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康宁杰瑞

ALPHAMAB ONCOLOGY

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康寧傑瑞生物製藥

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 9966)

VOLUNTARY ANNOUNCEMENT

ABSTRACTS ON CLINICAL DATA FROM PHASE II CLINICAL STUDY OF KN046 IN PATIENTS WITH ADVANCED NSCLC AND PRELIMINARY RESULTS OF KN046 IN PATIENTS WITH RARE THORACIC TUMORS FOR PRESENTATION AT WCLC 2020

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 clinical data from a Phase II clinical study of KN046 (a recombinant humanized PD-L1/CTLA-4 bispecific antibody) in patients with advanced NSCLC and (ii) the preliminary safety and efficacy results of KN046 from a Phase I clinical study of KN046 in treatment of patients with rare thoracic tumors have been accepted for the upcoming 2020 World Conference on Lung Cancer (“**WCLC 2020**”), the largest international gathering of clinicians, researchers and scientists in the field of lung cancer and thoracic oncology in the world. WCLC 2020 will be held from January 28, 2021 to January 31, 2021. The clinical data from the two studies will be released for poster presentation and oral presentation, respectively.

THE CLINICAL DATA FROM PHASE II CLINICAL STUDY OF KN046 IN PATIENTS WITH ADVANCED NSCLC (“KN046-201”)

KN046-201 is a phase II, open, multicenter clinical study designed to evaluate the efficacy, safety and tolerability of KN046 in subjects with advanced NSCLC. A total of 64 patients who had previously received first-line systematic therapy to treat NSCLC were enrolled.

- **Efficacy.** With a median follow up of 13 months, the median PFS was 3.68 months (95% CI: 3.35, 7.29): 7.29 months (95% CI: 3.68, 9.23) and 3.58 months (95% CI: 2.46, 5.52) for sq-NSCLC and non-sq NSCLC, respectively, which are numerically higher than historical data for PD-1 therapeutics in Chinese patients. 6-month survival rate was 85.6%, 12-month survival rate was 69.7%.
- **Safety.** 24 (37.5%) out of a total of 64 patients experienced the grade ≥ 3 TRAEs. TRAEs graded ≥ 3 related to KN046 are mainly infusion reactions (10.9%), anemia (4.7%), drug-induced liver injury (3.1%), abnormal liver function (3.1%), lung infection (3.1%), a decrease in neutrophil count (3.1%) and a decrease in white blood cell count (3.1%). The most frequent irAE included a decrease in neutrophil count (3.1%) and a decrease in white blood cell count (3.1%).

- *Conclusion.* KN046 was well tolerated and effective as a second-line treatment for advanced NSCLC, which indicated promising PFS and OS benefits in NSCLC.

THE PRELIMINARY SAFETY AND EFFICACY RESULTS OF KN046 IN SUBJECTS WITH RARE THORACIC TUMORS (“KN046-AUS-001”)

KN046-AUS-001 is a phase I clinical study conducted in Australia. Five subjects with rare thoracic tumors were enrolled, which include four patients with thymic epithelial tumor (two patients with thymic carcinoma (stage IV), two patients with thymoma (stage IV) and one patient with pleural mesothelioma (sarcomatoid variant, stage IIIB). The median duration of treatment was 22.7 weeks (range: 16-48).

- *Efficacy.* The study shows that KN046 has a confirmed ORR of 50%, a confirmed and unconfirmed ORR of 75% (2 confirmed PRs, 1 unconfirmed PR), and a DCR of 100% in thymic epithelial tumors.
- *Safety.* Most of TRAEs were grade 1 or 2. 14 irAEs occurred in three out of the five patients, and only one subject had two TRAEs at grade 3 autoimmune hepatitis and elevated ALT.
- *Conclusion.* KN046 has an acceptable safety profile and in line with other immune checkpoint inhibitors in patients with thymic epithelial tumors. It has preliminary but promising efficacy.

ABOUT KN046

KN046 is a global innovative PD-L1/CTLA-4 bispecific antibody independently developed by the Group. KN046 simultaneously targets two clinically-validated immune checkpoints, PD-L1 and CTLA-4. Currently, there are approximately 20 clinical trials of KN046 at multiple stages covering more than ten types of tumors including NSCLC, triple-negative breast cancer, esophageal squamous cell carcinoma, hepatocellular carcinoma and pancreatic cancer in Australia and China. The results of these clinical trials have demonstrated a preliminary profile of good safety and promising efficacy of KN046. Based on the clinical results obtained in China and Australia, the U.S. Food and Drug Administration has approved the Group to enter into a phase II trial of KN046 in the U.S. Currently, the phase III clinical trials that are designed to evaluate the efficacy and safety of combination therapy of KN046 and platinum-based chemotherapy in patients with locally advanced unresectable or metastatic squamous NSCLC have been launched in China.

The preclinical and clinical trial results of KN046 have shown promising efficacy, which indicate 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 and protein engineering. Differentiated in-house pipeline of the Company includes eight oncology drug candidates, including four in phase I-III clinical trial development stage, 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
“ALT”	alanine aminotransferase
“CTLA-4”	cytotoxic T-lymphocyte-associated protein 4
“DCR”	disease control rate
“irAE”	immune-related adverse event
“NSCLC”	non-small cell lung cancer
“ORR”	objective responses rate
“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
“OS”	overall survival
“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
“sq”	squamous
“the U.S.”	the United States of America, its territories, its possessions and all areas subject to its jurisdiction
“TRAE”	treatment-related adverse event

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, January 13, 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.