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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)

VOLUNTARY ANNOUNCEMENT

LATEST RESEARCH RESULTS OF TWO PHASE III CLINICAL STUDIES OF ANBENITAMAB (KN026) WERE PRESENTED AT THE 2026 ESMO CONGRESS AS LBA ORAL PRESENTATIONS

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 significant results for Anbenitamab (trade name: 恩尼妥®, R&D code: KN026), co-developed with JMT-Bio, a subsidiary of CSPC Group, as first-line treatment for HER2+ BC and the updated OS analysis of Anbenitamab as second-line or later treatment for HER2+ GC/GEJ were presented at the 2026 ESMO Congress as LBA oral presentations. Such research results are summarized below.

EFFICACY AND SAFETY OF ANBENITAMAB IN COMBINATION WITH HB1801 AS FIRST-LINE TREATMENT FOR PATIENTS WITH HER2+ ADVANCED BC

KN026-003/Healer is a randomized, controlled, open-label, multicenter phase III clinical study designed to evaluate the efficacy and safety of Anbenitamab in combination with docetaxel (albumin-bound) for injection (HB1801) versus trastuzumab in combination with pertuzumab and docetaxel (the “**THP Regimen**”) as first-line treatment for HER2+ recurrent or metastatic BC. The primary endpoint was PFS as assessed by BIRC. Patients with HER2+ advanced BC who had received no prior chemotherapy and HER2-targeted therapy for advanced disease were randomized 1:1 to receive Anbenitamab in combination with HB1801 (the “**Anbenitamab Group**”) or the THP Regimen (the “**THP Group**”). The study successfully met its primary endpoint following an assessment by the independent data monitoring committee in June 2026. The NDA for this regimen has been accepted by the NMPA and granted priority review status. The following results were also published in *The New England Journal of Medicine* concurrently with their presentation at the 2026 ESMO Congress.

A total of 885 patients were enrolled, including 445 patients in the Anbenitamab Group and 440 patients in the THP Group. The baseline characteristics of the two groups were generally balanced. Prior adjuvant or neoadjuvant treatment had been received by 37.1% and 36.6% of patients, hormone receptor-positive disease was observed in 54.8% and 55.2% of patients, and visceral metastases were present in 71.0% and 71.8% of patients, respectively. As of the interim analysis data cutoff date of April 30, 2026, the median follow-up was 21.4 months in the Anbenitamab Group and 20.8 months in the THP Group.

- **Efficacy:**

- **Primary endpoint of PFS:** Based on BIRC assessment, the median PFS was not reached in the Anbenitamab Group (95% CI: 24.9 to NE), compared with 14.3 months in the THP Group (95% CI: 12.4 to 16.4). Anbenitamab in combination with HB1801 significantly reduced the risk of disease progression or death by 54% compared with the THP Regimen (HR: 0.46; 95% CI: 0.37 to 0.56; $P < 0.0001$). The estimated 12-, 18 – and 24-month PFS rates were 80.2%, 66.9% and 58.5%, respectively, in the Anbenitamab Group, substantially higher than 56.9%, 42.4% and 34.4%, respectively, in the THP Group. The investigator-assessed PFS benefit was consistent with that assessed by BIRC (HR: 0.52). Subgroup analyses showed consistent PFS benefits in patients who had previously received trastuzumab (N=172; HR: 0.47) and patients with visceral metastases (N=632; HR: 0.47).
- **Other secondary endpoints:** The confirmed ORR assessed by BIRC was 87.6% in the Anbenitamab Group, significantly higher than 73.4% in the THP Group ($P < 0.001$). The investigator-assessed confirmed ORR was consistent with that assessed by BIRC. Median DoR was not reached in the Anbenitamab Group (95% CI: 27.0 to NE), compared with 16.6 months in the THP Group (95% CI: 12.5 to 20.8). The estimated 12-, 18 – and 24-month DoR rates were 80.1%, 67.2% and 58.9%, respectively, in the Anbenitamab Group, compared with 60.6%, 49.2% and 42.3%, respectively, in the THP Group, demonstrating a clear advantage in sustained response. OS data remained immature, while the Anbenitamab Group showed a trend toward an OS benefit.

- **Safety:**

- The safety profile of the Anbenitamab Group was generally comparable to that of the THP Group and was manageable, no new safety signals were observed. The most common adverse events were hematologic toxicities, alopecia and diarrhea.
- Grade 3 or above TEAEs occurred in 45.9% of patients in the Anbenitamab Group and 34.4% of patients in the THP Group. The most common grade 3 or above TEAEs were neutropenia (13.1% in the Anbenitamab Group and 8.4% in the THP Group) and leukopenia (9.7% in the Anbenitamab Group and 5.5% in the THP Group).
- SAEs occurred in 20.0% of patients in the Anbenitamab Group and 16.2% of patients in the THP Group. The most common SAEs were pneumonia (3.6% in the Anbenitamab Group and 2.1% in the THP Group) and pleural effusion (1.1% in the Anbenitamab Group, with no cases reported in the THP Group).

- **Conclusions:** KN026-003/Healer is the world's first phase III clinical study to evaluate a HER2 bispecific antibody in combination with chemotherapy as first-line treatment for HER2+ advanced BC. Compared with the current international standard THP Regimen, Anbenitamab in combination with HB1801 demonstrated a statistically significant and clinically meaningful improvement in PFS, reduced the risk of disease progression or death by 54%, and also significantly improved ORR, representing a historic breakthrough in first-line treatment while maintaining a favorable overall safety profile. With its breakthrough anti-tumor efficacy and unique advantages in ease of administration, dose-adjustment flexibility and greater accessibility, Anbenitamab in combination with HB1801 has the potential to change the existing treatment landscape and provide a new preferred first-line treatment option for patients with HER2+ advanced BC.

UPDATED OS ANALYSIS OF ANBENITAMAB IN COMBINATION WITH CHEMOTHERAPY AS SECOND-LINE OR LATER TREATMENT FOR HER2+ GC/GEJ

KN026-001/KC-WISE is a randomized, double-blind, controlled, multicenter phase III clinical study designed to evaluate the efficacy and safety of Anbenitamab in combination with chemotherapy in patients with HER2+ GC/GEJ who had failed at least one prior line of treatment. Enrolled patients with HER2+ GC/GEJ who experienced disease progression after trastuzumab-based treatment were randomized to receive Anbenitamab in combination with chemotherapy (the “**Treatment Group**”) or placebo in combination with chemotherapy (the “**Control Group**”). At the 2025 ESMO Congress, the first interim analysis results of KC-WISE demonstrated statistically significant and clinically meaningful PFS and OS benefits for Anbenitamab in combination with chemotherapy compared with placebo in combination with chemotherapy, with a favorable and manageable safety profile. For details, please refer to the announcement of the Company dated October 17, 2025. This regimen was approved for marketing by the NMPA through the priority review and approval pathway in May 2026. The prespecified interim OS analysis of KC-WISE were updated at the 2026 ESMO Congress.

As of July 15, 2026, a total of 246 patients were randomized and treated, including 125 patients in the Treatment Group and 121 patients in the Control Group. The median follow-up was 22.8 months in the Treatment Group and 22.3 months in the Control Group.

- **Efficacy:** The median OS was 19.6 months in the Treatment Group and 9.6 months in the Control Group (HR: 0.39; 95% CI: 0.28 to 0.54; P<0.0001). Consistent OS benefits were observed across all prespecified subgroups. The median PFS as assessed by the independent review committee was 7.1 months in the Treatment Group and 2.7 months in the Control Group (HR: 0.35; 95% CI: 0.26 to 0.48; P<0.0001). The investigator-assessed PFS benefit was consistent with that assessed by the independent review committee.
- **Safety:** Grade 3 or above TRAEs occurred in 69.4% of patients in the Treatment Group and 47.9% of patients in the Control Group. The most common grade 3 or above TRAEs were neutropenia (33.1% in the Treatment Group and 24.8% in the Control Group), leukopenia (27.4% in the Treatment Group and 25.6% in the Control Group) and anemia (24.2% in the Treatment Group and 12.4% in the Control Group). No TRAEs led to death in the Treatment Group, while TRAEs led to death in five patients in the Control Group.
- **Conclusions:** Compared with standard treatment, Anbenitamab in combination with chemotherapy significantly prolonged OS in patients with HER2+ GC/GEJ following failure of prior trastuzumab-containing treatment, with median OS more than doubling. These updated results provide further compelling evidence that Anbenitamab in combination with chemotherapy has the potential to become a new standard second-line treatment for HER2+ GC/GEJ and reshape the treatment landscape.

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 ADCC and 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+ GC/GEJ who have previously received at least one trastuzumab-containing regimen. The two NDAs for Anbenitamab as neoadjuvant treatment for HER2+ BC and as first-line treatment for HER2+ BC have been accepted by the NMPA. In addition, multiple registrational clinical studies of Anbenitamab for indications such as adjuvant treatment of HER2+ BC and first-line treatment of HER2+ GC/GEJ are ongoing.

Anbenitamab has been granted Orphan Drug Designation by the FDA for the treatment of HER2+ or HER2-low GC. It has also been granted two Breakthrough Therapy Designations by the NMPA for HER2+ GC (including GEJ) that has failed first-line standard treatment, and the first-line unresectable or metastatic HER2+ BC.

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 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 significant 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; and (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 BC and GC. The two NDAs for HB1801 as neoadjuvant treatment for HER2+ BC and as first-line treatment for HER2+ BC have been accepted by the NMPA. In addition, HB1801 has been granted Breakthrough Therapy Designation by the NMPA for the first-line unresectable or metastatic HER2+ BC.

ABOUT THE COMPANY

The Company is a leading biopharmaceutical company in the PRC with a fully integrated proprietary technology platform in ADCs, 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. Benefiting 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.

DEFINITIONS AND GLOSSARY OF TECHNICAL TERMS

“2025 ESMO Congress”	European Society for Medical Oncology Congress for the year of 2025
“2026 ESMO Congress”	European Society for Medical Oncology Congress for the year of 2026
“95% CI”	95% confidence interval, a commonly used concept in biostatistics, meaning in approximately 95 out of 100 times, the interval will contain the true mean value
“ADC(s)”	antibody-drug conjugate(s)
“ADCC”	antibody-dependent cell-mediated cytotoxicity
“BC”	breast cancer
“BIRC”	blinded independent review committee
“CDC”	complement-dependent cytotoxicity
“CSPC Group”	CSPC Pharmaceutical Group Limited (Stock Code: 1093)
“DoR”	duration of response
“FDA”	the United States Food and Drug Administration
“GC”	gastric cancer
“GEJ”	gastroesophageal junction cancer
“HER2”	human epidermal growth factor receptor 2
“HER2+”	human epidermal growth factor receptor 2-positive
“HR”	hazard ratio

“JMT-Bio”	Shanghai JMT-Bio Technology Co., Ltd. (上海津曼特生物科技有限公司), a subsidiary of CSPC Group
“NDA(s)”	new drug application(s)
“NMPA”	National Medical Products Administration of China (國家藥品監督管理局)
“ORR”	objective response rate
“OS”	overall survival
“PFS”	progression-free survival
“SAE(s)”	serious adverse event(s)
“TEAE(s)”	treatment emergent adverse event(s)
“TRAE(s)”	treatment-related adverse event(s)
“Tween-80”	polysorbate 80
“%”	per cent

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+ GC/GEJ 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, October 26, 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.