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ALPHAMAB ONCOLOGY

康寧傑瑞生物製藥

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 9966)

VOLUNTARY ANNOUNCEMENT

IND APPROVAL BY CDE FOR A PHASE I/II CLINICAL TRIAL OF JSKN033

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 a phase I/II clinical trial of JSKN033 (study number: JSKN033-102), a high-concentration subcutaneous co-formulation consisting of anti-HER2 bispecific antibody-drug conjugate (“**ADC**”) and PD-L1 immune checkpoint inhibitor, has been approved by receiving an investigational new drug (“**IND**”) approval from the Center for Drug Evaluation (the “**CDE**”) of the National Medical Products Administration (the “**NMPA**”).

JSKN033-102 is an open-label, multicenter, phase I/II clinical trial designed to evaluate the safety, tolerability, pharmacokinetics/pharmacodynamics and anti-tumor activity of JSKN033 in patients with advanced metastatic malignant tumors, and to determine the maximum tolerated dose and/or the recommended phase II dose.

The first-in-human phase I/II clinical study of JSKN033 conducted in Australia (JSKN033-101) demonstrated a favorable safety profile and encouraging anti-cancer activity in heavily treated patients. Detailed clinical data were presented at the Annual Meeting of the Society for Immunotherapy of Cancer in 2024, and it can be referred to the Company’s voluntary announcement dated November 10, 2024.

ABOUT JSKN033

JSKN033 is a global first subcutaneous co-formulation with JSKN003, the HER2 bispecific antibody-conjugated drug and Envafolelimab, the PD-L1 monoclonal antibody, developed by the Group. JSKN003 is a biparatopic HER2-targeting ADC, of which a topoisomerase I inhibitor is linked to the N glycosylation site of the antibody KN026 (a recombinant humanized anti-HER2 bispecific antibody) via the glycosite-specific conjugation. Envafolelimab is a Fc fusion protein consisting of humanized anti-PD-L1 single domain antibody and human Immunoglobulin G1 Fc fragment, which has been approved by the NMPA as the global-first subcutaneous injection PD-L1 inhibitor in November 2021.

ABOUT THE COMPANY

The Company is a leading biopharmaceutical company in China with a fully integrated proprietary technology platform in bispecific antibodies, multifunctional protein engineering and ADC. The Company's highly differentiated in-house pipeline consists of monoclonal antibodies, bispecific antibodies, and ADCs in staggered development status in oncology, including, among others, one approved for marketing by the NMPA and three in late clinical 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 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 JSKN033, JSKN003 and 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, December 24, 2024

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 Dr. GUO Zijian, Mr. WEI Kevin Cheng and Mr. WU Dong as independent non-executive Directors.