



## Allogene Therapeutics Reports Second Quarter 2020 Financial Results

August 5, 2020

- Initial Phase 1 Results from the ALLO-501 ALPHA Trial at ASCO Demonstrated an Overall Response Rate of 75% and Complete Response Rate of 44% in CAR T Naïve Relapsed/Refractory Non-Hodgkin Lymphoma Patients
- In the ALPHA Trial, Higher Dose ALLO-647 was Associated with Deeper Lymphodepletion, Delayed Host T Cell Recovery and a Higher Complete Response Rate
- Initiated Phase 1 Portion of ALPHA2 Trial for ALLO-501A, a Next-Generation anti-CD19 AlloCAR T™ Intended for Phase 2 Development
- Completed Initial Dose Escalation Portion of the Phase 1 ALLO-715 UNIVERSAL Trial in Relapsed/Refractory Multiple Myeloma with Data Expected in Q4 2020
- Investigational New Drug (IND) Application to Evaluate ALLO-316, an anti-CD70 AlloCAR T in Renal Cell Carcinoma Expected by Year End
- cGMP Production in Newark Manufacturing Facility On Track for 2021
- Ended Second Quarter with \$1.1 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., Aug. 05, 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 June 30, 2020.

"We are incredibly pleased with the progress we've made across our AlloCAR T platform, which now includes ongoing clinical trials for ALLO-501, ALLO-501A and ALLO-715," said David Chang, M.D., Ph.D., President, Chief Executive Officer and Co-Founder of Allogene. "The ALLO-501 data we presented at ASCO in May solidifies our belief in the potential of AlloCAR T therapy in hematologic malignancies. We look forward to presenting initial data in a second hematologic malignancy, multiple myeloma, later this year as we advance the same innovative approach to solid tumors in 2021."

### Recent Highlights

#### Anti-CD19 AlloCAR T Program

Initial data from ALLO-501's ALPHA trial provided support for the Company's approach to AlloCAR T therapy. Allogene intends to leverage ALLO-501 to optimize trial design and dose selection as it prepares for a potentially pivotal Phase 2 trial of ALLO-501A in 2021.

#### • ALLO-501 ALPHA Phase 1 Trial

In May 2020 at the American Society of Clinical Oncology (ASCO) annual meeting, the Company presented initial data from its dose escalation Phase 1 ALPHA study of ALLO-501 in relapsed/refractory non-Hodgkin lymphoma (NHL). This study utilizes ALLO-647, the Company's anti-CD52 monoclonal antibody (mAb), as a part of its differentiated lymphodepletion regimen. The next readout from this trial is expected to be in late 2020 or early 2021.

As per the ASCO presentation, 22 patients were evaluable for safety and 19 patients were evaluable for efficacy with at least one tumor assessment as of the May 2020 data cutoff.

- Responses were observed across all cell doses and NHL histologies (diffuse large B-cell lymphoma and follicular lymphoma).
  - Across all evaluable patients, there were seven complete responses (CR) and five partial responses (PR) for an overall response rate (ORR) of 63% and CR rate of 37%.
  - In CAR T naïve patients (n=16) the ORR was 75% and the CR rate 44%.
  - Higher dose ALLO-647 was associated with a higher CR rate.
  - With a median follow-up of 3.8 months, nine of the 12 responding patients (75%) remained in response as of the data cutoff on May 11, 2020.
  - No dose limiting toxicities, graft-vs-host disease, or Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) was observed. Cytokine release syndrome occurred in 32% of the patients, was mainly mild to moderate in severity and manageable with standard recommendations. Four patients (18%) experienced serious adverse events (SAE), all of which resolved.
- **ALLO-501A ALPHA2 Phase 1 Trial**  
ALLO-501A is a next generation anti-CD19 AlloCAR T intended for Phase 2 development. During the second quarter, the

Company initiated enrollment in the Phase 1 portion of the ALPHA2 trial. This abbreviated dose escalation study is a single-arm, open-label, multicenter trial of ALLO-501A in patients with R/R large B-cell lymphoma. The Company expects to begin the Phase 2 portion of this study in 2021.

#### **Anti-BCMA AlloCAR T Program**

The Company continues to progress its robust anti-BCMA strategy centered around ALLO-715 for the treatment of multiple myeloma (MM).

- **ALLO-715 UNIVERSAL Phase 1 Trial**

- The ALLO-715 Phase 1 UNIVERSAL trial in patients with relapsed/refractory MM utilizes ALLO-647 as part of the lymphodepletion platform. The initial dose escalation portion of the UNIVERSAL trial using 39mg of ALLO-647 is now complete. The trial continues to enroll patients with initial data anticipated in Q4 2020.

- **ALLO-715 + nirogacestat**

- An Investigational New Drug (IND) application is expected to be submitted in the second half of 2020 to evaluate ALLO-715 in combination with SpringWorks' investigational gamma secretase inhibitor, nirogacestat, in patients with relapsed/refractory MM.

- **ALLO-605 (TurboCAR™)**

- The Company presented preclinical data on its internally developed TurboCAR™ technology platform at the American Society of Gene & Cell Therapy (ASGCT) 23<sup>rd</sup> Annual Meeting in May. 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.

- In 2021, an IND is expected to be submitted for the Company's first TurboCAR candidate, ALLO-605, an investigational BCMA-directed AlloCAR T therapy for MM.

#### **Solid Tumor AlloCAR T Program**

- **ALLO-316 (anti-CD70)**

- The Company continues to progress pre-clinical work on ALLO-316, its anti-CD70 AlloCAR T clinical candidate. ALLO-316 has potential application in both hematologic malignancies and solid tumors. The initial focus for this investigational therapy will be renal cell carcinoma with an IND planned by the end of 2020.

#### **Manufacturing Update**

Construction continues on the Company's state-of-the-art cGMP cell manufacturing facility in Newark, California. The Company continues to expect to initiate cGMP manufacturing from this facility in 2021.

#### **Second Quarter Financial Results**

- Research and development expenses were \$47.3 million for the second quarter of 2020, which includes \$8.0 million of non-cash stock-based compensation expense.
- General and administrative expenses were \$15.9 million for the second quarter of 2020, which includes \$8.8 million of non-cash stock-based compensation expense.
- Net loss for the second quarter of 2020 was \$61.0 million, or \$0.53 per share, including non-cash stock-based compensation expense of \$16.8 million.
- In June, the Company closed on a follow-on offering that raised \$632.5 million in gross proceeds prior to deducting underwriting discounts, commissions and offering expenses. This included the exercise in full by the underwriters of their option to purchase additional shares of common stock. As a result, the Company had \$1.1 billion in cash, cash equivalents, and investments as of June 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 2189084. The webcast will be made available on the Company's website at [www.allogene.com](http://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](http://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 and establish favorable benefit:risk with 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, the 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, the ability to manufacture AlloCAR T™ therapies, including for use in clinical trials, the timing and ability to complete the Newark manufacturing facility, 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 technologies. ALLO-501 and ALLO-501A are anti-CD19 allogeneic CAR T (AlloCAR T™) therapies being jointly developed under a collaboration agreement between Servier<sup>1</sup> 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.

<sup>1</sup> 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,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	\$ 47,296	\$ 31,774	\$ 89,337	\$ 55,177
General and administrative	15,862	14,187	31,502	27,245
Total operating expenses	63,158	45,961	120,839	82,422
Loss from operations	(63,158)	(45,961)	(120,839)	(82,422)
Other income (expense), net:				
Interest and other income, net	2,340	4,559	5,600	9,384
Other expenses	(156)	—	(215)	—
Total other income (expense), net	2,184	4,559	5,385	9,384
Loss before income taxes	(60,974)	(41,402)	(115,454)	(73,038)
Benefit from income taxes	—	159	—	209
Net loss	(60,974)	(41,243)	(115,454)	(72,829)
Net loss per share, basic and diluted	\$ (0.53)	\$ (0.41)	\$ (1.03)	\$ (0.74)
Weighted-average number of shares used in computing net loss per share, basic and diluted	115,377,210	99,846,946	112,163,123	98,588,410

#### SELECTED BALANCE SHEET DATA

	As of June 30, 2020	As of December 31, 2019
Cash, cash equivalents and investments	\$ 1,110,444	\$ 588,855
Total assets	1,258,544	717,802
Total liabilities	95,125	88,779
Total stockholders' equity	1,163,419	629,023

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Source: Allogene Therapeutics, Inc.