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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

FIRST PATIENT DOSED IN A PHASE II/III CLINICAL TRIAL OF KN046 IN COMBINATION WITH LENVATINIB FOR THE TREATMENT OF PD-(L)1 REFRACTORY ADVANCED NSCLC

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 the first patient has been successfully dosed in a phase II/III clinical trial of KN046, a recombinant humanized PD-L1/CTLA-4 bispecific antibody invented and developed by the Company, in mainland China (excluding Hong Kong, Macau or Taiwan) (study code: ENREACH-LUNG-02).

ENREACH-LUNG-02 is a multi-center, open-label, randomized-controlled phase II/III pivotal clinical trial to evaluate the efficacy, safety and tolerability of KN046 combined with Lenvatinib versus Docetaxel in patients with advanced NSCLC who have progressed on anti-PD-(L)1 treatment.

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, pancreatic ductal adenocarcinoma and thymic carcinoma in China, the United States 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, pancreatic ductal adenocarcinoma 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 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 investigation new drug 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

“CTLA-4”	cytotoxic T-lymphocyte-associated protein 4, a protein expressed on all T-cells but which is expressed at the highest level on regulatory T-cells (Treg) and contributes to the suppressor function of Treg and acts as an off-switch to T-cell immune response to cancer cells
“Docetaxel”	a taxoid antineoplastic agent used in the treatment of various cancers, such as locally advanced or metastatic breast cancer, metastatic prostate cancer, gastric adenocarcinoma, and head and neck cancer
“Lenvatinib”	a kinase inhibitor used to treat certain types of cancer
“NSCLC”	non-small cell lung cancer
“PD-(L)1”	PD-1 and/or PD-L1
“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

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, October 28, 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.