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康宁杰瑞

ALPHAMAB ONCOLOGY

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康寧傑瑞生物製藥

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 9966)

INSIDE INFORMATION ANNOUNCEMENT

恩尼妥® (ANBENTAMAB INJECTION) OBTAINED MARKETING APPROVAL FROM THE NMPA

This announcement is made by Alphamab Oncology (the “**Company**”, together with its subsidiaries, the “**Group**”) pursuant to Rule 13.09(2)(a) of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the “**Listing Rules**”) and the inside information provision (as defined in the Listing Rules) under Part XIVA of the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong).

The board (the “**Board**”) of directors (the “**Director(s)**”) of the Company is pleased to announce that 恩尼妥® (Anbenitamab injection, human epidermal growth factor receptor 2 (“**HER2**”) bispecific antibody, 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), has obtained approval for marketing from the National Medical Products Administration (國家藥品監督管理局) of the PRC (the “**NMPA**”) for combination with chemotherapy as the treatment of adult patients with locally advanced or metastatic HER2-positive (“**HER2+**”) gastric cancer/gastroesophageal junction cancer (“**GC/GEJ**”) who have previously received at least one trastuzumab-containing regimen.

This marketing approval is based on the results of the pivotal phase II/III clinical study (KC-WISE), which enrolled patients with HER2+ GC/GEJ who had failed at least one prior line of therapy. The study results demonstrated that, compared to standard chemotherapy, the Anbenitamab combination therapy significantly prolonged median progression free survival (mPFS) (from 2.7 months to 7.1 months, with a hazard ratio (“**HR**”) of 0.25, representing a 75% reduction in the risk of disease progression or death) and median overall survival (mOS) (from 11.5 months to 19.6 months, with an HR of 0.29, representing a 71% reduction in the risk of death). The benefits were consistent across all patient subgroups, with similar positive trends observed for objective response rate (ORR) and duration of response (DOR). The adverse reactions were primarily chemotherapy-induced hematological toxicities, which were clinically manageable and controllable. Compared with similar competing products, it has lower incidence rates of cardiotoxicity, diarrhea, and infusion-related reactions, demonstrating a significant safety advantage.

China has a high incidence of GC, with approximately 358,700 new cases and approximately 260,400 deaths each year, among which 30% to 40% of patients are already at an advanced stage at the time of initial diagnosis, and the five-year survival rate after systemic treatment is less than 15%. HER2+ expression is strongly associated with poor prognosis in GC. Given its distinct biological characteristics and high targetability, HER2 has remained an important focus for the evolution of clinical treatment strategies. For over a decade since trastuzumab, in combination with chemotherapy, established its role as the standard first-line targeted therapy in 2010, progress in second-line anti-HER2 treatment for patients with disease progression following trastuzumab therapy has been slow, with limited clinical benefits, which remains far from sufficient to address the urgent therapeutic needs of these patients.

Second-line and later line HER2+ GC/GEJ is the first approved indication of 恩尼妥®. As the first HER2 bispecific antibody approved for marketing for the GC indication, 恩尼妥® demonstrates outstanding clinical efficacy and an excellent safety profile, and is expected to reshape the landscape of second-line treatment for advanced GC. Additionally, in March 2026, the Company announced that its phase III clinical study of Anbenitamab in combination with docetaxel (albumin-bound) for injection (HB1801) as neoadjuvant treatment for HER2+ early or locally advanced breast cancer (“BC”) met its primary endpoint of total pathological complete response (tpCR), with results that were both statistically significant and clinically meaningful. Please refer to the announcement of the Company dated March 31, 2026 for details. The results from the pivotal phase III registrational clinical study of Anbenitamab in combination with HB1801 for the first-line treatment of HER2+ BC are expected to be announced this year.

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 in China for combination with chemotherapy as the treatment of adult patients with locally advanced or metastatic HER2+ GC/GEJ who have previously received at least one trastuzumab-containing regimen. Currently, multiple registrational clinical trials of Anbenitamab for indications such as first-line treatment of HER2+ BC, neoadjuvant and adjuvant treatment of HER2+ BC and first-line treatment of HER2+ GC/GEJ 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 GC. It has also been granted Breakthrough Therapy Designation by the NMPA as second-line or above treatment of HER2+ GC/GEJ.

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 BC and GC indications within Mainland China (excluding Hong Kong, Macau, and Taiwan).

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 Listing Rules: The Company cannot guarantee that it will be able to develop and/or market KN026 for indications successfully other than the approved indication. 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, May 29, 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.