Legend Biotech Announces FDA Clearance of IND Application for LB2102 in Extensive Stage Small Cell Lung Cancer

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SOMERSET, N.J.--(BUSINESS WIRE)--Nov. 21, 2022-- Legend Biotech Corporation (NASDAQ: LEGN) (Legend Biotech), a global biotechnology company developing, manufacturing and commercializing novel therapies to treat life-threatening diseases, announced today that the U.S. Food and Drug Administration (FDA) has cleared Legend Biotech's Investigational New Drug (IND) application to proceed with the clinical development of LB2102, an investigational, autologous chimeric antigen receptor T-cell (CAR-T) therapy for the treatment of adult patients with extensive stage small cell lung cancer (SCLC).

LB2102 is designed to selectively target delta-like ligand 3 (DLL-3), a ligand that is highly restricted to various malignancies, including SCLC, large cell neuroendocrine carcinoma (LCNEC), certain other neuroendocrine tumors and some prostate cancers. DLL-3 has also been linked to tumor growth, migration and invasion.[1]

The Phase 1, first-in-human, open-label clinical study is designed to evaluate the safety and preliminary efficacy of LB2102 in subjects with extensive stage SCLC and patients with LCNEC, as well as to determine the recommended dose for Phase 2.

"Lung cancer is a debilitating disease that often spreads quickly. On average, only seven percent of patients with SCLC are alive five years after receiving their diagnosis," said Lida Pacaud, M.D., Vice-President of Clinical Development at Legend Biotech. "We are eagerly awaiting the start of this Phase 1 trial, and we hope that the study will provide much needed insight into the potential of this investigational CAR-T therapy."

About Small Cell Lung Cancer

Lung cancer is a leading cause of cancer deaths, contributing to 25 percent of all cancer-related fatalities annually in the United States.[2] Small cell lung cancer (SCLC) is the most aggressive, and accounts for roughly 10-15 percent of lung cancer cases in the United States.[3],[4] An estimated 30,000 to 35,000 people are newly diagnosed with the disease each year.[4] This cancer becomes more difficult to treat once it has spread and becomes extensive stage SCLC. Approximately 60 to 70 percent of SCLC patients are diagnosed with metastatic SCLC.[3,5]

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 allogeneic chimeric antigen receptor T-cell 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 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 LB2102, including potential indications for, and Legend Biotech's other expectations for, that investigational CAR-T therapy; statements about submissions for LB2102 to, and the progress of such submissions with, the U.S. Food and Drug Administration (FDA) and other regulatory authorities; the anticipated timing of, and ability to progress, clinical trials; 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 on Form 20-F 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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