# ALPHAMAB ONCOLOGY

**康寧傑瑞生物製藥**

*(Incorporated in the Cayman Islands with limited liability)*

**(Stock Code: 9966)**

## VOLUNTARY ANNOUNCEMENT

## PRELIMINARY SAFETY TOLERABILITY AND EFFICACY RESULTS OF KN046 IN COMBINATION WITH NAB-PACLITAXEL IN PATIENTS WITH METASTATIC TRIPLE-NEGATIVE BREAST CANCER RELEASED FOR E-POSTER PRESENTATION AT 2021 AACR 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 e-poster for the presentation of the preliminary safety, tolerability and efficacy results of KN046 (a recombinant humanized PD-L1/CTLA-4 bispecific antibody) in combination with nab-paclitaxel in patients with metastatic TNBC have been released at the 2021 American Association for Cancer Research annual meeting ("**2021 AACR Annual Meeting**"), one of the first and largest cancer research organizations dedicated to accelerating the conquest of cancer. The e-poster presentation material has been available on the Company's website at http://www.alphamabonc.com since April 12, 2021.

### THE PRELIMINARY SAFETY AND EFFICACY RESULTS OF KN046 IN COMBINATION WITH NAB-PACLITAXEL IN PATIENTS WITH METASTATIC TNBC ("KN046-203")

KN046-203 is an open-label, multi-center, phase Ib/II study for KN046 in combination with nab-paclitaxel in patients with metastatic TNBC. This study enrolled patients with treatment-naïve locally advanced inoperable or metastatic TNBC. Eligible patients received nab-paclitaxel plus KN046 at two dose levels (KN046 at 3 mg/kg Q2W or KN046 at 5 mg/kg Q2W). Primary endpoint was ORR and key secondary endpoints were PFS and OS. PD-L1 expression was measured using SP142 PD-L1 immunohistochemical assay.

As of March 8, 2021, 16 patients received KN046 at 3 mg/kg Q2W in combination with nab-paclitaxel and 11 patients received KN046 at 5 mg/kg Q2W in combination with nab-paclitaxel. All 27 patients were female. 15 patients had been treated with neoadjuvant or adjuvant taxane and anthracycline chemotherapy.

- *Efficacy*. Among all 27 enrolled patients with TNBC, the median follow-up time was 13.7 months. Median PFS was 7.3 (95% CI: 3.7, NE) months. Median OS has not been reached and the 15-month OS rate was 73.4% (95% CI: 46.1%, 88.4%). Among 25 evaluable patients, the ORR was 40% and the DCR was 96%, In subgroup with PD-L1 positive (IC PD-L1≥1%), the median PFS was 13.8 (95% CI: 1.6, NE) months and the 15-month OS rate was 77.1% (95% CI: 34.5%, 93.9%).

- *Safety*. No KN046 treatment related TEAE leading to death. Grade 3 or above KN046 treatment related TEAE occurred in 13 (48.1%) patients. KN046 treatment related SAE occurred in 4 (14.8%) patients. 11 (40.7%) patients experienced irAEs. The majority of irAEs were at grade 1 or 2 except that 3 patients experienced grade 3 irAEs with two immune-mediated hepatic disorders and one rash.

According to the study, the combination of KN046 and nab-paclitaxel is safe and tolerable, and has demonstrated encouraging anti-tumor activity and response for treatment of 1L metastatic TNBC. DCR was 96.0% in all evaluable patients, and mPFS was 13.8 months in PD-L1 positive patients. These data are amongst the best of those reported by other immunotherapies. We hope it will offer a new treatment option for patients with metastatic TNBC.

**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, TNBC, 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. and has granted orphan drug designation to KN046 for the treatment of thymic epithelial tumors. 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 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 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 15 oncology drug candidates with one BLA 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

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| "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" | adverse events |
| "CTLA-4" | cytotoxic T-lymphocyte-associated protein 4 |
| "DCR" | disease control rate |
| "irAEs" | immune related adverse events |
| "NE" | not evaluable |
| "NSCLC" | non-small cell lung cancer |
| "ORR" | objective response rate |
| "OS" | overall survival |
| "PD" | progressive disease |
| "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 |
| "Q2W" | once every two weeks |
| "Q8W" | once every eight weeks |
| "RECIST" | Response Evaluation Criteria in Solid Tumors, a set of rules developed and published in February 2000, and subsequently updated in 2009 by an international collaboration including the European Organisation for Research and Treatment of Cancer (EORTC), National Cancer Institute of the United States, and the National Cancer Institute of Canada Clinical Trials Group. The rules define when tumors in cancer patients improve, stay the same, or worsen during treatment |
| "SAE" | serious adverse event |
| "TEAE(s)" | treatment emergent adverse event |
| "the U.S." | 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, progesterone receptor and HER2/neu |

**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, April 12, 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.*