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 (ALBUMIN-BOUND) (HB1801) FOR NEOADJUVANT TREATMENT OF HER2+ 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 Anbenitamab Injection ("**KN026**"), co-developed by the Company's subsidiary Shanghai JMT-BIO Technology Co., Ltd. ("**JMT-BIO**") and Jiangsu Alphamab Oncology Co., Ltd. ("**Alphamab**"), in combination with Docetaxel for Injection (Albumin-bound) ("**HB1801**") independently developed by the Group, has met the pre-specified primary endpoint of total pathological complete response ("**tpCR**") in a Phase III clinical study (Study Protocol No.: KN026–004) for the neoadjuvant treatment of HER2-positive early or locally advanced breast cancer, and the results are highly statistically and clinically significant.

Breast cancer is the second most common malignancy among women in China, of which the HER2-positive subtype accounts for approximately 20%~30%. In China, about 75% of breast cancer patients are in the early or locally advanced stage at the time of initial diagnosis. Surgery combined with neoadjuvant and/or adjuvant therapy is the core means to achieve a radical cure for early or locally advanced breast cancer. Studies have shown that patients who achieve tpCR after neoadjuvant therapy have significantly improved event-free survival (EFS) and overall survival (OS), particularly in HER2-positive breast cancer. Despite this, after receiving the standard neoadjuvant treatment regimen-trastuzumab combined with pertuzumab and chemotherapy (THP/TCbHP)—only about half of the patients with early or locally advanced HER2-positive breast cancer can achieve tpCR. In addition, beyond improving tpCR, neoadjuvant therapy also aims to facilitate earlier and more timely surgical intervention. Therefore, there is still a clinical need to explore better neoadjuvant treatment regimens that can allow for earlier surgery.

Neo-Healer (KN026–004) is a randomised, controlled, open-label, multicenter Phase III clinical study, planning to enroll approximately 520 patients with early or locally advanced HER2-positive breast cancer, randomly assigned at a 1:1 ratio, aiming to compare the efficacy and safety of KN026 combined with HB1801± carboplatin versus trastuzumab combined with pertuzumab and docetaxel± carboplatin as neoadjuvant therapy for early and locally advanced HER2-positive breast cancer. Its primary study endpoint is tpCR assessed by a Blinded Independent Review Committee (BIRC). The study results showed that compared with the existing standard treatment, KN026 combined with HB1801± carboplatin significantly improved the tpCR of patients. The detailed data of this study will be announced at an international academic conference in the near future.

About Anbenitamab Injection (KN026)

Anbenitamab Injection is a HER2 bispecific antibody. Its New Drug Application (NDA) for the second-line and above treatment of HER2-positive advanced gastric cancer was accepted by the National Medical Products Administration (NMPA) in September 2025. Currently, multiple registrational clinical studies of Anbenitamab for indications such as first-line treatment of HER2-positive gastric cancer/gastroesophageal junction cancer, first-line treatment of HER2-positive breast cancer, and neoadjuvant and adjuvant treatment of HER2-positive breast cancer are ongoing. Anbenitamab has been granted Orphan Drug Designation by the U.S. Food and Drug Administration (FDA) for the treatment of HER2-positive or HER2-low expressing gastric cancer; it has also been granted Breakthrough Therapy Designation by the National Medical Products Administration (NMPA) for the treatment of HER2-positive gastric cancer (including gastroesophageal junction cancer) after failure of first-line standard treatment.

In August 2021, JMT-BIO reached a licensing agreement with Alphamab and obtained the exclusive development and commercialisation rights for KN026 in breast cancer and gastric cancer indications in Chinese Mainland (excluding Hong Kong, Macao and Taiwan regions).

About Docetaxel for Injection (Albumin-bound)

Docetaxel for Injection (Albumin-bound) is one of the representative drugs independently developed by the Group's nanomedicine technology platform. Currently, multiple modified drugs developed based on this technology platform have been approved for launch, including mitoxantrone liposome, irinotecan liposome and paclitaxel (albumin-bound). Docetaxel is a paclitaxel analogue that is currently widely used in clinical practice both domestically and overseas for the monotherapy or combination therapy of multiple solid tumors such as breast cancer, non-small cell lung cancer, gastric cancer and pancreatic cancer. However, docetaxel has high hydrophobicity, and current formulations need to use polysorbate 80 ("**Tween-80**") and ethanol as solvents, leading to many limitations in clinical application: it is easy to cause severe allergic reactions, can only be administered at low concentration and low drip rate; the product has poor compatibility and stability, requiring the use of infusion devices without polyvinyl chloride (PVC) material and making clinical use inconvenient. HB1801 encapsulates docetaxel in human serum albumin. Because it does not contain Tween-80 and ethanol, it has the following advantages compared with docetaxel injection: (1) Safety: no hypersensitivity reactions occur, and no hormone pretreatment is required. It can be administered rapidly at high concentration, with higher safety and patient compliance; (2) Efficacy: it has significant effects in multiple preclinical tumor models, and can be administered at a larger dose clinically, further improving efficacy.

Results of multiple early clinical studies at different stages showed that HB1801 demonstrated better anti-tumor efficacy and safety than docetaxel injection, achieving the goal of reducing toxicity and increasing efficacy. Currently, HB1801 has entered the pivotal registrational Phase III clinical trial stage in indications such as breast cancer and gastric cancer.

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

Hong Kong, 31 March 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.