

Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.



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 ANBENITAMAB (KN026) IN COMBINATION WITH DOCETAXEL FOR INJECTION (ALBUMIN-BOUND) (HB1801) FOR FIRST-LINE TREATMENT OF HER2-POSITIVE ADVANCED BREAST CANCER MEETS 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 the Phase III clinical study (Study Protocol No.: KN026-003) of Anbenitamab (“**KN026**”), co-developed by Shanghai JMT-BIO Technology Co., Ltd. (“**JMT-BIO**”), a subsidiary of the Company, and Jiangsu Alphamab Oncology Co., Ltd., in combination with the Group’s self-developed Docetaxel for Injection (Albumin-bound) (“**HB1801**”) for the first-line treatment of HER2-positive advanced breast cancer has successfully met the pre-specified primary endpoint of progression-free survival (“**PFS**”) as assessed by the Independent Data Monitoring Committee (the “**IDMC**”), yielding results that are both statistically significant and clinically meaningful, with a favourable safety profile.

Breast cancer is the second most common malignancy among women in China, of which the HER2-positive subtype accounts for approximately 20% to 30%. In China, approximately 20% of patients with breast cancer are already at an advanced stage upon initial diagnosis, and approximately 10% of patients with HER2-positive early breast cancer experience disease recurrence within 3 years after radical surgery. Trastuzumab in combination with pertuzumab and docetaxel (the “**THP regimen**”) currently remains the preferred first-line treatment for HER2-positive advanced breast cancer both domestically and overseas. Although this treatment regimen has significantly prolonged the PFS of these patients, approximately 50% of patients still experience disease progression within 2 years, representing an urgent unmet clinical need.

Healer (KN026–003) is a randomised, controlled, open-label, multicenter Phase III clinical study. It plans to enrol approximately 880 patients with HER2-positive advanced breast cancer, randomly assigned at a 1:1 ratio. The study aims to compare the efficacy and safety of KN026 in combination with HB1801 versus the THP regimen for the first-line treatment of HER2-positive advanced breast cancer. The primary endpoint is PFS as assessed by the Blinded Independent Review Committee (BIRC). As evaluated by the IDMC, KN026 in combination with HB1801 significantly prolonged

patients' PFS and reduced the risk of disease progression or death compared with the THP regimen, with a trend toward an overall survival (OS) benefit. Detailed data from this study will be presented at an upcoming international academic conference.

About Ennituo (恩尼妥®) (Anbenitamab Injection)

Anbenitamab Injection is a HER2 bispecific antibody. On 28 May 2026, the National Medical Products Administration (the “NMPA”) of the People’s Republic of China approved its marketing authorisation through the priority review and approval process, for use 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 one prior treatment regimen containing trastuzumab. The Phase III clinical study of Anbenitamab Injection for the neoadjuvant treatment of HER2-positive breast cancer has also met its primary endpoint, and a New Drug Application (NDA) will be submitted in the near future. In addition, multiple clinical studies of Anbenitamab Injection, including the adjuvant treatment of HER2-positive breast cancer and the first-line treatment of HER2-positive gastric cancer, are ongoing. Anbenitamab Injection has been granted Orphan Drug Designation by the U.S. Food and Drug Administration (FDA) for the treatment of HER2-expressing gastric cancer, and has also received Breakthrough Therapy Designation from the NMPA for the treatment of HER2-positive gastric cancer that has failed first-line standard treatment.

About Docetaxel for Injection (Albumin-bound) (HB1801)

Docetaxel for Injection (Albumin-bound) (HB1801) is one of the representative drugs independently developed by the Group’s nanomedicine technology platform. HB1801 encapsulates docetaxel in human serum albumin. As it does not contain polysorbate 80 (Tween-80) and ethanol, it offers the following advantages over docetaxel injection: (1) Safety: it causes no allergic reactions and requires no steroid premedication; it can be administered rapidly at high concentration, enhancing the safety profile and patient compliance; (2) Efficacy: preclinical and clinical studies have demonstrated significant anti-tumour activity, allowing for higher doses in clinical practice to further improve efficacy. Currently, HB1801 has entered Phase III clinical study stages in indications including breast cancer and gastric cancer.

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

Hong Kong, 10 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, 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.