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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
COMPLETION OF FIRST PATIENT ENROLLMENT IN PHASE III CLINICAL TRIAL FOR NEW INDICATION OF INNOVATIVE DRUG ANAPRAZOLE SODIUM IN REFLUX ESOPHAGITIS

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 Phase III clinical study (the "**Study**") of Anaprazole Sodium Enteric Coated Tablets (brand name: An Jiu Wei), a Class 1 innovative drug independently developed by the Group's non-wholly owned subsidiary, XuanZhu BioPharm Co., Ltd. ("**XuanZhu BioPharm**"), has completed the enrollment of its first patient for the treatment of reflux esophagitis. This marks **the second indication** being expanded for Anaprazole Sodium Enteric Coated Tablets..

This Study is a multicenter, randomized, double-blind, positive drug controlled phase III clinical trial evaluating the use of Anaprazole Sodium Enteric Coated Tablets in patients with reflux esophagitis. The study was led by Shanghai Changhai Hospital, with Academician Li Zhaoshen and Professor Du Yiqi serving as co-leading principal investigators, and is being conducted in collaboration with the gastroenterology departments of 32 authoritative institutions, including Peking Union Medical College Hospital, Ruijin Hospital affiliated to Shanghai Jiaotong University School of Medicine, and Qilu Hospital of Shandong Province, etc. The study aims to comprehensively evaluate the efficacy and long-term safety of Anaprazole Sodium Enteric Coated Tablets in treating reflux esophagitis, and provide key data to support the approval of this new indication.

Anaprazole Sodium Enteric Coated Tablets is a new generation proton pump inhibitor (PPI) drug independently developed by XuanZhu BioPharm, with global intellectual property rights. It is currently the first and only PPI fully independently developed in China, and the only innovative PPI drug in the country (with no generic versions approved to date). The drug offers the advantages such as multiple-enzyme and non-enzyme metabolism, dual-channel excretion (intestinal and renal), low risk of drug-drug interactions, and minimal impact from genetic polymorphism. According to the "Standardized Treatment of Gastroesophageal Reflux Disease in the Elderly" published in June 2025, elderly patients and those with renal insufficiency may benefit more from Anaprazole Sodium treatment for reflux esophagitis.

According to data from China Insights Consultancy (CIC), the number of patients with peptic ulcers (about 75% of which are duodenal ulcers) in China is estimated about 74.3 million in 2024, and is projected to increase to 81.2 million by 2032; The number of patients with reflux esophagitis in China is about 38.3 million, and it is expected to increase to 42.4 million by 2032. The indication of Anaprazole Sodium Enteric Coated Tablets for the treatment of duodenal ulcers has been approved for launch by the National Medical Products Administration (NMPA) in June 2023 and has commercialized. The expansion into this new indication is expected to significantly broaden the market potential in the future and create commercial synergies. At present, the market size of oral PPI in China exceeds RMB10 billion. Given its large target patient population and outstanding clinical performance, Anaprazole Sodium Enteric Coated Tablets is anticipated to hold substantial clinical and commercial value in the future.

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, 30 July 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.