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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

FIRST PATIENT DOSED IN A PHASE III CLINICAL TRIAL OF KN026 IN COMBINATION WITH HB1801 FOR THE FIRST-LINE TREATMENT OF HER2-POSITIVE METASTATIC BC

This announcement is made by Alphamab Oncology (the “**Company**”, together with its subsidiaries, the “**Group**”) on a voluntary basis to inform the shareholders and potential investors of the Company about the latest business advancement of the Group.

The board (the “**Board**”) of directors (the “**Directors**”) of the Company is pleased to announce that the first patient has been successfully dosed in a randomized, controlled, open-label, multi-center, phase III clinical trial of KN026 in China, the purpose of which is to compare the efficacy and safety of KN026 combined with HB1801 to trastuzumab combined with pertuzumab and docetaxel in the first-line treatment for HER2-positive recurrent or metastatic BC.

This clinical trial targets to enroll a total of 880 patients with recurrent or metastatic BC confirmed by histology and/or cytology, and without prior systemic chemotherapy and/or HER2-targeted therapy, who will be randomized 1:1 into the treatment group and control group. Patients in the treatment group will receive KN026 (30mg/kg, Q3W) and HB1801 (100mg/m², Q3W); Patients in the control group will receive pertuzumab (840mg loading dose followed by 420mg, Q3W), trastuzumab (8mg/kg loading dose followed by 6mg/kg, Q3W) and docetaxel (75mg/m², Q3W). The primary endpoint of such clinical trial is PFS as assessed by the blinded independent review committee according to RECIST v1.1.

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. Currently, two phase III clinical trials of KN026 as second-line or above treatment of HER2-positive GC (including GEJ) and as first-line treatment of HER2-positive BC are ongoing in China.

ABOUT THE COMPANY

The Company is a leading biopharmaceutical company in China with a fully integrated proprietary biologics platform in bispecific and protein engineering. Differentiated in-house clinical pipeline of the Company includes the oncology drug candidates with one approved for marketing by the National Medical Products Administration of China (國家藥品監督管理局), three in late clinical stage and two in phase I clinical trial 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 new drug candidates that could potentially benefit patients globally.

DEFINITIONS AND GLOSSARY OF TECHNICAL TERMS

“BC”	breast cancer
“docetaxel”	a chemotherapy medication used to treat a number of types of cancer
“GC”	gastric cancer
“GEJ”	gastroesophageal junction cancer
“HB1801”	a kind of docetaxel for injection (albumin binding) independently developed by CSPC Zhongqi Pharmaceutical Technology (Shijiazhuang) Co., Ltd. (石藥集團中奇製藥技術(石家莊)有限公司), a wholly-owned subsidiary of CSPC Pharmaceutical Group Limited, the shares of which are listed on the Main Board of The Stock Exchange of Hong Kong Limited (stock code: 1093)
“HER2”	human epidermal growth factor receptor 2
“HER2-positive”	HER2 with immunohistochemistry test score of 3+ or HER2 gene amplification
“pertuzumab”	a monoclonal antibody used in combination with trastuzumab and docetaxel for the treatment of metastatic HER2-positive BC
“PFS”	progression-free survival, the length of time during and after the treatment that a patient lives without the disease getting worse
“Q3W”	once every three weeks
“RECIST v1.1”	Response Evaluation Criteria in Solid Tumors, a standard way to measure the response of a tumor to treatment
“trastuzumab”	a monoclonal antibody used to treat BC and stomach cancer

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 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, July 28, 2023

As at the date of this announcement, the Board comprises Dr. XU Ting as the chairman and executive Director and Ms. LIU Yang as executive Director, and Dr. GUO Zijian, Mr. WEI Kevin Cheng and Mr. WU Dong as independent non-executive Directors.