Allogene Therapeutics Reports Third Quarter 2021 Financial Results and Business Update

Nov 4, 2021 at 4:02 PM EDT

- New Clinical Data from the ALPHA, ALPHA2 and UNIVERSAL AlloCAR T™ Trials to be Presented at the 63rd Annual Meeting of the American Society of Hematology
    - ALPHA2 Study Abstract Selected for Oral Presentation Highlights the Benefits of Consolidation Dosing with ALLO-501A in Patients with Relapsed/Refractory Large B Cell Lymphoma
    - ALPHA Study Abstract Selected for Poster Presentation Continues to Show Durability of Responses to ALLO-501 in Patients with Non-Hodgkin Lymphoma
    - UNIVERSAL Study Abstract Selected for Oral Presentation Reports Meaningful Activity of a Single Dose of ALLO-715 in Patients with Relapsed/Refractory Multiple Myeloma
- Discussions Ongoing as Company Seeks to Resolve FDA Clinical Hold
- Ended Third Quarter with $862 Million in Cash, Cash Equivalents and Investments
- Conference Call and Webcast Scheduled for 2:00 PM PT/5:00 PM ET

SOUTH SAN FRANCISCO, Calif., Nov. 04, 2021 (GLOBE NEWSWIRE) -- Allogene Therapeutics, Inc. (Nasdaq: ALLO), a clinical-stage biotechnology company pioneering the development of allogeneic CAR T (AlloCAR T™) therapies for cancer, today provided a corporate update and reported financial results for the quarter ended September 30, 2021.

“While our clinical studies are on hold, our work to bring AlloCAR T products to patients continues with a strong sense of urgency. We remain confident in our platform and the potential of our AlloCAR T candidates to meaningfully improve the lives of patients living with cancer,” said David Chang, M.D., Ph.D., President, Chief Executive Officer and Co-Founder of Allogene. “Our teams are busy progressing our preclinical programs, advancing production at our Cell Forge 1 manufacturing facility, and preparing for data presentations at the American Society of Hematology (ASH) Annual Meeting in December. In the meantime, we continue to work closely with the U.S. Food and Drug Administration (FDA) on the review of the end of Phase 1 materials in support of a pivotal trial for ALLO-501A as well as to resolve the clinical hold and we look forward to providing an update after further interaction with the agency.”

Pipeline Updates
The FDA placed a hold on the Company’s AlloCAR T clinical trials (ALPHA, ALPHA2, IGNITE, TRAVERSE, UNIVERSAL) following a report of a chromosomal abnormality in a single patient treated in the ALPHA2 study. Allogene is working with the FDA to address next steps to resolve the hold.

- In parallel with the clinical hold investigation, the FDA is actively reviewing the end of Phase 1 materials the Company submitted in support of the pivotal trial for ALLO-501A.

Anti-CD19 Program: ALPHA and ALPHA2 Trials

- Abstracts from the ALPHA (poster session) and ALPHA2 (oral session) trials were selected for presentation at the ASH meeting in early December. The data contained in the abstracts continue to show the utility of AlloCAR T therapy in patients with relapsed/refractory non-Hodgkin lymphoma. Updated results will be presented at the meeting.

- In the ALPHA2 trial, consolidation dosing appeared to be well tolerated with the potential for enhanced efficacy compared to a single dose of ALLO-501A. In the consolidation cohort, both the overall response rate (ORR) and complete response (CR) rate were 67% with all three partial responses (PRs) converting to CR following consolidation. All four consolidation patients who achieved a CR remained in CR as of the July 2021 data cut-off. The safety profile of ALLO-501A was manageable in both single dose and consolidation cohorts. Events of interest in the single dose cohort were previously reported at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting. In the consolidation cohort, there was no cytokine release syndrome (CRS), no graft-versus-host disease (GvHD), no immune effector cell-associated neurotoxicity syndrome (ICANS), no dose-limiting toxicities (DLTs), no dose reductions, no Grade 3+ infections and infusion-related reactions were Grade 2. Among all treated patients, cytopenias were the most common adverse event and occurred in 72% of patients.

- In the ALPHA trial as of the July data cutoff for the ASH abstract, five additional patients were treated relative to the data previously reported at the 2021 ASCO Annual Meeting. ORR and CR rates remain at 75% and 50%, respectively. In patients with LBCL (n=13), the ORR was 62% and the CR rate was 46%. In patients with FL (n=23), the ORR was 83% and the CR rate was 52%. Four of the seven patients (all FL) enrolled in the consolidation cohort were evaluable for assessment after consolidation dosing at the time of the data cutoff with an ORR and CR rate of 100% and 75%,

respectively. The percent of patients remaining in CR at six months following a single infusion was 36% in LBCL, which is similar to 6-month CR rates reported in the pivotal trials of autologous CAR T therapies, with the longest ongoing CR at 15+ months, as of the data cut-off. The 6-month CR rate in FL was 28%. No cases of GvHD or DLTs were observed. As noted previously, one case of Grade 3 ICANS was reported. Grade 1/2 CRS occurred in 22% of patients with one case of Grade 3 CRS. All were managed with standard protocols. Cytopenias were the most common adverse event and occurred in 83% of patients. Infection rates remained similar to those observed in autologous CAR T trials.

Anti-BCMA AlloCAR T Program: UNIVERSAL Trial

- In August, ALLO-715 received Orphan Drug Designation (ODD) from the FDA for the treatment of multiple myeloma (MM).

- Updated results from the UNIVERSAL trial investigating ALLO-715 as a monotherapy in patients with relapsed/refractory MM will be presented at an oral session at ASH. Findings from the UNIVERSAL trial indicate an allogeneic CAR T therapy can be delivered rapidly without the need for bridging therapy to patients with relapsed/refractory multiple myeloma, with single dose of therapy capable of inducing deep responses. The ORR was 62% with a very good partial response or better (VGPR+) rate of 39% in the 26 patients treated at the highest two dose levels (320 and 480 x 10^6 CAR+ cells). Median follow-up for these patients was 7.4 months with a median duration of response of 8.3 months. Of the 10 patients with a best response of VGPR+, eight were found to be minimal residual disease (MRD) negative. No GvHD was observed. The most common Grade 3+ adverse events included anemia, neutropenia, lymphopenia, and thrombocytopenia. CRS was reported in 52% of patients, in all cases Grade 1/2 except for one patient with Grade 3. One patient with Grade 2 CRS experienced Grade 1 neurotoxicity that resolved. Grade 3+ infections occurred in 13% of patients, including two previously reported Grade 5 events (fungal pneumonia and adenovirus hepatitis).

Third Quarter Financial Results

- Research and development expenses were $58.7 million for the third quarter of 2021, which includes $10.1 million of non-cash stock-based compensation expense.

- General and administrative expenses were $19.0 million for the third quarter of 2021, which includes $10.8 million of non-cash stock-based compensation expense.

- Net loss for the third quarter of 2021 was $78.2 million, or $0.57 per share, including non-cash stock-based compensation expense of $20.9 million.

- The Company had $861.7 million in cash, cash equivalents, and investments as of September 30, 2021.

2021 Financial Guidance

- Allogene continues to expect full year GAAP Operating Expenses to be between $300 and $330 million including estimated non-cash stock-based compensation expense of $80 to $90 million and excluding 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. To access the live conference call by telephone, please dial 1 (866) 940-5062 (U.S.) or 1 (409) 216-0618 (International). The conference ID number for the live call is 1924859. The 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™) therapies for cancer. Led by a management team with significant experience in cell therapy, Allogene is developing a pipeline of “off-the-shelf” CAR T cell therapy 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," "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: the ability to progress the Company’s clinical trials and present any data from the trials; clinical outcomes, which may materially change as more patient data become available; the ability to resolve the current clinical hold on the Company’s trials; the ability to manufacture AlloCAR T™ therapies; the potential benefits of AlloCAR T therapies; and the 2021 financial guidance. Various factors may cause differences between Allogene’s expectations and actual results as discussed in greater detail in Allogene’s filings with the SEC, including without limitation in its Form 10-Q for the quarter ended September 30, 2021. 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™ is a trademark of Allogene Therapeutics, Inc.

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. while Servier retains exclusive rights for all other countries. ALLO-715 targets BCMA. Allogene has an exclusive license to the Cellectis technology for allogeneic products directed at BCMA and holds all global development and commercial rights for these investigational candidates.

ALLOGENE THERAPEUTICS, INC.
SELECTED FINANCIAL DATA
(unaudited; in thousands, except share and per share data)

STATEMENTS OF OPERATIONS

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
Collaboration revenue - related party	$ 49	$ —	$ 38,438	$ —
Operating expenses:				
Research and development	$ 58,720	$ 51,421	$ 166,193	$ 140,759
General and administrative	18,999	16,619	54,144	48,122
Total operating expenses	77,719	68,040	220,337	188,881
Loss from operations	(77,670)	(68,040)	(181,899)	(188,881)
Other income (expense), net:				
Interest and other income, net	393	2,005	1,528	7,606
Other expenses	(909)	(162)	(1,766)	(376)
Total other income (expense), net	(516)	1,843	(238)	7,230
Net loss	(78,186)	(66,197)	(182,137)	(181,651)
Net loss per share, basic and diluted	$ (0.57)	$ (0.52)	$ (1.35)	$ (1.55)
Weighted-average number of shares used in computing net loss per share, basic and diluted	137,025,698	127,140,755	134,690,310	117,227,079

SELECTED BALANCE SHEET DATA

	As of September 30, 2021	As of December 31, 2020
Cash, cash equivalents and investments	$ 861,707	$ 1,032,118
Total assets	1,079,246	1,227,829
Total liabilities	109,304	148,212
Total stockholders' equity	969,942	1,079,617

Allogene Media/Investor Contact:
Christine Cassiano
Chief Communications Officer
(714) 552-0326
Christine.Cassiano@allogene.com

Source: Allogene Therapeutics, Inc.