Allogene Therapeutics Secures U.S. FDA IND Clearance for ALLO-329, Advancing its Next-Generation Allogeneic CAR T into Autoimmune Diseases

Jan 28, 2025 at 8:30 AM EST

- **Dual-Targeted CD19/CD70 Allogeneic CAR T:** Best-in-Class Design to Enhance Therapeutic Benefit and Expand Treatment Potential Across a Range of Autoimmune Disease Indications
- **Innovative Dagger® Technology:** Empowers ALLO-329 to Overcome Rejection, Potentially Reducing or Eliminating Reliance on Traditional Lymphodepletion
- **Phase 1 RESOLUTION Rheumatology Basket Trial:** Initiation Planned for Mid-2025, Targeting Proof-of-Concept to Demonstrate Allogeneic Potential and the Dagger® Effect on Lymphodepletion by Year-End 2025

SOUTH SAN FRANCISCO, Calif., Jan. 28, 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 the U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application for a rheumatology basket study of ALLO-329, an investigational allogeneic CAR T product.

The Phase 1 RESOLUTION basket trial will evaluate the safety and preliminary efficacy of ALLO-329 in patients with systemic lupus erythematosus, including lupus nephritis, idiopathic inflammatory myopathies, and systemic sclerosis. 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. The RESOLUTION trial is scheduled to begin in mid-2025, aiming to provide critical insights into the potential of ALLO-329 to transform the treatment landscape for autoimmune diseases.

“A year ago, we unveiled the concept of ALLO-329, an allogeneic CAR T product specifically designed to address the unique challenges faced by patients with autoimmune diseases. Today, with the FDA’s clearance of our IND, that vision has become a reality, achieved at an extraordinary pace thanks to Allogene’s unparalleled expertise in research, manufacturing, and clinical development,” said David Chang, M.D., Ph.D., President, CEO, and Co-Founder of Allogene. “Demonstrating the power of an allogeneic CAR T to reset the immune system, combined with the ability of our Dagger ® technology to reduce or eliminate lymphodepletion, could represent a transformative step forward. Successful proof-of-concept in this basket study has the potential to not only validate our best-in-class approach but also paves the way for expanding into a broad range of autoimmune indications beyond rheumatology.”

ALLO-329 represents a next-generation approach to autoimmune therapy, featuring a dual-targeting design against CD19+ B-cells and CD70+ activated T-cells. This innovative strategy is designed to deliver superior therapeutic benefit by addressing both B-cell and T-cell dysfunction, which drive immune dysregulation in autoimmune diseases. The incorporation of Allogene’s proprietary Dagger ® technology further empowers ALLO-329 to resist immune rejection, potentially reducing or eliminating the need for lymphodepletion before cell infusion. If successful, this CAR T advancement could significantly simplify treatment protocols, meet the potential scale required to treat autoimmune disease with the capacity to manufacture upwards of 60,000 doses per year, and expand access to transformative CAR T therapy across a wide range of autoimmune disease indications.

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,” “could,” “designed to,” “planned,” “will,” “advance,” “aim,” “scheduled,” “goal,” “empower,” 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 overcome, or prevent, rejection and reduce or eliminate lymphodepletion; our ability to initiate our Phase 1 RESOLUTION rheumatology basket trial by 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 ability to

target CD19+ B-cells and CD70+ activated T-cells to deliver superior therapeutic benefit; the ability for ALLO-329 to address both B-cell and T-cell dysfunction, drive immune dysregulation in autoimmune diseases, and simplify treatment protocols; the potential for ALLO-329 to transform the treatment landscape for autoimmune diseases; the potential for ALLO-329 to treat patients with systemic lupus erythematosus; the ability for an allogeneic CAR T to reset the immune system; the potential to expand into a broad range of autoimmune indications beyond rheumatology; 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: IND clearance 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 from our clinical trials 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-Q filed 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.

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.