# ALPHAMAB ONCOLOGY
# 康寧傑瑞生物製藥

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

**(Stock Code: 9966)**

## VOLUNTARY ANNOUNCEMENT

## KN035 (ENVAFOLIMAB) OBTAINED MARKETING APPROVAL IN CHINA FROM NMPA

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 November 25, 2021, KN035 (Envafolimab) (brand name: ENWEIDA，恩維達®), a recombinant humanized single domain antibody against programmed death ligand 1 ("**PD-L1**") fused with human Fc independently invented by the Company and co-developed with 3D Medicines (Beijing) Co., Ltd. ("**3D (Beijing) Medicines**"), has formally obtained the conditional approval for marketing issued by the National Medical Products Administration (國家藥品監督管理局) (the "**NMPA**"), applicable for the treatment of adult patients with advanced solid tumors who have unresectable or metastatic advanced microsatellite instability-high (MSI-H) phenotype/mismatch-repair deficiency ("**dMMR**"), including those patients with advanced colorectal cancer who have experienced disease progression after previous therapy with fluorouracil, oxaliplatin and irinotecan, as well as other patients with advanced solid tumors who have experienced disease progression after previous therapy and no satisfactory treatment alternatives.

KN035 (Envafolimab) is the world's first programmed death protein 1 ("**PD-1**")/PD-L1 antibody to be administered by subcutaneous injection. Its unique injection method differentiates itself from other PD-1/PD-L1 products currently available on the market, with the advantages of short administration time and good safety profile. The launch of KN035 (Envafolimab) will provide Chinese patients with a high quality and more convenient PD-L1 antibody.

On March 30, 2020, the Group entered into a cooperation agreement with Jiangsu Simcere Pharmaceutical Co., Ltd. ("**Jiangsu Simcere**") and 3D (Beijing) Medicines, pursuant to which, Jiangsu Simcere has been granted an exclusive marketing right in respect of oncology indications of KN035 (Envafolimab) in the People's Republic of China (except for Hong Kong Special Administrative Region, Macau Special Administrative Region and Taiwan) ("**Mainland China**") and the rights of first refusal for in-licenses or transfers in Mainland China, subject to the terms and conditions of the cooperation agreement. For details, please refer to the Company's announcement dated March 30, 2020.

**ABOUT KN035 (Envafolimab)**

KN035 (Envafolimab) 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 (Beijing) Medicines since 2016. On March 30, 2020, Jiangsu Alphamab Biopharmaceuticals Co., Ltd. ("**Jiangsu Alphamab**"), a wholly-owned subsidiary of the Company, Jiangsu Simcere, a subsidiary of Simcere Pharmaceutical Group Limited, the shares of which are listed on The Stock Exchange of Hong Kong Limited (the "**Stock Exchange**") (stock code: 2096), and 3D (Beijing) 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 nearly a total of 1,000 patients enrolled. On January 18, 2020, the Food and Drug Administration of the United States of America granted 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 antibody and protein engineering. Differentiated in-house pipeline of the Company includes fifteen oncology drug candidates with one approved for marketing by NMPA, three in late clinical stage, and three in schedule for investigation new drug submission, 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.

**Cautionary Statement required by Rule 18A.05 of the Rules Governing the Listing of Securities on the Stock Exchange:** The Company cannot guarantee that it will be able to ultimately market KN035 (Envafolimab), 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 25, 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. Guo Zijian, Mr. WEI Kevin Cheng and Mr. WU Dong as Independent Non-executive Directors.*