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)

INSIDE INFORMATION ANNOUNCEMENT

QX001S (SAILEXIN, USTEKINUMAB INJECTION) DRUG REGISTRATION CERTIFICATE APPROVED AND ISSUED BY THE NATIONAL MEDICAL PRODUCTS ADMINISTRATION

A. INTRODUCTION

This announcement is made by Qyuns Therapeutics Co., Ltd. (the "**Company**", together with its subsidiaries, the "**Group**") in accordance with Rule 13.09 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the "**Listing Rules**") and the Inside Information Provisions (as defined in the Listing Rules) under Part XIVA of the Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong).

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**"), and 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.

The board of directors (the "**Board**") of the Company is pleased to announce that on November 5, 2024, 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**"). 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. QX001S was initially developed independently by the Company. In August 2020, the Company reached a collaboration with Zhongmei Huadong to jointly advance the Phase III clinical trial of QX001S. Zhongmei Huadong, as the marketing authorization holder, is in charge of commercialization in Mainland China, while Cellularforce is in charge of production and supply of the product. QX001S is the first product approved for marketing in the Company's R&D pipeline, and it is also the first biosimilar drug of Ustekinumab Injection approved in China.

B. DETAILS OF THE DRUG AND THE APPROVAL

Common name:	Ustekinumab Injection
Trade name:	SAILEXIN
Form:	Injection
Specification:	Pre-filled syringes: 45mg (0.5ml)/piece
Registration classification:	Classification 3.3 of therapeutic biological products
Marketing authorization holder:	Zhongmei Huadong
Drug manufacturer:	Cellularforce
Drug approval number:	Guo Yao Zhun Zi (國藥准字) S20240050
Review conclusions:	According to the Drug Administration Law of the People's Republic of China and relevant regulations, upon review, this product meets the relevant requirements for drug registration, and is approved for registration and issued with a drug registration certificate.

C. ABOUT SAILEXIN (USTEKINUMAB INJECTION)

SAILEXIN 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-12Rβ1 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, as well as being sold by Janssen, a subsidiary of Johnson & Johnson, under the trade name of Stelara®. 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. Stelara® 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 and 2023 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 accepted in August 2023, and recently received approval. "A Multicenter, Randomized, Double-blind, Parallel-controlled Phase III Clinical Study Comparing the Efficacy and Safety of QX001S Injection and Ustekinumab Injection (Stelara®) in Adult Patients with Moderate-to-severe Plaque Psoriasis" has been completed with SAILEXIN, which is the first large-scale clinical study on the biosimilar drug of Ustekinumab Injection in China, providing further extensive clinical evidence and experience for the use of ustekinumab in Chinese population.

D. 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. At present, psoriasis treatment in China has entered the era of biologics, which have significant advantages over traditional treatment in terms of onset time, efficacy, safety, and treatment duration, and have played an active and effective role in treating severe, refractory, and special types of psoriasis. Among them, 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. The injection method for Ustekinumab Injection is an initial 45 mg subcutaneous injection, followed by the same dose after 4 weeks and every 12 weeks thereafter, and only four injections are needed per year over maintenance period, making it one of the biologics with the fewest number of injections for treating psoriasis currently available in clinical practice, and offering 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. With the approval of SAILEXIN for marketing, it is expected to provide more medication options for domestic patients with psoriasis and create a positive impact on the future performance improvement of the Company.

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

Hong Kong, November 5, 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.