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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**”, 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).

Reference is made to the announcement of the Company dated March 31, 2022, in relation to a phase III clinical trial of KN046 (study code: ENREACH-LUNG-01) (“**KN046-301**”), which completed the first interim analysis and reached the prespecified progress-free survival endpoint in March 2022.

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 PD-L1/CTLA-4 bispecific antibody invented and developed by the Company, in combination with the platinum-based chemotherapy in patients with advanced unresectable or metastatic sq NSCLC.

The board of directors of the Company (the “**Board**”) announces that KN046-301 recently has not successfully completed its unblinding because the OS has not yet reached statistically significant difference. Therefore, it was recommended by the independent data monitoring committee to continue the study and collect further follow-up OS data till final OS analysis.

Save as disclosed above, the Company currently does not expect the development progress of other clinical trials for KN046 or the Company’s other drug candidates would be affected.

## **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. Approximately 20 clinical trials of KN046 in different stages covering more than 10 types of tumors including NSCLC, triple-negative breast cancer, esophageal squamous cell carcinoma, hepatocellular carcinoma, PDAC and thymic carcinoma 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. Among them, the preliminary results of phase II clinical trials in China indicate promising activity of KN046 for NSCLC, pancreatic ductal adenocarcinoma, hepatocellular carcinoma and triple-negative breast cancer as a single therapy and in combination therapy with chemotherapy. The Group has published preliminary promising safety and efficacy data of KN046 in patients who have failed prior treatments with immune checkpoint inhibitors. The Group has initiated pivotal clinical trials in NSCLC, pancreatic ductal adenocarcinoma and thymic carcinoma. 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.

The preclinical and clinical trial results of KN046 have shown promising efficacy and indicated that KN046 is able to significantly reduce toxicity to human peripheral system. The Company believes that KN046 has the potential to become a breakthrough in cancer immunotherapy.

## **ABOUT THE COMPANY**

The Company is a leading biopharmaceutical company in China with a fully integrated proprietary biologics platform in bispecific and protein engineering. Differentiated in-house clinical pipeline of the Company includes the oncology drug candidates with one approved for marketing by the National Medical Products Administration of China (國家藥品監督管理局), three in late clinical stage and two in phase I clinical trial 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 new drug candidates that could potentially benefit patients globally.

## **DEFINITIONS AND GLOSSARY OF TECHNICAL TERMS**

“CTLA-4”	cytotoxic T-lymphocyte-associated protein 4
“NSCLC”	non-small cell lung cancer
“OS”	overall survival
“PD-L1”	programmed death ligand 1, a protein on the surface of a normal cell or a cancer cell that can attach to programmed cell death protein 1 on the surface of the T-cell that causes the T-cell to turn off its ability to kill the cancer cell
“PDAC”	pancreatic ductal adenocarcinoma
“sq NSCLC”	squamous non-small cell lung cancer

**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, 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.

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

Hong Kong, May 19, 2023

*As at the date of this announcement, the Board comprises Dr. XU Ting as the chairman and executive Director and Ms. LIU Yang as executive Director, Mr. XU Zhan Kevin as non-executive Director, and Dr. GUO Zijian, Mr. WEI Kevin Cheng and Mr. WU Dong as independent non-executive Directors.*