Allogene Therapeutics Receives FDA Regenerative Medicine Advanced Therapy (RMAT) Designation for Cemacabtagene Ansegedleucel (Cema-Cel) as First-Line Consolidation Therapy for Large B-Cell Lymphoma

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- FDA Granted RMAT Designation Based on ALPHA3 Trial Futility Analysis, Highlighting Cema-Cel's Potential to Transform Disease Treatment in First-Line LBCL Consolidation
  - Cema-Cel Induced Rapid and Substantial MRD Clearance of 58.3%, with a 97.7% Median Decrease in Plasma ctDNA at Day 45, Compared With a 26.6% Median Increase in the Observation Arm
  - Cema-Cel Was Well-Tolerated, With Most Patients Managed in the Outpatient Setting and No Hospitalizations for Treatment-Related Adverse Events
- FDA Also Granted Fast Track Designation to Cema-Cel for the ALPHA3 Development Program
- RMAT and Fast Track Status Enable Enhanced FDA Engagement and Support Potential Expedited Development and Review Pathways

SOUTH SAN FRANCISCO, Calif., July 29, 2026 (GLOBE NEWSWIRE) -- Allogene Therapeutics, Inc. (Nasdaq: ALLO), a clinical-stage biotechnology company pioneering allogeneic CAR T (AlloCAR T) products for cancer and autoimmune disease, today announced that the U.S. Food and Drug Administration (FDA) has granted Regenerative Medicine Advanced Therapy (RMAT) and Fast Track designations to cemacabtagene ansegedleucel (cema-cel) for the treatment of adult patients with large B-cell lymphoma (LBCL) who, at the completion of first-line (1L) therapy, are in complete or partial response suitable for observation but test positive for minimal residual disease (MRD). Together, the designations enable more frequent FDA engagement and support an efficient development and review process.

Cema-cel is an investigational allogeneic CAR T product being studied in the pivotal ALPHA3 trial as part of 1L treatment for patients with LBCL who are at high risk of relapse. The ALPHA3 trial uses Natera's CLARITY ™ MRD assay, which is powered by its phased variant MRD technology, to identify patients in remission but who are likely to experience disease recurrence following completion of 1L chemoimmunotherapy. Patients who test positive for MRD are enrolled and assigned to receive either a single dose of cema-cel or close observation, the current standard of care, with outcomes compared between the two groups.

"The FDA's decision to grant both RMAT and Fast Track designations provides additional validation for the strategy we defined with the ALPHA3 trial and strengthens our ability to work closely with the agency on an efficient path to advance cema-cel as a first-line consolidation therapy for large B-cell lymphoma," said Zachary Roberts, M.D., Ph.D., President and Chief Executive Officer of Allogene Therapeutics. "There is a shared goal across the treatment community to reach patients earlier in their disease course and reduce the barriers that limit access to CAR T therapy. The interim ALPHA3 findings, which showed rapid and substantial MRD reduction, with most patients treated in the outpatient setting, support cema-cel's potential as an off-the-shelf therapy that can be delivered at scale in community settings where approximately 80% of first-line patients receive their care."

The FDA granted RMAT designation for cema-cel as 1L consolidation therapy for patients with high-risk LBCL following full review of the interim futility analysis from the ongoing ALPHA3 trial, underscoring the continued need for new treatment options. At the protocol-defined data cutoff, triggered when the 24th patient enrolled in the ongoing study arms completed the Day 45 MRD assessment, 58.3% (7/12) of patients in the cema-cel arm achieved 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. Published literature and cross-study benchmarks suggest that MRD clearance differences of 25-30% may lead to clinically meaningful improvement at study completion.

Cema-cel was well-tolerated as of the data cutoff with no treatment-related serious adverse events. There were no cases of cytokine release syndrome (CRS), immune effector cell-associated neurotoxicity syndrome (ICANS), graft-versus-host disease (GvHD) or high-grade infections. No tocilizumab or steroids were administered for toxicity prophylaxis or treatment, and no patients were hospitalized for treatment-related adverse events. This profile compares favorably with the broader CAR T experience, where hospitalization for toxicity management remains common.

Regenerative Medicine Advanced Therapy (RMAT) designation is intended to expedite the development and review of regenerative medicine therapies intended to treat, modify, or cure a serious or life-threatening disease or conditions when preliminary clinical evidence indicates the therapy has the potential to address an unmet medical need for that disease or condition. Fast Track designation further supports expedited development and review, including potential eligibility for rolling review and priority review, if relevant criteria are met.

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 for Allogene

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. The press release may, in some cases, use terms such as “anticipate,” “expect,” “believe,” “aim,” “plan,” “goal,” “intend,” “seek,” “estimate,” “target,” “potential,” “may,” “could,” “will,” “would,” “should,” “designed to,” “suggest,” “support,” “enable,” “possible” and similar expressions to identify these forward-looking statements. Forward-looking statements include statements regarding intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things: the potential benefits and regulatory implications of the RMAT and Fast Track designations for cema-cel, including enhanced FDA engagement, an efficient or expedited development and review process, and potential eligibility for rolling review or priority review; the ongoing pivotal Phase 2 ALPHA3 trial and the potential for the trial or its results to support the advancement or regulatory approval of cema-cel; the potential clinical benefits, safety, tolerability, durability and efficacy of cema-cel, including its potential to transform treatment and enable earlier intervention for patients with LBCL who are at high risk of relapse; the interpretation and predictive value of the interim futility analysis and the reported MRD clearance and plasma ctDNA results, including whether the observed differences or literature-based benchmarks will translate into clinically meaningful improvement or improved clinical outcomes at study completion; the ability of Natera’s CLARITY™ MRD assay to identify patients who are likely to experience disease recurrence following first-line treatment; cema-cel’s potential as an off-the-shelf therapy that can be delivered at scale in outpatient and community settings and broaden patient access to CAR T therapy; comparisons of cema-cel’s safety, tolerability and outpatient administration profile with the broader CAR T experience; and Allogene’s ability to develop and deliver readily available allogeneic CAR T products 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 from a small number of patients may not be predictive of later or final results and may change as additional patients are enrolled and followed; uncertainties related to MRD and ctDNA testing and their clinical significance, reliability and ability to predict clinical outcomes, including whether MRD clearance will translate into improvements in event-free survival or other clinical endpoints; limitations of comparisons to published literature, cross-study benchmarks or other CAR T therapies; the occurrence of adverse safety events; patient enrollment and trial execution risks; regulatory risks and uncertainties, including that RMAT or Fast Track designation does not ensure expedited development or review or regulatory approval and that the FDA may disagree with Allogene’s clinical or regulatory plans, interpretation of results or proposed development pathway or may require additional data or trials; risks related to the development, regulatory approval and performance of the CLARITY™ MRD assay; 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 SEC, including under the heading “Risk Factors” in its Annual Report on Form 10-K for the year ended December 31, 2025, filed with the SEC on March 12, 2026, and its Quarterly Report on Form 10-Q for the quarter ended March 31, 2026, filed with the SEC on May 13, 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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