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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 PRELIMINARY POSITIVE RESULTS FROM THE COMBINATION THERAPY OF KN026 AND KN046 FOR POSTER PRESENTATION AT SITC 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 announces that the combination therapy of KN026 (a recombinant humanized anti-HER2 bispecific antibody) and KN046 (a recombinant humanized PD-L1/CTLA-4 bispecific antibody) (“**KN026+KN046 Combo**”) has achieved preliminary positive results in a clinical phase Ib trial for patients with HER2 aberrated solid tumors who have failed standard therapy. Abstracts on the relevant clinical data have been accepted for poster presentation at the upcoming 35th Annual Meeting of the Society for Immunotherapy of Cancer (“**SITC 2020**”), which will be held online this year. The abstracts will be posted on 8 a.m. on November 9, 2020 (U.S. Eastern Time) and the electronic poster will be presented online from 9:00 a.m. on November 11, 2020 to 5:00 p.m. on November 14, 2020 (U.S. Eastern Time), both of which will be available on the Company’s website at www.alphamabonc.com.

The clinical phase Ib trial is a dose-escalation and dose-expansion, open label, multi-center clinical study to evaluate the preliminary safety, tolerability and efficacy results of KN026+KN046 Combo for the treatment of patients with HER2 aberrated solid tumors who have failed standard therapy. As of September 8, 2020, a total of 25 patients with gastrointestinal tumors were enrolled and treated with three dose levels of KN026+KN046 Combo. The clinical data indicated that KN026+KN046 Combo was well tolerated and no dose-limiting toxicity was observed. The preliminary results of KN026+KN046 Combo are summarized below:

- **Efficacy.** KN026+KN046 Combo for 14 evaluable subjects with HER2-positive achieved an objective response rate (ORR) of 64.3% and a disease control rate (DCR) of 92.9%. The median progression-free survival (PFS) and intermediate overall survival (OS) has not yet been achieved. The antitumor activity of KN026+KN046 Combo was not affected by previous treatments from trastuzumab and anti-PD-1 immune checkpoint inhibitors and PD-L1 expression.

- *Incidence.* The incidence of treatment-related adverse events at grade 3 or higher levels ranged from approximately 23% to 24%. Common treatment-related adverse events included infusion-related reactions, anemia, leukopenia, diarrhea, elevated transaminases, and thrombocytopenia.
- *Conclusion.* KN026+KN046 Combo demonstrated a favorable efficacy and safety profile in patients with HER2 aberrated solid tumors who have failed standard therapy.

Based on the above encouraging efficacy data, a registration clinical trial for KN026+KN046 Combo (the “**SEARCH-01**”) will be initiated. The SEARCH-01 is planned to be carried out in 20 to 30 clinical research centers in China and 10 to 20 in the U.S. clinical research centers to evaluate the combination therapy for HER2-positive solid tumors, including the efficacy, safety and tolerability of HER2-positive GC/GEJ/esophageal adenocarcinoma.

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. KN026 has shown good preliminary efficacy in patients with advanced breast cancer.

The Group received an umbrella IND approval^{Note} for KN026 from the NMPA and an IND approval from the U.S. Food and Drug Administration in March 2018 and October 2018, respectively. The Group is currently conducting a phase II clinical trial of KN026 in China for first line HER2-positive breast cancer (combination with docetaxel), late line HER2-expressing breast cancer and GC/GEJ in China, and a phase I clinical trial for HER2-positive or HER2-expressing solid tumors, including but not limited to breast cancer and GC/GEJ, in the United States. Currently, the Company is communicating with key health authorities in China and the United States on the pivotal trials of KN026. The Company plans to start a pivotal phase III trial in first line HER2-positive breast cancer in the first half of 2021.

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 PD-L1/CTLA-4 bispecific antibody developed by the Group. KN046 simultaneously targets two clinically-validated immune checkpoints, PD-L1 and CTLA-4. KN046 has been under phase I clinical trials in Australia and China and has entered phase II clinical trials in the United States and China in 2020. Currently, there are over 10 clinical trials at multiple stages covering more than 10 types of tumors including non-small cell lung cancer, triple-negative breast cancer, esophageal squamous cell carcinoma and pancreatic cancer. The results of these clinical trials have demonstrated a preliminary profile of good safety and promising efficacy of KN046. The Group has launched in China a multi-center phase III clinical trial to evaluate efficacy and safety of combination therapy of KN046 and platinum-based chemotherapy in patients with stage IV squamous non-small cell lung cancer.

KN046 could potentially become one of the cornerstone drugs of the second-generation immune-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 includes eight oncology drug candidates, including four in 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 biological new drug candidates that could potentially benefit patients globally.

DEFINITIONS AND GLOSSARY OF TECHNICAL TERMS

“Board”	the board of directors of the Company
“BsAb”	bispecific monoclonal antibody
“CTLA-4”	cytotoxic T-lymphocyte-associated protein 4
“FISH+”	<i>fluorescence in situ</i> hybridization
“GC”	gastric cancer
“GEJ”	gastroesophageal junction cancer
“HER2”	human epidermal growth factor receptor 2
“HER2-positive”	HER2 IHC3+ or IHC2+ with FISH+
“IHC2+”	immunohistochemistry with weak to moderate complete membrane staining observed in more than 10% of tumor cells
“IHC3+”	immunohistochemistry with strong complete membrane staining observed in more than 10% of tumor cells
“IND”	investigational new drug or investigational new drug application, also known as clinical trial application in China and clinical trial notification in Australia
“NMPA”	the National Medical Products Administration of China (國家藥品監督管理局) or, where the context so requires, its predecessor, the China Food and Drug Administration (國家食品藥品監督管理總局)

- “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
- “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
- “U.S.” or “United States” the United States of America, its territories, its possessions and all areas subject to its jurisdiction

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/or 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, November 10, 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.