**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
# UPDATED RESEARCH RESULTS ON SATRI-CEL IN NATURE MEDICINE AND AT THE 2024 ASCO ANNUAL MEETING

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 Company's shareholders and potential investors about the latest business update of the Group.

The board of directors of the Company (the "**Board**") announces that the final follow-up results of the investigator-initiated trial CT041-CG4006 (NCT03874897) of satricabtagene autoleucel ("**satri-cel**", CT041) (an autologous CAR T-cell product candidate against Claudin18.2) have been published in *Nature Medicine* on June 3, 2024. Data were presented as an oral presentation at the 2024 American Society of Clinical Oncology ("**ASCO**") Annual Meeting on June 3, 2024, 12:30 pm-3:30 pm, Eastern Daylight Time. Further details have been posted on the corporate website **https://www.carsgen.com**.

The article in Nature Medicine was titled "Claudin18.2-specific CAR T Cells in gastrointestinal cancers: phase 1 trial final results".

The 2024 ASCO Annual Meeting abstract was titled "Claudin18.2-Targeted Chimeric Antigen Receptor T Cell Therapy for Patients with Gastrointestinal Cancers: Final Results of CT041-CG4006 Phase 1 Trial".

## ABOUT SATRI-CEL

Satri-cel is an autologous CAR T-cell product candidate against the protein Claudin18.2 that can potentially be the first-in-class globally. Satri-cel has been developed for the treatment of Claudin18.2 positive solid tumors with a primary focus on gastric cancer/gastroesophageal junction cancer (GC/GEJ) and pancreatic cancer (PC). Ongoing trials include investigator-initiated trials (CT041-CG4006, NCT03874897), a confirmatory Phase II clinical trial for advanced GC/GEJ in China (CT041-ST-01, NCT04581473), a Phase I clinical trial for PC adjuvant therapy in China (CT041-ST-05, NCT05911217), and a Phase 1b/2 clinical trial for advanced gastric or pancreatic adenocarcinoma in North America (CT041-ST-02, NCT04404595). Satri-cel was granted Regenerative Medicine Advanced Therapy (RMAT) designation by the U.S. FDA for the treatment of advanced GC/GEJ with Claudin18.2-positive tumors in January 2022 and was granted PRIME eligibility by the EMA for the treatment of advanced gastric cancer in November 2021. Satri-cel received an Orphan Drug designation from the U.S. FDA in 2020 for the treatment of GC/GEJ and an Orphan Medicinal Product designation from the EMA in 2021 for the treatment of advanced gastric cancer.

## 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 mission 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

| | |
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| "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" or "pivotal trial" | a controlled trial or study intended to demonstrate the required clinical efficacy and safety evidence before submission for drug marketing approval |
| "EMA" | European Medicines Agency |
| "FDA" or "U.S. FDA" | U.S. Food and Drug Administration |
| "Phase 1b" | a phase of clinical trials that primarily assesses safety, tolerability and pharmacokinetics/pharmacodynamics at multiple ascending dose levels prior to commencement of a Phase II or Phase III clinical trial |
| "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 |
| "PRIME" | PRIority MEdicine. A scheme launched by the EMA to offer early and proactive support to medicine developers to optimize the generation of robust data on a medicine's benefits and risks, and to accelerate the assessment of the applications, of medicines that target an unmet medical need with advantages over existing treatments |

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| "regenerative medicine advanced therapy" or "RMAT" | a special status granted by the FDA to regenerative medicine therapies, including cell therapies, that are intended to treat a serious or life-threatening disease or condition, and for which preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such a disease or condition |
| "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 |

**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 4, 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, 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.*