Poster
P1191

Updated Trends in Real-World Outpatient Administration of Axicabtagene Ciloleucel and Brexucabtagene Autoleucel in Relapsed/Refractory Non-Hodgkin Lymphoma

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BACKGROUND

- Chimeric antigen receptor (CAR) T-cell therapies, including axicabtagene ciloleucel (axi-cel) and brexucabtagene autoleucel (brexu-cel), have changed the treatment landscape for relapsed or refractory (R/R) non-Hodgkin lymphoma (NHL)[1]
- Historically, CAR T-cell therapy was administered inpatient due to the risk of serious adverse events (AEs), including cytokine release syndrome (CRS) and immune effector cell–associated neurotoxicity syndrome (ICANS)[2]
- Improvements in AE management of axi-cel[3,4] and brexu-cel[5] since their approvals support the potential for outpatient administration
- Outpatient administration of CAR-T therapy can help improve health system capacity, resource utilization, and treatment access[2,6]
- Early evidence indicates that CAR T-cell therapies can be administered outpatient at authorized treatment centers with suitable infrastructure and clinical workflow with a comparable safety profile to inpatient infusion[6,7]
  - A systematic literature review of 8 studies from 7 centers showed that outpatient CAR T-cell therapy is feasible and safe, with an AE profile comparable with ZUMA-1; overall hospitalization rate was reported to be 50-92%, with 23-85% of patients requiring early hospital admission (admitted within 3 days of infusion)[6]
  - Data from the hospital-based outpatient program at Mayo Clinic, Rochester, showed an overall hospitalization rate of 73% for patients with NHL and multiple myeloma, with 31% of patients requiring early hospital admission[7]
- Further evidence is needed for outpatient delivery of axi-cel and brexu-cel to understand the safety profile and optimize treatment and toxicity management strategies for patients with NHL in the outpatient setting

OBJECTIVE

- To assess updated trends in safety and hospitalization after axi-cel or brexu-cel at Mayo Clinic, Rochester, and associations with baseline patient and disease characteristics, with exploratory analyses of real-world outpatient effectiveness

METHODS

Figure 1. Study Design

Data Source

- Patients with R/R NHL who received axi-cel or brexu-cel between January 2018–December 2022 at Mayo Clinic, Rochester, with follow-up to November 2023

Outcomes of Interest

- Safety outcomes (CRS and ICANS)
- Hospital resource utilization
- Association of outcomes with baseline patient and disease characteristics
- Effectiveness outcomes (DOR, PFS, and OS), safety outcomes, and hospital resource utilization in patients with LBCL who received outpatient axi-cel

Statistical Analysis

- Safety outcomes and hospital utilization were analyzed descriptively by toxicity management strategy (early or late) and by treatment setting (inpatient or outpatient)
- Associations of baseline patient and disease characteristics were estimated with multivariable logistic regressions[a]
- Subanalyses of patients with LBCL who received outpatient axi-cel assessed safety, hospitalization, and effectiveness by EMP vs LMP
  - DOR, PFS, OS, and cumulative incidence of initial CRS and ICANS resolution were described by Kaplan-Meier estimate

[a] Model for Grade 3+ CRS/ICANS adjusted for age, prior lines, and elevated LDH at Day 0. Model for hospitalization in 3 days adjusted for age, prior lines, bridging therapy, elevated LDH and CRP at Day 0, and management period.
AE, adverse event; axi-cel, axicabtagene ciloleucel; brexu-cel, brexucabtagene autoleucel; CRP, C-reactive protein; CRS, cytokine release syndrome; DOR, duration of response; ICANS, immune effector cell–associated neurotoxicity syndrome; LBCL, large B-cell lymphoma; LDH, lactate dehydrogenase; NHL, non-Hodgkin lymphoma; OS, overall survival; PFS, progression-free survival; R/R, relapsed or refractory.

Figure 2. Early Management Period Versus Late Management Period

	Early Management Period (EMP)	Late Management Period (LMP)
Definition	Earlier intervention to treat AEs • Per ZUMA-1 Cohort 4: Earlier corticosteroid and tocilizumab intervention, and use of levetiracetam prophylaxis[4] • Per ZUMA-1 Cohort 6: Additional prophylactic corticosteroid[3]	Later intervention to treat AEs • No comprehensive EMP strategy
Treatment Timeframe	Applies to patients treated November 2021–December 2022	Applies to patients treated January 2018–October 2021

AE, adverse event.

RESULTS

ALL PATIENTS

- Among 155 patients, 32% were aged ≥65 years, and 14% were aged ≥70 years (**Table 1**)
  - 139 patients (90%) were infused outpatient, of which 131 patients (94%) received axi-cel and 8 (6%) received brexu-cel

Table 1. Baseline Patient Characteristics in All Patients

	EMP		LMP			
	Inpatient (n=4)	Outpatient (n=34)	Inpatient (n=12)	Outpatient (n=105)	*P*[a]	All Patients (N=155)
Age, years, median (IQR)	55.5 (39-71.5)	61 (58-68)	57.5 (38-63.5)	60 (52-66)	.152	60 (51-66)
Male sex, n (%)	3 (75)	22 (65)	5 (42)	69 (66)	.777	99 (64)
Disease subtype, n (%)						
LBCL	4 (100)	25 (74)	10 (83)	91 (87)	.051	130 (84)
FL	0 (0)	5 (15)	0 (0)	7 (7)		12 (8)
MCL	0 (0)	2 (6)	2 (17)	6 (6)		10 (6)
Other	0 (0)	2 (6)	0 (0)	1 (1)		3 (2)
Prior lines of therapy, n (%)						
1	0 (0)	5 (15)	0 (0)	1 (1)	**.007**	6 (4)
2	2 (50)	14 (41)	2 (17)	25 (24)		43 (28)
≥3	2 (50)	15 (44)	10 (83)	79 (75)		106 (68)
Stem cell transplant, n (%)	0 (0)	10 (29)	3 (25)	48 (46)	.058	61 (39)
Bridging therapy, n (%)	4 (100)	22 (65)	9 (75)	66 (63)	.627	101 (65)
Prophylactic corticosteroid (dexamethasone), n (%)	2 (50)	7 (21)	0 (0)	0 (0)	**<.0001**	9 (6)
ECOG performance status 0-1, n (%)	3 (75)	32 (94)	12 (100)	100 (95)	.442	147 (95)
Time from consult to infusion, days, median (IQR)	51 (44-70)	41 (34-48)	38 (31.5-47)	36 (34-43)	.132	37 (34-46)
Vein-to-vein time, days, median (IQR)	33 (30-40)	27 (26-31)	31.5 (25.5-37)	27 (26-32)	.109	27 (26-33)

[a] *P* value compares infusion time.
ECOG, Eastern Cooperative Oncology Group; EMP, early management period (Nov 2021–Dec 2022); FL, follicular lymphoma; IQR, interquartile range; LBCL, large B-cell lymphoma; LMP, late management period (Jan 2018–Oct 2021); MCL, mantle cell lymphoma.

- Prophylactic corticosteroids were used in the EMP as reflected by the addition to the USPI based on ZUMA-1 Cohort 6[3]
  - The low adoption of prophylactic corticosteroids in the EMP (24%) may be attributable, in part, to the timing of its addition to the USPI[8]
- Fewer EMP patients received ≥3 prior lines of therapy compared with LMP patients (45% vs 76%, respectively; *P*<.001), aligning with the timing of axi-cel approval in second-line LBCL[9]

Table 2. CRS and ICANS in All Patients

		EMP		LMP			
		Inpatient (n=4)	Outpatient (n=34)	Inpatient (n=12)	Outpatient (n=105)	*P*[a]	All Patients (N=155)
CRS	**Initial CRS within 30 days post-infusion, n (%)**	3 (75)	25 (74)	10 (83)	87 (83)	.211	125 (81)
	Grade ≥3, n (%)	1 (25)	0 (0)	2 (17)	3 (3)	.746	6 (4)
	No CRS, n (%)	1 (25)	9 (26)	2 (17)	18 (17)		30 (19)
	Recurrent CRS within 30 days post-infusion, n (%)						
	Grade ≥3, n (%)	0 (0)	0 (0)	0 (0)	0 (0)	.278	0 (0)
	No recurrent CRS, n (%)	4 (100)	30 (88)	10 (83)	97 (92)		141 (91)
	Any CRS onset within 3 days post-infusion, n (%)	0 (0)	7 (21)	6 (50)	39 (37)	**.023**	52 (34)
	Time to onset of initial CRS, days, median (IQR)	5 (4-5)	4 (3-6)	2.5 (1-4)	4 (2-6)	.118	4 (2-6)
	Time from onset of initial CRS to max grade, days, median (IQR)	2 (2-4)	1 (1-2)	2 (1-5)	1 (1-3)	.342	1 (1-3)
	Time to initial CRS resolution, days, median (IQR)	6 (3-7)	4 (3-5)	6.5 (3-9)	6 (3-8)	**.010**	5 (3-7)
ICANS	**Initial ICANS within 30 days post-infusion, n (%)**	2 (50)	15 (44)	9 (75)	60 (57)	.125	86 (55)
	Grade ≥3, n (%)	1 (25)	7 (21)	3 (25)	18 (17)	.351	29 (19)
	No ICANS, n (%)	2 (50)	19 (56)	3 (25)	45 (43)		69 (45)
	Recurrent ICANS within 30 days post-infusion, n (%)						
	Grade ≥3, n (%)	0 (0)	1 (3)	0 (0)	0 (0)	.333	1 (1)
	No recurrent ICANS, n (%)	4 (100)	33 (97)	12 (100)	101 (96)		150 (97)
	Any ICANS onset within 3 days post-infusion, n (%)	0 (0)	0 (0)	0 (0)	2 (2)	1	2 (1)
	Time to onset of initial ICANS, days, median (IQR)	7.5 (5-10)	8 (6-12)	7 (6-9)	7 (6-9)	.309	7 (6-9)
	Time from onset of initial ICANS to max grade, days, median (IQR)	2.5 (1-4)	1 (1-2)	2 (1-2)	1 (1-2)	.768	1 (1-2)
	Time to initial ICANS resolution, days, median (IQR)	9 (4-14)	3 (2-6)	7 (2-16)	5 (3-9)	.318	5 (3-9)
	Grade ≥3 CRS and/or ICANS within 30 days post-infusion, n (%)	1 (25)	8 (24)	5 (25)	20 (19)	.594	32 (21)
	Prescribed corticosteroids, n (%)[b]	3 (75)	22 (65)	8 (67)	45 (43)	**.028**	78 (50)

Time intervals were calculated as follows: (time interval) = (end date) – (start date) + 1. As such, same day interval had a value of 1. Initial CRS and ICANS is defined as the first occurrence of CRS or ICANS.
[a] *P* value compares infusion time periods (inpatient and outpatient in each time combined). CRS/ICANS incidence and grade were compared across individual grades. For continuous variables where medians are presented, the *P* value is based on Wilcoxon rank-sum test of sample distributions. [b] Excludes prophylactic corticosteroids.
CRS, cytokine release syndrome; EMP, early management period (Nov 2021–Dec 2022); ICANS, immune effector cell–associated neurotoxicity syndrome; IQR, interquartile range; LMP, late management period (Jan 2018–Oct 2021).

- Within 30 days of infusion, 81% of all patients had CRS (4% Grade ≥3) and 55% had ICANS (19% Grade ≥3; **Table 2**)
- Most events had an onset <14 days of infusion
  - Between 14-30 days of infusion, no patients had CRS, and 6% of patients had ICANS (all had prior CRS)
- Incidence of CRS within 3 days of infusion was statistically lower among EMP versus LMP patients (18% vs 38%, respectively; *P*=.023)
- Median time to CRS resolution was significantly shorter in the EMP versus LMP (4.5 vs 6 days; *P*<.01)
- More patients were prescribed corticosteroids for CRS and ICANS in the EMP versus LMP (66% vs 45%, respectively; *P*<.05)

Table 3. Hospital Utilization in All Patients Treated Outpatient

	EMP (n=34)	LMP (n=104)	*P*	Overall (N=138)
Any early hospital admissions (within 3 days post-infusion), n (%)	10 (29)	46 (44)	.137	56 (40)
Reasons for first hospitalization within 3 days post-infusion, n (%)				
Fever	6 (60)	40 (87)	.066	46 (82)
Elevated CRP without fever	2 (20)	2 (4)	.142	4 (7)
Neurotoxicity	0 (0)	1 (2)	1	1 (2)
Tachycardia	0 (0)	2 (4)	1	2 (4)
Mental fogginess	0 (0)	1 (2)	1	1 (2)
Other	2 (20)	2 (4)	.142	4 (7)
Treatment for first hospitalization within 3 days post-infusion (non-mutually exclusive), n (%)				
Tocilizumab	8 (80)	24 (52)	.162	32 (57)
Corticosteroid	1 (10)	7 (15)	1	8 (14)
Vasopressors	0 (0)	1 (2)	1	1 (2)
Supplemental oxygen	0 (0)	9 (20)	.189	9 (16)
Any hospital admissions within 30 days post-infusion, n (%)	27 (79)	94 (90)	.146	121 (87)
Duration of first hospitalization, days, median (IQR)	6 (4-9)	10 (6-13)	**.006**	9 (5-12)
Total inpatient stays 30 days post-infusion, days, median (IQR)	9 (6-12)	11 (7-13)	.211	10 (7-13)
Any ICU visits 30 days post-infusion, n (%)	2 (6)	22 (21)	.065	24 (17)
Total ICU stays 30 days post-infusion, days, median (IQR)	3 (3-3)	3.5 (2-5)	.708	3 (2-5)

Time intervals were calculated as follows: (time interval) = (end date) – (start date) + 1. As such, same day interval had a value of 1. Hospital/ICU stays described were limited to the 30-day period post-infusion; total stays could include multiple admissions within this period.
Reasons and treatment for first hospitalization within 30 days post-infusion are available in the Supplement (**Table S1**).
CRP, c-reactive protein; EMP, early management period (Nov 2021–Dec 2022); ICU, intensive care unit; IQR, interquartile range; LMP, late management period (Jan 2018–Oct 2021).

- Fever was the primary reason for hospitalization within 3 and 30 days (**Table 3** and **Table S1**)
- Within 30 days of infusion, tocilizumab was used in 81% versus 39% of EMP and LMP patients, respectively (*P*<.001; **Table 3**)
- EMP patients had a shorter median duration of the first hospitalization than LMP patients (6 vs 10 days, *P*<.01), and numerically fewer had an ICU visit (6% vs 21%, *P*=.065)
- Among the 16 patients who received inpatient infusion, median duration of total hospitalization (IQR) within 30 days of infusion was 15 days (10-23.5); median duration of total ICU stay (IQR) was 7 days (4-14)

Multivariate analysis for predicting events (all patients treated outpatient)

- In multivariable models, elevated lactate dehydrogenase levels at day 0 were associated with increased odds of Grade ≥3 CRS/ICANS within 30 days of infusion (odds ratio, 2.8; 95% CI, 1.0-7.3); bridging therapy was associated with increased odds of hospitalization within 3 days of infusion (odds ratio, 2.9; 95% CI, 1.2-6.7)

PATIENTS WITH LBCL WHO RECEIVED OUTPATIENT AXI-CEL

- The 116 patients with LBCL infused with axi-cel in the outpatient setting (25 EMP, 91 LMP) had similar baseline patient characteristics as the overall outpatient cohort

Table 4. Baseline Patient Characteristics in Patients with LBCL Who Received Outpatient Axi-Cel

	EMP (n=25)	LMP (n=91)	*P*[a]	Overall (N=116)
Age, years, median (IQR)	61 (58-68)	59 (48-65)	.089	60 (51.5-65)
Male sex, n (%)	16 (64)	60 (66)	.857	76 (66)
Prior lines of therapy, n (%)				
1	5 (20)	1 (1)	**.001**	6 (5)
2	12 (48)	18 (20)		30 (26)
≥3	8 (32)	72 (79)		80 (69)
Stem cell transplant, n (%)	10 (40)	44 (48)	.458	54 (47)
Bridging therapy, n (%)	17 (68)	57 (63)	.621	74 (64)
Prophylactic corticosteroid (dexamethasone), n (%)	6 (24)	0 (0)	**<.0001**	6 (5)
ECOG performance status 0-1, n (%)	23 (92)	87 (96)	.404	110 (95)
Time from consult to infusion, days, median (IQR)	39 (33-43)	36 (34-42)	.814	36 (34-42.5)
Vein-to-vein time, days, median (IQR)	27 (26-29)	27 (25-32)	.427	27 (26-30)

[a] *P* value compares infusion time periods.
axi-cel, axicabtagene ciloleucel; ECOG, Eastern Cooperative Oncology Group; EMP, early management period (Nov 2021–Dec 2022); FL, follicular lymphoma; IQR, interquartile range; LBCL, large B-cell lymphoma; LMP, late management period (Jan 2018–Oct 2021); MCL, mantle cell lymphoma.

Table 5. CRS and ICANS in Patients with LBCL Who Received Outpatient Axi-Cel

		EMP (n=25)	LMP (n=91)	*P*[a]	Overall (N=116)
CRS	**Initial CRS within 30 days post-infusion, n (%)**	19 (76)	77 (85)	.371	96 (83)
	Grade ≥3, n (%)	0 (0)	3 (3)	.784	3 (3)
	No CRS, n (%)	6 (24)	14 (15)		20 (17)
	Recurrent CRS within 30 days post-infusion, n (%)				
	Grade ≥3, n (%)	0 (0)	0 (0)	.783	0 (0)
	No recurrent CRS, n (%)	23 (92)	84 (92)		107 (92)
	Any CRS onset within 3 days post-infusion, n (%)	6 (24)	33 (36)	.340	39 (34)
	Time to onset of initial CRS, days, median (IQR)	4 (2-6)	4 (2-6)	.447	4 (2-6)
	Time from onset of initial CRS to max grade, days, median (IQR)	1 (1-2)	1 (1-3)	.294	1 (1-2.5)
	Time to initial CRS resolution, days, median (IQR)	4 (3-6)	5 (3-8)	**.039**	5 (3-7)
ICANS	**Initial ICANS within 30 days post-infusion, n (%)**	10 (40)	49 (54)	.222	59 (51)
	Grade ≥3, n (%)	5 (20)	15 (16)	.595	20 (17)
	No ICANS, n (%)	15 (60)	42 (46)		57 (49)
	Recurrent ICANS within 30 days post-infusion, n (%)				
	Grade ≥3, n (%)	1 (4)	0 (0)	.251	1 (1)
	No recurrent ICANS, n (%)	24 (96)	89 (98)		113 (97)
	Any ICANS onset within 3 days post-infusion, n (%)	0 (0)	2 (2)	1	2 (2)
	Time to onset of initial ICANS, days, median (IQR)	6 (6-8)	7 (5-8)	.878	6 (5-8)
	Time from onset of initial ICANS to max grade, days, median (IQR)	1 (1-2)	1 (1-2)	.868	1 (1-2)
	Time to initial ICANS resolution, days, median (IQR)	4.5 (3-6)	5 (3-9)	.422	5 (3-9)
	Grade ≥3 CRS and/or ICANS within 30 days post-infusion, n (%)	6 (24)	17 (19)	.576	23 (20)
	Prescribed corticosteroids, n (%)[b]	15 (60)	35 (38)	.054	50 (43)

Time intervals were calculated as follows: (time interval) = (end date) – (start date) + 1. As such, same day interval had a value of 1. Initial CRS and ICANS is defined as the first occurrence of CRS or ICANS.
[a] *P* value compares infusion time periods. CRS/ICANS incidence and grade were compared across individual grades. For continuous variables where medians are presented, the *P* value is based on Wilcoxon rank sum test of sample distributions. [b] Excludes prophylactic corticosteroids.
CRS, cytokine release syndrome; EMP, early management period (Nov 2021–Dec 2022); ICANS, immune effector cell–associated neurotoxicity syndrome; IQR, interquartile range; LBCL, large B-cell lymphoma; LMP, late management period (Jan 2018–Oct 2021).

- Within 30 days of infusion, 83% of patients with LBCL who received outpatient axi-cel had CRS (3% Grade ≥3) and 51% had ICANS (17% Grade ≥3; **Table 5**)
- Initial CRS and ICANS within 30 days post-infusion did not vary significantly in the EMP versus LMP (76% vs 85% CRS, *P*>.05; 40% vs 54% ICANS, *P*>.05)
- Median time to CRS resolution was shorter in the EMP versus LMP (4 vs 5 days; *P*<.05)
- Numerically more patients were prescribed corticosteroids for CRS and ICANS in the EMP versus LMP (60% vs 38%, respectively; *P*=.054)

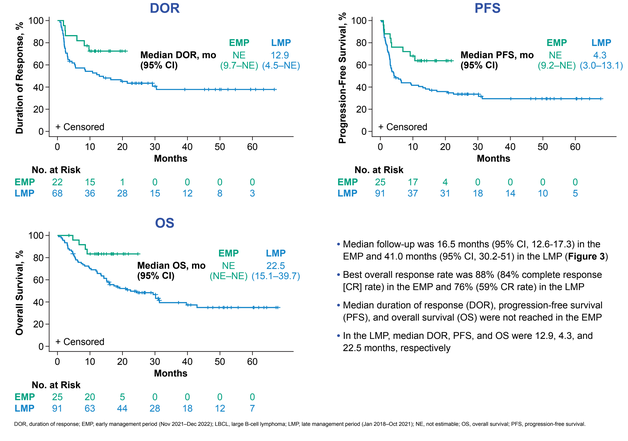
Table 6. Hospital Utilization in Patients with LBCL Who Received Outpatient Axi-Cel

	EMP (n=25)	LMP (n=91)	*P*	Overall (N=116)
Any early hospital admissions (within 3 days post-infusion), n (%)	7 (28)	40 (44)	.150	47 (41)
Reasons for first hospitalization within 3 days post-infusion, n (%)				
Fever	5 (71)	35 (88)	.276	40 (85)
Elevated CRP without fever	2 (29)	2 (5)	.100	4 (9)
Neurotoxicity	0 (0)	1 (3)	1	1 (2)
Tachycardia	0 (0)	2 (5)	1	2 (4)
Mental fogginess	0 (0)	1 (3)	1	1 (2)
Other	0 (0)	1 (3)	1	1 (2)
Treatment for first hospitalization within 3 days post-infusion (non-mutually exclusive), n (%)				
Tocilizumab	7 (100)	19 (48)	**.012**	26 (55)
Corticosteroid	0 (0)	7 (18)	.573	7 (15)
Vasopressors	0 (0)	1 (3)	1	1 (2)
Supplemental oxygen	0 (0)	8 (20)	.329	8 (17)
Any hospital admissions within 30 days post-infusion, n (%)	20 (80)	83 (91)	.150	103 (89)
Duration of first hospitalization, days, median (IQR)	7 (4.5-9.5)	10 (5-12)	.080	9 (5-12)
Total inpatient stays 30 days post-infusion, days, median (IQR)	9.5 (6.5-11.5)	11 (6-13)	.410	11 (6-13)
Any ICU visits 30 days post-infusion, n (%)	0 (0)	21 (23)	**.006**	21 (18)
Total ICU stays 30 days post-infusion, days, median (IQR)	0 (0)	4 (2-5)		4 (2-5)

Time intervals were calculated as follows: (time interval) = (end date) – (start date) + 1. As such, same day interval had a value of 1. Hospital/ICU stays described were limited to the 30-day period post-infusion; total stays could include multiple admissions within this period.
Reasons and treatment for first hospitalization within 30 days post-infusion are available in the Supplement (**Table S2**).
CRP, C-reactive protein; EMP, early management period (Nov 2021–Dec 2022); ICU, intensive care unit; IQR, interquartile range; LBCL, large B-cell lymphoma; LMP, late management period (Jan 2018–Oct 2021).

- Tocilizumab was used in 100% versus 48% of EMP and LMP patients within 3 days of infusion, respectively (*P*= .012; **Table 6**)
- ICU visits were only observed among LMP patients, with no EMP patients admitted to the ICU within 30 days of infusion (23% vs 0%, *P*<.01)

Figure 3. Effectiveness Outcomes in Patients with LBCL Who Received Outpatient Axi-Cel



DOR, duration of response; EMP, early management period (Nov 2021–Dec 2022); LBCL, large B-cell lymphoma; LMP, late management period (Jan 2018–Oct 2021); NE, not estimable; OS, overall survival; PFS, progression-free survival.

- Median follow-up was 16.5 months (95% CI, 12.6-17.3) in the EMP and 41.0 months (95% CI, 30.2-51) in the LMP (**Figure 3**)
- Best overall response rate was 88% (84% complete response [CR] rate) in the EMP and 76% (59% CR rate) in the LMP
- Median duration of response (DOR), progression-free survival (PFS), and overall survival (OS) were not reached in the EMP
- In the LMP, median DOR, PFS, and OS were 12.9, 4.3, and 22.5 months, respectively

CONCLUSIONS

- Results herein provide further evidence that outpatient administration of axi-cel and brexu-cel is feasible without increased AEs for patients with R/R NHL. These results align with previous studies on outpatient CAR T-cell administration, including rates of hospitalization, CRS, and ICANS[6,7]
- Safety outcomes and hospital utilization of patients with LBCL who received outpatient axi-cel were similar to those of the entire cohort
- Compared with late toxicity management, early toxicity management showed improved safety outcomes in patients with R/R NHL and may improve effectiveness outcomes among patients with LBCL who received outpatient axi-cel
- This study includes the following limitations:
  - It involves a single institution, an experienced tertiary academic center, limiting generalizability
  - Patient management evolved from 2018-2022, which may impact comparisons between the EMP and LMP
  - EMP patients had fewer prior lines of therapy, which may impact effectiveness outcomes
- A prospective clinical trial of outpatient axi-cel administration with prophylactic corticosteroids for patients with R/R LBCL and ≥1 prior line of therapy is underway (ZUMA-24, NCT05459571)[10]

REFERENCES

1. Khan AN, et al. *Eur J Haematol*. 2024;112:6-18.
2. Alexander M, et al. *Transplant Cell Ther*. 2021;27:558-570.
3. Oluwole OO, et al. *Bone Marrow Transplant*. 2024;59:366-372.
4. Topp MS, et al. *Br J Haematol*. 2021;195:388-398.
5. Oluwole OO, et al. *Blood*. 2023;142(Suppl 1):2120.
6. Ahmed N, et al. Presented at the 2024 EBMT-EHA 6th European CAR T-Cell Meeting; February 15-17, 2024; Valencia, Spain. Abstract 57.
7. Bansal R, et al. *J Clin Oncol*. 2023;41:1533.
8. U.S. FDA Approves New Label Update for CAR T-Cell Therapy Yescarta® Showing Prophylactic Steroid Use Improves Management of Cytokine Release Syndrome. Gilead *Sciences*. Published January 31, 2022. Accessed April 9, 2024. https://www.gilead.com/news-and-press/press-room/press-releases/2022/1/us-fda-approv[…]-steroid-use-improves-management-of-cytokine-release-syndrome.
9. Sharma P, et al. *Clin Cancer Res*. 2023;29:4331-4337.
10. Leslie AL, et al. Presented at the European Hematology Association Annual Scientific Meeting; June 13-16, 2024; Madrid, Spain. Abstract P1159.

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SUPPLEMENT

- The following additional data are available through the Quick Response (QR) code: Reasons and treatment for first hospitalization within 30 days of infusion in all patients and patients with LBCL who received outpatient axi-cel (**Table S1** and **Table S2**)

DISCLOSURES

- **RB:** travel support from Kite, a Gilead Company
- Full author disclosures are available through the QR code

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