

FDA approves first-line therapy for peripheral T-cell lymphoma

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(HealthDay)—The U.S. Food and Drug Administration on Friday

expanded approval for the use of Adcetris (brentuximab vedotin) injection in combination with chemotherapy for adult patients with specific types of peripheral T-cell lymphoma (PTCL).

The FDA stated in a press release that this approval is the first for treatment of newly diagnosed PTCL. Adcetris, a monoclonal antibody that binds to the CD30 protein, is now approved to treat previously untreated systemic anaplastic large cell lymphoma (ALCL) and other CD30-expressing PTCLs in combination with chemotherapy. In the past, the FDA approved Adcetris to treat [adult patients](#) with previously untreated stage III or IV classical Hodgkin lymphoma (cHL), cHL after relapse, cHL after stem cell transplant when there is a [high risk](#) for relapse or progression, systemic ALCL after failure of other treatment, and primary cutaneous ALCL or CD30-expressing mycosis fungoides after failure of other treatment.

The new approval was based on a clinical trial of 453 patients with certain PTCLs. Patients received first-line treatment of Adcetris plus chemotherapy or standard chemotherapy. Researchers found that progression-free survival was significantly longer (hazard ratio, 0.71; P = 0.01) among patients who received Adcetris (median 48 months compared with 21 months).

The FDA noted the following common side effects with Adcetris plus chemotherapy: [peripheral neuropathy](#), nausea and vomiting, diarrhea, low white blood cell counts, fatigue, mouth sores, constipation, hair loss, fever, and anemia. The FDA advises [health care providers](#) to monitor patients for infusion reactions, anaphylaxis, neuropathy, fever, gastrointestinal complications, infections, tumor lysis syndrome, serious skin reactions, pulmonary toxicity, and hepatotoxicity. The prescribing information includes a Boxed Warning advising of the risk for progressive multifocal leukoencephalopathy in patients receiving Adcetris.

More information: [More Information](#)

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