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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

JSKN003 WAS GRANTED BREAKTHROUGH THERAPY DESIGNATION 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 JSKN003 has been granted breakthrough therapy designation by the Center for Drug Evaluation (藥品審評中心) of the National Medical Products Administration of China (國家藥品監督管理局) (the “**NMPA**”) for the treatment of platinum-resistant recurrent epithelial ovarian cancer (“**PROC**”), primary peritoneal cancer, or fallopian tube cancer, not restricted by human epidermal growth factor receptor 2 (“**HER2**”) expression (the “**Indication**”).

The grant of breakthrough therapy designation is based on the pooled analysis of two clinical studies, JSKN003-101 and JSKN003-102. JSKN003-101 is a first-in-human, open-label and multi-center phase I clinical study divided into dose-escalation stage and dose-expansion stage in Australian patients with advanced/metastatic solid tumors. JSKN003-102 is a phase I (dose escalation and dose expansion) and phase II (cohort expansion) clinical study conducted in Chinese patients with advanced solid tumors. For details of the pooled analysis of JSKN003-101 and JSKN003-102, please refer to the Company’s announcement dated September 15, 2024. The phase III clinical study of JSKN003 for the Indication is currently in the enrollment phase and the study is progressing smoothly.

As a novel bispecific antibody-drug conjugate (“**ADC**”), JSKN003 leverages the synergistic mechanism of enzyme catalysis and click chemistry to enhance serum stability and bystander effects, while demonstrating superior efficacy. The grant of breakthrough therapy designation is expected to accelerate the clinical development, review and approval process of JSKN003, enabling more patients with PROC to benefit sooner.

ABOUT JSKN003

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. The click reaction-based conjugation confers better serum stability than maleimide-Michael reaction-based conjugation. The biparatopic HER2 targeting enables JSKN003 to have a stronger internalization induction and bystander killing effect, leading to potent anti-tumor activity in HER2 expression tumors.

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 and/or ultimately market JSKN003 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, March 18, 2025

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.