CSPC PHARMACEUTICAL GROUP LIMITED
石藥集團有限公司

(Incorporated in Hong Kong with limited liability)

(Stock Code: 1093)

VOLUNTARY ANNOUNCEMENT

JSKN003 GRANTED ANOTHER BREAKTHROUGH THERAPY DESIGNATION IN CHINA FOR THE TREATMENT OF PATIENTS WITH HER2-POSITIVE ADVANCED COLORECTAL CANCER

The Board of Directors (the "**Board**") of CSPC Pharmaceutical Group Limited (the "**Company**", together with its subsidiaries, the "**Group**") is pleased to announce that JSKN003, a biparatopic HER2-targeting antibody-drug conjugate co-developed by the Company's subsidiary, Shanghai JMTBIO Technology Co., Ltd., and Jiangsu Alphamab Biopharmaceuticals Co., Ltd., has been further granted Breakthrough Therapy Designation by the National Medical Products Administration ("**NMPA**") of the People's Republic of China for the intended indication of monotherapy for the treatment of patients with HER2-positive advanced colorectal cancer who have previously failed treatment with oxaliplatin, fluorouracil, and irinotecan (the "**Indication**").

Colorectal cancer is one of the most prevalent malignant tumors globally. According to data from the International Agency for Research on Cancer (IARC), there were 1,926,200 new cases and 903,900 deaths attributed to colorectal cancer worldwide in 2022, ranking third in incidence and second in mortality among all cancers. Colorectal cancer is particularly prevalent in China, where its incidence is second only to lung cancer, with over 500,000 new cases annually, and the number is increasing year by year. For patients with HER2-positive advanced colorectal cancer who have previously failed treatment with oxaliplatin, fluorouracil, and irinotecan, currently approved treatments such as regorafenib, fruquintinib, and trifluridine/tipiracil hydrochloride offer limited clinical benefit, with median progression-free survival ("**mPFS**") ranging from only 2 to 3.7 months and median overall survival (mOS) of approximately 7 to 10 months. Therefore, there remains a significant unmet clinical need within this patient population. Preliminary clinical studies of JSKN003 for the Indication have demonstrated robust efficacy and a favorable safety profile, showing meaningful clinical advantages over existing therapeutic options.

At the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting, a pooled analysis of two clinical trials evaluating JSKN003 monotherapy in patients with HER2-overexpressing (IHC3+) advanced gastrointestinal tumors was presented. This pooled analysis included data from a Phase I clinical study conducted in Australia (JSKN003-101) and a Phase I/II clinical study conducted in China (JSKN003-102). As at 28 February 2025, a total of 50 patients with HER2-overexpressing advanced gastrointestinal tumors, including 23 patients with colorectal cancer, were enrolled across the two studies, with 38% of these patients having previously received three or more prior lines of antitumor therapy. Preliminary results demonstrated that JSKN003 monotherapy exhibited notable efficacy and a favorable safety profile in patients with HER2-overexpressing advanced colorectal cancer. Among the 21 colorectal cancer patients who completed at least one tumor response assessment, the objective response rate ("**ORR**") was 61.9%, the disease control rate (DCR) was 95.2%, the mPFS was 13.77 months, and the median duration of response (mDoR) was 12.06 months. Among these patients, the ORR reached 65.0% in the 20 patients with BRAF V600E wild-type colorectal cancer. In terms of safety, among the 43 patients treated at the recommended Phase II dose (RP2D), only 6 patients (14.0%) experienced Grade 3 or higher treatment-related adverse events ("**TRAEs**"), 3 patients (7.0%) experienced treatment-related serious adverse events (TRSAEs), and 7 patients (16.3%) required dose reduction due to TRAEs. No TRAEs resulted in treatment discontinuation or death.

The Indication is the second Breakthrough Therapy Designation granted to JSKN003. In March 2025, JSKN003 also received Breakthrough Therapy Designation from the NMPA for the treatment of platinum-resistant recurrent epithelial ovarian cancer, primary peritoneal cancer, or fallopian tube cancer. JSKN003 is currently being evaluated in multiple Phase II and III clinical trials in China for the treatment of various solid tumors, including breast cancer, ovarian cancer, and gastric cancer. The granting of another Breakthrough Therapy Designation to JSKN003 will further expedite its development and review process, with the aim of bringing benefits to more cancer patients sooner.

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

Hong Kong, 20 October 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.