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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

PHASE III CLINICAL STUDY OF SYS6010 FOR EGFR-MUTATED LOCALLY ADVANCED OR METASTATIC NSCLC FOLLOWING FAILURE OF EGFR TKI THERAPY MEETS PRE-SPECIFIED PRIMARY ENDPOINT

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 met the pre-specified primary endpoint of progression-free survival (“**PFS**”), as reviewed and assessed by the Independent Data Monitoring Committee (“**IDMC**”), in its Phase III clinical study (“**SYNSTAR-01**”) evaluating the Product as a monotherapy versus platinum-based chemotherapy for epidermal growth factor receptor (“**EGFR**”)–mutated locally advanced or metastatic non-small cell lung cancer (“**NSCLC**”) following the failure of EGFR tyrosine kinase inhibitor (“**TKI**”) therapy. The study data demonstrated that the PFS of the Product was significantly superior to existing treatment regimens, with the efficacy difference being statistically significant and clinically meaningful, and the overall safety profile of the Product was favourable.

The Product is an EGFR-targeting antibody-drug conjugate (ADC) developed by the Group, comprising a humanised anti-EGFR monoclonal antibody conjugated to a topoisomerase I inhibitor payload via a cleavable linker. The Product specifically binds to EGFR receptors on the surface of tumour cells and, upon internalisation, releases the cytotoxic payload intracellularly, thereby exerting its anti-tumour pharmacological effects. Lung cancer ranks first in both incidence and mortality among malignancies in the Chinese Mainland, with approximately 1.176 million new cases in 2024. NSCLC accounts for approximately 85% of lung cancer cases, among which EGFR-mutated patients account for approximately 40–50%. At present, EGFR TKIs are the standard first-line treatment regimen for patients with EGFR-mutated advanced NSCLC. However, patients inevitably develop resistance following EGFR TKI therapy, and the efficacy of post-resistance treatment regimens is limited. If successfully approved for marketing, the Product will provide a new treatment option for patients, demonstrating high clinical application value and commercialisation prospects.

SYNSTAR-01 is a randomised, open-label, multi-centre Phase III clinical study designed to evaluate the efficacy and safety of the Product versus platinum-based chemotherapy in participants with EGFR-mutated locally advanced or metastatic NSCLC following the failure of EGFR TKI therapy. Its primary endpoint is PFS as assessed by the Independent Review Committee (IRC).

Currently, the study has successfully met its pre-specified primary endpoint and achieved positive results. Statistical analysis data confirmed that in the pre-specified interim analysis, the Product demonstrated a statistically significant and clinically meaningful improvement in PFS compared with platinum-based chemotherapy and showed a trend of benefit in overall survival (OS).

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

Hong Kong, 26 August 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.