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 U.S. LABEL UPDATE FOR CARVYKTI

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 ("**Legend Biotech**"), 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 (the "**U.S.**"), has filed a Form 6-K on 21 December 2023 (New York Time) with the U.S. Securities and Exchange Commission (the "**SEC**") in relation to the approval of a label update for CARVYKTI® to include additional efficacy and safety information from longer follow-up (median duration of 28 months) of the CARTITUDE-1 study by the U.S. Food and Drug Administration.

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/1801198/000115752323001857/0001157523-23-001857-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, 22 December 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*

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: December 21, 2023

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 Announces U.S. FDA Label Update for CARVYKTI® (ciltacabtagene autoleucel; cilta-cel)

On December 21, 2023, the United States Food and Drug Administration (FDA) approved a label update for CARVYKTI® to include additional efficacy and safety information from longer-term follow-up (median duration of 28 months) of the CARTITUDE-1 study.

In this label update, the following sentence is added to the Boxed Warning of the U.S. Prescribing Information: “Secondary hematological malignancies, including myelodysplastic syndrome and acute myeloid leukemia, have occurred following treatment with CARVYKTI.”

This update to the Boxed Warning follows the observation that myeloid neoplasms (myelodysplastic syndrome [MDS], acute myeloid leukemia [AML] or MDS followed by AML) occurred in 10% (10/97) of patients following treatment with CARVYKTI in the CARTITUDE-1 study. The median time to onset of myeloid neoplasms was 485 days (range: 162 to 1040 days) after treatment with CARVYKTI. Nine of these 10 patients died following the development of myeloid neoplasms. Four of the 10 cases of myeloid neoplasm occurred after initiation of subsequent antimyeloma therapy. Cases of myelodysplastic syndrome and acute myeloid leukemia have also been reported in the post marketing setting. These 10 patients were heavily pre-treated with a median of 7.5 prior therapies (range: 4 to 18). Some of these patients had genetic mutations present prior to receipt of CARVYKTI. A potential underlying mechanism between CARVYKTI and the development of myeloid neoplasms has not been established.

To date, more than 2,000 patients have been treated with cilta-cel in clinical and commercial settings.

This report on Form 6-K shall be deemed to be 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), to the extent not superseded by documents or reports subsequently filed.

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: December 21, 2023

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