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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 APPROVAL TO INITIATE A PHASE III CLINICAL TRIAL FOR NEW INDICATION OF ANAPRAZOLE SODIUM

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 recently been approved by the Center for Drug Evaluation (“**CDE**”) of the National Medical Products Administration of the People’s Republic of China (“**China**”) to initiate a Phase III clinical trial of bismuth-containing quadruple therapy comprising Anaprazole Sodium Enteric-coated Tablets (trade name: An Jiu Wei) for the eradication of *Helicobacter pylori*.

This Phase III clinical trial is a multi-centre, randomized, double-blind, double-dummy, active-drug parallel-controlled trial, which plans to enroll 556 adult subjects positive for *Helicobacter pylori*. Using bismuth-containing quadruple therapy containing esomeprazole magnesium as the active control, the trial aims to evaluate the efficacy, safety and population pharmacokinetic characteristics of bismuth-containing quadruple therapy containing anaprazole sodium administered continuously for 14 days for the eradication of *Helicobacter pylori*. The primary endpoint is the eradication rate of *Helicobacter pylori* confirmed by ¹³C-urea breath test (“**¹³C-UBT**”) on day 28 after the completion of treatment.

Helicobacter pylori is a Gram-negative microaerophilic pathogenic bacterium closely associated with a variety of gastric diseases, including gastric ulcer, chronic progressive gastritis and gastric cancer. According to Frost & Sullivan, the infection rate of *Helicobacter pylori* in China is approximately 44%, and the market size of drugs for the treatment of *Helicobacter pylori* infection continues to expand. The market size reached RMB5.5 billion in 2024, and is projected to increase to RMB6.8 billion in 2029 and reach RMB12.6 billion in 2035.

The approval of the Phase III clinical trial application for the new indication of Anaprazole Sodium helps to expand the product's indication scope, enhance Xuanzhu Biopharm's influence in the field of digestive disease treatment, and is of great significance to the long-term development and commercialization layout of Xuanzhu Biopharm.

ABOUT ANAPRAZOLE SODIUM ENTERIC-COATED TABLETS

Anaprazole Sodium Enteric-coated Tablets (trade name: An Jiu Wei) was approved for marketing by the National Medical Products Administration of China in June 2023 for the treatment of patients with duodenal ulcer. Anaprazole Sodium features an innovative structural design with characteristics including non-enzymatic plus multi-enzymatic metabolism and balanced intestinal-renal dual-channel excretion, with only 3.5% metabolized through CYP2C19, making it unaffected by CYP2C19 gene polymorphism. Compared with previous generations of proton pump inhibitors, Anaprazole Sodium has lower risk of drug-drug interactions, making it a safer choice for patients on multiple medications and those with renal impairment, and is a proton pump inhibitor more suitable for the Chinese population. As a Class 1 innovative drug in China, Anaprazole Sodium fills the gap in domestically developed proton pump inhibitors, bringing treatment options with both superior efficacy and safety to Chinese patients. In addition to the approved indication for duodenal ulcer, the phase III clinical study in China of Anaprazole Sodium Enteric-coated Tablets for the treatment of reflux esophagitis was fully launched in July 2025, and has successfully completed the enrolment of all subjects.

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, 15 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.