Allogene Therapeutics Initiates Industry's First Allogeneic CAR T Phase 2 Trial

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- ALPHA2 Trial, Evaluating ALLO-501A in Relapsed/Refractory Large B Cell Lymphoma Patients, is Designed to Leverage the Ease and Convenience of a Single Dose of ALLO-501A
- Protocol Supported by Clinical and Translational Data from Phase 1 Trial Indicating Deep Responses are Achievable with a Single Dose of ALLO-501A When Used with a Lymphodepletion Regimen That Includes an Optimized Dose of ALLO-647

SOUTH SAN FRANCISCO, Calif., Oct. 06, 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 initiation of the potentially pivotal Phase 2 clinical trial of ALLO-501A (ALPHA2 trial) in patients with relapsed/refractory (r/r) large B-cell lymphoma (LBCL). The Company is also in the process of initiating the EXPAND trial, which is intended to demonstrate the contribution of ALLO-647 to the standard fludarabine/cyclophosphamide lymphodepletion regimen. Assuming favorable outcomes and subject to discussions with the U.S. Food and Drug Administration (FDA), the Company expects these studies to support the regulatory approval of both ALLO-501A and ALLO-647.

"We are proud to initiate the industry's first potentially pivotal Phase 2 trial for an allogeneic CAR T product. This milestone paves the road for both ALLO-501A and our broader pipeline of innovative products with the potential to greatly increase patient access to cell therapy," said David Chang, M.D., Ph.D., President, Chief Executive Officer and Co-Founder of Allogene. "It is a culmination of years of hard work and perseverance, which could only be accomplished in collaboration with our dedicated staff, investigators, clinical trial site coordinators, regulatory authorities and most importantly the patients who have participated in our studies."

Allogene conducted an extensive Phase 1 program designed to evaluate and optimize all aspects of AlloCAR T, including doses and schedules of ALLO-501A and ALLO-647. In addition, the Company recently conducted a review of the Phase 1 program which determined a manufacturing process associated with robust clinical performance. Allogene's selected manufacturing process, named Alloy, will be deployed in the ALPHA2 and EXPAND trials.

Allogene received Chemistry Manufacturing and Controls (CMC) clearance to use newly manufactured product that did not utilize the Alloy process from its manufacturing facility, Cell Forge 1 (CF1). The Company is now in the process of implementing Alloy in this facility. As such, the Phase 2 trial will begin with previously manufactured material with the intent of transitioning to product from CF1 during the course of the ALPHA2 and EXPAND trials.

The single-arm Phase 2 ALPHA2 trial in r/r LBCL will utilize a single dose of ALLO-501A at 120 million CAR+ cells with an intended lymphodepletion regimen (FCA90) comprised of fludarabine (30 mg/m^2/day x 3 days) and cyclophosphamide (300 mg/m^2/day x 3 days) plus ALLO-647 (90 mg). The ALPHA2 trial will enroll approximately 100 patients who have received at least two prior lines of therapy and have not received prior anti-CD19 therapy. The primary endpoint is objective response rate (ORR).

The EXPAND trial is a separate potentially registrational trial for ALLO-647. Allogene is developing ALLO-647, its anti-CD52 monoclonal antibody, with the goal of potentially enabling expansion, persistence and improved clinical outcomes of AlloCAR T product candidates, including ALLO-501A. The randomized EXPAND trial is expected to enroll approximately 70 patients with r/r LBCL and is intended to demonstrate the safety of ALLO-647 and its contribution to the overall effectiveness of the lymphodepletion regimen. Patients will be randomized to receive the same single 120 million cell dose of ALLO-501A as in the ALPHA2 trial and either lymphodepletion with fludarabine and cyclophosphamide alone (control arm) or the same lymphodepletion regimen of the ALPHA2 trial (active arm).

In June, the FDA granted Regenerative Medicine Advanced Therapy (RMAT) designation to ALLO-501A in r/r LBCL. RMAT designation was based on data demonstrating the potential of ALLO-501A to address an unmet need for patients with relapsed/refractory disease. Previously presented data support the potential of ALLO-501A as an alternative to approved autologous CAR T therapies. In the ALLO-501A Phase 1 study, nearly all enrolled patients were able to receive therapy with the median time from enrollment to initiation of treatment of two days.

Allogene expects to provide an update on its CD19 program toward the end of 2022. This will include longer-term follow-up from the ALPHA and ALPHA2 Phase 1 trials, including patients treated with the Alloy manufacturing technology process.

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 ALPHA2 trial and initiate the EXPAND trial; whether either

of the ALPHA2 or EXPAND trials will be pivotal or registrational; clinical outcomes, which may materially change as more patient data become available; the ability to have a contract manufacturing organization manufacture AlloCAR T™ product candidates for use in ongoing clinical trials; the ability to transition the Alloy manufacturing process to CF1 and the ability of CF1 to manufacture AlloCAR T products for ALPHA2, EXPAND or other clinical trials; and the potential benefits of the Alloy process and 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 8-K filed on October 6, 2022, its Form 8-K filed on September 21, 2022, and its Form 10-Q for the quarter ended June 30, 2022. 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 T™ is a trademark of Allogene Therapeutics, Inc.

Allogene's AlloCAR T™ programs utilize the Cellectis TALEN® 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. with an option for exclusive rights for all other countries.

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