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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**

# THE INTERIM ANALYSIS OF A PIVOTAL PHASE II/III CLINICAL TRIAL OF KN026 HAS MET THE PRIMARY ENDPOINT OF PFS

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 II/III clinical trial of KN026 ("KN026-001"), co-developed with Shanghai JMT-Bio Technology Co., Ltd. (上海津曼特生物科技有限公司), a subsidiary of CSPC Pharmaceutical Group Limited (Stock Code: 1093), in combination with chemotherapy as second-line or above treatment of HER2-positive GC (including GEJ), has completed the first interim analysis and the results of the interim analysis have reached the primary endpoint of PFS.

Part 2 of KN026-001 is a randomized, double-blind, placebo-controlled Phase III study to evaluate the efficacy of KN026 in combination with chemotherapy for the treatment of patients with HER2-positive advanced unresectable or metastatic GC (including GEJ) who have failed first-line standard treatment. The primary endpoints of the study are PFS and overall survival (OS) assessed by the Independent Review Committee (IRC).

The first PFS interim analysis results from Part 2 of the KN026-001 study, which was reviewed by an independent data monitoring committee (IDMC), showed that the pre-specified primary endpoint of PFS was met with both statistical significance and clinical relevance. The interim analysis of PFS showed that KN026 in combination with chemotherapy significantly improved PFS as compared with the current standard treatment, which reduced the risk of disease progression or death, and showed a trend toward OS benefit. Detailed data from the study will be presented at an upcoming international academic conference.

### **ABOUT KN026**

KN026 was designed to be a global-level next-generation HER2-targeted therapy. With its innovative structure, it binds simultaneously to 2 distinct clinically validated epitopes of HER2 (paratope II and IV), and maintains a wild type Fc region. This results in (i) a dual blockade of HER2-related signaling pathways, (ii) strengthened binding to HER2 receptors, (iii) a reduction of HER2 proteins on the cell surface, and (iv) increased tumor killing effect through intact antibody dependent cell-mediated cytotoxicity. These binding mechanisms enable KN026 to have excellent tumor suppressive effect. Several phase I/II clinical trials of KN026 have shown good preliminary efficacy in patients with advanced HER2-positive BC and GC/GEJ. KN026 in combination with chemotherapy for the treatment of patients with HER2-positive GC (including GEJ) who have failed first-line standard treatment, was granted breakthrough therapy designation by the Center for Drug Evaluation (CDE) of the NMPA in November 2023.

Currently, three phase III clinical trials are undergoing in China, including KN026 in combination with docetaxel (albumin-bound) in the first-line treatment for HER2-positive BC, KN026 in combination with chemotherapy as second-line or above treatment of HER2-positive GC/GEJ, and KN026 in combination with docetaxel (albumin-bound) as neoadjuvant therapy of BC.

## ABOUT THE COMPANY

The Company is a leading biopharmaceutical company in China with a fully integrated proprietary technology platform in ADCs, bispecific antibodies and multifunctional 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.

#### DEFINITIONS AND GLOSSARY OF TECHNICAL TERMS

"ADC(s)" antibody-drug conjugate(s)

"BC" breast cancer

"China" the People's Republic of China

"Fc" fragment crystallizable region, which is the tail region of an antibody

that interacts with cell surface receptors called Fc receptors and some

proteins of the complement system

"GC" gastric cancer

"GEJ" gastroesophageal junction adenocarcinoma

"HER2" human epidermal growth factor receptor 2

"NMPA" National Medical Products Administration of China (國家藥品監督管

理局)

"PFS" progression-free survival

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 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, April 30, 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.