Patients With Large B-Cell Lymphoma Who Achieve Complete Response With Lisocabtagene Maraleucel Have Durable Remissions: Data From Real-World and Clinical Trial Settings

CT-410

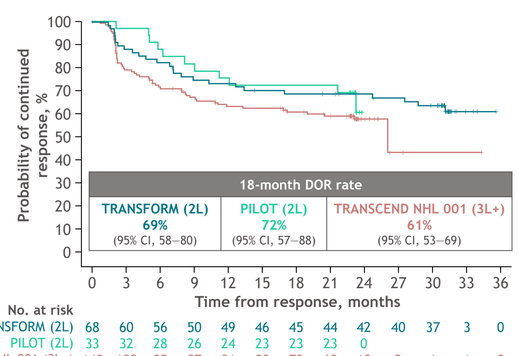
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Liso-cel-treated patients with R/R LBCL who achieve CR experience durable remissions and long-term survival benefits across clinical trial and real-world settings

Figure 2. DOR in liso-cel—treated patients with R/R LBCL who achieve CR in:

(A) Clinical trial setting



(B) Real-world setting

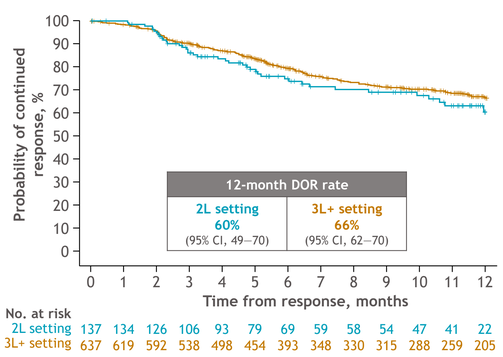
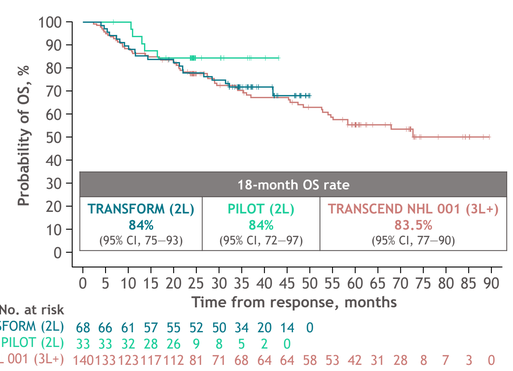
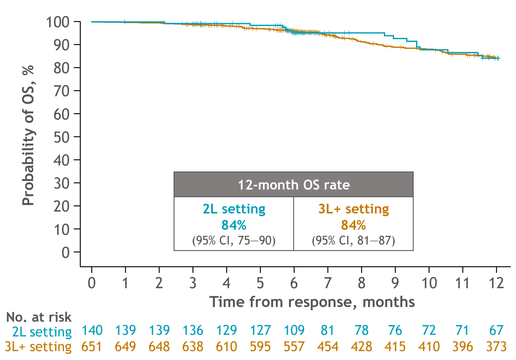


Figure 3. OS in liso-cel—treated patients with R/R LBCL who achieve CR in:

(A) Clinical trial setting



(B) Real-world setting



- In clinical trials, median (range) on-study follow-up was 33.9 months (0.9—53.0) for TRANSFORM, 18.2 months (1.2—47.0) for PILOT, and 20.3 months (0.2—89.4) for TRANSCEND NHL 001
- In the real-world setting, median (95% CI) on-study follow-up was 12.25 months (7.6—12.35) for 2L and 12.8 months (12.6—13.0) for 3L+ setting patients

Background

- In patients with R/R large B-cell lymphoma (LBCL), achieving and maintaining CR after CAR T cell therapy is a potential surrogate for long-term efficacy[1]
- Lisocabtagene maraleucel (liso-cel) is an autologous, CD19-directed, 4-1BB CAR T cell product that has shown favorable efficacy with manageable safety in clinical trials across B-cell malignancies, including R/R LBCL, CLL/SLL, FL, and MCL[2–7]
- In LBCL, liso-cel is approved by the FDA for use as second-line (2L) treatment in patients with disease refractory to or who relapsed within 12 months of first-line chemoimmunotherapy based on the TRANSFORM (NCT03575351) study,[2] as 2L treatment in patients not intended for HSCT based on the PILOT (NCT03483103) study,[3] and as third-line or later (3L+) treatment based on results from the TRANSCEND NHL 001 (NCT02631044) study[4]
- Here, we report time-dependent efficacy outcomes for liso-cel—treated patients with R/R LBCL who achieved CR in clinical trial and real-world (standard of care) settings

Methods

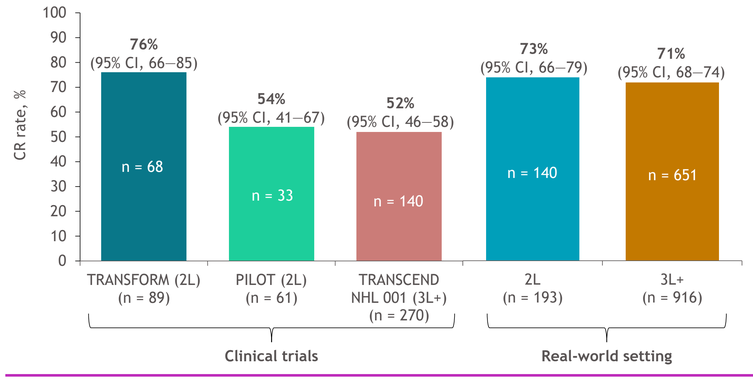
Study design

- Analyses included:
  - Liso-cel—treated patients with R/R LBCL from the TRANSFORM (data cutoff, 12/13/2023), PILOT (data cutoff, 12/01/2022), and TRANSCEND NHL 001 (data cutoff, 05/16/2024) clinical trials
  - Patients who received commercial liso-cel in the real-world setting as 2L or 3L+ treatment for R/R LBCL with ≥1 assessment for effectiveness and safety after infusion in the Center for International Blood and Marrow Transplant Research (CIBMTR) Registry between 02/05/2021—02/04/2025
- Informed consent was obtained in clinical trials and by the CIBMTR Registry
- Response assessments for patients in clinical trials were by independent review committee assessment based on Lugano 2014 criteria[8]; response assessments for patients treated with liso-cel in the real-world setting were as reported by treating physicians to the CIBMTR Registry
- Time-dependent efficacy outcomes assessed in patients with CR were duration of response (DOR) and OS
  - DOR was defined as time from first response (CR/PR) after liso-cel infusion to disease progression, or death (PILOT, TRANSCEND NHL 001, TRANSFORM) or additionally until start of new antineoplastic therapy due to efficacy concerns (TRANSFORM), whichever occurred first, in clinical trials and as time from initial response (continued CR [patients already in CR at the start of the preparative regimen]/CR/PR) to relapse, progression, or death for patients treated in the real-world setting
  - OS was defined as the time from liso-cel infusion to death from any cause for clinical trials, and as the time from infusion to death or last follow-up for the real-world setting
- Safety outcomes included the AEs of special interest as cytokine release syndrome (CRS), neurological events (NE)/immune effector cell—associated neurotoxicity syndrome (ICANS), grade ≥3 infections/clinically significant infections, second primary malignancies, and prolonged cytopenia

Results

Patients

Figure 1. CR rates in patients treated with liso-cel in clinical trial and real-world settings



Results

- CR rates were similar in liso-cel—treated patients from clinical trial and real-world settings (**Figure 1**)
  - In clinical trials, 76% of patients in TRANSFORM, 54% of patients in PILOT, and 52% of patients in TRANSCEND NHL 001 achieved CR
  - Similarly, in the real-world setting, 73% of 2L patients and 71% of 3L+ patients achieved CR

Table 1. Demographics and baseline characteristics in patients with CR

	Clinical trials			Real-world setting	
	TRANSFORM (2L) (n = 68)	PILOT (2L) (n = 33)	TRANSCEND NHL 001 (3L+) (n = 140)	2L (n = 140)	3L+ (n = 651)
Median (range) age, y	60 (20—74)	73 (55—84)	63.5 (20—81)	72 (27—85)	71 (21.5—91)
≥ 65 y, n (%)	25 (37)	30 (91)	66 (47)	102 (73)	478 (73)
Male, n (%)	29 (43)	22 (67)	88 (63)	78 (56)	368 (57)
ECOG PS, n (%)[a]					
0—1	68 (100)	25 (76)	139 (99)	119 (85)	535 (82)
≥ 2	0	8 (24)	1 (1)	6 (4)	35 (5)
Not reported/unknown	0	0	0	15 (11)	81 (12)
Disease indication/histology, n (%)					
DLBCL	45 (66)	25 (76)	108 (77)	117 (84)	526 (81)
DLBCL NOS	39 (57)	20 (61)	65 (46)	115 (82)	512 (79)
DLBCL transformed	6 (9)	5 (15)	43 (31)	26 (19)	158 (24)
HGBCL	13 (19)	7 (21)	20 (14)	17 (12)	81 (12)
PMBCL	8 (12)	0	8 (6)	3 (2)	5 (1)
FL3B	1 (1)	1 (3)	4 (3)	0	9 (1)
Other B-cell lymphoma	1 (1)	0	0	3 (2)	29 (4)
Not reported/unknown	0	0	0	0	1 (< 1)
Relapsed disease, n (%)	22 (32)	19 (58)	NA	73 (52)[b]	NA
Primary refractory disease, n (%)	46 (68)	14 (42)	NA	66 (47)[b]	NA
Chemotherapy refractory disease, n (%)	NA	NA	94 (67)	NA	NA
Received prior HSCT, n (%)	NA	NA	54 (39)	0	110 (17)
Autologous	NA	NA	54 (39)	0	102 (16)
Allogeneic	NA	NA	0	0	5 (1)
Not provided	NA	NA	0	0	3 (< 1)
Median (range) number of lines of prior systemic therapy[c]	NA	NA	2 (1—8)	2 (1—2)	3 (0—13)
Secondary CNS lymphoma, n (%)	1 (1)	0	4 (3)	3 (2)	27 (4)
Received bridging therapy, n (%)	43 (63)	16 (48)	69 (49)	100 (71)	362 (56)[d]

[a]At infusion for patients treated in the real-world setting and at screening for patients treated in clinical trials; [b]Relapsed versus refractory disease status data were missing for 1 patient; [c]Prior lines of therapy included bridging therapies for patients treated in the real-world setting; [d]History of bridging therapy was NA for 24 (4%) patients. FL3B, follicular lymphoma grade 3B; HGBCL, high-grade B-cell lymphoma; NA, not available; PMBCL, primary mediastinal large B-cell lymphoma.

- Demographics and baseline characteristics are reported in **Table 1**

Efficacy

Table 2. Time to event outcomes in patients with CR from clinical trials

	TRANSFORM (2L) (n = 68)	PILOT (2L) (n = 33)	TRANSCEND NHL 001 (3L+) (n = 140)
Median (95% CI) DOR,[a] months	NR (31.05—NR)	NR (21.65—NR)	26.05 (23.1—NR)
DOR rate, % (95% CI)[b]			
6 months	82 (73—91)	88 (77—99)	71 (63—78.5)
18 months	69 (58—80)	72 (57—88)	61 (53—69)
24 months	69 (58—80)	NA	58 (49—66)
Median (95% CI) OS,[a] months	NR (NR—NR)	NR (NR—NR)	NR (53.9—NR)
OS rate, % (95% CI)[b]			
12 months	85 (77—94)	94 (85—100)	86 (81—92)
18 months	84 (75—93)	84 (72—97)	83.5 (77—90)
36 months	72 (61—83)	84 (72—97)	68 (60—77)

[a]Based on KM estimates; [b]Based on Greenwood's formula.
NR, not reached.

Table 3. Time to event outcomes in patients with CR from the real-world setting

	2L (n = 140)	3L+ (n = 651)
Median (95% CI) DOR,[a] months	NR (12.0—NR)	NR (NR—NR)
DOR rate, % (95% CI)[a]		
6 months	75 (66—82)	79 (76—82.5)
12 months	60 (49—70)	66 (62—70)
Median (95% CI) OS,[a] months	NR (NR—NR)	NR (NR—NR)
OS rate, % (95% CI)[a]		
6 months	95 (90—98)	96 (94—97)
12 months	84 (75—90)	84 (81—87)

[a]Based on KM estimates.

- Among patients with CR, responses were durable with 18-month DOR of 69%, 72%, and 61% in TRANSFORM, PILOT, and TRANSCEND NHL 001, respectively (**Figure 2, Table 2**) and 12-month DOR of 60% and 66% in patients with 2L and 3L+ LBCL, respectively, treated in the real-world setting (**Figure 2, Table 3**)
- In the real-world setting, 12-month DOR was similar whether patients were in CR prior to infusion (68%) or achieved CR only after infusion (65%)
- OS was similarly high in patients with CR across settings, with 18-month OS rates of 84%, 84%, and 83.5% in TRANSFORM, PILOT, and TRANSCEND NHL 001 (**Figure 3, Table 2**) and 12-month OS rates of 84% in patients with 2L and 3L+ LBCL treated in the real-world setting (**Figure 3, Table 3**)

Safety

Table 4. AEs of special interest in patients with CR

	Clinical trials[a]			Real-world setting	
	TRANSFORM (2L) (n = 68)	PILOT (2L) (n = 33)	TRANSCEND NHL 001 (3L+) (n = 140)	2L (n = 140)	3L+ (n = 651)
CRS, n (%)[b]	35 (51)	12 (36)	55 (39)	60 (43)	338 (52)
Grade 1	26 (38)	7 (21)	35 (25)	48 (34)	237 (36)
Grade 2	8 (12)	5 (15)	19 (14)	10 (7)	93 (14)
Grade 3	1 (1)	0	1 (1)	0	2 (< 1)
Grade 4	0	0	0	1 (1)	4 (1)
Grade 5	0	0	0	0	0
Not provided	0	0	0	1 (1)	2 (< 1)
NEs/ICANS, n (%)[c]	8 (12)	13 (39)	43 (31)	22 (16)	174 (27)
Grade 1	2 (3)	7 (21)	14 (10)	9 (6)	72 (11)
Grade 2	2 (3)	4 (12)	18 (13)	5 (4)	31 (5)
Grade 3	4 (6)	2 (6)	10 (7)	6 (4)	43 (7)
Grade 4	0	0	1 (1)	1 (1)	11 (2)
Grade 5	0	0	0	0	3 (< 1)
Under review	0	0	0	1 (1)	14 (2)
Grade ≥ 3 infections/clinically significant infections, n (%)[d]	9 (13)	0	16 (11)	42 (30)	294 (45)
Second primary malignancy, n (%)	1 (1)	0	3 (2)	8 (6)	47 (7)
Prolonged cytopenia, n (%)[e]	30 (44)	7 (21)	53 (38)	12 (9)	73 (11)

[a]Includes treatment-emergent AEs, defined as AEs that started any time from liso-cel administration to within 90 days after infusion (PILOT and TRANSCEND NHL 001) and AEs occurring or worsening on or after the date of randomization and within 90 days after liso-cel infusion or start of new antineoplastic therapy, whichever occurs first as well as those occurring anytime thereafter suspected of being related to study treatment (TRANSFORM); [b]CRS was graded according to Lee 2014 criteria[9]; [c]For clinical trials, NEs were defined as investigator-identified neurological AEs related to liso-cel; for patients treated in the real-world setting, grade data reflect the maximum ICANS grade at 100 days; [d]For infections data, grade ≥ 3 infections were reported for clinical trials and clinically significant infections, defined as any infection requiring treatment, were reported in the CIBMTR Registry for patients treated in the real-world setting; [e]Defined as grade ≥ 3 laboratory result of anemia, neutropenia, or thrombocytopenia not resolved at the Day 29 study visit after liso-cel infusion for clinical trials and as grade 4 thrombocytopenia and/or neutropenia persistent at 30 days after liso-cel infusion for patients treated in the real-world setting.

- Incidences of CRS and ICANS/NEs were generally consistent across LBCL indications in both clinical trial and real-world settings (**Table 4**)
- Incidences of prolonged cytopenia and serious infections were similar within treatment settings; however, comparisons between settings are limited by differences in reporting and definitions for these AEs
- Second primary malignancies were uncommon across settings

Conclusions

- Liso-cel—treated patients with R/R LBCL who achieve CR experienced durable remissions and long-term survival, with consistent results in both clinical trials and routine clinical practice
  - CR rates were similar in liso-cel—treated patients from clinical trial and real-world settings
  - Among patients with CR, responses were durable, and OS rates were similarly high
- Rates of grade ≥ 3 CRS and NEs/ICANS were low in both clinical trials and routine clinical practice
- These results demonstrate the sustained efficacy of liso-cel in patients who achieved CR in clinical trial and real-world settings, with a safety profile consistent with that established for liso-cel across indications

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