Allogene Therapeutics Announces Poster Presentations at the 65th Annual Meeting of the American Society of Hematology

Nov 2, 2023 at 9:00 AM EDT

- Comprehensive Review of Overall Treatment Safety Profile of our ALLO-501/501A Candidate Used in Conjunction with Propriety Lymphodepletion with Investigational ALLO-647 from the Phase 1 ALPHA/ALPHA2 Studies
- Translational Overview of Patient Alloimmune Responses Affecting Allogeneic CAR T Cell Expansion and Rejection in Large B-Cell Lymphoma

SOUTH SAN FRANCISCO, Calif., Nov. 02, 2023 (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 that it will have two poster presentations focused on the importance of lymphodepletion in allogeneic cell therapy at the 65th Annual Meeting of the American Society of Hematology (ASH) taking place December 9-12, 2023 in San Diego, CA.

“All CAR T cells require lymphodepletion to support the expansion and persistence needed to eradicate malignant cells. Because of the risk of allorejection by the patient’s immune system, creating the necessary window of persistence for an off-the-shelf, allogeneic CAR T product may require an enhanced approach to lymphodepletion. These results reinforce our belief that Allogene’s strategy of adding ALLO-647, an anti-CD52 monoclonal antibody candidate, to the standard fludarabine/cyclophosphamide (flu/cy) lymphodepletion regimen in our ALPHA/ALPHA2 studies can safely achieve this,” said Zachary Roberts, M.D., Ph.D., Executive Vice President of Research & Development and Chief Medical Officer of Allogene. “Our unique and proprietary lymphodepletion regimen that includes ALLO-647 has been shown to potentially induce deep and durable remissions in relapsed and treatment-refractory cancers.”

The first poster is a comprehensive safety review of all 85 patients treated in the Phase 1 ALPHA/ALPHA2 studies in relapsed/refractory (r/r) Large B Cell Lymphoma (LBCL) and follicular lymphoma (FL) to characterize the overall safety profile when ALLO-647 is added to standard lymphodepletion.

In June 2023 at the International Conference on Malignant Lymphoma (ICML) in Lugano, Switzerland, the Company presented updated data from the Phase 1 ALPHA/ALPHA2 trials of investigational ALLO-501/501A in 33 CAR T naïve patients with r/r LBCL treated with the Alloy™ manufacturing process material across different CAR T dosing and lymphodepletion regimens. Data from the 12 patients, a subset of these 33 CAR T naïve patients, who received the regimen being utilized in ongoing Phase 2 trials was presented at the American Society of Clinical Oncology (ASCO) Annual Meeting. These data demonstrated that administration of the anti-CD19 allogeneic CAR T product candidate following a 3-day lymphodepletion regimen that includes fludarabine 30 mg/m^2 and cyclophosphamide 300-500 mg/m^2 (FC) and 39, 60, or 90 mg of ALLO-647 in divided doses can potentially yield durable responses and an acceptable safety profile in line with approved autologous CAR T therapies.

Title: ALLO-647 for Lymphodepletion in the Allogeneic CAR T Setting: Safety Experience with ALLO-501/501A in Patients (Pts) with Relapsed/Refractory (r/r) Large B-Cell and Follicular Lymphomas
Session: 704. Cellular Immunotherapies: Early Phase and Investigational Therapies: Poster I
Abstract: 2095
Presenter: Dr. Frederick Locke, M.D., Chair, Department of Blood and Marrow Transplant and Cellular Immunotherapy; program co-leader, Immuno-Oncology, Moffitt Cancer Center
Tampa, Florida
Session Date & Time: Saturday, December 9, 2023, 5:30 PM - 7:30 PM PT
Location: San Diego Convention Center, Halls G-H

The second poster showcases translational results from ALPHA2 generated through a collaboration with researchers from The University of Texas MD Anderson Cancer Center. This study compared expansion kinetics among 11 allogeneic CAR T recipients treated with investigational ALLO-501A in the ALPHA2 trial. The study revealed the impact of recipient alloreactive CD8+ T cells in allogeneic CAR T rejection. Results of this study could help define strategies to improve allogeneic CAR T expansion, persistence, and efficacy.

Title: Cellular Mechanisms Affecting Allogeneic CAR T Cell Expansion and Rejection in Large B-cell Lymphoma
Session: 703. Cellular Immunotherapies: Basic and Translational: Poster III
Abstract: #4832
Presenter: Andrew P. Jallouk, M.D., Ph.D,Vanderbilt / MD Anderson
Session Date & Time: Monday, December 11, 2023 6:00pm – 8:00pm PT
Location: San Diego Convention Center, Halls G-H

About ALLO-501 and ALLO-501A
ALLO-501 and ALLO-501A are anti-CD19 AlloCAR T investigational products for the treatment of large B cell lymphoma. ALLO-501A, a next-generation anti-CD19 AlloCAR T, eliminates the rituximab recognition domains in ALLO-501, which could allow for use in a broader patient population, including NHL patients with recent rituximab exposure. This product candidate is currently being studied in an ongoing potentially pivotal Phase 2 trial. In June 2022, the U.S. Food and Drug Administration granted Regenerative Medicine Advanced Therapy (RMAT) designation to ALLO-501A in r/r LBCL.

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 product 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 X (formerly 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," “can,” "could," "might," "will," "should,” “designed to” 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: Allogene’s ability to deliver readily available off-the shelf cell therapy on-demand, more reliably, and at greater scale to more patients; and the modes of action, the therapeutic effects and safety profile of Allogene’s product candidates including their ability to treat cancers at various stages or to treat broad populations. Various factors may cause material differences between Allogene’s expectations and actual results, including risks and uncertainties related to: our product candidates are based on novel technologies, which makes it difficult to predict the time and cost of product candidate development and obtaining regulatory approval; the FDA may disagree with our regulatory plan and we may fail to obtain regulatory approval of our CAR T cell product candidates; and our clinical trials may fail to demonstrate the safety and efficacy of any of our product candidates, which would prevent or delay regulatory approval and commercialization. These and other risks are discussed in greater detail in Allogene’s filings with the SEC, including without limitation under the “Risk Factor” Heading in its Form 10-Q filed for the quarter ended September 30, 2023, being filed with the SEC today. 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.

Caution should be exercised regarding statements comparing autologous CAR T data. There are differences in the clinical trial design, patient populations, published data, follow-up times and the product candidates themselves, and the results from the clinical trials of autologous products may have no interpretative value on Allogene’s existing or future results.

AlloCAR T™ and Alloy™ are trademarks of Allogene Therapeutics, Inc.

Allogene’s AlloCAR T™ programs utilize Cellectis technologies. ALLO-501 and ALLO-501A are anti-CD19 products being jointly developed under a collaboration agreement between Servier 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.

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