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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

NDA ACCEPTED BY NMPA FOR THE NEW INDICATION OF XUANZHU BIOPHARM'S ANAPRAZOLE SODIUM FOR THE TREATMENT OF REFLUX ESOPHAGITIS

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 the New Drug Application (“**NDA**”) for the new indication of Anaprazole Sodium Enteric-coated Tablets (trade name: An Jiu Wei (安久衛®)), a Class 1 innovative drug independently developed by Xuanzhu Biopharmaceutical Co., Ltd. (“**Xuanzhu Biopharm**”, stock code: 02575.HK), a non wholly-owned subsidiary of the Group, for the treatment of adult reflux esophagitis (“**RE**”) has been formally accepted by the National Medical Products Administration (“**NMPA**”) recently.

The acceptance of the NDA is based on the results of a Phase III registration clinical study conducted in Mainland China, which was a multi-centre, randomized, double-blind, double-dummy, active-controlled trial. The study used rabeprazole sodium as the active control, and the primary efficacy endpoint was the investigator-assessed endoscopic healing rate of RE at Week 8. Results showed that the healing rate was 88.4% (95% CI: 84.3%–92.5%) in the anaprazole sodium 60 mg group versus 84.6% (95% CI: 80.0%–89.2%) in the rabeprazole sodium 20 mg group, with a rate difference of 3.8% (95% CI: -2.4%–10.0%). The trial met its predefined primary endpoint, and the healing rate in the anaprazole sodium group was numerically higher than that in the control group.

Reflux esophagitis is a common subtype of gastroesophageal reflux disease characterized by mucosal erosion and damage, with typical symptoms of heartburn and regurgitation that severely impair patients' quality of life. Long-term recurrent episodes may lead to complications including esophageal stricture and Barrett's esophagus. According to China Insights Consultancy data, the prevalence of RE in China increased from 36.7 million in 2018 to 38.3 million in 2024, and is projected to reach 42.4 million in 2032, representing a large and growing clinical demand. RE is the second indication for which an NDA has been submitted for anaprazole sodium following duodenal ulcer, and is meaningful to fully unlocking its clinical value as a next-generation proton pump inhibitor. Upon approval, it is expected to provide a new and effective acid-suppressive treatment option for patients with RE, further enhancing the product's competitiveness and commercial potential.

ABOUT ANAPRAZOLE SODIUM ENTERIC-COATED TABLETS

Anaprazole Sodium Enteric-coated Tablets (trade name: An Jiu Wei (安久衛®)) was approved for marketing by the NMPA 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 of duodenal ulcer and the RE indication for which NDA is accepted for review herein, the Phase III clinical study in China of Anaprazole Sodium Enteric-coated Tablets for the eradication of *Helicobacter pylori* has recently successfully completed first patient dosing.

ABOUT XUANZHU BIOPHARM

Xuanzhu Biopharm was listed on the Main Board of the Stock Exchange of Hong Kong Limited in 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, 30 June 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.