

*Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.*



## **CSPC PHARMACEUTICAL GROUP LIMITED**

**石藥集團有限公司**

*(Incorporated in Hong Kong with limited liability)*

**(Stock Code: 1093)**

### **VOLUNTARY ANNOUNCEMENT**

#### **PIVOTAL PHASE II/III CLINICAL STUDY OF KN026 MET PRIMARY ENDPOINT OF PROGRESSION-FREE SURVIVAL (PFS) AT INTERIM ANALYSIS**

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 pivotal Phase II/III clinical study of KN026, a recombinant humanised anti-HER2 bispecific antibody injection co-developed by the Company’s subsidiary, Shanghai JMT-Bio Technology Co., Ltd., and Jiangsu Alphamab Oncology Co., Ltd., for the treatment of patients with HER2-positive locally advanced, recurrent, or metastatic gastric or gastroesophageal junction adenocarcinoma who have received and failed at least one prior systemic treatment (which must include trastuzumab in combination with chemotherapy) (KC-WISE), has met the pre-specified primary endpoint of progression-free survival (PFS) as evaluated by an Independent Data Monitoring Committee (IDMC), with both statistical significance and clinical relevance.

KN026 is a HER2 bispecific antibody that can simultaneously bind two non-overlapping epitopes of HER2, leading to HER2 signaling blockade, and has demonstrated superior therapeutic efficacy compared to the combination of trastuzumab and pertuzumab therapy. Multiple clinical studies at various stages showed that KN026 had favorable efficacy and safety profiles. Currently, a number of registration clinical trials are underway for indications such as breast cancer and gastric or gastroesophageal junction adenocarcinoma. In November 2023, KN026 in combination with chemotherapy for the treatment of HER2-positive gastric or gastroesophageal junction adenocarcinoma after failure of the first-line standard treatment was granted Breakthrough Therapy Designation by the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) of the People’s Republic of China.

The KC-WISE (KN026-001) study is a randomised, multicenter, Phase II/III clinical study designed to evaluate the efficacy and safety of KN026 in combination with chemotherapy in subjects with HER2-positive locally advanced, recurrent, or metastatic gastric or gastroesophageal junction adenocarcinoma who have failed first-line standard treatment. In the Phase III stage of this study, subjects with HER2-positive gastric or gastroesophageal junction adenocarcinoma who had previously received and failed at least first-line standard treatment were enrolled and randomised 1:1 to receive either KN026 in combination with chemotherapy or placebo in combination with chemotherapy. The primary endpoints of this study were PFS as assessed by an Independent Review Committee (IRC), and overall survival (OS). The main objective of this planned interim analysis was to evaluate the efficacy based on the IRC-assessed PFS. The interim analysis results indicated that compared to the current standard treatment, KN026 in combination with chemotherapy significantly improved PFS, reduced the risk of disease progression or death, and demonstrated a trend toward an OS benefit. Detailed data from this study will be presented at an upcoming international academic conference.

By order of the Board  
**CSPC Pharmaceutical Group Limited**  
**CAI Dongchen**  
*Chairman*

Hong Kong, 30 April 2025

*As at the date of this announcement, the Board comprises Mr. CAI Dongchen, 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.*