

*Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.*



**康宁杰瑞**

ALPHAMAB ONCOLOGY

**ALPHAMAB ONCOLOGY**

**康寧傑瑞生物製藥**

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

**(Stock Code: 9966)**

## **VOLUNTARY ANNOUNCEMENT**

### **JSKN003 FOR THE TREATMENT OF GC/GEJ WAS GRANTED ODD BY THE U.S. FDA**

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 Orphan Drug Designation (“**ODD**”) by the U.S. Food and Drug Administration (the “**FDA**”) for the treatment of gastric cancer and gastroesophageal junction cancer (“**GC/GEJ**”).

ODD is an FDA initiative aimed at encouraging the development of innovative drugs for the treatment of diseases affecting fewer than 200,000 people in the U.S. The designation of JSKN003 will be beneficial to obtain relevant policy supports for subsequent research and development (“**R&D**”), registration, and commercialization in the U.S., including funding for R&D costs, tax credits for clinical trial expenditures, waiver of prescription drug user fee, accelerated review and approval processes, etc., and, upon approval, the potential for seven years of market exclusivity in the U.S.

GC/GEJ remains a global health problem. It is the fifth most common cancer and the fifth leading cause of cancer death worldwide. According to the 2022 Global Cancer Statistics report released by the International Agency for Research on Cancer, a subsidiary of the World Health Organization, there are approximately 960,000 new cases diagnosed and 660,000 deaths worldwide annually. In the U.S., the SEER database model predicts that there will be 26,890 new cases and 10,880 new deaths of GC/GEJ in 2024, with a five-year overall survival rate of less than 40%.

Regarding the treatment options, Fluoropyrimidine and platinum-based regimen is commonly used as the first line therapy. Available second or late line therapies include paclitaxel plus ramucirumab, paclitaxel, docetaxel or irinotecan monotherapy, and best supportive care, the objective response rate of which is approximately 15-25%. Median overall survival is only about 8-9 months at second line and 4-6 months at late line.

## ABOUT JSKN003

JSKN003 is a biparatopic human epidermal growth factor receptor 2 (“**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 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. 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, three phase III clinical trials of JSKN003 in the treatment of HER2-positive breast cancer (“**BC**”), HER2-low expression BC and platinum-resistant recurrent epithelial ovarian cancer, primary peritoneal cancer, or fallopian tube cancer in China are undergoing.

## ABOUT THE COMPANY

The Company is a leading biopharmaceutical company in China 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 National Medical Products Administration of China (國家藥品監督管理局) 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, July 28, 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 Ms. WONG Yan Ki Angel, Dr. GAO Xiang and Mr. WU Dong as independent non-executive Directors.*