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 ANBENITAMAB (KN026) AND DOCETAXEL FOR INJECTION (ALBUMIN-BOUND) (HB1801) FOR NEOADJUVANT TREATMENT 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 Anbenitamab (KN026), co-developed by Shanghai JMT-Bio Technology Co., Ltd., 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 neoadjuvant treatment, has been accepted by the National Medical Products Administration (the "**NMPA**") of the People's Republic of China and has been included in the priority review and approval procedures. The indication for this new drug application is Anbenitamab in combination with docetaxel (albumin-bound) ± carboplatin as neoadjuvant therapy for the treatment of HER2-positive early or locally advanced breast cancer in adults.

Anbenitamab Injection is a HER2 bispecific antibody that can simultaneously bind two non-overlapping epitopes of HER2, blocking HER2 signalling, enhancing HER2 internalisation, downregulating HER2 expression, and retaining the Fc-mediated antibody-dependent cellular cytotoxicity (ADCC) effect. This product has been approved for marketing in China.

HB1801 is one of the representative drugs independently developed by the Group's nanomedicine technology platform. HB1801 encapsulates docetaxel in human albumin. It has the following advantages over docetaxel injection: (1) Safety: It causes no allergic reactions, does not require steroid premedication, and allows for high-concentration and rapid administration, improving safety and patient compliance; (2) Efficacy: Preclinical and clinical studies have shown that it exhibits significant antitumor activity, and it can be administered at a higher dose clinically, improving efficacy.

This marketing application is primarily based on a pivotal Phase III clinical trial (Study No.: KN026-004/Neo-Healer) that enrolled patients with early-stage or locally advanced HER2-positive breast cancer. The study results indicate that anbenitamab in combination with docetaxel for injection (albumin-bound) ± carboplatin as neoadjuvant therapy for HER2-positive early-stage or locally advanced breast cancer, compared with the current standard of care (trastuzumab in combination with pertuzumab and docetaxel ± carboplatin), can significantly improve the total pathological complete response rate ("**tpCR**"), with the efficacy improvement demonstrating both statistical significance and clinical meaningfulness, and the overall safety profile remaining manageable.

In China, approximately 75% of breast cancer patients are initially diagnosed at early-stage or locally advanced stages, and neoadjuvant therapy is the recommended standard of care for HER2-positive early-stage or locally advanced breast cancer. Achieving tpCR through neoadjuvant therapy is an effective means of improving long-term prognosis for these patients and carries significant clinical value. KN026-004/Neo-Healer is the world's first Phase III study in which a HER2 bispecific antibody in combination with docetaxel for injection (albumin-bound) has demonstrated superior efficacy over the existing neoadjuvant standard of care of anti-HER2 dual monoclonal antibodies plus chemotherapy, marking a historic breakthrough for bispecific antibody therapy in the neoadjuvant treatment of breast cancer, and represents the first Phase III study in China in which an independently developed product (combination) has achieved superior efficacy results compared with the current neoadjuvant standard of care, which is expected to provide a new promising treatment option for Chinese patients with HER2-positive breast cancer.

Currently, multiple pivotal registration clinical studies of anbenitamab in combination with docetaxel (albumin-bound) for indications including the first-line treatment of HER2-positive breast cancer and adjuvant therapy for HER2-positive breast cancer are underway. Recently, Anbenitamab and HB1801 have been granted Breakthrough Therapy Designation by the NMPA for the first-line treatment of unresectable or metastatic HER2-positive breast cancer.

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

Hong Kong, 4 August 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.