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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 PHASE III CLINICAL STUDY DATA OF XUANZHU BIOPHARM'S ANAPRAZOLE SODIUM FOR REFLUX ESOPHAGITIS PRESENTED AT UEG WEEK 2026

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 results from the Phase III registration clinical study of Anaprazole Sodium Enteric-coated Tablets, 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 reflux esophagitis were presented in the form of a Late-Breaking Abstract (LB25) oral presentation at the 34th UEG Week 2026 held in Barcelona, Spain.

This is a multi-centre, randomized, double-blind, double-dummy, active-controlled non-inferiority trial. A total of 500 subjects were randomized, of whom 467 were included in the Full Analysis Set (the “**FAS**”). Subjects were randomised in a 1:1 ratio to receive once-daily treatment with either Anaprazole Sodium or Rabeprazole Sodium. Notably, unlike previous studies that largely enrolled patients with mild Los-Angeles (LA) Grade A disease, this study enrolled only patients with LA Grade B-D moderate-to-severe erosive esophagitis and prospectively required no less than 20% of subjects to be LA Grade C/D. The enrolment criteria are among the strictest among publicly-available registration studies for comparable products. Given the more severe oesophageal mucosal injury and higher treatment difficulty of the study population, the efficacy data generated under such conditions carry greater clinical reference value.

Study results demonstrated that Anaprazole Sodium not only met the pre-defined primary endpoint, but also achieved numerically higher Week 8 endoscopic healing rates versus the active comparator Rabeprazole Sodium in both the FAS and Per-Protocol Set (the “PPS”), showing a trend of therapeutic benefit:

- Full Analysis Set (FAS): 88.4% in the Anaprazole Sodium group versus 84.6% in the Rabeprazole Sodium group, adjusted risk difference of 3.8% (95% CI: -2.3%-10.0%);
- Per-Protocol Set (PPS): 93.9% in the Anaprazole Sodium group versus 89.4% in the Rabeprazole Sodium group, adjusted risk difference of 4.8% (95% CI: -0.4%-10.0%).

The lower bounds of the confidence intervals (-2.3% and -0.4%) were well above the pre-specified non-inferiority margin of -10%, supporting a robust non-inferiority conclusion. Of note, the lower bound of the confidence interval for the PPS was close to zero. In this trial with strict enrolment of moderate-to-severe patients, the point-estimates for key efficacy endpoints of Anaprazole Sodium were higher than those of Rabeprazole Sodium, demonstrating a trend of therapeutic benefit. In addition, the Week 4 healing rate in the PPS reached 81.6%, indicating potential for early treatment benefit. Efficacy trends were consistent across all pre-specified subgroups, and the findings were robust. In terms of safety, all treatment-related adverse events were Grade 1–2, with no Grade 3 or above drug-related adverse events reported.

The clinical data for the treatment of reflux esophagitis were presented at the Late-Breaking session of UEG Week 2026, marking that the evidence-base of Anaprazole Sodium has garnered attention and recognition from international academic platforms and is expected to offer new treatment options for patients worldwide.

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 and the reflux-esophagitis indication for which the New Drug Application has been accepted, the Phase III clinical study of Anaprazole Sodium Enteric-coated Tablets for *Helicobacter pylori* eradication in China is progressing in parallel.

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 enterprise rooted in China with a global-minded vision. Focusing on major disease areas including gastroenterology, oncology and metabolism, the company is committed to the research and development (“**R&D**”), production and commercialisation of Class 1 new drugs with core independent intellectual property rights. As an R&D-driven commercial-stage biotech innovator empowered by AI, the company has built a synergistic technical system integrating small-molecule drug R&D platforms, biologic drug R&D platforms and AI-driven drug discovery platforms. This enables it to maintain one of the rare domestic product pipelines covering multiple modalities such as small-molecule chemicals, large-molecule biologics and antibody-drug conjugates (ADCs). Guided by unmet clinical needs, the company strives to evolve into a first-class innovative pharmaceutical enterprise with in-house capabilities for research-and-development, manufacturing and sales.

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 aesthetics 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, 21 October 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 and Ms. Chen Yanling; the non-executive director of the Company is Mr. Che Yuxuan; and the independent non-executive directors of the Company are Mr. Tsang Wah Kwong, Dr. Zhu Xun and Mr. Wang Guan.