# Allogene Granted Three U.S. FDA Fast Track Designations (FTD) for ALLO-329, a Next-Generation Dual-Targeted CD19/CD70 Allogeneic CAR T, for the Treatment of Lupus, Myositis and Scleroderma

Apr 7, 2025 at 8:30 AM EDT

- Designations Follow Recent Investigational New Drug (IND) Application Clearance for the RESOLUTION Basket Study of ALLO-329 in Rheumatology
- Dual CD19/CD70 CAR T Specifically Designed to Enhance Therapeutic Benefit, Expanding Treatment Potential Across a Range of Autoimmune Indications
- Leverages Proprietary Dagger® Technology to Reduce or Eliminate Lymphodepletion, Potentially Expanding Access to a Broader Patient Population
- Phase 1 RESOLUTION Trial Initiation Planned for Mid-2025 with Initial Proof-of-Concept by Year-End 2025

SOUTH SAN FRANCISCO, Calif., April 07, 2025 (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 that ALLO-329, an investigational dual-targeted CD19/CD70 allogeneic CAR T, has received three Fast Track Designations (FTD) from the U.S. Food and Drug Administration (FDA) for the treatment of adult patients with:

- active refractory moderate-to-severe systemic lupus erythematous (SLE);
- active severe/refractory idiopathic inflammatory myopathy (IIM), specifically dermatomyositis, immune mediated necrotizing myopathy and anti-synthetase syndrome; and
- active refractory diffuse systemic sclerosis (SSc).

"Receiving these designations for ALLO-329 underscores the versatility and transformative promise of this next-generation allogeneic CAR T investigational product in redefining the autoimmune treatment landscape," said Zachary Roberts, M.D., Ph.D., EVP of Research and Development and Chief Medical Officer of Allogene. "Leveraging our extensive expertise, we've developed this off-the-shelf CAR T specifically for autoimmune diseases, prioritizing both scalability and the reduction or elimination of lymphodepletion – a key barrier in this patient population."

The Company expects to initiate the Phase 1 RESOLUTION basket trial in mid-2025. The trial is designed to evaluate the safety and preliminary efficacy of ALLO-329 in patients with SLE, IIM, and SSc. This innovative trial design, which leverages the clinically validated Dagger® technology to drive CAR T cell expansion and prevent rejection, includes two distinct lymphodepletion arms: one using a dose of cyclophosphamide alone, which is used by rheumatologists, and another that eliminates lymphodepletion entirely. Proof-of-concept from the RESOLUTION trial is expected by year-end 2025, aiming to provide critical insights into the potential of ALLO-329 to transform the treatment landscape for autoimmune diseases.

FDA's Fast Track designation is designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening diseases and that demonstrate the potential to address unmet medical needs.

**About ALLO-329**

ALLO-329 is a CD19/CD70 dual AlloCAR T ™ investigational product being developed for the treatment of autoimmune diseases. 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 Allogene Therapeutics on X and LinkedIn.

**Cautionary Note on Forward-Looking Statements for Allogene**

This press release contains forward-looking statements for purposes of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. The press release may, in some cases, use terms such as “potential,” “designed to,” “planned,” “will,” “may,” “promise,” “aim,” “redefining,” “goal,” “expects,” “transform,” “target,” or other words that convey uncertainty of future events or outcomes 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 ability for a dual-targeted CD19/CD70 allogeneic Car T to enhance therapeutic benefit and expand treatment across a range of autoimmune indications; the potential for ALLO-329 and our Dagger technology to drive CAR T cell expansion and prevent rejection and reduce or eliminate lymphodepletion, and expand access to a broader patient population; our ability to initiate our Phase 1 RESOLUTION rheumatology basket trial in mid-2025, and achieve proof-of-concept to demonstrate the Dagger ™ effect on lymphodepletion by year-end 2025; the

potential benefits of ALLO-329 and our Dagger technology; the potential for ALLO-329 to transform the treatment landscape for autoimmune diseases; the potential for ALLO-329 to treat patients with SLE, IIM, or SSc; and our ability to manufacture to meet the scale required to treat autoimmune disease. Various factors may cause material differences between Allogene's expectations and actual results, including, risks and uncertainties related to: Fast Track designation may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval and the designation can be revoked if the criteria for eligibility ceases to be met; our product candidates are based on novel technologies, which makes it difficult to predict the time and cost of product candidate development and obtaining regulatory approval; the limited nature of our pre-clinical data and the extent to which such data may or may not be validated in any future clinical trial; our product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval or limit their commercial potential; the extent to which the Food and Drug Administration disagrees with our clinical or regulatory plans or the import of our clinical results, which could cause future delays to our clinical trials, including initiation of clinical trials, or require additional clinical trials; we may encounter difficulties enrolling patients in our clinical trials; we may not be able to demonstrate the safety and efficacy of our product candidates in our clinical trials, which could prevent or delay regulatory approval and commercialization; and the challenges with manufacturing or optimizing manufacturing of our product candidates. These and other risks are discussed in greater detail in Allogene's filings with the SEC, including without limitation under the "Risk Factors" heading in its Form 10-K filed for the year ended December 31, 2024. Any forward-looking statements that are made in this press release speak only as of the date of this press release. Allogene assumes no obligation to update the forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.



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

Source: Allogene Therapeutics, Inc.