Allogene Therapeutics Reports Fourth Quarter and Full Year 2023 Financial Results and Business Update

Mar 14, 2024 at 4:05 PM EDT

- **Cema-cel Pivotal ALPHA3 First Line (1L) Consolidation Trial in Large B-Cell Lymphoma (LBCL):** Start-Up Activities Underway; Enrollment to Begin Mid-2024
- **Cema-cel Phase 1 ALPHA2 Trial in Relapsed/Refractory Chronic Lymphocytic Leukemia (CLL):** Enrolling Patients with Initial Data Projected YE 2024
- **ALLO-329 in Autoimmune Disease (AID):** Differentiated Next-Generation CD19 Dagger® Program Designed for AID will Focus on Eliminating Lymphodepletion and Meeting Demand; Phase 1 Clinical Trials in Early 2025
- **ALLO-316 Phase 1 TRAVERSE Trial in Renal Cell Carcinoma (RCC):** Update on Safety Algorithm Planned for Publication in Q2 2024
- Ended 2023 with $448.7 Million in Cash, Cash Equivalents and Investments; Reiterates Cash Runway Projection into 2026
- Conference Call and Webcast Scheduled for Today at 2:00 PM PT/5:00 PM ET

SOUTH SAN FRANCISCO, Calif., March 14, 2024 (GLOBE NEWSWIRE) -- Allogene Therapeutics, Inc. (Nasdaq: ALLO), a clinical-stage biotechnology company pioneering the development of allogeneic CAR T (AlloCAR T™) products for cancer and autoimmune disease, today provided a corporate update and reported financial results for the quarter and year ended December 31, 2023.

“We are more enthusiastic than ever about the potential for allogeneic CAR T to transform the field,” said David Chang, M.D., Ph.D., President, Chief Executive Officer and Co-Founder of Allogene. “From our innovative ALPHA3 trial which is designed to embed cema-cel as part of a curative first-line regimen for patients with large B cell lymphoma, to specifically creating a CAR T that can meet the unique needs of patients with autoimmune disease and reduce reliance on lymphodepletion, our development approach focuses on the distinctive attributes of an off-the-shelf alternative and creates an advantage for our AlloCAR T™ programs.”

Core Program Updates

Cema-Cel: Pivotal ALPHA3 1L Consolidation Trial in Large B Cell Lymphoma (LBCL)
The Company continues to focus on the development of its investigational product cemacabtagene ansegedleucel, or cema-cel (previously known as ALLO-501A) as part of the first line (1L) treatment plan for LBCL patients who are likely to relapse following 1L chemoimmunotherapy.

This innovative trial takes advantage of the unique attributes of cema-cel, the only allogeneic cell therapy product with Phase 1 data comparable to that of an autologous therapy. With off-the-shelf availability and convenience, cema-cel will be administered as a one-time infusion immediately upon detection of minimal residual disease (MRD) at the completion of six cycles of R-CHOP or equivalent 1L chemoimmunotherapy. The potential outcome of this consolidation treatment could improve the cure rate and uniquely position cema-cel to become the standard “7th cycle” of frontline treatment available to all eligible patients with MRD.

The design of the ALPHA3 1L consolidation trial builds upon the results demonstrated in the cema-cel Phase 1 ALPHA2 trial and will leverage an investigational, cutting-edge diagnostic test for MRD developed by Foresight Diagnostics. ALPHA3 will randomize approximately 230 patients who are in clinical remission but remain MRD positive at the end of standard 1L chemoimmunotherapy to either consolidation with cema-cel or the current standard of care, observation, which means to “watch and wait” for the disease to relapse. The primary endpoint of the ALPHA3 trial is event free survival (EFS). The trial will initially test two lymphodepletion regimens (one with standard fludarabine and cyclophosphamide plus ALLO-647 and one without ALLO-647). One lymphodepletion arm will be discontinued following a planned interim analysis in mid-2025 designed to select the most appropriate regimen for this patient population.

Start-up activities for the ALPHA3 trial are underway and the trial is expected to begin in mid-2024. The ALPHA3 trial will be conducted in a wide array of cancer treatment centers, including community cancer centers where most earlier line patients seek care.

Cema-Cel: Phase 1 ALPHA2 Trial in Chronic Lymphocytic Leukemia (CLL)
In the first quarter, the Company began enrollment in the ALPHA2 trial of the investigational product cema-cel in patients with relapsed/refractory (r/r) CLL. While recent autologous CD19 CAR T data has been a positive step for patients with relapsed/refractory (r/r) CLL, T cell dysfunction and high circulating leukemia burden often found in patients with CLL, make the isolation of functional T cells for autologous CAR T manufacturing difficult. As a result, this trial has been driven by investigator enthusiasm for an allogeneic CAR T to potentially boost the curative power of CAR T.

Initial data readout from Phase 1 ALPHA2 CLL cohort (n=12) is projected by year-end 2024.

ALLO-329: CD19 Dagger® in Autoimmune Disease (AID)
The Company has applied its deep understanding of CAR T research and development to design next-generation allogeneic CAR T investigational products that the Company believes can sustain the scale of the AID market while also meeting the unique requirements for these patients where they seek care.

ALLO-329, the Company's first AlloCAR T investigational product for AID, incorporates the Dagger ® technology which is intended to reduce or eliminate the need for lymphodepletion while targeting CD19+ B-cells and CD70+ activated T-cells, both of which play a role in AID.

As part of its overarching AID 2.0 platform, the Company also announced a non-exclusive, global gene editing licensing agreement with Arbor Biotechnologies, Inc. for use of their proprietary CRISPR-based gene-editing technology.

ALLO-329 is expected to enter Phase 1 clinical trials in early 2025.

ALLO-316: TRAVERSE Trial in Renal Cell Carcinoma (RCC)
Building upon the field's understanding of how certain drugs can act as a "safety key" to mitigate treatment-associated adverse events without compromising CAR T function or efficacy, the Company has developed and implemented a diagnostic and treatment algorithm in its solid tumor trial that may mitigate the treatment-associated hyperinflammatory response without compromising the CAR T function needed to eradicate solid tumors with ALLO-316 in renal cell carcinoma (RCC).

Details on this potentially cornerstone discovery in the Phase 1 TRAVERSE trial is planned for a publication in Q2 2024. A more comprehensive data update from the ongoing trial with the updated protocol is planned for later in 2024.

Financial Updates
As noted in the February 16, 2024 press release, the Company has now issued restated financials for the years ended December 31, 2020, 2021 and 2022 and interim quarters during 2022 and 2023 due to non-cash accounting adjustments associated with the December 2020 formation of the Allogene Overland Biopharm joint venture in Asia. These restated financial statements have no impact on the Company's cash, cash equivalents and marketable investments, cash runway or business operations.

2023 Fourth Quarter and Year-End Financial Results

- Research and development expenses were $54.7 million for the fourth quarter of 2023, which includes $7.0 million of non-cash stock-based compensation expense. For the full year of 2023, research and development expenses were $242.9 million, which includes $31.9 million of non-cash stock-based compensation expense.
- General and administrative expenses were $17.2 million for the fourth quarter of 2023, which includes $8.2 million of non-cash stock-based compensation expense. For the full year of 2023, general and administrative expenses were $71.7 million, which includes $34.0 million of non-cash stock-based compensation expense.
- Net loss for the fourth quarter of 2023 was $85.8 million, or $0.51 per share, including non-cash stock-based compensation expense of $15.2 million and $13.2 million in non-cash impairment of long-lived asset expense. For the full year of 2023, net loss was $327.3 million, or $2.09 per share, including non-cash stock-based compensation expense of $66.0 million and $13.2 million in non-cash impairment of long-lived asset expense.
- The Company had $448.7 million in cash, cash equivalents, and investments as of December 31, 2023.

2024 Financial Guidance
The Company expects a decrease in cash, cash equivalents, and investments of approximately $190 million in 2024. Based on current assumptions, the Company continues to expect its cash runway to fund operations into 2026. GAAP Operating Expenses are expected to be approximately $280 million, including estimated non-cash stock-based compensation expense of approximately $60 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 and autoimmune disease. Led by a management team with significant experience in cell therapy, Allogene is developing a pipeline of "off-the-shelf" CAR T cell 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.

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," "designed to, " "can, ", "become," "build, " "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: ALPHA3 being a pivotal trial; the design of ALPHA3; the potential of ALPHA3 to be administered as a one-time infusion; the potential for cema-cel to become the standard of frontline treatment available to eligible patients with MRD; the potential for ALPHA3 to improve cure rates; plans to administer cema-cel in community cancer centers in the ALPHA3 trial; use of a Foresight Diagnostics test in ALPHA3 and its anticipated sensitivity; the potential for cema-cel's safety profile to further improve in patients with no radiological evidence of disease; the potential outcomes of ALPHA3; the pace, timing and extent to which we may initiate or enroll patients in our clinical trials or release data from such trials including ALPHA2, ALPHA3, ALLO-329, and TRAVERSE trials; statements related to ALPHA2, including expected enrollment timing, expected timing for data, the potential to isolate functional T cells in manufacturing allogeneic CAR T less difficult, and the potential to boost the curative potential of CAR T; clinical outcomes, which may materially change as more patient data become available; the design and potential benefits of our Dagger® technology including the ability to reduce or eliminate the need for

lymphodepletion, and the expected benefits therefrom, to treat autoimmune disease, and our plans to deploy the Dagger® technology; 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 to treat autoimmune disease; the potential ability of our diagnostic and treatment algorithm to address emerging safety findings or mitigate treatment-associated hyperinflammatory response without compromising CAR T function; our expectation that our cash runway extends into 2026; financial guidance for 2024; the modes of action or the biologic impacts of our product candidates; the potential for off-the-shelf CAR T products, including its potential to transform the field; and other statements related to future events or conditions. Various factors may cause material differences between Allogene's expectations and actual results, including, risks and uncertainties related to: changes in the macroeconomic environment or industry that impact our business; competition; risks related to third-party performance; 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; the limited nature of the 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; preliminary results may not be indicative of results that may be observed in the future; 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, including ALPHA2, ALPHA3, ALLO-329 and TRAVERSE trials; there is no guarantee that Foresight will successfully develop an MRD assay for use as a companion diagnostic with cema-cel, and without a companion diagnostic the prospects for cema-cel could be materially and negatively impacted; 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 or any companion diagnostic for use with our product candidates; and our ability to obtain additional financing to develop our product candidates 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, 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.

AlloCAR T™ and Dagger® are trademarks of Allogene Therapeutics, Inc.

Allogene's investigational AlloCAR T™ oncology products utilize Cellectis technologies. ALLO-501 and cemacabtagene ansegedleucel (previously known as ALLO-501A) are anti-CD19 AlloCAR T™ investigational 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 AlloCAR T program is licensed exclusively from Cellectis by Allogene and Allogene holds global development and commercial rights to this AlloCAR TTM program.

ALLOGENE THERAPEUTICS, INC.
SELECTED FINANCIAL DATA

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

STATEMENTS OF OPERATIONS

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Collaboration revenue - related party	$ 21	$ 26	$ 95	$ 156
Operating expenses:				
Research and development	54,661	75,419	242,914	256,387
General and administrative	17,224	21,002	71,673	79,305
Impairment of long-lived asset	13,245	-	13,245	-
Total operating expenses	85,130	96,421	327,832	335,692
Loss from operations	(85,109)	(96,395)	(327,737)	(335,536)
Other income (expense), net:				
Interest and other income, net	6,265	2,757	18,307	4,566
Other expenses	(6,934)	(3,637)	(17,835)	(9,444)
Total other income (expense), net	(669)	(880)	472	(4,878)
Net loss	(85,778)	(97,275)	(327,265)	(340,414)
Net loss per share, basic and diluted	$ (0.51)	$ (0.67)	$ (2.09)	$ (2.38)
Weighted-average number of shares used in computing net loss per share, basic and diluted	168,335,828	144,149,240	156,931,778	143,147,165

SELECTED BALANCE SHEET DATA

	As of December 31, 2023	As of December 31, 2022
Cash, cash equivalents and investments	$ 448,697	$ 576,471
Total assets	642,837	821,579
Total liabilities	130,604	154,697
Total stockholders' equity	512,233	666,882

Allogene Media/Investor Contact:
Christine Cassiano
EVP, Chief Corporate Affairs & Brand Strategy Officer
Christine.Cassiano@allogene.com

Source: Allogene Therapeutics, Inc.