

THE POWER OF SUPERIOR PFS vs R² IN 2L+ FL AND DURABLE RESPONSES IN 3L+ FL^{1,*}



2L+ FL [†]	PFS
Fixed-duration EPKINLY + R²	↓ 79% reduction in the risk of disease progression or death compared with R ² (HR=0.21 [‡] ; 95% CI, 0.13–0.33; $P<0.0001$ [§]) in 2L+ FL

Efficacy was based on PFS and ORR.

3L+ FL	mDOR	ORR	CR	PR
EPKINLY monotherapy	NOT REACHED n=104/127 (95% CI, 13.7 months–NR)	82% n=104/127 (95% CI, 74–88)	60% n=76/127 (95% CI, 51–68)	22% n=28/127 (95% CI, 15–30)

The efficacy and safety of EPKINLY in combination with R² vs R² alone were evaluated in EPCORE[®] FL-1, an open-label, randomized, multicenter, global trial that included 488 patients with R/R FL after at least 1 line of systemic therapy. The efficacy and safety of EPKINLY monotherapy were evaluated in EPCORE[®] 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.

*Efficacy results determined by Lugano criteria (2014) as assessed by IRC. In EPCORE[®] FL-1, efficacy results were based on a prespecified interim analysis. [†]The median duration of follow-up was 10.4 months in the ITT population. Patients received EPKINLY via subcutaneous injection in 28-day cycles for a total of 12 cycles or until disease progression or unacceptable toxicity, whichever occurred first. [‡]Cox proportional hazards hazard ratio stratified by disease history and region. [§]Log-rank P -value (one sided) stratified by disease history and region. ^{||}Based on Kaplan-Meier estimate. The median follow-up for DOR was 14.8 months.

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines[®]) Recommends²

NCCN CATEGORY 1 PREFERRED

Epcoritamab-bysp (EPKINLY) in combination with lenalidomide and rituximab as an **NCCN Category 1 preferred** treatment option for patients with relapsed or refractory follicular lymphoma^{*,#}

Epcoritamab-bysp as a **preferred** bispecific antibody for 3L and subsequent follicular lymphoma therapy[#] (Subsequent systemic therapy options include 2L therapy regimens that were not previously given)

*In the setting of CD20-negative lymphomas, the efficacy of CD3 x CD20 bispecific antibody therapy is poor. If clinically feasible, repeat biopsy to confirm antigen expression prior to the initiation of T-cell mediated therapy. [#]Refer to package insert for full prescribing information, dose modifications, and monitoring for adverse reactions: <https://www.accessdata.fda.gov/scripts/cder/dai/index.cfm>. 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.

INDICATIONS

- EPKINLY is indicated in combination with lenalidomide and rituximab for the treatment of adults with relapsed or refractory follicular lymphoma (FL).
- EPKINLY is indicated as monotherapy for the treatment of adults with relapsed or refractory FL after 2 or more lines of systemic therapy.

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.**

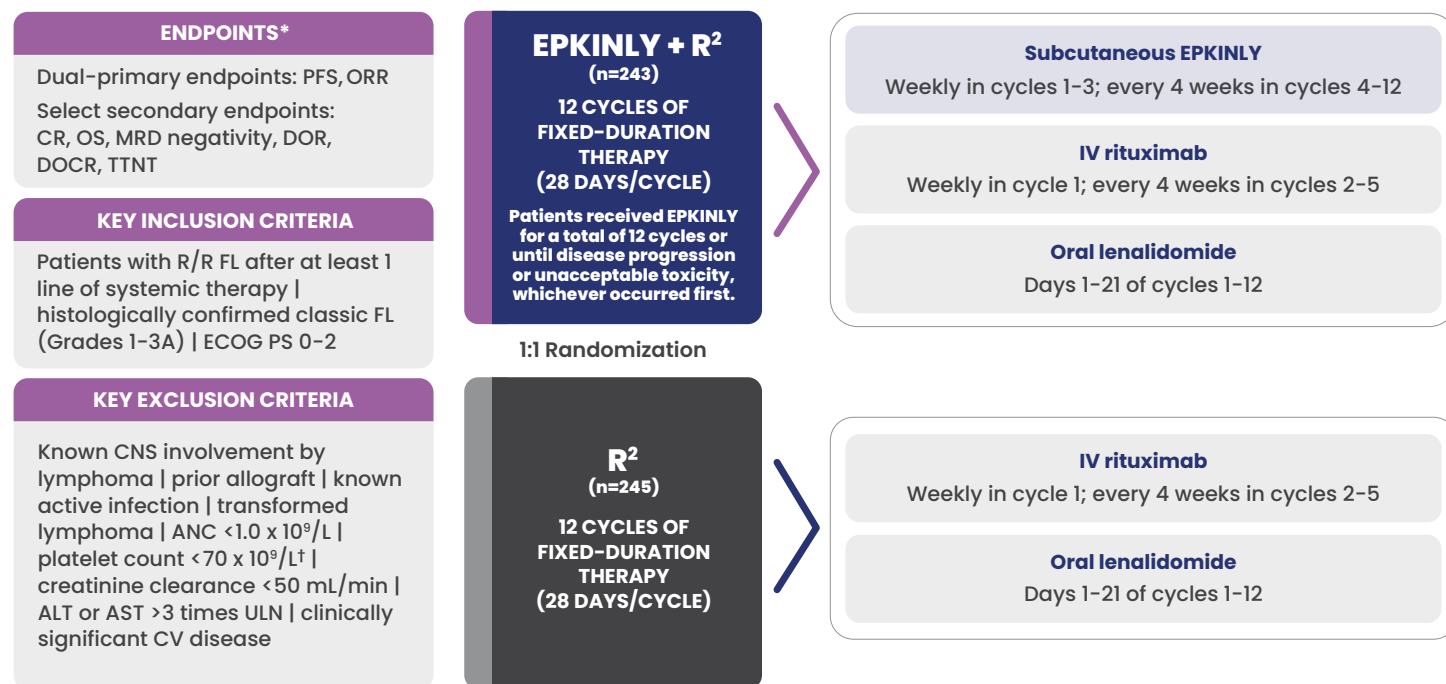
Additional Warnings & Precautions: Infections, Cytopenias, and Embryo-Fetal Toxicity.

Please see additional Important Safety Information throughout and on pages 15–17. Please see full Prescribing Information, including Boxed Warnings.

2L=second line; 3L=third line; CI=confidence interval; CR=complete response; DOR=duration of response; FL=follicular lymphoma; HR=hazard ratio; IRC=independent review committee; ITT=intent to treat; mDOR=median duration of response; NCCN=National Comprehensive Cancer Network; NHL=non-Hodgkin lymphoma; NR=not reached; ORR=overall response rate; PFS=progression-free survival; PR=partial response; R²=rituximab + lenalidomide; R/R=relapsed/refractory.

EPCORE® FL-1: designed for broad eligibility of FL patients with fixed-duration EPKINLY + R² 1,3

The efficacy and safety of EPKINLY + R² vs R² alone were evaluated in EPCORE® FL-1, a phase 3, open-label, randomized, multicenter, global trial that included patients with R/R FL after at least 1 line of systemic therapy



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

†Or <50 x 10⁹/L if bone marrow infiltration by lymphoma or splenomegaly.

ALT=alanine transaminase; ANC=absolute neutrophil count; AST=aspartate transaminase; CNS=central nervous system; CV=cardiovascular; DOCR=duration of complete response; ECOG PS=Eastern Cooperative Oncology Group performance status; IV=intravenous; MRD=minimal residual disease; OS=overall survival; TTNT=time to next treatment; ULN=upper limit of normal.

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 49% (42/86) of patients with FL receiving EPKINLY monotherapy at the recommended dosage schedule in EPCORE NHL-1 (45% Grade 1, 9% Grade 2) and recurred in 48% of patients. Most events (88%) occurred during Cycle 1. In Cycle 1, CRS events occurred in 12% of patients after the 0.16 mg dose (Cycle 1, day 1), 6% after the 0.8 mg dose (Cycle 1, day 8), 15% after the 3 mg dose (Cycle 1, day 15), and 37% after the first 48 mg dose (Cycle 1, day 22). The median time to onset of CRS from the most recent administered dose across all doses was 59 hours (range: 0.1–7 days). The median time to onset after the first full 48 mg dose was 61 hours (range: 0.1–7 days).

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, throughout and on pages 15–17. Please see full Prescribing Information, including Boxed Warnings.

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EPKINLY + R² was evaluated in a range of patients with indolent to high-risk disease characteristics^{1,4}

EPCORE[®] FL-1 included patients with 2L+ FL across a spectrum of characteristics, ranging from those whose disease progressed within 24 months to those who had a longer response¹

DEMOGRAPHICS All patients randomized (N=488)	
Age Median (range) ≥65 years	61 (24–89) 40%
Gender Male	57%
Race White Asian Black	72% 24% 2%
Ann Arbor stage III–IV	83%
Bulky disease (≥7 cm)	22%
ECOG PS 0 or 1 ECOG PS 2	98% 2%
FLIPI score 3–5	44%

TREATMENT HISTORY All patients randomized (N=488)	
Median number of prior lines of therapy (range)	1 (1–7)
Prior lines of therapy 1 2 ≥3	59% 24% 17%
Anti-CD20 antibody	100%
Anti-CD20 antibody with chemotherapy	98%
Refractory to first-line therapy	34%
Refractory to both anti-CD20 and alkylator therapy	37%
POD24	41%

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

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- CRS occurred in 24% (32/131) of patients with FL receiving EPKINLY at the recommended dosage schedule in combination with lenalidomide and rituximab in EPCORE FL-1 (19% Grade 1, 5% Grade 2, and 12% serious adverse reactions due to CRS) and recurred in 41% of patients. Most events (88%) occurred during Cycle 1. In Cycle 1, CRS occurred in 5% of patients after the 0.16 mg dose (Cycle 1, day 1), 3.8% after the 0.8 mg dose (Cycle 1, day 8), 2.3% after the 3 mg dose (Cycle 1, day 15), and 18% after the first 48 mg dose (Cycle 1, day 22). The median time to onset of CRS from the most recent EPKINLY dose was 78 hours (range: 0.2–12 days). The median time to onset after the first 48 mg dose was 41 hours (range: 0.3–12 days).

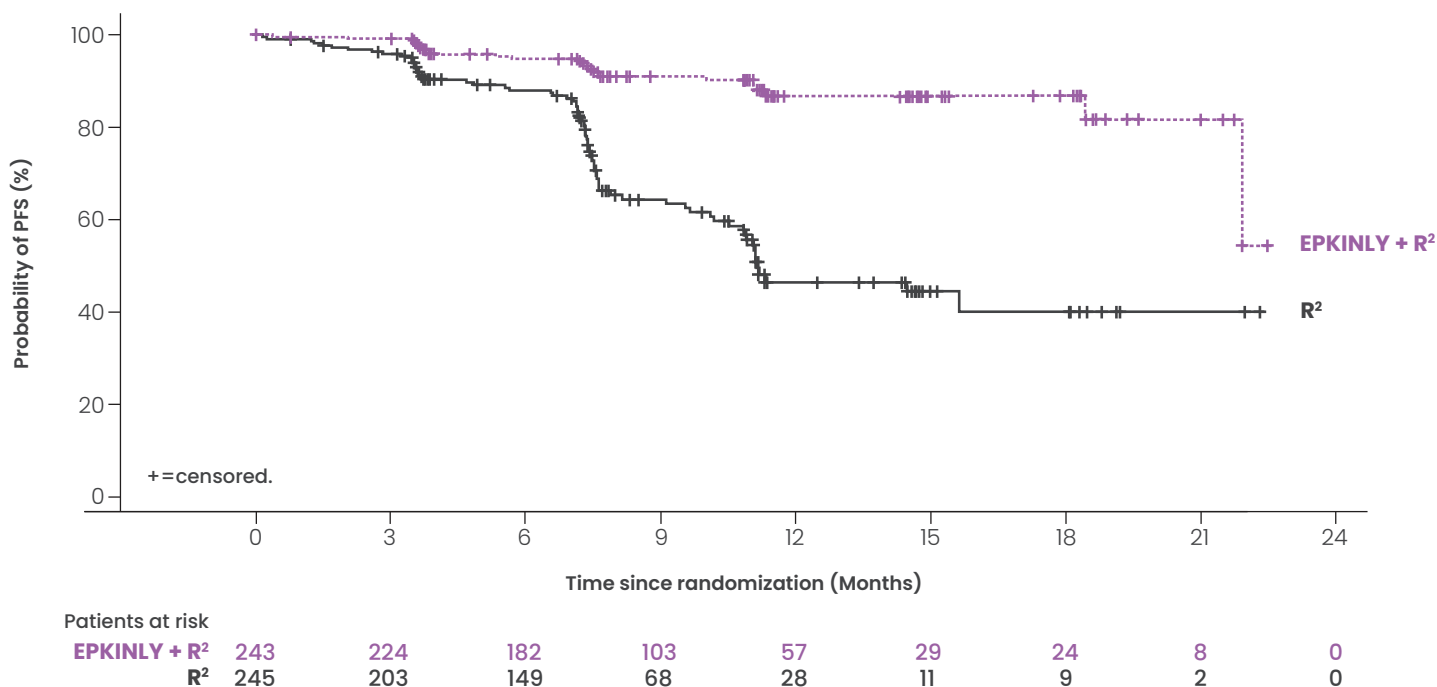
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The power of superior PFS with fixed-duration EPKINLY + R² vs R² 1,*,†

EPCORE® FL-1 pivotal analysis

EPKINLY + R² demonstrated a 79% reduction in the risk of disease progression or death vs R² (HR=0.21[‡]; 95% CI, 0.13–0.33; P<0.0001[§])



mPFS NOT REACHED
for EPKINLY + R² patients
(95% CI, 21.9 months-NR)

mPFS 11.2 MONTHS
for R² patients
(95% CI, 10.5 months-NR)

Date of analysis: January 10, 2025.⁴

*Efficacy results determined by Lugano criteria (2014) as assessed by IRC and based on a prespecified interim analysis.

†The median duration of follow-up was 10.4 months in the ITT population. ‡Cox proportional hazards hazard ratio stratified by disease history and region. §Log-rank P-value (one sided) stratified by disease history and region.

mPFS=median progression-free survival.

SELECT IMPORTANT SAFETY INFORMATION

- For patients with FL, 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 4.7% of patients with FL receiving EPKINLY monotherapy, and 1.5% of patients receiving EPKINLY in combination with lenalidomide and rituximab (reactions included headache, confusional state, tremors, dizziness, and ataxia). Administer pretreatment medications to reduce the risk of CRS. 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.

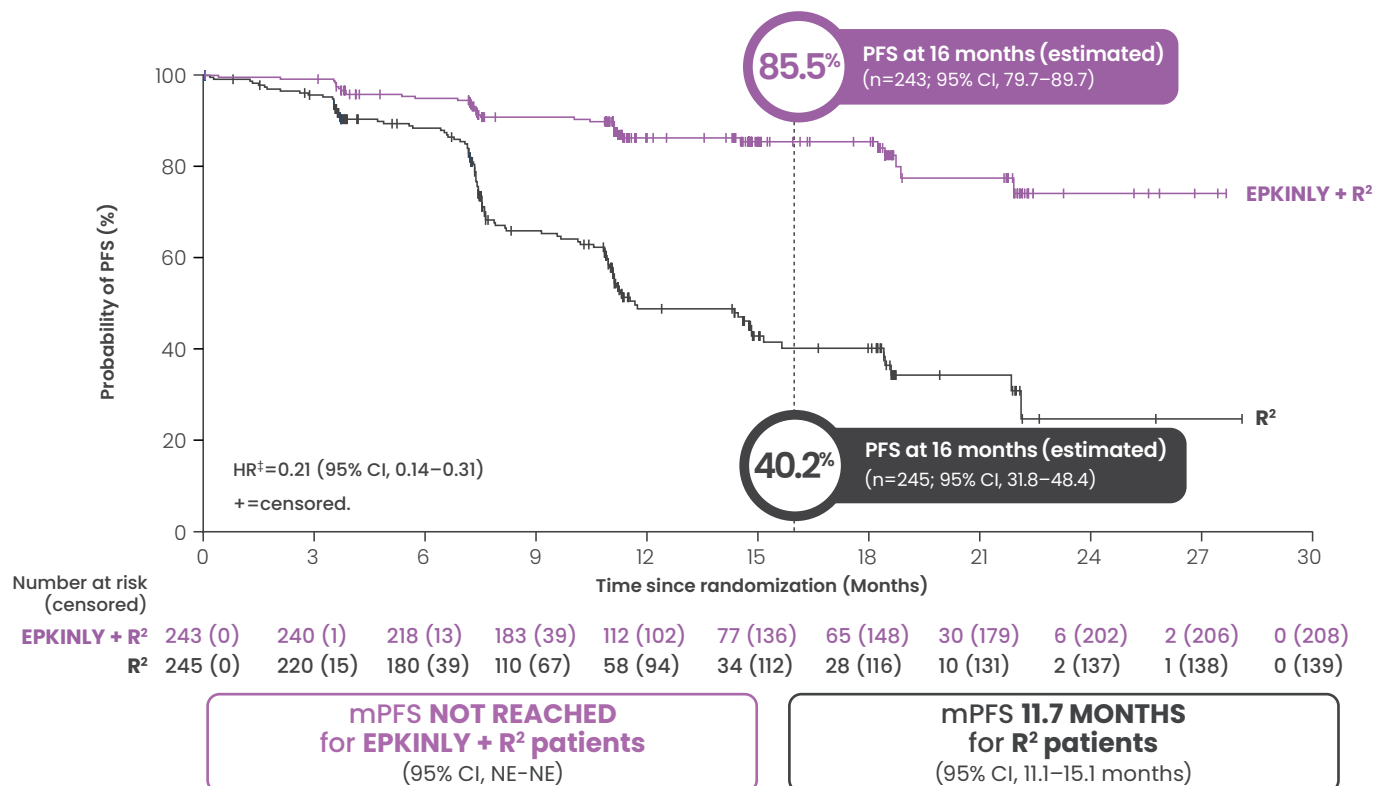
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PFS with EPKINLY + R² vs R² 4,*†

EPCORE® FL-1 prespecified follow-up analysis

EPKINLY + R² PFS benefit was consistent between the pivotal and follow-up analyses



This graph is adapted from Lorenzo Falchi, et al, © 2025, sourced from *The Lancet*, licensed under CC BY 4.0, available online at doi:10.1016/S0140-6736(25)02360-8.

Follow-up analysis: safety data^{4,5}

- In a subsequent analysis with a median follow-up of 14.8 months and median number of EPKINLY exposure of 12 cycles, serious adverse events occurred in 56% of patients, including serious infections in 33%. Fatal adverse events occurred in 2% of patients. Discontinuation due to an adverse event occurred in 9% of patients.

Data Limitation: These prespecified efficacy analyses are not multiplicity-controlled. All data are exploratory and descriptive in nature. No formal inference can be drawn.

Date of analysis: May 24, 2025.

*Efficacy results determined by Lugano criteria (2014) as assessed by IRC and based on prespecified interim analysis.

†The median duration of study follow-up was 14.8 months in the ITT population. Patients received EPKINLY via subcutaneous injection in 28-day cycles for a total of 12 cycles or until disease progression or unacceptable toxicity, whichever occurred first. ‡Stratified by disease status and history.

NE=not evaluable.

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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.

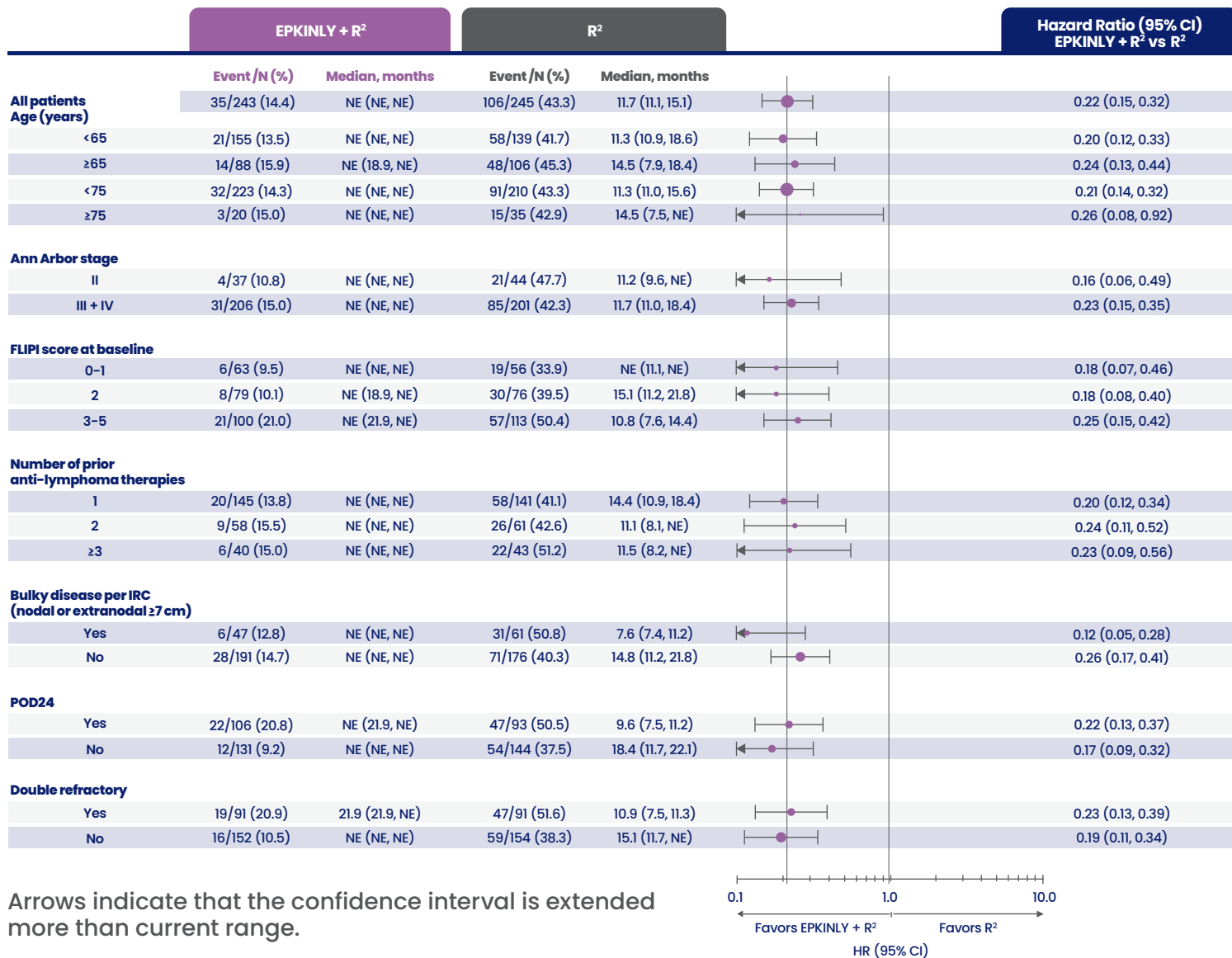
- ICANS occurred in 6% (8/127) of patients with FL receiving EPKINLY monotherapy following the 2-step up dosage schedule in EPCORE NHL-1 (3.9% Grade 1, 2.4% Grade 2). The median time to onset was 22 days (range: 14-66 days) from the start of treatment. Relative to the most recent administered dose, the median time to onset of ICANS was 3 days (range: 0.4-7 days). The median duration of ICANS was 2 days (range: 1-7 days), with ICANS resolving in 100% of patients.

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PFS observed across subgroups^{4,*†}

EPCORE® FL-1 prespecified follow-up analysis



This figure is adapted from Lorenzo Falchi, et al, © 2025, sourced from *The Lancet*, licensed under CC BY 4.0, available online at doi:10.1016/S0140-6736(25)02360-8.

Data Limitation: These prespecified analyses are not multiplicity-controlled. Data are exploratory and descriptive in nature. No formal inference can be drawn.

*Efficacy results determined by Lugano criteria (2014) as assessed by IRC and based on prespecified interim analysis.
[†]The median duration of study follow-up was 14.8 months in the ITT population. Patients received EPKINLY via subcutaneous injection in 28-day cycles for a total of 12 cycles or until disease progression or unacceptable toxicity, whichever occurred first.

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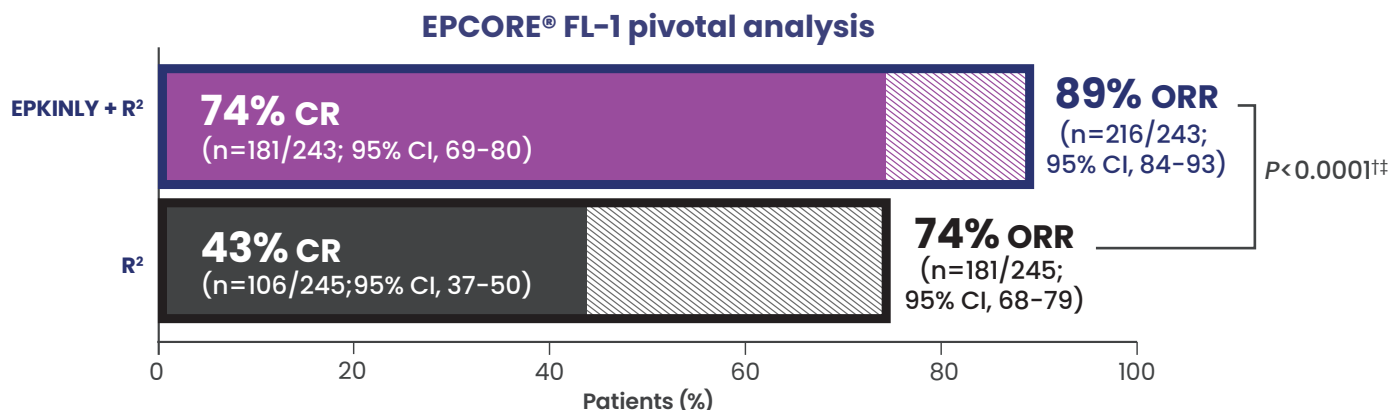
- Among patients with FL who received EPKINLY at the recommended dosage schedule in combination with lenalidomide and rituximab in EPCORE FL-1, ICANS occurred in 0.8% (1/131, Grade 1).

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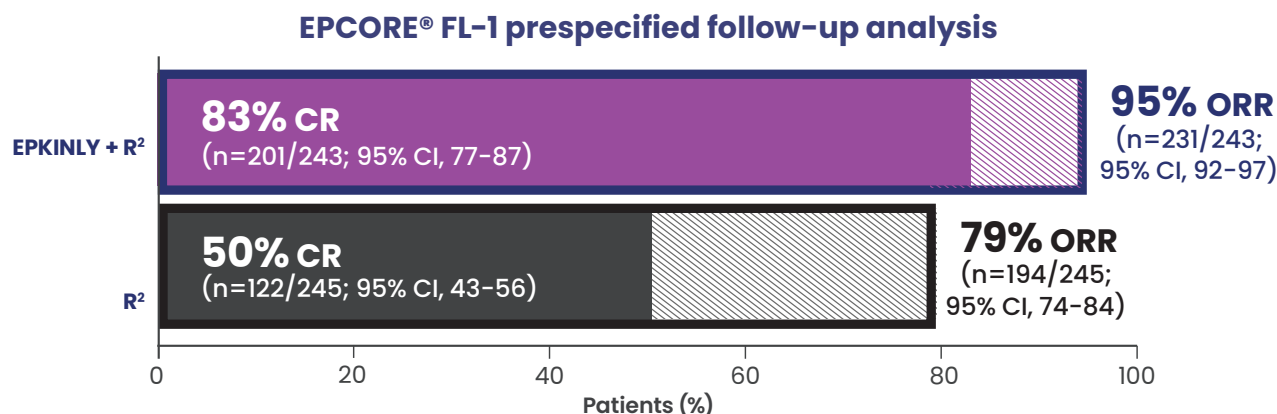
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EPKINLY + R² achieved remarkable responses vs R² 1,4

EPKINLY + R² achieved remarkable responses with a 31% higher CR vs R² 1,*



• The median duration of follow-up was 10.4 months in the ITT population



• The median duration of follow-up was 14.8 months in the ITT population

Data Limitation: These prespecified analyses are not multiplicity-controlled. Data are exploratory and descriptive in nature. No formal inference can be drawn.

*Efficacy results determined by Lugano criteria (2014) as assessed by IRC and based on a prespecified interim analysis.

†P-value is based on a prespecified analysis of the first 232 patients randomized.

‡P-value (one sided) is from a Cochran-Mantel-Haenszel test stratified by disease history and region.

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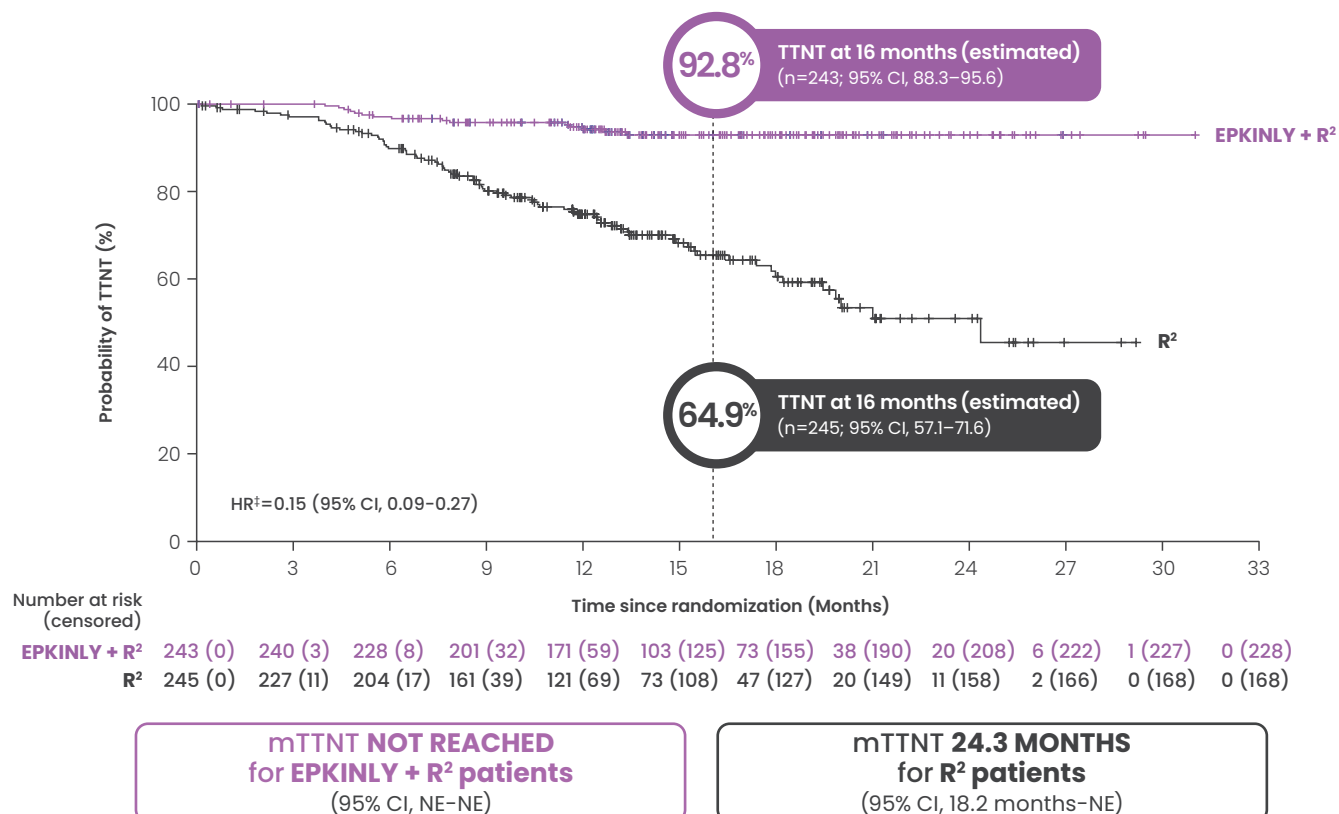
- The onset of ICANS can be concurrent with CRS, following resolution of CRS, or in the absence of CRS. Clinical manifestations of ICANS included, but were not limited to, confusional state, lethargy, tremor, dysgraphia, aphasia, and non-convulsive status epilepticus.
- Monitor patients for potential 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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Time to next treatment⁴

After 16 months, an estimated 93% of patients who received EPKINLY + R² had not initiated any subsequent therapy, compared with 65% who received R² *.[†]



This graph is adapted from Lorenzo Falchi, et al, © 2025, sourced from *The Lancet*, licensed under CC BY 4.0, available online at doi:10.1016/S0140-6736(25)02360-8.

• The median duration of follow-up was 14.8 months

Date of analysis: May 24, 2025.

Data Limitations:

- These prespecified analyses are not multiplicity-controlled. Data are exploratory and descriptive in nature. No formal inference can be drawn
- TTNT is subject to variability in treatment practice and can be subjective based on investigator interpretation of individual patient and disease characteristics
- This endpoint may also be confounded by other factors including safety reasons

*Efficacy results, inclusive of PFS and DOR assessed progressive disease (PD), determined by Lugano criteria as assessed by IRC and based on a prespecified interim analysis.

[†]Based on Kaplan-Meier estimate.

[‡]Stratified by disease status and history.

SELECT IMPORTANT SAFETY INFORMATION

Infections

- EPKINLY can cause fatal and serious infections. Serious infections, including opportunistic infections, were reported in 40% of patients with FL receiving EPKINLY monotherapy following the 2-step up dosage schedule in EPCORE NHL-1 (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).

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EPKINLY + R² has a manageable safety profile; generally consistent with the established profiles of EPKINLY and R² 1,6

Most common treatment-related ARs (≥10% all grade and ≥5% higher)¹

ADVERSE REACTION*	EPKINLY + R ²		R ²	
	All Grades (%)	Grade 3 or 4 (%)	All Grades (%)	Grade 3 or 4 (%)
	n=131		n=238	
Cytokine release syndrome	24 ^{†‡}	0	0.8	0
	n=243		n=238	
Rash [§]	46	11	34	6
Upper respiratory tract infections [§]	33	3.3	18	0.4
Fatigue [§]	31	4.9	24	2.1
Injection site reactions [§]	27	0	0.4	0
Constipation	26	0.8	21	0
Pneumonia [§]	24	16	8 [¶]	4.6
COVID-19 [§]	23	5	13	1.3
Fever	23	0.4	11	1.3
Neurological changes [§]	15	1.2	8	1.3
Insomnia	14	0	2.9	0
Mucositis [§]	12	0	3.4	0
Headache	11	0	3.8	0

*Adverse reactions were graded using CTCAE Version 5.0. CRS was graded using ASTCT consensus criteria (Lee et al., 2019).

[†]The frequency of CRS is based on 131 patients with FL who received EPKINLY at the recommended 3-step up dosage schedule. Grade 1 CRS: 19%; Grade 2 CRS: 5%.

[‡]The frequency of CRS among the 243 patients who received either the 2-step up or 3-step up dosage schedule was the following: any grade CRS: 35%; Grade 1 CRS: 28%; Grade 2 CRS: 7%.

[§]Term includes other related terms. See full Prescribing information.

^{||}Only Grade 3 adverse reactions occurred.

[¶]Includes 1 case with a fatal outcome.

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

SELECT IMPORTANT SAFETY INFORMATION

- Among 243 patients with FL who received EPKINLY in combination with lenalidomide and rituximab in EPCORE FL-1, serious infections occurred in 28% of patients. The most common serious infections were pneumonia (15%), COVID-19 (7%), opportunistic infections (5%) and upper respiratory infections (3.3%). The most common opportunistic infections of any grade were cytomegalovirus (CMV) infection (7%) and herpesvirus infection (7%).

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EPKINLY + R² has a manageable safety profile; generally consistent with the established profiles of EPKINLY and R² 1,6 (cont'd)

In 243 patients who received EPKINLY + R² 1

- The median duration of exposure was 10 cycles for EPKINLY and 9 cycles for lenalidomide
- Serious adverse reactions occurred in 51% of these patients, including serious infections in 28% of patients and serious CRS in 12% of patients. Fatal adverse reactions within 60 days of last treatment occurred in 0.8% of patients
- Adverse reactions led to permanent discontinuation of EPKINLY in 6% of patients and dose interruption in 75% of patients, with infection as a leading cause. Adverse reactions leading to interruption of EPKINLY in ≥5% of patients included respiratory tract infections, CRS, and rash
- In the EPKINLY arm, adverse reactions led to lenalidomide dose interruption in 72%, dose reduction in 22%, and permanent discontinuation in 15%
- Warnings and precautions include CRS, ICANS, infections, cytopenias, and embryo-fetal toxicity
- The most common Grade 3 to 4 laboratory abnormalities (≥10%) in the EPKINLY + R² arm vs the R² arm, respectively, were decreases in neutrophil count (67% vs 41%), decreases in lymphocyte count (62% vs 15%), and decreases in platelet count (10% vs 7%)

SELECT IMPORTANT SAFETY INFORMATION

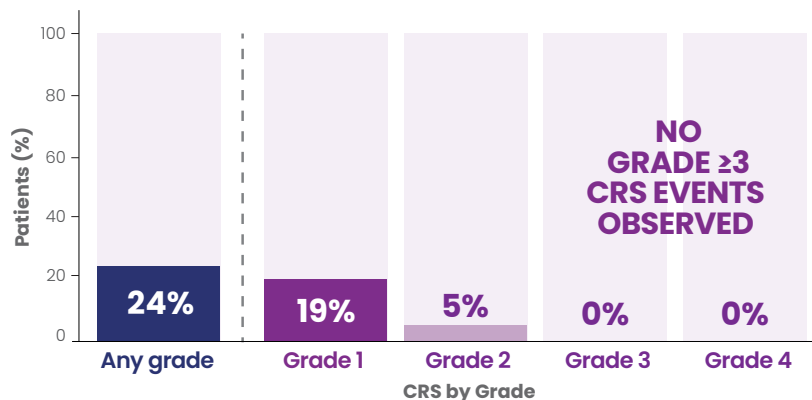
- Progressive multifocal leukoencephalopathy (PML), including fatal cases, has occurred in patients treated with EPKINLY. Across a broader clinical trial population, PML was reported in 0.4% (11/3,072) of patients, including in the first-line treatment setting. Of the 11 cases of PML, 6 resulted in fatal 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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CRS was low grade, predictable, and resolved^{1,4}

In patients with FL who received EPKINLY + R² at the recommended 3-step up dosage schedule (n=131) in EPCORE® FL-1¹



- In a pooled analysis of LBCL and FL patients, 98% of CRS events were resolved¹
 - Median duration of CRS events was 2 days (range: <1 to 27 days)
- In a follow-up analysis with a median time of 14.8 months, 100% of CRS events resolved⁴
- Serious adverse reactions due to CRS occurred in 12% of patients; recurrent CRS occurred in 41%¹
- Most CRS events (88%) occurred during cycle 1¹
 - In cycle 1, CRS occurred in 5% of patients after the 0.16-mg dose (day 1), 3.8% after the 0.8-mg dose (day 8), 2.3% after the 3-mg dose (day 15), and 18% after the first 48-mg dose (day 22)
- CRS symptoms that presented were fever (94%), hypotension (17%), and hypoxia (6%)⁵
- The median time to onset of CRS from the most recent EPKINLY dose was 78 hours (range: 0.2 to 12 days)¹
- The median time to onset after the first 48-mg dose was 41 hours (range: 0.3 to 12 days)¹

ICANS event was low grade¹

- ICANS occurred in 0.8% (1/131) of patients with FL who received EPKINLY at the recommended 3-step up dosage schedule in combination with R²
- The single ICANS event was reported as Grade 1

LBCL=large B-cell lymphoma.

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.

Administer pretreatment medications to reduce the risk of CRS and monitor patients for potential CRS or ICANS. At the first signs or symptoms of CRS, immediately evaluate patients for hospitalization, manage per current practice guidelines, and administer supportive care as appropriate. At the first signs or symptoms of ICANS, immediately evaluate patient, provide supportive therapy based on severity, and manage per current practice guidelines. Withhold or discontinue EPKINLY as recommended.

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

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, throughout and on pages 15–17. Please see full Prescribing Information, including Boxed Warnings.

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EPKINLY + R² can be administered outpatient¹

Hospitalization is not required to administer EPKINLY for R/R FL—assess each patient

- For patients with FL, 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
- 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

Administer EPKINLY according to the recommended 3-step up dosage schedule to reduce the incidence and severity of CRS

3-step up dosage schedule for FL

			R ²	
 EPKINLY (subcutaneous)			 rituximab (iv)	 lenalidomide (oral)
CYCLE 1	Week 1	0.16 mg	375 mg/m ² weekly	20 mg on days 1 to 21 of each cycle through 12 cycles
	Week 2	0.8 mg		
	Week 3	3 mg		
	Week 4	48 mg		
CYCLES 2-3	48 mg weekly		375 mg/m ² every 4 weeks	
CYCLES 4-5	48 mg every 4 weeks			
CYCLES 6-12				
			—	

Refer to the lenalidomide prescribing information and rituximab prescribing information for the respective dosage recommendations, including lenalidomide dosage recommendations for patients with renal insufficiency.

Continue EPKINLY for a total of 12 cycles (1 cycle=28 days) or until disease progression or unacceptable toxicity, whichever occurs first.

- Administer EPKINLY subcutaneously to well-hydrated patients
- Prior to starting EPKINLY, provide *Pneumocystis jirovecii* pneumonia prophylaxis and consider initiating prophylaxis against herpesvirus to prevent herpes simplex and herpes zoster
- Refer to the lenalidomide prescribing information for recommendations on prophylaxis for venous and arterial thrombotic events
- Premedicate before each dose in cycle 1
- If a dose of EPKINLY is missed or delayed, therapy may need to be restarted

EPKINLY is designed to improve tolerability and accessibility across practice settings¹

- Subcutaneous administration allows more gradual increases and lower peaks in plasma cytokine levels than IV administration⁷
- EPKINLY is an off-the-shelf treatment, available to treat patients at the moment of relapse^{1,8}

HCP=healthcare provider.

SELECT IMPORTANT SAFETY INFORMATION

Infections

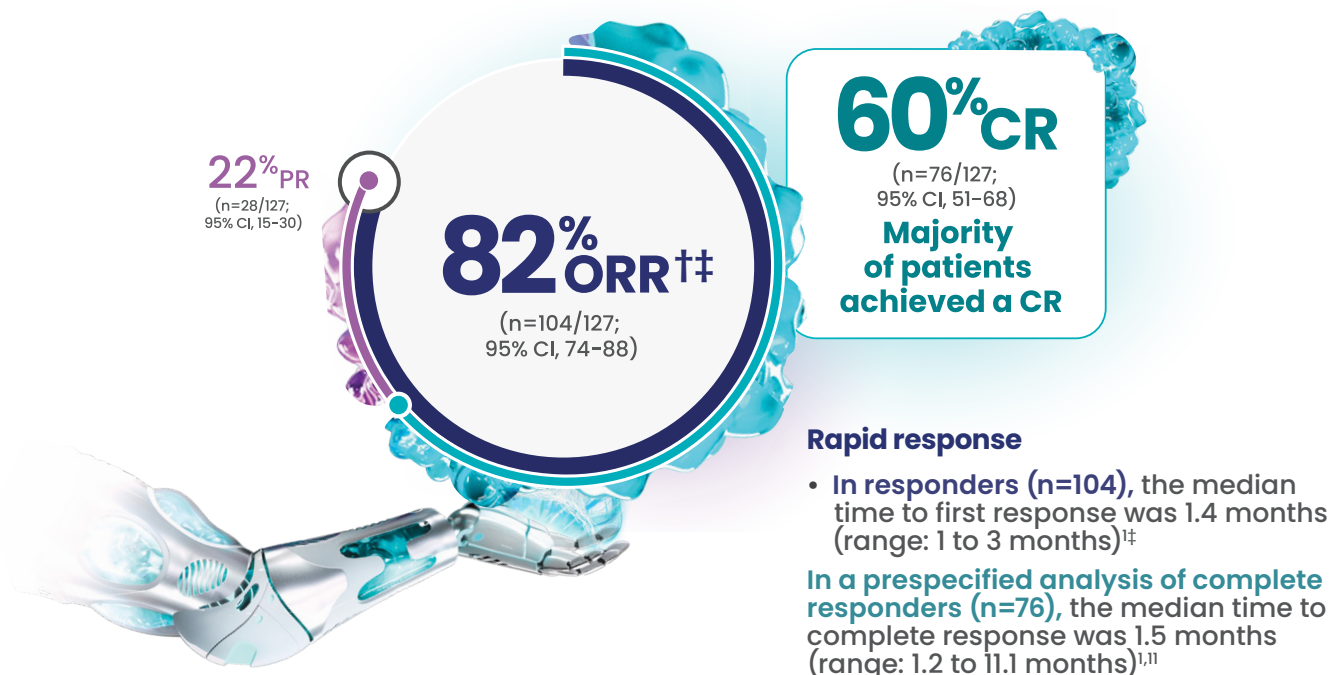
- EPKINLY can cause fatal and serious infections. Serious infections, including opportunistic infections, were reported in 40% of patients with FL receiving EPKINLY monotherapy following the 2-step up dosage schedule in EPCORE NHL-1 (most common: 20% COVID-19, 13% pneumonia, 3% urinary tract infections). Fatal infections occurred in 6% of patients (5% COVID-19, 0.8% pneumonia, 0.8% sepsis).

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, throughout and on pages 15–17. Please see full Prescribing Information, including Boxed Warnings.

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EPKINLY MONOTHERAPY: 3L+ FOLLICULAR LYMPHOMA

Even with a high enrollment of patients with difficult-to-treat disease,* 60% CR was observed in EPCORE® NHL-1^{9,10}



*Difficult-to-treat disease characteristics included age >65, double refractory, refractory to ≥2 consecutive lines of anti-lymphoma therapy, and POD24.

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

‡Median study follow-up was 17.4 months.¹²

STUDY DESIGN: The efficacy of EPKINLY was evaluated in 213 patients in EPCORE® NHL-1, an open-label, multicohort, multicenter, single-arm trial in patients with R/R FL after 2 or more lines of systemic therapy. The primary endpoint was ORR (CR+PR). Select secondary endpoints included CR rate, DOR, DOCR, and time to response.^{1,13}

[Learn more about EPKINLY monotherapy in 3L+ FL](#)

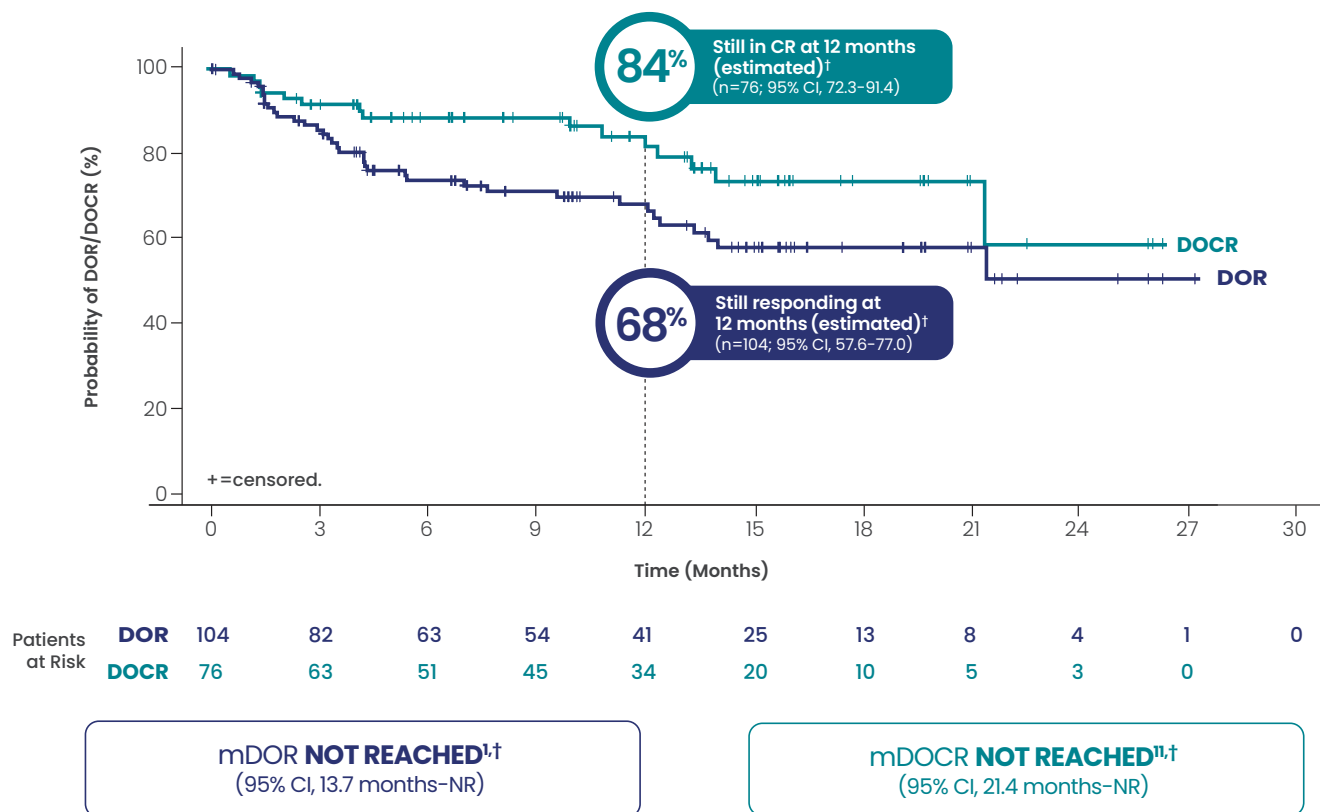
SELECT IMPORTANT SAFETY INFORMATION

- Among 243 patients with FL who received EPKINLY in combination with lenalidomide and rituximab in EPCORE FL-1, serious infections occurred in 28% of patients. The most common serious infections were pneumonia (15%), COVID-19 (7%), opportunistic infections (5%) and upper respiratory infections (3.3%). The most common opportunistic infections of any grade were cytomegalovirus (CMV) infection (7%) and herpesvirus infection (7%).
- 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.

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EPKINLY delivered durable responses, with mDOR not reached^{1,11,*†}



• The median follow-up for DOR was 14.8 months (range: 0.0+, 27.2+)^{1,11,‡}

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

Date of analysis: April 2023.¹¹

*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; R²=rituximab + lenalidomide.

When EPKINLY + R² isn't an option for your 3L+ FL patients, consider EPKINLY monotherapy for durable responses¹

SELECT IMPORTANT SAFETY INFORMATION

- 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.

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, throughout and on pages 15–17. Please see full Prescribing Information, including Boxed Warnings.

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INDICATIONS

- EPKINLY is indicated in combination with lenalidomide and rituximab for the treatment of adults with relapsed or refractory follicular lymphoma (FL).
- EPKINLY is indicated as monotherapy for the treatment of adults with relapsed or refractory FL after 2 or more lines of systemic therapy.

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.**

CRS

- CRS occurred in 49% (42/86) of patients with FL receiving EPKINLY monotherapy at the recommended dosage schedule in EPCORE NHL-1 (45% Grade 1, 9% Grade 2) and recurred in 48% of patients. Most events (88%) occurred during Cycle 1. In Cycle 1, CRS events occurred in 12% of patients after the 0.16 mg dose (Cycle 1, day 1), 6% after the 0.8 mg dose (Cycle 1, day 8), 15% after the 3 mg dose (Cycle 1, day 15), and 37% after the first 48 mg dose (Cycle 1, day 22). The median time to onset of CRS from the most recent administered dose across all doses was 59 hours (range: 0.1–7 days). The median time to onset after the first full 48 mg dose was 61 hours (range: 0.1–7 days).
- CRS occurred in 24% (32/131) of patients with FL receiving EPKINLY at the recommended dosage schedule in combination with lenalidomide and rituximab in EPCORE FL-1 (19% Grade 1, 5% Grade 2, and 12% serious adverse reactions due to CRS) and recurred in 41% of patients. Most events (88%) occurred during Cycle 1. In Cycle 1, CRS occurred in 5% of patients after the 0.16 mg dose (Cycle 1, day 1), 3.8% after the 0.8 mg dose (Cycle 1, day 8), 2.3% after the 3 mg dose (Cycle 1, day 15), and 18% after the first 48 mg dose (Cycle 1, day 22). The median time to onset of CRS from the most recent EPKINLY dose was 78 hours (range: 0.2–12 days). The median time to onset after the first 48 mg dose was 41 hours (range: 0.3–12 days).
- For patients with FL, 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 4.7% of patients with FL receiving EPKINLY monotherapy, and 1.5% of patients receiving EPKINLY in combination with lenalidomide and rituximab (reactions included headache, confusional state, tremors, dizziness, and ataxia).
- Administer pretreatment medications to reduce the risk of CRS. 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 15–17. Please see full [Prescribing Information](#), including Boxed Warnings.


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IMPORTANT SAFETY INFORMATION (CONTINUED)

ICANS

- ICANS occurred in 6% (8/127) of patients with FL receiving EPKINLY monotherapy following the 2-step up dosage schedule in EPCORE NHL-1 (3.9% Grade 1, 2.4% Grade 2). The median time to onset was 22 days (range: 14–66 days) from the start of treatment. Relative to the most recent administered dose, the median time to onset of ICANS was 3 days (range: 0.4–7 days). The median duration of ICANS was 2 days (range: 1–7 days), with ICANS resolving in 100% of patients.
- Among patients with FL who received EPKINLY at the recommended dosage schedule in combination with lenalidomide and rituximab in EPCORE FL-1, ICANS occurred in 0.8% (1/131, Grade 1).
- 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.

Infections

- EPKINLY can cause fatal and serious infections. Serious infections, including opportunistic infections, were reported in 40% of patients with FL receiving EPKINLY monotherapy following the 2-step up dosage schedule in EPCORE NHL-1 (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).
- Among 243 patients with FL who received EPKINLY in combination with lenalidomide and rituximab in EPCORE FL-1, serious infections occurred in 28% of patients. The most common serious infections were pneumonia (15%), COVID-19 (7%), opportunistic infections (5%) and upper respiratory infections (3.3%). The most common opportunistic infections of any grade were cytomegalovirus (CMV) infection (7%) and herpesvirus infection (7%).
- 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.

Cytopenias

- EPKINLY can cause serious or severe cytopenias. In the clinical trial of patients with FL who received EPKINLY monotherapy following the 2-step up dosage schedule, Grade 3 or 4 decreased neutrophils occurred in 30% (Grade 4, 17%), decreased hemoglobin in 10% (Grade 4, 0%), and decreased platelets in 8% (Grade 4, 4%) of patients. Febrile neutropenia occurred in 3.1% (Grade 4, 0%).
- In patients with FL who received EPKINLY in combination with lenalidomide and rituximab, Grade 3 or 4 decreased neutrophils occurred in 67% (Grade 4, 41%), decreased lymphocytes in 62% (Grade 4, 13%), decreased hemoglobin in 7%, and decreased platelets in 10% (Grade 4, 4.1%) of patients. Febrile neutropenia occurred in 6% (Grade 4, 2.1%).
- 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.

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, throughout and on pages 15–17. Please see full Prescribing Information, including Boxed Warnings.


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IMPORTANT SAFETY INFORMATION (CONTINUED)

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

- EPKINLY as monotherapy for FL: Most common ($\geq 20\%$) 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 ($\geq 10\%$) were decreased lymphocytes, decreased neutrophils, decreased hemoglobin, and decreased platelets.
- EPKINLY in combination with lenalidomide and rituximab for FL: Most common ($\geq 20\%$) adverse reactions were rash, upper respiratory tract infection, fatigue, injection site reactions, constipation, diarrhea, CRS, pneumonia, COVID-19, and fever. The most common Grade 3 to 4 laboratory abnormalities ($\geq 10\%$) were decreased neutrophils, decreased lymphocytes, and decreased platelets.

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 EPCORE NHL-1, 52% were ≥ 65 years old, and 13% were ≥ 75 years old. A higher rate of fatal adverse reactions, primarily infections, including COVID-19, was observed in patients ≥ 65 years old compared to younger adult patients. No overall difference in efficacy was observed.

[Learn more about EPKINLY for your patients with 2L+ FL](#)

References: 1. EPKINLY [package insert]. Plainsboro, NJ: Genmab US, Inc and North Chicago, IL: AbbVie Inc. 2026. 2. 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 August 3, 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. 3. A phase 3, open-label study to evaluate safety and efficacy of epcoritamab in combination with rituximab and lenalidomide (R2) compared to R2 in subjects with relapsed or refractory follicular lymphoma (EPCORE FL-1). ClinicalTrials.gov identifier: NCT05409066. Updated July 28, 2025. Accessed September 15, 2025. <https://clinicaltrials.gov/study/NCT05409066> 4. Falchi L, Nijland M, Huang H, et al. Epcoritamab, lenalidomide, and rituximab versus lenalidomide and rituximab for relapsed or refractory follicular lymphoma (EPCORE FL-1): a global, open-label, randomised, phase 3 trial. *Lancet*. Published online December 7, 2025. doi:10.1016/S0140-6736(25)02360-8 5. Supplement to: Falchi L, Nijland M, Huang H, et al. Epcoritamab, lenalidomide, and rituximab versus lenalidomide and rituximab for relapsed or refractory follicular lymphoma (EPCORE FL-1): a global, open-label, randomised, phase 3 trial. *Lancet*. Published online December 7, 2025. doi:10.1016/S0140-6736(25)02360-8 6. Leonard JP, Trneny M, Izutsu K, et al. AUGMENT: a phase III study of lenalidomide plus rituximab versus placebo plus rituximab in relapsed or refractory indolent lymphoma. *J Clin Oncol*. 2019;37(14):1188-1199. doi:10.1200/JCO.19.00010 7. 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 8. 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 9. 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 10. 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 11. Data on file. Plainsboro, NJ: Genmab US, Inc. and North Chicago, IL: AbbVie Inc. 2024. 12. 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 Haematol*. 2024;11(8):e593-e605. doi:10.1016/S2352-3026(24)001662-2 13. A phase 1/2, open-label safety trial of GEN3013 in patients with relapsed, progressive or refractory B-cell lymphoma. ClinicalTrials.gov identifier: NCT03625037. Updated November 4, 2025. Accessed November 22, 2025. <https://clinicaltrials.gov/study/NCT03625037>

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The power of superior PFS with fixed-duration

EPKINLY + R² vs R² 1,*,†

EPKINLY + R² is the first-and-only chemo-free bispecific antibody combination approved in 2L+ FL¹

2L+ FL	PFS
Fixed-duration EPKINLY + R²	↓ 79% reduction in the risk of disease progression or death compared with R ² (HR=0.21 [‡] ; 95% CI, 0.13–0.33; P<0.0001 [§]) in 2L+ FL

The efficacy and safety of EPKINLY in combination with R² vs R² alone were evaluated in EPCORE® FL-1, an open-label, randomized, multicenter, global trial in 488 patients with R/R FL after at least 1 line of systemic therapy. Efficacy was established based on PFS and ORR.¹

Manageable safety profile; generally consistent with the established profiles of EPKINLY and R² 1,6

- No Grade ≥3 CRS events were observed; CRS occurred in 24% of patients (19% Grade 1; 5% Grade 2)
- Warnings and precautions include CRS, ICANS, infections, cytopenias, and embryo-fetal toxicity
- Most common adverse reactions (≥20%) in patients who received EPKINLY + R² were rash, upper respiratory tract infections, fatigue, injection site reactions, constipation, diarrhea, CRS, pneumonia, COVID-19, and fever

Hospitalization is not required to administer EPKINLY for R/R FL—assess each patient¹

- For patients with FL, 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
- 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

*Efficacy results determined by Lugano criteria (2014) as assessed by IRC and based on a prespecified interim analysis.

†The median duration of follow-up was 10.4 months in the ITT population. Patients received EPKINLY via subcutaneous injection in 28-day cycles for a total of 12 cycles or until disease progression or unacceptable toxicity, whichever occurred first.

‡Cox proportional hazards hazard ratio stratified by disease history and region.

§Log-rank P-value (one sided) stratified by disease history and region.

INDICATIONS

- EPKINLY is indicated in combination with lenalidomide and rituximab for the treatment of adults with relapsed or refractory follicular lymphoma (FL).
- EPKINLY is indicated as monotherapy for the treatment of adults with relapsed or refractory FL after 2 or more lines of systemic therapy.

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 15–17.

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