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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)

INSIDE INFORMATION ANNOUNCEMENT CLINICAL HOLD IN THE U.S. DUE TO CMC RELATED QUESTIONS

This announcement is made by CARsgen Therapeutics Holdings Limited (the “**Company**”, together with its subsidiaries and consolidated affiliated entities, the “**Group**” or “**CARsgen**”) pursuant to Rule 13.09(2)(a) of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the “**Listing Rules**”) and the inside information provision (as defined in the Listing Rules) under Part XIVA of the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong).

The board of directors (the “**Board**”) of the Company announces that CARsgen Therapeutics Corporation, a subsidiary of the Company in the United States, has received a notice in the evening of December 11, Beijing time, from the U.S. Food and Drug Administration (“**FDA**”) to the effect that CT053, CT041, and CT071 be put on clinical hold pending resolution of the findings following an inspection of the manufacturing site located in Durham, North Carolina. The Company will conduct a comprehensive review and improvement on the Current Good Manufacturing Practice (cGMP), and is committed to working closely with the FDA to address the findings to ensure the smooth progress and production quality for clinical trials and launching applications.

DEFINITIONS AND GLOSSARY OF TECHNICAL TERMS

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| “CAR T cell” | chimeric antigen receptor T cell |
| “CMC” | chemistry, manufacturing, and controls processes in the development, licensure, manufacturing, and ongoing marketing of pharmaceutical products |
| “CT041” | an autologous CAR T-cell product candidate against the protein Claudin18.2, and targets the treatment of Claudin18.2 positive solid tumors with a primary focus on gastric/gastroesophageal junction cancer and pancreatic cancer |
| “CT053” | an upgraded fully human, autologous BCMA CAR T-cell product candidate for the treatment of refractory and/or relapsed multiple myeloma |

“CT071”

an autologous CAR T-cell therapy candidate targeting G protein-coupled receptor class C group 5 member D (GPC5D), for the treatment of relapsed/refractory multiple myeloma or relapsed/refractory primary plasma cell leukemia

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, December 12, 2023

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, Dr. Huabing LI and Ms. Xiangke ZHAO as the independent non-executive Directors.

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