Legend Biotech Achieves Milestone Under Collaboration Agreement with Janssen Biotech, Inc. for BCMA CAR-T

April 21, 2022

SOMERSET, N.J.--(BUSINESS WIRE)--Legend Biotech Corporation (NASDAQ: LEGN) (Legend Biotech), a global biotechnology company developing, manufacturing and commercializing novel therapies to treat life-threatening diseases, today announced the achievement of a $50 million milestone under its collaboration agreement with Janssen Biotech, Inc. (Janssen) for ciltacabtagene autoleucel (cilta-cel), now marketed in the United States under the brand name CARVYKTI™. Cilta-cel is a B-cell maturation antigen (BCMA)-directed chimeric antigen receptor T-cell (CAR-T) therapy.

Legend Biotech entered into the agreement with Janssen to develop, manufacture and commercialize cilta-cel for the treatment of multiple myeloma. Under the agreement, Legend Biotech received an upfront payment of $350 million and is entitled to receive additional payments upon achievement of landmarks for development, production performance, regulatory and sales.

The global agreement specifies a 50-50 cost and profit-sharing agreement in all markets, excluding Greater China, where the split is 70 percent for Legend and 30 percent for Janssen. Including the $50 million payment announced above, Legend has achieved $300 million in milestone payments during the collaboration.

About CARVYKTI™ (Ciltacabtagene autoleucel; cilta-cel)

CARVYKTI™ 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 CARVYKTI™ 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.

CARVYKTI™ received U.S. FDA approval for the treatment of adult patients with relapsed or refractory multiple myeloma in February 2022. In March 2022, CARVYKTI™ received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP). 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 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 LinkedIn.

Cautionary Statement:

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 March 31, 2022. 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.

Contacts

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

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

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