FDA Approves Brentuximab Vedotin for Classical Hodgkin Lymphoma

Approval was based on a study showing improved progression-free survival.

March 20, 2018 By Food and Drug Administration (FDA)

On March 20, 2018, the Food and Drug Administration approved brentuximab vedotin (Adcetris, Seattle Genetics, Inc.) to treat adult patients with previously untreated stage III or IV classical Hodgkin lymphoma (cHL) in combination with chemotherapy.

Approval was based on a randomized, open-label, two-arm, multicenter trial, ECHELON-1, that randomized 1,334 patients to receive either Adcetris plus doxorubicin, vinblastine, and dacarbazine (Adcetris + AVD) or bleomycin plus AVD (ABVD). Patients were randomized to receive up to 6 cycles of Adcetris + AVD or ABVD on Days 1 and 15 of each 28-day cycle.

Efficacy was established based on modified progression-free survival (mPFS), defined as progression, death, or receipt of additional anticancer therapy for patients who are not in a complete response after completion of frontline therapy. The estimated median mPFS was not reached in either arm, with a median follow-up time of 24.6 months. There were 117 events (18%) on the Adcetris + AVD arm and 146 events (22%) on the ABVD arm (hazard ratio 0.77; 95% CI: 0.60, 0.98; p=0.035), corresponding to a 23 percent reduction in the risk of an mPFS event. At the time of the mPFS analysis, an interim overall survival analysis did not demonstrate a significant difference.

The most common adverse reactions in at least 20% of patients treated with Adcetris across all clinical trials were neutropenia, anemia, peripheral sensory neuropathy, nausea, fatigue, constipation, diarrhea, vomiting, and pyrexia. Primary G-CSF prophylaxis is recommended with Adcetris plus chemotherapy for the frontline treatment of stage III or IV cHL.

The recommended dose of Adcetris in combination with chemotherapy for previously untreated stage III or IV cHL is 1.2 mg/kg as an intravenous infusion up to a maximum of 120 mg every 2 weeks for 12 doses.

Full prescribing information is available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/125388s097lbl.pdf.

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

Drugs and Biologics, available at: http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm358301.pdf.

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 by completing a form online at http://www.fda.gov/medwatch/report.htm, by faxing (1-800-FDA-0178) or mailing the postage-paid address form provided online, or by telephone (1-800-FDA-1088).

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