Legend Biotech Announces Submission of New Drug Application to Japanese Regulatory Authority for BCMA CAR-T Therapy Cilta-cel for the Treatment of Relapsed or Refractory Multiple Myeloma by Janssen

December 6, 2021

Submission based on data from pivotal CARTITUDE-1 trial

SOMERSET, N.J.--(BUSINESS WIRE)--Dec. 6, 2021-- Legend Biotech Corporation (NASDAQ: LEGN), a global, clinical-stage biotechnology company developing and manufacturing novel therapies, announced today the submission of a New Drug Application (NDA) to the Japanese Ministry of Health, Labour and Welfare (MHLW) for ciltacabtagene autoleucel (cilta-cel) by its collaboration partner, Janssen Pharmaceutical K.K. (Janssen). Cilta-cel is an investigational B-cell maturation antigen (BCMA)-directed chimeric antigen receptor (CAR)-T cell therapy for the treatment of adults with relapsed or refractory multiple myeloma who have received at least three prior therapies, including a proteasome inhibitor (PI), an immunomodulatory agent (IMiD), and an anti-CD38 antibody.

The submission is based on results from the Phase 1b/2 CARTITUDE-1 study conducted in the US and Japan, which evaluated the efficacy and safety of cilta-cel for patients with relapsed or refractory multiple myeloma.[1] Cilta-cel is currently under regulatory review by several health authorities around the world, including the United States and Europe.

“Today’s submission is an encouraging step in our mission to provide a potentially transformative cell therapy option to patients with multiple myeloma,” said Ying Huang, PhD, CEO and CFO of Legend Biotech. “We look forward to closely collaborating with our partner Janssen and the MHLW in order to make cilta-cel available to patients living with relapsed or refractory multiple myeloma, who have exhausted several standard-of-care treatments and are facing poor prognoses.”

About Ciltacabtagene Autoleucel
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. 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 the CARTITUDE-1 Study
CARTITUDE-1 (NCT03548207) is a Phase 1b/2, open-label, multicenter study evaluating the safety and efficacy of cilta-cel in adults with relapsed 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]

About Multiple Myeloma
Multiple myeloma, an incurable blood cancer that starts in the bone marrow and is characterized by an excessive proliferation of plasma cells.[2] In Japan, there were more than 7,000 new cases of multiple myeloma and nearly 5,000 deaths.[3] Although treatment may result in remission, most patients experience 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 by 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 Legend Biotech
Legend Biotech is a global, clinical-stage cell therapy company dedicated to treating, and one day curing, life-threatening diseases. Headquartered in Somerset, New Jersey, we are developing 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 options 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. This candidate is being studied in registrational clinical trials and has received priority review from the U.S. Food and Drug Administration for the first indication.

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 Legend Biotech’s strategies and objectives, the anticipated timing of, and ability to progress, clinical trials, the clinical data relating to the CARTITUDE Development Program and the potential benefits of our product candidates. 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 or preclinical study results, including as a result of additional analysis of existing data or unexpected new data; unexpected regulatory actions or delays, including requests for additional safety and/or efficacy data or analysis of data, or government regulation generally; unexpected delays as a result of actions undertaken, or failures to act, by our third party partners; uncertainties arising from challenges to Legend Biotech’s patent or other proprietary intellectual property protection, including the uncertainties involved in the US litigation process; competition in general; government, industry, and general public pricing and other political pressures; the duration and severity of the COVID-19 pandemic and governmental and regulatory measures implemented in response to the evolving situation; 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 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.

Source: Legend Biotech

---

[1] 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. Accessed December 2021.

[2] American Society of Clinical Oncology. Multiple myeloma: introduction. Available at: https://www.cancer.net/cancer-types/multiple-myeloma/introduction. Accessed December 2021.

[3] World Health Organization International Agency for Research on Cancer (IARC). *GLOBOCAN 2020: Japan Fact Sheet.* https://gco.iarc.fr/today/data/factsheets/populations/392-japan-fact-sheets.pdf. Accessed December 2021.

[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 December 2021.

[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/20211206005107/en/

Investor Contacts:
Joanne Choi, Senior Manager of Investor Relations and Corporate Communications, Legend Biotech joanne.choi@legendbiotech.com or investor@legendbiotech.com

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

Press Contact:
Tina Carter, Corporate Communications Lead, Legend Biotech
tina.carter@legendbiotech.com
(908) 331-5025

Source: Legend Biotech