ALPHAMAB ONCOLOGY
康寧傑瑞生物製藥
(Incorporated in the Cayman Islands with limited liability)
(Stock Code: 9966)

VOLUNTARY ANNOUNCEMENT
NDA FOR FIRST-LINE TREATMENT OF BTC OF KN035 WAS ACCEPTED BY THE NMPA

This announcement is made by Alphamab Oncology (the "**Company**", together with its subsidiaries, the "**Group**") on a voluntary basis to inform the shareholders (the "**Shareholders**") and potential investors of the Group about the latest business advancement of the Group.

The board (the "**Board**") of directors (the "**Directors**") of the Company is pleased to announce that the National Medical Products Administration (國家藥品監督管理局) of the PRC (the "**NMPA**") has formally accepted the new drug application (the "**NDA**") for KN035 (Envafolimab Injectable) (brand name: ENWEIDA, 恩維達®) in combination with the Gemcitabine and Oxaliplatin ("**GEMOX**") regimen for the first-line treatment of unresectable or metastatic biliary tract cancer ("**BTC**").

This acceptance is based on the clinical study results from the Phase III clinical trial (KN035-CN-005), a randomized, parallel-controlled, multicenter Phase III clinical trial designed for Chinese patients with advanced first-line BTC. The trial aims to evaluate the efficacy and safety of KN035 combined with the GEMOX regimen compared to the GEMOX regimen alone.

ABOUT KN035 (Envafolimab Injectable) (brand name: ENWEIDA, 恩維達®)

KN035 (Envafolimab Injectable) is a recombinant single domain antibody against programmed death ligand 1 ("**PD-L1**") fused with human Fc, a drug independently invented by the Company and co-developed with 3D Medicines (Beijing) Co., Ltd. (思路迪(北京)醫藥科技有限公司) ("**3D Medicines**") since 2016. On March 30, 2020, Jiangsu Alphamab Biopharmaceuticals Co., Ltd. (江蘇康寧傑瑞生物製藥有限公司) ("**Jiangsu Alphamab**"), a wholly-owned subsidiary of the Company, Jiangsu Simcere Pharmaceutical Co., Ltd. (江蘇先聲藥業有限公司) ("**Jiangsu Simcere**"), a subsidiary of Simcere Pharmaceutical Group Limited, the shares of which are listed on the Stock Exchange (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. In January 2024, we entered into a license agreement with 3D Medicines and Glenmark Specialty S.A. ("**Glenmark**"), pursuant

to which 3D Medicines and the Group agreed to grant Glenmark an exclusive license and the right to sublicence in respect of oncology indications of KN035 to, among others, develop and commercialize KN035 in India, Asia Pacific (excluding Singapore, Thailand and Malaysia), Middle East and Africa, Russia, Commonwealth of Independent States and Latin America in all fields of use in oncology. Furthermore, it has been approved by the NMPA 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**") as the global-first subcutaneous injection PD-L1 inhibitor in November 2021.

ABOUT THE COMPANY

The Company is a leading biopharmaceutical company in the PRC with a fully integrated proprietary technology platform in antibody-drug conjugate ("**ADC(s)**"), bispecific antibodies and multi-functional protein engineering. The Company's highly differentiated in-house pipeline consists of ADCs, monoclonal antibodies and bispecific antibodies in staggered development status in oncology, including, among others, one product approved for marketing by the NMPA and multiple products in phase III or pivotal clinical trial stages. 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 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 and/or market KN035 for indications successfully other than the approved indication in previously treated MSI-H/dMMR advanced solid tumors, and cannot guarantee that the NDA for first-line treatment for unresectable or metastatic BTC will be approved 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, January 9, 2026

As at the date of this announcement, the Board comprises Dr. XU Ting as the chairman of the Board and executive Director and Ms. LIU Yang as executive Director, Mr. CHO Man as non-executive Director, and Mr. WU Dong, Ms. WONG Yan Ki Angel and Dr. GAO Xiang as independent non-executive Directors.