Allogene Therapeutics Announces the FDA Granted Regenerative Medicine Advanced Therapy (RMAT) Designation to ALLO-501A for Large B Cell Lymphoma

June 8, 2022

- RMAT Designation Follows Positive Data from ALLO-501A ALPHA2 Trial in Heavily Pretreated Patients with Relapsed or Refractory Large B cell Lymphoma (LBCL)
  - Data Presented at the American Society of Hematology (ASH) 2021 Annual Meeting Demonstrated AlloCAR T™ Could be Safe and Effective in Producing Durable Responses
  - In the ALPHA Trials with ALLO-501 and ALLO-501A, Treatment was Initiated Approximately 2 Days from Enrollment, Eliminating Any Need for Bridging Therapy
- Company Intends to Initiate a Phase 2 Pivotal Trial in Mid-2022

SOUTH SAN FRANCISCO, Calif., June 08, 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) granted Regenerative Medicine Advanced Therapy (RMAT) designation to ALLO-501A in relapsed/refractory LBCL. The RMAT designation was based on the potential of ALLO-501A to address the unmet need for patients who have failed other therapies.

"The designation for ALLO-501A supports the patient need for access to an off-the-shelf CAR T product that can be delivered faster, more reliably, and at greater scale," said Rafael Amado, M.D., Executive Vice President of Research and Development and Chief Medical Officer. "Patients who are eligible for autologous CAR T therapy are often faced with treatment delays and manufacturing failures, placing them at risk for disease progression and disease-related complications. We look forward to initiating our pivotal trial on ALLO-501A and making this innovative product candidate readily available to patients."

Results from the ALPHA2 study were presented at an oral session of the American Society of Hematology (ASH) annual meeting in December 2021. Data support the potential of ALLO-501A to provide a safe and durable alternative to approved autologous CAR T therapies in CAR T naïve patients.

- ALLO-501A was associated with consistent and manageable safety with no dose limiting toxicities (DLTs) or graft-vs-host disease (GvHD) and minimal Grade 3 Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS), or Grade 3 cytokine release syndrome (CRS).
- There were no relapses observed in LBCL CAR T naïve patients who were in a complete response (CR) at six months with the longest ongoing CRs with ALLO-501A at 15+ months.
- Nearly all enrolled patients were able to receive therapy with the median time from enrollment to initiation of treatment of two days in ALPHA2.

Established under the 21st Century Cures Act, RMAT designation is a dedicated program designed to expedite the development and review processes for promising pipeline products, including cell therapies, that includes all the benefits of Fast Track and Breakthrough designation. An investigational cell therapy is eligible for RMAT designation if it is intended to treat, modify, reverse, or cure a serious or life-threatening disease; and preliminary clinical evidence indicates that the therapy has the potential to address unmet medical needs for that disease. Advantages of the RMAT designation include early interactions with FDA that may be used to discuss potential surrogate or intermediate endpoints and potential ways to satisfy post approval requirements.

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 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 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 "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 timing and ability to progress the ALPHA2 trial of ALLO-501A, including initiating a pivotal clinical trial of ALLO-501A, which remains subject to further patient follow-up and discussions with the U.S. Food and Drug Administration; the ability to commercialize ALLO-501A; clinical outcomes, which may materially change as patient enrollment continues and more patient data become available; and the potential benefits of AlloCAR T™. 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 March 31, 2022. 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.

Allogene's AlloCAR T™ programs utilize Cellectis technologies. ALLO-501 and ALLO-501A are anti-CD19 products 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 Media/Investor Contact:
Christine Cassiano
Chief Communications Officer
(714) 552-0326
Christine.Cassiano@allogene.com

Source: Allogene Therapeutics, Inc.