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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
APPROVALS OF MARKETING AUTHORISATION APPLICATION AND
SUPPLEMENTAL APPLICATION FOR QX001S
(USTEKINUMAB INJECTION)
FOR USE IN CROHN'S DISEASE

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 announcements published by the Company on November 5, 2024, December 2, 2024, February 12, 2025 and March 3, 2025.

The board of directors (the “**Board**”) of the Company is pleased to announce that recently, Zhongmei Huadong received the Drug Registration Certificate and the Notice of Approval of Supplemental Application for Drugs from the National Medical Products Administration (NMPA), and the marketing authorisation application and supplemental application for Ustekinumab Injection (Intravenous Infusion) (trade name: SAIJIENING) and Ustekinumab Injection (trade name: SAILEXIN; R&D code: QX001S/HDM3001-2) for use in Crohn's disease were approved.

A. BASIC INFORMATION OF THE DRUG

Common name	Ustekinumab Injection	Ustekinumab Injection (Intravenous Infusion)
Trade name	SAILEXIN	SAIJIENING
Application	Supplemental application for domestically manufactured drugs	Registration for domestically manufactured drugs
Form	Injection	Injection
Specification	Pre-filled syringes: 45mg (0.5ml)/piece	130mg (26ml)/vial
Acceptance No.	CYSB2500041	CXSS2500028
Drug approval number	Guo Yao Zhun Zi S20240050	Guo Yao Zhun Zi S20260029
Registration classification	Classification 3.3 of therapeutic biological products	
Indication	Crohn's disease. This product is indicated for adult patients with moderate-to-severe active Crohn's disease who are under-responsive, unresponsive or intolerant to conventional therapy or tumor necrosis factor α (TNF- α) antagonists.	
Marketing authorization holder/ manufacturer	Zhongmei Huadong/Cellularforce	
Review conclusions	<p>According to the Drug Administration Law of the People's Republic of China and relevant regulations, upon review, the application for the product meets the relevant requirements for drug registration, and is hereby approved for addition of indication with details as follows: this product is indicated for adult patients with moderate-to-severe active Crohn's disease who are under-responsive, unresponsive or intolerant to conventional therapy or tumor necrosis factor α (TNF-α) antagonists.</p>	<p>According to the Drug Administration Law of the People's Republic of China and relevant regulations, upon review, the product meets the relevant requirements for drug registration, and is hereby approved for registration with issuance of the Drug Registration Certificate.</p>

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 β 1 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 continued to be included in the 2025 NRDL.

The Phase III clinical trial and R&D of QX001S/HDM3001 was jointly advanced by the Company and Zhongmei Huadong. 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 (trade name: SAILEXIN), which is the first biosimilar drug of Ustekinumab Injection approved in China. In March 2025, the supplemental application for SAILEXIN to add the new indication of pediatric plaque psoriasis has been approved.

C. IMPACT ON THE COMPANY

Crohn's disease (CD) is a chronic inflammatory granulomatous disease with undetermined etiology involving the entire digestive tract and is classified as an inflammatory bowel disease (IBD). As a chronic and disabling disease, the common symptoms of CD are cramping abdominal pain, chronic diarrhea, fever, etc. Extra-intestinal abnormalities such as arthritis may also occur, and may be complicated by fistula, abdominal abscess, intestinal stenosis, intestinal obstruction, intestinal perforation, and perianal lesions, which can seriously affect the quality of life of patients. The incidence of CD is high in developed countries such as North America and Western Europe. The annual incidence rate has been reported to be as high as 29.3 per 100,000 people. The incidence rate in Asia is lower, but shows a clear and continuous upward trend. A study in 2023 reported that the incidence of Crohn's disease in urban areas of China was approximately 0.71 per 100,000 people, with a male prevalence at the age of 30 to 34 years and a female prevalence at the age of 25 to 29 years.

Currently, CD pharmacological therapy is mainly based on the use of glucocorticoids, immunosuppressive agents, biologics and small molecule drugs. Over the past 20 years, biologics have gained importance in the therapeutic field of IBD (Crohn’s disease and ulcerative colitis). According to the China Crohn’s Disease Diagnosis and Treatment Guidelines (2023, Guangzhou) (the “**2023 Diagnosis and Treatment Guidelines**”), it is recommended that patients with CD with high-risk factors or patients with mild active CD who have failed traditional medication may consider the use of biologics for remission-inducing treatment. For patients with high-risk factors, a “step-down” treatment strategy of early and aggressive intervention with biologics is advocated. Studies support that early treatment (within 2 years of CD diagnosis) with biologics in this group of patients results in higher clinical remission rates, lower recurrence rates, and higher mucosal healing rates than later treatment with biologics. The 2023 Diagnosis and Treatment Guidelines also recommended ustekinumab for induction of remission in patients with moderate-to-severe active CD and for the treatment of CD with associated anal fistula. Patients with CD who are recommended to use biologics to induce remission are recommended to continue maintenance therapy with the same biologics; biologics are effective in preventing and treating postoperative CD recurrence, and it is recommended that biologics that are effective preoperatively be continued in the postoperative period.

The approval of QX001S for the additional indication of Crohn’s disease will not have a material impact on the Company’s current financial condition and operating results, and the sales of the product in the future are subject to various factors such as changes in industry policies, market demand and competitive landscape, which may lead to uncertainty regarding the Company’s profit. The Company will actively ensure the supply of the product and fully support the commercialisation of the product.

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, May 21, 2026

As at the date of this announcement, the Board 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 Mr. Fung Che Wai, Anthony, Dr. Zou Zhongmei and Dr. Ling Jianqun as independent non-executive directors.