Allogene Therapeutics Reports Interim Futility Analysis from Pivotal ALPHA3 Trial Showing 58.3% MRD Clearance with Cemacabtagene Ansegedleucel (Cema-Cel) vs. 16.7% in Observation Arm in First-Line Consolidation LBCL

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- 41.6% Absolute Difference in the Cema-Cel Arm Over the Observation Arm Exceeded Clinically Meaningful Benchmark Based on Literature of 25-30%
- MRD Reduction Occurred Rapidly Following Cema-Cel Treatment with a 97.7% Median Decrease in Plasma ctDNA at Day 45 Compared to a 26.6% Median Increase in the Observation Arm
- Cema-Cel Treatment Well-Tolerated with Most Patients Managed Outpatient
    - No Cases of CRS, ICANS, GvHD, or Treatment-Related Serious Adverse Events
    - No Hospitalizations for Treatment-Related Adverse Events
- Community Cancer Centers, Including Sites New to CAR T Therapy, Accounted for Approximately 33% of Screening Activity and Cema-Cel Infusions
- Enrollment Expected to Complete by Year-End 2027, with an Interim Event-Free Survival (EFS) Analysis Anticipated in Mid-2027 and Primary EFS in Mid-2028
- Conference Call and Webcast Scheduled for Today at 5:30 AM PT/8:30 AM ET

SOUTH SAN FRANCISCO, Calif., April 13, 2026 (GLOBE NEWSWIRE) -- Allogene Therapeutics, Inc. (Nasdaq: ALLO), a clinical-stage biotechnology company pioneering the development of allogeneic CAR T (AlloCAR T) products for cancer and autoimmune disease, today reported data from the planned interim futility analysis of its pivotal, randomized Phase 2 ALPHA3 trial in first-line (1L) consolidation large B-cell lymphoma (LBCL).

At the protocol-defined data cutoff, which was triggered when the 24th patient completed Day 45 MRD assessment, 58.3% (7/12) of patients in the cemacabtagene ansegedleucel (cema-cel) arm achieved minimal residual disease (MRD) negativity compared to 16.7% (2/12) in the observation arm. This represents a 41.6% absolute difference in MRD clearance between the two arms. Based on literature,[1] [2] [3] a difference in percentage points of 25-30% in the MRD clearance could translate into meaningful clinical benefit at study completion. In addition, at the first MRD assessment (Day 45), plasma ctDNA levels decreased from baseline by a median of 97.7% in the cema-cel arm compared to a 26.6% median increase in the observation arm. The Company believes these interim data provide initial support for cema-cel's potential as a novel strategy for treating high-risk patients at the end of first-line treatment.

MRD status post-treatment has emerged as a strong predictor of relapse in LBCL, creating a potential opportunity to intervene earlier in the course of disease, when disease burden is low, but the risk of progression remains high.[4] [5] The ALPHA3 trial is the first randomized study in LBCL designed to assess whether MRD-guided intervention before relapse can eliminate residual disease and potentially prevent recurrence. The study identifies high-risk patients using Natera's CLARITY™ MRD assay which is powered by its phased variant MRD technology. Patients with LBCL who have completed curative-intent treatment in both front-line and later line settings, including autologous CAR T therapy, and who achieve MRD negative status by technology have demonstrated improved progression-free survival (PFS) and EFS compared to those who do not attain MRD-negative status.[6] [7]

"Early MRD clearance in this setting is encouraging and supports the potential for cema-cel to change how we approach high-risk LBCL at the end of first-line therapy," said Zachary Roberts, M.D., Ph.D., EVP, Research and Development and Chief Medical Officer of Allogene. "These interim data suggest that an off-the-shelf CAR T may be able to intervene during that important window before clinical relapse to eliminate residual disease and make earlier intervention feasible in routine clinical practice. We look forward to the next study milestones as the trial continues to further define the potential of cema-cel."

"Our goal has always been to move CAR T from a bespoke procedure available at a limited number of centers to a scalable therapy that can reach patients more broadly," said David Chang, M.D., Ph.D., President, Chief Executive Officer and Co-Founder of Allogene. "Although still early, the ALPHA3 results show encouraging MRD clearance and a favorable safety profile. Combined with the advantages of an off-the-shelf CAR T platform —rapid availability, operational simplicity, and potential for outpatient use—cema-cel, if approved, could leapfrog existing options and enable earlier intervention in the disease course."

SAFETY & HOSPITALIZATION

Cema-cel has been generally well-tolerated as of the data cutoff with no serious adverse events related to treatment. There were no cases of cytokine release syndrome (CRS), immune effector cell-associated neurotoxicity syndrome (ICANS) or graft-versus-host disease (GvHD) in the Treatment Emergent Adverse Events (TEAEs) of Special Interest category, which captures adverse events associated with CAR T.

TEAEs of Special Interest	Cema-cel Arm (N=12) n (%)	Observation Arm (N=12) n (%)
CRS (Any Grade)	0	-
ICANS (Any Grade)	0	-

GvHD (Any Grade)	0	-
Infection*	2 (16.7%)	2 (16.7%)
Infection (Grade ≥3)	0	0
Other Neurologic Events**	6 (50.0%)	1 (8.3%)
Other Neurologic Events (Grade ≥3)	0	0

**Infection events were low grade and limited to urinary tract infection, subcutaneous abscess, COVID19, and skin infection*
***Other neurologic events were low grade and limited to headache, dizziness, numbness or tingling in the hands or feet, and altered taste*

No Hospitalizations for Treatment Related Adverse Events: Ten of 12 patients who received cema-cel were managed entirely outpatient post-infusion. The remaining two patients were briefly hospitalized for events deemed unrelated to cema-cel treatment (atrial fibrillation and non-cardiac chest pain). One patient in the observation arm was hospitalized for febrile neutropenia. This contrasts with the broader CAR T experience where hospitalization for toxicity management remains common, even in outpatient programs, with approximately 70–90% of patients requiring admission and roughly 75% hospitalized for adverse events within 30 days.[8]

"The early safety profile, characterized by an absence of CRS and ICANS, is encouraging given its potential to enable safe outpatient management," said Nancy L. Bartlett, M.D., Professor of Medicine, Division of Oncology, Washington University School of Medicine in St. Louis and a Siteman Cancer Center physician. "When considered alongside the availability of an off-the-shelf product, these findings suggest the possibility of overcoming key logistical barriers that have historically limited broader use of CAR T, particularly in earlier lines of therapy. Coupled with the encouraging MRD clearance data, this approach may represent an important step toward improving outcomes while expanding patient access."

REAL-WORLD FEASIBILITY AND COMMUNITY USE

At the time of the interim futility analysis, community cancer centers accounted for approximately 33% of screening activity and cema-cel infusions, including several sites with little to no prior CAR T experience. Participation from these centers, where most patients receive care, underscores the feasibility of offering cema-cel in these settings and supports potential for broader adoption.

"In busy community practices, the goal is simple: bring the therapy to the patient, not the patient to the therapy," said Jeff Sharman, M.D., Chair, Lymphoma Research Executive Committees, SCRI at Willamette Valley Cancer Institute & Research Center. "Historically, CAR T has largely been out of reach for community practices. The ability to deliver an off-the-shelf CAR T safely in the community setting, potentially outpatient, could address far more patients and extend treatment reach across the communities we serve."

PATIENT CHARACTERISTICS

Both study arms consisted of patients with high-risk, aggressive lymphomas. Although limited by the small sample size, baseline characteristics show that a numerically greater number of patients in the cema-cel arm had more aggressive disease features, specifically stage III-IV disease and higher IPI scores, compared to the observation arm.

At Original Diagnosis	Cema-cel Arm (N=12) n (%)	Observation Arm (N=12) n (%)
History of Bone Marrow Involvement	4 (33.3%)	3 (25.0%)
Disease Stage		
I - II	0	2 (16.7%)
III - IV	12 (100%)	10 (83.3%)
IPI Score		
0 to 1	0	4 (33.3%)
2 to 3	7 (58.3%)	5 (41.7%)
4 to 5	5 (41.7%)	2 (16.7%)
Unknown	0	1 (8.3%)
Gene Alterations/Over Expression		
Double Hit	6 (50.0%)	2 (16.7%)
Triple Hit	0	2 (16.7%)
Double Expressor	2 (16.7%)	0

First-Line Regimens and PET/CT Response to the 1L Regimen: A high-intensity variant of R-CHOP, DA-EPOCH-R, was the most commonly administered 1L therapy across both arms, with a slightly higher proportion of patients in the cema-cel arm receiving this first line treatment regimen (58.3% vs. 41.7%). Twenty-five percent of patients in each arm entered the study after achieving a partial remission to 1L therapy.

	Cema-cel Arm (N=12) n (%)	Observation Arm (N=12) n (%)
First-Line Treatment		
R-CHOP	2 (16.7%)	3 (25.0%)
R-Pola-CHP	2 (16.7%)	2 (16.7%)
DA-EPOCH-R	7 (58.3%)	5 (41.7%)
R-miniCHOP	1 (8.3%)	2 (16.7%)
Most Recent PET/CT Response Before Randomization		
CR	9 (75.0%)	9 (75.0%)

PR	3 (25.0%)	3 (25.0%)

ALPHA3 TRIAL AND TIMELINE

This interim futility analysis was based on the first 24 patients randomized (12 in the cema-cel arm and 12 in the observation arm) and followed for post-treatment MRD assessment. MRD is assessed on Day 45, Month 3, and every 3 months during the first year of follow-up. The primary endpoint of EFS, along with key secondary endpoints of PFS and overall survival (OS), remains blinded. The study is enrolling across more than 60 sites, with additional sites coming online, and is expected to enroll approximately 220 patients. Study accrual is anticipated to be complete by the end of 2027. The study is powered to detect a 50% reduction in the risk of EFS events. EFS events include the initiation of new anti-lymphoma therapy, disease progression, or death. The Company anticipates an interim EFS analysis in mid-2027 and the primary EFS analysis in mid-2028. If positive, these results could support a Biologics License Application (BLA) submission.

Conference Call and Webcast Details

Allogene will host a live conference call and webcast today at 5:30 a.m. PT / 8:30 a.m. ET to discuss the interim futility analysis. If you would like the option to ask a question on the conference call, please use this link to register. Upon registering for the conference call, you will receive a personal PIN to access the call, which will identify you as the participant and allow you the option to ask a question. Please use this link to register for the listen-only webcast. The webcast will be made available on the Company's website at www.allogene.com under the Investors tab in the News and Events section. Following the live audio webcast, a replay will be available on the Company's website for approximately 30 days.

About Allogene Therapeutics

Allogene Therapeutics, with headquarters in South San Francisco, is a clinical-stage biotechnology company pioneering the development of allogeneic chimeric antigen receptor T cell (AlloCAR T) products for cancer and autoimmune disease. Led by cell therapy veterans applying proven CAR T experience, Allogene is developing a pipeline of off-the-shelf CAR T cell product candidates with the goal of delivering readily available cell therapy on-demand, more reliably, and at greater scale to more patients. For more information, please visit www.allogene.com, and follow Allogene Therapeutics on X and LinkedIn.

Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are based on management's current expectations and assumptions and involve risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. In some cases, forward-looking statements may be identified by words such as "anticipate," "expect," "believe," "aim," "plan," "goal," "intend," "seek," "estimate," "target," "potential," "may," "could," "will," "would," "should," "designed to," "suggest," "possible," and similar expressions. Forward-looking statements in this press release include, but are not limited to, statements regarding the ongoing Phase 2 ALPHA3 trial of cema-cel, including expected enrollment and the completion thereof and the timing for data announcements; the potential clinical benefits, safety, tolerability, durability, and efficacy of cema-cel, including its potential to enable earlier intervention in LBCL; its favorable safety profile, including as compared to other CAR T therapies, its potential to leapfrog existing options and its potential for rapid availability, operational simplicity and outpatient use; the interim futility analysis data providing initial support to suggest that cema-cel may offer a new strategy to treat high-risk patients at the end of first-line treatment and a fundamentally different approach to CAR T delivery; the potential for MRD-guided first-line consolidation to improve outcomes in LBCL, including the potential to eliminate residual disease, make earlier intervention feasible in routine clinical practice and potentially prevent recurrence; the participation from community cancer centers in the Phase 2 ALPHA3 trial underscoring the ability to offer cema-cel in the community settings and supporting the potential for broader adoption; the potential BLA submission for cema-cel; and Allogene's ability to develop and deliver readily available allogeneic CAR T products for the treatment of cancer and autoimmune disease on-demand, more reliably, and at greater scale to more patients. Actual results may differ materially from those indicated by these forward-looking statements as a result of various important factors, including, but not limited to, risks and uncertainties inherent in clinical development (including that interim or early data may not be predictive of later or final results and data from a small sample size may not be indicative of results that may be observed in a larger group), patient enrollment and trial execution risks, uncertainties related to MRD testing and its clinical significance and reliability, including whether MRD clearance improvements translate to meaningful clinical benefits, the occurrence of adverse safety events, regulatory risks and uncertainties, manufacturing and CMC risks, reliance on third parties and licensors, competitive developments, intellectual property and contractual risks, and financial risks, including the need for additional capital. These and other risks and uncertainties are described more fully in Allogene's filings with the Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in its most recent Annual Report on Form 10-K for the year ended December 31, 2025, filed with the SEC on March 12, 2026, and other filings that Allogene may make from time to time with the SEC. All forward-looking statements in this press release speak only as of the date of this press release, and Allogene undertakes no obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, except as required by law.

Allogene's investigational AlloCAR T oncology products utilize Cellectis technologies. Cemacabtagene ansegedleucel (cema-cel) was developed based on an exclusive license granted by Cellectis to Servier. Servier has granted Allogene exclusive rights to cema-cel in the U.S., all EU Member States and the United Kingdom.

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