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 TO PRESENT ZEVORCABTAGENE AUTOLEUCEL, CT071 AND CT0590 AT ASH 2024 ANNUAL CONGRESS

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 Company will present the clinical data of zevorcabtagene autoleucel (赛恺泽®, R&D code: CT053, an autologous CAR-T product against BCMA), CT071 (an autologous CAR T-cell therapy candidate targeting GPRC5D), and CT0590 (an allogeneic CAR T-cell product candidate against BCMA) at the 66th Annual Congress of the American Society of Hematology ("**ASH**"). Abstracts and further details will be announced after November 5, 2024 Eastern Time.

ABOUT ZEVORCABTAGENE AUTOLEUCEL

Zevorcabtagene autoleucel is a fully human, autologous BCMA CAR T-cell product for the treatment of Multiple Myeloma (MM). Zevorcabtagene autoleucel was approved by the NMPA on February 23, 2024 for the treatment of adult patients with R/R MM who have progressed after at least 3 prior lines of therapy (including a proteasome inhibitor and an immunomodulatory agent). CARsgen is conducting a separate Phase 1b/2 LUMMICAR STUDY 2 clinical trial in North America to evaluate the safety and efficacy of zevorcabtagene autoleucel in R/R MM.

Zevorcabtagene autoleucel received Regenerative Medicine Advanced Therapy (RMAT) and Orphan Drug designations from the U.S. FDA in 2019, as well as Priority Medicines (PRIME) and Orphan Medicinal Product designations from the European Medicines Agency (EMA) in 2019 and 2020, respectively.

ABOUT CT071

CT071 is a CAR T-cell therapy candidate developed utilizing the proprietary CARcelerate™ platform of CARsgen targeting GPRC5D for the treatment of relapsed/refractory MM or relapsed/refractory plasma cell leukemia (PCL). An IIT (NCT05838131) is ongoing in China to evaluate the preliminary safety and efficacy of CT071 for the treatment of relapsed/refractory multiple myeloma or plasma cell leukemia. Another investigator-initiated trial (NCT06407947) is ongoing in China for the treatment of newly diagnosed multiple myeloma (NDMM).

ABOUT CT0590

CT0590 is a BCMA-targeting allogeneic CAR T-cell product candidate deploying CARsgen's THANK-uCAR® technology. An IIT has been initiated in China to evaluate the preliminary safety and efficacy of CT0590 for the treatment of R/R MM.

ABOUT THE COMPANY

CARsgen is a biopharmaceutical company with operations in China and the U.S., focusing on innovative CAR T-cell therapies for the treatment of hematologic malignancies and solid tumors. CARsgen has established a comprehensive CAR T-cell research and development platform that covers target discovery, innovative CAR T-cell development, clinical trials, and commercial-scale production. Internally, CARsgen has developed novel technologies and a product pipeline with global rights to address significant challenges faced by existing CAR T-cell therapies. Efforts include improving safety profile, enhancing the efficacy in treating solid tumors, and reducing treatment costs. CARsgen's mission is to become a global biopharmaceutical leader that provides innovative and differentiated cell therapies for cancer patients worldwide and makes cancer curable.

"BCMA"	B-cell maturation antigen, a protein that is highly expressed in multiple myeloma with limited expression on normal tissues other than plasma cells
"CAR"	chimeric antigen receptor
"CAR T"	chimeric antigen receptor T cell
"EMA"	European Medicines Agency
"FDA" or "U.S. FDA"	U.S. Food and Drug Administration
"GPRC5D"	G protein-coupled receptor, class C, group 5, member D, GPRC5D, a protein that is highly expressed on the surface of malignant plasma cells with limited expression on normal tissues
"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 1b"	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 2 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
"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 a medicine's benefits and risks, and to accelerate the assessment of the applications of 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, that are intended to treat a serious or life-threatening disease or condition, and for which preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such a disease or condition
"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, zevorcabtagene autoleucel (outside mainland China), CT071 and CT0590, 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, October 17, 2024

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 and as the independent non-executive Directors.

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