FDA UPDATE

FDA REMOVES LIMITATIONS OF USE IN PATIENTS WITH PRIMARY CENTRAL NERVOUS SYSTEM LYMPHOMA (PCNSL) FOR YESCARTA®

See safety data inside and contact your Kite Representative for more information.

FDA=US Food and Drug Administration.

INDICATIONS

YESCARTA® is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of:

- Adult patients with large B-cell lymphoma that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy.
- Adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma.

IMPORTANT SAFETY INFORMATION

WARNING: CYTOKINE RELEASE SYNDROME, NEUROLOGIC TOXICITIES, and SECONDARY HEMATOLOGICAL MALIGNANCIES

- **Cytokine Release Syndrome (CRS), including fatal or life-threatening reactions, occurred in patients receiving YESCARTA. Do not administer YESCARTA to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab or tocilizumab and corticosteroids.**
- **Neurologic toxicities, including fatal or life-threatening reactions, occurred in patients receiving YESCARTA, including concurrently with CRS or after CRS resolution. Monitor for neurologic toxicities after treatment with YESCARTA. Provide supportive care and/or corticosteroids as needed.**
- **T cell malignancies have occurred following treatment of hematologic malignancies with BCMA- and CD19-directed genetically modified autologous T cell immunotherapies, including YESCARTA.**

Please see full **Prescribing Information**, including **BOXED WARNING** and Medication Guide.

YESCARTA® safety evaluated in patients with PCNSL[1*]

PCNSL: A challenging and complex disease that leaves patients with few treatment options[2,3]

- A rare yet aggressive form of NHL (~1% of all cases) that is confined to the CNS; the most common histological subtype is DLBCL
- Patients face poor prognosis and high rates of relapse and refractory disease
- Historically, patients with CNS involvement have had limited treatment options
- Treatment is particularly challenging due to the blood–brain barrier, which limits the effectiveness of many systemic therapies to the CNS

Up until now, all LBCL CAR T therapies carried FDA limitations of use excluding or cautioning use in this population due to concerns around neurotoxicity and limited safety data

YESCARTA is the first and only LBCL CAR T therapy to have the PCNSL limitations of use removed[1]

- Limitation removal is based on ongoing safety evaluations demonstrating manageable neurotoxicity
- Highlights the role of YESCARTA in addressing the significant unmet need in PCNSL

*The safety of YESCARTA was evaluated in a single-arm, single-center, open-label study which included 13 patients with relapsed or refractory PCNSL. Patients with a history or presence of non-malignant CNS disorders or autoimmune disease requiring systemic immunosuppression were ineligible.

CAR T=chimeric antigen receptor T cell; CNS=central nervous system; LBCL=large B-cell lymphoma; NHL=non-Hodgkin lymphoma; PCNSL=primary central nervous system lymphoma.

IMPORTANT SAFETY INFORMATION (Cont'd)

CYTOKINE RELEASE SYNDROME (CRS)

CRS, including fatal or life-threatening reactions, occurred following treatment with YESCARTA. CRS occurred in 90% (379/422) of patients with non-Hodgkin lymphoma (NHL), including ≥ Grade 3 CRS in 9%. CRS occurred in 93% (256/276) of patients with large B-cell lymphoma (LBCL), including ≥ Grade 3 in 9%. Among patients with LBCL who died after receiving YESCARTA, 4 had ongoing CRS events at the time of death. For patients with LBCL in Study 2, the median time to onset of CRS was 2 days following infusion (range: 1-12 days) and the median duration was 7 days (range: 2-58 days). For patients with LBCL in Study 1, the median time to onset of CRS was 3 days following infusion (range: 1-10 days) and the median duration was 7 days (range: 2-43 days).

CRS occurred in 84% (123/146) of patients with indolent non-Hodgkin lymphoma (iNHL) in Study 3, including ≥ Grade 3 CRS in 8%. Among patients with iNHL who died after receiving YESCARTA, 1 patient had an ongoing CRS event at the time of death. The median time to onset of CRS was 4 days (range: 1-20 days) and median duration was 6 days (range: 1-27 days) for patients with iNHL.

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YESCARTA® safety evaluated in patients with PCNSL[1*]

Investigator-Sponsored Study in PCNSL

Cytokine release syndrome (N=13)[1]	
85% OVERALL INCIDENCE (n=11/13)	**0%** GRADE ≥3 INCIDENCE

Neurologic toxicities (N=13)[1]	
85% OVERALL INCIDENCE (n=11/13)	**31%** GRADE ≥3 INCIDENCE (n=4/13)

- Most cases of CRS and NTs were low grade (Grade 1-2); no Grade ≥3 CRS and no Grade 4-5 NTs
- Median time to onset and resolution of NT (range, days)
  - Onset: 3 days (1-9); duration: 59 days (52-87)
- 45% (5/11) of patients had ongoing neurological toxicities at the time of study withdrawal, death, or data cut off

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CRS=cytokine release syndrome; NT=neurologic toxicities.

IMPORTANT SAFETY INFORMATION (Cont'd)

CYTOKINE RELEASE SYNDROME (CRS) (Cont'd)

Key manifestations of CRS (≥ 10%) in all patients combined included fever (85%), hypotension (40%), tachycardia (32%), chills (22%), hypoxia (20%), headache (15%), and fatigue (12%). Serious events that may be associated with CRS include, cardiac arrhythmias (including atrial fibrillation and ventricular tachycardia), renal insufficiency, cardiac failure, respiratory failure, cardiac arrest, capillary leak syndrome, multi-organ failure, and hemophagocytic lymphohistiocytosis/macrophage activation syndrome (HLH/MAS).

The impact of tocilizumab and/or corticosteroids on the incidence and severity of CRS was assessed in 2 subsequent cohorts of LBCL patients in Study 2. Among patients who received tocilizumab and/or corticosteroids for ongoing Grade 1 events, CRS occurred in 93% (38/41), including 2% (1/41) with Grade 3 CRS; no patients experienced a Grade 4 or 5 event. The median time to onset of CRS was 2 days (range: 1-8 days) and the median duration of CRS was 7 days (range: 2-16 days). Prophylactic treatment with corticosteroids was administered to a cohort of 39 patients for 3 days beginning on the day of infusion of YESCARTA. Thirty-one of the 39 patients (79%) developed CRS and were managed with tocilizumab and/or therapeutic doses of corticosteroids with no patients developing ≥ Grade 3 CRS. The median time to onset of CRS was 5 days (range: 1-15 days) and the median duration of CRS was 4 days (range: 1-10 days). Although there is no known mechanistic explanation, consider the risk and benefits of prophylactic corticosteroids in the context of pre-existing comorbidities for the individual patient and the potential for the risk of Grade 4 and prolonged neurologic toxicities.

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Adverse reactions observed in ≥10% patients with relapsed or refractory PCNSL (N=13)

ADVERSE REACTIONS	All Grades n (%)	Grade 3 or 4 n (%)
Cardiac Disorders		
Sinus tachycardia	12 (92)	0 (0)
Arrhythmia*	2 (15)	0 (0)
Eye Disorders		
Visual impairment	2 (15)	0 (0)
Gastrointestinal Disorders		
Diarrhea	7 (54)	0 (0)
Vomiting	7 (54)	0 (0)
Nausea	5 (38)	1 (8)
Constipation	5 (38)	0 (0)
Dry mouth	3 (23)	0 (0)

ADVERSE REACTIONS	All Grades n (%)	Grade 3 or 4 n (%)
General Disorders and Administration Site Conditions		
Pyrexia	11 (85)	1 (8)
Chills	7 (54)	0 (0)
Fatigue	7 (54)	0 (0)
Gait disturbance	4 (31)	1 (8)
Edema*	3 (23)	0 (0)
Immune System Disorders		
Cytokine Release Syndrome	11 (85)	0 (0)
Investigations		
Weight decreased	4 (31)	0 (0)
Musculoskeletal and Connective Tissue Disorders		
Musculoskeletal pain[a]	7 (54)	0 (0)
Muscular weakness	5 (38)	1 (8)

*Represents a composite of multiple, related preferred terms.
[a]Musculoskeletal pain also includes Arthralgia.

IMPORTANT SAFETY INFORMATION (Cont'd)

CYTOKINE RELEASE SYNDROME (CRS) (Cont'd)

Confirm that 2 doses of tocilizumab are available prior to infusion of YESCARTA. Monitor patients at least daily for 7 days following infusion for signs and symptoms of CRS. Monitor patients for signs or symptoms of CRS for 2 weeks after infusion. Counsel patients to seek immediate medical attention should signs or symptoms of CRS occur at any time. At the first sign of CRS, institute treatment with supportive care, tocilizumab, or tocilizumab and corticosteroids as indicated.

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Adverse reactions observed in ≥10% patients with relapsed or refractory PCNSL (N=13)

ADVERSE REACTIONS	All Grades n (%)	Grade 3 or 4 n (%)
Nervous System Disorders		
Headache	11 (85)	1 (8)
Encephalopathy[b]	9 (69)	2 (15)
Dizziness	5 (38)	0 (0)
Tremor	4 (31)	1 (8)
Hemiparesis	3 (23)	0 (0)
Seizure	2 (15)	2 (15)
Hypersomnia	2 (15)	0 (0)
Psychiatric Disorders		
Insomnia	4 (31)	0 (0)
Delirium[c]	3 (23)	0 (0)
Affective disorder[d]	2 (15)	0 (0)

ADVERSE REACTIONS	All Grades n (%)	Grade 3 or 4 n (%)
Renal and Urinary Disorders		
Acute kidney injury	2 (15)	0 (0)
Respiratory, Thoracic and Mediastinal Disorders		
Hypoxia	7 (54)	1 (8)
Cough	6 (46)	0 (0)
Dyspnea	4 (31)	0 (0)
Nasal congestion	3 (23)	0 (0)
Skin and Subcutaneous Tissue Disorders		
Rash maculo-papular	7 (54)	0 (0)
Vascular Disorders		
Hypotension*	8 (62)	3 (23)
Thrombosis[e]	5 (38)	1 (8)

*Represents a composite of multiple, related preferred terms.
[b]Encephalopathy includes Amnesia, Confusional state, Disturbance in attention, Dysarthria, Lethargy, Somnolence.
[c]Delirium includes Agitation, Irritability.
[d]Affective disorder incudes Anxiety, Depression.
[e]Thrombosis includes Deep vein thrombosis, Embolism.

IMPORTANT SAFETY INFORMATION (Cont'd)

NEUROLOGIC TOXICITIES

Neurologic toxicities including immune effector cell-associated neurotoxicity syndrome (ICANS) that were fatal or life-threatening occurred following treatment with YESCARTA. Neurologic toxicities occurred in 78% (330/422) of patients with NHL (excluding central nervous system lymphoma) receiving YESCARTA, including ≥ Grade 3 in 25% in Study 1, Study 2, and Study 3.

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IMPORTANT SAFETY INFORMATION

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WARNING: CYTOKINE RELEASE SYNDROME, NEUROLOGIC TOXICITIES, and SECONDARY HEMATOLOGICAL MALIGNANCIES

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- **Neurologic toxicities, including fatal or life-threatening reactions, occurred in patients receiving YESCARTA, including concurrently with CRS or after CRS resolution. Monitor for neurologic toxicities after treatment with YESCARTA. Provide supportive care and/or corticosteroids as needed.**
- **T cell malignancies have occurred following treatment of hematologic malignancies with BCMA- and CD19-directed genetically modified autologous T cell immunotherapies, including YESCARTA.**

CYTOKINE RELEASE SYNDROME (CRS)

CRS, including fatal or life-threatening reactions, occurred following treatment with YESCARTA. CRS occurred in 90% (379/422) of patients with non-Hodgkin lymphoma (NHL), including ≥ Grade 3 CRS in 9%. CRS occurred in 93% (256/276) of patients with large B-cell lymphoma (LBCL), including ≥ Grade 3 in 9%. Among patients with LBCL who died after receiving YESCARTA, 4 had ongoing CRS events at the time of death. For patients with LBCL in Study 2, the median time to onset of CRS was 2 days following infusion (range: 1-12 days) and the median duration was 7 days (range: 2-58 days). For patients with LBCL in Study 1, the median time to onset of CRS was 3 days following infusion (range: 1-10 days) and the median duration was 7 days (range: 2-43 days).

CRS occurred in 84% (123/146) of patients with indolent non-Hodgkin lymphoma (iNHL) in Study 3, including ≥ Grade 3 CRS in 8%. Among patients with iNHL who died after receiving YESCARTA, 1 patient had an ongoing CRS event at the time of death. The median time to onset of CRS was 4 days (range: 1-20 days) and median duration was 6 days (range: 1-27 days) for patients with iNHL.

Key manifestations of CRS (≥ 10%) in all patients combined included fever (85%), hypotension (40%), tachycardia (32%), chills (22%), hypoxia (20%), headache (15%), and fatigue (12%). Serious events that may be associated with CRS include, cardiac arrhythmias (including atrial fibrillation and ventricular tachycardia), renal insufficiency, cardiac failure, respiratory failure, cardiac arrest, capillary leak syndrome, multi-organ failure, and hemophagocytic lymphohistiocytosis/macrophage activation syndrome (HLH/MAS).

The impact of tocilizumab and/or corticosteroids on the incidence and severity of CRS was assessed in 2 subsequent cohorts of LBCL patients in Study 2. Among patients who received tocilizumab and/or corticosteroids for ongoing Grade 1 events, CRS occurred in 93% (38/41), including 2% (1/41) with Grade 3 CRS; no patients experienced a Grade 4 or 5 event. The median time to onset of CRS was 2 days (range: 1-8 days)

CYTOKINE RELEASE SYNDROME (CRS) (Cont'd)

and the median duration of CRS was 7 days (range: 2-16 days). Prophylactic treatment with corticosteroids was administered to a cohort of 39 patients for 3 days beginning on the day of infusion of YESCARTA. Thirty-one of the 39 patients (79%) developed CRS and were managed with tocilizumab and/or therapeutic doses of corticosteroids with no patients developing ≥ Grade 3 CRS. The median time to onset of CRS was 5 days (range: 1-15 days) and the median duration of CRS was 4 days (range: 1-10 days). Although there is no known mechanistic explanation, consider the risk and benefits of prophylactic corticosteroids in the context of pre-existing comorbidities for the individual patient and the potential for the risk of Grade 4 and prolonged neurologic toxicities.

Confirm that 2 doses of tocilizumab are available prior to infusion of YESCARTA. Monitor patients at least daily for 7 days following infusion for signs and symptoms of CRS. Monitor patients for signs or symptoms of CRS for 2 weeks after infusion. Counsel patients to seek immediate medical attention should signs or symptoms of CRS occur at any time. At the first sign of CRS, institute treatment with supportive care, tocilizumab, or tocilizumab and corticosteroids as indicated.

NEUROLOGIC TOXICITIES

Neurologic toxicities including immune effector cell-associated neurotoxicity syndrome (ICANS) that were fatal or life-threatening occurred following treatment with YESCARTA. Neurologic toxicities occurred in 78% (330/422) of patients with NHL (excluding central nervous system lymphoma) receiving YESCARTA, including ≥ Grade 3 in 25% in Study 1, Study 2, and Study 3.

Neurologic toxicities occurred in 87% (94/108) of patients with LBCL in Study 2, including ≥ Grade 3 in 31% and in 74% (124/168) of patients in Study 1 including ≥ Grade 3 in 25%. The median time to onset was 4 days (range: 1-43 days) and the median duration was 17 days for patients with LBCL in Study 2. The median time to onset for neurologic toxicity was 5 days (range: 1-133 days) and median duration was 15 days in patients with LBCL in Study 1. Neurologic toxicities occurred in 77% (112/146) of patients with iNHL, including ≥ Grade 3 in 21%. The median time to onset was 6 days (range: 1-79 days) and the median duration was 16 days. Ninety-eight percent of all neurologic toxicities in patients with LBCL and 99% of all neurologic toxicities in patients with iNHL occurred within the first 8 weeks of YESCARTA infusion. Neurologic toxicities occurred within the first 7 days of infusion in 87% of affected patients with LBCL and 74% of affected patients with iNHL.

The most common neurologic toxicities (≥ 10%) in all patients combined included encephalopathy (50%), headache (43%), tremor (29%), dizziness (21%), aphasia (17%), delirium (15%), and insomnia (10%). Prolonged encephalopathy lasting up to 173 days was noted. Serious events, including aphasia, leukoencephalopathy, dysarthria, lethargy, and seizures occurred. Fatal and serious cases of cerebral edema and encephalopathy, including late-onset encephalopathy, have occurred.

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IMPORTANT SAFETY INFORMATION

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NEUROLOGIC TOXICITIES (Cont'd)

The impact of tocilizumab and/or corticosteroids on the incidence and severity of neurologic toxicities was assessed in 2 subsequent cohorts of LBCL patients in Study 2. Among patients who received corticosteroids at the onset of Grade 1 toxicities, neurologic toxicities occurred in 78% (32/41) and 20% (8/41) had Grade 3 neurologic toxicities; no patients experienced a Grade 4 or 5 event. The median time to onset of neurologic toxicities was 6 days (range: 1-93 days) with a median duration of 8 days (range: 1-144 days). Prophylactic treatment with corticosteroids was administered to a cohort of 39 patients for 3 days beginning on the day of infusion of YESCARTA. Of those patients, 85% (33/39) developed neurologic toxicities; 8% (3/39) developed Grade 3 and 5% (2/39) developed Grade 4 neurologic toxicities. The median time to onset of neurologic toxicities was 6 days (range: 1-274 days) with a median duration of 12 days (range: 1-107 days). Prophylactic corticosteroids for management of CRS and neurologic toxicities may result in higher grade of neurologic toxicities or prolongation of neurologic toxicities, delay the onset, and decrease the duration of CRS.

Neurologic toxicities occurred in 85% (11/13) of patients with relapsed/refractory primary central nervous system lymphoma (PCNSL) in Study 4. 31% (4/13) of patients had Grade 3 neurologic toxicities. The median time to onset of neurologic toxicities was 3 days (range: 1 to 9 days) and the median time to onset of first Grade ≥ 3 neurologic toxicity was 9.5 days (range: 5 to 158 days). The median duration of neurologic toxicities was 59 days (range: 52 to 87 days) while 45% (5/11) of patients had ongoing neurological toxicities at the time of study withdrawal, death, or data cut off. The most common neurologic toxicities (≥ 10%) in patients with PCNSL included confusional state (38%), headache (31%), somnolence (31%), disturbance in attention (23%), lethargy (23%), tremor (23%), gait disturbance (15%), hypersomnia (15%), insomnia (15%), and seizures (15%).

Monitor patients for signs and symptoms of neurologic toxicities following infusion at least daily for 7 days; and for 2 weeks thereafter and treat promptly. Advise patients to avoid driving for at least 2 weeks following infusion.

HYPERSENSITIVITY REACTIONS

Allergic reactions may occur with the infusion of YESCARTA. Serious hypersensitivity reactions, including anaphylaxis, may be due to dimethyl sulfoxide (DMSO) or residual gentamicin in YESCARTA.

SERIOUS INFECTIONS

Severe or life-threatening infections occurred after YESCARTA infusion. Infections (all grades) occurred in 45% of patients with NHL. Grade 3 or higher infections occurred in 17% of patients, including ≥ Grade 3 infections with an unspecified pathogen in 12%, bacterial infections in 5%, viral infections in 3%, and fungal infections in 1%. YESCARTA should not be administered to patients with clinically significant active systemic infections. Monitor patients for signs and symptoms of infection before and after infusion and treat appropriately. Administer prophylactic antimicrobials according to local guidelines.

SERIOUS INFECTIONS (Cont'd)

Febrile neutropenia was observed in 36% of patients with NHL and may be concurrent with CRS. In the event of febrile neutropenia, evaluate for infection and manage with broad-spectrum antibiotics, fluids, and other supportive care as medically indicated.

In immunosuppressed patients, including those who have received YESCARTA, life-threatening and fatal opportunistic infections including disseminated fungal infections (e.g., candida sepsis and aspergillus infections) and viral reactivation (e.g., human herpes virus-6 [HHV-6] encephalitis and JC virus progressive multifocal leukoencephalopathy [PML]) have been reported. The possibility of HHV-6 encephalitis and PML should be considered in immunosuppressed patients with neurologic events and appropriate diagnostic evaluations should be performed.

Hepatitis B virus (HBV) reactivation, in some cases resulting in fulminant hepatitis, hepatic failure, and death, has occurred in patients treated with drugs directed against B cells, including YESCARTA. Perform screening for HBV, HCV, and HIV and management in accordance with clinical guidelines before collection of cells for manufacturing.

PROLONGED CYTOPENIAS

Patients may exhibit cytopenias for several weeks following lymphodepleting chemotherapy and YESCARTA infusion. Grade 3 or higher cytopenias not resolved by Day 30 following YESCARTA infusion occurred in 39% of all patients with NHL and included neutropenia (33%), thrombocytopenia (13%), and anemia (8%). Monitor blood counts after infusion.

HYPOGAMMAGLOBULINEMIA

B-cell aplasia and hypogammaglobulinemia can occur in patients receiving YESCARTA. Hypogammaglobulinemia was reported as an adverse reaction in 14% of all patients with NHL. Monitor immunoglobulin levels after treatment and manage using infection precautions, antibiotic prophylaxis, and immunoglobulin replacement.

The safety of immunization with live viral vaccines during or following YESCARTA treatment has not been studied. Vaccination with live virus vaccines is not recommended for at least 6 weeks prior to the start of lymphodepleting chemotherapy, during YESCARTA treatment, and until immune recovery following treatment.

SECONDARY MALIGNANCIES

Patients treated with YESCARTA may develop secondary malignancies. T cell malignancies have occurred following treatment of hematologic malignancies with BCMA- and CD19-directed genetically modified autologous T cell immunotherapies, including YESCARTA. Mature T cell malignancies, including CAR-positive tumors, may present as soon as weeks following infusion, and may include fatal outcomes.

Monitor life-long for secondary malignancies. In the event that a secondary malignancy occurs, contact Kite at 1-844-454-KITE (5483) to obtain instructions on patient samples to collect for testing.

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IMPORTANT SAFETY INFORMATION

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ADVERSE REACTIONS

The most common adverse reactions (incidence ≥ 30%) in:

- patients with LBCL in Study 1 included fever, CRS, fatigue, hypotension, encephalopathy, tachycardia, diarrhea, headache, musculoskeletal pain, nausea, and febrile neutropenia.
- patients with LBCL in Study 2 included CRS, fever, hypotension, encephalopathy, tachycardia, fatigue, headache, decreased appetite, chills, diarrhea, febrile neutropenia, nausea, hypoxia, tremor, and cough.
- patients with PCNSL in Study 4 included sinus tachycardia, CRS, pyrexia, headache, encephalopathy, hypotension, diarrhea, vomiting, chills, fatigue, musculoskeletal pain, hypoxia, rash maculo-papular, cough, nausea, constipation, musculoskeletal weakness, dizziness, thrombosis, gait disturbance, weight decreased, tremor, insomnia, and dyspnea.

The most common (≥30%) Grade 3-4 laboratory abnormalities in:

- patients with LBCL in Study 1 included leukocyte decrease, neutrophil decrease, lymphocyte decrease, and hemoglobin decrease.
- patients with LBCL in Study 2 included lymphocyte decrease, leukocyte decrease, neutrophil decrease, hemoglobin decrease, platelet decrease, and phosphate decrease.

References: 1. YESCARTA® (axicabtagene ciloleucel). Prescribing information. Kite Pharma, Inc; 2026. **2.** Roschewski M, Hodson DJ. Diffuse large B-cell lymphoma involving the central nervous system: biologic rationale for targeted therapy. *Haematologica*. 2024;109(2):388-400. doi:10.3324/haematol.2021.278613 **3.** Tang D, Chen Y, Shi Y, et al. Epidemiologic characteristics, prognostic factors, and treatment outcomes in primary central nervous system lymphoma: a SEER-based study. *Front Oncol*. 2022;12:817043. doi:10.3389/fonc.2022.817043

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