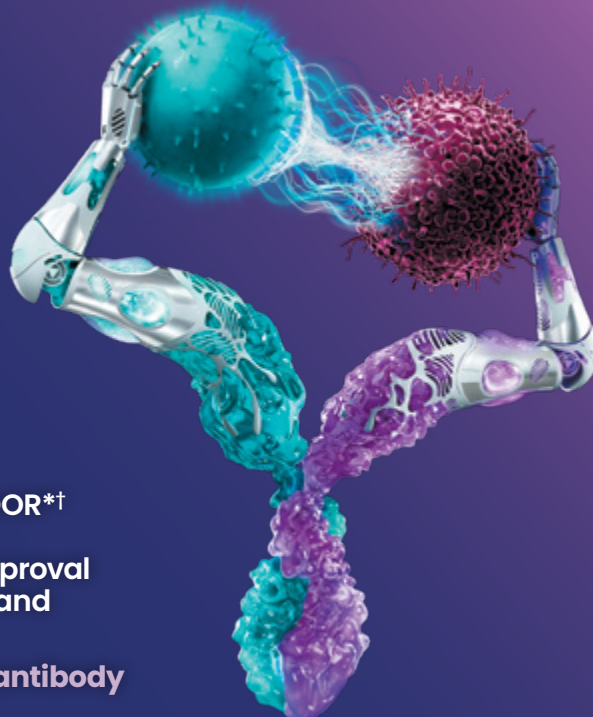


**FOR 3L+ FL**

# THE POWER FOR DURABLE RESPONSES<sup>†</sup>

EPKINLY demonstrated a remarkable 82% ORR\* with mDOR\*<sup>†</sup> not reached.<sup>†</sup> 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).

EPKINLY is the first-and-only subcutaneous bispecific antibody for adult patients with 3L+ FL<sup>†</sup>



**82%**  
ORR\*  
n=104/127  
95% CI, 74-88

**60%**  
CR  
n=76/127  
95% CI, 51-68

**22%**  
PR  
n=28/127  
95% CI, 15-30

**Not reached**  
mDOR\*<sup>†</sup>  
n=104/127  
95% CI, 13.7 months-NR

The efficacy of EPKINLY was evaluated in EPCORE<sup>®</sup> NHL-1, an open-label, multicohort, multicenter, single-arm trial in 127 patients with R/R FL after at least 2 lines of systemic therapy.<sup>†</sup>

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

<sup>†</sup>Based on Kaplan-Meier estimate. The median follow-up for DOR was 14.8 months.

**NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines<sup>®</sup>) Recommended**

The NCCN Guidelines<sup>®</sup> recommend epcoritamab-bysp (EPKINLY) as an NCCN Category 2A treatment option after 2 or more lines of systemic therapy for patients with R/R FL (**Category 2A preferred**)<sup>2‡</sup>

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.<sup>2</sup>

<sup>‡</sup>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 follicular lymphoma (FL) 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.**

**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; FL=follicular lymphoma; 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.



## EPCORE® NHL-1: Pivotal Phase 1/2 trial that evaluated subcutaneous EPKINLY for 3L+ FL patients<sup>1,3</sup>

An open-label, multicohort, multicenter, single-arm trial that included patients with R/R FL after at least 2 lines of systemic therapy<sup>1</sup>

Patients with 3L+ FL (N=213)<sup>1,3,4</sup>

ENDPOINTS		DOSAGE SCHEDULE	
<b>2-step up dosage schedule cohort (n=127), trial enrollment started June 2020:</b> Primary endpoint*: <b>ORR (CR+PR)</b> Select secondary endpoints*: <b>CR rate, DOR, DOCR, and TTR</b>		<b>2-step up dosage (n=127) cycle 1:</b> <ul style="list-style-type: none"> <li>0.16 mg on day 1</li> <li>0.8 mg on day 8</li> <li>48 mg on days 15 and 22</li> </ul>	
<b>3-step up dosage schedule cohort (n=86), trial enrollment started October 2022:</b> Primary endpoint: <b>Percentage of grade ≥2 CRS events and all grade CRS events</b> Select secondary endpoints†: <b>ORR (CR+PR)</b>		<b>3-step up dosage (n=86) cycle 1:</b> <ul style="list-style-type: none"> <li>0.16 mg on day 1</li> <li>0.8 mg on day 8</li> <li>3 mg on day 15</li> <li>48 mg on day 22</li> </ul>	
KEY INCLUSION CRITERIA		ALL PATIENTS (N=213)	
ECOG PS 0-2, prior CAR T and autologous HSCT allowed, patients who received 2 or more therapies		<ul style="list-style-type: none"> <li>Cycles 2-3: 48 mg on days 1, 8, 15, 22</li> <li>Cycles 4-9: 48 mg on days 1 and 15</li> <li>Cycles 10 and beyond: 48 mg on day 1</li> </ul>	
KEY EXCLUSION CRITERIA		Patients continued to receive subcutaneous EPKINLY until disease progression or unacceptable toxicity.	
CNS involvement of lymphoma; allogeneic HSCT or solid organ transplant; ongoing active infection; known impaired T-cell immunity; creatinine clearance <45 mL/min; alanine aminotransferase >3x ULN; cardiac ejection fraction <45%		Cycle=28 days.	

**The 3-step up dosage schedule is the recommended dosage for patients with 3L+ FL.** A separate dose optimization cohort evaluated the recommended 3-step up dosage schedule for CRS mitigation.<sup>1</sup>

\*Efficacy results determined by Lugano criteria (2014) as assessed by IRC.

†Assessed by investigator.

CAR T=chimeric antigen receptor T cell; CNS=central nervous system; CRS=cytokine release syndrome; DOCR=duration of complete response; DOR=duration of response; ECOG PS=Eastern Cooperative Oncology Group performance status; HSCT=hematopoietic stem cell transplant; TTR=time to response; ULN=upper limit of normal.

### SELECT IMPORTANT SAFETY INFORMATION

**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.**

- CRS occurred in 49% of patients with FL receiving the recommended 3-step up dosage schedule in the clinical trial (45% grade 1, 9% grade 2) and recurred in 23% of patients. Most events (88%) occurred during cycle 1, with 49% occurring after the 48 mg dose on cycle 1, day 22.
- 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 4.7% of patients with FL and included headache and dizziness.

**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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## EPKINLY was studied in a population that included challenging-to-treat patients with R/R FL<sup>1,5-8</sup>

EPKINLY was evaluated in 3L+ patients with characteristics linked to a poor prognosis<sup>1,5-8</sup>

### Select patient characteristics<sup>1,5</sup>

DEMOGRAPHICS (N=127, 2-step up dosage cohort)	
Age	
Median	65 yr (range: 39 to 84)
≥65 years	52%
Stage III-IV disease	85%
Bulky disease >6 cm	25%
ECOG PS 0 or 1	95%
ECOG PS 2	6%
FLIPI score 3 to 5	61%

In the 3-step up dosage cohort (n=86), the median age was 63.5 years (range: 33 to 90), 57% were male, and 100% had an ECOG performance status of 0 or 1.<sup>1</sup>

TREATMENT HISTORY (N=127, 2-step up dosage cohort)	
Double refractory*	70%
Refractory <sup>†</sup> to last prior therapy	69%
Refractory to ≥2 consecutive lines of anti-lymphoma therapy	55%
Refractory to prior anti-CD20 mAb therapy	79%
Median no. of prior therapies	3 (range: 2 to 9)
2 prior therapies	36%
3 prior therapies	32%
4+ prior therapies	32%
POD24	52%
Prior therapy	
Anti-CD20 mAb	100%
Alkylating agent	100%
Autologous HSCT	19%
CAR T cell therapy	5%
Rituximab + lenalidomide	21%

\*Double refractory: refractory to both an anti-CD20 mAb and alkylator therapy.<sup>5</sup>

<sup>†</sup>Refractory: patient with no response or relapse within 6 months after completing therapy.<sup>5</sup>

CD20=cluster of differentiation 20; FLIPI=Follicular Lymphoma International Prognostic Index; mAb=monoclonal antibody; POD24=progression of disease within 24 months of first systemic therapy.

### SELECT IMPORTANT SAFETY INFORMATION

- Administer pretreatment medications to reduce the risk of CRS. 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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# EPKINLY delivered an ORR of 82%, with 60% of patients achieving a deep response of CR<sup>1</sup>

**22% PR**  
(n=28/127;  
95% CI, 15-30)

**82% ORR\*†**  
(n=104/127;  
95% CI, 74-88)

**60% CR**

(n=76/127;  
95% CI, 51-68)

**Majority  
of patients  
achieved a CR**

### Rapid response

- In responders (n=104), the median time to first response was 1.4 months (range: 1 to 3 months)<sup>††</sup>

In a prespecified analysis of complete responders (n=76), the median time to complete response was 1.5 months (range: 1.2 to 11.1 months)<sup>1,5</sup>

\*Efficacy results determined by Lugano criteria (2014) as assessed by IRC.

†Median study follow-up was 17.4 months.

The investigator-assessed efficacy results of the 86 patients who received the recommended 3-step up dosage schedule<sup>†</sup> in the EPCORE<sup>®</sup> NHL-1 dose optimization cohort were comparable to the primary efficacy population<sup>1,4†</sup>

- ORR: 86% (n=74/86; 95% CI, 77-93)
- CR: 64% (n=55/86; 95% CI, 53-74)
- PR: 22% (n=19/86)

†Median study follow-up for the dose optimization cohort was 5.7 months.

### 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 FL receiving the 2-step up dosage schedule in the clinical trial (3.9% grade 1, 2.4% grade 2).
- 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, 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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## EPKINLY delivered durable responses, with mDOR\*† not reached<sup>1,5</sup>

In overall responders (82%, n=104/127)<sup>1,5\*</sup>:

mDOR **NOT REACHED**†  
(95% CI, 13.7 months–NR)

**68%** Still responding at  
12 months (estimated)†  
(95% CI, 57.6–77.0)

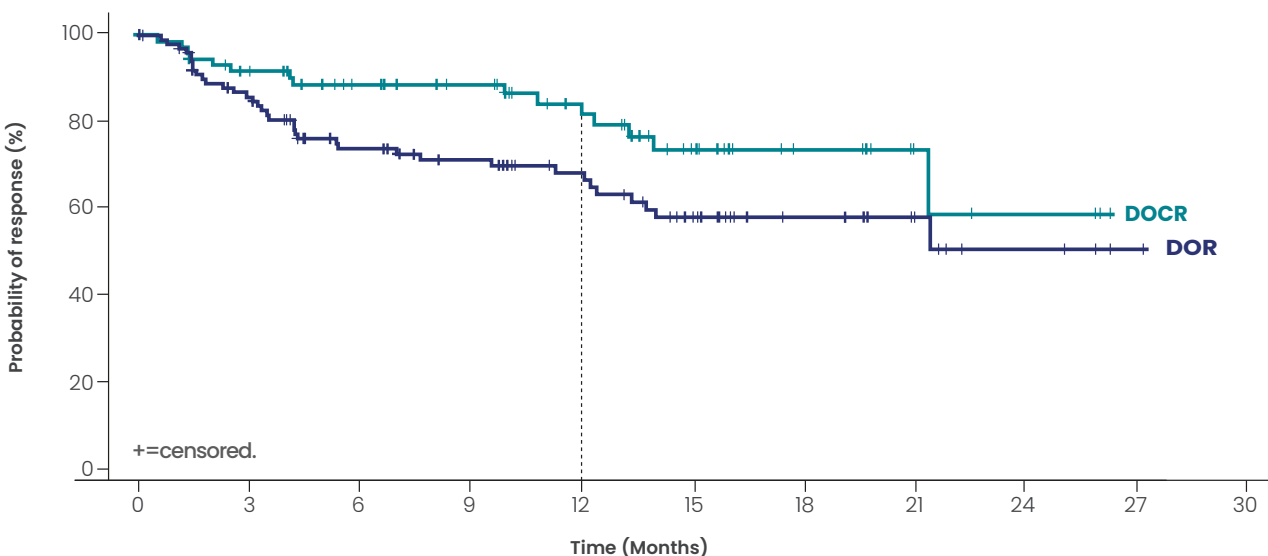
- The median follow-up for DOR was 14.8 months (range: 0.0+, 27.2+)‡

In a prespecified analysis of  
complete responders (60%, n=76/127)<sup>1,5\*</sup>:

mDOCR **NOT REACHED**†  
(95% CI, 21.4 months–NR)

**84%** Still responding at  
12 months (estimated)†  
(95% CI, 72.3–91.4)

- The median follow-up for DOCR was 13.2 months (range: 0.0+, 26.3+)‡



Patients at Risk	<b>DOR</b>	104	82	63	54	41	25	13	8	4	1	0
	<b>DOCR</b>	76	63	51	45	34	20	10	5	3	0	

\*Efficacy results determined by Lugano criteria (2014) as assessed by IRC.

†Based on Kaplan-Meier estimate.

‡Both lower and upper limits of the range indicate a censored value.

mDOCR=median duration of complete response.

### SELECT IMPORTANT SAFETY INFORMATION

#### Infections

- EPKINLY can cause serious and fatal infections. Serious infections, including opportunistic infections, were reported in 40% of patients with FL receiving the 2-step up dosage schedule in the clinical trial (most common: 20% COVID-19, 13% pneumonia, 3% urinary tract infections). Fatal infections occurred in 6% of patients (5% COVID-19, 0.8% pneumonia, 0.8% sepsis).
- 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, 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 follicular lymphoma (FL) 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.**
- **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

- CRS occurred in 49% of patients with FL receiving the recommended 3-step up dosage schedule in the clinical trial (45% grade 1, 9% grade 2) and recurred in 23% of patients. Most events (88%) occurred during cycle 1, with 49% occurring after the 48 mg dose on cycle 1, day 22.
- 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 4.7% of patients with FL and included headache and dizziness.
- Administer pretreatment medications to reduce the risk of CRS. 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 FL receiving the 2-step up dosage schedule in the clinical trial (3.9% grade 1, 2.4% grade 2).
- 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. Serious infections, including opportunistic infections, were reported in 40% of patients with FL receiving the 2-step up dosage schedule in the clinical trial (most common: 20% COVID-19, 13% pneumonia, 3% urinary tract infections). Fatal infections occurred in 6% of patients (5% COVID-19, 0.8% pneumonia, 0.8% sepsis).
- 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 7.  
Please see full [Prescribing Information](#), including Boxed Warnings.

  
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## IMPORTANT SAFETY INFORMATION (CONTINUED)

### Cytopenias

- EPKINLY can cause serious or severe cytopenias. In the clinical trial of patients with FL receiving the 2-step up dosage schedule, grade 3 or 4 events occurred in 30% (neutrophils decreased), 10% (hemoglobin decreased), and 8% (platelets decreased). Febrile neutropenia occurred in 3.1%.
- 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 injection site reactions, CRS, COVID-19, fatigue, upper respiratory tract infection, musculoskeletal pain, rash, diarrhea, pyrexia, cough, and headache. The most common grade 3 to 4 laboratory abnormalities ( $\geq 10\%$ ) were decreased lymphocytes, decreased neutrophils, decreased white blood cells, and decreased hemoglobin.

### Use in Specific Populations

- **Lactation:** Advise women not to breastfeed during treatment and for 4 months after the last dose of EPKINLY.
- **Geriatric Use:** In patients with relapsed or refractory FL who received EPKINLY in the clinical trial, 52% were  $\geq 65$  years old, and 13% were  $\geq 75$  years old. A higher rate of fatal adverse reactions, primarily infections, including COVID-19, was observed in patients  $\geq 65$  years old compared to younger adult patients. No overall difference in efficacy was observed.

Learn about adverse reactions for EPKINLY on the following pages

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, throughout and on page 6. Please see full [Prescribing Information](#), including Boxed Warnings.

  
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## Adverse reactions in the EPCORE<sup>®</sup> NHL-1 trial in patients with 3L+ FL<sup>1</sup>

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

Most common treatment-related adverse reactions (≥10%)

ADVERSE REACTION*	ALL GRADES (%)	GRADE 3 OR 4 (%)
	(n=86) <sup>†</sup>	
Cytokine release syndrome <sup>‡§</sup>	49	0
	(n=127)	
Injection site reactions <sup>  </sup>	58	0
COVID-19 <sup>¶</sup>	40	19
Fatigue <sup>  </sup>	37	5 <sup>#</sup>
Upper respiratory tract infection <sup>¶</sup>	29	2 <sup>#</sup>
Musculoskeletal pain <sup>  </sup>	28	0.8 <sup>#</sup>
Rash <sup>  </sup>	28	0
Pyrexia <sup>  </sup>	26	2 <sup>#</sup>
Diarrhea	26	1.6 <sup>#</sup>
Headache	20	0
Cough <sup>  </sup>	20	0
Pneumonia <sup>¶</sup>	17	13 <sup>#</sup>
Abdominal pain <sup>  </sup>	17	0.8 <sup>#</sup>
Dyspnea <sup>  </sup>	17	0
Edema <sup>  </sup>	17	0
Nausea	17	0
Constipation	16	0
Arthralgia	14	0.8 <sup>#</sup>
Urinary tract infection <sup>  </sup>	13	5 <sup>#</sup>
Peripheral neuropathy and paresthesia <sup>¶</sup>	13	1.6 <sup>#</sup>
Neurological changes <sup>¶</sup>	13	0
Insomnia	13	0
Herpes virus infection <sup>¶</sup>	12	1.6 <sup>#</sup>
Mucositis <sup>¶</sup>	12	0
Dizziness	11	0
Renal insufficiency <sup>¶</sup>	10	1.6 <sup>#</sup>

\*Adverse reactions were graded based on CTCAE Version 5.0.

<sup>†</sup>The frequency of CRS is based on 86 patients with FL who received the recommended 3-step up dosage schedule in EPCORE<sup>®</sup> NHL-1. See section 2.2 of the full Prescribing Information.

<sup>‡</sup>CRS was graded using ASTCT consensus criteria (Lee et al., 2019).

<sup>§</sup>The frequency of CRS based on the 127 patients with FL who received the 2-step up dosage schedule in EPCORE<sup>®</sup> NHL-1 was the following: any grade CRS 66%; grade 1 CRS: 50%; grade 2 CRS: 26%; grade 3 CRS: 1.6%.

<sup>||</sup>Includes related grouped terms.

<sup>¶</sup>Term includes other related terms. See full Prescribing Information.

<sup>#</sup>Only grade 3 adverse reactions occurred.

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

**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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# Adverse reactions in the EPCORE<sup>®</sup> NHL-1 trial in patients with 3L+ FL<sup>1</sup> (cont'd)

### In 86 patients who received EPKINLY following the recommended 3-step up dosage schedule

- The median duration of exposure was 5 cycles (range: 1 to 12 cycles)
- CRS occurred in 49% of patients (45% grade 1, 9% grade 2)
- Serious adverse reactions due to CRS occurred in 28% of patients
- Dose interruptions due to CRS occurred in 19% of patients

### In 127 patients who received EPKINLY following a 2-step up dosage schedule

- The median duration of exposure was 8 cycles (range: 1 to 33 cycles)
- Serious adverse reactions occurred in 66% of patients (reactions occurring in ≥5% included CRS, COVID-19, pneumonia, and second primary malignancies)
- Fatal adverse reactions occurred in 9% of patients, including COVID-19 (5%), pneumonitis (1.6%), cardiac failure (0.8%), pneumonia (0.8%), and sepsis (0.8%)
- Permanent discontinuation due to an adverse reaction occurred in 19% of patients
  - Adverse reactions resulting in permanent discontinuation in ≥2% of patients included COVID-19, Hepatitis E, pneumonitis, and second primary malignancy
- Dosage interruptions due to an adverse reaction occurred in 59% of patients (reactions requiring dosage interruption ≥5%: COVID-19, CRS, pneumonia, respiratory tract infection, and fatigue)
- The most common grade 3 to 4 laboratory abnormalities (≥10%) were decreased lymphocyte count, decreased neutrophil count, decreased white blood cell count, and decreased hemoglobin
- Clinically relevant adverse reactions in <10% of patients included vomiting, pruritus, hepatotoxicity, ICANS, lower respiratory tract infections, cardiac arrhythmias, respiratory tract infections, pneumonitis, second primary malignancy, vision changes, cellulitis, febrile neutropenia, cardiac failure, cytomegalovirus infection, and sepsis

ICANS=immune effector cell-associated neurotoxicity syndrome.

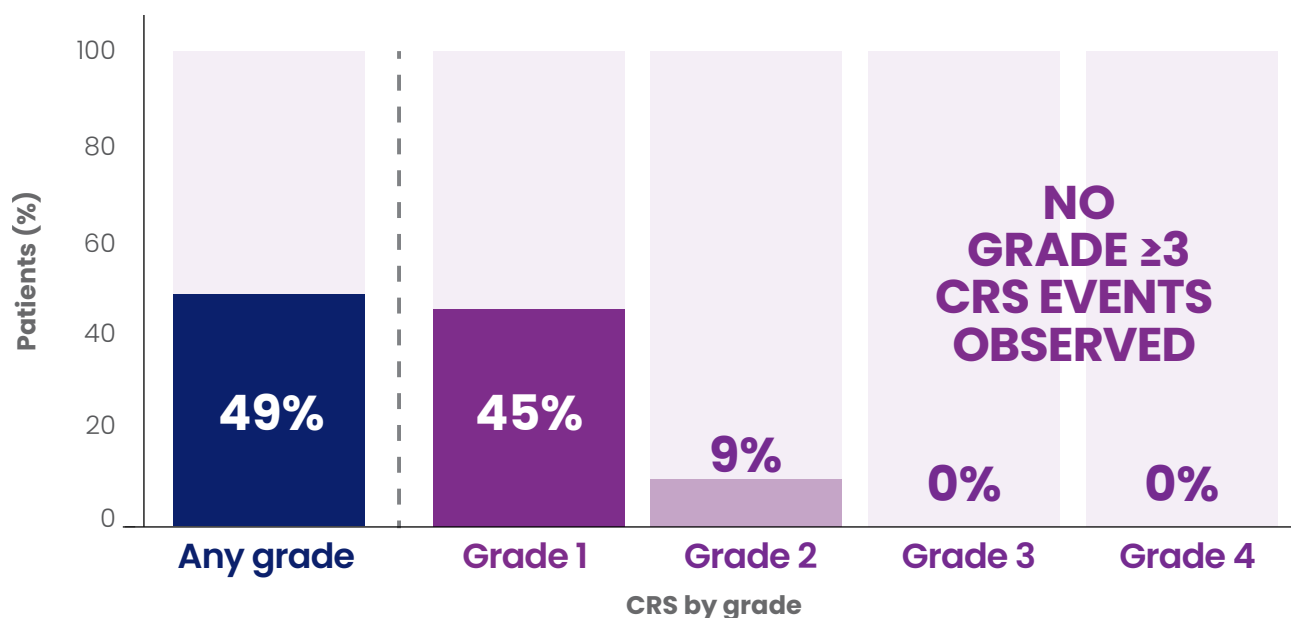
**Please see Important Safety Information, including Boxed Warnings for CRS and ICANS, throughout and on pages 6-7.**  
**Please see full [Prescribing Information](#), including Boxed Warnings.**

  
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SUBCUTANEOUS INJECTION 4mg/48mg



# CRS was primarily low grade, predictable, and manageable<sup>1</sup>

In patients who received EPKINLY at the recommended 3-step up dosage schedule (n=86) in the EPCORE<sup>®</sup> NHL-1 trial



- Recurrent CRS occurred in 23% of patients
- Most CRS events (88%) occurred during cycle 1
  - In cycle 1, 14% of CRS events occurred after the 0.16-mg dose (day 1), 7% after the 0.8-mg dose (day 8), 17% after the 3-mg dose (day 15), and 49% after the 48-mg dose (day 22)
- The median time to onset of CRS from the most recent administered EPKINLY dose across all doses was 59 hours (range: 0.1 to 7 days)
- The median time to onset after the first full 48-mg dose was 61 hours (range: 0.1 to 7 days)
- CRS resolved in 100% of patients
  - Median duration of CRS events was 2 days (range: 1 to 14 days)

*Monitor patient for potential CRS. At first signs or symptoms of CRS, manage per current practice guidelines and administer supportive care as appropriate. Withhold or discontinue EPKINLY as recommended.*

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

### SELECT IMPORTANT SAFETY INFORMATION

**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.**

- 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 4.7% of patients with FL and included headache and dizziness.
- Administer pretreatment medications to reduce the risk of CRS.

**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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SUBCUTANEOUS INJECTION 4mg/48mg



# ICANS events in EPCORE<sup>®</sup> NHL-1 in 3L+ FL patients<sup>1,4</sup>

## In patients with FL who received EPKINLY following the 2-step up dosage schedule (n=127)<sup>1</sup>

- ICANS events occurred in 6% (8/127) of patients with FL receiving EPKINLY, utilizing the 2-step up dosage schedule
  - 3.9% grade 1, 2.4% grade 2
- The median time to onset of ICANS was 21.5 days (range: 14 to 66 days) from the start of treatment
- Relative to the most recent administration, the median time to onset was 3 days (range: 0.4 to 7 days)
- ICANS resolved in 100% of patients
  - The median duration was 2 days (range: 1 to 7 days)
- The median duration of exposure for patients was 8 cycles (range: 1 to 33 cycles)

## In patients who received EPKINLY following the recommended 3-step up dosage schedule (n=86)<sup>1,4</sup>

- No ICANS events were observed at the time of analysis. The median exposure for patients in the dose optimization cohort was 5 cycles (range: 1 to 12 cycles). No conclusions regarding the rate of ICANS can be made, as exposure may not be sufficient in this cohort

*Monitor patient for potential ICANS. At first signs or symptoms of ICANS, manage per current practice guidelines and administer supportive care as appropriate. Withhold or discontinue EPKINLY as recommended.*

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

### 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.**

- 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.

**References:** **1.** EPKINLY [package insert]. Plainsboro, NJ: Genmab US, Inc. and North Chicago, IL: AbbVie Inc. 2024. **2.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines<sup>®</sup>) 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. **3.** A phase 1/2, open-label safety trial of GEN3013 in patients with relapsed, progressive or refractory B-cell lymphoma. ClinicalTrials.gov identifier: NCT03625037. Accessed April 1, 2024. <https://clinicaltrials.gov/study/NCT03625037> **4.** Linton KM, Vitolo U, Jurczak W, et al. Epcoritamab monotherapy in patients with relapsed or refractory follicular lymphoma (EPCORE NHL-1): a phase 2 cohort of a single-arm, multicentre study. *Lancet*. Published online June 15, 2024. [https://doi.org/10.1016/S2352-3026\(24\)00166-2](https://doi.org/10.1016/S2352-3026(24)00166-2) **5.** Data on file. Plainsboro, NJ: Genmab US, Inc. and North Chicago, IL: AbbVie Inc. 2024. **6.** Mozas P, Rivero A, Rivas-Delgado A, et al. Age and comorbidity are determining factors in the overall and relative survival of patients with follicular lymphoma. *Ann Hematol*. 2021;100(5):1231-1239. doi:10.1007/s00277-021-04470-7 **7.** Sarkozy C, Maurer MJ, Link BK, et al. Cause of death in follicular lymphoma in the first decade of the rituximab era: a pooled analysis of French and US cohorts. *J Clin Oncol*. 2019;37(2):144-152. doi:10.1200/jco.18.00400 **8.** Salles G, Schuster SJ, Fischer L, et al. A retrospective cohort study of treatment outcomes of adult patients with relapsed or refractory follicular lymphoma (ReCORD-FL). *HemaSphere*. 2022;6(7):e745. doi:10.1097/HS9.0000000000000745

**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.**

  
epcoritamab-bysp<sup>®</sup>  
SUBCUTANEOUS INJECTION 4mg/48mg



# EPKINLY: an off-the-shelf, subcutaneous treatment, administered outpatient<sup>1</sup>

## EPKINLY should be administered according to the recommended 3-step up dosage schedule to reduce the incidence and severity of CRS

- Administer EPKINLY subcutaneously in 28-day cycles to well-hydrated patients until disease progression or unacceptable toxicity. Please see Section 2.2 of the full Prescribing Information for the recommended EPKINLY dosage schedule
- See Section 2.4 of the full Prescribing Information for recommended pre- and post-administration medications to reduce the risk of CRS, or ask your representative to schedule time with our ONE team for more information

## Hospitalization is not required to administer EPKINLY for 3L+ FL

- 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 select adverse reactions

### NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines<sup>®</sup>) Recommended

The NCCN Guidelines<sup>®</sup> recommend epcoritamab-bysp (EPKINLY) as an NCCN Category 2A treatment option after 2 or more lines of systemic therapy for patients with R/R FL (**Category 2A preferred**)<sup>2\*</sup>

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.<sup>2</sup>

\*See NCCN Guidelines for the NCCN definitions of Categories of Preference and Categories of Evidence and Consensus.

For more information or questions about EPKINLY, contact a representative

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

### INDICATION

EPKINLY is indicated for the treatment of adults with relapsed or refractory follicular lymphoma (FL) 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.**

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

Please see additional Important Safety Information on pages 6-7 and throughout this brochure. Please see full [Prescribing Information](#).



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