Allogene Therapeutics Announces Removal of FDA Clinical Hold Across All AlloCAR T™ Clinical Trials

January 10, 2022

- Investigation Confirmed the Chromosomal Abnormality in a Single Patient was Not Observed in Any AlloCAR T Product and Not Related to Allogene Manufacturing Process or TALEN® Gene Editing
- Clinical Trials Across the AlloCAR T Platform to Resume
- Pivotal Phase 2 Trial of ALLO-501A in Relapsed/Refractory Large B Cell Lymphoma Expected to Commence in Mid-Year 2022 Pending FDA Discussions
- Company to Host Conference Call Today at 8:30 am PT/11:30 am ET

SOUTH SAN FRANCISCO, Calif., Jan. 10, 2022 (GLOBE NEWSWIRE) -- Allogene Therapeutics, Inc. (Nasdaq: ALLO), a clinical-stage biotechnology company pioneering the development of allogeneic CAR T (AlloCAR T™) products for cancer, today announced that the U.S. Food and Drug Administration (FDA) has removed the clinical hold on all of the Company's AlloCAR T clinical trials. Allogene previously announced on October 7, 2021 that the FDA had placed a hold on all five of the Company's AlloCAR T clinical trials based on a report of a chromosomal abnormality detected post-AlloCAR T administration in a single patient treated with ALLO-501A in the ALPHA2 study.

Investigations concluded that the chromosomal abnormality was unrelated to TALEN® gene editing or Allogene's manufacturing process and had no clinical significance. The abnormality was not detected in any manufactured AlloCAR T product or in any other patient treated with the same ALLO-501A lot. The abnormality occurred in the patient after the cell product was administered. It involved regions of the T cell receptor and immunoglobulin genes known to undergo rearrangement as part of the T cell or B cell maturation process.

Allogene will be working with clinical trial investigators to resume study activities across AlloCAR T development programs as quickly as possible. Pending final discussions with the FDA, the Company also plans to initiate its pivotal Phase 2 trial of ALLO-501A in relapsed/refractory Large B Cell Lymphoma (LBCL) mid-year 2022.

"We are thankful for the partnership between our teams at Allogene, our clinical trial investigators who remain steadfast in their support of our investigational therapies, and the FDA which expeditiously completed its review of our Complete Response Letter," said Rafael Amado, M.D., Executive Vice President of Research and Development and Chief Medical Officer. "Allogeneic CAR T therapy is a rapidly developing field that continues to evolve both in scope and impact, and the findings from our investigation will help advance innovation in the fields of gene editing and cell and gene therapy. As the leading developer of allogeneic cell products, we look forward to resuming our clinical trials as we work to fulfill our commitment to bring patients the first allogeneic CAR T product."

Conference Call and Webcast Details
Allogene will host a live conference call and webcast today at 8:30 a.m. Pacific Time / 11:30 a.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 8598466. 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™) products 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 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 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 ability and timing to reinitiate AlloCAR T trials and advance to the Phase 2 portion of the ALPHA2 trial of ALLO-501A; the final results of the investigation, including the clinical significance of the chromosomal abnormality and any relationship to gene editing or manufacturing; the ability to manufacture and 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 September 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.

Allogene therapies utilize TALEN® gene-editing technology pioneered and owned by Cellectis. ALLO-501 and ALLO-501A are anti-CD19 AlloCAR T™ therapies being jointly developed under a collaboration agreement between Servier and Allogene based on an exclusive license granted by Cellectis to Servier. Servier grants to Allogene exclusive rights to ALLO-501 and ALLO-501A in the U.S. while Servier retains exclusive rights for all

other countries. Allogene has an exclusive license to the Cellectis technology for allogeneic products directed at BCMA, FLT3, DLL3 and CD70.

AlloCAR T™ is a trademark of Allogene Therapeutics, Inc.
TALEN® is a registered trademark of Cellectis S.A.

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