

# Allogene Therapeutics Announces FDA Clearance of the IND for ALLO-715, a BCMA Allogeneic CAR T (AlloCAR T<sup>™</sup>) Therapy

June 4, 2019

- ALLO-715 Utilizes Gene-Editing of TRAC and CD52 Loci to Enable Allogeneic CAR T Therapy
- ALLO-715 will be Evaluated in Combination with ALLO-647, Allogene's Proprietary anti-CD52 Antibody as Part of the Lymphodepletion Regimen
- Allogene Plans to Initiate the UNIVERSAL Study for ALLO-715 in Relapsed/Refractory Multiple Myeloma in the Second Half of 2019

SOUTH SAN FRANCISCO, Calif., June 04, 2019 (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, today announced that thdJ.S. Food & Drug Administration (FDA) has cleared Allogene's Investigational New Drug (IND) application for ALLO-715 in patients with relapsed/refractory multiple myeloma. The Phase 1 portion of the UNIVERSAL study, which will include ALLO-647 as part of the lymphodepletion regimen, is expected to be initiated in the second half of 2019.

"We are very pleased to have received clearance for our second IND this year and look forward to initiating the UNIVERSAL trial in 2019," said David Chang, M.D., Ph.D., President, Chief Executive Officer and Co-Founder of Allogene. "We believe an "off-the-shelf" CAR T cell therapy could be game-changing for patients, and we plan to leverage learnings from our ALLO-501 ALPHA trial in non-Hodgkin lymphoma initiated in Q2 2019 to accelerate the development of ALLO-715."

Multiple myeloma is the second most common hematological malignancy in the United States, with 32,110 new cases and 12,960 deaths estimated in 2019.<sup>1</sup>

#### About ALLO-715

ALLO-715, an AlloCAR T therapy targeting B-cell maturation antigen (BCMA), is a potential novel treatment for multiple myeloma and other BCMA-positive malignancies. Multiple myeloma is characterized by abnormalities in plasma cells that reproduce uncontrollably in the bone marrow of people with the disease,<sup>2</sup> multiple myeloma is incurable for most patients, and most patients relapse despite the treatments available.<sup>3</sup> Preclinical study results for ALLO-715 were published in the journal *Molecular Therapy* validating the potential for an AlloCAR T to treat multiple myeloma and demonstrating the ability for ALLO-715 to sustain potent anti-tumor responses in pre-clinical models. Allogene expects completion of site initiation activities, production of additional ALLO-715 clinical supply, and initiation of the UNIVERSAL study in the second half of 2019.

ALLO-715 utilizes the TALEN® gene-editing technology pioneered and owned by Cellectis. Allogene has an exclusive license to the Cellectis technology for allogeneic products directed at the BCMA target. Allogene holds the global development and commercial rights for this investigational candidate.

#### **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  $T^{TM}$ ) 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.

### **Cautionary Note on Forward-Looking Statements**

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 complete site initiation activities, produce additional ALLO-715 clinical supply and initiate the UNIVERSAL study in the second half of 2019, the ability to develop additional AlloCAR T therapies for cancer and the potential benefits of ALLO-715 and 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 March 31, 2019. 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.

## <sup>1</sup> U.S. SEER database

<sup>2</sup> Multiple myeloma - Genetics Home Reference - NIH. Retrieved from <u>https://ghr.nlm.nih.gov/condition/multiple-myeloma#</u>

<sup>3</sup> Sonneveld P, Broijl A. Treatment of relapsed and refractory multiple myeloma. Haematologica. 2016;101(4):396-406

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



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