ALPHAMAB ONCOLOGY

康寧傑瑞生物製藥

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 9966)

VOLUNTARY ANNOUNCEMENT ABSTRACTS ON PRELIMINARY RESULTS FROM CLINICAL TRIALS OF KN026 AND KN046 ACCEPTED FOR POSTER PRESENTATION AT 2020 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 of directors of the Company (the "**Board**") announces that abstracts on (i) the preliminary safety, efficacy and pharmacokinetics (PK) results of a first-in-human, open-label, phase I clinical trial (the "**KN026-CHN-001 trial**") of KN026, a Fc-based anti-HER2 bispecific monoclonal antibody ("**BsAb**"), in China in patients with HER2-positive metastatic breast cancer and (ii) the preliminary efficacy and safety data of a dose escalation and expansion phase Ia/Ib clinical trial (the "**KN046-CHN-001 trial**") of KN046, a bispecific immune checkpoint inhibitor, in China in patients who have failed prior immune checkpoint inhibitors (ICI) have been accepted for poster presentation at the upcoming 2020 American Society of Clinical Oncology (the "**ASCO**") Annual Meeting. The poster presentation material will be available on the Company's website at www.alphamabonc.com on May 29, 2020.

PRELIMINARY RESULTS OF KN026 IN PATIENTS WITH HER2-POSITIVE METASTATIC BREAST CANCER

- As of January 22, 2020, 63 patients were enrolled in the KN026-CHN-001 trial and 62 patients were included in the efficacy analysis.

- 41 patients remained on treatment and 22 patients discontinued treatment due to disease progression (n = 21) and adverse events (n = 1).

- The median treatment duration was 12 weeks ranging from four to 62 weeks.

- Median prior lines of therapies are three, ranging from one to 15, and median prior lines of HER2 target therapies are two, ranging from one to 12. No dose-limiting toxicities (DLTs) were observed.

- TRAEs occurred in 49 patients and four patients experienced four grade 3 TRAEs (hypertension, infusion related reaction, transaminases increased and ventricular arrhythmia). The most common (≥10%) TRAEs were pyrexia (23.8%), diarrhea (19.0%), aspartate aminotransferase increase (15.9%), neutrophil count decrease (11.1%) and white blood cell count decrease (11.1%).

- The objective response rate at RP2D levels was 32.1% (95% CI 20.3, 46.0) and the disease control rate was 76.8% (95% CI 63.6, 87.0).

- Pharmacokinetic analysis showed C_{max} and AUC_{0-t} of KN026 increased approximately linearly with increasing dose level.

Conclusions: KN026 is well tolerated and has demonstrated encouraging anti-tumor activity in HER2-positive breast cancer patients who have failed standard anti-HER2 therapies. The RP2D of KN026 were 20 mg/kg Q2W (once every 2 weeks) and 30 mg/kg Q3W (once every 3 weeks).

PRELIMINARY EFFICACY AND SAFETY DATA OF KN046 IN PATIENTS WHO HAVE FAILED PRIOR IMMUNE CHECKPOINT INHIBITORS THERAPY

- 29 patients who have progressed on prior ICI therapies (25 anti-PD-1 antibody; 3 anti-OX40 antibody; and 1 anti-CD137 antibody) were enrolled in the KN046-CHN-001 trial and were included in the current analysis. Among the 29 patients, 19 were nasopharyngeal cancer (NPC) patients and 9 were non-small cell lung cancer (NSCLC) patients.

- The median duration of the exposure of KN046 was 12 weeks, ranging from two weeks to 40 weeks. 11 patients remained on the treatment and 18 discontinued due to disease progression (n = 13), AE (n = 1), death (n = 1) and other reasons (n = 3). 26 patients (89.7%) experienced TRAEs of all grades and 2 patients (6.9%) experienced grade≥3 TRAEs (one grade 3 anemia and one grade 3 infusion-related reaction). The most common (≥10%) TRAEs were pruritus (27.6%), rash (27.6%), asthenia (20.7%), fatigue (20.7%), pyrexia (17.2%), infusion related reaction (13.8%), alanine aminotransferase elevation (10.3%) and white blood cell count elevation (10.3%). 11 patients (37.9%) experienced irAEs. There were no grade≥3 irAEs.

- Objective responses were occurred in three patients, representing 12% of the 25 evaluable patients. The disease control rate was 52.0% (10 stable disease).

- Median PFS was 2.69 months (95% CI 1.31, 5.52). Median overall survival was not reached. PFS rates for 3 and 6 months were 41.0% (95% CI 18.5, 62.5) and 21.9% (95% CI 4.6, 47.3), respectively. OS rates for 6 and 9 months were 88% (95% CI 57.2, 97.1) and 58.7% (95% CI 8.3, 89.2), respectively.

Conclusion: KN046 showed a favorable safety profile and promising clinical benefit in advanced solid tumor patients who failed on prior ICI therapies.

ABOUT KN026

KN026 (a Fc-based anti-HER2 BsAb) is potentially a global next-generation HER2-targeted therapy that can simultaneously bind two distinct clinically-validated epitopes of HER2, resulting 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. These binding mechanisms may enable KN026 to have excellent tumor suppressive effect. Currently, several phase II clinical trials of KN026 have been conducting in China and a phase I clinical trial has been conducting in the United States of America ("**U.S.**"). KN026 has shown good preliminary efficacy in patients with advanced breast cancer.

The Group received an umbrella investigational new drug ("**IND**") approval [Note] for KN026 from the National Medical Products Administration of China ("**NMPA**") and an IND approval from the U.S. Food and Drug Administration ("**FDA**") in March 2018 and October 2018, respectively. The Group is currently conducting a phase II clinical trial of KN026 in China for breast cancer with a high level of HER2 expression in tumors and gastric/gastroesophageal junction cancer ("**GC/GEJ**") and is also conducting a phase II clinical trial for HER2-overexpressing GC/GEJ in China and a phase I clinical trial for HER2-overexpressing solid tumors, including but not limited to breast cancer and GC/GEJ, in the U.S.

Note: Pursuant to the Announcement of the NMPA Concerning Several Policies on Drug Registration Evaluation and Approval (國家食品藥品監督管理總局關於藥品註冊審評審批若干政策的公告) issued by the NMPA on November 11, 2015, the IND approval for new drugs shall be an overall approval of all phases of a new drug's clinical trials, instead of a phase-by-phase approval for each phase of a new drug's clinical trial

ABOUT KN046

KN046 is a global innovative programmed death ligand 1 ("**PD-L1**")/cytotoxic T-lymphocyte-associated protein 4 ("**CTLA-4**") bispecific antibody developed by the Group. KN046 simultaneously targets two clinically-validated immune checkpoints, PD-L1 and CTLA-4. The pre-clinical studies and clinical trials of KN046 have shown a favorable safety profile and the preliminary results of the phase I clinical trial which also indicate promising efficacy. KN046 is currently undergoing multiple phase II clinical trials for NSCLC, triple-negative breast cancer (TNBC), esophageal squamous cell carcinoma (ESCC) and pancreatic cancer. The result from these clinical trials is scheduled to be released in various occasions including medical conferences. KN046 could potentially become one of the cornerstones of the second-generation immuno-oncology treatment drugs.

ABOUT THE COMPANY

The Company is a leading clinical-stage biopharmaceutical company in China with a fully-integrated proprietary biologics platform in bispecific and protein engineering. Differentiated in-house pipeline of the Company consists of eight oncology drug candidates, including four in the phase I-III clinical trial development 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 bio-macromolecule 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
"AE(s)"	adverse event(s), any untoward medical occurrence in a patient or clinical investigation subject administered a drug or other pharmaceutical product during clinical trials and which does not necessarily have a causal relationship with the treatment
"AUC_{0-t}"	The area under the time-serum drug concentration curve (time from zero to time "t")
"CD137"	Also known 4-1BB or TNFRSF 9, tumor necrosis factor receptor superfamily member 9
"C_{max}"	maximum measured serum concentration
"HER2"	human epidermal growth factor receptor 2
"immune checkpoint inhibitor(s)" or "ICI"	molecules that release the natural brakes of immune response
"irAEs"	immune-related adverse events
"OS"	overall survival, the length of time from the first day of the treatment to the date of death
"OX40"	a secondary co-stimulatory immune checkpoint molecule, expressed after 24 to 72 hours following activation. Expression of OX40 is dependent on full activation of the T cell
"PD-1"	programmed cell death protein 1, an immune checkpoint receptor expressed on some T-cells, B-cells and macrophages that turns off the T-cell mediated immune response as part of the process that discourages a healthy immune system from attacking other cells in the body

"PFS"	progression-free survival, the length of time during and after the treatment that a patient lives without the disease getting worse
"RP2D"	recommended phase II dose
"stable disease"	cancer that is neither decreasing nor increasing in extent or severity
"TRAE(s)"	Treatment-related adverse event(s)

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 14, 2020

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.