Allogene Therapeutics Receives FDA Orphan Drug Designation (ODD) for ALLO-715 for the Treatment of Multiple Myeloma (MM)

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- ODD Follows RMAT Designation Granted to ALLO-715 by the U.S. Food and Drug Administration in Multiple Myeloma Patients
- Phase 1 Data from the ALLO-715 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
- Next Clinical Update from the ALLO-715 UNIVERSAL Trial Planned for Late 2021

SOUTH SAN FRANCISCO, Calif., Aug. 12, 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) has granted orphan-drug designation (ODD) to ALLO-715 for the treatment of multiple myeloma.

Initial results from the Phase 1 UNIVERSAL study of ALLO-715 in relapsed/refractory multiple myeloma were presented at an oral session of the American Society of Hematology annual meeting in December 2020. In April 2021, ALLO-715 was granted Regenerative Medicine Advanced Therapy (RMAT) designation by the U.S. Food and Drug Administration (FDA). The UNIVERSAL trial continues to enroll patients to ALLO-715 including in combination with nirogacestat, a gamma secretase inhibitor from SpringWorks Therapeutics and in consolidation therapy.

“We are pleased to have received ODD for ALLO-715 just months after the FDA granted RMAT designation. These designations from the FDA underscore the importance of bringing this important therapeutic option to patients with multiple myeloma,” said Rafael Amado, M.D., Executive Vice President of Research & Development and Chief Medical Officer of Allogene. “We look forward to presenting the next update from our UNIVERSAL trial by the end of 2021 and providing additional insight into the potential of our allogeneic cell therapy platform.”

Orphan-drug designation is granted by the FDA to a drug or biologic intended to treat a rare disease or condition, which generally includes a disease or condition that affects fewer than 200,000 individuals in the U.S. ODD granted therapies entitle companies to development incentives including tax credits for clinical testing, prescription drug user fee exemptions, and seven year marketing exclusivity in the event of regulatory approval. ODD does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

About ALLO-715
ALLO-715, an AlloCAR T therapy targeting B-cell maturation antigen (BCMA), is a potential novel treatment for multiple myeloma and other BCMA-positive malignancies. Multiple myeloma originates in the bone marrow, and it is characterized by abnormalities in plasma cells that reproduce uncontrollably in the bone marrow and other disease sites. Multiple myeloma is incurable for most patients, as relapses occur despite most treatments available. Initial results from the Phase 1 UNIVERSAL study of ALLO-715 in relapsed/refractory multiple myeloma were presented in December 2020 at an oral session of the American Society of Hematology (ASH) annual meeting. In April 2021, ALLO-715 was granted Regenerative Medicine Advanced Therapy (RMAT) designation by the U.S. Food and Drug Administration (FDA).

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 timing and ability to progress the UNIVERSAL trial and present any data from the trial; clinical outcomes, which may materially change as patient enrollment continues and more patient data become available; 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.

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 this investigational candidate.

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