Legend Biotech Announces U.S. FDA Clearance of IND Application for LB2501, an Investigational CD19/CD20 In Vivo CAR-T Therapy

October 15, 2026

- *LB2501 is an off-the-shelf in vivo CAR-T therapy designed to generate dual-targeting CD19/CD20 CAR-T cells directly within the patient after a single infusion, making it the first known dual-targeting in vivo CAR-T therapy to receive FDA IND clearance*

- *IND clearance supports planned U.S. Phase 1/2 study and advances Legend Biotech's in vivo cell engineering platform*

BRIDGEWATER, N.J., Oct. 15, 2026 (GLOBE NEWSWIRE) -- Legend Biotech Corporation (NASDAQ: LEGN) (Legend Biotech), a global leader in cell therapy, today announced that the U.S. Food and Drug Administration (FDA) has cleared the investigational new drug (IND) application for LB2501, an investigational *in vivo* CAR-T therapy designed to generate CD19/CD20 dual-targeting chimeric antigen receptor T (CAR-T) cells directly within the patient, for the treatment of relapsed or refractory B-cell malignancies, including B-cell non-Hodgkin lymphoma.

The planned U.S. Phase 1/2 study will evaluate the safety, tolerability, pharmacokinetics, and preliminary efficacy of LB2501. The clearance represents an advancement of Legend Biotech's strategy to develop the next generation of CAR-T therapies through innovative *in vivo* cell engineering.

LB2501 is designed as an off-the-shelf, single-infusion therapy that generates CAR-T cells directly within the patient, potentially avoiding several manufacturing steps required for conventional autologous CAR-T therapies. The therapy is being evaluated without lymphodepleting chemotherapy.

"We believe *in vivo* CAR-T represents the next frontier of cell therapy, with the potential to bring transformative, life-changing treatments to many more patients around the world," said Ingrid Zhang, Chief Executive Officer of Legend Biotech. "The FDA's clearance of our IND application marks an important step in advancing LB2501 and our broader *in vivo* cell engineering platform. Building on Legend's deep CAR-T experience, we are working to develop an approach that could help simplify access to and delivery of this important treatment class."

LB2501 is built on Legend Biotech's proprietary TaVec™ platform and uses an engineered, replication-incompetent lentiviral vector designed to selectively transduce T cells. Once transduced, the T cells generate a chimeric antigen receptor (CAR) that targets both CD19 and CD20. This dual-targeting approach is intended to help address antigen escape and other potential mechanisms of treatment resistance in B-cell malignancies.

ABOUT LB2501
LB2501 is an off-the-shelf *in vivo* CAR-T therapy designed to generate dual-targeting CD19/CD20 CAR-T cells directly within the patient after a single infusion, making it the first known dual-targeting *in vivo* CAR-T therapy to receive FDA IND clearance. LB2501 is currently being evaluated in an ongoing Phase 1, open-label study (NCT07002112) in China in patients with relapsed or refractory B-cell malignancies to assess safety, tolerability, and preliminary efficacy.[i]

ABOUT B-CELL NON-HODGKIN LYMPHOMA
B-cell malignancies encompass a clinically heterogeneous group of clonal lymphoproliferative neoplasms originating at various discrete stages along the B-lymphocyte ontogeny. It spans immature precursor subtypes like B-cell lymphoblastic leukemias to mature forms like B-cell non-Hodgkin lymphoma (B-NHL), chronic lymphocytic leukemia (CLL), and terminally differentiated plasma cell dyscrasias. B-NHL accounts for 90% of all malignant lymphomas. While treatment advances have improved outcomes for some patients, those with relapsed or refractory B-NHL, particularly after multiple lines of therapy, often face limited options.

ABOUT LEGEND BIOTECH
With over 3,000 employees, Legend Biotech is the largest standalone cell therapy company and a pioneer in treatments that change cancer care forever. Legend Biotech is at the forefront of the CAR-T cell therapy revolution with CARVYKTI®, a one-time treatment for relapsed or refractory multiple myeloma, which it develops and markets with collaborator Johnson & Johnson. Centered in the United States, Legend Biotech is building an end-to-end cell therapy company by expanding its leadership to maximize CARVYKTI's patient access and therapeutic potential. From this platform, Legend Biotech plans to drive future innovation across its pipeline of cutting-edge cell therapy modalities.

Learn more at https://legendbiotech.com and follow us on X, LinkedIn, and Instagram.

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 Phase 1 clinical trial, and the planned U.S. Phase 1/2 clinical trial, of LB2501, the potential benefits of LB2501, including the reproducibility and durability of any favorable results initially seen in patients dosed to date in clinical trials, and in vivo CAR-T representing the next frontier of cell therapy. 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 Legend Biotech's 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; government, industry, and general product pricing and other political pressures; as well as the other factors discussed in the "Risk Factors" section of Legend Biotech's most recent Annual Report on Form 20-F filed with the Securities and Exchange Commission. 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.

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[i] ClinicalTrials.gov. The CD19/CD20 Dual-Target in Vivo CAR-T Lentiviral Product in the Treatment of Relapsed/Refractory B-cell Malignancies. https://clinicaltrials.gov/study/NCT07002112. Accessed May 2026.