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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 USING TRANSLATIONAL TGI MODEL AND POPULATION PK ANALYSIS FOR KN026 ACCEPTED FOR POSTER PRESENTATION AT 2020 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 abstracts on using a translational tumor growth inhibition model (the “**Translational TGI Model**”) and population pharmacokinetics (“**PK**”) analysis to predict efficacious doses for KN026, a Fc-based bispecific monoclonal antibody (“**BsAb**”) against human epidermal growth factor receptor 2 (“**HER2**”), in patients with HER2-positive metastatic breast cancer have been accepted for poster presentation at the upcoming 2020 American Association for Cancer Research (the “**AACR**”) Annual Meeting. The Company will present a joint translational and population PK and exposure-response modeling framework incorporating preclinical and clinical data to predict recommended phase II doses for KN026. The poster presentation material will be available on the Company’s website at www.alphamabonc.com on June 22, 2020.

The clinical translation of bispecific antibody could be challenging due to altered target engagement and difference between preclinical and clinical tumors. In order to predict efficacious doses for KN026, the Company applied the Translational TGI Model based on tumor growth and KN026 transplantation tumor model data from mouse to determine the target dose range for KN026 in humans. Human population PK based on KN026 from patients in a first-in-human clinical trial was performed to optimize dose selection for KN026. Efficacious doses and dosing schedules for KN026 were predicated and subsequently validated by human efficacy data.

The simulation results from the Translational TGI Model indicate that the efficacious steady state dose levels of KN026 were predicted to be 20 mg/kg Q2W (once every 2 weeks) and 30 mg/kg Q3W (once every 3 weeks). Loading doses which provides higher dosing and drug exposure in the first dosing cycle were predicted to have the advantage of maximizing initial tumor killing.

The Company expects to use the Translational TGI Model to shorten the lead time from early stage development to full development, which helps boost the registration of KN026 in major regions.

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 (the “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 (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 breast cancer with a high level of HER2 expression in tumors and gastric cancer/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. Currently, the Company is communicating with key health authorities in China and the U.S. on the pivotal trials of KN026.

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 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.

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, May 18, 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.