Legend Biotech Announces Extension of PDUFA Date for Cilta-Cel

SOMERSET, N.J.— (BUSINESS WIRE)—November 1, 2021—Legend Biotech Corporation (NASDAQ: LEGN) (Legend Biotech), a global, clinical-stage biotechnology company developing and manufacturing novel therapies, today announced that the U.S. Food and Drug Administration has extended the Prescription Drug User Fee Act (PDUFA) target date for ciltacabtagene autoleucel (cilta-cel) to February 28, 2022. Cilta-cel is a BCMA-directed chimeric antigen receptor T cell (CAR-T) therapy being investigated for the treatment of adults with relapsed and/or refractory multiple myeloma. The Biologics License Application (BLA) was submitted by Legend Biotech's collaboration partner Janssen Biotech, Inc. (Janssen).

"We are working closely with Janssen and the FDA to facilitate an efficient and thorough review of the BLA for cilta-cel," said Ying Huang, Ph.D., Chief Executive Officer and Chief Financial Officer at Legend Biotech. "We remain confident that cilta-cel has shown great promise in patients with relapsed and refractory multiple myeloma, and we are focused on making this therapy available to them in the US as soon as possible."

The FDA notified Janssen on October 28, 2021 of the extension of the PDUFA date to allow sufficient time to review information recently submitted pertaining to an updated analytical method following an FDA information request. Legend and Janssen met with the FDA on November 1. No additional clinical data have been requested.

About Cilta-cel

Cilta-cel is an investigational chimeric antigen receptor T cell (CAR-T) therapy, formerly identified as JNJ-4528 in the U.S. and Europe 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 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. (Janssen) to develop and commercialize cilta-cel. In December 2020, Legend announced initiation of rolling submission of Biologics License Application to the FDA seeking approval of cilta-cel for the treatment of relapsed and/or refractory multiple Myeloma, which was accepted under Priority Review in May 2021. Cilta-cel was previously granted Breakthrough Therapy Designation (BTD) granted in the U.S. in December 2019, and Orphan Drug Designation in February 2019.

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.[1] Although treatment may result in remission, unfortunately, patients will most likely relapse.[2] 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.[3] Refractory multiple myeloma is when a patient's disease is non-responsive or progresses within 60 days of their last therapy.[4,5] 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.[6] Patients who relapse after treatment with standard therapies, including protease inhibitors and immunomodulatory agents, have poor prognoses and few treatment options available.[7]

About Legend Biotech
Legend Biotech is a global, clinical-stage biotechnology company dedicated to treating, and one day curing, life-threatening diseases. Headquartered in Somerset, New Jersey, we are developing advanced cell therapies across a diverse array of technology platforms, including autologous and allogenic chimeric antigen receptor T-cell, T-cell receptor (TCR-T), and natural killer (NK) cell-based immunotherapy. From our three R&D sites around the world, we apply these innovative technologies to pursue the discovery of safe, efficacious and cutting-edge therapeutics for patients worldwide.

We are currently engaged in a strategic collaboration to develop and commercialize our lead product candidate, ciltacabtagene autoleucel, an investigational BCMA-targeted CAR-T cell therapy for patients living with multiple myeloma. Applications seeking approval of cilta-cel for the treatment of patients with RRMM are currently under regulatory review by several health authorities around the world, including the U.S. Food and Drug Administration and the European Medicines Agency.

Learn more at www.legendbiotech.com and follow us on Twitter and LinkedIn.

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, 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 being reviewed by the FDA. 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; as well as the other factors discussed in the "Risk Factors" section of Legend Biotech's Annual Report on Form 20-F 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 presentation 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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