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

November 20 2018

(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