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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 CT071 RECEIVED IND CLEARANCE FROM THE FDA FOR THE TREATMENT OF PATIENTS WITH RELAPSED/REFRACTORY MULTIPLE MYELOMA OR RELAPSED/REFRACTORY PRIMARY PLASMA CELL LEUKEMIA

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 the U.S. Food and Drug Administration (FDA) has granted Investigational New Drug (IND) clearance for CT071, an autologous CAR T-cell therapy candidate targeting G protein-coupled receptor class C group 5 member D (GPCR5D), for the treatment of patients with relapsed/refractory multiple myeloma (MM) or relapsed/refractory primary plasma cell leukemia (PCL).

GPCR5D is emerging as an important target in the landscape of MM, a common but incurable hematologic malignancy characterized by the uncontrolled proliferation of plasma cells. The notable overexpression of GPCR5D on the surface of malignant plasma cells, coupled with its limited presence on normal tissues, makes GPCR5D an ideal candidate for the treatment of MM and PCL. CT071 incorporates a fully-human single-chain variable fragment (scFV) developed by CARsgen, specifically designed to target GPCR5D.

CT071 is manufactured with CARsgen’s proprietary CARcelerate™ platform, which shortens the manufacturing time to less than 2 days and therefore yields younger, healthier, and possibly more potent CAR T cells compared to conventional manufacturing. The improved manufacturing efficiency also enhances the supply capacity, reduces the manufacturing costs, and expedites the availability of the product to the patients.

An investigator-initiated trial (IIT) is already under way in China to assess the safety and efficacy of CT071 in treating relapsed/refractory MM or PCL (NCT05838131). Preliminary clinical data from the IIT shows an acceptable safety profile with preliminary efficacy.

ABOUT CT071

CT071 is a CAR T-cell therapy candidate developed utilizing proprietary CARcelerate™ platform of CARsgen targeting GPRC5D for the treatment of relapsed/refractory MM or relapsed/refractory PCL. An IIT (NCT05838131) is ongoing in China to evaluate the safety and efficacy of CT071 for the treatment of relapsed/refractory multiple myeloma or plasma cell leukemia.

ABOUT CARcelerate™

CARcelerate™ is a proprietary platform CARsgen developed that can shorten the manufacturing time for the CAR T cells to less than 2 days, as compared to the conventional CAR T manufacturing process. The CARcelerate™ platform produces CAR T cells that are younger, healthier, are more likely to remain in a ‘naïve’ state and less likely to be exhausted; as such, these CAR T cells from the CARcelerate™ platform are expected to exhibit more potent tumor killing activity.

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
“FDA” or “U.S. FDA”	United States Food and Drug Administration
“GPRC5D”	G protein-coupled receptor, class C, group 5, member D, GPRC5D, a protein that is highly expressed on the surface of malignant plasma cells with limited expression on normal tissues
“Investigator-Initiated Trial” or “IIT”	clinical trial sponsored and conducted by independent investigators
“IND”	investigational new drug or investigational new drug application, also known as clinical trial application in China
“United States” or “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, CT071, 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, December 4, 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.