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Celgene Announces Updated Safety and Efficacy Data from the TRANSCEND Trial of liso-cel (JCAR017) in Patients with Relapsed or Refractory B-cell non-Hodgkin Lymphoma at ASCO

Updated results with liso-cel underscore potential for best-in-class CAR T profile for patients with poor prognosis

SUMMIT, N.J.--(BUSINESS WIRE)-- Celgene Corporation (NASDAQ:CELG) today announced updated six-month safety and efficacy data from the TRANSCEND (NHL-001) study of lisocabtagene maraleucel (liso-cel; JCAR017), an investigational CD19-directed CAR T cell therapy, in patients with relapsed/refractory (r/r) aggressive B-cell non-Hodgkin lymphoma (NHL) in a presentation at the American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, IL.

"As liso-cel data mature, the durable response rates continue to demonstrate the potential of CAR T cell therapy in patients with DLBCL who have relapsed or are refractory to prior treatments," said principal investigator Jeremy Abramson, M.D., of Massachusetts General Hospital. "Added to the emerging side effect profile with liso-cel, this therapy has encouraging potential in diffuse large B-cell lymphoma."

The update provided today was based on a cutoff date of May 4, 2018 and included data from 114 liso-cel treated and 102 safety evaluable patients, of which 51 patients were treated at the pivotal dose of 100 million cells. Abramson highlighted 37 patients who meet the criteria for the planned pivotal patient population in TRANSCEND NHL-001 (including r/r DLBCL, transformed from follicular lymphoma (tFL), and poor-risk high-grade double/triple-hit lymphoma), and were treated with the pivotal cell dose. The new long-term follow up data add to those disclosed on May 16, 2018 in ASCO Abstract #7505.

At six months, 49% of patients remained in remission, with 46% maintaining a complete response (CR) in this cohort (n=37). When durability of response beyond six months was evaluated across all dosing levels ranging from 5×10^7 to 1×10^8 CAR T cells, 93% of patients in CR remained in CR at data cut off. Liso-cel therapy was available for 99% (132/134) of patients apheresed.

The most common treatment-emergent adverse events that occurred at ≥25% incidence included neutropenia (63%), anemia (53%), fatigue (46%), thrombocytopenia (34%), decreased appetite (29%), nausea (28%), hypotension (26%), cough (26%), headache (25%), dizziness (25%), constipation (25%), and diarrhea (25%). Cytokine release syndrome and neurotoxicity were observed at a rate of 37% and 23% for all grades, and 1% and 13% for grades 3 and 4, respectively (n=102). Based on this emerging safety profile, outpatient administration is being evaluated in the TRANSCEND trial.

"The updated efficacy and tolerability data for liso-cel continue to support a potential best-in-class CD19 CAR T profile," said Nadim Ahmed, President, Hematology and Oncology for Celgene. "With the TRANSCEND pivotal cohort now fully enrolled, we look forward to further progressing this critical program for poor-prognosis patients with relapsed or refractory aggressive NHL and investigating the clinical utility of liso-cel in earlier lines of therapy."

About Liso-cel and TRANSCEND

Liso-cel is an investigational defined composition CD19-directed CAR T cell product candidate using a 4-1BB costimulatory domain. TRANSCEND is an open-label, multicenter phase I study to determine the safety, pharmacokinetics, and antitumor activity of liso-cel in adult patients with relapsed or refractory diffuse large B cell lymphoma, primary mediastinal B-cell lymphoma, follicular lymphoma Grade 3B, and mantle cell lymphoma.

The pivotal cohort includes patients with DLBCL (NOS and transformed from follicular lymphoma) who are ECOG Performance Status 0-1. These patients represent a high-risk patient population, with approximately 90% of treated patients having one or more predictors of poor survival, including double or triple hit lymphoma, being chemorefractory to front-line or subsequent therapies, never reaching a complete remission with prior treatments, or never having undergone an autologous transplant.

About Celgene

Celgene Corporation, headquartered in Summit, New Jersey, is an integrated global biopharmaceutical company engaged primarily in the discovery, development and commercialization of innovative therapies for the treatment of cancer and inflammatory diseases through next-generation solutions in protein homeostasis, immuno-oncology, epigenetics, immunology and neuro-inflammation. For more information, please visit www.celgene.com. Follow Celgene on Social Media: @Celgene, Pinterest, LinkedIn, Facebook and YouTube.

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