Allogene Therapeutics Reports Second Quarter 2023 Financial Results and Business Update

Aug 2, 2023 at 4:02 PM EDT

- Presented Long-Term Data for an Allogeneic CD19 CAR T Product Candidate in Relapsed/Refractory Large B Cell Lymphoma (LBCL) at the American Society of Clinical Oncology (ASCO) Annual Meeting and International Conference on Malignant Lymphoma (ICML) Lugano
    - ALLO-501/501A Demonstrated Rates of Durable Complete Responses Similar to Approved Autologous CAR T Therapies
- Enrollment Ongoing in the ALLO-501A ALPHA2 and EXPAND Phase 2 Trials in LBCL
    - ALPHA2 Trial Expected to Complete Enrollment in 1H 2024 with the First Data Readout Planned by Year-End 2024
- Ended Q2 2023 with $545 Million in Cash, Cash Equivalents and Investments
    - Includes Approximately $88 Million in Net Proceeds from At-the-Market (“ATM”) Equity Financing Facility During the Second Quarter; Cash Runway Now Projected to Extend into 2H 2025
- Conference Call and Webcast Scheduled for Today at 2:00 PM PT/5:00 PM ET

SOUTH SAN FRANCISCO, Calif., Aug. 02, 2023 (GLOBE NEWSWIRE) -- Allogene Therapeutics, Inc. (Nasdaq: ALLO), a clinical-stage biotechnology company pioneering the development of allogeneic CAR T (AlloCAR T™) products for cancer, today provided a corporate update and reported financial results for the quarter ended June 30, 2023.

“The last few months have been exciting for cell therapy as the transformative potential of an allogeneic CAR T product becomes more evident. Within this framework, we are thrilled that our off-the-shelf CD19 AlloCAR T data continues to demonstrate what I believe to be both first-in-class and best-in class promise in hematological cancers,” said David Chang, M.D., Ph.D., President, Chief Executive Officer and Co-Founder of Allogene. “We remain focused on advancing the industry’s first potentially pivotal allogeneic CAR T trials in order to enable more patients to receive cell therapy.”

Pipeline Updates

ALLO-501A: Anti-CD19 AlloCAR T Program
The Company is enrolling patients in the industry’s first potentially pivotal Phase 2 allogeneic CAR T clinical trial with ALLO-501A across sites in the United States and Canada. The European Medicines Agency (EMA) recently approved the ALPHA2 Clinical Trial Application (CTA) and patient enrollment in Europe is expected to begin in Q3 2023 and in Australia by year-end.

The single-arm ALPHA2 trial in relapsed/refractory (R/R) large B cell lymphoma (LBCL) utilizes a single dose of ALLO-501A (120 million CAR+ cells) following lymphodepletion with FCA90 (fludarabine, 30 mg/m2; cyclophosphamide 300 mg/m2; and ALLO-647 30 mg, daily for 3 days). This trial will enroll approximately 100 patients who have received at least two prior lines of therapy and have not received prior anti-CD19 therapy. The primary endpoint is overall response rate (ORR), and the key secondary endpoint is duration of response (DoR). Patients may receive treatment as an outpatient at the investigator’s discretion. The Company expects to complete enrollment in 1H 2024 with the first data readout by the end of 2024.

Long-term follow up data from the Phase 1 ALPHA/ALPHA2 trials in LBCL was presented at both the American Society of Clinical Oncology (ASCO) Annual Meeting with an encore presentation at the European Hematology Association Congress, and the International Conference on Malignant Lymphoma (ICML) Lugano in June 2023. The Phase 1 trials enrolled heavily pre-treated patients with a median of three prior lines of therapy. Data from 33 CAR T-naïve LBCL patients receiving Alloy™ cell product including 12 patients treated with the Phase 2 regimen, are the first to demonstrate the potential for an allogeneic CAR T product to induce complete responses at rates and durability similar to approved autologous therapies. Treatment with ALLO-501/501A was generally well tolerated with no incidence of Grade 3 or greater cytokine release syndrome, and no cases of immune effector cell-associated neurotoxicity syndrome or graft versus host disease. Cytopenia and infections were manageable and comparable to the experience with autologous CAR T cell therapies in patients with r/r LBCL.

The EXPAND trial is also underway to support licensure of ALLO-647, the Company’s anti-CD52 monoclonal antibody used in conjunction with standard low-dose FC (fludarabine, 30 mg/m^2 and cyclophosphamide 300 mg/m^2, daily for 3 days) lymphodepletion regimens to control premature rejection of AlloCAR T cells by the patient’s immune system. At the ASCO and Lugano data presentations, the Company’s proprietary lymphodepletion strategy was shown to promote robust AlloCAR T cell expansion and best-in-class longest persistence without incurring significant changes in infectious or immunosuppressive complications as compared to autologous CAR T therapies.

The EXPAND trial, which is designed to demonstrate the contribution of ALLO-647 to the standard low dose FC lymphodepletion, will enroll approximately 70 patients with r/r LBCL who will be randomized to lymphodepletion with FCA90 (which includes 90 mg of ALLO-647) versus FC alone before receiving a single 120 million cell dose of ALLO-501A. The primary endpoint of the study is progression free survival (PFS).

ALLO-316: Anti-CD70 AlloCAR T Program
The ongoing Phase 1 dose escalation TRAVERSE study is enrolling patients with advanced or metastatic renal cell carcinoma (RCC) who have progressed on standard therapies including an immune checkpoint inhibitor and a VEGF-targeting therapy. Initial data from TRAVERSE were presented at the American Association of Cancer Research (AACR) conference in April and demonstrated the potential of an allogeneic CAR T product to treat CD70 expressing RCC. In this trial, ALLO-316 showed early anti-tumor activity with deepening responses over time and a trend toward

greater tumor shrinkage in patients with higher levels of CD70 expression.

The Dagger™ effect, which is a feature of ALLO-316, enables ALLO-316 CAR T cells to target and eliminate alloreactive host immune cells, thereby mitigating potential premature rejection of AlloCAR T cells by the patient's immune system. Translational results shared at AACR suggest this unique immunomodulatory effect of ALLO-316 contributed to robust AlloCAR T cell expansion and persistence, and clinical remissions.

The TRAVERSE trial is now deploying an investigational in vitro companion diagnostic (IVD) assay designed to prospectively assess CD70 expression levels in patients. Dose escalation in the TRAVERSE trial is expected to be completed in 2023.

Based on preclinical results demonstrating the ability to combine anti-CD19 and other AlloCARs™ with the Dagger technology, the Company intends to explore this approach to potentially enhance the activity of next generation AlloCAR T products candidates, including those that target other hematological and solid tumors.

ALLO-715: Anti-BCMA AlloCAR T Program
The Company previously presented ALLO-715 Phase 1 data from the UNIVERSAL trial which was the first study to demonstrate that an allogeneic anti-BCMA CAR T could produce response rates in multiple myeloma similar to an approved autologous CAR T therapy. As treatments in multiple myeloma advance, the Company is evaluating manufacturing process improvement across its BCMA candidates to achieve an improved competitive profile.

Second Quarter Financial Results

- The Company had $544.5 million in cash, cash equivalents, and investments as of June 30, 2023, which includes net proceeds of approximately $87.9 million raised in the second quarter from an at-the market (ATM) equity financing facility. Based on current expectations, the Company expects its cash runway to fund operations into 2H 2025.
- Research and development expenses were $62.0 million for the second quarter of 2023, which includes $6.9 million of non-cash stock-based compensation expense.
- General and administrative expenses were $18.5 million for the second quarter of 2023, which includes $9.7 million of non-cash stock-based compensation expense.
- Net loss for the second quarter of 2023 was $78.0 million, or $0.53 per share, including non-cash stock-based compensation expense of $16.6 million.

2023 Financial Guidance

- As previously reported, the Company expects a decrease in cash, cash equivalents, and investments of approximately $230 million in 2023. GAAP Operating Expenses are expected to be approximately $340 million, including estimated non-cash stock-based compensation expense of approximately $80 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. Led by a management team with significant experience in cell therapy, Allogene is developing a pipeline of "off-the-shelf" CAR T 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 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 "predicts," "projects," "believes," "potential," "proposed," "continue," "estimates," "anticipates," "expects," "plans," "intends," "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: ALPHA2 being a potentially pivotal trial; expected enrollment and related timelines; the expected timing to complete dose escalation; the potential of an allogeneic CAR T product to treat CD70 express RCC based on emerging data; study design; the timing and ability to progress the ALPHA2 and TRAVERSE trials; clinical outcomes, which may materially change as more patient data become available; the ability to achieve optimal clinical performance through manufacturing processes improvements; the design and potential benefits of our Dagger technology, including its ability to resist rejection of AlloCAR T cells by the host immune cells and the expected benefits therefrom, and our plans to deploy Dagger technology; the potential for our product candidates to be approved; the potential benefits of AlloCAR T products and 2023 financial guidance, including expected cash runway. 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; Servier's discontinuation of its involvement in the development of all CD19 products pursuant to our Exclusive License and Collaboration Agreement and our disputes with Servier may have adverse consequences; the limited nature of our 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; 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 COVID-19 adversely impacts our business, including our preclinical studies and clinical trials; 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; 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; and our ability to obtain additional financing to develop our products 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, 2022, and in its Quarterly Report on Form 10-Q for the quarter ended June 30, 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™, AlloCAR™ and Dagger™ are trademarks of Allogene Therapeutics, In

Allogene's AlloCAR T™ programs utilize Cellectis technologies. ALLO-501 and ALLO-501A are anti-CD19 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-BCMA and anti-CD70 AlloCAR T programs are licensed exclusively from Cellectis by Allogene and Allogene holds global development and commercial rights to these AlloCAR T programs.

ALLOGENE THERAPEUTICS, INC. SELECTED FINANCIAL DATA

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

STATEMENTS OF OPERATIONS

	Three Months Ended June 30,	
	2023	**2022**
Collaboration revenue - related party	$ 44	$ 86
Operating expenses:		
Research and development	$ 62,038	$ 57,171
General and administrative	18,524	19,509
Total operating expenses	80,562	76,680
Loss from operations	(80,518)	(76,594)
Other income (expense), net:		
Interest and other income, net	3,778	315
Other income (expenses)	(1,249)	1,492
Total other income, net	2,529	1,807
Net loss	(77,989)	(74,787)
Net loss per share, basic and diluted	$ (0.53)	$ (0.52)
Weighted-average number of shares used in computing net loss per share, basic and diluted	146,795,826	143,385,045

SELECTED BALANCE SHEET DATA

	As of June 30, 2023	**As of December 31, 2022**
Cash, cash equivalents and investments	$ 544,548	$ 576,471
Total assets	770,971	817,079
Total liabilities	148,065	151,209
Total stockholders' equity	622,906	665,870

Allogene Media/Investor Contact:
Christine Cassiano
Chief Communications Officer
Christine.Cassiano@allogene.com

Source: Allogene Therapeutics, Inc.