Allogene Therapeutics Awarded Grant from the California Institute for Regenerative Medicine to Advance Development of an Allogeneic CAR T in Renal Cell Carcinoma

Apr 26, 2024 at 8:30 AM EDT

- $15 million CIRM Grant Supports the Ongoing Phase 1 TRAVERSE Trial Evaluating ALLO-316 in Patients with Advanced or Metastatic Renal Cell Carcinoma (RCC)
- ALLO-316 Illustrates Proof-of-Concept in RCC and the Potential of Dagger® Technology to Optimize CAR T Cell Expansion and Persistence

SOUTH SAN FRANCISCO, Calif., April 26, 2024 (GLOBE NEWSWIRE) -- Allogene Therapeutics, Inc. (Nasdaq: ALLO), a clinical-stage biotechnology company pioneering the development of allogeneic CAR T (AlloCAR T™) products for cancer and autoimmune disease, announced that it has received a $15 million grant from the California Institute for Regenerative Medicine (CIRM) to support the clinical development of ALLO-316, an AlloCAR T™ investigational product targeting CD70 in development for the treatment of advanced or metastatic renal cell carcinoma (RCC).

“CAR T has transformed the treatment of hematologic malignancies but there remains a significant opportunity to apply this innovation to solid tumors,” said Zachary Roberts, M.D., Ph.D., Executive Vice President, Research & Development and Chief Medical Officer of Allogene. “We believe this CIRM award validates the remarkable inroads we have made in our TRAVERSE trial to date and the therapeutic potential ALLO-316 has for patients with advanced RCC who have failed standard therapies. We look forward to advancing this trial with the added support of this grant and are grateful for the recognition from the CIRM reviewers of the potential for ALLO-316 to make a difference for patients.”

Metastatic RCC is the most common kidney cancer globally and there are limited options for treatment after treatments with checkpoint blockers and targeted therapy have failed. It 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 17%[1].

The grant will support the ongoing Phase 1 TRAVERSE trial which assesses safety, tolerability and preliminary efficacy of ALLO-316 in advanced RCC that has progressed despite standard therapy. Initial data from the TRAVERSE trial, presented at AACR 2023, showed promising response rates and early anti-tumor activity with deepening responses over time in participants with a marked unmet medical need. In the TRAVERSE trial, ALLO-316 has demonstrated the potency of the Dagger® technology, which selectively eliminates CD70 positive, alloreactive host immune cells, thus delaying or preventing premature rejection of AlloCAR T cells by the patient’s immune system. ALLO-316 has shown marked expansion and persistence both in preclinical experiments and in clinical trial patients, even when combined with comparatively less-intense lymphodepletion regimens. The intent of this grant will be to facilitate completion of the Phase 1 portion of the trial, including expansion of clinical sites to increase access for diverse patient populations. Additionally, the grant will support translational and clinical analyses to inform a recommended Phase 2 regimen.

“This clinical study has the potential to demonstrate the value of Chimeric Antigen Receptor (CAR) T cell therapy in solid cancers such as kidney cancer with a high unmet medical need,” said Dr. Abla Creasey, PhD, Vice President of Therapeutics Development at CIRM.

Details on a potentially cornerstone safety algorithm discovered during the initial portion of the Phase 1 TRAVERSE trial, which may facilitate expanded use of CAR Ts in solid tumors, is planned for a publication in Q2 2024. A more comprehensive data update from the ongoing trial is planned for later in 2024.

About ALLO-316 (TRAVERSE)
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.

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 and autoimmune disease. Led by a management team with significant experience in cell therapy, Allogene is developing a pipeline of “off-the-shelf” CAR T cell product 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 X (formerly Twitter) and @Allogene Therapeutics on LinkedIn.

About the California Institute for Regenerative Medicine (CIRM)

At CIRM, we never forget that we were created by the people of California to accelerate stem cell treatments to patients with unmet medical needs, and act with a sense of urgency to succeed in that mission. To meet this challenge, our team of highly trained and experienced professionals actively partners with both academia and industry in a hands-on, entrepreneurial environment to fast track the development of today’s most promising stem cell technologies. With $5.5 billion in funding and more than 150 active stem cell programs in our portfolio, CIRM is one of the world’s largest institutions dedicated to helping people by bringing the future of cellular medicine closer to reality. For more information, go to www.cirm.ca.gov.

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," “projects, " "believes," "potential," "proposed," "continue," "estimates," "anticipates," "expects," "plans," "intends," "designed to," "developing," "advancing," "can," "become," "build," "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 pace, timing and extent to which we may initiate or enroll patients in our clinical trials or release data from such trials including the TRAVERSE trial; clinical outcomes, which may materially change as more patient data become available; the design and potential benefits of our Dagger® technology, including the ability to optimize CAR T expansion and persistence or to delay or prevent premature rejection of AlloCar T cells by the patient’s immune system, and the expected benefits therefrom, and our plans to deploy the Dagger® technology; the potential for our product candidates to be approved; the potential benefits of AlloCAR T products; the ability of our product candidates to treat various stages and types of cancers including solid tumors; the potential ability of our safety algorithm to facilitate expanded use of CAR Ts in solid tumors; the extent to which our clinical trials will support regulatory approval of our product candidates; the potential for off-the-shelf CAR T products; and other statements related to future events or conditions. Various factors may cause material differences between Allogene’s expectations and actual results, including, risks and uncertainties related to: risks related to third-party performance; 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 the 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 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 the Food and Drug Administration disagrees with our clinical or regulatory plans or the import of our clinical results, which could cause future delays to our clinical trials or require additional clinical trials; we may encounter difficulties enrolling patients in our clinical trials, including the TRAVERSE 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, including the ability to deliver readily available cell therapy on-demand, more reliably, and at a greater scale to more patients. These and other risks are discussed in greater detail in Allogene’s filings with the SEC, including without limitation under the “Risk Factors” heading in its Annual Report on Form 10-K for the year ended December 31, 2023. 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 investigational AlloCAR T™ oncology products 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
EVP, Chief Corporate Affairs & Brand Strategy Officer
Christine.Cassiano@allogene.com

1 *Survival rates for kidney cancer*. American Cancer Society. (n.d.). https://www.cancer.org/cancer/types/kidney-cancer/detection-diagnosis-staging/survival-rates.html

Source: Allogene Therapeutics, Inc.