Allogene Therapeutics Reports FDA Clinical Hold of AlloCAR T Trials Based on a Single Patient Case in ALPHA2 Trial

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- Testing in a Patient with Low Blood Counts Showed a Chromosomal Abnormality in ALLO-501A CAR T Cells of Unclear Clinical Significance; Patient Achieved a Partial Response to Therapy
- Investigation Ongoing to Further Characterize the Finding, Including Any Clinical Relevance, Evidence of Clonal Expansion, or Potential Relationship to Gene Editing
- Company Believes Data from the ALPHA Trials Demonstrates a Favorable Clinical Profile of ALLO-501A
- FDA Continues to Review End of Phase 1 Materials for a Phase 2 Pivotal Trial of ALLO-501A
- Company to Host Conference Call Today at 2:00 p.m. PT/5:00 p.m. ET

SOUTH SAN FRANCISCO, Calif., Oct. 07, 2021 (GLOBE NEWSWIRE) -- Allogene Therapeutics, Inc. (Nasdaq: ALLO), a clinical-stage biotechnology company pioneering the development of allogeneic CAR T (AlloCAR T™) therapies for cancer, today reported that following a report of a chromosomal abnormality in ALLO-501A CAR T cells in a patient treated in the ALPHA2 study, the U.S. Food and Drug Administration (FDA) has placed a hold on the Company's AlloCAR T clinical trials.

The Company expects to provide additional updates in the coming weeks following consultation with the FDA. The FDA continues to actively review the end of Phase 1 materials submitted in anticipation for an ALLO-501A pivotal Phase 2 trial.

"Patient safety is our highest priority, and we are committed to working closely with the FDA to evaluate any potential clinical implications of this finding, and determine next steps for advancing ALLO-501A and our clinical programs," said Rafael Amado, M.D., Executive Vice President of Research and Development and Chief Medical Officer. "As a leading developer of allogeneic cell therapies, we recognize our added responsibility to fully assess all aspects of our therapies to advance the field. We are grateful for the partnership with the patient community, clinical investigators, our Scientific Advisory Board, and the FDA as we work diligently toward understanding the clinical significance of this finding and to support the development of allogeneic CAR T therapy for cancer."

The clinical hold follows the Company's notification to the FDA of a chromosomal abnormality in an ALPHA2 study patient which was detected in a bone marrow biopsy undertaken to assess pancytopenia (low blood counts). An investigation is underway to further characterize the observed abnormality, including any clinical relevance, evidence of clonal expansion, or potential relationship to gene editing.

The single case involves a patient with Stage IV transformed follicular lymphoma and c-myc rearrangement whose cancer was refractory to two prior lines of immune-chemotherapy and additional radiation therapy. The patient could not receive an autologous CD19 CAR T cell therapy due to manufacturing failure associated with inadequate expansion of autologous CAR T cells.

Following infusion of ALLO-501A, the patient experienced Grade 1 CRS and Grade 2 ICANS, which required a course of high dose steroid therapy. The patient subsequently developed progressive pancytopenia and a bone marrow biopsy showed aplastic anemia and the presence of ALLO-501A CAR T cells with the chromosomal abnormality. Early translational data showed that the CAR T cells expanded, peaking on Day 28, and undergoing contraction thereafter. The patient had a partial response to ALLO-501A and subsequently underwent allogeneic stem cell transplantation. Prolonged cytopenia requiring rescue stem cell transplantation has been reported in autologous CAR T therapies.

Allogene has dosed more than 100 patients with its gene edited AlloCAR T products. The Company believes the data generated from the ALPHA trials support a favorable clinical profile for ALLO-501A in patients with large B cell lymphoma.

Conference Call and Webcast Details
Allogene will host a live conference call and webcast today at 2:00 p.m. Pacific Time / 5:00 p.m. Eastern Time to provide a business update. To access the live conference call by telephone, please dial 1 (866) 940-5062 (U.S.) or 1 (409) 216-0618 (International). The conference ID number for the live call is 9746209. The webcast will be made available on the Company's website at www.allogene.com under the Investors tab in the News and Events section. Following the live audio webcast, a replay will be available on the Company's website for approximately 30 days.

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™) therapies for cancer. Led by a management team with significant experience in cell therapy, Allogene is developing a pipeline of "off-the-shelf" CAR T cell therapy 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 Twitter and LinkedIn.

Cautionary Note on Forward-Looking Statements
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 "predicts," "believes," "potential," "proposed," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should" 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 clinical significance of the chromosomal abnormality and any relationship to gene editing, the clinical profile of ALLO-501A, the timing and result of additional communications with the FDA regarding the clinical hold or the ALLO-501A end of Phase 1 materials, the ability to develop allogeneic CAR T therapies for cancer, and the potential benefits of AlloCAR T therapy. Various factors may cause differences between Allogene's expectations and actual results as discussed in greater detail in Allogene's filings with the SEC, including without limitation in its Form 10-Q for the quarter ended June 30, 2021. 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.

AlloCAR T™ is a trademark of Allogene Therapeutics, Inc.

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