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 CLINICAL STUDY DATA OF NOVEL B7-H3 ANTIBODY-DRUG CONJUGATE SYS6043 PRESENTED IN AN ORAL SESSION AT THE 2026 ASCO ANNUAL MEETING

The Board of Directors (the "**Board**") of CSPC Pharmaceutical Group Limited (the "**Company**", together with its subsidiaries, the "**Group**") is pleased to announce that CSPC Megalith Biopharmaceutical Co., Ltd., a subsidiary of the Group, has presented the Phase I clinical study (the "**Study**") data of SYS6043 in an oral session at the 2026 American Society of Clinical Oncology ("**ASCO**") Annual Meeting.

SYS6043 is a novel antibody-drug conjugate (ADC) targeting B7-H3, with a topoisomerase I inhibitor as the payload and a drug-to-antibody ratio (DAR) of approximately 6. It utilises an Fcγ receptor effector silencing design and a cleavable linker, aimed at enhancing anti-tumour activity and reducing off-target toxicity. B7-H3 is widely and highly expressed in multiple tumour types, but is minimally expressed in normal tissues. The results of the Study indicated that SYS6043 had the potential to become a treatment option for multiple tumour types.

The Study is a multi-centre, open-label, single-arm Phase I/II clinical study (ChiCTR2400094683) conducted in China, designed to evaluate the safety, tolerability, pharmacokinetic profile, and preliminary efficacy of SYS6043 in patients with advanced solid tumours. The Study consists of two phases: dose escalation and dose expansion. In the dose escalation phase, the Study adopted the Bayesian Optimal Interval (BOIN) design to explore a total of eight treatment regimens, including 1.2 mg/kg, 2.4 mg/kg, 4 mg/kg, 6 mg/kg, 8 mg/kg, and 10 mg/kg once every 3 weeks (Q3W), as well as 4 mg/kg and 6 mg/kg once every 2 weeks (Q2W). The primary endpoints include safety, tolerability, and the recommended Phase II dose (for the Phase I stage), as well as the objective response rate (for the Phase II stage).

As at 31 March 2026, a total of 627 patients were enrolled in the Study, including 168 patients with lung cancer, 147 with gynaecological tumours, 137 with breast cancer, 66 with nasopharyngeal carcinoma, 50 with head and neck squamous cell carcinoma, 22 with oesophageal squamous cell carcinoma, 14 with liver cancer, and 23 with other tumour types. The median number of prior lines of therapy was 2 (range: 1–10), the median age was 57.0 years, and male patients accounted for 58.9%.

SYS6043 demonstrated favourable anti-tumour activity in patients across multiple tumour types. Among the 533 efficacy-evaluable patients, the objective response rate ("**ORR**") was 41.8%, the disease control rate (DCR) was 81.4%, and the median duration of response ("**mDoR**") was 6.9 months. The efficacy data for patients with various tumour types are as follows: for lung cancer (n=134), the ORR was 46.3% and the mDoR was 6.9 months (95% confidence interval [CI]: 4.3, not evaluable [NE]); for breast cancer (n=125), the ORR was 56.8% and the mDoR was 7.0 months (95% CI: 3.9, NE); for gynaecological tumours (n=139), the ORR was 42.4% and the mDoR was 6.9 months (95% CI: 5.6, NE); for nasopharyngeal cancer (n=63), the ORR was 28.6% and the mDoR was 5.8 months (95% CI: 4.4, NE); for oesophageal squamous cell carcinoma (n=19), the ORR was 15.8% and the mDoR was 4.5 months (95% CI: 1.3, NE); in addition, for head and neck squamous cell carcinoma (n=30), the ORR was 16.7%, and for liver cancer (n=7), the ORR was 42.9%.

The preliminary analysis results of the Study showed no significant correlation between B7-H3 expression levels and the efficacy of SYS6043. SYS6043 was generally well-tolerated, with only 2 cases of dose-limiting toxicities (DLT) occurring in the 10 mg/kg Q3W dose cohort, which were Grade 3 gastrointestinal disorders and Grade 4 febrile neutropenia, respectively. Treatment-related adverse events (TRAEs) occurred in 96.7% of the patients. The incidence of Grade ≥3 TRAEs was 37.2%, which was generally low and predominantly manifested as haematological toxicities. The most frequent TRAEs included anaemia (16.1%), neutropenia (12.6%), and leucopenia (9.7%), while the incidence of all other Grade ≥3 TRAEs was ≤3.5%.

Based on the positive results of the Study, the Group is currently actively advancing related studies in ovarian cancer, breast cancer, and small cell lung cancer.

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

Hong Kong, 2 June 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, Mr. WANG Huaiyu, 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.