# Lisocabtagene Maraleucel Demonstrates Superior Efficacy Across Inflammatory Risk Subgroups in Second-Line Large B-Cell Lymphoma: A Retrospective Analysis of the TRANSFORM Study



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## Introduction

- The InflaMix (INFLAmmation MIXture) model classifies the disease status of patients with R/R large B-cell lymphoma (LBCL) as inflamed or noninflamed based on routine preinfusion laboratory tests[1]
- In published data comprised primarily of patients with third-line or later (3L+) LBCL, this classification predicts response to CAR T cell therapy[1]
- As lisocabtagene maraleucel (liso-cel) has demonstrated deep and durable responses with curative potential in second-line (2L) LBCL,[2–5] we sought to understand the value of InflaMix stratification in this population
- Here, we retrospectively compared efficacy outcomes by treatment arm in inflamed versus noninflamed patients with 3L+ LBCL who received liso-cel in TRANSCEND NHL 001 and patients with 2L LBCL who received liso-cel or historical standard of care (SOC) in TRANSFORM[2,3]; safety outcomes in 2L LBCL are also presented

## Methods

- For patients with prospectively collected laboratory data from the respective studies, albumin, hemoglobin, AST, alkaline phosphatase, C-reactive protein, and LDH were retrospectively evaluated from the following predefined time points to support InflaMix stratification:
  - At the time of liso-cel infusion (as previously published[1]) and before leukapheresis from 256 patients with 3L+ LBCL in TRANSCEND NHL 001 (NCT02631044)
  - Before leukapheresis from 127 patients with 2L LBCL in TRANSFORM (NCT03575351) to enable liso-cel versus SOC comparison
- InflaMix was trained on the published derivation cohort with laboratory values taken at the time of infusion (n = 149; 98% had 3L+ LBCL)[1]
- Endpoints were PFS, CR rate, ORR, and rates of cytokine release syndrome (CRS) or neurological events (NE) in inflamed versus noninflamed patients
- PFS was analyzed using KM estimates with log-rank tests, and HRs were based on Cox proportional hazards models
- Categorical outcomes were compared with chi-square tests of association

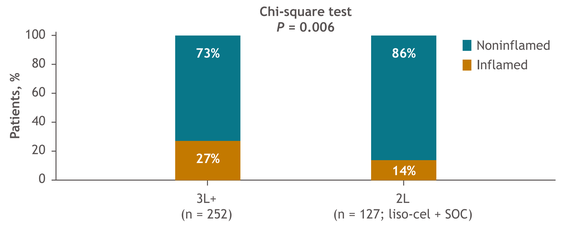
## Results

**Table 1. Model application for PFS in 3L+ LBCL at time of infusion and before leukapheresis to enable comparisons in 2L LBCL**

| | Stratification | HR (95% CI) for PFS |
|---|---|---|
| At infusion | Inflamed: n = 71<br>Noninflamed: n = 185 | 1.9 (1.3–2.7) |
| Before leukapheresis | Inflamed: n = 69<br>Noninflamed: n = 183 | 1.5 (1.1–2.2) |

- The results by InflaMix stratification in patients with 3L+ LBCL (**Table 1**) were consistent with published results of InflaMix[1]
- Using laboratory values for InflaMix stratification in 3L+ LBCL before leukapheresis allows stratification of TRANSFORM patients using laboratory values collected at the time of randomization, to enable comparison of liso-cel versus SOC

**Figure 1. Greater proportion of noninflamed patients in 2L versus 3L+ LBCL (before leukapheresis)**




**Liso-cel outperformed SOC in 2L LBCL regardless of InflaMix subgroup, demonstrating longer PFS even among inflamed patients receiving liso-cel versus noninflamed patients receiving SOC. These data reinforce liso-cel as a robust treatment option delivering deep and durable efficacy for a broad population of patients with 2L LBCL**

**Figure 2. PFS by InflaMix subgroup within each treatment arm 2L LBCL (before leukapheresis)**

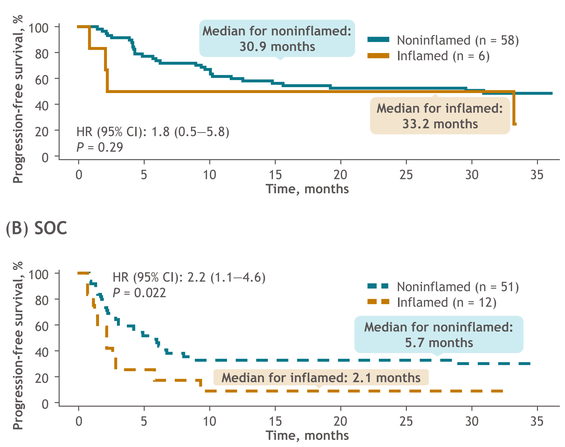
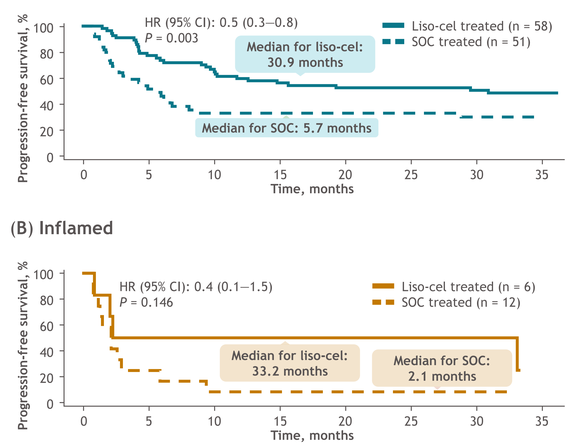



**Figure 3. PFS by InflaMix subgroup between treatment arms 2L LBCL (before leukapheresis)**




- A significantly greater proportion of patients were classified as noninflamed in the 2L setting compared with the 3L+ setting (**Figure 1**)
- In the liso-cel arm, median PFS was not significantly different in the inflamed and noninflamed patient groups (**Figure 2A**)
- In contrast, InflaMix was predictive of PFS in the SOC arm, with inflamed patients achieving significantly shorter PFS than noninflamed patients (**Figure 2B**), highlighting the utility of InflaMix to evaluate treatment modalities beyond CAR T cell therapies
- Across both inflamed and noninflamed patients, liso-cel outperformed SOC, resulting in longer median PFS, consistent with clinical results from TRANSFORM (**Figure 3**)[2,3]
  - The lack of statistical significance in inflamed patients was likely due to limited patient numbers in the inflamed subgroup for both arms
- Notably, liso-cel treatment in inflamed patients resulted in longer median PFS than SOC in noninflamed patients
- Differences in CR rate and ORR favored liso-cel in both noninflamed and inflamed patients, similar to PFS results (**Figure 4**)

**Figure 4. CR rate and ORR by InflaMix subgroup and treatment arm (2L LBCL [before leukapheresis])**

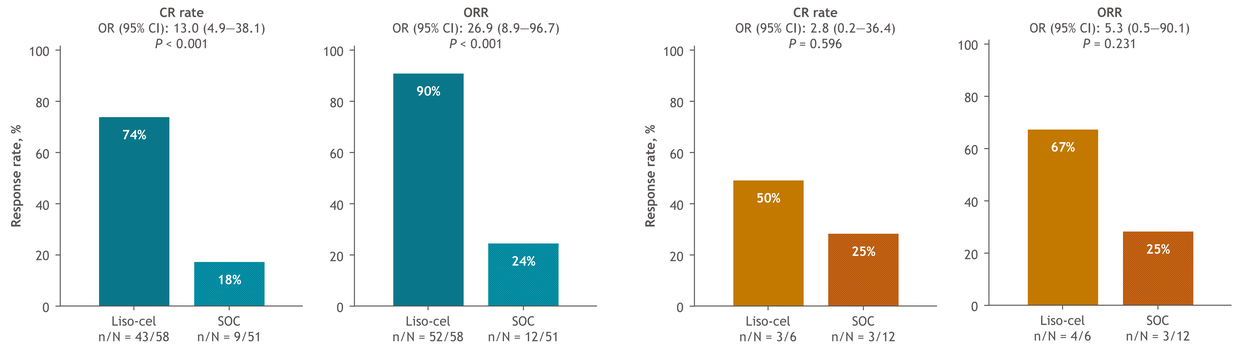
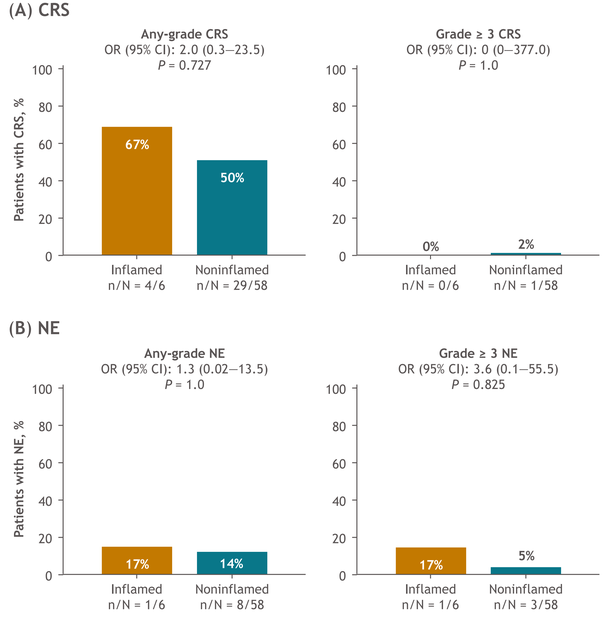



**Figure 5. CRS and NE by InflaMix subgroup and grade (liso-cel arm; 2L LBCL [before leukapheresis])**




NE was defined as investigator-identified neurological AEs related to liso-cel.

- InflaMix subgroup stratification was not associated with incidence of any grade or grade ≥ 3 CRS or NE (**Figure 5**)

## Conclusions

- A significantly greater proportion of patients were classified as noninflamed in the 2L setting compared with the 3L+ setting, supporting the earlier use of liso-cel in the 2L setting in patients with R/R LBCL
- In 2L LBCL, InflaMix stratified outcomes in patients treated with SOC, but not in those treated with liso-cel
- Importantly, liso-cel outperformed SOC in 2L regardless of inflammatory status, reinforcing the ability of liso-cel to deliver deep and durable efficacy for a broad population of patients with 2L LBCL
- The different PFS outcomes of inflamed versus noninflamed patients treated with SOC in the 2L setting, as well as those treated with bispecific antibodies,[6] support that the effect of baseline inflammation status is not limited to CAR T cell therapy outcomes in R/R LBCL

## References

1. Raj SS, et al. *Nat Med* 2025;31:1183–1194.
2. Abramson JS, et al. *Blood* 2023;141:1675–1684.
3. Kamdar M, et al. *J Clin Oncol* 2025;43:2671–2678.
4. Sehgal A, et al. *Lancet Oncol* 2022;23:1066–1077.
5. Sehgal A, et al. *Blood Adv* 2025;9:3694–3705.
6. Magno G, et al. *Blood* 2024;144(suppl 1):1714–1715.

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