Allogene Therapeutics Reports First Quarter 2021 Financial Results

May 5, 2021 at 4:02 PM EDT

CD19 Program Highlights

- Data from the ALLO-501 ALPHA Study and ALLO-501A ALPHA2 Study to be Presented at the American Society of Clinical Oncology (ASCO) Annual Meeting
- Longer Term Follow-Up from the ALPHA Study and Consolidation Dosing in Both ALPHA and ALPHA2 Study to be Included
- Allogene to Host Virtual CD19 Forum to Review ASCO Datasets on May 19, 2021 at 2:30 p.m. PT/5:30 p.m. ET

BCMA Program Highlights

- FDA Granted RMAT Designation to ALLO-715, the First for an AlloCAR T™ Candidate for Relapsed/Refractory Multiple Myeloma
- Initiated Combination Arm of the UNIVERSAL Trial with ALLO-715 and Nirogacestat
- FDA Cleared IND Application for ALLO-605, the First TurboCAR™ T Cell Candidate Targeting BCMA for Patients with Relapsed/Refractory Multiple Myeloma

Solid Tumor Program Highlights

- TRAVERSE Trial Initiated for ALLO-316 (anti-CD70) in Patients with Advanced or Metastatic Renal Cell Carcinoma
- Ended First Quarter with $964 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., May 05, 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 March 31, 2021.

"We've had a strong start to the year as evidenced by the significant clinical and regulatory progress made across our growing AlloCAR T portfolio, including the start of our first solid tumors study," said David Chang, M.D., Ph.D., President, Chief Executive Officer and Co-Founder of Allogene. "We believe our progress demonstrates our ability to advance the field of allogeneic CAR T cell therapy and we look forward to sharing data from our CD19 program on May 19th during our virtual forum event."

Pipeline Highlights

Anti-CD19 Program

- Updated data from the dose escalation Phase 1 ALPHA study of ALLO-501 in relapsed/refractory non-Hodgkin lymphoma (NHL) will be jointly presented with initial data from the ALPHA2 study of ALLO-501A at the American Society of Clinical Oncology (ASCO) annual meeting. The presentation will include longer-term follow-up from the initial cohort of patients reported at ASCO 2020, additional data on patients treated subsequent to ASCO 2020, dose escalation data from ALPHA2, and initial results from patients treated with consolidation dosing of ALLO-501 and ALLO-501A. A separate poster presentation will detail safety and biomarker findings from ALLO-647, Allogene's wholly owned antibody used for lymphodepletion with fludarabine (Flu)/cyclophosphamide (Cy) in patients with relapsed/refractory NHL and multiple myeloma.
- Subject to further study progress and data, the Company plans to initiate a potentially pivotal Phase 2 trial of ALLO-501A by the end of 2021.
- On May 19, 2021, the Company will host a virtual CD19 Forum focused on clinical data being presented at ASCO, along with the Company's vision for the future of CAR T therapy. In addition to presentations from Company management, the Forum will include a discussion with clinical investigators.

Anti-BCMA Program
The Company continues to execute on its portfolio of anti-B cell maturation antigen (BCMA) therapies in patients with multiple myeloma (MM).

- **ALLO-715 UNIVERSAL Trial**
  - The U.S. Food and Drug Administration (FDA) granted Regenerative Medicine Advanced Therapy (RMAT)

designation to ALLO-715, Allogene's most advanced AlloCAR T candidate for relapsed/refractory MM. The designation follows proof-of-concept data from the Phase 1 UNIVERSAL trial in heavily pretreated, relapsed/refractory MM patients, which demonstrated for the first time that an allogeneic CAR T therapy directed at BCMA can achieve clinical responses while eliminating the need for bridging therapy or delays in treatment associated with manufacturing.

  - Patient dosing has begun in the portion of the UNIVERSAL trial investigating ALLO-715 in combination with nirogacestat in patients with relapsed/refractory MM. Nirogacestat is an investigational gamma secretase inhibitor being developed by SpringWorks Therapeutics.

- **ALLO-605 TurboCAR™ IGNITE Trial**
  - The FDA cleared the Investigational New Drug (IND) application to evaluate ALLO-605, the first TurboCAR T cell therapy, for use in relapsed/refractory MM. TurboCAR technology allows cytokine activation signaling to be engineered selectively into CAR T cells to potentially improve efficacy, overcome exhaustion, and reduce cell dose requirements. The Phase 1 IGNITE trial will evaluate escalating doses of ALLO-605 beginning in mid-2021.

Solid Tumor Program

- **ALLO-316 TRAVERSE Trial**
  - Patient dosing has begun in the Phase 1 TRAVERSE trial examining safety, tolerability, anti-tumor efficacy, pharmacokinetics and pharmacodynamics of ALLO-316, Allogene's first CAR T candidate for solid tumors, in patients with advanced or metastatic clear cell renal cell carcinoma.

- **Expanded TurboCAR Platform**
  - In April 2021, at the American Association for Cancer Research (AACR) Annual Meeting, the Company reported on pre-clinical data that expands the TurboCAR technology platform to address the biology of solid tumor oncology. TurboCARs were engineered to confer cytokine signaling that is inducible upon binding to PDL1 in the tumor microenvironment or when stimulated with an anti-PD1 antibody while acting as a dominant negative for PDL1 and PDL2 immunosuppressive signaling. These TurboCARs are designed to overcome the challenges in solid tumors associated with an immuno-suppressive tumor microenvironment (TME) by turning negative signals into positive signals.

First Quarter Financial Results

- Research and development expenses were $55.2 million for the first quarter of 2021, which includes $7.9 million of non-cash stock-based compensation expense.

- General and administrative expenses were $16.4 million for the first quarter of 2021, which includes $8.9 million of non-cash stock-based compensation expense.

- Net loss for the first quarter of 2021 was $33.0 million, or $0.25 per share, including non-cash stock-based compensation expense of $16.8 million.

- The Company had $964.2 million in cash, cash equivalents, and investments as of March 31, 2021.

2021 Financial Guidance
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 9435559. 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.

Virtual CD19 Forum
Additional information on the Company's May 19 Virtual CD19 Forum will be made available in a separate press release and on the Company's website at www.allogene.com under the Investors tab in the News and Events section. Materials presented will be available on the Allogene website prior to the start of the event.

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 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 timing and ability to initiate a clinical trial of ALLO-605; the ability of ALLO-605 to improve efficacy, overcome exhaustion, and reduce cell dose requirements; the ability to expand the TurboCAR platform; the ability to manufacture AlloCAR T™ therapies, including for use in clinical trials, 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 March 31, 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™ 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 March 31,	
	2021	**2020**
Collaboration revenue - related party	$ 38,345	$ —
Operating expenses:		
Research and development	$ 55,183	$ 42,042
General and administrative	16,363	15,641
Total operating expenses	71,546	57,683
Loss from operations	(33,201)	(57,683)
Other income (expense), net:		
Interest and other income, net	511	3,261
Other expenses	(325)	(58)
Total other income (expense), net	186	3,203
Net loss	(33,015)	(54,480)
Net loss per share, basic and diluted	$ (0.25)	$ (0.50)
Weighted-average number of shares used in computing net loss per share, basic and diluted	132,165,014	108,963,522

SELECTED BALANCE SHEET DATA

	As of March 31, 2021	As of December 31, 2020
Cash, cash equivalents and investments	$ 964,154	$ 1,032,118
Total assets	1,179,044	1,227,829
Total liabilities	109,265	148,212
Total stockholders' equity	1,069,779	1,079,617

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Source: Allogene Therapeutics, Inc.