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: April 30, 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): ☐

Legend Biotech Announcement Regarding Submission of European Marketing Authorisation

On April 30, 2021, Legend Biotech Corporation (“Legend”) issued a press release announcing the submission of a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) seeking approval of ciltacabtagene autoleucel (cilta-cel) for the treatment of patients with relapsed and/or refractory multiple myeloma. The press release is attached to this Form 6-K as Exhibit 99.1.

EXHIBIT INDEX

Exhibit	Title
99.1	Press Release, dated April 30, 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)

April 30, 2021

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

Exhibit 99.1

Legend Biotech Announces Submission of European Marketing Authorisation Application for BCMA CAR-T Therapy Ciltacabtagene Autoleucel (cilta-cel) for the Treatment of Relapsed and/or Refractory Multiple Myeloma

Submission follows accelerated assessment granted by the Committee for Medicinal Products for Human Use of the European Medicines Agency of the application based on positive Phase 1b/2 CARTITUDE-1 study data

SOMERSET, N.J., April 30, 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, announced today the submission of a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) seeking approval of ciltacabtagene autoleucel (cilta-cel) for the treatment of patients with relapsed and/or refractory multiple myeloma.

Cilta-cel is an investigational B-cell maturation antigen (BCMA)-directed chimeric antigen receptor T cell (CAR-T) therapy being investigated as a treatment for multiple myeloma. The MAA is based on positive results from a Phase 1b/2 CARTITUDE-1 study, which were presented at the American Society of Hematology (ASH) 2020 Annual Meeting.[1] The submission was filed to the EMA by Janssen-Cilag International N.V., an affiliate of Janssen Biotech, Inc., Legend's collaboration partner for cilta-cel.

"Today's submission is a testimony to the promising results we have seen from the CARTITUDE-1 study showing the efficacy and safety of cilta-cel for treating patients with multiple myeloma who are heavily pretreated and in need of treatment options," said Ying Huang, PhD, CEO and CFO of Legend Biotech. "We are proud of our collaboration with Janssen and look forward to bringing this personalized treatment to patients in the EU following the accelerated assessment."

The EMA's Committee for Medicinal Products for Human Use (CHMP) granted accelerated assessment for this MAA. An accelerated assessment is granted when the CHMP determines that a medicinal product is of major public health interest and therapeutic innovation and can significantly reduce the review timelines to evaluate an MAA.[2] Cilta-cel previously received a PRIority MEdicines (PRIME) designation from the EMA. A Biologics License Application (BLA) seeking approval of cilta-cel based on the CARTITUDE-1 study is currently under review with the United States Food and Drug Administration.

About CARTITUDE-1

CARTITUDE-1 (NCT03548207) is an ongoing Phase 1b/2, open-label, multicenter study evaluating the safety and efficacy of cilta-cel in adults with relapsed and/or refractory multiple myeloma, 99 percent of whom were refractory to the last line of treatment; 88 percent of whom were triple-class refractory (to at least 1 immunomodulatory drug [IMiD], proteasome inhibitor [PI] and 1 anti-CD38 antibody).[3] The primary objective of the Phase 1b portion of the study was to characterize the safety and confirm the 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 Ciltacabtagene autoleucel (cilta-cel)

Cilta-cel is an investigational chimeric antigen receptor T cell (CAR-T) therapy, formerly identified as JNJ-4528 outside of China and LCAR-B38M CAR-T cells in China, that is being studied in a comprehensive clinical development program for the treatment of patients with relapsed and/or refractory multiple myeloma and in earlier lines of treatment. Cilta-cel is a differentiated CAR-T therapy 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 (BTD) granted in the U.S. in December 2019, cilta-cel received a BTD in China in August 2020. In addition, Orphan Drug Designation was granted for cilta-cel by the U.S. FDA in February 2019, and by the European Commission in February 2020.

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 until later stages of the disease, 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.[10]

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 800 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 cutting edge cell therapies for patients in need.

Legend is engaged in a strategic collaboration to develop and commercialize the lead product candidate, ciltacabtagene autoleucel, 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.

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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 Legend Biotech's clinical efforts, its partnership with Janssen, and the regulatory submissions and reviews relating to cilta-cel, including the EMA's accelerated assessment of the MAA for cilta-cel. 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. Legend Biotech's expectations could be affected by, among other things, uncertainties involved in the development of new pharmaceutical products; unexpected clinical trial results, including as a result of additional analysis of existing clinical data or unexpected new clinical data; unexpected regulatory actions or delays, including requests for additional safety and/or efficacy data or analysis of data, or government regulation generally; and unexpected delays as a result of actions undertaken, or failures to act, by our third party partners; as well as the other factors discussed in the "Risk Factors" section of the Company's Annual Report filed with the Securities and Exchange Commission on April 2, 2021. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described in this press release as anticipated, believed, estimated or expected. Legend Biotech specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

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1 Madduri, D et al. CARTITUDE-1: Phase 1b/2 Study of Ciltacabtagene Autoleucel, a B-Cell Maturation Antigen–Directed Chimeric Antigen Receptor T Cell Therapy, in Relapsed/Refractory Multiple Myeloma. Oral Presentation. Presented at 2020 American Society of Hematology Annual Meeting.

2 EMA. Accelerated Assessment. Available at: https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/accelerated-assessment. Last accessed April 2021.

3 ClinicalTrials.gov. A Study of JNJ-68284528, a Chimeric Antigen Receptor T Cell (CAR-T) Therapy Directed Against B-Cell Maturation Antigen (BCMA) in Participants With Relapsed or Refractory Multiple Myeloma (CARTITUDE-1). Available at: https://clinicaltrials.gov/ct2/show/NCT03548207. Last accessed April 2021.

4 American Society of Clinical Oncology. Multiple myeloma: introduction. Available at: https://www.cancer.net/cancer-types/multiple-myeloma/introduction. Accessed April 2021.

5 Abdi J, Chen G, Chang H, et al. Drug resistance in multiple myeloma: latest findings and new concepts on molecular mechanisms. Oncotarget. 2013;4:2186–2207.

6 National Cancer Institute. NCI dictionary of cancer terms: relapsed. Available at: https://www.cancer.gov/publications/dictionaries/cancer-terms?CdrID=45866. Accessed April 2021.

7 National Cancer Institute. NCI dictionary of cancer terms: refractory. Available at: https://www.cancer.gov/publications/dictionaries/cancer-terms?CdrID=350245. Accessed April 2021.

8 Richardson P, Mitsiades C, Schlossman R, et al. The treatment of relapsed and refractory multiple myeloma. Hematology Am Soc Hematol Educ Program. 2007:317-23.

9 American Cancer Society. Multiple myeloma: early detection, diagnosis and staging. Available at: https://www.cancer.org/content/dam/CRC/PDF/Public/8740.00.pdf. Accessed April 2021

10 Kumar SK, Lee JH, Lahuerta JJ, et al. Risk of progression and survival in multiple myeloma relapsing after therapy with IMiDs and bortezomib: a multicenter international myeloma working group study. Leukemia. 2012;26:149-57.