Legend Biotech Announces Initiation of Rolling Submission of Biologics License Application to U.S. FDA Seeking Approval of BCMA CAR-T Therapy Cilta-cel for the Treatment of Relapsed and/or Refractory Multiple Myeloma

Legend Biotech also achieves fifth milestone payment under its collaboration agreement with Janssen in clinical development of cilta-cel

SOMERSET, N.J., December 21, 2020 – 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 initiation of a rolling submission of a Biologics License Application (BLA) to the Food and Drug Administration (FDA) for ciltacabtagene autoleucel (cilta-cel), an investigational B-cell maturation antigen (BCMA)-directed chimeric antigen receptor (CAR) T cell therapy, for the treatment of adults with relapsed and/or refractory multiple myeloma.

The submission 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.[1] The latest data from the study were recently presented (Abstract #177) at the 62nd American Society of Hematology Annual Meeting.

"Initiation of the BLA submission is an important milestone in advancing this therapy for patients with multiple myeloma who are heavily pretreated and in need of treatment options," said Ying Huang, PhD, CEO and CFO of Legend Biotech. "Together with our collaborator Janssen, we look forward to working with the FDA to fulfill this unmet medical need with the goal of making this breakthrough treatment available to patients and healthcare providers in the future."

Based on this submission, Legend Biotech also announced, according to the terms and conditions of an agreement with Janssen Biotech, Inc. (Janssen), achievement of a $75M milestone payment relating to the clinical development of cilta-cel. Janssen, Legend Biotech's collaboration partner, initiated the submission of the BLA for cilta-cel. The FDA previously granted Breakthrough Therapy Designation (BTD) for cilta-cel and has agreed to a rolling review of the BLA in which completed portions of the application will be submitted and reviewed on an ongoing basis.

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], 1 proteasome inhibitor [PI] and 1 anti-CD38 antibody).[1]

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.[1]

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. 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 (BTD) 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. 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.[2] Although treatment may result in remission, unfortunately, patients will most likely relapse.[3] 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.[4] Refractory multiple myeloma is when a patient's disease is non-responsive or progresses within 60 days of their last therapy.[5,6] 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.[7] Patients who relapse after treatment with standard therapies, including protease inhibitors and immunomodulatory agents, have poor prognoses and few treatment options.[8]

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.

We are 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. 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 submission and review of the BLA 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, including the factors discussed in the "Risk Factors"

section of the prospectus filed with the Securities and Exchange Commission on June 8, 2020. 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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[1] CARTITUDE-1 (NCT03548207). Available: https://clinicaltrials.gov/ct2/show/NCT03548207. Accessed December 2020.
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