Allogene Therapeutics Announces Oral Presentation of Phase 1 Data on ALLO-316 at the American Association of Cancer Research (AACR) Annual Meeting

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- Initial Data Provide Proof-of-Concept for an anti-CD70 AlloCAR T Candidate in Patients with Renal Cell Carcinoma (RCC) Who Received Prior Immune Checkpoint Inhibitor and VEGF-Targeting Therapy
- ALLO-316 Data Also Highlight the Potential of Dagger™ Technology, a Next Generation Allogeneic Platform Designed to Control Immune Rejection of AlloCAR T Cells

SOUTH SAN FRANCISCO, Calif., March 14, 2023 (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 it will present interim data from its Phase 1 TRAVERSE trial of ALLO-316, the Company's first AlloCAR T candidate for solid tumors, in an oral presentation at the American Association for Cancer Research (AACR) Annual Meeting taking place in April in Orlando, Florida. The AACR conference presentation follows the release of preliminary ALLO-316 data reported at the Company's R&D Showcase event in November 2022.

"We are excited to present ALLO-316 data for the first time at a medical conference," said Zachary Roberts, M.D., Ph.D., Executive Vice President of Research & Development. "There is an urgent need for innovation for patients with renal cell carcinoma who have failed immune checkpoint inhibitors and targeted therapy. Initial data from this trial shared at our R&D Showcase in November 2022 demonstrated the potential of ALLO-316 in patients with CD70 expressing advanced or metastatic RCC, and we look forward to further exploring the potential of this AlloCAR T product candidate in RCC and potentially other CD70-expressing tumors."

Dagger™ technology is a proprietary platform designed to control rejection of AlloCAR T cells by the host immune cells and is an intrinsic property of ALLO-316. The results from this trial indicate that ALLO-316 possesses antitumor activity as well as the anti-rejection effect.

"The Dagger technology has been shown preclinically to counter premature rejection of AlloCAR T cells via the elimination of CD70 positive, alloreactive host T cells," said Barbra Sasu, Ph.D., Chief Scientific Officer of Allogene. "The demonstration of this novel mechanism of action in the clinic opens the possibility of combining the CD70 Dagger receptor with other anti-tumor CARs to create dual-targeting, rejection-resistant next generation products that may be less dependent on lymphodepletion."

Allogene presentation at the 2023 AACR Annual Meeting:

A phase 1 multicenter study (TRAVERSE) evaluating the safety and efficacy of ALLO-316 following conditioning regimen in pts with advanced or metastatic clear cell renal cell carcinoma (ccRCC)

Presenter: Dr. Samer Srour, MB ChB, MS, Assistant Professor, Department of Stem Cell Transplantation, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center, Houston, TX
Session Title: Promising Novel Antitumor Strategies in Early Phase Clinical Trials
Abstract #: CT011
Session Date and Time: Monday April 17, 2023 10:15 AM - 12:15 PM ET

Clear cell renal cell carcinoma is the most common type of RCC in adults, making up about 80% of all cases in the U.S., according to the National Cancer Institute (NCI). The five-year survival rate for patients with metastatic kidney cancer is less than 15%.[1]

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. The Company is testing the need to prospectively assess CD70 expression levels in tumors to enhance patient selection using *a* new investigational in vitro companion diagnostic (IVD) assay. TRAVERSE will continue to explore varying cell dose and lymphodepletion regimens.

ALLO-316 for the treatment of advanced or metastatic RCC was granted Fast Track Designation (FTD) by the U.S. FDA in March 2022.

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.

About ALLO-316
ALLO-316, an AlloCAR T™ investigational product targets CD70, which is highly expressed in renal cell carcinoma (RCC). 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. In March 2022, The U.S. Food and Drug Administration granted Fast Track Designation (FTD) based on the potential of ALLO-316 to address the unmet need for patients with difficult to treat RCC who have failed standard RCC therapies.

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 TRAVERSE trial; clinical outcomes, which may materially change as more patient data become available; the likelihood of success of the Phase 1 TRAVERSE trial, which is based on limited data; the ability to manufacture AlloCAR T products; the design and potential benefits of our Dagger technology, including its ability to control rejection of allogeneic CAR T cells; the potential for our product candidates to be approved; and the potential benefits of AlloCAR T products. Various factors may cause material differences between Allogene's expectations and actual results, including, risks and uncertainties related to: our product candidates are based on novel technologies, which makes it difficult to predict the time and cost of product candidate development and obtaining regulatory approval; the limited nature of our Phase 1 data from our clinical trials and the extent to which such data may or may not be validated in any future clinical trial; our ability to maintain intellectual property rights necessary for the continued development of our product candidates, including pursuant to our license agreements; our product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval or limit their commercial potential; the extent to which COVID-19 adversely impacts our business, including our preclinical studies and clinical trials; the extent to which the Food and Drug Administration disagrees with our regulatory plans, which could cause future delays to our clinical trials; we may encounter difficulties enrolling patients in our clinical trials; we may not be able to demonstrate the safety and efficacy of our product candidates in our clinical trials, which could prevent or delay regulatory approval and commercialization; challenges with manufacturing or optimizing manufacturing of our product candidates; and our ability to obtain additional financing to develop our products and implement our operating plans. These and other risks are discussed in greater detail in Allogene's filings with the SEC, including without limitation under the "Risk Factors" heading of its Form 10-K for the year ended December 31, 2022. 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.

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Allogene's AlloCAR T™ programs utilize Cellectis technologies. The anti-CD70 AlloCAR T program is licensed exclusively from Cellectis by Allogene and Allogene holds global development and commercial rights to this AlloCAR T program.

Allogene Media/Investor Contact:
Christine Cassiano
Chief Communications Officer
(714) 552-0326
Christine.Cassiano@allogene.com

Additional Allogene Media Contact:
Madeleine Goldstein
Manager, Corporate & Pipeline Communications
Madeleine.Goldstein@allogene.com

[1] https://www.cancer.gov/pediatric-adult-rare-tumor/rare-tumors/rare-kidney-tumors/clear-cell-renal-cell-carcinoma

Source: Allogene Therapeutics, Inc.