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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 THE INNOVATIVE DRUG DIROZALKIB TABLETS INDEPENDENTLY DEVELOPED BY XUANZHU BIOPHARM OBTAINED DRUG REGISTRATION APPROVAL FROM NMPA

The board of directors (the “**Board**”) of Sihuan Pharmaceutical Holdings Group Co., Ltd. (the “**Company**” or “**Sihuan Pharmaceutical**”, together with its subsidiaries, the “**Group**”) is pleased to announce that the Class 1 innovative drug anaplastic lymphoma kinase (ALK) inhibitor Dirozalkib Tablets (formerly known as “Dexitinib”, XZP-3621, brand name: Xuan Fei Ning) independently developed by the Group’s non-wholly owned subsidiary Xuanzhu Biopharmaceutical Co., Ltd. (“**Xuanzhu Biopharm**”), has obtained a drug registration approval from the National Medical Products Administration (the “**NMPA**”) for the treatment of ALK-positive advanced non-small cell lung cancer (“**NSCLC**”). **This product is the third Class 1 innovative drug approved for launch by Xuanzhu Biopharm, and also the second Class 1 innovative anti-tumor drug approved for launch by Xuanzhu Biopharm, this marks the continuous leap from breast cancer to lung cancer targeted treatment in the oncology research and development (“R&D”).**

Dirozalkib has four core advantages, including (1) Rapid onset of action: Dirozalkib significantly improves the bioavailability through its unique molecular structure design, which can quickly inhibit tumor progression and secure a critical treatment window for patients. (2) With excellent anti-tumor performance: In pivotal Phase III clinical trials, Dirozalkib demonstrated significantly superior efficacy compared to the marketed first- and second-generation ALK inhibitors in the treatment of ALK-positive advanced NSCLC patients, and showed strong inhibitory activity against drug-resistant mutations including G1202R and I1171N. (3) Persistent relief: The patient’s benefit time was significantly prolonged, laying a foundation for long-term disease stability. (4) Significant survival benefits: Dirozalkib can truly achieve the goal of “chronic disease management”.

In addition, Dirozalkib has successfully solved clinical problems and achieved a dual breakthrough in brain metastasis control and safety. It can penetrate the blood-brain barrier efficiently, effectively compensating for the shortcomings of existing therapies in central nervous system protection. In terms of safety, Dirozalkib has shown significant advantages, the main adverse reactions are diarrhea and vomiting, mostly of grade 1–2, which can be relieved or cured through symptomatic treatment and/or dosage adjustment. In addition, the risks of pleural effusion and liver toxicity were significantly reduced, which significantly improved the long-term medication adherence of patients.

According to data from China Insights Consultancy(CIC), there was about 91,200 ALK-positive NSCLC patients in China in 2024, and it is expected to reach 121,700 by 2032, with a compound annual growth rate of 3.7%; In 2024, the market size of ALK inhibitors in China was approximately RMB4.7 billion, and it is predicted to increase to RMB8.9 billion by 2032, with a compound annual growth rate of 8.3%.

Dirozalkib approved for launch this time, it is not only an important milestone in R&D of Xuanzhu Biopharm's innovative drug pipeline, but also provides a breakthrough treatment option for ALK-positive NSCLC patients in China. With its significant clinical advantages, it will effectively improve the quality of life of patients, accelerating the achievement of the cancer prevention and control goal of "Healthy China 2030".

ABOUT XUANZHU BIOPHARM

Xuanzhu Biopharm is the innovative drug subsidiary of Sihuan Pharmaceutical. It is an innovative pharmaceutical company with roots in China and a global perspective, focusing on major diseases such as digestion, oncology and non-alcoholic steatohepatitis, and is committed to the research and development, production and commercialization of class 1 drugs with core proprietary intellectual property rights. The company has a first-class R&D team, all core personnel have years of experience in new drug research and development. The company has two R&D platforms: small molecule chemistry and large molecule biologics. 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 research and development, 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, 22 August 2025

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.