



Allogene Therapeutics Announces Oral Presentation of Initial Results from its Phase 1 Dose Escalation Study of ALLO-715 in Relapsed/Refractory Multiple Myeloma at the 62nd Annual Meeting of the American Society of Hematology

Nov 4, 2020 at 9:03 AM EST

- ALLO-715, an Allogeneic BCMA CAR T Therapy Dosed with an ALLO-647 Based Lymphodepletion Regimen, Reported No Neurotoxicity or GvHD Across Three Cell Doses (40M, 160M, and 320M CAR+ cells) and Lower Dose (39mg) ALLO-647
- Dose Dependent Activity Was Observed with 320M Cell Dose of ALLO-715 (DL3) Associated with a 60% Overall Response Rate (ORR)
 - All DL3 Patients with a VGPR or Greater Achieved MRD Negative Status
- Results from Additional Patients, Including Patients Treated at Higher Doses of ALLO-715 and ALLO-647 Will Be Presented on December 5, 2020
- Study Continues Enrollment to Optimize Dosing and Lymphodepletion
- Preclinical Data Will Also be Presented on ALLO-605, a BCMA TurboCAR T™ Cell Therapy and ALLO-316 Targeting CD70 in Acute Myeloid Leukemia

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 announced that it will present initial data from its Phase 1 UNIVERSAL trial of ALLO-715, an anti-BCMA AlloCAR T therapy, in relapsed/refractory multiple myeloma in an oral presentation at the 62nd Annual Meeting of the American Society of Hematology (ASH), taking place virtually December 5 – 8, 2020. Preclinical findings from investigations of ALLO-316, an AlloCAR T targeting CD70 in acute myeloid leukemia and ALLO-605, a BCMA-directed TurboCAR T™ cell therapy in multiple myeloma, will also be presented in poster sessions.

"We're looking forward to presenting initial clinical data for our first anti-BCMA AlloCAR T therapy, ALLO-715, which we believe will provide insights into how we might optimize lymphodepletion and cell dose to reach its potential for patients in need of readily available treatments options," said Rafael Amado, M.D., Executive Vice President of Research & Development and Chief Medical Officer of Allogene. "These findings will help inform trial design for our BCMA platform as we look to advance ALLO-715, alone and in combination with a gamma secretase inhibitor, as well as ALLO-605, our first TurboCAR T clinical candidate."

In the initial dose escalation phase of the UNIVERSAL trial, patients received lymphodepletion (LD) followed by ALLO-715 at one of three dose levels (DL) in a 3+3 dose escalation design. At the time of the July 2020 abstract data cutoff, two LD regimens were being evaluated:

- FCA: Fludarabine 90 mg/m², Cyclophosphamide 900 mg/m², and ALLO-647 39 mg divided over three days; and
- CA: Cyclophosphamide 900 mg/m² and ALLO-647 39 mg divided over three days.

The ASH abstract includes preliminary data on the first 15 patients evaluable for efficacy and treated with escalating doses of ALLO-715 as well as lower dose (39mg) ALLO-647. Patients were in advanced stage of disease with a median of five prior lines of therapy. The trial did not permit bridging therapy.

In 15 evaluable patients, higher dose of ALLO-715 (DL3) achieved greater activity with 60% (3/5) patients responding (95% CI 14.7, 94.7). Of the three patients who received DL3 FCA, two responded (1 stringent complete response (sCR) and 1 very good partial response (VGPR)) and both were minimum residual disease (MRD) negative by local MRD testing.

LD Regimen and Cell Dose	FCA			CA		Overall DL3 (95% CI) (N=5)
	DL1 40 x 10 ⁶ CAR+ cells (N=3)	DL2 160 x 10 ⁶ CAR+ cells (N=4)	DL3 320 x 10 ⁶ CAR+ cells (N=3)	DL2 160 x 10 ⁶ CAR+ cells (N=3)	DL3 320 x 10 ⁶ CAR+ cells (N=2)	
ORR, n (%)	0 (0%)	2 (50%)	2 (66%)	0 (0%)	1 (50%)	3/5 (60%) (14.7, 94.7)

At the time of the data cutoff, 17 of the patients were evaluable for safety. No neurotoxicity or graft-vs-host disease (GvHD) was observed. Cytokine release syndrome (CRS) was reported in four patients (24%) with three Grade 1 and one Grade 2. All CRS was resolved without tocilizumab or corticosteroids. The most common Grade ≥ 3 adverse events were anemia (41.2%), neutropenia (41.2%), lymphopenia (29.4%), and thrombocytopenia (29.4%).

Four (23.5%) instances of Grade ≥ 3 infections were observed. Three of these were Grade 3 and resolved with treatment. The fourth was a Grade 5 event of suspected fungal pneumonia that occurred on day eight post-ALLO-715 infusion. The suspected fungal pneumonia was diagnosed on the day after cell infusion in this patient with advanced and rapidly progressing disease who had failed multiple lines of therapy. This event occurred in the CA cohort, and it was assessed by the investigator as related to progressive disease and the CA conditioning.

The oral 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 a higher dose 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.

The ASH abstracts are now available at www.hematology.org. Allogene will also host a conference call on December 5th following the virtual presentation. Details on the ASH presentations are as follows:

Allogene Oral Presentation

Session: 653. Myeloma/Amyloidosis: Therapy, Excluding Transplantation; CAR T Therapies for Myeloma: Novel Approaches and Longer-Term Follow Up Data

Abstract #129

Title: Universal: An Allogeneic First-in-Human Study of the Anti-BCMA ALLO-715 and the Anti-CD52 ALLO-647 in Relapsed/Refractory Multiple Myeloma

Presenter: Sham Mailankody, M.D., Memorial Sloan Kettering Cancer Center

Session Date & Time: Saturday, December 5, 2020; 9:30 a.m. - 11 a.m. PT

Allogene Poster Presentations

Session: 616. Acute Myeloid Leukemia: Novel Therapy, Excluding Transplantation: Poster II

Abstract #1972

Title: Investigation of ALLO-316: A Fratricide-Resistant Allogeneic CAR T Targeting CD70 As a Potential Therapy for the Treatment of AML

Presenter: Nguyen Tan, Allogene Therapeutics

Session Date & Time: Sunday, December 6, 2020; 7 a.m. - 3:30 p.m. PT

Session: 703. Adoptive Immunotherapy: Mechanisms and New Approaches: Poster III

Abstract #3258

Title: Preclinical Evaluation of ALLO-605, an Allogeneic BCMA TurboCAR TTM Cell Therapy for the Treatment of Multiple Myeloma

Presenter: Cesar Sommer, Ph.D., Allogene Therapeutics

Session Date & Time: Monday, December 7, 2020; 7 a.m. - 3 p.m. PT

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 TTM) 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 ability to progress the Phase 1 trial of ALLO-715; current data and clinical outcomes, which may materially change as patient enrollment continues and more patient data become available; the ability to initiate and progress a clinical trial of ALLO-715 with a gamma secretase inhibitor; the ability to initiate and progress a clinical trial of ALLO-605; the ability to manufacture AlloCAR TTM therapies; and the potential benefits of AlloCAR T therapies. Various factors may cause differences between Allogene's expectations and actual results as discussed in greater detail in Allogene's filings with the SEC, including without limitation in its Form 10-Q for the quarter ended September 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 TTM is a trademark of Allogene Therapeutics, Inc.

ALLO-715 (BCMA), ALLO-605 (BCMA) and ALLO-316 (CD70) utilize TALEN® gene-editing technology pioneered and owned by Collectis. Allogene has an exclusive license to the Collectis technology for allogeneic products directed at these targets and holds all global development and commercial rights for these investigational candidates.

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Source: Allogene Therapeutics, Inc.