Qyuns Therapeutics Co., Ltd.
江蘇荃信生物醫藥股份有限公司
(A joint stock company incorporated in the People's Republic of China with limited liability)
(Stock Code: 2509)

VOLUNTARY ANNOUNCEMENT
ACCEPTANCE OF SUPPLEMENTAL APPLICATION FOR QX001S (USTEKINUMAB INJECTION) FOR USE IN PEDIATRIC PLAQUE PSORIASIS

This announcement is made by Qyuns Therapeutics Co., Ltd. (the "**Company**") on a voluntary basis to inform its shareholders and potential investors of an update on the business developments of the Company.

References are made to the prospectus dated March 12, 2024 published by the Company in relation to the QX001S Framework Agreement entered into between the Company and Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd. ("**Zhongmei Huadong**"), the announcement published by the Company on September 12, 2024 in relation to the supplemental agreements to the Ustekinumab Entrusted Production Agreement entered into between Zhongmei Huadong and Jiangsu Cellularforce Biopharma Co., Ltd. ("**Cellularforce**"), a subsidiary of the Company, and setting the annual caps for the QX001S Framework Agreement, and the announcement published by the Company on November 5, 2024 in relation to the fact that Zhongmei Huadong has received the Drug Registration Certificate approved and issued by the National Medical Products Administration (國家藥品監督管理局) (the "**NMPA**"), and the marketing authorization application for Ustekinumab Injection (trade name: SAILEXIN, R&D code: QX001S/HDM3001) submitted by Zhongmei Huadong has been approved for the treatment of moderate-to-severe plaque psoriasis in adults.

The board of directors (the "**Board**") of the Company is pleased to announce that on December 2, 2024, the supplemental application for QX001S for use in pediatric plaque psoriasis was accepted.

A. BASIC INFORMATION OF THE DRUG

Common name:	Ustekinumab Injection
Application:	Supplemental application for domestically manufactured drugs
Registration classification:	Classification 3.3 of therapeutic biological products
Specification:	Pre-filled syringes: 45mg (0.5ml)/piece
Indication applied for:	Pediatric plaque psoriasis. This product is indicated for children and adolescents (60 kg to 100 kg) aged 6 years and above with moderate-to-severe plaque psoriasis who have inadequate response to or cannot tolerate other systemic therapies or phototherapy.
Applicant:	Zhongmei Huadong
Review conclusions:	According to the requirements of Article 32 of the Administrative License Law of the People's Republic of China, after review, it is decided to accept the application.

B. RESEARCH AND DEVELOPMENT AND REGISTRATION OF THE DRUG

QX001S is a biosimilar drug of originator-branded product of Stelara® (Ustekinumab Injection), and its mechanism of action is to block the combination of p40 subunit, shared by IL-12 and IL-23, to the IL-12R β1 receptor protein on the surface of target cells, thus inhibiting the signaling and cytokine cascade reaction mediated by IL-12 and IL-23. IL-12 and IL-23 are two natural cytokines, which play a key role in immune-mediated inflammatory diseases.

Stelara® was developed by Johnson & Johnson and was approved for marketing by the U.S. Food and Drug Administration (FDA) in 2009. Up to now, its indications approved in the United States include moderate-to-severe plaque psoriasis, active psoriatic arthritis, moderate-to-severe active Crohn's disease and moderate-to-severe active ulcerative colitis. The product was approved by the former China Food and Drug Administration (currently known as the NMPA) in 2017 under the trade name of Stelara®. The currently approved indications in China include plaque psoriasis in adults, pediatric plaque psoriasis, and Crohn's disease. Ustekinumab Injection was first included in the National Reimbursement Drug List for Basic Medical Insurance, Work-Related Injury Insurance and Maternity Insurance (2021 version) (the "**2021 NRDL**") through negotiation in 2021, and was subsequently renewed for inclusion in the 2022 NRDL, the 2023 NRDL and the 2024 NRDL. According to the 2023 annual report of Johnson & Johnson, the global sales of Stelara® in 2023 amounted to US$10.858 billion (approximately RMB76.729 billion). The data from Menet showed that the sales of Stelara® in China in 2023 were RMB1.322 billion.

The Phase III clinical trial and R&D of QX001S was jointly advanced by Zhongmei Huadong and the Company. The product obtained clinical trial approval in 2018, its Phase I clinical trial was completed in 2020, and the Phase III clinical study was completed in June 2023. Zhongmei Huadong, as the drug registration applicant, submitted the market application to the NMPA, which was approved in October 2024 for the treatment of moderate-to-severe plaque psoriasis in adults, which is the first biosimilar drug of Ustekinumab Injection approved in China. Recently, a supplemental application submitted by Zhongmei Huadong for QX001S for use in pediatric plaque psoriasis was accepted.

C. IMPACT ON THE COMPANY

Psoriasis is a chronic, recurrent, and inflammatory disease primarily affecting the skin and joint systems, which is currently incurable and requires long-term or even lifelong treatment, with plaque psoriasis being the most common type, accounting for approximately 80% to 90% of all psoriasis patients. According to the "Expert Consensus on Diagnosis and Treatment of Psoriasis in Children in China (2021)", the prevalence of psoriasis in children under 18 years of age is reported to be 0.7% to 1.2% in different countries, and the prevalence of psoriasis in children between 10 and 19 years of age is 0.18% in China; pediatric plaque psoriasis accounts for approximately 70% of pediatric psoriasis. Pediatric psoriasis has complex clinical manifestations with wide variations in type. Due to the special physiological characteristics of children, more attention should be paid to the safety of treatment. At present, psoriasis treatment in China has entered the era of biologics, which generally have better efficacy and good safety as compared to traditional treatment. In particular, interleukin inhibitors have advantages in efficacy and safety compared to TNF-α inhibitors, such as IL-12/23 inhibitors, IL-17A inhibitors and IL-23p19 inhibitors. Ustekinumab Injection is one of the biologics with the fewest number of administrations for treating psoriasis with high convenience of use, good safety and tolerability, and long-lasting efficacy. Ustekinumab Injection has been marketed globally for 16 years, and has accumulated extensive application experience in various clinical trials and real-world studies for psoriasis.

The receipt of the notice of acceptance of supplemental application for Ustekinumab Injection for use in pediatric plaque psoriasis marks another important milestone in the research and development of the drug, which is conducive to the expansion of patient coverage and will further enhance the core competitiveness of the Company in treatment of autoimmune diseases. According to the requirements of national laws and regulations related to drug registration, after the supplemental application being accepted by the NMPA, the drug above will be assessed by the Center for Drug Evaluation of the NMPA, and can be put into production and sales after receiving the approval of the supplemental application for the drug. There are many uncertainties regarding the duration of drug review, the results of the review and the competitive landscape of the product market in the future. The Company will actively advance the relevant work and make timely disclosure of information based on the progress of research and development.

Shareholders and potential investors of the Company are advised to exercise caution when dealing in the shares of the Company.

By order of the Board
Qyuns Therapeutics Co., Ltd.
Qiu Jiwan
Chairman of the Board and Executive Director

Hong Kong, December 2, 2024

As at the date of this announcement, the board of directors of the Company comprises Mr. Qiu Jiwan as chairman and executive director, Mr. Wu Yiliang and Mr. Lin Weidong as executive directors, Mr. Yu Xi, Mr. Wu Zhiqiang and Dr. Xue Mingyu as non-executive directors, and Dr. Zou Zhongmei, Dr. Ling Jianqun and Mr. Fung Che Wai, Anthony as independent non-executive directors.