# Allogene Therapeutics, with Collaborator Servier, Reports Positive Results from its Phase 1 ALPHA Study of ALLO-501 in Relapsed/Refractory Non-Hodgkin Lymphoma at the American Society of Clinical Oncology Annual Meeting

May 29, 2020

- ALLO-501 with ALLO-647 Lymphodepletion was Well Tolerated with No Dose-Limiting Toxicities, Graft-vs-Host Disease or Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS)
- In the Ongoing Study, 22 Patients were Evaluable for Safety and 19 Patients Were Evaluable for Efficacy with at Least One Tumor Assessment as of Data Cutoff
  - Seven Complete Responses (CR) and Five Partial Responses (PR) were Observed for an Overall Response Rate (ORR) of 63% and CR Rate of 37%
  - Higher Response Rates Observed in CAR T Naïve Patients (N=16) with an ORR of 75% and CR Rate of 44%
  - Nine of 12 (75%) Patients Remain in Response as of the Data Cutoff
  - Higher Dose ALLO-647 Associated with Higher CR Rates
- Phase 1 Trial Initiated for ALLO-501A, a Next Generation Anti-CD19 AlloCAR T™ Candidate Intended for Phase 2 Development
- Company to Host a Live Webinar on Friday, May 29 at 8:30 AM Eastern Time

SOUTH SAN FRANCISCO, Calif. and PARIS, France, May 29, 2020 (GLOBE NEWSWIRE) -- Allogene Therapeutics, Inc. (Nasdaq: ALLO), a clinical-stage biotechnology company pioneering the development of allogeneic CAR T (AlloCAR T ™) therapies for cancer, in collaboration with development partner Servier, an independent international pharmaceutical company, today announced positive initial results from Allogene's dose escalation Phase 1 ALPHA study of ALLO-501 in relapsed/refractory non-Hodgkin lymphoma (NHL). Data were presented at the American Society of Clinical Oncology (ASCO) annual meeting. This study utilizes ALLO-647, Allogene's anti-CD52 monoclonal antibody (mAb), as a part of its differentiated lymphodepletion regimen.

"We are very pleased with these initial Phase 1 results, which indicated that ALLO-501 and ALLO-647 were well tolerated and produced complete responses in patients with advanced NHL," said David Chang, M.D., Ph.D., President, Chief Executive Officer and Co-Founder of Allogene. "Based on these results, we believe we are on the right trajectory to make AlloCAR T therapy a reality for patients."

"Allogeneic CAR T therapies provide an off-the-shelf option that may make cellular therapies available to more patients," said Sattva S. Neelapu, M.D., Professor, Department of Lymphoma/Myeloma at The University of Texas MD Anderson Cancer Center in Houston, Texas. "While longer follow-up is required, the response to ALLO-501 appears promising with 75% of patients remaining in response. Together with the positive safety profile, these data suggest that ALLO-501 has the potential to be an effective option if confirmed in future studies."

As of the May 2020 data cutoff, 23 patients were enrolled and 22 patients received ALLO-501. One patient was removed from the study prior to lymphodepletion due to acute renal failure from urinary obstruction. The median time from enrollment to the start of therapy was five days.

For the efficacy analysis, 19 out of 22 patients reached at least one month assessment as of the May 2020 data cutoff. Responses were observed across all cell doses and tumor histologies (diffuse large B-cell lymphoma and follicular lymphoma) with an overall response rate (ORR) of 63% and complete response (CR) rate of 37%. Higher dose ALLO-647 was associated with a higher CR rate of 50%, deeper lymphodepletion and delayed host T cell recovery. With a median follow-up of 3.8 months, nine of the 12 responding patients (75%) remain in response as of the data cutoff.

| | 39mg ALLO-647 | | | | 90mg ALLO-647 | | | |
|---|---|---|---|---|---|---|---|---|
| Cell Dose and LD regimen | 40 x $10^6$ $CAR^+$ cells (N=4) | 120 x $10^6$ $CAR^+$ cells (N=4) | 360 x $10^6$ $CAR^+$ cells (N=3) | **All 39mg ALLO-647 (N=11)** | 120 x $10^6$ $CAR^+$ cells (N=6) | 360 x $10^6$ $CAR^+$ cells (N=2) | **All 90mg ALLO-647 (N=8)** | **All Patients (N=19) (95% CI)** |
| ORR, n (%) | 3 (75%) | 3 (75%) | 1 (33%) | **7 (64%)** | 4 (67%) | 1(50%) | **5 (63%)** | **12/19 (63%)** (38%, 84%) |
| CR, n (%) | 1 (25%) | 1 (25%) | 1 (33%) | **3 (27%)** | 4 (67%) | 0 (0%) | **4 (50%)** | **7/19 (37%)** (16%, 62%) |

One of the ongoing responders is a patient with an initial partial response (PR) who progressed by month two. This patient achieved a CR after re-treatment with the same dose of ALLO-501 and higher dose (90mg) ALLO-647. This patient is reflected as a PR in the table above and not as a CR.

Included in the overall efficacy analysis are three patients who were refractory to prior autologous CAR T therapy (the best response of progressive disease or disease progression within three months). These patients were also refractory to AlloCAR T therapy. In CAR T naïve patients, the ORR was 75% and the CR rate was 44%.

| | All Cell Doses + 39mg ALLO-647 (N=10) | 120 x $10^6$ and 360 x $10^6$ $CAR^+$ cells + 90mg ALLO-647 (N=6) | **All CAR T Naïve Patients (N=16)** |
|---|---|---|---|
| ORR, n (%) | 7 (70%) | 5 (83%) | **12/16 (75%)** (48%, 93%) |
| CR, n (%) | 3 (30%) | 4 (67%) | **7/16 (44%)** (20%, 70%) |

No dose limiting toxicities, graft-vs-host disease, or Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) was observed.

| **Adverse Events of Interest** | **Grade 1 N (%)** | **Grade 2 N (%)** | **Grade 3 N (%)** | **Grade 4 N (%)** | **Grade 5 N (%)** |
|---|---|---|---|---|---|
| Cytokine Release Syndrome | 2 (9%) | 4 (18%) | 1 (5%) | - | - |
| ICANS | - | - | - | - | - |
| Graft-versus-Host Disease | - | - | - | - | - |
| Infection | 5 (23%) | 4 (18%) | 2 (9%) | - | - |
| Infusion Reaction | 1 (5%) | 9 (41%) | 1 (5%) | - | - |
| Neutropenia | - | 1 (5%) | 7 (32%) | 7 (32%) | - |

Cytokine release syndrome occurred in 32% of the patients, was mainly mild to moderate in severity, manageable with standard recommendations, and all events resolved within a maximum of seven days. Patients treated with 90mg ALLO-647 did not experience an increase in infection as compared to those treated with 39mg ALLO-647.

Four patients (18%) experienced serious adverse events (SAE). One patient had Grade 2 pyrexia and Grade 2 cytomegalovirus (CMV) reactivation which resolved in two days and six days, respectively. One patient had Grade 3 rotavirus infection and Grade 3 hypokalemia which resolved in 15 days and two days, respectively. One patient had Grade 3 febrile neutropenia and Grade 3 hypotension which each resolved in two days. One patient had a Grade 3 upper GI hemorrhage which resolved in one day and Grade 3 CMV reactivation which resolved in 25 days.

Adverse events were observed across all dose levels of ALLO-501 and ALLO-647. SAEs were observed at ALLO-501 cell dose level 40 x $10^6$ and 120 x $10^6$ and at both dose levels of ALLO-647.

“We are pleased to see the progress made by Allogene in the ALPHA trial and the positive initial data for ALLO-501,” said Olivier Laureau, President of Servier. “Our teams are proud to play a role in helping to develop innovative therapies for patients in need.”

Allogene is the sponsor of the Phase 1 ALPHA trial which is designed to assess the safety and tolerability at increasing dose levels of ALLO-501 and ALLO-647 in the most common NHL subtypes of relapsed/refractory diffuse large B-cell lymphoma or follicular lymphoma.

ALLO-501A is a next generation anti-CD19 AlloCAR T devoid of the rituximab recognition domains found in ALLO-501. This could allow for use in a broader patient population, including those NHL patients with recent rituximab exposure. ALLO-501A is intended for Phase 2 development and enrollment has been initiated in the Phase 1 portion of the ALPHA2 trial of ALLO-501A.

**Webinar**
Please register for the webinar on the Company's website at www.allogene.com under the Investors tab in the News and Events section (https://ir.allogene.com/events) or by clicking the following link directly.

The webinar will be available as a live event only and the materials presented will be available on the Allogene website prior to the start of the event.

**About ALLO-501 (Allogene Sponsored)**
ALLO-501 is an anti-CD19 allogeneic CAR T (AlloCAR T™) therapy being jointly developed under a collaboration agreement between Servier and Allogene based on an exclusive license granted by Cellectis to Servier. ALLO-501 uses Cellectis technologies. Servier grants to Allogene exclusive rights to ALLO-501 in the U.S. while Servier retains exclusive rights for all other countries.

**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™) therapies 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 therapy 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.

**About Servier**
Servier is an international pharmaceutical company governed by a non-profit foundation, with its headquarters in France (Suresnes). With a strong international presence in 149 countries and a total revenue of 4.6 billion euros in 2019, Servier employs 22,000 people worldwide. Entirely independent, the Group invests on average 25% of its total revenue (excluding generics) every year in research and development and uses all its profits for its development. Corporate growth is driven by Servier’s constant search for innovation in five areas of excellence: cardiovascular, immune-inflammatory, and neurodegenerative diseases, cancer and diabetes, as well as by its activities in high-quality generic drugs. Servier also offers eHealth solutions beyond drug development. More information: www.servier.com

**Servier Group press contacts:**
Sonia Marques: presse@servier.com – Tel. +33 (0)1 55 72 40 21 / + 33 (0) 7 84 28 76 13
Jean-Clément Vergeau: presse@servier.com – Tel. +33 (0)1 55 46 16 / +33 6 79 56 75 96

**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. 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: clinical outcomes, which may materially change as patient enrollment continues and more patient data become available, the ability to progress the clinical trials of ALLO-501 and ALLO-501A, the potential for ALLO-501A to have similar clinical outcomes as ALLO-501, the ability to develop allogeneic CAR T therapies for cancer, and the potential benefits of AlloCAR T therapy. Various factors may cause differences between Allogene's expectations and actual results as discussed in greater detail in Allogene's filings with the Securities and Exchange Commission (SEC), including without limitation in its Quarterly Report on Form 10-Q for the quarter ended March 31, 2020. 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 Media/Investor Contact:**
Christine Cassiano
Chief Communications Officer
(714) 552-0326
Christine.Cassiano@allogene.com

Source: Allogene Therapeutics, Inc.