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