Monjuvi® (tafasitamab-cxix) – New indication

- On June 18, 2025, Incyte announced the FDA approval of Monjuvi (tafasitamab-cxix), **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.