FDA Approves Kymriah for Adults with Relapsed or Refractory Large B-Cell Lymphoma

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May 4, 2018 By Food and Drug Administration (FDA)

FDA approves tisagenlecleucel for adults with relapsed or refractory large B-cell lymphoma

On May 1, 2018, the Food and Drug Administration approved tisagenlecleucel (KYMRIAH, Novartis Pharmaceuticals Corp.) a CD19-directed genetically modified autologous T-cell immunotherapy, for adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma and DLBCL arising from follicular lymphoma.

Approval was based on a single-arm, open-label, multi-center, phase 2 trial (JULIET, NCT02445248) in adults with relapsed or refractory DLBCL and DLBCL after transformation from follicular lymphoma. Eligible patients must have been treated with at least two prior lines of therapy, including an anthracycline and rituximab, or relapsed following autologous hematopoietic stem cell transplant. Patients received a single infusion of tisagenlecleucel following completion of lymphodepleting chemotherapy.

The overall response rate (ORR) as assessed by an independent review committee for the 68 evaluable patients was 50% (95% CI: 37.6, 62.4) with a complete response (CR) rate of 32% (95% CI: 21.5, 44.8). With a median follow-up time of 9.4 months, the duration of response (DOR) was longer in patients with a best overall response of CR, as compared to a best overall response of partial response (PR). Among patients achieving CR, the estimated median DOR was not reached (95% CI: 10.0 months, not estimable [NE]). The estimated median response duration among patients in PR was 3.4 months (95% CI: 1.0, NE).

The most common adverse reactions (incidence >20%) in patients on the trial were cytokine release syndrome (CRS), infections-pathogen unspecified, pyrexia, diarrhea, nausea, fatigue, hypotension, edema, and headache. Because of the serious risks of CRS and neurologic toxicities, FDA approved tisagenlecleucel with a Risk Evaluation and Mitigation Strategy.

The recommended dose of tisagenlecleucel for relapsed or refractory adult DLBCL is 0.6 to 6.0 x

10^8 CAR-positive viable T cells. Tisagenlecleucel is not indicated for the treatment of patients with primary central nervous system lymphoma.

Full prescribing information is available at: KYMRIAH Package Insert

FDA granted this application priority review, breakthrough therapy designation, and orphan product designation. A description of FDA expedited programs is in the Guidance for Industry: Expedited Programs for Serious Conditions-Drugs and Biologics.

Healthcare professionals should report all serious adverse events suspected to be associated with the use of any medicine and device to FDA's MedWatch Reporting System or by calling 1-800-FDA-1088.

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