Legend Biotech Achieves Milestone Payments in BCMA CAR-T Collaboration with Janssen

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SOMERSET, N.J.--(BUSINESS WIRE)--Feb. 11, 2022-- Legend Biotech Corporation (NASDAQ: LEGN) (Legend Biotech), a global, clinical-stage biotechnology company developing and manufacturing novel therapies, has achieved two milestones under its collaboration agreement with Janssen Biotech, Inc. for ciltacabtagene autoleucel (cilta-cel), resulting in aggregate payments to Legend Biotech of $50 million. 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 payments announced above, Legend has achieved $250 million in milestone payments during the collaboration.

About Cilta-cel
Cilta-cel is an investigational chimeric antigen receptor T cell (CAR-T) therapy, formerly identified as JNJ-4528 in the United States 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 addition to a Breakthrough Therapy Designation (BTD) granted in the United States 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. Food and Drug Administration (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 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.

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. Applications seeking approval of cilta-cel for the treatment of patients with RRMM are currently under regulatory review by several health authorities around the world, including the U.S. Food and Drug Administration and the European Medicines Agency.

Learn more at www.legendbiotech.com and follow us on Twitter and 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 future milestone payments under our collaboration agreement with Janssen. 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.

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