

For 3L+ DLBCL

THE POWER FOR DURABLE RESPONSES

Discover subcutaneous EPKINLY, which demonstrated a remarkable **61% ORR with a mDOR* of 15.6 months.**¹ Granted accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

61% ORR n=90/148 95% CI, 53-69	38% CR n=56/148 95% CI, 30-46	23% PR n=34/148 95% CI, 17-31	15.6 Months mDOR* n=90/148 95% CI, 9.7 months-NR	Not Reached mDOCR ^{2*} n=56/148 95% CI, 14.3 months-NR
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The efficacy of EPKINLY was evaluated in EPCORE™ NHL-1, an open-label, multicohort, multicenter, single-arm trial in 148 patients with R/R DLBCL after 2 or more lines of systemic therapy.¹

*Based on Kaplan-Meier estimate.

3L=third line; CI=confidence interval; CR=complete response; DLBCL=diffuse large B-cell lymphoma; mDOCR=median duration of complete response; mDOR=median duration of response; NCCN=National Comprehensive Cancer Network; NHL=non-Hodgkin lymphoma; NR=not reached; ORR=overall response rate; PR=partial response; R/R=relapsed/refractory.

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines[®]) Recommended

The NCCN Guidelines [®] recommend epcoritamab-bysp (EPKINLY) as a NCCN Category 2A treatment option after 2 or more lines of systemic therapy for patients with ^{3†} :	R/R DLBCL CATEGORY 2A PREFERRED	Histological transformation of indolent lymphoma to DLBCL CATEGORY 2A RECOMMENDED
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NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

[†]See NCCN Guidelines for the NCCN definitions of Categories of Preference and Categories of Evidence and Consensus.

INDICATION

EPKINLY is indicated for the treatment of adults 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

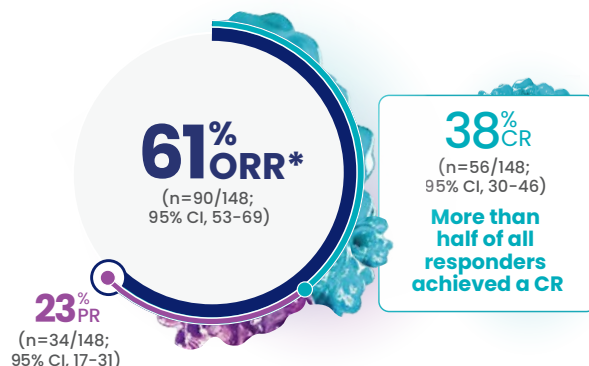
BOXED WARNINGS

- **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.**

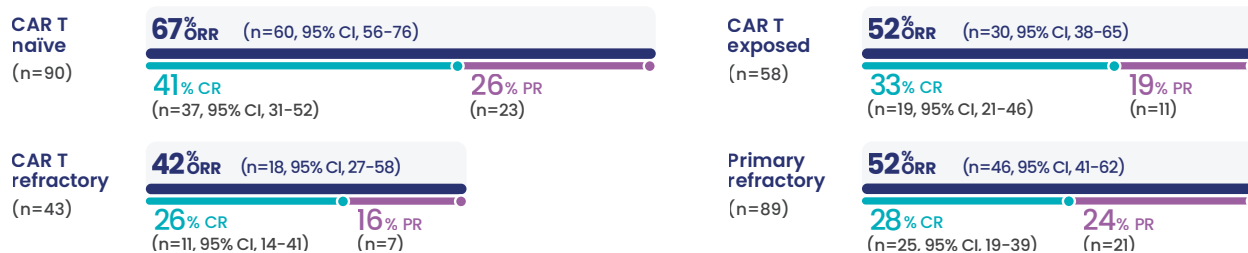
Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, throughout and on pages 4-5. Please see full [Prescribing Information](#) at [EPKINLYPI.com](#).



EPKINLY delivered an ORR of 61%, with 38% of patients achieving a deep response of CR¹



Responses in select prespecified subgroups were consistent with the overall population²



Data Limitation: Study was not powered to evaluate these prespecified subgroups. Data are exploratory and descriptive in nature. No formal inferences can be drawn.

STUDY DESIGN: The efficacy of EPKINLY was evaluated in 148 patients in EPCORE™ NHL-1, an open-label, multicohort, multicenter, single-arm trial in patients with R/R LBCL after 2 or more lines of systemic therapy. The primary endpoint was **ORR (CR+PR)**. Select secondary endpoints included **CR rate, DOR, DOCR, time to response**.^{1,4}

*Efficacy results determined by Lugano criteria (2014) as assessed by Independent Review Committee.

CAR T=chimeric antigen receptor T-cell therapy; LBCL=large B-cell lymphoma.

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- CRS occurred in 51% of patients in the clinical trial (37% grade 1, 17% grade 2, and 2.5% grade 3) and recurred in 16% of patients. Most events (92%) occurred during cycle 1, with 61% occurring after the 48 mg dose in cycle 1, day 15. In patients who experienced CRS, the signs and symptoms included 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.
- Administer pretreatment medications to reduce the risk of CRS. Following administration of the first 48 mg dose, patients should be hospitalized for 24 hours.
- Monitor patients for potential CRS. At the first signs or symptoms of CRS, manage per current practice guidelines and administer supportive care as appropriate.

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In overall responders (61%, n=90/148), EPKINLY delivered durable responses in heavily pretreated 3L+ DLBCL, NOS patients¹

RAPID

1.4 months median time to response
(range: 1.0–8.4)

DURABLE

mDOR*
15.6 months
(95% CI, 9.7 mo–NR)

SUSTAINED

63% still responding at 9 months*
(estimated; 95% CI, 52–72)

- In the efficacy population of 148 patients, the median number of prior therapies was 3 (range: 2–11), with 2 prior (30%), 3 prior (30%), and 4+ prior (40%). Prior therapies: autologous HSCT (18%), CAR T (39%). Refractory to last therapy (82%). Refractory to CAR T (29%)
- The median follow-up for DOR was 9.8 months (range: 0–17.3 months)

In a pre-specified analysis of complete responders (38%, n=56/148)^{1,2}:

2.6 months median time to complete response
(range: 1.2–10.2)

mDOCR*
NOT REACHED
(95% CI, 14.3 mo–NR)

89% still responding at 9 months*
(estimated; 95% CI, 75–95)

- Complete responses were achieved as late as 10.2 months²
- The median follow-up for DOCR was 9.7 months (range: 8.3–12.1 months)²

*Based on Kaplan–Meier estimate.

HSCT=hematopoietic stem cell transplant; NOS=not otherwise specified.

SELECT IMPORTANT SAFETY INFORMATION

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.

- ICANS occurred in 6% of patients in the clinical trial (4.5% grade 1, 1.3% grade 2, 0.6% fatal). Of the 10 ICANS events, 9 occurred in cycle 1 of treatment. The onset of ICANS can be concurrent with CRS, following resolution of CRS, or in the absence of CRS. Clinical manifestations of ICANS included, but were not limited to, confusional state, lethargy, tremor, dysgraphia, aphasia, and non-convulsive status epilepticus.
- Monitor patients for potential ICANS. At the first signs or symptoms of ICANS, manage per current practice guidelines and administer supportive care as appropriate.

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epkinly[®]
epcoritamab
SUBCUTANEOUS INJECTION 48mg/4mg



Indication and Important Safety Information

INDICATION

EPKINLY is indicated for the treatment of adults 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).

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.**

CRS

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- Administer pretreatment medications to reduce the risk of CRS. Following administration of the first 48 mg dose, patients should be hospitalized for 24 hours.
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ICANS

- ICANS occurred in 6% of patients in the clinical trial (4.5% grade 1, 1.3% grade 2, 0.6% fatal). Of the 10 ICANS events, 9 occurred in cycle 1 of treatment. The onset of ICANS can be concurrent with CRS, following resolution of CRS, or in the absence of CRS. Clinical manifestations of ICANS included, but were not limited to, confusional state, lethargy, tremor, dysgraphia, aphasia, and non-convulsive status epilepticus.
- Monitor patients for potential ICANS. At the first signs or symptoms of ICANS, manage per current practice guidelines and administer supportive care as appropriate.

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).
- Monitor patients for signs and symptoms of infection prior to and during treatment and treat appropriately. Avoid administration in patients with active infections. Withhold or consider permanent discontinuation of EPKINLY based on severity. Prior to starting EPKINLY, provide *Pneumocystis jirovecii* pneumonia (PJP) prophylaxis and consider prophylaxis against herpes virus.

Please see additional Important Safety Information on page 5. Please see full [Prescribing Information](#) at [EPKINLYPI.com](#).

Important Safety Information (continued)

Cytopenias

- EPKINLY can cause serious or severe cytopenias. In the clinical trial, grade 3 or 4 events occurred in 32% (neutropenia), 12% (anemia), and 12% (thrombocytopenia) of patients. 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 when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during treatment with EPKINLY and for 4 months after the last dose. Verify pregnancy status in females of reproductive potential prior to initiating EPKINLY.

Adverse Reactions

- Most common ($\geq 20\%$) adverse reactions were CRS, fatigue, musculoskeletal pain, injection site reactions, pyrexia, abdominal pain, nausea, and diarrhea. Most common grade 3 to 4 laboratory abnormalities ($\geq 10\%$) were decreased lymphocytes, decreased neutrophils, decreased white blood cells, decreased hemoglobin, and decreased platelets.

Lactation

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

Learn about adverse reactions and dosing for EPKINLY on the following pages

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on page 4. Please see full Prescribing Information at EPKINLYPI.com.

References: **1.** EPKINLY [package insert]. Plainsboro, NJ: Genmab US, Inc. and North Chicago, IL: AbbVie Inc. 2023. **2.** Data on file. Plainsboro, NJ: Genmab US, Inc. and North Chicago, IL: AbbVie Inc. 2023. **3.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines[®]) for B-Cell Lymphoma. V.1.2024. © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed January 23, 2024. To view the most recent and complete version of the guidelines, go online to NCCN.org. **4.** Thieblemont C, Phillips T, Ghesquieres H, et al. Epcoritamab, a novel, subcutaneous CD3xCD20 bispecific T-cell-engaging antibody, in relapsed or refractory large B-cell lymphoma: dose expansion in a phase I/II trial. *J Clin Oncol*. Published online December 22, 2022. doi:10.1200/JCO.22.01725 **5.** Hutchings M, Mous R, Clausen MR, et al. Dose escalation of subcutaneous epcoritamab in patients with relapsed or refractory B-cell non-Hodgkin lymphoma: an open-label, phase 1/2 study. *Lancet*. 2021;398(10306):1157-1169. doi:10.1016/S0140-6736(21)00889-8


epkinly[®]
epcoritamab
SUBCUTANEOUS INJECTION ^{48mg}/_{4mg}

Adverse reactions were manageable with subcutaneous EPKINLY¹

Majority of adverse reactions were mild to moderate (grade 1 or 2)¹
Most common treatment-related adverse reactions (≥10%, N=157)

ADVERSE REACTIONS*	ALL GRADES (%)	GRADE 3 OR 4‡ (%)
Cytokine release syndrome†	51	2.5
Fatigue§	29	2.5
Musculoskeletal pain§	28	1.3
Injection site reactions§	27	0
Pyrexia	24	0
Abdominal pain§	23	1.9
Nausea	20	1.3
Diarrhea	20	0
Rash§	15	0.6
Edema§	14	1.9
Headache	13	0.6
Vomiting	12	0.6
Decreased appetite	12	0.6
Cardiac arrhythmias§	10	0.6

*Adverse reactions were graded based on CTCAE Version 5.0.

‡Only grade 3 adverse reactions occurred.

†CRS was graded using ASTCT consensus criteria (Lee et al, 2019).

§Term includes other related terms. See full Prescribing Information.

- Serious adverse reactions occurred in 54% of patients (reactions occurring ≥2%: CRS, infections, pleural effusion, febrile neutropenia, fever, and ICANS)
- Fatal adverse reactions occurred in 3.8% of patients (1.3% COVID-19, 0.6% hepatotoxicity, 0.6% ICANS, 0.6% myocardial infarction, 0.6% pulmonary embolism)
- Most adverse reactions occurred early in treatment (C1-3), and incidence declined after 12 weeks⁴

Low discontinuation rate (3.8%) due to any adverse reaction¹

- Adverse reactions that led to discontinuation 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)

ASTCT=American Society for Transplantation and Cellular Therapy; C1-3=cycles 1-3; CRS=cytokine release syndrome; CTCAE=Common Terminology Criteria for Adverse Events; ICANS=immune effector cell-associated neurotoxicity syndrome.

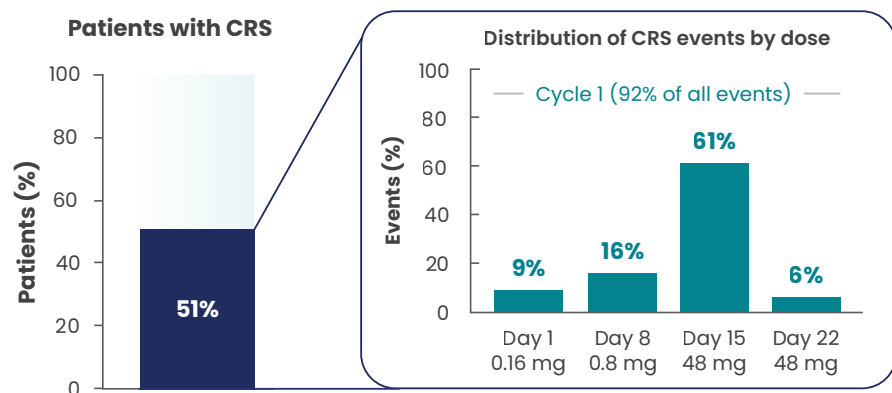
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CRS was primarily low grade, predictable, and manageable¹

- CRS occurred in 51% of the patients. The majority of these patients experienced a grade 1 (37%) or grade 2 (17%) CRS event
- Most CRS events (92%) occurred during cycle 1
 - In cycle 1, 9% occurred after the 0.16-mg dose (day 1), 16% after the 0.8-mg dose (day 8), 61% after the 48-mg dose (day 15), and 6% after the 48-mg dose (day 22)
- The median time to onset of CRS from the most recently administered dose of EPKINLY 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 in a median of 2 days (range: 1-27 days)

Management of CRS may require supportive therapy, which may include intensive care as appropriate. Withhold or discontinue EPKINLY based on the severity of CRS.

Most CRS events occurred following the first full dose



The majority of ICANS cases occurred within cycle 1¹

- ICANS occurred in 6% (10/157) of patients: grade 1 (4.5%), grade 2 (1.3%), grade 5 (0.6%; 1 patient)
- The median time from initiation of therapy to first ICANS onset was 16.5 days (range: 8-141 days)
- ICANS resolved in 90% (9/10) of patients with supportive care
 - The median duration of ICANS was 4 days (range: 0-8 days)

At the first signs or symptoms of ICANS, immediately evaluate patient and provide supportive therapy based on severity. Withhold or discontinue EPKINLY as recommended.

Please see Section 2.6 of the Prescribing Information for CRS and ICANS grading and management recommendations.

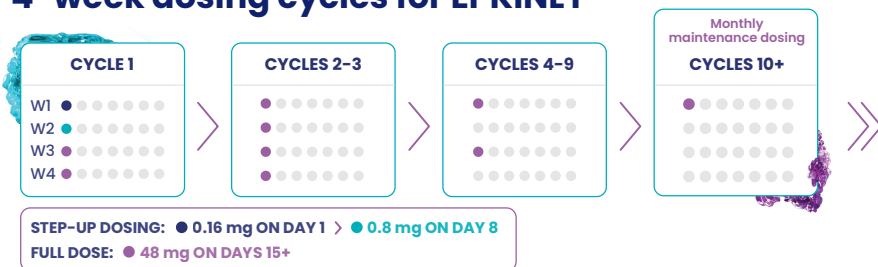
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epkinly[®]
epcoritamab
SUBCUTANEOUS INJECTION 48mg/4mg

Off-the-shelf EPKINLY enables accelerated treatment initiation¹

EPKINLY is available to treat patients at the moment of relapse^{1,5}

4-week dosing cycles for EPKINLY



Administer EPKINLY subcutaneously in 28-day cycles to well-hydrated patients until disease progression or unacceptable toxicity.

- Step-up dosing of EPKINLY is intended to increase tolerability and mitigate incidence and severity of CRS¹⁵
- Prior to starting EPKINLY, provide *Pneumocystis jirovecii* pneumonia prophylaxis and consider initiating prophylaxis against herpes virus to prevent herpes zoster reactivation
- Initiate treatment with the EPKINLY step-up dosing schedule and premedicate before each dose in cycle 1 to reduce the incidence and severity 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
- If a dose of EPKINLY is missed or delayed, therapy may need to be restarted. Refer to Missed or Delayed Dose table in full Prescribing Information

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

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

Please see additional Important Safety Information throughout and on pages 4-5.

Please see full [Prescribing Information at EPKINLYPI.com](https://www.epkinlyhcp.com).

Subcutaneous EPKINLY can be administered outpatient

- 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
- Healthcare systems can determine the appropriate level of monitoring for patients who will receive EPKINLY, which does not necessarily mean inpatient admission if suitable alternatives are available
- For subsequent doses, hospitalization may be needed to manage select adverse reactions

Learn more and find resources at [EPKINLYhcp.com](https://www.epkinlyhcp.com)