Outcomes of Lisocabtagene Maraleucel in Patients with Relapsed or Refractory Mantle Cell Lymphoma: First Real-World Data From the CIBMTR

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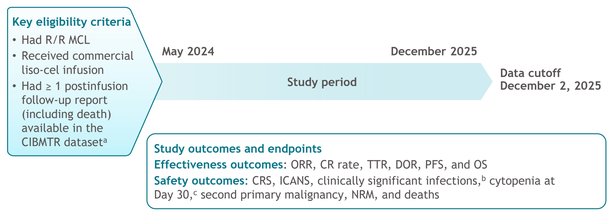
Background

- Lisocabtagene maraleucel (liso-cel) is an autologous, CD19-directed CAR T cell product that is currently approved by the FDA and EMA to treat R/R MCL after ≥ 2 prior lines of systemic therapy, including a Bruton tyrosine kinase inhibitor (BTKi)[1,2]
- Liso-cel demonstrated deep responses and durable disease control with manageable safety in patients with R/R MCL in the MCL cohort of TRANSCEND NHL 001 (TRANSCEND MCL) (NCT02631044)[3]
  - Response rates were high with an ORR of 83%, a CR rate of 72%, and a median duration of response (DOR) of 15.7 months in the efficacy set
  - The incidences of grade ≥ 3 cytokine release syndrome (CRS) (1%) and neurological events (NE) (9%) were low
- Here, we present the first report of real-world effectiveness and safety using Center for International Blood and Marrow Transplant Research (CIBMTR) data in patients with R/R MCL who received liso-cel after a median follow-up of 6 months

Methods

Figure 1. Study design

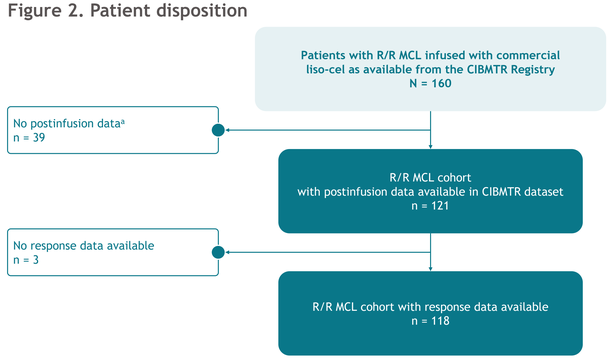


[a]Postinfusion data were collected at Day 100, Month 6, and annually thereafter; [b]Any infection requiring treatment with certain exceptions as noted in the CIBMTR Forms Instruction Manual[4]; [c]Grade 4 thrombocytopenia and/or neutropenia persistent at Day 30 after infusion; [d]The median duration of follow-up was estimated using the reverse KM method.
ICANS, immune effector cell–associated neurotoxicity syndrome; NRM, nonrelapse mortality; TTR, time to response.

- This retrospective, observational study included patients in the United States with R/R MCL who received commercial liso-cel between May 2024 and December 2025, with ≥ 1 postinfusion follow-up reported to CIBMTR (**Figure 1**)

Results

Figure 2. Patient disposition

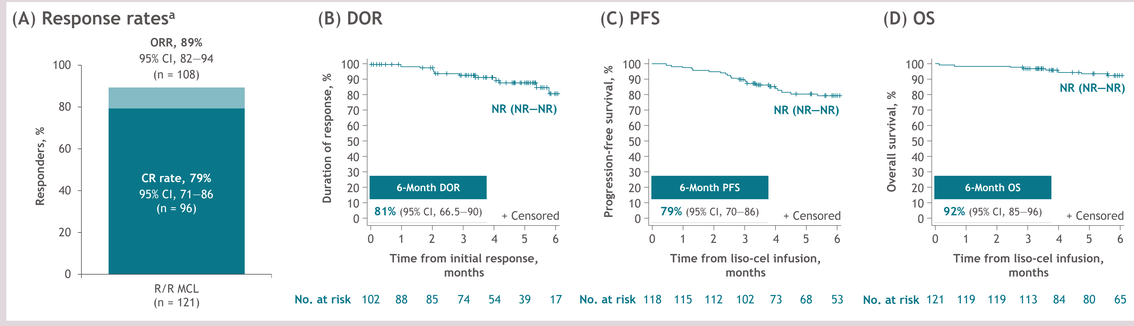


[a]Only patients with available 100-day post–liso-cel follow-up were included; baseline-only records were excluded as patient infusion status was known, but no additional data was available. Deaths ≤ 100 days are included when captured in follow-up.

- A total of 121 patients with R/R MCL who were infused with commercial liso-cel and had postinfusion assessment were eligible (**Figure 2**)

In real-world clinical practice, one-time infusion with liso-cel demonstrated deep responses and high rates of durability, PFS, and OS at 6 months in a broad population of patients with R/R MCL, consistent with clinical outcomes from TRANSCEND MCL

Figure 3. (A) Response rates, (B) DOR, (C) PFS, and (D) OS



Data reported within KM curves are median (95% CI). Median on-study follow-up of 6 months (95% CI, 5.9—6.2).
[a]ORR and CR rate are based on best overall response; calculations included all patients with postinfusion assessment; patients with best overall response "not assessed" or "not provided" (missing) were considered nonresponders when relapse, progression, or death was reported within 90 days after CAR T cell infusion. The 3 patients with no response data available were included in the computation of ORR/CR rate because they died within 90 days postinfusion (2 patients had recurrence/persistence/progression of primary disease for which CAR T cell therapy was given and 1 patient had pulmonary failure).
NR, not reached.

- High response rates were achieved with liso-cel in this real-world cohort of patients with R/R MCL (**Figure 3A**)
  - Rates of response were similar among patients who would have been ineligible for TRANSCEND MCL (53%, n = 64) with an ORR of 86% (95% CI, 75—93) and CR rate of 75% (95% CI, 63—85)
- At 6 months, the rate of continued response was 81%, and 6-month rates of PFS and OS were 79% and 92%, respectively (**Figure 3B—D**)

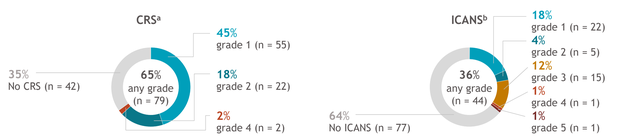
Table 1. Baseline demographics and disease characteristics

	R/R MCL (N = 121)
Median (range) age at infusion, y	71 (46—85)
≥ 65 y, n (%)	87 (72)
Male, n (%)	88 (73)
Race, n (%)	
White	103 (85)
Black/Asian/Not reported	9 (7)/4 (3)/5 (4)
Hispanic or Latino, n/N (%)	5/117 (4)
ECOG PS before infusion, n/N (%)	
0—1	113/119 (95)
≥ 2	6/119 (5)
Bulky disease (largest nodal mass > 10 cm), n/N (%)	10/78 (13)
Extranodal involvement before infusion, n (%)	59/113 (52)
≥ 2 extranodal sites involved	37 (31)
CNS involvement	5 (4)
Bone marrow involvement	8 (7)
GI involvement	5 (4)
Elevated LDH before infusion, n/N (%)[a]	41/119 (34)
Received bridging therapy, n/N (%)	87/120 (72.5)
Patients with ≥ 1 comorbidity, n/N (%)[b]	67/102 (66)
Cardiac/Cerebrovascular/Heart valve disease[c]	31/102 (30)
Pulmonary (moderate/severe)[c]	31/102 (30)
Obesity[c]	18/102 (18)
Renal (moderate/severe)[c]	7/102 (7)
***TP53* deletion at diagnosis (by FISH), n/N (%)**	5/29 (17)
Disease status at time of infusion, n/N (%)[c]	
Refractory	80/117 (68)
Relapsed	37/117 (32)
Median (range) number of prior lines of therapy	4 (2—12)
BTKi, n (%)	118 (98)
Covalent BTKi	115 (95)
Noncovalent BTKi	69 (57)
BCL2i, n (%)	32 (26)
HSCT, n (%)	27 (22)
Outpatient infusion, n (%)	47 (39)
Median (IQR) time from leukapheresis to infusion, days	36 (33—40)

For data reported as n/N, denominators represent patients with data available. All percentages are rounded to whole numbers except those with ".5%".
[a]The most recent LDH value was obtained immediately prior to the start of lymphodepleting therapy; [b]Collected based on criteria from the Hematopoietic Cell Transplantation-Comorbidity Index which identifies comorbidities relevant to transplant; [c]Most common comorbidities in > 5% of patients; [d]Determined using the CIBMTR variable "Disease status at CT," which is categorized as either "Refractory" or "Relapse."
BCL2i, B-cell lymphoma 2 inhibitor; FISH, fluorescence in situ hybridization; GI, gastrointestinal.

- Of the 121 patients included in the study, the median age was 71 years, and 66% had ≥ 1 clinically significant comorbidity (**Table 1**)
- Bulky disease (largest nodal mass > 10 cm) was observed in 13% of patients, and 31% had ≥ 2 extranodal sites involved; data on *TP53* mutation status was limited (**Table 1**)
- The median number of prior lines of therapy was 4, 72.5% received bridging therapy, and 39% had outpatient infusion (**Table 1**)

Figure 4. Incidence of CRS and ICANS



	R/R MCL (N = 121)	
	CRS	ICANS
Median (IQR) time to onset, days	4.0 (3.0—6.0)	7.0 (5.0—9.5)
Median (IQR) duration, days	3.0 (2.0—5.0)	4.5 (2.0—8.5)
Patients who received treatment/patients with event, n/N (%)	62/79 (78)	37/44 (84)
Treatments, n (%)		
Tocilizumab alone	30 (48)	1 (3)
Corticosteroids alone	1 (2)	16 (43)
Tocilizumab + corticosteroids only	26 (42)	3 (8)
Tocilizumab + corticosteroids + other	2 (3)	3 (8)
Corticosteroids + anakinra only	0	7 (19)
Other	3 (5)	7 (19)

[a]CRS was graded based on Lee 2014 criteria[5]; no grade 3 or 5 CRS events were reported; [b]One patient had grade 5 ICANS with disease persistence/progression as the primary cause of death and ICANS as a contributing cause.

- The safety profile was consistent with TRANSCEND MCL with 2 patients with grade 4 CRS (2%), no grade 5 CRS events, and low rates of grade ≥ 3 ICANS (14%) (**Figure 4**)
- There was 1 patient with grade 5 ICANS whose primary cause of death was reported as disease persistence/progression and ICANS as a contributing cause
- Median time from infusion to onset of CRS and ICANS was 4 days and 7 days, respectively
- The safety profile for patients infused in the outpatient setting (n = 47) was similar to safety in the overall population; any grade CRS occurred in 60% (no grade 3) and any grade ICANS occurred in 28% (grade 3, 11%) with no grade 4 or 5 CRS or ICANS events
- Of the 47 patients infused in the outpatient setting, 28 (60%) were hospitalized, with median (range) time to hospitalization of 5.5 days (1—51) after infusion, and median (range) duration of hospital stay of 5 days (1—32)

Table 2. Other AEs of special interest

	R/R MCL (N = 121)
Cytopenia at Day 30, n (%)[a]	21 (17)
Median (range) time to platelet/neutrophil recovery, days[b]	47 (32—187)
Clinically significant infection,[c] n (%)	29 (24)
Second primary malignancy, n (%)	8 (7)
Basal cell skin malignancy	3 (2)
Squamous cell skin malignancy	2 (2)
Breast cancer	1 (1)
Clonal cytogenetic abnormality without leukemia or myelodysplastic syndromes	1 (1)
Genitourinary malignancy	1 (1)
Grade 3/4 organ toxicity,[d] n (%)	1 (1)
Tumor lysis syndrome, n (%)	2 (2)
MAS/HLH, n (%)	0

[a]Grade 4 thrombocytopenia and/or neutropenia persistent at 30 days after infusion; [b]Defined as the later of the 2 recovery dates (platelet or neutrophil) for patients with prolonged cytopenia; [c]Any infection requiring treatment with certain exceptions as noted in the CIBMTR Forms Instruction Manual.[4] Included bacterial (17%), viral (9%), other (5%), and fungal (3%); "Other" reflects infections not captured in the predefined list in the CIBMTR form; [d]One patient had grade 4 organ toxicity (lung) and grade 4 organ toxicity (other organ, not specified) that started on day 42.
HLH, hemophagocytic lymphohistiocytosis; MAS, macrophage activation syndrome.

- The incidence of cytopenia at Day 30 was low (17%) (**Table 2**)
- Clinically significant infections occurred in 24% of patients; bacterial infection was the most common (17%) followed by viral (9%), other (5%), and fungal infection (3%)

Table 3. Deaths and NRM

	R/R MCL (N = 121)
Deaths, n (%)	14 (12)
Causes of death, n (%)	
Disease persistence/progression	10 (8)
Pulmonary failure	1 (1)
Septic shock	1 (1)
Traumatic subdural hemorrhage	1 (1)
Cause not provided	1 (1)
6-Month NRM rate, % (95% CI)	2 (0—5.5)
6-Month cumulative incidence of relapse or progression, % (95% CI)	19 (12—27)

NRM was defined as any death occurring before relapse/recurrence of the primary disease.

- Fourteen (12%) patients died, with most deaths due to disease persistence/progression (8%); the 6-month NRM rate was low (2%) (**Table 3**)

Conclusions

- These real-world results demonstrate that liso-cel achieves high response rates with encouraging early efficacy in a broad population of patients with R/R MCL, with outcomes consistent with the pivotal clinical trial
  - High response rates were observed with liso-cel in the real-world setting (ORR, 89%; CR rate, 79%) including in patients who would have been ineligible for TRANSCEND MCL (ORR, 86%; CR rate, 75%) consistent with clinical trial outcomes
  - At a median follow-up of 6 months, early benefits were observed with high 6-month rates of DOR, PFS, and OS
  - The safety profile was consistent with TRANSCEND MCL with predominantly low-grade CRS and ICANS and low incidences of cytopenia at Day 30 and infections
  - For patients who received outpatient infusion of liso-cel, safety was similar compared with the overall population with 40% not requiring any hospitalization
- Liso-cel represents an important treatment option for patients with R/R MCL, including patients with high-risk disease features who have limited treatment choices

References

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