# CSPC PHARMACEUTICAL GROUP LIMITED
# 石藥集團有限公司

*(Incorporated in Hong Kong with limited liability)*
**(Stock code: 1093)**

## VOLUNTARY ANNOUNCEMENT

## KN026 WAS GRANTED BREAKTHROUGH THERAPY DESIGNATION IN CHINA

The board of directors (the "**Board**") of CSPC Pharmaceutical Group Limited (the "**Company**", together with its subsidiaries, the "**Group**") is pleased to announce that 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., has been granted Breakthrough Therapy Designation by the National Medical Products Administration (NMPA) of the People's Republic of China for the intended indication of combination chemotherapy for the treatment of HER2-positive locally advanced, recurrent or metastatic gastric cancers (including gastroesophageal junction cancer) which have failed standard first-line treatment (trastuzumab combination chemotherapy) (the "**Indication**").

Gastric cancer and gastroesophageal junction cancer are one of the most common malignant tumors. HER2 is overexpressed in a variety of tumors (approximately 15-20% of gastric cancer). HER2 overexpression is associated with tumor invasion and poor prognosis and thus there is a huge unmet clinical need for patients with HER2-positive gastric cancer that has progressed or recurred after first-line treatment. KN026 has initially demonstrated breakthrough efficacy and good safety profile in the clinical trials for the Indication, with apparent clinical advantages over currently available therapies.

According to the results of a Phase II clinical trial for the evaluation of safety and efficacy of KN026 monotherapy in patients with HER2-expressing advanced gastric cancer or gastroesophageal junction cancer who failed at least one prior line of standard treatment published in the European Journal of Cancer in November 2022, a total of 45 patients were enrolled and received at least one dose of KN026. Among them, 27 had high-level HER2 expression, 14 had low-level HER2 expression, 4 had no HER2 expression, and 39 were included in the efficacy analysis. In the high-level HER2 cohort,

the objective response rate (ORR) was 56%, the median duration of response (DoR) was 9.7 months, the median follow-up was 14.7 months, the median progression-free survival (mPFS) was 8.3 months, and the median overall survival (mOS) was 16.3 months. The most common grade ≥3 adverse event was gastrointestinal disorders (5 patients, 11%), and no deaths were attributed to the drug. In the high-level HER2 cohort, an objective response rate (ORR) of 50% was achieved in 14 patients who had previously been treated with trastuzumab. The clinical data suggests that KN026 has significant efficacy in treating patients who have failed prior anti-HER2 treatment.

A Phase III clinical trial of KN026 for the Indication is at currently enrolment stage and progressing well. With the Breakthrough Therapy Designation granted, the pace of development and review of KN026 will be further accelerated, providing the potential for it to become the first second-line anti-HER2 drug for gastric cancer where HER2-targeted therapies have failed.

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

Hong Kong, 6 November 2023

*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. WANG Qingxi, Mr. CHAK Kin Man and Dr. JIANG Hao 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.*