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 III CLINICAL TRIAL OF QX002N FOR ANKYLOSING SPONDYLITIS REACHES PRIMARY ENDPOINT

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.

The board of directors (the "**Board**") of the Company is pleased to announce that Phase III clinical trial of QX002N injection independently developed by the Company for treatment of ankylosing spondylitis (AS) reached its primary endpoint. The data showed that QX002N exhibited excellent efficacy as well as good safety and tolerance in patients with moderate-to-severe active ankylosing spondylitis.

The trial is a multicentre, randomised, double-blind, placebo-controlled phase III clinical study led by Professor Zeng Xiaofeng of Peking Union Medical College Hospital to evaluate the efficacy and safety of QX002N injection in patients with active ankylosing spondylitis, and the initial analysis has been completed. A total of 641 subjects with moderate-to-severe active ankylosing spondylitis were enrolled in the study, including 322 in the QX002N group and 319 in the placebo group.

A. INITIAL ANALYSIS RESULTS OF THE TRIAL

Primary efficacy endpoint:	The ASAS40 response rate at week 16 in the treatment group receiving 160 mg of QX002N administered every four weeks (Q4W) was 40.4%, which was significantly higher than the 18.9% in the placebo group ($P < 0.0001$).
Key secondary endpoint:	There was a significant difference in the ASAS20 response rate between the two groups at week 16 (65.2% QX002N vs. 41.3% placebo; $P < 0.0001$).
Safety:	During the 16-week double-blind treatment period, most treatment-emergent adverse events (TEAEs) in the QX002N group were Grade I-II, and the incidence of adverse events (AEs) was comparable to that of marketed drugs in the same class, with no new safety signals identified.

B. ABOUT QX002N INJECTION

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. According to Frost & Sullivan, there were approximately 3.9 million AS patients in China in 2021, with an estimated increase to 4 million by 2030. Currently, biologics approved for clinical treatment of AS in China are limited to TNF inhibitors and IL-17 inhibitors, both recommended for AS patients with persistent disease activity despite non-steroidal anti-inflammatory drug therapy. Among these biologics, IL-17A inhibitors demonstrate significant clinical benefits for both TNF-α inhibitor-naïve patients and those who are intolerant to or unable to achieve adequate disease control with TNF-α inhibitors.

QX002N is a high-affinity monoclonal antibody targeting IL-17A. IL-17A is a member of the IL-17 superfamily of cytokines and a key player in the pathological mechanism of various autoimmune diseases. IL-17A enhances chronic inflammation by inducing the release of and working in synergy with pro-inflammatory cytokines such as interleukin-6 (IL-6) and chemokine CXCL1. Additionally, IL-17A is involved in the regulatory mechanism of bone remodeling and has been identified as a major factor in AS pathogenesis. QX002N injection 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 IL-17RA and IL-17RC, and preventing the subsequent activation of several pro-inflammatory signaling pathways, thereby inhibiting the onset and progression of inflammation.

Achievement of primary endpoint in Phase III clinical trial of QX002N injection for treatment of AS is an important milestone for the project, and the Company will actively facilitate the subsequent research and development 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.
Mr. Qiu Jiwan
Chairman of the Board and Executive Director

Hong Kong, February 24, 2025

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 and Mr. Wu Zhiqiang as non-executive directors, and Dr. Zou Zhongmei, Dr. Ling Jianqun and Mr. Fung Che Wai, Anthony as independent non-executive directors.