ALPHAMAB ONCOLOGY

康寧傑瑞生物製藥

(Incorporated in the Cayman Islands with limited liability)

(Stock code: 9966)

VOLUNTARY ANNOUNCEMENT

KN046 WAS GRANTED ORPHAN DRUG DESIGNATION 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 and potential investors of the Company about the latest business advancement of the Group.

The Company is pleased to announce that the Food and Drug Administration ("**FDA**") of the United States of America (the "**U.S.**") has granted Orphan Drug Designation ("**ODD**") to KN046, a recombinant humanized PD-L1/CTLA-4 (as defined below) bispecific antibody developed by Jiangsu Alphamab Biopharmaceuticals Co., Ltd. ("**Jiangsu Alphamab**"), a wholly-owned subsidiary of the Company, for the treatment of thymic epithelial tumors ("**TET**"). This is the Group's second ODD. Earlier in January 2020, KN035, a recombinant humanized single domain antibody developed by the Group was granted ODD by the U.S. FDA for the treatment of biliary tract cancer.

Originated from the Orphan Drug Act of 1983, an ODD is an incentive awarded by the U.S. FDA to promote the development of innovative drugs for the treatment of rare diseases and conditions that affect less than 200,000 people in the U.S. Drug candidates with ODD have the opportunity to gain seven years of market exclusivity, along with a series of comprehensive benefits provided by the U.S. FDA, including tax credits, exemption from biological license application fees, deduction of or exemption from prescription drug user fees, research and development funding support, protocol assistance, and accelerated regulatory approval.

TET primarily include thoracic tumors and thymic carcinoma. Thymic carcinoma cannot be treated by surgeries and metastatic thymic cancer has a very poor prognosis. Currently, there is no standard treatment under approval for patients who have failed platinum-based chemotherapy. The objective response rate of late-line chemotherapy or targeted therapy is less than 20%, and the median survival time of relapsed patients with multi-line treatment is less than 12 months[1]. There is an urgent need for effective drugs to improve patient treatment. KN046 has been observed to have a high response rate, long-lasting response, and favorable safety profile in patients with TET in the phase I clinical trial in Australia. The Company has initiated KN046 phase II registration clinical trials to treat thymic carcinoma in the U.S. and China.

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[1] Source: the Surveillance, Epidemiology, and End Results (SEER) Program of the National Cancer Institute

ABOUT KN046

KN046 is a globally innovative programmed death ligand 1 ("**PD-L1**")/cytotoxic T-lymphocyte-associated protein 4 ("**CTLA-4**") bispecific antibody developed by the Group. KN046 simultaneously targets two clinically-validated immune checkpoints, PD-L1 and CTLA-4. KN046 has been under phase I clinical trials in Australia and China and has entered phase II clinical trials in the U.S. and China in 2020. Currently, there are over 10 clinical trials at multiple stages covering more than 10 types of tumors including non-small cell lung cancer ("**NSCLC**"), triple-negative breast cancer, esophageal squamous cell carcinoma and pancreatic cancer. The results of these clinical trials have demonstrated a preliminary profile of good safety and promising efficacy of KN046. The Group has launched in China a multi-center phase III clinical trial to evaluate efficacy and safety of combination therapy of KN046 and platinum-based chemotherapy in patients with stage IV squamous NSCLC.

KN046 could potentially become one of the cornerstone drugs of the second-generation immuno-oncology treatment drugs.

ABOUT THE COMPANY

The Company is a leading clinical-stage biopharmaceutical company in China with a fully-integrated proprietary biologics platform in bispecific and protein engineering. Differentiated in-house pipeline of the Company includes 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 candidate 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, or ultimately market, KN046 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, September 3, 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.