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

In 3L+ DLBCL

THE POWER OF SUSTAINED REMISSION[1,2]



Discover subcutaneous EPKINLY
Granted 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 confirmatory trial(s).

61% ORR*	38% CR	15.6 Months mDOR†	Not Reached mDOCR[2†]
n=90/148 95% CI, 53-69	n=56/148 95% CI, 30-46	n=90/148 95% CI, 9.7 months-NR	n=56/148 95% CI, 14.3 months-NR

- **PR: 23% (n=34/148; 95% CI, 17-31)**

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]

*Efficacy results determined by Lugano criteria (2014) as assessed by Independent Review Committee (IRC).
†Based on Kaplan-Meier estimate. The median follow-up for DOR was 9.8 months (range: 0-17.3 months) and for DOCR was 9.7 months (range: 8.3-12.1 months).

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

The NCCN Guidelines® recommend epcoritamab-bysp (EPKINLY) as an 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

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 Categories of Evidence and Consensus and NCCN Categories of Preference.

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 (HGBCL) 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

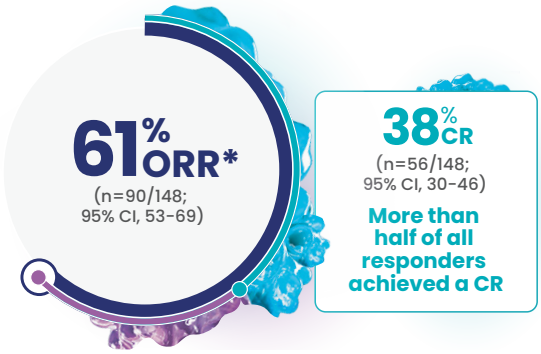
- **Cytokine release syndrome (CRS), including serious or fatal reactions, can occur in patients receiving EPKINLY. Initiate treatment with the EPKINLY step-up dosage schedule to reduce the incidence and severity of CRS. Withhold EPKINLY until CRS resolves or permanently discontinue based on severity.**
- **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 & Precautions: Infections, Cytopenias, and Embryo-Fetal Toxicity.

Please see additional Important Safety Information throughout and on pages 6-7. Please see full Prescribing Information, including Boxed Warnings.

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; NHL=non-Hodgkin lymphoma; NR=not reached; ORR=overall response rate; PR=partial response; R/R=relapsed/refractory.

EPKINLY delivered an ORR of 61%, with 38% of patients achieving a deep response of CR[1]



- **PR: 23% (n=34/148; 95% CI, 17-31)**

Responses in select prespecified subgroups were consistent with the overall population[2]

CAR T naïve (n=90)
67% ORR (n=60; 95% CI, 56-76)
41% CR (n=37; 95% CI, 31-52)
26% PR (n=23)

CAR T exposed (n=58)
52% ORR (n=30; 95% CI, 38-65)
33% CR (n=19; 95% CI, 21-46)
19% PR (n=11)

CAR T refractory (n=43)
42% ORR (n=18; 95% CI, 27-58)
26% CR (n=11; 95% CI, 14-41)
16% PR (n=7)

Primary refractory (n=89)
52% ORR (n=46; 95% CI, 41-62)
28% CR (n=25; 95% CI, 19-39)
24% PR (n=21)

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

SELECT IMPORTANT SAFETY INFORMATION

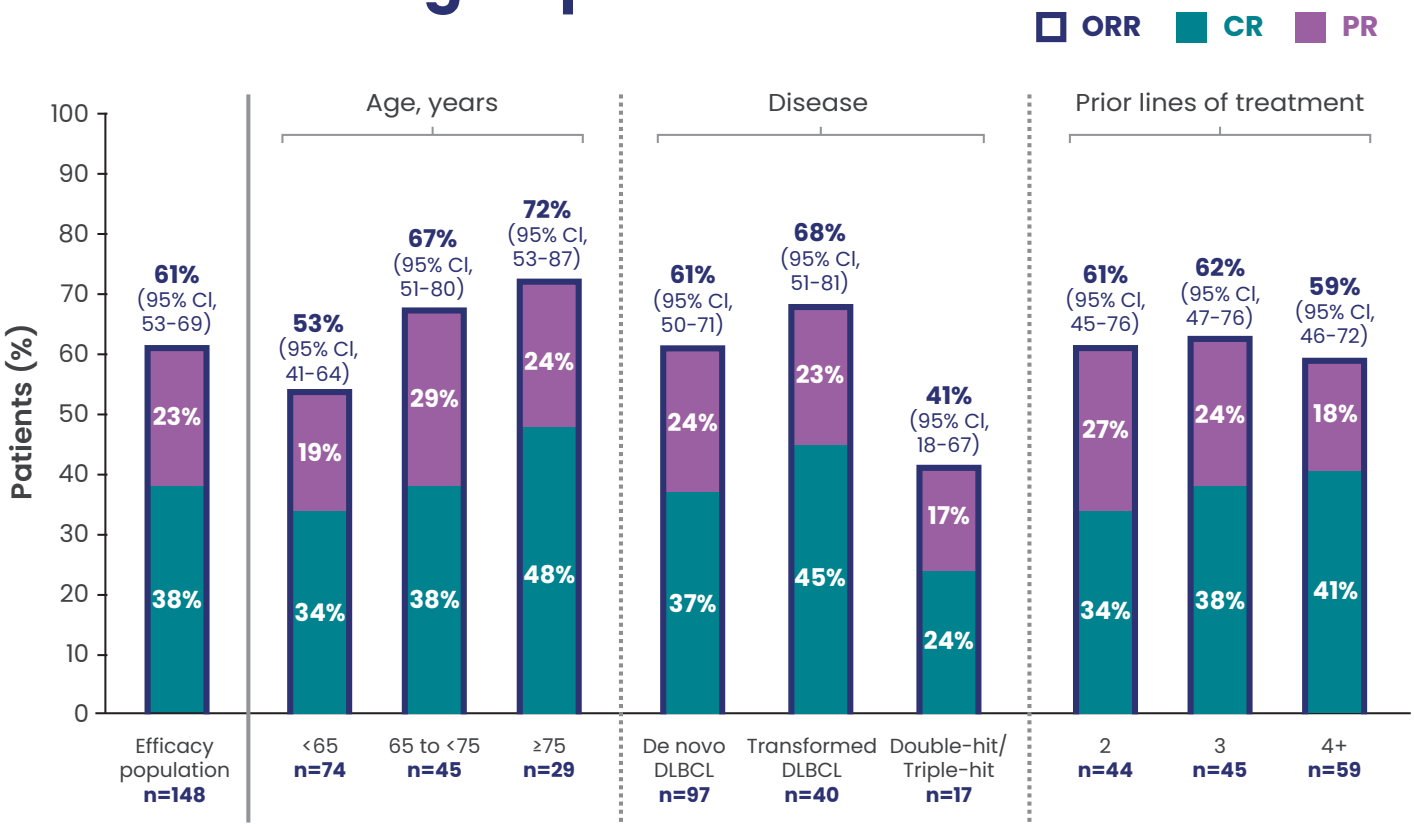
Cytokine release syndrome (CRS), including serious or fatal reactions, can occur in patients receiving EPKINLY. Initiate treatment with the EPKINLY step-up dosage schedule to reduce the incidence and severity of CRS. Withhold EPKINLY until CRS resolves or permanently discontinue based on severity.

- CRS occurred in 51% (80/157) of patients with large B-cell lymphoma (LBCL) receiving EPKINLY at the recommended dosage schedule in EPCORE NHL-1 (37% Grade 1, 17% Grade 2, and 2.5% Grade 3) and recurred in 31% of patients. Most events (92%) occurred during Cycle 1. In Cycle 1, CRS events occurred in 6% of patients after the 0.16 mg dose (Cycle 1, day 1), 12% after the 0.8 mg dose (Cycle 1, day 8), 43% after the first 48 mg dose (Cycle 1, day 15), and 5% after the next 48 mg dose (Cycle 1, day 22). The median time to onset of CRS from the most recent administered 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). Administer pretreatment medications to reduce the risk of CRS.
- For patients with LBCL, assess whether hospitalization or outpatient monitoring for the first 48 mg dose is appropriate based on comorbidities or other situational factors. During outpatient monitoring after the first 48 mg dose, patients should remain in proximity to a healthcare facility that can assess and manage CRS.
- 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.
- Monitor patients for potential CRS. At the first signs or symptoms of CRS, immediately evaluate patients for hospitalization, manage per current practice guidelines, and administer supportive care as appropriate.

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, throughout and on pages 6-7. Please see full Prescribing Information, including Boxed Warnings.

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ORR, CR, and PR rates observed across additional subgroups[1,2]*



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

*Determined by Lugano criteria (2014) as assessed by IRC.

See duration of response, including long-term follow-up data, on the following pages

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% (10/157) of patients with LBCL receiving EPKINLY at the recommended dosage schedule in the clinical trial (4.5% Grade 1, 1.3% Grade 2, 0.6% fatal). Of the 10 ICANS events, 9 occurred within Cycle 1 of treatment, with a median time to onset of 16.5 days (range: 8-141 days) from the start of treatment. Relative to the most recent administered dose, 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. 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, immediately evaluate patient, provide supportive therapy based on severity, and manage per current practice guidelines.

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In overall responders (61%, n=90/148), EPKINLY delivered sustained remission in 3L+ DLBCL, NOS patients[1]

mDOR* 15.6 months
(95% CI, 9.7 months-NR)[1]

- In overall responders (n=90/148), the median time to response was 1.4 months (range: 1.0-8.4 months)[1]
  - The median follow-up for DOR was 9.8 months (range: 0-17.3 months)

In a prespecified analysis of complete responders (38%, n=56/148)[1,2]:

mDOCR* NOT REACHED
(95% CI, 14.3 months-NR)[2]

- In complete responders (n=56/148), the median time to complete response was 2.6 months (range: 1.2-10.2 months)[2]
  - Complete responses were achieved as late as 10.2 months
  - The median follow-up for DOCR was 9.7 months (range: 8.3-12.1 months)

See long-term follow-up data with EPKINLY

*Based on Kaplan-Meier estimate.

NOS=not otherwise specified.

SELECT IMPORTANT SAFETY INFORMATION

Infections

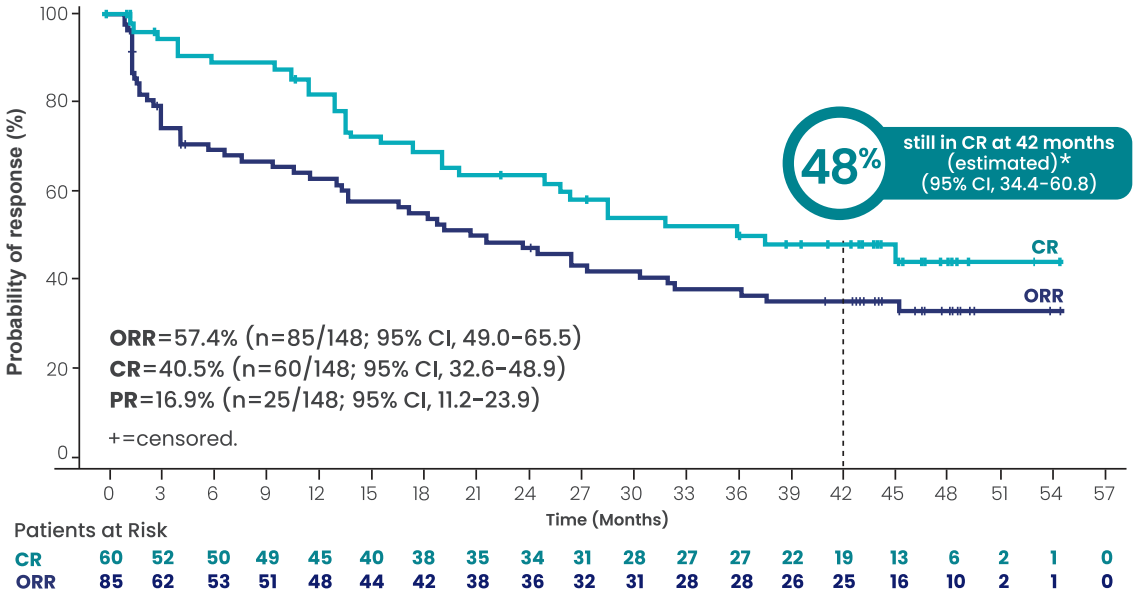
- EPKINLY can cause fatal and serious infections. Serious infections, including opportunistic infections, were reported in 15% of patients with LBCL (most common: 4.5% sepsis, 3.2% pneumonia). Fatal infections occurred in 1.3% of patients (1.3% COVID-19).
- Progressive multifocal leukoencephalopathy (PML), including fatal cases, has occurred in patients treated with EPKINLY. Across a broader clinical trial population, PML was reported in 0.4% (11/3,072) of patients, including in the first-line treatment setting. Of the 11 cases of PML, 6 resulted in fatal outcomes and 1 was unresolved at the time of death.
- Monitor patients for signs and symptoms of infection and treat appropriately. Avoid administration in patients with active infections. Withhold or consider permanent discontinuation of EPKINLY based on severity. Provide *Pneumocystis jirovecii* pneumonia (PJP) prophylaxis during treatment with EPKINLY and consider prophylaxis against herpesvirus.
- Consider monitoring immunoglobulin levels during treatment and administration of immunoglobulin treatment as appropriate.

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Long-term follow-up data[5]

Investigator-assessed DOR and DOCR at a median study follow-up of 4 years[5,6]



mDOCR*†
37.7 months
(95% CI, 20.2-NR)

mDOR*†
20.8 months
(95% CI, 13.0-32.0)

Overall median study follow-up was 49.2 months (95% CI: 47.8-50.2 months).‡
Efficacy results determined by Lugano criteria per investigator assessment (INV).
Data cutoff: May 2, 2025.

Long-term follow-up: Safety data§

- With a median study follow-up of 4 years, observations were consistent with the known epcoritamab safety profile. Discontinuation due to an adverse reaction occurred in 7.6% of patients
- Serious infections were reported in 33% of patients. Serious infections ≥5% were COVID-19 events‖ (17% of patients) and pneumonia (6% of patients). Fatal infections occurred in 16 patients, of which 12 were COVID-19 events‖

Data Limitations: No inference can be drawn from this data set. Follow-up analysis is exploratory and data are descriptive in nature. The Kaplan-Meier estimates may be unreliable at the tail end of the curve due to a smaller number of patients at risk.

*Based on Kaplan-Meier estimate.
†Median follow-up for DOR was 46.2 months (95% CI: 43.0-48.1 months). Median follow-up for DOCR was 44.1 months (95% CI: 41.3-46.6 months).‡
‡Based on reverse Kaplan-Meier estimate.
§The safety population was comprised of 157 patients with LBCL.[1]
‖COVID-19 events represent COVID-19 and COVID-19 pneumonia.

SELECT IMPORTANT SAFETY INFORMATION

Cytopenias

- EPKINLY can cause serious or severe cytopenias. In the clinical trial, Grade 3 or 4 decreased neutrophils occurred in 32% (Grade 4, 14%), decreased hemoglobin in 12% (Grade 4, 0%), and decreased platelets in 12% (Grade 4, 7%) of patients with LBCL. Febrile neutropenia occurred in 2.5% (Grade 4, 0.6%).
- 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.

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, throughout and on pages 6-7. Please see full Prescribing Information, including Boxed Warnings.

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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 (HGBCL) 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

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CRS

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- Monitor patients for potential CRS. At the first signs or symptoms of CRS, immediately evaluate patients for hospitalization, manage per current practice guidelines, and administer supportive care as appropriate.

ICANS

- ICANS occurred in 6% (10/157) of patients with large B-cell lymphoma (LBCL) receiving EPKINLY at the recommended dosage schedule in the clinical trial (4.5% Grade 1, 1.3% Grade 2, 0.6% fatal). Of the 10 ICANS events, 9 occurred within Cycle 1 of treatment, with a median time to onset of 16.5 days (range: 8-141 days) from the start of treatment. Relative to the most recent administered dose, 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. 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, immediately evaluate patient, provide supportive therapy based on severity, and manage per current practice guidelines.

Please see additional Important Safety Information on page 7.
Please see full Prescribing Information, including Boxed Warnings.

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Infections

- EPKINLY can cause fatal and serious infections. Serious infections, including opportunistic infections, were reported in 15% of patients with LBCL (most common: 4.5% sepsis, 3.2% pneumonia). Fatal infections occurred in 1.3% of patients (1.3% COVID-19).
- Progressive multifocal leukoencephalopathy (PML), including fatal cases, has occurred in patients treated with EPKINLY. Across a broader clinical trial population, PML was reported in 0.4% (11/3,072) of patients, including in the first-line treatment setting. Of the 11 cases of PML, 6 resulted in fatal outcomes and 1 was unresolved at the time of death.
- Monitor patients for signs and symptoms of infection and treat appropriately. Avoid administration in patients with active infections. Withhold or consider permanent discontinuation of EPKINLY based on severity. Provide *Pneumocystis jirovecii* pneumonia (PJP) prophylaxis during treatment with EPKINLY and consider prophylaxis against herpesvirus.
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- 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 (≥20%) adverse reactions were CRS, injection site reactions, fatigue, musculoskeletal pain, fever, diarrhea, COVID-19, rash, and abdominal pain. Most common Grade 3 to 4 laboratory abnormalities (≥10%) were decreased lymphocytes, decreased neutrophils, decreased hemoglobin, and decreased platelets.

Lactation

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

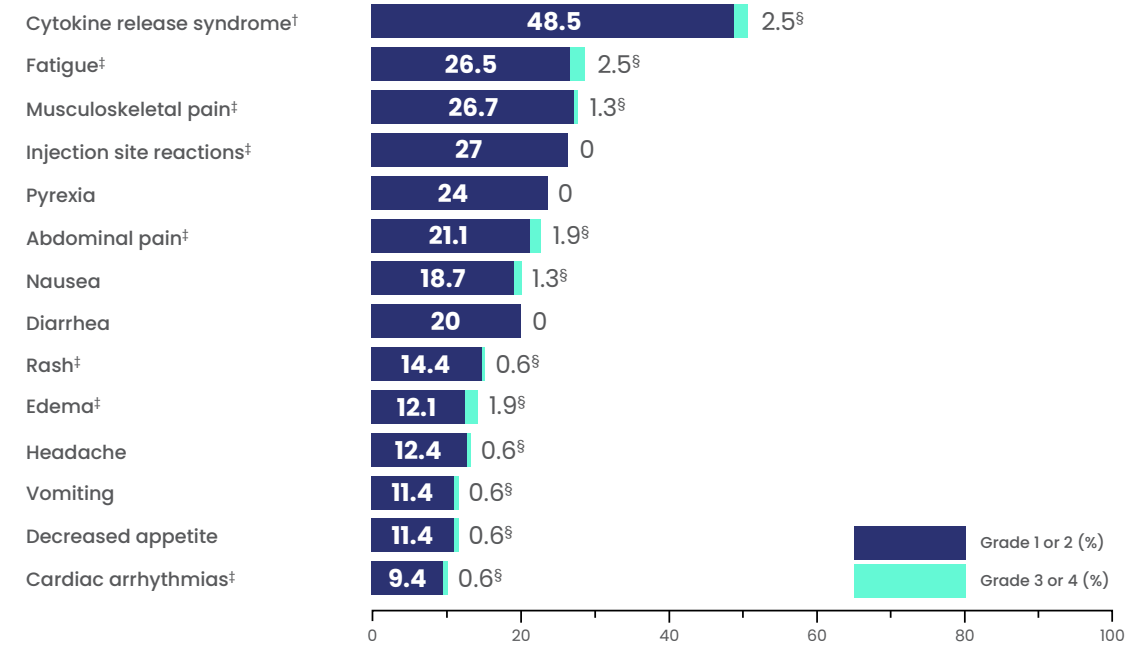
Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on page 6. Please see full Prescribing Information, including Boxed Warnings.

Learn about adverse reactions for EPKINLY on the following pages

Adverse reactions were manageable with EPKINLY[1]

Majority of adverse reactions were mild to moderate (Grade 1 or 2)[1]

MOST COMMON TREATMENT-RELATED ADVERSE REACTIONS (≥10%, N=157)*



*Adverse reactions were graded based on CTCAE Version 5.0.

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

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

§Only Grade 3 adverse reactions occurred.

- 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 (Cycles 1-3), and incidence declined after 12 weeks[4]

Low discontinuation rate (3.8%) due to any adverse reaction[1]:

- 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)

[‖]Infections included sepsis, COVID-19, pneumonia, and upper respiratory tract infections.

ASTCT=American Society for Transplantation and Cellular Therapy; CTCAE=Common Terminology Criteria for Adverse Events.

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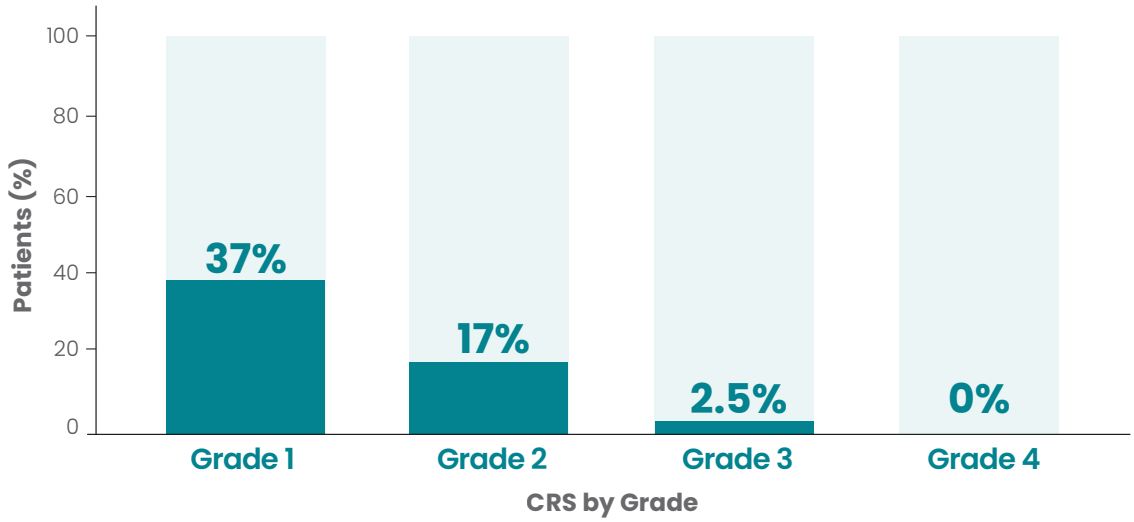
CRS was primarily low grade, predictable, and manageable[1]

Hospitalization is not required for monitoring with EPKINLY administration. Assess each patient.

- Due to the risk of CRS and ICANS, monitor all patients for signs and symptoms
  - For patients with DLBCL, assess whether hospitalization or outpatient monitoring for the first 48-mg dose is appropriate based on comorbidities or other situational factors
  - During outpatient monitoring after the first 48-mg dose, patients should remain in proximity to a healthcare facility that can assess and manage CRS
- Hospitalization may be needed to manage some adverse reactions

Please see Dosage and Administration requirements on page 13 of this brochure and Section 2 of the Prescribing Information.

CRS events reported in EPCORE® NHL-1



- CRS occurred in 51% (80/157) of the patients. The majority of these patients experienced a Grade 1 (37%) or Grade 2 (17%) event
- **Most CRS events (92%) occurred during Cycle 1**
  - In Cycle 1, CRS events occurred in 6% of patients after the 0.16-mg dose, 12% after the 0.8-mg dose, 43% after the first 48-mg dose, and 5% after the next 48-mg dose
- The median time to onset of CRS from the most recent dose of EPKINLY was 24 hours (range: 0-10 days)
  - The median time to onset after the first 48-mg dose was 21 hours (range: 0-7 days)
- **In patients with LBCL or FL across multiple studies, CRS resolved in 98% of patients**
  - The median time to resolution was 2 days (range: <1 to 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.

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

FL=follicular lymphoma.

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ICANS events reported in EPCORE® NHL-1[1]

The majority of ICANS cases occurred within Cycle 1[1]

- 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 ICANS grading and management recommendations.

References: 1. EPKINLY [package insert]. Plainsboro, NJ: Genmab US, Inc. and North Chicago, IL: AbbVie Inc. 2026. **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.4.2026. © National Comprehensive Cancer Network, Inc. 2026. All rights reserved. Accessed July 27, 2026. To view the most recent and complete version of the guidelines, go online to NCCN.org. 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. **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.** Data on file. Plainsboro, NJ: Genmab US, Inc. and North Chicago, IL: AbbVie Inc. 2025. **6.** Data on file. Plainsboro, NJ: Genmab US, Inc. and North Chicago, IL: AbbVie Inc. May 2025. **7.** A phase 2, open-label trial to evaluate safety of epcoritamab monotherapy in subjects with relapsed or refractory diffuse large B-cell lymphoma and classic follicular lymphoma (previously grade 1-3a) when administered in the outpatient setting. ClinicalTrials.gov identifier: NCT05451810. Updated January 24, 2025. Accessed April 4, 2026. https://clinicaltrials.gov/study/NCT05451810 **8.** Andorsky D, Torres Lopez A, Vaidya R, et al. Epcoritamab monotherapy as outpatient treatment for patients with relapsed/refractory diffuse large B-cell lymphoma: interim results from EPCORE NHL-6. *Clin Lymphoma Myeloma Leuk*. Published online February 19, 2026. doi:10.1016/j.clml.2026.02.006 **9.** Data on file. Plainsboro, NJ: Genmab US, Inc. and North Chicago, IL: AbbVie Inc. 2026. **10.** 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 **11.** Engelberts PJ, Hiemstra IH, de Jong B, et al. DuoBody-CD3xCD20 induces potent T-cell–mediated killing of malignant B cells in preclinical models and provides opportunities for subcutaneous dosing. *EBioMedicine*. 2020;52:102625. doi:10.1016/j.ebiom.2019.102625 **12.** Vaidya R, Torres Lopez A, Awan F, et al. Updated results from EPCORE NHL-6: Phase 2 study of subcutaneous epcoritamab as outpatient treatment for 2L+ relapsed/refractory diffuse large B-cell lymphoma (R/R DLBCL). *Clinical Lymphoma, Myeloma and Leukemia.* Poster presented at the Society of Hematologic Oncology Annual Meeting; September 3–6, 2025; Houston, TX, USA. https://flasco.org/wp-content/uploads/FLASCO25_Sundaram_NHL-6-Update_ENCORE-POSTER.pdf.

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Additional study on EPKINLY monotherapy with outpatient monitoring[7,8]

Study design

- A Phase 2, open-label, single-arm study (M23-362) evaluated the safety of EPKINLY monotherapy with outpatient monitoring after the first full dose in patients with R/R DLBCL who had received 1 or more prior lines of systemic therapy in an outpatient setting. 50/92 patients (54.3%) had 3L+ disease at baseline
- Patients received subcutaneous EPKINLY in 28-day cycles until disease progression or unacceptable toxicity, with Cycle 1 step-up dosing consisting of a 0.16-mg priming dose on Day 1, a 0.8-mg intermediate dose on Day 8, and subsequent full 48-mg doses on Day 15 and Day 22. Thereafter, full doses were given (Cycles 2-3, QW; Cycles 4-9, Q2W; Cycle 10 onward, Q4W) until progressive disease (PD) or unacceptable toxicity
- Primary endpoints: percentage of participants experiencing Grade 3 or higher CRS, ICANS, or neurologic events
- Median study follow-up for 3L+ DLBCL patients was 10.8 months (range: 8.2-14.8 months)
- **All patients in the study received treatment in the US, and study sites included both academic and community locations**
- Baseline characteristics: median age, 64.5 years (range: 28-86 years); DLBCL type, de novo 70% and transformed 30%; ECOG PS 0-1, 96%; R-IPI 3+, 48%; median prior lines of therapy, 3 (range: 2-7); prior CAR T, 44%; Ann Arbor staging III-IV, 86%

Cycle 1 CRS prophylaxis

Corticosteroid

- Dexamethasone (preferred) 15 mg IV or oral
- Administered on Days 1-4, Days 8-11, Days 15-18, and Days 22–25 of Cycle 1[12]

Other premedications

- Diphenhydramine and acetaminophen
- Administered prior to each EPKINLY dose on Day 1, Day 8, Day 15, and Day 22 of Cycle 1

Additional hydration (strongly recommended)

- Administer 2-3 L of oral fluids during the 24 hours prior to treatment with EPKINLY, 500 mL isotonic IV fluids immediately before treatment, and 2–3 L of oral fluids during the first 24 hours after treatment

Data Limitations: Data are descriptive in nature and not included in the Prescribing Information for EPKINLY. No conclusions regarding safety can be made.

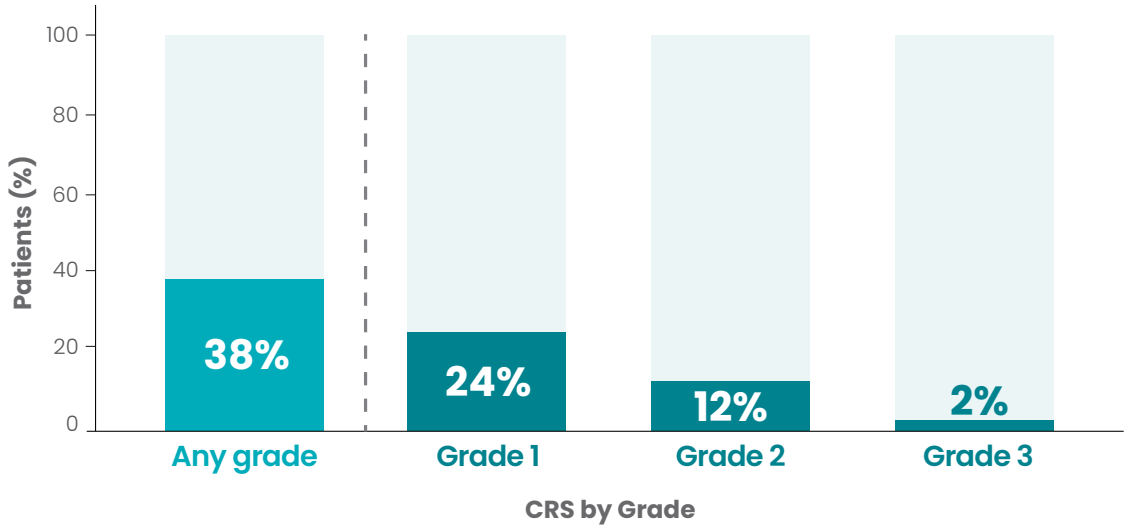
AE=adverse event; ECOG PS=Eastern Cooperative Oncology Group performance status; IV=intravenous; QW=once weekly; Q2W=once every 2 weeks; Q4W=once every 4 weeks; R-IPI=revised International Prognostic Index.

Please see Important Safety Information, including Boxed Warnings for CRS and ICANS, throughout and on pages 6-7.
Please see full Prescribing Information, including Boxed Warnings.

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SUBCUTANEOUS INJECTION 4mg|48mg

Additional study on EPKINLY monotherapy with outpatient monitoring[8,9] (cont'd)

Study results in 3L+ DLBCL subgroup (n=50)



100%
resolution with no discontinuations due to CRS

- Nineteen of 50 patients with 3L+ DLBCL experienced a CRS event
- In Cycle 1, CRS events occurred in 6% of patients after the 0.16-mg dose, 4.1% after the 0.8-mg dose, 28.3% after the first 48-mg dose, and 6.7% after the second 48-mg dose
- At the January 2025 data cutoff, 46/50 patients with 3L+ DLBCL had received their first full dose, including 3 who were monitored inpatient*
- Of the 10 patients who were monitored outpatient after first full dose and had a CRS event, 6 patients were managed inpatient
- The median time to onset of CRS after the first 48-mg dose was 32.2 hours (range: 11.9-165.1 hours)
- The median time to CRS resolution was 3 days (range: 1-24 days)
- Four patients (8%) had at least 1 ICANS event; 6% were Grade 1 and 2% were Grade 2
  - Four patients had resolution of ICANS (100%)
  - The median time to resolution of ICANS was 3 days (range: 1-6 days)
- Serious infections occurred in 15 patients (30%), with the most common being COVID-19 (n=8). Fatal infections occurred in 4 patients, of which 3 were due to COVID-19
- In this study that evaluated the safety of EPKINLY in the outpatient setting, the efficacy† is consistent with the Prescribing Information[1,8]

*Of the 3 patients monitored inpatient, 1 was admitted for logistical/social/medical reasons and 2 were admitted for adverse reactions other than CRS.

†Investigator-assessed.

Data Limitations: Data are descriptive in nature and not included in the Prescribing Information for EPKINLY. No conclusions regarding safety can be made.

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Subcutaneous EPKINLY is accessible across practice settings[1,4]

	EPKINLY (subcutaneous)	
CYCLE 1	Week 1	0.16 mg
	Week 2	0.8 mg
	Week 3	48 mg
	Week 4	48 mg
CYCLES 2-3	48 mg weekly	
CYCLES 4-9	48 mg every other week	
Monthly maintenance dosing CYCLES 10+	48 mg every 4 weeks	

- Administer EPKINLY subcutaneously in 28-day cycles to well-hydrated patients until disease progression or unacceptable toxicity[1]
- 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[1]

Hospitalization is not required for monitoring with EPKINLY administration. Assess each patient.[1]

- Assess whether hospitalization or outpatient monitoring for the first 48-mg dose is appropriate based on comorbidities or other situational factors
- During outpatient monitoring after the first 48-mg dose, patients should remain in proximity to a healthcare facility that can assess and manage CRS
  - Inform patients of the risk of CRS, and to immediately contact their HCP should signs and symptoms associated with CRS (eg, pyrexia, hypotension, hypoxia, chills, tachycardia, headache, and dyspnea) occur at any time
- EPKINLY should only be administered by a qualified HCP with appropriate medical support to manage severe reactions such as CRS and ICANS
- Due to the risk of CRS and ICANS, monitor all patients for signs and symptoms
- Hospitalization may be needed to manage some adverse reactions

EPKINLY is designed to improve tolerability[1]

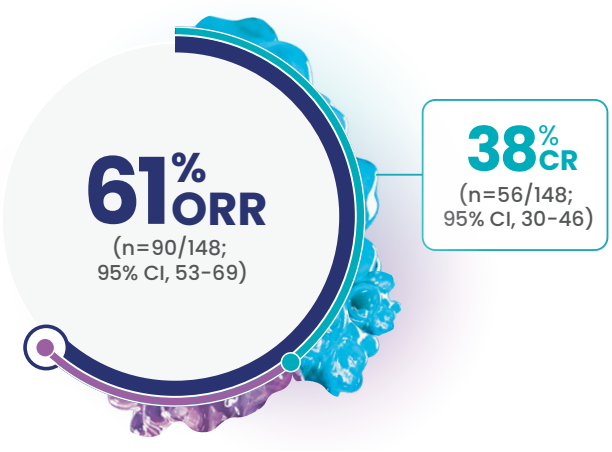
- Step-up dosing of EPKINLY is intended to increase tolerability and mitigate incidence and severity of CRS[1,10]
- Initiate treatment with the EPKINLY step-up dosing schedule and premedicate before each dose in Cycle 1 to reduce the incidence and severity of CRS[1]
- Provide *Pneumocystis jirovecii* pneumonia prophylaxis during treatment with EPKINLY and consider providing prophylaxis against herpesvirus to prevent herpes simplex and herpes zoster[1]
- Subcutaneous administration allows more gradual increases and lower peaks in plasma cytokine levels than IV administration[11]
- EPKINLY is an off-the-shelf treatment, available to treat patients at the moment of relapse[1,4]

Please see Important Safety Information, including Boxed Warnings for CRS and ICANS, throughout and on pages 6-7.
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With EPKINLY, sustained remission is within reach[1]

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



- **PR: 23% (n=34/148; 95% CI, 17-31)**

mDOR* 15.6 months
(n=90/148; 95% CI, 9.7 months-NR)[1]

- In an open-label, multicohort, single-arm trial in 157 patients. Efficacy results (n=148) determined by Lugano criteria (2014) as assessed by Independent Review Committee

*Based on Kaplan-Meier estimate.

Hospitalization is not required for monitoring with EPKINLY administration. Assess each patient.

- Due to the risk of CRS and ICANS, monitor all patients for signs and symptoms
  - For patients with DLBCL, assess whether hospitalization or outpatient monitoring for the first 48-mg dose is appropriate based on comorbidities or other situational factors
  - During outpatient monitoring after the first 48-mg dose, patients should remain in proximity to a healthcare facility that can assess and manage CRS
- Hospitalization may be needed to manage some adverse reactions

Manageable adverse reactions[1,4]

- 3.8% discontinued due to ARs: 34% experienced dosage interruptions
- Most common ARs (≥20%) were CRS, fatigue, musculoskeletal pain, injection site reactions, pyrexia, abdominal pain, nausea, and diarrhea
- CRS was primarily low grade, predictable, and manageable, with Grade 3 events occurring in 2.5% of patients and no Grade 4 events
- EPKINLY can cause serious side effects, including CRS, ICANS, infections, cytopenias, and embryo-fetal toxicity

Learn more and find resources at EPKINLYhcp.com

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 (HGBCL) 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 fatal reactions, can occur in patients receiving EPKINLY. Initiate treatment with the EPKINLY step-up dosage 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 & Precautions: Infections, Cytopenias, and Embryo-Fetal Toxicity.

Please see additional Important Safety Information throughout and on pages 6-7.
Please see full Prescribing Information, including Boxed Warnings.

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