HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use ADCETRIS safely and effectively. See full prescribing information for ADCETRIS.

ADCETRIS® (brentuximab vedotin) for injection, for intravenous use
Initial U.S. approval: 2011

WARNING: PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY (PML)
See full prescribing information for complete boxed warning.

JC virus infection resulting in PML and death can occur in patients receiving ADCETRIS (5.9, 6.1).

----------RECENT MAJOR CHANGES ----------

Indications and Usage (1.2)	11/2022
Dosage and Administration (2.1, 2.2, 2.3, 2.4)	11/2022
Warnings and Precautions (5.1)	11/2022

----------INDICATIONS AND USAGE----------

ADCETRIS is a CD30-directed antibody-drug conjugate indicated for treatment of:

- Adult patients with previously untreated Stage III or IV classical Hodgkin lymphoma (cHL), in combination with doxorubicin, vinblastine, and dacarbazine (1.1).
- Pediatric patients 2 years and older with previously untreated high risk classical Hodgkin lymphoma (cHL), in combination with doxorubicin, vincristine, etoposide, prednisone, and cyclophosphamide (1.2).
- Adult patients with classical Hodgkin lymphoma (cHL) at high risk of relapse or progression as post-autologous hematopoietic stem cell transplantation (auto-HSCT) consolidation (1.3).
- Adult patients with classical Hodgkin lymphoma (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 (1.4).
- Adult patients with previously untreated systemic anaplastic large cell lymphoma (sALCL) or other CD30-expressing peripheral T-cell lymphomas (PTCL), including angioimmunoblastic T-cell lymphoma and PTCL not otherwise specified, in combination with cyclophosphamide, doxorubicin, and prednisone (1.5).
- Adult patients with systemic anaplastic large cell lymphoma (sALCL) after failure of at least one prior multi-agent chemotherapy regimen (1.6).
- Adult patients with primary cutaneous anaplastic large cell lymphoma (pcALCL) or CD30-expressing mycosis fungoides (MF) who have received prior systemic therapy (1.7).

---------- DOSAGE AND ADMINISTRATION ----------

- Administer only as an intravenous infusion over 30 minutes (2.1).
- The recommended dosage as monotherapy for adult patients is 1.8 mg/kg up to a maximum of 180 mg every 3 weeks (2.1).
- The recommended dosage in combination with chemotherapy for adult patients with previously untreated Stage III or IV cHL is 1.2 mg/kg up to a maximum of 120 mg every 2 weeks for a maximum of 12 doses (2.1).
- The recommended dosage in combination with chemotherapy for pediatric patients 2 years and older with previously untreated high risk cHL is 1.8 mg/kg up to a maximum of 180 mg every 3 weeks for a maximum of 5 doses (2.1)
- The recommended dosage in combination with chemotherapy for adult patients with previously untreated PTCL is 1.8 mg/kg up to a maximum of 180 mg every 3 weeks for 6 to 8 doses (2.1).
- Avoid use in patients with severe renal impairment (2.2)
- Reduce dose in patients with mild hepatic impairment; avoid use in patients with moderate or severe hepatic impairment (2.3).

----------DOSAGE FORMS AND STRENGTHS----------

For injection: 50 mg lyophilized powder in a single-dose vial (3).

----------CONTRAINDICATIONS----------

Concomitant use with bleomycin due to pulmonary toxicity (4).

----------WARNINGS AND PRECAUTIONS ----------

- Peripheral neuropathy: Monitor patients for neuropathy and institute dose modifications accordingly (5.1).
- Anaphylaxis and infusion reactions: If an infusion reaction occurs, interrupt the infusion. If anaphylaxis occurs, immediately discontinue the infusion (5.2).
- Hematologic toxicities: Monitor complete blood counts. Monitor for signs of infection. Manage using dose delays and growth factor support (5.3).
- Serious infections and opportunistic infections: Closely monitor patients for the emergence of bacterial, fungal or viral infections (5.4).
- Tumor lysis syndrome: Closely monitor patients with rapidly proliferating tumor or high tumor burden (5.5).
- Hepatotoxicity: Monitor liver enzymes and bilirubin (5.8).
- Pulmonary toxicity: Monitor patients for new or worsening symptoms (5.10).
- Serious dermatologic reactions: Discontinue if Stevens-Johnson syndrome or toxic epidermal necrolysis occurs (5.11).
- Gastrointestinal complications: Monitor patients for new or worsening symptoms (5.12).
- Hyperglycemia: Monitor patients for new or worsening hyperglycemia. Manage with anti-hyperglycemic medications as clinically indicated (5.13).
- Embryo-Fetal toxicity: Can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to avoid pregnancy (5.14).

----------ADVERSE REACTIONS ----------

The most common adverse reactions (≥20% in any study) are peripheral neuropathy, fatigue, nausea, diarrhea, neutropenia, upper respiratory tract infection, pyrexia, constipation, vomiting, alopecia, decreased weight, abdominal pain, anemia, stomatitis, lymphopenia, mucositis, thrombocytopenia, and febrile neutropenia (6.1).

To report SUSPECTED ADVERSE REACTIONS, contact Seagen Inc. at 1-855-473-2436 or FDA at 1-800-FDA-1088 or www.fda.gov/Safety/MedWatch.

---------- DRUG INTERACTIONS ----------

Concomitant use of strong CYP3A4 inhibitors or inducers has the potential to affect the exposure to monomethyl auristatin E (MMAE) (7.1).

----------USE IN SPECIFIC POPULATIONS----------

- Moderate or severe hepatic impairment or severe renal impairment: MMAE exposure and adverse reactions are increased (6, 7, 8.6, 8.7).
- Lactation: Advise women not to breastfeed (8.2).

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 11/2022

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

WARNING: PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY (PML)

JC virus infection resulting in PML and death can occur in patients receiving ADCETRIS *[see Warnings and Precautions (5.9), Adverse Reactions (6.1)]*.

1 INDICATIONS AND USAGE

1.1 Previously Untreated Stage III or IV classical Hodgkin Lymphoma (cHL), in Combination with Chemotherapy

ADCETRIS is indicated for the treatment of adult patients with previously untreated Stage III or IV cHL, in combination with doxorubicin, vinblastine, and dacarbazine.

1.2 Previously Untreated High Risk classical Hodgkin Lymphoma (cHL), in Combination with Chemotherapy

ADCETRIS is indicated for the treatment of pediatric patients 2 years and older with previously untreated high risk cHL, in combination with doxorubicin, vincristine, etoposide, prednisone, and cyclophosphamide.

1.3 Classical Hodgkin Lymphoma (cHL) Consolidation

ADCETRIS is indicated for the treatment of adult patients with cHL at high risk of relapse or progression as post-autologous hematopoietic stem cell transplantation (auto-HSCT) consolidation.

1.4 Relapsed classical Hodgkin Lymphoma (cHL)

ADCETRIS is indicated for the treatment of adult patients with 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.

1.5 Previously Untreated Systemic Anaplastic Large Cell Lymphoma (sALCL) or other CD30-expressing Peripheral T-cell Lymphomas (PTCL), in Combination with Chemotherapy

ADCETRIS is indicated for the treatment of adult patients with previously untreated sALCL or other CD30-expressing PTCL, including angioimmunoblastic T-cell lymphoma and PTCL not otherwise specified, in combination with cyclophosphamide, doxorubicin, and prednisone.

1.6 Relapsed Systemic Anaplastic Large Cell Lymphoma (sALCL)

ADCETRIS is indicated for the treatment of adult patients with sALCL after failure of at least one prior multi-agent chemotherapy regimen.

1.7 Relapsed Primary Cutaneous Anaplastic Large Cell Lymphoma (pcALCL) or CD30-expressing Mycosis Fungoides (MF)

ADCETRIS is indicated for the treatment of adult patients with pcALCL or CD30-expressing MF who have received prior systemic therapy.

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dosage

The recommended ADCETRIS dosage is provided in Table 1. Administer ADCETRIS as a 30-minute intravenous infusion.

For recommended dosage for patients with renal or hepatic impairment, see *Dosage and Administration (2.2 and 2.3)*.

For dosing instructions of combination agents administered with ADCETRIS, see *Clinical Studies (*14.1 *and 14.2)* and the manufacturer's prescribing information.

Table 1: Recommended ADCETRIS Dosage

Indication	Recommended Dose*	Frequency and Duration
Adult patients with previously Untreated Stage III or IV classical Hodgkin Lymphoma	1.2 mg/kg up to a maximum of 120 mg in combination with chemotherapy	Administer every 2 weeks until a maximum of 12 doses, disease progression, or unacceptable toxicity
Pediatric patients with previously untreated high risk classical Hodgkin Lymphoma	1.8 mg/kg up to a maximum of 180 mg in combination with chemotherapy	Administer every 3 weeks with each cycle of chemotherapy for a maximum of 5 doses
Adult patients with classical Hodgkin Lymphoma Consolidation	1.8 mg/kg up to a maximum of 180 mg	Initiate ADCETRIS treatment within 4-6 weeks post-auto-HSCT or upon recovery from auto-HSCT. Administer every 3 weeks until a maximum of 16 cycles, disease progression, or unacceptable toxicity
Adult patients with relapsed classical Hodgkin Lymphoma	1.8 mg/kg up to a maximum of 180 mg	Administer every 3 weeks until disease progression or unacceptable toxicity
Adult patients with previously Untreated Systemic ALCL or Other CD30-expressing Peripheral T-Cell Lymphomas	1.8 mg/kg up to a maximum of 180 mg in combination with chemotherapy	Administer every 3 weeks with each cycle of chemotherapy for 6 to 8 doses
Adult patients with relapsed Systemic ALCL	1.8 mg/kg up to a maximum of 180 mg	Administer every 3 weeks until disease progression or unacceptable toxicity
Adult patients with relapsed Primary Cutaneous ALCL or CD30-expressing Mycosis Fungoides	1.8 mg/kg up to a maximum of 180 mg	Administer every 3 weeks until a maximum of 16 cycles, disease progression, or unacceptable toxicity

* The dose for patients weighing greater than 100 kg should be calculated based on a weight of 100 kg

2.2 Recommended Dosage in Patients with Renal Impairment

No dosage adjustment is required for mild renal impairment (CrCL greater than 50-80 mL/min) and moderate renal impairment (CrCL 30-50 mL/min).

Avoid use in patients with severe (CrCL less than 30 mL/min) renal impairment *[see Warnings and Precautions (5.6)]*.

2.3 Recommended Dosage in Patients with Hepatic Impairment

Adult patients with previously Untreated Stage III or IV classical Hodgkin Lymphoma

Reduce the dosage of ADCETRIS to 0.9 mg/kg up to a maximum of 90 mg every 2 weeks for patients with mild hepatic impairment (Child-Pugh A).

Avoid use in patients with moderate (Child-Pugh B) and severe (Child-Pugh C) hepatic impairment *[see Warnings and Precautions (5.7)]*.

All other indications

Reduce the dosage of ADCETRIS to 1.2 mg/kg up to a maximum of 120 mg every 3 weeks for patients with mild hepatic impairment (Child-Pugh A).

Avoid use in patients with moderate (Child-Pugh B) and severe (Child-Pugh C) hepatic impairment *[see Warnings and Precautions (5.7)]*.

2.4 Recommended Prophylactic Medications

In adult patients with previously untreated Stage III or IV cHL who are treated with ADCETRIS + doxorubicin, vinblastine, and dacarbazine (AVD), administer G-CSF beginning with Cycle 1.

In pediatric patients with previously untreated high risk cHL who are treated with ADCETRIS + doxorubicin, vincristine, etoposide, prednisone, and cyclophosphamide (AVEPC), administer G-CSF beginning with Cycle 1.

In adult patients with previously untreated PTCL who are treated with ADCETRIS + cyclophosphamide, doxorubicin, and prednisone (CHP), administer G-CSF beginning with Cycle 1.

2.5 Dosage Modifications for Adverse Reactions

Table 2: Dosage Modifications for Peripheral Neuropathy or Neutropenia in Adult Patients

Recommended ADCETRIS Dosage from Table 1*	Monotherapy or Combination Therapy	Severity	Dosage Modification
Peripheral Neuropathy			
1.2 mg/kg up to a maximum of 120 mg every 2 weeks	In combination with chemotherapy	Grade 2	Reduce dose to 0.9 mg/kg up to a maximum of 90 mg every 2 weeks
		Grade 3	Hold ADCETRIS dosing until improvement to Grade 2 or lower Restart at 0.9 mg/kg up to a maximum of 90 mg every 2 weeks Consider modifying the dose of other neurotoxic chemotherapy agents
		Grade 4	Discontinue dosing
1.8 mg/kg up to a maximum of 180 mg every 3 weeks	As monotherapy	New or worsening Grade 2 or 3	Hold dosing until improvement to baseline or Grade 1 Restart at 1.2 mg/kg up to a maximum of 120 mg every 3 weeks
		Grade 4	Discontinue dosing
	In combination with chemotherapy	Grade 2	Sensory neuropathy: Continue treatment at same dose Motor neuropathy: Reduce dose to 1.2 mg/kg up to a maximum of 120 mg every 3 weeks
		Grade 3	Sensory neuropathy: Reduce dose to 1.2 mg/kg, up to a maximum of 120 mg every 3 weeks Motor neuropathy: Discontinue dosing
		Grade 4	Discontinue dosing
Neutropenia			
1.2 mg/kg up to a maximum of 120 mg every 2 weeks	In combination with chemotherapy	Grade 3 or 4	Administer G-CSF prophylaxis for subsequent cycles for patients not receiving primary G-CSF prophylaxis
1.8 mg/kg up to a maximum of 180 mg every 3 weeks	In combination with chemotherapy	Grade 3 or 4	Administer G-CSF prophylaxis in subsequent cycles for patients not receiving primary G-CSF

Recommended ADCETRIS Dosage from Table 1*	Monotherapy or Combination Therapy	Severity	Dosage Modification
1.8 mg/kg up to a maximum of 180 mg* every 3 weeks	As monotherapy	Grade 3 or 4	Hold dosing until improvement to baseline or Grade 2 or lower Consider G-CSF prophylaxis for subsequent cycles
		Recurrent Grade 4 despite G-CSF prophylaxis	Consider discontinuation or dose reduction to 1.2 mg/kg up to a maximum of 120 mg every 3 weeks

* The dose for patients weighing greater than 100 kg should be calculated based on a weight of 100 kg

Table 3: Dosage Modifications for Peripheral Neuropathy or Neutropenia in Pediatric Patients

Recommended ADCETRIS Dosage from Table 1*	Severity	Dosage Modification
Peripheral Neuropathy†		
1.8 mg/kg up to a maximum of 180 mg every 3 weeks	Grade 2†	Reduce dose of vincristine per prescribing information Continue dosing with ADCETRIS If neuropathy improves to Grade ≤1 by day 8 of next cycle, then resume vincristine at full dose
	Grade 3†	Discontinue vincristine <u>First Occurrence:</u> Hold ADCETRIS dosing until improvement to ≤ Grade 2 then restart at 1.2 mg/kg up to a maximum of 120 mg <u>Second Occurrence:</u> Hold until improvement to ≤ Grade 2 then restart at 0.8 mg/kg up to a maximum of 80 mg <u>Third Occurrence:</u> Discontinue ADCETRIS
	Grade 4†	Discontinue ADCETRIS and vincristine
Neutropenia		
1.8 mg/kg up to a maximum of 180 mg every 3 weeks	Grade 3 or 4	Reduce dose to 1.2 mg/kg up to a maximum of 120 mg every 3 weeks in patients who are unable to start a cycle > 5 weeks after the start of the previous cycle (> 2-week delay) due to neutropenia

* The dose for patients weighing greater than 100 kg should be calculated based on a weight of 100 kg
† Peripheral Neuropathy was assessed using the Balis scale

2.6 Instructions for Preparation and Administration

Administration

- Administer ADCETRIS as an intravenous infusion only.
- **Do not mix ADCETRIS with, or administer as an infusion with, other medicinal products.**

Reconstitution

- Follow procedures for proper handling and disposal of hazardous drugs *[see References (15)]*.
- Use appropriate aseptic technique for reconstitution and preparation of dosing solutions.
- Determine the number of 50 mg vials needed based on the patient's weight and the prescribed dose *[see Dosage and Administration (2.1)].*
- Reconstitute each 50 mg vial of ADCETRIS with 10.5 mL of Sterile Water for Injection, USP, to yield a single-dose solution containing 5 mg/mL brentuximab vedotin.
- Direct the stream toward the wall of vial and not directly at the cake or powder.
- Gently swirl the vial to aid dissolution. **DO NOT SHAKE**.
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. The reconstituted solution should be clear to slightly opalescent, colorless, and free of visible particulates.
- Following reconstitution, dilute immediately into an infusion bag. If not diluted immediately, store the solution at 2° to 8°C (36° to46°F) and use within 24 hours of reconstitution. **DO NOT FREEZE.**
- Discard any unused portion left in the vial.

Dilution

- Calculate the required volume of 5 mg/mL reconstituted ADCETRIS solution needed.
- Withdraw this amount from the vial and immediately add it to an infusion bag containing 0.9% Sodium Chloride Injection, USP, 5% Dextrose Injection, USP or Lactated Ringer's Injection, USP to achieve a final concentration of 0.4 mg/mL to 1.8 mg/mL brentuximab vedotin.
- Gently invert the bag to mix the solution.
- Following dilution, infuse the ADCETRIS solution immediately. If not used immediately, store the solution at 2° to 8°C (36° to 46°F) and use within 24 hours of reconstitution. **DO NOT FREEZE.**

3 DOSAGE FORMS AND STRENGTHS

For injection: 50 mg of brentuximab vedotin as a sterile, white to off-white lyophilized, preservative-free cake or powder in a single-dose vial for reconstitution.

4 CONTRAINDICATIONS

ADCETRIS is contraindicated with concomitant bleomycin due to pulmonary toxicity (e.g., interstitial infiltration and/or inflammation) *[see Adverse Reactions (6.1)]*.

prior therapy. Fifty-eight (58) patients were treated with 1.8 mg/kg of ADCETRIS administered intravenously over 30 minutes every 3 weeks. An IRF performed efficacy evaluations which included overall response rate (ORR = complete response [CR] + partial response [PR]) and duration of response as defined by clinical and radiographic measures including computed tomography (CT) and positron-emission tomography (PET) as defined in the 2007 Revised Response Criteria for Malignant Lymphoma (modified).

The 58 patients ranged in age from 14–76 years (median, 52 years) and most were male (57%) and white (83%). Patients had received a median of 2 prior therapies; 26% of patients had received prior autologous hematopoietic stem cell transplantation. Fifty percent (50%) of patients were relapsed, and 50% of patients were refractory to their most recent prior therapy. Seventy-two percent (72%) were anaplastic lymphoma kinase (ALK)-negative.

The efficacy results are summarized in Table 16. Duration of response is calculated from date of first response to date of progression or data cutoff date.

Table 16: Efficacy Results in Patients with Systemic Anaplastic Large Cell Lymphoma (Study 2)

	N = 58		
		Duration of Response, in months	
	Percent (95% CI)	Median (95% CI)	Range
CR	57 (44, 70)	13.2 (10.8, NE*)	0.7 to 15.9+
PR	29 (18, 41)	2.1 (1.3, 5.7)	0.1 to 15.8+
ORR	86 (77, 95)	12.6 (5.7, NE*)	0.1 to 15.9+

*Not estimable

+ Follow up was ongoing at the time of data submission

14.4 Primary Cutaneous Anaplastic Large Cell Lymphoma and CD30-Expressing Mycosis Fungoides

Randomized Clinical Trial in Primary Cutaneous Anaplastic Large Cell Lymphoma and CD30-expressing Mycosis Fungoides (Study 4: ALCANZA, NCT01578499)

The efficacy of ADCETRIS in patients with primary cutaneous anaplastic large cell lymphoma (pcALCL) or mycosis fungoides (MF) requiring systemic therapy was studied in ALCANZA, a randomized, open-label, multicenter clinical trial. In ALCANZA, one hundred thirty-one (131) patients were randomized 1:1 to receive ADCETRIS 1.8 mg/kg intravenously over 30 minutes every 3 weeks or physician's choice of methotrexate (5 to 50 mg orally weekly) or bexarotene (300 mg/m^2 orally daily). The randomization was stratified by baseline disease diagnosis (MF or pcALCL). Patients could receive a maximum of 16 cycles (21-day cycle) of therapy every 3 weeks for those receiving brentuximab vedotin or 48 weeks of therapy for those in the control arm.

Patients with pcALCL must have received prior radiation or systemic therapy, and must have at least 1 biopsy with CD30-expression of ≥10%. Patients with MF must have received prior systemic therapy and have had skin biopsies from at least 2 separate lesions, with CD30-expression of ≥10% in at least 1 biopsy.

A total of 131 patients were randomized (66 ADCETRIS, 65 physician's choice). The efficacy results were based on 128 patients (64 patients in each arm with CD30-expression of ≥10% in at least one biopsy). Among 128 patients, the patients' age ranged from 22–83 years (median, 60 years), and 55% of them were male and 85% of them were white. Patients had received a median of 4 prior therapies (range, 0–15), including a median of 1 prior skin-directed therapy (range, 0–9) and 2 systemic therapies (range, 0–11). At study entry, patients were diagnosed as Stage 1 (25%), Stage 2 (38%), Stage 3 (5%), or Stage 4 (13%).

Efficacy was established based on the proportion of patients achieving an objective response (CR+PR) that lasts at least 4 months (ORR4). ORR4 was determined by independent review facility (IRF) using the global response score (GRS), consisting of skin evaluations per modified severity-weighted assessment tool (mSWAT), nodal and visceral radiographic assessment, and detection of circulating Sézary cells (MF patients only). Additional efficacy outcome measures included proportion of patients achieving a complete response (CR) per IRF, and progression-free survival (PFS) per IRF.

The efficacy results are summarized in Table 17 below and the Kaplan-Meier curves of IRF-assessed PFS are shown in Figure 6.

Table 17: Efficacy Results in Patients with Relapsed pcALCL or CD30-expressing MF (Study 4: ALCANZA)

	ADCETRIS N = 64	**Physician's Choice[a] N = 64**
ORR4[b]		
Percent (95% CI[c])	56.3 (44.1, 68.4)	12.5 (4.4, 20.6)
P-value[d]	<0.001	
ORR	67.2 (55.7, 78.7)	20.3 (10.5, 30.2)
CR		
Percent (95% CI[c])	15.6 (7.8, 26.9)	1.6 (0, 8.4)
P-value[d,e]	0.0066	
PR	51.6 (39.3, 63.8)	18.8 (9.2, 28.3)
PFS		
Number of events (%)	36 (56.3)	50 (78.1)
Median months (95% CI[c])	16.7 (14.9, 22.8)	3.5 (2.4, 4.6)
Hazard Ratio (95% CI[c])	0.27 (0.17, 0.43)	
Log-Rank Test P-value[d,e]	<0.001	

[a] Physician's choice of either methotrexate or bexarotene

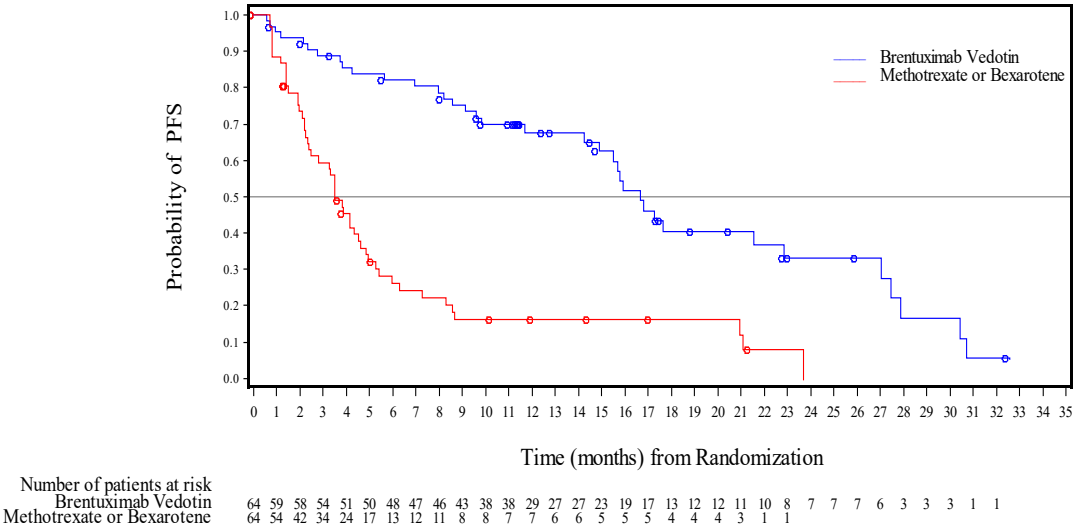
[b] ORR4 is defined as proportion of patients achieving an objective response (CR+PR) that lasts at least 4 months

[c] CI=Confidence Interval

[d] Test of the treatment difference was stratified by baseline disease diagnosis (MF or pcALCL)

[e] Adjusted for multiplicity

Figure 6: Kaplan-Meier Curve of Progression-free Survival (Study 4: ALCANZA)



Supportive trials include 2 single-arm trials, which enrolled patients with MF who were treated with ADCETRIS 1.8 mg/kg intravenously over 30 minutes every 3 weeks. Out of 73 patients with MF from the 2 pooled supportive trials, 34% (25/73) achieved ORR4. Among these 73 patients, 35 had 1% to 9% CD30-expression and 31% (11/35) achieved ORR4.

15 REFERENCES

1. OSHA Hazardous Drugs. *OSHA*. [Accessed on 30 July 2013, from http://www.osha.gov/SLTC/hazardousdrugs/index.html]

16 HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

ADCETRIS (brentuximab vedotin) for Injection is supplied as a sterile, white to off-white preservative-free lyophilized cake or powder in individually-boxed single-dose vials:

- NDC (51144-050-01), 50 mg brentuximab vedotin.

Storage

Store vial at 2° to 8°C (36° to 46°F) in the original carton to protect from light.

Special Handling

ADCETRIS is a hazardous product. Follow special handling and disposal procedures[1].

17 PATIENT COUNSELING INFORMATION

Peripheral Neuropathy

Advise patients that ADCETRIS can cause a peripheral neuropathy. They should be advised to report to their health care provider any numbness or tingling of the hands or feet or any muscle weakness *[see Warnings and Precautions (5.1)]*.

Fever/Neutropenia

Advise patients to contact their health care provider if a fever of 100.5°F or greater or other evidence of potential infection such as chills, cough, or pain on urination develops *[see Warnings and Precautions (5.3)]*.

Infusion Reactions

Advise patients to contact their health care provider if they experience signs and symptoms of infusion reactions including fever, chills, rash, or breathing problems within 24 hours of infusion *[see Warnings and Precautions (5.2)]*.

Hepatotoxicity

Advise patients to report symptoms that may indicate liver injury, including fatigue, anorexia, right upper abdominal discomfort, dark urine, or jaundice *[see Warnings and Precautions (5.8)]*.

Progressive Multifocal Leukoencephalopathy

Instruct patients receiving ADCETRIS to immediately report if they have any of the following neurological, cognitive, or behavioral signs and symptoms or if anyone close to them notices these signs and symptoms *[see Boxed Warning, Warnings and Precautions (5.9)]*:

- changes in mood or usual behavior
- confusion, thinking problems, loss of memory
- changes in vision, speech, or walking
- decreased strength or weakness on one side of the body

Pulmonary Toxicity

Instruct patients to report symptoms that may indicate pulmonary toxicity, including cough or shortness of breath *[see Warnings and Precautions (5.10)]*.

Acute Pancreatitis

Advise patients to contact their health care provider if they develop severe abdominal pain *[see Warnings and Precautions (5.12)]*.

Gastrointestinal Complications

Advise patients to contact their health care provider if they develop severe abdominal pain, chills, fever, nausea, vomiting, or diarrhea *[see Warnings and Precautions (5.12)]*.

Hyperglycemia

Educate patients about the risk of hyperglycemia and how to recognize associated symptoms *[see Warnings and Precautions (5.13)]*.

Females and Males of Reproductive Potential

ADCETRIS can cause fetal harm. Advise women receiving ADCETRIS to avoid pregnancy during ADCETRIS treatment and for 6 months after the last dose of ADCETRIS.

Advise males with female sexual partners of reproductive potential to use effective contraception during ADCETRIS treatment and for 6 months after the last dose of ADCETRIS *[see Use in Specific Populations (8.3)]*.

Advise patients to report pregnancy immediately *[see Warnings and Precautions (5.14)]*.

Lactation

Advise patients to avoid breastfeeding while receiving ADCETRIS *[see Use in Specific Populations (8.2)]*.

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