Allogene Therapeutics Announces Preclinical Publication Highlighting Superiority of Healthy Donor-Derived Allogeneic CAR T Cells Over Patient-Derived Cells in Multiple Myeloma

March 23, 2022

- Results Demonstrated Anti-BCMA CAR T Cells Derived from Healthy Donors Had Better Immune Fitness and Killing Activity
- Phase 1 AlloCAR T™ Trials Underway Evaluating ALLO-715 and ALLO-605 for the Treatment of Relapsed/Refractory Multiple Myeloma
    - BCMA Program Clinical Update Expected by the End of 2022

SOUTH SAN FRANCISCO, Calif., March 23, 2022 (GLOBE NEWSWIRE) -- Allogene Therapeutics, Inc. (Nasdaq: ALLO), a clinical-stage biotechnology company pioneering the development of allogeneic CAR T (AlloCAR T™) products for cancer, today announced the publication of preclinical study results demonstrating the superior long-term *in vitro* myeloma-killing activity of allogeneic anti-BCMA CAR T cells from healthy donors compared with anti-BCMA CAR T cells from patients with multiple myeloma. The findings were published in *Cancer Research Communications*, a journal of the American Association for Cancer Research.

“Despite the rapidly evolving treatment landscape for multiple myeloma, this hematologic cancer remains incurable. With so many patients experiencing aggressive disease progression, novel, effective and readily available therapies are needed,” said Reuben Benjamin, MBBS, FRCPath, Ph.D., co-author of the publication and Consultant Hematologist at King’s College Hospital in London. “This preclinical study provides strong evidence of the potential benefits of an allogeneic CAR T therapy derived from young healthy donors over an autologous approach in which a patient’s own T cells are genetically engineered to attack myeloma cancer cells. T cells derived from healthy donors were more abundant, had greater fitness and anti-cancer killing potential, and have the ability to be administered without delay.”

BCMA is a validated target in multiple myeloma due to its high specificity and broad expression. In this study led by Ana M. Metelo M.Sc. Ph.D., Postdoctoral Research Associate at King’s College London, anti-BCMA CAR T cells were generated from young healthy donors and from patients with relapsed/refractory multiple myeloma (median age: 61 years) and their profile, fitness and cytotoxic (anti-tumor) activity were compared. Results showed that:

- Healthy donors had higher T cell counts, a higher CD4/CD8 T cell ratio, and naïve/stem cell memory phenotype compared with patients with relapsed multiple myeloma.
- Anti-BCMA allogeneic CAR T cells derived from healthy donors showed efficient killing of primary multiple myeloma cells across different patient sub-groups including those with high-risk disease.
- In a subset of patient samples with low BCMA, the addition of a gamma secretase inhibitor increased the surface levels of BCMA and led to improved cytotoxic activity.

“These preclinical study results further support our approach to using allogeneic anti-BCMA CAR T cells to treat patients with multiple myeloma. As we presented at the American Society of Hematology annual meeting in December 2021, our ongoing Phase 1 UNIVERSAL trial of ALLO-715 is the first allogeneic trial to demonstrate safety and substantial efficacy in relapsed/refractory multiple myeloma,” said Rafael G. Amado, M.D., Executive Vice President of Research and Development and Chief Medical Officer.

Manufacturing T cells from a healthy donor allows for less product variability and eliminates both the risk of manufacturing failures and the requirement for bridging therapy by enabling treatment within days. In studies on the approved autologous CAR T therapies, up to 75% of patients required bridging therapy, up to 18% of patients received therapies that were not within the required manufacturing specifications, and up to 14% of patients did not receive cells in time for treatment.

As part of Allogene’s anti-BCMA strategy, the Company has two AlloCAR T™ trials underway investigating product candidates for the treatment of multiple myeloma. The first is a Phase 1 UNIVERSAL trial that includes cohorts evaluating ALLO-715 as a monotherapy, as a consolidated dosing strategy, and in combination with SpringWorks Therapeutics’ investigational gamma secretase inhibitor, nirogacestat. ALLO-715 was granted Regenerative Medicine Advanced Therapy (RMAT) designation in April 2021 and Orphan Drug Designation (ODD) in August 2021 by the U.S. Food and Drug Administration (FDA). The second is a Phase 1 IGNITE dose escalation trial that is evaluating ALLO-605, Allogene’s first TurboCAR™ candidate. 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. Allogene intends to provide a BCMA program clinical update by the end of 2022.

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™) products 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 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 UNIVERSAL and IGNITE trials, including to provide an update at year-end; the potential for promising pre-clinical data to translate to positive clinical data; clinical outcomes, which may materially change as more patient data become available; the ability to manufacture AlloCAR T™ products; and the potential benefits of AlloCAR T products. 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-K for the year ended December 31, 2021. 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's AlloCAR T™ programs utilize Cellectis technologies. The anti-BCMA AlloCAR T programs are licensed exclusively from Cellectis by Allogene and Allogene holds global development and commercial rights to these AlloCAR T programs.

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Source: Allogene Therapeutics, Inc.