

# American Society of Clinical Oncology (ASCO) Abstract Reports Initial ALLO-501 ALPHA Phase 1 Data in Relapsed/Refractory Non-Hodgkin Lymphoma

May 13, 2020

- ALLO-501 in Combination with ALLO-647 Based Lymphodepletion Regimen was Well Tolerated With No Dose-Limiting Toxicities or Evidence of Graft-vs-Host Disease
- Abstract Based on Data Cutoff in January 2020 Represents Limited Data Set of Nine Evaluable Patients Treated at Lower Dose (39mg) ALLO-647; Three Patients Achieved a Complete Response (CR)
- Results from Additional Evaluable Patients Including Those Treated at Higher Dose (90 mg) ALLO-647 Will Be Presented at the Virtual ASCO Meeting on May 29, 2020
- Allogene Continues Study Enrollment to Optimize Lymphodepletion

SOUTH SAN FRANCISCO, Calif. and PARIS, May 13, 2020 (GLOBE NEWSWIRE) -- Allogene Therapeutics, Inc. (Nasdaq: ALLO), a clinical-stage biotechnology company pioneering the development of allogeneic CAR T (AlloCAR T<sup>™</sup>) therapies for cancer, in collaboration with its development partner Servier, an independent international pharmaceutical company, announced the release of the abstract related to an upcoming oral presentation at the American Society of Clinical Oncology (ASCO) Annual Meeting. This will be the first data from Allogene's Phase 1 dose escalation ALPHA study of ALLO-501 in relapsed/refractory non-Hodgkin lymphoma (NHL). This study utilizes ALLO-647, Allogene's anti-CD52 monoclonal antibody (mAb), as a part of its differentiated lymphodepletion regimen.

"As we look ahead to the end of the month to the virtual ASCO meeting, we are excited to present initial clinical data from our first-in-human study of ALLO-501 and ALLO-647," said Rafael G. Amado, M.D., Executive Vice President of Research & Development and Chief Medical Officer of Allogene. "These findings will provide an early glimpse into the potential of our AlloCAR T pipeline and ALLO-647 based lymphodepletion strategy, which we believe will be foundational in driving the future success and broad applicability of AlloCAR T therapies."

The ASCO abstract includes preliminary data on the first nine patients treated with escalating doses of ALLO-501 and lower dose (39mg) ALLO-647. No dose limiting toxicities or graft-vs-host disease (GvHD) was observed. The most common Grade (Gr)  $\geq$  3 adverse events were neutropenia (55.6%), leukopenia (33.3%) and anemia (22.2%). Two patients (22.2%) developed cytokine release syndrome (one Gr1 and one Gr2) that resolved within 72 hours without steroids or tocilizumab. One patient developed Gr1 neurotoxicity that resolved without treatment. One patient developed upper respiratory tract infection (Gr2), CMV (Gr3) and EBV viremia (Gr1), which all resolved. One patient had a Gr2 infusion reaction to ALLO-647 which resolved with antihistamines.

In this limited dataset with a small number of patients, the overall response rate (ORR) was 78% (95% exact CI: 40%, 97%) with three complete responses (CR) and four partial responses (PR). As of the January 2020 data cutoff, there was a median follow up of 2.7 months with four patients in ongoing response and three patients having progressed at 2, 4 and 6 months.

The virtual presentation will include data on 11 patients across ALLO-501 cell dose cohorts and the lower dose (39mg) of ALLO-647, as well as additional patients treated with ALLO-501 and the higher dose (90mg) of ALLO-647. The Phase 1 ALPHA study continues to enroll patients with higher dose ALLO-647 in an effort to optimize lymphodepletion.

This virtual presentation will be available on demand when ASCO releases pre-recorded presentations on May 29, 2020 at 5:00 a.m. PT/8:00 a.m. ET. Allogene will also host a conference call on May 29<sup>th</sup> following the release of the presentation.

Oral Abstract Session: Hematologic Malignancies - Lymphoma and Chronic Lymphocytic Leukemia

Abstract #8002

Title: First-in-Human Data of ALLO-501 and ALLO-647 in Relapsed/Refractory Large B-cell or Follicular Lymphoma (R/R LBCL/FL): ALPHA Study. Presenter: Sattva S. Neelapu, MD, The University of Texas MD Anderson Cancer Center, Department of Lymphoma/Myeloma, Houston, TX Session Release Date & Time: May 29, 2020 at 5:00 a.m. PT/8:00 a.m. ET Location: On demand virtual presentation

Allogene is the sponsor of this Phase 1 trial which is designed to assess the safety and tolerability at increasing dose levels of ALLO-501 and ALLO-647 in patients with relapsed/refractory diffuse large B-cell lymphoma and follicular lymphoma.

Allogene expects to initiate enrollment in ALPHA2, a Phase 1 trial with abbreviated dose escalation of ALLO-501A, in Q2 2020. ALLO-501A is the next generation of ALLO-501, which eliminates the rituximab recognition domains, and it is intended for Phase 2 development.

### About ALLO-501 (Allogene Sponsored)

Allogene's AlloCAR T programs utilize Cellectis technologies. ALLO-501 is an anti-CD19 allogeneic CAR T (AlloCAR T<sup>™</sup>) therapy being jointly developed under a collaboration agreement between Servier and Allogene based on an exclusive license granted by Cellectis to Servier. 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<sup>™</sup>) 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 on-demand, more reliably, and at greater scale to more patients. For more information, please visit <u>www.allogene.com</u>, 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: <a href="https://www.servier.com">www.servier.com</a>

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## 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 to progress the Phase 1 trial of ALLO-501 and present data, the timing and ability to initiate and progress a clinical trial of ALLO-501A, the ability to manufacture AlloCAR T™ therapies, including ALLO-501A, 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.

AlloCAR T<sup>™</sup> is a trademark of Allogene Therapeutics, Inc.

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