FDA Approves Brentuximab Vedotin for Primary Cutaneous Anaplastic Large Cell Lymphoma

Approval was based on a phase 3, randomized, open-label, multicenter clinical trial (ALCANZA).

November 9, 2017 By Food and Drug Administration (FDA)

On November 9, 2017, the Food and Drug Administration granted regular approval to brentuximab vedotin (Adcetris, Seattle Genetics, Inc.) for the treatment of adult patients with primary cutaneous anaplastic large cell lymphoma (pcALCL) or CD30-expressing mycosis fungoides (MF) who have received prior systemic therapy.

Approval was based on a phase 3, randomized, open-label, multicenter clinical trial (ALCANZA) of brentuximab vedotin in patients with MF or pcALCL who had previously received one prior systemic therapy and required systemic treatment. The trial randomized 131 patients (1:1) to receive either brentuximab vedotin or the physician's choice of methotrexate or bexarotene.

Efficacy was established based on improvement in objective response rate lasting 4 months (ORR4), complete response (CR) rate, and progression-free survival (PFS) assessed by an independent review facility. ALCANZA demonstrated an improvement ($p<0.001$) in ORR4 in the brentuximab vedotin arm versus the physician's choice arm, 56% (95% CI: 44%, 68%) versus 12% (95% CI 4%, 21%), respectively. CR rate was also superior ($p=0.007$) in the brentuximab vedotin arm versus the physician's choice arm, 16% (95% CI: 8%, 27%) versus 2% (95%CI: 0, 8%). ALCANZA also demonstrated improvement in PFS with an estimated hazard ratio of 0.27 (95%CI 0.17, 0.43, $p<0.001$). The median PFS was 17 months in the brentuximab vedotin arm versus 4 months in the physician's choice arm.

The most common adverse reactions occurring in >20% of patients receiving brentuximab vedotin were anemia, peripheral sensory neuropathy, nausea, diarrhea, fatigue, and neutropenia. The most common adverse event leading to discontinuation was peripheral neuropathy.

The recommended dose of brentuximab vedotin is 1.8 mg/kg up to a maximum of 180 mg as an intravenous infusion over 30 minutes every 3 weeks until a maximum of 16 cycles, disease progression, or unacceptable toxicity.

Full prescribing information is available

at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125388s094lbl.pdf.

FDA granted Breakthrough Therapy Designation, Orphan Designation, and priority review to brentuximab vedotin for this indication. 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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This announcement originally appeared on the FDA website.
