Allogene Therapeutics Presents Preclinical Data for ALLO-329, an Allogeneic CD19/CD70 Dual CAR T for the Treatment of Autoimmune Disease at the American College of Rheumatology (ACR) Convergence

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- ALLO-329 Induces Deep, Transient Depletion of CD19+ B Cells and CD70+ T Cells, and Reduction in IgG and IgM without Lymphodepletion in Humanized Murine Models
- Proprietary Dagger® Technology Enables ALLO-329 to Overcome Rejection and Expand the Presence of Alloreactive T Cells
- Presented Data Demonstrates that ALLO-329 Could Be Effective in Treating Autoimmune Diseases with Reduced or No Lymphodepleting Chemotherapy
- ALLO-329 Investigational New Drug (IND) Submission Planned for Q1 2025

SOUTH SAN FRANCISCO, Calif., Nov. 18, 2024 (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 preclinical data for ALLO-329, an investigational allogeneic CD19/CD70 dual CAR T cell therapy being evaluated as a treatment for autoimmune diseases. The data, presented at the American College of Rheumatology (ACR) Convergence 2024, demonstrate the potential of ALLO-329 to specifically address key challenges associated with current autologous CAR T cell therapies in development for patients with autoimmune disease and highlights the promise of an allogeneic CAR T to reset the immune system.

ALLO-329 is the first CAR T designed to target both CD19+ B-cells and CD70+ activated T cells. Targeting of B cells has been shown to induce durable, treatment-free remissions in patients with certain autoimmune diseases. CD70 is expressed in activated T cells, which have been implicated in immune responses, including in autoimmunity. Simultaneous elimination of CD70+ T cells may enhance the therapeutic benefit and expand the list of addressable indications.

CD70+ activated T cells also include alloreactive T-cells – the patient's cells that would attack and reject an allogeneic CAR- T. ALLO-329 is designed to effectively eliminate alloreactive T-cells and render ALLO-329 resistant to rejection. Incorporation of Dagger® technology into ALLO-329 is intended to reduce or eliminate lymphodepletion prior to cell infusion.

"The CAR T space for autoimmune disease is highly competitive, with many approaches focusing only on isolated aspects of autoimmune pathogenesis," said Zachary Roberts, M.D., Ph.D., EVP, Research and Development and Chief Medical Officer of Allogene. "What sets ALLO-329 apart is its ability to target a greater spectrum of immune dysfunction, addressing both B cells and activated T-cells involved in the disease process, potentially improving disease outcomes with reduced or even no lymphodepletion. Coupled with its "off-the-shelf" accessibility, ALLO-329 has the potential to meet the substantial needs of a broad patient population. These preclinical findings reinforce our excitement as we move this therapy toward clinical development across multiple autoimmune conditions."

Key findings from the preclinical evaluation of ALLO-329 include:

- High CAR expression and cytotoxic activity: ALLO-329 produced through site-specific integration of a dual CAR construct into the TRAC locus demonstrated robust CAR expression and specific cytotoxic activity against both CD19+ B cells and CD70+ T cells *in vitro* and *in vivo*.
- Resistance to rejection: In mixed lymphocyte reaction (MLR) assays, ALLO-329 successfully eliminated CD70+ alloreactive T cells, demonstrating resistance to rejection and enhanced persistence compared to CD19 CAR T cells.
- B cell depletion and antibody reduction: ALLO-329 effectively eradicated B cells derived from healthy donors and patients with systemic lupus erythematosus (SLE) *in vitro* and *in vivo*, leading to a reduction in IgG and IgM production.
- Potential to eliminate lymphodepletion: In humanized pre-clinical models, ALLO-329 demonstrated engraftment, B cell depletion, and expansion even without lymphodepletion.
- Manufacturability: CRISPR-mediated, T-cell receptor alpha (*TRAC*) site-specific transgene integration leads to a highly consistent, dual CAR T-expressing product.

Based on these promising preclinical results, the Company plans to file an investigational new drug (IND) application with the FDA in the first quarter of 2025 and expects to have proof-of-concept by year-end 2025.

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 @AllogeneTx 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,” “develop,” “promise,” “designed to,” “explore,” “expects,” “plans,” “intends,” “may,” “could,” “would,” 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 timing of filing Investigational New Drug applications relating to ALLO-329 and the progress and success of such clinical program; clinical outcomes, which may materially change as more patient data become available; the design and potential benefits of ALLO-329 and our Dagger™ technology including the ability overcome rejection and expand the presence of alloreactive T-cells, to enhance engraftment, expansion and persistence of AlloCAR T cells, the ability to resist rejection of AlloCAR T cells by the host immune cells and the expected benefits therefrom, or the ability to target CD19+ B-cells and CD70+ activated T-cells that will induce durable, treatment-free remissions or enhance the therapeutic benefits in autoimmune disease, and our plans to deploy the Dagger ™technology; the potential that our dual CAR targeting B- and T-cell components of autoimmune disease will allow for broader application of CAR T across multiple autoimmune conditions; the potential benefits of AlloCAR T products; the ability of our product candidates to treat autoimmune disease; the potential for off-the-shelf CAR T products; our ability to deliver cell therapy on-demand, more reliably, and at greater scale to more patients. Various factors may cause material differences between Allogene’s expectations and actual results, including, risks and uncertainties related to: 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 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 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.

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