Outpatient Use of Lisocabtagene Maraleucel in Patients with Relapsed or Refractory Large B-Cell Lymphoma: Real-World Data from the CIBMTR Registry

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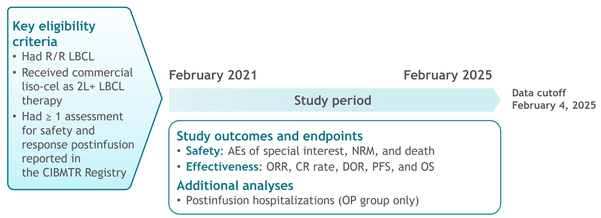
Introduction

- The autologous, CD19-directed CAR T cell product, lisocabtagene maraleucel (liso-cel), has demonstrated consistent efficacy in a broad population of patients with B-cell malignancies, including R/R large B-cell lymphoma (LBCL)[1–7]
- The well-established safety profile of liso-cel has made it feasible for outpatient (OP) delivery. This, combined with recent changes to the US prescribing information and EU summary of product characteristics that reduced the time patients are required to remain within proximity to a health care facility postinfusion from 4 to 2 weeks and driving restrictions from 8 to 2 weeks, is expected to further improve patient access to CAR T cell therapy
- Limited data are available on liso-cel outcomes by treatment setting in routine clinical practice
- Here, we describe real-world safety and effectiveness outcomes for patients with R/R LBCL who received liso-cel as standard of care (SOC) therapy in the inpatient (IP) or OP setting

Methods

Figure 1. Study design



The date of liso-cel infusion ranged from March 2021 to July 2024 in the IP group and April 2021 to July 2024 in the OP group.
2L+, second line or later; CIBMTR, Center for International Blood and Marrow Transplant Research; DOR, duration of response; NRM, nonrelapse mortality.

- This observational study included patients in the US with R/R LBCL who received commercial liso-cel as 2L+ treatment in the IP or OP setting as reported in the CIBMTR data collection forms/questionnaire between February 2021 and February 2025 (**Figure 1**)

Results

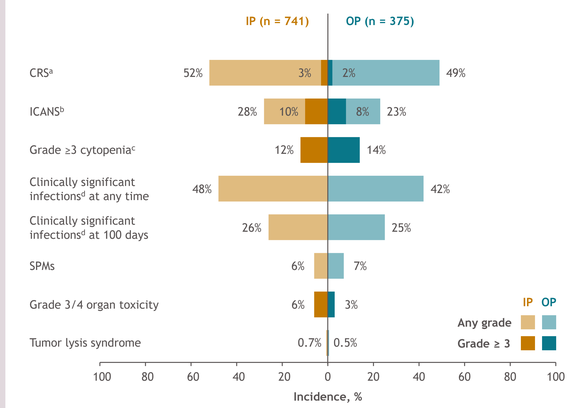
Table 1. Demographics and baseline characteristics

	IP (n = 741)	OP (n = 375)
Median (range) age, y	71.5 (21.5–91.2)	69.8 (25.0–86.1)
≥ 65 y, n (%)	554 (75)	253 (67)
Male, n (%)	440 (59)	227 (61)
Disease indication/histology, n (%)		
DLBCL	586 (79)	313 (83)
HGBCL	115 (16)	45 (12)
PMBCL	6 (1)	2 (1)
FL3B	7 (1)	2 (1)
Other B-cell lymphoma	25 (3)	13 (3)
Not reported/unknown	2 (< 1)	0
Extranodal involvement before infusion, n/N (%)[a]	387/673 (58)	171/341 (50)
Involvement of ≥ 2 sites	189/736 (26)	94/367 (26)
CNS involvement	35/673 (5)	14/341 (4)
ECOG PS, n/N (%)[a]		
0–1	592/656 (90)	326/336 (97)
≥ 2	64/656 (10)	10/336 (3)
Elevated LDH before infusion, n/N (%)[a]	319/666 (48)	125/342 (37)
Patients with ≥ 1 comorbidity, n/N (%)[a]	414/573 (72)	182/278 (65)
Most common comorbidities		
Cardiac/Cerebrovascular/Heart valve disease	205/573 (36)	88/278 (32)
Moderate or severe pulmonary disease	170/573 (30)	72/278 (26)
Obesity	74/573 (13)	44/278 (16)
Infection requiring ongoing antimicrobial treatment	36/573 (6)	7/278 (3)
Inflammatory bowel/rheumatological disease	35/573 (6)	12/278 (4)
Median (range) number of prior LOTs	3 (1–13)	3 (1–13)
Received bridging therapy, n/N (%)[a]	470/723 (65)	224/362 (62)

[a]Percentages were calculated from patients with available data.
FL3B, follicular lymphoma grade 3B; HGBCL, high-grade B-cell lymphoma; LOT, line of therapy; PMBCL, primary mediastinal B-cell lymphoma.

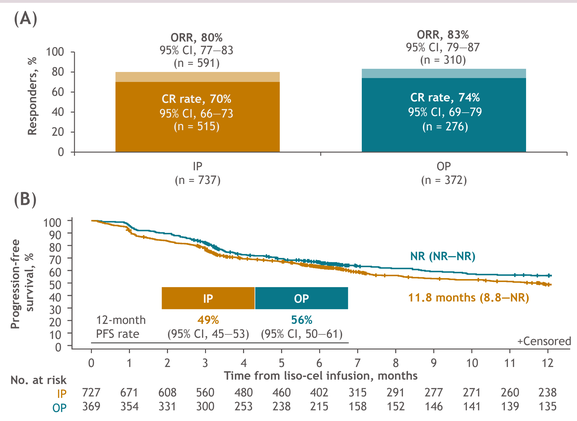
One-time infusion with liso-cel demonstrates consistent safety and effectiveness in both the IP and OP care settings in patients with R/R LBCL

Figure 2. AEs of special interest



[a]Graded by Lee 2014 criteria[8]; [b]ICANS data reflect the maximum grade according to American Society for Transplantation and Cellular Therapy 2019 criteria[9] at 100 days; [c]Defined as grade 4 thrombocytopenia and/or neutropenia at 30 days postinfusion; [d]Defined as any infections requiring treatment.
CRS, cytokine release syndrome; ICANS, immune-effector cell–associated neurotoxicity syndrome; SPM, second primary malignancy.

Figure 3. (A) Response rates[a] and (B) progression-free survival



Data reported within KM curve are median (95% CI).
[a]Patients with best overall response "not assessed" or "not provided" (missing) were considered as nonresponders when relapse, progression, or death was reported for these patients ≤ 90 days after CAR T cell infusion. Otherwise, they were not considered for the computation of ORR/CR rate.
NR, not reached.

Table 2. CRS and ICANS timing and treatment

	CRS		ICANS	
	IP (n = 741)	OP (n = 375)	IP (n = 741)	OP (n = 375)
Any CRS or ICANS event, n (%)	386 (52)	183 (49)	209 (28)	88 (23)
Median (IQR) time to onset, days	4 (3–6)	4 (3–6)	7 (4–9)	7 (6–10)
Median (IQR) duration, days	4 (2–6)	3 (2–5)	5 (2–10)	5 (2–9)
Patients who received treatment/patients with event, n/N (%)	278/386 (72)	145/183 (79)	181/209 (87)[a]	80/88 (91)
Treatment, n (%)				
Tocilizumab alone	147 (53)	77 (53)	4 (2)	2 (2.5)
Corticosteroids alone	8 (3)	12 (8)	80 (44)	35 (44)
Tocilizumab + corticosteroids	111 (40)	55 (38)	17 (9)	4 (0.5)
Siltuximab	6 (2)	0	1 (1)	0
Tocilizumab + corticosteroids + other	4 (1)	1 (1)	1 (1)	1 (1)
Antiepileptics ± other	0	0	67 (37)	36 (45)
Other	2 (1)	0	8 (4)	1 (1)

All percentages are rounded to whole numbers except those with ".5%".
[a]Three patients were reported to have received therapy for ICANS, but no specific therapy name was provided.

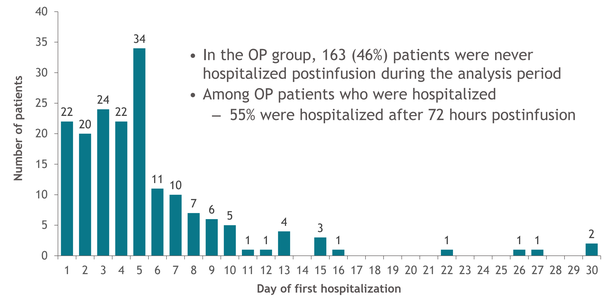
- The proportions of patients with HGBCL, ≥ 2 extranodal involvement sites, and secondary CNS involvement were similar for the IP and OP groups, respectively; in contrast, 48% vs 37% of patients in the IP vs OP groups, respectively, had elevated LDH before infusion and 10% vs 3% had ECOG PS ≥ 2 (**Table 1**)
- Median study follow-up was 12.7 months (95% CI,12.5–13.0) in the IP group and 12.6 months (95% CI, 12.4–12.8) in the OP group
- The overall incidences of CRS and ICANS events were similar between settings; most CRS and ICANS events were low grade with similar times to onset and duration (**Figure 2**, **Table 2**)
- Incidences of clinically significant infections were also similar between settings; most were viral or bacterial in both settings
- A total of 20 hematological SPMs were reported (IP, n = 13; OP, n = 7)
- Incidences of other AEs of special interest were low
- The most common cause of death was recurrence or progression of primary disease in both groups (**Table 3**)

Table 3. Deaths and NRM[a] rates

	IP (n = 741)	OP (n = 375)
Deaths, n (%)	274 (37)	111 (30)
Recurrence/Progression	183 (25)	78 (21)
12-month incidence of NRM (95% CI)	7.1 (5.2–9.4)	4.1 (2.2–6.8)
12-month cumulative incidence of relapse or progression (95% CI)	44.0 (40.1–47.8)	39.9 (34.5–45.2)

[a]Defined as death before disease progression/relapse.

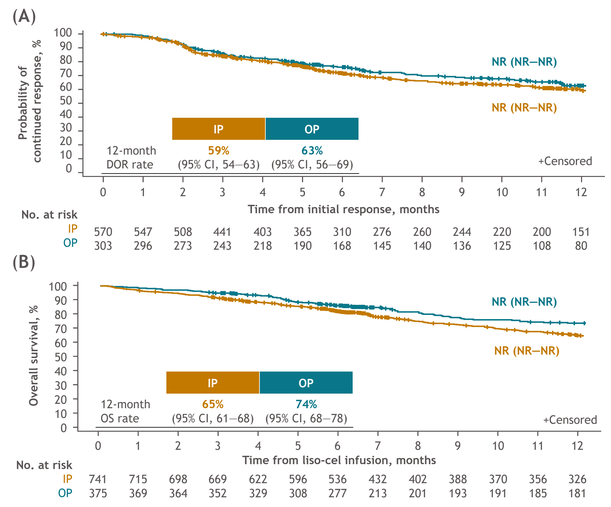
Figure 4. Hospitalization by day postinfusion in the OP group



Day 1 is the day of infusion. Eighteen patients in the OP group did not have postinfusion hospitalization data reported. After 30 days, an additional 18 patients were hospitalized (4 patients on Day 34 and 1 patient each on Days 39, 42, 47, 49, 60, 69, 70, 75, 86, 92, 95, 102, 107, and 524).

- Among OP patients who were hospitalized, median (IQR) time from infusion to hospitalization was 5 days (3–8) and median (IQR) duration of stay was 5 days (3–9) (**Figure 4**)

Figure 5. (A) Duration of response (B) and overall survival



Data reported within KM curves are median (95% CI).

- High response rates and sustained PFS were achieved with liso-cel in the IP and OP settings (**Figure 3**)
- At ~12 months of follow-up, median DOR and OS were not reached in both groups; 12-month rates were consistent in both treatment settings (**Figure 5**)

Conclusions

- These results reinforce that one-time infusion of liso-cel provides deep and durable efficacy in routine clinical practice, including IP and OP care settings, across a broad population of patients with R/R LBCL
- Despite the few differences in baseline characteristics, outcomes were consistent among patients treated in the IP and OP care settings
  – Rates of CRS and ICANS were similar, and most events were low grade
  – Response and survival rates were high with median DOR not reached after ~12 months of follow-up in both groups and 12-month OS rates of 65% in the IP and 74% in the OP group
- The well-established safety profile of liso-cel is conducive to OP treatment, allowing ~50% of patients to remain out of the hospital postinfusion
- These data highlight the feasibility of liso-cel use in the OP setting for eligible patients with R/R LBCL in routine clinical practice

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