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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)

CLARIFICATION ANNOUNCEMENT

This announcement is made by Alphamab Oncology (the “**Company**”, together with its subsidiaries, the “**Group**”) on a voluntary basis.

Reference is made to an abstract (the “**Abstract**”) of a phase II clinical trial of KN046 in combination with lenvatinib in the treatment of advanced unresectable or metastatic HCC (“**KN046-IST-05**”), which was published at the website of 2022 Annual ASCO Annual Meeting at <https://meetings.asco.org/abstracts-presentations/210636>.

The Company would like to clarify certain clinical data in relation to KN046-IST-05. The Company completed the preliminary data cleaning, statistical analysis and abstract preparation from January 7, 2022 to February 14, 2022, and submitted to the 2022 ASCO Annual Meeting the Abstract on February 15, 2022. Due to the limited time for preparation before the Chinese Spring Festival holidays and the various restrictions during the COVID-19 pandemic, certain clinical data in the Abstract was not entirely cleaned. After the submission of the Abstract, the Company observed abnormal safety data and death attribution during the follow-up data review. After communicating with investigators, the Company and investigators applied to withdraw the Abstract on April 11, 2022. However, the Company later noticed that the withdrawal was not successful and the Abstract was released at the official website of 2022 ASCO Annual Meeting at 5:00 p.m. (Eastern Daylight Time) on May 26, 2022.

As confirmed by the investigators, only one patient death in KN046-IST-05 might be related to KN046, while the other three were not. Details of the four death cases in KN046-IST-05 are hereby clarified as below:

- *Patient 1:* According to the Abstract, the patient death was attributed to the unknown causes which could be related to KN046. The investigators updated that it was caused by the disease progression of HCC, and not related to KN046.
- *Patient 2:* According to the Abstract, the patient death was attributed to hyponatremia. The investigators confirmed that the patient death was attributed to the disease progression of HCC, which occurred six months after hyponatremia and was not related to KN046.
- *Patient 3:* According to the Abstract, the patient death was attributed to interstitial pneumonia related to KN046. The investigators confirmed that the patient death was attributed to the disease progression of HCC, which occurred three months after terminating the treatment with KN046.

- *Patient 4:* According to the Abstract, the patient death was attributed to interstitial pneumonia, which could be related to KN046. At the end of January 2021, CT scan results and hemogram analysis showed that the patient had bacterial pneumonia. On February 10, 2022, the patient died of respiratory failure. The investigators could not rule out the possibility of interstitial pneumonia, which might be related to KN046.

At present, KN046-IST-05 is still undergoing and shows preliminary efficacy and the manageable safety profile of KN046. The Company will conduct follow-ups on this clinical study and will update and publish the safety and efficacy data in due course.

The Company is confident about the efficacy and safety of KN046 combined with lenvatinib in the first-line treatment of HCC. The Company plans to submit an initial new drug application for the phase III clinical trial of first-line treatment of HCC and the breakthrough therapy designation application of HCC to the Center for Drug Evaluation of National Medical Products Administration of China (國家藥品監督管理局藥品審評中心) in the near future.

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 non-small cell lung cancer, triple-negative breast cancer, esophageal squamous cell carcinoma, HCC, 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 non-small cell lung cancer, 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 two pivotal clinical trials in non-small cell lung cancer, a pivotal clinical trial in PDAC 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 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 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 three 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

“Board”	the board of the 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
“CT”	Computed Tomography
“CTLA-4”	cytotoxic T-lymphocyte-associated protein 4
“Director(s)”	the directors of the Company
“HCC”	hepatocellular carcinoma
“lenvatinib”	a kinase inhibitor used to treat certain types of cancer
“PDAC”	pancreatic ductal adenocarcinoma
“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
“2022 ASCO Annual Meeting”	the 2022 annual meeting of American Society of Clinical Oncology (ASCO), the world’s leading professional organization for physicians and oncology professionals caring for people with cancer, which will take place both online and in-person from June 3 to 7, 2022

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, May 30, 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.