Allogene Therapeutics Reports Third Quarter 2023 Financial Results and Business Update

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- Preclinical Posters to Be Presented at the Society for Immunotherapy of Cancer (SITC) Annual Meeting on the Next Generation AlloCAR T™ Platform
  - Cloak ™ and Dagger™ Technologies Highlighted Potential to Enhance Engraftment, Expansion and Persistence o AlloCAR T Cells
  - Preclinical Validation of ALLO-182, an AlloCAR T Candidate Targeting Claudin18.2 for the Treatment of Gastric and Pancreatic Cancers
- Posters Announced for the Upcoming Annual Meeting of the American Society of Hematology, Including Comprehensive Review of Overall Safety Profile of our ALLO-501/501A Candidates Used in Conjunction with Propriety Lymphodepletion With Investigational ALLO-647 From the Phase 1 ALPHA/ALPHA2 Studies
- Enrollment Continues in the Global ALPHA2 Phase 2 Trial with ALLO-501A in LBCL with Clinical Sites Open in the United States, Canada, Europe and Australia
- Ended Q3 2023 with $497.7 Million in Cash, Cash Equivalents and Investments with Continued Cash Runway Projection into the Second Half of 2025
- Conference Call and Webcast Scheduled for Today at 2:00 PM PT/5:00 PM ET

SOUTH SAN FRANCISCO, Calif., Nov. 02, 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 provided a corporate update and reported financial results for the quarter ended September 30, 2023.

“Our experience continues to deepen as we successfully execute across our platform, creating a code for allogeneic cell therapy that can be applied not just in the industry’s first potentially pivotal trial of an allogeneic CAR T product candidate, but in other harder modes such as earlier line trials, solid tumors, and next-generation products and indications,” said David Chang, M.D., Ph.D., President, Chief Executive Officer and Co-Founder of Allogene. “We look forward to the months ahead and sharing these insights, potentially unlocking new opportunities and broadening patient access to CAR T therapy.”

Pipeline Updates

Anti-CD19 AlloCAR T Program
ALPHA2 is the industry’s first potentially pivotal Phase 2 allogeneic CAR T clinical trial. This global trial for the ALLO-501A product candidate will enroll approximately 100 patients who have received at least two prior lines of therapy and have not received prior anti-CD19 therapy.

The single-arm ALPHA2 trial in relapsed/refractory (R/R) large B cell lymphoma (LBCL) utilizes a single dose of ALLO-501A (120 million CAR+ cells) following lymphodepletion with FCA90 (fludarabine, 30 mg/m2; cyclophosphamide 300 mg/m2; and investigational ALLO-647 30 mg, daily for 3 days). The primary endpoint is overall response rate (ORR), and the key secondary endpoint is duration of response (DoR). Patients may receive treatment as an outpatient at the investigator’s discretion. Enrollment is expected to be completed by the 1H 2024 with the first data readout by the end of 2024.

The Company announced it will have two poster presentations from the ALPHA/ALPHA2 trials focused on lymphodepletion in allogeneic cell therapy at the 65th Annual Meeting of the American Society of Hematology (ASH) December 2023.

The first poster is a comprehensive safety review of all 85 patients treated in the Phase 1 ALPHA/ALPHA2 studies in relapsed/refractory (r/r) Large B Cell Lymphoma (LBCL) and follicular lymphoma (FL) to characterize the overall safety profile when ALLO-647 is added to standard lymphodepletion.

The second poster showcases translational results from ALPHA2 generated through a collaboration with The University of Texas MD Anderson Cancer Center. This study compared expansion kinetics among 11 allogeneic CAR T recipients treated with the ALLO-501A product candidate in the ALPHA2 trial. The study revealed the impact of recipient alloreactive CD8+ T cells in allogeneic CAR T rejection. Results of this study could help define strategies to improve allogeneic CAR T expansion, persistence and efficacy.

Long-term follow up data was previously presented from the Phase 1 ALPHA/ALPHA2 trials in LBCL and has been extensively characterized in presentations earlier this year at the American Society of Clinical Oncology (ASCO) Annual Meeting, European Hematology Association Congress, and International Conference on Malignant Lymphoma (ICML) in Lugano.

The Phase 1 trials enrolled heavily pre-treated patients with a median of three prior lines of therapy. Data from 33 CAR T-naïve LBCL patients receiving Alloy™ cell product, including 12 patients treated with the Phase 2 regimen, are the first to demonstrate the potential for an investigational allogeneic CAR T product to induce complete responses at rates and durability similar to approved autologous therapies. Treatment with the ALLO-501/501A product candidates was generally well tolerated with no incidence of Grade 3 or greater cytokine release syndrome, and no cases of immune effector cell-associated neurotoxicity syndrome or graft versus host disease. Cytopenia and infections were manageable and comparable to the experience with autologous CAR T cell therapies in patients with r/r LBCL.

The EXPAND trial, enrolling in the United States and Europe, is expected to support licensure of ALLO-647, the Company's investigational anti-CD52 monoclonal antibody used in conjunction with standard low-dose FC (fludarabine, 30 mg/m^2 and cyclophosphamide 300 mg/m^2, daily for 3 days) lymphodepletion regimens. The trial will enroll approximately 70 patients with r/r LBCL who will be randomized to lymphodepletion with FCA90 (which includes 90 mg of ALLO-647) versus FC alone before receiving a single 120 million cell dose of ALLO-501A. The primary endpoint of the study is progression free survival (PFS).

Anti-CD70 AlloCAR T Program
The Phase 1 dose escalation TRAVERSE trial in patients with advanced or metastatic renal cell carcinoma (RCC) who have progressed on standard therapies including an immune checkpoint inhibitor and a VEGF-targeting therapy is ongoing. Dose escalation in the TRAVERSE trial is expected to be completed by early 2024. The Company intends to target an academic forum in early 2024 to provide an update from this trial.

Next Generation Technologies and Targets

Cloak™ and Dagger™ Platform Technologies

The Company recently announced three poster presentations from its next generation AlloCAR T Platform at the Society for Immunotherapy of Cancer (SITC) Annual Meeting. The meeting will spotlight its novel, targeted Cloak and Dagger platform technologies designed to enhance engraftment, expansion and persistence of AlloCAR T cells.

These innovative approaches are intended to simplify lymphodepletion for allogeneic CAR T products and may provide a path to further expand the potential of off-the-shelf CAR T products beyond current targets and indications.

The Cloak platform technology is designed to prevent AlloCAR T cells from being recognized by host T cells without triggering substantial natural killer (NK) cell rejection while preserving CAR T cell function.

The Dagger™ platform technology, a feature of our ALLO-316 candidate, is designed to engineer AlloCAR T cells to selectively eliminate CD70 positive, alloreactive host immune cells, thereby mitigating potential premature rejection of AlloCAR T cells by the patient's immune system. Translational results shared at AACR suggest this unique immunomodulatory effect of ALLO-316 contributed to robust AlloCAR T cell expansion and persistence, and clinical remissions.

Based on preclinical results demonstrating the ability to combine anti-CD19 and other AlloCARs™ with the Dagger technology, the Company intends to explore this approach to potentially enhance the activity of next generation AlloCAR T products candidates, including those that target other hematological and solid tumors.

ALLO-182

SITC will also include a review of research which provided early validation of ALLO-182, an AlloCAR T candidate currently in the IND-enabling phase of development targeting Claudin18.2 for the treatment of patients with gastric and pancreatic cancers.

Corporate Updates
The Company has recently announced two new appointments to the leadership team. In August, the Company announced Earl Douglas as General Counsel, overseeing all aspects of the Company's legal function. Following the close of the third quarter, the Company announced Geoffrey Parker as Executive Vice President, Chief Financial Officer, overseeing the Company's financial operations and business development activities.

Third Quarter Financial Results

- The Company had $497.7 million in cash, cash equivalents, and investments as of September 30, 2023.
- Research and development expenses were $46.0 million for the third quarter of 2023, which includes $6.7 million of non-cash stock-based compensation expense.
- General and administrative expenses were $17.0 million for the third quarter of 2023, which includes $8.6 million of non-cash stock-based compensation expense.
- Net loss for the third quarter of 2023 was $61.3 million, or $0.37 per share, including non-cash stock-based compensation expense of $15.4 million.

2023 Financial Guidance

- As previously provided, the Company expects a decrease in cash, cash equivalents, and investments of approximately $230 million in 2023. Based on current assumptions, the Company continues to expect its cash runway to fund operations into 2H 2025. GAAP Operating Expenses are expected to be approximately $340 million, including estimated non-cash stock-based compensation expense of approximately $80 million. These estimates exclude any impact from potential business development activities.

Conference Call and Webcast Details
Allogene will host a live conference call and webcast today at 2:00 p.m. Pacific Time / 5:00 p.m. Eastern Time to discuss financial results and provide a business update. If you would like the option to ask a question on the conference call, please use this link to register. Upon registering for the conference call, you will receive a personal PIN to access the call, which will identify you as the participant and allow you the option to ask a question. The listen-only webcast will be made available on the Company's website at www.allogene.com under the Investors tab in the News and Events section. Following the live audio webcast, a replay will be available on the Company's website for approximately 30 days.

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 product 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 X (formerly 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," “projects,” "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: ALPHA2 being a potentially pivotal trial; the pace, timing and extent to which we may enroll patients in our clinical trials or release data from such trials; the timing and ability to progress the ALPHA2 and TRAVERSE trials; clinical outcomes, which may materially change as more patient data become available; the design and potential benefits of our Cloak ™ and Dagger™ technologies including the ability to enhance engraftment, expansion and persistence of AlloCAR T cells or the ability to resist rejection of AlloCAR T cells by the host immune cells and the expected benefits therefrom, and our plans to deploy Cloak ™ and Dagger™ technologies; the potential for our product candidates to be approved; the potential benefits of AlloCAR T products; the ability of our product candidates to treat various stages and types of cancers including hematological and solid tumors or gastric and pancreatic cancers; our level of operating expenses and the extent of our cash runway; our ability to expand indications for our allogeneic CAR T product candidates; our ability to broaden patient access to CAR T therapy; the modes of action or the biologic impacts of our product candidates including the engraftment, expansion, persistence and efficacy of allogeneic CAR T cells, the ability of AlloCAR T cells from being recognized by host T cells without triggering an immune response, and the ability to selectively eliminate CD70 positive alloreactive host immune cells; the incidence, severity and manageability of side effects of allogeneic CAR T therapies; the extent to which our clinical trials will support regulatory approval of our product candidates; the extent to which and type of lymphodepletion strategies that may be required in conjunction with our product candidates; the potential for off-the-shelf CAR T products; our ability to deliver cell therapy on-demand, more reliably, and at greater scale to more patients. Various factors may cause material differences between Allogene’s expectations and actual results, including, risks and uncertainties related to: our 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; Servier’s discontinuation of its involvement in the development of all CD19 products pursuant to our Exclusive License and Collaboration Agreement and our disputes with Servier may have adverse consequences; the limited nature of our Phase 1 data from our clinical trials and the extent to which such data may or may not be validated in any future clinical trial; our ability to maintain intellectual property rights necessary for the continued development of our product candidates, including pursuant to our license agreements; our 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 the Food and Drug Administration disagrees with our clinical or regulatory plans or the import of our clinical results, which could cause future delays to our clinical trials or require additional clinical trials; we may encounter difficulties enrolling patients in our clinical trials; we may not be able to demonstrate the safety and efficacy of our product candidates in our clinical trials, which could prevent or delay regulatory approval and commercialization; challenges with manufacturing or optimizing manufacturing of our product candidates; and our ability to obtain additional financing to develop our products and implement our operating plans. These and other risks are discussed in greater detail in Allogene’s filings with the SEC, including without limitation under the “Risk Factors” heading in its Annual Report on Form 10-K for the year ended December 31, 2022, and in its Quarterly Report on Form 10-Q for the quarter ended September 30, 2023, being filed with the SEC today. 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 Cellectis 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-CD70 and anti-Claudin18.2 AlloCAR T programs are licensed exclusively from Cellectis by Allogene and Allogene holds global development and commercial rights to these AlloCAR T programs.

ALLOGENE THERAPEUTICS, INC. SELECTED FINANCIAL DATA

(unaudited; in thousands, except share and per share data)

STATEMENTS OF OPERATIONS

	Three Months Ended September 30,	
	2023	**2022**
Collaboration revenue - related party	$ 43	$ 49
Operating expenses:		
Research and development	$ 45,977	$ 63,641
General and administrative	17,041	18,897
Total operating expenses	63,018	82,538
Loss from operations	(62,975)	(82,489)
Other income (expense), net:		
Interest and other income, net	6,205	1,002
Other expenses	(4,545)	(1,661)
Total other income (expense), net	1,660	(659)
Net loss	(61,315)	(83,148)
Net loss per share, basic and diluted	$ (0.37)	$ (0.58)

Weighted-average number of shares used in computing net loss per share, basic and diluted	167,649,010	143,661,721

SELECTED BALANCE SHEET DATA

	As of September 30, 2023	As of December 31, 2022
Cash, cash equivalents and investments	$ 497,675	$ 576,471
Total assets	712,326	817,079
Total liabilities	129,224	151,209
Total stockholders' equity	583,102	665,870

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Source: Allogene Therapeutics, Inc.