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Prophylactic Corticosteroid Use with Axicabtagene Ciloleucel in Patients with Relapsed/Refractory Large B-Cell Lymphoma: One-Year Follow-Up of ZUMA-1 Cohort 6

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BACKGROUND

- ZUMA-1 is the registrational Phase 1/2 study of axicabtagene ciloleucel (axi-cel), an autologous anti-CD19 chimeric antigen receptor (CAR) T-cell therapy, in patients with refractory large B-cell lymphoma (LBCL)[1,2]
- In ZUMA-1 pivotal Cohorts 1+2
  - 83% objective response rate (ORR); 58% complete response (CR) rate[2]
  - With 63.1 months median follow-up: 25.8 months median overall survival (OS); 43% 5-year OS rate[3]
  - 13% Grade ≥3 cytokine release syndrome (CRS); 28% Grade ≥3 neurologic events (NEs)[1]
- Management of CRS and NEs has been under evaluation to optimize safety outcomes
  - In safety management Cohort 4, earlier corticosteroid and/or tocilizumab use appeared to reduce Grade ≥3 CRS and NE rates, without affecting CAR T-cell expansion or ongoing response rates[4]
  - Cohort 6 evaluated the addition of prophylactic corticosteroids to the Cohort 4 toxicity management regimen in further reducing the incidence and severity of CRS and NEs[5]
- At a median follow-up of 8.9 months in Cohort 6 (n=40), no Grade ≥3 CRS was observed, a low rate of Grade ≥3 NEs (13%) was present, and response rates were high (95% ORR, 80% CR rate)[5]

OBJECTIVE

- To present a 1-year updated analysis of Cohort 6 supported by a propensity score–based comparison of outcomes in Cohort 6 and Cohorts 1+2 to enable an accurate comparison of patients with highly similar characteristics across cohorts

METHODS

Figure 1. ZUMA-1 Study Design

Original AE Management		Revised AE Management
Phase 2 (n=101)		Phase 2 (n=40)
Cohort 1 Refractory DLBCL (n=77)	Cohort 2 Refractory PMBCL/TFL (n=24)	Cohort 6 R/R LBCL[a] (n=40)

Key eligibility criteria
- Cohorts 1+2: No response to last chemotherapy or relapse ≤12 months post-ASCT
- Cohort 6: R/R LBCL after ≥2 lines of therapy

Optional bridging therapy allowed in Cohort 6 only
- Dexamethasone,[b] high-dose methylprednisolone + rituximab,[c] or bendamustine + rituximab[d]

Conditioning regimen (all cohorts)
- Cyclophosphamide 500 mg/m^2 + fludarabine 30 mg/m^2 for 3 days

Axi-cel (all cohorts)
- 2×10^6 CAR+ T cells/kg[e]

Cohort 6 primary endpoint
- Incidence and severity of CRS and NEs

[a] Includes adult patients with DLBCL, PMBCL, TFL, and high-grade B-cell lymphoma after ≥2 systemic lines of therapy. [b] 20 to 40 mg/d or equivalent daily for 1 to 4 days, completed before conditioning chemotherapy. [c] Methylprednisolone 1 g/m^2 daily for 3 days + rituximab (375 mg/m^2 weekly), completed at least 7 days before conditioning chemotherapy. [d] Bendamustine 90 mg/m^2 daily for 2 days + rituximab (375 mg/m^2 for 1 day), completed at least 14 days before conditioning chemotherapy. [e] Flat dose of 2×10^8 CAR+ T cells/kg for patients with body weight >100 kg.
AE, adverse event; ASCT, autologous stem cell transplantation; axi-cel, axicabtagene ciloleucel; CAR, chimeric antigen receptor; CRS, cytokine release syndrome; DLBCL, diffuse large B-cell lymphoma; LBCL, large B-cell lymphoma; NE, neurologic event; PMBCL, primary mediastinal B-cell lymphoma; R/R, relapsed/refractory; TFL, transformed follicular lymphoma.

Figure 2. AE Management in ZUMA-1

		AE Grade 1	AE Grade 2	AE Grade 3	AE Grade 4
Cohorts 1+2 AE Mgmt	CRS	Tocilizumab: No Corticosteroid: No	Tocilizumab: Yes[a] Corticosteroid: Yes[a]	Tocilizumab: Yes Corticosteroid: Yes	Tocilizumab: Yes Corticosteroid: Yes
	NE	Tocilizumab: No Corticosteroid: No	Tocilizumab: Yes Corticosteroid: No	Tocilizumab: Yes Corticosteroid: Yes[b]	Tocilizumab: Yes Corticosteroid: Yes
Cohort 6 AE Mgmt	CRS	Tocilizumab: Yes[c] Corticosteroid: Yes[d]	Tocilizumab: Yes Corticosteroid: Yes	Tocilizumab: Yes Corticosteroid: Yes	Tocilizumab: Yes Corticosteroid: Yes, HD
	NE	Tocilizumab: No Corticosteroid: Yes	Tocilizumab: Yes[e] Corticosteroid: Yes	Tocilizumab: Yes[e] Corticosteroid: Yes, HD	Tocilizumab: Yes[e] Corticosteroid: Yes, HD

[a] Only in case of comorbidities or older age. [b] Only if no improvement with tocilizumab; use standard dose. [c] If no improvement after 24 hours of supportive care in Cohort 6. [d] If no improvement after 3 days. [e] Only for Grade ≥2 NEs with concurrent CRS in Cohort 6.
AE, adverse event; CRS, cytokine release syndrome; HD, high dose; Mgmt, management; NE, neurologic event.

- Patients in Cohort 6 received once-daily oral dexamethasone 10 mg on days 0 (before axi-cel infusion), 1, and 2
- Corticosteroids and tocilizumab were started earlier in Cohort 6 than in Cohorts 1+2 for toxicity management[1,5]

Table 1. Tocilizumab and Corticosteroid Guidelines for AE Management in Cohort 6

CRS Grade	Tocilizumab Dose[a]	Corticosteroid Dose[a]
1	If no improvement after 24 hours of supportive care, 8 mg/kg over 1 hour[b]; repeat every 4-6 hours as needed	If no improvement after 3 days, dexamethasone 10 mg ×1
2	8 mg/kg over 1 hour[b]; repeat every 4-6 hours as needed	Dexamethasone 10 mg ×1
3	Per Grade 2	Methylprednisolone 1 mg/kg IV twice daily or equivalent dexamethasone dose
4	Per Grade 2	Methylprednisolone 1000 mg/d IV for 3 days
NE Grade	**Tocilizumab Dose**	**Corticosteroid Dose**
1	N/A	Dexamethasone 10 mg ×1
2	Only in the case of concurrent CRS; 8 mg/kg over 1 hour; repeat every 4-6 hours as needed	Dexamethasone 10 mg 4 times/day
3	Per Grade 2	Methylprednisolone 1 g once daily
4	Per Grade 2	Methylprednisolone 1 g twice daily

[a] Therapy to be tapered on improvement of symptoms at investigator's discretion. [b] Not to exceed 800 mg.
AE, adverse event; CRS, cytokine release syndrome; IV, intravenous; N/A, not applicable; NE, neurologic event.

METHODS *(continued)*

Figure 3. Analyses and Follow-Up Time

1-Year Analysis	Data Cutoff Dates • Cohorts 1+2[1]: Aug 11, 2017 • Cohort 6: Dec 16, 2020	Median Follow-Up Times • Cohorts 1+2[1]: 15.4 months • Cohort 6: 14.9 months

Exploratory Propensity Score Analysis
- Propensity score–matched comparisons[6] were performed to compare clinical safety, efficacy, and PK profiles of patients in Cohort 6 and Cohorts 1+2 after balancing for known baseline disease characteristics
  - Tumor burden
  - IPI score
  - No. of prior lines of chemotherapy
  - Disease stage
  - LDH level
- Propensity score matching was used to select matching patient subgroups from Cohorts 1+2 and Cohort 6

IPI, International Prognostic Index; LDH, lactate dehydrogenase; PK, pharmacokinetic.

RESULTS

Cohort 6: 1-Year Analysis

- As of December 16, 2020, 40 patients with relapsed/refractory LBCL were treated with axi-cel and all 40 were eligible for efficacy and safety analyses
- The median patient age was 64.5 years (range, 37–85 years; ≥65 years, 50%); 55% of patients had Eastern Cooperative Oncology Group performance status score of 1, 65% had stage III or IV disease, and 38% had received ≥3 prior therapies

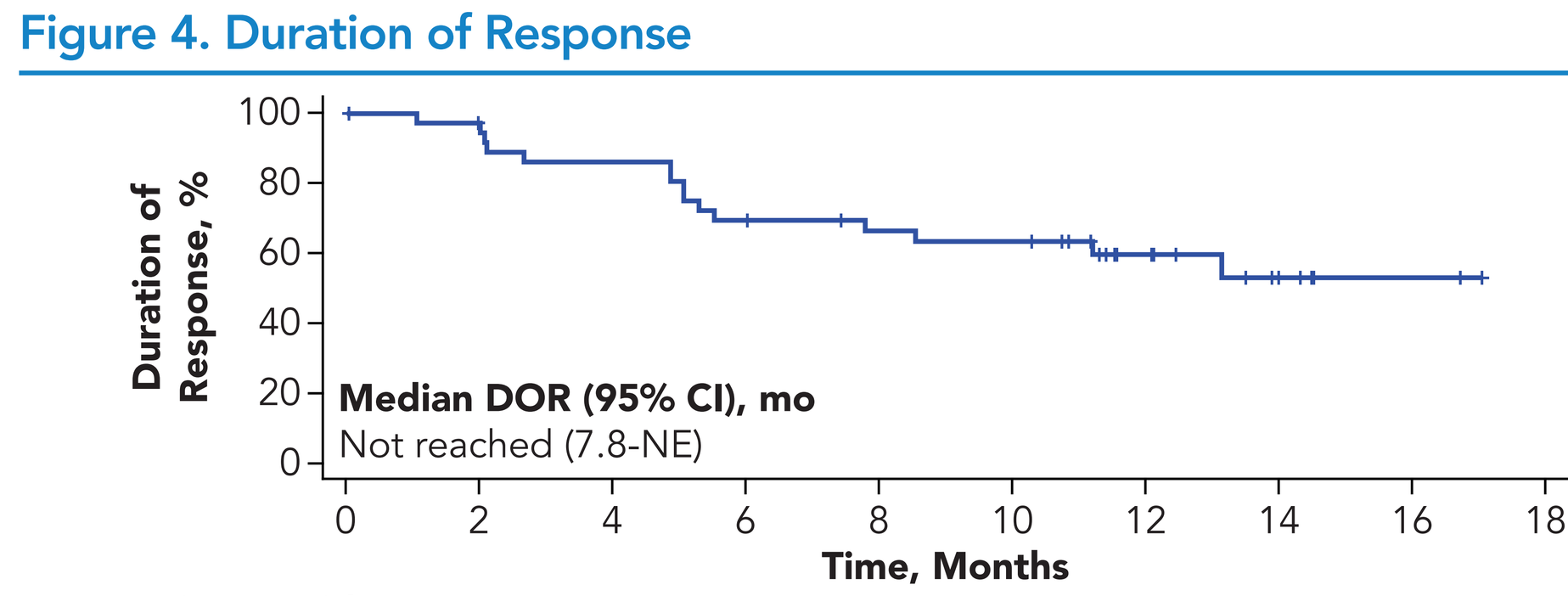
Table 2. Primary Endpoint: Incidence and Severity of CRS and Neurologic Events

	Cohort 6 (N=40)
CRS, n (%)	**32 (80)**
Worst Grade 1	14 (35)
Worst Grade 2	18 (45)
Worst Grade ≥3	0 (0)
Median time to onset (range), days	5 (1–15)
Median duration (range), days	4 (1–11)
Neurologic event, n (%)	**23 (58)**
Worst Grade 1	10 (25)
Worst Grade 2	7 (18)
Worst Grade ≥3	6 (15)
Median time to onset (range), days	6 (2–162)
Median duration (range), days	19 (1–438[a])

[a]Duration is defined as the end date of the last neurologic event minus the onset date of the first neurologic event +1. The maximum value is due to a late onset neurologic event that occurred on Day 441 and resolved on Day 442; if not for this late event, the maximum duration would be 79 days as the patient's second to last neurologic event ended on Day 83 (lasted 3 days).
Severity of CRS and neurologic events were graded per Lee et al criteria[7] and Common Terminology Criteria for Adverse Events version 4.03, respectively.
CRS, cytokine release syndrome.

- No Grade ≥3 CRS occurred in Cohort 6
- Grade ≥3 NEs were reported in 15% of patients
- Since the previous analysis[5]
  - No new cases of CRS
  - Four new axi-cel–related NEs in 2 patients
    - Patient 1: Grade 2 mental status changes and seizure-like phenomena both on Day 441 (duration, 2 days and 1 day, respectively)
    - Patient 2: Grade 1 dementia (occurred on Day 93 but was reported late; duration, 277 days) and Grade 5 toxic encephalopathy on Day 369 (resultant from a Grade 4 event that started on Day 351)
      - Investigator believed that a mild case of dementia may have predated the study
      - Workup was limited on the Grade 5 adverse event (AE) due to family refusal for diagnostic testing and autopsy; however, magnetic resonance imaging showed leukoencephalopathy but was not confirmed with lumbar puncture. The investigator suspected that the outcome may have resulted from an opportunistic infection due to prolonged immunosuppression
  - Two new infections of Grade 2 pneumonia on Day 474 (resolved on Day 479; unrelated to axi-cel) and Grade 1 bronchitis on Day 459 (resolved on Day 459; related to axi-cel)
  - One death due to progressive disease

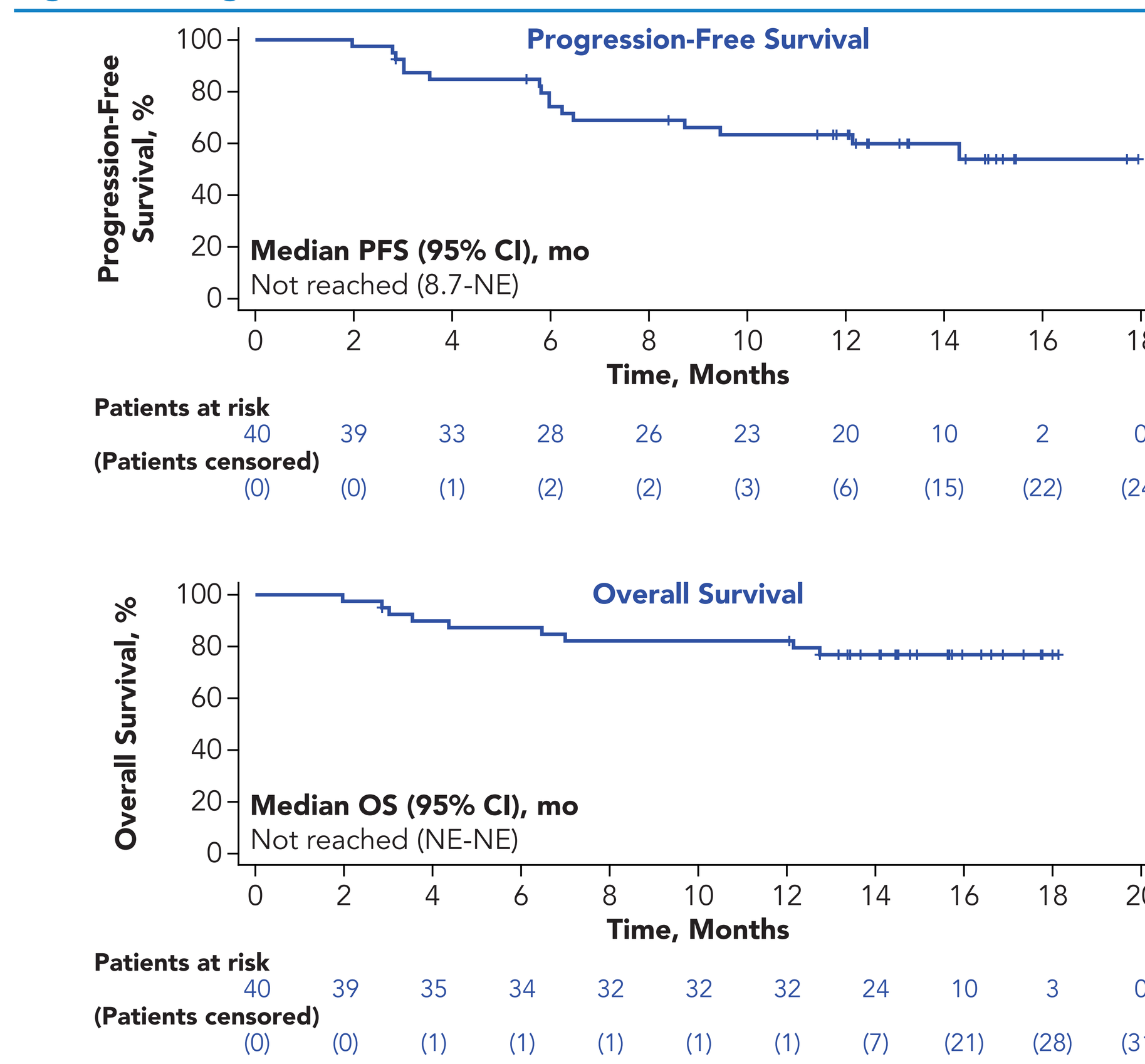
Figure 4. Duration of Response



DOR, duration of response; NE, not estimable.

RESULTS *(continued)*

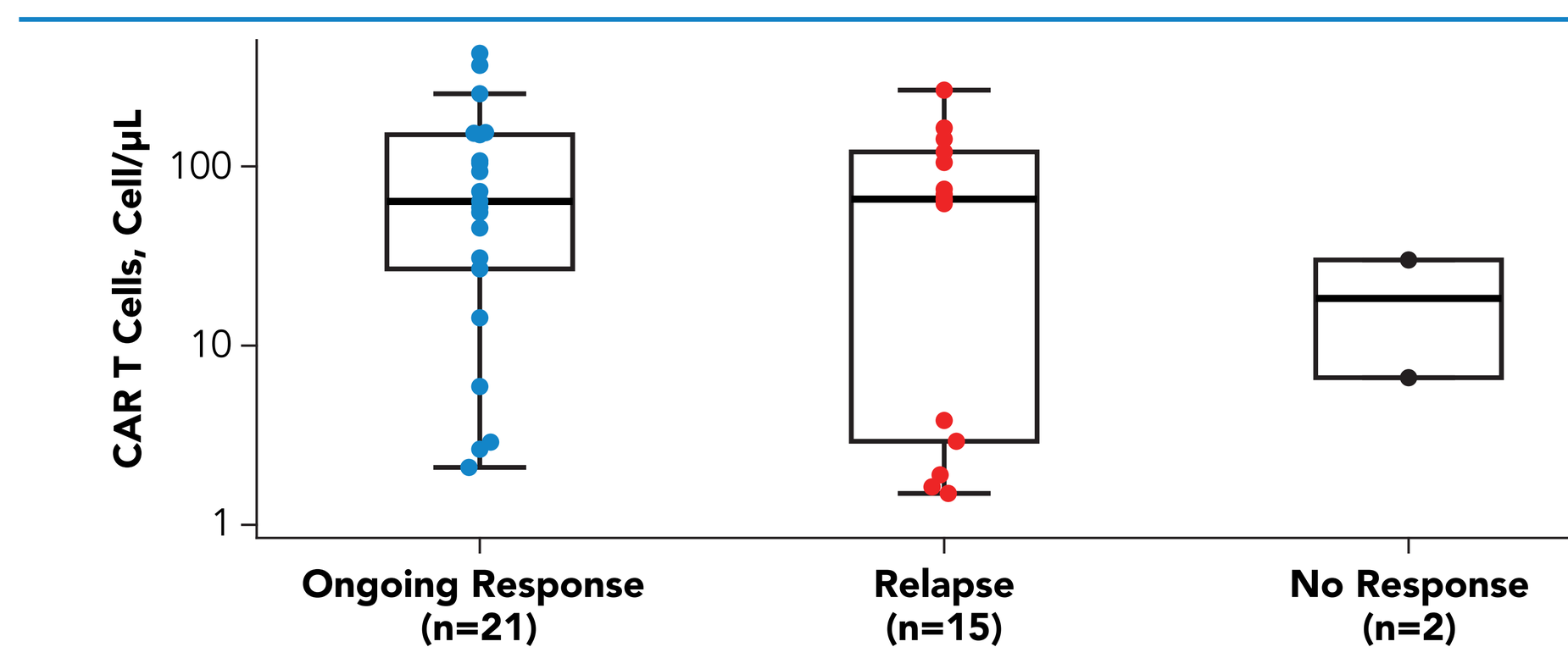
Figure 5. Progression-Free Survival and Overall Survival



NE, not estimable; OS, overall survival; PFS, progression-free survival.

- Median duration of response (DOR), progression-free survival (PFS), and OS were not reached
- KM estimates of the 12-mo DOR, PFS, and OS rates were 60%, 63%, and 82%, respectively
- The investigator-assessed ORR remained 95% (80% CR rate) with a median follow-up of 14.9 months
  - At data cutoff, 21 patients (53%) were in ongoing response

Figure 6. Associations Between Peak CAR T-Cell Levels and Response at 12 Months



CAR T cells were quantified using quantitative polymerase chain reaction.
CAR, chimeric antigen receptor.

- Median peak CAR T-cell levels were comparably high in patients with ongoing response and relapse (64 cells/μL [n=21] and 66 cells/μL [n=15], respectively) at 12 months and considerably lower in nonresponders (18 cells/μL [n=2])
  - A similar trend was observed with CAR T-cell expansion by area under the curve from Day 0 to 28

Propensity Score Matching Analysis

- In total, 32 matched patients each in Cohort 6 and Cohorts 1+2 were identified in propensity score matching analysis
  - Eight patients from Cohort 6 were not included due to nonavailability of matched patients in Cohorts 1+2
- Baseline characteristics (as noted in **Figure 3**) were comparable between the 32 matched patients[5]

Table 3. Propensity Score Comparison of CAR T-Cell and Cytokine Levels

Median (Q1, Q3)	Cohorts 1+2 Overall (N=101)	Cohort 6 Overall (N=40)	Cohorts 1+2 After Matching (n=32)	Cohort 6 After Matching (n=32[a])
Peak CAR T-cell levels				
CAR T-cell expansion, cells/μL	38 (15, 83)	64 (6, 131)	43 (14, 107)	65 (18, 146)
Peak cytokine levels				
IFN-γ, pg/mL	477 (196, 1097)	208 (87, 446)	481 (120, 1096)	227 (103, 424)
IL-2, pg/mL	22 (10, 38)	8 (3, 23)	23 (10, 58)	8 (3, 16)
GM-CSF, pg/mL	7 (2, 16)	2 (2, 5)	9 (2, 21)	2 (2, 4)
Ferritin, ng/mL	3001 (1326, 6683)	904 (489, 1529)	2312 (1225, 4777)	809 (489, 1529)
CRP, mg/L	214 (141, 353)	76 (39, 136)	175 (124, 345)	78 (44, 131)

[a] Eight patients were excluded due to nonavailability of matched patients in the pivotal cohorts.
CAR, chimeric antigen receptor; CRP, C-reactive protein; GM-CSF, granulocyte-macrophage colony-stimulating factor; IFN, interferon, IL, interleukin; Q, quartile.

Table 4. Propensity Score Comparison of Outcomes

	Cohorts 1+2 Overall (N=101)	Cohort 6 Overall (N=40)	Cohorts 1+2 After Matching (n=32)	Cohort 6 After Matching (n=32[a])
Efficacy				
Objective response, n (%)	**84 (83)**	**38 (95)**	**30 (94)**	**30 (94)**
Complete response, n (%)	59 (58)	32 (80)	25 (78)	24 (75)
Ongoing response at data cutoff date,[b] n (%)	**42 (42)**	**21 (53)**	**19 (59)**	**15 (47)**
Median duration of response (95% CI), mo	11.1 (3.9, NE)	NR (7.8, NE)	NR (8.1, NE)	13.1 (5.5, NE)
KM 12-month (95% CI), %	49 (37, 59)	60 (41, 74)	65 (45, 80)	56 (36, 72)
Median progression-free survival (95% CI), mo	5.9 (3.3, NE)	NR (8.7, NE)	NR (5.6, NE)	14.3 (6.5, NE)
KM 12-month (95% CI), %	44 (34, 54)	63 (46, 77)	61 (42, 76)	61 (41, 76)
Median overall survival (95% CI), mo	NR (12.8, NE)	NR (NE, NE)	NR (15.4, NE)	NR (NE, NE)
KM 12-month (95% CI), %	60 (50, 69)	82 (66, 91)	81 (63, 91)	78 (59, 89)
Safety				
CRS				
Worst Grade ≥2, n (%)	57 (56)	18 (45)	19 (59)	15 (47)
Worst Grade ≥3, n (%)	**12 (12)**	**0**	**4 (13)**	**0**
Median time to onset of any grade CRS (Q1, Q3), days	**2 (2, 3)**	**5 (4, 6)**	**2 (2, 4)**	**5 (4, 6)**
Neurologic events				
Worst Grade ≥2, n (%)	43 (43)	13 (33)	12 (38)	13 (41)
Worst Grade ≥3, n (%)	**29 (29)**	**6 (15)**	**7 (22)**	**6 (19)**
Median time to onset of any grade neurologic event (Q1, Q3), days	5 (3, 7)	6 (5, 9)	6 (3, 7)	6 (5, 8)
Median time to onset of Grade ≥3 neurologic event (Q1, Q3), days	**7 (5, 7)**	**12 (6, 30)**	**7 (6, 11)**	**12 (6, 30)**
Infections				
Worst any grade, n (%)	37 (37)	20 (50)	12 (38)	15 (47)
Worst Grade ≥3, n (%)	23 (23)	8 (20)	6 (19)	8 (25)[c]
Cumulative cortisone-equivalent corticosteroid dose (including prophylaxis), n	25	40	6	32
Median (Q1, Q3), mg	**6390 (2817, 15,760)**	**1252 (939, 6291)**	**7418 (2504, 11,579)**	**1252 (939, 6604)**
Cumulative tocilizumab use, n	43	23	11	19
Peak median (Q1, Q3), mg	1300 (800, 1800)	1000 (700, 1760)	1339 (772, 3310)	1000 (600, 1680)

[a] Eight patients were excluded due to nonavailability of matched patients in the pivotal cohorts. [b] Represents the number of patients in response at the data cutoff date among all treated patients. [c] Worst Grade 4 or 5 infections occurred in 3 patients (patient 1: Grade 4 sepsis [unrelated to treatment]; patient 2: Grade 4 human herpesvirus 6 encephalitis [related to conditioning chemotherapy] and Grade 5 urosepsis [unrelated to treatment]; and patient 3: Grade 4 *Aspergillus* infection and respiratory tract infection [related to conditioning chemotherapy and axi-cel]).
CRS, cytokine release syndrome; KM, Kaplan-Meier; NE, not estimable; NR, not reached; Q, quartile.

Propensity Score Matching Analysis Summary

- Incidence of Grade ≥3 CRS was lower in Cohort 6 (0%) compared with Cohort 1+2 before and after propensity score–based matching
- Median time to onset of any-grade CRS was delayed in Cohort 6 (5 days) versus Cohorts 1+2 (2 days) before and after matching
- Median time to onset of Grade ≥3 NEs appeared to be delayed in Cohort 6 versus Cohorts 1+2 before and after matching (12 days versus 7 days, respectively)
- Clinical efficacy remained comparable between patients in Cohort 6 and Cohorts 1+2 before and after propensity score–based matching
- Median cumulative corticosteroid dose including prophylaxis was ≈6-fold lower in Cohort 6 versus Cohorts 1+2 (1252 mg versus 7418 mg, respectively) after matching
- Although more patients in Cohort 6 versus Cohorts 1+2 required tocilizumab after matching, median peak cumulative tocilizumab dose was lower in Cohort 6 versus Cohorts 1+2 (1000 mg versus 1339 mg, respectively)
- Peak CAR T-cell levels were comparable and peak inflammatory biomarkers associated with CAR T-cell treatment-related AEs, including interferon-γ, interleukin-2, GM-CSF, and ferritin, were lower in Cohort 6 versus Cohorts 1+2 before and after propensity score matching, supporting clinical outcomes

CONCLUSIONS

- With ≥1-year follow-up for ZUMA-1 Cohort 6, prophylactic and earlier corticosteroid and/or tocilizumab intervention for toxicity management continued to demonstrate potential to improve the benefit/risk profile of axi-cel with no negative impact on pharmacokinetics and/or efficacy outcomes
- Although limited by retrospective and cross-cohort comparisons, findings were corroborated by propensity score–based matching analysis versus pivotal Cohorts 1+2
- Overall, these findings suggest that the Cohort 6 toxicity management strategy can improve long-term safety of axi-cel in relapsed/refractory LBCL without compromising its efficacy parameters, including the durability of responses

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