Allogene Therapeutics Reports Third Quarter 2020 Financial Results

Nov 4, 2020 at 7:30 AM EST

- Enrollment Ongoing in Phase 1 Trials of ALLO-501 (ALPHA), ALLO-501A (ALPHA2) and ALLO-715 (UNIVERSAL)
- Initial Phase 1 Results from the UNIVERSAL Trial in Relapsed/Refractory Multiple Myeloma to be Presented at a Medical Meeting in Q4 2020
- In 1H 2021, Initial ALLO-501A Data and Updated ALLO-501 Results in Non-Hodgkin Lymphoma are Planned in Preparation for a Potential Pivotal Study Initiation of ALLO-501A in 2021
- Three Investigational New Drug (IND) Applications to be Submitted; Two in Q4 2020 with ALLO-316, an Anti-CD70 AlloCAR T™, in Renal Cell Carcinoma and ALLO-715 in Combination with Nirogacestat in Relapsed/Refractory Multiple Myeloma, and One in 2021 with ALLO-605, the First TurboCAR™ Targeting BCMA
- Ended Third Quarter with $1.0 Billion in Cash, Cash Equivalents and Investments
- Conference Call and Webcast Scheduled for 5:30 AM PT/8:30 AM ET

SOUTH SAN FRANCISCO, Calif., Nov. 04, 2020 (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, 2020.

"We continue to see rapid advancement across our pipeline of AlloCAR T candidates and look forward to a number of firsts for Allogene over the coming months, starting with the first look at data from the Phase 1 UNIVERSAL trial of ALLO-715 for the treatment of multiple myeloma. The firsts will continue with the submission of our IND in solid tumors to evaluate ALLO-316 in renal cell carcinoma by the end of the year as well as an IND to evaluate ALLO-715 in combination with nirogacestat," said David Chang, M.D., Ph.D., President, Chief Executive Officer and Co-Founder of Allogene. "In the spirit of leading today and creating tomorrow as we advance allogeneic cell therapies for patients, we look forward to 2021 where we anticipate having five clinical trials underway, including our first pivotal trial."

Pipeline Highlights

Anti-BCMA AlloCAR T Program
The Company continues to execute on a three-pronged anti-BCMA strategy led by ALLO-715, a Phase 1 candidate for the treatment of relapsed/refractory multiple myeloma (MM).

- **ALLO-715 UNIVERSAL Phase 1 Trial**
  - Initial data from the ALLO-715 Phase 1 UNIVERSAL trial will be presented at a medical meeting in Q4 2020. The UNIVERSAL trial utilizes ALLO-647 (anti-CD52 mAb) together with the standard fludarabine and cyclophosphamide as the lymphodepletion regimen. The initial dose escalation portion of the UNIVERSAL trial studied ALLO-715 dosed at 40M, 120M and 320M cells following lymphodepletion with 39mg (low dose) of ALLO-647. Fifteen patients were treated in the study at the time of abstract submission.
  - The virtual presentation will include data on approximately 20 patients evaluable for efficacy across ALLO-715 cell dose cohorts and lower dose (39mg) of ALLO-647, as well as patients evaluable for efficacy who were treated with higher doses of ALLO-715 and higher doses of ALLO-647. The Phase 1 UNIVERSAL study continues to enroll patients at these higher doses in an effort to optimize the therapy.
  - This study is enrolling patients with relapsed/refractory MM who have been treated with at least three prior lines of therapy, including a proteasome inhibitor, immunomodulatory agent, and anti-CD38 antibody (unless contraindicated), and refractory to the last treatment line.

- **ALLO-715 + nirogacestat**
  - The Company is on track to submit an IND application by the end of 2020 to evaluate ALLO-715 in combination with SpringWorks' investigational gamma secretase inhibitor, nirogacestat, in patients with relapsed/refractory MM.

- **ALLO-605 (anti-BCMA TurboCAR™)**
  - An IND is expected to be submitted in the first half of 2021 for the Company's first TurboCAR candidate, ALLO-605, an investigational BCMA-directed AlloCAR T therapy for MM. TurboCAR technology allows cytokine activation signaling to be engineered selectively into CAR T cells. TurboCAR has the potential to improve efficacy, overcome cell exhaustion, and reduce dosing requirements of AlloCAR T therapy.

Anti-CD19 AlloCAR T Program

- The Company continues to leverage data from the Phase 1 ALPHA trial of ALLO-501 to inform and optimize trial design and dose selection of ALLO-501A and ALLO-647, a differentiated lymphodepleting agent.
- In the first half of 2021, additional data from the Phase 1 ALPHA study of ALLO-501 in relapsed/refractory non-Hodgkin lymphoma (NHL) and initial data from the Phase 1 dose escalation ALPHA2 study of ALLO-501A are planned for presentation. Data from these trials are expected to support trial design for a potentially pivotal Phase 2 trial planned for initiation in 2021.

Solid Tumor AlloCAR T Program

- **ALLO-316 (anti-CD70)**
  - The Company expects to submit an IND for ALLO-316, its first AlloCAR T candidate for the treatment of solid tumors, by the end of 2020. A study in renal cell carcinoma is expected to initiate in 2021. ALLO-316 targets CD70 and also has potential application in hematologic malignancies.

Corporate Highlights

- **Manufacturing**
  - Construction continues on the Company's state-of-the-art cGMP cell manufacturing facility in Newark, California with cGMP manufacturing from this facility expected in 2021.

- **Business Development**
  - The Company and The University of Texas MD Anderson Cancer Center announced a strategic five-year collaboration aimed at accelerating the development of a broad portfolio of AlloCAR T candidates across hematologic and solid tumors. Under the agreement, MD Anderson and the Company will collaborate on the design and conduct of preclinical and clinical studies with oversight from a joint steering committee.

Third Quarter Financial Results

- Research and development expenses were $51.4 million for the third quarter of 2020, which includes $8.8 million of non-cash stock-based compensation expense.
- General and administrative expenses were $16.6 million for the third quarter of 2020, which includes $9.0 million of non-cash stock-based compensation expense.
- Net loss for the third quarter of 2020 was $66.2 million, or $0.52 per share, including non-cash stock-based compensation expense of $17.8 million.
- The Company had $1.0 billion in cash, cash equivalents, and investments as of September 30, 2020.

2020 Financial Guidance

- Allogene continues to expect full year GAAP net losses to be between $260 million and $280 million including estimated non-cash stock-based compensation expense of $70 million to $75 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 5:30 a.m. Pacific Time / 8:30 a.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 2637139. 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: timing and ability to progress the clinical trials of ALLO-501, ALLO-501A and ALLO-715 and present any data from the trials; clinical outcomes, which may materially change as patient enrollment continues and more patient data become available; timing and ability to file an IND and initiate clinical trials of ALLO-316, ALLO-605 and the combination of ALLO-715 with SpringWorks' nirogacestat; ability to manufacture AlloCAR T™ therapies, including for use in clinical trials; timing and ability to complete the Newark manufacturing facility; ability of TurboCAR™ to improve any efficacy, overcome cell exhaustion and reduce dosing requirements; the potential benefits of AlloCAR T™ therapy; and the 2020 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, 2020. 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 T are trademarks of Allogene Therapeutics, Inc.

Allogene's AlloCAR T programs utilize Cellectis technology. ALLO-501 and ALLO-501A are anti-CD19 allogeneic CAR T (AlloCAR T™) therapies 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 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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	$ 51,421	$ 39,995	$ 140,759	$ 95,172
General and administrative	16,619	15,016	48,122	42,261
Total operating expenses	68,040	55,011	188,881	137,433
Loss from operations	(68,040)	(55,011)	(188,881)	(137,433)
Other income (expense), net:				
Interest and other income, net	2,005	4,309	7,606	13,693
Other expenses	(162)	—	(376)	—
Total other income (expense), net	1,843	4,309	7,230	13,693
Loss before income taxes	(66,197)	(50,702)	(181,651)	(123,740)
Benefit (expense) from income taxes	—	(33)	—	176
Net loss	(66,197)	(50,735)	(181,651)	(123,564)
Net loss per share, basic and diluted	$ (0.52)	$ (0.5)	$ (1.55)	$ (1.24)
Weighted-average number of shares used in computing net loss per share, basic and diluted	127,140,755	102,186,644	117,227,079	99,801,001

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

SELECTED BALANCE SHEET DATA

	As of September 30, 2020	As of December 31, 2019
Cash, cash equivalents and investments	$ 1,049,015	$ 588,855
Total assets	1,222,500	717,802
Total liabilities	103,769	88,779
Total stockholders' equity	1,118,731	629,023

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Source: Allogene Therapeutics, Inc.