



Legend Biotech Reports New and Updated Data from BCMA CAR-T Program at 2021 ASCO and EHA Meetings

May 12, 2021

- Longer term follow-up data from the pivotal CARTITUDE-1 study of cilta-cel in heavily pretreated patients with relapsed or refractory multiple myeloma
- The first presentation of data from the CARTITUDE-2 study of cilta-cel in earlier lines of multiple myeloma treatment

SOMERSET, N.J.--(BUSINESS WIRE)--May 12, 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, today announced that 15 abstracts have been accepted at the upcoming 2021 American Society of Clinical Oncology (ASCO) Annual Meeting and the European Hematology Association's (EHA) 2021 Virtual Congress, including new and updated data from the CARTITUDE clinical development program being led by Janssen Research & Development, LLC (Janssen) for the investigational B-cell maturation antigen (BCMA)-directed chimeric antigen receptor T cell (CAR-T) therapy, ciltacabtagene autoleucl (cilta-cel).

"The Legend Biotech team, together with our collaborator Janssen, look forward to sharing the updated efficacy and longer-term safety data for cilta-cel," said Ying Huang, PhD, CEO and CFO of Legend Biotech. "These exciting data and a wide range of other abstracts highlight our continued commitment and efforts to developing innovative treatments that will make a difference in the lives of those living with multiple myeloma."

Longer-term follow-up efficacy and safety results from the Phase 1b/2 CARTITUDE-1 study of cilta-cel in patients with relapsed/refractory multiple myeloma (Abstract #8005) will be featured in an oral presentation at the 2021 ASCO Meeting and as a poster presentation at EHA (Abstract #EP964). Results from this study supported recent [U.S.](#) and [European](#) regulatory filings submitted by Legend Biotech's collaborator, Janssen.

For the first time, data from Cohort A of the CARTITUDE-2 study evaluating the safety and efficacy of cilta-cel in patients with progressive multiple myeloma who have received 1-3 prior lines of therapy, will be presented, being featured as a poster presentation at ASCO (Abstract #8013) and in an oral presentation at EHA (Abstract # S190). Poster presentations at both meetings will provide additional efficacy and safety information with cilta-cel in comparison to standard of care therapies and neurological adverse event mitigation measures.

Select abstracts from both Congresses are below.

ASCO Presentations (June 4-8, 2021)

Abstract No.	Title	Date/ Time
Abstract #8005 Oral Presentation	Ciltacabtagene autoleucl, a B-cell maturation antigen (BCMA)-directed chimeric antigen receptor T-cell (CAR-T) therapy, in relapsed/refractory multiple myeloma (R/R MM): Updated results from CARTITUDE-1	Tuesday, June 8th 8:00-11:00 AM EDT
Abstract #8013 Poster Discussion	CARTITUDE-2: Efficacy and safety of ciltacabtagene autoleucl (cilta-cel), a BCMA-directed CAR T-cell therapy, in patients with progressive multiple myeloma (MM) after 1-3 prior lines of therapy	Friday, June 4th @ 9:00AM EDT
Abstract #8028 Poster Presentation	Incidence, mitigation, and management of neurologic adverse events in patients with multiple myeloma (MM) treated with ciltacabtagene autoleucl (cilta-cel) in CARTITUDE-2	Friday, June 4th @ 9:00 AM EDT
Abstract #8045 Poster Presentation	Comparison of outcomes with ciltacabtagene autoleucl (cilta-cel) in CARTITUDE-1 vs real-world standard of care (RW SOC) for patients (pts) with triple-class exposed relapsed/refractory multiple myeloma (RRMM)	Friday, June 4th @ 9:00 AM EDT
Abstract #8030 Poster Presentation	Cilta-cel vs. conventional treatment in patients with relapse/refractory multiple myeloma	Friday, June 4th @ 9:00 AM EDT
Abstract #8041 Poster Presentation	LocoMMotion: A prospective, non-interventional, multinational study of real-life current standards of care in patients with relapsed/refractory multiple myeloma (RRMM) receiving ≥3 prior lines of therapy.	Friday, June 4th @ 9:00 AM EDT

The abstracts will be released on [ASCO Meeting Library](#) on May 19th, 2021 at 5:00 PM EDT.

EHA Presentations (June 9-17, 2021)

Abstract No.	Title	Date/ Time
Abstract #S190 Oral	Efficacy and safety of the BCMA-directed CAR-T cell therapy, ciltacabtagene autoleucl, in patients with progressive multiple myeloma (MM) after 1-3 prior lines of therapy: Initial results from CARTITUDE-2	Available starting Friday, June 11th @ 9:00AM CEST

Abstract #EP964 EPoster	Updated CARTITUDE-1 results of ciltacabtagene autoleucl, a B-cell maturation antigen–directed chimeric antigen receptor T cell therapy, in relapsed/refractory multiple myeloma	Available starting Friday, June 11th @ 9:00AM CEST
Abstract #EP1003 EPoster	Incidence, mitigation, and management of neurologic adverse events in the phase 2 CARTITUDE-2 study of ciltacabtagene autoleucl in patients with multiple myeloma	Available starting Friday, June 11th @ 9:00AM CEST
Abstract #EP987 EPoster	A prospective, non-interventional, multinational study of real-life standard of care in patients with relapsed/refractory multiple myeloma receiving ≥3 prior lines of therapy: Interim data from LocoMMotion	Available starting Friday, June 11th @ 9:00AM CEST
Abstract #EP990 EPoster	Comparison of ciltacabtagene autoleucl versus conventional treatment in patients with relapsed/refractory multiple myeloma	Available starting Friday, June 11th @ 9:00AM CEST
Abstract #EP1049 EPoster	Ciltacabtagene autoleucl versus selinexor + dexamethasone in patients with relapsed/refractory multiple myeloma (RRMM) treated with ≥3 lines of prior therapy: A matching adjusted indirect comparison	Available starting Friday, June 11th @ 9:00AM CEST
Abstract #EP978 EPoster	Matching adjusted indirect comparison of ciltacabtagene autoleucl versus belantamab mafodotin in patients with relapsed/refractory multiple myeloma (RRMM) treated with ≥3 lines of prior therapy	Available starting Friday, June 11th @ 9:00AM CEST
Abstract #EP977 EPoster	Comparison of outcomes with ciltacabtagene autoleucl (cilta-cel) in CARTITUDE-1 versus standard of care in triple-class exposed multiple myeloma patients in clinical trials of daratumumab	Available starting Friday, June 11th @ 9:00AM CEST
Abstract # EP972 EPoster	Ciltacabtagene autoleucl for triple-class exposed multiple myeloma: Adjusted comparison of CARTITUDE-1 outcomes versus real world clinical practice observed in German registry	Available starting Friday, June 11th @ 9:00AM CEST

The abstracts are available on the EHA website at: <https://ehaweb.org/congress>.

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.¹ 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 CARTITUDE-2

CARTITUDE-2 ([NCT04133636](#)) is an ongoing Phase 2 multicohort study evaluating the safety and efficacy of cilta-cel in various clinical settings. Cohort A included patients who had progressive multiple myeloma after 1–3 prior lines of therapy, including PI and IMiD, were lenalidomide refractory, and had no prior exposure to BCMA-targeting agents. The primary objective was percentage of patients with negative minimal residual disease (MRD).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 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. A Biologics License Application seeking approval of cilta-cel was submitted to the U.S. FDA and a Marketing Authorization Application was submitted to 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 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 best-in-class cell therapies for patients in need.

Legend Biotech is engaged in a strategic collaboration to develop and commercialize the 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 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 Annual Report 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.

References

1. CARTITUDE-1 (NCT03548207). Available: <https://clinicaltrials.gov/ct2/show/NCT03548207>. Accessed November 2020.
2. CARTITUDE-2 (NCT04133636). Available: <https://clinicaltrials.gov/ct2/show/NCT04133636>. Accessed April 2021.
3. American Society of Clinical Oncology. Multiple myeloma: introduction. Available at: <https://www.cancer.net/cancer-types/multiple-myeloma/introduction>. Accessed November 2020.
4. 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.
5. National Cancer Institute. NCI dictionary of cancer terms: relapsed. Available at: <https://www.cancer.gov/publications/dictionaries/cancer-terms?CdrID=45866>. Accessed November 2020.
6. National Cancer Institute. NCI dictionary of cancer terms: refractory. Available at: <https://www.cancer.gov/publications/dictionaries/cancer-terms?CdrID=350245>. Accessed November 2020.
7. 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.
8. 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 November 2020.
9. 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.

View source version on businesswire.com: <https://www.businesswire.com/news/home/20210512005800/en/>

Media and Investor Relations

Jessie Yeung, Head of Corporate Finance and Investor Relations, Legend Biotech jessie.yeung@legendbiotech.com or investor@legendbiotech.com

Crystal Chen, Manager, Investor Relations and Corporate Communications, Legend Biotech crystal.chen@legendbiotech.com or media@legendbiotech.com

For Medical Affairs inquiries:

Tonia Nesheiwat, Executive Director, Medical Affairs, Legend Biotech
tonia.nesheiwat@legendbiotech.com or Medical.information@legendbiotech.com

Source: Legend Biotech