Allogene Therapeutics Receives FDA Fast Track Designation for its First Solid Tumor Candidate, ALLO-316 in the Treatment of Renal Cell Carcinoma

March 10, 2022

- ALLO-316 is an allogeneic CAR T therapy candidate targeting CD70, which Has Broad Potential Application Across a Variety of Solid Tumors and Hematologic Malignancies
- Phase 1 TRAVERSE Trial of ALLO-316 for the Treatment of Renal Cell Carcinoma (RCC) ongoing

SOUTH SAN FRANCISCO, Calif., March 10, 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 Fast Track designation (FTD) to ALLO-316, the Company's first AlloCAR T solid tumor clinical candidate for the treatment of patients with advanced or metastatic clear cell renal cell carcinoma (RCC). The FDA granted FTD based on the potential of ALLO-316 to address the unmet need for patients with difficult to treat renal cell carcinomas (RCC) who have failed standard RCC therapies.

RCC is a disease in need of innovation as current therapies are based on a few mechanistic targets and complete response rates are low. The five-year survival rate for patients with advanced kidney cancer is less than 15%[1].

“Metastatic solid tumors have historically been a challenge to treat regardless of treatment modality, creating a large unmet need for patients and a necessity for scientific innovation,” said Rafael Amado, M.D., Executive Vice President of Research and Development and Chief Medical Officer. “We have our sights set on confronting solid tumors where the need is unquestionably high. We remain optimistic for the potential of our AlloCAR T platform to address the challenge and we look forward to generating data from our ongoing Phase 1 trial.”

ALLO-316 targets CD70, which is highly expressed in RCC with limited normal tissue expression, making it an attractive CAR T. CD70 is also selectively expressed in several cancers, creating the potential for ALLO-316 to be developed across a variety of both hematologic malignancies and solid tumors. The ongoing Phase 1 TRAVERSE trial is designed to evaluate the safety, tolerability, and activity of ALLO-316 in patients with advanced or metastatic clear cell RCC.

Fast Track designation 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 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
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 TRAVERSE trial; the ability of ALLO-316 to address RCC and other solid tumor and hematological malignancies; the ability to manufacture AlloCAR T™ products; and the potential benefits of 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 because 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. The anti-CD70 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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[1] *Survival rates for kidney cancer. American Cancer Society. (2022). Retrieved March 2, 2022, from https://www.cancer.org/cancer/kidney-cancer/detection-diagnosis-staging/survival-rates.html*

Source: Allogene Therapeutics, Inc.