



THE POWER OF SUPERIOR PFS vs R² 1*†

**Fixed-duration
EPKINLY + R²**

↓ 79%

reduction in the risk of disease progression or death compared with R² (**HR=0.21**[‡]; 95% CI, 0.13–0.33; $P<0.0001$ [§]) in 2L+ FL

- ORR: 89% (n=216/243; 95% CI, 84–93) with EPKINLY + R² compared to 74% (n=181/245; 95% CI, 68–79) with R² ($P<0.0001$ ^{||¶})
- CR: 74% (n=181/243; 95% CI, 69–80) with EPKINLY + R² compared to 43% (n=106/245; 95% CI, 37–50) with R² ($P<0.0001$ [¶])

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. Efficacy was established based on PFS and ORR.

**Learn more about the EPCORE[®] FL-1 study,
published in *The Lancet*²**

[Access here](#)

*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.

|| 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.

2L=second line; CI=confidence interval; CR=complete response; FL=follicular lymphoma; HR=hazard ratio; IRC=independent review committee; ITT=intent to treat; ORR=overall response rate; PFS=progression-free survival; R²=rituximab + lenalidomide; R/R=relapsed/refractory.

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.**

Please see additional Important Safety Information on the following page. Please see full [Prescribing Information](#), including Boxed Warnings.

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.

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.

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.

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.

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

References: 1. EPKINLY [package insert]. Plainsboro, NJ: Genmab US, Inc and North Chicago, IL: AbbVie Inc. 2026. 2. 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*. 2026;407(10524):161-173. doi:10.1016/S0140-6736(25)02360-8

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