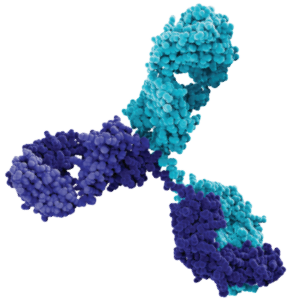


DOSING AND ADMINISTRATION GUIDE

THE **FIRST-AND-ONLY SUBCUTANEOUS** BISPECIFIC ANTIBODY IN DLBCL[1]

INDICATION

EPKINLY is indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified (NOS), including DLBCL arising from indolent lymphoma, and high-grade B-cell lymphoma (HGBL) after 2 or more lines of systemic therapy.

This indication is approved under accelerated approval based on response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

SELECT IMPORTANT SAFETY INFORMATION

BOXED WARNINGS

- **Cytokine release syndrome (CRS), including serious or life-threatening reactions, can occur in patients receiving EPKINLY. Initiate treatment with the EPKINLY step-up dosing schedule to reduce the incidence and severity of CRS. Withhold EPKINLY until CRS resolves or permanently discontinue based on severity.**
- **Immune effector cell–associated neurotoxicity syndrome (ICANS), including life-threatening and fatal reactions, can occur with EPKINLY. Monitor patients for neurological signs or symptoms of ICANS during treatment. Withhold EPKINLY until ICANS resolves or permanently discontinue based on severity.**

Additional Warnings and Precautions: Infections, Cytopenias, and Embryo-Fetal Toxicity.

Please see additional Important Safety Information on pages 17-18 and throughout this brochure.
Please see full Prescribing Information.

About EPKINLY[1]

EPKINLY is a humanized IgG1, T-cell engaging bispecific antibody that binds to CD20 on B cells and to CD3 on T cells.

CD20 is expressed on the surface of lymphoma cells and healthy B-lineage cells. In vitro, EPKINLY activated T cells, caused the release of proinflammatory cytokines, and induced lysis of B cells.

The efficacy of EPKINLY was evaluated based on results from EPCORE™ NHL-1, an open-label, multicohort, multicenter, single-arm trial in patients with R/R DLBCL after 2 or more lines of systemic therapy (N=148).*

EPKINLY provided ORR of 61% (95% CI, 53-69), including a CR rate of 38% (95% CI, 30-46) and a PR rate of 23% (95% CI, 17-31). Median DOR was 15.6 months (95% CI, 9.7-NR)†.

EPKINLY can cause serious side effects, including CRS, ICANS, infections, cytopenias, and embryo-fetal toxicity. The most common (≥20%) adverse reactions were CRS, fatigue, musculoskeletal pain, injection site reactions, pyrexia, abdominal pain, nausea, and diarrhea. The most common grade 3 to 4 laboratory abnormalities (≥10%) were decreased lymphocyte count, decreased neutrophil count, decreased white blood cell count, decreased hemoglobin, and decreased platelets.

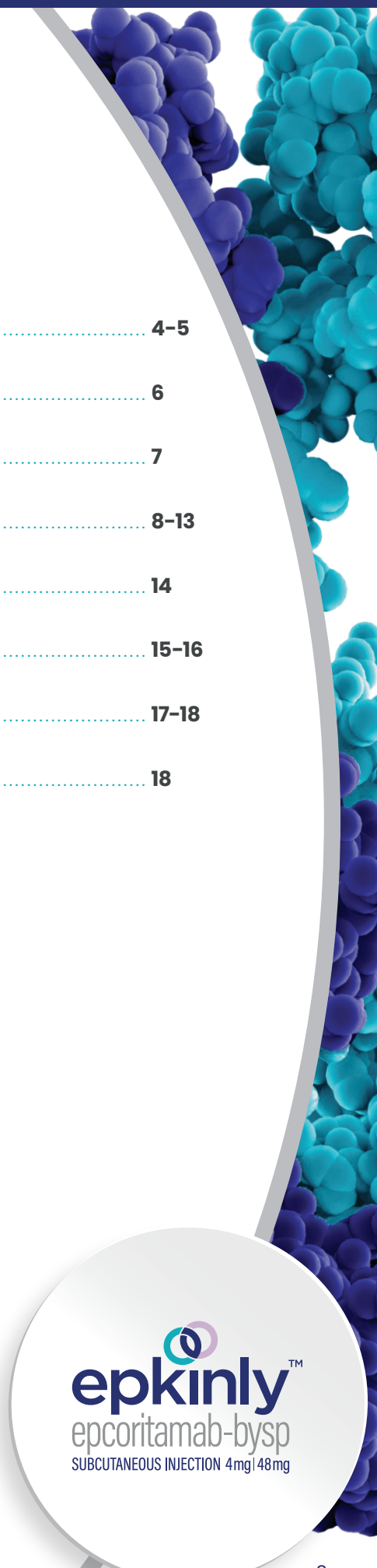
*Efficacy results determined by Lugano criteria (2014) as assessed by independent review committee.
†Among responders, the median follow-up for DOR was 9.8 months (range, 0-17.3 months).

CD3=cluster of differentiation 3; CD20=cluster of differentiation 20; CR=complete response; DOR=duration of response; IgG1=immunoglobulin G1; NHL=non-Hodgkin lymphoma; NR=not reached; ORR=overall response rate; PR=partial response; R/R=relapsed/refractory.

epkinly™
epcoritamab-bysp
SUBCUTANEOUS INJECTION 4mg|48mg

Please see Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 17-18 and throughout this brochure.
Please see full Prescribing Information.

TABLE OF CONTENTS



epkinly™
epcoritamab-bysp
SUBCUTANEOUS INJECTION 4mg|48mg

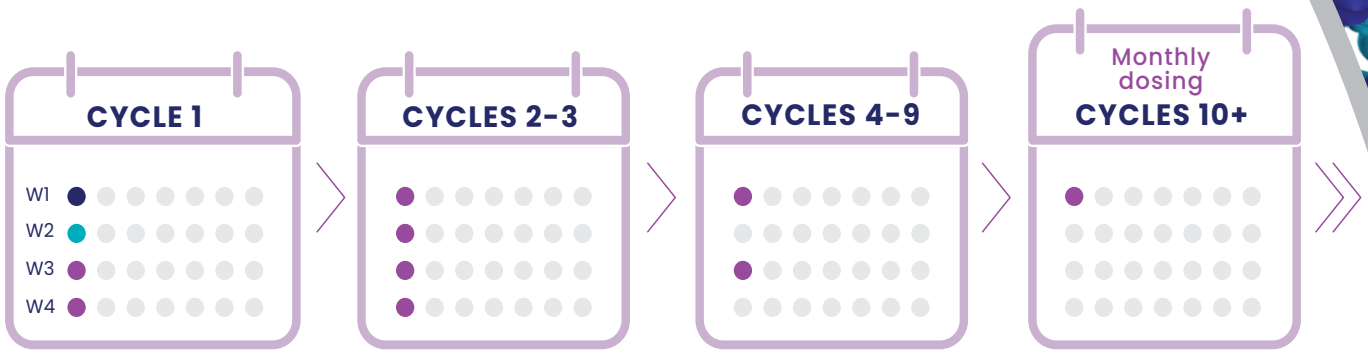
Please see Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 17-18 and throughout this brochure.
Please see full Prescribing Information.

EPKINLY is administered in 28-day cycles[1]

EPKINLY is for subcutaneous injection only.

Dosing schedule

STEP-UP DOSING: 0.16 mg ON DAY 1 > 0.8 mg ON DAY 8 **FULL DOSE:** 48 mg ON DAYS 15+



W1=week 1; W2=week 2; W3=week 3; W4=week 4.

- CRS occurred in 51% of patients in the clinical trial. Most CRS events (92%) occurred during cycle 1
- Median time to onset of CRS after first full 48 mg dose was 21 hours (range, 0-7 days)

CONTINUE UNTIL DISEASE PROGRESSION OR UNACCEPTABLE TOXICITY

Recommendations for restarting EPKINLY after dosage delay

Last dose administered	Time since the last dose administered	Action for next dose(s)[a]
0.16 mg on cycle 1, day 1	More than 8 days	Repeat 0.16 mg, then administer 0.8 mg the following week, followed by 2 weekly doses of 48 mg. Then resume the planned dosage schedule beginning with day 1 of the subsequent cycle
0.8 mg on cycle 1, day 8	14 days or less	Administer 48 mg, then resume the recommended dosage schedule
	More than 14 days	Repeat 0.16 mg, then administer 0.8 mg the following week, followed by 2 weekly doses of 48 mg. Then resume the planned dosage schedule beginning with day 1 of the subsequent cycle

[a]Administer pretreatment medication prior to EPKINLY dose and monitor patients accordingly.

epkinly™
epcoritamab-bysp
SUBCUTANEOUS INJECTION 4mg|48mg

Please see Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 17-18 and throughout this brochure.
Please see full Prescribing Information.

Recommendations for restarting EPKINLY after dosage delay[1] (continued)

Last dose administered	Time since the last dose administered	Action for next dose(s)[a]
48 mg on cycle 1, day 15 onwards	6 weeks or less	Administer 48 mg, then resume the recommended dosage schedule
	More than 6 weeks	Repeat 0.16 mg, then administer 0.8 mg the following week, followed by 2 weekly doses of 48 mg. Then resume the planned dosage schedule beginning with day 1 of the subsequent cycle

[a]Administer pretreatment medication prior to EPKINLY dose and monitor patients accordingly.

Important dosing information

- Administer EPKINLY to well-hydrated patients
- Initiate treatment with the EPKINLY step-up dosing schedule and premedicate before each dose in cycle 1 to reduce the risk of CRS
- EPKINLY should only be administered by a qualified healthcare professional with appropriate medical support to manage severe reactions such as CRS and ICANS
- Monitor patients for potential CRS and ICANS. Due to the risk of CRS and ICANS, patients should be hospitalized for 24 hours after administration of the cycle 1, day 15 dosage of 48 mg

Dosing discontinuation and delays in the clinical trial

- Discontinuation due to an adverse reaction occurred in 3.8% of patients (reactions included COVID-19, CRS, ICANS, pleural effusion, and fatigue)
- Dosage interruptions due to an adverse reaction occurred in 34% of patients (reactions occurring ≥3%: CRS, neutropenia, sepsis, and thrombocytopenia)

SELECT IMPORTANT SAFETY INFORMATION

Cytokine Release Syndrome (CRS)

- EPKINLY can cause CRS, including serious or life-threatening reactions. CRS occurred in 51% of patients at the recommended dose in the clinical trial (37% grade 1, 17% grade 2, and 2.5% grade 3). Recurrent CRS occurred in 16% of patients. Of all the CRS events, most (92%) occurred during cycle 1. In cycle 1, 9% of CRS events occurred after the 0.16 mg dose (cycle 1, day 1), 16% after the 0.8 mg dose (cycle 1, day 8), 61% after the 48 mg dose (cycle 1, day 15), and 6% after the 48 mg dose (cycle 1, day 22). The median time to onset of CRS from the most recently administered EPKINLY dose across all doses was 24 hours (range, 0-10 days). The median time to onset after the first full 48 mg dose was 21 hours (range, 0-7 days). CRS resolved in 98% of patients; the median duration of CRS events was 2 days (range, 1-27 days).

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 17-18 and throughout this brochure.
Please see full Prescribing Information.

epkinly™
epcoritamab-bysp
SUBCUTANEOUS INJECTION 4mg|48mg

Premedications[1]

Recommended premedications to reduce the risk of CRS

Cycle	Patients requiring premedication	Premedication	Administration
Cycle 1	All patients	• Prednisolone (100 mg oral or IV) or dexamethasone (15 mg oral or IV) or equivalent	• 30-120 minutes prior to each weekly administration of EPKINLY • And for 3 consecutive days following each weekly administration of EPKINLY in cycle 1
		• Diphenhydramine (50 mg oral or IV) or equivalent • Acetaminophen (650 to 1000 mg oral)	• 30-120 minutes prior to each weekly administration of EPKINLY
Cycles 2+	Patients who experienced grade 2 or 3[a] CRS with previous dose	• Prednisolone (100 mg oral or IV) or dexamethasone (15 mg oral or IV) or equivalent	• 30-120 minutes prior to next administration of EPKINLY after a grade 2 or 3[a] CRS event • And for 3 consecutive days following the next administration of EPKINLY until EPKINLY is given without subsequent CRS of grade 2 or higher

[a]Patients will be permanently discontinued from EPKINLY after grade 4 CRS.

Recommended prophylaxis

- Provide *Pneumocystis jirovecii* pneumonia (PJP) prophylaxis prior to starting treatment with EPKINLY
- Consider initiating prophylaxis against herpes virus prior to starting EPKINLY to prevent herpes zoster reactivation

IV=intravenous.

Cytokine Release Syndrome (CRS) (continued)

- Signs and symptoms of CRS can include pyrexia, hypotension, hypoxia, dyspnea, chills, and tachycardia. Concurrent neurological adverse reactions associated with CRS occurred in 2.5% of patients and included headache, confusional state, tremors, dizziness, and ataxia.
- Initiate EPKINLY according to the step-up dosing schedule. Administer pretreatment medications to reduce the risk of CRS and monitor patients for potential CRS. Following administration of the first 48 mg dose, patients should be hospitalized for 24 hours. At the first signs or symptoms of CRS, immediately evaluate patients for hospitalization, manage per current practice guidelines, and administer supportive care as appropriate. Withhold or discontinue EPKINLY based on the severity of CRS.

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 17-18 and throughout this brochure.
Please see full Prescribing Information.

epkinly™
epcoritamab-bysp
SUBCUTANEOUS INJECTION 4mg|48mg

EPKINLY is supplied as single-dose vials in 2 strengths[1]

EPKINLY is prepared and administered by a healthcare provider as a subcutaneous injection.

4 mg/0.8 mL for step-up doses

- Step-up dose 1 (0.16 mg) and step-up dose 2 (0.8 mg) of EPKINLY 4 mg/0.8 mL require **dilution** by a healthcare provider using aseptic technique prior to administration

48 mg/0.8 mL for full doses

- The 48-mg full dose of EPKINLY 48 mg/0.8 mL vial does not need to be diluted

FOR MORE INFORMATION ON PREPARING EPKINLY, SEE SECTION 2.7 OF THE FULL PRESCRIBING INFORMATION OR SEE THE DOSE PREPARATION OVERVIEW AT EPKINLYhcp.com/dosing-administration

SELECT IMPORTANT SAFETY INFORMATION

Cytokine Release Syndrome (CRS) (continued)

- Patients who experience CRS (or other adverse reactions that impair consciousness) should be evaluated and advised not to drive and to refrain from operating heavy or potentially dangerous machinery until resolution.

Immune Effector Cell–Associated Neurotoxicity Syndrome (ICANS)

- EPKINLY can cause life-threatening and fatal ICANS. ICANS occurred in 6% (10/157) of patients in the clinical trial (4.5% grade 1, 1.3% grade 2, 0.6% fatal: 1 event). Of the 10 ICANS events, 9 occurred in cycle 1 of treatment. The median time to onset was 16.5 days (range, 8-141 days) from the start of treatment. Relative to the most recent administration, the median time to onset was 3 days (range, 1-13 days). The median duration of ICANS was 4 days (range, 0-8 days), with ICANS resolving in 90% of patients with supportive care.
- Signs and symptoms of ICANS can include confusional state, lethargy, tremors, dysgraphia, aphasia, and nonconvulsive status epilepticus. The onset of ICANS can be concurrent with CRS, following resolution of CRS, or in the absence of CRS.
- Monitor for potential ICANS. At the first signs or symptoms of ICANS, immediately evaluate patient and provide supportive therapy based on severity. Withhold or discontinue EPKINLY per recommendations and consider further management per current practice guidelines.
- Patients who experience signs or symptoms of ICANS or any other adverse reactions that impair cognition or consciousness should be evaluated, including potential neurology evaluation, and patients at increased risk should be advised not to drive and to refrain from operating heavy or potentially dangerous machinery until resolution.

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 17-18 and throughout this brochure.
Please see full Prescribing Information.

epkinly™
epcoritamab-bysp
SUBCUTANEOUS INJECTION 4mg|48mg

Dosage modifications and management of adverse reactions[1]

Recommendations for management of CRS

- Identify CRS based on clinical presentation. Evaluate for and treat other causes of fever, hypotension, and hypoxia
- Withhold EPKINLY until CRS resolves
- Manage according to the recommendations below and consider further management per current practice guidelines
- Administer supportive therapy for CRS, which may include intensive care for severe or life-threatening CRS

Grade 1[a]	Actions
Temperature ≥100.4°F (38°C)[b]	**Withhold EPKINLY** • Manage per current practice guidelines • Ensure CRS symptoms are resolved prior to next dose of EPKINLY[c]

Grade 2[a]	Actions
Temperature ≥100.4°F (38°C)[b] **with** Hypotension not requiring vasopressors **and/or** Hypoxia requiring low-flow oxygen[e] by nasal cannula or blow-by	**Withhold EPKINLY** • Manage per current practice guidelines • Ensure CRS symptoms are resolved prior to next dose of EPKINLY[c] • Administer premedication[d] prior to next dose of EPKINLY • For the next dose of EPKINLY, monitor more frequently and consider hospitalization

[a]Based on ASTCT 2019 grading for CRS.
[b]Premedication may mask fever, therefore if clinical presentation is consistent with CRS, follow these management guidelines.
[c]Refer to Table 2 in Section 2.3 of the Prescribing Information for information on restarting EPKINLY after dose delays.
[d]If grade 2 or 3 CRS occurs with the second full dose (48 mg) or beyond, administer CRS premedications with each subsequent dose until an EPKINLY dose is given without subsequent CRS of any grade. Refer to Table 3 in Section 2.4 of the Prescribing Information for additional information on premedication.
[e]Low-flow oxygen defined as oxygen delivered at <6 L/minute; high-flow oxygen defined as oxygen delivered at ≥6 L/minute.

ASTCT=American Society for Transplantation and Cellular Therapy; BiPAP=bilevel positive airway pressure; CPAP=continuous positive airway pressure.

epkinly™
epcoritamab-bysp
SUBCUTANEOUS INJECTION 4mg|48mg

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 17-18 and throughout this brochure.
Please see full Prescribing Information.

Recommendations for management of CRS[1] (continued)

Grade 3[a]	Actions
Temperature ≥100.4°F (38°C)[b] **with** Hypotension requiring a vasopressor (with or without vasopressin) **and/or** Hypoxia requiring high-flow oxygen[e] nasal cannula, face mask, non-rebreather mask, or Venturi mask	**Withhold EPKINLY** • Manage per current practice guidelines, which may include intensive care • Ensure CRS symptoms are resolved prior to next dose of EPKINLY[c] • Administer premedication[d] prior to next dose of EPKINLY • Hospitalize for next dose of EPKINLY **Recurrent grade 3 CRS** **Permanently discontinue EPKINLY** • Manage CRS per current practice guidelines and provide supportive therapy, which may include intensive care

Grade 4[a]	Actions
Temperature ≥100.4°F (38°C)[b] **with** Hypotension requiring multiple vasopressors (excluding vasopressin) **and/or** Hypoxia requiring oxygen by positive pressure (eg, CPAP, BiPAP, intubation, and mechanical ventilation)	**Permanently discontinue EPKINLY** • Manage CRS per current practice guidelines and provide supportive therapy, which may include intensive care

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 17-18 and throughout this brochure.
Please see full Prescribing Information.

epkinly™
epcoritamab-bysp
SUBCUTANEOUS INJECTION 4mg|48mg

Recommendations for management of ICANS[1]

- Monitor patients for signs and symptoms of ICANS
- At the first sign of ICANS, withhold EPKINLY and consider neurology evaluation. Rule out other causes of neurological symptoms. Provide supportive therapy, which may include intensive care, for ICANS
- Manage ICANS according to the recommendations below and consider further management per current practice guidelines

Grade 1[a,b]	Actions
ICE score 7–9[c] **or** **Depressed level of consciousness[d]:** • Awakens spontaneously	**Withhold EPKINLY until ICANS resolves[e]** • Monitor neurologic symptoms and consider consultation with neurologist and other specialists for further evaluation and management, including consideration for starting nonsedating, antiseizure medicines for seizure prophylaxis

Grade 2[a,b]	Actions
ICE score 3–6[c] **or** **Depressed level of consciousness[d]:** • Awakens to voice	**Withhold EPKINLY until ICANS resolves[e]** • Administer dexamethasone[f] 10 mg intravenously every 6 hours. Continue dexamethasone use until resolution to grade 1 or less, then taper • Monitor neurologic symptoms and consider consultation with neurologist and other specialists for further evaluation and management, including consideration for starting nonsedating, antiseizure medicines for seizure prophylaxis

epkinly™
epcoritamab-bysp
SUBCUTANEOUS INJECTION 4mg|48mg

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 17-18 and throughout this brochure.
Please see full Prescribing Information.

Recommendations for management of ICANS[1] (continued)

Grade 3[a,b]	Actions
ICE score 0–2[c] **or** **Depressed level of consciousness[d]:** • Awakens only to tactile stimulus **or** **Seizures[d], either:** • Any clinical seizure, focal or generalized, that resolves rapidly, or • Nonconvulsive seizures on electroencephalogram (EEG) that resolve with intervention **or** **Raised intracranial pressure:** focal/local edema on neuroimaging[d]	**First occurrence of grade 3 ICANS** **Withhold EPKINLY until ICANS resolves[e]** • Administer dexamethasone[f] 10 mg intravenously every 6 hours. Continue dexamethasone use until resolution to grade 1 or less, then taper • Monitor neurologic symptoms and consider consultation with neurologist and other specialists for further evaluation and management, including consideration for starting nonsedating, antiseizure medicines for seizure prophylaxis • Provide supportive therapy, which may include intensive care **Recurrent grade 3 ICANS** **Permanently discontinue EPKINLY** • Administer dexamethasone[f] 10 mg intravenously every 6 hours. Continue dexamethasone use until resolution to grade 1 or less, then taper • Monitor neurologic symptoms and consider consultation with neurologist and other specialists for further evaluation and management, including consideration for starting nonsedating, antiseizure medicines for seizure prophylaxis • Provide supportive therapy, which may include intensive care

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 17-18 and throughout this brochure.
Please see full Prescribing Information.

epkinly™
epcoritamab-bysp
SUBCUTANEOUS INJECTION 4mg|48mg

Recommendations for management of ICANS[1] (continued)

Grade 4[a,b]	Actions
ICE score 0[c] or **Depressed level of consciousness[d], either:** • Patient is unarousable or requires vigorous or repetitive tactile stimuli to arouse, or • Stupor or coma **or** **Seizures[d], either:** • Life-threatening prolonged seizure (>5 minutes), or • Repetitive clinical or electrical seizures without return to baseline in between **or** **Motor findings[d]:** • Deep focal motor weakness, such as hemiparesis or paraparesis **or** **Raised intracranial pressure/cerebral edema[d], with signs/symptoms such as:** • Diffuse cerebral edema on neuroimaging, or • Decerebrate or decorticate posturing, or • Cranial nerve VI palsy, or • Papilledema, or • Cushing's triad	**Permanently discontinue EPKINLY** • Administer dexamethasone[f] 10 mg intravenously every 6 hours. Continue dexamethasone use until resolution to grade 1 or less, then taper • Alternatively, consider administration of methylprednisolone 1000 mg per day intravenously and continue methylprednisolone 1000 mg per day intravenously for 2 or more days • Monitor neurologic symptoms and consider consultation with neurologist and other specialists for further evaluation and management, including consideration for starting nonsedating, antiseizure medicines for seizure prophylaxis • Provide supportive therapy, which may include intensive care

[a]Based on ASTCT 2019 grading for ICANS.
[b]Management is determined by the most severe event, not attributable to any other cause.
[c]If patient is arousable and able to perform the ICE Assessment, assess: orientation; naming; following commands; writing; and attention. If patient is unarousable and unable to perform ICE Assessment (grade 4 ICANS) = 0 points. See Table 5 in Section 2.6 of the Prescribing Information for more information on the ICE Assessment.
[d]Not attributable to any other cause.
[e]See Table 2 in Section 2.3 of the Prescribing Information for recommendations on restarting EPKINLY after dose delays.
[f]All references to dexamethasone administration are dexamethasone or equivalent

ICE Assessment=Immune Effector Cell–Associated Encephalopathy Assessment.

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 17-18 and throughout this brochure.
Please see full Prescribing Information.

epkinly™
epcoritamab-bysp
SUBCUTANEOUS INJECTION 4mg|48mg

Recommended dosage modifications for other adverse reactions[1]

Adverse reaction[a]	Severity[a]	Action
Infections	Grades 1-4	**Withhold EPKINLY** • In patients with active infection, until the infection resolves[b] • For grade 4, consider permanent discontinuation
Neutropenia	Absolute neutrophil count (ANC) <0.5 x 10^9/L	**Withhold EPKINLY** • Until ANC ≥0.5 x 10^9/L
Thrombocytopenia	Platelet count <50 x 10^9/L	**Withhold EPKINLY** • Until platelet count ≥50 x 10^9/L
Other adverse reactions	Grade 3 or higher	**Withhold EPKINLY** • Until the toxicity resolves to grade 1 or baseline[b]

[a]Based on National Cancer Institute Common Terminology Criteria for Adverse Events, version 5.0.
[b]See Table 2 in Section 2.3 of the Prescribing Information for recommendations on restarting EPKINLY after dosage delays.

SELECT IMPORTANT SAFETY INFORMATION

Infections

- EPKINLY can cause serious and fatal infections. In the clinical trial, serious infections, including opportunistic infections, were reported in 15% of patients treated with EPKINLY at the recommended dose (14% grade 3 or 4, 1.3% fatal). The most common grade 3 or greater infections were sepsis, COVID-19, urinary tract infection, pneumonia, and upper respiratory tract infection.
- Monitor patients for signs and symptoms of infection prior to and during treatment with EPKINLY and treat appropriately. Avoid administration of EPKINLY in patients with active infections.
- Prior to starting EPKINLY, provide *Pneumocystis jirovecii* pneumonia (PJP) prophylaxis and consider prophylaxis against herpes virus.
- Withhold or consider permanent discontinuation of EPKINLY based on severity.

Cytopenias

- EPKINLY can cause serious or severe cytopenias, including neutropenia, anemia, and thrombocytopenia. Among patients who received the recommended dose in the clinical trial, grade 3 or 4 events occurred in 32% (decreased neutrophils), 12% (decreased hemoglobin), and 12% (decreased platelets). Febrile neutropenia occurred in 2.5%.
- Monitor complete blood counts throughout treatment. Based on severity of cytopenias, temporarily withhold or permanently discontinue EPKINLY. Consider prophylactic granulocyte colony-stimulating factor administration as applicable.

Embryo-Fetal Toxicity

- EPKINLY may cause fetal harm. Advise pregnant women of the potential risk to the fetus. Verify pregnancy status in females of reproductive potential prior to initiating EPKINLY. Advise females of reproductive potential to use effective contraception during treatment with EPKINLY and for 4 months after the last dose.

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 17-18 and throughout this brochure.
Please see full Prescribing Information.

epkinly™
epcoritamab-bysp
SUBCUTANEOUS INJECTION 4mg|48mg

Storage and handling for EPKINLY[1]

Before dilution and preparation

DO	DON'T
Store refrigerated at 2°C to 8°C (36°F to 46°F)	Freeze EPKINLY
Keep in the original carton to protect from light	Shake EPKINLY

After dilution and preparation

- Diluted EPKINLY solution should be used immediately or stored in a refrigerator at 2°C to 8°C (36°F to 46°F) for up to 24 hours or at room temperature at 20°C to 25°C (68°F to 77°F) for up to 12 hours
- The total storage time from the start of dose preparation to administration should not exceed 24 hours. Protect EPKINLY solution from direct sunlight
- Allow EPKINLY solution to equilibrate to room temperature for no more than 1 hour before administration
- Discard unused EPKINLY solution beyond the allowable storage time

Subcutaneous injections prepared and administered by a healthcare provider[1]

Administration of EPKINLY

- EPKINLY should be injected in the lower part of the abdomen (preferred injection site) or the thigh
  - Change of injection site from the left or right side or vice versa is recommended, especially during the weekly administrations (cycles 1-3)
- Do not inject into tattoos, scars, or areas where the skin is red, bruised, tender, hard, or not intact
- Discard the vial containing unused EPKINLY

SELECT IMPORTANT SAFETY INFORMATION

Adverse Reactions

- The most common (≥20%) adverse reactions were CRS, fatigue, musculoskeletal pain, injection site reactions, pyrexia, abdominal pain, nausea, and diarrhea. The most common grade 3 to 4 laboratory abnormalities (≥10%) were decreased lymphocyte count, decreased neutrophil count, decreased white blood cell count, decreased hemoglobin, and decreased platelets.

Lactation

- Advise women not to breastfeed during treatment and for 4 months after the last dose of EPKINLY.

Please see Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 17-18 and throughout this brochure.
Please see full Prescribing Information.

epkinly™
epcoritamab-bysp
SUBCUTANEOUS INJECTION 4mg|48mg

What to remember when starting EPKINLY[1]

Before treatment with EPKINLY

Treatment checklist	Treatment considerations
Does your patient understand the dosing schedule?	Patients will need to come back: • Once a week for 12 weeks, cycles 1-3 (~3 months) • Once every 2 weeks for 24 weeks, cycles 4-9 (~6 months) • Once every 4 weeks after that, cycles 10+
Is your patient hydrated?	EPKINLY should be administered to well-hydrated patients.
Have you administered the recommended premedications?	Please see page 6 or Section 2.4 of the full Prescribing Information for more information.
Have you confirmed the correct dose for the cycle and day?	Initial dosing for patients on EPKINLY is stepped up weekly from • 0.16 mg on day 1 to • 0.8 mg on day 8 to • 48 mg, the full dose for all doses on and after day 15
Have you checked the label on the syringe to confirm • Correct dose? • Diluted dose was prepared less than 24 hours ago if it was stored in a refrigerator? • Diluted dose was prepared less than 12 hours ago if it was stored at room temperature?	**Dosing is as follows:** • Cycle 1: 0.16 mg on day 1, 0.8 mg on day 8, 48 mg on days 15 and 22 • Cycles 2-3: 48 mg on days 1, 8, 15, and 22 • Cycles 4-9: 48 mg on days 1 and 15 • Cycles 10+: 48 mg on day 1 0.16-mg and 0.8-mg dose (diluted): Use immediately or store the solution refrigerated at 2°C to 8°C (36°F to 46°F) for up to 24 hours or at room temperature at 20°C to 25°C (68°F to 77°F) for up to 12 hours. The total storage time from the start of dose preparation to administration should not exceed 24 hours.

SELECT IMPORTANT SAFETY INFORMATION

EPKINLY can cause serious side effects, including **Cytokine release syndrome (CRS), Immune effector cell-associated neurotoxicity syndrome (ICANS)**, Infections, Cytopenias, and Embryo-Fetal Toxicity.

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 17-18 and throughout this brochure.
Please see full Prescribing Information.

epkinly™
epcoritamab-bysp
SUBCUTANEOUS INJECTION 4mg|48mg

Before treatment with EPKINLY[1] (continued)

Treatment checklist	Treatment considerations
Has the dose been allowed to come to room temperature?	0.16-mg and 0.8-mg dose (diluted): If not used immediately and stored refrigerated at 2°C to 8°C (36°F to 46°F) prior to administration, allow EPKINLY solution to equilibrate to room temperature for no more than 1 hour before administration. The total storage time from the start of dose preparation to administration should not exceed 24 hours. Discard unused EPKINLY solution beyond the allowable storage time. 48-mg dose: Allow the EPKINLY vial to come to room temperature for no more than 1 hour before withdrawing dose.
Have you determined whether the patient's last dose was on the left or right side of their body? Where would your patient prefer this injection?	EPKINLY should be injected preferably in the lower part of the abdomen or the thigh. Change of injection site from the left or right side or vice versa is recommended, especially during the weekly administration (cycles 1-3). Do not inject into tattoos, scars, or areas where the skin is red, bruised, tender, hard, or not intact.

After treatment with EPKINLY

Treatment checklist	Treatment considerations
Have you/your staff counseled the patient to watch for side effects and to call you right away if they're experiencing symptoms such as fever of 100.4°F (38°C) or higher, dizziness or light-headedness, trouble breathing, chills, fast heartbeat, feeling anxious, headache, confusion, shaking (tremors), problems with balance and movement, such as trouble walking, trouble speaking or writing, confusion and disorientation, drowsiness, tiredness or lack of energy, muscle weakness, seizures, or memory loss?	Monitor patients for potential CRS and ICANS. Due to the risk of CRS and ICANS, patients should be hospitalized for 24 hours after administration of the cycle 1, day 15 dosage of 48 mg. If you suspect your patient is showing symptoms of CRS or ICANS, withhold EPKINLY and refer to Section 2.6 of the full Prescribing Information or pages 8-12 of this brochure for more information. Patients who experience CRS should be monitored more frequently during next scheduled administrations of EPKINLY. Advise patients who experience symptoms of CRS and ICANS that impair consciousness to refrain from driving or operating heavy or potentially dangerous machinery until events resolve.
If this is the first time your patient has received EPKINLY, have you counseled your patient on use of prednisolone for three consecutive days?	Please refer to Section 2.4 of the full Prescribing Information or page 6 for more information.
Does your patient understand when to come back for the next dose?	Administer EPKINLY according to the Dosing Schedule in Section 2.2 of the full Prescribing Information or see pages 4-5 for more information.

Please see Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 17-18 and throughout this brochure.
Please see full Prescribing Information.

epkinly™
epcoritamab-bysp
SUBCUTANEOUS INJECTION 4mg|48mg

Indication & Important Safety Information

INDICATION

EPKINLY is indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified (NOS), including DLBCL arising from indolent lymphoma, and high-grade B-cell lymphoma (HGBL) after 2 or more lines of systemic therapy. This indication is approved under accelerated approval based on response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

BOXED WARNINGS

- **Cytokine release syndrome (CRS), including serious or life-threatening reactions, can occur in patients receiving EPKINLY. Initiate treatment with the EPKINLY step-up dosing schedule to reduce the incidence and severity of CRS. Withhold EPKINLY until CRS resolves or permanently discontinue based on severity.**
- **Immune effector cell–associated neurotoxicity syndrome (ICANS), including life-threatening and fatal reactions, can occur with EPKINLY. Monitor patients for neurological signs or symptoms of ICANS during treatment. Withhold EPKINLY until ICANS resolves or permanently discontinue based on severity.**

Cytokine Release Syndrome (CRS)

- EPKINLY can cause CRS, including serious or life-threatening reactions. CRS occurred in 51% of patients at the recommended dose in the clinical trial (37% grade 1, 17% grade 2, and 2.5% grade 3). Recurrent CRS occurred in 16% of patients. Of all the CRS events, most (92%) occurred during cycle 1. In cycle 1, 9% of CRS events occurred after the 0.16 mg dose (cycle 1, day 1), 16% after the 0.8 mg dose (cycle 1, day 8), 61% after the 48 mg dose (cycle 1, day 15), and 6% after the 48 mg dose (cycle 1, day 22). The median time to onset of CRS from the most recently administered EPKINLY dose across all doses was 24 hours (range, 0-10 days). The median time to onset after the first full 48 mg dose was 21 hours (range, 0-7 days). CRS resolved in 98% of patients; the median duration of CRS events was 2 days (range, 1-27 days).
- Signs and symptoms of CRS can include pyrexia, hypotension, hypoxia, dyspnea, chills, and tachycardia. Concurrent neurological adverse reactions associated with CRS occurred in 2.5% of patients and included headache, confusional state, tremors, dizziness, and ataxia.
- Initiate EPKINLY according to the step-up dosing schedule. Administer pretreatment medications to reduce the risk of CRS and monitor patients for potential CRS. Following administration of the first 48 mg dose, patients should be hospitalized for 24 hours. At the first signs or symptoms of CRS, immediately evaluate patients for hospitalization, manage per current practice guidelines, and administer supportive care as appropriate. Withhold or discontinue EPKINLY based on the severity of CRS.
- Patients who experience CRS (or other adverse reactions that impair consciousness) should be evaluated and advised not to drive and to refrain from operating heavy or potentially dangerous machinery until resolution.

Immune Effector Cell–Associated Neurotoxicity Syndrome (ICANS)

- EPKINLY can cause life-threatening and fatal ICANS. ICANS occurred in 6% (10/157) of patients in the clinical trial (4.5% grade 1, 1.3% grade 2, 0.6% fatal: 1 event). Of the 10 ICANS events, 9 occurred in cycle 1 of treatment. The median time to onset was 16.5 days (range, 8-141 days) from the start of treatment. Relative to the most recent administration, the median time to onset was 3 days (range, 1-13 days). The median duration of ICANS was 4 days (range, 0-8 days), with ICANS resolving in 90% of patients with supportive care.

epkinly™
epcoritamab-bysp
SUBCUTANEOUS INJECTION 4mg|48mg

Please see additional Important Safety Information on page 18.
Please see full Prescribing Information.

Immune Effector Cell–Associated Neurotoxicity Syndrome (ICANS) (continued)

- Signs and symptoms of ICANS can include confusional state, lethargy, tremors, dysgraphia, aphasia, and nonconvulsive status epilepticus. The onset of ICANS can be concurrent with CRS, following resolution of CRS, or in the absence of CRS.
- Monitor for potential ICANS. At the first signs or symptoms of ICANS, immediately evaluate patient and provide supportive therapy based on severity. Withhold or discontinue EPKINLY per recommendations and consider further management per current practice guidelines.
- Patients who experience signs or symptoms of ICANS or any other adverse reactions that impair cognition or consciousness should be evaluated, including potential neurology evaluation, and patients at increased risk should be advised not to drive and to refrain from operating heavy or potentially dangerous machinery until resolution.

Infections

- EPKINLY can cause serious and fatal infections. In the clinical trial, serious infections, including opportunistic infections, were reported in 15% of patients treated with EPKINLY at the recommended dose (14% grade 3 or 4, 1.3% fatal). The most common grade 3 or greater infections were sepsis, COVID-19, urinary tract infection, pneumonia, and upper respiratory tract infection.
- Monitor patients for signs and symptoms of infection prior to and during treatment with EPKINLY and treat appropriately. Avoid administration of EPKINLY in patients with active infections.
- Prior to starting EPKINLY, provide *Pneumocystis jirovecii* pneumonia (PJP) prophylaxis and consider prophylaxis against herpes virus.
- Withhold or consider permanent discontinuation of EPKINLY based on severity.

Cytopenias

- EPKINLY can cause serious or severe cytopenias, including neutropenia, anemia, and thrombocytopenia. Among patients who received the recommended dose in the clinical trial, grade 3 or 4 events occurred in 32% (decreased neutrophils), 12% (decreased hemoglobin), and 12% (decreased platelets). Febrile neutropenia occurred in 2.5%.
- Monitor complete blood counts throughout treatment. Based on severity of cytopenias, temporarily withhold or permanently discontinue EPKINLY. Consider prophylactic granulocyte colony-stimulating factor administration as applicable.

Embryo-Fetal Toxicity

- EPKINLY may cause fetal harm. Advise pregnant women of the potential risk to the fetus. Verify pregnancy status in females of reproductive potential prior to initiating EPKINLY. Advise females of reproductive potential to use effective contraception during treatment with EPKINLY and for 4 months after the last dose.

Adverse Reactions

- The most common (≥20%) adverse reactions were CRS, fatigue, musculoskeletal pain, injection site reactions, pyrexia, abdominal pain, nausea, and diarrhea. The most common grade 3 to 4 laboratory abnormalities (≥10%) were decreased lymphocyte count, decreased neutrophil count, decreased white blood cell count, decreased hemoglobin, and decreased platelets.

Lactation

- Advise women not to breastfeed during treatment and for 4 months after the last dose of EPKINLY.

Reference: 1. EPKINLY [package insert]. Plainsboro, NJ: Genmab US, Inc. and North Chicago, IL: AbbVie Inc.

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on page 17. Please see full Prescribing Information, including Boxed Warnings.

epkinly™
epcoritamab-bysp
SUBCUTANEOUS INJECTION 4mg|48mg

Additional resources are available to help you and your patients throughout the treatment journey

Adverse Reactions Management Guide

An essential guide to understanding and managing adverse reactions

Dose Preparation Overview

An easy-to-follow resource that provides step-by-step dilution and preparation instructions for EPKINLY

What to Expect With EPKINLY

A comprehensive patient resource containing useful information and tools designed to help patients understand their treatment

Patient Brochure

An overview of EPKINLY that informs patients and their care partners on what they need to know about starting treatment

TO DOWNLOAD THESE RESOURCES, VISIT EPKINLYhcp.com/support-resources

EPKINLY is available directly through specialty distributors and can be dispensed through an exclusive network of specialty pharmacies. For more information, visit **EPKINLYhcp.com**.

MyNavCare™ specialists can provide information and resources to get patients started with EPKINLY by providing resources to your office about billing, coding, and coverage information.

MyNavCare patient support begins with **Patient Access Specialists**, your main contact for helping patients start medication. A Patient Access Specialist can assist with:
Enrollment and onboarding | Benefits review, prior authorization, and appeals information | Co-pay assistance process for commercially insured patients and information about financial support options

Patients and care partners can receive ongoing support from **Patient Engagement Liaisons*** throughout their treatment journey.

MyNavCare™ PATIENT SUPPORT

Enroll your patient today by calling **1-866-NAV-CAR1** (1-866-628-2271), or by visiting **MyNavCare.com**.

TO LEARN MORE, VISIT **EPKINLYhcp.com**

Please see Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 17-18 and throughout this brochure. Please see full Prescribing Information.

**MyNavCare* Patient Engagement Liaisons are part of the *MyNavCare* Patient Support Program and do not provide medical advice or work under the direction of the prescribing healthcare providers. They are trained to direct patients to speak with their healthcare provider about any treatment-related questions.

Distributed and marketed by Genmab US Inc. 777 Scudders Mill Road, Plainsboro, NJ 08536.
Distributed and marketed by AbbVie Inc. 1 North Waukegan Road, North Chicago, IL 60064.

05/2023 COM-US-EPK-0000136

Genmab | abbvie

epkinly™ epcoritamab-bysp SUBCUTANEOUS INJECTION 4mg|48mg