Allogene Therapeutics Announces Journal of Clinical Oncology Publication of Phase 1 Results of ALLO-316 Highlighting First Durable Remissions Following Allogeneic CAR T for Treatment of Metastatic Solid Tumors

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- ALLO-316 Achieved a 31% Confirmed Response Rate with the Recommended Phase 2 Regimen in Patients with Stage IV Renal Cell Carcinoma (RCC) with High CD70 Expression
  - Single Dose of ALLO-316 Produced Durable Responses in this Cohort with All Responders Progression-Free at the Time of Analysis
  - Responses Range from 8 to 18+ Months, with Median Overall Survival Not Yet Reached
- Safety Profile was Manageable with Proactive Diagnostic and Management Strategies Effective in Mitigating IEC-HS
- ALLO-316 Demonstrated Robust Expansion and Tumor Infiltration Following Standard Lymphodepletion, Validating the Dagger® Technology as a Next-Generation Allogeneic CAR T Platform

SOUTH SAN FRANCISCO, Calif., July 15, 2026 (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 the publication of complete Phase 1 data from the TRAVERSE study of ALLO-316 in advanced or metastatic renal cell carcinoma (RCC) in the Journal of Clinical Oncology. TRAVERSE is being conducted as part of a strategic five-year collaboration with The University of Texas MD Anderson Cancer Center. ALLO-316, Allogene's CD70-targeting AlloCAR T investigational therapy incorporating the Dagger ® technology, achieved robust expansion, tumor infiltration, and durable antitumor activity in a solid tumor setting.

"TRAVERSE represents a potential breakthrough for both Allogene and the broader CAR T field," said Zachary Roberts, M.D., Ph.D., President and Chief Executive Officer of Allogene. "CAR T has transformed hematologic malignancies while solid tumors have remained one of the field's most difficult challenges. When we designed ALLO-316 with the Dagger® technology, our goal was to address two of the most persistent barriers in solid tumors – achieving robust CAR T expansion with standard lymphodepletion and translating that biology into durable responses. These results show that a well-designed allogeneic CAR T product, developed for a defined population, can expand, persist, and produce durable responses in metastatic, treatment refractory solid tumors. Importantly, the robust CAR T expansion and durable persistence in this trial provides clinical validation of our Dagger® technology platform and has direct read-through to our broader clinical and preclinical pipeline of next-generation AlloCAR T candidates."

Across the full Phase 1 TRAVERSE trial, 51 patients with Stage IV disease were enrolled, of whom 46 received ALLO-316 and had a median follow-up time of 28.8 months. The Phase 1b expansion cohort evaluated the safety and efficacy of the recommended Phase 2 regimen – ALLO-316 at a dose of 80M CAR T cells following a standard FC lymphodepletion regimen (fludarabine (30 mg/m²/day) and cyclophosphamide (500 mg/m²/day) for 3 days). The 22 patients in the Phase 1b safety population all had RCC resistant to immune checkpoint blockers and at least one tyrosine kinase inhibitor (TKI), 82% had received ≥2 prior TKIs, and 41% had received prior belzutifan. Twenty of these patients received ALLO-316. Sixteen of the ALLO-316-treated patients in Phase 1b had a high CD70 Tumor Proportion Score (TPS ≥50%). The median time from enrollment to the start of therapy was four days.

"Most patients in TRAVERSE had exhausted available therapies and faced a poor prognosis, with survival often measured in months," said Samer A. Srour, MB ChB, MS, associate professor of Stem Cell Transplantation and Cellular Therapy at UT MD Anderson. "In that context, the depth and durability of responses observed with a one-time ALLO-316 infusion are very promising, particularly in patients with high CD70-expressing tumors where all responders remained progression-free at the time of the published analysis. These findings support the continued clinical development of ALLO-316 and its evaluation as a potential new treatment approach for patients with advanced RCC."

A single dose of ALLO-316 produced disease control in half of patients in the Phase 1b cohort, with an overall confirmed response rate of 25% and a confirmed response rate of 31% in patients with CD70 TPS ≥50%. The median duration of response (mDOR) had not been reached (95% CI: 6.9 months to not estimable), with the longest ongoing response exceeding 18 months. Median overall survival in the Phase 1b population was 15.2 months (95% CI: 4.6 months to not estimable) and was not estimable in the CD70-high group (95% CI: 3.2 months to not estimable).

	CD70+ patients Phase 1b (N=20) n (%)
ORR (confirmed CR or PR per RECIST v1.1)	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 across the full Phase 1 trial. The

most frequent Grade ≥3 events were hematologic. Three previously reported treatment related Grade 5 adverse events occurred in the Phase 1a portion (cardiogenic shock, failure to thrive and sepsis). There were no Grade 5 adverse events in Phase 1b. A higher incidence of IEC-HS was reported in Phase 1b relative to Phase 1a, likely due in part to improved diagnosis and coding implemented during Phase 1b. Most IEC-HS events were mild to moderate and were successfully managed utilizing a protocol-defined diagnostic and management algorithm.

TEAEs ≥20% incidence	Phase 1b (N=22*) n (%)	
	Any Grades	Grade ≥3
Neutropenia	18 (82%)	18 (82%)
White blood cell count decreased	16 (73%)	16 (73%)
Anemia	13 (59%)	9 (41%)
Fatigue	5 (23%)	0
Nausea	8 (36%)	0
Thrombocytopenia	13 (59%)	7 (32%)
Pyrexia	8 (36%)	0
Peripheral edema	8 (36%)	0
ALT increased	7 (32%)	2 (9%)
Headache	5 (23%)	0
Arthralgia	8 (36%)	0
AST increased	6 (27%)	2 (9%)
Lymphopenia	5 (23%)	5 (23%)
AEs of Special Interest	Any Grade	Grade ≥3
CRS	15 (68%)	0
Infection	11 (50%)	9 (41%)
IEC-HS	8 (36%)	2 (9%)[a]
ICANS	4 (18%)	0
Graft-versus-host disease	0	0

* Two patients received lymphodepletion but did not receive ALLO-316: one due to progression of disease (altered mental status during lymphodepletion found to be brain metastases on imaging), and one due to liver and kidney failure during lymphodepletion. IEC-HS includes the preferred terms immune effector cell-associated HLH-like syndrome and Hemophagocytic lymphohistiocytosis.

[a] One patient experienced Grade 4 IEC-HS based on gastrointestinal bleeding with subsequent improvement; one patient experienced Grade 3 IEC-HS based on hypotension managed without vasopressors with subsequent improvement.

The findings also underscore the broader strategic potential of the Dagger® technology, which addresses rejection by the patient's immune system. By targeting CD70-expressing tumor cells as well as CD70-positive alloreactive host T cells, ALLO-316 is designed to support CAR T-cell expansion and persistence without requiring intensified lymphodepletion. In TRAVERSE, this design translated into robust expansion, durable persistence, and evidence of tumor infiltration – core attributes Allogene believes may be applicable across its next-generation clinical and pre-clinical allogeneic CAR T pipeline.

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 cell therapy veterans applying proven CAR T experience, 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 Allogene Therapeutics 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. Forward-looking statements include statements regarding, among other things: the potential of ALLO-316 as a treatment approach for patients with advanced or metastatic renal cell carcinoma, including patients with high CD70-expressing tumors; the continued clinical development and future evaluation of ALLO-316; the potential significance of the Phase 1 TRAVERSE results, including with respect to durable responses, expansion, persistence, tumor infiltration, overall survival, duration of response and progression-free status; the potential of ALLO-316 and the Dagger® technology to address challenges associated with solid tumors and allogeneic CAR T therapies, including host immune recognition or rejection of allogeneic CAR T cells, selective targeting or elimination of CD70-positive alloreactive host T cells, CAR T-cell expansion and persistence, and the ability to achieve activity following standard lymphodepletion; the potential applicability of the Dagger® technology and ALLO-316 findings to Allogene's broader clinical and preclinical allogeneic CAR T pipeline; the potential for ALLO-316 to be developed across additional cancers; and the potential benefits of off-the-shelf allogeneic CAR T therapies. Forward-looking statements are based on Allogene's current expectations and

assumptions and are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. These risks and uncertainties include, but are not limited to: the limited nature of the Phase 1 data from the TRAVERSE trial, including the small number of patients treated and the early-stage nature of the study; the possibility that clinical results, including response rates, duration of response, overall survival, progression-free status, safety, expansion, persistence and tumor infiltration, may not be replicated or may change as additional patients are treated or additional follow-up becomes available; the risk that ALLO-316 may not demonstrate sufficient safety, efficacy or durability in future clinical trials to support further development or regulatory approval; the risk that adverse events, including cytokine release syndrome, immune effector cell-associated hemophagocytic lymphohistiocytosis-like syndrome, infections, cytopenias, neurotoxicity or other toxicities, may be more frequent, severe or difficult to manage than expected; risks associated with the use of lymphodepletion and allogeneic CAR T therapies; uncertainties regarding the relationship between CD70 expression and clinical outcomes; the risk that the Dagger® technology may not provide the anticipated benefits, including with respect to expansion, persistence, tumor infiltration, resistance to host immune recognition or rejection, selective elimination of CD70-positive alloreactive host T cells, or applicability across other product candidates or disease settings; uncertainties related to clinical trial design, patient enrollment, manufacturing, regulatory interactions and the timing or success of future development activities; and the risks and uncertainties described under the heading “Risk Factors” in Allogene’s filings with the Securities and Exchange Commission, including its most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q. Any forward-looking statements in this press release speak only as of the date of this press release. Allogene undertakes no obligation to update any forward-looking statements, except as required by law.

Dagger® is a trademark 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.

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