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