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Real-World Study of the Effectiveness, Safety, and Health Care Resource Utilization of Lisocabtagene Maraleucel and Axicabtagene Ciloleucel in Patients With Relapsed or Refractory Large B-Cell Lymphoma in the Second-Line Treatment Setting

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Nathan Denlinger, DO, MS

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Introduction

- The use of CD19-directed CAR T cell therapies such as liso-cel and axi-cel has transformed the treatment landscape for patients with R/R LBCL[1,2]
- Current evidence from controlled clinical trials and retrospective cohort studies support the feasibility of delivering CAR T cell therapies in inpatient and outpatient settings; however, direct comparisons between individual therapies in these setting are lacking[3–5]
  - In the absence of direct comparisons, real-world data can bridge key gaps in clinical knowledge and inform evidence-based decision-making in routine clinical care
- Here, we report the results of a retrospective observational study evaluating the real-world effectiveness, safety, and health care resource utilization (HCRU) of liso-cel and axi-cel as 2L treatment for R/R LBCL

2L, second line; axi-cel, axicabtagene ciloleucel; liso-cel, lisocabtagene maraleucel; LBCL, large B-cell lymphoma.

1. Perales M-A, et al. *Transplant Cell Ther* 2022;28:546–559; 2. Thiruvengadam SK, et al. *Am J Hematol* 2025;100:236–248; 3. Hansen DK, et al. *Cancers (Basel)* 2023:15:5746; 4. Perez A, et al. *Front Immunol* 2024;15:1412002; 5. Patel AR, et al. *J Manag Care Spec Pharm* 2025;31:1110–1122.

Methods

DATA SOURCE: US Flatiron Health Research Database (FHRD)[1]

- Nationwide database of deidentified longitudinal patient data from electronic health records
- Includes data collected from academic medical centers and community oncology practices
- Data curated using natural language processing with machine learning and technology-enabled abstraction

STUDY PERIOD: April 1, 2022, to June 30, 2025[a]

INDEX PERIOD: Index date was on/before April 30, 2025[b]

ENDPOINTS:

- Primary: Describe OS and PFS
- Secondary: CAR T cell therapy—related AEs (CRS, ICANS, and cytopenia), AE management, and HCRU

INCLUSION CRITERIA[c]

- ≥ 18 years of age
- Diagnosed with NHL via structured ICD codes (ICD-9: 200x, 202x; ICD-10: C82x, C83x, C84x, C85x, C86x, C88x, C96x) that include diagnosis date on/after January 1, 2011
- LBCL treatment with CAR T cell therapy on/after January 1, 2011
- 2L treatment with axi-cel or liso-cel for R/R LBCL

EXCLUSION CRITERIA

- Lack of relevant unstructured documents in the FHRD for review
- Primary CNS lymphoma, confirmed via unstructured data
- Received off-specification CAR T cell therapy or treatment in an investigational clinical study setting

COVARIATE BALANCING: Stabilized inverse probability of treatment weighting (IPTW) adjustment methodology[d]

[a]Study period start date was chosen based on FDA approval of axi-cel for patients with 2L LBCL; [b]Index date of CAR T cell therapy infusion was on/before April 30, 2025, to allow for ≥ 2 months of follow-up before data cutoff on June 30, 2025; [c]For the HCRU analysis, only patients with ≥ 3 months of electronic health record activity after the index date were included; [d]Covariates balanced by IPTW adjustments based on methods described by Hamlin PA, et al.[2]

CRS, cytokine release syndrome; ICANS, immune effector cell—associated neurotoxicity syndrome; ICD-9, International Classification of Diseases, Ninth Revision; ICD-10, International Classification of Diseases, Tenth Revision; US, United States.

1. Flatiron Health Research Database: Flatiron Health. Database Characterization Guide. Flatiron.com. https://flatiron.com/database-characterization. Published March 18, 2025. Accessed January 20, 2026; 2. Hamlin PA, et al. *Blood* 2003;102:1989—1996.

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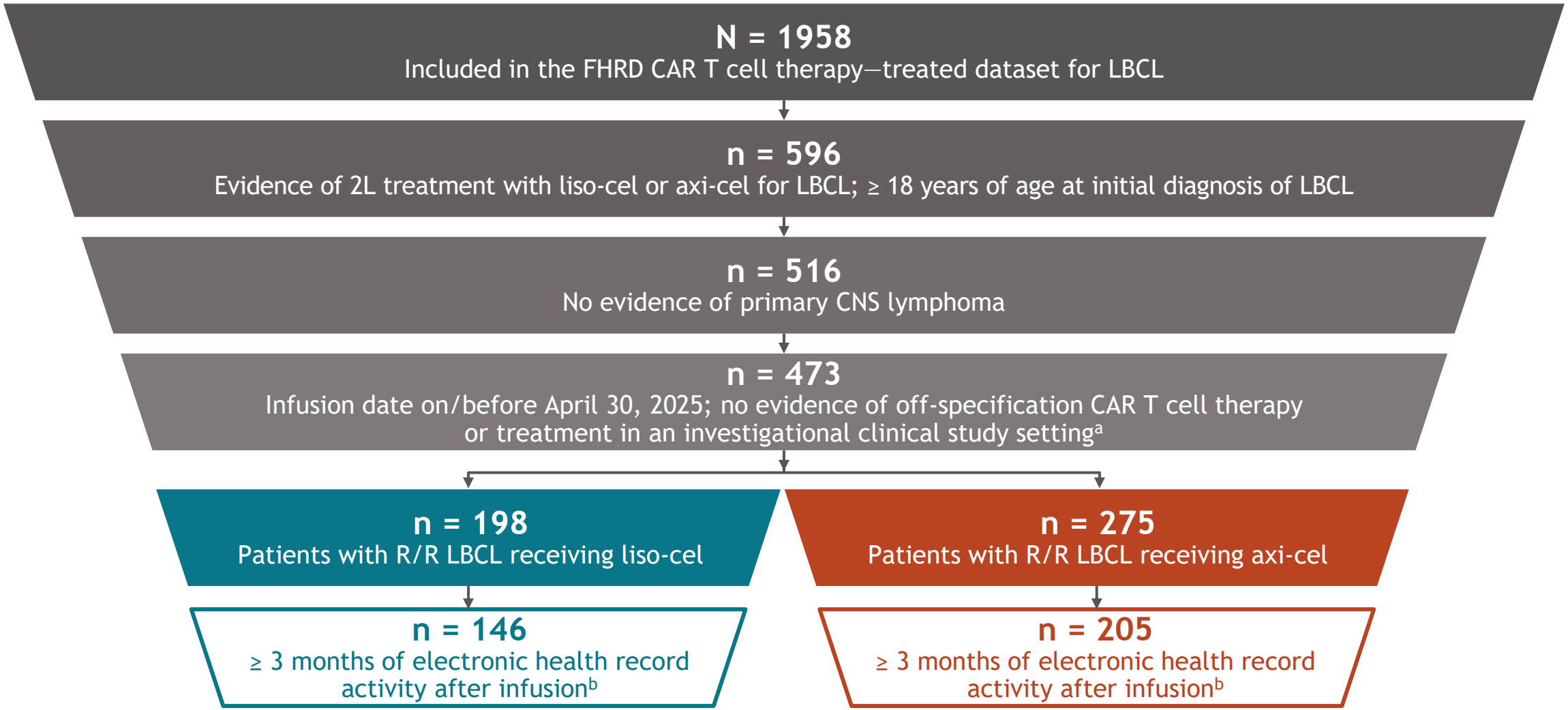
Identification of the study cohort



Patients who received CAR T cell therapy as part of a clinical study or for whom no documents were available are not included in the database.
[a]Eighteen patients with off-specification CAR T cell therapy and 25 patients with 2L CAR T cell therapy after April 30, 2025, were excluded; [b]Includes patients with known infusion setting (inpatient or outpatient) and date.

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Patient demographics and clinical characteristics

	Liso-cel (n = 198)	Axi-cel (n = 275)
Median (range) age,[a] y	70 (21–83)	62 (21–83)
Male, n (%)	111 (56)	171 (62)
Disease subtype, n (%)		
DLBCL NOS	165 (84)	219 (81)
Double-hit lymphoma	18 (9)	30 (11)
Primary mediastinal B-cell lymphoma	5 (3)	12 (4)
Other[b]	10 (5)	14 (5)
Cell of origin,[a,c] n (%)		
Germinal B cell	68 (34)	118 (43)
Nongerminal/activated B cell	84 (42)	82 (30)
Missing	46 (23)	75 (27)
ECOG PS of 0–1, n (%)	112 (57)	165 (60)
Missing	62 (31)	87 (32)
Chemotherapy resistant,[a,d] n (%)	142 (72)	237 (86)
CNS involvement, n (%)	3 (2)	8 (3)
Elevated LDH, n (%)	77 (39)	92 (33)
Bulky disease,[e] n (%)	134 (68)	203 (74)

	Liso-cel (n = 198)	Axi-cel (n = 275)
Median (IQR) time from apheresis to infusion,[a] days	41 (35–48)	31 (27–39)
Infusion setting,[a] n (%)		
Inpatient	137 (70)	232 (84)
Outpatient	39 (20)	15 (5)
Missing	22 (11)	28 (10)
Type of practice, n (%)		
Academic	151 (77)	216 (79)
Community[f]	37 (19)	48 (17)
Missing	10 (5)	11 (4)
Initiated 3L therapy for LBCL, n (%)	59 (30)	74 (27)
Initiated 4L therapy for LBCL, n (%)	23 (12)	34 (12)

- Aside from a few differences between cohorts, clinical and disease characteristics were generally similar

[a]Denotes a statistically significant difference ($P < 0.05$) between liso-cel and axi-cel; [b]Other included: primary cutaneous DLBCL (leg), T-cell/histiocyte-rich LBCL, EBV+ DLBCL, and HGBCL/triple-hit lymphoma; [c]Cell of origin designation determined per the Hans algorithm[1]; [d]Defined as resistant to first-line chemotherapy within 12 months; [e]Presence of bulky disease determined per Lugano criteria (mass of ≥ 10 cm)[2]; [f]Defined as non-NCI–designated community centers.
3L, third line; 4L, fourth line; EBV+, Epstein-Barr virus positive; HGBCL, high-grade B-cell lymphoma; NOS, not otherwise specified.
1. Hans CP, et al. *Blood* 2004;103:275–282; 2. Cheson BD, et al. *J Clin Oncol* 2014;32:3059–3068.

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Bridging therapy

	Liso-cel (n = 198)	Axi-cel (n = 275)
Evidence of bridging therapy, n (%)	155 (78)	195 (71)
Chemotherapy-based regimen,[a] n (%)		
Polatuzumab vedotin piiq ± rituximab ± bendamustine	81 (41)	83 (30)
GemOx ± rituximab	18 (9)	41 (15)
ICE ± rituximab	10 (5)	6 (2)
GDP	6 (3)	5 (2)
DHAP	1 (< 1)	5 (2)
Radiation therapy, n (%)	27 (14)	38 (14)
Other, n (%)	43 (22)	61 (22)
No evidence of bridging therapy, n (%)	43 (22)	80 (29)

[a]Chemotherapy-based regimens may have included rituximab.
DHAP, dexamethasone, high-dose cytarabine, and cisplatin; GDP, gemcitabine, dexamethasone, and cisplatin; GemOx, gemcitabine and oxaliplatin; ICE, Ifosfamide, carboplatin, and etoposide.

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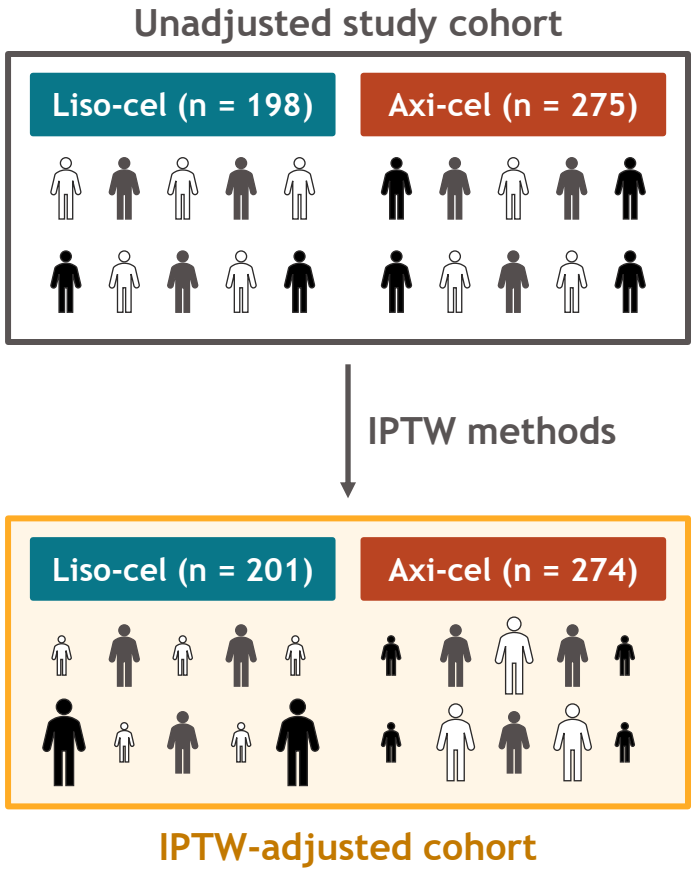
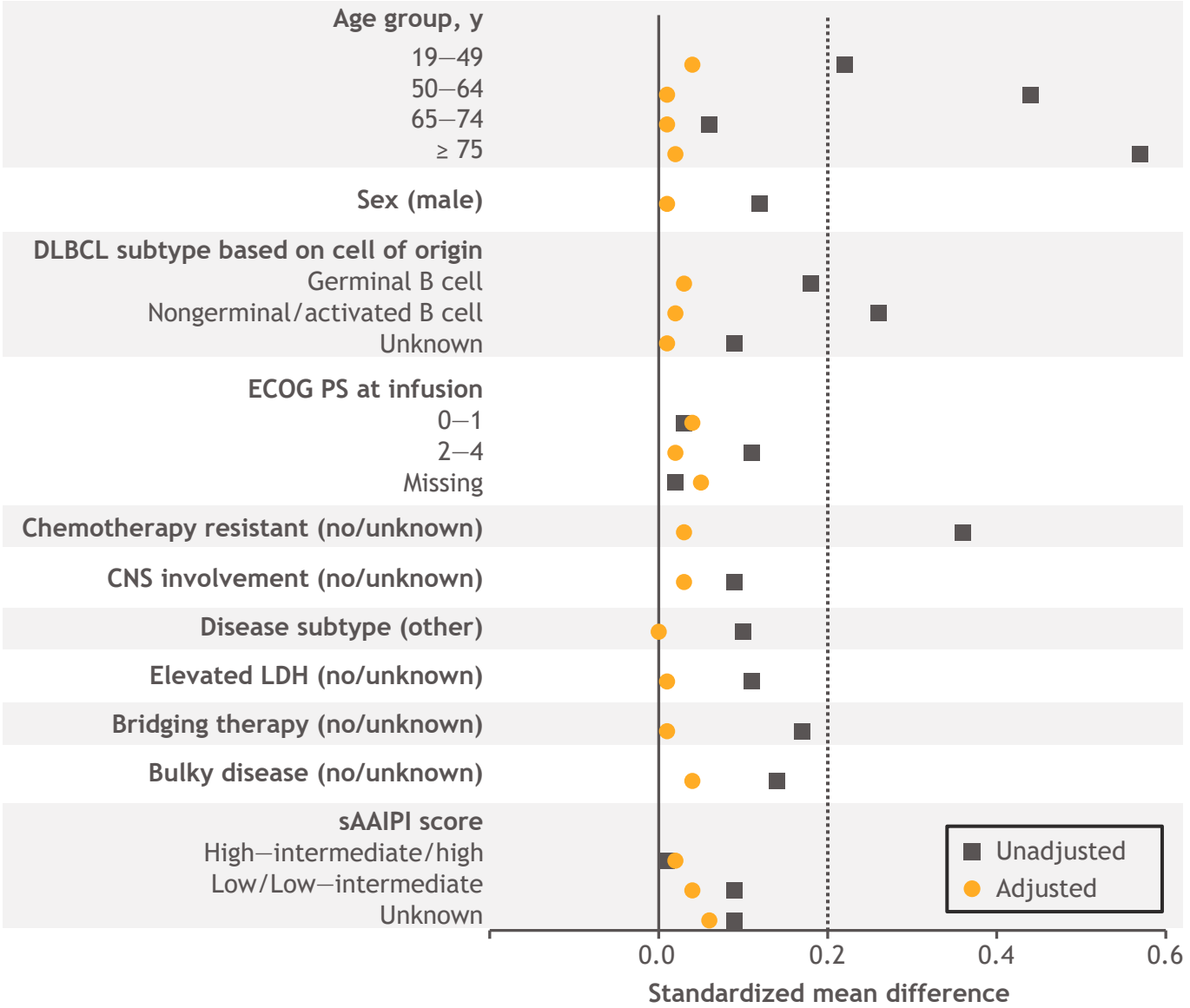
IPTW methods adjusted for potential differences in clinical covariates



- After IPTW adjustment, all characteristics were balanced



sAAIPI, secondary age-adjusted International Prognostic Index.

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Survival outcomes in patients treated with liso-cel or axi-cel

PFS estimates	Unadjusted			IPTW adjusted		
	Liso-cel (n = 196)	Axi-cel (n = 272)	HR (95% CI) *P* value	Liso-cel (n = 198)	Axi-cel (n = 271)	HR (95% CI) *P* value
6 months, % (95% CI)	69 (63–77)	71 (66–77)	1.05 (0.77–1.42) *P* = 0.77	65 (57–74)	70 (65–77)	1.14 (0.84–1.55) *P* = 0.38
9 months, % (95% CI)	62 (55–70)	65 (59–71)		57 (49–67)	65 (59–72)	

OS estimates	Unadjusted			IPTW adjusted		
	Liso-cel (n = 198)	Axi-cel (n = 275)	HR (95% CI) *P* value	Liso-cel (n = 201)	Axi-cel (n = 274)	HR (95% CI) *P* value
6 months, % (95% CI)	89 (84–94)	89 (85–93)	1.34 (0.89–2.03) *P* = 0.16	89 (83–95)	89 (85–93)	1.39 (0.89–2.16) *P* = 0.15
9 months, % (95% CI)	82 (76–89)	86 (82–91)		82 (75–90)	85 (81–90)	

- There were no statistically significant differences in early survival outcomes at 9 months between liso-cel and axi-cel therapy, with and without adjusting for key covariates

The median (range) follow-up from index was 8 months (0–34) for liso-cel and 12 months (0–37) for axi-cel.

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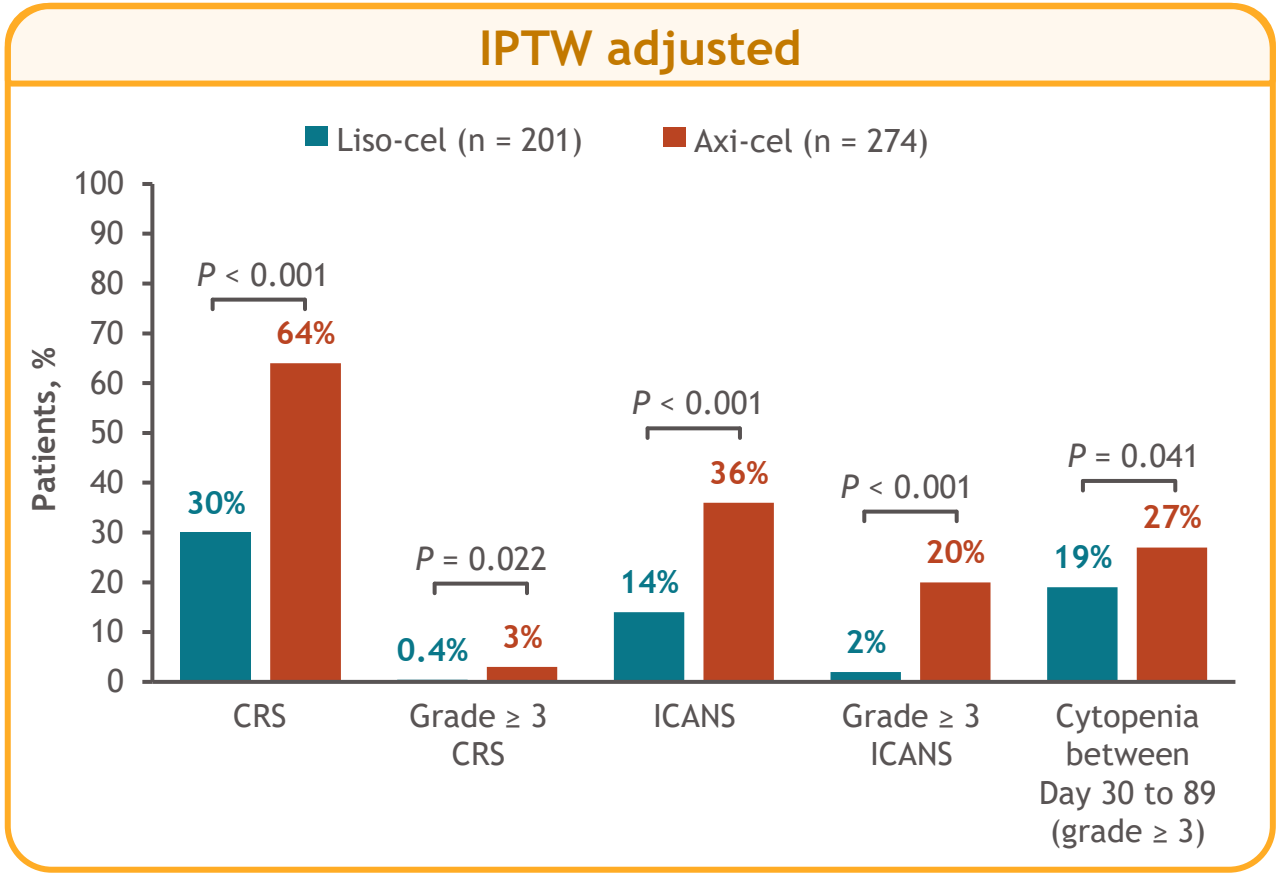
Prevalence of AEs of interest and pharmacologic management[a]



	Liso-cel (n = 198)	Axi-cel (n = 275)
Evidence of treatment for CRS and/or ICANS, n (%)	42 (21)	150 (55)
Tocilizumab only	15 (8)	31 (11)
Tocilizumab + steroid	19 (10)	86 (31)
Steroid only	4 (2)	8 (3)
Tocilizumab + anakinra/siltuximab + steroid	3 (2)	20 (7)

- Patients were significantly less likely to experience CRS or ICANS with liso-cel versus axi-cel, before and after adjusting for key covariates ($P < 0.05$)

[a]Treatment for CRS or ICANS (use records with administration date or start date from CAR T cell therapy infusion until start date of the next line of therapy or date of end of follow-up). Prophylactic tocilizumab and/or steroid use was not accounted for in these analyses.

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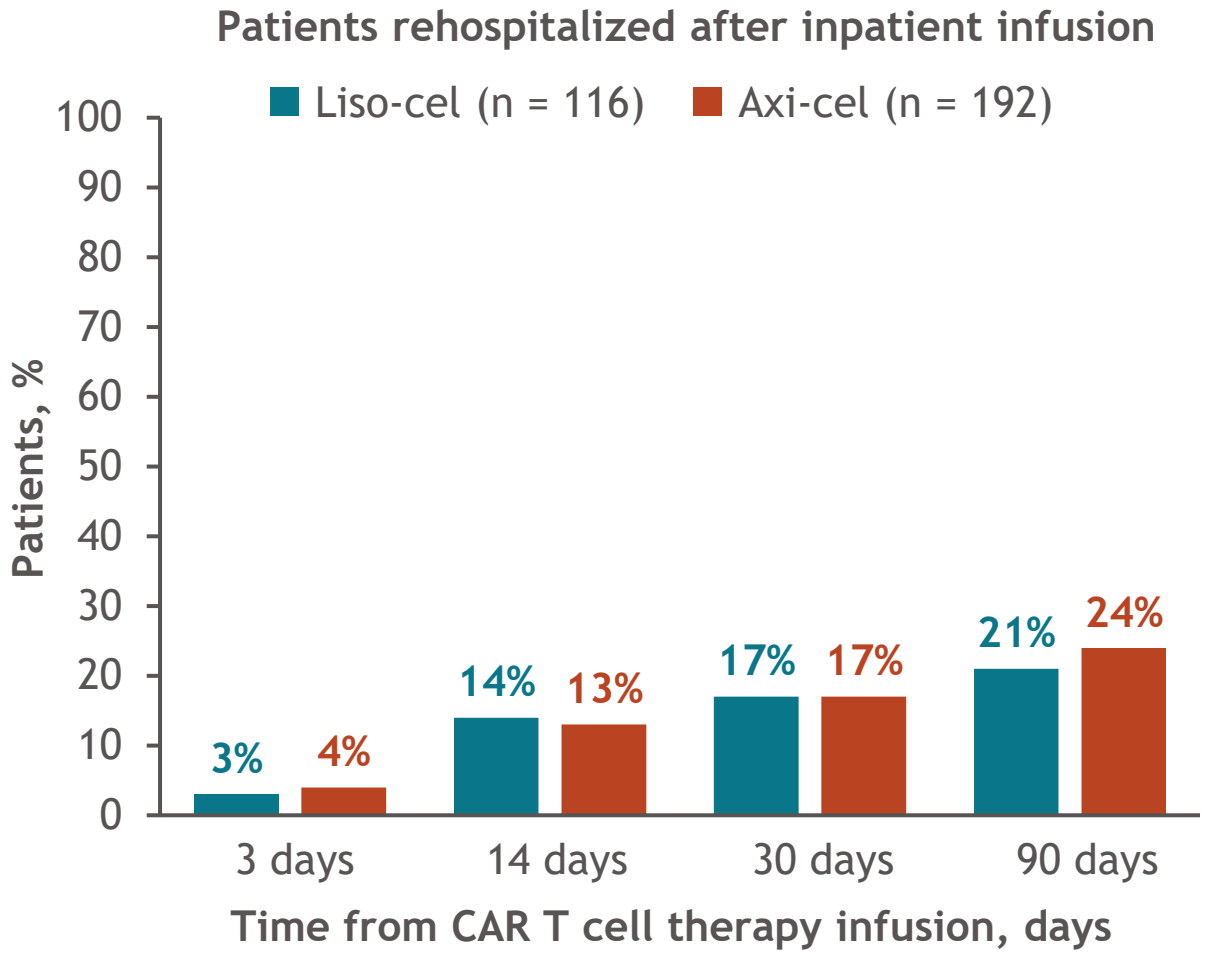
HCRU: Rehospitalizations after inpatient CAR T cell therapy infusion

	Liso-cel (n = 146)	Axi-cel (n = 205)
Infused at an inpatient setting, n (%)	116 (79)	192 (94)
Median (range) duration of infusion hospitalization, days	8 (0–36)	12 (0–377)
Rehospitalized, n/N (%)	38/116 (33)	77/192 (40)
Median (range) duration of rehospitalization, days	3 (1–32)	4 (0–41)
ICU admissions, n/N (%)	3/116 (3)	7/192 (4)



- Among those treated at an inpatient setting, liso-cel infusion resulted in significantly shorter median inpatient stay ($P < 0.001$) and lower rehospitalization rates compared with axi-cel

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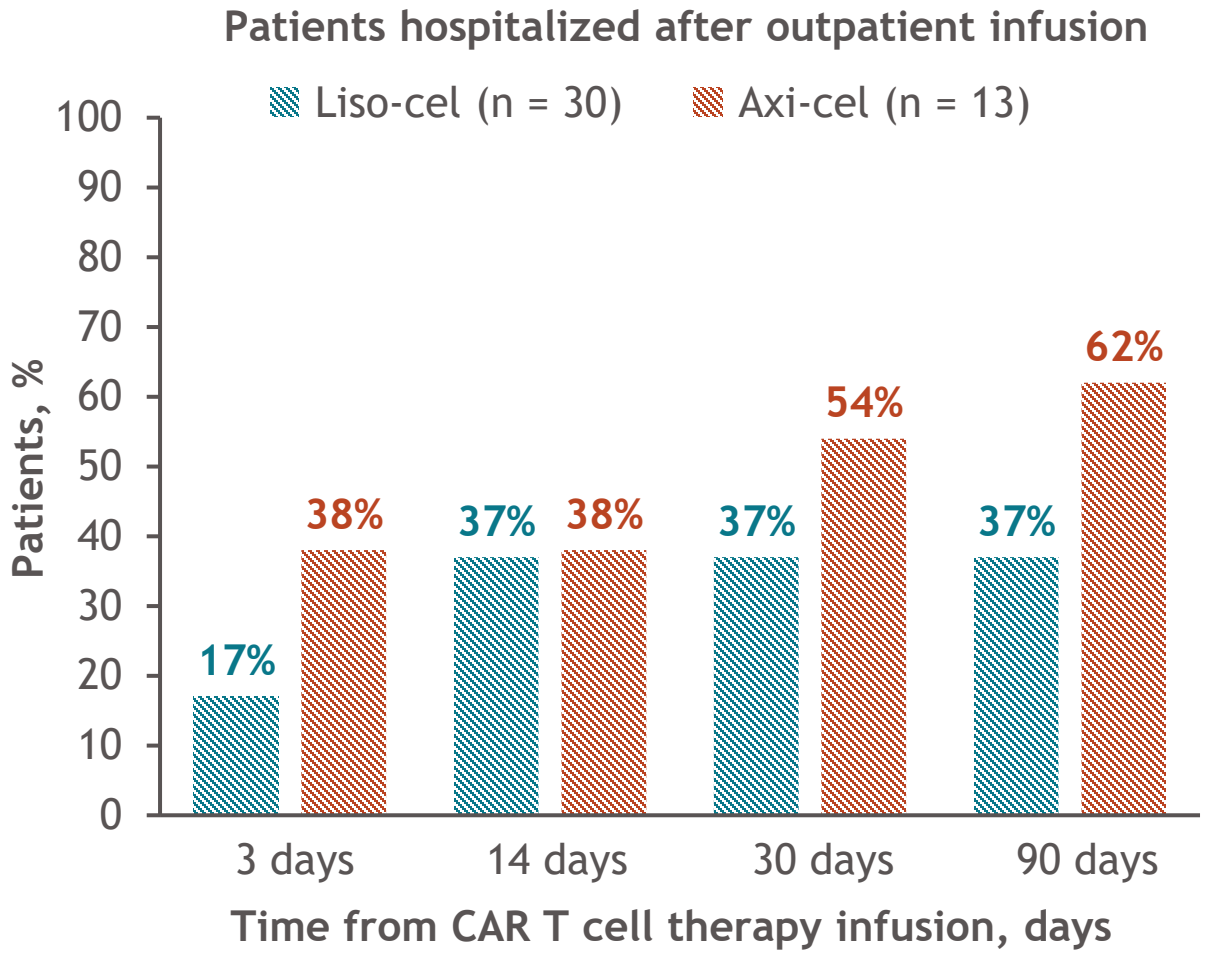
HCRU: Hospitalizations after outpatient CAR T cell therapy infusion

	Liso-cel (n = 146)	Axi-cel (n = 205)
Infused at an outpatient setting, n (%)	30 (21)	13 (6)
Hospitalized, n/N (%)	14/30 (47)	8/13 (62)
Median (range) duration of hospitalization, days	4 (1–34)	5.5 (2–13)
ICU admissions, n/N (%)	0/30 (0)	0/13 (0)



- Within 3 days of infusion from an outpatient setting, 17% of liso-cel–treated patients were hospitalized versus 38% with axi-cel

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Summary

- In this retrospective study, liso-cel demonstrated a favorable safety and resource utilization profile versus axi-cel with no clinically meaningful differences in efficacy outcomes between therapies
  - There was no statistically significant difference in OS or PFS between liso-cel and axi-cel
  - Patients who received liso-cel were significantly less likely to experience all-grade and grade ≥ 3 immune-related AEs (ie, CRS and ICANS) compared with axi-cel
  - Liso-cel required significantly fewer pharmacologic interventions for immune-related AEs (eg, tocilizumab, corticosteroids) than axi-cel
  - Liso-cel was associated with fewer hospitalizations, ICU admissions, and shorter hospital stays versus axi-cel across infusion settings
- Outcomes observed with liso-cel from the FHRD are consistent with similar analyses of other real-world databases (eg, DESCAR-T registry [France], ABC Consortium [US], and Cell Therapy Consortium [US])[1–3]
- Collectively, these findings further support liso-cel as a well-tolerated, patient-centered, and resource-efficient 2L treatment option for R/R LBCL compared with axi-cel

1. Brisou G, et al. *Blood* 2025;146(suppl 1):127–128; 2. Melody M, et al. *Blood* 2025;146(suppl 1):781–782; 3. Bachanova V, et al. *Blood* 2025;146(suppl 1):400–401.

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