

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

JMT101 GRANTED BREAKTHROUGH THERAPY DESIGNATION IN CHINA FOR THE TREATMENT OF 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 JMT101, developed by the Group, has been granted Breakthrough Therapy Designation by the Center for Drug Evaluation of the National Medical Products Administration of the People’s Republic of China for the proposed indication of use in combination with irinotecan for the treatment of RAS, RAF, EGFR ECD and PIK3CA exon 20 wild-type advanced colorectal cancer after failure of standard treatment in second-line or beyond (the “**Indication**”).

Colorectal cancer is the third most common cancer globally. In 2022, the number of new cases and deaths from colorectal cancer in China reached 517,000 and 240,000, respectively, ranking second and fourth among all malignant tumors in terms of new cases and deaths. For patients with advanced colorectal cancer who have failed standard treatment in second-line or beyond, current standard treatment options are associated with low objective response rates (ORR) of $\leq 5\%$ and short median progression-free survival (mPFS) of approximately 3 months, indicating a significant unmet clinical need.

JMT101 is a recombinant humanised anti-epidermal growth factor receptor (“**EGFR**”) IgG1 subtype monoclonal antibody injection with a novel molecular structure that exerts antibody-dependent cell-mediated cytotoxicity (ADCC) and complement-dependent cytotoxicity (CDC). JMT101 exhibits substantially higher target affinity than similar products and can significantly reduce immunogenicity and infusion-related reactions.

The results of a randomised, controlled, open-label phase II study of JMT101 in combination with irinotecan in patients with advanced colorectal cancer who have failed standard second-line treatment (the “**Study**”) showed that the combination of JMT101 and irinotecan achieved significantly better ORR, disease control rate (DCR) and mPFS compared to the control group. Specifically, the mPFS of the JMT101 in combination with irinotecan group was 7.4 months, far exceeding the 2.9 months of the control group. The promising clinical benefits from JMT101 in combination with irinotecan were observed in both EGFR-pretreated and EGFR-treatment-naïve patients. The results of the Study were orally presented at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting.

Clinical studies of JMT101 in combination with irinotecan for the Indication have primarily demonstrated breakthrough efficacy and favorable safety, showing clear clinical advantages over existing treatments and the potential to become a new standard treatment for later-line treatment of colorectal cancer. Currently, the Group has advanced a pivotal phase III clinical trial of JMT101 in combination with irinotecan for the Indication. In addition, JMT101 is undergoing multiple phase II and III clinical trials in China for the treatment of solid tumors including lung cancer, nasopharyngeal carcinoma, and head and neck squamous cell carcinoma in first-line and second-line and beyond. Based on the favorable efficacy and safety data of JMT101, the Breakthrough Therapy Designation granted this time will help further accelerate its research and development process.

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

Hong Kong, 2 June 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.