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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 APPROVALS BY NMPA FOR A PHASE IA/IB CLINICAL TRIAL OF KN052 IN THE TREATMENT OF ADVANCED SOLID TUMORS AND A PHASE II CLINICAL TRIAL OF KN046 IN COMBINATION WITH AXITINIB IN THE 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 is pleased to announce that, the Company recently received two IND approvals from the NMPA, the details of which are set out as follows: (i) an IND approval for initiating a phase Ia/Ib clinical trial for KN052, a PD-L1/OX40 bispecific antibody independently developed by the Group. This phase Ia/Ib clinical trial is designed to evaluate the safety, tolerability, pharmacokinetics/pharmacodynamics, and antineoplastic activity of KN052 in the treatment of advanced solid tumors. The study also includes expansion cohorts for specific tumor types at respective dose levels; and (ii) an IND approval for initiating a phase II clinical trial of KN046, a PD-L1/CTLA-4 bispecific antibody independently developed by the Group. This phase II clinical trial is 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 treatment of advanced NSCLC, and targets to enroll subjects with advanced or metastatic, PD-L1-positive (TPS \geq 1%) NSCLC without systemic therapy.

ABOUT KN052

KN052 is an innovative PD-L1/OX40 bispecific antibody independently developed by the Group using its bispecific antibody platform. It can simultaneously bind PD-L1 and OX40, effectively reversing tumor induced immune inhibition by blocking the PD-L1/PD-1 pathway and promoting the immune response by agonizing OX40. On the one hand, KN052 prevents the immune escape of tumor cell, on the other hand, it activates CTL T cells and attenuates Treg-mediated immunosuppression. Through synergistic mechanisms, KN052 is expected to exert strong antitumor efficacy.

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 triplenegative 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, a pivotal phase III clinical trial in PDAC 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 approved for marketing by the NMPA, three in late clinical stage, and three that have received IND approval or in schedule for the 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

“axitinib”	a small molecule tyrosine kinase inhibitor developed by Pfizer
“Board”	The board of directors of the Company
“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
“IND”	investigational new drug

“NMPA”	the National Medical Products Administration of China (中國國家藥品監督管理局)
“NSCLC”	non-small cell lung cancer
“OX40”	a type 1 transmembrane glycoprotein reported as a cell surface antigen expressed on activated T cells
“pharmacodynamics”	the study of how a drug affects an organism, which, together with pharmacokinetics, influences dosing, benefit, and adverse effects of the drug
“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
“PD-1”	programmed cell death protein 1
“PDAC”	pancreatic ductal adenocarcinoma
“pharmacokinetics”	the study of the bodily absorption, distribution, metabolism, and excretion of drugs, which, together with pharmacodynamics, influences dosing, benefit, and adverse effects of the drug
“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 Listing Rules: The Company cannot guarantee that it will be able to develop, or ultimately market, KN052 and 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, February 10, 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.