Xuanzhu Biopharmaceutical Co., Ltd.
軒竹生物科技股份有限公司

(a joint stock company incorporated in the People's Republic of China with limited liability)

(Stock Code: 2575)

VOLUNTARY ANNOUNCEMENT RESULTS OF PHASE III CLINICAL DATA OF DIROZALKIB FOR THE FIRST-LINE TREATMENT OF ALK POSITIVE ADVANCED NON-SMALL CELL LUNG CANCER PRESENTED AT THE 2026 AACR

The board of directors (the "**Board**") of Xuanzhu Biopharmaceutical Co., Ltd. (the "**Company**", together with its subsidiaries, the "**Group**") is pleased to announce that 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 April 17, 2026 to April 22, 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 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 the Group, 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.

This announcement is a voluntary announcement made by the Company for the purpose of keeping its shareholders and potential investors informed of the Group's latest business developments and does not contain any advertisement or intention regarding the use of any drugs, surgical equipment, treatments, or oral products.

By order of the Board
Xuanzhu Biopharmaceutical Co., Ltd.
Ms. Xu Yanjun
Chairperson of the Board and executive Director

Hong Kong, April 19, 2026

As of the date of this announcement, the Board comprises (i) Ms. Xu Yanjun, Dr. Li Jia Kui and Dr. Shih Cheng-Kon as executive directors; (ii) Ms. Li Huiying, Mr. Yu Lifeng and Ms. Chen Yanling as non-executive directors; and (iii) Mr. Liu Shuo, Ms. Wang Yu and Mr. Fan Chi Chiu as independent non-executive directors.