Allogene Therapeutics and Servier Present Pooled Data from Phase 1 Trials of Allogeneic UCART19 in Relapsed/Refractory Acute Lymphoblastic Leukemia

December 4, 2018

- 82 percent of Patients Achieved a Complete Remission when Lymphodepletion Regimen Included an anti-CD52 Monoclonal Antibody (mAb)
- Safety Profile of UCART19 Appears Manageable with No Evidence of Moderate or Severe Graft-vs-Host Disease (GvHD) and No Severe Neurotoxicities
- Analysis Suggests that an anti-CD52 mAb May Be an Important Contributor for AlloCAR T™ Cell Expansion and Now Mandated in the UCART19 Trials

SOUTH SAN FRANCISCO, Calif. and PARIS, Dec. 03, 2018 (GLOBE NEWSWIRE) -- Allogene Therapeutics, Inc. (Nasdaq: ALLO), a clinical-stage biotechnology company pioneering the development of allogeneic CAR T (AlloCAR T™) therapies for cancer, and Servier, an independent international pharmaceutical company, today announced results from an updated analysis of pooled clinical data from two ongoing Phase 1 studies of UCART19, the first allogeneic CAR T-cell therapy in clinical study, in pediatric (PALL) and adult (CALM) patients with relapsed/refractory B-cell acute lymphoblastic leukemia (ALL). The analysis showed that 82 percent (14/17) of patients who received a lymphodepletion regimen consisting of fludarabine, cyclophosphamide and an anti-CD52 mAb (FCA) achieved a complete remission (CR) or complete remission with incomplete blood recovery (CRi). In the four patients who received fludarabine and cyclophosphamide (FC) only, there was minimal UCART19 expansion and no response. Overall, 67 percent (14/21) of patients achieved a CR/CRi. These data suggest an anti-CD52 antibody is an important addition to the lymphodepletion regimen for allogeneic CAR T cell expansion. The most common adverse events were related to cytokine release syndrome (CRS) and were generally manageable. The findings were presented today by lead investigator Reuben Benjamin, MBBS, Ph.D., of King's College Hospital in London in an oral session at the 60th American Society of Hematology (ASH) Annual Meeting in San Diego.

"We are very encouraged by the data reported in this analysis which mandates further development of UCART19, the first allogeneic CAR T-cell therapy in the treatment of relapsed/refractory ALL," said Patrick Therasse M.D., Ph.D., Head of Oncology at Servier. "These data highlight the potential importance of adequate lymphodepletion for allogeneic CAR T therapies."

The updated pooled analysis from the Phase 1 CALM and PALL trials includes three additional patients since the previous update for a total of 21 patients. All enrolled patients received at least one UCART19 infusion and all were included in the analysis.

Trial	Patients Enrolled/ Treated	CR/CRi with FCA	CR/CRi Overall	G1 GvHD	G3 or 4 CRS	G4 Prolonged Cytopenia[1]	G3 or 4 Viral Infection	G3 or 4 Neurotoxicity
PALL	7	100% (6/6)	86% (6/7)	14% (1/7)	14% (1/7)	43% (3/7)	57% (4/7)	0% (0/7)
CALM	14	73% (8/11)	57% (8/14)	7% (1/14)	14% (2/14)	21% (3/14)	7% (1/14)	0% (0/14)
Pooled	21	82% (14/17)	67% (14/21)	10% (2/21)	14% (3/21)	29% (6/21)	24% (5/21)	0% (0/21)

Based on the Data cut-off date October 23, 2018

"UCART19, the first AlloCAR T therapy in clinical development, continues to provide key learnings and insights as we advance the development of our CD19 programs and broader pipeline," said David Chang, M.D., Ph.D., President, Chief Executive Officer and Co-Founder of Allogene. "The updated Phase 1 data highlight the potential importance of an anti-CD52 mAb for cell expansion and response. In our planned ALLO-501 Phase 1 study in non-Hodgkin lymphoma, we will introduce Allogene's proprietary anti-CD52 mAb (ALLO-647) as part of the required lymphodepletion regimen."

Upon enrollment, patients received a lymphodepletion regimen consisting of fludarabine, cyclophosphamide and anti-CD52 mAb (alemtuzumab) (FCA) or fludarabine and cyclophosphamide only (FC). Going forward, the PALL and CALM trials will require the use of an anti-CD52 mAb in the lymphodepletion regimen.

- Four patients did not receive an anti-CD52 antibody as part of their lymphodepletion regimen. Only minimal cell expansion was achieved in these patients and none responded. In contrast, CR/CRi was observed in 82 percent (14/17) of patients

when an anti-CD52 mAb-based lymphodepleting regimen was used.

- There was no Grade 2 or greater GvHD. Only two cases of Grade 1 acute GvHD of skin were observed.
- 90 percent (19/21) of patients experienced CRS. Grade 3 or 4 CRS was observed in 14 percent (3/21) of patients.
- 38 percent (8/21) of patients experienced neurological events and were limited to Grade 1 or 2.
- There were no new treatment-related deaths. As previously presented, there were two treatment-related deaths in the CALM study, one at day 15 post infusion as a result of Grade 4 CRS associated with Grade 5 neutropenic sepsis and one at day 82 post infusion in the post allogeneic stem-cell transplant setting.

The Phase 1 program for UCART19 for the treatment of relapsed/refractory ALL is sponsored by Servier. A Phase 1 trial of ALLO-501 for the treatment for relapsed/refractory non-Hodgkin lymphoma is expected to begin in the first half of 2019 and will be sponsored by Allogene.

UCART19 and ALLO-501 utilize the TALEN® gene-editing technology pioneered and owned by Cellectis.

---

[1] Defined as persistent Grade 4 neutropenia and/or thrombocytopenia beyond Day 42 post UCART19 infusion, except if >5 percent bone marrow blasts

UCART19, initially developed by Cellectis, is now exclusively licensed to Servier and is under joint clinical development between Servier and Allogene.

About UCART19
UCART19 is an allogeneic CAR T-cell product candidate being developed for treatment of CD19-expressing hematological malignancies. UCART19 is being developed in acute lymphoblastic leukemia (ALL) and is currently in Phase 1. The current approach with UCART19 is based on preliminary positive results from clinical trials using autologous products based on CAR technology. UCART19 has the potential to overcome the limitation of the current autologous approach by providing an allogeneic, “off-the-shelf” T cell based product. The trials for UCART19 are sponsored by Servier.

In November 2015, Servier acquired the exclusive rights to UCART19 from Cellectis. Following further agreements, Servier and Allogene Therapeutics began collaborating on a joint clinical development program for this cancer immunotherapy product. Allogene has exclusive rights from Servier to UCART19 and ALLO-501 in the United States, 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 world-class 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 faster, more reliably and at greater scale to more patients.

AlloCAR T™ cell therapies are engineered from cells of healthy donors, which is intended to allow for creation of inventory for on demand use in patients. This approach is designed to eliminate the need to create personalized therapy from a patient’s own cells, simplify manufacturing, and reduce the time patients must wait for CAR T cell treatment. The Allogene portfolio includes rights to 16 pre-clinical CAR T cell therapy assets and UCART19, an AlloCAR T™ therapy candidate currently in Phase 1 sponsored by Servier for the treatment of relapsed/refractory acute lymphoblastic leukemia (ALL). 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 headquarters in France (Suresnes). With a strong international presence in 149 countries and a turnover of 4.184 billion euros in 2018, Servier employs 21 700 people worldwide. Entirely independent, the Group reinvests 25% of its turnover (princeps drugs) in research and development and uses all its profits for the research and development of new therapeutic solutions. Corporate growth is driven by Servier’s constant search for innovation in five areas of excellence: cardiovascular, immune-inflammatory and neuropsychiatric 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

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: the ability of Servier to advance the Servier sponsored clinical trials, the ability of Allogene to advance the development of its sponsored clinical trials and broader pipeline, the timing of initiating the planned ALLO-501 Phase 1 study in non-Hodgkin lymphoma, the ability to introduce Allogene’s anti-CD52 mAb (ALLO-647) as part of the required lymphodepletion regimen, 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 Form 10-Q for the quarter ended September 30, 2018. 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

Servier Media Contacts:
Sonia Marques
+33 (0)1 55 72 40 21 / + 33 (0) 7 84 28 76 13
media@servier.com

Karine Bosseau
+33 (0)1 55 72 60 37 / + 33 (0) 6 49 92 16 05
media@servier.com

Source: Allogene Therapeutics, Inc.