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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 RECEIVED FOR A PHASE II CLINICAL TRIAL OF KN046 IN THE U.S.

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 (“**IND**”) approval for initiating an open-label, multi-center phase II clinical trial (“**KN046-205**”) in the United States for KN046, a global innovative PD-L1/CTLA-4 bispecific antibody independently developed by the Group, has been received from the U.S. Food and Drug Administration on March 5, 2021 (U.S. Eastern Standard Time). KN046-205 is a clinical trial designed to evaluate the efficacy, safety and tolerability of KN046 in the treatment of thymic carcinoma.

ABOUT KN046

KN046 is a global innovative PD-L1/CTLA-4 bispecific antibody independently developed by the Group. KN046 simultaneously targets two clinically-validated immune checkpoints, PD-L1 and CTLA-4. Currently, there are approximately 20 clinical trials of KN046 at multiple stages covering more than ten types of tumors including non-small cell lung cancer, triple-negative breast cancer, esophageal squamous cell carcinoma, hepatocellular carcinoma and pancreatic cancer in Australia and China. The results of these clinical trials have demonstrated a preliminary profile of good safety and promising efficacy of KN046. Based on the clinical results obtained in China and Australia, the U.S. Food and Drug Administration has approved the Group to enter into a phase II trial of KN046 in the U.S. and has granted orphan drug designation to KN046 for the treatment of thymic epithelial tumors. Currently, the phase III clinical trials that are designed to evaluate the efficacy and safety of combination therapy of KN046 and platinum-based chemotherapy in patients with locally advanced unresectable or metastatic squamous non-small cell lung cancer have been launched in China.

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 and protein engineering. Differentiated in-house pipeline of the Company includes 15 oncology drug candidates with one BLA submitted, three in late clinical stage, and three in schedule for IND submission in 2021, 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
“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
“the U.S.”	the United States of America, its territories, its possessions and all areas subject to its jurisdiction

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 8, 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. JIANG Hualiang, Mr. WEI Kevin Cheng and Mr. WU Dong as Independent Non-executive Directors.