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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**

### **THE FIRST INTERIM ANALYSIS OF A PHASE III CLINICAL TRIAL OF KN046 SUCCESSFULLY REACHED PRESPECIFIED PFS ENDPOINT**

This announcement is made by Alphamab Oncology (the “**Company**”, together with its subsidiaries, the “**Group**”) on a voluntary basis to inform the shareholders and potential investors of the Company about the latest business advancement of the Group.

The board of directors of the Company (the “**Board**”) is pleased to announce that a phase III clinical trial of KN046 (study code: ENREACH-LUNG-01) (“**KN046-301**”), has completed the first interim analysis and reached the prespecified PFS endpoint.

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 first interim analysis results of KN046-301, which was reviewed by an independent data monitoring committee (iDMC), indicate that the trial met its co-primary endpoint of PFS per the blinded independent review committee (BIRC) evaluation. 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. The safety profile is consistent with the relevant clinical research results of KN046 that we reported before. No new safety signal was observed. According to the study design of KN046-301 the co-primary endpoint of OS is not assessed in this interim analysis and is expected to be evaluated in the next interim analysis. Detailed study results of KN046-301 are expected to be published at international academic conferences in the future.

## **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. Currently, there are 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 in China, the United States of America and Australia. The results of these clinical trials have preliminarily shown a favorable safety profile and significant efficacy of KN046 in treatment. Among them, the preliminary results of the phase II clinical trials in China indicate promising activity of KN046 for NSCLC, PDAC 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 two pivotal phase III clinical trials in NSCLC, a pivotal clinical trial in PDAC and a pivotal trial in 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 Group has adopted a fast/first-to-market approach on selecting indications and the Group plans to submit the first biologic license application for KN046 in China in the middle of 2022.

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 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 three that have received investigational new drug approval or in schedule for the investigational new drug submission. 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
“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
“PFS”	progression-free survival
“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, March 31, 2022

*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 and Mr. QIU Yu Min as Non-executive Directors, and Dr. GUO Zijian, Mr. WEI Kevin Cheng and Mr. WU Dong as Independent Non-executive Directors.*