Allogene Therapeutics Initiates Pivotal Phase 2 Trial Investigating Cemacabtagene Ansegedleucel (cema-cel), an Allogeneic CAR T Product, as Part of First Line Treatment for Patients with Large B-Cell Lymphoma (LBCL) Likely to Relapse

Jun 20, 2024 at 8:30 AM EDT

- ALPHA3 Trial Has the Potential to Position Cema-cel as Part of First Line (1L) Treatment for LBCL to Improve Cure Rates
- First Prospective Trial to Incorporate the Foresight Diagnostics's Investigational CLARITY ™Test to Identify Patients with LBCL Who Have Minimal Residual Disease (MRD) and are Likely to Relapse Following Standard 1L Treatment
- Unique Profile of Investigational AlloCAR T™ Products May Expand Access to CAR T within Community Cancer Centers where Most 1L Patients are Managed
- ALPHA3 Expected to Complete Enrollment in 1H 2026; BLA Submission Anticipated in 2027

SOUTH SAN FRANCISCO, Calif. and BOULDER, Colo., June 20, 2024 (GLOBE NEWSWIRE) -- Allogene Therapeutics Inc. (Nasdaq: ALLO), a clinical-stage biotechnology company pioneering the development of allogeneic CAR T (AlloCAR T ™) products, and Foresight Diagnostics (Foresight), a leader in ultra-sensitive liquid biopsy-based minimal residual disease (MRD) detection, today announced the initiation of the pivotal Phase 2 ALPHA3 trial evaluating the use of cemacabtagene ansegedleucel (cema-cel) as part of the first line (1L) treatment regimen for newly diagnosed LBCL patients who are likely to relapse after standard 1L treatment and need further therapy.

"The transformative impact that the ALPHA3 trial could have on the treatment of first line LBCL is hard to overstate," said David Chang, M.D., Ph.D., President, Chief Executive Officer and Co-Founder of Allogene. "Our investigational allogeneic CAR T product is designed to eliminate the complex logistics that have hindered autologous CAR T adoption to date and open the door for access by doctors in the community setting. ALPHA3 will proactively offer this potentially curative modality only to those patients who are likely to relapse."

The ALPHA3 trial will screen patients who are likely to relapse after 1L treatment for enrollment in the trial by using the Foresight CLARITY ™ Investigational Use Only (IUO) MRD test, powered by PhasED-Seq ™, which recently received Investigational Device Exemption (IDE) approval from the U.S. Food and Drug Administration (FDA). Leveraging CLARITY's ultra-sensitive MRD technology, cema-cel will be administered as a one-time infusion immediately upon detection of MRD at the completion of six cycles of R-CHOP or other standard 1L chemoimmunotherapy regimen. When given as a "7 th cycle" of frontline treatment to eligible patients with MRD, consolidation treatment with cema-cel has the potential to meaningfully improve 1L cure rates in LBCL.

"Following the FDA Advisory Committee's recent recommendation to include MRD as an endpoint to accelerate clinical trials in multiple myeloma, the ALPHA3 trial is yet another step forward towards broader implementation of MRD detection in drug development and clinical decision making," said Dr. Sandra Close, Chief Operating and Compliance Officer at Foresight Diagnostics. "We believe the Foresight CLARITY MRD platform has the performance to enable actionable treatment decisions at end of therapy when residual disease levels are challenging to detect using conventional methods."

The ALPHA3 trial will be conducted in a wide array of cancer treatment centers, including community cancer centers where most earlier line patients seek care. This randomized study will enroll approximately 240 patients and is designed to demonstrate a meaningful improvement in event free survival (EFS) in patients treated with cema-cel relative to patients who receive the current standard of care (observation). Efficacy analyses are expected to occur in 2026 and will include an interim EFS analysis monitored by the independent Data Safety Monitoring Board (DSMB) in 1H 2026 and the data readout of the primary EFS analysis in 2H 2026 with a potential biologics license application (BLA) submission targeted for 2027.

About Foresight Diagnostics
Foresight Diagnostics is a privately-held cancer diagnostics company and CLIA-registered laboratory. Its liquid biopsy platform, Foresight CLARITY™, is a novel assay that measures minimal residual disease (MRD) with reported detection limits in parts per million[1]. The improved sensitivity of Foresight CLARITY has the potential to provide actionable information to physicians and biopharmaceutical companies to enable more personalized treatment approaches for patients with solid tumor and hematologic malignancies. For more information, please visit foresight-dx.com and follow us on Twitter and LinkedIn. Foresight CLARITY™ IUO is an investigational device. Limited by United States Law to investigational use.

About Cemacabtagene Ansegedleucel (cema-cel)
Cemacabtagene ansegedleucel, or cema-cel is a next generation anti-CD19 AlloCAR T ™investigational product for the treatment of large B cell lymphoma (LBCL). In June 2022, the U.S. Food and Drug Administration granted Regenerative Medicine Advanced Therapy (RMAT) designation to cema-cel in third line (3L) r/r LBCL. The ALPHA3 pivotal Phase 2 trial in first line (1L) consolidation for the treatment of LBCL launched in June 2024. Allogene has oncology rights to cema-cel in the US, EU and UK with options for rights in China and Japan.

About the ALPHA3 Trial
Over 60,000 patients are expected to be treated for LBCL annually in the US, the EU and the UK. While first line (1L) R-CHOP or other chemoimmunotherapy is effective for most patients, approximately 30% will relapse and require subsequent treatment. The current standard of care (SOC) after 1L treatment has been simply to "watch and wait" to see if the disease relapses. The pivotal Phase 2 ALPHA3 study takes advantage of cema-cel as a one-time, off-the-shelf treatment that can be administered immediately upon discovery of MRD following six cycles of R-CHOP or other

chemoimmunotherapy, positioning it to become the standard “7th cycle” of frontline treatment available to all eligible patients with MRD.

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 and autoimmune disease. Led by a management team with significant experience in cell therapy, Allogene is developing a pipeline of “off-the-shelf” CAR T cell 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 Allogene Therapeutics on X (formerly Twitter) and LinkedIn.

Cautionary Note on Forward-Looking Statements for Foresight
This press release contains forward-looking statements within the meaning of federal securities laws, including statements regarding the potential utilities, values, benefits and advantages of Foresight Diagnostics CLARITY MRD platform and its PhasED-Seq technology which involve risks and uncertainties that could cause the actual results to differ materially from the anticipated results and expectations expressed in these forward-looking statements. These statements are based on current expectations, forecasts and assumptions, and actual outcomes and results could differ materially from these statements due to a number of factors. The forward-looking statements in this press release are based on information available to Foresight Diagnostics as of the date hereof, and Foresight Diagnostics disclaims any obligation to update any forward-looking statements provided to reflect any change in its expectations or any change in events, conditions, or circumstances on which any such statement is based, except as required by law. These forward-looking statements should not be relied upon as representing Foresight Diagnostics’ views as of any date subsequent to the date of this press release.

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. This press release may, in some cases, use terms such as “advance,” “believes,” “targeted,” “anticipated, ” “potential,” “estimates,” “likely to,” “expects,” “plans,” “designed to,” “can,” “become,” “begin,” “build,” “may,” “could,” or “will,” including alternative verb forms thereof, 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: ALPHA3 being a pivotal trial; the pace, timing and extent to which Allogene may enroll patients in its clinical trials or release data from such trials; the timing and ability to progress the ALPHA3 trial; the potential for the ALPHA3 trial or the ability for Foresight’s minimal residual disease test to identify patients with LBCL who are likely to relapse following standard first line treatment; the potential for cema-cel to successfully treat first line patients; the potential for Allogene’s product candidates to be approved; the potential benefits of the ALPHA3 trial and of AlloCAR T ™ products, including the potential for ALPHA3 to transform treatment of first line LBCL; the ability of our product candidates to treat various stages and types of cancers; Allogene’s ability to broaden patient access to CAR T therapy; the incidence, severity and manageability of side effects of allogeneic CAR T products; the potential of ALPHA3 to demonstrate a meaningful improvement in event free survival in patients treated with cema-cel relative to patients who receive the current standard of care; the extent to which our clinical trials will support regulatory approval of our product candidates; the potential for off-the-shelf CAR T products; our ability to deliver cell therapy on-demand, more reliably, and at greater scale to more patients. 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 ability of ALPHA3 to offer a potentially curative modality to patients who are at risk of relapse; the ability that ALPHA3 can mitigate or avoid the risk of delivering unnecessarily intense therapy to patients; the extent to which the Food and Drug Administration disagrees with our clinical or regulatory plans or the import of our clinical results, which could cause future delays to our clinical trials or require additional clinical trials; we may encounter difficulties enrolling patients in our clinical trials; we may not be able to demonstrate the safety and efficacy of our product candidates in our clinical trials, which could prevent or delay regulatory approval and commercialization; and challenges with manufacturing or optimizing manufacturing of our product candidates. These and other risks are discussed in greater detail in Allogene’s filings with the Securities and Exchange Commission (SEC), including without limitation under the “Risk Factors” heading in its Quarterly Report on Form 10-Q for the quarter ended March 31, 2024. 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 investigational AlloCAR T™ oncology products utilize Cellectis technologies. These products are developed based on an exclusive license granted by Cellectis to Servier. Servier, which has an exclusive license to the anti-CD19 AlloCAR T™ investigational products from Cellectis, has granted Allogene exclusive rights to these products in the U.S., all EU Member States and the United Kingdom. Foresight CLARITY ™ IUO is for research use only. It is not intended for diagnostic procedures.

Allogene Media/Investor Contacts:
Christine Cassiano
EVP, Chief Corporate Affairs & Brand Strategy Officer
Christine.Cassiano@allogene.com

Leslie Bryant
Senior Communications Consultant
Leslie.Bryant@Allogene.com

Foresight Media/Investor Contacts:
Sara Head
VP of Marketing
Sara.head@foresight-dx.com

[1] Kurtz, et al. 2021; Isbell, et al. 2024

Source: Allogene Therapeutics, Inc.