Genscript Biotech Corporation
金斯瑞生物科技股份有限公司 *
(Incorporated in the Cayman Islands with limited liability)
(Stock Code: 1548)

VOLUNTARY ANNOUNCEMENT
RESEARCH AND DEVELOPMENT UPDATE

Reference is made to the voluntary announcement of Genscript Biotech Corporation (the "**Company**", together with its subsidiaries, the "**Group**") dated June 5, 2022.

The board (the "**Board**") of directors (the "**Directors**") of the Company is pleased to announce that, on November 3, 2022 (New York time, before trading hours on November 4, 2022 in Hong Kong), Legend Biotech Corporation ("**Legend Biotech**"), a non-wholly owned subsidiary of the Company, announced that seven company-sponsored studies were accepted for presentation at the 64th American Society of Hematology (ASH) Annual Meeting and Exposition (the "**ASH Meeting**") in New Orleans.

The presentations deliver the latest on the clinical development program for ciltacabtagene autoleucel (cilta-cel), the B-cell maturation antigen (BCMA)-directed chimeric antigen receptor T-cell (CAR-T) therapy for the treatment of multiple myeloma (RRMM). The poster presentations will detail an analysis from the Phase 1b/2 CARTITUDE-1 study assessing patients with sustained minimal residual disease (MRD) negativity (≥6 months, and ≥12 months), as well as updated data from CARTIFAN-1, a Phase 2 confirmatory trial of cilta-cel in China for the treatment of heavily pretreated Chinese patients with relapsed or refractory multiple myeloma (RRMM). This is the first time that data from CARTIFAN-1 will be presented at a conference (an earlier data cut has been published in Journal of Clinical Oncology).

Longer-term follow-up data from the ongoing multicohort Phase 2 study, CARTITUDE-2, will also be presented, communicating results from Cohort B, which is comprised of patients who had early relapse (≤12 months following autologous stem cell transplant ASCT or ≤12 months following the start of initial treatment with anti-myeloma therapy) and Cohort C, which includes patients with progressive multiple myeloma and previous exposure to a non-cellular anti-BCMA immunotherapy.

The study design of CARTITUDE-6/EMagine will also be presented at the meeting. This Phase 3 study seeks to evaluate the safety and efficacy of daratumumab, bortezomib, lenalidomide, and dexamethasone (DVRd) followed by cilta-cel vs DVRd followed by ASCT in newly diagnosed multiple myeloma patients.

A select list of abstracts from the meeting can be found below.

Abstract No.	**Title**	**Information**
Abstract #2030 Poster	Efficacy Outcomes and Characteristics of Patients with Multiple Myeloma (MM) Who Achieved Sustained Minimal Residual Disease Negativity After Treatment With Ciltacabtagene Autoleucel (cilta-cel) in CARTITUDE-1	**Session:** 705. Cellular Immunotherapies: Late Phase and Commercially Available Therapies: Poster I **Date:** Saturday, December 10, 2022 **Time:** 5:30 pm–7:30 pm CT
Abstract #3357 Poster	Phase 2, Open-label Study of Ciltacabtagene Autoleucel, an Anti-BCMA CAR-T Cell Therapy, in Chinese Patients with Relapsed/ Refractory Multiple Myeloma (CARTIFAN-1): 26-month Median Follow-up	**Session:** 705. Cellular Immunotherapies: Late Phase and Commercially Available Therapies: Poster II **Date:** Sunday, December 11, 2022 **Time:** 6:00 pm–8:00 pm CT
Abstract #3354 Poster	Ciltacabtagene Autoleucel (cilta-cel), a BCMA-directed CAR-T Cell Therapy, in Patients With Multiple Myeloma (MM) and Early Relapse After Initial Therapy: CARTITUDE-2 Cohort B 18-Month Follow-up	**Session:** 705. Cellular Immunotherapies: Late Phase and Commercially Available Therapies: Poster II **Date:** Sunday, December 11, 2022 **Time:** 6:00 pm–8:00 pm CT
Abstract #2028 Poster	Efficacy and Safety of Cilta-cel in Patients With Progressive Multiple Myeloma after Exposure to Non-cellular Anti-BCMA Immunotherapy	**Session:** 705. Cellular Immunotherapies: Late Phase and Commercially Available Therapies: Poster I **Date:** Saturday, December 10, 2022 **Time:** 5:30 pm–7:30 pm CT
Abstract #2023 Poster	DVRd Followed by Ciltacabtagene Autoleucel Versus DVRd Followed by ASCT in Patients With Newly Diagnosed Multiple Myeloma Who are Transplant Eligible: A Randomized Phase 3 Study (*EM*agine/CARTITUDE-6)	**Session:** 705. Cellular Immunotherapies: Late Phase and Commercially Available Therapies: Poster I **Date:** Saturday, December 10, 2022 **Time:** 5:30 pm–7:30 pm CT

Abstract No.	Title	Information
Abstract #1884 Poster	Effect of Predicted Fludarabine Lymphodepletion Exposure on Clinical Outcomes in Myeloma Patients Undergoing BCMA-CAR-T: An Exploratory Analysis from CARTITUDE-1	**Session:** 652. Multiple Myeloma and Plasma Cell Dyscrasias: Clinical and Epidemiological: Poster 1 **Date:** Saturday, December 10, 2022 **Time:** 5:30 pm–7:30 pm CT
Abstract #1883 Poster	Characteristics and Outcomes in Patients with Lenalidomide-Refractory Relapsed/Refractory Multiple Myeloma Treated with 1–3 Prior Lines of Therapy: Analysis of the Individual Patient-level Data from Daratumumab Clinical Trials	**Session:** 652. Multiple Myeloma and Plasma Cell Dyscrasias: Clinical and Epidemiological: Poster 1 **Date:** Saturday, December 10, 2022 **Time:** 5:30 pm–7:30 pm CT

About CARVYKTI™ (ciltacabtagene autoleucel; cilta-cel)

CARVYKTI™ is a BCMA-directed, genetically modified autologous T-cell immunotherapy, which involves reprogramming a patient's own T-cells with a transgene encoding a chimeric antigen receptor (CAR) that identifies and eliminates cells that express BCMA. BCMA is primarily expressed on the surface of malignant multiple myeloma B-lineage cells, as well as late-stage B-cells and plasma cells. The CARVYKTI™ CAR protein features two BCMA-targeting single domain antibodies designed to confer high avidity against human BCMA. Upon binding to BCMA-expressing cells, the CAR promotes T-cell activation, expansion, and elimination of target cells.

In December 2017, Legend Biotech entered into an exclusive worldwide license and collaboration agreement with Janssen Pharmaceuticals (Janssen) to develop and commercialize cilta-cel.

In February 2022, CARVYKTI™ was approved by the U.S. Food and Drug Administration (FDA) for the treatment of adults with relapsed or refractory multiple myeloma. In May 2022, the European Commission (EC) granted conditional marketing authorization of CARVYKTI™ for the treatment of adults with relapsed and refractory multiple myeloma. In September 2022, Japan's Ministry of Health, Labour and Welfare (MHLW) approved CARVYKTI™. Cilta-cel was granted Breakthrough Therapy Designation in the U.S. in December 2019 and in China in August 2020. In addition, cilta-cel received a PRIority MEdicines (PRIME) designation from the European Commission in April 2019. Cilta-cel also received Orphan Drug Designation from the U.S. FDA in February 2019, from the European Commission in February 2020, and from the Pharmaceuticals and Medicinal Devices Agency (PMDA) in Japan in June 2020. In May 2022, the European Medicines Agency's Committee for Orphan Medicinal Products recommended by consensus that the orphan designation for cilta-cel be maintained on the basis of clinical data demonstrating improved and sustained complete response rates following treatment.

About CARTITUDE-1

CARTITUDE-1 (NCT03548207) is a Phase 1b/2, open-label, multicenter study evaluating the safety and efficacy of cilta-cel in adults with relapsed and/or refractory with multiple myeloma who have received at least 3 prior lines of therapy or are double refractory to a proteasome inhibitor (PI) and immunomodulatory drug (IMiD), received a PI, an IMiD, and anti-CD38 antibody and documented disease progression within 12 months of starting the most recent therapy. The primary objective of the Phase 1b portion of the study was to characterize the safety and confirm the recommended Phase 2 dose of cilta-cel, informed by the first-in-human study with LCAR-B38M CAR-T cells (LEGEND-2). The Phase 2 portion further evaluated the efficacy of cilta-cel with overall response rate as the primary endpoint.

About CARTITUDE-2

CARTITUDE-2 (NCT04133636NCT04133636) is an ongoing Phase 2 multicohort study evaluating the safety and efficacy of cilta-cel in various clinical settings. Cohort A included patients who had progressive multiple myeloma after 1–3 prior lines of therapy, including a PI and an IMiD, were lenalidomide refractory, and had no prior exposure to BCMA-targeting agents. Cohort B included patients with early relapse after initial therapy that included a PI and an IMiD. Cohort C included patients with progressive MM after treatment with a PI, IMiD, anti-CD38 antibody, and non-cellular BCMA-targeting agent. The primary study objective was to measure the percentage of patients with negative minimal residual disease (MRD).

About CARTITUDE-6/EMagine

CARTITUDE-6 (NCT05257083) is a Phase 3, randomized, open-label, global study comparing the efficacy and safety of DVRd followed by cilta-cel and lenalidomide vs DVRd followed by ASCT, DVRd, and lenalidomide in patients with newly diagnosed multiple myeloma. The dual primary endpoints are progression-free survival (PFS) and minimal residual disease (MRD)-negative CR sustained for ≥12 months.

About CARTIFAN-1

CARTIFAN-1 (NCT03758417) is a Phase 2 open-label, confirmatory trial evaluating the efficacy and safety of cilta-cel in Chinese patients with RRMM who have received at least three prior lines of treatments including a PI and IMiD. The primary endpoint is overall response rate.

For details in relation to multiple myeloma, please refer to the voluntary announcement of the Company dated June 5, 2022.

For details of the important safety information of CARVYKTI™, please refer to the Form 6-K filed by Legend Biotech with the United States Securities and Exchange Commission (the "**SEC**") on November 3, 2022 (New York Time) in relation to the presentations at the ASH Meeting (the "**Form 6-K**"). The Form 6-K as published on the SEC's website is available at https://www.sec.gov/Archives/edgar/data/1801198/000115752322001523/0001157523-22-001523-index.htm.

Cautionary Note Regarding Forward-Looking Statements

Statements in this announcement about future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, constitute "forward-looking statements" within the meaning of The Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, statements relating to Legend Biotech's strategies and objectives; statements relating to CARVYKTI™, including Legend Biotech's expectations for CARVYKTI™, such as Legend Biotech's manufacturing and commercialization expectations for CARVYKTI™ and the potential effect of treatment with CARVYKTI™; statements about submissions for cilta-cel to, and the progress of such submissions with, the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), the Chinese Center for Drug Evaluation of National Medical Products Administration (CDE) and other regulatory authorities; the anticipated timing of, and ability to progress, clinical trials; the ability to maintain and progress the conditional marketing authorization for cilta-cel granted by the EMA; the submission of Investigational New Drug (IND) applications to, and maintenance of such applications with, regulatory authorities; the ability to generate, analyze and present data from clinical trials; and the potential benefits of Legend Biotech's product candidates. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors. Legend Biotech's expectations could be affected by, among other things, uncertainties involved in the development of new pharmaceutical products; unexpected clinical trial results, including as a result of additional analysis of existing clinical data or unexpected new clinical data; unexpected regulatory actions or delays, including requests for additional safety and/or efficacy data or analysis of data, or government regulation generally; unexpected delays as a result of actions undertaken, or failures to act, by our third party partners; uncertainties arising from challenges to Legend Biotech's patent or other proprietary intellectual property protection, including the uncertainties involved in the U.S. litigation process; competition in general; government, industry, and general public pricing and other political pressures; the duration and severity of the COVID-19 pandemic and governmental and regulatory measures implemented in response to the evolving situation; as well as the other factors discussed in the "Risk Factors" section of the Legend Biotech's Annual Report on Form 20-F filed with the Securities and Exchange Commission on March 31, 2022. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described in this announcement as anticipated, believed, estimated or expected. Any forward-looking statements contained in this announcement speak only as of the date of this announcement. The Group and Legend Biotech specifically disclaim any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

Shareholders and potential investors of the Company are advised to pay attention to investment risks and exercise caution when they deal or contemplate dealing in the securities of the Company.

By Order of the Board
Genscript Biotech Corporation
MENG Jiange
Chairman and Executive Director

Hong Kong, November 4, 2022

As at the date of this announcement, the executive Directors are Mr. Meng Jiange, Ms. Wang Ye and Dr. Zhu Li; the non-executive Directors are Dr. Zhang Fangliang, Dr. Wang Luquan, Mr. Pan Yuexin and Ms. Wang Jiafen; and the independent non-executive Directors are Mr. Guo Hongxin, Mr. Dai Zumian, Mr. Pan Jiuan and Dr. Wang Xuehai.

* *For identification purposes only*