Allogene Therapeutics Reports First Quarter 2024 Financial Results and Business Update

May 13, 2024 at 4:01 PM EDT

- **Cemacabtagene Ansegedleucel (Cema-Cel)**
  - Expanded CD19 Oncology Rights to Include all EU Member States and the United Kingdom, Reinforcing Company's Conviction in the Unique Opportunity in Large B Cell Lymphoma (LBCL) and Relapsed/Refractory (R/R) Chronic Lymphocytic Leukemia (CLL)
    - Extended Territory Rights Substantially Increase Market Opportunity in 1L Consolidation LBCL and R/R CLL From More Than $6 Billion in the US to More Than $9.5 Billion in the Combined U.S., EU Member States and the United Kingdom
    - Consolidated Rights Provide Greater Flexibility for Future Cema-Cel Partnerships to Expand Commercial Footprint
  - Pivotal Phase 2 ALPHA3 1L Consolidation LBCL Trial Expected to Begin Mid-2024
  - Initial Data from Phase 1 R/R CLL Trial Expected by YE 2024

- **ALLO-329 in Autoimmune Disease (AID)**
  - Next-Generation CD19/CD70 Dual CAR with Dagger® Technology Designed for AID with the Goal of Eliminating Lymphodepletion
  - IND Submission Planned for Q1 2025 with Proof-of-Concept Data Expected by YE 2025
- **ALLO-316 in Renal Cell Carcinoma (RCC)**
  - Awarded $15 Million Grant from the California Institute for Regenerative Medicine (CIRM) to Support Ongoing Phase 1 TRAVERSE Trial in RCC
  - Phase 1 TRAVERSE Data Update Expected by YE 2024

- Ended Q1 2024 with $397.3 Million in Cash, Cash Equivalents and Investments; 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., May 13, 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 March 31, 2024.

"We are very proud of the progress we've made across our portfolio, in particular the transformative potential of our pivotal ALPHA3 trial with cema-cel which is expected to readout in 2026. Securing the EU and UK rights reinforces our conviction in the cema-cel program," said David Chang, M.D., Ph.D., President, Chief Executive Officer and Co-Founder of Allogene. "We will continue to focus all of our resources on advancing these core programs and believe we are well-positioned to change the CAR T treatment landscape for the benefit of patients."

Key Corporate Updates

Expansion of CD19 Oncology Program Rights
The Company has obtained development and commercialization oncology rights to all EU Member States and the United Kingdom (Extended Territory) for its CD19-directed allogeneic cell therapy products from Servier.

These new expanded rights, combined with the U.S. rights already owned by the Company, substantially increase the potential total market opportunity from more than $6 billion in the U.S. alone to more than $9.5 billion in the combined U.S. and Extended Territory. It is expected that the future multibillion-dollar revenue potential for cema-cel now could increase by 50% with these expanded rights. The Company also has the ability to obtain the development and commercialization rights for cema-cel in Japan and China in the future at no additional cost, subject to Allogene demonstrating the resources to pursue those markets.

Program Updates

Cema-Cel: Pivotal Phase 2 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 at risk of relapse following 1L chemoimmunotherapy. 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.

This innovative trial will identify patients at high risk for relapse after 1L treatment by utilizing a novel and highly accurate test for minimal residual disease, or MRD. This investigational test is being developed by our partners Foresight Diagnostics and aims to offers improved prediction over existing methods for future relapse after completion of 1L treatment. ALPHA3 takes advantage of the allogeneic attributes of cema-cel. With off-the-shelf availability and convenience, cema-cel will be administered as a one-time infusion immediately upon detection of MRD at the completion

of six cycles of R-CHOP or other standard 1L chemoimmunotherapy regimen. The outcome of this consolidation treatment could potentially improve the cure rate and uniquely position cema-cel to become the standard "7 th cycle" of frontline treatment available to all eligible patients with MRD.

Start-up activities for the ALPHA3 trial are ongoing with a planned study initiation in mid-2024. This randomized study 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). Efficacy analyses are expected to occur in 2026 and will include the Independent Data Safety Monitoring Board (IDSMB) interim EFS analysis in 1H 2026 and the data readout of the primary EFS analysis in 2H 2026 with a Biologics License Application (BLA) submission 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. While recent approval of an autologous CD19 CAR T therapy has been a positive step for patients with 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. 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 the Phase 1 ALPHA2 CLL cohort (n=12) is projected by year-end 2024 with a Phase 2 pivotal study expected in 2025.

ALLO-329: CD19/CD70 Dual CAR with Dagger® Technology 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 could sustain the scale of the AID market while also meeting the unique requirements for these patients.

ALLO-329, the Company's CRISPR-based AlloCAR T™ investigational product for AID, incorporates the Dagger® technology which is intended to 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)

In April 2024, the Company announced a $15 million grant from the California Institute for Regenerative Medicine (CIRM) to support the ongoing TRAVERSE trial with ALLO-316 in RCC.

The Company has developed and implemented a diagnostic and treatment algorithm in the TRAVERSE trial that may mitigate the treatment-associated hyperinflammatory response without compromising the CAR T function needed to eradicate solid tumors. This builds upon the field's understanding of how certain drugs can act as a "safety key" to mitigate hyperinflammatory response without compromising CAR T function or efficacy.

Details on this potentially cornerstone discovery in the Phase 1 TRAVERSE trial are planned for release Q2 2024. A Phase 1 data update from approximately 20 patients with CD70 positive RCC is planned by YE 2024.

2024 First Quarter Financial Results

- Research and development expenses were $52.3 million for the first quarter of 2024, which includes $3.8 million of non-cash stock-based compensation expense.
- General and administrative expenses were $17.3 million for the first quarter of 2024, which includes $8.1 million of non-cash stock-based compensation expense.
- Net loss for the first quarter of 2024 was $65.0 million, or $0.38 per share, including non-cash stock-based compensation expense of $11.9 million.
- The Company had $397.3 million in cash, cash equivalents, and investments as of March 31, 2024.

Based on the cash runway as of March 31, 2024, the Company expects its cash runway to fund operations into 2026. The Company expects 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 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 Cemacabtagene Ansegedleucel (Previously Known as ALLO-501A)
Cemacabtagene ansegedleucel, or cema-cel is a next generation anti-CD19 AlloCAR T™ investigational product for the treatment of large B cell lymphoma (LBCL). The ALPHA3 pivotal Phase 2 trial in first line (1L) consolidation for the treatment of LBCL is expected to begin mid-2024. In June 2022, the U.S. Food and Drug Administration granted Regenerative Medicine Advanced Therapy (RMAT) designation to cema-cel in third line (3L) r/r LBCL.

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 on X (formerly Twitter) and @AllogeneTherapeutics on 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," "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: Allogene's belief that it is well-positioned to change the CAR T treatment landscape; the potential market opportunity for Allogene’s product candidates; the potential to boost the curative potential of CAR T; 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; 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 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 March 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.

Allogene’s investigational AlloCAR T™ oncology products utilize Cellectis technologies. These 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.

ALLOGENE THERAPEUTICS, INC.
SELECTED FINANCIAL DATA

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

STATEMENTS OF OPERATIONS

	Three Months Ended March 31,	
	2024	**2023**
Collaboration revenue - related party	$ 22	$ 30
Operating expenses:		
Research and development	$ 52,259	$ 80,238
General and administrative	17,267	18,884
Total operating expenses	69,526	99,122
Loss from operations	(69,504)	(99,092)
Other income (expense), net:		
Interest and other income, net	5,433	2,059
Other expenses	(929)	(2,935)
Total other income (expense), net	4,504	(876)
Net loss	(65,000)	(99,968)
Net loss per share, basic and diluted	$ (0.38)	$ (0.69)

Weighted-average number of shares used in computing net loss per share, basic and diluted	169,128,362	144,563,829

SELECTED BALANCE SHEET DATA

	As of March 31, 2024	As of December 31, 2023
Cash, cash equivalents and investments	$ 397,265	$ 448,697
Total assets	586,350	642,837
Total liabilities	124,983	130,604
Total stockholders' equity	461,367	512,233

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Source: Allogene Therapeutics, Inc.