Allogene Therapeutics Reports Positive Results from Phase 1 UNIVERSAL Study of Single Dose ALLO-715 AlloCAR T™ Cell Therapy in Relapsed/Refractory Multiple Myeloma at the 63rd American Society of Hematology Annual Meeting

December 13, 2021

- ALLO-715 UNIVERSAL Trial is the First Allogeneic anti-BCMA CAR T to Demonstrate Safety and Substantial Efficacy in Multiple Myeloma
  - Updated Data Demonstrate Responses Similar to Approved Autologous CAR T Therapy
- ALLO-715 Was Well Tolerated with No Graft-vs-Host Disease and Manageable Safety
- 71% Overall Response Rate (ORR) with FCA Lymphodepletion
  - 46% Achieved a Very Good Partial Response or Better (VGPR+) Including 25% Complete Response or Stringent Complete Response (CR/sCR)
  - 92% of Patients with VGPR+ Were Minimal Residual Disease (MRD) Negative
  - Median Duration of Response was 8.3 months
- Study Highlights the Ability to Initiate AlloCAR T Therapy within Five Days of Enrollment with No Bridging Therapy
- Company to Host a Conference Call and Webcast Today, Monday, December 13, at 1:30 p.m. PT/4:30 p.m. ET

SOUTH SAN FRANCISCO, Calif., Dec. 13, 2021 (GLOBE NEWSWIRE) -- Allogene Therapeutics, Inc. (Nasdaq: ALLO), a clinical-stage biotechnology company pioneering the development of allogeneic CAR T (AlloCAR T™) therapies for cancer, today announced positive updated results from the Phase 1 UNIVERSAL study of single dose ALLO-715 in relapsed/refractory (r/r) multiple myeloma. Data were presented today in an oral session by Sham Mailankody, MBBS, Assistant Attending Physician at Memorial Sloan Kettering Cancer Center in New York, during the 63rd American Society of Hematology (ASH) Annual Meeting in Atlanta. This study utilizes ALLO-647, Allogene's anti-CD52 monoclonal antibody, as a part of its differentiated lymphodepletion (LD) regimen.

“UNIVERSAL is the first study of an allogeneic anti-BCMA CAR T to demonstrate safety and substantial efficacy in patients with relapsed-refractory multiple myeloma,” said Dr. Mailankody. “Safety, response and durability are on par with the approved autologous CAR T therapy and appear to be superior to other readily available therapies for multiple myeloma. This is especially encouraging given the high percentage of penta-refractory patients enrolled in the study. The data validates the feasibility of ALLO-715 as an allogeneic, on demand CAR T product that may be an option for patients with rapidly progressing disease and limited treatment options.”

“We are encouraged by these updated findings from the UNIVERSAL study that show a single dose of an off-the-shelf AlloCAR T product is capable of inducing deep, clinically meaningful responses in patients with r/r multiple myeloma,” said Rafael Amado, M.D., Executive Vice President of Research & Development and Chief Medical Officer of Allogene. “This proof-of-concept data will form the basis for evaluating anti-BCMA strategies that include consolidated dosing of ALLO-715, ALLO-715 in combination with the gamma secretase inhibitor nirogacestat, and ALLO-605, our next-generation anti-BCMA TurboCAR™, with the goal of achieving even better outcomes for patients with refractory myeloma.”

As of the October 14, 2021 data cutoff, 48 patients were enrolled with 43 patients evaluable for safety and efficacy. Patients were refractory to their last line of myeloma therapy, had a median of five prior lines of therapy, and 42% were penta-refractory meaning the disease has ultimately become nonresponsive to other approved therapies. Five patients became ineligible for treatment due to rapidly progressing disease. The median time from enrollment to the start of therapy was five days.

The Phase 1 UNIVERSAL trial evaluated lymphodepletion followed by ALLO-715 at one of four dose levels (DL1=40M cells, DL2=160M cells, DL3=320M cells, DL4 = 480M cells) and two LD regimens (FCA: fludarabine, cyclophosphamide and ALLO-647 or CA: cyclophosphamide and ALLO-647 only). The updated presentation primarily focuses on the optimized DL3 cell dose and FCA lymphodepletion.

The higher CAR T cell doses were associated with an increased response rate and greater AlloCAR T cell expansion. In the DL3 cohort which was selected for cohort expansion, the overall response rate (ORR) increased from 60% reported at ASH 2020 to 71% with 46% of patients achieving a very good partial response (VGPR) or better (VGPR+) up from 40%. VGPR+ is defined as a stringent complete response (sCR), complete response (CR) or VGPR. Of the patients who achieved VGPR+, 92% were Minimal Residual Disease (MRD) negative.

	FCA			
Cell dose and LD regimen	DL3 320 x 10^6 CAR+ cells			
	Low ALLO-647 (N=11)	Mid ALLO-647 (N=10)	High ALLO-647 (N=3)	**ALL ALLO-647 (N=24)**
ORR, n (%)	7 (64%)	8 (80%)	2 (67%)	**17 (71%)**
VGPR+ Rate, n (%)	5 (46%)	5 (50%)	1 (33%)	**11 (46%)**
CR/sCR Rate, n (%)	3 (27%)	3 (30%)	0	**6 (25%)**

As of the data cutoff, the overall median follow-up for efficacy was 3.8 months. The median duration of response is 8.3 months, with nine patients remaining in ongoing response at the time of the data cut-off. The longest ongoing response after cell infusion is 12 months. Results showed that soluble BCMA levels were 10 times lower in responders at Day 28, suggesting soluble BCMA suppression is associated with response.

Of the 43 patients evaluable for safety, there was no graft-versus-host-disease (GvHD). Grade 1 and 2 cytokine release syndrome (CRS) was reported in 23 patients (53%) and was manageable with standard therapies. In this heavily pre-treated patient population, infection occurred in 54% of patients, which included three Grade 5 infections, two of which were previously reported. Grade 3+ neutropenia occurred in 70% of patients. Six patients (14%) experienced adverse events of low-grade neurotoxicity, which was reversible. Use of tocilizumab and steroids was infrequent (23% and 14%, respectively).

Adverse Events of Interest	Grade 1 N (%)	Grade 2 N (%)	Grade 3 N (%)	Grade 4 N (%)	Grade 5 N (%)	All Grades N (%)
CRS	13 (30%)	10 (23%)	1 (2%)	0	0	24 (56%)
Neurotoxicity	4 (9%)	2 (5%)	0	0	0	6 (14%)
GvHD	0	0	0	0	0	0
Infection	3 (7%)	10 (23%)	7 (16%)	0	3 (7%)	23 (54%)
Infusion Reaction to ALLO-647	7 (16%)	5 (12%)	0	0	0	12 (28%)

ALLO-715 has been granted Regenerative Medicine Advanced Therapy (RMAT) designation by the FDA for the treatment of r/r multiple myeloma.

As part of the Company's anti-BCMA strategy, the UNIVERSAL trial is also studying consolidated dosing of ALLO-715 using ALLO-647 to selectively extend the window of lymphodepletion. UNIVERSAL is also evaluating ALLO-715 in combination with SpringWorks Therapeutics' investigational gamma secretase inhibitor, nirogacestat. The Phase 1 dose escalation portion of the IGNITE trial evaluating ALLO-605, the Company's first TurboCAR™ candidate, was initiated in Q2 2021. TurboCAR technology allows cytokine activation signaling to be engineered selectively into CAR T cells and has shown the ability to improve the potency and persistence of allogeneic cells in preclinical models. Subject to the clinical hold currently in place, Allogene continues to target 2022 for data from these additional strategies.

Conference Call and Webcast Details
Allogene will host a live conference call and webcast today, Monday December 13, at 1:30 p.m. Pacific Time / 4:30 p.m. Eastern Time to discuss Allogene data presented at ASH. To access the live conference call by telephone, please dial 1 (866) 940-5062 (U.S.) or 1 (409) 216-0618 (International). The conference ID number for the live call is 1281484. The webcast will be made available on the Company's website at www.allogene.com under the Investors tab in the News and Events section. Following the live audio webcast, a replay will be available on the Company's website for approximately 30 days.

About ALLO-715
ALLO-715, an AlloCAR T therapy targeting B-cell maturation antigen (BCMA), is a potential novel treatment for multiple myeloma and other BCMA-positive malignancies. Multiple myeloma originates in the bone marrow. It is characterized by abnormalities in plasma cells that reproduce uncontrollably in the bone marrow and other disease sites. Multiple myeloma is incurable for most patients, as relapses occur despite most treatments available. ALLO-715 was granted Regenerative Medicine Advanced Therapy (RMAT) designation in April 2021 and Orphan Drug Designation (ODD) in August 2021 by the U.S. Food and Drug Administration (FDA). The Phase 1 UNIVERSAL trial is currently on clinical hold by the FDA.

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™) therapies for cancer. Led by a management team with significant experience in cell therapy, Allogene is developing a pipeline of "off-the-shelf" CAR T cell therapy 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 Twitter and LinkedIn.

Cautionary Note on Forward-Looking Statements
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," "believes," "potential," "proposed," "continue," "estimates," "anticipates," "expects," "plans," "intends," "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 ability and timing to progress the UNIVERSAL trial and IGNITE trial and present any data from the trials; clinical outcomes, which may materially change as more patient data become available; the ability to resolve the current clinical hold on the Company's trials; and the potential benefits of AlloCAR T™ therapy. Various factors may cause differences between Allogene's expectations and actual results as discussed in greater detail in Allogene's filings with the SEC, including without limitation in its Form 10-Q for the quarter ended September 30, 2021. 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.

Statements regarding autologous CAR T data are based on review of Berdeja, Lancet, 2021 and Munshi, NEJM, 2021. Caution should be exercised when interpreting results from separate trials involving separate product candidates. There are differences in the clinical trial design, patient populations, published data, follow-up times and the product candidates themselves, and the results from the clinical trial of the approved autologous CAR T product may have no interpretative value on our existing or future results.

AlloCAR T™ is a trademark of Allogene Therapeutics, Inc.

Allogene's AlloCAR T™ programs utilize Cellectis technology. ALLO-715 and ALLO-605 target BCMA. Allogene has an exclusive license to the Cellectis technology for allogeneic products directed at BCMA and holds all global development and commercial rights for these investigational candidates.

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