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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 FTD BY THE U.S. FDA FOR THE TREATMENT OF PROC

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 Fast Track Designation (the “**FTD**”) by the U.S. Food and Drug Administration (the “**FDA**”) for the treatment of platinum-resistant recurrent epithelial ovarian cancer, primary peritoneal cancer, or fallopian tube cancer (collectively referred to as “**PROC**”), not restricted by human epidermal growth factor receptor 2 (“**HER2**”) expression. This marks another significant milestone in the global development of JSKN003.

In addition, JSKN003 has received the U.S. FDA approval to initiate a phase II clinical trial in the treatment of PROC not restricted by HER2 expression and has been granted Breakthrough Therapy Designations 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 both PROC and colorectal cancer (“**CRC**”) and has been granted an Orphan Drug Designation by the U.S. FDA for gastric cancer and gastroesophageal junction cancer (GC/GEJ). Furthermore, the phase III clinical trial of JSKN003 in the treatment of PROC not restricted by HER2 expression is progressing successfully in China. This FTD further demonstrates the international regulatory community’s confidence in JSKN003’s clinical potential and its importance as a novel therapeutic candidate.

The grant of FTD is based on the promising clinical data of JSKN003. The Company has presented a pooled analysis of the phase I clinical study in Australia (JSKN003-101) and the phase I/II clinical study in China (JSKN003-102) at the 2025 Annual Meeting of the American Society of Clinical Oncology. As of February 28, 2025, 46 patients with PROC, including 21 patients (45.7%) with HER2 IHC 0 and 18 patients (39.1%) with HER2 IHC 1+, 2+, 3+, were enrolled. Among all 46 patients, the objective response rate (“**ORR**”) was 63.0%, the median progression-free survival (“**mPFS**”) was 7.7 months. In patients with HER2 IHC 1+, 2+ and 3+, the ORR was 72.2%, the mPFS was 9.4 months. JSKN003 demonstrated robust PFS improvement in PROC, and the efficacy was observed across different HER2 expressions. See the announcement of the Company dated June 3, 2025 for details.

Ovarian cancer is one of the most common malignant tumors of the female reproductive system. The majority of patients are diagnosed at an advanced stage and face a high recurrence rate and poor prognosis. For patients with PROC, treatment options remain limited. According to clinical data and published guidelines, current non-platinum single-agent chemotherapies (with or without targeted therapy such as bevacizumab) have an ORR of only approximately 10% to 15%, a mPFS of about 3 to 4 months, and a median overall survival of roughly 12 months, underscoring a significant unmet clinical need. The Company believes that this FTD will further expedite the clinical development and regulatory review of JSKN003 and bring new choice to patients with PROC worldwide.

ABOUT JSKN003

JSKN003 is a biparatopic HER2-targeting antibody-drug conjugate (“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 chemistry-based conjugation confers better serum stability than maleimide-Michael reaction-based conjugation. The biparatopic HER2 targeting enhances internalization and bystander killing effect, resulting in potent anti-tumor activity in HER2-expression tumors. In September 2024, the Company entered into a licensing agreement with Shanghai JMT-Bio Technology Co., Ltd. (上海津曼特生物科技有限公司) to develop, sell, offer for sale and commercialize JSKN003 for the treatment of tumor-related indications in mainland China. Currently, multiple phase III clinical trials of JSKN003 in the treatment of HER2-positive breast cancer (“BC”), HER2-low expression BC, PROC and CRC in China are undergoing.

ABOUT THE COMPANY

The Company is a leading biopharmaceutical company in the PRC with a fully integrated proprietary technology platform in ADCs, 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 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, October 27, 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 Mr. WU Dong, Ms. WONG Yan Ki Angel and Dr. GAO Xiang as independent non-executive Directors.