Allogene Therapeutics Activates Three Community Cancer Centers as First Sites for the Pivotal Phase 2 ALPHA3 Trial Evaluating Cemacabtagene Ansegedleucel (cema-cel) as First Line (1L) Consolidation Treatment for Patients with Large B-Cell Lymphoma (LBCL)

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- Patient Screening is Underway at Rocky Mountain Cancer Centers, Part of the US Oncology Network and Sarah Cannon Research Institute; Astera Cancer Care, Part of the OneOncology Network; and Norton Cancer Institute
- ALPHA3 Will be the First Pivotal Trial to Offer CAR T as Part of First Line (1L) Treatment at Community Cancer Centers, Where 80% of Patients Receive Care
- ALPHA3 Expected to Complete Enrollment in 1H 2026; Potential BLA Submission in 2027

SOUTH SAN FRANCISCO, Calif., July 01, 2024 (GLOBE NEWSWIRE) -- Allogene Therapeutics Inc. (Nasdaq: ALLO), a clinical-stage biotechnology company pioneering the development of allogeneic CAR T (AlloCAR T ™) products for cancer and autoimmune disease, today announced that Rocky Mountain Cancer Centers (RMCC), part of the US Oncology Network and Sarah Cannon Research Institute (SCRI); Astera Cancer Care (ACC), a multi-specialty community oncology practice and part of the OneOncology network; and Norton Cancer Institute, are open for enrollment in the pivotal Phase 2 ALPHA3 trial.

The ALPHA3 trial is evaluating the use of cemacabtagene ansegedleucel (cema-cel) as part of the first line (1L) consolidation treatment regimen for newly diagnosed and treated large B-cell lymphoma (LBCL) patients who remain positive for minimal residual disease (MRD). Detection of MRD will be done using the Foresight CLARITY ™ Investigational Use Only (IUO) MRD test, powered by PhasED-Seq ™. 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 for patients with LBCL who are likely to relapse.

"We believe community physicians have been waiting for a trial like ALPHA3 that offers cutting-edge CAR T without the inherent complexities associated with autologous therapies," said David Chang, M.D., Ph.D., President, Chief Executive Officer and Co-Founder of Allogene. "The differentiated attributes of cema-cel eliminate many of the complex logistics that have hindered CAR T adoption in the community setting. The fact that community-based practices are the first sites to open for enrollment in the ALPHA3 trial is a significant symbolic step forward in expanding patient access to this powerful modality and will serve as a catalyst for our cema-cel development program."

RMCC is the largest multidisciplinary practice in Colorado with 19 locations across the state dedicated solely to providing care for patients with cancer and diseases of the blood. RMCC is a part of SCRI, a combination of two nationally recognized oncology research institutes – US Oncology and SCRI. This combination creates a leading oncology research organization participating in community-based clinical trials. Patients undergoing treatment for newly diagnosed LBCL throughout the RMCC network will be considered for enrollment in ALPHA3.

"Current 1L chemoimmunotherapy is effective in most patients, but the reality is that 30% will relapse," said John M. Burke, M.D., a Blood Cancer Specialist at RMCC. "The ALPHA3 trial will be answering two key questions. First, can measuring circulating tumor DNA in the blood be used to select lymphoma patients destined to relapse for early intervention? And second, does treating these high-risk lymphoma patients with cema-cel increase cure rates compared with conventional surveillance? These are critically important questions that have the potential to change the lymphoma treatment paradigm."

ACC is an independent and physician-owned multi-specialty community oncology practice serving more than 22,000 new patients annually in Central New Jersey. The practice is part of the OneOncology platform which is a partnership of over 20 independent community oncology practices nationally. Astera's specialists practice at 13 distinct locations in Middlesex, Somerset, Bergen, Hudson, Hunterdon, Mercer and Monmouth counties in New Jersey and Langhorne, Pennsylvania and have a robust clinical trial platform for cancer therapy with one of the only community-based clinical trial programs in CAR T cell therapies in the nation. Patients undergoing treatment for newly diagnosed LBCL throughout the ACC network will be considered for enrollment in ALPHA3.

According to Edward J. Licitra, M.D., PhD, oncologist and Chairman and Chief Executive Officer at ACC, relapsed LBCL is much more difficult to treat, and physicians often consider enrollment in clinical trials to allow access to promising therapies. "I have watched with interest the acceleration of CAR T research in LBCL, but because most patients live more than two hours from the nearest treatment center, it's not feasible for them to participate. Having access to an "off-the-shelf" CAR T product with a manageable safety profile changes that equation dramatically for me, and my patients. We are excited to help define a new treatment standard in LBCL. An approved "off-the-shelf" CAR T product would allow for greater access to cutting edge technologies for patients in their local communities and this could improve outcomes for many more cancer patients."

With more than 21 locations serving Louisville, Kentucky and Southern Indiana, Norton Cancer Institute (NCI) treats more than 4,000 newly diagnosed cancer patients each year. NCI's network of multidisciplinary clinics offers patients the latest treatments and access to more than 100 clinical trials.

"Kentucky has one of the highest cancer death rates in the United States[1] and a big contributor to this is lack of patient access to cutting-edge treatments," said Don A. Stevens, M.D., a hematologist-oncologist at Norton Cancer Institute. "Offering investigational cema-cel to our first line patients has the potential to improve cure rates for the 30% we know will relapse after chemoimmunotherapy. This could change how we treat these patients in the future."

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 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 “believes,” “potential,” “likely to,” “expect,” “can,” “become,” “may,” “could,” or “will,” including alternative 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 and the extent to which it will support regulatory approval of cema-cel; 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 1L treatment; the potential for cema-cel to become the standard “7th cycle” of frontline treatment; the timing for completion of ALPHA3 enrollment or cema-cel BLA submission; delivery of cema-cel with fewer complexities associated with autologous therapies; expanding patient access to cutting edge technologies such as CAR T; the extent to which patients throughout various networks will be considered for enrollment in ALPHA3; the incidence of LBCL including the extent to which patients will relapse and require subsequent treatment; the potential for our product candidates to be approved; the potential benefits of the ALPHA3 trial and of AlloCAR T™ products, including the potential for ALPHA3 to change the lymphoma treatment paradigm, define a new LBCL treatment standard, or improve cure rates or patient outcomes; cema-cel’s safety profile; the ability of ALPHA3 to answer various questions; our ability to broaden patient access to CAR T therapy and 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 and extent that cema-cel will be administered as a one-time infusion; 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.

The Foresight CLARITY ™ MRD test, powered by PhasED-Seq ™ is for investigational use only.

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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.

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[1] US News & World Report. You’re More Likely to Die of Cancer if You Live in This State (usnews.com). Accessed 25June2024.

Source: Allogene Therapeutics, Inc.