Legend Biotech Announces ASH 2020 Data Presentations for Ciltacabtagene Autoleucel (cilta-cel), an Investigational BCMA CAR-T Cell Therapy in Development for Patients with Relapsed and/or Refractory Multiple Myeloma (RRMM)

November 5, 2020

- New Results from Phase 1b/2 CARTITUDE-1 Study of BCMA-directed CAR-T Cell Therapy Cilta-cel in Treatment of Patients with RRMM to be Featured in Oral Presentation

SOMERSET, N.J.--(BUSINESS WIRE)--Nov. 5, 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, today announced that new and updated data from CARTITUDE-1 and LEGEND-2 studies, respectively, will be presented at the 62nd American Society of Hematology (ASH) Annual Meeting and Exposition taking place virtually December 5-8, 2020.

CARTITUDE-1 data for oral presentation will highlight Phase 1b/2 efficacy and safety results for the B-cell maturation antigen (BCMA)-targeted chimeric antigen receptor T cell (CAR-T) therapy ciltacabtagene autoleucel (cilta-cel). Additional poster presentations for cilta-cel data will include detailed analyses of cytokine release syndrome and health-related quality of life outcomes from CARTITUDE-1. LEGEND-2 data in patients with relapsed or refractory multiple myeloma and extramedullary disease will also be presented as a poster.

"We look forward to sharing new data from the CARTITUDE-1 study in the US and the LEGEND-2 study in China," said Ying Huang, PhD, interim-CEO and CFO of Legend Biotech. "With our successful clinical efforts and the Company's collaboration with Janssen, we are uniquely positioned to deliver a novel therapy to patients with multiple myeloma."

On Saturday, December 5th, during the Myeloma session entitled: *Myeloma/Amyloidosis: Therapy, excluding Transplantation: Novel Therapies Targeting B Cell Maturation Antigen in Relapsed/Refractory Multiple Myeloma,* the Phase 1b/2 clinical efficacy and safety data for cilta-cel from the CARTITUDE-1 study will be presented.

Following are details of the five abstracts that have been accepted for presentation at the 62nd ASH Annual Meeting & Exposition. For additional information visit: https://www.hematology.org/meetings/annual-meeting/schedule-and-program.

Abstract No.	Title	Date/Time
Oral Presentation		
Abstract #177	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	Saturday, Dec. 5 12:00 p.m. PT
Poster Presentations		
Abstract #1412	Patient Expectations and Perceptions of Treatment in CARTITUDE-1: Phase 1b/2 Study of Ciltacabtagene Autoleucel in Relapsed/Refractory Multiple Myeloma	Saturday, Dec. 5 7:00 a.m. - 3:30 p.m. PT
Abstract #2291	Health-Related Quality of Life in the CARTITUDE-1 Study of Ciltacabtagene Autoleucel for Relapsed/Refractory Multiple Myeloma	Sunday, Dec. 6 7:00 a.m. - 3:30 p.m. PT
Abstract #2304	Chimeric Antigen Receptor T Cell Therapy in the Relapsed or Refractory Multiple Myeloma with Extramedullary Disease--a Single Institution Observation in China (LEGEND-2)	Sunday, Dec. 6 7:00 a.m. - 3:30 p.m. PT
Abstract #3240	Cytokine Release Syndrome in Patients With Relapsed/Refractory Multiple Myeloma Treated With Ciltacabtagene Autoleucel in the Phase 1b/2 CARTITUDE-1 Study	Monday, Dec. 7 7:00 a.m. - 3:30 p.m. PT

About CARTITUDE-1
Cilta-cel is currently being investigated in the Phase 1b/2 CARTITUDE-1 (MMY2001, NCT03548207) registration study conducted in the US and Japan for the treatment of patients with multiple myeloma who have received at least 3 prior lines of therapy or are double refractory to a PI and IMiD®, received a PI, an IMiD, and anti-CD38 antibody and documented disease progression within 12 months of starting the most recent therapy.[1]

About LEGEND-2
LEGEND-2 (NCT03090659) is an ongoing single-arm, open-label Phase 1 study of 74 patients being conducted at four participating hospitals in China evaluating the efficacy and safety of LCAR-B38M CAR-T cells for the treatment of relapsed or refractory multiple myeloma.[2]

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.[3] Although treatment may result in remission, unfortunately, patients will most likely relapse.[4] 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.[5] Refractory multiple myeloma is when a patient's disease is non-responsive or progresses within 60 days of their last therapy.[6,7] 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.[8] Patients who relapse after treatment with standard therapies, including protease inhibitors and immunomodulatory agents, have poor prognoses and few treatment options available.[9]

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 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 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 with Janssen Biotech, Inc. 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.

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 data relating to CARTITUDE-1 and LEGEND-2 studies. 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.

References

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