

CLINICAL TRIALS AND OBSERVATIONS

Five-year survival outcomes of lisocabtagene maraleucel in R/R LBCL from the TRANSCEND NHL 001 study

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KEY POINTS

- In 3L+ treatment of patients with R/R LBCL, liso-cel achieved 5-year OS of 38% and DSS of 52%.
- The durable long-term survival rates support the curative potential of liso-cel in patients with R/R LBCL.

We present 5-year survival results in patients with relapsed or refractory (R/R) large B-cell lymphoma (LBCL) from TRANSCEND NHL 001 (TRANSCEND), including data from the separate long-term follow-up (LTFU) study. Overall, 345 patients were leukapheresed and 270 received lisocabtagene maraleucel (liso-cel). Among 257 patients who were efficacy-evaluable, median overall survival (OS) was 27.5 months (95% confidence interval [CI], 16.2-47.3; leukapheresed set: 15.2 months; 95% CI, 11.5-23.4); estimated 5-year OS was 38% (95% CI, 32-45; leukapheresed set: 33%; 95% CI, 28-39). Median disease-specific survival (DSS; excludes deaths unrelated to disease progression) was 67.8 months (95% CI, 23.5 to not reached [NR]; leukapheresed set: 27.4 months; 95% CI, 14.4-69.7); estimated 5-year DSS was 52% (95% CI, 45-59; leukapheresed set: 47%; 95% CI, 41-52). Among patients from TRANSCEND who were efficacy-evaluable, alive at study completion, and enrolled in the LTFU (n = 84), median OS and DSS were NR (95% CI, NR to NR); estimated 5-year OS and DSS were 78% (95% CI, 67-86) and 92% (95% CI, 84-97), respectively. Most deaths occurred ≤2 years after infusion; no new safety signals were observed with low rates of late severe infections and second primary malignancies. These data support the curative potential of liso-cel in patients with R/R LBCL. This trial was registered at www.clinicaltrials.gov as NCT02631044 and NCT03435796.

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Introduction

In the pivotal TRANSCEND NHL 001 study (TRANSCEND; NCT02631044), the autologous, CD19-directed, 4-1BB chimeric antigen receptor (CAR) T-cell product lisocabtagene maraleucel (liso-cel) demonstrated an objective response rate (ORR) of 73% and a complete response (CR) rate of 53% with grade ≥3 cytokine release syndrome in 2% of patients and neurological events in 10% as third-line or later treatment in patients with relapsed or refractory (R/R) large B-cell lymphoma (LBCL).¹ In the 2-year follow-up of TRANSCEND, liso-cel showed durable remissions (median duration of response [DOR], 23.1 months; median overall survival [OS], 27.3 months)

and no new safety signals.² Here, we present 5-year survival results in the LBCL cohort of TRANSCEND, including data from the separate long-term follow-up (LTFU) study (NCT03435796).

Study design

Study design, participants, and procedures

TRANSCEND was a multicenter, multicohort, seamless design, pivotal study evaluating the efficacy and safety of liso-cel in patients with R/R LBCL after ≥2 previous lines of systemic treatment.¹ The study was conducted in accordance with the Declaration of Helsinki, the International Conference on Harmonisation Good Clinical Practice guidelines, and applicable

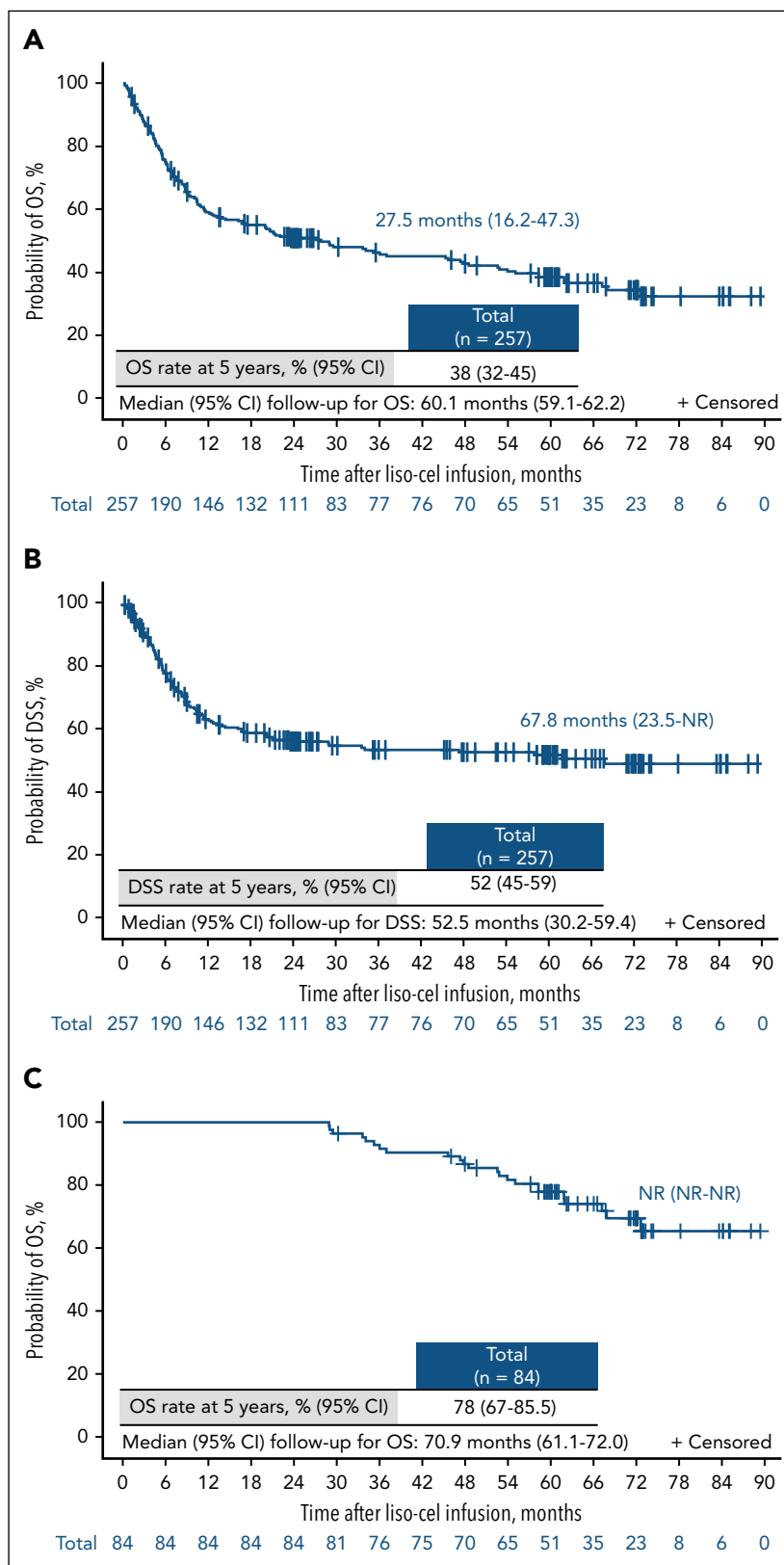


Figure 1. OS and DSS. (A-D) Kaplan-Meier estimates of OS (A) and DSS (B) in the total efficacy-evaluable set and OS (C) and DSS (D) in the efficacy-evaluable LTFU subset. Data on Kaplan-Meier curves are expressed as median (95% CI). For DSS, only deaths because of disease progression were considered events; all other deaths were censored. One additional patient was determined to have died because of PD after the data cutoff date and is not accounted for in the DSS Kaplan-Meier curves. PD, progressive disease.

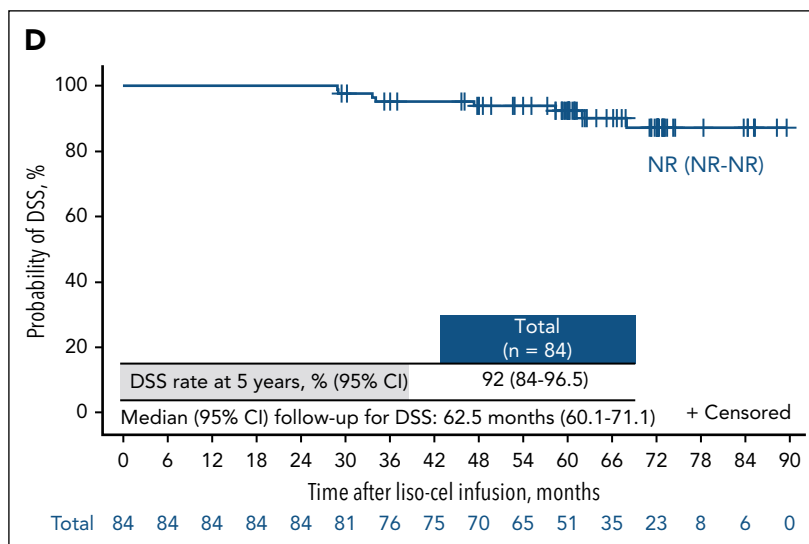


Figure 1 (continued)

regulatory requirements. The study protocol and amendments were approved by institutional review boards at participating sites. All patients provided written informed consent.

Full TRANSCEND study procedures have been previously described and are briefly summarized in the supplemental Methods, available on the *Blood* website.¹ As a part of the TRANSCEND study design, all patients who completed the 2-year follow-up period or withdrew from TRANSCEND after receiving ≥ 1 dose of liso-cel met eligibility criteria for and were asked to enroll in a separate LTFU study (ClinicalTrials.gov identifier: NCT03435796) assessing safety and OS for up to 15 years after liso-cel infusion. Timing of assessments in the LTFU study is summarized in the supplemental Methods.

End points and assessments

The end points of TRANSCEND have been described previously.^{1,2} The end points of the LTFU study are reported in supplemental Table 1. Disease-specific survival (DSS; censors deaths unrelated to disease progression) assessments were conducted post hoc. Response assessments were not collected in the LTFU study; therefore, response-based outcomes (ORR, CR rate, DOR, and progression-free survival [PFS]) are based on data from the 2-year TRANSCEND study. OS, DSS, safety, and liso-cel persistence also included data available from the LTFU study. Liso-cel transgene levels were measured over time in peripheral blood by polymerase chain reaction assessment.²

Statistical analysis

Efficacy analyses included all patients with confirmed positron-emission tomography–positive disease before receiving ≥ 1 dose of liso-cel (efficacy-evaluable set). Safety analyses included all patients who received ≥ 1 dose of liso-cel (liso-cel–treated set). Efficacy, safety, and persistence outcomes were also assessed in the subset of patients from TRANSCEND who enrolled in the LTFU study. All results are reported descriptively.

Results and discussion

Patients

As previously described, 345 patients were leukapheresed, 270 received liso-cel (liso-cel–treated set),² and 124 completed the study (supplemental Figure 1). Among 138 patients eligible for the LTFU (including 124 patients who completed TRANSCEND and 14 patients who discontinued TRANSCEND for any reason other than death), 88 enrolled.

Demographics and baseline characteristics for the total liso-cel–treated set have been previously reported.² In the subset of patients who enrolled in the LTFU, tumor burden was slightly lower than in the total liso-cel–treated set; otherwise, baseline characteristics were generally similar between groups (supplemental Table 2). At data cutoff (16 May 2024), median (range) on-study follow-up was 20.3 months (0.2–89.4) in the total liso-cel–treated set, including the LTFU and 61.0 months (range, 28.9–89.4) in the LTFU (n = 88).

Efficacy

Response-associated outcomes (ORR, CR rate, DOR, and PFS) are reported for the total efficacy-evaluable set (n = 257) and the efficacy-evaluable LTFU subset (n = 84) in supplemental Table 3 and supplemental Figures 2 and 3. PFS, OS, and DSS are reported for the leukapheresed set in supplemental Table 4.

In the total efficacy-evaluable set, 107 patients (42%) remained alive at data cutoff, with a median OS of 27.5 months (95% confidence interval [CI], 16.2–47.3) and 5-year OS probability of 38% (95% CI, 32–45) (Figure 1A; supplemental Table 3). Median DSS was 67.8 months (95% CI, 23.5 to not reached [NR]), with 5-year DSS probability of 52% (95% CI, 45–59) (Figure 1B; supplemental Table 3). In patients who achieved CR, 84 of 136 remained alive at data cutoff, with 5-year OS probability of 56% (95% CI, 46–65) and 5-year DSS probability of 74% (95% CI, 65–82) (supplemental Table 3; supplemental Figure 4A–B). Subsequent anticancer therapies after disease progression are reported in supplemental Table 5.

Table 1. AEs in the post-TE period

	Liso-cel–treated set with data in the post-TE period* (n = 249)			Liso-cel–treated set enrolled in the LTFU (n = 88)		
	Any grade	Grade 2	Grade ≥3	Any grade	Grade 2	Grade ≥3
Any AE, n (%)	111 (45)	26 (10)	62 (25)	10 (11)	14 (16)	7 (8)
Any SAE, n (%)	46 (18)	—	—	5 (6)	—	—
AEs occurring in ≥5% of patients, n (%)						
Neutropenia	22 (9)	2 (1)	18 (7)	1 (1)	2 (2)	1 (1)
Anemia	20 (8)	1 (<1)	16 (6)	1 (1)	0	0
Fatigue	18 (7)	8 (3)	1 (<1)	0	1 (1)	0
Thrombocytopenia	16 (6)	2 (1)	10 (4)	0	1 (1)	0
Nausea	15 (6)	6 (2)	0	0	1 (1)	0
Diarrhea	13 (5)	5 (2)	2 (1)	1 (1)	1 (1)	1 (1)
Grade ≥3 infections, n (%)†,‡		14 (6)			2 (2)	
Pneumonia		4 (2)			0	
Sepsis		2 (1)			0	
Atypical pneumonia		1 (<1)			0	
Bronchopulmonary aspergillosis		1 (<1)			0	
Cellulitis		1 (<1)			1 (1)	
COVID-19 pneumonia§		1 (<1)			1 (1)	
Influenza		1 (<1)			0	
Pneumonia bacterial		1 (<1)			0	
Pneumonia respiratory syncytial viral		1 (<1)			0	
Progressive multifocal leukoencephalopathy		1 (<1)			0	
Pseudomonal bacteremia		1 (<1)			0	
Septic shock¶		1 (<1)			0	
Staphylococcal bacteremia		1 (<1)			0	
Staphylococcal infection		1 (<1)			0	
Streptococcal bacteremia		1 (<1)			0	
Upper respiratory tract infection		1 (<1)			0	
Urinary tract infection		1 (<1)			0	
SPM, n (%)†		19 (8)			2 (2)	
MDS		9 (4)			2 (2)	
Basal cell carcinoma#		5 (2)			0	
Squamous cell carcinoma#		4 (2)			0	
Acute myeloid leukemia		2 (1)			0	
Bladder transitional cell carcinoma		1 (<1)			0	
Neoplasm of appendix		1 (<1)			0	
Squamous cell carcinoma of lung		1 (<1)			0	
Transitional cell carcinoma		1 (<1)			0	

SAE, serious adverse event.

*The post-TE period included AEs occurring ≥91 days after liso-cel infusion or initiation of another anticancer therapy or liso-cel retreatment, whichever was first.

†Some patients had >1 event.

‡Includes any grade ≥3 AEs in the infections and infestations system organ class.

§Grade 5 event; patient died on day 1660 after infusion and 1525 days after subsequent anticancer therapy (received on day 135).

||Grade 5 event; patient died on day 775 after infusion.

¶Grade 5 event; patient died on day 79 after infusion and 5 days after subsequent anticancer therapy.

#Subcategory: nonmelanoma skin cancer; 2 patients had both basal cell carcinoma and squamous cell carcinoma.

In the efficacy-evaluable LTFU subset, which included predominantly responders (75/84 patients), 61 patients (73%) remained alive at data cutoff. Median OS and DSS were both NR (95% CI, NR to NR); 5-year OS probability was 78% (95% CI, 67-85.5), and 5-year DSS probability was 92% (95% CI, 84-96.5) (Figure 1C-D; supplemental Table 3). In patients who achieved CR, 51 of 70 remained alive at data cutoff; 5-year probability of OS and DSS was 75% (95% CI, 63-84) and 91% (95% CI, 80.5-96), respectively (supplemental Table 3; supplemental Figure 4C-D).

In the leukapheresed set, 126 patients (36.5%) remained alive at data cutoff, with a median OS of 15.2 months (95% CI, 11.5-23.4) and 5-year OS probability of 33% (95% CI, 28-39) (supplemental Table 4). Median DSS was 27.4 months (95% CI, 14.4-69.7), with 5-year DSS probability of 47% (95% CI, 41-52).

Safety

A total of 249 liso-cel-treated patients had data available in the posttreatment-emergent (TE) period (day 91 to end of study); the most common post-TE adverse events (AE) are shown in Table 1. In the post-TE period, 14 patients (6%) had grade ≥ 3 infections, including 3 grade 5 infections (Table 1). There were 2 grade ≥ 3 infections reported in the LTFU, including 1 patient with grade 3 cellulitis and 1 patient with grade 5 COVID-19 pneumonia. Nineteen patients (8%) had second primary malignancies (SPM) in the post-TE period, most commonly myelodysplastic syndrome (MDS; $n = 9$) and nonmelanoma skin cancers ($n = 7$) (Table 1). Two SPMs (both MDS) were reported in the LTFU. All additional AEs are shown in supplemental Table 6.

Among the 345 patients who were leukapheresed in TRANSCEND, 175 died (51%) after CAR T-cell infusion, with 30 deaths (9%) occurring >2 years after CAR T-cell infusion, including 10 because of progressive disease, 1 because of AE of progressive multifocal leukoencephalopathy, 1 because of AE of COVID-19 pneumonia, 8 because of unknown reasons, and 10 because of other reasons, including 2 with COVID-19; the 3 patients who died of COVID-19 had all received COVID-19 vaccination after liso-cel infusion (supplemental Table 7). Of the 30 patients who died >2 years after infusion, 24 were enrolled in the LTFU. The cumulative incidence of nonrelapse mortality at 2 years after infusion was 7.2% (95% CI, 4.5-10.8) overall (supplemental Figure 5).

Liso-cel persistence

Persistence of the liso-cel transgene was observed long-term in 13 of 38 patients (34%) enrolled in the LTFU with samples available at 5 years after infusion (supplemental Figure 6).

These long-term data in patients with R/R LBCL from TRANSCEND demonstrate durable efficacy for liso-cel, with an estimated 5-year OS of 38% and DSS of 52%. These results are encouraging, given the heavily pretreated nature of the patient population. Our data are consistent with long-term efficacy results from other CAR T-cell therapy trials that reported median and 5-year OS rates of 25.8 months and 42.6%, respectively, for axicabtagene ciloleucel (median follow-up, 63 months), and median OS of 11.1 months for tisagenlecleucel (median follow-up, 40.3 months); however, comparisons

should be made with caution because of differences in study designs (eg, TRANSCEND required patients to enroll in a separate LTFU study after 2 years, whereas all treated patients were followed up for OS in ZUMA-1 and JULIET).^{3,4} The safety profile of liso-cel remained consistent in longer follow-up, with low rates of grade ≥ 3 post-TE AEs (most commonly cytopenias) and few AEs reported in the LTFU study; only 2 additional grade ≥ 3 infections and 2 SPMs (both MDS) were reported since the 2-year follow-up.

The efficacy results were superior in the LTFU subset of TRANSCEND, which included predominantly responders (75/84 patients who were efficacy-evaluable [89%]), with an estimated 5-year OS of 78% and DSS of 92%. Although improved outcomes were expected based on the LTFU-enrolled population, these results confirm the possibility of a cure in patients with heavily pretreated R/R LBCL.

These results provide insights into 2 remaining questions on the long-term efficacy and safety of liso-cel. First, it confirmed that patients who were alive 2 years after liso-cel infusion had increased chances of prolonged survival, and second, 5 years of follow-up showed limited late-onset AEs and SPMs, consistent with expectations for patients who received several lines of previous therapy. This evidence can support informed decision-making when selecting the appropriate therapeutic approach in R/R LBCL.

This study has some limitations. TRANSCEND was designed to follow patients for up to 2 years after liso-cel infusion. After completion of TRANSCEND or discontinuation for any reason other than death, patients were asked to enroll in the separate LTFU study assessing OS and safety for up to 15 years after infusion. Of the 138 patients eligible to enroll in the LTFU, 50 did not enroll, possibly because of disinterest, a lack of response, progressive disease, the long-term commitment, or being lost to follow-up. In addition, independent review committee response assessments were only performed in the 2-year TRANSCEND study, and investigator assessments were collected when available during the LTFU but were not mandated at specific time points. This likely led to an underestimation of time-to-event outcomes reliant on response assessments (ie, DOR and PFS) because of censoring at the last response assessment, making these end points unevaluable beyond 2 years.

Responses to liso-cel continue to be durable after longer follow-up, with 5-year OS and DSS rates of 38% and 52%, respectively. Liso-cel continued to exhibit low post-TE AE rates, with no new safety signals observed. Collectively, these data support the curative potential of liso-cel in patients with R/R LBCL.

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Authorship

Contribution: J.S.A. and D.G.M. contributed to the conception and design of the study, data acquisition, and data interpretation; T.S., L.I.G., M.L., M.W., J.A., M.K., M.S., C.A., A. Sehgal, S.R.S., N.G., and M.L.P. contributed to data acquisition and data interpretation; J.E.H.-L. contributed to data acquisition, data analysis, and data interpretation; J.W., X.D., K.O., and A. Singh contributed to data analysis and data interpretation; and all authors contributed to and approved the manuscript.

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Footnotes

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Bristol Myers Squibb policy on data sharing is available at <https://www.bms.com/researchers-and-partners/independent-research/data-sharing-request-process.html>.

The online version of this article contains a data supplement.

There is a [Blood Commentary](#) on this article in this issue.

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