

Hong Kong Exchanges and Clearing Limited, The Stock Exchange of Hong Kong Limited and Hong Kong Securities Clearing Company Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.



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

CT0596 RECEIVED IND CLEARANCE FROM THE NMPA FOR THE TREATMENT OF PATIENTS WITH RELAPSED/REFRACTORY MULTIPLE MYELOMA (R/R MM)

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 CT0596, an allogeneic CAR T-cell product targeting BCMA, has achieved Investigational New Drug (IND) clearance from the National Medical Products Administration (NMPA) for the treatment of patients with relapsed/refractory multiple myeloma (R/R MM). The research results of the investigator-initiated trials of CT0596 have been presented as the poster presentation at the 2026 Annual Congress of the European Hematology Association. Details have been provided on our corporate website www.carsgen.com.

ABOUT CT0596

CT0596 is an allogeneic BCMA-targeted CAR T-cell therapy developed using CARsgen’s proprietary THANK-u Plus™ platform. It is currently being evaluated in investigator-initiated trials for R/R MM or plasma cell leukemia. CT0596 demonstrated preliminary favorable tolerability and encouraging efficacy signals. Further investigation is planned in additional plasma cell malignancies and autoimmune diseases mediated by autoreactive plasma cells.

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 cell”	chimeric antigen receptor T cell
“IIT”	clinical trial sponsored and conducted by independent investigators
“IND”	investigational new drug or investigational new drug application, also known as clinical trial application in China
“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 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

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, CT0596, 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, August 4, 2026

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. 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.