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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 RELEASE OF THE FIRST CLINICAL BATCH FROM THE RTP GMP MANUFACTURING FACILITY IN NORTH CAROLINA

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**”) is pleased to announce that the Company’s Current Good Manufacturing Practice (CGMP) manufacturing facility located at the Research Triangle Park (RTP) in North Carolina, the United States of America (“**The RTP GMP Manufacturing Facility**”) has started GMP production of autologous CAR T cell products and successfully released the first GMP batch for the clinical trials.

The RTP GMP Manufacturing Facility, with a total gross floor area of approximately 3,300 sq.m, will provide CARsgen additional manufacturing capacity of autologous CAR T-cell products for 700 patients annually to support clinical studies and early commercial launch in North America and Europe.

Apart from several ongoing clinical studies in China, the Company has two active INDs, including a Phase 2 pivotal study of CT053 for relapsed/refractory multiple myeloma and a Phase 1b study of CT041 for advanced gastric and pancreatic cancers, both cleared by the U.S. FDA and the Health Canada. CARsgen is rapidly expanding the in-house capacity of manufacturing and quality testing in the United States. The Company will accelerate the ongoing clinical studies by providing more promising CAR T-cell products to the global patients.

The successful release of the first U.S. patient product at the RTP GMP Manufacturing Facility is a remarkable milestone for CARsgen. By taking advantage of the vertically integrated production at CARsgen, our world-class CMC team efficiently completed the global technology transfer from our China manufacturing facility and then advance to the clinical manufacturing effectively. The commencement of clinical production at the RTP GMP Manufacturing Facility will greatly reduce current risks of global supply chain shortage and strengthen the value chain of CARsgen.

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 tumors. The Company has built an integrated cell therapy platform with in-house capabilities that span target discovery, 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 tumors, 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

“CAR T cell”	chimeric antigen receptor T cell
“China manufacturing facility”	the clinical manufacturing facility in Xuhui, Shanghai and the commercial GMP manufacturing facility in Jinshan, Shanghai
“CMC”	chemistry, manufacturing, and controls processes in the development, licensure, manufacturing, and ongoing marketing of pharmaceutical products
“CT041”	an autologous CAR T-cell product candidate against the protein Claudin18.2, and targets the treatment of Claudin18.2 positive solid tumors with a primary focus on gastric/gastroesophageal junction cancer and pancreatic cancer
“CT053”	an upgraded fully human, autologous BCMA CAR T-cell product candidate for the treatment of refractory and/or relapsed multiple myeloma
“FDA” or “U.S. FDA”	U.S. Food and Drug Administration
“GMP”	Good Manufacturing Practice
“IND”	investigational new drug or investigational new drug application, also known as clinical trial application in China
“solid tumor”	an abnormal mass of tissue that usually does not contain cysts or liquid areas
“United States” or “U.S.”	the United States of America, its territories, its dependencies and all areas subject to its jurisdiction

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

Hong Kong, September 1, 2022

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. Chunhai FAN, 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.