**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, 11 November 2018, 4 December 2018, 4 April 2019, 16 April 2019 and 7 November 2019. The board (the "**Board**") of directors (the "**Directors**") of the Company is pleased to announce that the China Center for Drug Evaluation ("**CDE**"), National Medical Products Administration ("**NMPA**") has recommended Breakthrough Therapy Designation ("**BTD**") for ciltacabtagene autoleucel (cilta-cel; LCAR-B38M CAR-T cells), an investigational B-cell maturation antigen ("**BCMA**") targeted chimeric antigen receptor T-cell ("**CAR-T**") therapy being studied for the treatment of adults with relapsed or refractory multiple myeloma ("**RRMM**"). As per the Working Procedure for BTD (Trial) (2020 No.82)* ( 突破性治療藥物認定審評工作程序 ( 試行 ) (2020 年第 82 號 )) issued by the NMPA on 8 July 2020, the CDE had completed the review and recommended to grant the BTD on 4 August 2020, and the BTD will be granted after five working days of the publicity period (from 5 August 2020 to 12 August 2020) on the website of the CDE.

The BTD for cilta-cel (LCAR-B38M CAR-T cells) is based on the ongoing phase 2 CARTIFAN-1 study being conducted in China (MMY2002, NCT03758417, CTR20181007), the ongoing phase 1b/2 CARTITUDE-1 study of cilta-cel (JNJ-4528) being conducted in the United States (MMY2001, NCT03548207) and Japan and the phase 1, first-in-human LEGEND-2 study conducted in China (NCT03090659). Cilta-cel refers to both LCAR-B38M CAR-T cells and JNJ-4528. LCAR-B38M CAR-T cell identifies the investigational product being studied in China and JNJ-4528 identifies the investigational product being studied outside of China, both of which are representative of the same CAR-T cell therapy.

The BTD procedure is part of the recently revised Drug Registration Regulation* ( 藥品註冊管理辦法 ) which went into effect on July 1, 2020. The BTD process is designed to expedite the development and review of therapies that are intended for treatment of serious diseases for which there is no existing treatment where preliminary evidence indicates advantages of the therapy over available treatment options. Cilta-cel is the first product that has been recommended for BTD in China.

In December 2017, (i) Legend Biotech USA Inc., a non-wholly-owned subsidiary of the Company, (ii) Legend Biotech Ireland Limited, a non-wholly-owned subsidiary of the Company, and (iii) Janssen Biotech, Inc. ("**Janssen**"), one of the Janssen Pharmaceutical Companies of Johnson & Johnson, entered into a worldwide collaboration and license agreement to jointly develop and commercialize cilta-cel in patients with multiple myeloma. Cilta-cel is a structurally differentiated CAR-T cell therapy containing a 4-1BB co-stimulatory domain and two BCMA-targeting single domain antibodies designed to confer avidity.

"The Breakthrough Therapy Designation recommendation by the China CDE of NMPA represents an important regulatory milestone in the continued development of cilta-cel in multiple myeloma patients in China," said Frank Zhang, PhD, CEO of Legend Biotech Corporation, (NASDAQ: LEGN) ("**Legend**"), a subsidiary of the Company. "Legend, in collaboration with Janssen, will continue to advance this investigational therapy in China and globally."

## About CARTIFAN-1

The phase 2 CARTIFAN-1 confirmatory trial (MMY2002, NCT03758417, CTR20181007) is being conducted in China to further evaluate cilta-cel (LCAR-B38M CAR-T cells) in patients with RRMM who have received at least 3 prior lines of therapy and have received a proteasome inhibitor (PI) and an immunomodulatory drug (IMiD®), and documented disease progression within 12 months of starting the most recent therapy.

**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**
**Zhang Fangliang**
*Chairman*

Hong Kong, 6 August 2020

*As at the date of this announcement, the executive Directors are Ms. Wang Ye and Mr. Meng Jiange; 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 and Mr. Pan Jiuan.*

* *For identification purposes only*