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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

LIFT OF THE U.S. CLINICAL HOLDS FOR ZEVORCABTAGENE AUTOLEUCEL, SATRICABTAGENE AUTOLEUCEL AND CT071 BY FDA

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.

The board of directors (the “**Board**”) of the Company announces that the U.S. Food and Drug Administration (“**FDA**”) lifted the clinical holds on clinical trials of zevorcabtagene autoleucel (zevor-cel, CT053, an autologous CAR-T product against BCMA), satricabtagene autoleucel (satri-cel, CT041, an autologous CAR-T product against Claudin18.2), and CT071 (an autologous CAR-T product against GPRC5D) in the United States. The clinical holds mentioned above were related to the observations issued after the FDA inspection of our clinical manufacturing site in Durham, North Carolina in December 2023.

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.

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, November 1, 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 as the independent non-executive Directors.

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