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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)

CHANGE OF AUDITOR

This announcement is made by the board (the “**Board**”) of directors (the “**Directors**”) of CARsgen Therapeutics Holdings Limited (the “**Company**”, together with its subsidiaries and consolidated affiliated entities, the “**Group**” or “**CARsgen**”) pursuant to Rule 13.51(4) of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the “**Stock Exchange**”) (the “**Listing Rules**”).

SUMMARY

The Board announces that PricewaterhouseCoopers (“**PwC**”) has resigned as the auditor of the Company with effect from January 12, 2024, given that PwC could not reach a consensus with the Company on a mutually acceptable audit timetable for the Group’s financial results for the year ended December 31, 2023 (the “**2023 Annual Results**”).

The Board, with the recommendation of the audit committee of the Company (the “**Audit Committee**”), has resolved to appoint Ernst & Young (“**E&Y**”) as the auditor of the Company with effect from January 12, 2024 to fill the vacancy following the resignation of PwC and to hold office until the conclusion of the next annual general meeting of the Company.

RESIGNATION OF AUDITOR

PwC stated in its resignation letter dated January 12, 2024 that, in the process of planning for the audit of the 2023 Annual Results, PwC was made aware of that CARsgen Therapeutics Corporation (the “**U.S. Subsidiary**”), a subsidiary of the Company in the United States, has received a notice on December 11, 2023 from the U.S. Food and Drug Administration (the “**FDA**”) to the effect that CT053, CT041, and CT071 be put on clinical hold pending resolution of the FDA’s findings following its inspection of the manufacturing site located in Durham, North Carolina (the “**FDA Inspection**”). In addition, PwC’s resignation letter stated that it was made aware of certain matters relating to the U.S. Subsidiary, including its controls over use of its corporate credit card, overstay in the United States of the Company’s Chinese employees, and certain practices not in line with the FDA’s guidance on Good Documentation Practice (the “**Certain Matters**”, together with the FDA

Inspection, collectively, the “**Resignation Letter Issues**”). According to PwC, as the Company’s assessments and internal review are ongoing and PwC has not been able to obtain all information in connection with matters mentioned above, PwC was unable to determine and perform the necessary additional audit procedures which it may consider necessary subject to the outcomes of the Company’s assessments and internal review, and is therefore not in a position to commit to a definite timeline for completion of its audit and issuance of its audit opinion for the year ended December 31, 2023.

Up to and until the date of this announcement and save for those disclosed in this announcement, the Company has not received any other confirmation from PwC notifying the Company of any matters that need to be brought to the attention of shareholders and creditors of the Company.

The Board and the Audit Committee also confirmed that, save as disclosed in this announcement, there are no other matters in respect of the resignation of PwC as the auditor of the Company that need to be brought to the attention of shareholders and creditors of the Company.

CLARIFICATION ON RESIGNATION LETTER ISSUES

The Company hereby makes further clarification on certain matters related to the above Resignation Letter Issues.

FDA Inspection

To address the issues disclosed in the Company’s announcement dated December 12, 2023, the Company has conducted a comprehensive review and recently submitted the response and Corrective and Preventive Actions (CAPA) plan with a timetable. The Company has started implementing the plan and is working closely with the FDA to address the observations to ensure the smooth progress and production quality for clinical trial and launching applications. Accordingly, the Company believes that the management is in a good position to assess the impact of the matter on the 2023 Annual Results.

Certain Matters

To the best knowledge, information and belief of the Company, PwC learned about the Certain Matters through verbal interviews with one employee of the U.S. Subsidiary. The Company believes that it has already conducted necessary internal review on these Certain Matters. Moreover, the Company has taken appropriate measures to further enhance internal controls as response to these unconfirmed Certain Matters.

The Company has internal control systems in place in relation to the subject matter of the Certain Matters. For clarification purposes only, the Company would like to further elaborate on the specific circumstances of the Certain Matters as follows:

- (i) In respect of the use of the U.S. Subsidiary’s corporate credit card, the Company conducted a review of the relevant credit card transaction reconciliation record after departure of the former employee of the U.S. Subsidiary who returned the corporate credit card in his custody to the Company upon his leaving, and no actual unauthorized use of credit card spending has been spotted. Furthermore, the Company conducted a full population review on the use of credit cards for the relevant periods, and no abnormality was noted. The Company in any event has a right to claim against any employee for misappropriations of Company’s asset. The Company has also updated its Credit Card Policy in November 2023 to enhance internal control on the use of credit cards by its employees;
- (ii) In respect of the overstay in the United States of the Company’s Chinese employees, the Company completed a thorough internal review and confirmed that none of its employees overstayed beyond the period stipulated in their visas without submitting timely applications for extension of stay and no overstay in the United States or breach of relevant regulations, has been identified; and
- (iii) In respect of certain practices not in line with the FDA’s guidance on Good Documentation Practice (the “**Deviations**”), the Company had noted, kept a record of, and taken appropriate remedial actions for the Deviations, which were administrative in nature and regulated under the FDA regulatory framework for current Good Manufacturing Practice (CGMP).

Work and Views of the Audit Committee

The Audit Committee has reviewed and agreed with the views and clarifications of the Company as stated above. The Audit Committee took the initiative to convene a meeting with PwC to understand the circumstances regarding the Resignation Letter Issues, sought to find solutions towards reaching a consensus on the audit timetable, and followed up with the Company’s management on the relevant communications with PwC. Given that the Company could not reach a consensus with PwC on a mutually acceptable audit timetable for the 2023 Annual Results, the Audit Committee considered it appropriate to change the auditor for the Audit Work having considered the information available at the material time.

The Company would like to take this opportunity to sincerely thank PwC for the professional and quality services provided to the Company in the past.

APPOINTMENT OF NEW AUDITOR

The Audit Committee has considered a number of factors in assessing the appointment of E&Y as the auditor, including but not limited to (i) team members’ rich experiences and capabilities, including their industry knowledge and technical competence in providing audit work for companies listed on the Stock Exchange; (ii) the audit methodology of E&Y; (iii) their familiarity with the requirements under the Listing Rules and the Hong Kong Financial Reporting Standards; (iv) its independence from the Group and objectivity; (v) its reputation in the market; (vi) its resources and capabilities; and (vii) the guidelines issued by the Accounting and Financial Reporting Council. The Audit Committee requested E&Y to work closely with the Company and the Audit Committee to ensure the quality of its audit work, as well as to maintain timely communication with the Company and the Audit Committee regarding the progress of its work and issues.

Based on the above, the Audit Committee has assessed and considered that E&Y is eligible and suitable to act as the auditor for audit for the year ended December 31, 2023, and made a recommendation to the Board regarding E&Y's appointment. The Board, with the recommendation of the Audit Committee, has resolved to appoint E&Y as the new auditor of the Company.

The Board would like to take this opportunity to welcome E&Y as the auditor of the Company.

By order of the Board
CARsgen Therapeutics Holdings Limited
Dr. Zonghai LI
Chairman

Hong Kong, January 12, 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, 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.