**ALPHAMABONCOLOGY**

**康寧傑瑞生物製藥**

*(Incorporated in the Cayman Islands with limited liability)*

**(Stock Code: 9966)**

# VOLUNTARY ANNOUNCEMENT
# ACCEPTANCE OF NDA FOR ANBENITAMAB (KN026) AS NEOADJUVANT TREATMENT FOR HER2+ BREAST CANCER BY THE NMPA

This announcement is made by Alphamab Oncology (the "**Company**", together with its subsidiaries, the "**Group**") on a voluntary basis to inform the shareholders (the "**Shareholders**") and potential investors of the Group about the latest business advancement of the Group.

The board (the "**Board**") of directors (the "**Directors**") of the Company is pleased to announce that the new drug application (the "**NDA**") for Anbenitamab (trade name: 恩尼妥®, R&D code: KN026), co-developed with Shanghai JMT-Bio Technology Co., Ltd. (上海津曼特生物科技有限公司) ("**JMT-Bio**"), a subsidiary of CSPC Pharmaceutical Group Limited ("**CSPC Group**") (Stock Code: 1093), in combination with the docetaxel (albumin-bound) for injection (HB1801), as neoadjuvant treatment for human epidermal growth factor receptor 2 ("**HER2**")-positive ("**HER2+**") early or locally advanced breast cancer, has been accepted by the National Medical Products Administration of China (國家藥品監督管理局) (the "**NMPA**") and included in the priority review and approval procedure.

The NDA is primarily supported by a pivotal phase III clinical study (study number: KN026-004/Neo-Healer), which enrolled patients with HER2+ early or locally advanced breast cancer. The study results showed that Anbenitamab in combination with HB1801, with or without Carboplatin, as neoadjuvant treatment for HER2+ early or locally advanced breast cancer, significantly improved total pathological complete response rate ("**tpCR**") compared with the current standard therapy of trastuzumab in combination with pertuzumab and docetaxel, with or without Carboplatin. The tpCR assessed by the Blinded Independent Review Committee (BIRC) reached 62.4% (95% CI: 56.20 to 68.23), with a one-sided P=0.0036, establishing superiority with efficacy improvement of both statistical and clinical value and a manageable overall safety profile. Please refer to the Company's announcement dated June 1, 2026 for further details.

In China, approximately 75% of the patients with breast cancer are initially diagnosed at the early or locally advanced stage. Neoadjuvant treatment is a recommended standard treatment for HER2+ early or locally advanced breast cancer, and achieving tpCR through neoadjuvant treatment is an effective means of improving the long-term prognosis of such patients, with significant clinical value. The KN026-004/Neo-Healer study is the first head-to-head phase III clinical study to demonstrate that a HER2 bispecific antibody outperformed the dual-antibody combination therapy of trastuzumab and pertuzumab, with a manageable safety profile, marking a historic breakthrough for bispecific antibodies in the field of neoadjuvant treatment for breast cancer. The combination therapy of Anbenitamab and HB1801 is expected to become a new standard neoadjuvant treatment for HER2+ early or locally advanced breast cancer.

**ABOUT 恩尼妥® (ANBENITAMAB INJECTION)**

恩尼妥® (Anbenitamab injection, R&D code: KN026) is an anti-HER2 bispecific antibody independently developed by the Company using the proprietary Fc-based heterodimer bispecific platform technology called CRIB (Charge Repulsion Induced Bispecific). Anbenitamab can simultaneously bind two non-overlapping epitopes of HER2, resulting in HER2 signal blockade. Through antibody-induced receptor clustering, it enhances antibody-dependent cell-mediated cytotoxicity (ADCC) and complement-dependent cytotoxicity (CDC) effects while promoting the down-regulation of HER2 receptors on the cell surface.

In May 2026, 恩尼妥® obtained approval for marketing from the NMPA through the priority review and approval pathway for combination with chemotherapy as the treatment of adult patients with locally advanced or metastatic HER2+ gastric cancer/gastroesophageal junction cancer who have previously received at least one trastuzumab-containing regimen. The NDA for Anbenitamab as neoadjuvant treatment for HER2+ breast cancer has been accepted by the NMPA. The phase III study of Anbenitamab for first-line treatment of HER2+ breast cancer has met its primary endpoint, and an NDA will be submitted in the near future. In addition, multiple registrational clinical studies of Anbenitamab for indications such as adjuvant treatment of HER2+ breast cancer and first-line treatment of HER2+ gastric cancer/gastroesophageal junction cancer are ongoing.

Anbenitamab has been granted Orphan Drug Designation by the U.S. Food and Drug Administration (FDA) for the treatment of HER2+ or HER2-low gastric cancer. It has also been granted two Breakthrough Therapy Designations by the NMPA, for HER2+ gastric cancer (including gastroesophageal junction cancer) that has failed first-line standard treatment, and the first-line unresectable or metastatic HER2+ breast cancer.

In August 2021, we entered into a licensing agreement with JMT-Bio, pursuant to which JMT-Bio was granted exclusive development and commercialization rights for Anbenitamab in breast cancer and gastric cancer indications within Mainland China (excluding Hong Kong, Macau, and Taiwan).

**ABOUT DOCETAXEL (ALBUMIN-BOUND) FOR INJECTION (HB1801)**

Docetaxel (Albumin-Bound) for Injection (HB1801) is one of the flagship drugs independently developed by CSPC Group on its proprietary nanomedicine technology platform. With docetaxel encapsulated in human serum albumin and free of Tween-80 and ethanol, HB1801 has the following advantages over conventional docetaxel injection: (1) Safety: No steroid premedication is needed. It can be rapidly administered at high concentrations, featuring superior safety and better patient compliance; (2) Efficacy: It has exhibited remarkable efficacy in multiple preclinical tumor models and several clinical studies. Higher doses can be applied clinically to further improve therapeutic outcomes.

HB1801 has currently entered pivotal phase III registrational clinical trials for indications including breast cancer and gastric cancer. HB1801 has been granted Breakthrough Therapy Designation by the NMPA for the first-line unresectable or metastatic HER2+ breast cancer.

## ABOUT THE COMPANY

The Company is a leading biopharmaceutical company in the PRC with a fully integrated proprietary technology platform in antibody-drug conjugates ("**ADC(s)**"), bispecific antibodies and multi-functional protein engineering. The Company's highly differentiated in-house pipeline consists of ADCs, monoclonal antibodies and bispecific antibodies in staggered development status in oncology, including, among others, two products approved for marketing by the NMPA and multiple products in phase III or pivotal clinical trial stages. The Company has developed various technologies and platforms of antibody-based therapies for oncology treatment and expertise in this regard. Benefitting from the proprietary protein engineering platforms and structure-guided molecular modeling expertise, the Company is able to create a new generation of multi-functional biological drug candidates that could potentially benefit patients globally.

**Cautionary Statement required by Rule 18A.05 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited:** The Company cannot guarantee that KN026 will be successfully developed and/or marketed for indications other than the use in combination with chemotherapy for the treatment of adult patients with locally advanced or metastatic HER2+ gastric cancer/gastroesophageal junction cancer who have previously received at least one trastuzumab-containing treatment regimen. Shareholders and potential investors of the Company are advised to exercise due care when dealing in the shares of the Company.

By Order of the Board
**Alphamab Oncology**
**Dr. XU Ting**
*Chairman and Executive Director*

Hong Kong, August 4, 2026

*As at the date of this announcement, the Board comprises Dr. XU Ting as the chairman of the Board and executive Director and Ms. LIU Yang as executive Director, Mr. CHO Man as non-executive Director, and Mr. WU Dong, Ms. WONG Yan Ki Angel and Dr. GAO Xiang as independent non-executive Directors.*