Allogene Therapeutics Presents Positive Phase 1 Data on ALLO-501 and ALLO-501A in Relapsed/Refractory Non-Hodgkin Lymphoma at the 2021 Annual Meeting of the American Society of Clinical Oncology

June 4, 2021

- ASCO Posters Detail Results from ALLO-501 ALPHA and ALLO-501A ALPHA2 Trials in Non-Hodgkin Lymphoma and Safety and PK/PD Data of ALLO-647 with Flu/Cy Across the ALPHA, ALPHA2 and UNIVERSAL Studies
- Results from Most Recent Data Discussed at Allogene's CD19 Forum Demonstrated Six Month Complete Response (CR) Rate of 36% in CAR T Naïve LBCL Patients Treated with ALLO-501
    - Longest Ongoing CR at 15 Months in Both Large B Cell Lymphoma (LBCL) and Follicular Lymphoma (FL)
    - Overall Response Rate (ORR) of 75% and CR Rate of 50% Across Histologies in CAR T Naïve Patients on Par with Autologous CAR T Therapies
    - 98% of Enrolled Patients Received ALLO-501 With a Median Time of 5 Days from Enrollment to Start of Therapy
- ALLO-501A Demonstrated Comparable Efficacy and Safety to ALLO-501
- Consolidation Dosing was Well Tolerated and Shows Early Promise with Four Patients Converting from Partial Response (PR) to CR Following Second Dose of ALLO-501 or ALLO-501A
- No Dose Limiting Toxicities or Graft-vs-Host Disease; Limited Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) and Cytokine Release Syndrome (CRS)
- Initiation of a Potentially Pivotal Trial of ALLO-501A Expected by End of 2021; Next CD19 Program Clinical Update Planned for Late 2021

SOUTH SAN FRANCISCO, Calif., June 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 presented data from multiple studies across lead anti-CD19 AlloCAR T therapy programs in two poster presentations at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting being held virtually June 4 – 8, 2021.

"Allogene is demonstrating that allogeneic CAR T has the potential to compete with autologous therapies, as well as expand the use of cell therapy by leveraging the unique benefits of an off-the-shelf product to treat every eligible patient," said David Chang, M.D., Ph.D., President, Chief Executive Officer and Co-Founder of Allogene Therapeutics. "We are very pleased with the data presented at ASCO and our CD19 Forum and are increasingly confident in the path forward as we plan to initiate a potential pivotal trial for ALLO-501A in late 2021."

The ASCO presentations include data from Phase 1 ALPHA (ALLO-501) and ALPHA2 (ALLO-501A) trials in relapsed/refractory non-Hodgkin lymphoma (NHL), developed in collaboration with Servier, and presented in the Developmental Therapeutics – Immunotherapy session (Abstract #2529) by Frederick L. Locke, M.D., Co-Leader, Moffitt Immuno-Oncology Program, Vice Chair and Associate Member Department of Blood and Marrow Transplant and Cellular Immunotherapy, Moffitt Cancer Center. Safety, pharmacokinetic (PK) and pharmacodynamic (PD) data from ALLO-647, a component of the Company's differentiated lymphodepletion regimen, will be presented in the same session (Abstract #2527) by Michael Tees, M.D., M.P.H., Associate Member Physician, Colorado Blood Cancer Institute, Sarah Cannon Research Institute.

Due to the virtual nature of the meeting, the ASCO presentations were finalized in advance of Allogene's CD19 Forum on May 19, 2021. As such, data presented at the CD19 Forum, accessible via this link and included below, is more comprehensive and reflects information collected as of May 12, 2021 from the ALPHA and ALPHA2 studies.

The Company intends to initiate a Phase 2 trial with ALLO-501A, pending regulatory feedback, by the end of 2021. The next clinical update on the CD19 program is planned for Q4 2021.

Phase 1 ALLO-501 ALPHA Trial
Data presented from the ALPHA trial supports the ability of a single administration of ALLO-501 to generate deep and durable responses at a rate that is similar to approved autologous CAR T therapies. As of the April 19, 2021 data cutoff, 42 patients were enrolled and 41 received ALLO-501, including nine who had previously received autologous CAR T treatment. The one patient not treated was enrolled but removed from the study prior to lymphodepletion due to lymphoma related obstructive kidney disease. In the trial, 98% of patients received ALLO-501 and the median and mean time from enrollment to the start of therapy was five days.

Responses were observed across all cell doses and tumor histologies (large B-cell lymphoma (LBCL) and follicular lymphoma (FL)). In CAR T naïve patients, response rates were:

	LBCL (N=11)	FL (N=21)	**All Patients** (N=32)
ORR (95% CI)	7 (64%) (31, 89)	17 (81%) (58, 95)	**24 (75%)** **(57, 89)**

CR (95% CI)	5 (46%) (17, 77)	11 (52%) (30, 74)	**16 (50%)** **(32, 68)**

The percent of these patients remaining in complete response at six months following a single infusion was 29%, with 36% in LBCL and 24% in FL. An additional four FL patients in response have yet to reach the six month timepoint. As of May 12, 2021, three LBCL patients remain in CR and eight FL patients remain in CR, with the longest ongoing CRs at 15 months.

Redosing led to clinical responses, with an overall Treatment Failure Free Survival (TFFS) for autologous naïve patients of 64% and 61% at six months for FL and LBCL, respectively.

ALLO-647 was used in lymphodepletion with fludarabine (Flu)/cyclophosphamide (Cy) at doses ranging from 39mg to 90mg. No dose limiting toxicities or graft-vs-host disease (GvHD) were observed and one (2%) case of Grade 3 Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) was reported. Cytokine release syndrome (CRS) occurred in 27% of patients, was limited to Grade 1 or 2, and was manageable with standard protocols. Infection rates were similar to those observed in autologous CAR T trials. During this study, there were five treatment-emergent deaths in the absence of disease progression, one each from pneumonia, arrythmia, and stroke, and two instances of COVID-19 acquired in the community setting. Three of these patients were in ongoing CR at the time of death.

	ALLO-647 39 mg (N=11)		**ALLO-647 60 mg (N=6)**		**ALLO-647 90 mg (N=24)**		**All Patients (N=41)**	
Adverse Events of Interest	**All Gr**	**Gr 3+**	**All Gr**	**Gr 3+**	**All Gr**	**Gr 3+**	**All Gr**	**Gr 3+**
IRR	5 (46%)	-	3 (50%)	-	18 (75%)	1 (4)	26 (63%)	1 (2%)
CRS	2 (18%)	-	1 (17%)	-	8 (33%)	-	11 (27%)	-
ICANS	-	-	-	-	1 (4%)	1 (4%)	1 (2%)	1 (2%)
GvHD	-	-	-	-	-	-	-	-
Infection	7 (64%)	1 (9%)	1 (17%)	1 (17%)	17 (71%)	8 (33%)	25 (61%)	10 (24%)

Phase 1 ALLO-501A ALPHA2 Trial
ALLO-501A is a next generation anti-CD19 AlloCAR T candidate intended for a pivotal trial and is engineered without the rituximab recognition domains included in ALLO-501. This trial is only enrolling patients with relapsed/refractory LBCL.

Following promising efficacy data from patients (N=4) treated at dose level 2 (120 x 10^6 CAR+ cells; DL2), patient enrollment in ALPHA2 focused on exploration of a consolidated dosing strategy that enabled patients who did not progress following an initial dose of ALLO-501A to receive a second, scheduled dose of cells. In consolidation dosing, 60mg ALLO-647 was provided with Flu/Cy for lymphodepletion before the first cell administration at DL2, and 30mg ALLO-647 with no Flu/Cy was provided for lymphodepletion before the second cell infusion at DL2 to patients with selective hematologic criteria.

As of the April 19, 2021 data cutoff, 13 patients were enrolled and 12 patients were treated with ALLO-501A. One patient was treated with ALLO-647 but not ALLO-501A and deemed unable to proceed due to disease progression. Nine patients treated at the targeted 120M cell dose were evaluable for efficacy were CAR T naïve, except for one who received prior autologous CAR T and previously had a 16-week CR followed by relapse. Data from these nine patients demonstrate efficacy and safety for ALLO-501A consistent with that observed for ALLO-501 in the ALPHA trial:

	DL2 (N=4)	Consolidation (N=5)	**All Patients** (N=9)
ORR (95% CI)	2 (50%) (7, 93)	3 (60%) (15, 95)	**5 (56%)** **(21, 86)**
CR (95% CI)	2 (50%) (7, 93)	3 (60%) (15, 95)	**5 (56%)** **(21, 86)**

As of May 12, 2021, all of the CRs remain ongoing, with a median follow-up of 2.3 months. Of the eight patients treated in the consolidation cohorts across both ALPHA studies, the ORR was 75% and CR rate was 63%, with four patients converting from a partial response at day 28 to a CR at day 56.

No dose limiting toxicities, GvHD or ICANS were observed in ALPHA2.

	DL 1 40 x 10^6 (40M) (N=1)		**DL2 120 x 10^6 (120M) CAR+ cells (N=5)**		**Consolidation (120M + 120M) (N=6)**		**All Patients (N=13)***	
Adverse Events of Interest	**All Gr**	**Gr 3+**	**All Gr**	**Gr 3+**	**All Gr**	**Gr 3+**	**All Gr**	**Gr 3+**
IRR	1 (100%)	-	2 (40%)	-	2 (33%)	-	5 (39%)	-
CRS	1 (100%)	1 (100%)	1 (20%)	-	-	-	2 (15%)	1 (8%)
ICANS	-	-	-	-	-	-	-	-
GvHD	-	-	-	-	-	-	-	-
Infection	1 (100%)	-	4 (*80*%)	1 (20%)	2 (33%)	-	7 (54%)	1 (8%)

* One patient was treated with ALLO-647 but not ALLO-501A due to disease progression.

About ALLO-501 (Allogene Sponsored)
ALLO-501 is an anti-CD19 allogeneic CAR T (AlloCAR T™) therapy being jointly developed under a collaboration agreement between Servier and Allogene based on an exclusive license granted by Cellectis to Servier. ALLO-501 uses Cellectis technologies. Servier grants to Allogene exclusive

rights to ALLO-501 in the U.S. while Servier retains exclusive rights for all other countries.

About ALLO-501A (Allogene Sponsored)
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. Like ALLO-501, ALLO-501A is being jointly developed under a collaboration agreement between Servier and Allogene based on an exclusive license granted by Cellectis to Servier and utilizing Cellectis technologies. ALLO-501A uses the Cellectis TALEN technology. Servier grants to Allogene exclusive rights to ALLO-501A in the U.S. while Servier retains exclusive rights for all other countries.

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 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 "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 timing and ability to progress the ALPHA and ALPHA2 trials, including progressing to the Phase 2 portion of the ALPHA2 trial; clinical outcomes, which may materially change as patient enrollment continues and more patient data become available; and the potential benefits of AlloCAR T™ therapy and the Company’s lymphodepletion strategy. Various factors may cause differences between Allogene’s expectations and actual results as discussed in greater detail in Allogene’s filings with the Securities and Exchange Commission (SEC), including without limitation in its Form 10-Q for the quarter ended March 31, 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 Kymriah United States product insert (USPI), Schuster S et al NEJM 2019; Yescarta USPI, Locke, AACR 2017; and Breyanzi USPI. 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, and the product candidates themselves, and the results from the clinical trials of autologous products 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 technologies. ALLO-501 and ALLO-501A are anti-CD19 allogeneic CAR T (AlloCAR T™) therapies 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.

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