Allogene Therapeutics Positions 2026 as a Program-Defining Year for Scalable, Real-World Allogeneic CAR T

Jan 8, 2026 at 8:30 AM EST

- **1H 2026 Catalyst Stack Anticipated to Validate Scalable, Off-the-Shelf CAR T in Oncology and Autoimmune Disease**
  - Interim Futility Analysis of MRD Clearance from the Pivotal Phase 2 ALPHA3 Trial with Cemacabtagene Ansegedleucel (Cema-Cel) in First-Line (1L) Consolidation Large B-Cell Lymphoma (LBCL) Planned for Early Q2 2026
  - Initial Proof-of-Concept for ALLO-329, the Dual CD19/CD70 AlloCAR T Leveraging the Dagger® Technology to Reduce or Eliminate Lymphodepletion in the Treatment of Autoimmune Diseases, Slated by the End of 1H 2026
- **Cash Runway Continues into 2H 2027**

SOUTH SAN FRANCISCO, Calif., Jan. 08, 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 outlined 2026 as a program-defining year for allogeneic CAR T, with multiple first-half clinical readouts expected to test, and potentially validate, whether off-the-shelf CAR T can be delivered at biologic-like scale, in real-world settings, across oncology and autoimmune disease.

After nearly eight years of platform development and treatment of more than 200 patients across six clinical studies, Allogene has built an off-the-shelf CAR T platform designed to deliver clinical utility, broad patient access, predictable manufacturing, and scalable economics which are core requirements for cell therapy to move beyond a bespoke process toward routine medical practice.

“We believe 2026 is a program-defining year for allogeneic CAR T and Allogene with value-defining readouts and clinical maturity unmatched in the allogeneic field,” said David Chang, M.D., Ph.D., President, Chief Executive Officer and Co-Founder of Allogene. “With multiple first-half clinical milestones, we aim to demonstrate that CAR T can be delivered at biologic-like scale in real-world settings.”

A Biologic-Like CAR T Platform Built for Real-World Demand
The Company’s off-the-shelf approach is purpose-built seeking to deliver the attributes required for sustainable growth and broad patient access, including:

- Rapid, on-demand availability
- Consistent, predictable product performance
- Simplified administration compatible with outpatient use and deployment beyond academic centers into community settings
- Manufacturing scalability of approximately 30,000 - 60,000+ doses annually
- Efficient cost-of-goods profile (<$10K - 20K/dose)

Together, these attributes will position Allogene’s platform to support broad deployment across hematologic malignancies, autoimmune disease, and solid tumors – enabling CAR T therapy to reach patients earlier, more reliably, and in care settings where most patients are treated.

Cema-Cel: Giving LBCL Patients a Second Chance at First-Line Success
Allogene’s lead program, cemacabtagene ansegedleucel (cema-cel), is being evaluated in the pivotal Phase 2 ALPHA3 trial, a randomized study designed to test whether early, MRD-guided consolidation with cema-cel can prevent recurrence of large B-cell lymphoma (LBCL).

ALPHA3 seamlessly integrates cema-cel as a “7th cycle” of first-line therapy, without altering existing first-line treatment workflows, enabling early, MRD-guided treatment intervention for patients at high risk of relapse. The trial is enrolling patients across both academic and community cancer centers to improve patient access as the majority of LBCL patients are treated in the community cancer setting in the US.

An early Q2 2026 interim futility analysis focused on MRD clearance represents the first program-defining test of whether early, MRD-guided allogeneic CAR T can prevent recurrence of lymphoma. A 25–30% improvement in MRD clearance versus observation could signal one of the most meaningful advances in LBCL since the introduction of rituximab, based on historical benchmarks and growing data linking MRD clearance to long-term outcomes.

ALLO-329: Purpose-Built Allogeneic CAR T for Autoimmune Disease with Built-In Lymphodepletion
ALLO-329 is a next-generation dual-targeted CD19/CD70 AlloCAR T incorporating Allogene’s proprietary Dagger ® technology, which provides built-in, targeted lymphodepletion by selectively depleting cells in the patient that are responsible for rejecting AlloCAR T products: activated CD70-positive T cells.

This approach could reduce or eliminate the need for conventional cytotoxic lymphodepletion and significantly expand access, especially for:

- Younger patients and women of child-bearing age for whom cytotoxic lymphodepletion is problematic
- Settings where rheumatologists, not oncologists, are the primary treating physicians
- Patients with moderate disease where a streamlined treatment could improve adoption

The Phase 1 RESOLUTION trial, a 3+3 dose escalation study, is enrolling patients across multiple autoimmune indications, including systemic lupus erythematosus, lupus nephritis, scleroderma, and inflammatory myositis. The trial plans to test up to four cell dose levels from a starting cell dose of 20 million CAR T cells in two parallel cohorts (one with a low intensity lymphodepletion and one with no lymphodepletion).

Initial proof-of-concept data are expected by the end of 1H 2026. Expected to be included in the initial data release are early clinical outcome and supporting translational data covering disease-related biomarkers, CAR T expansion, and immune reconstitution from the first dose level (20 million CAR T cells) cohorts.

If successful, ALLO-329 could open one of the largest new markets in cell therapy, where scalable manufacturing, reduced toxicity, and accessibility to rheumatologists become critical competitive differentiators.

ALLO-316: TRAVERSE Trial Establishes CAR T Potential in Solid Tumors
ALLO-316 has demonstrated early, durable responses in heavily pretreated patients with renal cell carcinoma (RCC), representing one of the first credible signals that CAR T – autologous or allogeneic – may deliver meaningful benefit in solid tumors. The Phase 1 trial demonstrated:

- Robust CAR T cell expansion following standard Flu/Cy-based lymphodepletion, providing proof-of-concept for the Dagger® technology platform
- 31% confirmed ORR with a single ALLO-316 dose[1] in patients with high CD70 expression, which represents ~2/3 of clear cell RCC
- All responses were durable beyond 6 months after ALLO-316 with no further treatment[2]
- The Company continues pathway exploration for its continued development

“Each of our programs represents a different frontier where our products can change the trajectory of disease,” said Zachary Roberts, M.D., Ph.D., Executive Vice President of Research and Development and Chief Medical Officer. “Cema-cel has the potential to reshape first-line lymphoma treatment by reaching patients destined to suffer a cancer recurrence before they relapse. ALLO-329 is designed to bring CAR T into the autoimmune setting with a therapy that is scalable, precise, and potentially deliverable without traditional lymphodepletion. And ALLO-316 has shown promising activity in a metastatic solid tumor context – something many considered unattainable for cell therapy. What these programs collectively demonstrate is that allogeneic CAR T is no longer a theoretical platform. It is a clinical reality advancing across multiple major therapeutic areas.”

Cash Runway into 2H 2027
The Company continues to expect its cash runway to extend into the second half of 2027, excluding any impact from potential business development activities.

Together, these catalysts position Allogene to enter 2026 with an increasingly differentiated platform, strengthening fundamentals and the potential to reshape multiple high-value therapeutic categories through scalable, real-world allogeneic CAR T.

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 “expect,” “believe,” “aim,” “plan,” “intend,” “seek,” “estimate,” “target,” “potential,” “may,” “could,” “will,” “would,” “should,” “designed to,” and similar expressions. Forward-looking statements in this press release include, but are not limited to, statements regarding: expectations regarding 2026 as a program-defining year; the timing, design, conduct, and results of clinical trials and analyses, including the interim futility analysis and MRD clearance outcomes from the Phase 2 ALPHA3 trial of cemacabtagene ansegedleucel (cema-cel) and anticipated proof-of-concept data from the Phase 1 RESOLUTION trial of ALLO-329; the potential clinical benefits, safety, durability, and efficacy of Allogene’s product candidates; the potential to deliver CAR T therapy at biologic-like scale and in real-world or community care settings; expectations regarding simplified administration, outpatient compatibility, and broader physician adoption; expectations regarding manufacturing scalability, production capacity, cost-of-goods targets, and operational efficiency; the potential to reduce or eliminate lymphodepletion; the size, accessibility, and expansion of current or future markets, including in autoimmune disease and solid tumors; the continued development path for ALLO-316; and expectations regarding Allogene’s financial position, cash runway, and operating outlook. 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 the possibility that early-stage or interim data may not be predictive of later or final results; the novelty of Allogene’s allogeneic CAR T approach and the unproven nature of certain treatment settings, including first-line consolidation in LBCL and autoimmune disease indications; risks related to patient enrollment, trial execution, data interpretation, and timing of clinical readouts; the occurrence of adverse safety events; regulatory risks and uncertainties, including potential delays, disagreements with regulatory authorities, or requirements for additional studies or data; manufacturing and CMC risks, including challenges in achieving consistent, scalable, and cost-effective manufacturing; reliance on third parties and licensors; competitive developments; and financial risks, including continued operating losses and 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 Quarterly

Report on Form 10-Q 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.

Dagger® is a trademark of Allogene Therapeutics, Inc.

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. The anti-CD70 AlloCAR T program is licensed exclusively from Cellectis by Allogene and Allogene holds global development and commercial rights to this AlloCAR T program. ALLO-329 (CD19/CD70) in autoimmune disease uses CRISPR gene-editing technology.

Allogene Media/Investor Contact:
Christine Cassiano
EVP, Chief Corporate Affairs & Brand Strategy Officer
Christine.Cassiano@allogene.com

---

[1] ASCO 2025 data presentation

[2] Ruf et al., Clin Can Res. 2015

Source: Allogene Therapeutics, Inc.