

Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.



康宁杰瑞

ALPHAMAB ONCOLOGY

ALPHAMAB ONCOLOGY

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 PDAC

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 (i) the voluntary announcement of the Company dated February 9, 2022 in relation to a phase III clinical trial of KN046 (“**KN046-303**”) which completed its first patient dosage in February 2022; and (ii) the voluntary announcement of the Company dated May 30, 2022 which sets out the design of KN046-303 for presentation at the 2022 annual meeting of American Society of Clinical Oncology.

KN046-303 is a multi-center, randomized, double-blind, placebo-controlled phase III clinical trial designed to evaluate the efficacy and safety of KN046 in combination with nab-paclitaxel/gemcitabine versus placebo in combination with nab-paclitaxel/gemcitabine, for the treatment of locally advanced unresectable or metastatic PDAC without systemic treatment. As of the data cut-off date (“**COD**”), August 31, 2023, its median follow-up was less than one year.

The board (the “**Board**”) of directors (the “**Directors**”) of the Company announces that, on November 14, 2023 (after trading hours), it was notified by the independent data monitoring committee (the “**iDMC**”) that no additional safety signal was identified in the interim analysis of KN046-303 (COD: August 31, 2023). It was recommended by the iDMC to continue the study and collect further follow-up OS data till final OS analysis.

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 non-small cell lung cancer, 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 non-small cell lung cancer, PDAC, 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 is conducting pivotal clinical trials in non-small cell lung cancer and PDAC. 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, 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.

GLOSSARY OF TECHNICAL TERMS

“CTLA-4”	cytotoxic T-lymphocyte-associated protein 4
“gemcitabine”	an anti-cancer chemotherapy drug
“nab-paclitaxel”	an albumin-bound, solvent-free, formulation of paclitaxel that does not require steroid premedication
“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

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, November 14, 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, and Dr. GUO Zijian, Mr. WEI Kevin Cheng and Mr. WU Dong as independent non-executive Directors.