Allogene Therapeutics Reports Second Quarter 2024 Financial Results and Business Update

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- **Cemacabtagene Ansegedleucel (Cema-Cel): 1L Consolidation in Large B-Cell Lymphoma (LBCL)**
  - Pivotal Phase 2 ALPHA3 Trial Initiated in June 2024
  - Patient Screening for Minimal Residual Disease (MRD) and Enrollment Proceeding as Planned with Ten Community and Academic Sites Opened to Date Across the US
  - Enrollment Completion Expected in 1H 2026 and Potential BLA Submission in 2027
- **ALLO-329 in Autoimmune Disease (AID)**
  - Investigational New Drug (IND) Application for Next-Generation CD19/CD70 Dual CAR with Dagger® Technology Designed for AID on Track for Q1 2025 with Proof-of-Concept Data Expected by YE 2025
- **ALLO-316 in Renal Cell Carcinoma (RCC)**
  - Phase 1 TRAVERSE Data Update Including Details on the Diagnostic and Treatment Algorithm Planned for YE 2024
- Ended Q2 2024 with $444.6 Million in Cash, Cash Equivalents and Investments; Cash Runway Continues to be Projected into 2H 2026
- Conference Call and Webcast Scheduled for Today at 2:00 PM PT/5:00 PM ET

SOUTH SAN FRANCISCO, Calif., Aug. 07, 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 corporate updates and reported financial results for the quarter ended June 30, 2024.

“The second quarter has been an excellent example of the power of momentum, particularly as we bring into the fold community cancer centers who are eager to be a part of our pivotal Phase 2 ALPHA3 trial and we are now manufacturing all of our CAR T investigational products in-house,” said David Chang, M.D., Ph.D., President, Chief Executive Officer and Co-Founder of Allogene. “Beyond the progress we’ve seen across our four core programs with cema-cel in blood cancers, ALLO-329 in autoimmune disease, and ALLO-316 in relapsed and refractory renal cell carcinoma, there is renewed energy from investigators, clinical trial sites, and top-tier investors as it becomes increasingly apparent that we have the potential to reshape the future of CAR T therapies.”

Program Updates

Cema-Cel: Pivotal ALPHA3 1L Consolidation Trial in Large B Cell Lymphoma (LBCL)
The pivotal Phase 2 ALPHA3 trial was initiated in June 2024 and site activation is ahead of schedule with ten community cancer and academic centers opened in less than two months. Patient screening for minimal residual disease (MRD) and enrollment are proceeding as planned.

This groundbreaking study is evaluating the use of cemacabtagene ansegedleucel (cema-cel) as part of the first line (1L) treatment regimen for patients with LBCL who are likely to relapse after standard 1L treatment. ALPHA3 is the first pivotal trial to offer CAR T as part of 1L treatment consolidation.

This innovative ALPHA3 trial will identify patients at high risk for relapse after 1L treatment by utilizing the Foresight CLARITY™ Investigational Use Only (IUO) MRD test, powered by PhasED-Seq™. This randomized trial will enroll approximately 240 patients and is designed to demonstrate a meaningful improvement in event free survival (EFS) in patients treated with cema-cel relative to patients who receive the current standard of care (observation). ALPHA3 is expected to complete enrollment in 1H 2026. Efficacy analyses are expected to occur in 2026 and will include an interim EFS analysis monitored by the independent Data Safety Monitoring Board (DSMB) in 1H 2026 and the data readout of the primary EFS analysis YE 2026. A potential biologics license application (BLA) submission is targeted for 2027.

Cema-Cel: Phase 1 Trial in Chronic Lymphocytic Leukemia (CLL)
Enrollment is ongoing in the relapsed/refractory (r/r) CLL cohort of the Phase 1 ALPHA2 trial of cema-cel. Initial data readout from the CLL cohort is projected by early 2025.

ALLO-329: CD19/CD70 Dual CAR with Dagger® Technology in Autoimmune Disease (AID)
ALLO-329, the Company’s first CRISPR-based 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 are likely to play a role in AID. The Company plans to file an investigational new drug (IND) application in Q1 2025 and expects to have proof-of-concept by YE 2025.

ALLO-316: TRAVERSE Trial in Renal Cell Carcinoma (RCC)
A Phase 1 data update from approximately 20 patients with CD70 positive RCC, which will include details on the diagnostic and treatment algorithm used to mitigate treatment-associated hyperinflammatory response seen in some patients, is planned by YE 2024. In April 2024, the Company announced a $15 million award from the California Institute for Regenerative Medicine (CIRM) to support the ongoing TRAVERSE trial with ALLO-316 in RCC.

2024 Second Quarter Financial Results

- Research and development expenses were $50.4 million for the second quarter of 2024, which includes $5.3 million of non-cash stock-based compensation expense.
- General and administrative expenses were $16.1 million for the second quarter of 2024, which includes $8.2 million of non-cash stock-based compensation expense.
- Net loss for the second quarter of 2024 was $66.4 million, or $0.35 per share, including non-cash stock-based compensation expense of $13.6 million and $5.0 million in non-cash impairment of long-lived asset expense.
- The Company had $444.6 million in cash, cash equivalents, and investments as of June 30, 2024.

Based on the cash runway as of June 30, 2024, the Company continues to expect its cash runway to fund operations into the second half of 2026. Guidance remains unchanged from the most recent update with an expectation of a decrease in cash, cash equivalents, and investments of approximately $200 million in 2024. GAAP Operating Expenses are expected to be approximately $300 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 PM PT/5:00 PM ET 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 Allogene Therapeutics 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 “proceeding as planned,” “on track,” “ahead,” “targeted,” “ongoing,” “likely to,” “believes,” “potential,” “continue,” “estimates,” “expects,” “plans,” “intends,” “designed to, “ “can, “, “become,” “may,” “could,” “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: Allogene's belief that it has the potential to reshape the future of CAR T therapies; the potential market opportunity for Allogene’s product candidates; ALPHA3 being a pivotal trial; the design of ALPHA3; the potential of ALPHA3 to be administered as part of 1L treatment consolidation; the potential for cema-cel to become the part of the first line treatment regimen available to patients with LBCL who are likely to relapse after standard 1L treatment; plans to administer cema-cel in community cancer centers in the ALPHA3 trial; 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; 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; 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, including manufacturing our CAR T product candidates in-house, 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 Securities and Exchange Commission (SEC), including without limitation under the “Risk Factors” heading in its Quarterly Report on Form 10-Q for the quarter ended June 30, 2024, 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.
CLARITY™ and PhasED-Seq™ are trademarks of Foresight Diagnostics.

Allogene's investigational AlloCAR T™ oncology products utilize Cellectis technologies. The anti-CD19 oncology products are developed based on an exclusive license granted by Cellectis to Servier. Servier, which has an exclusive license to the anti-CD19 AlloCAR T™ investigational products from Cellectis, has granted Allogene exclusive rights to these products in the U.S., all EU Member States and the United Kingdom. The anti-CD70 AlloCAR T program is licensed exclusively from Cellectis by Allogene and Allogene holds global development and commercial rights to this AlloCAR T™ program. ALLO-329 (CD19/CD70) in autoimmune disease uses CRISPR gene-editing technology.

ALLOGENE THERAPEUTICS, INC.
SELECTED FINANCIAL DATA

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

STATEMENTS OF OPERATIONS

	Three Months Ended June 30,	
	2024	**2023**
Collaboration revenue - related party	$ —	$ 22
Operating expenses:		
Research and development	$ 50,355	$ 62,038
General and administrative	16,087	18,524
Impairment of long-lived assets	4,989	—
Total operating expenses	71,431	80,562
Loss from operations	(71,431)	(80,540)
Other income (expense), net:		
Interest and other income, net	4,988	3,778
Other income and expense, net	85	(2,470)
Total other income (expense), net	5,073	1,308
Net loss	(66,358)	(79,232)
Net loss per share, basic and diluted	$ (0.35)	$ (0.54)
Weighted-average number of shares used in computing net loss per share, basic and diluted	190,026,638	146,795,826

SELECTED BALANCE SHEET DATA

	As of June 30, 2024	**As of December 31, 2023**
Cash, cash equivalents and investments	$ 444,628	$ 448,697
Total assets	646,883	642,837
Total liabilities	131,845	130,604
Total stockholders' equity	515,038	512,233

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Source: Allogene Therapeutics, Inc.