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
PHASE II CLINICAL TRIAL DATA OF QX005N INJECTION FOR TREATMENT OF PRURIGO NODULARIS (PN) RELEASED AT THE 29TH ANNUAL MEETING OF CHINESE SOCIETY OF DERMATOLOGY

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 latest business developments of the Company.

The Company is pleased to announce that data from the Phase II clinical trial (CTR20223174) of QX005N, an injection for prurigo nodularis ("**PN**") was released through oral presentation at the 29th Annual Meeting of Chinese Society of Dermatology. This is the first clinical trial of biologic drug conducted by a Chinese domestic enterprise for the indication of PN in China. Based on the data from such trial, QX005N obtained the Breakthrough Therapy Designation by the Center for Drug Evaluation of the National Medical Products Administration on January 31, 2024.

This is a multi-center, randomized, double-blind and placebo-controlled Phase II clinical study to evaluate the efficacy and safety of QX005N injection administered by multiple subcutaneous injections in adult patients with PN and to observe PK characteristics, PD effects and immunogenicity. A total of 120 subjects were randomized 1:1:1:1 to the 300 mg group (first dose of 600 mg), 450 mg group, 600 mg group, and placebo group, and were administered once every two weeks for 16 weeks of treatment, followed by an 8-week follow-up period, for a total study length of 24 weeks. The primary endpoint of this trial was the percentage of patients with an improvement of ≥4 points in WI-NRS[1] score from baseline at week 16, and other efficacy metrics included IGA PN-S[2] score, IGA PN-A[3] score, etc.

[1] Worst Itch Numerical Rating Scale
[2] Investigator's Global Assessment Prurigo Nodularis Stage
[3] Investigator's Global Assessment Prurigo Nodularis Activity

The results of the study showed that the primary endpoint of this clinical trial was fully met in all dose groups. In terms of WI-NRS score, the percentage of patients who achieved an improvement of ≥4 points in WI-NRS score from baseline at week 16 in the 300 mg, 450 mg and 600 mg groups were 76.7%, 83.3% and 76.7%, respectively, which were significantly better than 30.0% in the placebo group, with a p-value of <0.0001, showing the significant efficacy of QX005N in relieving itch. In addition, QX005N had a rapid onset of action in the first week of administration, and the efficacy of itch improvement was maintained from completion of administration at week 16 to the end of follow-up at week 24.

In terms of improvement in skin lesions, the percentage of patients achieving an IGA PN-S score of 0 or 1 at week 16 was 26.7%, 30.0%, 16.7% and 6.7% in the 300 mg, 450 mg, 600 mg and placebo groups, respectively; and the percentage of patients achieving an IGA PN-A score of 0 or 1 at week 16 was 30.0%, 50.0%, 33.3% and 10.0%, both scores were significantly better in each dose group than in the placebo group.

In terms of safety, QX005N injection was administered for 16 weeks with good safety and tolerability, with no grade 3 or higher drug-related adverse events (AE), no drug-related serious adverse events (SAE), and no other specific safety signals observed.

ABOUT PRURIGO NODULARIS

PN is a chronic pruritus and inflammatory skin disease, which is clinically manifested as pruritus papules and nodules that are highly keratotic and symmetrically distributed on the limbs. The itchiness of the disease is more severe than that of other skin disorders such as atopic dermatitis, and scratching exacerbates the condition, making control of itching a core concern for patients. In addition, long-standing refractory pruritus has a profound psychological impact on patients and significantly impairs their quality of life. The etiology of the disease is currently unknown, and it can be induced by skin disorders, systemic diseases as well as neurological or psychogenic/psychological factors. According to Frost & Sullivan, the number of PN patients in China was approximately 2,000,000 in 2022. There exists urgent and substantial unmet clinical needs for treatment of the disease and there are no domestically developed innovative drugs available on the market.

ABOUT QX005N

QX005N is an innovative humanized monoclonal antibody targeting the human IL-4 receptor alpha subunit (IL-4R α). Through specific binding with IL-4R α, QX005N blocks the binding of IL-4R α with both IL-4 and IL-13, and also inhibits the signaling pathways and biological effects mediated by IL-4 and IL-13, thus exerting therapeutic effects on type 2 inflammatory allergic diseases. QX005N injection has received seven IND approvals for various indications, including moderate-to-severe atopic dermatitis in adults, PN and chronic rhinosinusitis with nasal polyps. Currently, QX005N Phase III clinical trials enrollments are underway for both moderate-to-severe atopic dermatitis in adults and PN.

Cautionary Statement as required by Rule 18A.08(3) of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited: There is no assurance that the Company will ultimately develop, market and/or commercialize QX005N successfully. 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.
Mr. Qiu Jiwan
Chairman of the Board and Executive Director

Hong Kong, June 14, 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.