Allogene Therapeutics Announces ASCO 2025 Abstract Publication Featuring Oral Presentation of ALLO-316 in Kidney Cancer and ALPHA3 TIP Poster for Cema-Cel

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SOUTH SAN FRANCISCO, Calif., May 22, 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 the publication of two abstracts on the American Society of Clinical Oncology (ASCO) website in advance of the 2025 ASCO Annual Meeting, taking place May 30-June 3 in Chicago, Illinois.

An oral presentation will feature ALLO-316, an investigational AlloCAR T product targeting CD70. ALLO-316 is currently being studied in patients with advanced or metastatic renal cell carcinoma (RCC). Leveraging the proprietary Dagger® technology to enable robust CAR T cell expansion, it stands as the first and only allogeneic CAR T product to show promise in treating solid tumors. The upcoming presentation will share updated data from the Phase 1 TRAVERSE study with a focus on the Phase 1b expansion cohort in which patients were treated with a standard regimen of cyclophosphamide and fludarabine followed by a single dose of 80 million CAR T cells.

In addition, a Trial-in-Progress (TIP) poster will highlight the innovative design of the ongoing pivotal Phase 2 ALPHA3 trial evaluating cemacabtagene ansegedleucel (cema-cel) as part of a first line (1L) consolidation strategy in patients with large B-cell lymphoma (LBCL) who remain minimal residual disease (MRD) positive at the completion of 1L chemoimmunotherapy.

Allogene Presentations at the 2025 ASCO Annual Meeting:

ALLO-316 in advanced clear cell renal cell carcinoma (ccRCC): Updated results from the phase 1 TRAVERSE study.
Presenter: Samer A. Srour, M.D., The University of Texas MD Anderson Cancer Center
Session Title: Oral Abstract Session – Genitourinary Cancer – Kidney and Bladder
Abstract: #4508
Location: Hall D2
Session Date and Time: Sunday, June 1, 9:45AM-12:45PM CT
Presentation Time: 12:21 PM-12:33 PM CT

ALPHA3: A pivotal phase 2 study of first line (1L) consolidation with cemacabtagene ansegedleucel (cema-cel) in patients with large B-cell lymphoma (LBCL) and minimal residual disease (MRD) after response to standard therapy.
Presenter: Jason Westin, MD, MS, FACP, The University of Texas MD Anderson Cancer Center
Session Title: Poster Session – Hematologic Malignancies – Lymphoma and Chronic Lymphocytic Leukemia
Abstract: TPS7085
Poster Board: #267a
Location: Hall A
Poster Session Display Date and Time: Sunday, June 1, 9:00AM-12:00PM CT

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 ALLO-316 (TRAVERSE)

ALLO-316 is an AlloCAR T ™ investigational product targeting CD70, which is highly expressed in renal cell carcinoma (RCC). CD70 is also selectively expressed in several cancers, creating the potential for ALLO-316 to be developed across a variety of both hematologic malignancies and solid tumors. The ongoing Phase 1 TRAVERSE trial is designed to evaluate the safety, tolerability, and activity of ALLO-316 in patients with advanced or metastatic clear cell RCC. In October 2024 the U.S. Food and Drug Administration (FDA) granted Regenerative Medicine Advanced Therapy (RMAT) designation based on the potential of ALLO-316 to address the unmet need for patients with advanced or metastatic CD70+ RCC. The FDA previously granted Fast Track Designation (FTD) to ALLO-316 in March 2023. In April 2024, the Company announced an award from the California Institute for Regenerative Medicine (CIRM) to support the ongoing TRAVERSE trial with ALLO-316 in RCC.

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% who initially respond 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,” “expect,” “can,” “see if,” “positioning,” “become,” “may,” “could,” “designed to,” 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 cema-cel to be part of a first-line consolidation strategy in patients with large B-cell lymphoma (LBCL) and minimal residual disease (MRD); the potential for cema-cel to become the standard “7th cycle” of frontline treatment; 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; the potential of ALLO-316 as a treatment for patients with advanced or metastatic CD70+ RCC; the potential for ALLO-316 and CAR T-cell therapy to treat hematologic malignancies and solid tumors; 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 our clinical trials and the extent to which such data may or may not be validated in any future clinical trials; 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 year ended March 31, 2025. 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 investigational AlloCAR T ™ oncology products utilize Cellectis technologies. The 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.

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Source: Allogene Therapeutics, Inc.