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四环医药
SihuanPharm

Sihuan Pharmaceutical Holdings Group Ltd.

四環醫藥控股集團有限公司

(incorporated in Bermuda with limited liability)

(Stock Code: 0460)

VOLUNTARY ANNOUNCEMENT RESULTS OF PHASE III CLINICAL DATA OF DIROZALKIB FOR THE FIRST-LINE TREATMENT OF ALK POSITIVE ADVANCED NSCLC PRESENTED AT THE 2026 AACR

The board of directors (the “**Board**”) of Sihuan Pharmaceutical Holdings Group Ltd. (the “**Company**” or “**Sihuan Pharmaceutical**”, together with its subsidiaries, the “**Group**”) is pleased to announce that, Xuanzhu Biopharmaceutical Co., Ltd. (“**Xuanzhu Biopharm**”, stock code: 02575.HK), a non wholly-owned subsidiary of the Group, has presented the results of the Phase III clinical trial of dirozalkib for the first-line treatment of anaplastic lymphoma kinase (“**ALK**”)-positive advanced non-small cell lung cancer (“**NSCLC**”) (the “**DIAMOND-2 Study**”) in an oral presentation at the 2026 American Association for Cancer Research Annual Meeting (“**2026 AACR**”) held from 17 April 2026 to 22 April 2026, 2026.

The DIAMOND-2 Study (NCT05204628) is a multicenter, randomized, open-label Phase III clinical trial conducted in the People’s Republic of China, using crizotinib as the active comparator, to evaluate the efficacy and safety of dirozalkib versus crizotinib in the first-line treatment of patients with ALK-positive advanced NSCLC. A total of 275 subjects were enrolled in the study and randomized 1:1 to receive dirozalkib (500 mg once daily) or crizotinib (250 mg twice daily). The primary endpoint was progression-free survival (“**PFS**”) assessed by the investigator, and the secondary endpoints included objective response rate (“**ORR**”), duration of response (“**DoR**”), intracranial objective response rate (“**IC-ORR**”) and safety.

Data presented at 2026 AACR showed that dirozalkib demonstrated statistically and clinically significant efficacy advantages in the first-line treatment of ALK-positive advanced NSCLC. In the modified intention-to-treat (“**mITT**”) population, the investigator-assessed median PFS was 31.3 months in the dirozalkib group, significantly longer than 12.9 months in the control group, representing a 53% reduction in the risk of disease progression (HR=0.47, P<0.0001). Meanwhile, the ORR of the dirozalkib group was 88.5%, median DoR was 32.10 months, and disease control rate (“**DCR**”) was 95.4%, indicating significantly deeper and more durable tumor responses versus the control group.

In patients with measurable intracranial lesions at baseline, dirozalkib exhibited prominent intracranial anti-tumor activity, with an IC-ORR of 91.7% compared with only 11.1% in the control group. Dirozalkib also significantly prolonged intracranial PFS and reduced the risk of intracranial disease progression by 55% (HR=0.45, P=0.0003). In terms of safety, dirozalkib demonstrated a favorable overall tolerability profile, with mostly Grade 1–2 gastrointestinal adverse events, and the proportion of patients who discontinued treatment due to dirozalkib-related adverse events was only 1.5%, supporting its favorable clinical safety profile.

ABOUT DIROZALKIB

Dirozalkib tablets (trade name: Xuan Fei Ning) are a next-generation oral ALK inhibitor independently developed by Xuanzhu Biopharm, specifically designed for the treatment of ALK rearranged advanced non-small cell lung cancer (NSCLC). Dirozalkib features a novel molecular structure with stronger affinity for the ATP-binding site within the ALK kinase domain, demonstrating potent inhibitory activity against common resistance mutations associated with first-generation and most second-generation ALK inhibitors, including G1202R and I1171N, and is capable of achieving significant intracranial anti-tumor efficacy through efficient penetration of the blood-brain barrier. In August 2025, Dirozalkib was approved by the NMPA for the treatment of patients with ALK-positive locally advanced or metastatic NSCLC who have not been previously treated with an anaplastic lymphoma kinase (ALK) inhibitor.

ABOUT XUANZHU BIOPHARM

Xuanzhu Biopharm was listed on the Main Board of The Stock Exchange of Hong Kong Limited in October 2025 (stock code: 02575.HK). It is an innovative pharmaceutical company rooted in China with a global perspective, focusing on major diseases such as digestion, oncology and non-alcoholic steatohepatitis, and is committed to the research and development (“**R&D**”), production and commercialization of class 1 innovative drugs with core proprietary intellectual property rights. The company has a first-class R&D team that all core personnel have years of experience in new drug R&D. The company has two R&D platforms: small molecule chemistry and large molecule biopharmaceuticals. The dual engines drive the company’s innovation and development, forming a product pipeline that covers small molecule chemistry, large molecule biopharmaceuticals, antibody-drug conjugate (ADC) and other types of products. With a focus on unmet major clinical needs, the company is committed to developing into a first class innovative pharmaceutical company with independent R&D, production, and sales capabilities.

ABOUT SIHUAN PHARMACEUTICAL

Founded in 2001 and listed on the Main Board of The Stock Exchange of Hong Kong Limited in 2010, Sihuan Pharmaceutical is an international medical aesthetic and pharmaceutical company led by innovation, with an independent and leading research and development technology platform, a rich global product pipeline, strong product registration capability, a full dosage form production platform with high efficiency and low cost and a mature and excellent sales system. Adhering to the overall strategic goal for the “full promotion of a two-wheel drive strategy of its medical aesthetics and biopharmaceutical businesses”, Sihuan Pharmaceutical endeavors to build itself into a leading medical aesthetics and biopharmaceutical company in China.

This announcement is being made by the Company on a voluntary basis to update the investing public on the Group’s latest business development, and does not constitute, and is not intended to be, an advertisement regarding the use of any medicine, surgical appliance, treatment or orally consumed product.

By order of the Board
Sihuan Pharmaceutical Holdings Group Ltd.
Dr. Che Fengsheng
Chairman and Executive Director

Hong Kong, 20 April 2026

As at the date of this announcement, the executive directors of the Company are Dr. Che Fengsheng (Chairman), Dr. Guo Weicheng (Deputy Chairman and Chief Executive Officer), Dr. Zhang Jionglong, Ms. Chen Yanling and Ms. Miao Guili; and the independent non-executive directors of the Company are Mr. Tsang Wah Kwong, Dr. Zhu Xun and Mr. Wang Guan.