Oncology Learning Network

Niktimvo™ (axatilimab-csfr) in Chronic Graft-Versus-Host Disease (cGVHD): Adverse Event (AE) Management

Quick Reference

Indications and Dosage[1]

- Adult and pediatric patients weighing ≥40 kg with **cGVHD after failure with ≥2 prior lines** of systemic therapy
- The recommended dosage is **0.3 mg/kg (maximum 35 mg)** every 2 weeks administered as an IV infusion over 30 minutes. Continue until progression or unacceptable toxicity

Baseline and Ongoing Monitoring[1]

- Prior to first dose: Monitor aspartate aminotransferase (AST), alanine aminotransferase (ALT), alkaline phosphatase (ALP), creatine phosphokinase (CPK), amylase, and lipase
- After first dose: Every 2 weeks for 1 month, then every 1 to 2 months until abnormalities resolve

Infusion-Related Reactions (IRRs)[1]

- Signs to monitor for during and after infusion: fever, chills, rash, flushing, dyspnea, and hypertension
- For patients who have previously experienced an IRR to axatilimab-csfr, premedicate with an antihistamine and an antipyretic

Recommended Dosage Modifications for Adverse Reactions[1,*]

- **Grade 1 or 2**: Temporarily interrupt until resolution, or decrease infusion rate by 50%; initiate symptomatic treatment; resume the infusion at 50% of the prior rate
- **Grade 3 or 4**: Permanently discontinue

*Grades per National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) v5.

Lab Abnormalities & Dose Modifications[1]

Hepatic (on day of dosing):

IF

- Elevated AST or ALT
- Grade 3 with total bilirubin ≤ Grade 1

THEN

- Withhold until recovery to Grade 2, then resume at 0.2 mg/kg (maximum 23 mg) every 2 weeks

Suspected DILI (at any time):

- Elevation of AST or ALT (regardless of the time of the reaction)
- ALT or AST ≥3 times ULN with total bilirubin ≥2 times ULN and ALP <2 times ULN
- Withhold and evaluate for DILI. If confirmed, permanently discontinue

Pancreatic and muscle enzymes:

- Elevation of CPK, amylase, or lipase
- ≥Grade 3; lab results show no evidence of end-organ damage, continue treatment without dose reduction
- Symptomatic ≥Grade 3; lab results show evidence of end-organ damage, permanently discontinue

Other non-hematologic adverse reactions:

Withhold until recovery to Grade 2:

- If delayed by ≤4 weeks from planned infusion, resume at 0.2 mg/kg (maximum 23 mg) every 2 weeks
- If delayed by >4 weeks from planned infusion, permanently discontinue

Grade 4: Permanently discontinue

Prior to starting treatment, special populations need additional assessment and careful review to determine their suitability for this type of therapy.[1]

Infection Vigilance

In the AGAVE-201 trial, serious AEs included infection (unspecified pathogen, viral) and respiratory failure. Permanent discontinuation due to an AE occurred in 10% of patients. Dose interruptions due to an AE occurred in 44% of patients.[1,2]

Maintain a low threshold for workup/therapy interruption per clinical status.[1,2]

Clinical Efficacy Context

In the AGAVE-201 trial, efficacy was based on an ORR through Cycle 7, Day 1 at the approved regimen; median time to first response was 1.5 months.[1,2]

ALT/AST, alanine transaminase/aspartate transaminase; CPK, creatine phosphokinase; DILI, drug-induced liver injury; ORR, overall response rate; ULN, upper limit of normal.

References

1. NIKTIMVO™ (axatilimab-csfr). Prescribing Information. Incyte; 2025.
2. Le R, et al. FDA approval summary: axatilimab for adult and pediatric patients weighing at least 40 kilograms with chronic GVHD after two prior lines of systemic therapy. *Clin Cancer Res.* 2025;OF1–OF6. doi.org/10.1158/1078-0432.CCR-25-0896