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 18 May 2022.

The board (the "**Board**") of directors (the "**Directors**") of the Company is pleased to announce that Legend Biotech Corporation ("**Legend Biotech**"), a non-wholly owned subsidiary of the Company, whose shares are listed by way of American Depositary Shares on the Nasdaq Global Select Market in the United States (the "**U.S.**"), presented on 4 June 2022 new and updated results from the CARTITUDE clinical development program studying ciltacabtagene autoleucel (cilta-cel) in the treatment of multiple myeloma at the 2022 American Society of Clinical Oncology Annual Meeting (the "**2022 ASCO Annual Meeting**"). Earlier data from the CARTITUDE-1 study supported recent regulatory approvals for CARVYKTI™ by the U.S. Food and Drug Administration and the European Commission, and ongoing results from the multi-cohort CARTITUDE-2 study are being used to inform future trials of CARVYKTI™ treatment in multiple patient populations and treatment settings.

Longer-Term CARTITUDE-1 Data Continue to Show Deep and Durable Responses

Data from the ongoing Phase 1b/2 CARTITUDE-1 study continue to show deep and durable responses in heavily pretreated patients with relapsed or refractory multiple myeloma at a median 28-month follow up (MFU), with an overall response rate (ORR) of 98 percent (95 percent Confident Interval [CI], 92.7–99.7).

Responses in 97 patients treated with CARVYKTI™ were sustained from the 22-month median follow-up data previously presented at the 2021 American Society of Hematology (the "**ASH**") Annual Meeting, with 83 percent of patients achieving a stringent complete response (sCR) at median 28 MFU. Median progression-free survival (PFS) and median overall survival (OS) were not reached at time of follow-up, suggesting long-term durability of responses and survival for patients. Two-year PFS and OS rates were 55 percent (95 percent CI, 44.0–64.6) and 70 percent (95 percent CI, 60.1–78.6), respectively. Sixty-one patients had samples evaluable for minimal residual disease (MRD) status, and of those, 92 percent achieved MRD negativity at the 10^{-5} threshold. Of those evaluable, MRD negativity was sustained for more than 6 months in 68 percent and more than 12 months in 55 percent of patients. Two-year PFS rates in patients who achieved sustained MRD negativity for 6 months or longer and 12 months or longer were 73 percent (95 percent CI, 52.1 to 85.9) and 79 percent (95 percent CI, 51.5 to 91.8), respectively. In these same patients, two-year OS rates were 94 percent (95 percent CI, 76.1 to 98.3) and 91 percent (95 percent CI, 67.7 to 97.6), respectively.

The CARTITUDE-1 study included patients who received a median of six prior treatment regimens (range, 3–18). All patients were triple-class [immunomodulatory agent (IMiD), proteasome inhibitor (PI) and anti-CD38 antibody] exposed, while 42 percent of patients were penta-drug refractory and 99 percent of patients were refractory to the last line of therapy.

Median time to first response was one month (range, 0.9–10.7 months), with responses deepening over time. Additionally, median time to best response was 2.6 months (range, 0.9–17.8 months) and median time to complete response (CR) or better was 2.9 months (range, 0.9–17.8 months).

At 28-month median follow up, the most common hematologic adverse events (AEs) observed were neutropenia (96 percent); anemia (81 percent); thrombocytopenia (79 percent); leukopenia (62 percent); and lymphopenia (54 percent). Since the primary 12-month publication, no new events of CRS (no changes in incidence, time to onset, or duration) occurred and one new case of Parkinsonism (also referred to as movement and neurocognitive treatment-emergent adverse events (TEAEs) occurred.

CARTITUDE-2 Data Reinforce Potential for Use in Earlier-Line of Treatment

Results from the multicohort Phase 2 CARTITUDE-2 study (NCT04133636) evaluating cilta-cel safety and efficacy in various clinical settings for patients with multiple myeloma were also presented at the 2022 ASCO Annual Meeting, demonstrating the promise of CARVYKTI™ earlier in the course of multiple myeloma treatment.

Updated data from Cohort A examined the safety and efficacy of cilta-cel in 20 patients with multiple myeloma after one to three prior lines of therapy and who are lenalidomide-refractory (Abstract #8020). At a median follow-up of 17.1 months, the ORR was 95 percent, which included 90 percent of patients achieving CR or better and 95 percent achieving very good partial response (VGPR) or better. The median time to first response was one month and the median time to best response was 2.6 months. The 15-month PFS rate was 70 percent. Of the 16 patients who were MRD-evaluable, all achieved MRD negativity at 10^{-5}.

Results from Cohort B of the study, evaluating the safety and efficacy of cilta-cel in patients relapsed or refractory multiple myeloma who received one prior line of therapy including a PI and IMiD and had disease progression 12 or more months after treatment with autologous stem cell transplant (ASCT), or 12 or more months from the start of antimyeloma therapy for patients who have not had ASCT, were also presented (Abstract #8029). At a median of 13 months follow-up, 19 patients treated in this cohort achieved an ORR of 100 percent, with 90 percent of patients achieving a CR or better, and 95 percent of patients achieving a VGPR or better. Median time to first response was one month (range, 0.9–9.7) and median time to best response was 5.1 months. The 12-month PFS rate was 90 percent. Of the 15 patients who were MRD-evaluable, 14 achieved MRD negativity at 10^{-5}.

In both of these cohorts from CARTITUDE-2, the overall safety profile, including incidence of CRS and most common hematologic AEs, was consistent with that of CARTITUDE-1.

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 Corporation entered into an exclusive worldwide license and collaboration agreement with Janssen Biotech, Inc. (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. 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.

For details in relation the important safety information of CARVYKTI™, please refer to the press release published on the Legend Biotech's website available at https://investors.legendbiotech.com/news-releases/news-release-details/longer-term-datacartitude-program-continue-show-deep-and.

About Multiple Myeloma

Multiple myeloma is an incurable blood cancer that starts in the bone marrow and is characterized by an excessive proliferation of plasma cells. In 2022, it is estimated that more than 34,000 people will be diagnosed with multiple myeloma, and more than 12,000 people will die from the disease in the U.S. While some patients with multiple myeloma have no symptoms at all, most patients are diagnosed due to symptoms that can include bone problems, low blood counts, calcium elevation, kidney problems or infections. Although treatment may result in remission, unfortunately, patients will most likely relapse. Patients who relapse after treatment with standard therapies, including protease inhibitors, immunomodulatory agents, and an anti-CD38 monoclonal antibody, have poor prognoses and few treatment options available.

For details in relation to CARTITUDE-1 and CARTITUDE-2, please refer to the voluntary announcement of the Company dated 18 May 2022.

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, including patient enrollment and the resumption of the Phase 1 clinical trial of LB1901; 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, 5 June 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*