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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 announcements of GenScript Biotech Corporation (the “**Company**”, together with its subsidiaries, the “**Group**”) dated 22 December 2017, 17 December 2018, 28 July 2019, 8 December 2019, 28 January 2020 and 21 December 2020.

The board (the “**Board**”) of directors (the “**Directors**”) of the Company is pleased to announce that, on 26 May 2021 (New York time), Legend Biotech Corporation (“**Legend Biotech**”), a non-wholly owned subsidiary of the Company, announced that the U.S. Food and Drug Administration (the “**FDA**”) has accepted for priority review the Biologics License Application (BLA) submission for ciltacabtagene autoleucel (cilta-cel), an investigational BCMA-directed CAR-T therapy (the “**Acceptance**”). The Prescription Drug User Fee Act (PDUFA) date has been set for 29 November 2021.

Priority review is usually granted to investigational therapies which, if approved, may have the ability to offer significant improvements in the treatment, prevention or diagnosis of a serious condition. Cilta-cel previously received Breakthrough Therapy Designation (the “**BTB**”) in December 2019, intended to expedite the development and review time for a potential new medicine. For details of the BTB, please see the announcement of the Company dated 8 December 2019.

The regulatory submission for cilta-cel was based on results from the pivotal Phase 1b/2 CARTITUDE-1 study which evaluated the efficacy and safety of cilta-cel in the treatment of patients with relapsed and/or refractory multiple myeloma. Updated 18-month follow up data will be featured at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting (Abstract #8005) and European Hematology Association’s (EHA) Virtual Congress (Abstract #EP964) next month.

The Company believes that cilta-cel has shown great promise in patients with heavily pretreated multiple myeloma in clinical trial data seen to date, and the Acceptance under priority review is a significant milestone. Along with Legend Biotech’s partners at Janssen, the Group looks forward to working with the FDA to bring this transformative therapy to patients who are seeking new, effective treatment options.

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, 27 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*