Allogene Therapeutics Reports Second Quarter 2025 Financial Results and Business Update

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- **Pivotal Phase 2 ALPHA3 Trial with Cemacabtagene Ansegedleucel (Cema-Cel) in First Line (1L) Consolidation in Large B-Cell Lymphoma (LBCL)**
  - ALPHA3 Proceeding as a Two-Arm Randomized Trial Comparing Cema-cel After Standard Fludarabine and Cyclophosphamide (FC) Lymphodepletion vs. Observation
  - More than 50 sites Activated Across the U.S. and Canada, with Additional International Expansion Underway; Scheduled Futility Analysis Remains on Track for 1H 2026
- **Phase 1 RESOLUTION Trial with ALLO-329 in Autoimmune Disease (AID)**
  - Initiated RESOLUTION Basket Trial in Rheumatology
  - Proof-of-Concept Data Remains Planned for 1H 2026
- **Phase 1 TRAVERSE Trial with ALLO-316 in Renal Cell Carcinoma (RCC)**
  - Updated Phase 1B Results Presented at ASCO 2025 Highlighted Clinical Responses and the Potential of the Dagger® Technology Platform to Drive Robust Expansion and Persistence of Allogeneic CAR T Cells
  - Aligned with FDA on Pivotal Trial Design, Supporting Potential Partnership Discussions to Advance the Program
- Ended Q2 2025 with $302.6 Million in Cash, Cash Equivalents and Investments; Cash Runway Projected Into 2H 2027
- Conference Call and Webcast Scheduled for Today at 2:00 PM PT/5:00 PM ET

SOUTH SAN FRANCISCO, Calif., Aug. 13, 2025 (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, 2025.

“This quarter marked a significant inflection point for Allogene as we advance the streamlined ALPHA3 trial toward its next key milestone, initiate clinical enrollment in our first autoimmune indications with ALLO-329, and aligned with the FDA on a pivotal path forward for ALLO-316 in solid tumors,” said David Chang, M.D., Ph.D., President, Chief Executive Officer and Co-Founder of Allogene. “Our progress reflects a focused and disciplined execution strategy, and a clear path to value creation as we advance the next wave of scalable and accessible cell therapies with potentially durable results.”

Program Updates

Cema-Cel: Pivotal Phase 2 ALPHA3 1L Consolidation Trial in LBCL

The Company has selected standard fludarabine and cyclophosphamide (FC) as the lymphodepletion regimen to be used in its ALPHA3 study. The amended ALPHA3 trial now proceeds as a randomized study with two arms, comparing cema-cel after standard FC lymphodepletion to observation, the current standard of care.

The selection of FC as the lymphodepletion regimen in the ALPHA3 trial reflects strategic advantages supported by preliminary safety and biomarker data. Early observations indicate an encouraging minimal residual disease (MRD) conversion rate and a favorable safety profile when cema-cel is administered following standard FC. The regimen also offers operational benefits, including ease of administration and the potential for broader adoption within community cancer centers, and is enthusiastically supported by study investigators. In contrast to the relapsed/refractory setting, where a higher disease burden may necessitate more intensive lymphodepletion, standard FC may be sufficient to support the eradication of microscopic disease in earlier lines of treatment.

The next milestone will be the futility analysis comparing MRD conversion between the two arms and is expected to occur 1H 2026. The Company expects to provide the rates of MRD conversion between the two arms at the time of this announcement. To date, over 50 clinical sites are activated across the United States and Canada, including community cancer centers and major academic institutions.

ALLO-329: CD19/CD70 Dual CAR with Dagger® Technology in AID

The Phase 1 RESOLUTION basket trial in rheumatology launched in Q2 2025 and represents a significant step in evaluating CAR T therapy across multiple autoimmune conditions, including systemic lupus erythematosus (with or without lupus nephritis), idiopathic inflammatory myopathies, and systemic sclerosis. The trial features two lymphodepletion arms: one with cyclophosphamide alone and one with no lymphodepletion. The first clinical update, expected in 1H 2026, will include biomarker data and clinical proof-of-concept data.

ALLO-329 is a first-in-class allogeneic CD19/CD70 dual CAR T product designed to target both CD19+ B cells and CD70+ activated T cells, which are key drivers of autoimmune disease. It leverages CRISPR-based site-specific integration and incorporates the Company’s clinically validated Dagger ® technology, which aims to reduce or eliminate the need for lymphodepletion to facilitate broader CAR T adoption in autoimmune indications.

ALLO-316: TRAVERSE Trial in RCC

ALLO-316 is the only allogeneic CAR T therapy to show potential in solid tumors. Enrollment has been completed in the Phase 1b cohort, which evaluated the safety and efficacy of ALLO-316 at DL2 (80M CAR T cells) in patients with heavily pretreated advanced or metastatic RCC. The Company presented updated Phase 1b cohort data in an oral presentation at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting

and has since met with the FDA to align on the design of a pivotal trial, laying the groundwork for potential partnership discussions to advance the program.

2025 Second Quarter Financial Results

- Research and development expenses were $40.2 million for the second quarter of 2025, which includes $2.6 million of non-cash stock-based compensation expense.
- General and administrative expenses were $14.3 million for the second quarter of 2025, which includes $6.1 million of non-cash stock-based compensation expense.
- Net loss for the second quarter of 2025 was $50.9 million, or $0.23 per share, including non-cash stock-based compensation expense of $8.7 million and non-cash impairment of long-lived asset expense of $2.4 million.
- The Company had $302.6 million in cash, cash equivalents, and investments as of June 30, 2025.

The Company's cash runway is expected to extend into the second half of 2027. Guidance for 2025 is an expected decrease in cash, cash equivalents, and investments of approximately $150 million. GAAP Operating Expenses are expected to be approximately $230 million, including estimated non-cash stock-based compensation expense of approximately $45 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. PT/5:00 p.m. 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 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 "expected," "projected," "potential," "targeted," "believes," "will," "aims to," "scheduled," "drive," "guidance," "estimated," "may," "could," "designed to," "can," 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 our product candidates to offer scalable and accessible cell therapy with potentially durable results; ALPHA3 being a pivotal trial and the extent to which it will support regulatory approval of cema-cel; plans to expand the ALPHA3 trial footprint outside of the U.S.; the expected timing for biomarker and proof-of-concept data; the expected timing for the announcement of the MRD conversion rate; the expected timing for the futility analysis milestone in the ALPHA3 trial; the potential advantages of the FC lymphodepletion regimen and the potential MRD conversion rate and safety profile indicated by early observations, as well as the potential sufficiency of standard FC to support the eradication of microscopic disease in earlier lines of treatment; the potential benefits of our Dagger® technology; the potential for partnership discussions for ALLO-316; the pace, timing and extent to which we may initiate or enroll patients in our clinical trials or release data from such trials; our expectation that our cash runway extends into the second half of 2027; financial guidance for 2025; 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: 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 our pre-clinical and Phase 1 data and the extent to which such data may or may not be validated in any future clinical trial; our product candidates may cause undesirable side effects, including serious adverse events, or have other properties that could result in clinical holds, otherwise halt their clinical development, prevent their regulatory approval or limit their commercial potential; the potential for the FDA to disagree with our clinical or regulatory plans or the import of our clinical results, which could cause future delays to our clinical trials, including initiation of clinical trials, or require additional clinical trials; we may encounter difficulties enrolling or retaining 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; competition in our industry; we have in the past and may in the future decide to deprioritize certain programs as a result of program and cash resource considerations; and the challenges with manufacturing or optimizing manufacturing of our product candidates. 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, 2025, 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.

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

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,	
	2025	**2024**
Operating expenses:		
Research and development	$ 40,156	$ 50,355
General and administrative	14,281	16,087
Impairment of long-lived assets	2,382	4,989
Total operating expenses	56,819	71,431
Loss from operations	(56,819)	(71,431)
Other income (expense), net:		
Interest and other income, net	6,187	4,988
Interest expense	(268)	—
Other income (expenses), net	(43)	85
Total other income (expense), net	5,876	5,073
Net loss	$ (50,943)	$ (66,358)
Net loss per share, basic and diluted	$ (0.23)	$ (0.35)
Weighted-average number of shares used in computing net loss per share, basic and diluted	218,929,548	190,026,638

SELECTED BALANCE SHEET DATA

	As of June 30, 2025	**As of December 31, 2024**
Cash, cash equivalents and investments	$ 302,630	$ 373,149
Total assets	470,593	548,710
Total liabilities	126,032	126,531
Total stockholders' equity	344,561	422,179

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Source: Allogene Therapeutics, Inc.