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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 ZEVORCABTAGENE AUTOLEUCEL ACCEPTED FOR POSTER AT 2022 ASH ANNUAL MEETING

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 an abstract of Zevorcabtagene Autoleucel (“**zevor-cel**”, R&D code: CT053, an autologous CAR-T product candidate against BCMA) has been accepted for the poster presentation at the upcoming 2022 American Society of Hematology (the “**ASH**”) Annual Meeting. Details are set out below:

Name of the Research Study	Publication Number	Publication Type	Abstract Release Time (Eastern Standard Time)	Presentation Time (Eastern Standard Time)
Phase II Study of Fully Human BCMA-Targeting CAR-T Cells (Zevorcabtagene Autoleucel) in Patients with Relapsed/ Refractory Multiple Myeloma	1994	poster	November 3, 2022 at 9 am	December 10, 2022 at 5:30-7:30 pm

ABOUT ZEVOR-CEL

Zevor-cel (CT053) is a fully human, autologous BCMA CAR T-cell product candidate for the treatment of R/R MM. The NDA for zevor-cel based on the data from Phase I/II clinical trial (LUMMICAR STUDY 1) in China has been accepted by NMPA. CARsgen is conducting a Phase 1b/2 clinical trial (LUMMICAR STUDY 2) in North America to evaluate the safety and efficacy of zevor-cel for R/R MM. The Company also plans to conduct additional clinical trials to develop zevor-cel as an earlier line of treatment for multiple myeloma.

Zevor-cel received Regenerative Medicine Advanced Therapy (RMAT) and Orphan Drug designations from the U.S. FDA in 2019, as well as the PRIority MEDicines (PRIME) and Orphan Medicinal Product designations from the European Medicines Agency (EMA) in 2019 and 2020, respectively. Zevor-cel also received Breakthrough Therapy designation from the NMPA in 2020.

The Company believes that zevor-cel is well positioned to potentially reshape the treatment paradigm for multiple myeloma and become a foundational treatment for multiple myeloma patients.

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, lead 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

“BCMA”	B-cell maturation antigen, a protein that is highly expressed in a number of hematologic malignancies
“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
“MM” or “R/R MM”	multiple myeloma, a type of cancer that forms in the white blood cells; cancer that relapses or does not respond to treatment is called relapsed and/or refractory multiple myeloma
“NDA”	new drug application
“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 trials
“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 final trial or study to demonstrate clinical efficacy and safety evidence required 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 tumors” an abnormal mass of tissue that usually does not contain cysts or liquid areas

“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 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. Zonghai LI
Chairman

Hong Kong, November 1, 2022

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. Chunhai FAN, Dr. Guangmei YAN and Mr. Tak Young SO as the independent non-executive Directors.

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