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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 COLLABORATION AGREEMENT FOR ZEVORCABTAGENE AUTOLEUCEL WITH HUADONG MEDICINE**

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 of the Company (the “**Board**”) announces that CARsgen and Huadong Medicine (Hangzhou) Co., Ltd., a wholly-owned subsidiary of Huadong Medicine Co., Ltd. (SZ. 000963) (“**Huadong Medicine**”) entered into a collaboration agreement (the “**Agreement**”) for the commercialization of CARsgen’s lead drug candidate, zevorcabtagene autoleucel (“**zevor-cel**”, R&D code: CT053, an autologous CAR T-cell product candidate against BCMA) in mainland China. Pursuant to the Agreement, Huadong Medicine is granted the exclusive right to commercialize zevor-cel in mainland China. The collaboration will leverage the strong commercialization capability and commercial presence in hematology of Huadong Medicine, to enhance the successful commercialization of zevor-cel in mainland China.

Under the terms of the Agreement, CARsgen will receive an upfront payment of RMB200 million and is eligible to receive regulatory and commercial milestone payments up to RMB1,025 million. CARsgen will continue to be responsible for the development, regulatory approval, and manufacturing of CT053 in mainland China.

To the best knowledge and belief of the Company, as of the date of this announcement, Huadong Medicine is independent of, and not connected with, the Company and its connected persons (as defined in the Listing Rules). The transactions contemplated under the Agreement do not constitute any notifiable transactions or connected transactions of the Company under the Listing Rules.

## **ABOUT HUADONG MEDICINE**

Huadong Medicine Co., Ltd. (SZ.000963) is a leading large-scale comprehensive pharmaceutical listed company based in Hangzhou, China. Founded in 1993, Huadong Medicine has fully integrated R&D, manufacturing, distribution, sales, and marketing capabilities. Huadong Medicine's product portfolio and pipeline are specialized in oncology, immunology, nephrology, and diabetes. Huadong Medicine has 12,000 employees and highly extensive commercial coverage and marketing capabilities in China. 'Patient Centered, Science Driven' is Huadong Medicine's value.

## **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 New Drug Application (NDA) for zevor-cel based on the phase I/II data from LUMMICAR STUDY 1 in China has been accepted by NMPA. CARsgen is conducting the phase 1b/2 LUMMICAR STUDY 2 clinical trial in North America to evaluate the safety and efficacy of zevor-cel for R/R MM in that population. 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.

## **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 tumours. 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 tumours, 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
“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
“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, January 16, 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 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.*