CSPC PHARMACEUTICAL GROUP LIMITED
石藥集團有限公司

(Incorporated in Hong Kong with limited liability)

(Stock Code: 1093)

VOLUNTARY ANNOUNCEMENT

NEW DRUG APPLICATION FOR KN026 (ANBENITAMAB INJECTION) ACCEPTED BY THE NMPA

The Board of Directors (the "**Board**") of CSPC Pharmaceutical Group Limited (the "**Company**", together with its subsidiaries, the "**Group**") is pleased to announce that the new drug application for KN026 (Anbenitamab Injection) (the "**Product**") co-developed by CSPC Shanghai JMT-Bio Technology Co., Ltd., a subsidiary of the Company, and Jiangsu Alphamab Oncology Co., Ltd. has been accepted by the National Medical Products Administration (the "**NMPA**") of the People's Republic of China.

The Product has been applied for as a Class 1 therapeutic biological product. Its indication is for use in combination with chemotherapy for the treatment of patients with HER2-positive locally advanced, recurrent, or metastatic gastric or gastroesophageal junction cancer who have failed at least one prior systemic therapy (which must include trastuzumab in combination with chemotherapy). Previously, the Product was granted Breakthrough Therapy Designation on 4 November 2023 and Priority Review on 28 August 2025 by the Center for Drug Evaluation of the NMPA.

The Product is an anti-HER2 bispecific antibody that can simultaneously bind two non-overlapping epitopes of HER2, leading to HER2 signaling blockade. The results of a Phase II clinical trial of the Product were first presented at the European Society for Medical Oncology (ESMO) Congress 2024. The study results demonstrated that the Product in combination with chemotherapy achieved an objective response rate of 40.0%, with a median progression-free survival of 8.6 months and a median overall survival of 13.2 months as assessed by the Independent Review Committee (IRC). This new drug application is primarily based on a pivotal Phase II/III clinical trial (KC-WISE). The first interim analysis results of the Phase III clinical study indicated that, compared to the current standard of care, the Product in combination with chemotherapy significantly improved clinical efficacy by prolonging progression-free survival and overall survival, with no new safety signals, a low incidence of cardiotoxicity, and low immunogenicity in terms of safety profile.

Currently, there are no approved anti-HER2 drugs for the second-line treatment of HER2-positive gastric cancer. The Product is the first anti-HER2 bispecific antibody drug in China to achieve positive results in the second-line treatment of gastric cancer. Based on the first interim analysis results of the pivotal Phase II/III clinical study (KC-WISE) of the Product, the Group submitted the new drug application to the NMPA on 7 September 2025. Meanwhile, the Group is also actively promoting multiple clinical trials of the Product for different indications of solid tumors, among which the development for indications of gastric cancer and breast cancer has entered the pivotal Phase III clinical trial stage, with the aim of benefiting more patients.

By Order of the Board
CSPC Pharmaceutical Group Limited
CAI Dong Chen
Chairman

Hong Kong, 11 September 2025

As at the date of this announcement, the Board comprises Mr. CAI Dong Chen, Mr. ZHANG Cuilong, Mr. WANG Zhenguo, Mr. PAN Weidong, Mr. WANG Huaiyu, Dr. LI Chunlei, Dr. YAO Bing, Mr. CAI Xin and Mr. CHEN Weiping as executive directors; and Mr. WANG Bo, Mr. CHEN Chuan, Prof. WANG Hongguang, Mr. AU Chun Kwok Alan, Mr. LAW Cheuk Kin Stephen and Ms. LI Quan as independent non-executive directors.