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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**

#### **DOCETAXEL FOR INJECTION (ALBUMIN-BOUND) (HB1801) AND ANBENITAMAB (KN026) GRANTED BREAKTHROUGH THERAPY DESIGNATION IN CHINA FOR THE FIRST-LINE TREATMENT OF ADVANCED HER2-POSITIVE BREAST CANCER**

The Board of Directors (the “**Board**”) of CSPC Pharmaceutical Group Limited (the “**Company**”, together with its subsidiaries, the “**Group**”) is pleased to announce that Docetaxel for Injection (Albumin-bound) (HB1801), independently developed by the Group, and Anbenitamab (KN026), a human epidermal growth factor receptor 2 (“**HER2**”) bispecific antibody drug co-developed by Shanghai JMT-BIO Technology Co., Ltd., a subsidiary of the Company, and Jiangsu Alphamab Biopharmaceuticals Co., Ltd., have been granted Breakthrough Therapy Designation by the National Medical Products Administration (the “**NMPA**”) of the People’s Republic of China for the intended indication of Docetaxel (Albumin-bound) in combination with Anbenitamab for the first-line treatment of unresectable or metastatic HER2-positive breast cancer in adults (the “**Indication**”). Previously, Anbenitamab has been granted Breakthrough Therapy Designation by the NMPA for the treatment of HER2-positive advanced gastric cancer following the failure of first-line treatment.

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 progression-free survival (“**PFS**”) of these patients, approximately 50% of patients still experience disease progression within 2 years, representing an urgent unmet clinical need.

As announced on 10 June 2026, the Phase III clinical study (Healer, KN026–003) for the Indication had successfully achieved its primary endpoint of PFS, as assessed by the Independent Data Monitoring Committee (IDMC). The study results demonstrated that the combination therapy of Docetaxel for Injection (Albumin-bound) and Anbenitamab exhibited significantly superior PFS compared to the current standard-of-care THP regimen, with differences that are both statistically significant and clinically meaningful, while maintaining a favourable overall safety profile. Detailed clinical data from this study will be presented at an upcoming international academic conference, and the Group plans to submit a New Drug Application (NDA) for the Indication in the near future.

The combination therapy of Docetaxel for Injection (Albumin-bound) and Anbenitamab has now completed the comprehensive clinical layout across the entire disease course for HER2-positive breast cancer, encompassing neoadjuvant, adjuvant, and first-line advanced settings. The research and development (R&D) of Docetaxel for Injection (Albumin-bound) for indications such as breast cancer and gastric cancer have also entered Phase III clinical trials. The Breakthrough Therapy Designation granted to Docetaxel for Injection (Albumin-bound) and Anbenitamab will further accelerate their R&D and regulatory review processes for HER2-positive advanced breast cancer, and is expected to reshape the first-line treatment landscape of such disease.

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

Hong Kong, 14 July 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.*