

Novartis announces new CTL019 study data demonstrating overall response in adult patients with certain types of lymphoma

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- - Overall response rate at 3 months was 47% (7/15) in diffuse large B-cell lymphoma and 73% (8/11) in follicular lymphoma
- - Successful technology transfer enabling commercial scale-up of CTL019 cell processing to support global trials reported in other ASH presentation
- - Novartis global Phase II CTL019 clinical trials expanded to EU, Canada and Australia, marking first industry-sponsored CART trials to be opened outside US

EAST HANOVER, N.J., Dec. 6, 2015 /PRNewswire/ -- Findings from an ongoing Phase IIa study to evaluate the safety and efficacy of investigational chimeric antigen receptor T cell (CART) therapy CTL019 in certain types of relapsed or refractory (r/r) non-Hodgkin lymphoma will be presented in an oral session at the 57th American Society of Hematology (ASH) annual meeting. The study, conducted by the University of Pennsylvania's Perelman School of Medicine (Penn), found an overall response rate (ORR) at three months of 47% (7/15) in adult patients with r/r diffuse large B-cell lymphoma (DLBCL) and an ORR of 73% (8/11) in adult patients with follicular lymphoma (FL)¹. Results will be presented in an oral session at ASH on Sunday, December 6 (Abstract #183, 8 a.m.)¹.

"These data add to the growing body of clinical evidence on CTL019 and illustrate its potential benefit in the treatment of relapsed and refractory non-Hodgkin lymphoma, a disease with few effective options," said lead investigator Stephen Schuster, M.D., Associate Professor, Division of Hematology/Oncology at the University of Pennsylvania, Abramson Cancer Center. "We look forward to continuing this study to further understand longer-term patient response."

The study findings include 26 adult patients (15 with DLBCL and 11 with FL) who were evaluable for response. The study found that three patients with DLBCL who achieved a partial response (PR) to treatment at three months converted to complete response (CR) by six months. In addition, three patients with FL who achieved a PR to treatment at three months converted to CR by six months. One DLBCL patient with a PR to treatment at three months experienced disease progression at six months after treatment. One FL patient with a PR to treatment at three months who remained in PR at nine months experienced disease progression at approximately 12 months after treatment. Median progression-free survival (PFS) was 11.9 months for patients with FL and 3.0 months for patients with DLBCL.

In the study, four patients developed cytokine release syndrome (CRS) of grade 3 or higher. CRS has been observed after CTL019 infusion when the engineered cells become activated and multiply in the patient's body. During CRS, patients typically experience varying degrees of flu-like symptoms with high fevers, nausea, muscle pain, and in some cases, low blood pressure and breathing difficulties. Neurologic toxicity occurred in two patients, including one grade three episode of delirium and one possibly related grade five encephalopathy¹.

In contrast to typical small molecule or biologic therapies, CTL019 is specifically manufactured for each individual patient. A patient's T cells are collected through a specialized blood draw called leukapheresis and then transferred to the Novartis manufacturing facility in Morris Plains, New Jersey. There the cells are reprogrammed to hunt cancer and other B-cells expressing CD19. The patient's own modified cells are then transferred back to the treatment center where they are administered to the patient.

A poster presentation on December 6, 6-8 p.m., will report on how the successful transfer of cell processing technology from Penn to the Novartis cell manufacturing center in Morris Plains has enabled the scale-up of CTL019 production (Abstract #3100)². The Morris Plains facility is the first FDA-approved Good Manufacturing Practices quality site for a cell therapy production in the US and is now processing cells to support ongoing Phase II multi-center global studies of CTL019 in specific leukemias and lymphomas.

"The company's investment in our state-of-the-art manufacturing facility has given us the capacity and scalability needed to support our growing global clinical trial program," said Usman Azam, MD, Global Head, Cell & Gene Therapies Unit, Novartis Pharmaceuticals. "Novartis is proud to be the first healthcare company to initiate Phase II CART therapy trials in the US, Europe, Canada and Australia. This is a significant step forward in our mission to help address unmet medical needs of patients." A list of participating trial centers is available at <https://clinicaltrials.gov>.

Because CTL019 is an investigational therapy, the safety and efficacy profile has not yet been established. Access to investigational therapies is available only through carefully controlled and monitored clinical trials. These trials are designed to better understand the potential benefits and risks of the therapy. Because of uncertainty of clinical trials, there is no guarantee that CTL019 will ever be commercially available anywhere in the world.

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References

1. Schuster, Stephen J. et al. (6 December 2015). Sustained Remissions Following Chimeric Antigen Receptor Modified T Cells Directed Against CD19 (CTL019) in Patients with Relapsed or Refractory CD19+ Lymphomas [oral presentation]. 57th American Society of Hematology Annual Meeting & Exposition: Abstract 183
2. Boyd, Jeffrey A. et al. (6 December 2015). Successful Translation of Chimeric Antigen Receptor (CAR) Targeting CD19 (CTL019) Cell Processing Technology from Academia to Industry [poster presentation]. 57th Society of Hematology Annual Meeting & Exposition: Abstract 3100

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