Allogene Therapeutics to Showcase Clinical Data from the ALPHA, ALPHA2 and UNIVERSAL AlloCAR T™ Trials at the 63rd Annual Meeting of the American Society of Hematology

Nov 4, 2021 at 9:05 AM EDT

- ALPHA2 Study Abstract Selected for Oral Presentation Highlights the Benefits of Consolidation Dosing with ALLO-501A in Patients with Relapsed/Refractory Large B Cell Lymphoma
- ALPHA Study Abstract Selected for Poster Presentation Continues to Show Durability of Responses to ALLO-501 in Patients with Non-Hodgkin Lymphoma
- UNIVERSAL Study Abstract Selected for Oral Presentation Reports Meaningful Activity of a Single Dose of ALLO-715 in Patients with Relapsed/Refractory Multiple Myeloma
- Presentations Scheduled for December 13, 2021

SOUTH SAN FRANCISCO, Calif., Nov. 04, 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 that it will present updated data from its blood cancer portfolio at the 63rd Annual Meeting of the American Society of Hematology (ASH) taking place December 11 – 14, 2021. Allogene will have two oral presentations, one focused on the Phase 1 ALPHA2 study of ALLO-501A in large B-cell lymphoma (LBCL) and one on the Phase 1 UNIVERSAL single dose cohorts of ALLO-715 in relapsed/refractory multiple myeloma (MM). The Company will also present data on the Phase 1 ALPHA study of ALLO-501 in relapsed/refractory non-Hodgkin's lymphoma (NHL) during a poster session. Updated data will be included in the oral and poster sessions on December 13, 2021.

"We are looking forward to sharing additional data from our lead AlloCAR T programs at the ASH Annual Meeting," said Rafael Amado, M.D., Executive Vice President of Research & Development and Chief Medical Officer of Allogene. "We believe that our allogenic CAR T therapies have the potential to enable a new and more hopeful future for blood cancer patients who are in need of alternative treatment options. The findings within our ASH abstracts continue to support the promise and differentiation of our platform as we look ahead to future development."

Phase 1 ALPHA2 Trial (ALLO-501A) Abstract
ALLO-501A is a next generation anti-CD19 AlloCAR T engineered without the rituximab recognition domains in ALLO-501. The Phase 1 dose escalation portion of the ALPHA2 trial in relapsed/refractory LBCL was designed to confirm that the profile of ALLO-501A is similar to ALLO-501 prior to advancing ALLO-501A into a pivotal Phase 2 trial.

As of the ASH abstract data cutoff date of July 9, 2021, 12 patients (six each in single dose and consolidation dose cohorts) were treated with follow-up for response at dose levels from 40 to 120 X 10^6 CAR+ cells of ALLO-501A. Consolidation dosing appeared to be well tolerated with the potential for enhanced efficacy compared to a single dose of ALLO-501A. In the consolidation cohort, both the overall response rate (ORR) and complete response (CR) rate were 67% with all three partial responses (PRs) converting to CR following consolidation. All four consolidation patients who achieved a CR remained in CR as of the data cut-off.

The safety profile was manageable in both single dose and consolidation cohorts. Events of interest in the single dose cohort were previously reported at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting. In the consolidation cohort, there was no cytokine release syndrome (CRS), no graft-versus-host disease (GvHD), no immune effector cell-associated neurotoxicity syndrome (ICANS), no dose-limiting toxicities (DLTs), no dose reductions, no Grade 3+ infections and infusion-related reactions were Grade 2. Among all treated patients, cytopenias were the most common adverse event and occurred in 72% of patients.

ALPHA2 (ALLO-501A) Oral Presentation (Abstract #649)
Session: 704. Cellular Immunotherapies: Allogeneic CARs and CARs for T Cell Lymphomas
Title: ALPHA2 Study: ALLO-501A Allogeneic CAR T in LBCL, Updated Results Continue to Show Encouraging Safety and Efficacy with Consolidation Dosing
Presenter: Lazaros J. Lekakis, MD, University of Miami Health System
Presentation Date & Time: Monday, December 13, 2021; 10:30 AM ET

Phase 1 ALPHA Trial (ALLO-501) Abstract
ALLO-501 is a first generation anti-CD19 AlloCAR T product for the treatment of relapsed/refractory NHL. Updated data from ALPHA highlight that allogeneic CAR T therapy can be effectively and conveniently delivered to enrolled patients with relapsed/refractory NHL with responses observed across all cell doses and tumor histologies (DLBCL and follicular lymphoma (FL)). In CAR T naïve patients (n=36), response rates continued to be similar to those seen in autologous CAR T therapy trials and the modified-intent-to-treat (mITT) population remained nearly identical to the intent-to-treat (ITT) population.

As of the July 9, 2021 ASH abstract data cutoff, five additional patients were treated relative to the data previously reported at the 2021 ASCO Annual Meeting. ORR and CR rates remain at 75% and 50%, respectively. In patients with LBCL (n=13), the ORR was 62% and the CR rate was 46%. In patients with FL (n=23), the ORR was 83% and the CR rate was 52%. Four of the seven patients (all FL) enrolled in the consolidation cohort were evaluable for assessment after consolidation dosing at the time of the data cutoff with an ORR and CR rate of 100% and 75%, respectively.

The percent of patients remaining in CR at six months following a single infusion was 36% in LBCL, which is similar to 6-month CR rates reported in the pivotal trials of autologous CAR T therapies, with the longest ongoing CR at 15+ months, as of the data cut-off. The 6-month CR rate in FL was 28%.

No cases of GvHD or DLTs were observed. As noted previously, one case of Grade 3 ICANS was reported. Grade 1/2 CRS occurred in 22% of patients with one case of Grade 3 CRS. All were managed with standard protocols. Cytopenias were the most common adverse event and occurred in 83% of patients. Infection rates remained similar to those observed in autologous CAR T trials. There were no new treatment-emergent deaths reported in this trial.

ALPHA (ALLO-501) Poster Presentation (Abstract #3878)
Session: 704. Cellular Immunotherapies: Clinical: Poster III
Title: ALPHA Study: ALLO-501 Produced Deep and Durable Responses in Patients with Relapsed/Refractory Non-Hodgkin's Lymphoma Comparable to Autologous CAR T
Presenter: Sattva S. Neelapu, MD, The University of Texas, MD Anderson Cancer Center
Session Date & Time: Monday, December 13, 2021; 6:00 PM - 8:00 PM ET

Phase 1 UNIVERSAL Trial (ALLO-715) Abstract
ALLO-715 is an allogenic CAR T-cell therapy that targets B-cell maturation antigen (BCMA). UNIVERSAL is a Phase 1 trial in adults with relapsed/refractory MM who have received greater than three prior lines of therapy. Data from the UNIVERSAL trial featured at ASH represents one of several strategies that the Company is pursuing that targets BCMA in MM.

Findings from the UNIVERSAL trial indicate an allogeneic CAR T therapy can be delivered rapidly without the need for bridging therapy to patients with refractory multiple myeloma, with single dose of therapy capable of inducing deep responses. The ASH abstract contains data as of June 21, 2021. As of the data cut-off, 47 patients were enrolled and 42 patients were treated with escalating doses of ALLO-715 and doses of ALLO-647 ranging from 39mg to 90mg. The median time from enrollment to lymphodepletion was five days. Patients were in advanced stage of disease with a median of five prior lines of therapy and 43% of patients being penta refractory. The trial did not permit bridging therapy.

The efficacy analysis at the time of the abstract is focused on the 26 patients treated at the highest two dose levels ((320 and 480 x 10^6 CAR+ cells) with fludarabine, cyclophosphamide and ALLO-647 lymphodepletion. The ORR was 62% with a very good partial response or better (VGPR+) rate of 39%. Median follow-up for these patients was 7.4 months with a median duration of response of 8.3 months. Of the 10 patients with a best response of VGPR+, eight were found to be minimal residual disease (MRD) negative.

No GvHD was observed. The most common Grade 3+ adverse events included anemia, neutropenia, lymphopenia, and thrombocytopenia. CRS was reported in 52% of patients, in all cases Grade 1/2 except for one patient with Grade 3. One patient with Grade 2 CRS experienced Grade 1 neurotoxicity that resolved. Grade 3+ infections occurred in 13% of patients, including two previously reported Grade 5 events (fungal pneumonia and adenovirus hepatitis).

UNIVERSAL (ALLO-715) Oral Presentation (Abstract #651)
Session: 704. Cellular Immunotherapies: Allogeneic CARs and CARs for T Cell Lymphomas
Title: Universal Updated Phase 1 Data Validates the Feasibility of Allogeneic Anti-BCMA ALLO-715 Therapy for Relapsed/Refractory Multiple Myeloma
Presenter: Sham Mailankody, MBBS, Memorial Sloan Kettering Cancer Center
Presentation Date & Time: Monday, December 13, 2021; 11:00 AM ET

The ASH abstracts are now available at www.hematology.org.

About ALLO-501/ALLO-501A (Allogene Sponsored)
ALLO-501 and ALLO-501A are an anti-CD19 allogeneic CAR T (AlloCAR T™) products in development for the treatment for relapsed or refractory non-Hodgkin lymphoma (NHL). ALLO-501A, a next-generation anti-CD19 AlloCAR T™ intended for Phase 2 development, eliminates the rituximab recognition domains in ALLO-501, which could allow for use in a broader patient population, including NHL patients with recent rituximab exposure. These trials are currently on clinical hold by the FDA.

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 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). This 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 to progress the ALPHA, ALPHA2 and UNIVERSAL trials and present any data from the trial; 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 June 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.

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

Allogene's AlloCAR T™ programs utilize Cellectis technologies. ALLO-501 and ALLO-501A are anti-CD19 products being jointly developed under a collaboration agreement between Servier[1] and Allogene based on an exclusive license granted by Cellectis to Servier. Servier grants to Allogene exclusive rights to ALLO-501 and ALLO-501A in the U.S. while Servier retains exclusive rights for all other countries. ALLO-715 targets 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.

Allogene Media/Investor Contact:
Christine Cassiano
Chief Communications Officer
(714) 552-0326
Christine.Cassiano@allogene.com

1 Servier is an independent international pharmaceutical company governed by a non-profit foundation, with its headquarters in France (Suresnes).

Source: Allogene Therapeutics, Inc.