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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

UPDATES IN RELATION TO A PHASE III CLINICAL TRIAL OF KN046 FOR THE TREATMENT OF ADVANCED SQ NSCLC

This announcement is made by Alphamab Oncology (the “**Company**”) 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).

Reference is made to the inside information announcement of the Company dated May 19, 2023 in relation to a phase III clinical trial of KN046 (study code: ENREACH-LUNG-01) (“**KN046-301**”), which was recommended to continue and collect further follow-up overall survival (“**OS**”) data till final OS analysis by the independent data monitoring committee following its unsuccessful unblinding because the OS did not reached statistically significant difference in May 2023.

KN046-301 is a multi-center, randomized, double-blind, placebo-controlled phase III clinical trial to evaluate the efficacy and safety of KN046, a recombinant humanized programmed death ligand 1 (“**PD-L1**”) / cytotoxic T-lymphocyte-associated protein 4 (“**CTLA-4**”) bispecific antibody invented and developed by the Company, in combination with the platinum-based chemotherapy in patients with advanced unresectable or metastatic squamous non-small cell lung cancer (“**sq NSCLC**”). In order to maximize the benefits of the subjects, patients enrolled in the chemotherapy arms were allowed to receive KN046 monotherapy or crossover treatment of other anti-PD-1/PD-L1 immune checkpoint inhibitors approved by the National Medical Products Administration of China (國家藥品監督管理局) (“**NMPA**”) randomly after occurrence of disease progression.

KN046-301 completed the first interim analysis and reached the prespecified progression-free survival (“**PFS**”) endpoint in March 2022. The interim analysis results demonstrated that, compared with chemotherapy only, KN046 in combination with the platinum-based chemotherapy shows both clinical meaningful and significant statistical improvement in the PFS in patients with sq NSCLC, reaching the prespecified superior standard of efficacy. For further details, please refer to the Company’s announcement dated March 31, 2022.

The board (the “**Board**”) of directors (the “**Directors**”) of the Company announces that the final OS analysis of KN046-301 indicated that 66.3% of the total patients enrolled in the chemotherapy arm had received crossover immunotherapy. After calibration of the effect of the late-line immunotherapy through reasonable model, KN046 in combination with platinum-based chemotherapy demonstrated statistically significant OS improvement versus placebo in combination with platinum-based chemotherapy in patients with sq NSCLC. Additionally, the group received KN046 in combination with chemotherapy demonstrated significant improvement in the PFS in the final PFS analysis.

The Company will publish the research updates of KN046-301 at industry conferences and determine next steps after sufficient analysis on the data. Due to the uncertainty in the review and approval processes by Center for Drug Evaluation (藥品審評中心) of the NMPA, the Company cannot guarantee that the new drug application of KN046 for treatment of sq NSCLC will be accepted and approved by the regulatory authorities.

Cautionary Statement required by Rule 18A.05 of the Listing Rules: The Company cannot guarantee that it will be able to develop and/or ultimately market KN046 successfully. Shareholders and potential investors of the Company are advised to exercise due care when dealing in the shares of the Company.

ABOUT KN046

KN046 is a global innovative PD-L1/CTLA-4 bispecific antibody independently developed by the Group, targeting both PD-L1 and CTLA-4 with a clear structural differentiation to improve localization with the tumor microenvironment and to reduce off-target toxicity. Multiple clinical trials of KN046 in different stages covering various indications, including, among others, non-small cell lung cancer, have been conducted in China, the United States of America and Australia. The results of these clinical trials have demonstrated a preliminary profile of good safety and promising efficacy of KN046. The Group is also exploring cooperation opportunities to conduct clinical trials of KN046 in combination with its business partners' drug candidates, to achieve better therapeutic effects.

ABOUT THE COMPANY

The Company is a leading biopharmaceutical company in China with a fully integrated proprietary technology platform in bispecific antibodies, multifunctional protein engineering and antibody drug conjugate. The Company's highly differentiated in-house pipeline consists of monoclonal antibodies, bispecific antibodies, and antibody drug conjugates in staggered development status in oncology, including, among others, one approved for marketing by the NMPA and three in late clinical stage. 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.

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

Hong Kong, September 8, 2024

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, and Dr. GUO Zijian, Mr. WEI Kevin Cheng and Mr. WU Dong as independent non-executive Directors.