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 THE NMPA APPROVES THE NEW DRUG APPLICATION FOR THE CLAUDIN18.2 CAR T-CELL THERAPY PRODUCT SATRICABTAGENE AUTOLEUCEL FOR THE TREATMENT OF PATIENTS WITH CLAUDIN18.2-POSITIVE, HER2-NEGATIVE ADVANCED GASTRIC/GASTROESOPHAGEAL JUNCTION ADENOCARCINOMA (G/GEJA) WHO HAVE FAILED AT LEAST TWO PRIOR LINES OF THERAPY

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**") is pleased to announce that as informed by the National Medical Products Administration ("**NMPA**") on June 22, 2026, the New Drug Application ("**NDA**") of satricabtagene autoleucel ("**satri-cel**"), the proprietary autologous humanized Claudin18.2 CAR T-cell therapy product, was approved for the treatment of patients with Claudin18.2-positive, HER2-negative advanced gastric/ gastroesophageal junction adenocarcinoma (G/GEJA) who have failed at least two prior lines of therapy. This is the world's first approved CAR T-cell therapy product for the treatment of solid tumors.

Claudin18.2 is a highly selective marker protein that is expressed only in differentiated gastric mucosal epithelial cells, with highly limited expression in normal healthy tissues, and is highly expressed in gastric cancer cells. Satri-cel is an autologous CAR T-cell therapy product targeting Claudin18.2. It is genetically modified to express a CAR construct consisting of a humanized Claudin18.2-specific single-chain fragment variant (hu8E5-2I), a CD8α hinge region, a CD28 transmembrane region, a CD28 intracellular signal domain (CD28 ICD), and a CD3ζ intracellular signal region. To our knowledge, we were the first in the world to successfully identify, validate and report the solid tumor-associated antigen Claudin18.2 as a valid target for CAR T-cell therapy. To further address the challenges of the tumor microenvironment in treating solid tumors, we independently developed an innovative, patent-protected preconditioning regimen which is to be administered prior to infusion of satri-cel. This regimen features the addition of low-dose nab-paclitaxel to the conventional lymphodepletion regimen comprising cyclophosphamide and fludarabine to enhance the infiltration and anti-tumor efficacy of CAR T cells. The Company has implemented global patent layout around satri-cel, covering the target, indications, dosage, and preconditioning regimens, among others.

The approval of satri-cel is based on an open-label, multi-center, confirmatory randomized controlled Phase II clinical trial (CT041-ST-01, NCT04581473) conducted in China. The research data have been published in *The Lancet* and at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting, and satri-cel demonstrated encouraging efficacy and a favorable safety profile.

Gastric cancer is defined as a primary epithelial-derived malignant tumor arising from the stomach mucosa. As a high-incidence region globally, China ranks gastric cancer as the fifth most prevalent malignancy, in accordance with data released by the National Cancer Center of China (NCC). In 2022, the number of new gastric cancer cases in China approximated 358,700[1]. With the rapid advancement of population aging in China, the disease burden of gastric cancer in the elderly population has become increasingly prominent. It is projected that the number of new gastric cancer cases across China will reach 607,000 by 2050[2].

ABOUT SATRICABTAGENE AUTOLEUCEL

Satri-cel is an autologous CAR T-cell therapy product against the protein Claudin18.2 that is the first-in-class globally. Satri-cel targets the treatment of Claudin18.2-positive solid tumors. It was approved by the NMPA in June 2026 for the treatment of Claudin18.2-positive, HER2-negative advanced gastric/gastroesophageal junction adenocarcinoma in patients who have failed at least two prior lines of therapy, making it the world's first approved CAR T-cell therapy product for solid tumors.

The Company is actively expanding satri-cel application in early-line treatment and perioperative treatment of cancer, including an ongoing Phase I clinical trial for pancreatic cancer adjuvant therapy in China (NCT05911217), an IIT for consolidation treatment following adjuvant therapy in patients with resected G/GEJA (NCT06857786) and an IIT for sequential therapy following first-line treatment for G/GEJA (NCT07179484).

ABOUT THE COMPANY

CARsgen is a biopharmaceutical company focusing on developing innovative CAR T-cell therapies to address the unmet clinical needs including but not limited to hematologic malignancies, solid tumors and autoimmune diseases. CARsgen has established end-to-end capabilities for CAR T-cell research and development covering target discovery, preclinical research, product clinical development, and commercial-scale production. CARsgen has developed novel in-house technologies and a product pipeline with global rights to address challenges faced by existing CAR T-cell therapies. Efforts include improving safety profile, enhancing the efficacy in treating solid tumors, and reducing treatment costs, etc. CARsgen's mission is to be a global biopharmaceutical leader that provides innovative and differentiated cell therapies for patients worldwide and makes cancer and other diseases curable.

DEFINITIONS AND GLOSSARY OF TECHNICAL TERMS

"CAR"	chimeric antigen receptor
"CAR T"	chimeric antigen receptor T cell

"Claudin18.2"	a protein found on the cells of certain solid tumors such as gastric cancer and pancreatic cancer, which makes the protein an attractive target for treatment
"confirmatory trial"	the controlled trial or study intended to demonstrate the required clinical efficacy and safety evidence before submission for drug marketing approval
"IIT"	clinical trial sponsored and conducted by independent investigators
"Phase II clinical trial"	a study in which a drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the drug for a specific targeted disease, and to determine dosage tolerance and optimal dosage
"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

Reference list

1. Han BF, Zheng RS, Zeng HM, Wang SM, Sun KX, Chen R, Li L, Wei WQ, He J. Cancer incidence and mortality in China, 2022. J Natl Cancer Center. 2024;4:47-53.

2. Yu WY, Li X, Zhu J, Ding YM, Tao HQ, Du LB. Epidemiological characteristics of gastric cancer in China and worldwide. Zhonghua Zhong Liu Za Zhi. 2025;47:468-476.

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, satri-cel, 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, June 22, 2026

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. 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.