FDA Approves Treatment for Peripheral T-Cell Lymphoma Under New Review Program

Adcetris plus chemotherapy approved under pilot program that aims to speed drug review and approval.

November 16, 2018 By Food and Drug Administration (FDA)

The U.S. Food and Drug Administration today expanded the approved use of Adcetris (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.

“The Real-Time Oncology Review (RTOR) program allows the FDA to access key data prior to the official submission of the application allowing the review team to begin their review earlier and communicate with the sponsor prior to the application’s actual submission,” said Richard Pazdur, MD, director of the FDA’s Oncology Center of Excellence and acting director of the Office of Hematology and Oncology Products. “When the sponsor submits the completed application, the review team will already be familiar with the data and be able to conduct a more efficient, timely and thorough review. RTOR allowed the FDA to approve this indication within two weeks of the completed application’s submission.”

PTCLs are rare, fast-growing non-Hodgkin lymphomas that develop from white blood cells called T-cells. The T-cells often spread quickly throughout the body and are hard to treat.

Adcetris is a monoclonal antibody that binds to a protein (called CD30) found on some cancer cells. Adcetris is now approved to treat previously untreated systemic anaplastic large cell lymphoma (ALCL) and other CD30-expressing PTCLs in combination with chemotherapy. Adcetris was previously approved by the FDA 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 Adcetris plus chemotherapy or a standard chemotherapy (CHOP) as first-line treatment.

Progression-free survival (the amount of time a patient stays alive without the cancer growing) was significantly longer (hazard ratio 0.71, P-value 0.01) in the Adcetris arm (median 48 months, compared to 21 months with CHOP). Overall survival and overall response rates were also significantly better in the Adcetris arm.

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

Health care providers are advised to monitor patients for infusion reactions, life-threatening allergic reactions (anaphylaxis), neuropathy, fever, gastrointestinal complications and infections. Patients should also be monitored for tumor lysis syndrome (a complication from many tumor cells being killed off at the same time), serious skin reactions, lung side effects (pulmonary toxicity) and liver damage (hepatotoxicity).

Women who are pregnant or breastfeeding should not take Adcetris because it may cause harm to a developing fetus or newborn baby. The prescribing information for Adcetris includes a Boxed Warning to advise health care professionals and patients about the risk of a fatal or life-threatening infection of the brain (progressive multifocal leukoencephalopathy) in patients receiving Adcetris.

The FDA granted this application Priority Review and Breakthrough Therapy designation.

The FDA granted the approval of Adcetris to Seattle Genetics.

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