Allogene Therapeutics R&D Showcase Features Hematologic and Solid Tumor Advances Across its AlloCAR T™ Platform

November 29, 2022

- **Hematology Franchise: Lead CD19 and BCMA Programs Demonstrated Deep, Durable Responses**
  - CD19 Program: Phase 1 Studies Support Ongoing ALLO-501A Potentially Pivotal Phase 2 Trial in Relapsed/Refractory (R/R) Large B Cell Lymphoma (LBCL)
    - One-Time Cell Dosing with Proprietary Lymphodepletion (Single Dose FCA90) Resulted in 67% Overall Response Rate (ORR) and 58% Complete Response (CR) Rate
    - Responses in Patients that Received Single Dose FCA90 Were Durable with a 50% CR Rate at Both Six and 12 Months with Longest CR Ongoing at 26+ Months
    - No Observed Dose Limiting Toxicities (DLTs), Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) or Graft-vs-Host Disease (GvHD)
    - 92% of Enrolled Patients Received Investigational Product, 100% Manufactured and Released Per Product Specifications, and Treatment Initiation Within Two Days of Enrollment
  - BCMA Program: Phase 1 ALLO-715 Expansion Cohorts Provide Encouraging Responses Supporting Continued Advancement in R/R Multiple Myeloma (MM)
    - Single Infusion of 320 Million CAR+ cells with FCA60 Lymphodepletion Resulted in 67% ORR and 42% Very Good Partial Response or Better (VGPR+); 100% of VGPR+ Were Minimal Residual Disease (MRD) Negative
    - Median Duration of Response 9.2 Months with Longest Ongoing Response at 24 Months
    - No Observed DLTs or GvHD
    - 92% of All Enrolled Patients Received Investigational Product, 100% Manufactured and Released Per Product Specifications, and Treatment Initiation Within Five Days of Enrollment with No Bridging Therapy
    - Regulatory Discussions Planned for Potentially Pivotal Phase 2 Trial
- **Solid Tumor Franchise: Proof-of-Concept for anti-CD70 AlloCAR T in Patients with Renal Cell Carcinoma (RCC) Who Received Prior Immune Checkpoint Inhibitor and VEGF-Targeting Therapy**
  - Single Infusion of ALLO-316 Demonstrated Clear Anti-Tumor Activity in CD70 Expressing RCC with Deepening Responses Over Time
    - 100% Disease Control Rate (DCR) in Known CD70 Positive RCC, with Three of Nine in Partial Response
    - Higher CD70 Expression Correlated with Likelihood of Response; New Investigational Diagnostic Assay Being Deployed to Enhance Patient Selection
- Company Reveals its Dagger™ Technology, a Next Generation Allogeneic Platform Designed to Control Rejection of AlloCAR T cells

SOUTH SAN FRANCISCO, Calif., Nov. 29, 2022 (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 hosted an R&D Showcase providing an extensive overview of pipeline advances from three clinical stage AlloCAR T programs. The event also included panel discussions with leading experts on the potential for these programs to substantially improve patient care and access if approved. Clinical updates on the Company's hematologic franchises focused on investigational products targeting CD19 and BCMA for the treatment of large B cell lymphoma (LBCL) and multiple myeloma (MM), respectively. The solid tumor presentation provided the first look at initial clinical data on ALLO-316, an AlloCAR T product candidate targeting CD70 for the treatment of clear cell renal cell carcinoma (RCC).

The Company also unveiled its Dagger™ technology, the Company's next generation allogeneic platform technology designed to prevent immune rejection and enable a window of persistence during which AlloCAR T cells can expand and actively target and destroy cancer cells. Dagger has the potential to enable a pipeline of innovative product candidates.

"From the very beginning, one of the biggest questions facing the field of allogeneic CAR T has been whether an off-the-shelf product can match the high durability bar set by autologous therapies. We believe the longer-term follow up data from our Phase 1 studies establish that this is indeed possible," said David Chang, M.D., Ph.D., President, Chief Executive Officer and Co-Founder of Allogene. "As we look to confirm our exciting results in the first allogeneic CAR T Phase 2 trial for which we are enrolling, I believe we are entering a new phase of development for AlloCAR T, one in which the field can turn its attention to "when" and not "if" these product candidates will begin to provide great benefit to patients with cancer."

"We have undertaken a rigorous step-by-step process to evaluate, understand and optimize our AlloCAR T platform. Our continuous learning approach has enabled an industry-leading pipeline of off-the-shelf AlloCAR T product candidates for hematologic and solid tumor malignancies, and we are delighted to be sharing some initial, highly promising data in solid tumors," said Rafael Amado M.D., Executive Vice President of Research and

Development at Allogene. “Our focus is to advance this pipeline, including the execution of our Phase 2 trial for ALLO-501A and preparation for a potential Phase 2 trial on ALLO-715. We believe success in this endeavor will enable us to bring the promise of cell therapy to far more patients in need.”

CD19 Program: ALPHA Studies

The Company conducted an extensive Phase 1 program designed to evaluate and optimize all aspects of its lead product candidate, including the dose and schedule of ALLO-501A and ALLO-647. In addition, following a review of the Phase 1 program, the Company determined that its Alloy™ manufacturing process was associated with robust performance. Alloy is being deployed in the ongoing Phase 2 ALPHA2 trial.

A single infusion of CAR+ cells with FCA90 lymphodepletion regimen consisting of fludarabine (30 mg/m2/day x 3 days) and cyclophosphamide (300 mg/m2/day x 3 days) (standard flu/cy) plus 90 mg of ALLO-647 (Single Dose FCA90) was deemed preferrable to two infusions of CAR+ cells (Consolidation Regimen). In the Consolidation Regimen, ALLO-647 dosing was split into 60 mg and 30 mg prior to the first and second infusion of CAR+ cells. This finding underscores the importance of optimizing lymphodepletion in allogeneic cell therapy.

Data from the Phase 1 trials of ALLO-501 and ALLO-501A support the ability of a single administration of CAR T cells to generate deep and durable responses similar to approved autologous CAR T therapies. As of the October 25, 2022 data cutoff, 33 autologous CAR T naïve patients with relapsed/refractory (r/r) LBCL were treated with Alloy process material. Ninety-two percent (92%) of all enrolled patients received investigational product with 100% of infused product manufactured and released as per product specifications. Patients were able to initiate treatment within two days of enrollment.

Responses in the ALPHA trials were overall durable. Of the nine patients treated with Alloy process material who achieved a complete response (CR) at six months, eight remain in remission with the longest complete response ongoing at 26+ months.

Among 12 patients treated with the Single Dose FCA90 regimen, the overall response rate (ORR) was 67% and 58% achieved CRs. Among the eight patients in the Single Dose FCA90 cohort who had the opportunity to be followed for six months or more, four (50%) were in CR at both six and 12 months.

		Alloy Process		
	All LBCL (n = 48)	All Alloy (n=33)	Consolidation Regimen (n=15)	**Single Dose FCA90 (n=12)**
Overall Response Rate (ORR), n (%)	23 (48)	19 (58)	8 (53)	**8 (67)**
Complete Response (CR), n (%)	14 (29)	14 (42)	6 (40)	**7 (58)**
6 Month CR Rate, n (%)	9 (23)	9 (31)	5 (33)	**4 (50)**
12 Month CR Rate, n (%)	8 (21)	8 (28)	4 (27)	**4 (50)**

The ALPHA Phase 1 trials demonstrated a manageable safety profile. There were no observed dose limiting toxicities (DLTs) or graft-vs-host disease (GvHD). Among patients treated with Single Dose FCA90, there was no Grade 3+ cytokine release syndrome (CRS) or neurotoxicity. One patient (8%) experienced a Grade 3+ infection and two (17%) experienced prolonged Grade 3+ cytopenia. As previously reported, one Grade 5 event occurred. No new Grade 5 events have occurred.

			Alloy Process					
	All LBCL (n=48)		All Alloy (n=33)		Consolidation Regimens (n=15)		Single Dose (n=12)	
Adverse Events of Interest	All Grs n (%)	Gr 3+ n (%)	All Grs n (%)	Gr 3+ n (%)	All Grs n (%)	Gr 3+ n (%)	All Grs n (%)	Gr 3+ n (%)
CRS	11 (23)	0	8 (24)	0	3 (20)	0	4 (33)	0
Neurotoxicity	15 (31)	3 (6)	12 (36)	2 (6)	6 (40)	2 (13)	4 (33)	0
ICANS	0	0	0	0	0	0	0	0
GvHD	0	0	0	0	0	0	0	0
Infection	25 (52)	9 (19)	19 (58)	5 (15)	8 (53)	3 (20)	8 (67)	1 (8)
Prolonged Gr3+ cytopenia	-	9 (19)	-	4 (12)	-	2 (13)	-	2 (17)

The Company has initiated the industry’s first potentially pivotal Phase 2 allogeneic CAR T clinical trial (ALPHA2 trial) with ALLO-501A in patients with r/r LBCL. The single-arm trial will utilize a single dose of ALLO-501A (120 million CAR+ cells) with the FCA90 lymphodepletion regimen. The ALPHA2 trial will enroll approximately 100 patients who have received at least two prior lines of therapy and have not received prior anti-CD19 therapy. The primary endpoint of this trial is ORR, and the key secondary endpoint is duration of response (DoR).

BCMA Program: UNIVERSAL Study

The Phase 1 UNIVERSAL study is a dose escalation trial in patients with heavily pretreated r/r multiple myeloma (MM). Dose expansion cohorts comprised of a single dose of ALLO-715 (320 million CAR+ cells) and either FCA39 lymphodepletion (standard flu/cy plus 39 mg of ALLO-647) or FCA60 lymphodepletion (standard flu/cy plus 60 mg of ALLO-647) demonstrated substantial and durable responses. Importantly, 92% of all enrolled patients received investigational product with 100% of infused product manufactured and released as per product specifications. Patients were able to initiate treatment within five days of enrollment and no bridging therapy was required.

Through a median follow-up of 14.8 months as of the October 11, 2022 data cutoff, the ORR was 67% in the FCA60 cohort and the very good partial response or better rate (VGPR+) was 42%. All VGPR+ were minimal residual disease (MRD) negative. The median duration of response was 9.2 months, with the longest ongoing response at 24 months.

	Expansion Cohorts

LD Regimen	Total (n=23*)	FCA39 (n=11)	FCA60 (n=12)
ORR*, n (%)	15 (65)	7 (64)	8 (67)
VGPR+ rate, n (%)	11(48)	6 (54)	5 (42)
CR/sCR rate, n (%)	5 (22)	3 (27)	2 (17)
Median DOR	8.3	8.3	9.2

* Five patients with best responses ranging from stable disease to partial response are not included due to limited follow-up.

Safety profile was manageable with low-grade and reversible neurotoxicity and no GvHD. In the expansion cohorts, there was low use of tocilizumab (32%) and steroids (25%). Eight patients (29%) experienced Grade 3+ infections and prolonged Grade 3+ cytopenias. As previously reported, one Grade 5 event occurred in the expansion cohorts and no new Grade 5 events have occurred.

	Expansion Cohorts (N=28)	
Adverse Events of Interest	All Grades n (%)	Grade 3+ n (%)
CRS	19 (68)	1 (4)
Neurotoxicity	17 (61)	0
ICANS	1 (4)	0
GvHD	0	0
Infection	19 (68)	8 (29)
Prolonged Gr3+ Cytopenia	-	8 (29)

The Company is planning a potentially pivotal Phase 2 trial for ALLO-715 in r/r MM, including planned regulatory discussions, optimizing the manufacturing process and transitioning manufacturing of ALLO-715 to the Company's own manufacturing facility, Cell Forge 1.

As part of the Company's BCMA strategy, the Company has also been conducting a Phase 1 clinical trial (the IGNITE trial) of ALLO-605, the first product candidate to incorporate TurboCAR ™ technology. TurboCAR technology allows cytokine signaling to be engineered selectively into CAR T cells and has shown the ability to improve the potency and persistence of the cells and to delay exhaustion of the cells in preclinical models. The Company is currently reviewing the manufacturing process for ALLO-605 and is not enrolling patients in the IGNITE trial at this time.

CD70 Program: TRAVERSE Study
ALLO-316, the Company's first AlloCAR T candidate for solid tumors, targets CD70, an antigen expressed on clear cell renal cell carcinoma (RCC) and other malignancies. The ongoing Phase 1 TRAVERSE study is enrolling patients with advanced or metastatic RCC who have progressed on or intolerant to standard therapies, including an immune checkpoint inhibitor and a VEGF-targeting therapy. Initial data from this trial has demonstrated the promise of an AlloCAR T to treat CD70 expressing RCC with ALLO-316 inducing anti-tumor activity with deepening responses over time. Observed anti-tumor activity was largely confined to patients with CD70 expressing tumors.

As of the data extract date of November 17, 2022, in the nine patients with tumors known to express CD70, the disease control rate (DCR) was 100% including three patients who achieved a partial response (PR) (two confirmed and one unconfirmed with the longest response lasting until month eight). Cell expansion in patients with CD70 positive disease was robust, and there was a trend toward greater tumor shrinkage in patients with the highest levels of CD70 expression.

	All Patients (n=17)	**CD70+ Patients (n=9)**
ORR, n (%)	3 (18)	**3 (33)**
DCR, n (%)	14 (82)	**9 (100)**
PR, n (%)	3 (18)	**3 (33)**

ALLO-316 has demonstrated a generally manageable safety profile with no GvHD. One dose limiting toxicity of liver enzyme elevation occurred in the second dose level. Grade 3+ prolonged cytopenia was observed in three patients (18%). CRS was all low grade with the exception of one case of Grade 3 CRS. Neurotoxicity was low grade, reversible and seen in only three patients (18%). No grade 5 events have occurred.

	All Patients (n=17)	
	All Grades n (%)	Gr 3+ n (%)
CRS	11 (65)	1 (6)
Neurotoxicity	3 (18)	0
ICANS	0	0
GvHD	0	0
Infection	9 (53)	5 (30)
Prolonged Gr3+ Cytopenia	-	3 (18)

The Company has developed an investigational *in vitro* companion diagnostic (IVD) assay designed for use in determining CD70 expression levels for patient selection in TRAVERSE. The trial is now deploying the IVD assay for the purposes of identifying patients most likely to benefit from ALLO-316. TRAVERSE will continue to explore varying cell dose and lymphodepletion regimens, including FC and FCA in CD70 positive RCC patients. Subject to ongoing results in the TRAVERSE trial, the Company may investigate ALLO-316 for other CD70 expressing solid tumors and hematologic indications.

Next Generation Platform Technology
Allogene has pursued an integrated strategy within Research and Development aimed at matching technology with insights obtained from the clinic to create solutions designed to advance patient outcomes. One of these is Dagger, a proprietary technology designed to control rejection of AlloCAR T cells by the host immune cells. This technology deploys a CD70 CAR on AlloCAR T cells in an effort to recognize and deplete CD70 positive alloreactive host T cells. The Company plans to deploy the Dagger technology in the next generation of AlloCAR T products to delay rejection, while inducing CAR T proliferation and increased tumor killing.

The R&D Showcase also included two panel presentations, one discussing perspectives on the future of allogeneic CAR T therapy in hematologic cancers and one focused on the potential of an allogeneic CAR T product to treat renal cell carcinoma. Panelists included:

Hematologic Panel

- **Frederick L. Locke**, M.D., Chair, Department of Blood & Marrow Transplant and Cellular Immunotherapy; program co-leader, Immuno-Oncology, Moffitt Cancer Center
- **Adriana Rossi, M.D.,** Assistant Professor Hematology and Medical Oncology; Co-Director CAR T and Stem Cell Transplant Center, The Mount Sinai Hospital
- **Herbert Eradat, M.D.,** Internal Medicine Specialist, Ronald Reagan UCLA Medical Center and UCLA Santa Monica Medical Center
- **Nikhil C. Munshi, M.D.,** Professor, Medical Oncology, Dana-Farber Cancer Institute

RCC/Solid Tumor Panel

- **Arie Belldegrun, M.D.,** Executive Chairman and Co-Founder of Allogene and Director & Founder, UCLA Institute of Urologic Oncology; Professor of Urology, Research; Chief, Division of Urologic Oncology, Emeritus, David Geffen School of Medicine, UCLA Health
- **Robert J. Motzer, M.D.,** Section Head, Kidney Cancer, Genitourinary Oncology Service; Jack and Dorothy Byrne Chair in Clinical Oncology, Memorial Sloan Kettering Cancer Center
- **Ritesh Kotecha, M.D.,** Assistant Attending Physician, Memorial Sloan Kettering Cancer Center
- **Malcolm K. Brenner, M.D., Ph.D.,** Founding Director, Center for Cell and Gene Therapy, Baylor College of Medicine

Conference Call and Webcast Details
A replay of today's event and copy of the presentation can be found on the Company's website at www.allogene.com under the Investors tab in the News and Events section. A replay will be available on the Company's website for approximately 30 days.

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™ in a Phase 2 clinical trial, 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. 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 ALLO-715
ALLO-715, an AlloCAR T investigational product 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, and 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. The Phase 1 UNIVERSAL trial with ALLO-715 is the first allogeneic BCMA CAR T to demonstrate feasibility in myeloma. In April 2021, ALLO-715 was granted Regenerative Medicine Advanced Therapy (RMAT) designation by the U.S. Food and Drug Administration.

About ALLO-316
ALLO-316, an AlloCAR T investigational product targets CD70, which is highly expressed in renal cell carcinoma (RCC). CD70 is also selectively expressed in several cancers, creating the potential for ALLO-316 to be developed across a variety of both hematologic malignancies and solid tumors. The ongoing Phase 1 TRAVERSE trial is designed to evaluate the safety, tolerability, and activity of ALLO-316 in patients with advanced or metastatic clear cell RCC. In March 2022, The U.S. Food and Drug Administration granted Fast Track Designation (FTD) based on the potential of ALLO-316 to address the unmet need for patients with difficult to treat RCC who have failed standard RCC therapies.

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 timing and ability to progress the ALPHA2, UNIVERSAL, and TRAVERSE trials; the

likelihood of success of the ALPHA2 Phase 2 trial, which is based on limited data from the ALPHA Phase 1 trials across two different product candidates and various doses of ALLO-501 or ALLO-501A; advancing to a Phase 2 UNIVERSAL trial; broadening the TRAVERSE trial or ALLO-316 program to other indications; clinical outcomes, which may materially change as more patient data become available; trial designs; the ability to manufacture AlloCAR T™ products, including with the Alloy process, with consistent and reproducible product characteristics; the ability to enroll patients in clinical trials; the design and potential benefits of Allogene's Dagger technology; the potential for Allogene's product candidates to be approved; and the potential benefits of AlloCAR T products, including the potential to substantially improve patient care and access. 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 8-K filed on November 29, 2022 and under the "Risk Factors" heading of its Form 10-Q for the quarter ended September 30, 2022. 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 our existing or future results.

Allogene's AlloCAR T™ programs utilize the Cellectis TALEN® technologies. ALLO-501 and ALLO-501A are anti-CD19 products 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. The anti-BCMA and anti-CD70 AlloCAR T programs are licensed exclusively from Cellectis by Allogene and Allogene holds global development and commercial rights to these AlloCAR T programs.

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