



Allogene Therapeutics Reports Fourth Quarter and Full Year 2019 Financial Results

February 27, 2020

- Initial Results from the Phase 1 ALLO-501 ALPHA Trial in Relapsed/Refractory Non-Hodgkin Lymphoma and Phase 1 ALLO-715 UNIVERSAL Trial in Relapsed/Refractory Multiple Myeloma On-Track for Q2 2020 and Q4 2020, Respectively
- ALLO-501A, the Next Generation anti-CD19 AlloCAR T Intended for Phase 2 Development, Received IND Clearance from the U.S. FDA. Company Expects to Initiate an Abbreviated Phase 1 Trial in Q2 2020
- Combination Trial of ALLO-715 and SpringWorks Therapeutics' Gamma Secretase Inhibitor, Nirogacestat, Expected to Commence in the Second Half of 2020
- IND Submission for Next Clinical Candidate, ALLO-316, an anti-CD70 AlloCAR T™, Targeted for Year End 2020
- Ended 2019 with \$589 Million in Cash, Cash Equivalents and Investments
- Conference Call and Webcast Scheduled for 5:30 AM PT/8:30 AM ET

SOUTH SAN FRANCISCO, Calif., Feb. 27, 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 fourth quarter and full-year 2019 financial results for the periods ended December 31, 2019.

"2019 was a very successful year for Allogene. We accomplished all of our corporate goals, which includes the establishment of world-class capabilities across multiple new functions and the initiation of our first clinical trials in patients with relapsed or refractory aggressive non-Hodgkin lymphoma and multiple myeloma," said David Chang, M.D., Ph.D., President, Chief Executive Officer and Co-Founder of Allogene. "Our momentum and focus towards making AlloCAR T therapies and their life-saving potential a reality for patients will continue at full speed in 2020. This year will be an important one as we look to demonstrate proof-of-concept data from two key programs and plan for potential pivotal studies."

Recent Highlights

ALLO-501 (anti-CD19 AlloCAR T)

- In 2019, Allogene initiated the ALLO-501 Phase 1 ALPHA trial in patients with relapsed/refractory non-Hodgkin lymphoma (NHL). This study utilizes ALLO-647, Allogene's anti-CD52 monoclonal antibody (mAb) as a part of the lymphodepletion regimen. Initial data is planned to be presented at a medical meeting in Q2 2020.
- The U.S. Food and Drug Administration cleared the Investigational New Drug Application (IND) for ALLO-501A, the Company's next generation anti-CD19 AlloCAR T construct devoid of the rituximab off-switch. ALLO-501A, previously referred to as ALLO-501.1, was created to eliminate the rituximab recognition domains in ALLO-501, allowing for use in a broader patient population, including those NHL patients with recent rituximab exposure.
- The Company expects to initiate an abbreviated Phase 1 portion of the ALLO-501A trial (ALPHA2) in the second quarter of the year. The ALPHA2 trial will leverage the findings of the ALPHA trial to finalize the ALLO-501A cell dose and the ALLO-647 based lymphodepletion regimen for a potential pivotal Phase 2 trial.

ALLO-715 (anti-BCMA AlloCAR T)

- The Company has created a robust anti-BCMA strategy centered around ALLO-715 for the treatment of multiple myeloma (MM).
- In 2019, Allogene initiated the ALLO-715 Phase 1 UNIVERSAL trial in patients with relapsed/refractory MM, designed to assess the safety and tolerability of ALLO-715. This trial is also intended to identify the optimal dose of ALLO-647 and includes the potential to evaluate lymphodepletion regimens that do not include fludarabine and cyclophosphamide. UNIVERSAL continues to accrue as planned with initial data anticipated in Q4 2020.
- In January 2020, Allogene entered into a clinical collaboration with SpringWorks Therapeutics to evaluate ALLO-715 in combination with SpringWorks' investigational gamma secretase inhibitor, nirogacestat, in patients with relapsed/refractory MM. The Company expects to initiate this combination trial in the second half of 2020.
- The Company nominated ALLO-605 as its first TurboCAR™ candidate and part of its larger MM strategy. The TurboCAR technology provides the effects of cytokine stimulation to AlloCAR T cells with the goal of enhancing their potency, expansion and persistence. ALLO-605 is advancing in preclinical development with a potential IND in 2021.

Additional Pipeline Updates

- The Company nominated ALLO-316, an anti-CD70 AlloCAR T, as its next clinical candidate for potential development in acute myeloid leukemia, T-cell malignancies and/or renal cell carcinoma. Submission of the IND for ALLO-316 is expected by year end 2020.

Fourth Quarter Financial Results

- As of December 31, 2019, Allogene had \$588.9 million in cash, cash equivalents, and investments.
- Research and development expenses were \$49.4 million for the fourth quarter of 2019, which includes \$6.4 million of non-cash stock-based compensation expense and \$10.0 million in expenses associated with the signing of our collaboration with Notch Therapeutics. For the full year of 2019, research and development expenses were \$144.5 million. Research and development expense for the year includes \$19.4 million of non-cash stock-based compensation expense.
- General and administrative expenses were \$15.2 million for the fourth quarter of 2019, which includes \$7.5 million of non-cash stock-based compensation expense. For the full year of 2019, general and administrative expenses were \$57.5 million, which includes \$26.6 million of non-cash stock-based compensation expense.
- Net loss for the fourth quarter of 2019 was \$61.0 million, or \$0.58 per share, including non-cash stock-based compensation expense of \$13.9 million. For the full year of 2019, our net loss was \$184.6 million, or \$1.83 per share, including non-cash stock-based compensation expense of \$46.1 million.

2020 Financial Guidance

- Allogene expects 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 2981059. 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 world-class 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 clinical trials of ALLO-501 and ALLO-715 and present any proof-of-concept data from the trials, the timing and ability to initiate and progress a clinical trial of ALLO-501A, our collaborator's ability to obtain any necessary rights to ALLO-501A, the timing and ability to initiate a clinical trial of ALLO-715 in combination with SpringWorks' nirogacestat, the timing and ability to file an IND and initiate clinical trials of ALLO-316 and ALLO-605, the ability to manufacture AlloCAR T™ therapies, including ALLO-501A, ALLO-316 and ALLO-605 for use in clinical trials, 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 September 30, 2019. 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.

ALLOGENE THERAPEUTICS, INC.

SELECTED FINANCIAL DATA

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

STATEMENTS OF OPERATIONS

	Three Months Ended December 31,		Year Ended December 31,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	\$ 49,363	\$ 18,503	\$ 144,535	\$ 151,860
General and administrative	15,212	14,543	57,473	40,982
Total operating expenses	64,575	33,046	202,008	192,842
Loss from operations	(64,575)	(33,046)	(202,008)	(192,842)
Other income (expense), net:				
Change in fair value of convertible note payable	—	(1,796)	—	(19,415)
Interest expense	—	—	—	(3,358)
Interest and other income, net	3,658	4,216	17,351	1,573
Other expenses	(268)	—	(268)	—

Loss before income taxes	(61,185)	(30,626)	(184,925)	(211,622)
Benefit from income taxes	155		117		331		117	
Net loss	(61,030)	(30,509)	(184,594)	(211,505)
Net loss per share, basic and diluted	\$ (0.58)	\$ (0.37)	\$ (1.83)	\$ (7.31)
Weighted-average number of shares used in computing net loss per share, basic and diluted	104,800,502		82,064,497		101,061,149		28,948,386	

SELECTED BALANCE SHEET DATA

	As of December 31, 2019	As of December 31, 2018
Cash, cash equivalents and investments	\$ 588,855	\$ 721,350
Total assets	717,802	773,855
Total liabilities	88,779	70,691
Total stockholders' equity	629,023	703,164

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Source: Allogene Therapeutics, Inc.