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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

AB011 IN COMBINATION WITH ATEZOLIZUMAB MONOCLONAL ANTIBODY AND CHEMOTHERAPY (CAPECITABINE AND OXALIPLATIN) ACHIEVED IND CLEARANCE FROM THE NMPA FOR FIRST-LINE TREATMENT CLDN18.2 POSITIVE UNRESECTABLE LOCALLY ADVANCED, RECURRENT OR METASTATIC GASTRIC CANCER/GASTROESOPHAGEAL JUNCTION 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 that AB011 in combination with atezolizumab monoclonal antibody, Roche’s PD-L1 checkpoint inhibitor, along with chemotherapy (capecitabine and oxaliplatin) achieved IND clearance from the CDE for first-line treatment Claudin18.2 (CLDN18.2) positive unresectable locally advanced, recurrent or metastatic gastric cancer/gastroesophageal junction cancer.

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. We have completed the Phase I monotherapy and combination with chemotherapy cohorts enrollment. Data updates from the Phase Ib study (AB011-ST-01, NCT04400383) were reported as a poster presentation at the 2023 ASCO Gastrointestinal (GI) Cancers Symposium in January 2023.

ABOUT THE COMPANY

CARsgen is a biopharmaceutical company with operations in China and the U.S. mainly focused on innovative CAR T-cell therapies for the treatment of hematologic malignancies and solid tumors. The Company 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. Our 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 T cell”	chimeric antigen receptor T cell
“CDE”	Center for Drug Evaluation, an institution under the NMPA
“CLDN18.2”	Claudin18.2, a protein found on the cells of certain solid tumors such as gastric cancer and pancreatic cancer, which makes the protein an attractive target for treatment
“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
“NMPA”	National Medical Products Administration (國家藥品監督管理局), the successor of the China Food and Drug Administration (國家食品藥品監督管理總局), or the CFDA, the State Food and Drug Administration (國家食品藥品監督管理局), or the SFDA and the State Drug Administration (國家藥品監督管理局), or the SDA
“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 tumor” an abnormal mass of tissue that usually does not contain cysts or liquid areas

“United States” or “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, CT041, successfully. Shareholders and potential investors of the Company are advised to exercise caution when dealing in the shares of the Company.

FORWARD-LOOKING STATEMENTS

All statements in this announcement that are not historical fact or that do not relate to present facts or current conditions are forward-looking statements. Such forward-looking statements express the Company’s current views, projections, beliefs and expectations with respect to future events as of the date of this announcement. Such forward-looking statements are based on a number of assumptions and factors beyond the Company’s control. As a result, they are subject to significant risks and uncertainties, and actual events or results may differ materially from these forward-looking statements and the forward-looking events discussed in this announcement might not occur. Such risks and uncertainties include, but are not limited to, those detailed under the heading “Principal Risks and Uncertainties” in our most recent annual report and interim report and other announcements and reports made available on our corporate website, <https://www.carsgen.com>. No representation or warranty is given as to the achievement or reasonableness of, and no reliance should be placed on, any projections, targets, estimates or forecasts contained in this announcement.

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

Hong Kong, May 4, 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. Huabing LI, 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.