

ADCETRIS® (brentuximab vedotin)

PATIENT MANAGEMENT - INDICATIONS AND DOSING

The purpose of this meeting will be to educate healthcare professionals on the role of ADCETRIS® (brentuximab vedotin) for injection in the treatment of adult patients with relapsed classical Hodgkin lymphoma.

Healthcare Professionals including Hematologist Oncologists, Medical Oncologists, Pathologists, Pharmacists, PAs, NPs, and RNs are encouraged to participate in this valuable dialogue.



Date/Time:



RSVP

To RSVP or for information regarding ADCETRIS, contact your local Seattle Genetics Account Manager,

Venue:



INDICATIONS

ADCETRIS® (brentuximab vedotin) is indicated for the treatment of adult patients with:

- Classical Hodgkin lymphoma (cHL) at high risk of relapse or progression as post-autologous hematopoietic stem cell transplantation (auto-HSCT) consolidation.
- cHL after failure of auto-HSCT or after failure of at least two prior multi-agent chemotherapy regimens in patients who are not auto-HSCT candidates.
- Primary cutaneous anaplastic large cell lymphoma (pcALCL) or CD30-expressing mycosis fungoides (MF) who have received prior systemic therapy.

Important Safety Information

BOXED WARNING

PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY (PML): JC virus infection resulting in PML and death can occur in ADCETRIS-treated patients.

Please see additional Important Safety Information, including BOXED WARNING, on the next page and full Prescribing Information attached or at adcetrispro.com.

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Contraindication

ADCETRIS® (brentuximab vedotin) concomitant with bleomycin due to pulmonary toxicity (e.g., interstitial infiltration and/or inflammation).

Warnings and Precautions

- Peripheral neuropathy (PN): ADCETRIS causes PN that is predominantly sensory. Cases of motor PN have also been reported. ADCETRIS-induced PN is cumulative. Monitor for symptoms such as hypoesthesia, hyperesthesia, paresthesia, discomfort, a burning sensation, neuropathic pain, or weakness. Institute dose modifications accordingly.
- Anaphylaxis and infusion reactions: Infusion-related reactions
 (IRR), including anaphylaxis, have occurred with ADCETRIS. Monitor
 patients during infusion. If an IRR occurs, interrupt the infusion
 and institute appropriate medical management. If anaphylaxis
 occurs, immediately and permanently discontinue the infusion and
 administer appropriate medical therapy. Premedicate patients with
 a prior IRR before subsequent infusions. Premedication may include
 acetaminophen, an antihistamine, and a corticosteroid.
- Hematologic toxicities: Prolonged (≥1 week) severe neutropenia and Grade 3 or 4 thrombocytopenia or anemia can occur with ADCETRIS. Febrile neutropenia has been reported with ADCETRIS. Monitor complete blood counts prior to each ADCETRIS dose. Consider more frequent monitoring for patients with Grade 3 or 4 neutropenia. Monitor patients for fever. If Grade 3 or 4 neutropenia develops, consider dose delays, reductions, discontinuation, or G-CSF prophylaxis with subsequent doses.
- Serious infections and opportunistic infections: Infections such as pneumonia, bacteremia, and sepsis or septic shock (including fatal outcomes) have been reported in ADCETRIStreated patients. Closely monitor patients during treatment for bacterial, fungal, or viral infections.
- Tumor lysis syndrome: Closely monitor patients with rapidly proliferating tumor and high tumor burden.
- Increased toxicity in the presence of severe renal impairment: The frequency of ≥Grade 3 adverse reactions and deaths was greater in patients with severe renal impairment compared to patients with normal renal function. Avoid use in patients with severe renal impairment.
- Increased toxicity in the presence of moderate or severe hepatic impairment: The frequency of ≥Grade 3 adverse reactions and deaths was greater in patients with moderate or severe hepatic impairment compared to patients with normal hepatic function. Avoid use in patients with moderate or severe hepatic impairment.
- Hepatotoxicity: Serious cases of hepatotoxicity, including fatal outcomes, have occurred in ADCETRIS-treated patients. Cases were consistent with hepatocellular injury, including elevations of transaminases and/or bilirubin, and occurred after the first ADCETRIS dose or rechallenge. Preexisting liver disease, elevated baseline liver enzymes, and concomitant medications may increase the risk. Monitor liver enzymes and bilirubin. Patients with new, worsening, or recurrent hepatotoxicity may require a delay, change in dose, or discontinuation of ADCETRIS.

- PML: JC virus infection resulting in PML and death has been reported in ADCETRIS-treated patients. First onset of symptoms occurred at various times from initiation of ADCETRIS, with some cases occurring within 3 months of initial exposure. Other possible contributory factors other than ADCETRIS include prior therapies and underlying disease that may cause immunosuppression.
 Consider PML diagnosis in patients with new-onset signs and symptoms of central nervous system abnormalities. Hold ADCETRIS if PML is suspected and discontinue ADCETRIS if PML is confirmed.
- Pulmonary toxicity: Noninfectious pulmonary toxicity events
 including pneumonitis, interstitial lung disease, and acute
 respiratory distress syndrome, some with fatal outcomes, have
 been reported. Monitor patients for signs and symptoms, including
 cough and dyspnea. In the event of new or worsening pulmonary
 symptoms, hold ADCETRIS dosing during evaluation and until
 symptomatic improvement.
- Serious dermatologic reactions: Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), including fatal outcomes, have been reported with ADCETRIS. If SJS or TEN occurs, discontinue ADCETRIS and administer appropriate medical therapy.
- Gastrointestinal (GI) complications: Acute pancreatitis, including fatal outcomes, has been reported. Other fatal and serious GI complications include perforation, hemorrhage, erosion, ulcer, intestinal obstruction, enterocolitis, neutropenic colitis, and ileus. Lymphoma with preexisting GI involvement may increase the risk of perforation. In the event of new or worsening GI symptoms, including severe abdominal pain, perform a prompt diagnostic evaluation and treat appropriately.
- Embryo-fetal toxicity: Based on the mechanism of action and animal studies, ADCETRIS can cause fetal harm. Advise females of reproductive potential of the potential risk to the fetus, and to avoid pregnancy during ADCETRIS treatment and for at least 6 months after the final dose of ADCETRIS.

Most Common (≥20%) Adverse Reactions

Peripheral sensory neuropathy, fatigue, nausea, diarrhea, neutropenia, upper respiratory tract infection, and pyrexia.

Drug Interactions

Concomitant use of strong CYP3A4 inhibitors or inducers, or P-gp inhibitors, has the potential to affect the exposure to monomethyl auristatin E (MMAE).

Use in Specific Populations

Moderate or severe hepatic impairment or severe renal impairment: MMAE exposure and adverse reactions are increased. Avoid use.

Advise males with female sexual partners of reproductive potential to use effective contraception during ADCETRIS treatment and for at least 6 months after the final dose of ADCETRIS. Advise patients to report pregnancy immediately and avoid breastfeeding while receiving ADCETRIS.

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