Legend Biotech Announces U.S. FDA Clearance of IND Application for Solid Tumor CAR-T, LB1908 for Relapsed or Refractory Gastric, Esophageal and Pancreatic Cancers

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SOMERSET, N.J.--(BUSINESS WIRE)--Jun. 3, 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 U.S. Food and Drug Administration (FDA) has cleared its investigational new drug (IND) application to evaluate LB1908 in a Phase 1 clinical trial in the United States. LB1908 is an investigational, autologous chimeric antigen receptor T-cell (CAR-T) therapy selectively targeting Claudin 18.2 through a high-affinity VHH antibody for the treatment of adults with relapsed or refractory gastric, esophageal (including gastro-esophageal junction) or pancreatic cancers. Claudin18.2 is a tight junction protein commonly expressed in patients with these cancer subtypes.[1]

The Phase 1, first-in-human, open-label, multicenter clinical study seeks to characterize the safety and tolerability of LB1908, as well as determine the recommended dose for Phase 2 and evaluate preliminary efficacy. Study will have dose escalation and dose expansion phases. Patients enrolled in the study must sufficiently express Claudin 18.2.

A Phase 1 investigator-initiated trial evaluating LB1908 for advanced gastric cancers is also ongoing in China (NCT04467853).

“Treatment options for patients with esophageal, stomach and pancreatic cancers have improved in the last ten years, but patients in the advanced stages still face poor prognoses worldwide. Thousands of people have no symptoms until their cancers have moved into late phases and at that point, surgery is no longer an option,” said Lida Pacaud, M.D., Vice-President of Clinical Development. “Based on prevailing research, we are optimistic that a CAR-T therapy targeting Claudin 18.2 can be integrated in future treatment strategies for those with relapsed or refractory gastrointestinal cancers. We look forward to the start of the trial.”

About Gastric, Esophageal and Pancreatic Cancers
Stomach, esophageal and pancreatic cancers affect the tissue or glands lining these organs. They are often diagnosed when the diseases have progressed to advanced stages. In the U.S., there are an estimated 123,920 people living with stomach cancer and 49,084 living with esophageal cancers.[2,3] An estimated 89,248 people in the U.S. live with pancreatic cancer. While all three cancers are treatable, the five-year survival rate is just 32% for gastric cancer; 20% for esophageal cancer; and 11.5% for pancreatic cancer, with definitive treatment at all stages of progression.[4,5,6]

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 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.

References

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