

Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.



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 announcement of GenScript Biotech Corporation (the “**Company**”, together with its subsidiaries, the “**Group**”) dated 28 May 2021.

The board (the “**Board**”) of directors (the “**Directors**”) of the Company is pleased to announce that, on 4 November 2021 (New York time), Legend Biotech Corporation (“**Legend Biotech**”), a non-wholly owned subsidiary of the Company, announced that 12 company-sponsored studies were accepted for presentation at the 63rd American Society of Hematology (ASH) Annual Meeting and Exposition including two oral presentations and 10 poster presentations from 11 December 2021 to 14 December 2021 (New York time).

Presentation highlights include updates from the CARTITUDE clinical development program for the investigational B-cell maturation antigen (BCMA) directed chimeric antigen receptor T cell (CAR-T) therapy, ciltacabtagene autoleucel (cilta-cel), for the treatment of patients with relapsed or refractory multiple myeloma (RRMM). Presentations will detail longer-term follow-up data and new sub-group analysis results from the Phase 1b/2 CARTITUDE-1 study as well as adjusted indirect comparison of CARTITUDE-1 patient outcomes relative to standard-of-care therapies in real-world clinical practice from the LocoMMotion study. First data release from Cohort B and longer-term follow-up data from Cohort A of the CARTITUDE-2 study in earlier lines of treatments will be presented.

Additionally, Legend Biotech will share the first preclinical in vivo data on its novel tri-specific single-domain antibody (VHH) CAR-T (LCAR-AIO). LCAR-AIO targets three antigens-CD19, CD20 and CD22-with the potential for development as a treatment for patients with relapsed B cell lymphoma and prior CD19 CAR-T therapies.

A select list of abstracts from the meeting can be found below.

Abstract No.	Title	Information
Abstract #549 Oral	Updated Results From CARTITUDE-1: Phase 1b/2 Study of Ciltacabtagene Autoleucel, a B-cell Maturation Antigen — Directed Chimeric Antigen Receptor T Cell Therapy, in Patients with Relapsed/Refractory Multiple Myeloma	Session Title: 704. Cellular Immunotherapies: Cellular Therapies for Myeloma Date/Time: Sunday, December 12, 2021 4:30 PM–6:00 PM EST Presentation time: 5:00 PM EST Room: Georgia World Congress Center, Hall C2–C3
Abstract #550 Oral	Ciltacabtagene Autoleucel for Triple-Class Exposed Multiple Myeloma: Adjusted Comparisons of CARTITUDE-1 Patient Outcomes Versus Therapies from Real-World Clinical Practice from the LocoMMotion Prospective Study	Session Title: 704. Cellular Immunotherapies: Cellular Therapies for Myeloma Date/Time: Sunday, December 12, 2021 4:30 PM–6:00 PM EST Presentation time: 5:15 PM EST Location: Georgia World Congress Center, Hall C2–C3
Abstract #3938 Poster	Efficacy and Safety of Ciltacabtagene Autoleucel in Patients with Relapsed/Refractory Multiple Myeloma: CARTITUDE-1 Subgroup Analysis	Session Title: 731. Autologous Transplantation: Clinical and Epidemiological: Poster III Date/Time: Monday, December 13, 2021 6:00 PM–8:00 PM EST Location: Georgia World Congress Center, Hall B5
Abstract #2812 Poster	Anakinra Targeting Cytokine Release Syndrome Associated with Chimeric Antigen Receptor T-cell Therapies	Session Title: 704. Cellular Immunotherapies: Clinical: Poster II Date/Time: Sunday, December 12, 2021 6:00 PM–8:00 PM EST Location: Georgia World Congress Center, Hall B5

Abstract No.	Title	Information
Abstract #3866 Poster	Efficacy and Safety of Ciltacabtagene Autoleucel (Cilta-cel), a B-cell Maturation Antigen — Directed Chimeric Antigen Receptor T-cell Therapy, in Lenalidomide-Refractory Patients with Progressive Multiple Myeloma After 1–3 Prior Lines of Therapy: Updated Results From CARTITUDE-2	Session Title: 704. Cellular Immunotherapies: Clinical: Poster III Date/Time: Monday, December 13, 2021 6:00 PM–8:00 PM EST Location: Georgia World Congress Center, Hall B5
Abstract #2910 Poster	CARTITUDE-2: Efficacy and Safety of Ciltacabtagene Autoleucel (Cilta-cel), a B-cell Maturation Antigen (BCMA) — Directed Chimeric Antigen Receptor T Cell (CAR T) Therapy, in Patients with Multiple Myeloma and Early Relapse After Initial Therapy	Session Title: 731. Autologous Transplantation: Clinical and Epidemiological: Poster II Date/Time: Sunday, December 12, 2021 6:00 PM–8:00 PM EST Location: Georgia World Congress Center, Hall B5
Abstract #1835 Poster	Bortezomib, Lenalidomide, and Dexamethasone (VRd) Followed by Ciltacabtagene Autoleucel vs VRd Followed by Lenalidomide and Dexamethasone (Rd) Maintenance in Patients with Newly Diagnosed Multiple Myeloma Not Intended for Transplant: A Randomized, Phase 3 Study (CARTITUDE-5)	Session Title: 731. Autologous Transplantation: Clinical and Epidemiological: Poster I Date/Time: Saturday, December 11, 2021 5:30 PM–7:30 PM EST Location: Georgia World Congress Center, Hall B5
Abstract #3057 Poster	LocoMMotion: A Prospective, Non-interventional, Multinational Study of Real-life Current Standards of Care in Patients with Relapsed/Refractory Multiple Myeloma Who Received ≥ 3 Prior Lines of Therapy	Session Title: 905. Outcomes Research — Lymphoid Malignancies: Poster II Date/Time: Sunday, December 12, 2021 6:00 PM–8:00 PM EST Location: Georgia World Congress Center, Hall B5

Abstract No.	Title	Information
Abstract #1676 Poster	Meta-analysis of Ciltacabtagene Autoleucel versus Physician's Choice in the Treatment of Patients with Relapsed or Refractory Multiple Myeloma	Session Title: 653. Myeloma and Plasma Cell Dyscrasias: Clinical-Pro prospective Therapeutic Trials: Poster I Date/Time: Saturday, December 11, 2021 5:30 PM–7:30 PM Location: Georgia World Congress Center, Hall B5
Abstract #4075 Poster	Real-World Outcomes for Standard-Of-Care Treatments in Patients with Relapsed/Refractory Multiple Myeloma	Session Title: 905. Outcomes Research — Lymphoid Malignancies: Poster III Date/Time: Monday, December 13, 2021 6:00 PM–8:00 PM EST Location: Georgia World Congress Center, Hall B5
Abstract #1932 Poster	Considerations for optimal administration of Chimeric Antigen Receptor (CAR) T-Cell therapy programs: a multi-stakeholder qualitative analysis	Session Title: 902. Health Services Research — Lymphoid Malignancies: Poster I Date/Time: Saturday, December 11, 2021 5:30 PM–7:30 PM Location: Georgia World Congress Center, Hall B5
Abstract #1700 Poster	Tri-specific CD19xCD20xCD22 VHH CAR-T cells (LCAR-AIO) eradicate antigen-heterogeneous B cell tumors, enhance expansion, and prolong persistence in preclinical <i>in vivo</i> models	Session Title: 703. Cellular Immunotherapies: Basic and Translational: Poster I Date: Saturday, December 11, 2021 5:30–7:30 PM Location: Georgia World Congress Center, Hall B5

About CARTITUDE-1

CARTITUDE-1 (NCT03548207) 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 previously received a proteasome inhibitor (PI), an immunomodulatory agent (IMiD) and an anti-CD38 antibody, and who had disease progression on or after the last regimen.¹ The primary objective of the Phase 1b portion of the study was to characterize the safety and confirm the recommended Phase 2 dose of cilta-cel, informed by the first-in-human study with LCAR-B38M CAR-T cells (LEGEND-2). The Phase 2 portion further evaluated the efficacy of cilta-cel with overall response rate as the primary endpoint. Of the 97 patients enrolled in the trial, 99 percent were refractory to the last line of treatment and 88 percent were triple-class refractory, meaning their cancer did not respond, or no longer responds, to an IMiD, a PI and an anti-CD38 antibody.

About CARTITUDE-2

CARTITUDE-2 (NCT04133636) is an ongoing Phase 2 multicohort study evaluating the safety and efficacy of cilta-cel in various clinical settings. Cohort A included patients who had progressive multiple myeloma after 1–3 prior lines of therapy, including PI and IMiD, were lenalidomide refractory, and had no prior exposure to BCMA-targeting agents. Cohort B included patients with early relapse after initial therapy that included a PI and IMiD. The primary objective was percentage of patients with negative minimal residual disease (MRD).

About CARTITUDE-5

CARTITUDE-5 (NCT04923893) is a Phase 3 open-label study of bortezomib, lenalidomide, and dexamethasone (VRd) followed by cilta-cel vs. VRd followed by Rd maintenance, in patients with newly diagnosed MM for whom autologous stem cell transplant (ASCT) is not planned as initial therapy.

About LocoMMotion

LocoMMotion (NCT04035226) is a prospective non-interventional study evaluating the safety and efficacy of real-life standard-of-care treatments under routine clinical practice over a 24-month period in patients with RRMM. This study aims to understand the effectiveness of current standards of care in heavily pretreated patients with RRMM (reflecting real-world practice in the patient population progressing after PIs, IMiDs and anti-CD38 antibodies).

About Cilta-cel

Cilta-cel is an investigational chimeric antigen receptor T cell (CAR-T) therapy, formerly identified as JNJ-4528 in the U.S. 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, Inc. entered into an exclusive worldwide license and collaboration agreement with Janssen Biotech, Inc. (Janssen) to develop and commercialize cilta-cel. In addition to a Breakthrough Therapy Designation (BTD) granted in the U.S. in December 2019, cilta-cel received a Priority Medicines (PRiME) 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 U.S. 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 U.S. FDA and a Marketing Authorization Application was submitted to the European Medicines Agency.

For details in relation to Multiple Myeloma, please refer to the voluntary announcement of the Company dated 28 May 2021.

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 preclinical data relating to LCAR-AIO, and the potential benefits of its 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 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 2 April 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 announcement as anticipated, believed, estimated or expected. 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, 4 November 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