Allogene Therapeutics Announces FDA Regenerative Medicine Advanced Therapy (RMAT) Designation Granted to ALLO-715, an AlloCAR T™ Cell Therapy in Development for Relapsed/Refractory Multiple Myeloma

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- RMAT Designation Follows Proof-of-Concept Data from ALLO-715 UNIVERSAL Trial in Heavily Pretreated, Refractory Multiple Myeloma Patients
- UNIVERSAL Trial Demonstrated for the First Time that an Allogeneic CAR T Therapy Directed at BCMA Can Achieve Clinical Responses While Eliminating the Need for Bridging Therapy or Delays in Treatment Associated with Manufacturing

SOUTH SAN FRANCISCO, Calif., April 21, 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 announced that the U.S. Food and Drug Administration (FDA) granted Regenerative Medicine Advanced Therapy (RMAT) designation to ALLO-715 in relapsed/refractory multiple myeloma. The FDA granted RMAT designation based on the potential of ALLO-715 to address the growing unmet need for patients who have failed other multiple myeloma therapies.

“RMAT designation was granted based on our encouraging initial clinical experience in heavily pretreated patients. ALLO-715 demonstrated for the first time that an allogeneic CAR T therapy directed at BCMA can achieve deep clinical responses while eliminating the need for bridging therapy and delays associated with autologous CAR T manufacturing,” said Rafael Amado, M.D., Executive Vice President of Research and Development and Chief Medical Officer. “We look forward to completing the UNIVERSAL study and working closely with the FDA as we seek to rapidly advance this important therapeutic alternative to patients with advanced multiple myeloma.”

Initial results from the UNIVERSAL study were presented at an oral session of the American Society of Hematology (ASH) annual meeting in December 2020. As part of the Company’s anti-BCMA strategy, the Phase 1 UNIVERSAL study continues to optimize the dosing regimen of ALLO-715 and ALLO-647. The UNIVERSAL study is also enrolling patients to receive ALLO-715 in combination with SpringWorks Therapeutics’ investigational gamma secretase inhibitor, nirogacestat.

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™) 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 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 ability to progress the Phase 1 UNIVERSAL trial of ALLO-715; data and clinical outcomes, which may materially change as patient enrollment continues and more patient data become available; and the potential benefits of AlloCAR T therapies. 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-K for the year ended December 31, 2020. 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-715 utilizes TALEN® gene-editing technology pioneered and owned by Cellectis. Allogene has an exclusive license to the Cellectis technology for allogeneic products directed at BCMA and holds all global development and commercial rights for these investigational candidates.

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