Allogene Therapeutics Receives FDA Orphan-Drug Designation for ALLO-605, its First TurboCAR™ T Cell Product Candidate, for the Treatment of Multiple Myeloma

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- ODD Follows FDA Fast Track Designation Granted for ALLO-605 in Q2 2021
- ALLO-605 is in Phase 1 in the IGNITE Trial and Part of Allogene's Multi-Pronged Strategy Targeting BCMA
- BCMA Program Clinical Updates are Planned for Late 2022

SOUTH SAN FRANCISCO, Calif., April 27, 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 granted orphan-drug designation (ODD) to ALLO-605, the Company's next-generation AlloCAR T product candidate targeting BCMA for the treatment of multiple myeloma.

ALLO-605 is the Company's first TurboCAR™ product candidate. TurboCAR™ is a proprietary, next generation platform technology based on a programmable cytokine signaling, designed to control T cell exhaustion and to improve T cell function and potency. These properties may enable CAR T products to succeed in more difficult to treat hematologic malignancies and solid tumors. The FDA granted Fast Track designation to ALLO-605 in Q2 2021 based on the potential for the product candidate to address an unmet need for patients who have failed other standard multiple myeloma therapies. The Phase 1 study evaluating ALLO-605 is ongoing.

"Orphan-drug designation marks an important step towards developing our anti-BCMA portfolio for patients with multiple myeloma and making allogeneic CAR T products readily available for patients," said Rafael Amado, M.D., Executive Vice President of Research and Development and Chief Medical Officer. "We look forward to providing an update on our BCMA clinical assets by the end of the year with an eye toward prioritizing a strategy for the next stage of development."

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 and prescription drug user fee exemptions. If a product that has ODD subsequently receives the first FDA approval for the designated disease, the FDA may not approve any other applications to market the same biologic for the same indication for seven years, except in limited circumstances. ODD does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

About ALLO-605
ALLO-605, a next-generation AlloCAR T™ known as a TurboCAR™, is an investigational product 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. The Phase 1 study evaluating ALLO-605 is underway.

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 products 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 IGNITE trial, including to provide an update at year-end on the IGNITE trial and other Allogene BCMA strategies; the potential for promising pre-clinical data to translate to positive clinical data; the ability to manufacture AlloCAR T™ products; and the potential benefits of TurboCAR technology and AlloCAR T products. 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, 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's AlloCAR T™ programs utilize Cellectis technologies. The anti-BCMA AlloCAR T programs are licensed exclusively from Cellectis by Allogene and Allogene holds global development and commercial rights to these AlloCAR T programs.

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