Allogene Therapeutics Reports First Clinical Data from Phase 1 RESOLUTION Study of ALLO-329 in Autoimmune Disease

Nov 9, 2026 at 8:00 AM EST

- Favorable Early Safety Profile in 18 Patients with No DLTs, IEC-HS, ICANS, GvHD or Grade ≥3 CRS
- Initial Efficacy Analysis Focused on Skin-Predominant Systemic Sclerosis (SSc/Scleroderma), a Severe Autoimmune Disease with Significant Unmet Need
- Clinical Activity Observed in SSc Across All Lymphodepletion Approaches, Including No Lymphodepletion
- Eight of 10 Patients Treated for SSc Achieved and Maintained a Clinically Meaningful Improvement in Modified Rodnan Skin Score (mRSS); Nine of 10 Remained Off Background Immunosuppressive Therapy
- Webinar Scheduled for Today at 6:00 a.m. PT/9:00 a.m. ET Followed by a Poster Presentation at the 2026 American College of Rheumatology (ACR) Convergence

SOUTH SAN FRANCISCO, Calif., Nov. 09, 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 announced preliminary safety, efficacy and translational data from the ongoing Phase 1 RESOLUTION study evaluating ALLO-329, an investigational, next-generation, off-the-shelf allogeneic CAR T product designed specifically for autoimmune disease. The data are being presented today at the American College of Rheumatology (ACR) Convergence in Orlando, Florida.

ALLO-329 incorporates Allogene's proprietary Dagger ® technology, designed to enhance allogeneic CAR T activity while potentially reducing or eliminating conventional cytotoxic lymphodepletion (LD). The RESOLUTION trial is evaluating escalating doses of ALLO-329 with three LD conditioning regimens: no LD, cyclophosphamide (Cy) alone, or fludarabine plus cyclophosphamide (Flu/Cy). As of the September 21, 2026 data cutoff, 18 patients with systemic sclerosis (SSc/scleroderma), idiopathic inflammatory myopathies (IIM/myositis), or systemic lupus erythematosus (SLE/lupus) had received a single dose of ALLO-329 and completed the 28-day dose-limiting toxicity assessment period.

"These initial results provide a solid foundation for ALLO-329, our first dual targeting CAR T product to emerge from our Dagger pipeline," said Zachary Roberts, M.D., Ph.D., President and Chief Executive Officer of Allogene Therapeutics. "We are seeing meaningful and durable clinical improvement in patients with scleroderma across very different conditioning approaches, including without lymphodepletion, and even at the lowest cell doses studied. Our goal has always been to develop ALLO-329 with safety as the top priority while also delivering meaningful clinical benefit at a reduced treatment burden for patients with chronic autoimmune disease."

Favorable Early Safety Profile Across Lymphodepletion Approaches
ALLO-329 demonstrated a favorable early safety profile across all 18 patients. There were no dose-limiting toxicities (DLTs), immune effector cell-associated hemophagocytic syndrome (IEC-HS), immune effector cell-associated neurotoxicity syndrome (ICANS), graft-versus-host disease (GvHD) or Grade ≥3 CRS events in any patient. Four patients (22%) experienced CRS (three with Grade 1, and one with Grade 2). All patients experienced at least one TEAE with 83% being Grade 1 or Grade 2. No patients in the no-LD cohorts experienced any TEAEs greater than Grade 2.

Summary of Adverse Events

	20M/40M no LD (n=6)	20M/40M/80M + Cy (n=9)	40M + FC (n=3)	Total (N=18)
TEAEs, n (%)				
Any grade	6 (100.0)	9 (100.0)	3 (100.0)	18 (100.0)
Grade ≥3	0	3 (33.3)	0	3 (16.7)
TESAEs, n (%)				
Any grade	1 (16.7)	4 (44.4)	1 (33.3)	6 (33.3)
Grade ≥3	0	1 (11.1)	0	1 (5.6)
TEAEs of special interest, n (%)				
CRS, any grade	1 (16.7)	2 (22.2)	1 (33.3)	4 (22.2)
CRS, Grade ≥3	0	0	0	0
ICANS, any grade	0	0	0	0
IEC-HS, any grade	0	0	0	0
Infections, any grade	0	2 (22.2)	1 (33.3)	3 (16.7)
Infections, Grade ≥3	0	0	0	0
GvHD, any grade	0	0	0	0
Prolonged Grade ≥3 cytopenia	0	1 (11.1)	0	1 (5.6)

DLTs, n (%)	0	0	0	0

Early, Clinically Meaningful Activity in Scleroderma
The initial efficacy analysis focuses on 10 patients with skin-predominant SSc, a serious autoimmune disease associated with substantial morbidity and mortality for which current therapies are largely chronic, immunosuppressive and organ-directed. No therapy has been shown to reliably halt or reverse disease progression. Four patients with IIM, two patients with SLE, and two patients with non-skin-predominant SSc were also treated as of the data cutoff and are expected to be the focus of future presentations.

Preliminary efficacy was observed in these 10 patients with early and durable improvements in modified Rodnan skin score (mRSS), a validated measure of skin involvement. Improvements were observed as early as Day 14 across all three ALLO-329 dose levels and LD approaches evaluated as of the data cutoff, including without LD. Eight of 10 patients achieved and maintained a five-point or greater improvement in mRSS, with several patients experiencing rapid and substantially greater reductions of 10 points or more. Notably, four patients achieved total mRSS scores below 10, reflecting a low level of skin involvement, despite having progressive disease at baseline. Nine of 10 patients remained off background immunosuppressive therapy as of the data cutoff, with the longest treatment-free interval ongoing beyond eight months.

Individual patient assessments showed improvements beyond skin score, including in validated measures of patient-reported disease impact and physical function. In one patient treated with 40 million cells plus Cy, improvement in mRSS was accompanied by improvement in Patient Global Assessment, resolution of tendon friction rubs, and improvement in the Health Assessment Questionnaire-Disability Index (HAQ-DI), a validated measure of functional disability. In a second patient treated with 40 million cells and no-LD, digital ulcers and tendon friction rubs resolved, and HAQ-DI improved from 1.63 to 0, a change that substantially exceeds published estimates of the minimal clinically important difference for HAQ-DI in systemic sclerosis. These multidimensional improvements are notable in a disease where approved therapies have generally demonstrated benefit in specific organ-based endpoints rather than across skin, function and patient-reported outcomes simultaneously.

“Systemic sclerosis remains a disease with substantial unmet need, particularly for patients who continue to progress despite immunosuppressive therapy,” said Vivek Nagaraja, M.D., FACR, Mayo Clinic Arizona and lead author of the ACR poster presentation. “In this early cohort, we observed clinically meaningful reductions in skin involvement across the treatment approaches evaluated, including in patients who stopped their immunosuppressant regimens and received ALLO-329 without lymphodepleting chemotherapy. The consistency of the initial clinical improvement across conditioning regimens is encouraging, particularly given that these observations are occurring early in dose escalation. Continued follow-up will provide further insight into the durability of these encouraging early skin responses.”

Study Design Provides Insight into the Role of Lymphodepletion
RESOLUTION’s novel parallel dose-escalation design enables systematic evaluation of conditioning intensity, helping distinguish ALLO-329–mediated effects from those of chemotherapy-based conditioning and define the minimum lymphodepletion, if any, needed for meaningful clinical activity.

B-cell suppression occurred across all LD approaches, with the depth of B-cell and total lymphocyte suppression increasing with lymphodepletion intensity. Pre-treatment B-cell and lymphocyte counts recovered most rapidly in patients with no LD. Importantly, durable clinical improvement occurred without complete peripheral B-cell depletion, raising the possibility that peripheral B-cell aplasia may not be required to achieve an immune reset.

“RESOLUTION was designed not only to determine whether ALLO-329 can treat autoimmune disease, but to understand which components of the treatment regimen are contributing to clinical activity,” said Eric Zollars, M.D., Ph.D., Vice President, Clinical Development in Autoimmune Disease at Allogene. “Clinical improvement across the three lymphodepletion regimens at these early doses, as well as clear differences in depth and duration of lymphocyte count suppression, should help us to identify a regimen that optimizes benefit and risk while reducing chemotherapy and lengthy intervals of immune suppression.”

RESOLUTION Study Next Steps
RESOLUTION (NCT07085104) is a first-in-human Phase 1 study evaluating escalating doses of ALLO-329 with and without lymphodepletion in adults with active SSc, IIM and SLE. The dose-escalation portion includes five planned ALLO-329 dose levels (20 million, 40 million, 80 million, 160 million and 320 million cells). Enrollment began in November 2025 and dose escalation continues to inform selection of a Phase 2 regimen. The next data readout is planned for 2027.

ALLO-329 Webinar
The Company will host a webinar on Monday, November 9, 2026, at 6:00 a.m. PT/9:00 a.m. ET to review preliminary safety and efficacy data from the ongoing Phase 1 RESOLUTION study of ALLO-329 in adults with autoimmune diseases. The conference call will precede the poster presentation of the first clinical results from the program at American College of Rheumatology (ACR) Convergence.

- **Listen-Only Version of the Webinar**
  The listen-only webinar will be made available on the Company's website at www.allogene.com under the Investors tab in the News and Events section. A replay will be available on the Company's website for approximately 30 days.
- **Webinar Registration for Questions**
  If you would like the option to ask a question on the webinar, please use this link to register. Upon registering for the webinar, you will receive a personal PIN to access the call.

ACR Poster Presentation Details:

- **Session:** Systemic Sclerosis & Related Disorders - Treatment Poster Session B
- **Title:** Preliminary Safety and Efficacy Results from a First-in-Human Phase 1 Clinical Study of ALLO-329, a Dual Anti-CD19/Anti-CD70 Allogeneic CAR T-Cell Therapy for Autoimmune Disease
- **Presenting Author:** Vivek Nagaraja, MD, FACR, Mayo Clinic Arizona
- **Date/Time:** Monday, November 9, 2026, 10:30 a.m.-12:30 p.m. ET

About ALLO-329
ALLO-329 is a CD19/CD70 dual targeted investigational product being developed for the treatment of autoimmune diseases. In April 2025, the U.S. Food and Drug Administration granted three Fast Track Designations (FTD) to ALLO-329 for the treatment of adult patients with lupus, myositis, and scleroderma. ALLO-329 utilizes CRISPR-based site-specific integration for dual CAR expression. This approach targets both CD19+ B cells and CD70+ T cells, which play a role in autoimmune disease pathogenesis. Additionally, ALLO-329 incorporates Allogene's clinically validated Dagger® technology, designed to reduce or eliminate the need for lymphodepletion, a pre-treatment regimen that may be a significant barrier to CAR T cell therapy adoption in autoimmune indications.

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 a management team with significant experience in cell therapy, 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 @AllogeneTx on X (formerly Twitter) 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. 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," "anticipate," "support," "designed to" and similar expressions. Forward-looking statements in this press release include, but are not limited to, statements regarding the timing, design, conduct, advancement and results of the RESOLUTION trial of ALLO-329, including continued dose escalation, selection of a Phase 2 regimen and the timing of future data readouts; the potential safety, tolerability, efficacy and durability of ALLO-329; the potential for ALLO-329 to provide clinical benefit in patients with autoimmune diseases, including systemic sclerosis, idiopathic inflammatory myopathies and systemic lupus erythematosus; the potential for ALLO-329 and Allogene's Dagger® technology to reduce or eliminate the need for conventional lymphodepletion and reduce treatment burden; the potential significance of clinical activity observed across different lymphodepletion approaches and dose levels; the potential relationship between B-cell depletion, lymphodepletion and clinical activity, including whether peripheral B-cell aplasia is necessary to achieve an immune reset; and the potential value and advantages of allogeneic CAR T therapies in autoimmune disease. 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 preliminary, interim or early clinical data, including data from a small number of patients, may not be predictive of later or final results or clinical outcomes; the potential for additional data or longer follow-up to differ from initial results; patient enrollment and clinical trial execution risks; 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 Quarterly Report on Form 10-Q filed with the SEC and in Allogene's subsequent filings 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.

ALLO-329 (CD19/CD70) in autoimmune disease uses CRISPR gene-editing technology.

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

Leslie Bryant
Executive Director, Corporate Communications
Leslie.Bryant@allogene.com