ALPHAMAB ONCOLOGY
康寧傑瑞生物製藥

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 9966)

VOLUNTARY ANNOUNCEMENT

RESEARCH RESULTS ON KN046 AND KN026 FOR PRESENTATION AT 2021 ASCO 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.

Reference is made to the Company's voluntary announcement dated May 7, 2021. The board of directors of the Company (the "**Board**") announces that the research results on KN046 (a recombinant humanized PD-L1/CTLA-4 bispecific antibody) and KN026 (a Fc-based anti-HER2 bispecific antibody) will be presented at the 2021 annual meeting of American Society of Clinical Oncology ("**2021 ASCO Annual Meeting**"), the world's leading professional organization for physicians and oncology professionals caring for people with cancer. The abstracts will be available at 5:00 p.m. (Eastern Time) on May 19, 2021 and the e-poster presentation materials will be available at 9:00 p.m. (Central Time) on June 4, 2021 at **http://conferences.asco.org/am/**. Summaries of the research results are set out below:

EFFICACY AND SAFETY OF KN046 PLUS NAB-PACLITAXEL/GEMCITABINE AS FIRST-LINE TREATMENT FOR UNRESECTABLE LOCALLY ADVANCED OR METASTATIC PDAC

This study is an ongoing uncontrolled, phase II, investigator sponsored study of KN046 in combination with standard chemotherapy for systemic therapy naïve Chinese patients with locally advanced or metastatic PDAC. KN046 was administered at 5mpk plus nab-paclitaxel and gemcitabine in standard dose for four to six 4-weekly cycles, followed by maintenance therapy with KN046 at 5mpk once every two weeks. The primary endpoint is ORR. Key secondary endpoints are TTP, DCR, DOR, PFS, OS and safety.

As of January 15, 2021, 17 patients were enrolled, of which 9 were eligible to a preliminary efficacy evaluation, median aged 56 years old. 9 and 8 patients had ECOG PS 1 and 0, respectively. 7 patients had liver metastases. The median KN046 exposure time was 9.5 weeks.

- *Efficacy*. In overall response assessment with 9 patients evaluable for preliminary efficacy, the ORR (limited to PR at the time of analyses) was 55.6% (5 out of 9) and the DCR was 88.9%

- *Safety*. The overall incidence of KN046 related TRAEs was 64.7% (11 out of 17), with 29.4% (5 out of 17) at grade 3. The most common KN046 related TEAEs (≥10%) were alanine aminotransferase increased (n=5, 29.4%), nausea (n=3, 17.6%), rash (n=3, 17.6%), aspartate aminotransferase increased (n=2, 11.8%), diarrhoea (n=2, 11.8%), hyperphosphataemia (n=2, 11.8%), pyrexia (n=2, 11.8%), vomiting (n=2, 11.8%). Only one SAE was related with KN046, which was rash. No TRAEs at grade 4 or 5 were found, and no patient discontinued treatment due to TRAE with KN046.

Conclusions: This preliminary analysis indicates promising activity, safety and tolerability for the combination of KN046 with nab-paclitaxel and gemcitabine as first-line treatment for patients with unresectable locally advanced or metastatic PDAC, which confirms the rationale and feasibility for further evaluation. Further confirmation in controlled trials is warranted.

A PHASE II, OPEN-LABEL, MULTICENTER STUDY TO EVALUATE THE EFFICACY, SAFETY, AND TOLERABILITY OF KN046 IN COMBINATION WITH CHEMOTHERAPY IN SUBJECTS WITH ADVANCED NSCLC

This study is a phase II, open-label, multi-center study enrolling Chinese treatment naïve patients with stage IV metastatic NSCLC to receive KN046 in combination with standard platinum doublet chemotherapy.

As of January 19, 2021, 87 patients in two cohorts according to histology (cohort 1 for non-squamous (n=51) and cohort 2 for squamous (n=36)) were enrolled; PD-L1 ≥1% were 55.4% and PD-L1<1% were 44.6%. The median treatment duration of KN046 was 21 weeks, ranging from 1.6 weeks to 68.7 weeks.

- *Efficacy.* In 81 efficacy evaluable patients, the overall ORR was 50.6% (95% CI: 39.3% to 61.9%) and the DCR was 87.7% (95% CI: 78.5% to 93.9%). The ORR and DCR in patients with non-squamous NSCLC (n=48) were 45.8% (95% CI: 31.4% to 60.8%) and 89.6% (95% CI: 77.3% to 96.5%), respectively. The ORR and DCR in patients with squamous NSCLC (n=33) were 57.6% (95% CI: 39.2% to 74.5%) and 84.8% (95% CI: 68.1% to 94.9), respectively. Patients with the PFS and OS events accounted for 53% and 18%, respectively. The mPFS was 5.9 (95% CI: 5.3 to 8.7) months. The mOS was not reached. The OS rate at 12 and 15 months were both 74.9%. Preliminary OS was similar for patients with PD-L1≥1% and PD-L1<1%. Among patients with PD-L1≥1%, the mPFS was 6.7 months, 10.8 months for patients with PD-L1≥1% squamous NSCLC.

- *Safety.* TRAEs occurred in 92% patients. 25.3% patients experienced TRAEs at grade 3 or higher levels.

Conclusions: KN046 combined with platinum doublet chemotherapy was well tolerated and has shown promising clinical benefit in patients with stage IV NSCLC, so far particularly pronounced in patients with PD-L1 expression and squamous histology. The encouraging preliminary results supported a phase III registration trial in patients with squamous NSCLC, which were launched in the third quarter of 2020.

EFFICACY AND SAFETY OF KN046 PLUS PACLITAXEL/CISPLATIN AS FIRST-LINE TREATMENT FOR UNRESECTABLE LOCALLY ADVANCED, RECURRENT OR METASTATIC ESCC

This study is an ongoing phase II trial in China designed to evaluate the efficacy and safety of KN046 monotherapy or KN046 in combination with chemotherapy for unresectable locally advanced, recurrent or metastatic ESCC. Patients were enrolled in 3 cohorts. In cohort 3, which is reported here, patients with unresectable locally advanced, recurrent or metastatic ESCC were treated with KN046 in combination with paclitaxel and cisplatin for four to six cycles, followed by maintenance with KN046 monotherapy until progression or unacceptable toxicity. The primary endpoint was investigator-assessed ORR. Key secondary endpoints were DCR, safety, PK and immunogenicity.

As of January 14, 2021, this study enrolled 15 male patients with 52.3% aged over 60 years old, 64% in ECOG PS 1 and 80% with distant metastasis. The median exposure time to KN046 was 11.4 weeks and the average KN046 treatment was 2.4 cycles. 12 patients were included in the efficacy analysis and 15 patients in the safety analysis.

- *Efficacy.* The ORR and DCR were 58.3% and 91.6%, respectively. 7 patients (58.3%) had PR including one complete response of target lesions. 4 patients (33.3%) had SD, among whom three showing more than 20% of tumor burden reduction.

- *Safety.* The overall incidence of KN046 related adverse events was 80.0% (12 out of 15), with 13.3% (2 out of 15) graded 3 or above. The incidence of infusion-related adverse events was 7.8%, most of which were mild. The occurrence of irAEs were 53.3%, where the most common grade 3 irAEs were nausea (n=1, 6.7%) and rash (n=1, 6.7%). There is no KN046 related SAE nor adverse events at grade 4 or 5. One patient discontinued treatment due to mild hypersensitivity.

Conclusions: KN046 plus paclitaxel/cisplatin was active and well tolerated as first-line treatment for patients with advanced ESCC.

THE PRELIMINARY EFFICACY OF KN026 IN ADVANCED GC/GEJ PATIENTS WITH HER2 EXPRESSION

In this study, GC/GEJ patients who failed at least one line of previous therapy were enrolled into 2 cohorts according to HER2 over expression (cohort 1: IHC 3+ or IHC 2+ ISH+) or low expression (cohort 2: IHC 1+/2+ ISH – or IHC 0/1+ISH+), and treated with KN026 at 10mpk once every week, at 20mpk once every two weeks, or 30mpk at once every three weeks, until progression of disease, intolerable toxicity, or 2 years.

As of December 25, 2020, a total of 31 patients received KN026 treatment, including 20 patients in cohort 1 and 11 patients in cohort 2. The median drug exposure period was around 20 weeks and 6 weeks in two cohorts, respectively.

- *Efficacy.* Among 18 efficacy-evaluable patients in cohort 1, the ORR was 55.6% (10 out of 18) and the DCR was 72.2% (13 out of 18). The 9-month PFS rate was 60.4% (95% CI: 24.4% to 83.5%) in cohort 1, while the DOR, mPFS and mOS were not reached. Among nine patients receiving prior-HER2 treatment, the median time from the first dose of KN026 to last prior HER2 treatment was 55 days. The ORR was 44.4% (4 out of 9), the DOR was 4.1 months, and the DCR was 66.7% (6 out of 9). The mPFS and mOS were 5.6 months (95% CI: 1.3 to NE) and 11.0 months (95% CI: 1.4 to NE), respectively. In cohort 2, PR was observed in two out of nine efficacy-evaluable patients. The ORR and DCR were both 22.2% (2 out of 9) with mPFS of 1.4 months (95% CI: 1.0 to 5.9) and mOS of 9.6 months (95% CI: 3.0 to NE).

- *Safety.* The overall incidence of KN026 related adverse events was 87.1% (27 out of 31), with 9.7% (3 out of 31) at grade 3. The most common TRAEs were aspartate aminotransferase increased (n=8, 25.8%), rash (n=6, 19.4%), anaemia (n=5, 16.1%),alanine aminotransferase increased (n=4, 12.9%) and weight decreased (n=4, 12.9%). The TRAEs graded ≥3 were infusion related reaction (n=1, 3.2%), blood pressure increased (n=1, 3.2%), and ureteral stricture with hydronephrosis (n=1, 3.2%). No KN026 related death was reported.

Conclusions: KN026 demonstrated favorable safety and promising efficacy in Chinese HER2 over expressing GC/GEJ patients, both, either pretreated with or without anti-HER2 treatments. Further confirmation in confirmatory studies is warranted.

ABOUT KN046

KN046 is a global-level innovative 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 at multiple stages in multiple combinations, covering more than ten different cancer indications including NSCLC, TNBC, ESCC, HCC, PDAC and thymic carcinoma in China, the United States and Australia. The results of these clinical trials have demonstrated a preliminary profile of high tolerability and promising activity of KN046. Based on the clinical results obtained in China and Australia, the U.S. Food and Drug Administration has approved of a pivotal trial of KN046 in the U.S. and has granted orphan drug designation to KN046 for the treatment of thymic epithelial tumors. Currently, a phase III clinical trial to evaluate the efficacy and safety of a combination therapy of KN046 and platinum-based chemotherapy in patients with locally advanced unresectable or metastatic squamous NSCLC in China have been launched.

The preclinical and clinical trial results of KN046 have shown promising activity and indicated that KN046 has the potential to reduce off-target toxicity. KN046 is developed to be a breakthrough in cancer immunotherapy.

ABOUT KN026

KN026 was designed to be a global-level next-generation HER2-targeted therapy. With its innovative structure, it binds simultaneously to 2 distinct clinically-validated epitopes of HER2 (paratope II and IV), and maintains a wild type Fc region. This results in (i) a dual blockade of HER2-related signaling pathways, (ii) strengthened binding to HER2 receptors, (iii) a reduction of HER2 proteins on the cell surface, and (iv) increased tumor killing effect through intact ADCC. These binding mechanisms enable KN026 to have excellent tumor suppressive effect.

The Group received an umbrella IND approval for KN026 from the NMPA and an IND approval from the U.S. Food and Drug Administration in March 2018 and October 2018, respectively. Currently, several phase I/II clinical trials of KN026 are being conducted in China and a phase I clinical trial is being conducted in the United States. KN026 has shown good preliminary efficacy in patients with advanced HER2+ breast cancer and GC/GEJ.

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 15 oncology drug candidates with one biologic license application submitted, three in late clinical stage, and two to 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

"95% CI"	95% confidence interval, a commonly used concept in biostatistics, meaning for an indefinitely repeated procedure, the interval will contain the true parameter value in 95 out of 100 times
"BsAb"	bispecific monoclonal antibody
"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, the percentage of patients with advanced or metastatic cancer who have achieved complete response, partial response and stable disease to a therapeutic intervention in clinical trials of anticancer agents
"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
"ESCC"	esophageal squamous cell carcinoma
"GC/GEJ"	gastric or gastroesophageal junction cancer
"HCC"	hepatocellular cancer
"HER2"	human epidermal growth factor receptor 2
"IHC"	immunohistochemistry
"IND"	investigational new drug or investigational new drug application, also known as clinical trial application in China and clinical trial notification in Australia
"irAE(s)"	immune-related adverse events
"ISH"	in situ hybridization, a laboratory technique in which a single-stranded DNA or RNA sequence called a probe is allowed to form complementary base pairs with DNA or RNA present in a tissue or chromosome sample
"NE"	not evaluable
"NMPA"	the National Medical Products Administration of China (國家藥品監督管理局)
"NSCLC"	non-small cell lung cancer
"mpk"	mg per kilogram
"mOS"	median OS
"mPFS"	median PFS
"ORR"	objective response rate, which is equal to the sum of complete response (CR) and PR
"OS"	overall survival, refers to the time from randomization to death from any cause
"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
"PK"	pharmacokinetics, refers to 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
"PR"	partial response, refers to a decrease in the size of a tumor, or in the extent of cancer in the body, in response to treatment
"SAE"	serious adverse event
"SD"	stable disease, refers to cancer that is neither decreasing nor increasing in extent or severity
"TEAE(s)"	treatment-emergent adverse event
"the U.S." or "the United States"	the United States of America, its territories, its possessions and all areas subject to its jurisdiction
"TNBC"	triple negative breast cancer, any breast cancer that does not express the genes for estrogen receptor (ER), progesterone receptor (PR) and HER2/neu
"TRAE(s)"	treatment-related adverse event
"TTP"	time to progression, refers to the length of time from the date of diagnosis or the start of treatment for a disease until the disease starts to get worse or spread to other parts of the body

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 and KN026, 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 20, 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.