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CSPC PHARMACEUTICAL GROUP LIMITED

石藥集團有限公司

(Incorporated in Hong Kong with limited liability)

(Stock Code: 1093)

VOLUNTARY ANNOUNCEMENT

SYS6010 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 SYS6010 (the Humanized Anti-human EGFR Monoclonal Antibody-JS-1 Conjugate Injection) (the “**Product**”) developed by CSPC Megalith Biopharmaceutical Co., Ltd., a subsidiary of the Company, 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 monotherapy for EGFR mutation-positive advanced non-small cell lung cancer (NSCLC) after failure of EGFR TKIs and platinum-based chemotherapy (the “**Indication**”).

Lung cancer is the most common malignant tumor with the highest incidence rate and mortality rate in China and worldwide, posing a serious threat to human health. Lung cancer patients are often diagnosed at a late stage, with a 5-year survival rate of around 20% for stage III patients, and a 5-year survival rate of less than 5% and a median survival time of 7 months for stage IV patients.

Asian and Chinese NSCLC patients have an EGFR gene mutation rate of 40–50%. The relation between the efficacy of targeted-therapy and molecular subtypes in EGFR mutation-positive advanced NSCLC has been confirmed in clinical practice. EGFR-TKI has become the standard first-line treatment for EGFR mutation-positive advanced NSCLC. After failure of TKI treatment, the standard treatment is platinum-based chemotherapy+/-bevacizumab. However, for EGFR mutation-positive NSCLC patients who have failed TKIs and chemotherapy, the overall prognosis is poor, thus there is an unmet clinical need for these patients.

Currently, the development of the Product in various solid tumors is underway. The existing clinical data has confirmed that the efficacy of the Product as a single agent for the Indication is significantly better than the standard treatment. The Breakthrough Therapy Designation granted to the Product will further facilitate communication with the regulatory agency and expedite the development progress.

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

Hong Kong, 2 January 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.