Allogene Therapeutics, in Collaboration with Servier, Announces FDA Clearance of the IND for ALLO-501, an anti-CD19 Allogeneic CAR T (AlloCAR T™) Therapy

January 28, 2019

- Allogene to Initiate the ALPHA Study for ALLO-501 in Relapsed/Refractory Non-Hodgkin Lymphoma
- ALLO-647, Allogene's Proprietary anti-CD52 Antibody, Will be Administered as Part of the Lymphodepletion Regimen

SOUTH SAN FRANCISCO, Calif. and PARIS, Jan. 28, 2019 (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 its development partner Servier, an independent international pharmaceutical company, today announced that the U.S. Food & Drug Administration (FDA) has cleared Allogene's Investigational New Drug (IND) application for ALLO-501 in patients with relapsed/refractory non-Hodgkin lymphoma (NHL). Allogene is the sponsor of the ALLO-501 program.

The Phase 1 portion of the study is designed to assess the safety and tolerability at increasing dose levels of ALLO-501 in the most common NHL subtypes of relapsed/refractory diffuse large B-cell lymphoma (DLBCL) or follicular lymphoma (FL). ALLO-501 will be administered following lymphodepletion with fludarabine/cyclophosphamide (Flu/Cy) and ALLO-647, Allogene's proprietary anti-CD52 monoclonal antibody. The ALPHA Phase 1 trial will treat up to 24 patients and is on track for initiation in the first half of 2019.

"I am very pleased with the Allogene team's ability to accelerate the ALLO-501 program by securing the FDA's clearance of our IND," said David Chang, M.D., Ph.D., President, Chief Executive Officer and Co-Founder of Allogene. "This significant milestone for the company, as well as the planned initiation of the ALPHA trial, brings us one step closer to making CAR T therapy 'on demand' and more broadly accessible to patients when they are at a critical stage in their disease."

NHL is the most common hematological malignancy in the United States, with 74,680 new cases and 19,910 deaths estimated in 2018.[1] B-cell lymphomas, such as DLBCL and FL, make up approximately 85 percent of NHL cases in the United States. DLBCL is the most common type of NHL in the United States, accounting for one out of every three cases.[2] A retrospective analysis of patients with relapsed/refractory DLBCL, who were not treated with autologous CAR T therapy, found that outcomes in this population are poor, with a median overall survival of approximately six months and only seven percent attaining a complete response.[3]

"We are delighted that this program will soon be moving into the clinic. The upcoming clinical study will enable the teams to investigate the potential benefits of allogeneic CAR T therapy in patients with non-Hodgkin lymphoma, one of the largest hematological indications," declared Patrick Therasse, M.D., Ph.D., Head of Servier Research and Development Oncology Department of Servier.

UCART19 and ALLO-501 are being developed under a joint clinical development collaboration between Servier and Allogene, and are exclusively licensed from Cellectis. UCART19 and ALLO-501 utilize the TALEN® gene-editing technology pioneered and owned by Cellectis. Both ALLO-501 and UCART19 feature the same construct and editing but are manufactured using a different process. The UCART19 clinical program for the treatment of relapsed/refractory acute lymphoblastic leukemia (ALL) is sponsored by Servier. Allogene has exclusive rights to UCART19 and ALLO-501 in the U.S. while Servier retains exclusive rights for all other countries.

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

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.

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 timing and ability of Allogene to initiate the ALLO-501 Phase 1 study in patients with relapsed/refractory non-Hodgkin lymphoma, the ability to introduce Allogene's anti-CD52 mAb (ALLO-647) as part of the required lymphodepletion regimen, the ability to progress the ALLO-501 Phase 1 study, 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.

[1] U.S. SEER database

[2] https://www.cancer.org/cancer/non-hodgkin-lymphoma/about/b-cell-lymphoma.html

[3] SCHOLAR-1 study: Blood 2017;130:1800-1808

Allogene Media/Investor Contact:
Christine Cassiano
Chief Communications Officer
(714) 552-0326
Christine.Cassiano@allogene.com

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

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

Source: Allogene Therapeutics, Inc.