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 announcements of GenScript Biotech Corporation (the "**Company**", together with its subsidiaries, the "**Group**") dated 28 May 2021 and 4 November 2021.

The board (the "**Board**") of directors (the "**Directors**") of the Company is pleased to announce that, on 13 December 2021 (New York time), Legend Biotech Corporation ("**Legend Biotech**"), a non-wholly owned subsidiary of the Company, announced new and updated results from the CARTITUDE clinical development program studying ciltacabtagene autoleucel (cilta-cel) in the treatment of multiple myeloma, which were presented at the 63rd American Society of Hematology (the "**ASH**") Annual Meeting and Exposition. Cilta-cel is an investigational B-cell maturation antigen (BCMA)-directed chimeric antigen receptor T cell (CAR-T) therapy being studied as a one-time treatment for multiple myeloma.

CARTITUDE-1 Data Continues to Support the Exceptional Efficacy of Cilta-cel

In an oral presentation (Abstract #549), longer-term results from the Phase 1b/2 CARTITUDE-1 study in 97 patients with relapsed or refractory multiple myeloma (RRMM) continued to show a very high overall response rate (ORR) of 98 percent. After 21.7 months of follow-up, 83 percent of patients treated with cilta-cel achieved a stringent complete response (sCR) — higher than the 67 percent sCR rate reported at a median of ~1 year of follow up. Further, 95 percent of patients achieved a very good partial response (VGPR) or better. Median progressive-free survival (PFS) and median overall survival (OS) have not been reached, but the 2-year PFS rate was 61 percent (95 percent Confidence Interval [CI], 48.5–70.4) and the 2-year OS rate was 74 percent (95 percent CI, 61.9–82.7). Of the 61 patients evaluable for minimal residual disease (MRD), 92 percent were MRD-negative at 10^{-5}. The two-year PFS rates in patients with sustained MRD negativity for ≥6 and ≥12 months were 91 percent (95 percent CI, 67.1–97.8) and 100 percent, respectively.

The median time to first response was one month (range, 0.9–10.7); the median time to best response was 2.6 months (range, 0.9–17.8); and the median time to complete response or better was 2.9 months (range, 0.9–17.8). The longer-term data showed no new safety signals and there were no new events of cilta-cel-related neurotoxicity or movement and neurocognitive treatment emergent adverse events (TEAEs) (MNT) reported since the median ~1 year follow-up. Implementation of MNT mitigation measures has decreased the incidence rate to 0.5 percent in the CARTITUDE clinical development program.

In the 18-month follow-up data previously presented at ASCO 2021, the most common hematologic adverse events (AEs) observed were neutropenia (96 percent); anemia (81 percent); thrombocytopenia (79 percent); leukopenia (62 percent); and lymphopenia (53 percent). At 18-months, 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. 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.

In a subgroup analysis of CARTITUDE-1 (Abstract #3938), responses to cilta-cel were durable up to 2 years in most subgroups of patients with heavily pretreated RRMM. An ORR range of 95 to 100 percent was observed in patients across all subgroups, including those with high-risk cytogenetics, International Staging System (ISS) stage III, baseline bone marrow cells ≥60 percent, and presence of baseline plasmacytomas. In patients with ISS stage III, high risk cytogenetics and with baseline plasmacytomas, median duration of response, 2-year PFS and OS appeared lower. The cilta-cel safety profile across the subgroups was consistent with the overall population, with no new safety signals.

Additionally, an adjusted indirect comparison of CARTITUDE-1 patient outcomes relative to standard-of-care therapies in real-world clinical practice (RWCP) was also featured in an oral presentation (Abstract #550). The adjusted comparisons versus CARTITUDE-1 demonstrate a significantly improved ORR, complete response or better (≥CR), VGPR or better (≥VGPR), PFS and OS for the patients receiving cilta-cel compared to a diverse set of RWCP.

CARTITUDE-2 Data Explores Use of Cilta-cel in Earlier-Line MM Settings

The Phase 2 multicohort CARTITUDE-2 study is evaluating cilta-cel safety and efficacy in various clinical settings for patients with multiple myeloma. Updated data from Cohort A of the study examined the efficacy and safety of cilta-cel in 20 patients with progressive multiple myeloma after 1–3 prior lines of therapy and who are lenalidomide-refractory (Abstract #3866). At a longer median follow-up of 14.3 months, patients experienced early and deep responses with a manageable safety profile consistent with the CARTITUDE-1 study. ORR was 95 percent, which included 85 percent of patients achieving CR or better and 90 percent achieving VGPR or better. The median time to first response was one month (range, 0.7–3.3) and the median time to best response was 2.6 months (range, 0.9–7.9). The 6-month and 12-month PFS rates were 95 percent (95 percent CI, 69.5–99.3) and 84 percent (95 percent CI, 59.1–94.7), respectively. Of the 13 patients with MRD evaluable samples at the 10^{-5} cutoff threshold, 92 percent (95 percent CI, 64.0–99.8) were MRD negative.

The first data from Cohort B was also presented at the ASH annual meeting (Abstract #2910). Cohort B included 19 patients who were in early relapse after initial therapy that included a proteasome inhibitor (PI) and immunomodulatory drug (IMiD). Data showed early and deep responses with a manageable safety profile. At a median follow-up of 10.6 months, ORR was 95 percent, which included 79 percent of patients achieving CR or better and 90 percent of patients achieving VGPR or better. The median time to first response was one month (range, 0.9–2.6) and the median time to best response was 2.5 months (range, 0.9–11.8). The 6-month and 12-month PFS rates were 90 percent (95 percent CI, 64.1–97.3) and 84 percent (95 percent CI, 57.9–94.5), respectively. Of the 13 patients with MRD evaluable samples at the 10^{-5} cutoff threshold, 92 percent (95 percent CI, 64.0–99.8) were MRD-negative.

The safety profile seen in CARTITUDE-2 Cohorts A and B were consistent with data previously reported from CARTITUDE-1. CRS occurred in 95 percent of patients in Cohort A and 84 percent of patients in Cohort B, which were mostly grades 1/2 with median time to onset of 7–8 days and median duration of ~4 days.

The new and updated longer-term data for CARTITUDE-1 and Cohorts A and B of CARTITUDE-2 shows that responses continue to be deep and durable over time and illustrate the potential of cilta-cel to provide a new treatment option for those patients that need it the most. The Group is excited to continue to present these strong efficacy and safety results as we work toward the first regulatory approval for cilta-cel and from our robust cell therapy pipeline.

Regulatory Approval in Europe

The European Medicines Agency (the "**Agency**")'s Committee for Medicinal Products for Human Use (CHMP) has reverted the Marketing Authorisation Application (MAA) review begun under the accelerated assessment mechanism to a standard review timeline in order to allow the Agency to conduct a good manufacturing practice GMP inspection and provide a GMP certificate, which could not be accommodated in the timetable of an accelerated assessment.

Regulatory Submission Filing in China

Legend Biotech has extended the timeline for its anticipated regulatory submission seeking approval of cilta-cel in China. Based on feedback from the Center for Drug Evaluation (the "**CDE**") in China, Legend Biotech intends to provide data from more Chinese patients receiving cilta-cel as manufactured through the current process in order to support the application. Legend Biotech will continue to work with the CDE in preparation for the submission.

LCAR-AIO

At the ASH annual meeting, Legend Biotech also presented the first preclinical in vivo data on its novel tri-specific, single-domain antibody (VHH) CAR-T, known as LCAR-AIO. LCAR-AIO targets three antigens — CD19, CD20 and CD22. The tri-specific CAR-T technology may have the potential for development as a treatment for patients with relapsed B cell lymphoma who have already received CD19 CAR-T therapies.

Other Information

For details in relation to Multiple Myeloma, please refer to the voluntary announcement of the Company dated 28 May 2021. For details in relation to CARTITUDE-1, CARTITUDE-2, LocoMMotion and Cilta-cel, please refer to the voluntary announcement of the Company dated 5 November 2020.

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 overall strategies and objectives; the anticipated timing of, and ability to progress, preclinical studies and clinical trials; clinical data relating to CARTITUDE-1 and CARTITUDE-2 studies; the timing of regulatory submissions, including the BLA filing with CDE in China; the preclinical data for LCAR-AIO and the potential of LCAR-AIO as a treatment for development; and the potential benefits of our 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 or preclinical study results, including as a result of additional analysis of existing data or unexpected new 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 US 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 Legend Biotech's Annual Report on Form 20-F filed with the Securities and Exchange Commission on 2 April 2021. 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. The Group and Legend Biotech specifically disclaims 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, 13 December 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*