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: May 26, 2021

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): ☐

U.S. Food and Drug Administration Grants BCMA CAR-T Cilta-cel Priority Review for the Treatment for Relapsed/Refractory Multiple Myeloma

On May 26, 2021, Legend Biotech Corporation (the "Company") issued a press release, which is attached to this Form 6-K as Exhibit 99.1, announcing that the U.S. Food and Drug Administration (FDA) has accepted for priority review the Biologics License Application (BLA) submitted by Janssen Biotech, Inc. (Janssen) for ciltacabtagene autoleucel (cilta-cel), an investigational B-cell maturation antigen (BCMA)-directed chimeric antigen receptor T cell (CAR-T) therapy.

EXHIBIT INDEX

Exhibit	Title
99.1	Press Release, dated May 26, 2021.

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
(Registrant)

May 26, 2021

By: /s/ Ying Huang
Ying Huang, Ph.D.
Chief Executive Officer and Chief Financial Officer

U.S. Food and Drug Administration Grants BCMA CAR-T Cilta-cel Priority Review for the Treatment for Relapsed/Refractory Multiple Myeloma

SOMERSET, N.J.— (BUSINESS WIRE)— May 26, 2021 —Legend Biotech Corporation (NASDAQ: LEGN) (Legend Biotech), a global clinical-stage biopharmaceutical company engaged in the discovery and development of novel cell therapies for oncology and other indications, has announced that the U.S. Food and Drug Administration (FDA) has accepted for priority review the Biologics License Application (BLA) submitted by Janssen Biotech, Inc. (Janssen) for ciltacabtagene autoleucel (cilta-cel), an investigational B-cell maturation antigen (BCMA)-directed chimeric antigen receptor T cell (CAR-T) therapy. The Prescription Drug User Fee Act (PDUFA) target action date has been set for November 29, 2021.

Priority review is usually granted to investigational therapies which, if approved, may offer significant improvements in the treatment, prevention or diagnosis of a serious condition. [1] Cilta-cel previously received Breakthrough Therapy Designation in December 2019, which is intended to expedite the development and review time for a potential new medicine. [2]

“Cilta-cel has shown great promise in the treatment of patients with heavily pretreated multiple myeloma according to study findings reported to date. Today’s priority review designation marks another significant milestone for this cell therapy,” said Ying Huang, PhD, CEO and CFO of Legend Biotech. “We look forward to our continued collaborative efforts with Janssen and in working with the FDA to bring this transformative therapy to patients who are in need of new treatment options.”

The regulatory submission for cilta-cel is based on results from the pivotal Phase 1b/2 CARTITUDE-1 study which evaluated the efficacy and safety of cilta-cel in the treatment of patients with relapsed and/or refractory multiple myeloma. Updated longer term follow up data will be featured at the upcoming American Society of Clinical Oncology (ASCO) Annual Meeting (Abstract #8005) and European Hematology Association’s (EHA) Virtual Congress (Abstract #EP964) next month.

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 and/or refractory with multiple myeloma who have received at least 3 prior lines of therapy or are double refractory to a proteasome inhibitor (PI) and immunomodulatory drug (IMiD), received a PI, an IMiD, and anti-CD38 antibody and documented disease progression within 12 months of starting the most recent therapy.[3] 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.

About Multiple Myeloma

Multiple myeloma is an incurable blood cancer that starts in the bone marrow and is characterized by an excessive proliferation of plasma cells.[4] Although treatment may result in remission, unfortunately, patients will most likely relapse.[5] Relapsed myeloma is when the disease has returned after a period of initial, partial or complete remission and does not meet the definition of being refractory.[6] Refractory multiple myeloma is when a patient's disease is non-responsive or progresses within 60 days of their last therapy.[7,8] While some patients with multiple myeloma have no symptoms at all, most patients are diagnosed due to symptoms that can include bone problems, low blood counts, calcium elevation, kidney problems or infections.[9] Patients who relapse after treatment with standard therapies, including protease inhibitors and immunomodulatory agents, have poor prognoses and few treatment options available.[10]

About Cilta-cel

Cilta-cel is an investigational chimeric antigen receptor T cell (CAR-T) therapy 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. to develop and commercialize cilta-cel. In addition to a Breakthrough Therapy Designation 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. Orphan Drug Designations were also 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 has been accepted by the U.S. FDA and a Marketing Authorisation Application has been accepted by the European Medicines Agency.

About Legend Biotech

Legend Biotech is a global clinical-stage biopharmaceutical company engaged in the discovery and development of novel cell therapies for oncology and other indications. Our team of over 900 employees across the United States, China and Europe, along with our differentiated technology, global development, and manufacturing strategies and expertise, provide us with the strong potential to discover, develop, and manufacture best-in-class cell therapies for patients in need.

We are engaged in a strategic collaboration to develop and commercialize our lead product candidate, cilta-cel, an investigational BCMA-targeted CAR-T cell therapy for patients living with multiple myeloma. This candidate is currently being studied in registrational clinical trials.

To learn more about Legend Biotech, visit us on LinkedIn, or on Twitter @LegendBiotech or at www.legendbiotech.com.

Cautionary Note Regarding Forward-Looking Statements

Statements in this press release about future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, may 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 the timing and outcome of regulatory reviews relating to cilta-cel, including the BLA accepted by the U.S. FDA and the MAA accepted by the EMA, and the potential for cilta-cel as a safe and effective treatment. 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, including the factors discussed in the “Risk Factors” section of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on April 2, 2021. Any forward-looking statements contained in this press release speak only as of the date hereof, and Legend Biotech specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise. Readers should not rely upon the information on this page as current or accurate after its publication date.

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