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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

NEW DRUG APPLICATION FOR ANBENITAMAB (KN026) AND DOCETAXEL FOR INJECTION (ALBUMIN-BOUND) (HB1801) FOR THE FIRST-LINE TREATMENT OF ADVANCED BREAST CANCER 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 the first-line treatment of advanced breast cancer, 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 procedure. The indication for this new drug application is Anbenitamab in combination with Docetaxel (Albumin-bound) for the first-line treatment of unresectable or metastatic human epidermal growth factor receptor 2 (“**HER2**”)–positive breast cancer in adults. Previously, the combination therapy of KN026 and HB1801 for this indication was granted Breakthrough Therapy Designation by the NMPA.

Anbenitamab 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 antibody-dependent cellular cytotoxicity (ADCC) effect. This product has already 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 traditional docetaxel injection: (1) Safety: It causes no allergic reactions, does not require steroid premedication, and allows for high-concentration and rapid administration, effectively improving safety and patient compliance; (2) Efficacy: Preclinical and clinical studies have shown that it exhibits excellent antitumor activity, and it can be administered at a higher dose clinically, further improving efficacy.

This New Drug Application is primarily based on a pivotal Phase III clinical trial (Study No.: KN026-003/Healer). The study results indicate that the combination therapy of KN026 and HB1801 for the first-line treatment of advanced HER2-positive breast cancer demonstrated significantly superior progression-free survival (“PFS”) compared to the current standard of care (trastuzumab in combination with pertuzumab and docetaxel), with differences that are both statistically significant and clinically meaningful, and the overall safety profile remaining favourable. Detailed clinical data from this study will be presented at an upcoming international academic conference.

In China, approximately 20% of breast cancer patients 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. Currently, trastuzumab in combination with pertuzumab and docetaxel 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. The Healer study is the world’s first Phase III clinical trial of a HER2 bispecific antibody in combination with HB1801 for HER2-positive advanced breast cancer to demonstrate superior efficacy over the “trastuzumab and pertuzumab plus docetaxel” regimen in a head-to-head comparison. The success of this study marks a historic breakthrough for the aforementioned novel combination therapy in the first-line treatment of HER2-positive advanced breast cancer. It is expected to provide a new treatment option with superior efficacy, a favourable safety profile, and more convenient administration for domestic patients with HER2-positive advanced breast cancer.

Currently, the combination therapy of KN026 and HB1801 has completed the comprehensive clinical layout across the entire disease course for HER2-positive breast cancer, encompassing neoadjuvant, adjuvant, and first-line advanced settings. Notably, the New Drug Application for this combination regimen for the neoadjuvant treatment of HER2-positive early or locally advanced breast cancer in adults was accepted by the NMPA on 4 August 2026 and included in the priority review and approval procedure.

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

Hong Kong, 18 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.