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ORIGINAL RESEARCH

Fixed Treatment Duration Mosunetuzumab in Patients With Relapsed or Refractory Follicular Lymphoma: Perspectives From US Advanced Practice Providers

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Abstract

Background: Mosunetuzumab is a CD20xCD3 T-cell engaging bispecific antibody that has demonstrated a manageable safety profile in patients with relapsed or refractory (R/R) non-Hodgkin lymphoma in a pivotal phase II study (GO29781; NCT02500407). Rapid identification and appropriate management of adverse events (AEs) are key for patients receiving mosunetuzumab, and advanced practice providers (APPs) play a vital role. **Methods:** Six APPs were surveyed, including nurse practitioners, a research nurse, clinical pharmacists, and physician assistants, from four US academic centers involved in the phase II GO29781 study of mosunetuzumab administered intravenously in patients with R/R follicular lymphoma. Advanced practice providers provided their perspectives and experiences on their roles in the education of staff and patients, and in the monitoring and management of AEs associated with mosunetuzumab treatment. **Results:** APPs provided education to staff and patients around the signs and symptoms of potential AEs as well as mosunetuzumab's mechanism of action, route of administration, and dosing schedule. They were involved in monitoring patients for AEs using clinical assessments and laboratory tests and were responsible for managing AEs, ordering necessary interventions, deciding when to interrupt treatment, clearing patients for their next dose, and advising the wider medical team on steps for patient

management. **Conclusions:** APPs play a key role as part of a multidisciplinary team to ensure the safety and comfort of patients receiving mosunetuzumab in the outpatient setting. The APP experiences presented here may be used to inform future clinical practice and care coordination for mosunetuzumab treatment.

Follicular lymphoma (FL) is the second most common form of non-Hodgkin lymphoma (NHL) (Freedman & Jacobsen, 2020). Treatment for repeated episodes of relapse is associated with decreasing response duration and poor survival (Batlevi et al., 2020; Ghione et al., 2023; Rivas-Delgado et al., 2019). Therefore, novel therapies are needed to improve outcomes for patients with relapsed or refractory (R/R) FL.

Mosunetuzumab (Lunsumio) is a readily available CD20xCD3 T-cell engaging bispecific antibody that redirects T cells to eliminate B cells, including those that cause malignant disease (Sun et al., 2015). Mosunetuzumab, as an intravenous (IV) infusion or subcutaneous injection, is approved for the treatment of patients with R/R FL after ≥ 2 prior lines of systemic therapy (European Medicines Agency, 2025; US Food and Drug Administration, 2022; US Food and Drug Administration, 2025a; F. Hoffmann-La Roche Ltd, 2025). Mosunetuzumab IV is administered as a fixed duration treatment in 21-day cycles with step-up dosing in Cycle (C)1 (C1 Day [D]1, 1 mg; C1D8, 2 mg; C1D15/C2D1, 60 mg; C3D1 and onward, 30 mg). Patients who achieved a complete response by C8 completed treatment; those with a partial response or stable disease continued treatment for up to 17 cycles. In the GO29781 pivotal phase II study (NCT02500407), after a median 4 years of follow-up, mosunetuzumab IV induced high overall and complete response rates of 77.8% and 60.0%, respectively, with durable responses in patients with R/R FL who received ≥ 2 prior therapies (median duration of response and duration of complete response of 46.4 and 51.8 months, respectively; Budde et al., 2022; Shadman et al., 2024).

Mosunetuzumab has a manageable safety profile, allowing for administration as an outpatient regimen with no hospitalization (Table 1; Budde et al., 2022). In the pivotal phase II study, cytokine release syndrome (CRS) was the most common adverse event (AE) among 90 patients with FL, with the majority being grade 1 and 2 (*N* = 40; 44.4%; grade 1, 25.6%; grade 2, 16.7%; grade 3, 1.1%; grade 4, 1.1%; Budde et al., 2022; Matasar et al., 2024; Shadman et al., 2024), consistent with the safety profile observed with other T-cell engaging therapies (Bannerji et al., 2022; Dickinson et al., 2022; Fowler et al., 2022; Hutchings et al., 2021a; Hutchings et al., 2021b; Jacobson et al., 2022). Cytokine release syndrome primarily occurred during C1, and the risk of severe CRS was mitigated by step-up dosing during C1 and corticosteroid premedication during C1 to C2 (Budde et al., 2022; Matasar et al., 2024). Other common AEs included fatigue (*N* = 33; 36.7%) and headache (*N* = 28; 31.1%). Adverse events of interest included neurologic AEs (*N* = 49; 54.4%), tumor flare (*N* = 3; 3.3%), tumor lysis syndrome (TLS; *N* = 1; 1.1%), neutropenia (*N* = 26; 28.9%), and infections (*N* = 46; 51.1%; Matasar et al., 2024).

Appropriate identification and management of AEs, including CRS, are key when treating patients with T-cell engaging therapies. Advanced practice providers (APPs) play a key role in the identification, monitoring, and management of AEs. Perspectives of APPs on their role in the education, monitoring, and management of AEs in patients with R/R FL treated with mosunetuzumab IV monotherapy in the pivotal phase II study are summarized here.

METHODS

Phase II GO29781 Study

This is an open-label phase II study of mosunetuzumab in patients with R/R NHL; study design and statistical analyses have been described previously (Budde et al., 2022). Eligible patients were ≥ 18 years and had histologically confirmed R/R NHL, including FL (grade 1–3a), with ≥ 2 prior lines of therapy. Guidance on the management of specified AEs outlined in the study protocol was previously published and is summarized in Table 2 (Matasar et al., 2024).

Table 1. Summary of AEs in Patients With R/R FL From the GO29781 Study

N (%)	R/R FL (*N* = 90)
Any AE	90 (100)
Treatment-related AE	83 (92.2)
Grade 3/4 AE	63 (70.0)
Treatment-related grade 3/4 AE	46 (51.1)[a]
Serious AE	42 (46.7)
Treatment-related serious AE	30 (33.3)
Grade 5 AE	2 (2.2)[b]
AE leading to mosunetuzumab discontinuation	4 (4.4)
Treatment-related AE leading to mosunetuzumab discontinuation	2 (2.2)
AE leading to mosunetuzumab dose modification	5 (5.6)
AE leading to mosunetuzumab dose interruption	33 (26.7)

Note. Adapted from Matasar et al. (2024). Clinical cutoff date: August 27, 2021. AE = adverse event; FL = follicular lymphoma; R/R = relapsed or refractory.
[a]Includes all patients who experienced grade 3/4 AEs during initial treatment. Some of these patients could have also experienced a grade 5 event as their worst grade event.
[b]Including grade 5 progressive disease (*N* = 1).

APP Perspectives

Approaches to AE monitoring, management, and education from the perspective of APPs were collected through a survey of six APPs from four US academic centers who participated in the GO29781 study.

RESULTS

APP Role in Staff Education and Coordination Around AEs

All APPs surveyed (nurse practitioner, *N* = 3; research nurse, *N* = 1; clinical pharmacist, *N* = 1; physician assistant, *N* = 1) played a key role in providing in-service education for the multidisciplinary team involved in mosunetuzumab treatment (Figure 1), including education around the mechanism of action, route of administration, and dosing schedule, as well as potential AEs and their symptoms. Education was role dependent; research nurses and nurse practitioners educated nurses who administered mosunetuzumab on the signs and symptoms of potential AEs, particularly CRS events, to support timely identification. Key symptoms highlighted were fever, chills, drop in blood pressure, lightheadedness or dizziness, increased heart rate, breathing difficulties, and headaches. The study protocol, handouts on specific AEs of interest, and quick-reference guides created by the APPs' institutions were often leveraged to educate the nursing team.

Education was also provided around the utilization of premedications in C1 and C2 to reduce the risk of CRS (corticosteroids administered 1 hour prior, and diphenhydramine and acetaminophen at least 30 minutes prior to mosunetuzumab infusion). Building these premedications directly into the Order Set was recommended. Patients' vital signs and temperature were closely monitored before, every 30 minutes during, and after mosunetuzumab infusion. For example, blood pressure was measured every 30 minutes during infusion, and APPs and physicians were notified of any changes from baseline (e.g., rapid increase in temperature or drop in blood pressure). Tocilizumab was readily available in case of CRS occurrence. Consideration was also given to submission of an insurance claim for tocilizumab in parallel with a claim for mosunetuzumab, to ensure that if required, patients could receive tocilizumab in the outpatient clinic without delay.

Advanced practice providers played an essential role in the education of nursing staff who triaged patient phone calls; nursing staff were taught to recognize symptoms of potential AEs, particularly CRS, and that the time to onset of CRS during step-up dosing was considered comparable to other therapies such as chimeric antigen receptor (CAR) T-cell therapy. They were advised that many AEs occurred after patients left the clinic.

Before treatment	During treatment	After treatment
• Educate the nursing team on signs and symptoms of potential AEs, particularly CRS, and around premedications » Utilize the study protocol and AE handouts » Build premedications into the Order Set » Recommend that patient's vital signs are closely monitored during all stages of treatment • Educate the pharmacy team on management of treatment delays and management of AEs • Counsel patients on the logistics of treatment: » Schedule of visits » Premedications » Duration of infusions • Educate patients and family members on symptoms of potential and common AEs associated with mosunetuzumab treatment • Ensure patients are well-hydrated to mitigate the risk of CRS » Implement IV hydration where needed • Assess TLS, tumor flare, and infection risk and prophylactic medications/hydration	• Provide frequent reminders to patients on AE symptoms, particularly during the initial treatment cycles » Provide patients with educational materials (e.g., wallet cards, handouts) » Ask patients to repeat back instructions provided to ensure understanding » Implement follow-up calls for patients who need more frequent reminders • Reassure patients of the monitoring and management protocols in place should an AE occur • Encourage patients to contact the clinic nursing triage phoneline if they experience AE symptoms outside of the clinic, or to go to the emergency room • Make patients aware of social care and support services available during their treatment	• Monitor for AEs » Advise patients to self-monitor for symptoms after leaving the clinic after infusions, particularly for CRS » Assess and diagnose AEs, including CRS, using clinical assessments and laboratory tests • Manage symptoms if/when they arise » Order interventions (e.g., G-CSF for hematological AEs, treatment for CRS, or antibiotics for infections) » Decide when to interrupt treatment » Clear patients to receive their next dose after AE resolution » Advise the wider medical team on steps for AE management » Escalate to attending physician where required

Figure 1. Summary of APP roles and responsibilities throughout the course of mosunetuzumab treatment. AE = adverse event; APP = advanced practice provider; CRS = cytokine release syndrome; G-CSF = granulocyte colony-stimulating factor; IV = intravenous; TLS = tumor lysis syndrome.

They were also advised that when patients contacted the clinic with potential AEs, those experiencing fever accompanied by shortness of breath, headaches, shaking, chills, confusion, or slurred speech were advised to return to the clinic or seek immediate medical attention.

Pharmacists educated the pharmacy team on managing mosunetuzumab treatment delays, including recommendations for restarting treatment and effectively addressing AEs, such as CRS. The reinitiation of step-up dosing after a prolonged delay is required to gradually resensitize the immune system, thereby mitigating the risk of a severe inflammatory response due to the replenishment of targeted B cells. Guidance on restarting therapy with mosunetuzumab after dose delay can be found in the product prescribing information (US Food and Drug Administration, 2022). Additionally, strategies for minimizing the risk of AE recurrence and steps for prompt intervention were emphasized to enhance the overall quality of patient care and safety.

APP Role in Patient Education

APPs play a key role in patient education (Figure 1), advising patients that AEs experienced with mosunetuzumab treatment are different from those with traditional chemotherapy. Cytokine release syndrome occurs predominantly during C1, and is generally well tolerated thereafter, particularly after step-up dosing.

Prior to mosunetuzumab initiation, patients were counseled on logistical aspects of treatment, including treatment schedule, necessary premedications, and expected duration of infusions. Patients were prepared for frequent communication with their medical team, especially during the step-up dosing phase. In addition, patients were advised to expect to spend at least 6 hours at the clinic for the C1 infusion (administered

Table 2. Summary of Guidance for the Management of Adverse Events During Mosunetuzumab IV Treatment, Adapted From the GO29781 Study Protocol

AE	Adapted Study Protocol Measures
CRS	Premedication • Cycles 1 and 2: steroids 60 minutes before, and acetaminophen plus diphenhydramine 30 minutes before, mosunetuzumab administration. • Cycle 3 onwards: continue premedication if CRS event occurred with a previous dose. Infusion • Cycle 1: administer over a minimum of 4 hours during step-up doses on Day 1, Day 8, and Day 15. • Cycle 2: administer over 2 hours if infusions in Cycle 1 were well tolerated. • For patients who are at increased risk of CRS, or patients who experienced CRS with prior doses of mosunetuzumab, the infusion time may be extended up to 8 hours in Cycle 1, or 4 hours in Cycle 2 and onwards. Management[a] • Grade 1 (fever ≥ 38.0°C [100.4°F]): interrupt infusion until symptoms resolve; restart at the same rate. If symptoms recur, interrupt treatment, do not resume. » Supportive care: treat symptoms; consider hospitalization until symptoms completely resolve. » Anti-IL6/corticosteroid therapy: for prolonged CRS (> 2 days) after symptomatic management, consider dexamethasone[b] and/or tocilizumab.[c] » Next dose: symptoms should be resolved for at least 72 hours prior to next infusion; administer premedications; consider 50% (or lower) rate of infusion and more frequent monitoring. • Grade 2 (fever ≥ 38.0°C [100.4°F] and hypotension not requiring vasopressors OR hypoxia requiring low-flow O2 by nasal cannula or blow-by): interrupt infusion until symptoms resolve; consider restarting infusion at 50% rate. If symptoms recur with re-administration at a decreased infusion rate, do not resume. » Supportive care: treat symptoms and consider ICU admission for hemodynamic monitoring. For hypotension, administer IV fluid bolus as needed; for persistent refractory hypotension (e.g., after two fluid boluses and anti-IL6 therapy), start vasopressors and manage per Grade 3. » Anti-IL6/corticosteroid therapy: if no improvement occurs after symptomatic management, dexamethasone,[b] and/or tocilizumab[c] should be considered. Manage per grade 3 if no improvement within 24 hours after starting tocilizumab. » Next dose: patient may receive the next dose if symptoms resolve to grade ≤ 1 for at least 72 hours. Consider maximizing premedications as appropriate and consider a 50% (or lower) rate of infusion with more frequent monitoring of the patient.

Note. Adapted from Matasar et al. (2024). AE = adverse event; ASTCT = American Society for Transplantation and Cellular Therapy; BiPAP = bilevel positive airway pressure; CPAP = continuous positive airway pressure; CRS = cytokine release syndrome; G-CSF = granulocyte colony-stimulating factor; HLH = hemophagocytic lymphohistiocytosis; ICU = intensive care unit; IL6 = Interleukin 6; IV = intravenous; TLS = tumor lysis syndrome.

[a]CRS grading is per ASTCT 2019 criteria. If CRS is refractory to management, consider other causes including HLH. Pre-medication may mask fever; therefore, if clinical presentation is consistent with CRS, follow these management guidelines.

[b]Dexamethasone should be administered at 10 mg IV every 6 hours (or equivalent) until clinical improvement.

[c]In Study GO29781, tocilizumab was administered at a dose of 8 mg/kg IV (not to exceed 800 mg per infusion), as needed for CRS management. If no clinical improvement in the signs/symptoms of CRS occurs after the first dose, a second dose of tocilizumab 8 mg/kg IV may be administered at least 8 hours apart (maximum 2 doses per CRS event). Within each time period of 6 weeks of mosunetuzumab treatment, the total amount of tocilizumab doses should not exceed 3 doses. This dosage has been modified from previous protocol guidance to maintain tocilizumab exposure within established clinical boundaries for the safety and efficacy of tocilizumab.

[d]Antifungal prophylaxis should be strongly considered in patients receiving steroids for treatment of CRS.

[e]Resumption of mosunetuzumab may be considered in patients who are deriving a treatment benefit and have fully recovered from the AE.

[f]Not included in study protocol guidance, based on a separate analysis of tocilizumab.

[g]Neurologic AEs not otherwise specified.

Table 2. Summary of Guidance for the Management of Adverse Events During Mosunetuzumab IV Treatment, Adapted From the GO29781 Study Protocol (cont.)

AE	Adapted Study Protocol Measures
CRS (cont.)	Management (cont.) • Grade 3 (fever ≥ 38.0°C [100.4°F] and hypotension requiring a vasopressor [with or without vasopressin] OR hypoxia requiring high-flow O2 by nasal cannula, face mask, non-rebreather mask, or Venturi mask): stop infusion and do not resume. » Supportive care: treat symptoms, admit to ICU for hemodynamic monitoring. For hypotension, administer IV fluid bolus and vasopressors as needed. » Anti-IL6/corticosteroid therapy: dexamethasone[b] and tocilizumab[c] should be administered.[d] If CRS is refractory to dexamethasone and tocilizumab, alternative immunosuppressants and methylprednisolone 1,000 mg/day IV should be administered until clinical improvement. » Next dose: patient may receive the next dose if CRS event was responsive to treatment and symptoms resolve to grade ≤ 1 for at least 72 hours. Patients should be hospitalized for the next infusion, maximize premedications as appropriate and administer next infusion at 50% (or lower) rate. • Grade 4 (fever ≥ 38.0°C [100.4°F] and hypotension requiring multiple vasopressors [excluding vasopressin] OR hypoxia requiring oxygen by positive pressure [e.g., CPAP, BiPAP, intubation, and mechanical ventilation]): stop infusion, do not resume. » Supportive care: ICU admission and hemodynamic monitoring; mechanical ventilation, IV fluids, and vasopressors as needed. Treat symptoms. » Anti-IL6/corticosteroid therapy: dexamethasone[b] and tocilizumab[c] should be administered.[d] If CRS is refractory to dexamethasone and tocilizumab, alternative immunosuppressants, and methylprednisolone 1,000 mg/day IV should be administered until clinical improvement. » Next dose: permanently discontinue mosunetuzumab.[e] Tocilizumab administration • Tocilizumab should be administered at a dose of 8 mg/kg IV over 1 hour; doses > 800 mg per infusion are not recommended. • If no clinical improvement in CRS signs and symptoms after the first dose, a second dose of tocilizumab 8 mg/kg IV may be administered at least 8 hours apart (maximum 2 doses per CRS event).[f] • Maximum of 3 doses of tocilizumab in any 6-week time period.[f]
HLH	Management • Suspected HLH: withhold mosunetuzumab, consider hematology referral. » Initiate supportive care per institutional guidelines and consider appropriate HLH treatment. • Confirmed HLH: permanently discontinue mosunetuzumab and refer to hematologist. » Initiate supportive care per institutional guidelines and start appropriate HLH treatment per institutional standards or published guidance (Schram & Berliner, 2015; Vallurupalli & Berliner, 2019).

Note. Adapted from Matasar et al. (2024). AE = adverse event; ASTCT = American Society for Transplantation and Cellular Therapy; BiPAP = bilevel positive airway pressure; CPAP = continuous positive airway pressure; CRS = cytokine release syndrome; G-CSF = granulocyte colony-stimulating factor; HLH = hemophagocytic lymphohistiocytosis; ICU = intensive care unit; IL6 = Interleukin 6; IV = intravenous; TLS = tumor lysis syndrome.

[a]CRS grading is per ASTCT 2019 criteria. If CRS is refractory to management, consider other causes including HLH. Pre-medication may mask fever; therefore, if clinical presentation is consistent with CRS, follow these management guidelines.

[b]Dexamethasone should be administered at 10 mg IV every 6 hours (or equivalent) until clinical improvement.

[c]In Study GO29781, tocilizumab was administered at a dose of 8 mg/kg IV (not to exceed 800 mg per infusion), as needed for CRS management. If no clinical improvement in the signs/symptoms of CRS occurs after the first dose, a second dose of tocilizumab 8 mg/kg IV may be administered at least 8 hours apart (maximum 2 doses per CRS event). Within each time period of 6 weeks of mosunetuzumab treatment, the total amount of tocilizumab doses should not exceed 3 doses. This dosage has been modified from previous protocol guidance to maintain tocilizumab exposure within established clinical boundaries for the safety and efficacy of tocilizumab.

[d]Antifungal prophylaxis should be strongly considered in patients receiving steroids for treatment of CRS.

[e]Resumption of mosunetuzumab may be considered in patients who are deriving a treatment benefit and have fully recovered from the AE.

[f]Not included in study protocol guidance, based on a separate analysis of tocilizumab.

[g]Neurologic AEs not otherwise specified.

Table 2. Summary of Guidance for the Management of Adverse Events During Mosunetuzumab IV Treatment, Adapted From the GO29781 Study Protocol (cont.)

AE	Adapted Study Protocol Measures
Neurologic AEs[g]	Management • Grade 1: consider withholding mosunetuzumab during evaluation. • Grade 2: withhold further mosunetuzumab treatment, consider corticosteroid treatment and neurology consultation. » Mosunetuzumab may be resumed when symptoms have returned to baseline for ≥ 3 consecutive days without medical management and with confirmation of baseline neurologic examination. • Grade 3: withhold further mosunetuzumab treatment, consider corticosteroid treatment, and obtain neurology consultation. » Consider discontinuation if symptoms persist > 7 days. » Study treatment may resume at reduced dose when symptoms have returned to baseline for ≥ 3 consecutive days without medical management and with confirmation of baseline neurologic examination. » Permanently discontinue study treatment for recurrent grade 3 event. • Grade 4: permanently discontinue mosunetuzumab and obtain neurology consultation.
Tumor flare	Evaluation and monitoring • Evaluate lymphoma distribution prior to treatment initiation to anticipate the potential spectrum of clinical manifestations of tumor flare. • Patients with tumors involving critical anatomic locations (e.g., major vessels, tracheobronchial tree and upper airway, heart, and pericardium) should be closely monitored for tumor flare, and prospective preventive or interventional measures may need to be considered or planned prior to dosing. • Proactive monitoring of vital signs, physiologic parameters, or implementation of prophylactic procedures (e.g., tracheostomy) may be required. Further medical and/or surgical management may be necessary (e.g., anti-inflammatory agents, airway management, decompression, tracheostomy, stenting, prolonged hospitalization).

Note. Adapted from Matasar et al. (2024). AE = adverse event; ASTCT = American Society for Transplantation and Cellular Therapy; BiPAP = bilevel positive airway pressure; CPAP = continuous positive airway pressure; CRS = cytokine release syndrome; G-CSF = granulocyte colony-stimulating factor; HLH = hemophagocytic lymphohistiocytosis; ICU = intensive care unit; IL6 = Interleukin 6; IV = intravenous; TLS = tumor lysis syndrome.

[a]CRS grading is per ASTCT 2019 criteria. If CRS is refractory to management, consider other causes including HLH. Pre-medication may mask fever; therefore, if clinical presentation is consistent with CRS, follow these management guidelines.

[b]Dexamethasone should be administered at 10 mg IV every 6 hours (or equivalent) until clinical improvement.

[c]In Study GO29781, tocilizumab was administered at a dose of 8 mg/kg IV (not to exceed 800 mg per infusion), as needed for CRS management. If no clinical improvement in the signs/symptoms of CRS occurs after the first dose, a second dose of tocilizumab 8 mg/kg IV may be administered at least 8 hours apart (maximum 2 doses per CRS event). Within each time period of 6 weeks of mosunetuzumab treatment, the total amount of tocilizumab doses should not exceed 3 doses. This dosage has been modified from previous protocol guidance to maintain tocilizumab exposure within established clinical boundaries for the safety and efficacy of tocilizumab.

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[e]Resumption of mosunetuzumab may be considered in patients who are deriving a treatment benefit and have fully recovered from the AE.

[f]Not included in study protocol guidance, based on a separate analysis of tocilizumab.

[g]Neurologic AEs not otherwise specified.

Table 2. Summary of Guidance for the Management of Adverse Events During Mosunetuzumab IV Treatment, Adapted From the GO29781 Study Protocol (cont.)

AE	Adapted Study Protocol Measures
TLS	Prophylaxis • Hydration: In the outpatient setting, fluid intake of 2–3 L/day should start 24–48 hours prior to the first dose and be maintained for at least 24 hours after mosunetuzumab administration. • Modification of fluid intake should be considered for individuals with specific medical needs. Hyperuricemic therapy: administration of an agent to reduce uric acid should be considered. • Allopurinol (e.g., 300 mg/day orally beginning 72 hours prior to mosunetuzumab and continuing for 3–7 days afterwards) should be administered for patients at low/intermediate risk of TLS. • For patients with elevated uric acid levels prior to mosunetuzumab treatment or considered to be at high risk for TLS, rasburicase (e.g., 0.2 mg/kg IV over 30 minutes prior to first mosunetuzumab dose, and daily for up to 5 days thereafter) should be administered, unless contraindicated. • Allopurinol/rasburicase should continue as specified above, or if laboratory evidence of TLS is observed, treatment should be continued until normalization of serum uric acid or other laboratory parameters. Management • Although TLS is rare with mosunetuzumab, all patients, especially those with known risk factors (e.g., high tumor burden, reduced renal function), should be monitored for signs and symptoms of TLS and treated according to standard guidelines. • TLS must be resolved prior to further treatment with mosunetuzumab. Consider TLS prophylaxis and monitoring with the next mosunetuzumab dose.
Neutropenia	Management • Patients with neutropenia should receive growth factor support per institutional guidelines and standard of care; G-CSF may be considered in patients with fever and neutropenia who are at high risk for infection-associated complications or who have prognostic factors predictive of poor clinical outcomes (Lee et al., 2014). • Febrile neutropenia should be managed according to local guidelines or as per institutional practice.
Infections	Management • Active infection must be resolved prior to treatment with mosunetuzumab. • Caution should be exercised in patients with underlying conditions that may result in predisposition to infections. • Patients should receive appropriate vaccinations (e.g., against COVID-19, influenza, pneumonia, shingles). • Anti-infective prophylaxis for viral (including COVID-19), fungal, bacterial, and opportunistic infections (e.g., *Pneumocystis jirovecii* pneumonia) should be used in accordance with institutional practice.

Note. Adapted from Matasar et al. (2024). AE = adverse event; ASTCT = American Society for Transplantation and Cellular Therapy; BiPAP = bilevel positive airway pressure; CPAP = continuous positive airway pressure; CRS = cytokine release syndrome; G-CSF = granulocyte colony-stimulating factor; HLH = hemophagocytic lymphohistiocytosis; ICU = intensive care unit; IL6 = Interleukin 6; IV = intravenous; TLS = tumor lysis syndrome.

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[b]Dexamethasone should be administered at 10 mg IV every 6 hours (or equivalent) until clinical improvement.

[c]In Study GO29781, tocilizumab was administered at a dose of 8 mg/kg IV (not to exceed 800 mg per infusion), as needed for CRS management. If no clinical improvement in the signs/symptoms of CRS occurs after the first dose, a second dose of tocilizumab 8 mg/kg IV may be administered at least 8 hours apart (maximum 2 doses per CRS event). Within each time period of 6 weeks of mosunetuzumab treatment, the total amount of tocilizumab doses should not exceed 3 doses. This dosage has been modified from previous protocol guidance to maintain tocilizumab exposure within established clinical boundaries for the safety and efficacy of tocilizumab.

[d]Antifungal prophylaxis should be strongly considered in patients receiving steroids for treatment of CRS.

[e]Resumption of mosunetuzumab may be considered in patients who are deriving a treatment benefit and have fully recovered from the AE.

[f]Not included in study protocol guidance, based on a separate analysis of tocilizumab.

[g]Neurologic AEs not otherwise specified.

over ~4 hours), with the infusion duration likely to be reduced in subsequent cycles (to ~2 hours). Patients were also advised that premedications (a corticosteroid [dexamethasone or methylprednisolone] 1 hour prior plus diphenhydramine and acetaminophen 30 minutes prior to mosunetuzumab infusion) would be administered to reduce the risk of CRS. No driving immediately following treatment (vs. for at least 2 weeks after CAR T-cell therapy; US Food and Drug Administration, 2025b) was recommended because of potential drowsiness caused by premedication. Patients were informed that mosunetuzumab would be received for a fixed duration, rather than until disease progression, as with other bispecific antibody therapies. They were educated on the frequency of clinic visits: weekly during C1, then every 3 weeks for 8 or 17 cycles (~6 months–1 year) depending on their response to treatment, with consideration given to providing a calendar outlining the treatment schedule.

Advanced practice providers ensured patients and caregivers were well-informed about the potential for common AEs and their management. During the initial treatment cycles, particularly after each step-up dose, patients were reminded of the potential AEs associated with mosunetuzumab treatment and reassured about the protocols in place to monitor for and treat AEs should they occur. Educational materials such as wallet cards containing the clinic phone number and informational handouts were provided to patients, some of which were created by the nursing team and pharmacists. Patients were encouraged to always keep the wallet cards with them, both physically and as a digital copy, to show this to any clinicians.

Patients were advised to call the clinic's nursing triage phone line, their physician, or APP if they experienced CRS symptoms or other AEs listed on the wallet card at any time. They were directed to go immediately to the emergency room if certain scenarios developed, including but not limited to: a fever over 100.4°F that does not respond to dexamethasone (if prescribed by their provider) or acetaminophen treatment; or a fever accompanied by low blood pressure, fast or irregular heartbeat, dizziness or lightheadedness, shortness of breath, painful headache, new-onset confusion, or chest pains.

Patients had repeated education by multiple staff members to reiterate these unique symptoms requiring clinical attention and were encouraged to repeat back instructions confirming their understanding. Patients who were most knowledgeable, with sufficient education around the signs and symptoms of CRS, were more likely to contact the nursing team when experiencing symptoms. Challenges securing enough time to provide education were managed by careful scheduling of patient visits to ensure APPs had sufficient time.

Lastly, patients experiencing anxiety around their treatment were informed about the availability of social care and supportive services, and resources such as social workers, anxiety support groups, patient advocacy organizations, support networks, and psychiatric specialists to help ease their anxiety and provide comprehensive care.

CRS and Other AEs of Interest

Cytokine release syndrome was the most common AE reported during the phase II study (N = 40; 44.4%), occurred primarily during C1 (Appendix A), and was mostly low grade (Matasar et al., 2024). Cytokine release syndrome events were managed with steroids, tocilizumab, fluids, or oxygen (Appendix B); including the two patients with grade 3 and 4 CRS, 23% of patients were admitted to the hospital for monitoring and treatment of CRS.

In addition to CRS, other AEs required additional monitoring and considerations around their management, such as neurologic AEs, tumor flare, TLS, hematologic events, and infections, although not all were commonly observed during the study (Appendix A).

APP Perspectives on Monitoring and Management of CRS

To mitigate CRS-related complications and enhance patient safety, patients were well-hydrated before, during, and after mosunetuzumab infusions; IV hydration (500–1,000 mL saline) was implemented if indicated by renal and electrolyte results. Additionally, some sites extended mosunetuzumab infusion times (e.g., over 6 hours) for patients considered to be at high risk for CRS.

Monitoring for CRS was largely conducted by the nursing team and physicians, with APPs

advising on steps for patient management if CRS was suspected. Some centers implemented protocols for escalation to the attending physician or principal investigator when necessary. In addition, elderly and/or frail patients, and those with high tumor burden or bulky disease, were considered at an increased risk for CRS, requiring closer monitoring. One site admitted high-risk patients for the first step-up dose to ensure they were closely monitored. Clear protocols for managing patients at high risk, along with comprehensive communication between APPs and the nursing team, improved patient safety and care.

Patients were monitored in the clinic for at least 90 minutes following each infusion. Additionally, during the first 2 cycles, they were advised to self-monitor for 3 days post-infusion for symptoms of CRS or any other new symptoms. This included monitoring for fever, rash, skin changes, shortness of breath, changes in mental status, headaches, fatigue, and appetite changes, as well as regularly checking their temperature (e.g., every 6 hours). In one center, the nursing team would call the patient 24 to 48 hours post-infusion of the first full dose and would encourage the patient and family members to proactively contact the clinic if any symptoms of CRS occurred.

Advanced practice providers play key roles in the acute management of CRS events, including the assessment and diagnosis of patients with suspected CRS, implementing interventions as detailed in the study protocol (Table 2) or site guidelines, deciding whether to interrupt mosunetuzumab treatment, and clearing patients to receive their next dose. Some APPs manage grade 1 CRS with minimal intervention (no extra monitoring beyond standard care and antipyretics), while CRS above grade 1 may warrant hospitalization for observation if clinically indicated.

When CRS occurred during the infusion, treatment was stopped, the APP independently evaluated the CRS event, implemented initial management strategies per study protocol, and engaged in collaborative decision-making with the physician to determine the appropriateness of resuming treatment. Upon restarting treatment, premedication was readministered, the infusion rate was reduced by 50%, and hydration was implemented to mitigate the risk of recurrence. Additional monitoring was also implemented, e.g., daily or twice-daily calls to patients for 2 to 3 days post-infusion to inquire about symptoms, request for patients to stay local to the clinic for 24 hours post-infusion in case AEs occurred, or additional outpatient visits. For grade 2 CRS, hospitalization was considered for the next dose; for grade 3 CRS, the patient was hospitalized for the next dose, and mosunetuzumab was discontinued if grade 4 CRS occurred.

APP Perspectives on Monitoring and Management of Other AEs

The role of APPs in monitoring for other AEs of interest mainly involved performing regular laboratory tests and clinical assessments, and interpreting and documenting results (Figure 1).

For neurologic AEs, assessment for immune effector cell–associated neurotoxicity syndrome was implemented, and a baseline neurologic assessment for future comparisons was recommended (Crombie et al., 2024). Neurologic AEs arising during mosunetuzumab treatment were managed similarly to neurologic AEs occurring in patients treated with other T-cell engaging therapies.

Occurrence of tumor flare was monitored via clinical examinations. Symptoms of tumor flare and FL often overlap, making it challenging to differentiate between the two. Risk factors for tumor flare include disease extent and location, and palpable adenopathy. Patients with bulky tumors or disease located near critical anatomical locations (e.g., airways, vital organs) were monitored closely for signs and symptoms of compression or obstruction during initial therapy.

Advanced practice providers serve as the clinical leaders in the assessment and management of TLS, including evaluating patient risk, closely monitoring laboratory results, initiating TLS prophylaxis, and coordinating appropriate hydration strategies. Within their scope of practice, APPs play a central role in ensuring the safe continuation of therapy and determining when treatment interruption is warranted. Decisions regarding TLS prophylaxis were guided by clinical risk factors such as circulating disease burden, presence of bulky disease, elevated lactate dehydrogenase, impaired renal function, and hyperuricemia. High-risk patients, including

those with bulky disease and individuals who are elderly and/or frail, were managed in the inpatient setting when appropriate. Care coordination was led by the APP and involved collaboration with the hematologist, primary care physician, patient, and other members of the oncology care team to support timely intervention and patient safety.

For hematologic AEs, APPs were involved in ordering interventions such as granulocyte colony-stimulating factor along with deciding when treatment interruption was needed. Blood counts were monitored throughout treatment; mosunetuzumab infusion was not typically delayed in the presence of hematologic AEs unless clinically significant symptoms were present. It was considered important that the patient's disease control was balanced against any neutropenia-related risks. Advanced practice providers were responsible for arranging laboratory tests to exclude febrile neutropenia in patients presenting with fever, although no cases of febrile neutropenia occurred in the study.

When managing patients treated with mosunetuzumab, it is crucial to closely monitor for infection-related AEs, including cytopenias and signs of infection, and initiate antimicrobial/antiviral prophylaxis where appropriate. Advanced practice providers played a pivotal role in the monitoring process by ordering diagnostic tests and regularly screening for symptoms indicative of infection. Tests included complete blood counts (CBC) to detect cytopenias as well as performing physical assessments. In the presence of an infection, APPs initiated appropriate interventions, such as prescribing antibiotic therapy and providing supportive care to manage symptoms (e.g., pain, fever, and fatigue) that are commonly associated with infections. Mosunetuzumab treatment was paused until full resolution of the infection, and step-up dosing was repeated if required when mosunetuzumab was restarted per the study protocol. Prophylaxis against *Pneumocystis jirovecii* pneumonia and varicella-zoster virus was initiated, and standard vaccines against influenza and COVID-19 were recommended. Immunoglobulin levels were regularly monitored, and replacement immunoglobulin was considered for patients with frequent infections per institutional guidelines.

DISCUSSION

Although the roles of APPs varied, all participants described playing a central role in the monitoring and management of AEs associated with mosunetuzumab treatment and identified themselves as vital members of the multidisciplinary oncology care team. Advanced practice provider involvement in the care of patients receiving bispecific antibodies supported comprehensive assessment and management of AEs, facilitated by patient education regarding which symptoms to report and when to report them as they emerged. This proactive engagement between APPs and patients enabled timely clinical evaluation and appropriate intervention, contributing to the delivery of safe and high-quality patient care.

The perspectives and experiences of APPs outlined here align closely with consensus recommendations published on the management of toxicities associated with CD20xCD3 bispecific antibody therapies (Crombie et al., 2024). Recommendations include close monitoring of patients who may be considered at high risk for CRS, ensuring patients are provided with education and resources on AEs, and ensuring patients are aware of who to contact if symptoms arise, as noted by the APPs surveyed here.

The learnings and experiences of APPs involved in the GO29781 study will help to inform future clinical practice and care coordination for treatment with bispecific antibodies and management of patients with associated AEs. Advanced practice provider experiences support that mosunetuzumab is suitable for administration in the outpatient setting by a knowledgeable, multidisciplinary team of care providers.

One limitation of this report is that the perspectives reported here are taken from a small number of APPs from US academic centers and therefore may not be representative of the wider APP experience. In addition, these recommendations are applicable only to IV mosunetuzumab treatment, and not bispecific antibodies more widely.

In conclusion, fixed treatment duration mosunetuzumab IV monotherapy has a manageable safety profile in patients with R/R FL, supporting administration as an outpatient regimen. Advanced practice providers play a key role in the education, monitoring, and management of AEs associated

with mosunetuzumab treatment. Their involvement as part of a multidisciplinary team is vital to ensure the safety and comfort of patients receiving mosunetuzumab in the outpatient setting.

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Disclosure

Maria Guerrero has no conflicts of interest to report. Barbara Averill reports travel and reimbursement for expenses to attend meetings from Roche/Genentech and Ipsen/Epizyme. Lauren Clermont reports receipt of honoraria to attend The NCCN 2023 Annual Congress: Hematologic Malignancies, 2023 JADPRO Insight Forum: Best Practice Summit, Management of Cutaneous T-Cell Lymphoma (2024), NCCN Tumor Boards: T-cell Engager Therapy in DLBCL (2025), and 2024 JADPRO Insight Forum: Best Practice Summit. Stacy Pak reports receipt of honoraria to attend NCCN Tumor Board Webinar and Association of Cancer Care Centres. Justina Kiernan has no conflicts of interest to report. Mei Wu, Dominic Lai, Iris To, and Rona Farighi are employees of Genentech and hold equity/stock in Roche/Genentech. Mandy Piela has no conflicts of interest to report.

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Appendix A. Summary of AEs of Interest in Patients With R/R FL in the GO29781 Study

N (%)	R/R FL (*N* = 90)
CRS	40 (44.4)
Grade 1	23 (25.6)
Grade 2	15 (16.7)
Grade 3	1 (1.1)
Grade 4	1 (1.1)
SAE	21 (23.3)
AE leading to mosunetuzumab discontinuation	2 (2.2)
AE leading to mosunetuzumab dose modification or interruption	7 (7.8)
Recurrent CRS events	19 (21.0)
Neurologic AEs[a]	49 (54.4)
Most common	
Headache	28 (31.1)
Insomnia	11 (12.2)
Peripheral neuropathy	10 (11.1)
Dizziness	9 (10.0)
Grade ≥ 3	2 (2.2)
Tumor flare[b]	3 (3.3)
Grade ≥ 3	2 (2.2)
SAEs	2 (2.2)
Tumor lysis syndrome[c]	1 (1.1)
Grade ≥ 3[d]	1 (1.1)
Hematologic events	
Neutropenia[e]	26 (28.9)
Grade ≥ 3	24 (26.7)
SAE	1 (1.1)
Anemia[f]	12 (13.3)
Grade ≥ 3	7 (7.7)
Thrombocytopenia[g]	9 (10.0)
Grade ≥ 3	4 (4.4)

Note. Adapted from Matasar et al. (2024). Clinical cutoff date: August 27, 2021. AE = adverse event; CRS = cytokine release syndrome; FL = follicular lymphoma; ICANS = immune effector cell-associated neurotoxicity syndrome; R/R = relapsed or refractory; SAE = serious adverse event; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; TLS = tumor lysis syndrome.

[a]One grade 2 neurologic AE potentially consistent with ICANS was reported in 1 patient (1.1%) who had confusion concurrently with grade 3 CRS following Cycle 2 Day 1 mosunetuzumab administration.

[b]Grade 2 pleural effusion (*N* = 1) and grade 3 tumor flare (*N* = 2). No patients had their treatment interrupted due to tumor flare, and all events resolved.

[c]Fifty-one patients (56.7%) received prophylaxis with allopurinol for TLS at study entry, and a further 27 patients (30.0%) initiated treatment during the study. Five patients (5.6%) initiated rasburicase prophylaxis during the study.

[d]One patient experienced a grade 4 TLS event with concurrent CRS on Day 24 of the study. The patient received prophylaxis with allopurinol, and the event resolved.

[e]No neutropenia events led to mosunetuzumab discontinuation. No events of febrile neutropenia were reported

[f]Anemia led to mosunetuzumab treatment interruption in 1 patient (1.1%) and 3 patients (3.3%) received a red blood cell transfusion.

[g]Thrombocytopenia led to mosunetuzumab treatment interruption in 2 patients (2.2%), and 3 patients (3.3%) received a platelet transfusion.

[h]Mosunetuzumab treatment was interrupted due to infection in 11 patients (12.2%) and 1 patient (1.1%) had treatment discontinued due to Epstein–Barr viremia. At the data cut-off, there were 13 patients with at least one unresolved infection.

[i]All SARS-CoV-2 infections resolved. One patient received treatment with convalescent plasma.

Appendix A. Summary of AEs of Interest in Patients With R/R FL in the GO29781 Study (cont.)

N (%)	R/R FL (*N* = 90)
Infections[h]	46 (51.1)
Most common	
Urinary tract infections	9 (10.0)
Upper respiratory tract infections	8 (8.9)
Pneumonia	5 (5.6)
SARS-CoV-2 infection[i]	4 (4.4)
Grade ≥ 3	15 (16.7)
SAE	18 (20.0)

Note. Adapted from Matasar et al. (2024). Clinical cutoff date: August 27, 2021. AE = adverse event; CRS = cytokine release syndrome; FL = follicular lymphoma; ICANS = immune effector cell-associated neurotoxicity syndrome; R/R = relapsed or refractory; SAE = serious adverse event; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; TLS = tumor lysis syndrome.
[a]One grade 2 neurologic AE potentially consistent with ICANS was reported in 1 patient (1.1%) who had confusion concurrently with grade 3 CRS following Cycle 2 Day 1 mosunetuzumab administration.
[b]Grade 2 pleural effusion (*N* = 1) and grade 3 tumor flare (*N* = 2). No patients had their treatment interrupted due to tumor flare, and all events resolved.
[c]Fifty-one patients (56.7%) received prophylaxis with allopurinol for TLS at study entry, and a further 27 patients (30.0%) initiated treatment during the study. Five patients (5.6%) initiated rasburicase prophylaxis during the study.
[d]One patient experienced a grade 4 TLS event with concurrent CRS on Day 24 of the study. The patient received prophylaxis with allopurinol, and the event resolved.
[e]No neutropenia events led to mosunetuzumab discontinuation. No events of febrile neutropenia were reported
[f]Anemia led to mosunetuzumab treatment interruption in 1 patient (1.1%) and 3 patients (3.3%) received a red blood cell transfusion.
[g]Thrombocytopenia led to mosunetuzumab treatment interruption in 2 patients (2.2%), and 3 patients (3.3%) received a platelet transfusion.
[h]Mosunetuzumab treatment was interrupted due to infection in 11 patients (12.2%) and 1 patient (1.1%) had treatment discontinued due to Epstein–Barr viremia. At the data cut-off, there were 13 patients with at least one unresolved infection.
[i]All SARS-CoV-2 infections resolved. One patient received treatment with convalescent plasma.

Appendix B. Management of CRS Events in Study GO29781

N (%)	*N* = 90
Steroids	10 (11.1)
Tocilizumab	7 (7.8)
Steroids + tocilizumab	4 (4.4)
Pressors (single or multiple)	2 (2.2)[a]
Low flow oxygen	8 (8.9)
High flow oxygen	1 (1.1)
ICU admission	5 (5.6)

Note. Adapted from Matasar et al. (2024). Clinical cutoff date: August 27, 2021. CRS = cytokine release syndrome; ICU = intensive care unit.
[a]One patient received treatment with a single pressor (1.1%) and 1 patient received treatment with multiple pressors (1.1%).