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)

OVERSEAS REGULATORY ANNOUNCEMENT
LEGEND BIOTECH ANNOUNCES UPDATE ON U.S. FDA AND EMA APPLICATIONS FOR EXPANDED USE OF CARVYKTI® AND U.S. FDA LABEL UPDATE FOR CAR-T CELL IMMUNOTHERAPIES

This announcement is made by the board of directors (the "**Board**") of Genscript Biotech Corporation (the "**Company**") pursuant to Rule 13.10B of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited.

Legend Biotech Corporation, 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, has filed a Form 6-K with the United States Securities and Exchange Commission (the "**SEC**") and announced (i) the update on the applications to The U.S. Food and Drug Administration (the "**U.S. FDA**") and The European Medicines Agency Committee (the "**EMA**") for expanded use of CARVYKTI® (ciltacabtagene autoleucel) in earlier lines of treatment for relapsed/refractory multiple myeloma, and (ii) the approval of a label update for CAR-T Cell immunotherapies, including CARVYKTY® by the U.S. FDA.

For details, please refer to the attached Form 6-K. The attachment is the full Form 6-K as published on the SEC's website available at https://www.sec.gov/Archives/edgar/data/1801198/000115752324000092/0001157523-24-000092-index.html.

This announcement has been issued in the English language with a separate Chinese language translation. If there is any inconsistency or ambiguity between the English version and the Chinese version, the English version shall prevail.

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, 23 January 2024

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*

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

Report of Foreign Private Issuer
Pursuant to Rule 13a-16 or 15d-16
of the Securities Exchange Act of 1934

Date of Report: January 23, 2024

Commission File Number: 001-39307

Legend Biotech Corporation
(Exact Name of Registrant as Specified in its Charter)

2101 Cottontail Lane
Somerset, New Jersey 08873
(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

Legend Biotech Provides Update on U.S. FDA and EMA Applications for Expanded Use of CARVYKTI® (ciltacabtagene autoleucel) in Earlier Lines of Treatment for Relapsed/Refractory Multiple Myeloma; FDA Label Update for CAR-T Cell Immunotherapies

On January 23, 2024, Legend Biotech announced that applications seeking to expand the use of CARVYKTI® in earlier lines of treatment for relapsed/refractory multiple myeloma supported by results from the Phase 3 CARTITUDE-4 study have been referred to health authority advisory committees, specifically:

- The U.S. Food and Drug Administration's (FDA) Oncologic Drugs Advisory Committee (ODAC) intends to meet to review data supporting the supplemental Biologics License Application for CARVYKTI® (ciltacabtagene autoleucel; cilta-cel) for the treatment of adult patients with relapsed and lenalidomide-refractory multiple myeloma who have received at least one prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent. The date of the ODAC meeting will be announced in the Federal Register.

- The European Medicines Agency Committee for Advanced Therapies (CAT) will convene a Scientific Advisory Group Oncology (SAG-O) meeting to review data supporting the submission of a Type II variation application seeking expanded use of CARVYKTI® in the treatment of patients with relapsed and lenalidomide-refractory multiple myeloma who received one to three prior lines of therapy. The date of the SAG-O meeting has not yet been announced by the CAT.

Separately, U.S. FDA Communicates Labeling Updates for Approved CAR-T Cell Immunotherapies, Including CARVYKTI®

On November 28, 2023, the U.S. FDA announced that it was investigating a serious safety signal of T-cell malignancies identified in patients who received treatment with BCMA-directed or CD19-directed autologous CAR-T cell immunotherapies. The FDA considered this information to be 'new safety information' and that it is applicable to all currently approved BCMA-directed and CD19-directed genetically modified autologous CAR-T cell immunotherapies, including CARVYKTI®.

On January 19, 2024, the FDA announced that it has determined that new safety information should be included in the labeling of all BCMA- and CD19-directed genetically modified autologous CAR-T cell immunotherapies, including CARVYKTI®.

This report on Form 6-K is hereby incorporated by reference in the registration statements of Legend Biotech on Form F-3 (Nos. 333-272222, 333-257609 and 333-257625) and Form S-8 (No. 333-239478).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

LEGEND BIOTECH CORPORATION

Date: January 23, 2024

By: /s/ Ying Huang
Name: Ying Huang, Ph.D.
Title: Chief Executive Officer