

Supplemental Approvals

Generic Name (Trade Name) Company

November 29, 2018

Brentuximab vedotin

Uses/Notes

On November 16, [FDA approved](#) brentuximab vedotin injection in combination with chemotherapy for adult patients with certain types of peripheral T-cell lymphoma (PTCL). This is the first FDA approval for treatment of newly diagnosed PTCL, and the agency used a new review program to complete the approval more quickly.

PTCLs are rare, fast-growing non-Hodgkin's lymphomas that develop from T-cells. The T-cells often spread quickly throughout the body and are hard to treat.

Brentuximab vedotin is a monoclonal antibody that binds to a CD30 protein found on some cancer cells.

The drug was previously approved to treat adult patients with previously untreated stage III or IV classical Hodgkin lymphoma (cHL), cHL after relapse, cHL after stem cell transplant when a patient is at a high risk of 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 452 patients with certain PTCLs who received either brentuximab vedotin plus chemotherapy or a standard chemotherapy (CHOP) as first-line treatment.

The most common adverse effects of brentuximab vedotin plus chemotherapy included nerve damage (peripheral neuropathy), nausea and vomiting, diarrhea, low white blood cell counts, fatigue, mouth sores, constipation, hair loss, fever, and anemia.

Health care providers are advised to monitor patients for infusion reactions, life-threatening allergic reactions, neuropathy, fever, GI complications and infections. Patients should also be monitored for tumor lysis syndrome, serious skin reactions, lung adverse effects, and liver damage.

Women who are pregnant or breastfeeding should not take brentuximab vedotin because it may cause harm to

(Adcetris—Seattle Genetics)

a developing fetus or newborn baby.

FDA approves expanded use for first-line treatment of peripheral T-cell lymphoma

The prescribing information includes a boxed warning to advise health professionals and patients about the risk of a fatal or life-threatening infection of the brain (progressive multifocal leukoencephalopathy) in patients receiving the drug.

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<http://www.aphanet.org/supplemental-approvals/fda-approves-expanded-use-first-line-treatment-peripheral-t-cell-lymphoma>

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