Legend Biotech Begins Phase 1 Clinical Trial in the US to Evaluate Investigational Anti-CD4 CAR-T Therapy for Relapsed or Refractory T-Cell Lymphoma

SOMERSET, N.J.— (BUSINESS WIRE)—September 13, 2021—Legend Biotech Corporation (NASDAQ: LEGN) (Legend Biotech), a global clinical-stage biopharmaceutical company engaged in the discovery and development of novel cell therapies for oncology and other indications, has announced the start of a Phase 1 clinical trial in the United States for LB1901, an investigational autologous CD4-targeted chimeric antigen receptor T-cell (CAR-T) therapy for the treatment of adults with relapsed or refractory peripheral T-cell lymphoma (PTCL) or cutaneous T-cell lymphoma (CTCL). LB1901 targets CD4, a surface membrane glycoprotein uniformly expressed in most TCL subtypes. The trial follows the U.S. Food and Drug Administration (FDA) clearance of the Investigational New Drug (IND) application submitted by Legend Biotech.

The Phase 1 trial is being led by Dr. Swaminathan P. Iyer, Professor of Lymphoma & Myeloma at The University of Texas MD Anderson Cancer Center, and is an open label, multi-center and multicohort clinical study in patients with relapsed or refractory PTCL or CTCL (NCT04712864). Recruitment in the trial has begun in the U.S.

"We are excited by the promise of LB1901, and we look forward to further evaluating the safety and tolerability of LB1901. Determining the optimal dose for subsequent evaluation is one of the key objectives of this trial," said Dr. Lida Pacaud, Vice President of Clinical Development at Legend Biotech. "The number of patients who relapse or are refractory to current TCL treatments is significant, and this trial will provide important information about the potential of CAR-T therapy to treat this disease."

T-cell lymphoma is a heterogeneous group of lymphoid malignancies that account for less than 15 percent of non-Hodgkin's lymphoma cases in the US.[i,ii] PTCL comprises subtypes that are uncommon and often aggressive, with a 5-year overall survival of only 39%.[iii,iv] CTCL are a group of T-cell malignancies that occur primarily in the skin.[v] Despite current treatment options, a substantial proportion of patients with PTCL or CTCL experiences relapse. A high unmet medical need remains for patients with relapsed or refractory PTCL and CTCL.

About the Clinical Development Program

LB1901-TCL-001 (NCT04712864) is a Phase 1 open-label, multicenter study of LB1901 in patients with histologically confirmed CD4+ RR PTCL (PTCL not otherwise specified, or PTCL-NOS, and angioimmunoblastic T cell lymphoma, or AITL) or RR CTCL (mycosis fungoides and Sézary syndrome). The primary objectives are to characterize the safety and tolerability of LB1901 and determine the optimal dose.

About Legend Biotech

Legend Biotech is a global clinical-stage biopharmaceutical company engaged in the discovery and development of novel cell therapies for oncology and other indications. Our team of over 900 employees across the United States, China and Europe, along with our differentiated technology, global development, and manufacturing strategies and expertise, provide us with the strong potential to discover, develop, and manufacture best-in-class cell therapies for patients in need. We are engaged in a strategic collaboration to develop and commercialize our lead product candidate, cilta-cel, an investigational BCMA-targeted CAR-T cell therapy for patients living with multiple myeloma. This candidate is currently being studied in registrational clinical trials.

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; the anticipated timing of, and ability to progress, the Phase 1 clinical trial of LB1901 in RR PTCL and RR CTCL; patient enrollment in the LB1901 Phase 1 clinical trial; and the potential benefits of LB1901 or any of our other 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 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 presentation 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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