Allogene Therapeutics Reports Fourth Quarter and Full Year 2020 Financial Results and Corporate Update

February 25, 2021

- Presented Initial Phase 1 UNIVERSAL Trial Data on ALLO-715 at The American Society of Hematology (ASH) Meeting Providing First Proof-of-Concept for an AlloCAR T™ Therapy in Relapsed/Refractory Multiple Myeloma
- Updated ALLO-501 and Initial ALLO-501A AlloCAR T Data in Non-Hodgkin Lymphoma (NHL) Planned for Q2 2021
- ALLO-501A Granted FDA Fast Track Designation for Relapsed/Refractory Diffuse Large B Cell Lymphoma (DLBCL), a Type of NHL
- Two Investigational New Drug (IND) Applications Cleared; Allogene's First in Solid Tumors with ALLO-316 in Renal Cell Carcinoma and ALLO-715 in Combination with Nirogacestat for Relapsed/Refractory Multiple Myeloma
- On Track to Submit IND in 1H 2021 for ALLO-605 in Multiple Myeloma, the First TurboCAR™ Targeting BCMA
- Cell Forge 1 Construction Completed; cGMP Manufacturing Facility to Begin Production in 2021
- Ended 2020 with $1.0 Billion in Cash, Cash Equivalents and Investments
- Conference Call and Webcast Scheduled for 2:00 PM PT/5:00 PM ET

SOUTH SAN FRANCISCO, Calif., Feb. 25, 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 fourth quarter and full year financial results for the periods ended December 31, 2020.

"By all measures, 2020 was a year of exceptional growth and success as we progressed development of our AlloCAR T candidates and continued to establish Allogene as a leader in the cell therapy field. We've now treated over 75 patients with our AlloCAR T therapies, more than any other company in the field. Continued progress on our first three Phase 1 trials, ALPHA, ALPHA2, and UNIVERSAL, two new IND submissions, including our first in solid tumors, and the establishment of our Allogene Overland Biopharm joint venture highlight our executional capabilities," said David Chang, M.D., Ph.D., President, Chief Executive Officer and Co-Founder of Allogene. "Looking ahead to key milestones this year, we are looking forward to presenting an update on our CD19 program and the possibility of launching our first pivotal trial as well as operationalizing our state-of-the-art AlloCAR T production facility in Newark, California."

Pipeline Highlights

Anti-CD19 AlloCAR T Program

- 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 ALPHA2 study of ALLO-501A are planned for Q2 2021. The Company intends to initiate a potentially pivotal Phase 2 trial of ALLO-501A by the end of 2021.
- ALLO-501A was recently granted Fast Track Designation (FTD) by the U.S. Food and Drug Administration (FDA) for the treatment of relapsed/refractory diffuse large B cell lymphoma (DLBCL), a type of NHL. FTD is intended to facilitate the development, and expedites the review of, medicines to treat serious conditions and fill unmet medical need. FTD allows for potentially greater access to the FDA for the purpose of expediting the drug product candidate's development, review and potential approval.

Anti-BCMA AlloCAR T Program
The Company continues to expand its portfolio of anti-BCMA therapies to realize the potential benefits of an allogeneic approach to patients with multiple myeloma.

- **ALLO-715 UNIVERSAL Trial**
  - In December 2020, at an oral session of the 62nd Annual Meeting of the American Society of Hematology (ASH), the Company reported initial data on ALLO-715, its first AlloCAR T candidate for relapsed/refractory multiple myeloma (MM). The Phase I UNIVERSAL trial utilizes a proprietary lymphodepletion regimen consisting of ALLO-647 (anti-CD52 mAb) and chemotherapy.
  - As per the ASH presentation, 31 ALLO-715 treated patients were evaluable for safety and 26 patients were evaluable for efficacy.
    - Higher CAR T cell doses were associated with an increased response rate and greater AlloCAR T cell expansion.
    - In the DL3 cohort (320M CAR T+ cells), the overall response rate (ORR) was 60% with 40% of patients achieving a very good partial response (VGPR) or better (VGPR+).

- Minimal Residual Disease (MRD) was assessed in five patients with VGPR+ and all five were MRD negative.
- Approximately 90% of patients were treated within five days of study enrollment. No bridging therapy was required.
- No graft-vs-host disease or Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) was observed. Cytokine Release Syndrome (Grade 1 or 2) was reported in 14 patients (45%) and was manageable with standard therapies. The rate of Grade 3+ infection events was similar to what has been reported in other advanced MM studies. Any Grade 3+ adverse events reported as serious adverse events occurred in 19% of patients. A single Grade 5 event related to progressive myeloma and a cyclophosphamide and ALLO-647 conditioning regimen was reported.

- **ALLO-715 + nirogacestat**
  - The FDA cleared the Investigational New Drug Application (IND) to evaluate ALLO-715 in combination with the investigational gamma secretase inhibitor nirogacestat, in patients with relapsed/refractory MM. Enrollment has been initiated. Nirogacestat is being developed by SpringWorks Therapeutics.

- **ALLO-605 TurboCAR™**
  - An IND submission is planned for 1H 2021 for ALLO-605, the first anti-BCMA TurboCAR™ T cell therapy, for use in relapsed/refractory MM. Upon clearance, the IGNITE trial is expected to begin this year. The Company presented preclinical findings supporting ALLO-605 at ASH in December 2020. 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.

Solid Tumor AlloCAR T Program

- **ALLO-316 (anti-CD70) – TRAVERSE Trial**
  - The FDA cleared an IND to evaluate ALLO-316, Allogene's first CAR T candidate for solid tumors. The Company expects to initiate the Phase 1 TRAVERSE trial in Q1 2021 to examine safety, tolerability, anti-tumor efficacy, pharmacokinetics, and pharmacodynamics of ALLO-316 in patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC).
  - ALLO-316 also has potential application in hematologic malignancies. The Company presented preclinical findings of ALLO-316 targeting CD70 in models of acute myeloid leukemia (AML) at ASH in December and plans to explore AML as a potential second indication for ALLO-316.

Corporate Highlights

- **Establishment of Allogene Overland Biopharm**
  - The Company and Overland Pharmaceuticals, which is backed by Hillhouse Capital, announced the formation of Allogene Overland Biopharm. The joint venture will have an exclusive license to develop, manufacture and commercialize specific Allogene candidates targeting BCMA, CD70, FLT3, and DLL3 in the licensed territories.

- **Cell Forge 1 Manufacturing Facility**
  - Construction of the Company's new state-of-the-art cGMP cell manufacturing facility, Cell Forge 1, in Newark, California has been completed. cGMP manufacturing from this facility is expected to begin in 2021.

Fourth Quarter Financial Results

- Research and development expenses were $52.2 million for the fourth quarter of 2020, which includes $7.9 million of non-cash stock-based compensation expense. For the full year of 2020, research and development expenses were $193.0 million. Research and development expense for the year includes $31.3 million of non-cash stock-based compensation expense.
- General and administrative expenses were $17.1 million for the fourth quarter of 2020, which includes $8.6 million of non-cash stock-based compensation expense. For the full year of 2020, general and administrative expenses were $65.3 million, which includes $34.0 million of non-cash stock-based compensation expense.
- Net loss for the fourth quarter of 2020 was $68.6 million, or $0.53 per share, including non-cash stock-based compensation expense of $16.5 million. For the full year of 2020, net loss was $250.2 million, or $2.08 per share, including non-cash stock-based compensation expense of $65.3 million.
- The Company had $1.0 billion in cash, cash equivalents, and investments as of December 31, 2020.

2021 Financial Guidance

- Allogene expects 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 4973969. 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 and UNIVERSAL 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 file an IND and initiate a clinical trial of ALLO-605, the ability to manufacture AlloCAR T™ therapies, including for use in clinical trials, the timing and ability to initiate cGMP manufacturing at the Company’sNewark 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-K for the year ended December 31, 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 technologies. 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.

[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 December 31,		Year Ended December 31,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	$ 52,228	$ 49,363	$ 192,987	$ 144,535
General and administrative	17,134	15,212	65,256	57,473
Total operating expenses	69,362	64,575	258,243	202,008
Loss from operations	(69,362)	(64,575)	(258,243)	(202,008)
Other income (expense), net:				
Interest and other income, net	1,558	3,658	9,164	17,351
Other expenses	(766)	(268)	(1,142)	(268)
Loss before income taxes	(68,570)	(61,185)	(250,221)	(184,925)
Benefit from income taxes	—	155	—	331
Net loss	(68,570)	(61,030)	(250,221)	(184,594)
Net loss per share, basic and diluted	$ (0.53)	$ (0.58)	$ (2.08)	$ (1.83)
Weighted-average number of shares used in computing net loss per share, basic and diluted	129,835,293	104,800,502	120,370,177	101,061,149

SELECTED BALANCE SHEET DATA

	As of December 31, 2020	As of December 31, 2019
Cash, cash equivalents and investments	$ 1,032,118	$ 588,855
Total assets	1,227,829	717,802
Total liabilities	148,212	88,779
Total stockholders' equity	1,079,617	629,023

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Source: Allogene Therapeutics, Inc.