CSPC PHARMACEUTICAL GROUP LIMITED
石藥集團有限公司

(Incorporated in Hong Kong with limited liability)

(Stock Code: 1093)

VOLUNTARY ANNOUNCEMENT

NEW DRUG APPLICATION FOR TRASTUZUMAB ENVEDOTIN INJECTION ACCEPTED BY THE NMPA

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 new drug application for Trastuzumab Envedotin Injection (the "**Product**") developed by the Group has been accepted by the National Medical Products Administration (the "**NMPA**") of the People's Republic of China. The Product has been filed as a Class 1 therapeutic biological product, and its indication is for the treatment of unresectable or metastatic HER2-positive breast cancer in adult patients who have received one or more prior anti-HER2 therapies.

Trastuzumab Envedotin Injection is a HER2-targeted antibody-drug conjugate (ADC). The Product binds to the HER2 receptors on HER2-positive tumour cells and induces internalisation, followed by lysosomal hydrolysis to release MMAE, thereby inhibiting tubulin polymerisation during the tumour cell division cycle, ultimately inducing tumour cell apoptosis and exerting anti-tumour effects.

The new drug application for the Product is primarily based on a pivotal Phase III clinical trial, which enrolled patients with unresectable or metastatic HER2-positive breast cancer who had previously received at least trastuzumab and taxane. The results demonstrated that, compared with T-DM1, the Product significantly prolonged progression-free survival (PFS) in the second-line and beyond treatment of HER2-positive advanced breast cancer, with a statistically significant and clinically meaningful benefit. Results from other secondary endpoints and subgroup analyses consistently demonstrated that the Product had superior anti-tumour efficacy compared with T-DM1. Meanwhile, the Product demonstrated favourable safety and tolerability profiles.

Based on its advantages in efficacy and safety, the Product has favourable clinical application value and is expected to bring benefits to a greater number of patients.

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

Hong Kong, 17 July 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.