

Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited (the “**Stock Exchange**”) take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.



康宁杰瑞

ALPHAMAB ONCOLOGY

ALPHAMAB ONCOLOGY

康寧傑瑞生物製藥

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 9966)

VOLUNTARY ANNOUNCEMENT

BLA ACCEPTED BY THE NMPA FOR KN035 IN THE TREATMENT OF MSI-H/dMMR SOLID TUMORS

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**”) is pleased to announce that, on December 17, 2020, the National Medical Products Administration of China (the “**NMPA**”) accepted the biologic license application (“**BLA**”) for KN035, a recombinant humanized single domain antibody against programmed death ligand 1 (“**PD-L1**”) in the treatment of advanced solid tumors with microsatellite instability-high (“**MSI-H**”) phenotype/mismatch-repair deficiency (“**dMMR**”). The BLA for KN035 is the first BLA of the Company. Independently invented by the Company and co-developed with 3D Medicines (Beijing) Co., Ltd. (“**3D Medicines**”) since 2016, KN035 has undergone clinical trials for multiple tumor indications in China, the United States and Japan and the results demonstrated a manageable safety profile with promising clinical efficacy. KN035 is expected to become the first PD-1/PD-L1 antibody with subcutaneous injection globally upon the approval.

The BLA for KN035 is based on the result of a phase II clinical trial of KN035 in China. 103 patients with MSI-H/dMMR advanced cancers were enrolled at 25 centers. The overall objective response rate (“**ORR**”) was 42.7%. The ORR for patients with colorectal cancer (“**CRC**”) (n=65), gastric cancer (n=18) and other cancers (n=20) assessed and confirmed by the Blinded Independent Review Committee were 43.1%, 44.4%, and 40.0%, respectively.

ABOUT KN035

KN035 is a recombinant single domain antibody against PD-L1 fused with human Fc, a drug independently invented by the Company and co-developed with 3D Medicines since 2016. On March 30, 2020, Jiangsu Alphamab Biopharmaceuticals Co., Ltd. (“**Jiangsu Alphamab**”), a wholly-owned subsidiary of the Company, Jiangsu Simcere Pharmaceutical Co., Ltd. (“**Jiangsu Simcere**”), a subsidiary of Simcere Pharmaceutical Group Limited (“**Simcere Pharmaceutical**”), the shares of which are listed on the Stock Exchange with the stock code 2096, and 3D Medicines entered into a cooperation agreement (the “**Simcere Agreement**”). Pursuant to the Simcere Agreement, Jiangsu Simcere has been granted an exclusive marketing right in respect of oncology indications of KN035 and the rights of first refusal for in-licenses or transfers in Mainland China. KN035 has undergone clinical trials for multiple tumor indications in China, the United States and Japan, with a total of more than 900 patients enrolled. On January 18, 2020, the U.S. Food and Drug Administration (FDA) rewarded KN035 with orphan drug designation in treating advanced biliary tract cancer. TRACON Pharmaceuticals, Inc. (the shares of which are listed on the Nasdaq Global Select Market (Ticker Symbol: TCON)) was granted the exclusive and nontransferable license in the United States, Canada, Mexico and each of their dependent territories for KN035 in the field of human therapeutic applications for sarcoma.

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.

ABOUT 3D MEDICINES

3D Medicines is a clinical-stage biopharmaceutical company with a mission to help people with cancer live longer and better. Envisioning a future when cancer is managed as a chronic disease, 3D Medicines focuses on the development of differentiated next-generation immuno-oncology drugs, helping cancer patients live with prolonged survival time and a better quality of life. 3D Medicines has established a pipeline with both next-generation biological macromolecule and chemotherapeutic small-molecule drugs, as well as a professional team capable of global development, registration and commercialization operation.

ABOUT SIMCERE PHARMACEUTICAL

Sincere Pharmaceutical is a company engaged in the R&D, production and commercialization of pharmaceuticals with the national key laboratory of translational medicine and innovative pharmaceuticals. Sincere Pharmaceutical has a diversified product portfolio in strategically focused therapeutic areas, including, (i) oncology (including cell therapy), (ii) central nervous system diseases and (iii) autoimmune diseases, with leading positions in their respective therapeutic segments and/or established track record. Sincere Pharmaceutical continues to source innovative therapies globally and established extensive strategic partnership with several multinational companies.

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, KN035 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, December 21, 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.