Allogene Therapeutics Receives FDA Regenerative Medicine Advanced Therapy (RMAT) Designation for ALLO-316, an AlloCAR T™ Investigational Product for Adult Patients with Advanced or Metastatic Renal Cell Carcinoma (RCC)

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- RMAT Designation Follows Positive Proof-of-Concept Data from the ALLO-316 TRAVERSE Trial in Adult Patients with Advanced or Metastatic CD70 Positive Renal Cell Carcinoma (RCC) Who Received Prior Immune Checkpoint Inhibitor and VEGF-Targeting Therapy
- ALLO-316 Advances Scientific Understanding and Applicability of the Dagger® Technology as the Next-Generation Allogeneic Platform to Maximize the Potential of a Single Infusion of an “Off-the-Shelf” CAR T Product
- Company to Present Updated Phase 1 Data from the TRAVERSE Trial at the Society for Immunotherapy of Cancer (SITC) Annual Meeting
- ALLO-316 was Previously Granted Fast Track Designation (FTD) in March 2022 by the U.S. Food and Drug Administration

SOUTH SAN FRANCISCO, Calif., Oct. 29, 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 the U.S. Food and Drug Administration (FDA) granted Regenerative Medicine Advanced Therapy (RMAT) designation to ALLO-316 for the treatment of adult patients with CD70 positive advanced or metastatic renal cell carcinoma (RCC). The RMAT designation was based on clinical data from the TRAVERSE trial indicating the potential of ALLO-316 to address the unmet need for patients with difficult-to-treat RCC who have failed multiple standard RCC therapies, including an immune checkpoint inhibitor and a VEGF-targeting therapy. The ongoing development of ALLO-316 continues to advance the scientific understanding and applicability of the Dagger® technology as the next-generation allogeneic platform to maximize the potential of a single infusion of “off-the-shelf” CAR T product in solid tumors.

“The RMAT designation for ALLO-316 highlights the transformative potential of our AlloCAR T™ platform to offer new hope for heavily pretreated patients with renal cell carcinoma who have exhausted standard treatment options,” said Zachary Roberts, M.D., Ph.D., Executive Vice President of Research & Development and Chief Medical Officer. “This important milestone moves us closer to fulfilling the promise of “off-the-shelf” CAR T therapy —delivering faster, more reliable, and widely accessible treatments. We remain optimistic about the future of ALLO-316 and its potential to be an important advancement for patients.”

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. Initial results from the TRAVERSE trial were presented in an oral presentation at the American Association for Cancer Research (AACR) Annual Meeting in Orlando, Florida, in 2023. The Company will present updated Phase 1 data from the TRAVERSE trial at the Society for Immunotherapy of Cancer (SITC) annual meeting.

The RMAT designation is intended to accelerate the development and review of promising investigational products, including cell therapies. To qualify, a product must be designed to treat, modify, reverse, or cure a serious or life-threatening disease, with preliminary clinical evidence suggesting it can address unmet medical needs. The RMAT designation offers several key advantages, including early and frequent interactions with the FDA to discuss potential surrogate or intermediate endpoints, as well as strategies to meet post-approval requirements, potentially streamlining the path to market approval.

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.

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,” “intend,” “will,” “advance,” “move,” “offer,” “goal,” 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 extent to which ALLO-316 TRAVERSE Trial data may establish proof-of-concept or advance scientific understanding; whether the Dagger® Technology will become the next-generation allogeneic platform or maximize the potential of a one-time Infusion of a CAR T product; the Dagger® technology's ability to optimize CAR T cell expansion and persistence and maximize the potential efficacy in solid tumors with a one-time infusion; the potential of ALLO-316 to address the unmet need for any patient population; the transformative potential of our AlloCAR T™ platform; ALLO-316's potential to be an important advancement for patients; potential advantages of the RMAT designation, including acceleration of the development and review of our investigational products, early and frequent interactions with the FDA, or streamlining the path to market approval; the potential for ALLO-316 to be developed across a variety of both hematologic malignancies and solid tumors; or our 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: RMAT designation may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval and the designation can be revoked if the criteria for eligibility ceases to be met; 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 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, including initiation of clinical trials, or require additional 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; 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 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.

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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