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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**

Reference is made to the voluntary announcements of Genscript Biotech Corporation (the “**Company**”, together with its subsidiaries, the “**Group**”) dated 13 March 2018, 6 August 2020 and 5 June 2022.

The board (the “**Board**”) of directors (the “**Directors**”) of the Company is pleased to announce that on 30 December 2022, the National Medical Products Administration of China (“**NMPA**”) has formally accepted Legend Biotech Corporation’s New Drug Application for ciltacabtagene autoleucel (cilta-cel).

Cilta-cel is a chimeric antigen receptor T-cell (CAR-T) therapy featuring two B-cell maturation antigen (BCMA)-targeting single domain antibodies. In March 2018, cilta-cel received the first-ever permission of a clinical trial for CAR-T therapy granted by the China Food and Drug Administration (CFDA). In August 2020, cilta-cel became the first investigational product being recommended for Breakthrough Therapy Designation (BTD) in China. For details, please refer to the announcements of the Company dated 13 March 2018 and 6 August 2020.

This submission is based on data from the confirmatory clinical study CARTIFAN-1 (NCT03758417), which evaluated the efficacy and safety of cilta-cel in adult patients with relapsed/refractory multiple myeloma (RRMM) in China. Administered as a one-time infusion, the therapy is being evaluated for the treatment of adults with RRMM who have received at least three prior therapies, including a proteasome inhibitor (PI), an immunomodulatory agent (IMiD) and an anti-CD38 antibody.

**About CARTIFAN-1**

CARTIFAN-1 (NCT03758417) is a Phase 2 open-label, confirmatory trial evaluating the efficacy and safety of cilta-cel in Chinese patients with relapsed/refractory multiple myeloma who have received at least three prior lines of treatments including a proteasome inhibitor and immunomodulatory agent. The primary endpoint is overall response rate.

For details in relation to cilta-cel and multiple myeloma, please refer to the announcement of the Company dated 5 June 2022.

## **About Legend Biotech Corporation**

Legend Biotech Corporation (NASDAQ: LEGN) (“**Legend Biotech**”) is 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.

## **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 ciltacabtagene autoleucl, including potential indications for, and Legend Biotech’s other expectations for, that investigational CAR-T therapy; statements about submissions for ciltacabtagene autoleucl to, and the progress of such submissions with, the U.S. Food and Drug Administration (FDA) and other regulatory authorities; the anticipated timing of, and ability to progress, clinical trials; the submission of New Drug Application (NDA) 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, 2 January 2023

*As at the date of this announcement, the executive Directors are Dr. Zhang Fangliang, 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*