ALPHAMAB ONCOLOGY
康寧傑瑞生物製藥
(Incorporated in the Cayman Islands with limited liability)
(Stock Code: 9966)

VOLUNTARY ANNOUNCEMENT

PRESENTATION OF RESEARCH UPDATES ON KN026 AT THE SABCS 2023

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 ("**Directors**") of the Company announces that two and a half years follow-up data of KN026 combined with docetaxel as first-line treatment for HER2-positive recurrent or metastatic BC has been released during a poster session (presentation ID: P01-29-02) at the SABCS 2023, which is held in San Antonio, Texas, the United States of America from December 5, 2023 to December 9, 2023. Such research updates of KN026 are summarized as below.

TWO AND A HALF YEARS FOLLOW-UP DATA OF KN026 COMBINED WITH DOCETAXEL AS FIRST-LINE TREATMENT FOR HER2-POSITIVE RECURRENT OR METASTATIC BC

The preliminary safety and efficacy results of KN026, a novel HER2-targeted bispecific antibody, combined with docetaxel as first-line treatment for HER2-positive recurrent or metastatic BC were presented at the SABCS 2022 and its two years follow-up data was published at the 2023 congress of the European Society for Medical Oncology, both showing a promising efficacy and tolerability of KN026 as first-line treatment for HER2-positive BC, the details of which were set out in the Company's voluntary announcements dated December 9, 2022 and October 23, 2023. The two and a half years follow-up results are updated below.

This clinical trial enrolled eligible patients with recurrent or metastatic BC, HER2-positive and treatment-naïve. Patients were given KN026 30mg/kg combined with docetaxel 75mg/m^2 Q3W until the occurrence of disease progression, unacceptable toxicity, or other reasons. The primary endpoints were ORR and DoR. The secondary endpoints included safety, PFS and OS.

As of September 15, 2023, the date of data cut-off, 57 patients with the median age of 52 years old (aged from 30 to 67) were enrolled. All patients were female, among whom 52 patients (91.2%) were at stage IV. The most common sites of metastasis were lymph nodes, bone, lung and liver. 22 (38.6%) and 35 (61.4%) enrolled patients had an ECOG PS of 0 and 1, respectively.

- **Efficacy.**

  Among 55 evaluable patients, the confirmed ORR was 76.4% (95% CI: 62.98 to 86.77), the DoR was not reached (95% CI: 20.73 to NE). The mPFS was 27.7 months (95% Cl: 17.97 to NE) with a median follow-up of 30.6 months (95% CI: 29.11 to 31.77). The mPFS of patients with visceral metastasis was 23.6 months and that without visceral metastasis was not reached; the mPFS of patients with brain metastasis were 13.7 months and that without brain metastasis was 28.1 months; and the mPFS of 48 patients with high HER2 expression (IHC3+) was 28.1 months.

  The mOS was not reached, and the 12-month, 24-month and 30-month OS rates were 93.0% (95% Cl: 82.37 to 97.31), 84.1% (95% Cl: 71.73 to 91.41) and 78.5% (95% Cl: 65.16 to 87.17), respectively.

- **Safety.**

  Among all patients, the incidence of TEAEs at grade 3 or higher levels was 63.2% and there was no death resulting from KN026-related adverse events in this study. The incidence of KN026-related TRAEs at grade 3 or higher levels was 43.9%, including neutrophil count decreased (14 of 57, 24.6%), white blood cell count decreased (7 of 57, 12.3%), hypokalaemia (4 of 57, 7.0%), diarrhoea (2 of 57, 3.5%) and others (less than 2.0%). The incidence of serious adverse events related to KN026 was 12.3%.

Conclusions: KN026 in combination with docetaxel is well tolerated and has shown promising clinical benefit as first-line treatment for HER2-positive BC. After the follow-up of two and a half years, the mPFS was 27.7 months and the 24-month OS rate was 84.1%, which demonstrated very promising efficacy results without observing any new safety signal.

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 BC and GC/GEJ.

Currently, two phase III clinical trials of KN026 as second-line or above treatment of HER2-positive GC/GEJ and as first-line treatment of HER2-positive BC are ongoing in China.

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

"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
"BC"	breast cancer
"docetaxel"	a chemotherapy medication used to treat a number of types of cancer
"DoR"	duration of response
"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
"HER2"	human epidermal growth factor receptor 2
"HER2-positive"	HER2 IHC 3+ or HER2 gene amplification
"IHC"	Immunohistochemistry, which tests whether or not the cancer cells have HER2 receptors and/or hormone receptors on their surface
"mPFS"	median progression-free survival
"NE"	not evaluable
"ORR"	objective response rate
"OS"	overall survival

"PFS"	progression-free survival
"Q3W"	once every three weeks
"SABCS"	San Antonio Breast Cancer Symposium, an international forum for interaction, communication, and education for a broad spectrum of researchers, health professionals, and those with a special interest in BC
"SABCS 2023"	the 46th San Antonio Breast Cancer Symposium
"TEAE(s)"	treatment emergent adverse event(s)
"TRAE(s)"	treatment-related adverse event(s)
"%"	per cent

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 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, December 7, 2023

As of the date of this announcement, the Board comprises Dr. XU Ting as the chairman and executive Director and Ms. LIU Yang as executive Director, and Dr. GUO Zijian, Mr. WEI Kevin Cheng and Mr. WU Dong as independent non-executive Directors.