Allogene Therapeutics CD19 Forum Highlights Positive Results from Phase 1 Studies of ALLO-501 and ALLO-501A in Relapsed/Refractory Non-Hodgkin Lymphoma and Plan to Initiate Pivotal Study in 2021

May 19, 2021

- ALLO-501 ALPHA Trial Produced Durable Complete Responses (CR) with 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 Data from Pivotal Trials of Autologous CAR T Therapies
  - Six Month CR Rate of 36% with One Time Treatment in CAR T Naïve Patients with LBCL
  - 98% of Enrolled Patients Received ALLO-501 With a Median Time of 5 Days from Enrollment to Start of Therapy
- Interim Phase 1 ALPHA2 Data Demonstrated a Comparable Efficacy and Safety Profile for ALLO-501A Relative 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)
- Safety and PK/PD Data of ALLO-647 with Flu/Cy Across ALPHA, ALPHA2 and UNIVERSAL (ALLO-715 in Multiple Myeloma) Trials Demonstrated Manageable Safety Profile; Exposure-Dependent Deep Lymphodepletion Correlated with AlloCAR T Cell Expansion and Clinical Responses
- Initiation of Pivotal Trial of ALLO-501A Planned for Late 2021
- Two Posters to be Presented at the Annual Meeting of the American Society of Clinical Oncology on June 4, 2021 on ALLO-501, ALLO-501A and ALLO-647
- Company to Host May 19 Virtual CD19 Forum at 5:30 PM Eastern Time

SOUTH SAN FRANCISCO, Calif., May 19, 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 will discuss progress on its AlloCAR T platform during today's virtual CD19 Forum. The Forum will include results from Phase 1 ALPHA (ALLO-501) and ALPHA2 (ALLO-501A) trials in relapsed/refractory non-Hodgkin lymphoma (NHL), developed in collaboration with Servier, as well as safety, pharmacokinetic (PK) and pharmacodynamic (PD) data from ALLO-647. ALLO-647 is part of the Company's differentiated lymphodepletion regimen. The Forum will also discuss the Company's approach for optimizing the unique benefits of its allogeneic CAR T therapy platform and the potential role of AlloCAR T therapy in NHL based upon views from clinical trial investigators and early market research.

These data will also be featured in poster presentations at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting being held virtually June 4 – 8, 2021.

"We are delighted to present updated data on what we believe to be the most advanced allogeneic CAR T program in development. Longer-term data from the ALPHA trial of ALLO-501 in combination with ALLO-647 demonstrate for the first time the ability of an off-the-shelf cell therapy to induce durable responses in NHL patients similar to that seen in trials of autologous therapies," said Rafael Amado, M.D., Executive Vice President of Research and Development and Chief Medical Officer at Allogene.

The Forum will include a panel of leading physicians discussing perspectives on the future of allogeneic CAR T therapy in NHL. The panel, moderated by Dr. Amado, includes:

- **Lazaros J. Lekakis**, M.D, Associate Professor of Clinical Medicine, Transplantation and Cellular Therapy, Sylvester Cancer Center, University of Miami
- **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
- **Michael Tees**, M.D., M.P.H., Associate Member Physician, Colorado Blood Cancer Institute, Sarah Cannon Research Institute

"Our vision for allogeneic cell therapy is to go beyond the boundaries of autologous products and establish new standards for CAR T therapy that, anchored on fundamentals of allogeneic cell therapy, fully explore the unique benefits of an off-the-shelf product including consolidation dosing. We believe the data presented today demonstrates our ability to shape, define and advance the field of CAR T therapy, and we look forward to potentially moving toward a pivotal trial for ALLO-501A in late 2021," said David Chang, M.D., Ph.D., Chief Executive Officer, President and Co-Founder of Allogene.

Phase 1 ALLO-501 ALPHA Trial
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 similar to those seen in autologous CAR T therapy trials:

	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. Data reported following the data cutoff to May 12, 2021 indicate three LBCL patients remain in CR and eight FL patients remain in CR, with the longest ongoing CRs at 15 months.

ALLO-647 was used in lymphodepletion with fludarabine (Flu)/cyclophosphamide (Cy) at doses ranging from 39mg to 90mg.

	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%)

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 fungal 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.

Phase 1 ALLO-501A ALPHA2 Trial
ALLO-501A is a next generation anti-CD19 AlloCAR T candidate intended for Phase 2 development and is engineered without the rituximab recognition domains found in ALLO-501. The Phase 1 dose escalation portion of the ALPHA2 trial was designed to confirm that the profile of ALLO-501A is similar to ALLO-501 prior to advancing ALLO-501A into Phase 2. 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 to cell infusion. Nine patients treated at the targeted 120M cell dose evaluable for efficacy were CAR T naïve patients, except for one patient who received prior autologous CAR T and previously achieved a 16-week CR followed by relapse. Interim data reported following the data cutoff to May 12, 2021 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 and deemed unable to proceed to cell infusion.

The Company plans to collect additional data from the consolidation arms of the ALPHA and ALPHA2 studies, finalize a dose and schedule of ALLO-501A and lymphodepletion for a potential Phase 2 trial, and discuss the Phase 2 trial design with regulatory authorities. Pending the collection of data and regulatory feedback, the Company plans to move to the Phase 2 portion of ALPHA2 by the end of 2021.

ALLO-647 Consolidated Safety and PK/PD Analysis
The safety and PK/PD profile of ALLO-647 was evaluated as part of a proprietary lymphodepletion regimen that also deploys Flu/Cy. Patients treated as part of the ALPHA, ALPHA2 and UNIVERSAL (anti-BCMA candidate ALLO-715 in relapsed/refractory multiple myeloma) trials were included in the analyses.

The data show that ALLO-647, when used in combination with Flu/Cy, induced deep, durable exposure-dependent lymphodepletion. Lymphodepletion is designed to provide a window for AlloCAR T persistence, and exposure to ALLO-647 correlated with lymphocyte depletion, CAR T cell expansion and greater clinical response. ALLO-647 in combination with Flu/Cy had a manageable safety profile with rates of Grade 3 infection similar to autologous CAR T therapies.

TRIAL	**Multiple Myeloma UNIVERSAL (N=34)**			**Non-Hodgkin Lymphoma ALPHA (N=41) & ALPHA2 (N=13)**			
ALLO-647 Dose	**39 mg (N=22)**	**60 mg (N=9)**	**90 mg (N=3)**	**39 mg (=11)**	**60 mg (N=14)**		**90 mg (N=29)**
					FCA60 & Consolidation (N=14)	**Consolidation (N=9)**	**Gr 3+**
ALL TEAES[+]	22 (100%)	9 (100%)	3 (100%)	11 (100%)	13 (93%)	8 (89%)	29 (100%)
Grade ≥3 AEs	2 (9%)	3 (33%)	-	-	2 (14%)	1 (11%)	7 (24%)
All Infection[++]	12 (55%)	6 (67%)	1 (33%)	7 (64%)	4 (29%)	3 (33%)	21 (72%)
Grade ≥3 Infection	5 (23%)	4 (44%)	-	1 (9%)	2 (14%)	1 (11%)	8 (28%)
Infusion Related Reaction to ALLO-647 (All Grades)	6 (27%)	2 (22%)	1 (33%)	5 (45%)	6 (43%)	4 (44%)	20 (69%)
Grade ≥3 Hematologic AEs							
Anemia	7 (32%)	2 (22%)	-	2 (18%)	3 (21%)	-	12 (41%)
Thrombocytopenia	6 (27%)	3 (33%)	1 (33%)	3 (27%)	5 (36%)	2 (22%)	14 (48%)
Neutropenia	11 (50%)	6 (67%)	2 (67%)	9 (82%)	8 (57%)	4 (44%)	21 (72%)

+Number of patients with AE occurring from the start of study drug up to subsequent anti-cancer therapy. For patients reporting more than one AE within a preferred term, only one AE with the maximum grade is reported.
++All infections (bacterial, fungal, and viral) included.

The UNIVERSAL trial, which enrolled heavily pre-treated myeloma patients, including those with rapidly progressing disease, included two Grade 5 events. One previously disclosed event was attributed to progressive myeloma and lymphodepletion with cyclophosphamide and ALLO-647. The second was a 78-year-old male, heavily pretreated and with ongoing lymphopenia prior to therapy, who had adenovirus reactivation.

ALLO-715 was recently granted Regenerative Medicine Advanced Therapy (RMAT) designation by the FDA for the treatment of relapsed refractory multiple myeloma.

Virtual CD19 Forum
The virtual CD19 Forum will take place Wednesday, May 19 at 2:30 p.m. PT / 5:30 p.m. ET and can be accessed via the Company's website at www.allogene.com under the Investors tab in the News and Events section or by clicking the following link directly. Materials presented will be available on the Allogene website at the start of the event.

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.

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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