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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**

## **CT011 ACHIEVED IND CLEARANCE FROM THE NMPA FOR PATIENTS WITH GPC3-POSITIVE STAGE IIIa HEPATOCELLULAR CARCINOMA AT HIGH RISK OF RECURRENCE AFTER SURGICAL RESECTION**

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 CT011, an autologous CAR T-cell product candidate against Glypican-3 (GPC3), has achieved Investigational New Drug (IND) clearance from the National Medical Products Administration (NMPA) for patients with GPC3-positive stage IIIa hepatocellular carcinoma who are at high risk of recurrence after surgical resection.

### **ABOUT CT011**

CT011 is an autologous GPC3 CAR T-cell product candidate for the treatment of hepatocellular carcinoma (HCC). CT011 received IND clearance from the NMPA in 2019 for the treatment of patients with GPC3-positive solid tumor which was China’s first IND clearance for CAR T-cell therapy against solid tumors and CARsgen has completed enrollment of this Phase I trial in China.

## ABOUT THE COMPANY

CARsgen is a biopharmaceutical company with operations in China and the U.S. and is focused 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, encompassing target discovery, innovative CAR T-cell development, clinical trials, and commercial-scale production. 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. CARsgen's 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

“CAR”	chimeric antigen receptor
“CAR T cell”	chimeric antigen receptor T cell
“GPC3”	Glypican-3, an oncofetal antigen expressed in a variety of tumors including certain liver and lung cancers
“IND”	investigational new drug or investigational new drug application, also known as clinical trial application in China
“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 I”	a study in which a drug is introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage, tolerance, absorption, metabolism, distribution, excretion, and if possible, to gain an early indication of its effectiveness

**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, CT011, 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, January 15, 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.*