# Allogene Therapeutics Granted FDA Fast Track Designation for ALLO-605, the First TurboCAR™ T Cell Therapy, for the Treatment of Relapsed/Refractory Multiple Myeloma

June 30, 2021

- Phase 1 IGNITE Dose Escalation Trial of ALLO-605 Initiated in Q2 2021
- ALLO-605 is the Third Prong of the Company's Clinical Strategy to Target BCMA for the Treatment of Multiple Myeloma
- TurboCAR™ Technology Provides Selective, Programmable Cytokine Signaling Designed to Improve Function and Potency of AlloCAR T™ Cells

SOUTH SAN FRANCISCO, Calif., June 30, 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 Fast Track designation to ALLO-605, the Company's next-generation AlloCAR T therapy targeting BCMA for the treatment of relapsed or refractory multiple myeloma. The FDA granted Fast Track designation based on the potential of ALLO-605 to address the unmet need for patients who have failed other standard multiple myeloma therapies. The Phase 1 dose escalation portion of the IGNITE trial evaluating ALLO-605 was initiated in Q2 2021.

ALLO-605 is the Company's first TurboCAR™ clinical candidate. TurboCAR is a proprietary, next generation platform technology based upon programmable cytokine signaling designed to improve the function and potency of AlloCAR T™ cells. These properties may also enable CAR T therapy to succeed in solid tumors and increase efficacy in hematologic malignancies. Preclinical results from the ALLO-605 study were presented in a poster session at the American Society of Hematology (ASH) annual meeting in December of 2020.

"We are very pleased with the continued momentum of our anti-BCMA portfolio for patients with multiple myeloma and look forward to making allogeneic CAR T therapy a potential option for these patients," said Rafael Amado, M.D., Executive Vice President of Research and Development and Chief Medical Officer. "With studies now underway for ALLO-715 alone and in combination with a gamma secretase inhibitor, as well as ALLO-605 as our next generation CAR T, we are taking an aggressive three-pronged approach aimed at exploring the unique attributes of AlloCAR T therapies for patients with rapidly progressing disease."

Initial results from the Phase 1 UNIVERSAL study of ALLO-715 in relapsed/refractory multiple myeloma were presented at an oral session of the ASH annual meeting in December 2020. In April 2021, ALLO-715 was granted Regenerative Medicine Advanced Therapy (RMAT) designation by the FDA. Separately, the UNIVERSAL study began enrolling patients in the first half of 2021 to evaluate ALLO-715 in combination with SpringWorks Therapeutics' investigational gamma secretase inhibitor, nirogacestat.

Fast Track is designed to accelerate the development and review of treatments for serious and life-threatening diseases where no treatment exists or where the treatment in discovery may be better than what is currently available.

**About ALLO-605**
ALLO-605 is a next-generation AlloCAR T investigational therapy that targets the B-cell maturation antigen (BCMA) for the treatment of patients with relapsed/refractory multiple myeloma and other BCMA-positive malignancies. This study uses ALLO-647, Allogene's proprietary monoclonal antibody (mAb), as a part of its differentiated lymphodepletion regimen. ALLO-605 incorporates Allogene's proprietary TurboCAR technology, which allows for cytokine activation signaling to be engineered selectively into CAR T cells. Preclinical results with ALLO-605 were presented at the American Society of Hematology (ASH) annual meeting in December 2020. In June 2021, ALLO-605 was granted Fast Track designation by the U.S. Food and Drug Administration (FDA) for the potential treatment of relapsed/refractory multiple myeloma.

**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 ability to progress the Phase 1 IGNITE trial of ALLO-605; the ability of ALLO-605 and other TurboCAR™ candidates to improve the function and potency of AlloCAR T™ cells, enable success in solid tumors and increase efficacy in hematologic malignancies; 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 March 31, 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™ and TurboCAR™ are trademarks of Allogene Therapeutics, Inc.

ALLO-605 and ALLO-715 utilize 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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