Allogene Therapeutics Presents Updated ALLO-501/501A Phase 1 Data in Large B Cell Lymphoma at the American Society of Clinical Oncology (ASCO) Annual Meeting

June 3, 2023

- Long Term Follow Up Data from Phase 1 ALPHA/ALPHA2 Trials Demonstrate Potential of Allogeneic CD19 CAR T to Generate Durable Complete Responses Similar to Approved Autologous Therapies
  - Presentation Focused on Patients (n=12) Treated with Phase 2 Regimen
  - 67% Overall Response Rate (ORR) and 58% Complete Response (CR) Rate
  - Five Patients (42%) Maintained a CR at Month 6; Four of Five CRs (80%) Ongoing Beyond Six Months, Including Two at 30+ Months and One at 24+ Months
- Clinical Safety and Immune Recovery Comparable to Autologous Therapies
- Robust AlloCAR T Cell Expansion and Persistence Documented in Responding Patients
- Allogeneic CAR T Treatment Initiated at a Median of Three Days After Enrollment Without Need for Leukapheresis or Bridging Therapy; 100% Received Allogeneic CAR T Product Candidates Meeting Manufacturing Specifications
- Enrollment in Potentially Pivotal Phase 2 ALPHA2 Trial Ongoing with Expected Completion 1H2024

SOUTH SAN FRANCISCO, Calif., June 03, 2023 (GLOBE NEWSWIRE) -- Allogene Therapeutics, Inc. (Nasdaq: ALLO), a clinical-stage biotechnology company pioneering the development of allogeneic CAR T (AlloCAR T™) products for cancer, today presented long-term follow up data from the Phase 1 ALPHA/ALPHA2 trials of ALLO-501/501A in patients with relapsed/refractory (r/r) large B-cell lymphoma (LBCL) at the American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, Illinois. These data will also be presented in a poster session at the European Hematology Association (EHA) Hybrid Congress on June 9, 2023.

“We are excited to be the first to demonstrate the potential of allogeneic CD19 CAR T to induce durable complete remissions at a rate similar to approved autologous CD19 CAR T therapies. Our Phase 2 regimen also had a safety profile, including immune recovery, in line with approved options,” said Zachary Roberts, M.D., Ph.D., Executive Vice President, Research & Development and Chief Medical Officer. “We believe our AlloCAR T product candidates have the potential to break down widespread access barriers to CAR T, and ultimately establish a new paradigm in cell therapy. These data underlie the excitement we and investigators have for our ongoing potentially pivotal Phase 2 ALPHA2 trial.”

The updated analysis of ALPHA/ALPHA2 examined data from 12 CAR T-naïve patients with r/r LBCL who received a single dose of ALLO-501/501A manufactured using the Alloy™ process following a lymphodepletion regimen (FCA90) comprised of fludarabine (30 mg/m^2/day x 3 days) and cyclophosphamide (300 mg/m^2/day x 3 days) plus ALLO-647 (30 mg/day x 3 days). The median time from enrollment to the start of therapy was three days and all 12 patients were followed through a minimum of six months (data cutoff April 20, 2023).

	Patients Treated with Phase 2 Regimen (n=12)
Overall Response Rate (ORR), n (%)	8 (67)
Complete Response Rate (CR), n (%)	7 (58)
6 Month Complete Response, n (%)	5 (42)

As of the data cutoff, 7 of 12 (58%) patients achieved a CR and five (42%) maintained a CR through Month 6. Of the five patients who were in CR at 6 months, four (80%) remained in CR. The fifth patient had disease progression at 24 months. The median duration of response was 23.1 months with three patients remaining in remission for over 24 months and the longest remaining in remission for over 31 months.

	All r/r CAR T naïve LBCL (N=33)		Patients Treated with Phase 2 Regimen (N=12)	
	All Gr N (%)	Gr 3+ N (%)	All Gr N (%)	Gr 3+ N (%)
CRS	8 (24)	0	4 (33)	0
ICANS	0	0	0	0
Neurotoxicity	13 (39)	2 (6)	4 (33)	0
GvHD	0	0	0	0
IRR	16 (49)	3 (9)	8 (67)	0
Infection	19 (58)	5 (15)	8 (67)	1 (8)
Prolonged Gr3+ Cytopenia	-	4 (12)	-	2 (17)

A safety analysis of 33 CAR T-naïve LBCL patients receiving Alloy™ process ALLO-501/501A product candidates at any dose and lymphodepletion schedule, including the 12 patients treated with the Phase 2 regimen, was also conducted. Treatment was generally well tolerated with no incidences of Grade 3 or greater cytokine release syndrome, and no cases of immune effector cell-associated neurotoxicity syndrome or graft versus host

disease. Cytopenias and infections were manageable and comparable to the experience with autologous CAR T cell therapies in patients with r/r LBCL.

The ALPHA/ALPHA2 Phase 1 trials were designed to assess the safety, tolerability, and preliminary efficacy at increasing dose levels of ALLO-501 and ALLO-501A, allogeneic CAR T cell product candidates that target CD19. In addition to exploring cell doses, these studies evaluated various doses of ALLO-647, Allogene's proprietary lymphodepleting antibody designed to prevent premature rejection of AlloCAR T cells. Allogene is currently enrolling the potentially pivotal Phase 2 ALPHA2 trial of ALLO-501A in LBCL and expects to complete enrollment in 1H2024.

About ALLO-501 and ALLO-501A
ALLO-501 and ALLO-501A are anti-CD19 AlloCAR T investigational products for the treatment of large B cell lymphoma. ALLO-501A, a next-generation anti-CD19 AlloCAR T, 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. This product candidate is currently being studied in an ongoing potentially pivotal Phase 2 trial. In June 2022, the U.S. Food and Drug Administration granted Regenerative Medicine Advanced Therapy (RMAT) designation to ALLO-501A in r/r LBCL.

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. Led by a management team with significant experience in cell therapy, Allogene is developing a pipeline of "off-the-shelf" CAR T cell 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 potential of allogeneic CD19 CAR T to generate durable complete responses similar to approved autologous therapies; ALPHA2 being a potentially pivotal trial; expected completion of enrollment in ALPHA2 in the first half of 2024; the potential safety profile of Allogene's Phase 2 lymphodepletion and cell dose regimen; the potential of Allogene's AlloCAR T product candidates to break down access barriers to CAR 2 and establish a new paradigm in cell therapy; and the potential benefits of the Alloy process and AlloCAR T products. Various factors may cause material differences between Allogene's expectations and actual results, including risks and uncertainties related to: Allogene's product candidates are based on novel technologies, which makes it difficult to predict the time and cost of product candidate development and obtaining regulatory approval; Phase 1 data from Allogene's clinical trials is limited and may change as more patient data become available or may not be validated in any future or advanced clinical trial; Allogene's ability to maintain intellectual property rights necessary for the continued development of its product candidates, including pursuant to its license agreements; Allogene's product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval or limit their commercial potential; the extent to which COVID-19 adversely impacts Allogene's business, including its clinical trials; the extent to which the FDA disagrees with Allogene's clinical or regulatory plans, which could cause future delays to Allogene's clinical trials or require additional clinical trials; Allogene may encounter difficulties enrolling patients in its clinical trials; Allogene may not be able to demonstrate the safety and efficacy of its product candidates in its clinical trials, which could prevent or delay regulatory approval and commercialization; challenges with manufacturing or optimizing manufacturing of Allogene's product candidates; and Allogene's ability to obtain additional financing to develop its products and implement its operating plans. These and other risks are discussed in greater detail in Allogene's filings with the SEC, including without limitation in its Form 10-Q filed for the quarter ended March 31, 2023. 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.

Caution should be exercised regarding statements comparing autologous CAR T data. 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 trials of autologous products may have no interpretative value on Allogene's existing or future results.

Allogene's AlloCAR T™ programs utilize the Cellectis TALEN® technologies. ALLO-501 and ALLO-501A are anti-CD19 product candidates being jointly developed under a collaboration agreement between Servier 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. with an option for exclusive rights for all other countries.

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