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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 STRATEGIC COLLABORATION WITH SANOFI ON KN026 IN HER2+ BREAST CANCER

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 of directors of the Company (the "**Board**") is pleased to announce that on June 9, 2020, Jiangsu Alphamab Biopharmaceuticals Co., Ltd. ("**Jiangsu Alphamab**"), a wholly-owned subsidiary of the Company, and Sanofi (China) Investment Co., Ltd. ("**Sanofi**") entered into an exclusive option agreement (the "**Agreement**") for the strategic collaboration to advance clinical studies investigating KN026, a Fc-based heterodimer bispecific monoclonal antibody ("**BsAb**") against human epidermal growth factor receptor 2 ("**HER2**"), in combination with Sanofi's product Taxotere® in patients with HER2-positive breast cancer ("**HER2+ breast cancer**").

Under the Agreement, Jiangsu Alphamab is responsible for the ongoing clinical trials on KN026 and the new combination study of KN026 and Taxotere® (the "**R&D Programs**"). Sanofi is responsible for supplying Taxotere® in a certain quantity to Jiangsu Alphamab for the intended combination study. Jiangsu Alphamab is entitled to all rights, titles and interests in and to any and all R&D Programs. Subject to the terms and conditions of the Agreement, Sanofi is granted an exclusivity period to negotiate an exclusive license for research, development, manufacturing, supply and/or commercialization of KN026 worldwide upon achievement of certain clinical milestones.

The Company believes that through the collaboration with Sanofi, a global leading biopharmaceutical company, the Group will further drive KN026's development strategy in China and the globe, expedite the delivery of meaningful improvement to the lives of millions of patients, as well as expand to address other HER2-positive solid tumors in the future. The Company believes that this cooperation will bring a positive impact on the research, development and commercialization of KN026 and that the Agreement is in the interests of the Company and its shareholders as a whole.

## ABOUT KN026

KN026, a Fc-based anti-HER2 BsAb, is potentially a global next-generation HER2-targeted therapy that can simultaneously bind two distinct clinically-validated epitopes of HER2, resulting 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. These binding mechanisms may enable KN026 to have excellent tumor suppressive effect. Currently, several phase II clinical trials of KN026 have been conducting in China and a phase I clinical trial has been conducting in the United States of America (the "U.S."). KN026 has shown good preliminary efficacy and excellent safety profile in patients with advanced breast cancer.

The Group received an umbrella investigational new drug ("IND") approval<sup>Note</sup> for KN026 from the National Medical Products Administration of China (the "NMPA") and an IND approval from the U.S. Food and Drug Administration in March 2018 and October 2018, respectively. The Group is currently conducting a phase II clinical trial of KN026 in China for breast cancer with a high level of HER2 expression in tumors and gastric cancer/gastroesophageal junction cancer ("GC/ GEJ") and is also conducting a phase II clinical trial for HER2-overexpressing GC/GEJ in China and a phase I clinical trial for HER2-overexpressing solid tumors, including but not limited to breast cancer and GC/GEJ, in the U.S. Currently, the Company is communicating with key health authorities in China and the U.S. on the pivotal trials of KN026.

Note: Pursuant to the Announcement of the NMPA Concerning Several Policies on Drug Registration Evaluation and Approval (國家食品藥品監督管理總局關於藥品註冊審評審批若干政策的公告) issued by the NMPA on November 11, 2015, the IND approval for new drugs shall be an overall approval of all phases of a new drug's clinical trials, instead of a phase-by-phase approval for each phase of a new drug's clinical trial.

## **ABOUT TAXOTERE®**

Taxotere<sup>®</sup> (Docetaxel) is a microtubule inhibitor that interferes with the growth and spread of cancer cells in the body. It is used to treat breast cancer, lung cancer, prostate cancer and gastric cancer. In China, Taxotere<sup>®</sup> is indicated for breast cancer including (i) single agent for locally advanced or metastatic breast cancer after chemotherapy failure; (ii) with trastuzumab for the first line treatment of metastatic breast cancer patients with HER2 overexpression; and (iii) with doxorubicin and cyclophosphamide as adjuvant treatment of operable node-positive breast cancer.

#### **ABOUT SANOFI**

Sanofi is a leading global biopharmaceutical company focused on human health. It is committed to introducing innovative medicines and vaccines more rapidly in China, and to leading digital innovations to serve the broadest base of the Chinese people. Sanofi China has a diversified business that ranges from pharmaceuticals and human vaccines to consumer healthcare.

#### ABOUT THE COMPANY

The Company is a leading clinical-stage biopharmaceutical company in China with a fullyintegrated proprietary biologics platform in bispecific and protein engineering. Differentiated inhouse pipeline of the Company consists of eight oncology drug candidates, including four in the phase I-III clinical trial development 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 could potentially create a new generation of multi-functional bio-macromolecule new drug candidates that 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, 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, June 9, 2020

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, Mr. XU Zhan Kevin and Mr. QIU Yu Min as Non-executive Directors, and Dr. JIANG Hualiang, Mr. WEI Kevin Cheng and Mr. WU Dong as Independent Non-executive Directors.