Outcomes of Lisocabtagene Maraleucel in Patients With Relapsed or Refractory Chronic Lymphocytic Leukemia: First Real-World Data From the CIBMTR

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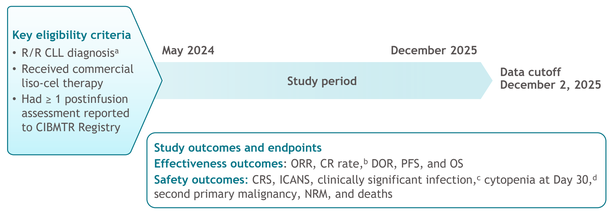
Background

- Lisocabtagene maraleucel (liso-cel), an autologous, CD19-directed CAR T cell product, has shown consistent efficacy across a broad population of patients with B-cell malignancies, including R/R CLL or SLL[1–7]
- In the pivotal TRANSCEND CLL 004 study (NCT03331198), liso-cel demonstrated promising efficacy (ORR, 48%; CR or CR with incomplete marrow recovery rate, 18%), durable responses (12-month duration of response [DOR] rate, 83.5%) and manageable safety (grade ≥ 3 cytokine release syndrome [CRS], 9%; grade ≥ 3 neurological events, 19%) in patients with third-line or later R/R CLL/SLL after disease progression on a previous Bruton tyrosine kinase inhibitor (BTKi), including those previously exposed to a B-cell lymphoma 2 inhibitor (BCL2i)[5]
- Here, we present the first real-world report of effectiveness and safety of commercial liso-cel in patients with R/R CLL based on data collected in the Center for International Blood and Marrow Transplant Research (CIBMTR) Registry

Methods

Figure 1. Study design

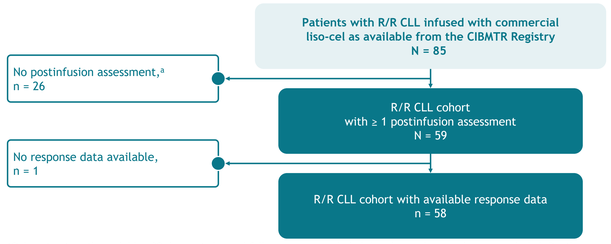


[a]CIBMTR collected data for patients with R/R CLL or SLL treated with commercial liso-cel; distinction between the proportions of patients with CLL versus SLL was not possible in the dataset; [b]CR was determined according to iwCLL criteria[8]; [c]Any infection requiring treatment with certain exceptions as noted in the CIBMTR Forms Instruction Manual[9]; [d]Grade 4 thrombocytopenia and/or neutropenia persistent at Day 30 after infusion; [e]The median duration of follow-up was estimated using the reverse KM method.
ICANS, immune effector cell—associated neurotoxicity syndrome; iwCLL, International Workshop on Chronic Lymphocytic Leukemia; NRM, nonrelapse mortality.

- This was an observational study of US patients with R/R CLL in the CIBMTR Registry who received commercial liso-cel between May 2024 and December 2025 (**Figure 1**)
- The CIBMTR Registry collects long-term effectiveness and safety data from recipients of cellular immunotherapies and is the largest source of patient outcome data for CAR T cell therapies

Results

Figure 2. Patient disposition



[a]Only patients with available 100-day post—liso-cel follow-up were included; baseline-only records were excluded. Deaths ≤ 100 days are included when captured in follow-up.

- A total of 59 patients with R/R CLL were infused with commercial liso-cel and had ≥ 1 postinfusion assessment available; 58 were response-evaluable (**Figure 2**)

One-time infusion with liso-cel demonstrated deep responses and high rates of durability, PFS, and OS at 6 months in real-world clinical practice among patients with R/R CLL

Figure 3. Response rates

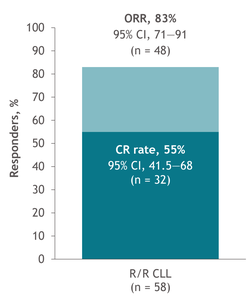
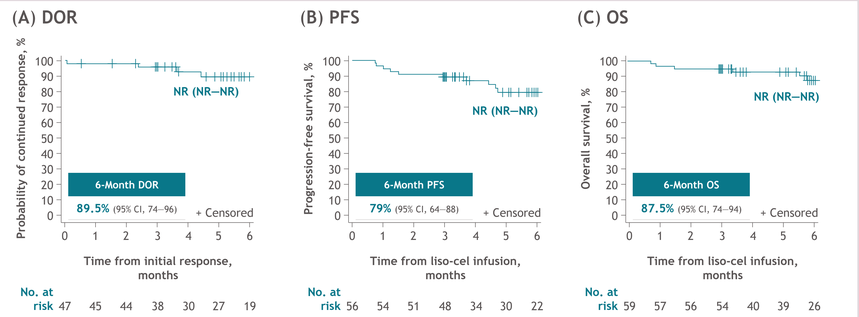


Figure 4. Time to event outcomes: (A) DOR, (B) PFS, and (C) OS



Data reported within KM curves are median (95% CI).
NR, not reached.

- Of the 22 patients who achieved CR and had measurable residual disease (MRD) data reported, 18 (82%) were MRD negative
- Among responders (n = 48), the 6-month estimated probability of continued response was 89.5% (**Figure 4A**)
- Liso-cel demonstrated promising durability and high survival rates; 6-month PFS and OS estimates were 79% and 87.5%, respectively (**Figure 4B** and **4C**)

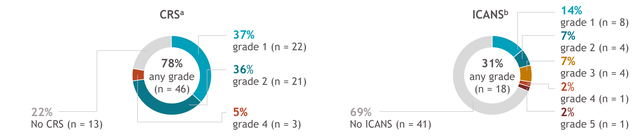
Table 1. Baseline clinical and disease characteristics

	R/R CLL (N = 59)
Median (range) age, y	63 (43—88)
≥ 65 y, n (%)	29 (49)
Male, n (%)	41 (69)
Active disease at time of infusion,[a] n/N (%)	45/48 (94)
Elevated LDH before infusion, n/N (%)	20/57 (35)
IGHV unmutated, n (%)	52 (88)
CNS involvement before infusion, n/N (%)	3/57 (5)
ECOG PS 0—1 before infusion, n/N (%)	56/57 (98)
Patients with ≥ 1 comorbidity, n/N (%)	32/49 (65)
Most common comorbidities,[b] n/N (%)	
Pulmonary (moderate or severe)	13/49 (27)
Cardiac/Cerebrovascular/Heart valve disease	12/49 (24)
Median (range) number of prior lines of therapy	6 (1—10)
Prior HSCT, n (%)	
Allogeneic	0
Autologous	2 (3)
Prior therapy, n (%)	
Anti-CD20—targeted agent	56 (95)
Covalent BTKi[c]	55 (93)
Noncovalent BTKi (pirtobrutinib)	32 (54)
BCL2i (venetoclax)	57 (97)
Covalent BTKi and BCL2i	54 (92)
Received bridging therapy, n/N (%)	30/55 (55)
Outpatient infusion,[d] n (%)	26 (44)

For data reported as n/N, denominators represent patients with data available.
[a]Patients not in CR at the time of liso-cel infusion; [b]Comorbidities occurring in ≥ 10% of patients reported; [c]Covalent BTKis included ibrutinib (n = 46), acalabrutinib (n = 17), and zanubrutinib (n = 6); [d]Of the 26 patients infused in the outpatient setting, 11 (42%) were not hospitalized after infusion.
HSCT, hematopoietic stem cell transplantation; IGHV, immunoglobulin heavy-chain variable region.

- Of the 59 real-world patients included, the median age was 63 years (range, 43—88) and 49% were ≥ 65 years of age at infusion (**Table 1**)
- Elevated LDH was reported for 35% (20/57) of patients and unmutated IGHV was observed in 88%
- Patients had a median of 6 previous lines of therapy, including covalent and noncovalent BTKis (93% and 54%, respectively); 92% reported double exposure to a covalent BTKi and BCL2i

Figure 5. Incidence of CRS and ICANS



	R/R CLL (N = 59)	
	CRS	ICANS
Median (IQR) time to onset, days	3 (1—6)	9 (8—12)
Median (IQR) duration, days	6.5 (3.5—9)	5 (3—10)
Patients who received treatment/patients with event, n/N (%)	42/46 (91)	17/18 (94)
Treatments, n (%)		
Tocilizumab alone	15 (36)	2 (12)
Corticosteroids alone	2 (5)	5 (29)
Tocilizumab + corticosteroids	15 (36)	1 (6)
Tocilizumab + corticosteroids + other	7 (17)	0
Other	3 (7)[c]	9 (53)[d]

[a]CRS was graded based on Lee 2014 criteria[10]; no grade 3 or 5 CRS events were reported; [b]Summed percentages for grouped grades within each graph may not equal the any-grade percentage due to rounding; 1 patient had grade 5 ICANS with chest wall hematoma as the primary cause of death along with multiple contributing causes including ICANS; [c]Included anakinra with (n = 1) or without tocilizumab (n = 1) and corticosteroids pulse dose with tocilizumab (n = 1); [d]Included anakinra with corticosteroids (n = 3); antiepileptics with corticosteroids (n = 2); anakinra, corticosteroids, corticosteroids pulse dose with (n = 1) or without other drug (n = 1); corticosteroids and siltuximab with (n = 1) or without anakinra (n = 1).

- Any-grade CRS occurred in 78% of patients and most events were grade 1 or 2 (93% [43/46]); 3 patients experienced grade 4 events and no patients experienced grade 3 or 5 CRS events (**Figure 5**)
- Any-grade ICANS occurred in 31% of patients and most events were grade 1 or 2 (67% [12/18]); grade ≥ 3 ICANS events were experienced by 6 patients
- There was 1 patient with grade 5 ICANS whose primary cause of death was reported as chest wall hematoma along with multiple contributing causes of hypofibrinogenemia, thrombocytopenia, and ICANS
- The most common treatment patients received for CRS and ICANS was tocilizumab with or without corticosteroids (36% of patients each) and corticosteroids alone (29%), respectively

Table 2. Other AEs of special interest

	R/R CLL (N = 59)
Cytopenia at Day 30,[a] n (%)	9 (15)
MAS/HLH, n (%)	6 (10)
Clinically significant infection,[b] n (%)	26 (44)
Bacterial	12 (20)
Viral	12 (20)
Fungal	2 (3)
Other	5 (8)
Second primary malignancy,[c] n (%)	2 (3)
Grade 3/4 organ toxicity, n (%)	5 (8)
Tumor lysis syndrome, n (%)	4 (7)

[a]Grade 4 thrombocytopenia and/or neutropenia persistent at 30 days after infusion; 2 patients died before Day 30; [b]Any infection requiring treatment, with certain exceptions as noted in the CIBMTR Forms Instruction Manual[9]; [c]Included 2 patients with basal cell carcinoma on Days 34 and 362 after infusion, respectively.
HLH, hemophagocytic lymphohistiocytosis; MAS, macrophage activation syndrome.

- Incidence of cytopenia at Day 30 was generally low, occurring in 15% of patients (**Table 2**)
- Bacterial and viral infections were the most common AEs of special interest reported (20% of patients each)

Table 3. Deaths and NRM

	R/R CLL (N = 59)
Deaths, n (%)	6 (10)
Causes of death, n (%)	
Disease persistence/progression	3 (5)
Infection[a]	2 (3)
Other[b]	1 (2)
6-Month NRM rate, % (95% CI)	4 (1—11)
6-Month cumulative incidence of relapse or progression, % (95% CI)	17 (8—30)

NRM was defined as any death occurring before relapse/recurrence of the primary disease.
[a]Included 1 patient with bacterial and fungal infection, and 1 patient with septic shock secondary to MRSA infection; [b]Multiple causes of death reported, including chest wall hematoma.
MRSA, methicillin-resistant *Staphylococcus aureus*.

- The most common cause of death was disease persistence/progression (**Table 3**)
- The 6-month cumulative NRM rate was 4%

Conclusions

- In the real-world setting, one-time infusion with liso-cel achieves deep responses, and high rates of durability and survival at 6 months in patients with R/R CLL
  - ORR was 83% and 55% of patients achieved CR
  - While the median DOR, PFS, and OS were not reached, estimated probabilities of DOR, PFS, and OS at 6 months were 89.5%, 79%, and 87.5%, respectively
- The safety profile of liso-cel was manageable and consistent with the TRANSCEND CLL 004 study
  - The majority of CRS and ICANS events were grade 1 or 2; cytopenia at Day 30 and infections were the most common other AEs of interest reported (15% and 44% of patients, respectively)
- These real-world data support the use of liso-cel as an effective option for a broad population of patients with R/R CLL, including those with high-risk disease features

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