Allogene Therapeutics Expands Strategic Partnership with Foresight Diagnostics to Advance Joint Development Activities Outside the US Across Europe, UK, Canada, and Australia

Feb 25, 2025 at 4:10 PM EST

SOUTH SAN FRANCISCO, Calif., Feb. 25, 2025 (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 an expanded strategic collaboration with Foresight Diagnostics, Inc. to include the development of Foresight's minimal residual disease (MRD) assay as a companion diagnostic to identify patients with large B-cell lymphoma (LBCL) for treatment with cemacabtagene ansegedleucel (cema-cel).

Under the Amended and Restated Strategic Collaboration Agreement, Allogene and Foresight will work together to support the development of Foresight Diagnostics' MRD assay as a companion diagnostic in the EU, UK, Canada and Australia in support of Allogene's clinical development of cema-cel. Cema-cel is being studied in the groundbreaking randomized controlled pivotal ALPHA3 trial as part of a first-line (1L) treatment to potentially improve the cure rate in patients with LBCL. In the ALPHA 3 trial, patients who achieve remission following initial treatment but remain positive for MRD will be identified by using Foresight Diagnostics' ultra-sensitive ctDNA-based Foresight CLARITY™ investigational use only (IUO) assay, powered by PhasED-Seq™. Patients who remain MRD positive may be at high-risk of relapse, and therefore will have an opportunity to receive cema-cel as a one-time consolidation dose to prevent disease recurrence.

"The continued collaboration with Foresight Diagnostics strengthens our commitment to advancing next-generation cancer therapies by integrating MRD detection as a powerful tool in patient care," said David Chang, M.D., Ph.D., President, Chief Executive Officer and Co-Founder of Allogene. "We believe that this strategic expansion will help accelerate the development and potential approval of cema-cel as we continue our mission to transform the LBCL treatment landscape for patients beyond the United States."

As part of this agreement, Allogene will invest approximately $37.3 million for MRD assay development, milestone payments for U.S., and certain international regulatory submissions and clinical sample testing. Both companies have committed to use commercially reasonable efforts to obtain regulatory approvals of their respective products and execute the agreed-upon work plan to support and enable the joint development activities.

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 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 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 "develop," "potential," "advance," "expect," "can," "see if," "positioning," "become," "be identified," "powered," "help," "accelerate," "continue," "may," "could," "believe," "improve," "support," "enable," "improve," "designed to," "predict," 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 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 the ALPHA3 trial and an investigational 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 design of the ALPHA3 trial and expected benefits therefrom; that cema-cel could be a promising therapeutic option for patients with MRD; that cema-cel can be administered immediately upon discovery of MRD following six cycles of R-CHOP or other chemoimmunotherapy; the timing for completion of ALPHA3 enrollment or cema-cel BLA submission; 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; 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: the limited nature of our Phase 1 data from the ALPHA/ALPHA2 trial and the extent to which such data may or may not be validated in the ALPHA3 trial and any future clinical trials; the ability for Foresight to develop and obtain regulatory approval for its

MRD assay as a companion diagnostic to identify patients with LBCL; the ability and extent that cema-cel will be administered only to patients at high risk for relapse as a one-time consolidation dose before disease recurrence; 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 September 30, 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.

AlloCAR T ™ is a trademark of Allogene Therapeutics, Inc.
CLARITY™ and PhasED-Seq™ are trademarks of Foresight Diagnostics.

Allogene's investigational AlloCAR T ™ oncology products utilize Cellectis technologies. These anti-CD19 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.

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

Source: Allogene Therapeutics, Inc.