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
FDA GRANTED REGENERATIVE MEDICINE ADVANCED THERAPY DESIGNATION TO CT041 FOR THE TREATMENT OF ADVANCED GASTRIC OR GASTROESOPHAGEAL JUNCTION ADENOCARCINOMA WITH CLDN 18.2 POSITIVE

This announcement is made by CARsgen Therapeutics Holdings Limited (the "**Company**", together with its subsidiaries, 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 the United States Food and Drug Administration (FDA) granted Regenerative Medicine Advanced Therapy (RMAT) Designation to CT041 for the treatment of advanced gastric or gastroesophageal junction adenocarcinoma with CLDN 18.2 positive tumor.

ABOUT CT041

CT041 is an autologous CAR T-cell product candidate against the protein CLDN18.2 and has the potential to be the first-in-class globally. CT041 targets the treatment of CLDN18.2 positive solid tumours with a primary focus on gastric/gastroesophageal junction cancer (GC/GEJ) and pancreatic cancer (PC). CT041 has demonstrated promising therapeutic efficacy and favourable safety in ongoing clinical trials. The Company believes that CT041 has the potential to become a backbone therapy for GC/GEJ and PC and benefit a large population of patients worldwide.

As of the date of this announcement, CT041 is the only CLDN18.2-targeted CAR T-cell product candidate globally that is being studied in clinical trials with IND/CTA approvals from the FDA, the NMPA, and Health Canada. In addition to the investigator-initiated trials in China, CARsgen has initiated a Phase Ib/II clinical trial for advanced GC/GEJ and PC in China, and a Phase 1b clinical trial for advanced gastric or pancreatic adenocarcinoma in North America. 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. In November 2021, CT041 was granted PRIME eligibility by the EMA for the treatment of advanced gastric cancer. CARsgen also intends to conduct a pivotal Phase 2 clinical trial in North America in 2022.

ABOUT REGENERATIVE MEDICINE ADVANCED THERAPY (RMAT)

The RMAT designation program is intended to help the FDA facilitate an efficient development program for any drug that (1) qualifies as a RMAT, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products; (2) is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (3) has preliminary clinical evidence to indicate the drug has the potential to address unmet medical needs for such a disease or condition.

RMAT designation grants all the benefits of fast track and breakthrough designation including more frequent meetings with the FDA to discuss the development plan for the product candidate and eligibility for rolling review and priority review. Products granted RMAT designation may also be eligible for accelerated approval.

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 tumours. 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 tumours, 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.

"CAR T cell"	chimeric antigen receptor T cell
"CLDN18.2"	claudin18.2, a protein found on the cells of certain solid tumours such as gastric cancer and pancreatic cancer, which makes the protein an attractive target for treatment
"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

"pivotal trial"	the controlled trial or study intended to demonstrate the required clinical efficacy and safety evidence before submission for drug marketing approval
"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 life-threatening 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 tumour"	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.

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

Hong Kong, January 10, 2022

As at the date of this announcement, the board of directors of the Company comprises Dr. Li Zonghai and Dr. Wang Huamao as executive Directors; Mr. Guo Bingsen, Mr. Guo Huaqing, Mr. Xie Ronggang and Ms. Zhao Yachao as non-executive Directors; Dr. Fan Chunhai, Dr. Yan Guangmei and Mr. So Tak Young as the independent non-executive Directors.