Legend Biotech Establishes Clinical Proof-of-Concept for LB2501, a Potential First-in-Class In Vivo CD19/CD20 Dual-Targeting CAR-T, in Relapsed/Refractory B-Cell Non-Hodgkin Lymphoma

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- *Achieved 100% ORR and 83.3% CR rate at dose level 2 following a single infusion in patients with relapsed/refractory B-NHL in an ongoing Phase 1 study*
- *Single infusion of LB2501 generated dose-dependent in vivo CAR-T expansion without lymphodepletion*
- *No dose-limiting toxicities, serious adverse events, ICANS, or deaths were reported; infusion-related reactions and CRS were Grade 1–2, and none required glucocorticoids for CRS management*
- *Additional translational data showed rapid vector clearance, polyclonal vector integration, and no evidence of non-specific transduction*
- *Proof-of-concept progress demonstrates leadership in next-generation cell therapies, with results presented in a late-breaking session at EHA 2026*

BRIDGEWATER, N.J., June 14, 2026 (GLOBE NEWSWIRE) -- Legend Biotech Corporation (NASDAQ: LEGN) (Legend Biotech), a global leader in cell therapy, today announced first clinical proof-of-concept data for LB2501, its investigational *in vivo* CD19/CD20 dual-targeting CAR-T cell therapy, in patients with relapsed or refractory B-cell non-Hodgkin lymphoma (R/R B-NHL). The results are being presented today in a late-breaking session at the European Hematology Association (EHA) 2026 Congress (Abstract #LB5006).

In the ongoing Phase 1 study, a single infusion of LB2501 generated dose-dependent *in vivo* CAR-T expansion without lymphodepletion. At the higher dose level (DL2), LB2501 achieved a 100% objective response rate (ORR) (6/6) and an 83.3% complete response rate (CR) (5/6), with all responses ongoing at the time of data cutoff. LB2501 also showed a favorable safety profile, with no dose-limiting toxicities (DLTs), serious adverse events (SAEs), immune effector cell-associated neurotoxicity syndrome (ICANS), or deaths reported.

"*In vivo* CAR-T represents a compelling frontier in cell therapy, enabling the generation of CAR-T cells directly within the patient, with the potential to simplify treatment and expand access over time," said Ying Huang, Ph.D., Chief Executive Officer of Legend Biotech. "LB2501 is our step toward realizing that vision and reflects further progress toward our goal of leading the future of cell therapy. Backed by the commercial and scientific foundation we have built with CARVYKTI, we are well-positioned to advance this next generation of CAR-T delivery. These early data, with deep responses from a single infusion across patients, give us confidence in the path ahead."

LB2501 Demonstrates *In Vivo* CAR-T Generation and Early Clinical Activity

In an ongoing Phase 1 study, 12 patients with R/R B-NHL received LB2501 across two dose levels, DL1 (n=6) and DL2 (n=6). Patients had received a median of three prior lines of therapy, and 58.3% were refractory to their most recent treatment. The open-label, multi-center, dose-escalation study is evaluating safety, recommended Phase 2 dose, pharmacokinetics, and preliminary efficacy in adults with R/R B-NHL. The study was conducted without lymphodepletion.

At DL2, LB2501 achieved a 100% ORR (6/6) and an 83.3% CR rate (5/6), with responses observed across patients with diffuse large B-cell lymphoma (DLBCL), mantle cell lymphoma (MCL), and follicular lymphoma (FL). Across both dose levels, the ORR was 50.0% (6/12), and the CR rate was 41.7% (5/12). At the time of data cutoff, all responses at DL2 were ongoing.

LB2501 showed a favorable safety profile. No DLTs, SAEs, ICANS, or deaths were reported. Infusion-related reactions (IRR) and cytokine release syndrome (CRS) were the most common adverse events of special interest and were all Grade 1–2. Infusion-related reactions occurred in 75.0% (9/12) of patients overall, with a median onset of 1.4 hours after infusion and a median recovery time of 18.6 hours. CRS occurred in 66.7% (8/12) of patients overall, with a median onset at Day 11 and a median duration of 4.5 days. IRR and CRS were all Grade 1–2, no patients required glucocorticoids for CRS management. Four patients received tocilizumab.

Pharmacokinetic analyses showed dose-dependent *in vivo* CAR-T expansion in 100% (6/6) of patients at DL2 and 83% (5/6) of patients at DL1. CAR-T cells remained detectable in peripheral blood for up to 116 days. Viral copy number in peripheral blood peaked immediately after infusion and decreased to undetectable concentrations within 24 hours.

Additional translational analyses further characterized the *in vivo* profile of LB2501. No evidence of non-specific transduction was detected in NK cells or other non-T/B/NK lymphocyte populations. Vector integrations were highly polyclonal and diverse. These findings support proof-of-concept for *in vivo* T-cell engineering, with polyclonal vector integration and rapid vector clearance.

"These early clinical findings are encouraging in a heavily pretreated relapsed or refractory B-cell non-Hodgkin lymphoma population," said Lei Fan, M.D., Ph.D., Professor, Doctoral Supervisor, and Administrative Director, Hematology Department, Jiangsu Province Hospital, Nanjing, China. "The responses observed at the higher dose level achieved a 100% objective response rate, together with a favorable safety profile and the absence of lymphodepletion, support further investigation of LB2501 as a novel *in vivo* CAR-T approach. The additional pharmacokinetic and translational findings presented at EHA further support the feasibility of generating CAR-T cells directly within the patient." ‡

ABOUT LB2501

LB2501 is an investigational, potential first-in-class CD19/CD20 dual-targeting *in vivo* CAR-T therapy designed to generate CAR-T cells directly within the patient following a single intravenous infusion. It is being evaluated in an ongoing Phase 1, open-label study (NCT07002112) in patients with relapsed/refractory B-cell malignancies[i] to assess safety, tolerability, and preliminary efficacy.[i]

ABOUT B-CELL NON-HODGKIN LYMPHOMA

Non-Hodgkin lymphoma (NHL) is a group of cancers that originate in lymphocytes, a type of white blood cell that plays a key role in the body's immune system.[ii] B-cell lymphomas account for approximately 85% of NHL cases and arise from abnormal growth of B lymphocytes (B cells), which are responsible for producing antibodies. These malignancies include a range of subtypes that vary in aggressiveness, from slow-growing to highly aggressive disease.[iii]

While treatment advances have improved outcomes for some patients, those with relapsed or refractory B-cell 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, Instagram, 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, the Phase 1 clinical trial of LB2501, and 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 LB2501's potential to be first-in-class. 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 Annual Report on Form 20-F filed with the Securities and Exchange Commission on March 10, 2026. 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.

‡ Lei Fan, M.D., Ph.D., Professor, Doctoral Supervisor, and Administrative Director, Hematology Department, Jiangsu Province Hospital, Nanjing, China, has provided consulting and advisory services to Legend Biotech; he has not been paid for any media work.

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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

[ii] American Cancer Society. "What Is Non-Hodgkin Lymphoma?". Available at: https://www.cancer.org/cancer/types/non-hodgkin-lymphoma/about/what-is-non-hodgkin-lymphoma.html.Accessed May 2026.

[iii] American Cancer Society. "Types of B-cell Lymphoma." Available at: https://www.cancer.org/cancer/types/non-hodgkin-lymphoma/about/b-cell-lymphoma.html.Accessed May 2026.