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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

ABSTRACT OF RESEARCH RESULTS ON SATRI-CEL FOR ADJUVANT THERAPY OF PANCREATIC CANCER ACCEPTED FOR POSTER PRESENTATION AT ESMO CONGRESS 2025

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 the preliminary results of the Phase Ib registrational clinical trial of satricabtagene autoleucel (“**satri-cel**”, CT041) (an autologous CAR T-cell product candidate against protein Claudin18.2) for pancreatic cancer (PC) adjuvant therapy in China (CT041-ST-05, NCT05911217) has been accepted for poster presentation at European Society for Medical Oncology (ESMO) Congress 2025. Abstract will be released at 00:05 CEST on Monday, October 13, 2025 on the ESMO official website. Further details will be provided on our corporate website www.carsgen.com.

ABOUT SATRI-CEL

Satri-cel is an autologous CAR T-cell product candidate against the protein Claudin18.2 that has the potential to be the first-in-class globally. Satri-cel targets the treatment of Claudin18.2-positive solid tumors with a primary focus on gastric/gastroesophageal junction adenocarcinoma (G/GEJA) and pancreatic cancer (PC). Initiated trials include investigator-initiated trials (CT041-CG4006, NCT03874897), a confirmatory Phase II clinical trial for advanced G/GEJA in China (CT041-ST-01, NCT04581473), a Phase Ib registrational trial for PC adjuvant therapy in China (CT041-ST-05, NCT05911217), an investigator-initiated trial for satri-cel be used as consolidation treatment following adjuvant therapy in patients with resected G/GEJA (CT041-CG4010, NCT06857786), and a Phase 1b/2 clinical trial for advanced gastric or pancreatic adenocarcinoma in North America (CT041-ST-02, NCT04404595).

The Center for Drug Evaluation (CDE) of National Medical Products Administration (NMPA) of China has accepted the New Drug Application (NDA) for satri-cel for the treatment of Claudin18.2-positive advanced G/GEJA in patients who have failed at least two prior lines of therapy on June 25, 2025. It has been granted Priority Review in May 2025 and Breakthrough Therapy Designation in March 2025 by the CDE. Satri-cel was granted Regenerative Medicine Advanced Therapy designation by U.S. FDA for the treatment of advanced G/GEJA with Claudin18.2-positive tumors in January 2022. Satri-cel received Orphan Drug designation from the U.S. FDA for the treatment of G/GEJA in September 2020.

ABOUT THE COMPANY

CARsgen is a biopharmaceutical company focusing on developing innovative CAR T-cell therapies to address the unmet clinical needs including but not limited to hematologic malignancies, solid tumors and autoimmune diseases. CARsgen has established end-to-end capabilities for CAR T-cell research and development covering target discovery, preclinical research, product clinical development, and commercial-scale production. CARsgen has developed novel in-house technologies and a product pipeline with global rights to address challenges faced by existing CAR T-cell therapies. Efforts include improving safety profile, enhancing the efficacy in treating solid tumors, and reducing treatment costs, etc. CARsgen's mission is to be a global biopharmaceutical leader that provides innovative and differentiated cell therapies for patients worldwide and makes cancer and other diseases curable.

DEFINITIONS AND GLOSSARY OF TECHNICAL TERMS

“CAR”	chimeric antigen receptor
“CAR T”	chimeric antigen receptor T cell
“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
“FDA” or “U.S. FDA”	U.S. Food and Drug Administration
“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 a specific targeted disease, and to determine dosage tolerance and optimal dosage

“confirmatory trial”	the controlled trial or study intended to demonstrate the required clinical efficacy and safety evidence before submission for drug marketing approval
“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, satri-cel, 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 Group’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 Group’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, July 22, 2025

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, Ms. Xiangke ZHAO and Dr. Wen ZHOU as the independent non-executive Directors.

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