CARVYKTI® (ciltacabtagene autoleucel) Receives Positive CHMP Opinion for the Treatment of Patients with Relapsed and Refractory Multiple Myeloma

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Ciltacabtagene autoleucel, if approved by the European Commission (EC), will be Legend Biotech's first EC-approved product

SOMERSET, N.J.--(BUSINESS WIRE)--Mar. 25, 2022--

Legend Biotech Corporation (NASDAQ: LEGN) (Legend Biotech), a global biotechnology company developing, manufacturing and commercializing novel therapies to treat life-threatening diseases, today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) recommended Janssen Pharmaceutica NV's marketing authorization of CARVYKTI ® (ciltacabtagene autoleucel; cilta-cel) for the treatment of adults with relapsed and refractory multiple myeloma who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 antibody and have demonstrated disease progression on the last therapy.

Cilta-cel is a chimeric antigen receptor T-cell (CAR-T) therapy featuring two B-cell maturation antigen (BCMA)-targeting single domain antibodies.[1] CAR-T therapy is a highly personalized technology where a person's own T-cells are engineered to target and kill cancer cells in a single infusion. [2]

Data from the ongoing pivotal CARTITUDE-1 study supported the positive CHMP opinion. Two-year follow-up results were presented at the American Society of Hematology (ASH) 2021 Annual Meeting (Abstract #549).[1]

"The positive CHMP opinion reinforces the potential of cilta-cel for patients with multiple myeloma around the world," said Ying Huang, Ph.D., Chief Executive Officer and Chief Financial Officer of Legend Biotech. "We look forward to the EMA to the potential of European Commission approval in the future and continued progress in the development of cilta-cel."

Multiple myeloma is an incurable blood cancer affecting a type of white blood cell called plasma cells, which are found in the bone marrow.[3] The majority of patients relapse after undergoing initial treatment and face poor prognoses after treatment with three major drug classes, including an immunomodulatory agent, a proteasome inhibitor and anti-CD38 monoclonal antibody.[4,5,6]

This CHMP Opinion follows the approval of cilta-cel by the U.S. Food and Drug Administration (FDA) on February 28, 2022.

About Ciltacabtagene autoleucel (cilta-cel)

Cilta-cel is a BCMA-directed, genetically modified autologous T-cell immunotherapy, which involves reprogramming a patient's own T-cells with a transgene encoding a chimeric antigen receptor (CAR) that identifies and eliminates cells that express BCMA. BCMA is primarily expressed on the surface of malignant multiple myeloma B-lineage cells, as well as late-stage B-cells and plasma cells. The cilta-cel CAR protein features two BCMA-targeting single domain antibodies designed to confer high avidity against human BCMA. Upon binding to BCMA-expressing cells, the CAR promotes T-cell activation, expansion, and elimination of target cells.

In December 2017, Legend Biotech Corporation entered into an exclusive worldwide license and collaboration agreement with Janssen Biotech, Inc. to develop and commercialize cilta-cel.

In April 2021, Legend announced the submission of a Marketing Authorisation Application to the European Medicines Agency seeking approval of cilta-cel for the treatment of patients with relapsed and/or refractory multiple myeloma. In addition to U.S. Breakthrough Therapy Designation granted in December 2019, cilta-cel received a Breakthrough Therapy Designation in China in August 2020. Cilta-cel also received Orphan Drug Designation from the U.S. FDA in February 2019, and from 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.3 In Europe, it is estimated that more than 50,900 people were diagnosed with multiple myeloma in 2020, and approximately 32,500 multiple myeloma patients died that year.[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] Although treatment may result in remission, unfortunately, patients will most likely relapse.[4] Patients who relapse after treatment with standard therapies, including protease inhibitors, immunomodulatory agents, and an anti-CD38 monoclonal antibody, have poor prognoses and few treatment options available.[5,6]

About Legend Biotech

Legend Biotech is a global 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.

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; statements relating to CARVYKTI™, including Legend Biotech's expectations for CARVYKTI™, such as Legend Biotech's manufacturing and commercialization expectations for CARVYKTI™ and the potential effect of treatment with CARVYKTI™; statements about submissions for cilta-cel to, and the progress of such submissions with, the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), the Chinese Center for Drug Evaluation of National Medical Products Administration (CDE) and other regulatory authorities; the anticipated timing of, and ability to progress, clinical trials, including patient enrollment; the submission of Investigational New Drug (IND) applications to, and maintenance of such applications with, regulatory authorities; the ability to generate, analyze and present data from clinical trials; and the potential benefits of Legend Biotech's 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 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; 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 U.S. 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 the Legend Biotech's Annual Report 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. Any forward-looking statements contained in this press release speak only as of the date of this press release. 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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[1] Martin, T. Updated Results From CARTITUDE-1: Phase 1b/2 Study of Ciltacabtagene Autoleucel, a B-cell Maturation Antigen–Directed Chimeric Antigen Receptor T Cell Therapy, in Patients With Relapsed/Refractory Multiple Myeloma. Abstract #549 [Oral]. Presented at the 2021 American Society of Hematology (ASH) Annual Meeting & Exposition Annual Meeting.

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[3] American Society of Clinical Oncology. Multiple myeloma: introduction. https://www.cancer.net/cancer-types/multiple-myeloma/introduction. Accessed February 2022.

[4] Rajkumar SV. Multiple myeloma: 2020 update on diagnosis, risk-stratification and management. Am J Hematol. 2020;95(5),548-567. doi:10.1002/ajh.25791.

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Investor:
Joanne Choi, Senior Manager of Investor Relations, Legend Biotech
joanne.choi@legendbiotech.com

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

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

Source: Legend Biotech