

Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.



ALPHAMAB ONCOLOGY

康寧傑瑞生物製藥

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 9966)

VOLUNTARY ANNOUNCEMENT

RESEARCH UPDATES ON KN026 IN COMBINATION WITH KN046 FOR PRESENTATION AT 2023 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.

The board (the “**Board**”) of directors (the “**Directors**”) of the Company announces that the updated research results of a phase II clinical trial of KN026 in combination with KN046 for the treatment of locally advanced unresectable or metastatic HER2-positive solid tumors other than BC or GC/GEJ (Abstract number: 3621, Poster number: 321) have been presented at the 2023 ASCO Annual Meeting, which have also been presented at the Company’s website at <http://www.alphamabonc.com>, correspondingly. Summary of research results are set out below:

EFFICACY AND SAFETY OF KN026 IN COMBINATION WITH KN046 IN PATIENTS WITH LOCALLY ADVANCED UNRESECTABLE OR METASTATIC HER2-POSITIVE OTHER SOLID TUMORS

This is an open-label, multi-center, phase II clinical trial designed to evaluate the efficacy and safety of KN026 (30mg/kg, Q3W, C1D1 and C1D8 loading) combined with KN046 (5mg/kg, Q3W) in patients with HER2-positive solid tumors other than BC or GC/GEJ. The primary endpoints were ORR and DOR according to RECIST v1.1.

As of November 10, 2022, 26 patients with HER2-positive tumor(s) other than BC or GC/GEJ were enrolled. The median age was 56 years old (aged from 37 to 67). Among them, 15 patients (57.7%) had CRC, five patients (19.2%) had NSCLC, four patients (15.4%) had gallbladder cancer, one patient (3.8%) had renal pelvis cancer, and one patient (3.8%) had PDAC.

Among all enrolled patients, (i) 15 patients (57.7%) had experienced liver metastasis; (ii) 24 patients (92.3%) including all CRC patients had received two or more lines of prior treatment; and (iii) 5 patients (19.2%) and 6 patients (23.1%) had received prior anti-HER2 and anti-PD-(L)1 therapy, respectively.

- *Efficacy:*

For 26 enrolled patients evaluable for efficacy, according to RECIST v1.1, the confirmed ORR was 53.8% (95% CI: 33.4 to 73.4) with the median DOR of 6.8 months (95% CI: 2.9 to 15.3). The median PFS was 5.6 months (95% CI: 2.9 to 16.5) and 12-month OS rate was 80.4% (95% CI: 59.1 to 91.4) with the median follow-up of 16.6 months.

For 15 CRC patients, the confirmed ORR was 53.3% (95% CI: 26.6 to 78.7) with the median DOR of 11.7 months (95% CI: 3.2 to NE). The median PFS was 12.2 months (95% CI: 2.7 to NE). The 12-month OS rate was 80.0% (95% CI: 50.0 to 93.1) with the median follow-up of 16.0 months.

- *Safety:*

Common TRAEs include infusion related reaction (38.5%), AST increased (34.6%), alanine aminotransferase increased (26.9%), conjugated bilirubin increased (26.9%), rash (26.9%), anemia (26.9%) and blood bilirubin increased (26.9%), most of which were at grade 1 or grade 2. The most common TRAEs at grade 3 or higher levels were conjugated bilirubin increased (7.7%) and AST increased (7.7%). There was no treatment-related death.

Conclusion: KN026 combined with KN046 treatment demonstrated favorable efficacy and safety profile in HER2-positive solid tumors other than BC or GC/GEJ, and especially very promising efficacy was observed in the treatment of three or more lines of HER2-positive CRC.

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 antibody-dependent cell-mediated cytotoxicity. These binding mechanisms enable KN026 to have excellent tumor suppressive effect. Several phase I/II clinical trials of KN026 have shown good preliminary efficacy in patients with advanced HER2-positive breast cancer and GC/GEJ. Currently, two phase III clinical trials of KN026 as second-line or above treatment of HER2-positive GC (including GEJ) and as first-line treatment of HER2-positive BC are ongoing in China.

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. 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 have been conducted in China, the United States of America and Australia. The results of these clinical trials have demonstrated a preliminary profile of good safety and promising efficacy of KN046. Among them, the preliminary results of phase II clinical trials in China indicate promising activity of KN046 for NSCLC, PDAC, hepatocellular carcinoma 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 is conducting pivotal clinical trials in NSCLC and PDAC. 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 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 clinical pipeline of the Company includes the oncology drug candidates with one approved for marketing by the National Medical Products Administration of China (國家藥品監督管理局), three in late clinical stage and two in phase I clinical trial stage. 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

“2023 ASCO Annual Meeting”	the 2023 annual meeting of American Society of Clinical Oncology, the world’s leading professional organization for physicians and oncology professionals caring for people with cancer
“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
“AST”	aspartate aminotransferase
“BC”	breast cancer
“C1D1”	cycle 1 day 1
“C1D8”	cycle 1 day 8
“CRC”	colorectal cancer
“CTLA-4”	cytotoxic T-lymphocyte-associated protein 4
“DOR”	duration of response
“GC”	gastric cancer
“GEJ”	gastroesophageal junction cancer
“HER2”	human epidermal growth factor receptor 2

“HER2-positive”	HER2 with immunohistochemistry test score of 3+ or HER2 gene amplification
“NE”	not evaluable
“NSCLC”	non-small cell lung cancer
“ORR”	objective response rate, which is equal to the sum of complete response and partial response
“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 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
“PFS”	progression-free survival, the length of time during and after the treatment that a patient lives without the disease getting worse
“Q3W”	once every three weeks
“RECIST v1.1”	Response Evaluation Criteria in Solid Tumors, a standard way to measure the response of a tumor to treatment
“TRAEs”	treatment-related adverse events

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, June 6, 2023

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 as non-executive Director, and Dr. GUO Zijian, Mr. WEI Kevin Cheng and Mr. WU Dong as independent non-executive Directors.