Adcetris FDA approval expanded to include later-stage Hodgkin's

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(HealthDay)—U.S. Food and Drug Administration approval of Adcetris

(brentuximab vedotin) has been expanded to include adults with untreated stage III or IV classical Hodgkin's lymphoma, the agency said Tuesday in a news release.

The approval for Adcetris was based on a clinical trial involving 1,334 patients. After receiving an average of six 28-day cycles of treatment, patients treated with Adcetris plus Adriamycin (doxorubicin), vinblastine, and dacarbazine (AVD) were 23 percent less likely to experience progression, death, or initiation of new therapy compared with patients receiving AVD plus bleomycin.

Common side effects of Adcetris include neutropenia, anemia, peripheral neuropathy, nausea, fatigue, constipation, vomiting, and fever. The drug has a boxed label warning of greater-than-usual risk of the John Cunningham viral infection, which could lead to progressive multifocal leukoencephalopathy. Since Adcetris could harm a developing fetus, women who are pregnant or could be pregnant should avoid the drug, the FDA said.

"Today's approval represents an improvement in the initial treatment regimens of advanced Hodgkin lymphoma that were introduced into clinical practice more than 40 years ago," Richard Pazdur, M.D., director of the agency's Oncology Center of Excellence, said in a statement. "This approval demonstrates our commitment to approving advancements in treatment that give prescribers and patients different options for care."

Adcetris is produced by Seattle Genetics of Bothell, Wash.

More information: More Information

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