Written By: Sarah Rockwell, PharmD, BCOP
Institution: Florida Cancer Specialists and Research Institute

Initiating Mosunetuzumab-axgb (Lunsumio™) in Relapsed/Refractory Follicular Lymphoma

Description: The purpose of this PQI is to provide background on bispecific T-cell engagement and discuss the proper patient selection and prevention of adverse events related to the administration of mosunetuzumab-axgb in patients with relapsed/refractory (R/R) follicular lymphoma (FL) after two or more lines of systemic therapy.

Background:
Mosunetuzumab-axgb is a bispecific CD20-directed CD3 T-cell engager indicated in adult patients with:[1,2]

- R/R FL after two or more lines of systemic therapy

Most common adverse reactions (≥ 20%):[1]

- Cytokine release syndrome, fatigue, rash, pyrexia, and headache
- Grade 3 or 4 laboratory abnormalities (≥ 10%): decreased lymphocyte count, decreased phosphate, increased glucose, decreased neutrophil count, increased uric acid, decreased white blood cell count, decreased hemoglobin, and decreased platelets

PQI Process:

- Confirm appropriateness utilizing the patient's chart – R/R FL after ≥2 lines of systemic therapy
- Ensure appropriate dose and schedule based on day of treatment, cycle, and any treatment delays (see Supplemental Information Table 1 and Table 2), which aims to reduce risk of CRS
  - Administer for a total of 8 cycles if complete response achieved; administer a total of 17 cycles if partial response achieved, unless a patient experiences unacceptable toxicity or disease progression
  - CRS risk is highest during cycle 1, especially day 1 and day 15; however, CRS can occur at any point in therapy
- Ensure appropriate pre-medications are ordered for CRS and infusion reaction prevention
  - Corticosteroid 60 minutes pre-infusion and antihistamine and antipyretic 30 minutes pre-infusion
    - All patients in Cycle 1 and Cycle 2
    - Any patients who experienced CRS with the prior dose, regardless of cycle (e.g., Cycle 3 Day 1 if patient experienced CRS with Cycle 2 Day 1)
    - All patients repeating step-up dosing outside of Cycles 1 and 2
- Review adverse effects and necessary interventions as needed (see Product Labeling)
- Consider supportive care measures for patients at risk for tumor lysis syndrome (especially during Cycle 1 where the risk is highest) or infection
- Note risk of tumor flare, which can include pleural effusions and/or swelling at lymphoma sites

Patient-Centered Activities:

- Educate patient on schedule of administration: Highlight weekly step-up dosing with Cycle 1

- Discuss with patient the risk of Cytokine Release Syndrome and to report any symptoms that include, but are not limited to: fever, chills, fast or irregular heartbeat, tiredness or weakness, difficulty breathing, headache, confusion dizziness or light-headedness, nausea, and vomiting
- Discuss with patient the risk of neurotoxicity/ICANS and to report any symptoms that include, but are not limited to: headache, peripheral neuropathy, dizziness, and mental status changes (confusional state, disturbance in attention, cognitive disorder, delirium, somnolence)
- Educate the patient on risk of infection associated with bone marrow suppression and how to mitigate, including contacting care team for fever, as above with CRS
- Educate the patient on the signs of tumor flare, pleural effusions, and/or swelling at lymphoma sites
- Monitor lab values before each cycle and prior to each dose during step-up schedule, focusing on neutropenia, thrombocytopenia, electrolyte abnormalities (including phosphorus) and changes in liver function tests and/or blood glucose, at minimum
- Recommend female patient use effective contraception during therapy and for 3 months after last dose
- Patient Financial Assistance: NCODA Financial Assistance Tool

References:
1. Lunsumio™ (mosunetuzumab-axgb) [prescribing information]. South San Francisco, CA: Genentech, Inc.; November 2024.
2. National Comprehensive Cancer Network (NCCN Guidelines®). B-Cell Lymphomas. Version 2.2025. https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed May 19, 2025

Supplemental Information:

Table 1: Recommended mosunetuzumab-axgb Dose and Schedule (21-day Treatment Cycles)

Day of treatment		Dose of mosunetuzumab-axgb IV	Rate of Infusion
Cycle 1	Day 1	1 mg	Administer over a minimum of 4 hours; note rate may need to be prolonged in any cycle if toxicity occurs (see product labeling)
	Day 8	2 mg	
	Day 15	60 mg	
Cycle 2	Day 1	60 mg	Administer over 2 hours if infusions from Cycle 1 were well-tolerated
Cycles 3+	Day 1	**30 mg***	

*Note dose change from 60 mg to 30 mg for Cycle 3 and beyond, provided no dose delays

Table 2: Recommendations for Restarting mosunetuzumab-axgb after a Dose Delay Due to Toxicity or Other Cause

Last dose administered	Time since last dose administered	Action for next dose(s)
1 mg Cycle 1 Day 1	1 to 2 weeks	Resume planned treatment schedule (2 mg Cycle 1, Day 8)
	Greater than 2 weeks	Repeat 1 mg (Cycle 1 Day 1), then resume planned treatment schedule (2 mg Cycle 1, Day 8)
2 mg Cycle 1 Day 8	1 to 2 weeks	Resume planned treatment schedule (60 mg Cycle 1, Day 15)
	Greater than 2 weeks but less than 6 weeks	Repeat 2 mg (Cycle 1 Day 8), then resume planned treatment schedule (60 mg Cycle 1, Day 15)

	6 weeks or more	Repeat entire step-up schedule: 1 mg (Cycle 1, Day 1), then 2 mg (Cycle 1 Day 8), then 60 mg (Cycle 1, Day 15)
60 mg Cycle 1 Day 15	1 week to less than 6 weeks	Resume planned treatment schedule (60 mg Cycle 2, Day 1)
	6 weeks or more	Repeat entire step-up schedule: 1 mg (Cycle 2, Day 1), then 2 mg (Cycle 2, Day 8), then 60 mg (Cycle 2, Day 15), then 30 mg (Cycle 3, Day 1)
60 mg Cycle 2 Day 1	3 weeks to less than 6 weeks	Resume planned treatment schedule (30 mg Cycle 3, Day 1)
	6 weeks or more	Repeat 1 mg (Cycle 3, Day 1) and 2 mg (Cycle 3, Day 8), then administer **30 mg** (Cycle 3, Day 15)*, then resume planned treatment schedule (30 mg Cycle 4, Day 1)
30 mg Cycle 3+	3 weeks to less than 6 weeks	Resume planned treatment schedule with 30 mg on Day 1 of subsequent cycle
	6 weeks or more	Repeat 1 mg (Day 1) and 2 mg (Day 8), then **30 mg** (Day 15)*, then resume planned treatment schedule with 30 mg on Day 1 of subsequent cycles

* For the Day 1, Day 8, and Day 15 doses in the next cycle, administer premedication for all patients

Table 3: Premedication

Treatment Cycle	Patients Requiring Premedication	Premedication	Dosage	Administration
Cycles 1 & 2	All patients	Corticosteroid	Dexamethasone 20 mg IV or methylprednisolone 80 mg IV	Complete at least 1 hour prior to infusion
		Antihistamine	Diphenhydramine 50 mg-100 mg or equivalent oral or IV antihistamine	At least 30 minutes prior to infusion
		Antipyretic	Oral acetaminophen (500 mg-1,000 mg)	At least 30 minutes prior to infusion
Cycles +3	Patients who experienced any grade CRS with the previous dose	Corticosteroid	Dexamethasone 20 mg IV or methylprednisolone 80 mg IV	Complete at least 1 hour prior to infusion
		Antihistamine	Diphenhydramine 50 mg -100 mg or equivalent oral or IV antihistamine	At least 30 minutes prior to infusion
		Antipyretic	Oral acetaminophen (500 mg-1,000 mg)	At least 30 minutes prior to infusion