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 RESULTS OF ANBENITAMAB (KN026) IN COMBINATION WITH DOCETAXEL FOR INJECTION (ALBUMIN-BOUND) (HB1801) FOR NEOADJUVANT TREATMENT OF HER2-POSITIVE BREAST CANCER SELECTED FOR LBA ORAL PRESENTATION 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 the results of the Phase III clinical study (Study No.: KN026–004/Neo-Healer) of the HER2 bispecific antibody Anbenitamab (brand name: Ennituo (恩尼妥®) ("**KN026**"), co-developed by Shanghai JMT-BIO Technology Co., Ltd., a subsidiary of the Company, and Jiangsu Alphamab Biopharmaceuticals Co., Ltd. ("**Alphamab**"), in combination with the Group's self-developed Docetaxel for Injection (Albumin-bound) ("**HB1801**") for the neoadjuvant treatment of HER2-positive breast cancer, have been selected for a Late-Breaking Abstract ("**LBA**") oral presentation at the 2026 American Society of Clinical Oncology ("**ASCO**") Annual Meeting.

STUDY OVERVIEW

Neo-Healer is a randomised, controlled, open-label, multicentre Phase III clinical trial designed to compare the efficacy and safety of anbenitamab in combination with HB1801±carboplatin versus the standard THP±carboplatin regimen as a neoadjuvant treatment for patients with early and locally advanced HER2-positive breast cancer. The primary endpoint was the total pathological complete response ("**tpCR**") rate assessed by a Blinded Independent Review Committee ("**BIRC**"). A total of 521 patients were enrolled in the study and randomly assigned in a 1:1 ratio to either the experimental group (anbenitamab plus HB1801±carboplatin) or the control group (trastuzumab plus pertuzumab and docetaxel±carboplatin), both receiving 6 cycles of treatment. Patients were stratified at enrolment based on three factors: (i) clinical stage; (ii) hormone receptor status; and (iii) planned use of carboplatin.

KEY RESULTS

Efficacy:

- Assessed by BIRC, the tpCR rate in the experimental group was 62.4% (95% Confidence Interval ("**CI**"): 56.2–68.2), which was significantly higher than the 51.2% (95% CI: 44.9–57.4) in the control group (one-sided P=0.0036), showing a statistically significant difference. Stratification by carboplatin use showed consistent advantages in the experimental group (carboplatin subgroup: 66.7% vs 54.5%; non-carboplatin subgroup: 59.2% vs 48.6%).

- Similar results were observed for the investigator-assessed tpCR rate, which was 63.9% (95% CI: 57.8–69.7) in the experimental group and 51.2% (95% CI: 44.9–57.4) in the control group (one-sided P=0.0011), further validating the efficacy of the regimen.

- In most pre-specified subgroups (including stratification by hormone receptor status, clinical stage, and planned use of carboplatin), the tpCR benefits assessed by BIRC were similar. The breast pathological complete response ("**bpCR**") rate assessed by BIRC was also significantly higher in the experimental group at 64.6%, compared to 55.0% in the control group (one-sided P=0.0099); the investigator-assessed bpCR rate was 65.8% in the experimental group and 55.4% in the control group (one-sided P=0.0057).

Safety:

- The incidence of Grade 3 or above treatment-emergent adverse events ("**TEAEs**") was 29.3% in the experimental group and 28.3% in the control group. The proportion of patients who temporarily suspended any study drug due to TEAEs was 5.7% and 7.4% in the experimental and control groups, respectively, while the proportion of patients who permanently discontinued treatment due to TEAEs was 4.9% and 3.5%, respectively.

- The most common Grade 3 or above TEAEs in the experimental and control groups included neutrophil count decreased (11.4% vs. 10.9%), white blood cell count decreased (7.6% vs. 8.5%), anaemia (6.5% vs. 5.0%), platelet count decreased (3.0% vs. 0.8%), and diarrhoea (3.0% vs. 2.7%). The safety profiles of both groups were similar, mainly manifesting as haematological and gastrointestinal toxicities, and no new safety signals were identified. The observed toxicities were consistent with the known safety profiles of each individual drug, with no obvious additive toxicities.

STUDY CONCLUSIONS

The study results indicate that the anbenitamab plus HB1801±carboplatin regimen significantly improved the tpCR rate compared to the current standard dual HER2 blockade plus chemotherapy regimen, with an overall manageable safety profile. It has the potential to become a new standard therapy for the neoadjuvant treatment of HER2-positive early or locally advanced breast cancer, providing a more effective treatment option for this patient population.

About Ennituo (恩尼妥®) (Anbenitamab Injection)

Ennituo (恩尼妥®) (Anbenitamab Injection) is a HER2 bispecific antibody developed by Alphamab using its proprietary Fc-based heterodimer platform technology (CRIB). It can simultaneously bind two non-overlapping epitopes of HER2, resulting in HER2 signal blockade. Through antibody-induced receptor clustering, it enhances antibody-dependent cellular cytotoxicity (ADCC) and complement-dependent cytotoxicity (CDC) effects, while promoting the down-regulation of HER2 receptors on the cell surface.

In August 2021, Shanghai JMT-BIO Technology Co., Ltd. entered into a licence agreement for development and commercialisation with Alphamab, obtaining the exclusive development and commercialisation rights for KN026 in breast cancer and gastric cancer indications in the Chinese mainland (excluding Hong Kong, Macao and Taiwan).

In May 2026, Ennituo (恩尼妥®) was approved for marketing in China. In combination with chemotherapy, it is indicated 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. Currently, multiple registrational clinical studies are ongoing for indications including neoadjuvant and adjuvant therapy for HER2-positive breast cancer, and first-line treatment for HER2-positive gastric or gastroesophageal junction adenocarcinoma.

About HB1801

HB1801 is one of the representative drugs independently developed by the Group's nanomedicine technology platform. HB1801 encapsulates docetaxel in human albumin. Because it does not contain polysorbate 80 (Tween-80) and ethanol, it has the following advantages over docetaxel injection: (1) Safety: It does not require steroid premedication, allows for high-concentration and rapid administration, and offers higher safety and patient compliance; (2) Efficacy: It has shown significant efficacy in multiple preclinical tumour models and early clinical studies, and can be administered at a higher dose clinically, further improving efficacy. Currently, HB1801 has entered the pivotal Phase III clinical trial stage for indications such as breast cancer and gastric cancer.

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

Hong Kong, 1 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.