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)

CLARIFICATION ON CHINESE VERSION OF VOLUNTARY ANNOUNCEMENT RESEARCH AND DEVELOPMENT UPDATE

Reference is made to the previous voluntary announcement of GenScript Biotech Corporation (the "**Company**", together with its subsidiaries, the "**Group**") dated 27 September 2022 (the "**Previous Announcement**"). The Company would like to clarify an inadvertent typographical error that appear on page 1 in the Chinese version of the Previous Announcement, and the relevant amendment is underlined on page 1 in the Chinese version of this announcement for ease of reference. Save for the clarification and amendment as underlined in the Chinese version of this announcement, all information in the English and Chinese versions of the Previous Announcement remains unchanged.

The board (the "**Board**") of directors (the "**Directors**") of the Company is pleased to announce that on 27 September 2022, Legend Biotech Corporation ("**Legend Biotech**"), a non-wholly owned subsidiary of the Company, announced that Japan's Ministry of Health, Labour and Welfare (MHLW) has approved CARVYKTI® (ciltacabtagene autoleucel; cilta-cel), a B-cell maturation antigen ("**BCMA**")-directed chimeric antigen receptor T cell ("**CAR-T**") therapy, for the treatment of adults with relapsed or refractory multiple myeloma ("**RRMM**"), limited to cases meeting both of the following conditions:

- patients have no history of CAR-positive T cell infusion therapy targeting BCMA; and

- patients who have received three or more lines of therapies, including a proteasome inhibitor ("**PI**"), an immunomodulatory agent ("**IMiD**"), and an anti-CD38 monoclonal antibody, and in whom multiple myeloma not responded to or has relapsed following the most recent therapy.

The New Drug Application was submitted by Legend Biotech's collaboration partner, Janssen Pharmaceuticals ("**Janssen**"). Legend entered into an exclusive worldwide license and collaboration agreement with Janssen to develop and commercialize ciltacabtagene autoleucel (cilta-cel) in December 2017.

CARVYKTI® features two BCMA-targeting single domain antibodies, and is specifically developed for each individual patient and is administered as a single infusion.

The approval is based on data from the pivotal phase 1b/2 CARTITUDE-1 study, and included patients who received a median of six prior treatment regimens (range, 3-18), and previously received a PI, an IMiD and an anti-CD38 monoclonal antibody. In the study, a one-time treatment with cilta-cel resulted in durable responses, with 96.9 percent (95 percent Confidence Interval ("**CI**"), 91.2-99.4) of patients with RRMM in the non-Japanese population responding to therapy (n=97). Notably, 67 percent (95 percent CI, 56.7-76.2) of the patients (n=65) achieved a stringent complete response (sCR), a measure for which a physician is unable to observe any signs or symptoms of disease via imaging or other tests after treatment. The efficacy results were also observed in Japanese patients with multiple myeloma, which were consistent with that of the non-Japanese population. At a median of 18 months follow-up, the median duration of response (DOR) was 21.8 months in non-Japanese patients.

The safety of cilta-cel was evaluated in 106 adult patients in the CARTITUDE-1 study, including 97 non-Japanese participants and 9 Japanese participants. Adverse reactions were observed in 105 (99.1%) of 106 patients treated with cilta-cel. The most common adverse reactions included cytokine release syndrome (94.3%), cytopenia (79.2%), neutropenia (75.5%), thrombocytopenia (59.4%), anemia (51.9%), neurologic events (39.6%), infections (19.8%) and hypogammaglobulinemia (11.3%).

CARVYKTI® was approved by the Food and Drug Administration ("**FDA**") of the United States ("**U.S.**") in February 2022 and was granted conditional marketing authorization by the European Commission ("**EC**") in May 2022.

About CARVYKTI® (Ciltacabtagene autoleucel; cilta-cel)

CARVYKTI® (Ciltacabtagene autoleucel; cilta-cel) 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 the target cells.

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

In February 2022, CARVYKTI® was approved by the U.S. FDA for the treatment of adults with relapsed or refractory multiple myeloma. In May 2022, the EC granted conditional marketing authorization of CARVYKTI® for the treatment of adults with RRMM. 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 EC in April 2019. Cilta-cel also received Orphan Drug Designations respectively from the U.S. FDA in February 2019, from the EC 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 ("**EMA**") 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, single arm, multi-center trial evaluating cilta-cel for the treatment of adult patients with RRMM, who previously received at least three prior lines of therapy including a PI, an IMiD and an anti-CD38 monoclonal antibody, and who demonstrated disease progression on or after the last regimen. All patients in the study had received a median of six prior treatment regimens (range, 3-18).

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 Japan, approximately 7,800 people were diagnosed with multiple myeloma in 2018 and about 4,200 patients died in 2020. 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 PI, IMiD, and an anti-CD38 monoclonal antibody, have poor prognoses and few treatment options available.

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. FDA, the 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 Legend Biotech's 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 31 March 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 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, 28 September 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*