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

HOSPITALIZATION IS NOT REQUIRED FOR MONITORING WITH EPKINLY ADMINISTRATION. ASSESS EACH PATIENT.[1]

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

Learn more about the dosing and administration of EPKINLY, including outpatient monitoring requirements

HCP=healthcare provider.

INDICATIONS

DLBCL and High-grade B-cell Lymphoma

- 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 confirmatory trial(s).

Follicular Lymphoma

- 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.**

Please see additional Important Safety Information throughout. Please see full Prescribing Information.

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

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

EPKINLY dosing schedule in 3L+ DLBCL[1]

3L+ DLBCL: 2-step up dosage schedule

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

Administer EPKINLY in 28-day cycles until disease progression or unacceptable toxicity.

EPKINLY dosing schedule in 2L+ FL[1]

2L+ FL: 3-step up dosage schedule (fixed duration)*

			R²	
		EPKINLY (subcutaneous)	rituximab (IV)	lenalidomide (oral)
CYCLE 1	Week 1	0.16 mg	375 mg/m² 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/m² 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.

*Administer EPKINLY in 28-day cycles for a total of 12 cycles or until disease progression or unacceptable toxicity, whichever occurs first.

2L=second line; 3L=third line; IV=intravenous; R²=rituximab + lenalidomide.

3L+ FL: 3-step up dosage schedule

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

Administer EPKINLY in 28-day cycles until disease progression or unacceptable toxicity.

EPKINLY is a subcutaneous injection that offers the flexibility of outpatient or inpatient monitoring following administration, based on patient needs and clinical judgment[1]

- **Treatment premedication and monitoring are the same across both indications and all EPKINLY regimens[1]**
- Step-up dosing of EPKINLY is intended to **increase tolerability** and **mitigate incidence and severity** of CRS[1,2]
- Subcutaneous administration allows more gradual increases and lower peaks in plasma cytokine levels than IV administration[3]
- Provide *Pneumocystis jirovecii* pneumonia prophylaxis during treatment with EPKINLY and **consider providing prophylaxis** against herpesvirus to prevent herpes simplex and herpes zoster[1]
- Initiate treatment with the EPKINLY step-up dosing schedule and **premedicate before each dose in cycle 1** to reduce the incidence and severity of CRS[1]
- If a dose of EPKINLY is missed or delayed, **therapy may need to be restarted**. Refer to Missed or Delayed Dose table in the full Prescribing Information[1]

IMPORTANT SAFETY INFORMATION (CONTINUED)

CRS

- CRS occurred in 51% (80/157) of patients with large B-cell lymphoma (LBCL) receiving EPKINLY at the recommended dosage schedule in EPCORE NHL-1 (37% Grade 1, 17% Grade 2, and 2.5% Grade 3) and recurred in 31% of patients. Most events (92%) occurred during Cycle 1. In Cycle 1, CRS events occurred in 6% of patients after the 0.16 mg dose (Cycle 1, day 1), 12% after the 0.8 mg dose (Cycle 1, day 8), 43% after the first 48 mg dose (Cycle 1, day 15), and 5% after the next 48 mg dose (Cycle 1, day 22). The median time to onset of CRS from the most recent administered dose across all doses was 24 hours (range: 0-10 days). The median time to onset after the first full 48 mg dose was 21 hours (range: 0-7 days).

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

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THE POWER OF SUSTAINED REMISSION FOR 3L+ DLBCL AND SUPERIOR PFS* IN 2L+ FL[1,4]

- EPKINLY monotherapy demonstrated remarkable responses, with a 61% ORR† and an mDOR‡ of 15.6 months in adult patients with 3L+ DLBCL; in adult patients with 3L+ FL, ORR† was 82% and mDOR§ was not reached[1]
- Fixed-duration EPKINLY + R^2 demonstrated a 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 adult patients with 2L+ FL[1]†**

The efficacy of EPKINLY was evaluated in 2 trials. EPCORE® NHL-1 was an open-label, multi-cohort, multicenter, single-arm trial in 148 patients with R/R DLBCL and 127 patients with R/R FL after ≥2 lines of systemic therapy. EPCORE® FL-1 was 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 dual primary endpoints of PFS and ORR.[1]

*Compared with R^2 in EPCORE® FL-1.
†Efficacy results determined by Lugano criteria (2014) as assessed by Independent Review Committee.
‡Based on Kaplan-Meier estimate. The median follow-up for DOR was 9.8 months (range: 0-17.3 months).
§Based on Kaplan-Meier estimate. The median follow-up for DOR was 14.8 months.
‖In EPCORE® FL-1, efficacy results were based on a prespecified interim analysis.
¶Cox proportional hazards hazard ratio stratified by disease history and region.
#Log-rank *P*-value (one sided) stratified by disease history and region.
**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.

CI=confidence interval; DOR=duration of response; HR=hazard ratio; ITT=intent to treat; mDOR=median duration of response; ORR=overall response rate; PFS=progression-free survival; R/R=relapsed/refractory.

IMPORTANT SAFETY INFORMATION (CONTINUED)

CRS (CONTINUED)

- 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 LBCL and 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. CRS resolved in 98% of patients; the median duration of CRS events was 2 days (range: <1-27 days). Concurrent neurological adverse reactions associated with CRS occurred in 2.5% of patients with LBCL, 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.

ICANS

- ICANS occurred in 6% (10/157) of patients with LBCL receiving EPKINLY at the recommended dosage schedule in EPCORE NHL-1 (4.5% Grade 1, 1.3% Grade 2, 0.6% fatal). Of the 10 ICANS events, 9 occurred within Cycle 1 of treatment, with a median time to onset of 16.5 days (range: 8-141 days) from the start of treatment. Relative to the most recent administered dose, the median time to onset was 3 days (range: 1-13 days). The median duration of ICANS was 4 days (range: 0-8 days), with ICANS resolving in 90% of patients with supportive care.
- 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.

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

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IMPORTANT SAFETY INFORMATION (CONTINUED)

Infections

- EPKINLY can cause fatal and serious infections. Serious infections, including opportunistic infections, were reported in 15% of patients with LBCL in EPCORE NHL-1 (most common: 4.5% sepsis, 3.2% pneumonia). Fatal infections occurred in 1.3% of patients (1.3% COVID-19).
- 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.

Cytopenias

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

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 LBCL or FL: Most common (≥20%) adverse reactions were CRS, injection site reactions, fatigue, musculoskeletal pain, fever, diarrhea, COVID-19, rash, and abdominal pain. Most common Grade 3 to 4 laboratory abnormalities (≥10%) were decreased lymphocytes, decreased neutrophils, decreased hemoglobin, and decreased platelets.
- EPKINLY in combination with lenalidomide and rituximab for FL: Most common (≥20%) adverse reactions were rash, upper respiratory tract infections, fatigue, injection site reactions, constipation, diarrhea, CRS, pneumonia, COVID-19, and fever. The most common Grade 3 to 4 laboratory abnormalities (≥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.

INDICATIONS

DLBCL and High-grade B-cell Lymphoma

- 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 confirmatory trial(s).

Follicular Lymphoma

- 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.**

Please see additional Important Safety Information throughout. Please see accompanying full Prescribing Information.

Learn more about the dosing and administration of EPKINLY, including outpatient monitoring requirements.

EPKINLYhcp.com

References: 1. EPKINLY [package insert]. Plainsboro, NJ: Genmab US, Inc. and North Chicago, IL: AbbVie Inc. 2026. **2.** 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 **3.** 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 **4.** Data on file. Plainsboro, NJ: Genmab US, Inc. and North Chicago, IL: AbbVie Inc. 2023.

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