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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**

### **KN026 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 and potential investors of the Company about the latest business advancement of the Group.

The board (the “**Board**”) of the directors (the “**Directors**”) of the Company is pleased to announce that KN026 (a human epidermal growth factor receptor 2 (“**HER2**”)-targeted bispecific antibody), in combination with chemotherapy, has been granted breakthrough therapy designation for the treatment of patients with HER2-positive gastric cancer (“**GC**”) (including gastroesophageal junction cancer (“**GEJ**”)) who have failed first-line standard treatment (trastuzumab in combination with chemotherapy) by the Center for Drug Evaluation (藥品審評中心) (“**CDE**”) of the National Medical Products Administration of China (國家藥品監督管理局) (“**NMPA**”). The breakthrough therapy designation was applied jointly by Jiangsu Alphamab Biopharmaceuticals Co., Ltd. (江蘇康寧傑瑞生物製藥有限公司), a wholly-owned subsidiary of the Company, and Shanghai JMT-Bio Technology Co., Ltd. (上海津曼特生物科技有限公司), a wholly-owned subsidiary of CSPC Pharmaceutical Group Limited the shares of which are listed on The Stock Exchange of Hong Kong Limited (the “**Stock Exchange**”) (stock code: 1093).

Breakthrough therapy designation is for innovative or modified new drugs that treat a condition that is seriously life-threatening or has serious quality-of-life impairment, and such condition has no effective therapies or compared with currently available therapies, sufficient evidence demonstrates an obvious advantage in clinic treatment of the new drugs. According to the Measures for the Administration of Drug Registration (《藥品註冊管理辦法》) and the announcement of the NMPA’s publication of three documents including the Working Procedures for Review of Breakthrough Therapeutics (Trial) (No. 82 of 2020) (《國家藥監局關於發佈〈突破性治療藥物審評工作程序(試行)〉等三個文件的公告》(2020年第82號)), drugs that have been granted the breakthrough therapy designation are prioritized by the CDE in communications and guidance to promote the drug development progress. The Company believes that this designation will accelerate the clinical development of KN026 in the second-line or above treatment of HER2-positive GC/GEJ and its marketing progress.

## **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 breast cancer and GC/GEJ.

Currently, two phase III clinical trials of KN026 as second-line or above treatment of HER2-positive GC/GEJ and as first-line treatment of HER2-positive breast cancer 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 NMPA, 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.

**Cautionary Statement required by Rule 18A.05 of the Rules Governing the Listing of Securities on the Stock Exchange:** 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, November 6, 2023

*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, and Dr. GUO Zijian, Mr. WEI Kevin Cheng and Mr. WU Dong as independent non-executive Directors.*