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

For 3L+ DLBCL

THE POWER FOR DURABLE RESPONSES[1,2]

Discover subcutaneous EPKINLY, which demonstrated a remarkable 61% ORR* with a mDOR*† of 15.6 months.[1] 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%	38%	23%	15.6 Months	Not Reached
ORR*	**CR**	**PR**	**mDOR†**	**mDOCR[2]†**
n=90/148 95% CI, 53-69	n=56/148 95% CI, 30-46	n=34/148 95% CI, 17-31	n=90/148 95% CI, 9.7 months-NR	n=56/148 95% CI, 14.3 months-NR

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 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 (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

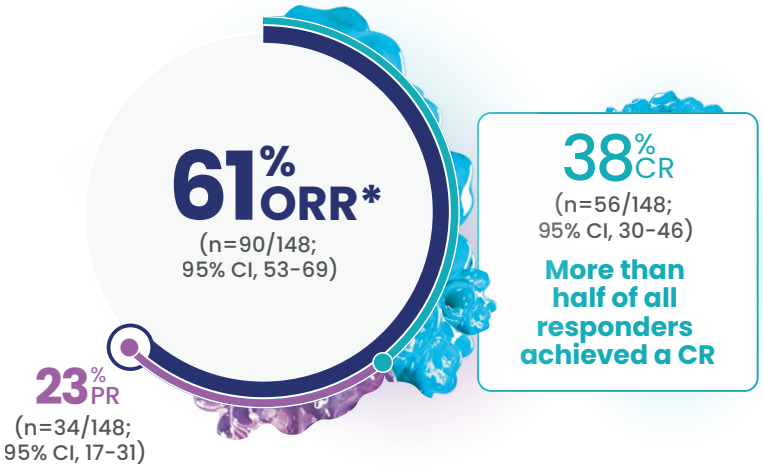
BOXED WARNINGS

- **Cytokine release syndrome (CRS), including serious or life-threatening 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.**

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; NCCN=National Comprehensive Cancer Network; 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]



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.

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- CRS occurred in 51% of patients with large B-cell lymphoma (LBCL) 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 with DLBCL or high-grade B-cell lymphoma 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.

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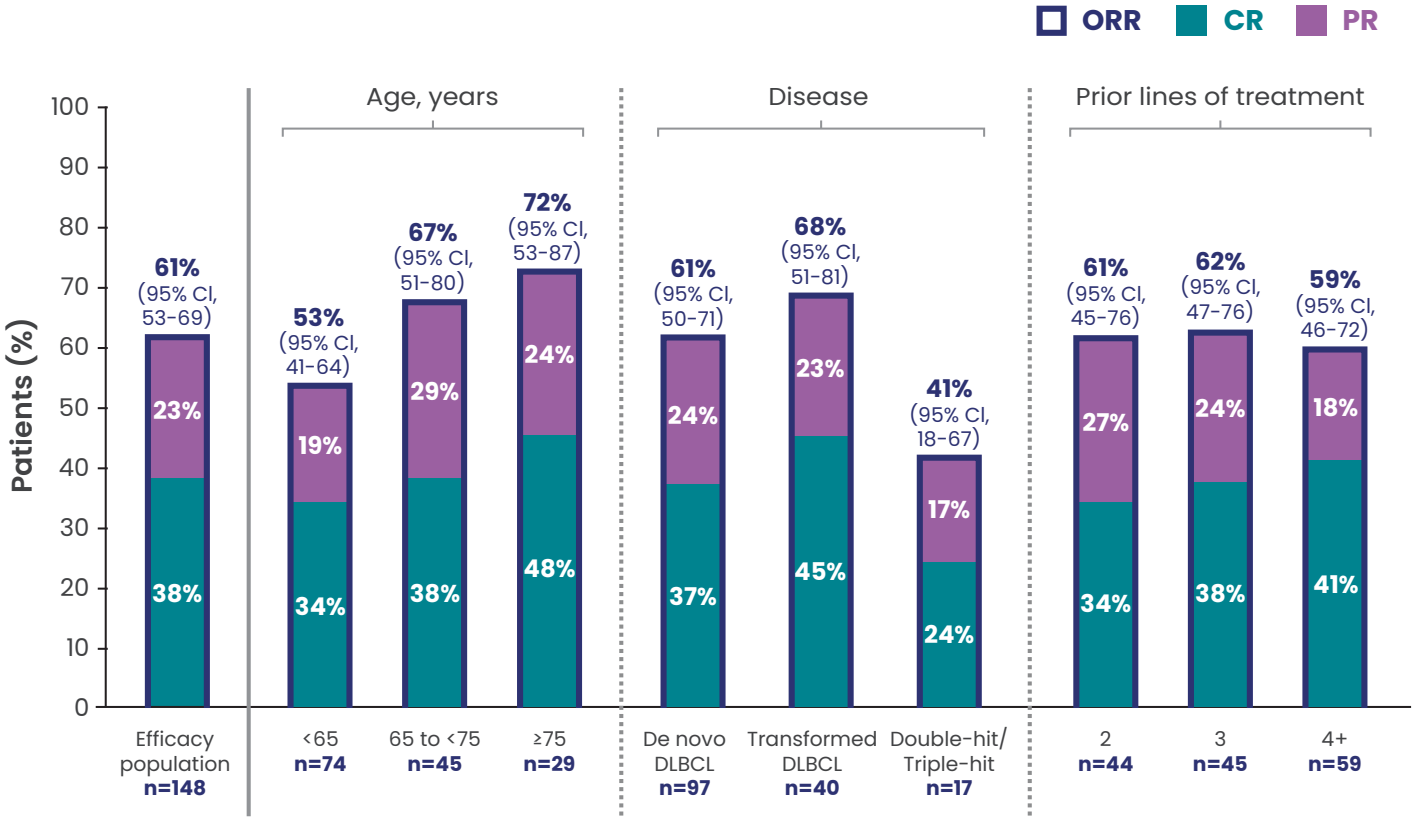
ORR, CR, and PR rates observed across additional subgroups[1,2]*



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% of patients with LBCL 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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In overall responders (61%, n=90/148), EPKINLY delivered durable responses in heavily pretreated 3L+ DLBCL, NOS patients[1]

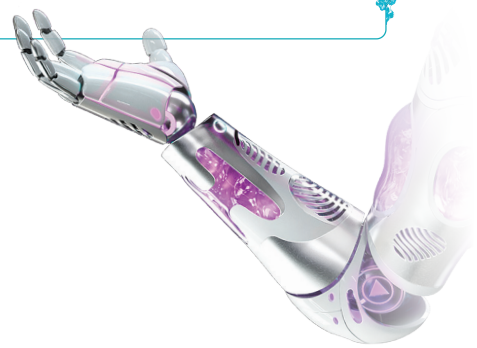
RAPID	DURABLE	SUSTAINED
1.4 months median time to response (range: 1.0-8.4)	mDOR* **15.6 months** (95% CI, 9.7 mo-NR)	**63%** still responding at 9 months* (estimated; 95% CI, 52-72)

- 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 prespecified 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 months[2]
- 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

Infections

- EPKINLY can cause serious and fatal infections. In the clinical trial, 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).
- 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.

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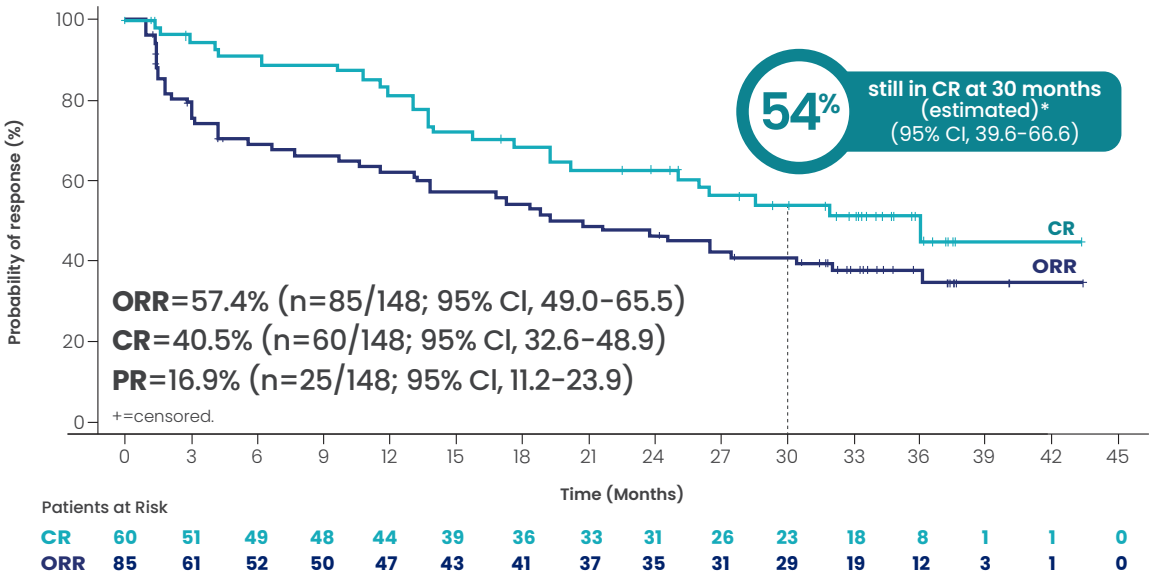
Long-term follow-up data[5]

Investigator-assessed DOR and DOCR at a median study follow-up of 3 years



mDOCR*†
36.1 months
(95% CI, 20.2-NR)

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

Overall median study follow-up was 37.2 months (range: 0.3+, 45.5).‡
Efficacy results determined by Lugano criteria per investigator assessment (INV).
Data cutoff: May 3, 2024.

Long-term follow-up: Safety data

- With a median study follow-up of 3 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 31% of patients. Serious infections ≥5% were COVID-19 events§ (17% of patients), and pneumonia (5% of patients). Fatal infections occurred in 14 patients, of which 10 were COVID-19 events§

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 33.6 months (range: 32.7-37.2 months). Median follow-up for DOCR was 33.4 months (range: 31.8-34.9 months).‡
‡Based on reverse Kaplan-Meier estimate.
§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 events occurred in 32% (neutrophils decreased), 12% (hemoglobin decreased), and 12% (platelets decreased) of patients with LBCL. 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.

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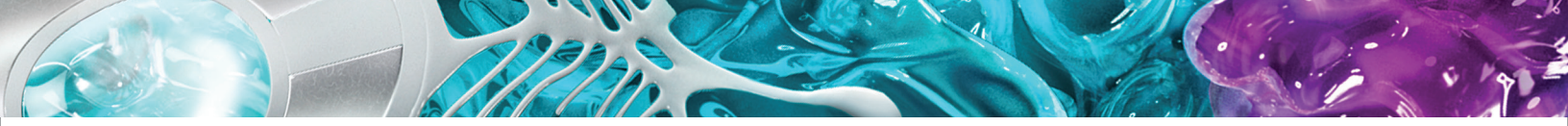

INDICATION

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

- **Cytokine release syndrome (CRS), including serious or life-threatening 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.**
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CRS

- CRS occurred in 51% of patients with large B-cell lymphoma (LBCL) 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 with LBCL 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 with DLBCL or high-grade B-cell lymphoma 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.

ICANS

- ICANS occurred in 6% of patients with large B-cell lymphoma (LBCL) 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.

Please see additional Important Safety Information on page 7.
Please see full Prescribing Information.

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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, fatigue, musculoskeletal pain, injection site reactions, pyrexia, abdominal pain, nausea, and diarrhea. Most common grade 3 to 4 laboratory abnormalities (≥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.

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

Learn about adverse reactions for EPKINLY on the following pages

References: 1. EPKINLY [package insert]. Plainsboro, NJ: Genmab US, Inc. and North Chicago, IL: AbbVie Inc. 2024. **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.3.2024. © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed August 26, 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*. 2023;41(12):2238-2247. doi:10.1200/JCO.22.01725 **5.** Data on file. Plainsboro, NJ: Genmab US, Inc. and North Chicago, IL: AbbVie Inc. October 2024. **6.** 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

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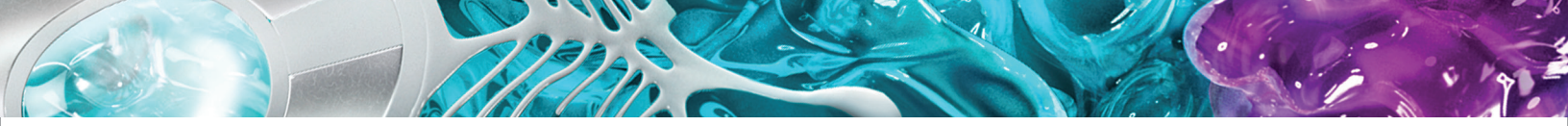

Adverse reactions were manageable with subcutaneous EPKINLY[1]

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

Most common treatment-related adverse reactions (≥10%, N=157)

ADVERSE REACTIONS*	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.

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

‡Only grade 3 adverse reactions occurred.

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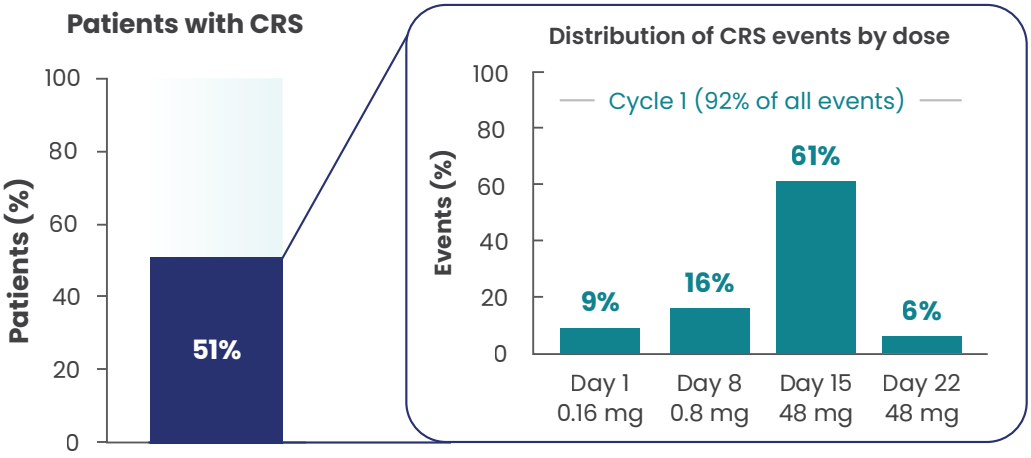
CRS was primarily low grade, predictable, and manageable[1]

- 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 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)

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 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 CRS and ICANS grading and management recommendations.

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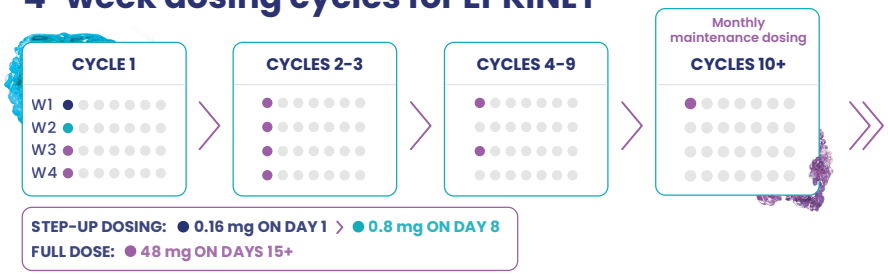
Off-the-shelf EPKINLY enables accelerated treatment initiation[1]

EPKINLY is available to treat patients at the moment of relapse[1,4]

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 CRS[1,6]
- 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.

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

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- **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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