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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**

#### **ENNITUO (恩尼妥®) (ANBENITAMAB INJECTION) RECEIVES MARKETING AUTHORISATION FROM 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 Anbenitamab Injection (brand name: Ennituo (恩尼妥®)) (the “**Product**”), co-developed by Shanghai JMT-BIO Technology Co., Ltd., a subsidiary of the Company, and Jiangsu Alphamab Biopharmaceuticals Co., Ltd., has received marketing authorisation from the National Medical Products Administration of the People’s Republic of China (“**NMPA**”).

The Product is a recombinant humanised bispecific antibody (IgG1 type) targeting human epidermal growth factor receptor 2 (“**HER2**”). The approved indication is for the use of the Product in combination with chemotherapy for the treatment of adult patients with locally advanced or metastatic HER2-positive gastric or gastroesophageal junction adenocarcinoma who have received at least one prior treatment regimen containing trastuzumab (the “**Indication**”).

This approval is mainly based on a pivotal Phase II/III clinical trial (KC-WISE), which enrolled patients with HER2-positive gastric or gastroesophageal junction adenocarcinoma who had failed at least one prior line of therapy. The study results demonstrated that compared with standard chemotherapy, the Product in combination with chemotherapy significantly prolonged progression-free survival (PFS) (7.1 months vs 2.7 months, hazard ratio (“**HR**”) = 0.25, representing a 75% reduction in the risk of disease progression or death) and overall survival (OS) (19.6 months vs 11.5 months, HR = 0.29, representing a 71% reduction in the risk of death). The trends of benefit were consistent across all patient subgroups. Consistent trends of benefit were also observed in terms of both objective response rate (ORR) and duration of response (DOR), with a favourable safety profile.

The Indication is the first approved indication for the Product. In addition, a Phase III clinical study of the Product in combination with the Group's self-developed docetaxel for injection (albumin-bound) (“**HB1801**”) for the neoadjuvant treatment of HER2-positive early or locally advanced breast cancer also met its pre-specified primary endpoint of total pathological complete response (tpCR) rate in March 2026, with statistically and clinically significant results. The results of the pivotal registrational Phase III clinical study of the Product in combination with HB1801 as first-line treatment for HER2-positive breast cancer are expected to be announced this year.

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

Hong Kong, 29 May 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.*