ALPHAMAB ONCOLOGY
康寧傑瑞生物製藥

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 9966)

VOLUNTARY ANNOUNCEMENT

UPDATES ON CLINICAL DATA FROM PHASE II CLINICAL STUDY OF KN046 COMBINED WITH CHEMOTHERAPY IN THE FIRST-LINE TREATMENT OF PDAC FOR PRESENTATION AT 2021 CSCO ANNUAL MEETING

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 the updated clinical data from a phase II clinical study (study number: KN046-IST-04) of KN046 (an anti-PD-L1/CTLA-4 bispecific antibody) combined with chemotherapy in the first-line treatment of PDAC will be presented at the 2021 annual meeting of Chinese Society of Clinical Oncology ("**2021 CSCO annual meeting**"), a professional academic group that is voluntarily constituted by clinical oncology professionals, relevant enterprises and public institutions. The 2021 CSCO annual meeting will be held from September 25, 2021 to September 29, 2021. The electronic poster will be available on the Company's website at **www.alphamabonc.com**. A summary of the updated clinical data is set out below:

EFFICACY AND SAFETY RESULTS OF KN046 IN COMBINATION WITH NAB-PACLITAXEL/GEMCITABINE IN THE FIRST-LINE TREATMENT OF LOCALLY ADVANCED UNRESECTABLE OR METASTATIC PDAC

This is a phase II clinical trial conducted in China designed to evaluate the efficacy and safety of KN046 in combination with nab-paclitaxel/gemcitabine in the first-line treatment of locally advanced unresectable or metastatic PDAC. The enrolled patients with ECOG PS 0 to 1 received KN046 at 5mg/kg Q2W combined with nab-paclitaxel at 125mg/m^2 on day 1, 8 and 15 Q4W and gemcitabine at 1000mg/m^2 on day 1, 8 and 15 Q4W for 4 to 6 cycles. Patients without disease progression received single-drug maintenance therapy of KN046 at 5mg/kg Q2W. Tumor evaluation was performed in accordance with RECIST v1.1 every 8 weeks. The primary endpoint was ORR and the secondary endpoints were DCR, DOR, TTP, PFS, OS and safety.

As of May 26, 2021, 29 patients were enrolled, among whom 20 (69.0%) patients were still under treatment and 17 (58.6%) patients had distant metastases. The median exposure duration of KN046 was 14.1 (2.0, 52.7) weeks.

- *Efficacy*. Among the 22 patients who underwent at least one tumor assessment, the complete response rate was 4.5% (1/22), the PR rate was 45.5% (10/22), and the stable disease rate was 45.5% (10/22). The ORR was 50.0% (95% CI: 28.2% to 71.8%) and the DCR was 95.5% (95% CI: 77.2% to 99.9%). 4 patients achieved PR after 4 to 6 cycles of treatment and received the surgical treatment, who met the criteria for surgical resection according to MDT assessment. The six-month PFS rate was 62.3% (95% CI: 30.4% to 82.9%).

- *Safety*. 29 patients were included in the safety analysis data set and the incidence rate of TRAEs was 55.2%, 27.6% of which at grade 3 or higher levels. 3 patients (10.3%) had experienced immune-related adverse events related to KN046 at grade 3 or higher levels, of whom 1 patient with skin rash and infusion reaction, 1 patient with autoimmune hepatitis, and 1 patient with elevated transaminase who was later confirmed to have biliary obstruction. The incidence rate of serious adverse events related to KN046 and adverse events related to KN046 leading to treatment termination was 3.4% and 6.9%, respectively. There were no adverse events leading to death.

Conclusion: KN046 combined with nab-paclitaxel/gemcitabine in the first-line treatment of locally advanced unresectable or metastatic PDAC demonstrated excellent efficacy results and the ORR was significantly improved as compared with the traditional chemotherapy. The patients were well tolerated by the combination therapy which is expected to provide a better option to patients with advanced pancreatic cancer.

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 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 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 first half 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 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

"95% CI"	95% confidence interval, a commonly used concept in biostatistics, meaning in approximately 95 out of 100 times, the interval will contain the true mean value
"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
"DCR"	disease control rate
"DOR"	duration of response, the length of time between the initial response to therapy and subsequent disease progression or relapse
"ECOG PS"	ECOG Scale of Performance Status, one standard criteria describing a patient's level of functioning in terms of their ability to care for themself, daily activity and physical ability (walking, working, etc.). ECOG PS 0 means the patient is fully active, able to carry on all pre-disease performance without restriction. ECOG PS 1 means the patient is restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
"GC"	gastric cancer
"GEJ"	gastroesophageal junction cancer
"gemcitabine"	an anti-cancer chemotherapy drug
"IND"	investigational new drug or investigational new drug application, also known as clinical trial application in China and clinical trial notification in Australia
"MDT"	multiple disciplinary team, a group of health care workers who are members of different disciplines, each providing specific services to the patient

"NSCLC"	non-small cell lung cancer
"ORR"	objective response rate
"OS"	overall survival
"paclitaxel"	a chemotherapy drug used to treat different cancers, including ovarian, breast, and NSCLC
"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 PD-1 on the surface of the T-cell that causes the T-cell to turn off its ability to kill the cancer cell
"PFS"	progression-free survival, the length of time during and after the treatment that a patient lives without the disease getting worse
"PR"	partial response
"Q2W"	every two weeks
"Q4W"	every four weeks
"RECIST" or "RECIST v1.1"	Response Evaluation Criteria in Solid Tumors, a standard way to measure the response of a tumor to treatment
"the United States"	the United States of America, its territories, its possessions and all areas subject to its jurisdiction
"TRAEs"	treatment-related adverse events
"TTP"	time to disease progression

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, September 17, 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.