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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)

**VOLUNTARY ANNOUNCEMENT
NDA FOR KN026 (ANBENITAMAB INJECTION) ACCEPTED
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**”) of KN026 in combination with chemotherapy for the treatment of patients with human epidermal growth factor receptor 2 (“**HER2**”) – positive (“**HER2+**”) locally advanced, recurrent, or metastatic gastric or gastroesophageal junction cancer (“**GC/GEJ**”) who have failed at least one prior systemic therapy (which must include trastuzumab in combination with chemotherapy), co-developed with Shanghai JMT-Bio Technology Co., Ltd. (上海津曼特生物科技有限公司), a subsidiary of CSPC Pharmaceutical Group Limited (Stock Code: 1093), was accepted by the National Medical Products Administration (國家藥品監督管理局) of the People’s Republic of China (the “**PRC**”) (the “**NMPA**”). The NDA is primarily supported by a pivotal phase II/III clinical trial. The interim analysis results of which indicated that, compared with the current standard of care, KN026 in combination with chemotherapy significantly improved clinical efficacy by prolonging progression-free survival (“**PFS**”) and overall survival (“**OS**”) of patients with no new safety signals, a low incidence of cardiotoxicity, and low immunogenicity in terms of safety profile. In addition, KN026 was granted breakthrough therapy designation by the Center for Drug Evaluation (藥品審評中心) of the NMPA on November 4, 2023 and received priority review status on August 28, 2025.

Currently, there are no approved anti-HER2 therapies for second-line treatment of HER2+ gastric cancer. KN026 is the first anti-HER2 bispecific antibody in the PRC to achieve positive results in the second-line treatment of gastric cancer. The results of a phase II clinical trial of KN026 were first presented at the 2024 European Society for Medical Oncology Congress, demonstrating that KN026 in combination with chemotherapy achieved an objective response rate of 40.0%, with a median PFS of 8.6 months as assessed by an independent review committee.

ABOUT KN026

KN026 was designed to be a global-level next-generation HER2-targeted therapy. With its innovative structure, it binds simultaneously to 2 distinct clinically validated epitopes of HER2 (paratope II and IV), and maintains a wild type Fc region. This results in (i) a dual blockade of HER2-related signaling pathways, (ii) strengthened binding to HER2 receptors, (iii) a reduction of HER2 proteins on the cell surface, and (iv) increased tumor killing effect through intact antibody dependent cell-mediated cytotoxicity. These binding mechanisms enable KN026 to have excellent tumor suppressive effect.

Currently, multiple phase III clinical trials are undergoing in the PRC, including KN026 in combination with docetaxel (albumin-bound) in the first-line treatment for HER2+ breast cancer (“BC”), KN026 in combination with chemotherapy as second-line or above treatment of HER2+ GC/GEJ, and KN026 in combination with docetaxel (albumin-bound) as neoadjuvant therapy of BC.

ABOUT THE COMPANY

The Company is a leading biopharmaceutical company in the PRC with a fully integrated proprietary technology platform in antibody-drug conjugates (“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, one product 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 it will be able to develop and/or ultimately market KN026 successfully. 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, September 11, 2025

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.