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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

IND APPROVAL BY NMPA FOR 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**”) 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**”) announces that an investigational new drug (the “**IND**”) approval for initiating a multi-center, randomized, double-blind and placebo-controlled phase III clinical trial (“**KN046-303**”) has been approved by the Center for Drug Evaluation of the National Medical Products Administration of China (the “**NMPA**”). KN046-303 is a 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 in the treatment of locally advanced unresectable or metastatic PDAC without systemic treatment, and targets to enroll 408 patients.

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 2 pivotal phase III clinical trials in NSCLC, and a pivotal trial of KN046 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 clinical-stage biopharmaceutical company in China with a fully-integrated proprietary biologics platform in bispecific antibody and protein engineering. Differentiated in-house pipeline of the Company includes fifteen oncology drug candidates with one biologic license application submitted, three in late clinical stage, and three in schedule for IND submission, and a COVID-19 multifunctional antibody. 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

“COVID-19”	coronavirus disease, an infectious disease caused by the most recently discovered coronavirus (severe acute respiratory syndrome coronavirus 2), first reported in December 2019
“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
“NSCLC”	non-small cell lung cancer
“PD-L1”	programmed death ligand 1, a protein on the surface of a normal cell or a cancer cell that can attach to PD-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 23, 2021

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.