

Monjuvi® (tafasitamab-cxix) - New indication

- On June 18, 2025, <u>Incyte announced</u> the FDA approval of <u>Monjuvi (tafasitamab-cxix)</u>, in combination with lenalidomide and rituximab, for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL).
 - Monjuvi is not indicated and is not recommended for the treatment of patients with relapsed or refractory marginal zone lymphoma outside of controlled clinical trials.
- Monjuvi is also approved in combination with lenalidomide, for the treatment of adult patients
 with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified,
 including DLBCL arising from low grade lymphoma, and who are not eligible for autologous
 stem cell transplant.
- The approval of Monjuvi for the new indication was based on inMIND, a randomized, double-blind, placebo-controlled study in 548 patients with relapsed or refractory FL. Patients were randomized to receive Monjuvi or placebo in combination with lenalidomide and rituximab. The major outcome measure was progression-free survival (PFS).
 - Median PFS was 22.4 months and 13.9 months in the Monjuvi and placebo arms, respectively (hazard ratio 0.43, 95% CI: 0.32, 0.58; p < 0.0001).
- The most common adverse reactions (≥ 20%) excluding laboratory abnormalities, with Monjuvi use in patients with relapsed or refractory FL were respiratory tract infections, diarrhea, rash, fatigue, constipation, musculoskeletal pain, and cough. The most common grade 3 or 4 laboratory abnormalities (≥ 20%) were decreased neutrophils and decreased lymphocytes.
- The recommended dose of Monjuvi is 12 mg/kg based on actual body weight administered as an
 intravenous infusion in combination with lenalidomide and rituximab. During cycles 1 to 3, Monjuvi
 should be administered on days 1, 8, 15, and 22. During cycles 4 to 12, Monjuvi should be
 administered on days 1 and 15.
- Refer to the Monjuvi drug label for dosing for DLBCL.



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