**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 announcements of GenScript Biotech Corporation (the "**Company**", together with its subsidiaries, the "**Group**") dated 8 December 2019, 9 December 2019, 14 May 2020 and 27 May 2021.

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, announced that new and updated results for ciltacabtagene autoleucel (cilta-cel), an investigational BCMA-directed CAR-T therapy for the treatment of relapsed or refractory multiple myeloma (RRMM), will be featured at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting (the "**2021 ASCO Annual Meeting**") and at the European Hematology Association (EHA) Virtual Congress

At a median follow-up of 18 months, updated results from the Phase 1b/2 CARTITUDE-1 study including 97 heavily pretreated patients with RRMM demonstrated an overall response rate (ORR) of 98 percent, with 80 percent of patients achieving a stringent complete response (sCR), highlighting a deepening response over time (from 67 percent reported at ASH 2020). The 18-month progression-free survival (PFS) rate was 66 percent (95 percent confidence interval CI, 54.9–75.0) and overall survival rate (OS) rate was 81 percent (95 percent CI, 71.4–87.6). Patients had received a median of six prior lines of therapy (range, 3–18); 88 percent were triple-refractory and 42 percent were penta-refractory. Response rates were comparable (range, 95-100 percent) across prespecified subgroups, including number of prior lines of treatment, extramedullary plasmacytomas and cytogenetic risk.

These data will be featured in an oral presentation at the 2021 ASCO Annual Meeting on Tuesday, 8 June 2021 (Abstract #8005) and as a poster presentation at the 2021 EHA Virtual Congress on Friday, 11 June 2021 (Abstract #EP964). The CARTITUDE-1 study supported the Biologics License Application for cilta-cel by Legend Biotech's collaborator, Janssen Biotech, Inc. (Janssen), which has been accepted for priority review by the U.S. Food and Drug Administration (FDA) with a Prescription Drug User Fee Act (PDUFA) target action date of 29 November 2021.

Median time to first response was one month (range, 0.9–10.7 months) and responses deepened over time. Out of 61 minimal residual disease (MRD) evaluable patients, 92 percent achieved MRD negativity status at $10^{-5}$ at a median of one month (range, 0.8–7.7 months) post infusion.

Cilta-cel data showed a safety profile consistent with what has been previously reported and no new safety signals were observed with longer-term follow-up. The most common hematologic adverse events (AEs) observed in the CARTITUDE-1 study were neutropenia (96 percent); anemia (81 percent); thrombocytopenia (79 percent); leukopenia (62 percent); and lymphopenia (53 percent). Cytokine release syndrome (CRS) of any grade was observed in 95 percent of patients, with a median duration of four days (range, 1–97), and median time to onset of seven days (range, 1–12). Of the 92 patients with CRS, 95 percent experienced Grade 1/2 events and CRS resolved in 91 patients (99 percent) within 14 days of onset. There was no new incidence of neurotoxicity; neurotoxicity of any grade was observed in 21 percent (n=20) of patients, with Grade 3 or higher neurotoxicity observed in 10 percent (n=10) of patients.

The Group excited to share these latest results from the CARTITUDE-1 study which continue to show deep and sustained benefits for patients who have been treated with cilta-cel. The Group is continuing its efforts to build a robust pipeline of next-generation cell therapies with the potential to address unmet needs. It looks forward to its continued collaborative efforts with Janssen towards bringing this personalized treatment to patients, pending regulatory approvals.

## New Data from CARTITUDE-2

For the first time, data will also be reported from Cohort A of CARTITUDE-2 (NCT04133636), a Phase 2 study evaluating the safety and efficacy of cilta-cel in patients with multiple myeloma (MM) in earlier-line settings. Cohort A included 20 patients who had progressive MM after 1–3 prior lines of therapy and were refractory to lenalidomide, including 1 patient treated in an outpatient setting. Data showed early and deep responses with a manageable safety profile consistent with what has been observed in the CARTITUDE clinical development program. At a median follow-up of 5.8 months, ORR was 95 percent with 75 percent of patients achieving sCR/CR. These initial results will be showcased in a poster discussion at ASCO 2021 (Abstract #8013) and as an oral presentation at the 2021 EHA Congress (Abstract #S190).

Results in a separate poster (HYPERLINK “https://meetinglibrary.asco.org/record/195448/abstract” Abstract #8028) will provide details on movement and neurocognitive AEs that have been observed in CARTITUDE-2 and the broader CARTITUDE program. Overall, patients with 2 or more risk factors (i.e. high tumor burden, Grade 2 or greater CRS, ICANS of high CAR-T-cell expansions) appear to be associated with these AEs. Since April 2020, new patient management strategies have been implemented, focusing on enhanced bridging therapy to reduce tumor burden, more aggressive treatment of CRS and ICANS and handwriting assessments and extended monitoring. In the poster on CARTITUDE-2 Cohort A, these patient management strategies to prevent or reduce these AEs appear to have been successful, with a lower rate of neurotoxicities (20%, n=4) and no movement and neurocognitive treatment-emergent AEs or Grade 3 neurotoxicity events observed. More broadly, more than 100 patients have been treated across the CARTITUDE program using these new patients management strategies which appear to be successful in preventing or reducing these AEs. Cilta-cel is being investigated in patients with MM in various clinical settings as part of CARTITUDE-2 and a Phase 3 study (CARTITUDE-4, NCT04181827) in earlier settings.

## 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 (NCT04133636) is an ongoing, multi-cohort, Phase 2 study evaluating the safety and efficacy of cilta-cel in with multiple myeloma. CARTITUDE-2 Cohort A includes patients who had progressive multiple myeloma after 1–3 prior lines of therapy, including PI and IMiD, were lenalidomide refractory, and had no prior exposure to BCMA-targeting agents. The primary objective was percentage of patients with negative minimal residual disease (MRD) status at $10^{-5}$.

## 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. Although treatment may result in remission, unfortunately, patients will most likely relapse. Relapsed myeloma is when the disease has returned after a period of initial, partial or complete remission and does not meet the definition of being refractory. 9 Refractory multiple myeloma is when a patient's disease is non-responsive or progresses within 60 days of their last therapy. 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. Patients who relapse after treatment with standard therapies, including protease inhibitors and immunomodulatory agents, have poor prognoses and few treatment options available.

## About Cilta-cel

Cilta-cel is an investigational chimeric antigen receptor T cell (CAR-T) therapy that is being studied in a comprehensive clinical development program for the treatment of patients with relapsed or refractory multiple myeloma and in earlier lines of treatment. The design consists of a structurally differentiated CAR-T with two BCMA-targeting single domain antibodies. In December 2017, Legend Biotech, Inc. entered into an exclusive worldwide license and collaboration agreement with Janssen Biotech, Inc. to develop and commercialize cilta-cel. In addition to a Breakthrough Therapy

Designation (BTD) granted in the U.S. in December 2019, cilta-cel received a PRIority MEdicines (PRiME) designation from the European Commission in April 2019, and a BTD in China in August 2020. In addition, Orphan Drug Designation was granted for cilta-cel by the U.S. FDA in February 2019, and by the European Commission in February 2020. A Biologics License Application seeking approval of cilta-cel was accepted by the U.S. FDA and a Marketing Authorisation Application has been accepted by the European Medicines Agency.

**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, 28 May 2021

*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. 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*