Allogene Therapeutics Presents Comprehensive Safety Data of Proprietary Lymphodepletion Agent ALLO-647 at the 65th Annual Meeting of the American Society of Hematology

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- Comprehensive Review of All Patients in the Phase 1 ALPHA/ALPHA2 Trials Demonstrate that Adding Investigational ALLO-647 to Standard Lymphodepletion Can Yield Durable Responses and a Safety Profile Comparable to Approved Autologous CAR T Therapies
- Company Received Fast Track Designation for ALLO-647 for Use in Adult Patients with Relapsed/Refractory Large B-Cell Lymphoma in November 2023

SOUTH SAN FRANCISCO, Calif., Dec. 09, 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 the presentation of data from a comprehensive safety review of patients treated in the Phase 1 ALPHA/ALPHA2 trials with ALLO-501/501A at the 65th Annual Meeting of the American Society of Hematology (ASH) in San Diego, CA.

The safety review, which encompasses all 87 Phase 1 patients treated in both relapsed/refractory (r/r) Large B Cell Lymphoma (LBCL) and follicular lymphoma (FL), demonstrates that investigational ALLO-647 added to standard lymphodepletion can safely provide a window for the expansion and persistence of AlloCAR T cells, and has the potential to induce deep and durable remissions in relapsed and treatment-refractory cancers.

"We believe in the immense potential of off-the-shelf CAR T products to not only address the limitations of current autologous CAR T cell therapy, but to also provide greater access to patients in need," said Zachary Roberts, M.D., Ph.D., Executive Vice President of Research & Development and Chief Medical Officer of Allogene. "We fully understand the importance of lymphodepletion to achieving optimal outcomes, and ALLO-647 is just the first generation of our innovative approaches to enhancing lymphodepletion to promote expansion of CAR T cells."

The inclusion of our ALLO-647 candidate in the lymphodepletion regimen is designed to selectively prevent host rejection of allogeneic CAR T cell products. As previously presented in the Phase 1 ALPHA/ALPHA2 studies[1], CAR T cell-naive patients with r/r LBCL were able to obtain a durable response, including a complete remission rate of 42% and a median duration of response of 23.1 months.

In the studies, lymphodepletion consisted of three daily doses of 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 prior to ALLO-501/501A infusion. The addition of ALLO-647 to standard lymphodepletion did not result in adverse events beyond those commonly observed with autologous CAR T cell therapy.

No unexpected safety concerns were observed. Neutropenia and anemia were the most common any-grade treatment-emergent adverse events (or TEAEs) and neutropenia, anemia, and thrombocytopenia were the most common Grade 3 or higher TEAEs. Grade 3 or higher cytopenias decreased over time from Day 28 to Month 4 and were consistent across all subsets of patients. Incidence of Grade 3 or higher cytopenias were consistent with that reported for autologous CAR T cell therapy.[2-4]

Safety: TEAEs of Special Interest

			LBCL					
	All (N=87)		All LBCL (n=61)		CAR T Cell–Naive Pts Who Received ALLO-501/501A Manufactured With The Phase 2 Selected Process (n=33)		FL (n=26)	
TEAEs, n (%)	Any Grade	Grade ≥3	Any Grade	Grade ≥3	Any Grade	Grade ≥3	Any Grade	Grade ≥3
CRS	21 (24)	1 (1)	17 (28)	1 (2)	8 (24)	0	4 (15)	0
ICANS	1 (1)	0	1 (2)	0	0	0	0	0
Neurotoxicity	24 (28)	3 (3)	19 (31)	3 (5)	13 (39)	2 (6)	5 (19)	0
GvHD	0	0	0	0	0	0	0	0
IRR	48 (55)	5 (6)	31 (51)	4 (7)	16 (48)	3 (9)	17(65)	1 (4)
Infections	50 (57)	18 (21)	34 (56)	13 (21)	19 (58)	5 (15)	16 (62)	5 (19)

There were no reports of graft-versus-host disease (GvHD) or Grade 3 or higher immune effector cell-associated neurotoxicity syndrome (ICANS). In total, 24% of patients experienced low-grade CRS, and there was 1 Grade 3 CRS event. Infection events were primarily low grade and manageable, with the most common being cytomegalovirus reactivation with an any-grade incidence of 25% and a Grade 3 or higher incidence of 9%. Incidence of infections were consistent with that reported for autologous therapy following lymphodepletion (12%-33% percent of patients).[3-5] Eight patients experienced fatal adverse events not related to study treatment.

The EXPAND trial, currently enrolling in the United States and Europe, is expected to support licensure of ALLO-647, used in conjunction with

standard low-dose FC lymphodepletion regimens. The trial will enroll approximately 70 patients with r/r LBCL who will be randomized to lymphodepletion with FCA90 (which includes 90 mg of ALLO-647) versus FC alone before receiving a single 120 million cell dose of ALLO-501A. The primary endpoint of the study is progression free survival (PFS).

Separately, the Company announced that the U.S. Food and Drug Administration (FDA) granted Fast Track Designation (FTD) for the investigation of ALLO-647 in adult patients with r/r LBCL based on its potential to enhance standard lymphodepletion. FTD designation is intended to accelerate the development and review of treatments for serious and life-threatening diseases where no treatment exists or where the treatment in discovery may be better than what is currently available. ALLO-647 is investigated as a lymphodepleting agent in combination with flu/cy prior to infusion of allogeneic CD19-directed CAR T cells with genomes edited to knock out CD52.

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™ product, 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; the potential safety profile of the Company’s lymphodepletion and cell dose regimen; 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.

1. Locke FL, Lekakis L, Eradat H, et al. Durable Responses with Anti-CD19 Allogeneic CAR T ALLO-501/501A in Phase 1 Trials of Relapsed/Refractory Large B-Cell Lymphoma (r/r LBCL). Oral presentation at the International Conference on Malignant Lymphoma. June 13-17, 2023. Abstract 48. 2. Logue JM, et al. *Haematologica.* 2021;106(4):978-986. 3. KYMRIAH. Prescribing Information. Novartis Pharmaceuticals Corp.; 2022. 2022. 4. BREYANZI. Prescribing Information. Juno Therapeutics, Inc.;5. YESCARTA. Prescribing information. Kite Pharma, Inc; 2022.

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