Allogene Therapeutics Reports Positive Initial Results from Phase 1 UNIVERSAL Study of ALLO-715 AlloCAR T™ Cell Therapy in Relapsed/Refractory Multiple Myeloma at the 62nd American Society of Hematology Annual Meeting

Dec 5, 2020 at 12:30 PM EST

- First Reported Allogeneic CAR T Data in Multiple Myeloma Highlights Initial Safety and Efficacy in Heavily Pretreated, Refractory Patients
- In the Ongoing Study, 31 Patients Were Evaluable for Safety and 26 Patients Were Evaluable for Efficacy as of Data Cutoff
    - Approximately 90% of Patients Treated Within Five Days of Study Enrollment
    - No Bridging Therapy Required Prior to Treatment
- ALLO-715 with ALLO-647 Lymphodepletion Were Well Tolerated with No Graft-vs-Host Disease or Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS)
- 60% Overall Response Rate (ORR) with Higher Cell Dose ALLO-715 (320M) and FCA Lymphodepletion; 40% Achieved a Very Good Partial Response (VGPR) or Better
    - Minimal Residual Disease (MRD) Assessed in Five Patients with VGPR or Better Response. All Five were MRD Negative
    - ALLO-715 Cell Expansion and Persistence Observed Through Month Four
- Company to Host a Webinar on Saturday, December 5 at 11:00 AM PT/2:00 PM ET

SOUTH SAN FRANCISCO, Calif., Dec. 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 announced positive initial results from the Phase 1 UNIVERSAL study of ALLO-715 in relapsed/refractory multiple myeloma (MM). Data were presented at an oral session of the American Society of Hematology (ASH) annual meeting. This study utilizes ALLO-647, Allogene's anti-CD52 monoclonal antibody (mAb), as a part of its differentiated lymphodepletion regimen.

“We are excited to demonstrate for the first time that an allogeneic CAR T therapy directed at BCMA can achieve deep clinical responses. We believe these initial results support that we are on the right track to bring the benefits of an off-the-shelf therapy to patients with refractory multiple myeloma,” said David Chang, M.D., Ph.D., President, Chief Executive Officer and Co-Founder of Allogene. “We look forward to optimizing multiple aspects of this therapy in the ongoing UNIVERSAL trial.”

“These data highlight the potential for an off-the-shelf CAR T therapy to treat patients within a matter of days, which eliminates the need for bridging therapy, a significant benefit in this refractory myeloma population,” said Sham Mailankody, MBBS, Assistant Attending Physician, Memorial Sloan Kettering Cancer Center in New York, New York. “I am encouraged by the initial data from this trial, including the feasibility, safety and the ability of ALLO-715 to produce MRD negative responses.”

As of the October 30, 2020 data cutoff, 35 patients were enrolled with 31 patients evaluable for safety and 26 patients evaluable for efficacy. Patients were refractory to their last line of myeloma therapy, had a median of five prior lines of therapy, and 94% were penta-exposed. Four patients became ineligible for treatment due to rapidly progressing disease. The median time from enrollment to the start of therapy was five days.

In the initial dose escalation phase of the UNIVERSAL trial, patients received lymphodepletion (LD) followed by ALLO-715 at one of three dose levels (DL1 = 40M cells, DL2 = 160M cells, DL3 = 320M cells) in a 3+3 dose escalation design. DL4 (480M cells) was added in a subsequent cohort. Two LD regimens were evaluated, with the trial enrollment primarily focused on the FCA lymphodepletion regimen:

- FCA: **F**ludarabine 90 mg/m^2, **C**yclophosphamide 900 mg/m^2, and **A**LLO-647 from 39 to 90mg divided over three days; and
- CA: **C**yclophosphamide 900 mg/m^2 and **A**LLO-647 39mg divided over three days.

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+). VGPR+ is defined as a stringent complete response (sCR), complete response (CR) or VGPR. Across all cohorts and lymphodepletion regimens, six patients achieved VGPR+, five of whom were in the FCA lymphodepletion regimen. Minimal residual disease (MRD) assessment was completed in five of the six patients with a VGPR+ response and all achieved an MRD negative status.

As of the data cutoff, the overall median follow-up for efficacy was 3.2 months and six out of the nine patients treated with DL3 or DL4 with a response remain in response. The longest response was ongoing at six months from the DL3 cohort with FCA lymphodepletion.

Cell Dose	FCA	CA

and LD regimen	DL1 40 x 10^6 CAR+ cells	DL2 160 x 10^6 CAR+ cells	**DL3 320 x 10^6 CAR+ cells**			DL4 480 x 10^6 CAR+ cells	DL2 160 x 10^6 CAR+ cells	DL3 320 x 10^6 CAR+ cells
	Low ALLO-647 (N=3)	Low ALLO-647 (N=4)	Low ALLO-647 (N=6)	High ALLO-647 (N=4)	**ALL ALLO-647 (N=10)**	Low ALLO-647 (N=3)	Low ALLO-647 (N=3)	Low ALLO-647 (N=3)
ORR, n (%)	-	2 (50%)	3 (50%)	3 (75%)	**6 (60%)**	1 (33%)	-	2 (67%)
VGPR+ Rate, n (%)	-	1 (25%)	3 (50%)	1 (25%)	**4 (40%)**	-	-	1 (33%)

Of the 31 patients evaluable for safety, there was no graft-vs-host disease (GvHD) or Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) observed. Grade 1 and Grade 2 cytokine release syndrome (CRS) was reported in 14 patients (45%) and was manageable with standard therapies. Infection events ≥ Grade 3 in the trial was similar to what has been reported in other advanced MM studies. Adverse events ≥ Grade 3 reported as serious adverse events occurred in 19% of patients. As previously reported, a single Grade 5 event related to progressive myeloma and conditioning regimen occurred in the CA cohort.

Adverse Events of Interest	**Grade 1 N (%)**	**Grade 2 N (%)**	**Grade 3 N (%)**	**Grade 4 N (%)**	**Grade 5 N (%)**	**All Grades N (%)**
Cytokine Release Syndrome	5 (16%)	9 (29%)	-	-	-	14 (45%)
ICANS	-	-	-	-	-	-
Graft-versus-Host Disease	-	-	-	-	-	-
Infection	2 (7%)	6 (19%)	4 (13%)	-	1 (3%)	13 (42%)
Infusion Reaction to ALLO-647	4 (13%)	3 (10%)	-	-	-	7 (23%)

As part of the Company's three-pronged anti-BCMA strategy, the Phase 1 UNIVERSAL study continues to enroll patients at higher doses of ALLO-715 and ALLO-647 in an effort to optimize the therapy. The UNIVERSAL study is expected to begin enrolling patients in the first half of 2021 to evaluate ALLO-715 in combination with SpringWorks Therapeutics' investigational gamma secretase inhibitor, nirogacestat. An investigational new drug application (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 and has shown the ability to improve the potency and persistence of allogeneic cells in preclinical models.

Webinar
Allogene will be hosting a webinar to discuss the data from UNIVERSAL on December 5 at 11:00 a.m. PT/2:00 p.m. ET. Please register for the webinar on the Company's website at www.allogene.com under the Investors tab in the News and Events section (https://ir.allogene.com/events) or by clicking the following link directly.

The webinar will also be available in replay and the materials presented will be posted on the Allogene website prior to the start of the event.

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 for Allogene
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 timing and ability to initiate and progress a clinical trial of ALLO-715 with a gamma secretase inhibitor; the timing and ability to submit and IND and initiate a clinical trial of ALLO-605; the ability to manufacture AlloCAR T™ 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.

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

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