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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 I/II CLINICAL TRIAL DATA OF SYS6010 IN COMBINATION WITH ENLONSTOBART FOR THE TREATMENT OF SYSTEMIC TREATMENT-NAIVE, ACTIONABLE GENOMIC ALTERATION-NEGATIVE ADVANCED NSCLC ORALLY PRESENTED AT THE 2026 WORLD CONFERENCE ON LUNG CANCER (WCLC)

The Board of Directors (the “**Board**”) of CSPC Pharmaceutical Group Limited (the “**Company**”, together with its subsidiaries, the “**Group**”) is pleased to announce that the Group has orally presented the Phase I/II clinical trial (the “**Study**”) data of SYS6010 in combination with Enlonstobart for the treatment of systemic treatment-naive, actionable genomic alteration-negative advanced non-small cell lung cancer (“**NSCLC**”) at the 2026 World Conference on Lung Cancer (WCLC) hosted by the International Association for the Study of Lung Cancer (IASLC).

OVERVIEW OF THE STUDY

The Study is a multi-centre Phase I/II clinical trial (ChiCTR2400089402) led by Professor Zhou Caicun from Shanghai East Hospital, aiming to evaluate the safety, tolerability, pharmacokinetic profile and preliminary efficacy of SYS6010 in combination with Enlonstobart Injection (a programmed cell death protein-1 (PD-1) inhibitor), with or without chemotherapy, in patients with epidermal growth factor receptor (“**EGFR**”) and anaplastic lymphoma kinase (ALK) wild-type advanced NSCLC and other advanced solid tumours.

At this conference, the Group announced the results of the randomised controlled trial from the Study regarding SYS6010 in combination with Enlonstobart Injection for the treatment of systemic treatment-naive, actionable genomic alteration-negative advanced NSCLC. The Study evaluated two dosing regimens: SYS6010 at 4.2 mg/kg in combination with Enlonstobart at 360 mg administered once every 3 weeks (Arm 1); and SYS6010 at 3.6 mg/kg in combination with Enlonstobart at 240 mg administered once every 2 weeks (Arm 2).

As at 13 July 2026, a total of 123 participants were enrolled and received treatment under the aforementioned two dosing regimens, comprising 62 in Arm 1 and 61 in Arm 2. The median follow-up time was 10.8 months. The relevant safety and efficacy data are as follows:

- In terms of safety, the safety profile of both dosing regimens of SYS6010 in combination with Enlonstobart was generally manageable. The incidences of Grade 3 and above treatment-related adverse events were 51.6% (Arm 1) and 52.5% (Arm 2), respectively, while the incidences of treatment-related adverse events leading to treatment discontinuation were 9.7% (Arm 1) and 8.2% (Arm 2), respectively.
- In terms of efficacy, both regimens demonstrated preliminary efficacy in the study population. Among them, the benefits were more prominent in patients with non-squamous cell carcinoma and high expression of programmed death-ligand 1 (“**PD-L1**”), and efficacy was observed in both squamous and non-squamous cell carcinoma patients with high PD-L1 expression. The confirmed objective response rate (ORR) of the overall population and each subgroup is shown in the table below:

	Arm 1	Arm 2
Overall population	58.9%	49.2%
Non-squamous cell carcinoma patients	64.1%	56.1%
PD-L1 positive (tumour proportion score (“ TPS ”) $\geq 1\%$) patients	58.5%	63.2%
PD-L1 high expression (TPS $\geq 50\%$) patients	77.8%	82.4%
Squamous cell carcinoma patients with high PD-L1 expression	71.4%	60.0%
Non-squamous cell carcinoma patients with high PD-L1 expression	81.8%	91.7%

Currently, the combination therapy of SYS6010 and Enlonstobart Injection has entered Phase III clinical trials, and the Group intends to develop it for the first-line treatment of PD-L1 positive locally advanced or metastatic NSCLC (NCT07633873).

ABOUT SYS6010

SYS6010 is an antibody-drug conjugate (ADC) targeting EGFR independently 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. SYS6010 specifically binds to EGFR on the surface of tumour cells and releases the cytotoxic payload intracellularly upon internalisation, thereby exerting anti-tumour effects. Given the widespread high expression of EGFR in various solid tumours, SYS6010 has broad development prospects, and the Group has made strategic layouts in multiple solid tumour fields.

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

Hong Kong, 14 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.