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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 CLINICAL TRIAL OF KN046 COMBINED WITH AXITINIB FOR THE FIRST-LINE TREATMENT OF 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 clinical trial of KN046 (“**KN046-209**”). KN046-209 is a multi-center and open-label phase II clinical trial designed to evaluate the efficacy, safety and tolerability of KN046 in combination with Inlyta[®] (axitinib), which is developed by Pfizer Inc. (NYSE: PFE), in the first-line treatment of locally advanced or metastatic PD-L1-positive (TPS \geq 1%) NSCLC in patients without previous systemic treatment. This trial targets to enroll 54 subjects approximately and the primary endpoint is objective response rate.

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, pancreatic ductal adenocarcinoma and thymic carcinoma have been conducted 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 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 two pivotal clinical trials in NSCLC, a pivotal clinical trial in pancreatic ductal adenocarcinoma 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 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 two 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

“axitinib”	a targeted cancer drug used to treat kidney cancer after previous treatment has not been effective
“CTLA-4”	cytotoxic T-lymphocyte-associated protein 4
“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 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
“TPS”	Tumor Proportion Score, the percentage of viable tumor cells showing partial or complete membrane staining at any intensity

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, August 8, 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 as Non-executive Director, and Dr. GUO Zijian, Mr. WEI Kevin Cheng and Mr. WU Dong as Independent Non-executive Directors.