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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 GRANTED BREAKTHROUGH THERAPY DESIGNATION BY NMPA IN CHINA FOR THE TREATMENT OF PATIENTS WITH ACTIONABLE GENOMIC ALTERATION-NEGATIVE NON-SQUAMOUS NON-SMALL CELL LUNG 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 SYS6010 (the “**Product**”), developed by the Group, has recently been granted Breakthrough Therapy Designation by the National Medical Products Administration (“**NMPA**”) of the People’s Republic of China. The proposed indication is for recurrent or metastatic actionable genomic alteration-negative non-squamous non-small cell lung cancer (“**NSCLC**”) that has failed prior immunotherapy and platinum-based chemotherapy.

The Product is an antibody-drug conjugate (ADC) targeting the epidermal growth factor receptor (“**EGFR**”) developed by the Group, which is composed of a humanised anti-EGFR monoclonal antibody conjugated to a topoisomerase I inhibitor payload via a cleavable linker. The Product specifically binds to EGFR on the surface of tumour cells and releases the cytotoxic payload intracellularly upon internalisation, thereby exerting anti-tumour effects.

Lung cancer is one of the leading causes of cancer incidence and mortality worldwide. According to the “2024 Analysis of Regional Cancer Incidence in China” released by the National Cancer Center of China, approximately 1.176 million new lung cancer cases were diagnosed in China in 2024, with approximately 743,000 associated deaths, representing the highest incidence and mortality rates globally. NSCLC is the predominant pathological subtype of lung cancer, accounting for approximately 85% of all lung cancer cases. Among patients with NSCLC, those who are actionable genomic alteration-negative account for approximately 40%, and the incidence rate within this patient population is increasing annually. Immunotherapy in combination with platinum-based chemotherapy is the standard first-line treatment regimen for actionable genomic alteration-negative NSCLC. Following the

failure of first-line treatment, the standard second-line treatment still predominantly relies on single-agent chemotherapy, which exhibits suboptimal overall clinical efficacy and provides limited survival benefits for patients.

The Product significantly increased the objective response rate of patients with actionable genomic alteration-negative non-squamous NSCLC, and demonstrated a durable response period. Its progression-free survival (PFS) was more than twice as long as that of standard treatment, indicating that patients treated with the Product derived substantial survival benefits. Its clinical efficacy was significantly superior to that of existing standard treatments. The Product has demonstrated outstanding clinical value. It is anticipated that upon marketing approval, it will provide patients with enhanced treatment options and exhibit significant market potential. Currently, a randomised, open-label, multicentre Phase III clinical trial is underway to evaluate the Product as a monotherapy for the treatment of actionable genomic alteration-negative locally advanced or metastatic non-squamous NSCLC that has failed standard treatment.

Previously, the Product has been granted three Breakthrough Therapy Designations by the NMPA for the following proposed indications: as a monotherapy for EGFR mutation-positive advanced non-small cell lung cancer (NSCLC) after failure of EGFR-TKIs and platinum-based chemotherapy; unresectable locally advanced or metastatic esophageal squamous cell carcinoma (ESCC) in patients who have failed prior first-line treatment with platinum-based chemotherapy and immune checkpoint inhibitors (ICIs); and recurrent or metastatic head and neck squamous cell carcinoma (R/M HNSCC) in patients who have failed prior immunotherapy and platinum-based chemotherapy.

By order of the Board
CSPC Pharmaceutical Group Limited
CAI Dong Chen
Chairman

Hong Kong, 15 September 2026

As at the date of this announcement, the Board comprises Mr. CAI Dong Chen, Dr. CAI Lei, Mr. WEI Qingjie, Mr. ZHANG Cuilong, Mr. WANG Zhenguo, Dr. LI Chunlei, Dr. YAO Bing, Mr. CAI Xin, Mr. CHEN Weiping, Mr. QU Zhiyong and Mr. ZHANG Yiwei 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.