Allogene Therapeutics Reports Fourth Quarter and Full Year 2024 Financial Results and Business Update

Mar 13, 2025 at 4:02 PM EDT

- **Momentum Builds Across Programs with Key Data Milestones Expected in 2025**
- **Cemacabtagene Ansegedleucel (Cema-Cel): First-Line (1L) Consolidation in Large B-Cell Lymphoma (LBCL)**
  - Ongoing Pivotal Phase 2 ALPHA3 Trial Advancing with Site Activation and Patient Enrollment
  - Lymphodepletion Selection and Futility Analysis Anticipated Around Mid-2025
  - Primary EFS Data Expected Around YE 2026 with Potential BLA Submission in 2027
- **ALLO-329 in Autoimmune Disease (AID)**
  - Secured Investigational New Drug (IND) FDA Clearance for the RESOLUTION Basket Trial in Rheumatology
  - Trial Initiation Targeted for Mid-2025; Proof-of-Concept Data Expected Around YE 2025
- **ALLO-316 in Renal Cell Carcinoma (RCC)**
  - Presented Positive Phase 1 Data Highlighting Meaningful Response Rates in Patients with Advanced Renal Cell Carcinoma and the Potential of the CD70 Dagger® Technology to Promote Robust CAR T Cell Expansion and Persistence
  - Phase 1b Expansion Cohort Enrollment Completed with Data Expected Mid-2025
- Ended Q4 2024 with $373.1 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., March 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 and full year ended December 31, 2024.

“In 2024, we focused on delivering on our bold strategy to achieve what no CAR T has accomplished before,” said David Chang, M.D., Ph.D., President, Chief Executive Officer, and Co-Founder of Allogene. “Our recent data, published in the *Journal of Clinical Oncology*, from the Phase 1 ALPHA/ALPHA2 trials in relapsed/refractory LBCL provided compelling evidence that cema-cel can induce durable remissions comparable to approved autologous CD19 CAR T therapies. With the ALPHA3 first line consolidation trial evaluating cema-cel in LBCL now underway, the ALLO-329 IND clearance to launch the RESOLUTION trial in autoimmune disease, and completion of the Phase 1b cohort with ALLO-316 in the TRAVERSE trial in RCC, we are demonstrating that Allogene’s vision for an “off-the-shelf” cell therapy may not just be a possibility, it could be a reality in hematology, autoimmune diseases, and solid tumors. We believe 2025 will be the year allogeneic CAR T broadly begins to demonstrate its potential to surpass autologous CAR T therapy by reaching more patients with greater accessibility.”

Program Updates

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

The pivotal Phase 2 ALPHA3 trial remains a central program for the Company. The trial, which initiated in June 2024, now has 40 sites activated and continues to generate strong enthusiasm from both community cancer centers and academic institutions.

This groundbreaking study is evaluating consolidation treatment with cema-cel as part of the 1L treatment regimen for patients with LBCL with minimal residual disease (MRD) after standard 1L treatment with R-CHOP or other chemoimmunotherapy. ALPHA3 is the first pivotal trial to offer CAR T to potentially eradicate MRD to improve cure rates in LBCL.

This innovative ALPHA3 trial will identify patients at high risk for relapse after 1L treatment by utilizing Foresight CLARITY™ powered by PhasED-Seq™, a novel Investigational Use Only (IUO) test for MRD. 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). The lymphodepletion selection and futility analysis are anticipated around mid-2025. Efficacy analyses from the ALPHA3 trial 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 around YE 2026. A potential biologics license application (BLA) submission is targeted for 2027.

In February 2025, the *Journal of Clinical Oncology* published data from the Company’s Phase 1 ALPHA/ALPHA2 trials of cema-cel in relapsed/refractory LBCL, demonstrating durable responses comparable to approved autologous CD19 CAR T therapies. In addition, the Company announced that it had expanded its strategic partnership with Foresight Diagnostics to support the development of Foresight Diagnostics’ MRD assay as a companion diagnostic in the EU, UK, Canada and Australia in support of Allogene’s clinical development of cema-cel.

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

ALLO-329 offers a novel approach to treating autoimmune diseases as the first allogeneic CD19/CD70 dual CAR T product specifically designed to target CD19+ B-cells and CD70+ activated T-cells, both of which are key players in autoimmune diseases. The investigational product utilizes

CRISPR-based site-specific integration and incorporates the Company's clinically validated Dagger technology, which aims to reduce or eliminate the need for lymphodepletion, believed to be a potentially significant obstacle to the wider adoption of CAR T therapies in autoimmune indications.

In January 2025, the FDA cleared the IND application to initiate clinical trials of ALLO-329 in patients with systemic lupus erythematosus, including lupus nephritis, idiopathic inflammatory myopathies, and systemic sclerosis. The innovative design of the RESOLUTION basket trial includes two distinct lymphodepletion arms: one using a dose of cyclophosphamide alone and another that eliminates lymphodepletion entirely. The trial is scheduled to begin in mid-2025, aiming to provide proof-of-concept around year-end 2025.

During the fourth quarter, the Company presented pre-clinical data for ALLO-329, at the American College of Rheumatology's annual meeting, showcasing its potential to address both B-cell and T-cell dysfunction in autoimmune diseases.

ALLO-316: TRAVERSE Trial in RCC
ALLO-316 is the only allogeneic CAR T therapy to show potential in solid tumors. In Q4 2024, the Company announced positive Phase 1 data from the TRAVERSE trial highlighting a manageable safety profile and significant anti-tumor activity of ALLO-316 in heavily pretreated patients with advanced or metastatic RCC.

Enrollment has completed in the Phase 1b expansion cohort, which is evaluating safety and efficacy of ALLO-316 at DL2 (80M CAR T cells). As the product that brought clinical validation of the Dagger effect, clinical activity of ALLO-316 at this dose level is achieved without ALLO-647-enhanced lymphodepletion and follows a standard lymphodepletion regimen with fludarabine and cyclophosphamide. Data from this cohort is planned for mid-2025.

Also during the quarter, the Company announced that it had received Regenerative Medicine Advanced Therapy (RMAT) designation for ALLO-316 for adult patients with advanced or metastatic RCC based on the Phase 1 clinical data from the TRAVERSE trial.

2024 Fourth Quarter and Year-End Financial Results

- Research and development expenses were $45.0 million for the fourth quarter of 2024, which includes $5.6 million of non-cash stock-based compensation expense. For the full year of 2024, research and development expenses were $192.3 million, which includes $20.4 million of non-cash stock-based compensation expense.
- General and administrative expenses were $15.5 million for the fourth quarter of 2024, which includes $7.3 million of non-cash stock-based compensation expense. For the full year of 2024, general and administrative expenses were $65.2 million, which includes $31.3 million of non-cash stock-based compensation expense.
- Net loss for the fourth quarter of 2024 was $59.9 million, or $0.28 per share, including non-cash stock-based compensation expense of $12.9 million. For the full year of 2024, net loss was $257.6 million, or $1.32 per share, including non-cash stock-based compensation expense of $51.7 million and $15.7 million in non-cash impairment of long-lived asset expense.
- The Company had $373.1 million in cash, cash equivalents, and investments as of December 31, 2024.

Based on its cash, cash equivalents and investments as of December 31, 2024, the Company continues to expect its cash runway to fund operations into the second half of 2026. Guidance for 2025 is an expected decrease in cash, cash equivalents, and investments of approximately $170 million. GAAP Operating Expenses are expected to be approximately $250 million, including estimated non-cash stock-based compensation expense of approximately $50 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," "anticipated," "projected," "potential," "targeted," "believes," "will," "aims to," "scheduled to," "continue," "guidance," "estimated," "planned," "may," "could," "designed to," "aims 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: momentum for development programs; timing around clinical milestones and regulatory filings such as trial initiations and enrollment, interim analyses, lymphodepletion selection, data announcements and BLA filings; allogeneic CAR T potential versus autologous CAR T, including relative durability of responses; potential for our product candidates to safely treat cancer or autoimmune diseases, including as an "off-the-shelf" product; potential business development activities; our projected financial position, including financial guidance and projected cash runway; 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 and our partners' novel technologies and potential adverse effects; the success, cost, and timing of Allogene's product development activities and clinical trials, including trial initiation and enrollment; the regulatory approval process; the ability of Allogene to obtain and maintain regulatory approval of its product candidates; potential delays or difficulties in product manufacturing; competition from other biopharmaceutical companies; obtaining additional funding to develop Allogene's product candidates and implement its operating plans; and general economic and market conditions. 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 Annual Report on Form 10-K for the year ended December 31, 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 December 31,		Year Ended December 31,	
	2024	**2023**	**2024**	**2023**
Collaboration revenue - related party	$ —	$ 21	$ 22	$ 95
Operating expenses:				
Research and development	44,972	54,661	192,299	242,914
General and administrative	15,518	17,224	65,205	71,673
Impairment of long-lived asset	—	13,245	15,717	13,245
Total operating expenses	60,490	85,130	273,221	327,832
Loss from operations	(60,490)	(85,109)	(273,199)	(327,737)
Other income (expense), net:				
Interest and other income, net	3,027	6,265	20,153	18,307
Interest expense	(81)	—	(181)	—
Other expenses, net	(1,952)	(6,934)	(3,920)	(17,835)
Total other income (expense), net	994	(669)	16,052	472
Loss before income taxes	(59,496)	(85,778)	(257,147)	(327,265)
Income tax expense	(443)	—	(443)	—
Net loss	(59,939)	(85,778)	(257,590)	(327,265)
Net loss per share, basic and diluted	$ (0.28)	$ (0.51)	$ (1.32)	$ (2.09)
Weighted-average number of shares used in computing net loss per share, basic and diluted	210,572,295	168,335,828	194,811,756	156,931,778

SELECTED BALANCE SHEET DATA

	As of December 31, 2024	As of December 31, 2023
Cash, cash equivalents and investments	$ 373,149	$ 448,697
Total assets	548,710	642,837
Total liabilities	126,531	130,604
Total stockholders' equity	422,179	512,233

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

Source: Allogene Therapeutics, Inc.