CARsgen Therapeutics Holdings Limited
科濟藥業控股有限公司
(Incorporated in the Cayman Islands with limited liability)
(Stock Code: 2171)

VOLUNTARY ANNOUNCEMENT COLLABORATION AGREEMENT TO EVALUATE AB011 IN COMBINATION WITH PD-L1 CHECKPOINT INHIBITOR TO TREAT GASTRIC CANCER

This announcement is made by CARsgen Therapeutics Holdings Limited (the "**Company**", together with its subsidiaries and consolidated affiliated entities, the "**Group**" or "**CARsgen**") on a voluntary basis to inform the shareholders and potential investors of the Company about the latest business update of the Group.

The board of directors of the Company (the "**Board**") announces CARsgen's execution of a collaboration agreement with F. Hoffmann-La Roche Ltd ("**Roche**") to evaluate CARsgen's investigational drug AB011, the first humanized monoclonal antibody against Claudin18.2 (CLDN18.2) that received IND clearance globally, in combination with atezolizumab, Roche's PD-L1 checkpoint inhibitor, along with standard-of-care chemotherapy in patients with gastric or gastroesophageal junction carcinoma. Under the terms of the agreement, Roche will be responsible for operation and conduct of the trial while both companies co-share the costs of the AB011 treatment arms in the study. As part of the clinical collaboration, CARsgen's proprietary CLDN18.2 IHC test kit, which has showed excellent specificity and sensitivity profiles, will be applied to evaluate CLDN18.2 expression in the gastric cancer patients.

The co-funded study of AB011 in combination with atezolizumab will be conducted as part of Roche's Morpheus Platform. The Morpheus Platform is a collection of Phase 1b/2 clinical trials in multiple cancers with high unmet clinical needs including gastrointestinal cancer, designed to assess the safety and early efficacy to enable more rapid and efficient development of novel cancer treatment combinations.

Gastric cancer is one of the most common cancer types worldwide and the treatment options for gastric cancer patients are still very limited. CLDN18.2 is a promising therapeutic target for the treatment of solid tumors, including gastric cancer, pancreatic cancer, etc. Since 2014, CARsgen team has developed several innovative medicines against CLDN18.2 in the pipeline, including CAR T-cell therapies and AB011. AB011 is an important asset in the CLDN18.2 franchise of CARsgen and is the first monoclonal antibody against CLDN18.2 that received IND clearance in China. Through this collaboration, CARsgen is excited to evaluate the combination of AB011 and atezolizumab which can potentially bring greater clinical benefits to gastric cancer patients.

ABOUT AB011

AB011 is a humanized Claudin18.2 monoclonal antibody (mAb) product that has received an investigational new drug (IND) approval from the National Medical Products Administration (NMPA) for the treatment of Claudin18.2 positive solid tumors. CARsgen is conducting a Phase I clinical trial of AB011 for the treatment of Claudin18.2 positive solid tumors in China to evaluate the safety, tolerability, pharmacokinetics, and preliminary efficacy of AB011 infusion.

ABOUT CARSGEN

CARsgen is a biopharmaceutical company with operations in China and the U.S. and is focused on innovative CAR T-cell therapies for the treatment of hematologic malignancies and solid tumors. CARsgen has built an integrated cell therapy platform with in-house capabilities that span target discovery, antibody development, clinical trials, and commercial-scale manufacturing. CARsgen has internally developed novel technologies and a product pipeline with global rights to address major challenges of CAR T-cell therapies, such as improving the safety profile, enhancing the efficacy in treating solid tumors, and reducing treatment costs. CARsgen vision is to become a global biopharmaceutical leader that brings innovative and differentiated cell therapies to cancer patients worldwide and makes cancer curable.

DEFINITIONS AND GLOSSARY OF TECHNICAL TERMS

"CAR"	chimeric antigen receptor
"CAR T"	chimeric antigen receptor T cell
"IHC"	immunohistochemistry, which is the identification of antigens in tissues using antibodies that are linked to enzymes, fluorescent dyes, or radioactive labels. IHC is used to diagnose and track specific cellular anomalies, such as cancers
"IND"	investigational new drug or investigational new drug application, also known as clinical trial application in China
"mAb"	monoclonal antibodies, or antibodies that are made by identical immune cells that are all clones belonging to a unique parent cell

"PD-L1"	PD-1 ligand 1, which is a protein on the surface of a normal cell or a cancer cell that attaches to PD-1 on the surface of the T cell that causes the T cell to turn off its ability to kill the cancer cell
"Phase I"	a study in which a drug is introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage, tolerance, absorption, metabolism, distribution, excretion, and if possible, to gain an early indication of its effectiveness
"solid tumors"	an abnormal mass of tissue that usually does not contain cysts or liquid areas
"U.S."	the United States of America, its territories, its dependencies and all areas subject to its jurisdiction

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, AB011 successfully. Shareholders and potential investors of the Company are advised to exercise caution when dealing in the shares of the Company.

By order of the Board
CARsgen Therapeutics Holdings Limited
Dr. Zonghai LI
Chairman

Hong Kong, January 31, 2023

As at the date of this announcement, the board of directors of the Company comprises Dr. Zonghai LI, Dr. Huamao WANG and Dr. Hua JIANG as executive Directors; Mr. Bingsen GUO, Mr. Huaqing GUO and Mr. Ronggang XIE as non-executive Directors; Dr. Guangmei YAN and Mr. Tak Young SO as the independent non-executive Directors.

In the case of inconsistency, the English text of this announcement shall prevail over the Chinese text.