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
CT041 ACHIEVED IND CLEARANCE FROM THE NMPA FOR THE POSTOPERATIVE ADJUVANT THERAPY OF PANCREATIC 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 CT041, an autologous CAR T-cell product candidate against the protein Claudin18.2 (CLDN18.2), has achieved IND clearance from the National Medical Products Administration (NMPA) for the postoperative adjuvant therapy of CLDN18.2 positive pancreatic cancer (PC).

ABOUT CT041

CT041 is an autologous CAR T-cell product candidate against the protein CLDN18.2 that has the potential to be the first-in-class globally. CT041 targets the treatment of CLDN18.2 positive solid tumors with a primary focus on gastric cancer/gastroesophageal junction cancer (GC/GEJ) and PC.

Active trials in CARsgen include investigator-initiated trials, a Phase Ib clinical trial for advanced GC/GEJ and PC and a confirmatory Phase II clinical trial for advanced GC/GEJ in China (CT041-ST-01, NCT04581473), and a Phase 1b/2 clinical trial for advanced gastric or pancreatic adenocarcinoma in North America (CT041-ST-02, NCT04404595). In January 2022, CT041 was granted Regenerative Medicine Advanced Therapy (RMAT) Designation by U.S. FDA for the treatment of advanced gastric or gastroesophageal junction adenocarcinoma with CLDN18.2 positive tumors. In November 2021, CT041 was granted PRIME Eligibility by the EMA for the treatment of advanced gastric cancer. In 2020 and 2021, CT041 received Orphan Drug designation from the U.S. FDA for the treatment of GC/GEJ and Orphan Medicinal Product designation from the EMA for the treatment of advanced gastric cancer. A Phase 2 clinical trial of CT041 in the U.S. is planned to initiate in the first half of 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
"confirmatory trial" or "pivotal trial"	the controlled trial or study intended to demonstrate the required clinical efficacy and safety evidence before submission for drug marketing approval
"CTA"	Clinical Trial Application
"EMA"	European Medicines Agency
"FDA" or "U.S. FDA"	United States Food and Drug Administration
"Health Canada"	the department of Canada's government with responsibility for national public health
"IND"	investigational new drug or investigational new drug application, also known as clinical trial application in China
"investigator-initiated trial"	clinical trial sponsored and conducted by independent investigators
"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

"Phase Ib"	a phase of clinical trials that primarily assesses safety, tolerability and pharmacokinetics/pharmacodynamics at multiple ascending dose levels prior to commencement of a Phase II or Phase III clinical trial
"Phase II clinical trial"	a study in which a drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the drug for specific targeted disease, and to determine dosage tolerance and optimal dosage
"PRIME"	PRIority MEdicine. A scheme launched by the EMA to offer early and proactive support to medicine developers to optimize the generation of robust data on medicine's benefits and risks, and accelerate assessment of medicines applications, for medicines that target an unmet medical need with advantages over existing treatments
"regenerative medicine advanced therapy" or "RMAT"	a special status granted by the FDA to regenerative medicine therapies, including cell therapies, intended to treat a serious or lifethreatening disease or condition, and preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such disease or condition
"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.

CAUTIONARY LANGUAGE REGARDING 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, April 19, 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, Mr. Tak Young SO and Dr. Huabing LI as the independent non-executive Directors.

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