Allogene Therapeutics Reports Second Quarter 2021 Financial Results

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CD19 Program Highlights

- Phase 1 ALPHA Data at ASCO 2021 Showed a Single Dose of ALLO-501 was Associated with Overall Response, Complete Response and Durable Response Rates on Par with Autologous CD19 CAR T Therapies in CAR T Naïve Patients with Relapsed/Refractory Non-Hodgkin Lymphoma
- Next CD19 Program Clinical Update Planned for Q4 2021
- ALLO-501A Pivotal Trial on Track for Initiation in Late 2021

BCMA Program Highlights

- Updated Phase 1 UNIVERSAL Data on ALLO-715 Planned for Q4 2021
- Began Dosing Patients in Phase 1 IGNITE Trial of ALLO-605, the First TurboCAR™ T Cell Therapy, for Relapsed/Refractory Multiple Myeloma
- ALLO-605 Granted Fast Track Designation by the FDA

Solid Tumor Program Highlights

- Phase 1 TRAVERSE Trial Ongoing for ALLO-316 (anti-CD70) in Advanced or Metastatic Renal Cell Carcinoma. Initial Clinical Readout Expected in 2022

Corporate Highlights

- Appointed Liz Barrett and Vicki Sato, Ph.D., Executives with Significant Strategic and Commercial Expertise, to the Board of Directors
- State-of-the-Art cGMP Manufacturing Facility in Newark, California to Support Industry's First Allogeneic Pivotal Trial and Future Commercial Launch
- Ended Second Quarter with $913 Million in Cash, Cash Equivalents and Investments

- Quarterly Conference Call and Webcast Scheduled for 2:00 PM PT/5:00 PM ET

SOUTH SAN FRANCISCO, Calif., Aug. 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 second quarter 2021 financial results for the quarter ended June 30, 2021.

"We have made exceptional progress across our broad pipeline of AlloCAR T candidates, bringing our goal of revolutionizing cell therapy for patients with blood cancers and solid tumors closer to reality," said David Chang, M.D., Ph.D., President, Chief Executive Officer and Co-Founder of Allogene. "Our foundational and ongoing work has the potential to drive us toward an industry first - our planned pivotal trial for ALLO-501A in relapsed/refractory non-Hodgkin lymphoma which we expect to initiate at the end of this year. This month, we are also marking an exciting milestone with the planned inauguration of our state-of-the-art manufacturing facility, Cell Forge 1. This facility is intended to allow us to control manufacturing of ALLO-501A and future therapies and prepare us for potential commercialization."

Pipeline Highlights

Anti-CD19 Program: ALPHA and ALPHA2 Trials

- Updated data from the ongoing Phase 1 ALPHA (ALLO-501) and ALPHA2 (ALLO-501A) trials in relapsed/refractory non-Hodgkin lymphoma (NHL) presented at the Company's CD19 Forum in May and Annual Meeting of the American Society of Clinical Oncology (ASCO) in June.
- Data from the ALPHA trial supports the ability of a single administration of ALLO-501 to generate deep and durable responses at a rate that is similar to approved autologous CAR T therapies. In the trial, 98% of patients received ALLO-501 with an average time from enrollment to the start of therapy of five days.
    - Durable complete responses (CR) were observed with the longest ongoing CR at 15 months in both large B cell lymphoma (LBCL) and follicular lymphoma.
    - Overall response rate (ORR) of 75% and CR rate of 50% across histologies in CAR T naïve patients, and on par with data from pivotal trials of autologous CAR T therapies.

- Six-month CR rate of 36% in CAR T naïve patients with LBCL.
- Interim Phase 1 ALPHA2 data demonstrated a comparable efficacy and safety profile for ALLO-501A relative to ALLO-501.
  - Consolidation dosing was well tolerated and showed early promise with four patients converting from partial response (PR) to CR following second dose of ALLO-501 or ALLO-501A.
  - 75% ORR and 63% CR among patients (n=8) treated in the consolidation cohorts across ALPHA studies.
- ALLO-501 and ALLO-501A demonstrated a manageable safety profile with no dose limiting toxicities or graft-vs-host disease, limited immune effector cell-associated neurotoxicity syndrome (ICANS) and cytokine release syndrome (CRS) observed.
- Next readout from this program is expected in late 2021.
- The Company plans to collect additional data from the consolidation arms of the ALPHA and ALPHA2 studies, finalize a dose and schedule of ALLO-501A and lymphodepletion for a pivotal Phase 2 trial, and discuss the Phase 2 trial design with regulatory authorities.
- Pending regulatory feedback, the Company plans to move to the Phase 2 Pivotal ALPHA2 trial at the end of 2021.

Anti-BCMA AlloCAR T Program

The Company continues to advance its portfolio of allogeneic therapies targeting the B cell maturation antigen (BCMA) for patients with multiple myeloma (MM).

- **ALLO-715 UNIVERSAL Trial**
  - The UNIVERSAL trial, investigating ALLO-715 as a monotherapy and in combination with nirogacestat, SpringWorks Therapeutics' investigational gamma secretase inhibitor, continues to enroll patients with relapsed/refractory MM.
  - Updated data from the monotherapy arm of the study are anticipated in Q4 2021.
  - In April, ALLO-715 was granted Regenerative Medicine Advanced Therapy (RMAT) designation by the U.S. Food and Drug Administration (FDA).

- **ALLO-605 TurboCAR™ IGNITE Trial**
  - The Phase 1 dose escalation portion of the IGNITE trial evaluating ALLO-605, the first anti-BCMA TurboCAR T cell therapy, began dosing patients.
  - In June, the FDA granted ALLO-605 Fast Track designation based on the potential of ALLO-605 to address the unmet need for patients who have failed other standard MM therapies.

Solid Tumor AlloCAR T Program

- **ALLO-316 (anti-CD70) TRAVERSE Trial**
  The Phase 1 TRAVERSE trial of ALLO-316, Allogene's first CAR T candidate for solid tumors, in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC) continues to progress with initial data anticipated in 2022. The trial is examining safety, tolerability, anti-tumor efficacy, pharmacokinetics and pharmacodynamics of ALLO-316.

Corporate Highlights

- **Manufacturing Updates**
  - The Company plans to unveil its state-of-the-art cGMP cell manufacturing facility, Cell Forge 1, in Newark, California in preparation for a pivotal trial of ALLO-501A and future commercialization. Company is on track to begin cGMP production in this facility in the second half of 2021.

- **Allogene Overland Biopharm**
  - Allogene Overland Biopharm, a joint venture created with Overland Pharmaceuticals, appointed Shuyuan Yao, Ph.D., as Chief Executive Officer. Dr. Yao brings 15 years of scientific and management experience in advanced cell and gene therapy development, manufacturing and commercialization, and will lead Allogene Overland in its mission to bring certain AlloCAR T therapies to patients in China and other Asian Pacific markets.

Second Quarter Financial Results

- Research and development expenses were $52.3 million for the second quarter of 2021, which includes $10.5 million of non-cash stock-based compensation expense.
- General and administrative expenses were $18.8 million for the second quarter of 2021, which includes $10.6 million of non-cash stock-based compensation expense.
- Net loss for the second quarter of 2021 was $70.9 million, or $0.53 per share, including non-cash stock-based compensation expense of $21.1 million.
- The Company had $913.2 million in cash, cash equivalents, and investments as of June 30, 2021.

Allogene continues to expect full year GAAP Operating Expenses to be between $300 million and $330 million including estimated non-cash stock-based compensation expense of $80 million to $90 million and excluding any impact from potential new 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 8080137. 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 timing and ability to progress the ALPHA, ALPHA2, UNIVERSAL, IGNITE and TRAVERSE trials, including progressing to the Phase 2 portion of the ALPHA2 trial, and present any data from the trials; clinical outcomes, which may materially change as patient enrollment continues and more patient data become available; the ability to manufacture AlloCAR T™ therapies, including for use in clinical trials and at the Company’s manufacturing facility; the potential benefits of AlloCAR T™ therapy; 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 Securities and Exchange Commission (SEC), including without limitation in its Form 10-Q for the quarter ended June 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.

Comparative statements regarding autologous CAR T data are based on review of Kymriah United States product insert (USPI), Schuster S et al NEJM 2019; Yescarta USPI, Locke, AACR 2017; and Breyanzi USPI. Caution should be exercised when interpreting results from separate trials involving separate product candidates. There are differences in the clinical trial design, patient populations, published data, 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 TurboCAR™ are trademarks of Allogene Therapeutics, Inc.

Allogene’s CD19 AlloCAR T program utilizes Cellectis technologies. ALLO-501 and ALLO-501A are being jointly developed under a collaboration agreement between Servier[1] 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. The anti-BCMA and anti-CD70 AlloCAR T programs, which utilize the Cellectis TALEN® technology, are licensed exclusively from Cellectis by Allogene and Allogene holds global development and commercial rights to these AlloCAR T programs.

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[1] Servier is an independent international pharmaceutical company governed by a non-profit foundation, with its headquarters in France (Suresnes).

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

STATEMENTS OF OPERATIONS

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Collaboration revenue - related party	$ 44	$ —	$ 38,389	$ —
Operating expenses:				
Research and development	$ 52,290	$ 47,296	$ 107,473	$ 89,337
General and administrative	18,783	15,862	35,146	31,502
Total operating expenses	71,073	63,158	142,619	120,839
Loss from operations	(71,029)	(63,158)	(104,230)	(120,839)
Other income (expense), net:				
Interest and other income, net	624	2,340	1,135	5,600
Other expenses	(531)	(156)	(856)	(215)
Total other income (expense), net	93	2,184	279	5,385
Net loss	(70,936)	(60,974)	(103,951)	(115,454)
Net loss per share, basic and diluted	$ (0.53)	$ (0.53)	$ (0.78)	$ (1.03)
Weighted-average number of shares used in computing net loss per share, basic and diluted	134,826,805	115,377,210	133,503,262	112,163,123

SELECTED BALANCE SHEET DATA

	As of June 30, 2021	As of December 31, 2020
Cash, cash equivalents and investments	$ 913,230	$ 1,032,118
Total assets	1,126,724	1,227,829
Total liabilities	102,912	148,212
Total stockholders' equity	1,023,812	1,079,617

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Source: Allogene Therapeutics, Inc.