Allogene Therapeutics Provides Updated Phase 1 Data Highlighting Durable Responses with ALLO-316 in Heavily Pretreated Advanced Renal Cell Carcinoma at ASCO

Jun 1, 2025 at 10:45 AM EDT

- Data Highlights Transformative Promise of CAR T in Solid Tumors
- Phase 1 Trial with ALLO-316 Demonstrated Potential to Provide Meaningful Clinical Benefit in Patients with CD70 TPS ≥ 50% Advanced or Metastatic RCC
    - A Single Dose of ALLO-316 Achieved a 31% Confirmed Response Rate
    - Four of Five Confirmed Responders Remain in Response Including One Ongoing Remission Over 12 Months
- Robust Expansion, Persistence, and Tumor Infiltration of ALLO-316 Seen with Standard Lymphodepletion, Showcasing Dagger® Technology as a Next-Generation Allogeneic Platform
- Phase 1 Safety Profile was Manageable; Proactive Diagnostic and Management Strategies Proved Effective in Mitigating IEC-HS While Preserving Efficacy

SOUTH SAN FRANCISCO, Calif., June 01, 2025 (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, presented updated data from the Phase 1 TRAVERSE study of ALLO-316 in renal cell carcinoma (RCC) during an oral presentation at the 2025 ASCO Annual Meeting. The Phase 1 TRAVERSE trial enrolled patients with advanced or metastatic renal cell RCC. Leveraging the proprietary Dagger® technology to enable robust CAR T cell expansion, it stands as the first and only allogeneic CAR T product to show promise in treating solid tumors. The presentation focused on the Phase 1b expansion cohort from the Phase 1 TRAVERSE study in which patients were treated with a standard regimen of cyclophosphamide and fludarabine followed by a single dose of 80 million AlloCAR T ™ cells.

“ALLO-316 is showing clear evidence of targeted antitumor activity in patients who had failed most or all approved therapies for advanced or metastatic renal cell carcinoma,” said Zachary Roberts, M.D., Ph.D., EVP, Research and Development and Chief Medical Officer at Allogene. “Our proprietary Dagger technology allows the use of a standard cyclophosphamide and fludarabine-based lymphodepletion regimen with a single dose of ALLO-316. Strong CAR T-cell kinetics and extensive infiltration of tumor tissue by CAR T cells are combining to generate deep and durable remissions. These are results that were previously considered out of reach for patients with advanced solid tumors.”

“Patients diagnosed with advanced or metastatic renal cell carcinoma often face a median survival in months after exhausting standard therapies,” said Samer A. Srour, MB ChB, MS, Associate Professor of Stem Cell Transplantation and Cellular Therapy at The University of Texas MD Anderson Cancer Center and lead investigator of the TRAVERSE trial. “These updated results from a larger cohort of patients with confirmed CD70 positive tumors provide compelling evidence that treatment with ALLO-316 can reduce tumor burden, control disease, and in some cases deliver durable responses. These findings underscore the clinical promise of an allogeneic CAR T to address the significant unmet needs in solid tumors and offer hope to patients who have exhausted other options.”

In the Phase 1b expansion cohort, 22 patients whose tumors had progressed on multiple prior therapies were treated with lymphodepletion and 20 were treated with ALLO-316. All patients had tumors resistant to immune checkpoint blockers and at least one tyrosine kinase inhibitor (TKI), 82% had ≥2+ prior TKI, and 41% had prior belzutifan. Sixteen of the ALLO-316 treated patients had a high CD70 Tumor Proportion Score (TPS >50%). The Phase 1b expansion cohort evaluated the safety and efficacy of ALLO-316 at DL2 (80M CAR T cells) following a standard FC lymphodepletion regimen (fludarabine (30 mg/m^2/day) and cyclophosphamide (500 mg/m^2/day) for 3 days). The median time from enrollment to the start of therapy was four days.

A single dose of ALLO-316 stabilized or reversed disease progression in the majority of patients. In the 16 patients with CD70 TPS ≥50%, the trial demonstrated a Confirmed Overall Response Rate (ORR) of 31% with 44% achieving a minimum of 30% reduction in tumor burden. Of the five confirmed responders, four maintain ongoing responses, with one in sustained remission for over 12 months. The median duration of response (mDOR) has not yet been reached, indicating the potential for long-term disease control.

	CD70+ patients Phase 1b (N=20)
ORR (confirmed CR or PR per RECIST v1.1), n/N (%)	5/20 (25)
CD70 TPS ≥50%	5/16 (31)
CD70 TPS <50%	0/4 (0)

RECIST v1.1, Response Evaluation Criteria in Solid Tumors, version 1.1; TPS, tumor proportion score

The safety profile of ALLO-316 was manageable and consistent with lymphodepletion and an active CAR T product. The most frequent Grade ≥3 events were hematologic and there were no treatment-related Grade 5 events. The most common all-grade adverse events were cytokine release syndrome (CRS) (68%; with no grade ≥3), neutropenia (68%), decreased white blood cell count (68%), anemia (59%), and thrombocytopenia (55%). Immune effector cell-associated neurotoxicity syndrome (ICANS) was 18% (with no grade ≥3) and no graft-versus-host disease (GvHD) occurred. Improved recognition of IEC-HS symptoms led to diagnosis in 36% of patients with 2 patients (9%) experiencing a short-term Grade 3 (one) or Grade 4

(one patient) event. Newly implemented diagnostic and management algorithms significantly mitigated IEC-HS, with no associated Grade 5 events.

TEAEs ≥20% incidence in Phase 1b, n (%)	Phase 1b (N=22[a])	
	All Grades	Grade ≥3
Neutropenia	15 (68)	15 (68)
White blood cell count decreased	15 (68)	15 (68)
Anemia	13 (59)	9 (41)
Thrombocytopenia	12 (55)	6 (27)
Nausea	8 (36)	0
ALT increased	7 (32)	2 (9)
Peripheral edema	7 (32)	0
Pyrexia	7 (32)	0
Arthralgia	6 (27)	0
AST increased	6 (27)	2 (9)
Fatigue	5 (23)	0
Headache	5 (23)	0
AEs of Special Interest	Any Grade	Grade ≥3
CRS	15 (68)	0
Infection	10 (45)	8 (36)
IEC-HS	8 (36)	2 (9)[b]
ICANS	4 (18)	0
Graft-versus-host disease	0	0

IEC-HS includes the preferred terms immune effector cell-associated HLH-like syndrome and Hemophagocytic lymphohistiocytosis.

[a] Includes 2 patients who received LD but did not receive ALLO-316

[b] One patient experienced G4 IEC-HS based on GI bleeding with subsequent improvement and 1 patient experienced G3 IEC-HS based on hypotension managed without pressors with subsequent improvement.

About ALLO-316 (TRAVERSE)

ALLO-316 is an AlloCAR T ™ investigational product targeting 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 October 2024 the U.S. Food and Drug Administration (FDA) granted Regenerative Medicine Advanced Therapy (RMAT) designation based on the potential of ALLO-316 to address the unmet need for patients with advanced or metastatic RCC. The FDA previously granted Fast Track Designation (FTD) to ALLO-316 in March 2023. In April 2024, the Company announced an award from the California Institute for Regenerative Medicine (CIRM) to support the ongoing TRAVERSE trial with ALLO-316 in RCC.

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. This press release may, in some cases, use terms such as “develop,” “potential,” “expect,” “can,” “enable,” “showing,” “generate,” “may,” “could,” “designed to,” “promise,” “hope,” “ongoing,” “indicating,” “mitigate,” “evaluate,” “pioneer,” “goal” or “will,” including alternative forms thereof, 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 potential of ALLO-316 to treat patients with advanced or metastatic RCC or to provide meaningful clinical benefit in patients with advanced RCC; the potential for ALLO-316 to be developed across a variety of both hematologic malignancies and solid tumors and to generate deep and durable remissions; the potential that ALLO-316 can reduce tumor burden, control disease, and deliver durable responses; the design and potential benefits of our Dagger technology; whether the Dagger® technology will become the next-generation allogeneic platform; ALLO-316 and the Dagger technology’s ability to enable robust CAR T cell expansion and persistence and tumor infiltration; the potential of ALLO-316 to address the unmet need in solid tumors or offer hope to patients who have exhausted other options; the transformative potential of our AlloCAR T™ in solid tumors; the potential advantages of the RMAT and Fast Track designation; and our ability to deliver cell therapy on-demand, 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 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 trials; 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; 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; RMAT and Fast Track designations 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 designations can be revoked if the criteria for eligibility cease to be met; and challenges with manufacturing or optimizing manufacturing of our product candidates. These and other risks are discussed in

greater detail in Allogene's filings with the Securities and Exchange Commission (SEC), including without limitation under the "Risk Factors" heading in its Quarterly Report on Form 10-Q for the year ended March 31, 2025. 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.

AlloCAR T ™ and Dagger® are trademarks of Allogene Therapeutics, Inc.

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

Source: Allogene Therapeutics, Inc.