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**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**

The board (the “**Board**”) of directors (the “**Directors**”) of GenScript Biotech Corporation (the “**Company**”, together with its subsidiaries, the “**Group**”) is pleased to announce that, Legend Biotech Corporation (“**Legend Biotech**”), a non-wholly owned subsidiary of the Company, announced the submission of New Drug Application to the Japanese Ministry of Health, Labour and Welfare (MHLW) for ciltacabtagene autoleucel (“**cilta-cel**”) by its collaboration partner, Janssen Pharmaceutical K.K.. Cilta-cel is an investigational B-cell maturation antigen (“**BCMA**”)-directed chimeric antigen receptor-T (“**CAR-T**”) cell therapy for the treatment of adults with relapsed or refractory multiple myeloma who have received at least three prior therapies, including a proteasome inhibitor (“**PI**”), an immunomodulatory agent (“**IMiD**”) and an anti-CD38 antibody.

The submission is based on results from the Phase 1b/2 CARTITUDE-1 study conducted in the US and Japan, which evaluated the efficacy and safety of cilta-cel for patients with relapsed or refractory multiple myeloma. Cilta-cel is currently under regulatory review by several health authorities around the world, including the US and Europe.

### **About Ciltacabtagene Autoleucel**

Cilta-cel is an investigational CAR-T cell therapy, formerly identified as JNJ-4528 in the US and Europe and LCAR-B38M CAR-T cells in China, 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 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 US in December 2019, cilta-cel received a Priority Medicines 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 US Food and Drug Administration (“**FDA**”) in February 2019, and by the European Commission in February 2020. A Biologics

License Application seeking approval of cilta-cel was submitted to the US FDA and a Marketing Authorization Application was submitted to the European Medicines Agency.

## **About the CARTITUDE-1 Study**

CARTITUDE-1 is a Phase 1b/2, open-label, multicenter study evaluating the safety and efficacy of cilta-cel in adults with relapsed or refractory with multiple myeloma who have received at least 3 prior lines of therapy or are double refractory to a 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.

## **About Multiple Myeloma**

Multiple myeloma, an incurable blood cancer that starts in the bone marrow and is characterized by an excessive proliferation of plasma cells. In Japan, there were more than 7,000 new cases of multiple myeloma and nearly 5,000 deaths. Although treatment may result in remission, most patients experience 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. 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 by symptoms that can include bone problems, low blood counts, calcium elevation, kidney problems or infections. Patients who relapse after treatment with standard therapies, including PIs, an IMiD, 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, the anticipated timing of, and ability to progress, clinical trials, the clinical data relating to CARTITUDE-1 and CARTITUDE-2 studies 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 April 2, 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 press release 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, 6 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.*