects. The secondary endpoints include PK parameters and immunogenicity of intravenous injection of QX004N and to recommend dosing regimens for the Phase II clinical trials. The exploratory endpoints include PD parameters of intravenous injection of QX004N in these subjects. We plan to enroll a total of 40 participants, who will be assigned to 5 groups with 8 participants in each group (6 receiving QX004N and 2 receiving placebo). The trial will start with the first group receiving a single intravenous injection of 300 mg and the subsequent four groups each receiving an increased single dose of 600 mg, 900 mg, 1200 mg and 1600 mg, respectively. Each participant will receive only one corresponding dose of QX004N (or placebo). The trial will proceed from one dose level to the next only if the safety of such previous dose level is confirmed after a 15-day follow-up period. In the event where termination may be warranted, the sponsor and the investigator will determine whether to terminate the trial or resume the trial with the median level of the previous and current dose levels.

Trial status: Subject enrollment commenced in February 2023 and was completed in August 2023. A total of 41 subjects were enrolled, including 6 receiving QX004N and 2 receiving placebo in each of the 300 mg, 600 mg, 900 mg, 1200 mg and 1600 mg groups and one withdrawn from the study. We had completed drug administration for all subjects as of the Latest Practicable Date.

Summary of Preclinical Study Results

We conducted a series of preclinical studies to characterize the PD, PK and toxicity of QX004N, which demonstrated that QX004N has potency comparable to risankizumab and superior to guselkumab. See "—Psoriasis—Summary of Preclinical Study Results."

Material Communications and Next Steps

We obtained the IND approval of the Phase I, Phase II and Phase III clinical trials of QX004N for treatment of CD from the NMPA in November 2022. As of the Latest Practicable Date, we were conducting the Phase Ia clinical trial of QX004N for CD in China and had completed drug administration of all subjects. We plan to complete the Phase Ia clinical trial in China in the second quarter of 2024 and initiate a Phase Ib clinical trial in China depending the data from the Phase Ia clinical trial to evaluate the safety, efficacy, PK and tolerability of multiple intravenous injections of QX004N in adult patients with CD. As of the Latest Practicable Date, we had not received any relevant regulatory agency's concerns or objections to our clinical development plans. No material adverse changes had occurred since we obtained the IND approval and up to the Latest Practicable Date.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET QX004N SUCCESSFULLY.

QX006N

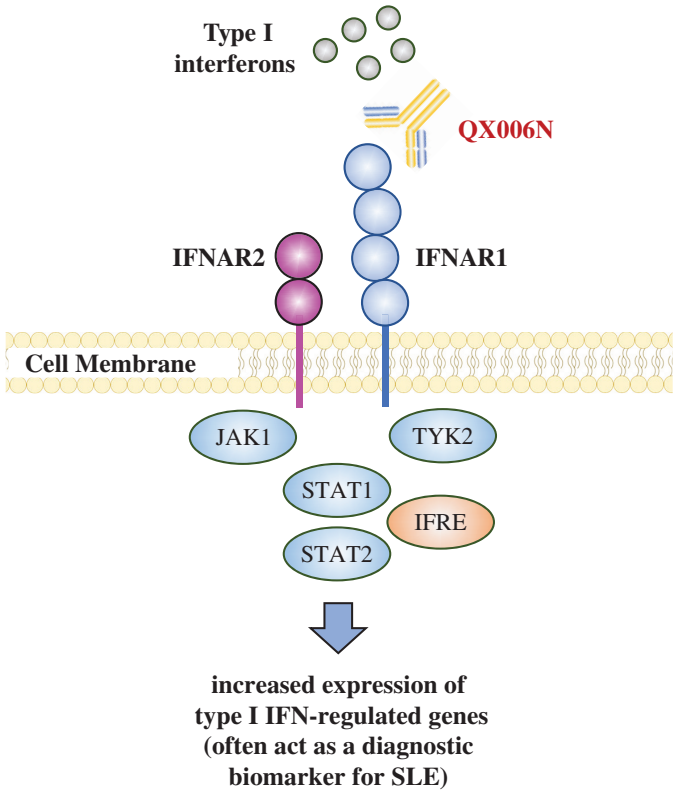
QX006N is one of the only two IFNAR1 inhibitors developed by Chinese domestic companies that had entered the clinical stage for SLE in China as of the Latest Practicable Date. Clinical research in SLE therapeutics has been met with limited success in recent years. SAPHNELO (anifrolumab), a first-in-class IFNAR1 inhibitor, was approved by the FDA in 2021, making it the only new SLE treatment in more than 10 years. The type I IFNs are a group of pleiotropic (having multiple traits) cytokine affecting a wide variety of immune cells. They are involved in multiple aspects of lupus etiology and pathogenesis and exert their bioeffect by binding to their common receptor. Anifrolumab had demonstrated clear clinical benefit in patients with moderate-to-severe SLE in previous studies. As of the Latest Practicable Date, there was no IFN receptor antibody approved by the NMPA for SLE treatment and only one such drug approved by the FDA, indicating a huge market potential for such drugs.

We received IND approval of QX006N for SLE from the NMPA in September 2021. We completed our Phase Ia clinical trial in healthy subjects in July 2023. As of the Latest Practicable Date, we had initiated a Phase Ib clinical trial in SLE patients.

Mechanism of Action

SLE is a highly heterogeneous, multiorgan autoimmune disease characterized by the overproduction of diverse autoantibodies. Autoantibodies attack one's own body tissues and form antigen-antibody complexes that could be deposited to multiple organs or tissues throughout the body, triggering a complex chain reaction leading to local inflammatory responses. Although the etiology of SLE is not fully understood and likely to be multifactorial, Type I IFNs, particularly IFN-α, have been established to be pivotal to the disease pathogenesis. In SLE patients, IFN-α could amplify the inflammatory responses and fuel autoimmunity through its interactions with a host of immune cells, including, among others, facilitating the differentiation of B cells into autoantibody-producing plasma cells and promoting the maturation of dendritic cells (DCs) as the key antigen-presenting cells that help activate autoreactive T helper cells and B cells.

Type I IFNs signal through their common receptor complex, comprised of subunits IFNAR1 and IFNAR2, on the cell surface, resulting in the activation of the pro-inflammatory Janus kinase-signal transducers and activators of transcription (JAK/STAT) signaling pathway. QX006N is a humanized IgG4 mAb that is designed to specifically bind to the type I IFN receptor, in particular, IFNAR1, thereby blocking the signal pathway and biological functions of IFNs. The following diagram illustrates the mechanism of action of QX006N.



Source: the Company

Systemic Lupus Erythematosus

Systemic lupus erythematosus (SLE) is an autoimmune disease associated with substantial morbidity and mortality. It is the most common type of lupus, characterized by widespread inflammation and tissue damage in the affected organs. SLE patients may experience a variety of symptoms such as fatigue, skin rashes, fevers and pain or swelling in the joints. The severity of symptoms varies from patient to patient, ranging from mild to life-threatening. SLE could also affect multiple organs in the patient, including the brain, lungs and, most commonly, the kidneys. Lupus nephritis (LN) is the most common severe complication of SLE.

There is no cure for SLE and currently available treatments aim to provide symptom relief. We are developing QX006N, a humanized mAb targeting the receptor for type I interferons (IFNs), a key mediator of the human immune system, for the treatment of SLE.

Market Opportunity and Competition

According to Frost & Sullivan, the SLE patient population in China reached approximately 1 million in 2022 and is expected to remain relatively stable over the next decade.

The types of drugs that have been used to treat SLE mainly include corticosteroids, traditional DMARDs (such as hydroxychloroquine), NSAIDs and biologic drugs. Corticosteroids are recommended as initial treatment for SLE patients. Low-dose corticosteroids, hydroxychloroquine or NSAIDs are recommended for patients with mild symptoms. For SLE patients with more severe conditions, combined therapies of corticosteroids, biologic drugs and traditional DMARDs are recommended. High doses of corticosteroids can be helpful in severe cases of SLE, but the patients face considerable risk of disease progression, relapse over time and serious side effects, including osteoporosis (weak bones), high blood pressure and diabetes. In addition, treatment with traditional DMARDs may result in an increased risk of serious infections and certain types of cancer. Hydroxychloroquine may offer relief for SLE-related symptoms, such as arthritis, fatigue and rashes, but is associated with increased risk of retinopathy. There remain significant unmet needs for new therapeutics for SLE that effectively control disease activity, have a favorable safety profile and improve the patients' quality of life.

Over the past decades, there has been growing interest in the development of biologic drugs indicated for SLE, including, most importantly, B cell depletion therapies aiming to inhibit autoreactive B cell activation and autoantibody production, and IFN receptor inhibitors. According to Frost & Sullivan, the market for biologic drugs for SLE in China is estimated to increase from US$111.5 million in 2022 to US$2.4 billion in 2030, representing a CAGR of 46.5%. We believe QX006N will primarily compete with IFNAR1 inhibitors and other biologic drugs in China.

As of the Latest Practicable Date, there were two approved B cell depletion therapies in China indicated for SLE, namely, belimumab and telitacicept. Belimumab is a human monoclonal antibody that inhibits B lymphocyte stimulator (BLyS), also known as B cell activating factor (BAFF), a member of the TNF cytokine family produced by myeloid lineage cells, such as DCs and macrophages, and a key factor in the differentiation and survival of B cells. Telitacicept targets two cell-signaling molecules critical for B cell development: BLyS and a proliferation inducing ligand (APRIL). Belimumab was approved by the FDA in 2011, making it the first new drug approved for SLE treatment in more than 50 years.

However, studies have found that the survival of certain types of B cells involved in the autoimmune responses, such as memory B cells and long-lived plasma cells, are independent of BLyS or APRIL, suggesting potential limits in the depletion effect of BLyS or APRIL inhibitors. Patients under BLyS or APRIL inhibition therapies showed considerable variability in their responses in several clinical trials. Considering the substantial heterogeneity of SLE pathogenesis, BLyS or APRIL inhibitors may be effective in certain subsets of patients while ineffective in others and there is no reliable objective marker to predict patients' response.

As of the Latest Practicable Date, only one IFN receptor inhibitor, anifrolumab, had been approved by the FDA for SLE and no drug of the same target had been approved for SLE by the NMPA. As of the same date, in addition to our QX006N, there were 15 biologic drug candidates for SLE in the clinical stage in China, two of which were IFNAR1 inhibitors. Other targets under investigation include BAFF and various membrane/transmembrane proteins, such as CD38 and CD22. The following table sets forth details of QX006N and biologic drugs and drug candidates in the clinical stage for SLE in China as of the Latest Practicable Date.

Marketed Targeted Biologics for SLE in China

Target	Brand Name	INN	Company	NMPA Approval Time	Median Price[(1)]	NRDL Inclusion
BAFF	Benlysta	Belimumab	GSK	2019	727.5	Yes
BAFF/APRIL	Tai'ai (泰愛)	Telitacicept	Remegen	2021	818.8	Yes

Clinical-Stage Biologic Drug Candidates for SLE in China

Target	Drug Code	Company	Status	First Posted Date
IFNAR1	Anifrolumab	AstraZeneca	Phase III	2021-08-09
	GR1603	Genrix Bio	Phase I/II	2021-12-03
	QX006N	**the Company**	**Phase I**	**2021-11-23**
BAFF	UBP1213sc	Junshi Bioscience	Phase I	2022-02-18
BAFFR	VAY736	Novartis	Phase III	2023-01-09
CLEC4C	BIIB059	Biogen; Vetter Pharma-Fertigung	Phase III	2022-06-07
CD20	Obinutuzumab	Roche	Phase III	2022-10-27
	MIL62	Mabworks	Phase II/III	2023-02-08
CD40L	Dapirolizumab Pegol	UCB Pharma	Phase III	2022-11-07
	IBI355	Innovent Bio	Phase I	2023-10-19
CD38	CM313	Keymed Bioscience	Phase I/II	2022-07-08
	SG301	Shangjian Biotech	Phase I	2023-11-06
CD22	SM03	Longrui	Phase I	2015-01-07
CD79B, FCGR2B	PRV-3279	Zhongmei Huadong	Phase II	2023-08-02
Undisclosed	SHR-2001	Hengrui	Phase I	2023-07-10
APRIL, BAFF	ALPN-303	Ajinomoto Bio-Pharma	Phase I	2023-12-22

Source: Frost & Sullivan Report (based on annual reports of relevant companies and information published by the NMPA)

Note:

(1) Reflects the NRDL median price for minimum formulation unit in 2022 in RMB.

Our Advantages

Taking into account the significant unmet needs for new therapeutics for SLE, we believe our QX006N, as an IFNAR1 antibody, has the potential to be a favorable option for SLE patients with a promising efficacy and safety profile. Anifrolumab, the FDA-approved IFNAR1 inhibitor, demonstrated clear clinical benefit in patients with moderate-to-severe SLE in a Phase III study (TULIP-2) and a Phase IIb study (MUSE). QX006N showed a good safety profile based on results from our Phase Ia clinical trial, and potency and affinity comparable to those of an internally prepared anifrolumab analog in our preclinical studies. See "—Summary of Clinical Trials" below for more details.

In addition, a large population of SLE patients in China have an urgent need for more affordable medical treatments as the currently available biologic treatments impose significant economic burden on patients with moderate income. According to Frost & Sullivan, in 2022, the estimated annual treatment cost of belimumab and telitacicept in China was around RMB49,000 to RMB52,000 and RMB85,000, respectively. However, leveraging our integrated R&D and manufacturing platform and cost control measures, we aim to provide QX006N at a competitive price.

Summary of Clinical Trials

We commenced a Phase Ia clinical trial in healthy subjects in December 2021 and completed such trial in July 2023. We also initiated a Phase Ib clinical trial in SLE patients in March 2023, which was ongoing as of the Latest Practicable Date.

Ongoing Phase Ib Clinical Trial

Trial design: The Phase Ib clinical trial in China is a multi-center, randomized, double-blind and placebo-controlled multiple-dose escalation trial in moderate-to-severe SLE patients. The primary objective of this trial is to evaluate the safety, tolerability and PK properties of multiple doses of QX006N in moderate-to-severe SLE patients. The secondary objectives are to evaluate the PD characteristics and immunogenicity of QX006N, and to determine a recommended dose for a Phase II clinical trial. A total of 30 patients are expected to be enrolled and assigned to three dose groups (150 mg group, 300 mg group and 600 mg group) with ten patients in each group. Within each group, eight patients would receive QX006N and two patients would receive placebo. Patients in each group would receive intravenous infusion of QX006N of the designated dose level (or placebo) on day 1, day 15 and day 29, and then proceed to a follow-up period till day 85. The trial will proceed from one dose level to the next only if the safety and tolerability of the previous dose level is confirmed by the evaluation on day 15.

Trial status: The Phase Ib clinical trial was initiated in March 2023. As of the Latest Practicable Date, we had enrolled 22 patients and we expect to complete patient enrollment in the first quarter of 2024.

Phase Ia Clinical Trial

Trial design: The Phase Ia clinical trial in China was a single-center, randomized, double-blind and placebo-controlled single-dose escalation trial in healthy subjects. The primary objective of this trial was to evaluate the safety and tolerability of single escalating dose of QX006N in healthy subjects. The secondary objectives were to evaluate the PK and immunogenicity of QX006N, and to determine the recommended dose for a Phase Ib clinical trial. A total of 45 subjects would be assigned to five groups receiving single intravenous infusions of 0.3 mg/kg, 1.0 mg/kg, 3.0 mg/kg, 6.0 mg/kg and 10.0 mg/kg QX006N or placebo, respectively. Five subjects would be assigned to the 0.3 mg/kg group and ten subjects would be assigned to each of the remaining four dose groups. Within each dose group, the ratio of subjects receiving QX006N to those receiving placebo would be 4:1.

Trial status: The Phase Ia clinical trial was initiated in December 2021. We completed patient enrollment for the trial in August 2022, with a total of 55 subjects enrolled. Ten extra subjects were enrolled for the 3.0 mg/kg group as the data collection for the initially enrolled subjects were interrupted due to the COVID-19 pandemic. We completed the Phase Ia clinical trial in July 2023.

Safety results: QX006N was well-tolerated and showed a good safety profile in healthy subjects in all dose groups. No death, SAE or TEAE of grade 3 (severe or medically significant but not immediately life-threatening as defined in CTCAE 5.0) or above were reported. 27 (out of 44, 61.4%) subjects in QX006N groups and 6 (out of 11, 54.5%) subjects in the placebo group reported 63 TEAEs, none of which led to a subject's withdrawal from the trial. Most subjects recovered from such TEAEs without medical intervention. The overall incidence rate of TEAE in the QX006N groups (61.4%) was close to that of the placebo group (54.5%).

PK: In the dose range from 0.3mg/kg to 10.0mg/kg, with the increase of the dose level, the $T_{1/2}$ of QX006N showed an increasing trend before reaching a stable level. The clearance (L/h) gradually decreased with the increasing dose level. The C_{max} increased in a proportional manner with the increasing dose level, while AUC_{0-t} and AUC_{0-inf} increased in a greater-than-proportional manner with the increasing dose level.

Immunogenicity: for all groups (except the 0.3 mg/kg group and the placebo group), the ADA positive rates gradually increased with time, reaching their peak at D57 (62.5% to 87.5%). The ADA positive rates were similar across such dose groups. The 0.3 mg/kg dose group and the placebo group showed no significant increase in their ADA positive rates over time and had lower positive rates. Overall, QX006N exhibited certain immunogenicity compared to the placebo group.

Conclusion: The trial met its primary and secondary endpoints. In this trial, QX006N was well-tolerated in healthy subjects in all dose groups, and demonstrated a good safety profile, non-dose-proportional PK and certain level of immunogenicity compared to the placebo group.

Summary of Preclinical Study Results

We conducted a series of preclinical studies in order to characterize the PD, PK and toxicity profile of QX006N. In our *in vitro* PD studies, QX006N demonstrated potency and affinity comparable to those of an internally prepared anifrolumab analog. In particular, in whole blood and THP-1 cells (a commonly used model for human monocytes), QX006N demonstrated suppressing effects comparable to that of anifrolumab analog on IFN-α-induced secretion of IP-10, which plays an important role in the pathological process of SLE. In our preclinical PK studies, QX006N exhibited nonlinear PK in cynomolgus monkeys over a dose range from 1 mg/kg to 30 mg/kg following single subcutaneous or intravenous administration. Systemic exposure (as measured by AUC) of QX006N increased in a greater-than-proportional manner with increasing dose. In our preclinical toxicological studies, QX006N demonstrated no obvious systemic toxicity. The MTD in single-dose intravenous-administration toxicity study of QX006N in cynomolgus monkeys was at least 600 mg/kg.

Material Communications and Next Steps

We received IND approval of the Phase I, Phase II and Phase III clinical trials of QX006N for SLE from the NMPA in September 2021. As of the Latest Practicable Date, we were conducting the Phase Ib clinical trial of QX006N for the treatment of SLE in China. We plan to complete the ongoing Phase Ib clinical trial in the fourth quarter of 2024. We have not received any relevant regulatory agency's concerns or objections to our clinical development plans as of the Latest Practicable Date. No material adverse changes had occurred since we obtained the IND approval and up to the Latest Practicable Date.

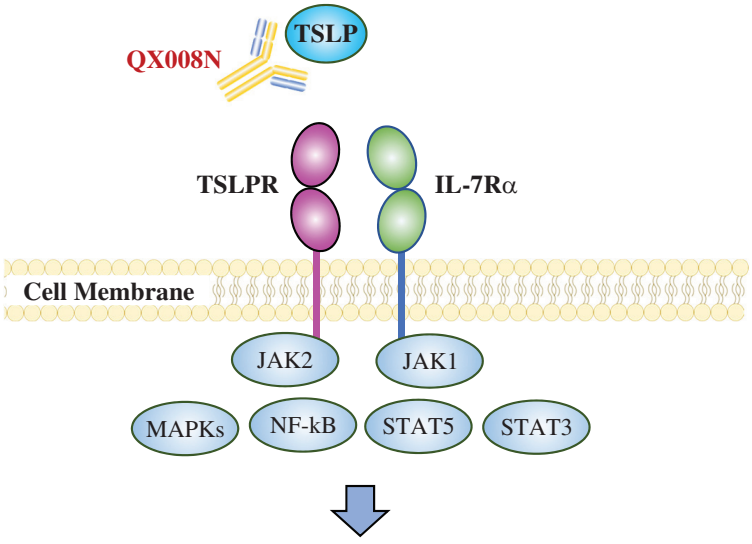
WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET QX006N SUCCESSFULLY.

QX008N

QX008N is a humanized IgG1 monoclonal antibody targeting thymic stromal lymphopoietin (TSLP). TSLP plays a critical role as an upstream cytokine mediating multiple inflammatory pathways. While the efficacy of non-TSLP targeting biologics have shown to be correlated to the levels of certain type 2 biomarkers, TSLP inhibitors can be a treatment for patients with low-level or no expression of type 2 biomarkers. We are developing QX008N for the treatment of asthma and moderate-to-severe COPD, including those with low-level or no type 2 inflammation biomarkers. We obtained IND approvals of QX008N for treatment of asthma and moderate-to-severe COPD from the NMPA in May 2022. We also obtained an IND approval of QX008N for treatment of severe asthma from the FDA in September 2022. We entered into a technology transfer agreement in January 2024 to grant Joincare Pharmaceutical Group Industry Co., Ltd. an exclusive license to develop, manufacture and commercialize QX008N in mainland China, Hong Kong and Macau. See "—Licenses, Rights and Obligations" below for details.

Mechanism of Action

The epithelial cell–derived cytokine TSLP is a pleiotropic cytokine that acts on multiple cell lineages, including dendritic cells, T cells, B cells, neutrophils, mast cells, eosinophils and innate lymphoid cells, affecting their maturation, survival and recruitment. TSLP initiates intracellular signaling by establishing a complex with its specific receptor, TSLP receptor (TSLPR), and IL-7Rα. The TSLP complex can transduce pro-inflammatory signals which promote the maturation and differentiation of DCs and naïve $CD4^+$ T cells into allergen-specific Th2 cells, and the secretion of IL-4, IL-5 and IL-13. TSLP has also been shown to enhance cytokine production from multiple types of innate immune cells and to promote the development and function of a subset of basophils. Finally, TSLP may have effects on both Th1 and Th17 cells, although likely to a much lesser extent than observed effects on Th2 cells. Given its position at the top of the inflammatory cascade, TSLP can exert broad influence over airway inflammation through its impact on multiple cell types and pathways. TSLP/TSLPR/IL-7Rα pathway has been implicated in the initiation and persistence of inflammatory responses in airway diseases. QX008N is designed to specifically bind to TSLP and block the binding of TSLP to its receptor TSLPR-IL-7Rα, thus inhibiting the activation of its signaling pathway for the treatment of allergic diseases, including asthma and COPD. The following diagram illustrates the mechanism of action of QX008N.



Source: the Company

Licenses, Rights and Obligations

We entered into a technology transfer agreement with Joincare Pharmaceutical Group Industry Co., Ltd. ("Joincare") in January 2024 (the "QX008N Agreement"), to grant Joincare an exclusive license of the know-how and patents controlled by us to develop, manufacture and commercialize QX008N in mainland China, Hong Kong and Macau. For the avoidance of doubt, we retain the exclusive rights to develop, manufacture and commercialize QX008N outside the licensed territory.

Pursuant to the QX008N Agreement, Joincare will be responsible for the clinical development (including certain preclinical studies required for BLA approval), regulatory activities, manufacturing and commercialization of QX008N in the licensed territory at its own costs and expenses (other than a part of the Phase Ib clinical trial in China that we have already initiated). Joincare will be the MAH of QX008N in the licensed territory, once QX008N is approved.

Pursuant to the QX008N Agreement, we shall be responsible for the supplemental study required for the Phase Ia clinical trial of QX008N in China and supplemental preclinical studies, if any. We shall also provide Joincare with our existing sample products of QX008N and relevant placebo for the clinical development of QX008N. If additional QX008N sample products and placebo are required for the clinical development of QX008N, we may manufacture and provide such sample and/or placebo to Joincare at cost plus a reasonable profit margin. In addition, we shall transfer to Joincare relevant manufacturing process know-how.

Under the QX008N Agreement, we are entitled to receive (i) two non-refundable upfront payments; (ii) payments upon achievement of certain development and regulatory approval milestones with respect to QX008N's first approved indication; (iii) payment(s) upon subsequent marketing approvals for up to two indication expansions of QX008N; (iv) payment(s) upon reaching certain sales targets; and (v) tiered royalties on the net sales of QX008N in the licensed territory. As of the Latest Practicable Date, we had received the first upfront payment.

Pursuant to the QX008N Agreement, we shall exclusively own all intellectual property that we developed, owned or controlled prior to entering into the QX008N Agreement and any intellectual property solely invented or developed by or on behalf of us after entering into the QX008N Agreement. Joincare is licensed to use the patents and know-how of QX008N solely for the purpose of developing, manufacturing and commercializing QX008N in the licensed territory. For any patents we obtained in the process of commercializing QX008N outside the licensed territory, we shall grant exclusive license of such patents to Joincare for its use within the licensed territory at no extra cost.

Asthma

We are developing QX008N for the treatment of moderate-to-severe asthma. We entered into a technology transfer agreement in January 2024 to grant Joincare Pharmaceutical Group Industry Co., Ltd. an exclusive license to develop, manufacture and commercialize QX008N in mainland China, Hong Kong and Macau. See "—Licenses, Rights and Obligations" above for details. We commenced a Phase Ib clinical trial of QX008N for the treatment of moderate-to-severe asthma in China in August 2023. In addition to QX008N, to address the unmet medical needs of a broad asthma patient population, we are also developing (i) QX005N, an anti-IL-4Rα antibody, as an alternative drug candidate aiming to reach a major portion of asthma patient population and (ii) QX007N, an anti-IL-33 antibody, as another alternative drug candidate for asthma patients. See "—Our Core Products—QX005N—Asthma" and "—Our Other Product Candidates—QX007N—Asthma" for details.

Market Opportunity and Competition

Biologic drugs and candidates for asthma in China primarily include IgE inhibitors, IL-5 inhibitors, IL-4Rα inhibitors and TSLP inhibitors. While current antibodies targeting IL-5/IL-5R, IL-4R and IgE are shown to reduce exacerbations and improve symptoms and quality of life in patients with asthma, the efficacy of these biologic treatment has shown to be correlated to the levels of certain type 2 biomarkers, such as blood eosinophil counts and IgE. According to Frost & Sullivan, approximately 50% of patients with severe asthma are estimated to have low-level or no expression of type 2 biomarkers and classified as having type 2-low or non-type 2 allergic diseases. For patients without the elevation of those biomarkers, there continue to be important and unmet medical needs. As TSLP is at the top of multiple inflammatory cascades and involved in over-reactive immune response in multiple allergic disorders, TSLP inhibitors can be a treatment for patients with low-level or no expression of type 2 biomarkers. Based on published clinical data, asthma patients receiving anti-TSLP antibody treatment of experienced significantly fewer exacerbations irrespective of their type 2 biomarker status. Thus, the development of TSLP-targeting biologic treatment may be a promising strategy for addressing the clinical needs of patients with type 2-low allergic diseases. As of the Latest Practicable Date, no TSLP-targeting biologics had been approved in China and there were ten anti-TSLP candidates in the clinical stage in China. See "—Our Core Products—QX005N—Asthma—Market Opportunity and Competition" above for details of the approved biologic drug and biologic drug candidates in the clinical stage in China as of the Latest Practicable Date.

Our Advantages

We believe our QX008N has the following potential advantages in comparison with the approved drugs and drug candidates indicated for asthma:

- *Key target with great potential.* Treatment of asthma is modified in a continuous cycle of assessment, treatment, adjustment and review response. Growing incidence of asthma and chronic disorders are expected to further drive the growth of the asthma treatment market. According to Frost & Sullivan, approximately 50% of patients with severe asthma are estimated to have low-level or no expression of type 2 biomarkers and classified as having type 2-low or non-type 2 allergic diseases. QX008N, as a TSLP-targeting biologic drug candidate, can be a promising candidate to address the clinical needs of such patients. In addition, the prevalence of asthma-COPD overlap (ACO) accounted for approximately 26.5% of the asthma patient population, according to Frost & Sullivan. As QX008N is designed for the treatment of both asthma and COPD, we expect QX008N to address the clinical needs of ACO patients.

- *Promising preclinical efficacy profile*. Based on our preclinical studies, QX008N has high affinity and a potency superior to an internally prepared analog of tezepelumab, the only FDA-approved TSLP targeting biologic drug.

- *Good safety profile*. QX008N exhibited a good safety profile in our Phase Ia clinical trial and in our preclinical studies where no significant systemic toxic reaction was observed. The NOAEL observed in our preclinical studies was 300 mg/kg, which was higher than its proposed clinical maximum dose, thus leaving a wide safety window. We believe that such feature will enable QX008N to bring clinical benefits to patients without severe side effects.

- *Promising accessibility*. As of the Latest Practicable Date, tezepelumab was the only FDA-approved TSLP-targeting biologic drug and no TSLP-targeting biologics had been approved in China. The high costs of tezepelumab as well as other biologics may in turn limit patients' access. We aim to make QX008N more accessible to patients in China, especially those with low-level or no expression of type-2 biomarkers.

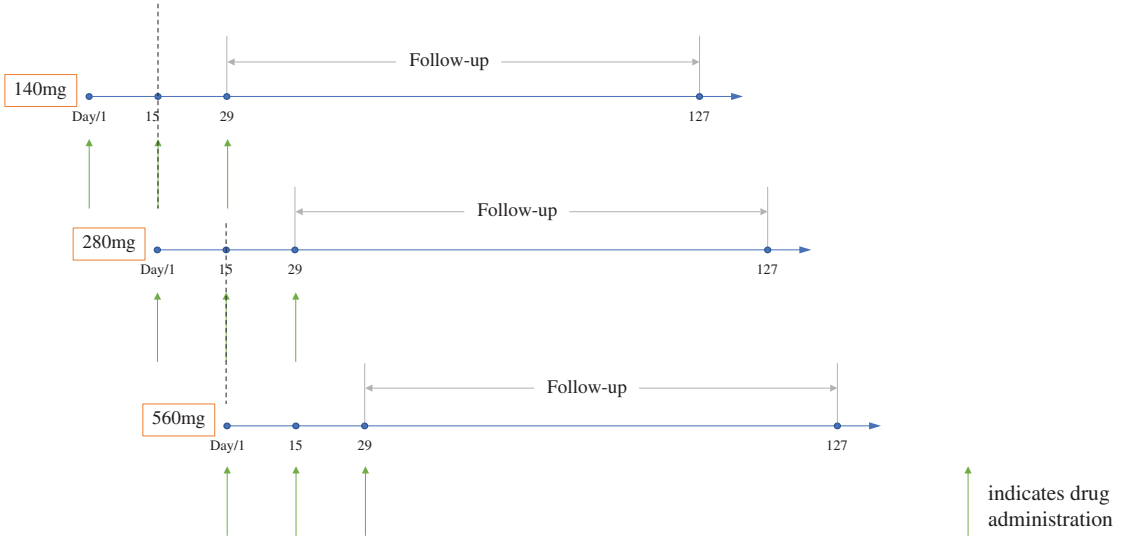
Summary of Clinical Trials

We commenced the Phase Ia clinical trial of QX008N in healthy subjects in China in August 2022 and completed such trial in July 2023. We commenced a Phase Ib clinical trial of QX008N in adult patients with moderate-to-severe asthma in China in August 2023. Pursuant to the QX008N Agreement, Joincare will continue with the remainder of the Phase Ib clinical trial.

Ongoing Phase Ib Clinical Trial

We have designed the Phase Ib clinical trial in China to be a multi-center, randomized, double-blind, placebo-controlled and multiple-ascending-dose clinical study to evaluate the efficacy, safety, tolerability, immunogenicity and PK profile of QX008N in adult patients with moderate-to-severe asthma. In January 2024, we entered into a technology transfer agreement with Joincare, pursuant to which, among other things, Joincare will conduct the remainder of the Phase Ib clinical trial and subsequent trials. The design of the Phase Ib clinical trial will therefore be subject to any modifications that Joincare may choose to pursue.

Trial design: The primary objective of this trial is to evaluate the safety and tolerability of multiple subcutaneous injections of QX008N in adult patients with moderate-to-severe asthma. The secondary objectives of this trial are to evaluate the efficacy, PK and immunogenicity of multiple subcutaneous injections of QX008N in adult patients with moderate-to-severe asthma, and to determine the recommended dose for a Phase II clinical trial. We planned to enroll a total of 30 patients, who would be assigned to 3 groups with 10 patients in each group (8 receiving QX008N and 2 receiving placebo). Each group would receive three doses of either QX008N or placebo at their designated dose level (140 mg, 280 mg and 560 mg, respectively), to be administered on day 1, day 15 and day 29, followed by safety follow-up until day 127. The trial would proceed from one dose level to the next only if the safety evaluation on the previous dose level group on day 15 has been completed. In the event where termination may be warranted, the sponsor and investigator would determine whether to terminate the trial or resume the trial with the median level of the previous and current dose levels. The chart below summarizes the design of this trial.



Trial status: As of the Latest Practicable Date, we had enrolled seven subjects for this clinical trial. Joincare will continue with the remainder of the trial pursuant to the QX008N Agreement.

Phase Ia Clinical Trial

The Phase Ia clinical trial in China was a single-center, randomized, double-blind, placebo-controlled, single-dose escalation clinical study to evaluate the safety, tolerability, PK and immunogenicity of QX008N in healthy subjects.

Trial design: The primary endpoints include safety and tolerability of a single subcutaneous injection of QX008N in healthy subjects. The secondary endpoints include PK and immunogenicity of a single subcutaneous injection of QX008N and to recommend dosing regimens for the Phase II clinical trials. The exploratory endpoints include PD parameters of QX008N in these subjects. We planned to enroll 44 healthy subjects, who will be assigned to five groups with four participants in the first group (three receiving QX008N and one receiving placebo) and ten participants in each of the other four groups (eight receiving QX008N and two receiving placebo). The trial will start with the first group receiving a single subcutaneous injection of 42 mg and the subsequent four groups each receiving an increased single dose of 140 mg, 280 mg, 560 mg and 840 mg, respectively. Each participant will receive only one corresponding dose of QX008N (or placebo). The trial will proceed from one dose level to the next only if the safety of such previous dose level is confirmed after a two-week follow-up period. In the event where termination may be warranted, the sponsor and investigator will determine whether to terminate the trial or resume the trial with the median level of the previous and current dose levels.

Trial status: We commenced the Phase Ia clinical trial in August 2022 and completed such trial in July 2023. A total of 44 subjects were enrolled and 42 subjects completed the trial as two subjects withdrew from the study for personal reasons.

Safety results: In this trial, QX008N had a good safety profile in healthy subjects. 29 (82.9%) subjects in QX008N groups reported a total of 81 AEs and 8 (88.9%) subjects in the placebo groups reported 21 AEs, none of which led to a subject's withdrawal from the trial. One subject in the placebo groups reported an SAE (grade 3 AE as defined in the CTCAE version 5.0), which had no relationship with the drug. All other AEs observed in this trial were of Grade 1 (mild) or 2 (moderate) using CTCAE version 5.0. Most of the subjects fully recovered from the AEs at the end of the study. No significant difference was observed in the incidence of AEs between the QX008N groups and the control group.

PK: QX008N exhibited dose-proportional PK in healthy subjects over a dose range from 42 mg to 840 mg following single subcutaneous administration.

Immunogenicity: In this trial, four subjects (one in the 42 mg group, one in the 280 mg group and two in the 560 mg group) showed positive ADA responses on day 85, but no negative impact on QX008N's PK was observed.

Conclusion: In this trial, QX008N demonstrated a good safety profile and dose-proportional PK. Based on the trial results, we have initiated a Phase Ib clinical trial to further evaluate QX008N for the treatment of moderate-to-severe asthma in China.

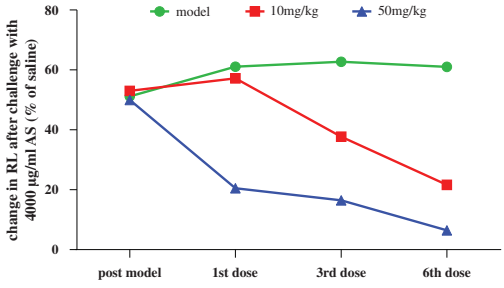
Summary of Preclinical Study Results

We conducted preclinical studies to evaluate the PD, PK and toxicity of QX008N and achieved favorable results to support clinical development. The major preclinical studies were summarized as below:

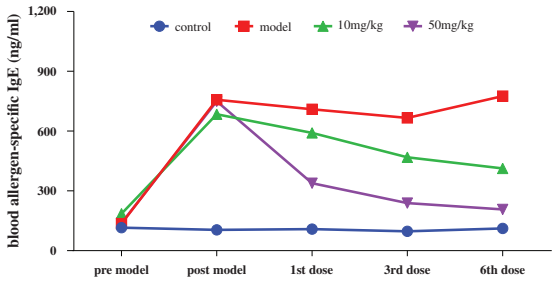
PD: In our *in vitro* studies, QX008N demonstrated a high affinity comparable to and a potency superior to an internally prepared tezepelumab analog.

In the *in vivo* studies, QX008N demonstrated a potency comparable to tezepelumab analog. We established an asthma model in cynomolgus monkeys, which is characterized by typical type 2 immune responses, specifically, elevated levels of serum IgE, TSLP and eosinophils. In such studies, QX008N significantly improved respiratory functions and reduced eosinophils, TSLP and IgE levels at the dose levels of 10 mg/kg and 50 mg/kg in a dose-dependent manner. The charts below illustrate the improvement of lung function and reduction of IgE level by QX008N *in vivo* at the dose levels of 10 mg/kg and 50 mg/kg in our preclinical studies.

Lung resistance (RL) change from baseline-dose profile



Blood allergen-specific IgE level-dose profile



Toxicity: Toxicological studies showed that QX008N had no obvious systemic toxicity. The MTD observed in a study of single administration (subcutaneous or intravenous) of QX008N in cynomolgus monkeys were at least 700 mg/kg. In the toxicity studies of repeated subcutaneous administrations of QX008N in cynomolgus monkeys once a week for 4 and 26 consecutive weeks, respectively, the NOAEL was 300 mg/kg and 100mg/kg, respectively. In another study of repeated intravenous administrations of QX008N in cynomolgus monkeys (once a week for 26 consecutive weeks), the NOAEL was 30mg/kg.

Material Communications and Next Steps

We obtained an IND approval of the Phase I, Phase II and Phase III clinical trials of QX008N for treatment of asthma from the NMPA in May 2022 and obtained an IND approval of the Phase I clinical trial of QX008N for treatment of severe asthma from the FDA in September 2022. We commenced a Phase Ia clinical trial in August 2022, which was completed in July 2023. We commenced a Phase Ib clinical trial for the treatment of moderate-to-severe asthma in August 2023, the remainder of which will be completed by Joincare. We plan to formulate a clinical development plan in the United States depending on the data from our Phase Ia and Phase Ib clinical trials in China. As of the Latest Practicable Date, we had not received any relevant regulatory agency's concerns or objections to our clinical development plans. No material adverse changes had occurred since we obtained the IND approval and up to the Latest Practicable Date.

Chronic Obstructive Pulmonary Disease

We are developing QX008N for the treatment of moderate-to-severe COPD. We entered into a technology transfer agreement in January 2024 to grant Joincare Pharmaceutical Group Industry Co., Ltd. an exclusive license to develop, manufacture and commercialize QX008N in mainland China, Hong Kong and Macau. See "—Licenses, Rights and Obligations" above for details. Similar to the pathogenesis of asthma, high levels of TSLP were also detected in bronchial mucosa of COPD patients, suggesting a potential for TSLP inhibitors to become a biologic treatment for COPD. In addition to QX008N, to address the unmet medical needs of a broad COPD patient population, we are also developing (i) QX005N, an anti-IL-4R antibody, as a drug candidate for patients with eosinophilic COPD; and (ii) QX007N, an anti-IL-33 antibody, as a drug candidate with particular promising efficacy for patients with prior smoking history. See "—Our Core Product—QX005N—Chronic Obstructive Pulmonary Disease" and "—Our Other Product Candidates—QX007N—Chronic Obstructive Pulmonary Disease" for details.

Market Opportunity and Competition

As of the Latest Practicable Date, no biologics had been approved for the treatment of COPD. As of the same date, there were seven biologic drug candidates for COPD in the clinical stage in China and none of such candidates targets TSLP. See "Industry Overview—Overview of the Allergic Disease Drug Market—Major Allergic Diseases—Chronic Obstructive Pulmonary Disease" for details.

Our Advantages

We believe QX008N, as an anti-TSLP antibody, can be a promising treatment for COPD patients with or without expression of type 2 biomarkers, given its promising preclinical efficacy profile, good safety profile and promising accessibility. See "—Asthma—Our Advantages" for more details.

Summary of Clinical Trial and Preclinical Studies

We completed a single-center, randomized, double-blind, placebo-controlled, single-dose escalation Phase Ia clinical trial evaluating the safety, tolerability, PK and anti-drug antibody of QX008N in healthy subjects in July 2023. See "—Asthma—Summary of Clinical Trials—Phase Ia Clinical Trial."

We conducted a series of preclinical studies on the PD, PK and toxicity of QX008N. See "—Asthma—Summary of Preclinical Study Results" for more details.

Material Communications and Next Steps

We obtained an IND approval of the Phase I, Phase II and Phase III clinical trials of QX008N for treatment of moderate-to-severe COPD from the NMPA in May 2022. As of the Latest Practicable Date, we had not received any relevant regulatory agency's concerns or objections to our clinical development plans. No material adverse changes had occurred since we obtained the IND approval and up to the Latest Practicable Date.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET QX008N SUCCESSFULLY.

Our Other Product Candidates

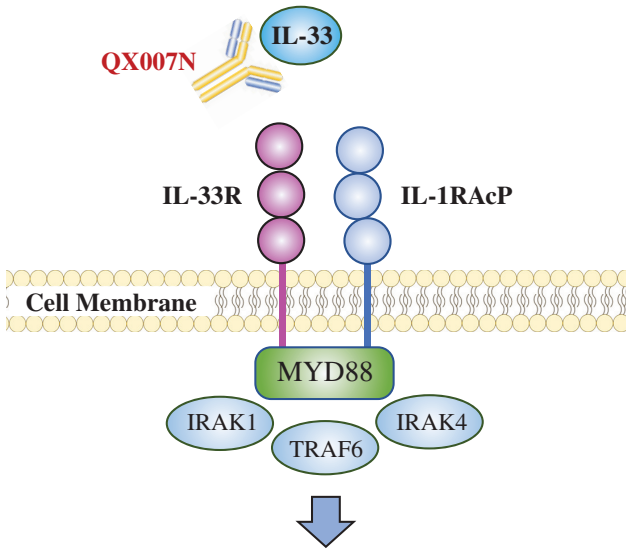
QX007N

QX007N is a humanized IgG1 monoclonal antibody targeting IL-33, one of the recently discovered members of the IL-1 family. We are developing QX007N for the treatment for moderate-to-severe COPD and asthma. As of the Latest Practicable Date, we had submitted the IND applications for QX007N for such indications. On February 19, 2024, we obtained an IND approval of the Phase I, Phase II and Phase III clinical trials of QX007N for the treatment of COPD from the NMPA.

Mechanism of Action

IL-33, an alarmin and pleotropic cytokine involved in type 2 immune responses, can cause the activation, migration and recruitment of immune cells and drive allergic airway disease pathogenesis by binding to its receptor, consisting of IL-33R and IL-1RAcP (IL-1 receptor accessory protein). Abundantly expressed in lung epithelial cells, IL-33 plays a critical role in both innate and adaptive immune responses in mucosal organs. In innate immune responses, IL-33 and group 2 innate lymphoid cells (ILC2s) provide an essential axis for rapid immune responses and tissue homeostasis. In adaptive immune responses, IL-33 interacts with dendritic cells, Th2 cells, follicular T cells and regulatory T cells, where IL-33 influences the development of chronic airway inflammation and tissue remodeling. Smoking is a key inducer of COPD and it not only activates IL-33 production by epithelial and endothelial cells, but also induces the expression of IL-33 in peripheral blood mononuclear cells. IL-33 is one of the inflammatory mediators involved in pathogenesis of COPD. QX007N, as a recombinant

humanized IgG1 monoclonal antibody, is designed to bind to IL-33 and block the interaction of IL-33 with its receptor, thus inhibiting inflammatory responses in COPD. The following diagram illustrates the mechanism of action of QX007N.



Source: the Company

Chronic Obstructive Pulmonary Disease

We are developing QX007N for the treatment of COPD. Studies have shown that smoking promotes an amplified IL-33 cytokine response and progression of COPD. We believe that QX007N, as an IL-33 inhibitor, has particular promising efficacy for patients with prior smoking history. We obtained an IND approval of the Phase I, Phase II and Phase III clinical trials of QX007N for the treatment of COPD from the NMPA in February 2024.

In addition to QX007N, to address the unmet medical needs of a broad COPD patient population, we have two other drug candidates in our COPD pipeline, namely: (i) QX005N, an anti-IL-4R antibody, as a drug candidate for patients with eosinophilic COPD; and (ii) QX008N, an anti-TSLP antibody, as a drug candidate for COPD patients, including those with low-level or no expression of type 2 inflammation biomarkers. See "—Our Core Product—QX005N—Chronic Obstructive Pulmonary Disease" and "—Our Other Key Product Candidates—QX008N—Chronic Obstructive Pulmonary Disease" for details.

Market Opportunity and Competition

As of the Latest Practicable Date, no biologics had been approved for treatment of COPD and there were seven biologic drug candidates for COPD in the clinical stage in China, two of which targets IL-33. See "Industry Overview—Overview of the Allergic Disease Drug Market—Major Allergic Diseases—Chronic Obstructive Pulmonary Disease" for details.

Our Advantages

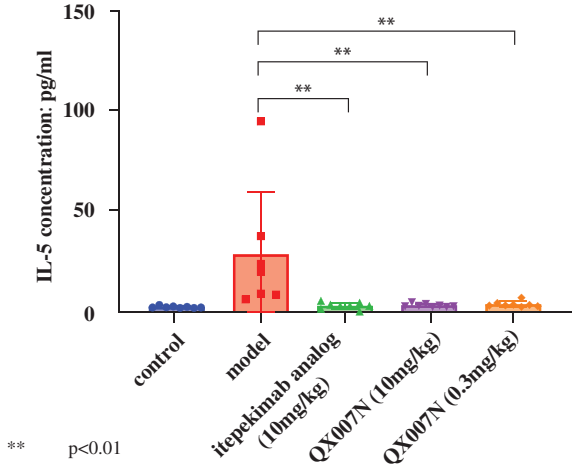
Itepekimab, one of the few IL-33 targeting biologic drug candidates for the treatment of COPD, have demonstrated in its Phase IIa clinical trial efficacy in improving lung functions of COPD patients with prior smoking history. Accordingly, we expect QX007N, as an IL-33 inhibitor, to be a drug candidate with promising efficacy for COPD patients, especially those with prior smoking history.

Summary of Preclinical Study Results

We have conducted a series of preclinical studies to assess the PD, PK and toxicity of QX007N. The major preclinical studies are summarized below:

PD: In our *in vivo* studies, QX007N significantly reduced human IL-33-induced inflammation in mice. In such studies, 56 mice (including eight in the model group, eight in each of the five QX007N dose groups and eight in the 10 mg/kg itepekimab analog group.) were administered with human IL-33 daily for seven consecutive days. The model group exhibited increased serum IL-5 content compared to the control group and the QX007N groups exhibited significant reduction of IL-5 concentration in mouse serum at the dose levels of 0.3 mg/kg, 1 mg/kg, 3 mg/kg, 5 mg/kg and 10 mg/kg. The chart below illustrates the PD profile of QX007N *in vivo* at dose levels of 0.3 mg/kg and 10 mg/kg in comparison with itepekimab analog at dose level of 10 mg/kg in our preclinical studies.

IL-5 level comparison between QX007N and itepekimab analog



** p<0.01

PK: In our studies of single subcutaneous or intravenous administration of QX007N in 24 cynomolgus monkeys (six in the 5 mg/kg intravenous administration group and six in each of the three subcutaneous administration dose groups), QX007N exhibited dose-proportional pharmacokinetics over a dose range of 0.5 mg/kg, 5 mg/kg and 50 mg/kg. The mean $T_{1/2}$ of QX007N ranged from 9.73 days to 12.3 days. The bioavailability after subcutaneous administration ranged from 81.1% to 99.2%.

Toxicity: Our toxicological studies showed that QX007N had no obvious systemic toxicity. The MTD observed in a toxicity study of single administration (subcutaneous or intravenous) of QX007N in cynomolgus monkeys were at least 750 mg/kg. In another study of repeated administrations (subcutaneous or intravenous) of QX007N in cynomolgus monkeys (once a week over 4 consecutive weeks), the NOAEL was 300 mg/kg.

Asthma

We are developing QX007N for the treatment of asthma. Similar to the pathogenesis of COPD, IL-33 is one of the inflammatory mediators involved in pathogenesis of asthma, suggesting a potential for IL-33 inhibitors to become a biologic treatment for asthma. In addition to QX007N, to address the unmet medical needs of a broad asthma patient population, we have two other drug candidates in our asthma pipeline, namely: (i) QX005N, an anti-IL-4Rα antibody, as an alternative drug candidate aiming to reach a major portion of asthma patient population; and (ii) QX008N, an anti-TSLP antibody, as a drug candidate for asthma patients, including those with low-level or no expression of type 2 inflammation biomarkers. See "—Our Core Product—QX005N—Asthma" and "—Our Other Key Product Candidates—QX008N—Asthma" for details.

As of the Latest Practicable Date, no biologics targeting IL-33 had been approved for the treatment of asthma in China and none of the biologic drug candidates in China targets IL-33. See "Industry Overview—Overview of the Allergic Disease Drug Market—Major Allergic Diseases—Asthma" for details.

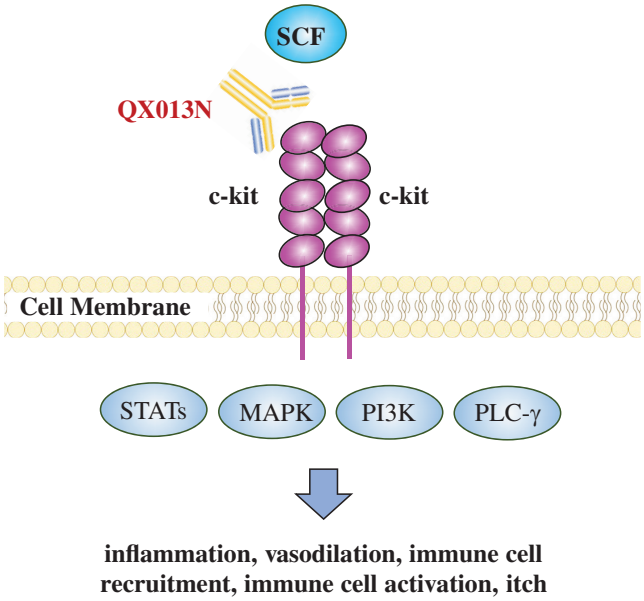
We conducted a series of preclinical studies on the PD, PK and toxicity of QX007N. See "—Chronic Obstructive Pulmonary Disease—Summary of Preclinical Study Results" for more details.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET QX007N SUCCESSFULLY.

QX013N

QX013N is a humanized IgG1 mAb targeting c-kit (a type III receptor tyrosine kinase) and indicated for CSU. In February 2024, we submitted an IND application to the NMPA for QX013N for the treatment of CSU, which was under formal review as of the Latest Practicable Date. For details of the pathogenesis and unmet clinical need of CSU, see "—Our Core Products—QX005N—Chronic Spontaneous Urticaria." QX013N is designed to bind to c-kit to

block the interaction between a stem cell growth factor (SCF) and c-kit, which activates the SCF/c-kit signal transduction pathway and causes the differentiation, maturation, survival, proliferation and degranulation of mast cells that lead to the release of histamine and other mediators. As urticaria is considered a disease driven mainly by mast cell degranulation, QX013N is designed to downregulate the downstream signaling and inhibit the development of CSU. The diagram below illustrates the mechanism of action of QX013N.



Source: the Company

Summary of Preclinical Study Results

As of the Latest Practicable Date, we had conducted a series of preclinical studies to characterize the PK, toxicity and PD of QX013N and assessed its potency in comparison to an internally prepared barzolvolimab analog. Barzolvolimab is another humanized anti-c-kit IgG1 monoclonal antibody at the Phase II clinical trial stage with positive topline Phase II clinical trial results for patients with antihistamine–refractory CSU (characterized by uncontrolled symptoms of patients treated with antihistamines incombination with other standard therapies). QX013N demonstrated good and comparable potency to the barzolvolimab analog in terms of inhibition of SCF-c-kit–induced activities in our preclinical studies.

PK: QX013N exhibited nonlinear PK in cynomolgus monkeys over a dose range from 3 mg/kg to 30 mg/kg following a single subcutaneous administration. Systemic exposure (as measured by AUC) of QX013N increased in a greater-than-proportional manner with the increasing dose level.

Toxicity: QX013N did not show any obvious systemic toxicity in our preclinical toxicity studies. The MTD of QX013N in cynomolgus monkeys was 100 mg/kg through the subcutaneous injection. QX013N was repeatedly administered through subcutaneous injections in cynomolgus monkeys every two weeks for four consecutive weeks, with the NOAEL of 75 mg/kg.

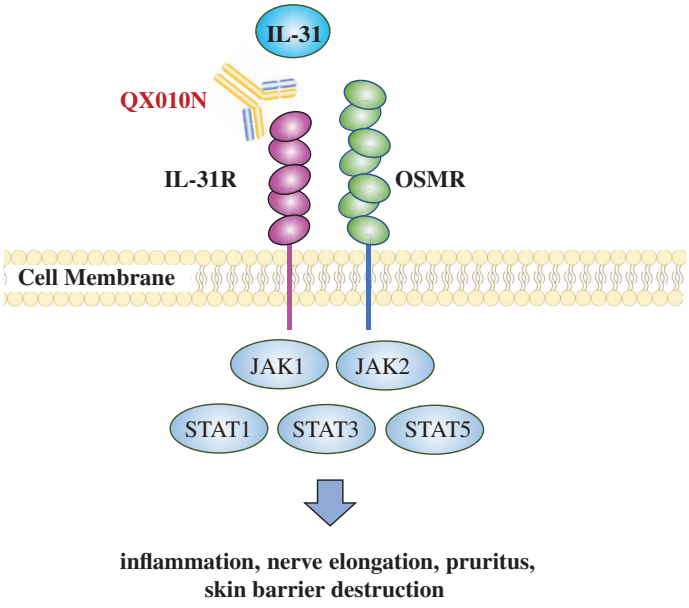
PD: Our *in vivo* study in an urticaria mouse model showed that QX013N (3 mg/kg, 10 mg/kg and 30 mg/kg) effectively reduced the leakage of Evan's Blue Concentration (a common selective dye marker for measuring microvascular leakage in animal models) in the ear tissue of the model, with an effective dose of 3 mg/kg and demonstrating a dose-dependent relationship within the dose range from 3 mg/kg to 30 mg/kg.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET QX013N SUCCESSFULLY.

QX010N

QX010N is a humanized IgG1 mAb targeting IL-31R and indicated for pruritus, which was in the preclinical stage as of the Latest Practicable Date. Pruritus, which means itchy skin, is an uncomfortable, irritating sensation that makes the patient want to scratch. The itch-scratch cycle is difficult to break and may lead to skin injury, infection and scarring. Severe or chronic pruritus could affect the patients' quality of life, interrupt their daily routine and sleep, or even cause mental illness such as anxiety or depression. Pruritus is the clinical manifestation of many diseases, which means it can be difficult to diagnose the underlying causes and there has been no effective long-term treatment strategy, indicating a huge market potential for this condition, according to Frost & Sullivan. Biologic drugs are a relatively new class of drugs under investigation for treating pruritus, which have not yet been recommended as a main treatment option by prevailing clinical guidelines. In addition, we may investigate QX010N for indication expansion to PN.

IL-31 is induced mainly by IL-4 and IL-33 activated $CD4^+$ T cells and plays an important role in the development of pruritus. By binding to its receptor, a heterodimer consisting of IL-31R and OSMR, IL-31 activates downstream JAK-STAT pathways that cause inflammation, nerve elongation, itch and skin barrier destruction. QX010N is designed to bind to IL-31R to block the interaction between IL-31 and IL-31R to downregulate the downstream signaling, thus inhibiting the development of pruritus. The diagram below illustrates the mechanism of action of QX010N.



Source: the Company

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET QX010N SUCCESSFULLY.

RESEARCH AND DEVELOPMENT

We are a clinical-stage biotech company exclusively focused on biologic therapies for autoimmune and allergic diseases, with a self-developed drug pipeline. We have built a broad pipeline that covers the four major disease areas in the field, including skin, rheumatic, respiratory and digestive diseases. We believe research and development is critical to our ability to grow into a biopharmaceutical company and remain competitive in the industry. We have developed all of our innovative biologic drug candidates in-house, with proprietary know-how across the entire process, and are dedicated to continuing to expand our innovative product pipeline. Our R&D also includes selected biosimilar product.

We conduct our R&D activities through an in-house team as well as engagement of external CROs, as is in line with industry practice. We have established an integrated R&D platform to support our drug development from discovery to clinical trial. We believe that our R&D activities have laid a solid foundation for the future regulatory approval, manufacturing and commercialization of our drug candidates. We incurred research and development expenses of RMB151.9 million, RMB257.2 million and RMB263.3 million in the years ended December 31, 2021 and 2022 and the nine months ended September 30, 2023, respectively. During the Track Record Period, our R&D expenses increased significantly, primarily as a result of the advancement and expansion of preclinical and clinical studies of our drug candidates. For details, see "Financial Information—Description of Certain Key Items of the Consolidated Statement of Profit or Loss and Other Comprehensive Income—Research and Development Expenses."

Our Rabbit Antibody Development Platform

Early development of therapeutic antibodies normally includes three stages: (i) antibody screening to get mAbs with high affinity and specificity to a specific target human antigen, (ii) antibody engineering of the screened antibodies to get humanized antibody leads with strong bioactivity and good physical/chemical and PK/PD properties, and (iii) pre-clinical *in vivo* studies including pharmacodynamic, toxicology, *etc.*, to determine an antibody molecule for further CMC development and clinical studies. At present, the majority of mAbs designed to target human antigens are murine mAbs, based on mice. However, in recent decades, there have been growing interest in the industry toward the development of rabbit mAbs as many studies have shown that the unique features of B-cell ontogeny and antibody repertoire make rabbits a valuable source for antibodies that have high affinity and specificity, which could potentially translate into strong bioactivity, and are easier to humanize, leading to lower risk of immunogenicity.

Our rabbit antibody discovery platform covers the development stages (i) and (ii) described above, and integrates nine technical steps as illustrated by the diagram below. It begins with immunizing rabbits with a target immunogen using our specific immunization strategy. With B-cell isolation and culture techniques, a wider range of antigen-specific B cells can be isolated and high titer of antibodies in culture can be reached, which permit high-throughput screening using functional assays to get rabbit mAbs with strong bioactivity in the early development stage. It significantly increases efficiency of antibody screening and the following humanization and antibody engineering of the selected rabbit antibodies.

Our platform not only facilitates the selection of rabbit mAbs with strong bioactivity, but also helps evaluate their viability to be further developed into commercial-grade biological drugs, aiming to avoid excessive modifications to reduce uncertainties in subsequent CMC process development, and assess immunogenicity as early as possible to reduce the risk of high immunogenicity during clinical development. In general, we can complete the screening and evaluation of the lead antibody in about one year and complete the humanization of the lead antibody and the initial druggability evaluation within three months. Moreover, we do not need additional time for affinity maturation due to the innate high affinity features of rabbit antibodies. The average time leading from cell line development to IND approval for our drug candidates is approximately 20 months.

Supported by the platform and a research team with extensive experience in rabbit mAb research and development, we are able to discover and develop new antibodies with novel targets. As of the Latest Practicable Date, we had developed all of our eight innovative mAb drug candidates through our rabbit antibody development platform, among which five had proceeded to clinical development stage (*i.e.*, QX002N, QX005N, QX004N, QX006N and QX008N). For details, see "—Our Drug Candidates" above. We engage qualified CROs for animal studies involved in the discovery and development of antibodies and require them to carry out such studies in strict compliance with our protocol and relevant laws and regulations regarding laboratory practice, including animal studies.

In-house R&D capabilities

Our in-house R&D team consisted of 122 members as of the Latest Practicable Date, including 20 for new drug discovery, 4 for technological development, 10 for translational medicine, 37 for clinical development, 6 for pharmaceutical affairs, 3 for quality management and 42 for CMC-related research and development. Our R&D team is led by senior management members with a proven track record in drug R&D, including Ms. Fang Min (our deputy general manager, who is primarily responsible for clinical development) and Dr. Li Jianwei (the chief operating officer and deputy general manager of our Company and the general manager of Cellularforce, who is primarily responsible for CMC-related research and development), both of which have extensive experience in their respective field of work. See "Directors, Supervisors and Senior Management—Senior Management" for further details on their past experience. As of the Latest Practicable Date, approximately 60% of our R&D team members had a master's degree or above in biology/pharmacy or related field.

The development of our Core Products, QX002N and QX005N, involved core members from each function of our R&D team, such as Ms. Fang Min (head of clinical development), Mr. Kong Yong (director of new drug discovery), Mr. Chen Wei (director of antibody engineering), Mr. Chen Tao (director of pharmacology) and Mr. Qiao Huaiyao (senior director of CMC-related research and development), all of whom have strong academic background and professional experience for R&D of biologic drugs and joined our Group early on. In particular, 42, 66 and 85 employees in our R&D team participated in the development of QX002N in 2021 and 2022 and the nine months ended September 30, 2023, respectively. The development of QX002N incurred research and development expenses of RMB18.0 million, RMB49.5 million and RMB57.2 million in 2021 and 2022 and the nine months ended September 30, 2023, respectively, representing 11.9%, 19.3% and 21.7% of our total research and development expenses in the respective periods. 49, 83 and 109 employees in our R&D team participated in the development of QX005N in 2021 and 2022 and the nine months ended September 30, 2023, respectively. The development of QX005N incurred research and development expenses of RMB37.5 million, RMB66.2 million and RMB88.5 million in 2021 and 2022 and the nine months ended September 30, 2023, respectively, representing 24.7%, 25.7% and 33.6% of our total research and development expenses in the respective periods.

During the Track Record Period, we engaged one external individual consultant for the preclinical development of our drug candidates and another for the clinical development of our drug candidates. Both consultants are experts with extensive experience in their respective fields, *i.e.,* preclinical/clinical evaluation of innovative drugs, and have worked in various entities in the industries, including regulatory agencies, hospitals and/or pharmaceutical companies. We entered into a one-year consultancy agreement with our preclinical consultant and a two-year consultancy agreement with our clinical consultant. Pursuant to such agreements, the responsibilities of the external consultants primarily include assisting our preclinical/clinical team in formulating preclinical/clinical evaluation strategies, reviewing study designs, organizing preclinical/clinical expert communication and providing related personnel training. Under the consultancy agreements, we have the ownership and may fully and freely utilize or transfer to third parties within the scope of our business any intellectual property rights or other rights related to inventions or creations resulting from the performance of duties by the consultants or the direct or indirect use of our materials, technologies and business information during the period of engagement of the consultants. For the determination of consultancy fees, we took into account various factors, including the academic qualifications, professional experience and reputation of the consultants, their expected responsibilities and the market fee levels. In 2021 and 2022 and the nine months ended September 30, 2023, we have incurred consultancy fees of nil, RMB60,000 and RMB180,000, respectively, relating to our preclinical consultant and RMB144,000, RMB144,000 and RMB183,000, respectively, relating to our clinical consultant. To the best of our knowledge, neither of the two consultants have any past or present relationships with our Group, our shareholders, directors or senior management, or any of their respective associates, except in their capacity as external consultants.

Drug Discovery and Preclinical Development

Our drug discovery team is dedicated to the discovery of novel biologic drug candidates indicated for autoimmune and allergic diseases to address unmet clinical needs. Multiple departments, covering R&D, manufacturing and commercialization, participate early in our research and development process, ensuring the implementation of our differentiated strategy in target and indication selection and perform in-house market forecasts and financial analysis for the potential product. We aim to maintain our exclusive focus on autoimmune and allergic diseases, solidifying and expanding our comprehensive coverage of the four major disease areas, namely, skin diseases, rheumatic diseases, respiratory diseases and digestive diseases.

Our antibody discovery and development capabilities are driven by innovative technologies and guided by our expertise in immunology and structural biology. Leveraging our rabbit antibody development platform, our team can accurately screen for antigen-specific monoclonal antibodies, analyze their biological function and determine their viability to be further developed as therapeutics. Our team has developed a series of *in vitro* functional assay platforms to examine the biological function of selected antibodies and employs structure-based antibody engineering to ensure efficient antibody humanization. Our internal research and development team takes a leading role in the design and management of the research projects and outsources certain daily execution tasks, such as pharmacologic, pharmacokinetic and toxicologic evaluation, to multiple CROs. For details, see "—Collaboration with CROs" below.

Clinical Development

Our clinical development department is comprised of the following functional teams: (i) clinical operation team, which is responsible for the overall execution and supervision of clinical trials, (ii) medical team, which is responsible for providing medical support and addressing medical-related problems in clinical trials, (iii) quality control team, which is responsible for monitoring clinical trials and conducting self-inspection of our in-house R&D activities to ensure the authenticity, accuracy and completeness of our clinical trial data, (iv) pharmacovigilance (PV) team, which is responsible for ensuring our compliance with applicable regulations and standard operating procedures in drug safety management and clinical trials, and (v) statistics team, which is responsible for managing statistic issues during clinical studies. We have set up two clinical development centers in Beijing and Shanghai, managed by our clinical development department. As of the Latest Practicable Date, the Beijing center had 15 clinical staff members, while the Shanghai center had 11 clinical staff members. The primary functions of the development centers revolve around the management of clinical projects, providing support for medical inquiries and medical monitoring of clinical projects, and offering quality control assistance throughout the progression of clinical trials. The development centers in Beijing and Shanghai play a crucial role in ensuring the smooth operation and successful execution of our clinical research endeavors. Our clinical development department manages all stages of clinical trials, including clinical trial design, implementation and the collection and analysis of trial data. The department also cooperates with top-notch research institutions, such as well-known hospitals and CROs, and experienced experts (as leading PIs) for our clinical trials.

Chemistry, Manufacturing and Controls (CMC)

CMC is an integral part of our R&D and manufacturing process. Our CMC team performs vital roles including process development, scale-up and optimization. It provides technical support and analysis from druggability and production perspective during lead screening and selection, and works closely with our clinical development department to manage the supply of tested drugs during preclinical and clinical development. In addition, our CMC team is also responsible for the commercial-scale manufacturing of our drug candidates at our manufacturing facility in Taizhou, Jiangsu. To address anticipated increase in demand after future commercialization of our drug candidates and achieve competitive pricing, our CMC team also focuses on process scale-up and optimization, with an aim to increase the yield of our production line, ensure large-scale delivery of biologic drugs and drug candidates and reduce unit manufacturing costs. We have completed the manufacturing of multiple batches of drug substance and drug products. For further details, see "—Manufacturing" below.

Our CMC team is led by Dr. Li Jianwei, our chief operating officer and deputy general manager and the general manager of Cellularforce, who has over 14 years of experience in the R&D and manufacturing of recombinant protein drugs. Prior to joining us, Dr. Li worked in a number of global biopharmaceutical companies, where his responsibilities included process development and manufacturing of recombinant protein therapeutics.

Collaboration with CROs

In line with industry practice, we engage reputable CROs to support our preclinical and clinical studies from time to time. We proactively seek well-known CROs with good reputation in the industry, and evaluate self-recommendations from CROs offering services to us. We also select CROs through tenders for projects with high value and typically evaluate three to four CROs for a specific preclinical or clinical study. When selecting CROs, we consider a number of factors, including their past experience in biologics-related preclinical and clinical studies, their reputation and influence in the industry, their qualifications, professional experience of their employees and pricing. When determining service fees for CROs, we would discuss with the CRO and set the pricing based on various factors, including the academic and professional qualifications of its team, its experience in the industry and market fee levels. The involvement and roles of CROs in the development of novel biologic drug candidates are typically standardized and similar among different projects. The work scope of these third parties in the development of our drug candidates may vary, subject to our overall management and instructions. We engaged 28, 37 and 31 CROs in 2021, 2022 and the nine months ended September 30, 2023, respectively, all of which were Independent Third Parties to the best of our knowledge.

With respect to preclinical studies, CROs typically provide us with services related to preclinical PK, PD and toxicity evaluations, both *in vitro* and *in vivo*, of our drug candidates in accordance with our study design and under our supervision. We engaged CROs to conduct preclinical PK, PD and toxicity studies for both QX002N and QX005N. With respect to clinical studies, CROs typically provide us with a comprehensive suite of services required in complex clinical trials in accordance with our trial design and under our supervision. We engaged CROs for all completed and ongoing clinical trials of QX002N and QX005N. CROs generally assist us in the implementation and management of clinical trials, including day-to-day site management, trial preparation, source data verification, clinical safety management, data management and report preparation.

After we select a CRO to support our clinical trial, we will sign an agreement with the CRO, which sets out, among other things, the purpose and content of the clinical trial, responsibilities of each party, research procedures and the payment schedule. We have set in place various procedures regarding the management and monitoring of the performance by CROs. Our clinical development department is responsible for managing the overall clinical trial process and overseeing CROs' work. We hold regular progress meetings with CROs and provide specific directions to ensure the quality and efficiency of the trial execution. We conduct regular and *ad hoc* on-site audits of CROs, including interviewing their employees, reviewing documentations and records, such as relevant trial data and reports. We would keep formal records of such audits and follow up regarding issues discovered in the process. For clinical CROs, we would also refer to the NMPA compliance record of their previous clinical trials. Our CROs are also required to fully cooperate with our monitoring and inspection activities and rectify any issue identified during such inspections. If the CROs fail to conduct the studies in compliance with the relevant laws and regulations, we may be subject to liability. See "Risk Factors—Risks Relating to Our Operations—Our employees, CROs, collaboration

partners and others with whom we deal may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, which could harm our reputation and subject us to penalties and significant expenses that have a material adverse effect on our business, financial condition and results of operations" for further details. Under the agreements, we own all intellectual property and trial results and the CROs must maintain strict confidentiality with respect to the information they acquire during clinical trials. There was no material non-compliance incidence during our cooperation with CROs and we did not have any material disputes or disagreements with the engaged CROs during the Track Record Period and up to the Latest Practicable Date.

On December 20, 2022, we entered into a five-year collaboration framework agreement (the "Tigermed Framework Agreement") with Hangzhou Tigermed Consulting Co., Ltd. ("Tigermed") for the future development of our drug candidates, including QX002N, QX005N and others, in China. Tigermed is one of the industry-leading CROs in China, whose business covers the development and registration of innovative pharmaceutical candidates. It is listed on the Shenzhen Stock Exchange (stock code: 300347) and the Stock Exchange (stock code: 03347). Pursuant to the Tigermed Framework Agreement, we will treat Tigermed as a preferred CRO service provider and Tigermed will set up a strategic service group responsible for future coordination. We and Tigermed will further enter into independent service contracts governing the development of specific drug candidates. As of the Latest Practicable Date, we had entered into service contracts with Tigermed with respect to the Phase III clinical trial of QX002N for AS and the Phase II clinical trials of QX005N for PN and CRSwNP. We also expect to enter into contracts with Tigermed with respect to relevant CRO services for future Phase III clinical trials of QX005N for AD, PN and CRSwNP, among others. The Tigermed Framework Agreement sets forth an overall service fee range agreed upon by both parties, which was determined based on a series of variables including the phase of the clinical trial, the number of trial sites/subjects involved and Tigermed's customary fee levels. We also took into account the market fee level, Tigermed's experience in the industry and our own budget when negotiating the fee range. The service fee for a specific development project will be set forth in the relevant service contract and within the determined fee range, unless the aforementioned variables (such as the number of trial sites/subjects) deviate significantly from contemplated scenarios, in which case the parties will negotiate separately for the service fee for such project. Service fees incurred pursuant to the Tigermed Framework Agreement shall be recorded as third-party contracting costs under the research and development expenses in our consolidated statements of profit or loss and other comprehensive income. We believe this framework agreement with Tigermed will enable us to leverage its extensive experience in clinical trial execution and help ensure smooth development and registration of our drug candidates.

REGULATORY AFFAIRS

Our regulatory affairs team is responsible for the regulatory approval process of our drug candidates from clinical research to commercialization stage, including assembling application dossiers for IND applications and BLAs, addressing inquiries from relevant regulatory authorities and monitoring ongoing R&D projects to ensure compliance with relevant laws and

regulations. Our regulatory team members are deeply familiar with regulatory processes of relevant governmental agencies, such as the NMPA, and had successfully obtained 18 IND approvals (17 from the NMPA and 1 from the FDA) for our drug candidates as of February 20, 2024. We believe our team's extensive experience in navigating the regulatory process will be critical for our commercial success.

MANUFACTURING

Manufacturing Facility

We are one of only a few Chinese biotech companies that are focused on autoimmune and allergic diseases and have an established commercial-scale in-house manufacturing capability, according to Frost & Sullivan. Cellularforce, our CMC-focused subsidiary, is equipped with a manufacturing facility established according to the cGMP standards of China, the United States and the EU (although not GMP-certified due to the termination of the certification mechanism by relevant government agencies in China since 2019). Our manufacturing facility is located at our headquarters in Taizhou, Jiangsu and occupies 57,977 sq.m. of land (the "Taizhou Manufacturing Facility"). In April 2021, we received a Drug Manufacturing Certificate from Jiangsu Medical Products Administration for the production of QX001S at Taizhou Manufacturing Facility.

We have a CMC team of more than 150 members at our Taizhou Manufacturing Facility, covering the full-cycle development of monoclonal antibodies, including cell-line development, process development, formulation development, analytical development, drug substance manufacturing, drug product manufacturing, quality control (QC) and quality assurance (QA). Our drug substance manufacturing site has four 2,000L single-use bioreactors and one downstream purification/production line with an annual manufacturing capacity of 40 batches of drug products (approximately 300 kg therapeutic antibodies). Our drug product manufacturing site has one vial fill-finish and packaging production line for 2 ml, 10 ml and 30 ml vials, with a manufacturing capacity of 18,000 vials/hour, and one prefilled syringe production line for 1 ml and 2 ml syringes, with a manufacturing capacity of 9,000 syringes/hour. We have manufactured more than 30 batches of drug substance, including seven batches of 2,000L of QX001S for scale-up research, Phase III clinical trial and BLA-required process validation, four batches of 2,000L of QX002N for Phase III clinical trial and three batches of 2,000L of QX005N for Phase II clinical trial, as well as other batches for various clinical trials. We have completed the manufacturing of more than 30 batches of drug products in vials (with 2,000 to 5,000 vials per batch) and more than 10 batches of drug products in prefilled syringes (with 3,000 to 30,000 syringes per batch) for various clinical trials and BLA-required process validation for QX001S drug products. With production of 15 batches in 2023, the utilization rate of our Taizhou Manufacturing Facility was 37.5%, including the manufacturing of our own drug candidates under development (11 batches, or 27.5% of our manufacturing capacity), the expected commercial production of QX001S (2 batches, or 5.0% of our manufacturing capacity) and CDMO services provided to Zhongmei Huadong (2 batches, or 5.0% of our manufacturing capacity) pursuant to relavant service contract. The anticipated commercial production of QX001S will be a small portion of our manufacturing activities and we do not expect it to have a material impact on the utilization of our manufacturing capacities.

To satisfy anticipated market demand for our products, assure stable production in a cost-effective measure and meet the requirements of regulatory authorities for quality control, we plan to continuously optimize our drug substance manufacturing process to improve production efficiency. We could achieve a competitive drug substance production yield of 5-9 g/L for different antibodies.

Additionally, we have successfully developed a new drug substance upstream process, which starts a production run with high cell-density and large volume of working cell bank, and therefore could significantly shorten the production time required for each batch, improve capacity utilization and lower unit manufacturing costs. Additionally, in order to ensure the stability of the supply chain and further reduce manufacturing costs, we have established strategic cooperations with domestic suppliers of cell culture media and disposables, which we expect to reduce related one-off costs significantly. We also plan to further expand our Taizhou Manufacturing Facility after we officially launch the commercial productions of our products.

While prioritizing internal R&D and commercialization demands, we plan to further enhance the utilization of our production capacity through retaining the manufacturing rights of drug candidates for which we established strategic collaborations. We will also continue to develop external CDMO services to diversify our source of revenue and better utilize our manufacturing capacity. Through Cellularforce, we intend to provide comprehensive CDMO services, including molecular design and evaluation, process development, analysis and quality management, registration application and commercial production of antibody drugs, to external clients, primarily Chinese biopharmaceutical companies. We entered into a service contract with Zhongmei Huadong in February 2023 as part of our strategic cooperation with it regarding CDMO services, pursuant to which Cellularforce will provide a series of development and manufacturing services to Zhongmei Huadong, covering cell line and cell banking services, formulation development and process development, scale-up and validation. Cellularforce will provide such services in accordance with the cGMP standards and further requirements or procedures set out by Zhongmei Huadong. See "Connected Transactions—(B) Continuing Connected Transactions subject to the Reporting, Annual Review and Announcement Requirements but Exempt from the Circular and Independent Shareholders' Approval Requirements—CDMO Services Framework Agreement" for further details. We do not expect CDMO services offered to external parties to affect the manufacturing of our own products because we have sufficient manufacturing capacity to accommodate the production plans of our own products. With the estimated utilization rate of our manufacturing facility for 2023 at approximately 40% (taking into account the manufacturing of our own drug candidates under development, the expected commercial production of QX001S and CDMO services to be provided to Zhongmei Huadong pursuant to relevant service contract), we are able to provide CDMO services to external parties as a measure to improve the utilization rate of our spare manufacturing capacity on the premise of ensuring the production plans of our own products. We have built an efficient project management system to allocate our manufacturing capacity and review/prioritize our manufacturing plans monthly.

Quality Management

We have established QA and QC teams to oversee the development, manufacturing, and commercialization quality systems of our drug candidates. Our QA team ensures that our products and procedures meet regulatory standards and guidelines, while our QC team implements comprehensive testing and analysis to ensure that our materials and products meet the preset quality standards and the relevant testing methods are stable and reliable.

We have established an internal quality management system that covers the entire lifecycle of our drug candidates in accordance with cGMP standards of the NMPA, FDA and EMA. We continually review and update our quality management system through ongoing monitoring of our laboratory control system, production system, materials system, facilities and equipment system and packaging and labeling system to ensure compliance with regulatory requirements. We utilize advanced information management systems such as the Warehouse Management System (WMS) and Document Management System (DMS) to implement dynamic control over materials and products throughout the entire process, ensuring reliable and traceable data.

Our QC function comprises seven components: physical and chemical analysis, instrumental analysis, materials analysis, biochemical analysis, microbiological analysis, environmental monitoring and cGMP laboratory operations. Cellularforce has an industry-standard Laboratory Information Management System and a comprehensive analysis system covering the lifecycle of our drug candidates, which has supported multiple batch release testing, method verification and audit inspections. Our large molecule drug quality control platform is in compliance with the requirements of both the FDA and the NMPA for the production of biological drugs and drug candidates at the clinical and commercial stages. However, additional clinical trials and/or regulatory approval would be required before any manufactured products could be sold in overseas markets, including the U.S. We conduct quality testing on materials in accordance with the drug quality system principles outlined in the Q10 Guideline issued by the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) and strictly follow cGMP requirements for the release testing and stability studies of drug substance and drug products.

COMMERCIALIZATION

We currently do not have any products approved yet. However, we are in the process of formulating our commercialization plans in anticipation of multiple potential product launches within the next few years. Leveraging our management team's accumulated knowledge of and extensive experience in the biopharmaceutical industry in China, especially in the field of autoimmune and allergic diseases, we expect to develop our commercialization strategies for each close-to-market drug candidate reflecting its market positioning, taking into consideration of key factors such as pricing, dose regimen, economic, social and demographic characteristics of patients, market access and reimbursement policies.

Based on the indication coverage of our product pipeline and the current development status, we have adopted a practical commercialization model, first cooperating with established pharmaceutical companies on the commercialization of our future drugs for diseases with patients located in vast, geographically dispersed areas, and then establishing a relatively small, indication-specialized in-house commercialization team.

External Partnerships

We are seeking partnerships with well-known companies in the pharmaceutical industry that can offer access to established distribution channels, recognized branding, an experienced sales force and longstanding connections with target physicians and hospitals. When selecting commercialization partners, we will also consider their expertise in the relevant therapeutic area and their regulatory know-how.

The patients of autoimmune and allergic diseases are scattered geographically and many of them are of moderate income. According to Frost & Sullivan, a significant proportion of autoimmune and allergic disease patients (*e.g.,* Ps patients) in China initially receive treatment in local hospitals, so an extensive sales network providing robust coverage of local sales channels is essential. However, as we are at an early stage of preparation for future commercialization of our drug candidates, building a large commercialization team would be time-consuming and expensive, which would increase our commercial risk and distract us from our R&D efforts. To address this conundrum, we choose to cooperate with well-known pharmaceutical companies to promote the commercialization of our drugs in a cost-effective manner. In August 2020, we entered into a strategic cooperation agreement with Zhongmei Huadong, a subsidiary of Huadong Medicine, with regard to the joint development and exclusive commercialization of QX001S in mainland China. See "—Collaboration with Zhongmei Huadong" for further details on the key terms of our agreement. Huadong Medicine has established and comprehensive commercialization capabilities, with a sales team of more than 7,000 members experienced in the management of chronic diseases, such as diabetes and autoimmune diseases, an area it has focused on for over 30 years. According to Frost & Sullivan, Huadong Medicine has top-tier commercialization capabilities for autoimmune drugs in China, covering over 3,000, or more than 90% of all, Grade IIIA hospitals in China and over 15,500 hospitals of Grade II and below. We believe this collaboration with Huadong Medicine will enable us to leverage its nationwide sales and marketing network targeting the autoimmune and allergic disease field as well as its extensive experience in chronic disease management to ensure effective and efficient commercialization of QX001S.

We will continue to explore our commercialization partnerships with recognized pharmaceutical companies once we develop and start commercialization of more approved drugs and for additional indications. In addition, we also plan to seek cooperation opportunities, which include, but are not limited to, co-promotion and product out-licensing with global and domestic industry players, to commercialize subsequent pipeline products in other countries outside China.

In-house Commercialization Capability

In the future, leveraging our accumulated knowledge of autoimmune and allergic diseases and China's biopharmaceutical market, we also plan to build a relatively small, indication-specialized in-house commercialization team with medical and scientific background. The in-house team would be responsible for the commercialization of a few selected drug candidates and indications, beginning with those for which the patient population is relatively small and the clinical centers are relatively concentrated and therefore do not require a huge marketing network covering expansive geographic areas. We believe an internal commercialization team will be sufficient for patient management and effective market coverage for such indications. In addition, biological therapies have limited awareness in such specialized indications and more customer education is needed before marketing our biologic drugs. We believe we are well-positioned to provide such education given our deep knowledge in the relevant diseases and their respective biological therapies.

Our commercialization team will market our future approved biologic drug candidates to physicians and hospitals using a physician-targeted, academic marketing model, focusing on promoting the clinical benefits and accessibility of our products. We will also focus on long-term patient management. For example, we plan to host medical lectures or seminars for patients to promote their awareness of autoimmune diseases and allergic diseases, as means to increase the rate of diagnosis and treatment, through patient advocacy. In addition, we intend to track and follow the treatment and improvement of patients using our drugs, and procure potential patients through the referrals and word of mouth.

COLLABORATION WITH ZHONGMEI HUADONG

QX001S Framework Agreement

On August 14, 2020, we entered into a collaboration agreement (as supplemented on December 7, 2023, the "QX001S Framework Agreement," and together with the QX001S Production Quality Agreement and the QX001S Supply Agreement (as defined below), the "QX001S Agreements") with Zhongmei Huadong, a subsidiary of Huadong Medicine, with respect to the joint development and exclusive commercialization of QX001S in China. As of the Latest Practicable Date, Zhongmei Huadong and Cellularforce had also entered into the QX001S Production Quality Agreement and the QX001S Supply Agreement for the Product Supply (as defined below) as individual agreements under the QX001S Framework Agreement based on the principles provided in the QX001S Framework Agreement. During our ordinary course of business, we became acquainted with China Grand through its business development department. We then became acquainted with Zhongmei Huadong through introduction by China Grand. China Grand holds approximately 41.67% interest in Huadong Medicine and is its controlling shareholder. Huadong Medicine is a leading PRC pharmaceutical company listed on the Shenzhen Stock Exchange, whose business covers the whole pharmaceutical industrial chain, integrating R&D, manufacturing and sales of medicine. Zhongmei Huadong is one of our [**REDACTED**] Investors and a wholly owned subsidiary of Huadong Medicine. See "Connected Transactions—(A) Continuing Connected Transactions Fully Exempt from the Reporting, Annual Review, Announcement, Circular and Independent Shareholders' Approval Requirements—QX001S Framework Agreement" for details. This collaboration reflected the

parties' mutual interest in the commercialization of new drug candidates targeting autoimmune and allergic diseases in China. We believe this collaboration with Huadong Medicine will enable us to leverage its market access, nationwide sales and marketing network targeting the autoimmune and allergic disease field as well as its extensive experience in chronic disease management, which will be crucial to ensure rapid commercialization of QX001S.

The respective contributions and responsibilities of our Company, Zhongmei Huadong and Jiangsu Cellularforce Biopharma Co., Ltd. ("Cellularforce"), our CMC-focused subsidiary, in China under the QX001S Framework Agreement are summarized as follows:

Contributions and responsibilities		Commencement and completion of preclinical and clinical trials	Responsible party	Party bearing related expenses	Whether related expenses are deductible from pre-tax profit
Upfront payment and milestone payment		–	Zhongmei Huadong	Zhongmei Huadong, who paid the upfront payment and milestone payment on August 28, 2020 and July 16, 2021, respectively	Non-deductible
R&D	Preclinical	October 2016-May 2017	Our Company	Our Company	Non-deductible
	Phase I	November 2018-May 2020	Our Company	Our Company	Non-deductible
	Phase III[(1)]	June 2021-June 2023 (for Ps treatment)	Joint development committee (the "JDC")	Zhongmei Huadong	Non-deductible
Manufacturing	Sample production for clinical trials and process optimization	–	Cellularforce	Our Company	Non-deductible
	Commercial production and quality control	–	Cellularforce	Zhongmei Huadong	Deductible
Regulatory communication and registration	Preclinical	–	Our Company	Our Company	Non-deductible
	Phase I	–	Our Company	Our Company	Non-deductible
	Phase III and post clinical trials	–	JDC	Zhongmei Huadong	Non-deductible
Commercialization (plan and decision)		–	Joint sales committee (the "JSC")	N/A	N/A
Sales and marketing		–	Zhongmei Huadong	Zhongmei Huadong	Deductible

Note:

(1) A Phase III clinical trial of QX001S for Ps was commenced after completion of the Phase I clinical trial as Phase II clinical trials are not required for biosimilars such as QX001S.

We consider all costs and expenses incurred for commercialization of QX001S deductible, which is reflected in the deductible items on the table above. Particularly, it was understood by the parties that the upfront payment and the milestone payment made by Zhongmei Huadong are to recover part of our development expenses incurred before the joint development. During the joint development, we will be responsible for the CMC expenses while Zhongmei Huadong bears the costs associated with the Phase III clinical trial, which allows both parties to share the development expenses. It is also consistent with our profit sharing arrangement as the parties will share profit after deduction of the relevant commercialization expenses incurred for QX001S.

Key terms of the QX001S Framework Agreement are summarized as follows:

Scope of Collaboration

The parties agree to conduct joint development and exclusive commercialization of QX001S for the diagnosis, prevention and treatment of human diseases, including but not limited to, psoriasis, active psoriatic arthritis, Crohn's disease and ulcerative colitis, in China.

We agree to grant Zhongmei Huadong joint clinical development, manufacturing and exclusive commercialization rights of QX001S in China, which shall not be sub-licensed to a third party without written approval from us. Cellularforce shall be solely responsible for the commercial production of QX001S. We retain the full development and commercialization rights of QX001S outside China.

Term

The QX001S Framework Agreement has a term of 15 years commencing from August 14, 2020 and ending on August 13, 2035, which can be extended for a further term of five years unless terminated earlier in accordance with the terms of the QX001S Framework Agreement. It may be terminated by mutual agreement of the parties or other triggering events, such as one party's uncured material breach, bankruptcy, liquidation or receivership, as stipulated in the QX001S Framework Agreement.

Development Costs

Zhongmei Huadong shall make an upfront payment of RMB30 million to us within ten days upon the execution of the QX001S Framework Agreement. Zhongmei Huadong shall also make a milestone payment of RMB20 million to us within ten days after we complete the sample production of QX001S for a Phase III clinical trial and have, upon a consultation with the CDE, obtained consent to proceed with such trial. Pursuant to the QX001S Framework Agreement, both the upfront payment and the milestone payment are non-refundable, and Zhongmei Huadong paid us the upfront payment and the milestone payment on August 28, 2020 and July 16, 2021, respectively, totaling RMB50 million. The upfront payment and the milestone payment under the QX001S Framework Agreement were determined after arm's-length negotiations between our Group and Zhongmei Huadong, having taken into account various factors, including but not limited to the expenses incurred and to be incurred for the development of QX001S, expected prospects of the development and commercialization of QX001S in the PRC, rights and obligations of both parties under the QX001S Framework Agreement and the reasons and benefits of the transactions contemplated under the QX001S Framework Agreement. In particular, during the Track Record Period, for supporting the development of QX001S, the Group incurred total expenses of approximately RMB31.0 million, RMB32.3 million and RMB13.8 million in 2021, 2022 and the nine months ended September 30, 2023, respectively. It was understood by the parties that the upfront payment and the milestone payment are to recover part of these development expenses incurred before the completion of production of sample drugs for the Phase III clinical trial of QX001S, and our Directors are of the view that the upfront payment and the milestone payment in a total of RMB50 million under the QX001S Framework Agreement are fair and reasonable.

In addition, during the parties' joint development, Zhongmei Huadong shall be responsible for any expenses related to the clinical trials and regulatory communication and registration for QX001S; we shall be responsible for expenses related to the sample production and process development and optimization prior to the commercialization of QX001S.

Joint Clinical Development

The parties agree to establish a JDC to manage the joint clinical development of QX001S, which shall be responsible for overseeing the development, clinical trials and registrational matters of QX001S before its commercial launch, within which, the JDC's detailed authorities include (i) determining when a development project shall be carried out; (ii) reviewing and approving modifications of development plans; (iii) monitoring and updating the implementation progress of development plans; (iv) discussing and making decisions on the application, maintenance and protection of intellectual property rights; and (v) any other matters that either us or Zhongmei Huadong considers necessary for discussion. The JDC shall contain six representatives, including three representatives from each of us and Zhongmei Huadong, who shall have comprehensive experience and knowledge in drug development and work experience of at least five years in the medicine development industry. We and Zhongmei Huadong each shall have one vote (*i.e.*, collectively one vote for the three representatives from us and the three representatives from Zhongmei Huadong, respectively) when making decisions within the JDC's responsibility scope. Any decisions made by the JDC must be subject to its unanimous consent, and when such consent is not reached, the relevant issue shall be submitted to the senior management of both us and Zhongmei Huadong for consideration. If consent is still not achieved upon review by the senior management, an independent third party agency may be engaged to resolve such dispute.

In addition to the aforementioned development costs that each party is responsible for, we shall be responsible for completing the relevant ongoing preclinical studies and the Phase I clinical trial of QX001S for the treatment of Ps before the date of execution of the QX001S Framework Agreement as well as conducting any subsequent supplemental preclinical and clinical studies that the NMPA may require prior to the Phase III clinical trial for this indication at our cost.

The parties agree to jointly register the Phase III clinical trial of QX001S with the relevant regulatory authorities, with us being the clinical trial sponsor.

Product Supply

During the term of the QX001S Framework Agreement, we and Cellularforce will exclusively manufacture and supply QX001S to Zhongmei Huadong in the PRC (the "Product Supply") and relevant quality control. Except when Cellularforce is unable to meet the manufacturing demand, Zhongmei Huadong cannot engage other manufacturers. Cellularforce shall supply QX001S to Zhongmei Huadong at a unit supply price which will be determined by taking into account our actual costs expected to be incurred for manufacturing of QX001S and a cost-plus margin of 25% for such manufacturing (the "Markup"), and on a priority basis. When registering QX001S for commercial manufacturing, Zhongmei Huadong shall be the applicant for the drug registration certificate and Cellularforce shall be the drug manufacturer. For further details, see "—QX001S Supply Agreement" below.

Except for being the manufacturer of QX001S, Cellularforce does not have control over QX001S in any other material aspects, including its R&D development plan and execution, clinical trials, commercialization and intellectual property (including technical know-how).

Commercialization

The parties agree to establish a JSC for the commercialization of QX001S, which shall be responsible for overseeing the commercialization, manufacturing and marketing expense proposal of QX001S and other commercialization-related work, within which, the JSC's detailed authorities include (i) discussing and communicating on marketing and production plans; (ii) reviewing disputes arising from deductible expenses in the pre-tax profit sharing arrangement; and (iii) any other matters that either us or Zhongmei Huadong considers necessary for discussion. The JSC shall contain six representatives, including three representatives from each of us and Zhongmei Huadong, who shall have comprehensive experience and knowledge in drug production or commercialization as well as work experience of at least five years in the medicine production or commercialization industry. We and Zhongmei Huadong each shall have one vote (*i.e.*, collectively one vote for the three representatives from us and the three representatives from Zhongmei Huadong, respectively) when making decisions within the JSC's responsibility scope. Any decisions made by the JSC must be subject to its unanimous consent, and when such consent is not reached, the relevant issue shall be submitted to the senior management of both us and Zhongmei Huadong for consideration. If consent is still not achieved upon review by the senior management, Zhongmei Huadong shall have the right of spontaneous decision making, provided that both parties' mutual interests are protected.

- Commercialization in China

  Zhongmei Huadong shall be the MAH of QX001S for the treatment of Ps and for any potential expansion of indications in China to exclusively conduct marketing activities and commercialization of QX001S. Zhongmei Huadong shall make commercially reasonable efforts to promote such commercialization. We plan to establish a development and commercialization plan of QX001S in China with Zhongmei Huadong at a later stage in accordance with the QX001S Framework Agreement and depending on the regulatory approval progress of QX001S after completion of the Phase III clinical trial for Ps.

- Commercialization overseas

  We retain the exclusive commercialization rights of QX001S outside China and are entitled to use any intellectual property and other proprietary information associated with the QX001S Framework Agreement outside China. As of the Latest Practicable Date, we did not have any concrete plan for the overseas expansion of QX001S.

Termination

The QX001S Framework Agreement may be terminated by either party in writing if (i) a party fails to perform, refuses to perform or delays its performance overdue under the QX001S Framework Agreement, which constitutes a major breach, and the breaching party fails to remedy within 30 days after the no-fault party demands remedy in writing; (ii) a party undergoes restructuring, winding-up, takeover, dissolution, suspension or cancellation of operation permits or insolvency; (iii) the parties mutually agree to termination; (iv) the commercialization of QX001S is interrupted due to its infringement of a third party's legal rights or its intellectual property being challenged; and (v) a party undergoes a change of control.

We may terminate the QX001S Framework Agreement with 30-day written notice if (i) Zhongmei Huadong fails to make relevant payments to us pursuant to the QX001S Framework Agreement; (ii) Zhongmei Huadong's breach causes the projects to fail; or (iii) during the term of the QX001S Framework Agreement, Zhongmei Huadong develops other biologics targeting IL-12/IL-23p40 or provide clinical data and other trade secrets under the QX001S Framework Agreement to third parties.

In addition, Zhongmei Huadong may terminate the QX001S Framework Agreement with 30-day written notice if (i) the Phase III clinical trial of QX001S cannot be commenced before June 30, 2021 due to disapproval of the clinical trial or request of additional information from the NMPA; (ii) the Phase III clinical trial of QX001S fails to reach its primary endpoint and its clinical data is insufficient to support an application for marketing approval; (iii) the NMPA refuses the marketing approval application of QX001S; (iv) Cellularforce fails to provide Zhongmei Huadong with a sufficient quantity of drug samples qualified for clinical studies by June 30, 2021; or (v) we fail to transfer the MAH to Zhongmei Huadong pursuant to the QX001S Framework Agreement.

Dispute Resolution

In the event of a dispute due to execution of the QX001S Framework Agreement, the disputing party shall send a written notice to the other party and state the nature of the dispute. Within 14 days after receiving the dispute notice, the parties shall organize a meeting at a mutually agreed time and place to resolve the dispute. If the dispute is not resolved within 30 days of a mutually agreed time or within 60 days after first receiving the dispute notice, either party may file the dispute with a court with jurisdiction at the filing party's place of residence.

Profit Sharing

The parties agree that the accumulative pre-tax profit generated from sales of QX001S in China (as calculated pursuant to the QX001S Framework Agreement), after setting off the accumulative losses attributable to the commercialization of QX001S incurred in prior years (if any), shall be shared by the two parties on a 50:50 basis, provided that 50% of the Markup for the manufacturing of QX001S will be further deducted from our portion of the pre-tax profit receivable and attributed to Zhongmei Huadong's portion instead. Our Directors are of the view that the basis of the profit sharing ratio, having taken into account various factors, including but not limited to the expenses incurred and to be incurred for the development of QX001S borne by both parties, expected prospects of the development and commercialization of QX001S in the PRC, rights and obligations of both parties under the QX001S Framework Agreement and the reasons and benefits of the transactions contemplated under the QX001S Framework Agreement, is fair and reasonable. In addition, the parties are entitled to engage an independent certified public accountant mutually agreed upon to audit and verify items included in the calculation of the profit sharing, whose audit results shall be the final basis for determining the profit sharing within 30 days after the end of each calendar year. The fees incurred in engaging such third party auditor shall be included in the expenses to be set off from the accumulative pre-tax profit. Zhongmei Huadong shall pay us the corresponding profit share within 10 days after the audit results are issued.

Intellectual Property

We are the sole owner of all intellectual property rights (including trade secrets) associated with QX001S that were developed by us independently before the date of the QX001S Framework Agreement. We and Zhongmei Huadong shall be the co-owners of any intellectual property rights (including trade secrets) (the "Co-Developed IP rights") associated with QX001S that are developed since the date of the QX001S Framework Agreement. Any of the aforementioned intellectual property rights (including trade secrets) may be used at no cost by both parties in China and solely by us outside China.

With respect to the Co-Developed IP rights, Zhongmei Huadong shall be primarily responsible for the relevant application and registrational matters in China while we shall be responsible for such application and registrational matters outside China. If a party decides to abandon any intellectual property (including trade secrets) mentioned therein, the other party shall be entitled to a priority transfer.

Our PRC Legal Advisors are of the view that (i) we and Zhongmei Huadong will co-own the clinical data developed since the date of the QX001S Framework Agreement, and either party shall provide the other party with preclinical and clinical research protocols and reports, complete production process and formula reports as well as any raw data in a timely manner; (ii) we are the sole owner of any intellectual property (including trade secrets) associated with QX001S developed before the date of the QX001S Framework Agreement, while we and Zhongmei Huadong will co-own the Co-Developed IP rights; and (iii) in an event of a major breach of the QX001S Framework Agreement by a party, the other party is entitled to request remedy within a specified time period, and may terminate the agreement and demand compensation for all of its loss due to the breach, if the breaching party fails to remedy.

Non-competition — During the term of the QX001S Framework Agreement, neither party shall develop any other biologics targeting IL-12/IL-23p40 without the other party's consent.

Confidentiality — Both parties are under strict confidentiality with respect to any information that is received from the other party under the QX001S Framework Agreement and may reasonably be considered confidential.

Since the date of the QX001S Framework Agreement and up to the Latest Practicable Date, we had not had any disputes in relation to the development of QX001S with Zhongmei Huadong.

QX001S Production Quality Agreement

On June 16, 2022, to ensure that the Product Supply is in compliance with the relevant regulations and technical specifications, Zhongmei Huadong and Cellularforce entered into a production quality agreement (as amended on October 25, 2022, March 16, 2023 and April 26, 2023, the "QX001S Production Quality Agreement"). The key terms of the QX001S Production Quality Agreement are summarized below:

Term	The QX001S Production Quality Agreement shall be effective from June 16, 2022 to at least one year after the expiration date of the last commercial batch of QX001S if the parties terminate the commissioned production arrangement.
Purpose	To ensure that the Product Supply shall stay compliant with relevant drug laws and regulations and technical standards; and each party shall be responsible for carrying out respective duties as required by the relevant law or regulation.
Zhongmei Huadong's responsibilities	Zhongmei Huadong shall assume the corresponding legal responsibilities as the MAH with respect to the R&D application, production, distribution and use of QX001S.
Cellularforce's responsibilities	Cellularforce shall assume the relevant legal responsibilities as the drug manufacturer with respect to the drug production process.
Personnel and facilities	Cellularforce shall ensure that (i) relevant personnel are trained and qualified in accordance with GMP requirements; and (ii) the facilities, equipment and internet system related to the Product Supply and its inspection are in working conditions and verified.
Raw materials	Zhongmei Huadong shall be responsible for the selection, management, review and approval of suppliers for raw materials and the procurement of raw materials for the Product Supply. Cellularforce shall be responsible for quality control of the procured raw materials.
Verification	Cellularforce shall be responsible for verification work as specified in the QX001S Production Quality Agreement.

Documentation	Cellularforce shall be responsible for documentation and recording of the production activities as specified in the QX001S Production Quality Agreement.
Non-compliance	In an event of non-compliance with the relevant law or regulation, the responsible party shall bear the corresponding responsibility pursuant to such law or regulation.

QX001S Supply Agreement

On September 28, 2022, Zhongmei Huadong and Cellularforce entered into a supply agreement (the "QX001S Supply Agreement") with respect to the Product Supply. The key terms of the QX001S Supply Agreement are summarized below:

Scope	As the MAH of QX001S, Zhongmei Huadong may place production orders of QX001S with Cellularforce after Zhongmei Huadong completes the onsite assessment and verification of Cellularforce's manufacturing facility and obtains approval for the Product Supply as required by the relevant regulatory authorities. As of the Latest Practicable Date, Zhongmei Huadong had completed the onsite assessment and verification of the manufacturing facility.
Production facilities	Cellularforce shall provide certain designated manufacturing facility, quality control lab and storage center for the Product Supply to Zhongmei Huadong as specified in the QX001S Supply Agreement.
Term	The term of the QX001S Supply Agreement is one year from the first batch of commercial production and may be renewed automatically for another year if the parties agree.
Zhongmei Huadong's responsibilities	Zhongmei Huadong shall be responsible for the commercial release of final products.
Zhongmei Huadong's rights	Zhongmei Huadong is entitled to examine the production and inspection process of Cellularforce from time to time and request Cellularforce to immediately terminate production or take remedial or rectification measures in the event of Cellularforce's breach or violation of the QX001S Supply Agreement, GMP requirements or operation procedures.

Cellularforce's responsibilities	Cellularforce shall ensure that the Product Supply is in compliance with GMP requirements and other regulatory requirements. Cellularforce shall also complete sampling, inspection and production release within 30 days upon completion of a production instruction.
Cellularforce's rights	Cellularforce is entitled to commission fees per orders completed, the calculation and settlement of which shall be determined in subsequent supplemental agreements between the parties.

Information about Zhongmei Huadong

While Huadong Medicine (including Zhongmei Huadong) is a large comprehensive pharmaceutical company with strong sales networks for autoimmune and allergic drugs, we do not consider it to be our competitor primarily because (i) for the same skin disease indications, such as Ps and AD, Huadong Medicine's focus is primarily on developing systematic topical drugs that are more commonly used for mild diseases, which would not directly compete with our biologic drug candidates that are intended for more severe cases and instead are complementary to our business; (ii) while Zhongmei Huadong had a biologic drug candidate for SLE in the clinical trial stage as of the Latest Practicable Date, we do not consider it to be a direct competitor to QX006N as these two drug candidates have different mechanisms of action and both are still in early clinical trial stage with considerable time before their commercialization (if at all); and (iii) in 2022, Huadong Medicine obtained the commercialization right of etanercept (a TNF inhibitor) and tofacitinib (a JAK inhibitor), both developed by Pfizer, for the treatment of AS in China, but we believe they will primarily cover a different patient population from QX002N as QX002N targets IL-17A, a promising target that has shown clear clinical benefit in AS patients who are intolerant to or fail to achieve adequate disease control with TNF-α inhibitors and there still remain concerns over the safety profile of JAK inhibitors.

TERMINATION OF NEGOTIATIONS WITH SENECA

On August 5, 2019, we entered into a mutual non-disclosure agreement (the "Seneca NDA") with Neuralstem, Inc., a Delaware corporation that later changed its name to Seneca Biopharma, Inc. ("Seneca"), to engage in discussions regarding and to evaluate Seneca's potential exclusive licensing of certain product candidates developed by us, including QX005N, QX002N, QX004N and QX006N. On October 31, 2019, we further entered into a term sheet with Seneca, which outlined the proposed terms of the potential licensing, which were non-binding and conditioned upon the execution of a definitive licensing agreement between the parties. In addition, the term sheet contained certain binding terms, including terms detailing the establishment of an interim working group and the initial development plan for the potential licensing, as well as confidentiality and exclusivity clauses. On January 6, 2020, the parties ceased negotiations as a result of not being able to reach agreement on certain terms of the potential license.

During the negotiations and before the termination, we disclosed early-stage clinical data of certain projects for relevant product candidates (*i.e.*, QX005N, QX002N, QX004N and QX006N) to Seneca, which shall be protected pursuant to the Seneca NDA, which provides that a party's obligation to protect the confidential information disclosed by another party under the Seneca NDA shall survive the termination or expiration of the Seneca NDA for a period of five years and no license with respect to confidential information is granted by the disclosing party for any purpose. Furthermore, pursuant to the binding confidentiality clause in the term sheet, the contents of the term sheet and all confidential information (as defined in the Seneca NDA) disclosed by the parties in relation to the term sheet or the potential license will be subject to the Seneca NDA.

Under the exclusivity clause in the term sheet, during the 180-day period commencing on the execution of the term sheet (which has since expired), we shall not, directly or indirectly, through any affiliate, officer, director, agent or otherwise, make, solicit, initiate or encourage submission of any proposal or offer from any third party relating to a sale or license of the rights to any relevant product candidates, or any other transaction that would effectively prohibit Seneca from negotiating the proposed license. We do not bear any liability nor have incurred any payable compensation to Seneca as a result of the termination.

INTELLECTUAL PROPERTY

Intellectual property rights are the basis for the success of our business, and we are committed to the development and protection of our intellectual property. Our success depends in part on our ability to obtain and maintain patents and other intellectual property and proprietary protections for commercially important technologies, inventions and know-how. Our success also depends in part on our ability to defend and enforce our patents, preserve the confidentiality of our trade secrets and operate without infringing, misappropriating or otherwise violating the valid, enforceable intellectual property rights of third parties.

As of the Latest Practicable Date, we held 37 patents in China, including 31 invention patents and 6 utility models, as well as 9 patents overseas. As of the same date, we also had 44 patent applications pending in China and overseas. In particular, with respect to our Core Products, we had eight registered patents and two pending patent applications for QX002N and five registered patents and four pending patent applications for QX005N.

We conduct our business under the brand name of "Qyuns ("荃信")." As of the Latest Practicable Date, we had registered 83 trademarks in the PRC and Hong Kong. As of the same date, we were also the registered owner of 21 domain names in the PRC. See "Appendix VIII—Statutory and General Information" to this document for further information.

The actual protection provided by a patent varies on a claim-by-claim and country-by-country basis and depends upon many factors, including the type of patent, the scope of its coverage, the availability of any patent term extensions or adjustments, the availability of legal remedies in a particular country and the validity and enforceability of the patent. We cannot provide any assurance that patents will be issued with respect to any of our owned or licensed pending patent applications or any such patent applications that may be filed in the future, nor can we provide any assurance that any of our owned or licensed issued patents or any such patents that may be issued in the future will be commercially useful in protecting our biologic drug candidates and methods of manufacturing the same. See "Risk Factors—Risks Relating to Our Intellectual Property Rights" for further details. During the Track Record Period and up to the Latest Practicable Date, we had not been involved in any material proceeding in respect of, and we had not received notice of any material claim of infringement of, any intellectual property rights that may be threatened or pending, in which we may be a claimant or a respondent that may have a material adverse impact on us.

The table below lists the material patents and patent applications of our Core Products, QX002N and QX005N, as of the Latest Practicable Date. Inventors of each of the QX002N patents or patent applications listed below include Mr. Qiu, Dr. Qiu Zhihua, Mr. Chen Wei, Mr. Kong Yong, Mr. Wu Yiliang and other key members of our R&D team. Inventors of each of the QX005N patents or patent applications listed below include Mr. Qiu, Dr. Qiu Zhihua, Mr. Chen Wei, Mr. Wu Yiliang, Mr. Qiao Huaiyao and other key members of our R&D team. We do not expect there to be material legal impediments in obtaining approval for our pending patent applications.

Product	Patent/Application Number	Type of Patent	Patent/Application Name	Scope of Patent/ Application Protection	Jurisdiction	Status	Application Date	Expected Approval Date	Expiration Date
QX002N	201810473679.4	Invention	Anti-human interleukin 17A monoclonal antibody and application thereof (抗人白介素17A單克隆抗體及其應用)	Molecular Entity	China	Granted	May 17, 2018	Granted	May 17, 2038
QX002N	US17/055,789	Invention	Anti-human interleukin 17A monoclonal antibody and application thereof	Molecular Entity	US	Pending	May 17, 2018	December 31, 2024	NA
QX002N	CA3100092	Invention	Anti-human Interleukin 17A monoclonal antibody and application thereof	Molecular Entity	Canada	Pending	May 17, 2018	December 31, 2025	NA
QX002N	EP18919093.7	Invention	Anti-human Interleukin 17A monoclonal antibody and application thereof	Molecular Entity	Europe	Granted	May 17, 2018	Granted	May 17, 2038
QX002N	AU2018423921	Invention	Anti-human interleukin 17A monoclonal antibody and application thereof	Molecular Entity	Australia	Granted	May 17, 2018	Granted	May 17, 2038
QX002N	JP2020565275	Invention	Anti-human Interleukin 17A monoclonal antibody and application thereof (抗ヒトインターロイキン１７Ａモノクローナル抗体およびその使 用)	Molecular Entity	Japan	Granted	May 17, 2018	Granted	May 17, 2038
QX005N	201811592427.X	Invention	Anti-human interleukin-4 receptor α monoclonal antibody and application thereof (抗人白介素4受體α單克隆抗體及其應用)	Molecular Entity	China	Granted	December 25, 2018	Granted	December 25, 2038
QX005N	US 17/418,571	Invention	Monoclonal antibody against human interleukin-4 receptor alpha and use thereof	Molecular Entity	US	Pending	December 25, 2019	December 31, 2025	NA
QX005N	CA3124726	Invention	Monoclonal antibody against human interleukin-4 receptor alpha and use thereof	Molecular Entity	Canada	Pending	December 25, 2019	December 31, 2026	NA
QX005N	EP19902812.7	Invention	Monoclonal antibody against human interleukin-4 receptor alpha and use thereof	Molecular Entity	Europe	Pending	December 25, 2019	December 31, 2024	NA
QX005N	AU2019416486	Invention	Monoclonal antibody against human interleukin-4 receptor alpha and use thereof	Molecular Entity	Australia	Granted	December 25, 2019	Granted	December 25, 2039
QX005N	JP2021537939	Invention	Monoclonal antibody against human interleukin-4 receptor alpha and use thereof (抗ヒトインターロイキン-受容體のモノクローナル抗體およびその使用)	Molecular Entity	Japan	Granted	December 25, 2019	Granted	December 25, 2039

RAW MATERIALS AND SUPPLIERS

Our Raw Materials

We procure raw materials from both domestic and overseas suppliers according to our drug development plans. Our raw materials for our biologic drug candidates primarily include biological and chemical materials, such as chromatography media and culture media, as well as disposable consumables, such as buffer preparation bags and filters.

For the selection and management of raw material suppliers, we maintain a list of qualified suppliers and review their qualifications on an annual basis by taking into consideration their production capacity, production quality, product delivery and feedback efficiency, pricing, reputation and compliance with relevant regulations and industry standards. Our functional departments will initiate the purchase plan of raw materials based on the status of research and development activities and our inventory level. Our procurement department is responsible for placing orders with qualified suppliers and managing suppliers. Our clinical development department and QA and QC teams are also involved in the procurement process and participate in raw material quality control. To monitor the quality of supplies, we implemented a standardized operating system, setting out the procedures and guidelines for the procurement and acceptance of raw materials, quality control inspection, warehousing, testing and storage.

Our Suppliers

During the Track Record Period, our suppliers primarily consisted of suppliers of third-party contracting services for preclinical and clinical studies of our drug candidates, as well as raw materials, consumables and equipment. We have established stable collaboration relationships with qualified suppliers for raw materials and R&D services, which we believe have sufficient capacity to meet our demand. We also believe that adequate alternative sources for such supplies exist.

During the Track Record Period, we did not encounter any material dispute with our suppliers or any material breach of our purchase agreements, nor did we experience any material shortage, delay or price fluctuation in the supply of our raw materials. For risks related to supply of our raw materials, see "Risk Factors—Risks Relating to the Manufacturing and Commercialization of Our Drug Candidates—Scarcity of available raw materials or increases in our raw material costs may negatively impact our business, financial condition and results of operations."

For each of the years ended December 31, 2021 and 2022 and the nine months ended September 30, 2023, our purchases from our five largest suppliers were RMB39.4 million, RMB55.0 million and RMB54.9 million, respectively, accounting for approximately 26.3%, 27.4% and 25.2%, respectively, of our total purchases for the respective periods. In the same periods, purchases from our largest supplier were RMB12.4 million, RMB24.3 million and RMB25.9 million, respectively, accounting for approximately 8.3%, 12.1% and 11.9%, respectively, of our total purchases for the respective periods.

The following table sets forth details of our five largest suppliers during each year/period of the Track Record Period.

Supplier*	Principal Business	Products purchased	Credit terms	Commencement of business relationship	Purchase amount	% of total purchases in same period
					(Renminbi in thousands)	
For the nine months ended September 30, 2023						
A	Product development for pharmaceutical-related industries and health-related industries	Clinical and discovery CRO services	Settle in accordance with the milestones in the contract	2016	25,898	11.9
B	New drug research, development and production services, inspection and testing services, technology development, clinical and consulting services for the biomedical industry	Clinical and discovery CRO services	Settle in accordance with the milestones in the contract	2018	12,570	5.8
C	Develop ability research, process scale-up optimization, quality research and pilot and commercial production for global innovative drug R&D institutions	Preclinical service	Settle in accordance with the milestones in the contract	2016	6,371	2.9
D	Biotechnology development and technical consulting	Sample-testing service	Settle in accordance with the milestones in the contract	2018	5,131	2.4
E	Medical and nursing care services	Clinical trial services	Settle in accordance with the milestones in the contract	2021	4,949	2.3
Total					54,919	25.2

Supplier*	Principal Business	Products purchased	Credit terms	Commencement of business relationship	Purchase amount	% of total purchases in same period
					(Renminbi in thousands)	
For the year ended December 31, 2022						
F	Non-clinical efficacy, pharmacokinetics, toxicology evaluation and clinical sample testing for pharmaceutical enterprises	Preclinical service	Settle in accordance with the milestones in the contract	2015	24,303	12.1
B	New drug research, development and production services, inspection and testing services, technology development, clinical and consulting services for the biomedical industry	Clinical and discovery CRO services	Settle in accordance with the milestones in the contract	2018	9,464	4.7
G	R&D services for biological products, R&D technical consultation for biological products and biochemical drugs, technical detection services for medical devices	Sample test service and raw materials	Settle in accordance with the milestones in the contract	2016	7,837	3.9
H	Medical and nursing care services	Clinical trial services as trial site	Settle in accordance with the milestones in the contract	2018	6,719	3.4
I	Laboratory filling services and distribution services as an imported filler distributor	Raw materials	30 days	2021	6,656	3.3
Total					54,979	27.4

Supplier*	Principal Business	Products purchased	Credit terms	Commencement of business relationship	Purchase amount	% of total purchases in same period
					(Renminbi in thousands)	
For the year ended December 31, 2021						
F	Non-clinical efficacy, pharmacokinetics, toxicology evaluation and clinical sample testing for pharmaceutical enterprises	Preclinical service	Settle in accordance with the milestones in the contract	2015	12,410	8.3
B	New drug research, development and production services, inspection and testing services, technology development, clinical and consulting services for the biomedical industry	Clinical and discovery CRO services	Settle in accordance with the milestones in the contract	2018	10,427	7.0
J	Sales of biological devices, raw materials and consumables, and the distribution of related imported products	Raw materials and equipment	30 days after invoice date	2020	7,421	5.0
K	Power generation, transmission, and power supply	Electricity	N/A	2015	4,763	3.2
L	Medical and nursing care services	Clinical trial services as trial site	Settle in accordance with the milestones in the contract	2020	4,340	2.9
Total					39,361	26.3

Note:

* We have masked the identities of the suppliers because we believe that the information disclosed above, including the suppliers' principal businesses, purchased products, credit terms, commencement of business relationship, purchase amount and the corresponding percentage of the total purchase in the same period, is sufficient to enable an understanding of the background of such suppliers and the nature/significance of our transactions with them.

To the best of our knowledge, all of our five largest suppliers during each year/period of the Track Record Period are independent third parties. As of the Latest Practicable Date, none of our Directors, their close associates or any Shareholders which, to the best knowledge of our Directors, owned more than 5% of our share capital, had any interest in any of our five largest suppliers during each year/period of the Track Record Period.

COMPETITION

The development and commercialization of innovative biologic drugs are highly competitive and subject to rapid and significant changes. We believe that our comprehensive portfolio, deep knowledge of key therapeutic pathways, commercial-scale in-house manufacturing capacity and practical commercialization model provide us with strong competitive advantages. We face potential competition from many different sources working to develop therapies targeting the same indications for which we develop our drug candidates, in particular in the autoimmune and allergic disease areas. These include major pharmaceutical companies as well as specialty pharmaceutical companies of various sizes. Our Core Products and key drug candidates face competition from approved and clinical-stage drug candidates that focus on similar indications and target patient population with us, and these competing products may have significant competitive strengths and advantages when compared to our drug candidates. For competitive landscape of our products and products candidates, see "—Our Drug Candidates" and "Industry Overview" in this document.

EMPLOYEES

As of September 30, 2023, we had 323 employees in total. The following table sets forth the details of our employees by function:

Function	Number of employees	Percentage
R&D	119	36.8%
Manufacturing	155	48.0%
Management and administrative	49	15.2%
Total	323	100.0%

All of our employees are based in China. In compliance with the applicable labor laws, we enter into individual employment contracts with our employees covering matters such as wages, employee benefits, workplace safety and grounds for termination. Our standard employment contract also contains a confidentiality clause and an assignment clause, under which we own all the rights to all inventions, technologies, know-how and trade secrets derived during the course of our employee's work. We also enter into standard non-compete agreements with our key personnel, including all employees in our R&D team and employees of manager level or above in other departments.

To maintain a stable workforce and retain key personnel in our Company, we offer our employee competitive remuneration packages. Our employees' remuneration comprises salaries, legally required welfare, such as social insurance, paid annual leave and high-temperature subsidies, and additional welfare, such as supplementary medical insurance for employees and their families, lunch subsidies, annual physical examinations and annual trip.

We offer remuneration packages based on individuals' qualifications and experiences and generally match the market rate for salary to stay competitive in the labor market. We also take into consideration the long-term growth and advancement of our employees and offer opportunities for both job promotion and technical development. We have a triple-tier internal training system, covering company, department and post level policies, procedures and professional knowledge. We also provide opportunities for external trainings, such as industry forums/summits, special skills training and various job qualification trainings. Additionally, we established an Employee Share Incentive Scheme to better retain and motivate our employees, with eligible participants comprising core management members and key technical/business personnel of our Group. During the Track Record Period and up to the Latest Practicable Date, we did not experience any strikes or labor disputes which had a material effect on our business. Some of our employees are currently represented by labor unions, and we consider our relations with our employees to be good.

In accordance with PRC laws and regulations, we are obliged to contribute to social insurance and housing provident funds for our employees. During the Track Record Period, we did not make full contribution to social insurance and housing provident funds for some of our employees and engaged third-party agents to make the payment of social insurance and housing provident fund on behalf of us for certain employees. We made full provisions for the total amount of such shortfall of RMB3.8 million, RMB5.4 million and RMB3.9 million to our consolidated statements of profit or loss and other comprehensive income for the years ended December 31, 2021 and 2022 and the nine months ended September 30, 2023, respectively. As advised by our PRC Legal Advisors, according to the relevant PRC laws and regulations in respect of social insurance and housing provident funds contribution, if the relevant government authorities are of the view that our contribution did not satisfy the requirements under the relevant PRC laws and regulations, we may be ordered to rectify the shortfall in our contribution within a prescribed period and if we fail to do so within the prescribed period, we could be subject to related fines, the potential maximum amount of which equals three times the amount of our outstanding social insurance contribution and a late fee of 0.05% of the outstanding amount for each day of delay. As advised by our PRC Legal Advisors, the risk of us being penalized for such shortfall is remote, provided that we rectify such shortfall in a timely manner after receiving notices from the relevant PRC authorities.

During the Track Record Period and up to the Latest Practicable Date, we had not received any notifications from the relevant government authorities requiring us to rectify the shortfall or pay related late payment fees. Our Company and all of our subsidiaries which did not make full contribution and/or engaged third parties for such contribution had obtained written confirmations from competent local government authorities, which confirmed that no penalties had been imposed on us with respect to social insurance and housing provident funds during the Track Record Period. During the Track Record Period and up to the Latest Practicable Date, we were not aware of any material employee complaints nor involved in any material labor disputes with our employees with respect to social insurance and housing provident fund contributions. In addition, we have implemented relevant internal control measures to strengthen our oversight and management in relation to the social insurance and housing provident funds, including studying official rules and regulations promulgated by the

government, organizing relevant personnel to participate in related training provided by government agencies and reviewing the social insurance and housing provident funds contribution for all eligible employees on an annual basis. For further details on the risks associated with the shortfall in our contribution, see "Risk Factors—Risks Relating to Our Operations—We may be required to pay late payment fines or other penalties in connection with our failure to contribute to social insurance and housing provident funds."

INSURANCE

We maintain insurance policies that are required under PRC laws and regulations as well as based on our assessment of our operational needs and industry practice. In line with industry practice in China, we maintain different types of insurance policies, such as personal accident insurance and clinical trials liability insurance. Considering that we have not commercialized our products, we have not purchased certain types of insurance, such as product liability insurance, except for product candidates in clinical trials. Our Directors consider that our existing insurance coverage is generally in line with the industry practice in China. See "Risk Factors—Risks Relating to Our Operations—Our insurance coverage may not sufficiently cover the risks related to our business operations." for risks relating to our insurance coverage.

SOCIAL, HEALTH, WORK SAFETY AND ENVIRONMENTAL MATTERS

We are subject to various social, health, safety and environmental laws and regulations and our operations are regularly inspected by local government authorities. We believe we have adequate policies ensuring compliance with all social, health, safety and environmental protection regulations. Particularly, we believe our continued growth rests on integrating social values into our business. We intend to create a lasting positive environmental, social and governance ("ESG") impact on our customers, suppliers and the broader community whom our operation may impact. We acknowledge our responsibilities on environmental protection, social responsibilities and are aware of the climate-related issues that may have impact on our business. We are committed to complying with ESG reporting requirements upon [**REDACTED**].

Our core management team is responsible for adopting and adjusting our overall ESG vision and principle and our Administrative, Human Resources and Operational Support (under Cellularforce) departments are collectively responsible for assessing and managing our ESG-related risks and monitoring the compliance of our operations with environment, health and safety laws and regulations. We have adopted company-wide environmental, health and safety (EHS) manuals and standard operating procedures in relation to waste treatment, process safety management, worker health and safety requirements and emergency planning and response, and provide regular trainings to our employees on related issues.

As a biotech company, we face a variety of environmental, health or safety-related risks associated with our operations over the short-, medium- and long-term. For example, our operations involve the use of hazardous materials, including chemicals, and may produce hazardous waste products to the environment. If we fail to process the hazardous materials in

compliance with relevant laws and regulation, cause injury to persons involved or contaminate the environment, we could incur significant costs associated with administrative, civil or criminal fines and penalties, lose our permit/certificate or be ordered to make substantial alternation to our business operations. See "Risk Factors—Risks Relating to Our 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 our business" for more details on the potential impact of such risks. Additionally, we are also subject to potential risks arising from changes in social trends and political policies related to ESG issues. See "Risk Factors—Risks Relating to Our Operations—Changes in social trends and political policies related to environmental, social, and governance issues may adversely affect our business operation" for further details.

To better identify, assess and manage ESG-related risks, we use the LEC (likelihood, exposure and consequences) method to evaluate potential impact of the risks. In the short term, we will endeavor to manage these risks by (i) ensuring strict compliance with existing laws and regulations, including the environmental impact assessment requirements and pollutant discharge permit reviews, (ii) engaging qualified third parties for the disposal of hazardous waste from our operations and (iii) further improving our internal monitoring of ESG-related operations through advanced technical systems, such as the sewage online monitoring system. In the medium- and long-term, as a company that is committed to sustainability and responsible business practices, we will keep abreast of the regulatory standards and advancements in scientific and technical solutions to environmental issues and update our related policies, procedures and resources accordingly.

Resource Consumption and Emissions

We rely on various metrics to measure the impact of our business on the environment, which are broadly aligned with industry standards. Such metrics include the amount of resource consumption, amount of waste (including wastewater and solid waste) generated and greenhouse gas emissions. We have also set various goals to reduce our environmental impact, and we continue to take significant steps toward these targets. The following table sets forth our resource use and emission-related indicators during the Track Record Period.

	Year ended December 31,		Nine months ended September 30,
	2021	2022	2023
Resource consumption			
Electricity (MWh)			
— Total amount	7,645	8,355	6,115
— Intensity* (MWh/sq.m.)	0.175	0.192	0.140
Water (tons)			
— Total amount	78,658	77,055	59,136
— Intensity* (t/sq.m.)	1.805	1.768	1.357

	Year ended December 31,		Nine months ended September 30,
	2021	2022	2023
Emission			
Wastewater (tons)			
— Total amount	8,829	6,541	8,647
— Intensity* (t/sq.m.)	0.203	0.150	0.198
Hazardous solid waste (tons)			
— Total amount	10	26	27
— Intensity* (kg/sq.m.)	0.22	0.61	0.63
Greenhouse gas emissions (tons of CO2 equivalent)	7,677	8,348	5,951
— Scope 1 (direct emissions)	248	204	103
— Scope 2 (indirect emissions)	7,429	8,144	5,848

Note:

* Calculated as the total amount of resource consumption or emission divided by the gross floor area of our manufacturing facility

The total amount of discharged wastewater in 2021 was higher than that in 2022, primarily because we conducted wastewater treatment procedure testing in 2021 in the early stage of our manufacturing to ensure the quality of discharged wastewater, which caused additional wastewater discharge. The total amount of discharged wastewater in the nine months ended September 30, 2023 was higher than that in 2022, primarily because of the relatively heavy rainfall during this period, which led to an increased inflow of rainwater into the sewage network, and an increase in our manufacturing activities. The total amount of discharged hazardous solid waste increased in 2022 and the nine months ended September 30, 2023, primarily due to increase in our manufacturing activities.

Resource Consumption

We incorporate the concept of resource conservation into our corporate culture and the daily operation of our laboratories and offices, monitor our resource consumption and established internal resource consumption management systems for laboratories and offices. We actively implement energy-saving measures in our daily operation, such as installing energy-efficient devices (*e.g.*, variable frequency air conditioners), timely turning off idle equipment and lighting in laboratories and offices and adjusting the operation load of air conditioners and switching the heating mode of air-conditioning water heater systems between single and double plates.

We focus on water resources issue and actively shoulder the social responsibility of protecting water resources. Municipal water supply networks are the main incoming source of our Company's water, and we did not encounter major difficulties seeking suitable water sources during the Track Record Period. Since we have not yet started commercial-scale production, our water resources are mainly used for laboratories and manufacturing facilities to support our in-house research and development activities, and daily use in offices during the Track Record Period.

Emissions

The waste we produce is divided into hazardous waste (such as chemical waste and liquid) and non-hazardous waste (such as waste from general office operations). The hazardous waste generated in our in-house research and development process are processed by qualified third-party waste treatment companies. We have set up an online monitoring system to monitor real-time wastewater discharge and a water treatment system to pre-treat concentrated wastewater for collection. We use single-use bioreactors in our manufacturing facilities, which can significantly reduce the need for sterilization. With respect to exhaust gas emission, we utilize natural gas boilers with low-nitrogen combustion technology to reduce greenhouse gas emissions. Additionally, we installed various gas collection devices such as ventilation hoods and range hoods to collect exhaust gas, which would be treated with activated carbon adsorbents before being discharged.

Our greenhouse gas emissions primarily consist of Scope 1 and Scope 2 emissions. Scope 1 direct emissions include the direct greenhouse gas emissions from our own manufacturing and other facilities. Scope 2 energy indirect emissions primarily include the greenhouse gas emissions from our usage of purchased electricity, calculated based on the "Accounting Methods and Reporting Guidelines for Greenhouse Gas Emissions of Enterprises in Other Industries" (Trial) issued by the National Development and Reform Commission. In response to the national target of carbon neutrality, we actively focus on reducing the greenhouse gas emissions generated during our operations. Other indirect emissions that occur outside of our operation but are related to our activities and ESG goals are categorized as Scope 3 indirect emissions. Such emissions include both upstream and downstream emissions, such as emissions by our suppliers in their production of raw materials or disposables and in product transport, emissions from business travels by our employees and emissions due to electricity used for sewage processing by the relevant government agency. While we have limited control over the activities that directly contribute to Scope 3 emissions, we firmly believe in the positive impact by fostering an environmentally conscious operational culture in our own operation. This includes opting for qualified domestic suppliers to minimize energy consumption and greenhouse gas emissions during product transport, prioritizing virtual meetings over unnecessary business trips, as well as upgrading our manufacturing facilities/methods as appropriate to reduce waste production and thereby reduce downstream emissions.

Measures and Targets

With the expansion of our business and anticipated commercialization of our drug candidates, we endeavor to curb the increase in our resource consumption and emissions and aim to keep them relatively stable. We will continue to adopt a wide range of environment-conservation measures to limit resource consumption and emissions. With respect to resource consumption, we will (i) install energy efficient facilities for our daily office operation and manufacturing process; (ii) limiting business air travels and replacing long-journey in-person meetings with virtual conferences where possible; and (iii) cultivate a corporate culture of environmental protection through employee training and office policies, such as switching off certain equipment or setting up automatic power shutdown for certain systems and devices when not in use. With respect to waste generation and greenhouse gas emissions, we will (i) regularly monitor and assess sources of hazardous waste generation and update to more environment-friendly manufacturing processes and facilities when appropriate; and (ii) continue to work with qualified professional waste processors and enhance our on-site waste treatment capacities.

In 2023, we aim to control our (i) total amount and intensity of resource consumption (primarily electricity and water) at approximately 90% to 95% of that recorded in 2022, (ii) total amount and intensity of wastewater and solid waste generation at approximately 170% to 180% and 145% to 150% of those recorded in 2022, respectively, and (iii) greenhouse gas emission at 90% to 95% of that recorded in 2022.

Our Board will set targets for each material KPIs at the beginning of each financial year in accordance with the disclosure requirements of the Listing Rules and other relevant rules and regulations upon [**REDACTED**]. The relevant targets on material KPIs will be reviewed on an annual basis to ensure that they remain appropriate to the needs of our Group. In setting targets for the ESG-related KPIs, we will take into account our respective historical consumption or discharge levels during the Track Record Period, and our future business expansion in a thorough and prudent manner with a view of balancing business growth and environmental protection to achieve sustainable development.

Social Responsibilities

In respect of social responsibilities, we are committed to offering a fair and caring working environment to our employees. We have transparent policies on recruitment, compensation, dismissal, equal opportunities, diversity and anti-discrimination. We hire employees based on their merits and it is our corporate vision to offer equal opportunities to our employees. We encourage our employees who encounter any discrimination to seek immediate assistance, which also allows us to conduct timely investigation and follow up as needed. In addition, we provide training programs on industry and regulatory developments to our employees.

In light of the COVID-19 pandemic, we have endeavored to provide a safe work environment by implementing company-wide self-protection policies for employees, including providing protective masks and sanitization to our employees.

Work Safety

To ensure our compliance with applicable EHS laws and regulations and to maintain a healthy and safe environment for our employees, we (i) inspect our equipment and facility regularly to identify and eliminate safety hazards, (ii) assign designated personnel to manage EHS issues during daily operations, (iii) provide regular safety awareness training to our employees, (iv) conduct annual health examinations for all employees, and (v) conduct regular fire safety inspections, maintenance of fire-fighting equipment and regular emergency drills.

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, with an aim of minimizing adverse environmental impact.

Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste such as wastewater and biological solid waste. All waste generated during our operations will be stored in accordance with our internal policies and applicable laws and regulations and discharged following harmless treatment by qualified service providers. See "Regulatory Overview—Principal Regulatory Provisions—Laws and Regulations on Environmental Protection" for details on relevant PRC environmental laws and regulations. We also actively monitor our resource consumption for our manufacturing function.

We believe we have maintained good relationships with the communities surrounding our manufacturing facility. 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 and the nine months ended September 30, 2023, our expenses in relation to environmental protection amounted to RMB0.6 million, RMB0.4 million and RMB0.4 million, respectively. We expect our costs of complying with current and future environmental protection laws to increase in the future, as we further our R&D efforts and commence commercial manufacturing of our products after regulatory approval. We incorporate a sustainable development approach in our daily business operation decisions.

PROPERTIES

We are headquartered in Taizhou, Jiangsu province. As of the Latest Practicable Date, we owned the buildings of our Taizhou Manufacturing Facility of 43,571 sq.m. in gross floor area and the parcel of land housing our Taizhou Manufacturing Facility of 57,977 sq.m. As advised by our PRC Legal Advisors, during the Track Record Period and up to the Latest Practicable Date, we had obtained the real estate title certificate for such land parcel and properties. For further details with respect to our property interests, see "Appendix IV—Valuation Report" to this document. As of the Latest Practicable Date, we leased eight properties with an aggregate gross floor area of 3,969 square meters in Shanghai, Beijing and Taizhou for our daily business operations, R&D functions and staff dormitory.

As of the Latest Practicable Date, we had not completed lease registrations for seven of our leases, with an aggregate gross floor area of 1,229 sq.m., with the relevant regulatory authorities due to the inaction of the landlords to cooperate with the registration procedure. As advised by our PRC Legal Advisors, the non-registration of lease agreements will not affect the validity of such lease agreements, but the relevant local housing administrative authorities can require us to complete registrations within a specified timeframe and we may be subject to a fine between RMB1,000 and RMB10,000 per lease for any delay in making these registrations, which we do not believe would have a material adverse impact on our operation. However, we will consult with our legal advisors and aim to address the issue appropriately during the lease negotiation process in the future. As of the Latest Practicable Date, we were not subject to any penalties arising from the non-registration of the lease agreements. See "Risk Factors—Risks Relating to Our Operations—We may be required to pay administrative fines for our failure to register some of our lease agreements with housing administration authorities."

AWARDS AND RECOGNITIONS

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

Year	Award or Recognition	Issuing Authority
2023	China Biopharmaceutical Industry Value List Top 10 Most Promising CDMO Enterprises (Cellularforce) (中國生物醫藥產業價值榜最具成長性CDMO企業TOP10 (賽孚士))	Huayi Research Institution (華醫研究院)
2023	China Biopharmaceutical Science and Technology Innovation Value List Top 10 Most Promising Biopharmaceutical Enterprises (中國生物醫藥科技創新價值榜最具成長性生物藥企業TOP10)	Shanghai Biopharmaceutical Industry Association (上海市生物醫藥行業協會); Yiyun Technology (醫耘科技)

Year	Award or Recognition	Issuing Authority
2022-2023	Top 50 Chinese Enterprises in terms of biopharmaceutical R&D capability (中國生物藥研發實力排行榜50強)	China Pharmaceutical Industry Journal Publisher (中國藥業雜誌社); Yaozhi Web (藥智網)
2022-2023	Top 100 Chinese Enterprises in terms of comprehensive pharmaceutical R&D capability (中國藥品研發綜合實力排行榜100強)	China Pharmaceutical Industry Journal Publisher (中國藥業雜誌社); Yaozhi Web (藥智網)
2022	China Biopharmaceutical Technology Innovation Rank – Top 20 Most Influential Antibody Biotech Companies (中國生物醫藥科技創新價值榜"最具影響力抗體藥企業TOP20")	Shanghai Biopharmaceutical Industry Association (上海市生物醫藥行業協會); Yiyun Technology (醫耘科技)
2022	Top 50 Chinese Innovative Biotech Enterprises (生物科技創新50企業)	KPMG China
2021-2022	Top 100 Chinese Seed Enterprises in terms of Pharmaceutical Innovation (中國醫藥創新種子企業100強)	Healthcare Executive (E藥經理人)
2021-2022	Potential Unicorn Enterprise of Jiangsu Provincial High-Tech Industrial Development Area (江蘇省高新技術產業開發區潛在獨角獸企業)	Productivity Center of Jiangsu Province (江蘇省生產力促進中心)
2021-2022	Top 30 Most Innovative Chinese Antibody Therapeutics Enterprises (中國抗體藥物企業創新力TOP30)	Menet (米內網)
2021	Jiangsu Autoimmune Diseases Antibody Engineering Research Center (江蘇省免疫性疾病抗體工程研究中心)	Jiangsu Provincial Development and Reform Commission (江蘇省發展和改革委員會)
2021	High and New Tech Enterprise (高新技術企業)	Jiangsu Science and Technology Department (江蘇省科學技術廳)
2021	Top 10 Most Promising Enterprises of Antibody Innovative Drugs (年度最具發展潛力的抗體創新藥藥企TOP10)	CHUJIETECH (觸界科技)

LICENSES, PERMITS AND APPROVALS

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

License/Permit	Holder	Issuing Authority	Issue Date	Expiration Date
Drug Manufacturing Certificate (藥品生產許可證)	Cellularforce	Jiangsu Medical Products Administration	April 15, 2021 (last renewed on October 18, 2023)	March 27, 2026

LEGAL PROCEEDING AND COMPLIANCE

During the Track Record Period and up to the Latest Practicable Date, we had not been involved in any litigation, arbitration or administrative proceedings which could have a material adverse impact on our business, financial condition or results of operations. As of the Latest Practicable Date, we were not aware of any pending or threatened litigation, arbitration or administrative proceedings against us which may have a material and adverse impact on our business, financial condition or results of operations.

During the Track Record Period and as of the Latest Practicable Date, we had not had any non-compliance incidents which our Directors believe would, individually or in the aggregate, have a material operational or financial impact on our company as a whole.

RISK MANAGEMENT AND INTERNAL CONTROL

We are subject to various risks during our operations. See "Risk Factors—Risks Relating to Our Operations." We have established a consolidated risk management system and relevant policies and procedures which we consider suitable for our business operations. Our policies and procedures are aimed at managing and monitoring our business performance.

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

- establish an audit committee to review and supervise our financial reporting process and internal control system. Our audit committee consists of three members: Mr. Fung Che Wai, Anthony, chairman of the committee, Mr. Wu Zhiqiang and Dr. Ling Jianqun. For the qualifications and experiences of these members, see "Directors, Supervisors and Senior Management";

- adopt various policies to ensure the compliance with the Listing Rules, including but not limited to policies in respect of risk management, connected transactions and information disclosure;

- provide regular anti-corruption and anti-bribery compliance training for senior management and employees in order to enhance their knowledge of and compliance of applicable laws and regulations; and

- arrange our Directors and senior management to attend training seminars on Listing Rules requirements and the responsibilities as directors of a Hong Kong-listed company.

We have appointed an internal control consultant to review the effectiveness of our internal control measures related to our major business processes, to identify the deficiencies for improvement, advise on the rectification measures and review the implementation of such measures. During the review process of our internal control consultant, certain internal control matters were identified, and we have adopted corresponding internal control measures to improve on these matters. We have adopted the recommendations made by the internal control consultant and our internal control consultant has completed the follow-up procedures on our internal control system and have not identified any material deficiencies in our internal control system.