Allogene Therapeutics to Present New Data Demonstrating the Potential of ALLO-316 in Heavily Pretreated Adult Patients with CD70 Positive Advanced Renal Cell Carcinoma (RCC) at the International Kidney Cancer Symposium (IKCS) and Society for Immunotherapy of Cancer (SITC) Annual Meeting

Nov 5, 2024 at 9:10 AM EST

- ALLO-316, an “Off-the-Shelf” AlloCAR T ™ Anti-CD70 CAR T Product, is Currently Under Investigation in the Phase 1 TRAVERSE Trial for Patients with Renal Cell Carcinoma (RCC) Previously Treated with Immune Checkpoint Inhibitors and VEGF-Targeting Therapies
- Data Presented Advances Scientific Understanding and Applicability of the Dagger® Technology as the Next-Generation Allogeneic Platform to Maximize the Potential of a Single Infusion, AlloCAR T Product
- Ongoing Phase 1 Data Supported the FDA's Recent RMAT Designation for ALLO-316 as a Promising Treatment to Address an Unmet Medical Need for Adults with Advanced or Metastatic CD70 Positive RCC Who Have Failed Standard RCC Therapies

SOUTH SAN FRANCISCO, Calif., Nov. 05, 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, today announced that it will present new data from the ongoing Phase 1 TRAVERSE trial at the 2024 International Kidney Cancer Symposium (IKCS) and the Society for Immunotherapy of Cancer's (SITC) annual meeting. The trial evaluates ALLO-316, the Company’s first AlloCAR T product candidate for the potential treatment of solid tumors. These presentations will highlight data from 26 heavily pretreated patients with CD70 positive renal cell carcinoma (RCC) and will include details on the diagnostic and treatment algorithm used to mitigate treatment-associated hyperinflammatory response seen in some patients. The ongoing Phase 1 data supported the U.S. Food and Drug Administration’s (FDA) October 2024 decision to grant Regenerative Medicine Advanced Therapy (RMAT) designation for ALLO-316 based on clinical data from the TRAVERSE trial indicating its to address the unmet need for adult patients with advanced or metastatic CD70 positive RCC who have failed multiple standard RCC therapies, including an immune checkpoint inhibitor and a VEGF-targeting therapy.

“We are looking forward to presenting the most recent Phase 1 data from our ongoing TRAVERSE trial at both SITC and IKCS,” said Zachary Roberts, M.D., Ph.D., EVP of Research & Development and Chief Medical Officer. “There is significant unmet need for these heavily pretreated patients with advanced RCC. In treating their disease, these patients rarely get any form of treatment break as their disease quickly progresses. This data highlights the potential of ALLO-316 to elicit a response from a single infusion, suggesting a breakthrough in allogeneic CAR T therapy for solid tumors. As the Phase 1 data matures, we plan to seek FDA’s input for the next stage of clinical development.”

2024 International Kidney Cancer Symposium (IKCS)
Title: TRAVERSE: Updated safety and efficacy of ALLO-316 in advanced/metastatic clear cell renal cell carcinoma (ccRCC)
Presenter: Ritesh Kotecha, M.D., Memorial Sloan Kettering Cancer Center
Session Date and Time: Friday, November 8, 11:50 a.m. ET

The Society for Immunotherapy of Cancer's (SITC) Annual Meeting
Title: ALLO-316 in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC): Updated safety and efficacy from the phase 1 TRAVERSE multicenter study
Presenter: Samer Srour, M.D., The University of Texas MD Anderson Cancer Center
Abstract Number: 322
Date and Time: Saturday, November 9, 12:15-1:45 p.m. CT, 7:00-8:30 p.m. CT

The ongoing Phase 1 TRAVERSE trial is designed to evaluate the safety, tolerability, and activity of ALLO-316 in patients with advanced or metastatic RCC. The development of ALLO-316 continues to advance the scientific understanding and applicability of the Dagger technology as the next-generation allogeneic platform with the ability to maximize the potential of a one-time infusion. In April 2024, the Company announced a $15 million award from the California Institute for Regenerative Medicine (CIRM) to support the ongoing TRAVERSE trial with ALLO-316 in RCC.

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. ALLO-316 utilizes the Dagger® technology to optimize CAR T cell expansion and persistence to maximize the potential efficacy in solid tumors with a one-time infusion. 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 (FDA) granted Fast Track Designation (FTD) to ALLO-316, and in October 2024 the FDA granted Regenerative Medicine Advanced Therapy (RMAT) designation to ALLO-316 based on its potential to address the unmet need for adult patients with CD70 positive advanced or metastatic 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 and 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. CIRM is one of the world’s largest institutions dedicated to helping people by bringing the future of regenerative medicine closer to reality.

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 “potential,” “continue,” “plans,” “will,” “advance,” “goal,” or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Forward-looking statements are statements that are not historical facts, including statements regarding intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things: the future development, timing, and success of clinical trials and product candidates; statements regarding the potential of ALLO-316 as a treatment for patients with advanced renal cell carcinoma (RCC); the advancement of Allogene’s Dagger® technology as a next-generation allogeneic platform; the anticipated benefits of a one-time infusion therapy; Allogene’s plans to seek additional FDA input for the clinical development of ALLO-316; and Allogene’s ability to deliver cell therapy on-demand, faster, more reliably, and at greater scale to more patients. Various factors may cause material differences between Allogene’s expectations and actual results, including, risks and uncertainties related to the ongoing clinical trial for ALLO-316 and potential adverse effects; uncertainties regarding regulatory interactions, including future feedback from the U.S. Food and Drug Administration and implications of the RMAT designation; risks relating to the development of allogeneic cell therapy and CAR T products; the impact of competitive and market conditions; uncertainties relating to our novel technologies which makes it difficult to predict the time and cost of product candidate development and obtaining regulatory approval; difficulties we may encounter enrolling patients in our clinical trials; and uncertainties regarding 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 in its Form 10-Q filed for the quarter ended June 30, 2024, filed with the SEC on August 7, 2024. 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 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.

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